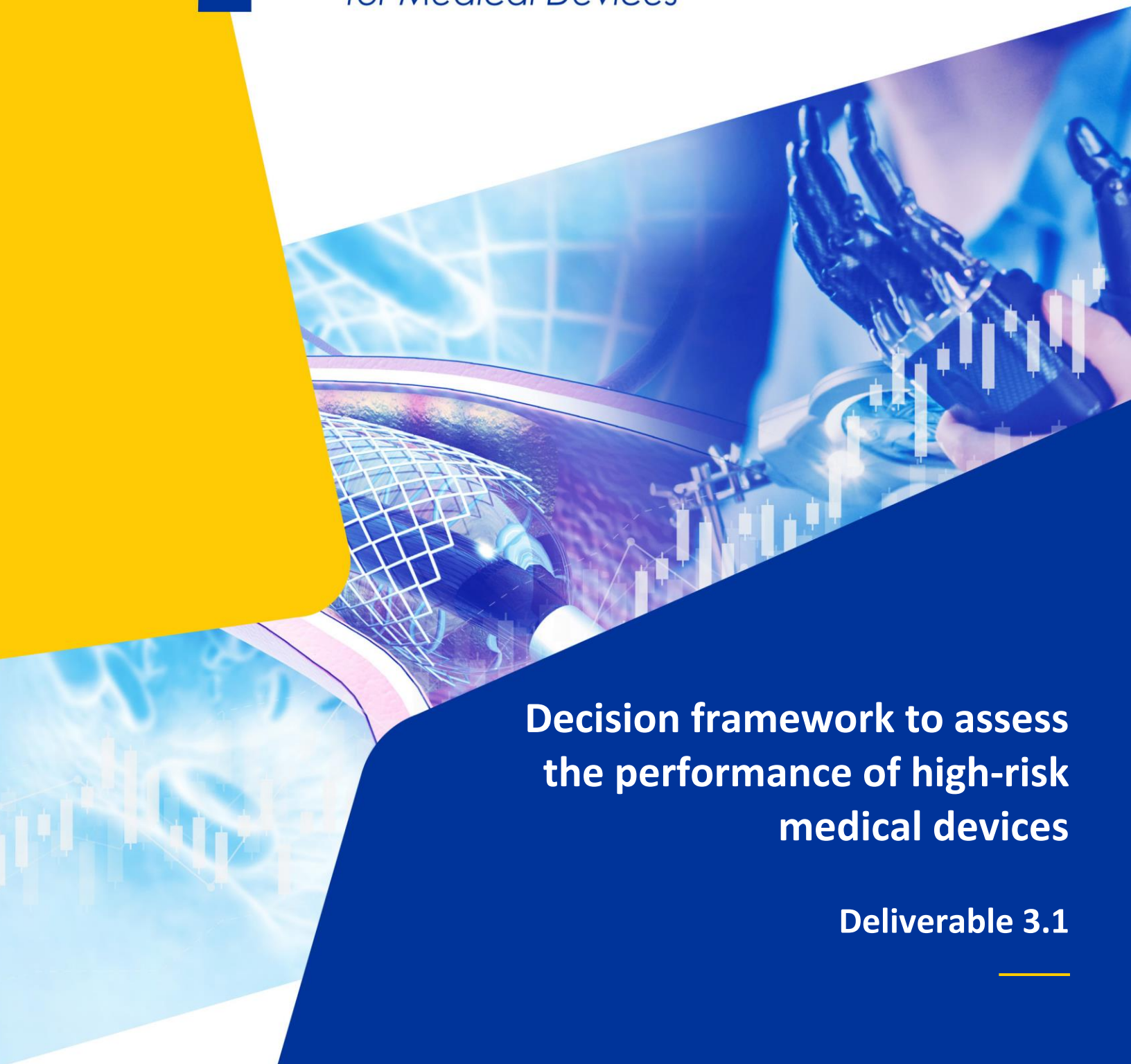
CORE-MD

Coordinating Research and Evidence for Medical Devices



Decision framework to assess the performance of high-risk medical devices

Deliverable 3.1

Deliverable factsheet

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Acronyms and abbreviations

ASA	American Society of Anesthesiologists
EHDEN	European Health Data and Evidence Network
EMA	European Medicines Agency
FDA	Food and Drug Administration
IMDRF	International Medical Device Regulators Forum
MACE	Major cardiovascular event
MDR	Medical Device Regulation
NICE	National Institute for Health and Care Excellence
ODEP	Orthopaedic Data Evaluation Panel
PMS	Post-market surveillance
PROM	Patient Reported Outcome Measure
RCT	Randomized Controlled Trial
SN	Safety Notice
THA	Total hip arthroplasty

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Executive Summary

This report presents the results of the CORE-MD project task 3.1 focused on aggregating insights from registries and other real-world data within the CORE-MD project. The main aim of this task was to provide insights how registry data can be leveraged to supplement evidence from RCTs on performance and safety of high-risk medical devices in the post-marketing phase, using cardiovascular and orthopaedic registries as an example. To achieve this aim we developed a decision framework capturing both characteristics to judge the quality of registry data, endpoints used to determine performance and safety, and propose methodology and criteria to assess performance of these medical devices.

First, we reviewed 20 cardiovascular (coronary stents and valve repair/replacement) and 26 orthopaedic (hip/knee prostheses) European registries on the extent to which 33 structural and methodological variables were reported that influence the quality of registry data, as well as the definitions used and endpoints included to assess performance of these devices. We found large heterogeneity and incomplete transparency in quality items related to their structure and methodology as well as differences in the endpoints used and definitions. These results imply that it is currently difficult for registries to agree upon common principles to be used by regulators to judge the quality of these registry data. Furthermore, this heterogeneity hampers current collection and reporting on comparable information across Europe. Current initiatives within the orthopaedic registries aim to harmonize this.

We considered whether existing benchmark systems using registry data such as the Orthopaedic Data Evaluation Panel (ODEP) could be used to provide evidence on the performance and safety of medical devices. To that end, we conducted an external validation of ODEP-ratings across 9 registries as a current ODEP-rating can be based on endpoint data (i.e. revision surgery) of a single registry or other data sources (i.e. data from industry or article). Our findings indicate variable performance of the same hip implant across registries, with only a minority of the highest ODEP-rated hip cups and stems receiving this highest rating based on the pooled evidence across registries. This indicates that performance assessed in one country to comply with an absolute benchmark or standard such as ODEP would not necessarily translate to other countries. Moreover, data from multiple registries would provide stronger evidence for quality of an implant.

Combining registry data with other real-world data sources to signal safety problems might provide additional insights and we therefore assessed the extent to which safety notices would signal the same implants as procedures within registries to identify implants with outlier performance. Taking knee implants as the example, we showed that there was overlap but also that publicly available safety notices issued by manufacturers and published by competent national authorities did not signal about a quarter of the outlier total knee implants identified by registries (based on having significantly higher revision rates). On the other hand, safety notices also pointed to 12 implants not (yet) identified by registries. This highlights the potential of adopting a multifaceted approach, integrating various real-world data sources and methods to combine information to enhance medical device safety signal detection which would be beneficial for manufacturers, clinicians as well as competent authorities and ultimately to patients.

Based on the results from the systematic review and the knowledge obtained from the previous parts, we conducted a Delphi study to achieve consensus on a minimum dataset needed to assess the quality and analysis of registry data for the regulation of medical device performance during post-market surveillance. Across 50 experts from different stakeholder groups we reached consensus on the minimal dataset for registries to report on 15 items on quality of registry data and 8 items on quality of analysis to allow regulators to better judge the utility of registry data during post-market surveillance of medical devices. Completeness of procedures, reporting missing data, definition of the outcome analysed and a minimum number of patients at risk to analyse performance were considered most important. The assigned importance to items may guide regulators when assessing registry data as registries will often have better scores on some items and worse scores on others.

Finally, the results were used to construct a decision framework to assess the performance of medical devices. Drawing on previously published regulatory guidance on real-world evidence, we used relevance and reliability as the guiding principles, and arrived at data suitability, data governance, data quality and data analysis as the key factors to be assessed. Items from the minimal dataset were mapped to these key factors and combined with the ranking obtained in the Delphi study, might guide regulators on which items they should place most weight when using registry data to assess performance of medical devices. This framework is expected to have high added value for all stakeholders: for manufacturers to perform the required clinical evaluation and for notified bodies to do their assessment, for competent authorities to perform their market surveillance tasks and for clinicians and patients to establish their own insights on a device.

1 Introduction

1.1 Background

The life cycle of implants starts with the pre-market phase and ends with post-market surveillance. Evidence generated during post-market surveillance can be used to improve new implant development. During pre-market evaluation of new medical devices, Randomized Controlled Trials (RCTs) are the gold standard, but these may pose methodological challenges and difficulties, mainly related to randomization, timing of assessment, acceptability and participation of patients, blinding, choice of the comparator group as well as considerations on the learning curve and difficulties in determining all relevant outcomes given the limited follow-up during these trials [1]. Therefore, to obtain insight in the post-marketing phase into the performance and safety of medical devices (i.e. long-term outcome), RCTs should be supplemented with evidence from registry data and potentially other real-world data sources.

The International Medical Device Regulators Forum (IMDRF) defines a medical device registry as "an organized system with a primary aim to increase the knowledge on medical devices contributing to improve the quality of patient care that continuously collects relevant data, evaluates meaningful outcomes and comprehensively covers the population defined by exposure to particular device(s) at a reasonably generalizable scale (e.g. international, national, regional, and health system)"[2]. A medical device registry is thus an unselected population-based health information system collecting large numbers of real-world data regarding safety and performance of specific devices over time, across longer follow-up than in RCTs, which makes them well suited to provide clinical evidence on post-market clinical follow-up of devices as required for the EU Medical Device Regulation (MDR).

Key considerations in regulatory guidance on real-world evidence by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) are data quality, validity and transparency.

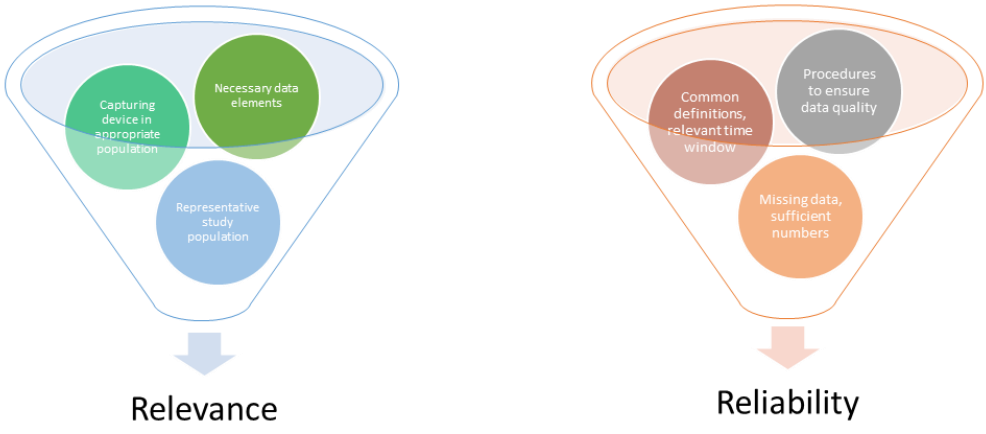


Figure 1. Factors to assess real-world data for regulatory purposes

Factors such as necessary data elements being available and coverage of the population determine the relevance, and factors such as data quality procedures and common definitions influence the reliability of real world data (Figure 1), which should be taken into account by regulators in order to use these data as part of the post-market clinical follow-up of medical devices.

Registries differ in design and organization (e.g. manufacturers or an independent organization) [3] as well as in the methods used for data collection and the type of endpoints defined and collected. All these variables influence the quality of the data collected and thereby their use and value for relevant stakeholders like clinicians, patients and manufacturers but also national and EU regulators. It is unknown if existing medical device registries in Europe would allow manufacturers to meet the MDR requirements to an acceptable standard.

Less frequent severe or long-term adverse effects will typically not have been detected during the follow-up in clinical trials. Even individual registries may not have sufficient sample size for some less frequently used medical devices, requiring coordination and collaboration of registries across countries to detect low frequency adverse effects early. Legal and privacy concerns will often prevent data to be pooled. Distributed network analysis may be a feasible method to allow for local data access and privacy regulations to remain in place, while still being able to take advantage of the increase in power by combining data [4], such as the European Health Data and Evidence Network (EHDEN) [5].

To comply with the MDR, a device should meet the general safety and performance requirements (GSPR). Demonstration of conformity with the GSPR includes a clinical evaluation which includes that evidence-based parameters are used to determine the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device. To do this in a proper and systematic way, guidance is needed on the minimum information needed to judge the quality of the analysis assessing the performance and benefit-risk ratio of the medical device such as the minimum number of patients and follow-up needed, and how to create groups of similar types of devices to ensure fair comparison (building on the work of the European Medical Device Nomenclature (EMDN) working group).

1.2 Aims of the task

This task aimed to provide insights in how registry data can be leveraged to supplement evidence from RCTs on performance and safety of high-risk medical devices in the post-marketing phase, using cardiovascular and orthopaedic registries as an example. To achieve this aim we developed a decision framework capturing both characteristics to judge the quality of registry data, endpoints used to determine performance and safety, and propose methodology and criteria to assess performance of these medical devices. This framework is expected to have high added value for all stakeholders: for manufacturers to perform the required clinical evaluation and for notified bodies to do their assessment,

for competent authorities to perform their market surveillance tasks and for clinicians and patients to establish their own insights based on clinical evidence and safety of a device.

1.3 Deliverable structure

The first step was to review European cardiovascular and orthopaedic medical device registries on the extent to which structural and methodological variables were reported that influence the quality of registry data, as well as the definitions used and endpoints included to assess performance of these devices (Chapter 2). Second, we considered whether existing benchmark systems using registry data could be used to provide evidence on the performance and safety of medical devices. The Orthopaedic Data Evaluation Panel (ODEP) is an example of such a system that provides ratings for total hip and total knee implants based on objective performance criteria. ODEP-ratings can be based on different data sources including registry data, and is increasingly used in various countries. But because different data sources can be used by manufacturers in their application for an ODEP-rating, these data may come from a single registry or from studies of these implants (article or data from manufacturers) which are not representative of daily clinical practice. Therefore, before submission to ODEP, manufacturers have to declare that "the clinical data submitted is representative of all studies that have been conducted in relation to it". However, external validation of ODEP-ratings across multiple registries with thousands of patients, has never been undertaken. The latter is needed for such a benchmark to be used across multiple EU countries. Therefore, we assessed across nine registries whether higher ODEP-rated hip and knee implants would have better performance than lower ODEP-rated implants, and the extent to which the higher rated implants would also receive this higher rating based on pooled performance across registries (Chapter 3). Variable performance for the same device across registries would indicate that performance assessed in one country to comply with an absolute benchmark or standard such as ODEP would not necessarily translate to other countries, and that data from multiple registries would provide stronger evidence.

We explored the feasibility of combining data across registries, to allow for timely detection particularly for less frequently occurring adverse outcomes. Besides measuring the same endpoints with the same definitions, we need to ensure that performance and safety are assessed in the same patient group. Therefore, as a first step to test the procedures needed for individual registries to submit data for a federated network analysis, we assessed the extent to which patient characteristics for the same medical device differed across registries, taking knee implants as an example (Chapter 4). This may point to different patient selections for which implants are used, and thereby relevant for fair comparison as these patient characteristics may influence the device performance. We also assessed whether specific knee implants are used across all registries, in at least two registries or in a single registry. If only used in a single registry, pooling data across registries will not have any added value, and therefore will not provide important information for regulators who need to judge the safety of such a device in the EU market.

We then explored the feasibility of combining different types of real-world data sources to signal safety problems. Incident reporting data could point to potential problems, but as reporting is often voluntary and therefore influenced by reporting behaviour, an increase in incidents reported or difference between devices cannot be taken as a difference in safety [6]. In addition, data on the denominator i.e. the number of times a medical device was implanted is generally not included, whilst this is needed for judgements on potential safety problems. We therefore considered safety notices, as these are typically prepared by the manufacturer as mandatory during post-market surveillance and shared with competent authorities, meet the definition of a serious incident and therefore requires legal action of the manufacturer. However, safety notices are issued for a wide variety of safety issues (e.g. from packaging and labelling to material integrity) which is not always associated with safety or performance of a particular medical device. Registries on the other hand, may have procedures in place to detect medical devices with an outlier performance i.e. performing significantly worse than other comparable devices, but there have to be sufficient numbers for meaningful analysis and it may take years to identify such outliers. Therefore, we aimed to gain insight into the extent of overlap between both data sources by assessing the extent to which safety notices and outliers identified by registries would signal the same or different devices as well as explore reasons for possible discrepancies, taking knee implants as an example (Chapter 5).

Based on the results from the systematic review and the knowledge obtained from the previous parts, we conducted a Delphi study to achieve consensus on a minimum dataset needed to assess the quality and analysis of registry data for the regulation of medical device performance during post-market surveillance (Chapter 6). Registries reporting on the variables included this minimum dataset would allow regulators to better judge the utility of registry data in post-market surveillance of medical devices. The results are used to construct a final decision framework to assess the performance of medical devices (Chapter 7).

2 Systematic review on the quality and utility of EU cardiovascular and orthopaedic registries for regulatory evaluation of medical device safety and performance

The methods used to conduct systematic review has been published in the International Journal of Health Policy and Management [7] which is included as Appendix 1. Below is a summary of the main findings.

2.1 Reported items needed to judge the quality of registry data for regulatory purposes

We identified 20 cardiovascular (coronary stents and valve repair/replacement) and 26 orthopaedic (hip/knee prostheses) registries of which annual reports, peer-reviewed publications and websites were reviewed to extract publicly available information for 33 items related to structure and methodology in six domains and also for reported outcomes. The items and domains are described in Table 1.

Table 1. Description of the items in each domain that were extracted for each registry. Source: [7]

	Description of item extracted for each registry
Identification	
1	Class of device (cardiovascular registries – stents/cardiovascular registries – valves/cardiovascular registries – combined)/(orthopaedic arthroplasty registries – combined/orthopaedic arthroplasty registries – hips/orthopaedic arthroplasty registries – knees)
2	Name of registry
3	Initial motivation/goal to set up the registry
4	Country (country or countries in which the registry is conducted)
5	Design (regional/national/multi-country)
6	Website (available yes/no)
Maturity	
7	Starting year (year of first patient/procedure included)
8	First annual report (year of publication)
9	Most recent (or last, if registry no longer active) annual report (year of publication)
Governance	
10	Mandatory (if mandatory for surgeons/hospitals to submit to the registry; yes/no)
11	Patients' consent (patients' consent required before entering their data to the registry; required/not-required)
12	Funding (public/private/both)

13	Who can access the data and see results?
14	Privacy regulation for patients' identifiable information (privacy regulation reported as implemented: yes/no? And if yes: how?)
Coverage, design & organisation	
15	Number of participating hospitals and % of hospital-level coverage (defined as number of participating hospitals relative to the total number of eligible hospitals)
16	Number of patients/procedures (cumulative total in registry)
17	Number of selected patients/procedures in study population (if cumulative total in registry is not reported)
18	Annual number of patients/procedures in registry
19	Data capture and collection method (e.g., electronic/manual/barcodes-industry/surgeon-reported)
20	Method of access to registry for users/members (e.g., dashboard/real-time/secure server)
21	Level of information provided (data is reported at hospital/medical device/surgeon level)
22	Data linkage with other sources (e.g., registry data is linked to hospital statistics/manufacturer vigilance data/national competent authority on medical devices)
Data quality & completeness	
23	Quality assurance system defined/quality check of data (e.g., data verification)
24	Missing data for patients' characteristics reported (%) (e.g., BMI, ASA classification, gender)
25	Methods for handling missing data described
26	Data completeness reported at patient/procedure-level (%)
Safety & performance	
27	Frequency of feedback provided to surgeons/hospitals (e.g., annually/quarterly)
28	Level of feedback information provided (e.g., hospital/medical device/surgeon level)
29	Feedback time period (the duration of observation before assessment of performance is possible)
30	Outlier reports procedures (the type of outlier reports or procedures a registry has established and published methods to define outlier performance)
31	Accessibility of outlier results (e.g., publicly available or only accessible for individual hospitals/surgeons/members)
32	Definition of an outlier (e.g., using funnel plots)
33	Number of outliers identified (has this registry identified and published details of any specific hospitals/medical devices/surgeons with outlier performance?)

Across all domains, a median of 33% (IQR 14-71%) of the predefined 33 quality items were reported by cardiovascular registries and 60% (IQR 28-100%) by orthopaedic registries. The highest median value was reached for the domain 'Identification' since almost all registries reported information on e.g. the type of registry: 75% (IQR 69-100%) for cardiovascular and 100% (IQR 100-100%) for orthopaedic registries (Figure 2). The lowest percentages were observed for the domains 'Data quality & completeness' and 'Safety & performance'; for cardiovascular registries these were respectively 25% (IQR 0-25%) and 0% (IQR 0-4%) and for orthopaedic registries they were 38% (IQR 0-69%) and 50% (IQR 0-71%) (Figure 2).

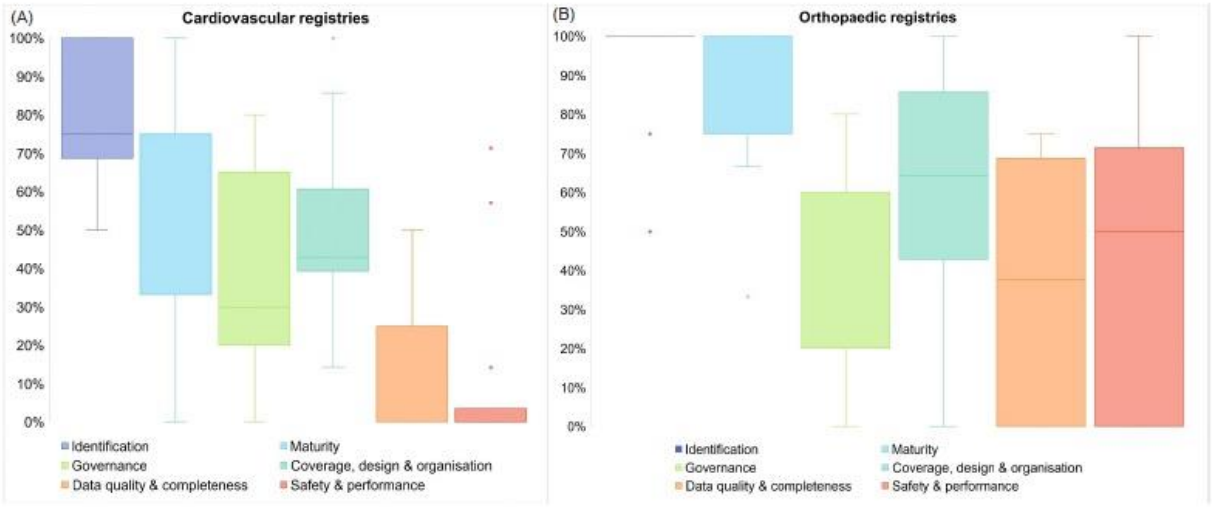


Figure 2. Reported items by cardiovascular (A) and orthopaedic (B) registries in each domain indicating the variation in reporting across registries. Source: [7]

For the domain data quality & completeness, none of the cardiovascular registries reported patient/procedure-level data completeness. Techniques to handle missing data were described in only one cardiovascular registry (5%), which applied a data completeness threshold (i.e. a certain variable will only be analyzed if its completeness is ≥95%). Most (55%) cardiovascular registries reported on procedures to check the quality of their data, such as checking on the range and consistency of entries, and verification by audits or an external electronic tool. Patient/procedure-level completeness was reported by 16 (62%) orthopaedic registries, which varied from 19% for hip prostheses in the Irish National Orthopaedic Register to 98-99% for knee prostheses in the Danish Knee Arthroplasty Register. Both registries used data linkage with national patient databases to determine patient/procedure-level completeness. Techniques to handle missing data were clearly described by only one orthopaedic registry (4%), which sent requests for missing data to each orthopaedic department once every three months. Almost half (46%) of the orthopaedic registries reported that they implemented techniques for quality assurance of the data, which in the majority consisted of comparing registry data with national patient databases or implant databases.

For the domain safety & performance, public reporting on how feedback on e.g. devices, hospitals, and surgeons is provided was reported by three (15%) cardiovascular registries. Managerial procedures to detect individual hospitals or specific devices using an outlier performance analysis based on benchmark thresholds was reported by one (5%) cardiovascular registry, the British Cardiovascular Intervention Society (BCIS) registry. The outlier was defined using funnel plots, with 2 and 3 standard deviations (SD). Outlier results regarding the timing of treatment (to assess any delay before treatment is delivered) compared between hospitals, as well as adverse outcomes per hospital, were publicly available. However, outlier reports on patients' survival data per hospital were only disclosed confidentially to each hospital. No outlier reports for specific implants were reported by cardiovascular registries. Public reporting on the frequency of feedback provided was reported by 14 (54%) orthopaedic registries. Most registries report that they provide annual feedback, while two registries (the Irish National Orthopaedic Register and the Swiss national registry for hip and knee replacement) do so both annually and quarterly. The majority provided feedback both at the hospital level and for individual devices. Details of outlier procedures including statistical testing were reported by eight (31%) registries, of which three reported solely on outlier devices, two solely on outlier hospitals, two on both hospital and individual surgeon performances, one on outlier devices and hospitals, and one on outlier devices, hospitals, and surgeons. Outlier procedures were mostly publicly available. No registries shared the same definition of an outlier (e.g. above the 95% control limit in the funnel plot versus revision rates of more than twice compared to the relevant group). Overall, in all annual reports, a total of 95 total hip arthroplasty (THA) component combinations, three THA cups, two THA stems, and 24 total knee arthroplasty (TKA) implants were identified by these five registries as outlier implants. Overall, registries all identified different outlier implants, with only one outlier implant (a THA component combination) identified by more than one registry.

2.2 Reported end points, definitions and duration of follow-up

A wide variety of outcomes as well as variety in their definitions and durations of follow-up were reported by both cardiovascular and orthopaedic registries. The most frequently reported outcome in cardiovascular registries was mortality; reported by 18 (90%) registries. Mortality was reported using 70 different time-points, from in-hospital mortality to mortality at 21 years, the majority of registries (80%) reported on 30-day mortality. Major cardiovascular events (MACE) were reported as combined end-points by eight (40%) registries, but with 17 different combinations of complications included in this endpoint and seven different time intervals with most (50%) registries reporting on 1-year MACE. Reporting on other single outcomes also showed large variability, ranging from three to 40 outcome variables per registry.

In orthopaedic registries, revision surgery (for any cause) was the most frequently reported outcome, reported by 20 (77%) registries. It was mostly reported as the revision rate or cumulative revision risk but at 30 different time-points up to 25 years, with the most common end-point being the 1-year revision rate which was reported by 10 registries (38%). Specific reasons for revision were reported by 19 (73%)

registries, but these reasons for revision varied between registries (e.g. infection, loosening, component failure, etc.). Patient-reported outcome measurements (PROMs) were reported by five (19%) orthopaedic registries, with a total of eight different scores for knee surgery patients and 11 scores for hip surgery patients. All registries measuring PROMs reported pre-operative PROMs, but post-operative PROMs were measured at different time-points up to 10-years post-operatively. Other outcomes (e.g. renal failure, hip dislocation, deep venous thrombosis, etc.) were inconsistently reported by 13 (50%) registries, the majority (77%) reported on mortality.

2.3 Conclusion and recommendations

Medical device registries are potentially well suited for post-market surveillance as they may collect data from unselected patient populations and monitor safety and performance throughout the lifetime of specific devices. However, we found heterogeneity and incomplete transparency in quality items related to their structure and methodology, implying that it would be difficult currently for registries to agree upon common principles, to report the information needed by regulators to judge the quality of their data, and to collect and report comparable information across Europe.

Effort is needed from registries to agree upon a minimum set of quality criteria that all registries should publicly report to provide information needed by regulators to judge the quality of registry data and use them for medical device safety surveillance. The International Society of Arthroplasty Registries (ISAR) has already taken the initiative to ask all of their member registries to report on the reported items found in the systematic review, to be published on their website, which is an important first step towards implementation. Developing comprehensive and trustworthy medical device registries will be tremendously valuable, not only for manufacturers to meet the requirements of the MDR for PMCF of their devices, but also for healthcare professionals and patients to support evidence-based choices of devices and contribute to their long-term safety and efficacy.

3 Validation of Orthopaedic Data Evaluation Panel ratings across registries

The methods used to validate the Orthopaedic Data Evaluation Panel ratings are described in a paper currently under revision for the Journal of Bone & Joint Surgery (Am), which is included as Appendix 2. Below is a summary of the main findings.

3.1 Orthopaedic Data Evaluation Panel (ODEP) ratings

ODEP-ratings are available for: i) TH-components (cups/stems); ii) TK-implants (tibial-femoral combinations); iii) unicondylar knee implants; iv) shoulder components (glenoid/stems); v) reverse shoulder implants; vi) total elbow implants, and vii) spine implants (cervical discs). The ODEP benchmarks implants based on revision data from observational studies (e.g. single-centre studies, manufacturers in-house data sources or registry data).

The submitted data is supplied by manufacturers using standardised ODEP-submission forms. Not all implants on the market are submitted to ODEP as data submission is voluntary, but surgeons and hospitals in multiple countries are encouraged to use ODEP-rated implants. As different data sources can be used by manufacturers to obtain an ODEP-rating, these data may not be representative to daily-clinical practice. Therefore, before submission, manufacturers have to declare that "the clinical data submitted is representative of all studies that have been conducted in relation to it". The data submitted to ODEP is evaluated by a voluntary independent panel of orthopaedic-experts. To prevent camouflage (i.e. the performance of a specific implant design variant concealed because different variants exist under the same implant name), the ODEP-panel reviews implants at the product-code-level

The ODEP-rating includes a number (postoperative years of evidence) and a letter (strength of evidence). The latter denotes performance of implants based on an OPC at specific timepoints (3/5/7/10/13/15-years), i.e. minimum number of centers and surgeons, size of the cohort, patients at risk, and the maximum revision rate. Implants can be rated as A* (highest), A (lower), B (where usage is limited but the implant is extremely important or for new implants introduced in a limited manner), starting from 3-years of evidence. After being assigned an ODEP-rating, manufacturers have to resubmit new evidence at every ODEP-milestone to prevent their implants from being lapsed. Implants not meeting the ODEP benchmark-criteria (Table 2) do not receive a rating.

Table 2. ODEP criteria for total hip and total knee implants

Total hip A* criteria	3A*	5A*	7A*	10A*	13A*	15A*
Minimum number of centres outside development centre(s)	3	3	3	3	3	3
Minimum number of surgeons outside of development centre(s)	3	3	3	3	3	3

Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	150	225	300	400	400	400
Maximum revision rate†	3.0%	3.5%	4.0%	5.0%	6.5%	8.0%
Total hip A criteria	**3A**	**5A**	**7A**	**10A**	**13A**	**15A**
Minimum number of centres and surgeons	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	72	66	60	51	42	40
Maximum revision rate†	5.0%	5.5%	6.0%	7.0%	8.5%	10.0%
Total hip B criteria	**3B**	**5B**	**7B**	**10B**	**13B**	**15B**
Minimum number of centres and surgeons	1	1	1	1	1	1
Minimum total cohort	100	100	100	100	100	100
Minimum at risk at benchmark time	40	40	40	40	40	40
Maximum value of 95% lower confidence limit for revision rate	3.0%	3.5%	4.0%	5.0%	6.5%	8.0%
Total knee A* criteria	**3A***	**5A***	**7A***	**10A***	**13A***	**15A***
Minimum number of centres outside development centre(s)	3	3	3	3	3	3
Minimum number of surgeons outside of development centre(s)	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	150	225	300	400	400	400
Maximum revision rate†	3.5%	4.0%	4.5%	5.0%	6.0%	6.5%
Total knee A criteria	**3A**	**5A**	**7A**	**10A**	**13A**	**15A**
Minimum number of centres and surgeons	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	66	60	55	51	51	45
Maximum revision rate†	5.5%	6.0%	6.5%	7.0%	8.0%	8.5%
Total knee B criteria	**3B**	**5B**	**7B**	**10B**	**13B**	**15B**
Minimum number of centres and surgeons	1	1	1	1	1	1
Minimum total cohort	100	100	100	100	100	100

Minimum at risk at benchmark time	66	60	55	51	45	42
Maximum value of 95% lower confidence limit for revision rate	3.5%	4.0%	4.5%	5.0%	6.0%	6.5%

†The upper 95% confidence interval for KM revision rate (1-Survival) must be lower than the specified level. Pre-entry A*-criteria: product launched under Beyond Compliance. Pre-entry A-criteria: product details supplied to ODEP.

We aimed to assess across multiple registries whether: 1) Higher (A*) ODEP-rated total hip and total knee implants have lower cumulative revision risks (i.e. better performance) than lower (A) ODEP-rated implants; and 2) the extent to which A*-rated implants would receive the A*-rating based on pooled revision risks across registries (i.e. using information about performance from all registries combined). Since the maximum revision rate for A*-rated implants is lower than for A-rated implants, we hypothesised that A*-rated implants have lower revision risks across registries than A-rated implants. Furthermore, we expected the majority of A*-rated implants to be A*-rated based on the pooled registries cumulative revision risk, as revision risks are also influenced by e.g. surgeon factors potentially affecting implant performances. We did not consider implants with a B-rating because they are assigned for implants with limited usage.

3.2 Main findings

European registries as identified in Chapter 2 were supplemented by non-European registries as listed on the website of the Australian registry. We matched the cumulative revision risks for specific hip and knee implants as reported by each registry to ODEP-ratings as reported on the ODEP-website based on implant name.

Nine registries reported on 583 unique total hip cups (2,615,890 implants), 618 total hip stems (2,567,442 implants), and eight registries on 634 total hip implants (2,266,864 implants) and 508 total knee implants (2,940,899 implants), of which 313 (54%) hip cups, 356 (58%) hip stems, 218 (34%) total hip implants, and 68 (13%) total knee implants were matched to ODEP-ratings. Percentages of ODEP-matching varied widely between registries: ranging 35-69% (hip cups), 46-80% (hip stems), 22-55% (total hip implants) and 6-20% (total knee implants). Reasons why implants could not be matched included that no ODEP-rating was available or that we could not assign an ODEP-rating because the registry information was not specific enough so that multiple (different) ODEP-ratings were possible. Since only 13% of the total knee implants were matched, they were not further analysed.

ODEP-matched cups and stems had significantly lower 5- and 10-year (cups also 3-year) cumulative revision risks (i.e. better performance) than unmatched cups and stems without an ODEP-rating, but had comparable cumulative revision risks compared to unmatched cups and stems with multiple ODEP-ratings (Table 3). ODEP-matched total hip implants had significantly lower CRR at all follow-up points compared with ODEP-unmatched total hip implants (Appendix 2).

Table 3. Performance of ODEP-matched versus ODEP-unmatched hip implants

	Matched implants		Unmatched – multiple ODEP ratings			Unmatched – no ODEP rating		
	Revision risk	N	Revision risk	N	Mean diff	Revision risk	N	Mean diff
Cups – 3 year	2.6%	1,270,520	2.5%	645,191	0.1% (-0.25;0.39)	3.2%	379,345	**-0.6% (-0.32;-0.94)**
Cups – 5 year	3.1%	1,406,957	3.2%	631,813	-0.1% (-0.49;0.30)	5.1%	370,942	**-2.0% (-1.37;-2.58)**
Cups – 10 year	5.6%	944,820	5.4%	506,671	0.2% (-0.79;1.11)	11.8%	196,116	**-6.3% (-4.43;-8.09)**
Stems – 3 year	2.7%	1,423,161	2.7%	165,456	0.0% (-0.47;0.46)	2.9%	692,944	-0.2% (-0.09;0.46)
Stems – 5 year	3.4%	1,418,673	3.4%	162,655	0.0% (-0.82;0.82)	4.2%	675,774	**-0.7% (-0.16;-1.30)**
Stems – 10 year	6.7%	1,004,520	5.7%	112,264	1.0% (-1.73;3.80)	8.8%	606,571	**-2.0% (-0.33;-3.74)**

Bold values indicate statistically significant differences ($p<0.05$)

With regard to the first research question, we found no overall differences in cumulative revision risks were found between A*- and A-rated total hip implants, but there was moderate to high heterogeneity within each group indicating substantial variation between implants. Exploring this heterogeneity, analyses were repeated by fixation which again showed no significant differences in cumulative revision risks for all analysed groups and heterogeneity remained. Within total hip implants where cups and stems from the same manufacturer were used, A*A*-implants had significantly lower 3- and 5-year cumulative revision risks than AA-implants. Within different manufacturer total hip implants, no significant differences were found. With regard to the second research question, we found that within the ODEP-matched A*-rated cups and stems, 39% cups and 42% stems would also get an A*-rating based on the pooled registries cumulative revision risk at 3-year, 44% cups and 35% stems at 5-year, and 30% cups and 5% stems at 10-year (Figure 3)

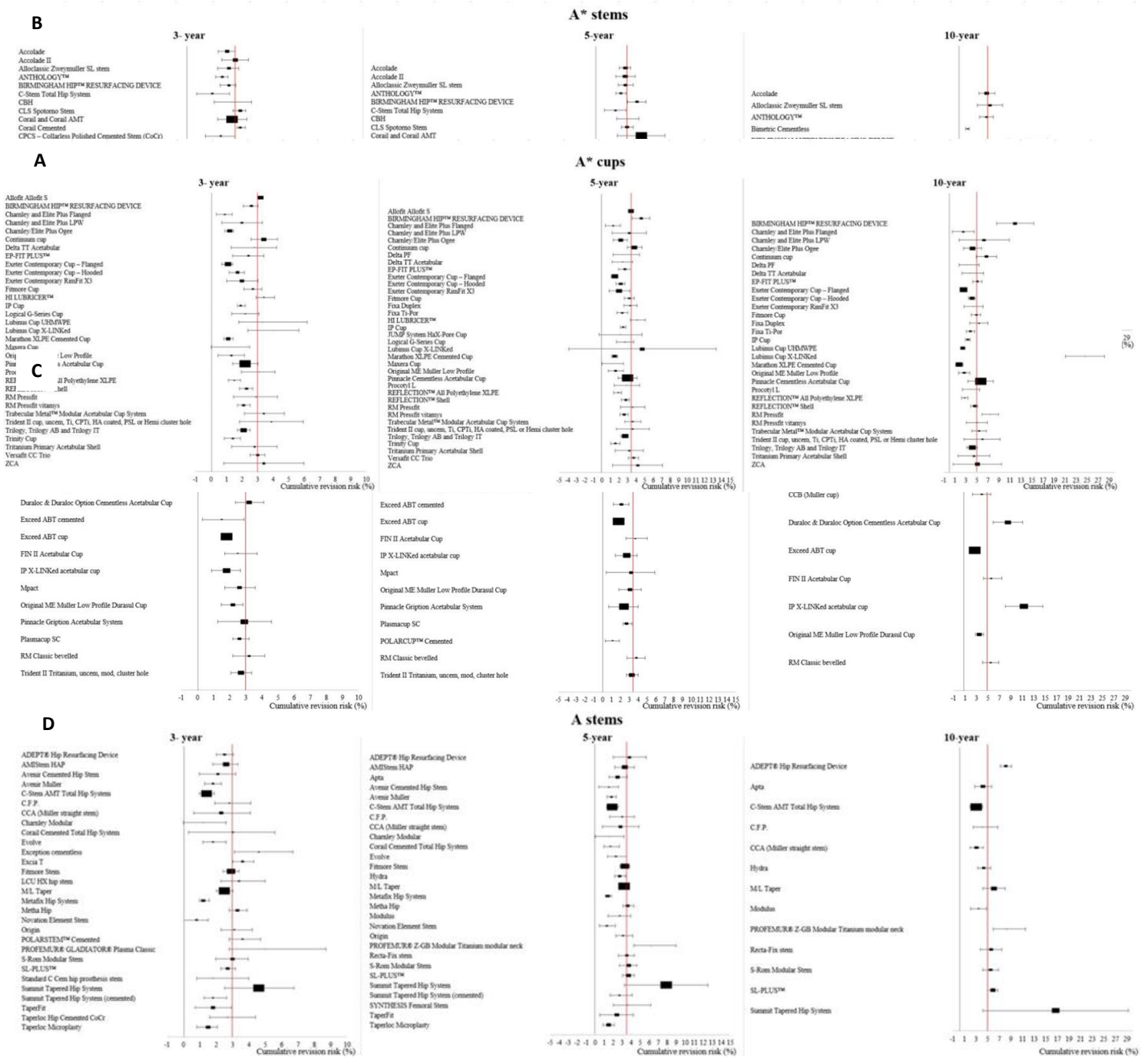


Figure 3. Pooled cumulative revision risks (3/5/10-year) across nine registries for A*-rated hip cups (A), A*-rated hip stems (B), A-rated hip cups (C) and A-rated hip stems (D) with the redline indicating the ODEP-benchmark

Cups and stems qualifying for an A*-rating based on the pooled registries cumulative revision risks, would get an A*-rating in a median of 1 registry at all follow-up points (range:0-4 (cups) and 0-6 (stems)). Three cups and stems would consistently get an A*-rating in all registries at 3-year, 4 cups and 2 stems at 5-year, and 3 cups and 0 stems at 10-year. Within ODEP-matched A-rated cups and stems, 24% cups and 31% stems would get an A*-rating based on the pooled registries cumulative revision risks at 3-year, 24% cups and 32% stems at 5-year, and 22% cups and 23% stems at 10-year (Figure 3). Cups qualifying for an A*-rating based on the pooled registries cumulative revision risks, would get an A*-rating in a median of 0 registries at all follow-up points (range:0-5). For stems these were: a median of 1 registry (range:0-2) at 3-year, 1 registry (range:0-2) at 5-year, and 0 registries (range:0-1) at 10-year. Zero cups and 1 stem would consistently receive an A*-rating in all registries at 3-year, 1 cup and 2 stems at 5-year, and no cup or stem at 10-year.

3.3 Conclusion and recommendations

ODEP-matched total hip implants had significantly better performance than unmatched total hip implants without an ODEP-rating, suggesting that clinicians and hospitals should be encouraged to use implants with an ODEP-rating. Within matched total hip implants, higher ODEP-rated implants did not differ in performance than lower ODEP-rated implants. Total knee implants were not analysed as only 13% of total knee implants reported by registries could be matched to an ODEP-rating, due to insufficiently detailed registry information so that multiple ODEP-ratings were possible.

A minority of A*-rated cups and stems (39% and 42% respectively) would be eligible for an A*-rating based on the pooled registries cumulative revision risks and assigned ODEP-ratings varying across registries, indicating that implants' performances vary across countries. In addition, part of the A-rated cups and stems (24% and 31%) would also receive an A*-rating based on the pooled revision risks across registries (i.e. information on performance from all registries). Therefore, registries should first validate ODEP-ratings to better guide implant selection in their country and preferable at the product-code-level to prevent camouflage (i.e. a total knee design may have different sub-types with the same brand name). Since ODEP-use is increasing globally, using revision data from at least two regional/national/multi-country registries with >95% implant-level completeness would increase the strength of evidence supporting ODEP-ratings.

4 Feasibility study to combine data across registries

4.1 Background and aim

Orthopaedic arthroplasty registries are well suited to play an important role in the post-market surveillance of knee arthroplasty implants as the majority of these registries provide publicly available annual reports including implants' survivorship data [7-10]. Registry data have proven that not all KA perform equally well, with some implants performing better (i.e. lower revision rates) compared with other comparable implants, while other implants have comparable performances (i.e. comparable revision rates), or worse performance (i.e. higher revision rates) [9,11,12]. These differences in performance can be caused by a variety of reasons such as differences in implant characteristics, surgeon related factors e.g. experience and performance, and patient characteristics such as Body Mass Index (BMI), age, American Society of Anesthesiologists (ASA) score (i.e. a measure of the health status of patients at the start of surgery), and gender [13,14]. Also, differences between registries have been found regarding the use of unicompartimental knee arthroplasty implants which may influence the characteristics of patients receiving total knee arthroplasty [15].

Only a few studies have assessed differences in patient characteristics across countries [16-18]. However, the majority of these papers only focused on variations in preoperative pain and function, and importantly, all these studies analysed all knee arthroplasty implants combined instead of analysing differences in patient characteristics on the implant level. Hence, a more comprehensive analysis of the similarities and differences in patients receiving specific knee arthroplasty implants is required to better understand differences in implants' performances across registries.

We therefore aimed to assess to which extent 1) patient characteristics for the same knee arthroplasty implants differ across registries, and 2) knee arthroplasty implants are used across all registries, at least in two registries or in a single registry.

4.2 Data and methods

We invited 8 registries to participate in this study: Danish Knee Arthroplasty Register, Dutch Arthroplasty Register, Italian Arthroplasty Registry, German Arthroplasty Registry, Norwegian Arthroplasty Register, Swedish Arthroplasty Register, Swiss National Hip & Knee Joint Registry and The National Joint Registry for England, Wales, Northern Ireland, the Isle of Man and Guernsey. We requested aggregated implant-level data based on all patients undergoing a primary knee arthroplasty between January 1, 2010 and December 31, 2021, separately for total knee arthroplasty and unicompartimental knee arthroplasty.

As the primary outcome, we compared each knee construct (i.e. tibia/femur combination) with other similar implants on the following patient characteristics across registries: mean age, mean BMI, % smokers, % with osteoarthritis diagnosis and % with ASA score≥3. Similar groups of implants were created based on 4 characteristics of knee implant designs: fixation (cemented/cementless/hybrid (i.e.

uncemented femoral component with cemented tibial component)/reverse hybrid (i.e. cemented femoral component-uncemented tibial component)), mobility (fixed/mobile+rotating), patella usage (yes/no), and stabilisation (fully stabilised/hinged/medial pivot/minimally (CR)/posterior (PS)).

Each registry would run the analyses as defined by a syntax supplied by the coordinating center (LUMC), which needed to be adapted to fit each specific registry due to e.g. different variable names. The syntax resulted in aggregated implant-level data on patient characteristics in that registry, to be sent to the coordinating center where data were pooled using meta-analysis methods. Data were first requested from the Dutch Arthroplasty register to develop and test the syntax.

4.3 Challenges encountered and recommendations

All registries were interested to participate but to supply the data required internal procedures to get approval, which required considerable time. In addition, testing the syntax on a new registry revealed that some adjustments needed to be made to fit the available data from all registries. Furthermore, preparing the data after approval required time and effort from local researchers for which no funds were available which meant it could not be prioritized and thereby caused further delay. The coordinating center with a designated researcher working on the project tried to help, for instance by manually classifying implant names in the Italian Register into the 4 characteristics required to create similar groups, as it was not available in the registry.

We started this feasibility study in October 2022, and by January 2024 have received data from 3 registries with 1 registry indicating to send their data in January and 1 registry where it is unclear when to expect the data. The analyses have therefore been delayed and will be conducted in February, to be followed by writing a paper.

We recommend future studies trying to combine data from several registries using federated network analysis to ensure time and funding for local registries, to harmonize the data into a common model.

5 Combining different sources of real-world data to detect safety problems

Methods to combine these safety notices with registry data are described in a draft paper that we aim to submit to the Journal of Bone & Joint Surgery (Am), which is included as Appendix 3. Below is a summary of the main findings.

5.1 Main findings

We compared published safety notices for total knee implants across 13 countries, with outlier total knee implants as identified by registries. The CORE-MD PMS tool (described in deliverable D3.2) was used to identify total knee implants with published safety notices on the websites of competent authorities in the following EU countries: Czechia, Denmark, France, Germany, Greece, Ireland, Italy, Portugal, Spain, Sweden and the Netherlands. In addition, the Australian (System for Australian Recall Actions (SARA)) and the USA (MD Recall Database) safety notices data were included. We included only the safety notices for total knee implants currently on the market, by using the brand names of total knee implants from the most recent annual reports of 8 registries as input for the CORE-MD PMS model (6 European registries, the Australian and American registry). Reported outlier total knee implants currently on the market were identified by screening the last annual reports and up-to-date websites from European registries identified in Chapter 2, as well as non-European registries as listed on the website of the Australian registry.

The CORE-MD PMS tool identified 104,638 safety notices of which 1,327 related to a total knee implant identified in the latest registry reports. Of these, 540 safety notices were excluded because they were not related to the knee implant itself (but e.g. associated with surgical protocols) which resulted in 787 safety notices included. These 787 safety notices were relevant to 38 unique total knee brand names. Most safety notices originated from the USA and the majority was associated with the Nexgen (Zimmer Biomet) (n=243, 31%). Four national registries (from Australia, United Kingdom, Sweden and Switzerland) reported outlier implants. In total, 35 unique outlier total knee brand names were identified. Combining the brand names of the 38 total knee implants identified by safety notices with the 35 outlier knee implants identified by registries resulted in 47 unique total knee brand names (Figure 4), of which 26 (55%) were in the “both” group, 12 (26%) in the “safety notices only” group, and 9 (19%) in the “outlier only” group.

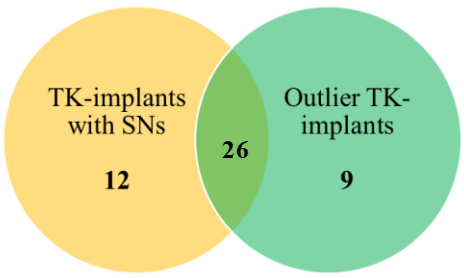


Figure 4. Overlap in safety notices (SNs) and outliers in registries signaling the same total knee (TK) implants

Considering the 26 total knee brand names in the "both" group, there was missing information in the safety notice on fixation for 7 (27%) implants, 9 (35%) had no information about their stability and 15 (57%) no information about their mobility, which would be needed to determine whether the exact same total knee implant was concerned. Focusing on specific variants to prevent camouflage, we could match 5 out of 26 (19%) cemented and 6 (23%) uncemented total knee implants with the same fixation. Two out of 26 (8%) cruciate retaining, 2 (8%) hinged and 9 (35%) posterior stabilised total knee implants had the same stability. One (4%) fixed, 1 (4%) mobile and 5 (19%) rotating total knee implants had the same mobility. However, 14 out of 26 (54%) cemented and 3 (12%) uncemented total knee implants were shown not to correspond to the same total knee implant. Six out of 26 (23%) cruciate retaining, 2 (8%) hinged and 7 (27%) posterior stabilised TK-implants did not correspond and 3 (12%) fixed, 5 (19%) mobile and 2 (8%) rotating total implants.

Part of the explanation for lack of overlap may be that the safety notices in the "safety notices only" group relate to a different type of problem that would not be expected to affect the performance of the knee prosthesis to require revision (on which outlier reports are based). All safety notices were therefore classified into IMDRF medical device problem codes. For the 26 implants in the "both" group, 728 safety notices were published with the most frequently reported problem "A02-Manufacturing, Packaging or Shipping" (43%), followed by "A23-Use of Device" (16%). The most frequent type of problem found was similar for the 12 implants in the "safety notices only" group (n= 59 safety notices published): "A02-Manufacturing, Packaging or Shipping" (44%). The only differences found between the two groups, is that problems relevant to "A05-Mechanical Problem" (6%) and "A17-Compatibility Problem" (8%) were also reported for the "both" group, whereas these were not encountered for the "safety notices only" group.

We also assessed whether implants in the "safety notices only" group had lower cumulative revision risks (i.e. better performance) than those in the "both" group, which might indicate why they were not yet identified as outliers. The pooled median 1-, 5-, and 10-year cumulative revision risks for the "safety notices only" group were 0.7% (range:0.3-1.2), 2.8% (range:1.4-4.0), and 3.9% (range:3.1-5.1) respectively, which were lower than the 1.6% (range:0.9-9.5), 6.3 (range:3.6-23.8), and 8.1% (range:5.6-23.8) for the "both" group.

5.2 Conclusion and recommendations

Publicly available safety notices issued by manufacturers and published by competent national authorities did not signal 9 of the 35 (26%) outlier total knee implants identified by registries with significantly higher revision rates, but also pointed to 12 implants not (yet) identified by registries. Safety notices might thus provide the first signal of a possible performance problem which could be used by registries, to analyse specific implants with released safety notices so that they can observe potential adverse trends in performance earlier. This highlights the potential of adopting a multifaceted approach, integrating various real-world data sources and methods to combine information to enhance medical device safety signal detection which would be beneficial for manufacturers, clinicians as well as competent authorities.

6 Achieving consensus on a minimal dataset to judge the quality and analysis of registry data

Methods to achieve consensus by using a Delphi approach are described in a draft paper that we aim to submit to Health Policy, which is included as Appendix 4. Below is a summary of the main findings.

6.1 Delphi study

A total of 101 international experts were invited across 4 stakeholder groups: i) 30 regulators and notified bodies, ii) 28 healthcare professionals particularly from the orthopaedic and cardiovascular field as these represent the majority of high-risk medical devices, iii) 24 experts involved in registries, and iv) 19 methodological experts e.g. on analysis of medical device performance. We aimed for at least 10 participants per stakeholder group to ensure sufficient sample size and distribution across groups.

A three-round Delphi study was conducted to achieve consensus, consisting of two online surveys and one online consensus-meeting. In round 1, participants created their individual minimum dataset by selecting items from an initial set of 27 items based on literature review (described in Chapter 2) and expert advice, and could add items which they felt were also required. We defined consensus as that a specific item was selected in at least 70% of the datasets across participants. In round 2, participants were first shown on which items there was already consensus, followed by discussion and voting which of the remaining items were needed in addition to those already selected. In round 3, participants were asked to rank the items included in the final minimum dataset across all participants, by assigning points to each item (from a total of 100 points). Even though all items in the minimum dataset were considered to be required, some more be more important than others and the average rank may guide regulators how much weight they should place on an item, as in practice a registry may score low on one item but higher on another.

6.2 Main findings

Of the 101 invited experts, 51 (50%) participated in the first round of whom 30 (59%) participated in the consensus-meeting and 38 (75%) completed round 3. After round 1, there was consensus on 10 of the 17 (59%) data quality items and 8 of the 10 (80%) items concerning analysis of medical device performance (Figure 5).

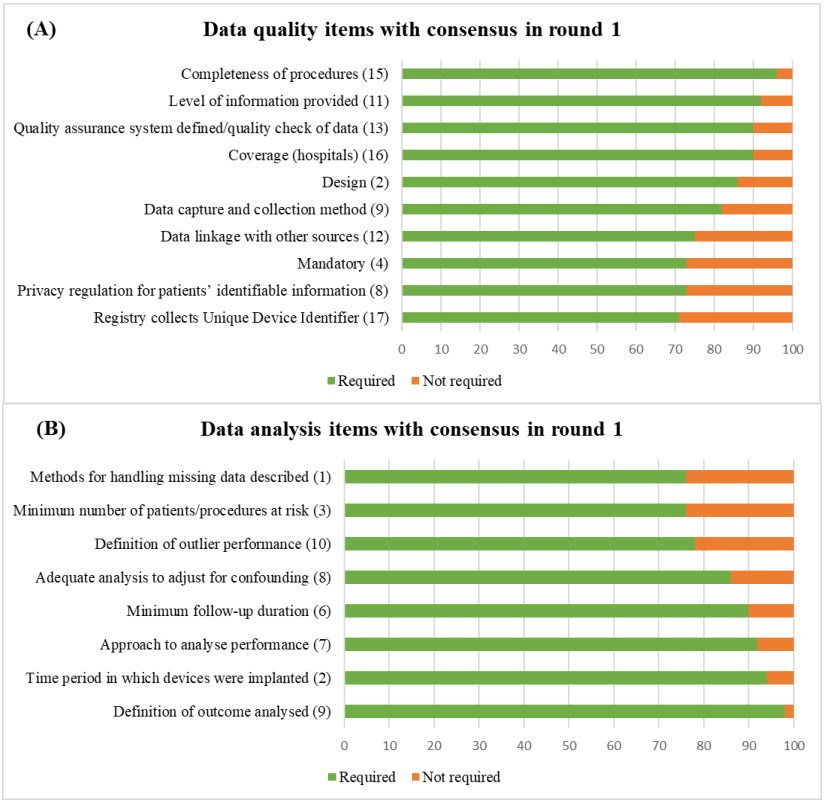
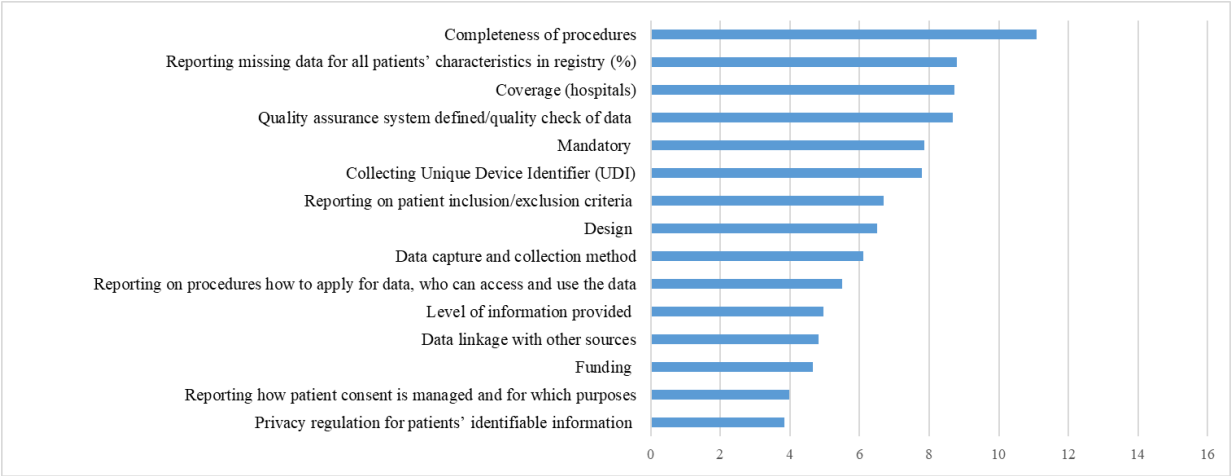


Figure 5. Items to be included in the minimum dataset after round 1, showing frequency by which each item was selected

During the consensus-meeting, 5 data quality items were added including 1 item suggested by one of the participants, and no data analysis items. The final minimum dataset thereby included 15 data quality of which reporting on the "Completeness of procedures" was considered most important, and 8 data analysis items of which reporting the "Definition of the outcome analysed" was considered most important (Figure 6).



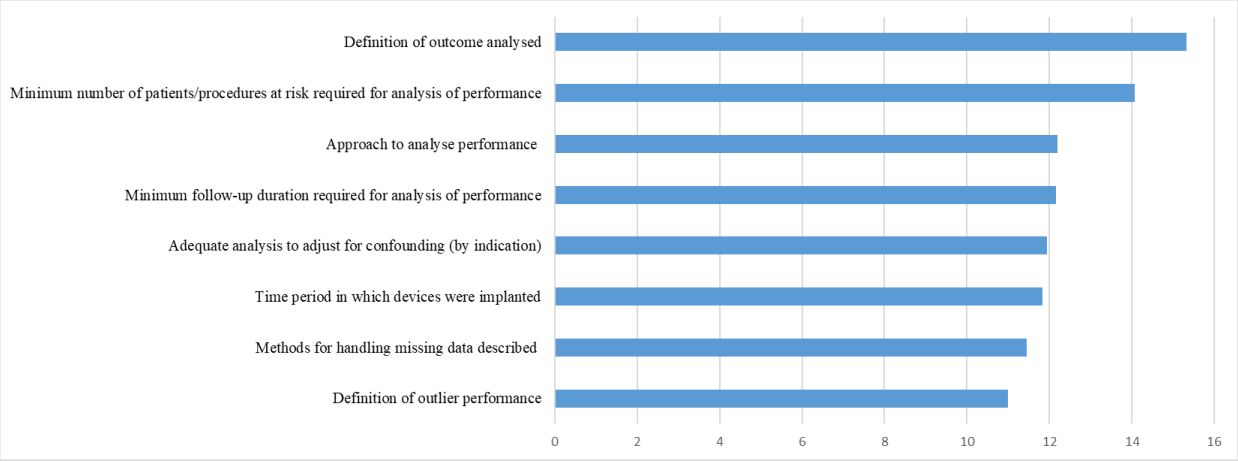


Figure 6. Data quality and data analysis items included in the minimum dataset, with the mean number of points assigned per participant

6.3 Conclusion and recommendations

Registries publicly reporting all 15 items on quality of registry data and all 8 items on quality of analysis would allow regulators to better judge the utility of registry data for the regulation of medical device performance and thereby increase their confidence in registry data during post-market surveillance. These items will often be known by registries but not always publicly reported. They provide more detail to previous reports that emphasized the importance of data completeness and accuracy [19,20]. Compared with FDA guidance, several selected items are similar such as common data capture, data verification procedures and data completeness [21] but also add new items such as reporting on funding or definition of outlier performance.

Achieving consensus on what items registries need to report to judge the quality of registry data and analysis of performance is an important first step. However, it does not make clear what constitutes sufficient quality data, particularly when good scores on some items are combined with worse scores on others. The ranking provided in the current study may guide regulators on which items the highest weight should be placed.

7 Decision framework to assess the performance of medical devices

The results from the activities conducted within Task 3.1 (on Aggregating insights from registries, big data, and clinical experience) exposed in the previous sections were used to construct a decision framework that can be used by regulators to assess the performance of medical devices during post-marketing surveillance, using registry data.

7.1 Background and development of the framework

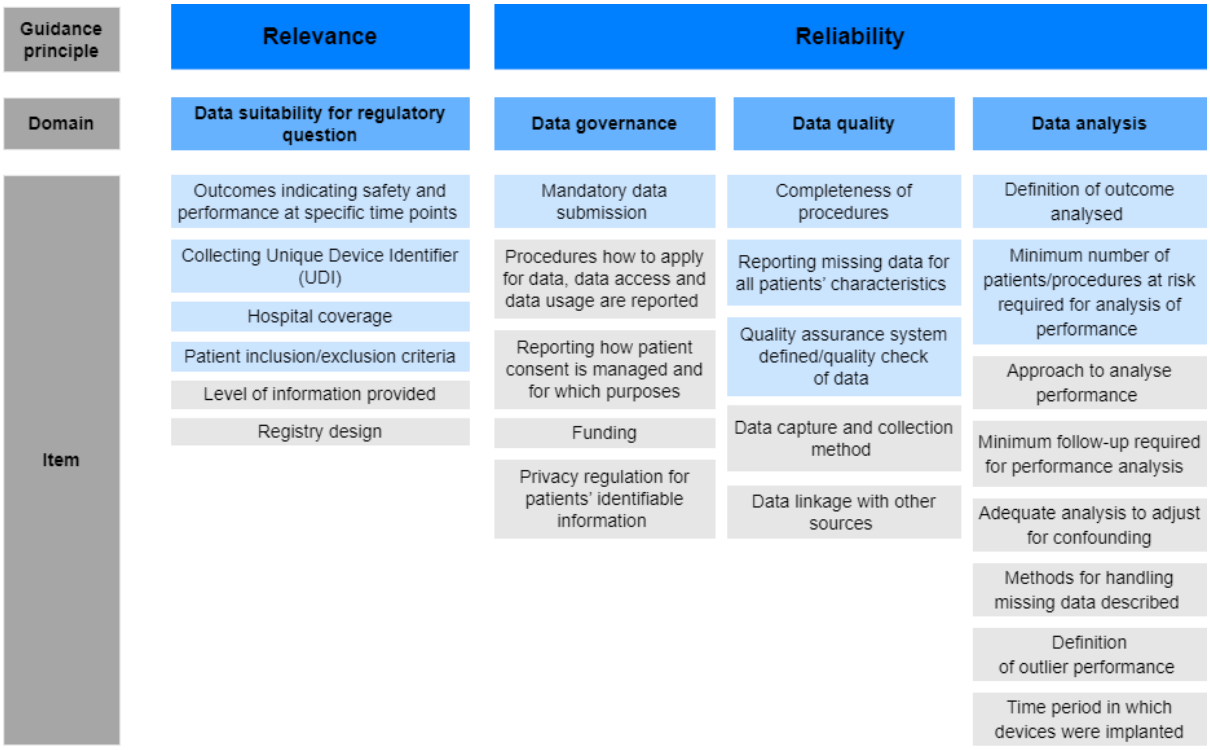
The FDA previously indicated that Relevance and Reliability were key factors when assessing real-world data [21], so we used these as guiding principles to construct the framework. They indicate under **Relevance** that the real-world data should contain sufficient detail to capture the use of the device, exposure and outcomes of interest in an appropriate population, and also specify that "the use of the device in a real-world population is representative as captured within the data source, and is generalizable to the relevant population being evaluated" [21]. In addition, they specify that the data elements available should be able to address the question at hand when valid, and that appropriate analytic methods are used. **Reliability** covers varies aspects of data collection such as common definition and a relevant time window, but also data quality such as adherence to source verification procedures.

The recently published UK NICE real-world evidence framework is not specifically developed for regulatory decision-making or specifically focused on medical devices, but more broadly it covers various sources of real-world data (including registries) to support those developing evidence to inform NICE guidance [20]. As principles, they highlight that data should be "of good provenance, relevant and of sufficient quality to answer the research question", that evidence should be generated in a transparent way and using "analytical methods that minimise risk of bias and characterize uncertainty". [20]. Under **data provenance**, they consider knowledge about the purpose and methods of data collection to be important, as well as data coverage and governance. Relevance focuses on generalizable and robust results, where completeness and accuracy are key factors considered for data quality.

In both FDA and NICE guidances, rather general descriptions are given (with some examples) but they also indicate that other factors may be considered and that contextual factors may determine the acceptability of the evidence; e.g. high-quality evidence may be more difficult to generate for rare diseases. Thus they do not specify a minimum dataset of what registries should report, to allow regulators to assess the quality of the data showing the performance of medical devices. We therefore mapped the items on which consensus was achieved in the Delphi study (Chapter 6) to the more generic principles and domains as found in previous FDA and NICE guidance.

Within the relevance principle, we considered whether the data were suitable to answer regulatory questions, which requires consideration of the outcome of interest (to assess safety and performance),

an appropriate representative population, and sufficient detail on device characteristics to allow fair comparison with similar devices (Figure 7).



Items in light blue boxes were assigned higher relative weight by respondents in the Delphi study.

Figure 7. Decision framework to assess performance of medical devices

As shown in our systematic review of European medical device registries, there is large heterogeneity in the outcomes captured by registries and in the time-points at which outcomes are recorded, as well as lack of clarity about which of these outcomes could be included to calculate the benefit-risk ratio for the intended purpose of a particular medical device [7]. Three items from the minimal dataset (Chapter 6) can be used to gain insight into the extent to which an appropriately representative population has been captured (i.e. coverage, patient inclusion and exclusion criteria, and registry design), one item on the level of information which determines the type of question for which the data can be used (hospital-level, surgeon-level, or medical-device level), and one item to ensure that sufficiently detailed information has been documented about the performance of the device (Unique Device Identifier). The last of these can also be used to create groups of similar devices, as shown in the feasibility study to combine data from different registries (Chapter 4). With respect to the reliability principle, the recommended framework distinguishes characteristics related to data governance (5 items), data quality (5 items) and data analysis (8 items).

7.2 Methods to disseminate the framework

Several methods can be used to disseminate the framework so that all stakeholders will become aware of the value of the framework and how it can be used in the regulatory process for evaluating performance and safety (benefit / risk) of the medical device. Part of these methods have already been employed and others are recommended for further dissemination.

As the first step, the framework and how it was developed has been presented and discussed at two conferences: the CORE-MD conference (15-3-2024) and during a dedicated regulatory session at the annual International Society of Arthroplasty Registries (ISAR) conference (2-6-2024). These conferences were attended by various stakeholders, including healthcare professionals, registry experts, manufacturers, notified body experts, and regulators. We have also submitted the manuscript describing the results of the Delphi study to a scientific journal, in which the framework is included in the discussion (see updated Appendix A4). Once accepted for publication, the framework will also be made available online on the CORE-MD website with reference to the scientific paper. These activities provide stakeholders with access and increase the knowledge of the framework.

As noted in Chapter 2, the International Society of Arthroplasty Registries has already taken further initiatives towards implementation of this framework, by recommending all of their member registries to report on these items, to be published on their website and in a scientific paper. This would mean that the items included in the framework will be readily available across these orthopaedic registries, not only for the benefit of regulators, notified bodies and manufacturers, but also to improve data comparison and interoperability between registries when analysing orthopedic medical devices. Combining data from medical device registries is crucial to detect any safety and performance concerns related to medical devices as early as possible, in order to prevent patient harm, which will only be achieved if the data are of sufficient quality. As for cardiovascular medical devices, the EuroHeart registry can use the above framework in a similar way when supplementing the disease information in their registry with data to be collected for medical devices. Given the generic nature of the framework and items included, it can likely also be used by other registries outside the orthopaedic and cardiovascular fields (e.g. registries on outcome of surgical oncology procedures).

As next steps, registries can define what is considered sufficient e.g. with regard to completeness of data, and sufficient for their context e.g. with regard to the minimum number of patients at risk and follow-up duration to analyse performance. In addition, they may consider harmonizing definitions of outcomes and outlier performance across registries, to work towards common registry outcome data that will facilitate pooling of data in federated network analysis using data across several registries.

Further work is needed to ensure different stakeholders will use the framework in the regulatory process and to evaluate the experience with the framework when evaluating medical devices. Manufacturers can use the framework to validate the quality of their data on real-world outcomes for patients receiving a specific medical device across all clinical practices (and not only in a selective study population), which is

also required by the MDR as part of post-market surveillance. If registry data are submitted to regulators and all items, or at least the items deemed most important (indicated in blue), indicate good quality data and analysis, then such real-world evidence can be considered trustworthy. To achieve this, may require additional guidance (in an annex) to specify the quality of the real-world evidence and to refer to the framework for the items to be considered. Notified bodies may use the framework as part of their assessment whether manufacturers have planned and conducted the post-market surveillance in a correct manner, by checking whether the quality of the real-world evidence has been validated and is of sufficient quality.

As the expert panels under the MDR evaluate also the reports of notified bodies in case of novelty of a medical device, dissemination of the framework to these expert panel members as well as education with respect to judging quality of data and analysis (e.g. signal detection) is important. Prof. Nelissen is chair of the thematic expert panel orthopaedics, traumatology, rehabilitation, rheumatology as well as an active member of the CORE-MD consortium. He will facilitate further dissemination by acting as champion with good knowledge of the framework as well as interpretation of real-world evidence and how to use this to inform on clinical evidence and the benefit-risk ratio of these medical devices.

Developing further education for stakeholders (e.g. expert panels, manufacturers) on methodologies of evaluating medical devices and on the use of real-world data, while applying the CORE-MD framework to check the validity of data and also including aspects such as signal detection, will further facilitate the safe introduction of innovative implants. Regulators may also use the framework to determine whether the data may be reliable for the evaluation of medical device safety and performance, guided particularly by the items deemed more important, but might also benefit from additional education on interpretation and use of real-world evidence. Finally, since registries could score "sufficient" on one item, but "insufficient" on another, further investigations are needed to determine the thresholds to indicate sufficient quality data, for each item as well as for various combinations. Next steps may also include what is considered acceptable uncertainty when presented with different quality of real-world evidence, which may vary for different situations or stages (e.g. rare diseases or unmet medical need).

8 Summary and conclusions

A decision framework was developed capturing both characteristics to judge the quality of registry data, endpoints used to determine performance and safety, and propose methodology and criteria to assess performance of these medical devices so that registry data can be leveraged to supplement evidence from RCTs on performance and safety of high-risk medical devices in the post-marketing phase. Cardiovascular and orthopaedic registries were used as an example as they constitute the majority of high-risk medical devices.

In our review of 20 cardiovascular (coronary stents and valve repair/replacement) and 26 orthopaedic (hip/knee prostheses) European registries we found large heterogeneity and incomplete transparency in quality items reported that relate to their structure and methodology as well as in the endpoints used and definitions. This suggests that it would currently be difficult for registries to report on common principles. The latter is needed for regulators to judge the quality of evidence generated by registry data. Registries should agree on such common principles with respect to defining variables and collecting data, thus reporting on comparable information across Europe.

The external validation of ODEP-ratings across 9 registries showed variable performance of the same hip implants across registries, with only a minority of the highest rated hip cups and stems receiving the same rating based on the pooled evidence across all registries. Therefore, performance assessed in one country, which complies with an absolute benchmark such as ODEP, would not necessarily translate to other countries. This emphasizes the importance that data from multiple registries would provide stronger evidence on the performance of a medical device, thereby safeguarding patient safety.

We encountered multiple challenges when assessing the feasibility to combine patient-level data across registries using a federated network analysis approach. Even though all registries were willing to participate, harmonizing the data requires significant time and effort for which no funds were available and resulted in delay. Future studies undertaking federated network analysis might benefit from first defining common registry outcome data and having funds available to ensure sufficient time and priority.

Combining registry data with evidence from safety notices showed that there was overlap but also that safety notices did not signal about a quarter of the outlier total knee implants identified by registries as having significantly higher revision rates. On the other hand, safety notices also pointed to 12 implants not (yet) identified by registries. This highlights the potential of adopting a multifaceted approach, integrating various real-world data sources and methods to combine information to enhance medical device safety signal detection which would be beneficial for manufacturers, clinicians as well as competent authorities.

In our Delphi study, we achieved consensus across 50 experts from different stakeholder groups on the minimal dataset for registries to report 15 items on quality of registry data and 8 items on quality of analysis to allow regulators to better judge the utility of registry data during post-market surveillance. Completeness of procedures, reporting missing data, definition of the outcome analysed and a minimum

number of patients at risk to analyse performance were considered most important, which may guide regulators when assessing registry data as they will often have better scores on some items and worse on others.

The final decision framework incorporated these findings and used relevance and reliability as the guiding principles, to follow previous regulatory guidance on real-world evidence. Data suitability, data governance, data quality and data analysis were taken as the key factors to be assessed, and items from the minimal dataset could be mapped within these factors. This framework is likely valuable for manufacturers to perform the required clinical evaluation and for notified bodies to do their assessment, for competent authorities to perform their market surveillance tasks and for clinicians and patients to establish their own insights on a device.

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Appendices

A.1 Appendix 1: Systematic review published in Int J Health Policy Manag

Quality and Utility of European Cardiovascular and Orthopaedic Registries for the Regulatory Evaluation of Medical Device Safety and Performance Across the Implant Lifecycle: A Systematic Review (Int J Health Policy Manag 2023:12:7648. doi: 10.34172/ijhpm.2023.7648)

Background

A vital mechanism for assuring safety and performance of high-risk medical devices in patients is that they are subject to systematic post-market surveillance, which includes the collection of high-quality clinical data by registries. For regulatory purposes, such post-market clinical follow-up (PMCF) is mandatory for cardiovascular devices like stents and valves and for orthopaedic devices like hip and knee implants.

The International Medical Device Regulators Forum (IMDRF) defines a medical device registry as “an organized system with a primary aim to increase the knowledge on medical devices contributing to improve the quality of patient care that continuously collects relevant data, evaluates meaningful outcomes and comprehensively covers the population defined by exposure to particular device(s) at a reasonably generalizable scale (eg, international, national, regional, and health system).”[1] A medical device registry is thus an unselected population-based health information system collecting large numbers of real-world data regarding safety and performance of specific devices over time, with the aim to improve the quality of patient care,[1-4] and therefore well suited to provide clinical evidence on PMCF of devices for regulatory purposes.

The European Medical Device Regulation (MDR) requires manufacturers to plan and conduct surveillance of their devices (see Article 83 of (EU) 2017/7455), but the list of sources of available information that can be used for this purpose includes “relevant specialist or technical literature, databases and/or registers” and “information, including feedbacks and complaints, provided by users, distributors and importers” (see Annex III, clause 1.1(a)).[5] Real-world data collected by medical device registries are particularly useful as they enable continuous benchmarking across longer follow-up in many more patients than enrolled in clinical trials.[6-10] The utility of medical device registries organized by medical professional associations is exemplified by the case of the ‘‘Metal on Metal’’ (MoM) hip implants. Originally developed as a more durable alternative to implants with ceramic or polyethylene components, mid-term follow-up registry data of patients with MoM showed far higher revision rates when compared with other implants.[11] The Australian Orthopaedic Association National Joint Replacement Registry identified these implants as having an outlier performance, three years before their withdrawal from the market in 2010.[12-14] For cardiovascular diseases, device registries

have provided important insights on the safety of coronary stents, by documenting increased rates of low-frequency events such as stent thrombosis with specific stent platforms.[15,16]

Principles have been proposed by regulators to evaluate whether the quality of clinical data on medical devices meets the scientific standards to be used for PMCF. They include coverage (ie, extent of participation in data collection), completeness (ie, data used in analyses are consistently captured), accuracy (ie, data recorded is an accurate reflection of the healthcare event), consistency (ie, uniformity in following the same procedures for data capture), integrity (ie, consistent recording of unique identification of medical devices), and reliability (ie, reproducibility of data elements).[1] Specific criteria have not been proposed, however, and it is therefore unknown if existing medical device registries in Europe would allow manufacturers to meet the MDR requirements to an acceptable standard. As part of the Coordinating Research and Evidence for Medical Devices (CORE-MD) project, this systematic review therefore aims to: (1) identify current European cardiovascular and orthopaedic medical device registries, and (2) review these registries by 33 items that related to their structures, methodologies, and quality of data.

Methods

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and MetaAnalyses (PRISMA) 2020 guidelines,[17] and it was registered in the Center for Open Science in October 2021 (https://osf. io/7yuwx/) prior to data collection.

Search Strategy

A previous study identified European registries on implantable medical devices [18] from which we adapted and updated its search strategy in order to identify new registries and expand the list of registries for this systematic review. Eight literature libraries (Centre for Reviews and Dissemination York, Cochrane library, Embase, Emcare, Google Scholar, Medline, PubMed, and Web of Science) were searched for publications between January 1, 2013 and July 7, 2021, using a systematic search strategy (Supplementary file 1) created by a librarian (JWS). References were imported to EndNote (Version X9, Clarivate Analytics, Philadelphia, the USA) which was used to remove duplicate publications, and subsequently exported to the web application Rayyan (Doha, Qatar) [19] which was used for study selection.

Study Selection

Two reviewers (LAH and THG) independently screened titles and abstracts and then independently assessed eligibility of full texts. Discrepancies were resolved by discussion. If consensus could not be reached, the senior researcher (PJMvdM) was consulted for a decisive vote. Studies were included firstly if they described a European regional, national, or multi-country cardiovascular medical device registry in which data were captured on coronary stents and/or on percutaneous or surgical valve repair or replacement. We focused on coronary artery stents as they are commonly used high-risk devices with a

low frequency of adverse events so that a large number of patients is needed to detect safety issues, and on valve prostheses because there are many new devices for which guidance is needed on benchmarking safety and performance. Secondly, we also included European registries capturing data on hip and/or knee prostheses since they are the most common orthopaedic high-risk devices. By applying these criteria and by excluding multicenter studies, we complied with the IMDRF definition of a registry,1 which is particularly relevant to evaluate implant performance in the entire population receiving such a device in daily practice, rather than in selected (high performing) centers. Additional inclusion criteria were: (i) an active/accessible website at the time of study collection; or (ii) at least one publication and/or annual report containing registries' data between 2013 and 2021. We defined an "active registry" as a registry that published at least one annual report and/or peer-reviewed paper containing registries' data, during or later than 2018. The reason for making a distinction between "active" and "non-active" registries is to give a better estimate regarding the number of registries able to contribute evidence for regulatory purposes in practice. In addition, "active" registries may also report the structural and methodological characteristics determining the quality of the data more consistently. No language restriction was applied. Data were extracted from any peer-reviewed publication(s) that described the registries' structure and methodology, and combined with data from the most recent published annual report(s) (if available) and/or registries' website (if available). To identify any more registries that were not yet included in this review, the references in publications and annual reports were checked, and clinical experts were consulted (five for the cardiovascular and eight for the orthopaedic field). For orthopaedic registries, we also checked the list on the EFORT —Network of Orthopaedic Registries of Europe (NORE)— website (https://efortnet.efort.org/nore-map/#/nore/map-all).

Data Extraction and Analysis

Based on the literature including a study reporting best practice recommendations,[20] LAH and PJMvdM developed a list of items that could be used to assess registries' structures and methodological characteristics, reflecting the previously mentioned principles [1] and therefore relevant to judge the quality of registry data for regulatory purposes as required by the MDR. These were sent to 13 experts in the cardiovascular (n=7) and/or orthopaedic (n=6) fields, for feedback and suggestions of relevant additional items. Consensus was reached on a total of 33 quality items covering six domains: (1) Identification (6 items) to understand which population the registry intends to describe; (2) Maturity (3 items) to contextualize the numbers of procedures and extent to which longer-term outcomes may already be captured; (3) Governance (5 items) to enable assessment of the integrity of data; (4) Coverage, design & organisation (8 items) to reflect the aforementioned principles of coverage and consistency; (5) Data quality & completeness (4 items) to reflect the aforementioned principles of completeness and accuracy, and (6) Safety & performance (7 items) to capture reliability of data in using standard definitions to assess safety; details of each item are given in Box 1. Data were also collected on: (i) the number of peer-reviewed publications since foundation of the registry, as an indicator of

scientific utility; (ii) the number of included manufacturers and the total number of patients/ procedures, to indicate the average experience with a specific device, that would potentially be relevant when assessing the performance based on a minimum sample size to obtain reliable estimates, and (iii) reported outcomes, including definitions and durations of follow-up. Using a prespecified format, publicly available data were extracted independently by LAH and THG for each registry and each item. Otherwise, items were recorded as ‘‘Not reported” (N/R). Median values (given the skewed distributions) and interquartile ranges (IQRs) were calculated for the percentage of items reported per domain and across all domains, for both cardiovascular and orthopaedic registries. Analyses were performed using Microsoft Excel (Excel version 2012, Microsoft, Redmond, the USA).

Box 1: Description of the items in each domain that were extracted for each registry

Identification 1. Class of device (cardiovascular registries – stents / cardiovascular registries – valves / cardiovascular registries – combined) / (orthopaedic arthroplasty registries – combined / orthopaedic arthroplasty registries – hips / orthopaedic arthroplasty registries – knees) 2. Name of registry 3. Initial motivation / goal to set up the registry 4. Country (country or countries in which the registry is conducted) 5. Design (regional/national/multi-country) 6. Website (available yes/no)
Maturity 7. Starting year (year of first patient/procedure included) 8. First annual report (year of publication) 9. Most recent (or last, if registry no longer active) annual report (year of publication)
Governance 10. Mandatory (if mandatory for surgeons/hospitals to submit to the registry; yes/no) 11. Patients’ consent (patients’ consent required before entering their data to the registry; required/not-required) 12. Funding (public/private/both) 13. Who can access the data and see results? 14. Privacy regulation for patients’ identifiable information (privacy regulation reported as implemented: yes/no? And if yes: how?)
Coverage, design & organisation 15. Number of participating hospitals and % of hospital-level coverage (defined as number of participating hospitals relative to the total number of eligible hospitals)

16. Number of patients/procedures (cumulative total in registry) 17. Number of selected patients/procedures in study population (if cumulative total in registry is not reported) 18. Annual number of patients/procedures in registry 19. Data capture and collection method (e.g. electronic/manual/barcodes-industry/surgeon-reported) 20. Method of access to registry for users/members (e.g. dashboard/real-time/secure server) 21. Level of information provided (data is reported at hospital/medical device/surgeon level) 22. Data linkage with other sources (e.g. registry data is linked to hospital statistics/manufacturer vigilance data/national competent authority on medical devices)
Data quality & completeness 23. Quality assurance system defined/quality check of data (e.g. data verification) 24. Missing data for patients' characteristics reported (%)(e.g. BMI, ASA classification, gender) 25. Methods for handling missing data described 26. Data completeness reported at patient/procedure-level (%)
Safety & performance 27. Frequency of feedback provided to surgeons/hospitals (e.g. annually/quarterly) 28. Level of feedback information provided (e.g. hospital/medical device/surgeon level) 29. Feedback time period (the duration of observation before assessment of performance is possible) 30. Outlier reports procedures (the type of outlier reports or procedures a registry has established and published methods to define outlier performance) 31. Accessibility of outlier results (e.g. publicly available or only accessible for individual hospitals/surgeons/members). 32. Definition of an outlier (e.g. using funnel plots) 33. Number of outliers identified (has this registry identified and published details of any specific hospitals/medical devices/surgeons with outlier performance?)

Results

Literature Search

The searches identified 4538 cardiovascular and 4485 orthopaedic publications, of which 1727 cardiovascular and 1360 orthopaedic publications remained after removing duplicates. Title and abstract screening identified a total of 81 cardiovascular and 27 orthopaedic registries, mentioned in publications from January 2013 to July 2021 (Figure 1). Twelve cardiovascular registries were excluded because they focused on other cardiovascular devices (eg, pacemakers) (n=11) or no devices (n=1) and a further 51 cardiovascular and seven orthopaedic registries were excluded during full-text screening, mostly because of reporting on a single or multicenter study, or due to registry mergers (Figure 1). Manual search identified two additional cardiovascular [21,25] and six orthopaedic registries,[47,51,53,57,60,66] that did not publish any peer-reviewed papers and therefore were not

found in the literature search. Thus, a total of 20 cardiovascular [21-40] and 26 orthopaedic registries [41-66] were selected for data extraction.

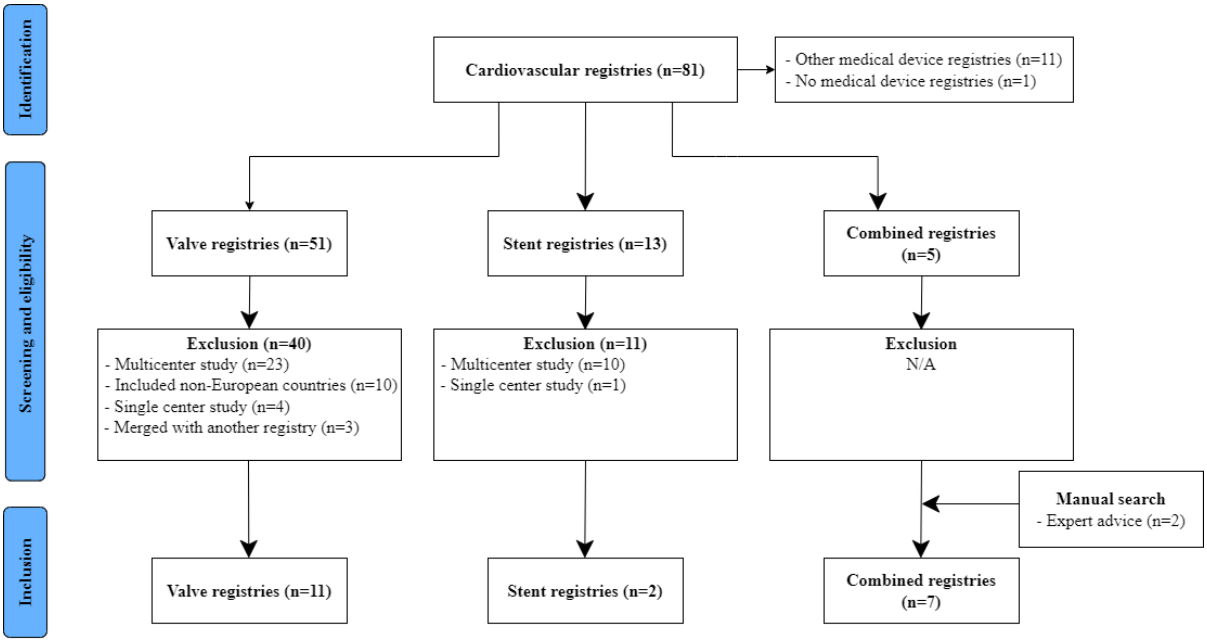

Figure 1A: PRISMA flowchart – Cardiovascular registries

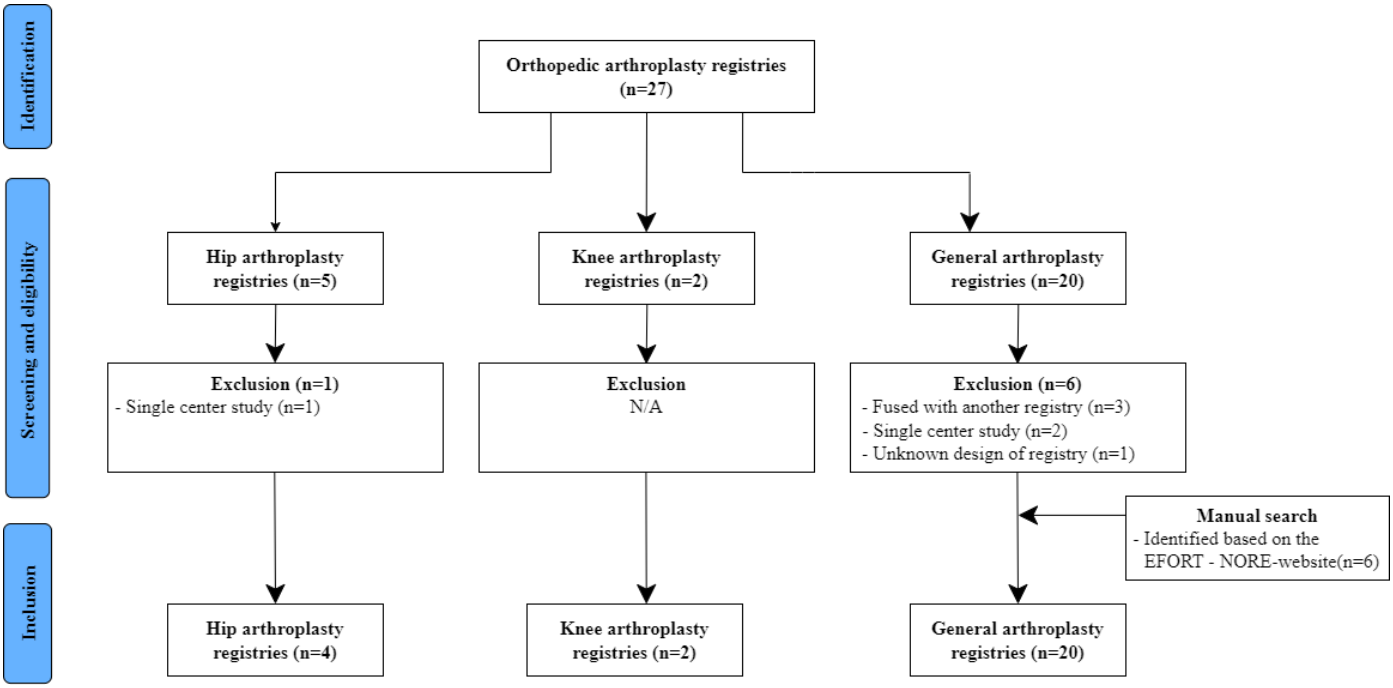

Figure 1B: PRISMA flowchart – Orthopaedic registries

Overall Findings

Across all domains, a median of 33% (IQR 14%-71%) of the predefined 33 quality items were reported by cardiovascular registries and 60% (IQR 28%-100%) by orthopaedic registries. The highest median value was reached for the domain 'Identification' since almost all registries reported information on eg, the type of registry: 75% (IQR 69%- 100%) for cardiovascular and 100% (IQR 100%-100%) for orthopaedic registries (Figure 2). The lowest percentages were observed for the domains 'Data quality & completeness' and 'Safety & performance'; for cardiovascular registries these were respectively 25% (IQR 0%-25%) and 0% (IQR 0%-4%) and for orthopaedic registries they were 38% (IQR 0%-69%) and 50% (IQR 0%-71%) (Figure 2).

Domains "Identification" and "Maturity"

The majority of included registries (41 out of 46; 89%) were national registries, [21-26,28-48,51,53,54,56-66] with only 3 (7%) regional registries [27,52,55] and 2 (4%) multi-country registries [49,50] (Table S1A and S1B, Supplementary files 2 and 3). The first cardiovascular registry was founded in 1978 [23] and the two most recent in 2013, [35,37] while the first orthopaedic registry was established in 1975 [65] and the most recent in 2019.[53] Initial motivations to set up a registry were mostly reported (by 60% of cardiovascular [21,23,25-27,29,33,35-37,39,40] and 92% of orthopaedic registries [42-44,46-66]) and often involved ensuring patients' safety. More orthopaedic than cardiovascular registries publish annual reports (77% versus 30%), although for some registries (35%) data were last reported more than four years ago and therefore labelled as ''non-active'' (Table). Of the active registries (65%), a median of 43% (IQR 25%-80%) of the 33 quality items were reported by cardiovascular registries and 75% (IQR 41%-100%) by orthopaedic registries (Figure 3).

Domains "Governance" and "Coverage, Design & Organisation"

Mandatory enrolment of eligible patients was implemented in 8 (40%) cardiovascular [22,24,27,29,30,37,39,40] and 12 (46%) orthopaedic registries [42,43,46,48,50,51,55,56,59,60,62,64] (Table S2A and S2B). Few cardiovascular [21,24,27,29,35-37,39,40] and orthopaedic [42-44,46,53,54,61-63,65] registries have reported on their funding and few report on the patient informed consent process [24,25,27,29,31,33-37,39,40,42,44,46,48,50, 54,60,63,64] (Table S3A and S3B). The number of participating hospitals per registry varied largely, with a median of 28 (IQR 17-89) hospitals for cardiovascular registries and 71 (IQR 42-116) hospitals for orthopaedic registries (Table S4A and S4B). The proportion of all eligible hospitals that participated in the registry (ie, hospital-level coverage) was only reported by 6 (30%) cardiovascular registries, [24,26-28,31,34] with a median hospital-level coverage of 100% (IQR 98%-100%) and by 9 (35%) orthopaedic registries, [44-46,48,52,54,60,64,65] also with a median hospital-level coverage of 100% (IQR 95%-100%) (Table S4A and S4B).

In general, cardiovascular registries report on studies for which selected patient groups are included, so

data on the total number of patients receiving an implant were reported by only 4 (20%) registries. [21,25,29,34] The median for stents was 12 395 (IQR 3985-201 647) and the median for valves was 2325 (IQR 861-10 479) (Table S4A and S4B). Given the regular publication of annual reports, the total and annual volume of implant procedures in orthopaedic registries was mostly reported; details were on both items was not available for 7 (27%) registries. [41,45,47,49,53,54,61] Overall, orthopaedic registries reported on a median of 120 408 (IQR 52 391-218 445) hip implants and a median of 102 649 (IQR 51 700-194 076) knee implants (Table S4A and S4B). Data linkage with other sources—mostly national clinical databases—was reported by 8 (40%) cardiovascular [21,24,27,29,34,36,37,39] and 14 (54%) orthopaedic registries. [42,44-46,48,50,52,54,55,60,62-65]

Information was mostly provided on hospital and/or device-level, while in some cases also surgeon-level information was provided. There were more different types of implants in orthopaedic than in cardiovascular registries, shown by totals of 37 different manufacturers for knee implants and 63 for hip implants compared with 13 different manufacturers of valves and 11 of stents (Table S5A and S5B).

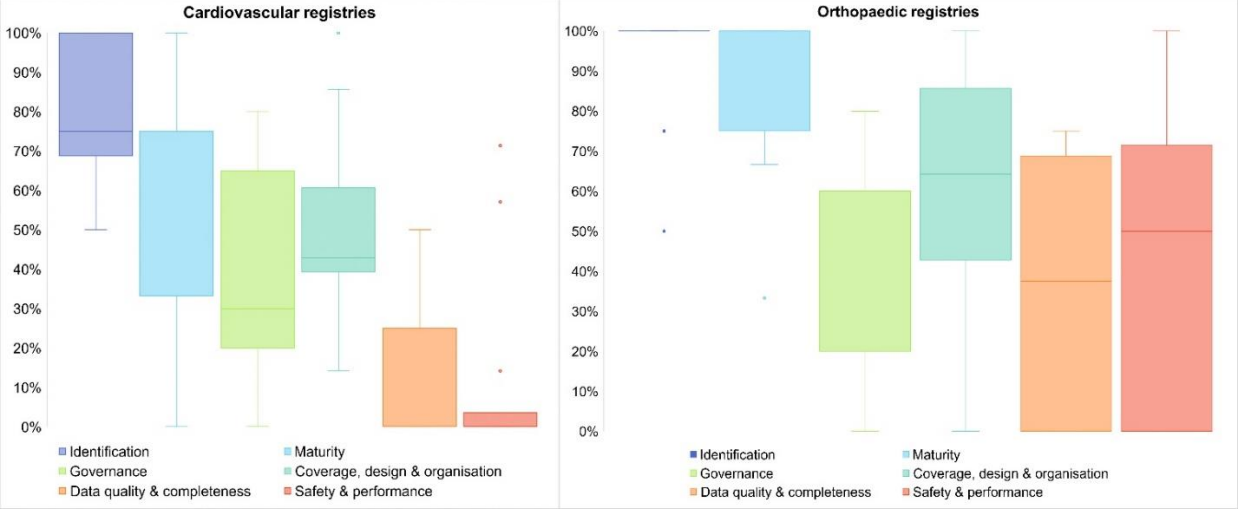

Figure 2: Reported items by cardiovascular (left) and orthopaedic (right) registries in each domain indicating the variation in reporting across registries (with the lower end of the boxes representing the 1st quartile and the higher upper end the 3rd quartile; the solid lines in the boxes representing the median values (if not visible the solid lines are at the same level as the 1st or 3rd quartile); the T-shaped whiskers the maximum or minimum values (without outliers); the individual points representing outlier values)

	Published paper(s) containing registries'data (2018 and beyond)	Published annual report(s) containing registries'data (2018 and beyond)	Active registry
Cardiovascular registries – combined			5 out of 7 (71%)
British Cardiovascular Intervention Society	No	Yes	Yes
East Denmark Heart Registry	No	No	No
German Society for Thoracic and Cardiovascular Surgery	Yes	Yes	Yes
Polish National Database of Cardiac Surgery Procedures	Yes	No	Yes
Portuguese National Registry of Intervention Cardiology	No	No	No
Spanish Cardiac Catheterization and Coronary Intervention Registry	Yes	Yes	Yes
Western Denmark Heart Registry	Yes	No	Yes
Cardiovascular registries – stents			2 out of 2 (100%)
Polish National Percutaneous Coronary Intervention Registry	Yes	No	Yes
Swedish Coronary Angiography and Angioplasty Registry	Yes	Yes	Yes
Cardiovascular registries – valves			4 out of 11 (36%)
Quality Assurance Registry on Aortic Valve Replacement	No	No	No
Austrian-TAVI Registry	No	No	No
Belgian TAVI Registry	No	No	No
Czech TAVI Registry	No	No	No
FinnValve Registry	No	No	No
FRANCE-TAVI Registry	No	No	No
German Aortic Valve Registry	Yes	No	Yes
Polish Registry of Transcatheter Aortic Valve Implantation	Yes	No	Yes
Spanish Registry of Heart Valves Repair	No	No	No
Swedish Transcatheter Cardiac Intervention Registry	Yes	Yes	Yes
Swiss TAVI Registry	Yes	No	Yes
Orthopaedic arthroplasty registries – combined			14 out of 20 (70%)
Croatian Register of endoprothesis	No	No	No
German Arthroplasty Register	Yes	Yes	Yes
Finnish Arthroplasty Register	No	Yes	Yes
Irish National Orthopaedic Register	No	Yes	Yes
Lithuanian Arthroplasty Register	Yes	No	Yes

Dutch Arthroplasty Register	Yes	Yes	Yes
Hungarian Arthroplasty Register	No	No	No
Norwegian Arthroplasty Register	Yes	Yes	Yes
Nordic Arthroplasty Register Association	Yes	No	Yes
National Joint Registry for England, Wales, Northern Ireland, the Isle of Man, and the States of Guernsey	Yes	Yes	Yes
Belgian National Arthroplasty Register	No	Yes	Yes
Catalan Arthroplasty Register	No	No	No
National Arthroplasty Registry of Slovenia	No	Yes	Yes
Italian Arthroplasty Registry	No	Yes	Yes
Emilia-Romagna Region Arthroplasty Register	Yes	Yes	Yes
Romanian National Arthroplasty Register	No	No	No
Portuguese National Arthroplasty Register	No	No	No
Scottish Arthroplasty Project Joint Registry	No	Yes	Yes
Slovakian National Arthroplasty Register	No	No	No
Swiss Arthroplasty Register	No	Yes	Yes
Orthopaedic arthroplasty registries – hips			3 out of 4 (75%)
Czech Republic Arthroplasty Register	No	No	No
French Arthroplasty Register	No	Yes	Yes
Danish Hip Arthroplasty Register	Yes	Yes	Yes
Swedish Hip Arthroplasty Register	Yes	Yes	Yes
Orthopaedic arthroplasty registries – knees			2 out of 2 (100%)
Danish Knee Arthroplasty Register	Yes	No	Yes
Swedish Knee Arthroplasty Register	Yes	Yes	Yes

Table: Recent activity of included registries

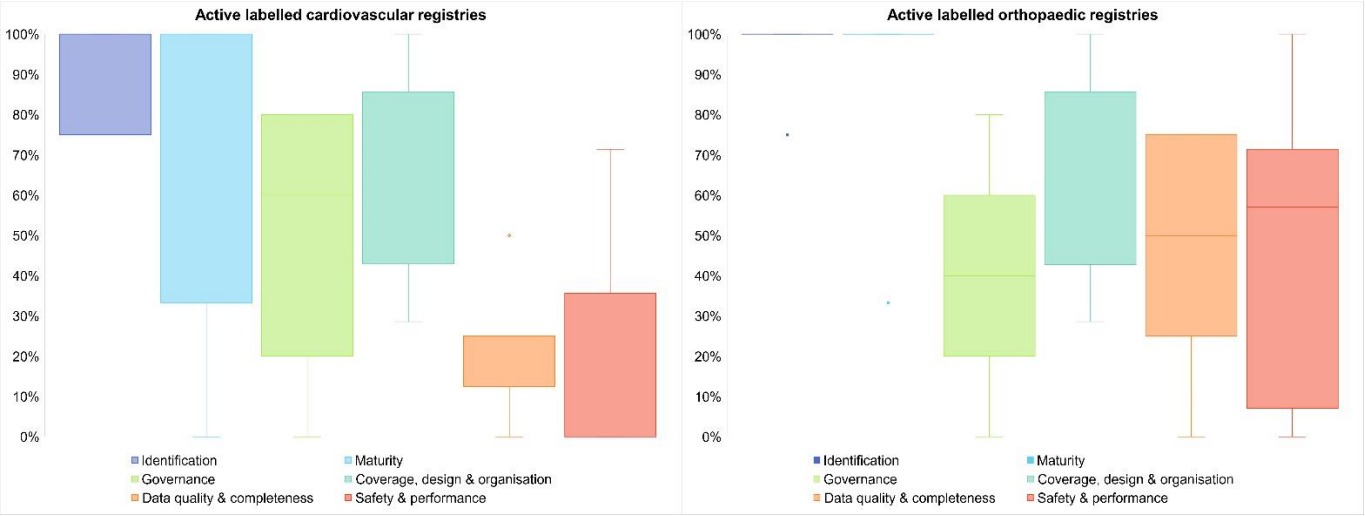

Figure 3: Reported items by the active labelled cardiovascular (left) and orthopaedic (right) registries in each domain indicating the variation in reporting across registries (with the lower end of the boxes representing the 1st quartile and the higher upper end the 3rd quartile; the solid lines in the boxes representing the median values (if not visible the solid lines are at the same level as the 1st or 3rd quartile); the T-shaped whiskers the maximum or minimum values (without outliers); the individual points representing outlier values)

Domain "Data Quality & Completeness"

None of the cardiovascular registries reported patient/ procedure-level data completeness (Table S6A and S6B). Techniques to handle missing data were described in only 1 cardiovascular registry (5%), [21] which applied a data completeness threshold (ie, a certain variable will only be analyzed if its completeness is ≥95%). Most (55%) cardiovascular registries [21,23,26,27,29,30,34-37,40] reported on procedures to check the quality of their data, such as checking on the range and consistency of entries, and verification by audits or an external electronic tool.

Patient/procedure-level completeness was reported by 16 (62%) orthopaedic registries, [42-46,48,50,52-55,60,62-65] which varied from 19% for hip prostheses in the Irish National Orthopaedic Register to 98%-99% for knee prostheses in the Danish Knee Arthroplasty Register. Both registries used data linkage with national patient databases to determine patient/procedure-level completeness (Table S6A and S6B). Techniques to handle missing data were clearly described by only 1 orthopaedic registry (4%), [50] which sent requests for missing data to each orthopaedic department once every three months. Almost half (46%) of the orthopaedic registries, [42,43,46,50,52-55,60,63-65] reported that they implemented techniques for quality assurance of the data, which in the majority consisted of comparing registry data with national patient databases or implant databases.

Reported Outcomes, Definitions, and Duration of Follow-up

The number of peer-reviewed publications per registry in the period January 2013 – July 2021 varied, with a median of 11 (IQR 3-33) published articles among cardiovascular registries and 9 (IQR 2-45) among orthopaedic registries. A wide variety of outcomes as well as their definitions and durations of follow-up were reported by both cardiovascular and orthopaedic registries (Table S7A and S7B).

The most frequently reported outcome in cardiovascular registries was mortality; reported by 18 (90%) registries. [21-24,26-37,39,40] Mortality was reported using 70 different time-points, from in-hospital mortality to mortality at 21 years, the majority of registries (80%) reported on 30- day mortality. [21,22, 24,27-37,39,40] Major cardiovascular events (MACE) were reported as combined end-points by 8 (40%) registries, [21,27-29,32,36,37,40] but with 7 different combinations of complications included in this endpoint and 7 different time intervals with most (50%) registries reporting on 1-year MACE. [28,29,36,40] Reporting on other single outcomes also showed large variability, ranging from 3 to 40 outcome variables per registry (Table S7A and S7B).

In orthopaedic registries, revision surgery (for any cause) was the most frequently reported outcome, reported by 20 (77%) registries. [42-44,46,48,50-60,62,63,65] It was mostly reported as the revision rate or cumulative revision risk but at 30 different time-points up to 25 years, with the most common endpoint being the 1-year revision rate which was reported by 10 registries (38%).- [42,43,46,50-52,56,59,60,66] Specific reasons for revision were reported by 19 (73%) registries, [42-44,46,48,50-57,59,60,62,63,65,66] but these reasons for revision varied between registries (eg, infection, loosening, component failure, etc). Patient reported outcome measurements (PROMs) were reported by 5 (19%) orthopaedic registries, [44,46,48,63,65] with a total of 8 different scores for knee surgery patients and 11 scores for hip surgery patients. All registries measuring PROMs reported pre-operative PROMs, but post-operative PROMs were measured at different time-points up to 10-years postoperatively. Other outcomes (eg, renal failure, hip dislocation, deep venous thrombosis, etc) were inconsistently reported by 13 (50%) registries, [44,46,48,50,51,54-56,58,60,62,63,65] the majority (77%) reported on mortality- [44,50,51,55,56,58,60,62,63,65] (Table S7A and S7B).

Domain "Safety & Performance"

Public reporting on how feedback on eg, devices, hospitals, and surgeons is provided was reported by 3 (15%) cardiovascular registries [21,29,36] (Table S8A and S8B). Managerial procedures to detect individual hospitals or specific devices using an outlier performance analysis based on benchmark thresholds was reported by 1 (5%) cardiovascular registry, the British Cardiovascular Intervention Society registry (BCIS). The outlier was defined using funnel plots, with 2 and 3 standard deviations. Outlier results regarding the timing of treatment (to assess any delay before treatment is delivered) compared between hospitals, as well as adverse outcomes per hospital, were publicly available. However, outlier reports on patients' survival data per hospital were only disclosed confidentially to each hospital. No outlier reports for specific implants were reported by cardiovascular registries.

Public reporting on the frequency of feedback provided was reported by 14 (54%) orthopaedic registries. [42-44,46,48, 50,53,55,58,60,62,63,65,66] Most registries report that they provide annual feedback, while 2 registries (the Irish National Orthopaedic Register and the Swiss national registry for hip and knee replacement) do so both annually and quarterly. The majority provided feedback both at the hospital level and for individual devices. Details of outlier procedures including statistical testing were reported by 8 (31%) registries, of which 3 reported solely on outlier devices, [59,60,66] 2 solely on outlier hospitals, [58,62] 1 on outlier devices and hospitals, [65] and 2 on outlier devices, hospitals, and surgeons. [50,63] Outlier procedures were mostly publicly available. No registries shared the same definition of an outlier (eg, above the 95% control limit in the funnel plot versus revision rates of more than twice compared to the relevant group). Overall, in all annual reports, a total of 95 total hip arthroplasty (THA) component combinations, 3 THA cups, 2 THA stems, and 24 total knee arthroplasty (TKA) implants were identified by these 8 registries as outlier implants. Overall, registries all identified different outlier implants, with only 1 outlier implant (a THA component combination) identified by more than 1 registry.

Discussion

In this systematic review we have evaluated structural and methodological characteristics as well as the data quality of 46 European cardiovascular and orthopaedic medical device registries, in an attempt to gain insight into the usability of these data sources for regulatory purposes. Medical device registries are potentially well suited for post-market surveillance as they may collect data from unselected patient populations and monitor safety and performance throughout the lifetime of specific devices. However, we found heterogeneity and incomplete transparency in quality items related to their structure and methodology, implying that it would be difficult currently for registries to agree upon common principles, to report the information needed by regulators to judge the quality of their data, and to collect and report comparable information across Europe.

The European Union (EU) has regulatory requirements relating to the PMCF of medical devices. [67-69] As stated by the MDR in Article 83, manufacturers have to set up, document, maintain, and update a post-market surveillance system for each device, in which relevant data on the quality, performance, and safety of an implant are evaluated, directly after Conformité Européenne (CE) approval and throughout the entire expected lifetime of a device. [68] To allow for lifetime evaluation and benchmarking of implants, registries need clearly defined methods to detect outliers and to report safety concerns for specific implants, but these were reported by only 5% of the cardiovascular and 31% of the orthopaedic registries that were included in this systematic review. Even more, none of the registries used the same definition, making it difficult for manufacturers, regulators, but also patients to assess whether the device performs worse in all or only in some settings. Furthermore, four orthopaedic registries identified >100 components and combinations of implants as outliers, with only one outlier implant identified by more than one registry, which may partly result from the different definitions used

from the fact that and that not all implants are used in all countries and/or regions and thereby included in the registry.

Another way to enable benchmarking of implants across registries is to implement objective performance classification systems such as the Orthopaedic Data Evaluation Panel (ODEP). The ODEP rating provides benchmarks for orthopaedic prostheses (hip, knee, and shoulder implants) based on the number of years for which the product has been monitored and on the strength of the evidence provided by different data sources, including registry data, randomized controlled trials, peer-reviewed publications, podium presentations, and manufacturers' in-house data sources. [70,71] The ODEP rating can be considered as an absolute benchmark to identify if implants meet the benchmark criteria, whereas others have suggested relative benchmark approaches within a given registry eg, comparing with the best implant construct [72-75] or with all other similar implants.[8]

The MDR in Article 108 states that registries need to establish common principles, so that they can collect comparable information and thereby contribute to the independent evaluation of the long-term safety and performance of devices.[69] They need to capture the same outcomes, based on the same definitions and the same durations of follow-up, before they can be used to benchmark devices and pool data for early detection of safety concerns. Current European device registries do not meet these recommended principles, however, since our systematic review showed large heterogeneity between recorded outcomes, definitions of outcome variables, and time-points for follow-up. Comparable findings were reported by a recent study of the quality of cardiac registries across all subspecialties of cardiac care, in which several registries gave explicit definitions for only a low percentage of variables.[76] Similar findings were also observed for orthopaedic registries, with considerable heterogeneity in captured outcomes and definitions used for revision procedures.[77-79] Another aspect to consider before outcomes across registries can be pooled, is whether registries use the same implant library to classify implants by relevant device characteristics.[80] The European Medical Device nomenclature is a generic classification intended for this purpose, but more detailed libraries are used by registries to capture their specialty-specific characteristics as well. For orthopaedic devices for instance, the International Society of Arthroplasty Registers (ISAR) has proposed a global registry library in 2019 to ensure the same classification of orthopaedic devices across registries.[80] Also, this problem of using different implant libraries can be solved if registries document the unique device identifier for each implant.

In combination, these findings highlight the importance of international agreement on definitions of data and outcomes, as well as time-points used for measuring outcomes within registries. This might be reached by developing consensus frameworks to achieve common datasets that must be captured by registries [81] such as the clinical outcome endpoints in heart failure trials created by the European Society of Cardiology Heart Failure Association, the common dataset for acute coronary syndromes and percutaneous coronary interventions created by the EuroHeart data science group, the benchmarking document for hip and knee arthroplasties by the ISAR, and the common dataset for

demographics and implant survival following THA by the Nordic Arthroplasty Register Association.[82-85]

In addition to these common data specifications, the IMDRF states that registries should include at least 95% of all patients receiving a device, to have sufficiently robust highquality data to inform regulatory decisions.[1] As shown in our systematic review, patient/procedure-level completeness was not reported publicly by any of the cardiovascular registries, but it was available for the majority (65%) of orthopaedic registries. Of the latter only 11 of 13 orthopaedic registries reported recent data (2018 and beyond) that reached a patient/procedure-level completeness of 95% or above. Similar findings were shown for European THA and TKA registries by Lübbeke et al, with 67% reporting patient-level completeness, [79] and for cardiovascular registries, of which the majority had data completeness below 50% or not available.[76]

Making it mandatory to enroll all patients in a registry would help to increase patient/procedure-level completeness.[86] In this systematic review, however, none of the mandatory cardiovascular registries and only 75% of the mandatory orthopaedic registries reported patient/procedure-level completeness. Since completeness of patients is often checked against electronic medical records, it could also help to automatically populate certain data fields regarding patient and implant characteristics from the electronic medical records, so that less information needs to be entered by medical professionals, thereby preventing data loss as well as double data entry. However, rather than considering single items that on their own will contribute to higher quality data, the quality of the evidence provided by registry data is ultimately determined by the combination of multiple factors.

The strength of this systematic review is its' comprehensiveness. We updated the search strategy used by Niederländer et al, [18] and expanded it with support from an experienced librarian. In addition, experts in the field (cardiologists and orthopaedic surgeons) were consulted, resulting in the addition of two cardiovascular registries. Furthermore, European orthopaedic registries listed on the EFORT – NORE-website were checked for their eligibility, resulting in an additional six orthopaedic registries and the completeness of included European cardiovascular registries as well as orthopaedic registries was checked by experts in the relevant field. Thus the likelihood of missing relevant registries is very low. However, some limitations remain. Firstly, we relied on publicly available information regarding registries' structure and methodological characteristics as well as outcomes, which means that some items that we did not find may have been available if we had approached each registry directly. Therefore, the regulatory utility of the data generated by some registries may be higher than that found by this analysis. Secondly, this systematic review only focuses on cardiovascular and orthopaedic registries, because they represent the most commonly used high-risk medical devices aiming to reduce patients' mortality and morbidity.[87] However, the items used to determine the regulatory utility of these registries would also be applicable to other (high-risk) medical device registries.

An overview of publicly available information, as summarized in this systematic review, demonstrates the transparency of European cardiovascular and orthopaedic medical device registries and what information could already be available for regulators. We have proposed characteristics that can be used to interpret whether the data provided by registries are of sufficient quality, and we have identified registries that had an active/accessible website at the time of study selection and/or that published at least one paper or annual report between 2013 and 2021. No data were collected since 2018 were available for 35% of these registries (shown in Table), and so there is a chance that some are no longer active and thereby would not be able to contribute evidence for regulatory purposes. However, the cut-off point to define an active registry was arbitrary and we therefore highlighted that the median of items reported across all domains among active registries was higher than items reported across all registries combined (ie, both “active” and “in-active” labelled registries).

Conclusion

This systematic review showed large heterogeneity and incomplete public transparency related to structure and methodological characteristics of the registries that were reviewed, which implies that it would be difficult to combine and judge the regulatory utility of data reported by registries. Effort is needed from registries to agree upon a minimum set of quality criteria that all registries should publicly report to provide information needed by regulators to judge the quality of registry data and use them for medical device safety surveillance. Developing comprehensive and trustworthy medical device registries will be tremendously valuable, not only for manufacturers to meet the requirements of the MDR for PMCF of their devices, but also for healthcare professionals and patients to support evidence-based choices of devices and contribute to their long-term safety and efficacy.

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Supplementary file 1

Centre for Reviews and Dissemination York – Orthopaedic registries

(2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022)

(("Hip" OR "hips" OR "Knee" OR "knees" OR "Shoulder" OR "Shoulders" OR "Ankle" OR "ankles") AND ("Prosthesis" OR "Prostheses" OR "Implants" OR "Implant" OR "replacement" OR "replacements" OR "arthroplasty" OR "arthroplast*") AND ("Register" OR "registers" OR "registry" OR "registries"))

Centre for Reviews and Dissemination York – Cardiovascular registries

(2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022)

(("cardiac implantable electronic device" OR "artificial heart pacemaker" OR "pacemaker" OR "pacemakers" OR "Artificial Heart" OR "artificial heart" OR "artificial hearts" OR "Heart Assist Device" OR "Artificial Heart" OR "Artificial Ventricle" OR "Artificial Ventricles" OR "Heart Assist Device" OR "Heart Assist Devices" OR "Heart Assist Pump" OR "Heart Assist Pumps" OR "Vascular Assist Device" OR "Vascular Assist Devices" OR "Ventricle Assist Device" OR "Ventricle Assist Devices" OR "Ventricular Assist Device" OR "Ventricular Assist Devices" OR "Heart Valve Prosthesis" OR "Heart Valve Prosthesis" OR "Heart Valve Prosthesis" OR "Cardiac Valve Prosthesis" OR "Cardiac Valve Prostheses" OR "Heart Prosthesis" OR "Heart Prosthesis" OR "Cardiac Prosthesis" OR "Cardiac Prostheses" OR "artificial heart valves" OR "artificial heart valve" OR "artificial valves" OR "artificial valves" OR "Implantable Defibrillator" OR "Implantable Defibrillator" OR "Implantable Defibrillators" OR "Implantable Cardioverter Defibrillator" OR "Implantable Cardioverter Defibrillators" OR "bioresorbable vascular stent" OR "bioresorbable vascular scaffold" OR "bioresorbable vascular scaffolds" OR "transcatheter aortic valve implantation" OR "transcatheter aortic valve implantation" OR "transcatheter aortic valve implant" OR "transcatheter aortic valve implants" OR "TAVI" OR "transseptal mitral valve-in-ring" OR "TMVR" OR "LAAOC") AND ("Register" OR "registers" OR "registry" OR

"registries")) OR (("Heart" OR "cardiac") AND ("Prosthesis" OR "Prostheses" OR "Implants" OR "Implant" OR "replacement" OR "replacements") AND ("Register" OR "registers" OR "registry" OR "registries"))

Cochrane library – Orthopaedic registries (("Hip Replacement" OR "Hip Prosthesis" OR "hip replacement" OR "hip replacement*" OR "hip arthroplasty" OR "hip arthroplast*" OR "hip prosthesis" OR "hip prosthe*" OR "THA" OR "THR" OR "hip implant" OR "hip implants" OR "Knee Replacement" OR "Knee Prosthesis" OR "knee replacement" OR "knee replacement*" OR "knee arthroplasty" OR "knee arthroplast*" OR "knee prosthesis" OR "knee prosthe*" OR "TKA" OR "TKR" OR "knee implant" OR "knee implants" OR "Shoulder Replacement" OR "Shoulder Prosthesis" OR "shoulder replacement" OR "shoulder replacement*" OR "shoulder arthroplasty" OR "shoulder arthroplast*" OR "shoulder prosthesis" OR "shoulder prosthe*" OR "shoulder implant" OR "knee implants" OR "Ankle Replacement" OR "Ankle Prosthesis" OR "ankle replacement" OR "ankle replacement*" OR "ankle arthroplasty" OR "ankle arthroplast*" OR "ankle prosthesis" OR "ankle prosthe*" OR "ankle implant" OR "ankle implants" OR (("Hip" OR "hip" OR "hips" OR "Knee" OR "knee" OR "knees" OR "Shoulder" OR "Shoulder" OR "Shoulders" OR "Ankle" OR "ankle" OR

"ankles") AND ("Prosthesis" OR "Prostheses" OR "Prosthesis" OR "Implants" OR "Implant" OR

"replacement" OR "replacements" OR "arthroplasty" OR "arthroplast*"))) AND ("Register" OR "register"

OR "registers" OR "registry" OR "registries") AND ("European Union" OR "European Union" OR

"European Community" OR "European Coal and Steel Community" OR "Common Market" OR "EEC"

OR "European Economic Community" OR "European Common Market" OR "European Economic Area"

OR "Europe" OR "Albania" OR "Andorra" OR "Armenia" OR "Armenia" OR "Austria" OR "Azerbaijan"

OR "Republic of Belarus" OR "Belgium" OR "Bosnia and Herzegovina" OR "Bulgaria" OR "Croatia"

OR "Czech Republic" OR "Denmark" OR "England" OR "Estonia" OR "Finland" OR "France" OR

"Georgia" OR "Germany" OR "Gibraltar" OR "Greece" OR "Hungary" OR "Iceland" OR "Ireland" OR

"Italy" OR "Kazakhstan" OR "Kosovo" OR "Kyrgyzstan" OR "Latvia" OR "Liechtenstein" OR

"Lithuania" OR "Luxembourg" OR "Malta" OR "Moldova" OR "Monaco" OR "Montenegro" OR

"Netherlands" OR "Republic of North Macedonia" OR "Northern Ireland" OR "Norway" OR "Poland"

OR "Portugal" OR "Romania" OR "Russia" OR "San Marino" OR "Scotland" OR "Serbia" OR

"Slovakia" OR "Slovenia" OR "Spain" OR "Sweden" OR "Switzerland" OR "Turkey" OR "Ukraine" OR

"United Kingdom" OR "Uzbekistan" OR "Vatican City" OR "Wales" OR "Albanian" OR "Armenian" OR

"Austrian" OR "Belgian" OR "Bosnian" OR "Bulgarian" OR "Croatian" OR "Czech" OR "Danish" OR

"British" OR "Estonian" OR "Finnish" OR "French" OR "Georgian" OR "German" OR "Greek" OR

"Hungarian" OR "Icelandic" OR "Irish" OR "Italian" OR "Kosovan" OR "Latvian" OR "Lithuanian" OR "Moldovan" OR "Dutch" OR "Macedonian" OR "Norwegian" OR "Polish" OR "Romanian" OR "Russian" OR "Scottish" OR "Serbian" OR "Slovakian" OR "Slovenian" OR "Spanish" OR "Swedish" OR "Swiss" OR "Turkish" OR "Ukrainian" OR "Welsh")):ti,ab,kw AND (2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022).yr

Cochrane library – Cardiovascular registries

(("cardiac implantable electronic device" OR "artificial heart pacemaker" OR "pacemaker" OR "pacemakers" OR "Artificial Heart" OR "artificial heart" OR "artificial hearts" OR "Heart Assist Device" OR "Artificial Heart" OR "Artificial Ventricle" OR "Artificial Ventricles" OR "Heart Assist Device" OR "Heart Assist Devices" OR "Heart Assist Pump" OR "Heart Assist Pumps" OR "Vascular Assist Device" OR "Vascular Assist Devices" OR "Ventricle Assist Device" OR "Ventricle Assist Devices" OR "Ventricular Assist Device" OR "Ventricular Assist Devices" OR "Heart Valve Prosthesis" OR "Heart Valve Prosthesis" OR "Heart Valve Prosthesis" OR "Cardiac Valve Prosthesis" OR "Cardiac Valve Prostheses" OR "Heart Prosthesis" OR "Heart Prosthesis" OR "Cardiac Prosthesis" OR "Cardiac Prostheses" OR "artificial heart valves" OR "artificial heart valve" OR "artificial valves" OR "artificial valves" OR "Implantable Defibrillator" OR "Implantable Defibrillator" OR "Implantable Defibrillators" OR "Implantable Cardioverter Defibrillator" OR "Implantable Cardioverter Defibrillators" OR "bioresorbable vascular stent" OR "bioresorbable vascular scaffold" OR "bioresorbable vascular scaffolds" OR "transcatheter aortic valve implantation" OR "transcatheter aortic valve implantation" OR "transcatheter aortic valve implant" OR "transcatheter aortic valve implants" OR "TAVI" OR "transseptal mitral valve-in-ring" OR "TMVR" OR "LAAOC" OR (("Heart" OR "heart" OR "cardiac") AND ("Prosthesis" OR "Prostheses" OR "Prosthesis" OR "Implants" OR "Implant" OR "replacement" OR "replacements"))) AND ("Register" OR "register" OR "registers" OR "registry" OR "registries") AND ("European Union" OR "European Union" OR "European Community" OR "European Coal and Steel Community" OR "Common Market" OR "EEC" OR "European Economic Community" OR "European Common Market" OR "European Economic Area" OR "Europe" OR "Albania" OR "Andorra" OR "Armenia" OR "Armenia" OR "Austria" OR "Azerbaijan" OR "Republic of Belarus" OR "Belgium" OR

"Bosnia and Herzegovina" OR "Bulgaria" OR "Croatia" OR "Czech Republic" OR "Denmark" OR "England" OR "Estonia" OR "Finland" OR "France" OR "Georgia" OR "Germany" OR "Gibraltar" OR "Greece" OR "Hungary" OR "Iceland" OR "Ireland" OR "Italy" OR "Kazakhstan" OR "Kosovo" OR "Kyrgyzstan" OR "Latvia" OR "Liechtenstein" OR "Lithuania" OR "Luxembourg" OR "Malta" OR "Moldova" OR "Monaco" OR "Montenegro" OR "Netherlands" OR "Republic of North Macedonia" OR "Northern Ireland" OR "Norway" OR "Poland" OR "Portugal" OR "Romania" OR "Russia" OR "San Marino" OR "Scotland" OR "Serbia" OR "Slovakia" OR "Slovenia" OR "Spain" OR "Sweden" OR "Switzerland" OR "Turkey" OR "Ukraine" OR "United Kingdom" OR "Uzbekistan" OR "Vatican City" OR "Wales" OR "Albanian" OR "Armenian" OR "Austrian" OR "Belgian" OR "Bosnian" OR "Bulgarian" OR "Croatian" OR "Czech" OR "Danish" OR "British" OR "Estonian" OR "Finnish" OR "French" OR "Georgian" OR "German" OR "Greek" OR "Hungarian" OR "Icelandic" OR "Irish" OR "Italian" OR "Kosovan" OR "Latvian" OR "Lithuanian" OR "Moldovan" OR "Dutch" OR "Macedonian" OR "Norwegian" OR "Polish" OR "Romanian" OR "Russian" OR "Scottish" OR "Serbian" OR "Slovakian" OR "Slovenian" OR "Spanish" OR "Swedish" OR "Swiss" OR "Turkish" OR "Ukrainian" OR "Welsh")):ti,ab,kw AND (2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022).yr

Embase – Orthopaedic registries

(((exp *"Hip Replacement"/ OR exp *"Hip Prosthesis"/ OR "hip replacement".ti OR "hip replacement*".ti OR "hip arthroplasty".ti OR "hip arthroplast*".ti OR "hip prosthesis".ti OR "hip prosthe*".ti OR "THA".ti OR "THR".ti OR "hip implant".ti OR "hip implants".ti OR exp *"Knee Replacement"/ OR exp *"Knee Prosthesis"/ OR "knee replacement".ti OR "knee replacement*".ti OR "knee arthroplasty".ti OR "knee arthroplast*".ti OR "knee prosthesis".ti OR "knee prosthe*".ti OR "TKA".ti OR "TKR".ti OR "knee implant".ti OR "knee implants".ti OR exp *"Shoulder Replacement"/ OR exp *"Shoulder Prosthesis"/ OR "shoulder replacement".ti OR "shoulder replacement*".ti OR "shoulder arthroplasty".ti OR "shoulder arthroplast*".ti OR "shoulder prosthesis".ti OR "shoulder prosthe*".ti OR "shoulder implant".ti OR "knee implants".ti OR exp *"Ankle Replacement"/ OR "Ankle Prosthesis"/ OR "ankle replacement".ti OR "ankle replacement*".ti OR "ankle arthroplasty".ti OR "ankle

arthroplast*".ti OR "ankle prosthesis".ti OR "ankle prosthe*".ti OR "ankle implant".ti OR "ankle implants".ti OR ((exp *"Hip"/ OR "hip".ti OR "hips".ti OR exp *"Knee"/ OR "knee".ti OR "knees".ti OR exp *"Shoulder"/ OR "Shoulder".ti OR "Shoulders".ti OR exp *"Ankle"/ OR "ankle".ti OR "ankles".ti) AND (exp *"Prosthesis"/ OR "Prostheses".ti OR "Prosthesis".ti OR "Implants".ti OR "Implant".ti OR "replacement".ti OR "replacements".ti OR "arthroplasty".ti OR "arthroplast*".ti))) AND (exp "Register"/ OR "register".ti,ab OR "registers".ti,ab OR "registry".ti,ab OR "registries".ti,ab OR "register".in OR "registers".in OR "registry".in OR "registries".in) AND (exp "European Union"/ OR "European Union".ti,ab OR "European Community".ti,ab OR "European Coal and Steel Community".ti,ab OR "Common Market".ti,ab OR "EEC".ti,ab OR "European Economic Community".ti,ab OR "European Common Market".ti,ab OR "European Economic Area".ti,ab OR exp "Europe"/ OR "Albania"/ OR "Andorra"/ OR "Armenia"/ OR "Armenia"/ OR "Austria"/ OR "Azerbaijan"/ OR "Republic of Belarus"/ OR "Belgium"/ OR "Bosnia and Herzegovina"/ OR "Bulgaria"/ OR "Croatia"/ OR "Czech Republic"/ OR "Denmark"/ OR "England"/ OR "Estonia"/ OR "Finland"/ OR "France"/ OR "Georgia"/ OR "Germany"/ OR "Gibraltar"/ OR "Greece"/ OR "Hungary"/ OR "Iceland"/ OR "Ireland"/ OR "Italy"/ OR "Kazakhstan"/ OR "Kosovo"/ OR "Kyrgyzstan"/ OR "Latvia"/ OR "Liechtenstein"/ OR "Lithuania"/ OR "Luxembourg"/ OR "Malta"/ OR "Moldova"/ OR "Monaco"/ OR "Montenegro"/ OR "Netherlands"/ OR "Republic of North Macedonia"/ OR "Northern Ireland"/ OR "Norway"/ OR "Poland"/ OR "Portugal"/ OR "Romania"/ OR "Russia"/ OR "San Marino"/ OR "Scotland"/ OR "Serbia"/ OR "Slovakia"/ OR "Slovenia"/ OR "Spain"/ OR "Sweden"/ OR "Switzerland"/ OR "Turkey"/ OR "Ukraine"/ OR "United Kingdom"/ OR "Uzbekistan"/ OR "Vatican City"/ OR "Wales"/ OR "Europe".ti,ab OR "European".ti,ab OR "Albania".ti,ab OR "Andorra".ti,ab OR "Armenia".ti,ab OR "Armenia".ti,ab OR "Austria".ti,ab OR "Azerbaijan".ti,ab OR "Belarus".ti,ab OR "Belgium".ti,ab OR "Bosnia".ti,ab OR "Bulgaria".ti,ab OR "Croatia".ti,ab OR "Czech Republic".ti,ab OR "Denmark".ti,ab OR "England".ti,ab OR "Estonia".ti,ab OR "Finland".ti,ab OR "France".ti,ab OR "Georgia".ti,ab OR "Germany".ti,ab OR "Gibraltar".ti,ab OR "Greece".ti,ab OR "Herzegovina".ti,ab OR "Hungary".ti,ab OR "Iceland".ti,ab OR "Ireland".ti,ab OR "Italy".ti,ab OR "Kazakhstan".ti,ab OR "Kosovo".ti,ab OR "Kyrgyzstan".ti,ab OR "Latvia".ti,ab OR "Liechtenstein".ti,ab OR "Lithuania".ti,ab OR "Luxembourg".ti,ab OR "Malta".ti,ab OR "Moldova".ti,ab OR "Monaco".ti,ab OR "Montenegro".ti,ab OR "Netherlands".ti,ab OR "North Macedonia".ti,ab OR

"Northern Ireland".ti,ab OR "Norway".ti,ab OR "Poland".ti,ab OR "Portugal".ti,ab OR "Romania".ti,ab OR "Russia".ti,ab OR "San Marino".ti,ab OR "Scotland".ti,ab OR "Serbia".ti,ab OR "Slovakia".ti,ab OR "Slovenia".ti,ab OR "Spain".ti,ab OR "Sweden".ti,ab OR "Switzerland".ti,ab OR "Turkey".ti,ab OR "Ukraine".ti,ab OR "United Kingdom".ti,ab OR "Uzbekistan".ti,ab OR "Vatican City".ti,ab OR "Wales".ti,ab OR "Albanian".ti,ab OR "Armenian".ti,ab OR "Austrian".ti,ab OR "Belgian".ti,ab OR "Bosnian".ti,ab OR "Bulgarian".ti,ab OR "Croatian".ti,ab OR "Czech".ti,ab OR "Danish".ti,ab OR "British".ti,ab OR "Estonian".ti,ab OR "Finnish".ti,ab OR "French".ti,ab OR "Georgian".ti,ab OR "German".ti,ab OR "Greek".ti,ab OR "Hungarian".ti,ab OR "Icelandic".ti,ab OR "Irish".ti,ab OR "Italian".ti,ab OR "Kosovan".ti,ab OR "Latvian".ti,ab OR "Lithuanian".ti,ab OR "Moldovan".ti,ab OR "Dutch".ti,ab OR "Macedonian".ti,ab OR "Norwegian".ti,ab OR "Polish".ti,ab OR "Romanian".ti,ab OR "Russian".ti,ab OR "Scottish".ti,ab OR "Serbian".ti,ab OR "Slovakian".ti,ab OR "Slovenian".ti,ab OR "Spanish".ti,ab OR "Swedish".ti,ab OR "Swiss".ti,ab OR "Turkish".ti,ab OR "Ukrainian".ti,ab OR "Welsh".ti,ab)) OR ((exp *"Hip Replacement"/ OR exp *"Hip Prosthesis"/ OR "hip replacement".ti,ab OR "hip replacement*".ti,ab OR "hip arthroplasty".ti,ab OR "hip arthroplast*".ti,ab OR "hip prosthesis".ti,ab OR "hip prosthe*".ti,ab OR "THA".ti,ab OR "THR".ti,ab OR "hip implant".ti,ab OR "hip implants".ti,ab OR exp *"Knee Replacement"/ OR exp *"Knee Prosthesis"/ OR "knee replacement".ti,ab OR "knee replacement*".ti,ab OR "knee arthroplasty".ti,ab OR "knee arthroplast*".ti,ab OR "knee prosthesis".ti,ab OR "knee prosthe*".ti,ab OR "TKA".ti,ab OR "TKR".ti,ab OR "knee implant".ti,ab OR "knee implants".ti,ab OR exp *"Shoulder Replacement"/ OR exp *"Shoulder Prosthesis"/ OR "shoulder replacement".ti,ab OR "shoulder replacement*".ti,ab OR "shoulder arthroplasty".ti,ab OR "shoulder arthroplast*".ti,ab OR "shoulder prosthesis".ti,ab OR "shoulder prosthe*".ti,ab OR "shoulder implant".ti,ab OR "knee implants".ti,ab OR exp *"Ankle Replacement"/ OR "Ankle Prosthesis"/ OR "ankle replacement".ti,ab OR "ankle replacement*".ti,ab OR "ankle arthroplasty".ti,ab OR "ankle arthroplast*".ti,ab OR "ankle prosthesis".ti,ab OR "ankle prosthe*".ti,ab OR "ankle implant".ti,ab OR "ankle implants".ti,ab OR ((exp *"Hip"/ OR "hip".ti,ab OR "hips".ti,ab OR exp *"Knee"/ OR "knee".ti,ab OR "knees".ti,ab OR exp *"Shoulder"/ OR "Shoulder".ti,ab OR "Shoulders".ti,ab OR exp *"Ankle"/ OR "ankle".ti,ab OR "ankles".ti,ab) AND (exp *"Prosthesis"/ OR "Prostheses".ti,ab OR "Prosthesis".ti,ab OR "Implants".ti,ab OR "Implant".ti,ab OR "replacement".ti,ab OR "replacements".ti,ab OR

"arthroplasty".ti,ab OR "arthroplast*".ti,ab))) AND (exp *"Register"/ OR "register".ti OR "registers".ti OR "registry".ti OR "registries".ti OR "register".in OR "registers".in OR "registry".in OR "registries".in) AND (exp "European Union"/ OR "European Union".ti,ab OR "European Community".ti,ab OR "European Coal and Steel Community".ti,ab OR "Common Market".ti,ab OR "EEC".ti,ab OR "European Economic Community".ti,ab OR "European Common Market".ti,ab OR "European Economic Area".ti,ab OR exp "Europe"/ OR "Albania"/ OR "Andorra"/ OR "Armenia"/ OR "Armenia"/ OR "Austria"/ OR "Azerbaijan"/ OR "Republic of Belarus"/ OR "Belgium"/ OR "Bosnia and Herzegovina"/ OR "Bulgaria"/ OR "Croatia"/ OR "Czech Republic"/ OR "Denmark"/ OR "England"/ OR "Estonia"/ OR "Finland"/ OR "France"/ OR "Georgia"/ OR "Germany"/ OR "Gibraltar"/ OR "Greece"/ OR "Hungary"/ OR "Iceland"/ OR "Ireland"/ OR "Italy"/ OR "Kazakhstan"/ OR "Kosovo"/ OR "Kyrgyzstan"/ OR "Latvia"/ OR "Liechtenstein"/ OR "Lithuania"/ OR "Luxembourg"/ OR "Malta"/ OR "Moldova"/ OR "Monaco"/ OR "Montenegro"/ OR "Netherlands"/ OR "Republic of North Macedonia"/ OR "Northern Ireland"/ OR "Norway"/ OR "Poland"/ OR "Portugal"/ OR "Romania"/ OR "Russia"/ OR "San Marino"/ OR "Scotland"/ OR "Serbia"/ OR "Slovakia"/ OR "Slovenia"/ OR "Spain"/ OR "Sweden"/ OR "Switzerland"/ OR "Turkey"/ OR "Ukraine"/ OR "United Kingdom"/ OR "Uzbekistan"/ OR "Vatican City"/ OR "Wales"/ OR "Europe".ti,ab OR "European".ti,ab OR "Albania".ti,ab OR "Andorra".ti,ab OR "Armenia".ti,ab OR "Armenia".ti,ab OR "Austria".ti,ab OR "Azerbaijan".ti,ab OR "Belarus".ti,ab OR "Belgium".ti,ab OR "Bosnia".ti,ab OR "Bulgaria".ti,ab OR "Croatia".ti,ab OR "Czech Republic".ti,ab OR "Denmark".ti,ab OR "England".ti,ab OR "Estonia".ti,ab OR "Finland".ti,ab OR "France".ti,ab OR "Georgia".ti,ab OR "Germany".ti,ab OR "Gibraltar".ti,ab OR "Greece".ti,ab OR "Herzegovina".ti,ab OR "Hungary".ti,ab OR "Iceland".ti,ab OR "Ireland".ti,ab OR "Italy".ti,ab OR "Kazakhstan".ti,ab OR "Kosovo".ti,ab OR "Kyrgyzstan".ti,ab OR "Latvia".ti,ab OR "Liechtenstein".ti,ab OR "Lithuania".ti,ab OR "Luxembourg".ti,ab OR "Malta".ti,ab OR "Moldova".ti,ab OR "Monaco".ti,ab OR "Montenegro".ti,ab OR "Netherlands".ti,ab OR "North Macedonia".ti,ab OR "Northern Ireland".ti,ab OR "Norway".ti,ab OR "Poland".ti,ab OR "Portugal".ti,ab OR "Romania".ti,ab OR "Russia".ti,ab OR "San Marino".ti,ab OR "Scotland".ti,ab OR "Serbia".ti,ab OR "Slovakia".ti,ab OR "Slovenia".ti,ab OR "Spain".ti,ab OR "Sweden".ti,ab OR "Switzerland".ti,ab OR "Turkey".ti,ab OR "Ukraine".ti,ab OR "United Kingdom".ti,ab OR "Uzbekistan".ti,ab OR "Vatican City".ti,ab OR "Wales".ti,ab OR

"Albanian".ti,ab OR "Armenian".ti,ab OR "Austrian".ti,ab OR "Belgian".ti,ab OR "Bosnian".ti,ab OR "Bulgarian".ti,ab OR "Croatian".ti,ab OR "Czech".ti,ab OR "Danish".ti,ab OR "British".ti,ab OR "Estonian".ti,ab OR "Finnish".ti,ab OR "French".ti,ab OR "Georgian".ti,ab OR "German".ti,ab OR "Greek".ti,ab OR "Hungarian".ti,ab OR "Icelandic".ti,ab OR "Irish".ti,ab OR "Italian".ti,ab OR "Kosovan".ti,ab OR "Latvian".ti,ab OR "Lithuanian".ti,ab OR "Moldovan".ti,ab OR "Dutch".ti,ab OR "Macedonian".ti,ab OR "Norwegian".ti,ab OR "Polish".ti,ab OR "Romanian".ti,ab OR "Russian".ti,ab OR "Scottish".ti,ab OR "Serbian".ti,ab OR "Slovakian".ti,ab OR "Slovenian".ti,ab OR "Spanish".ti,ab OR "Swedish".ti,ab OR "Swiss".ti,ab OR "Turkish".ti,ab OR "Ukrainian".ti,ab OR "Welsh".ti,ab))) AND (2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022).yr NOT (conference review or conference abstract).pt

Embase – Cardiovascular registries

(((exp *"cardiac implantable electronic device"/ OR exp *"artificial heart pacemaker"/ OR "pacemaker".ti
OR "pacemakers".ti OR exp *"Artificial Heart"/ OR "artificial heart".ti OR "artificial hearts".ti OR exp *"Heart Assist Device"/ OR "Artificial Heart".ti OR "Artificial Ventricle".ti OR "Artificial Ventricles".ti OR "Heart Assist Device".ti OR "Heart Assist Devices".ti OR "Heart Assist Pump".ti OR "Heart Assist Pumps".ti OR "Vascular Assist Device".ti OR "Vascular Assist Devices".ti OR "Ventricle Assist Device".ti OR "Ventricle Assist Devices".ti OR "Ventricular Assist Device".ti OR "Ventricular Assist Devices".ti OR exp *"Heart Valve Prosthesis"/ OR "Heart Valve Prosthesis".ti OR "Heart Valve Prosthesis".ti OR "Cardiac Valve Prosthesis".ti OR "Cardiac Valve Prostheses".ti OR "Heart Prosthesis".ti OR "Heart Prosthesis".ti OR "Cardiac Prosthesis".ti OR "Cardiac Prostheses".ti OR "artificial heart valves".ti OR "artificial heart valve".ti OR "artificial valves".ti OR "artificial valves".ti OR exp *"Implantable Defibrillator"/ OR "Implantable Defibrillator".ti OR "Implantable Defibrillators".ti OR "Implantable Cardioverter Defibrillator".ti OR "Implantable Cardioverter Defibrillators".ti OR exp *"bioresorbable vascular stent"/ OR "bioresorbable vascular scaffold".ti OR "bioresorbable vascular scaffolds".ti OR exp *"transcatheter aortic valve implantation"/ OR "transcatheter aortic valve implantation".ti OR "transcatheter aortic valve implant".ti OR "transcatheter aortic valve implants".ti OR

"TAVI".ti OR "transseptal mitral valve-in-ring".ti OR "TMVR".ti OR "LAAOC".ti OR ((exp *"Heart"/ OR "heart".ti OR "cardiac".ti) AND (exp *"Prosthesis"/ OR "Prostheses".ti OR "Prosthesis".ti OR "Implants".ti OR "Implant".ti OR "replacement".ti OR "replacements".ti))) AND (exp "Register"/ OR "register".ti,ab OR "registers".ti,ab OR "registry".ti,ab OR "registries".ti,ab OR "register".in OR "registers".in OR "registry".in OR "registries".in) AND (exp "European Union"/ OR "European Union".ti,ab OR "European Community".ti,ab OR "European Coal and Steel Community".ti,ab OR "Common Market".ti,ab OR "EEC".ti,ab OR "European Economic Community".ti,ab OR "European Common Market".ti,ab OR "European Economic Area".ti,ab OR exp "Europe"/ OR "Albania"/ OR "Andorra"/ OR "Armenia"/ OR "Armenia"/ OR "Austria"/ OR "Azerbaijan"/ OR "Republic of Belarus"/ OR "Belgium"/ OR "Bosnia and Herzegovina"/ OR "Bulgaria"/ OR "Croatia"/ OR "Czech Republic"/ OR "Denmark"/ OR "England"/ OR "Estonia"/ OR "Finland"/ OR "France"/ OR "Georgia"/ OR "Germany"/ OR "Gibraltar"/ OR "Greece"/ OR "Hungary"/ OR "Iceland"/ OR "Ireland"/ OR "Italy"/ OR "Kazakhstan"/ OR "Kosovo"/ OR "Kyrgyzstan"/ OR "Latvia"/ OR "Liechtenstein"/ OR "Lithuania"/ OR "Luxembourg"/ OR "Malta"/ OR "Moldova"/ OR "Monaco"/ OR "Montenegro"/ OR "Netherlands"/ OR "Republic of North Macedonia"/ OR "Northern Ireland"/ OR "Norway"/ OR "Poland"/ OR "Portugal"/ OR "Romania"/ OR "Russia"/ OR "San Marino"/ OR "Scotland"/ OR "Serbia"/ OR "Slovakia"/ OR "Slovenia"/ OR "Spain"/ OR "Sweden"/ OR "Switzerland"/ OR "Turkey"/ OR "Ukraine"/ OR "United Kingdom"/ OR "Uzbekistan"/ OR "Vatican City"/ OR "Wales"/ OR "Europe".ti,ab OR "European".ti,ab OR "Albania".ti,ab OR "Andorra".ti,ab OR "Armenia".ti,ab OR "Armenia".ti,ab OR "Austria".ti,ab OR "Azerbaijan".ti,ab OR "Belarus".ti,ab OR "Belgium".ti,ab OR "Bosnia".ti,ab OR "Bulgaria".ti,ab OR "Croatia".ti,ab OR "Czech Republic".ti,ab OR "Denmark".ti,ab OR "England".ti,ab OR "Estonia".ti,ab OR "Finland".ti,ab OR "France".ti,ab OR "Georgia".ti,ab OR "Germany".ti,ab OR "Gibraltar".ti,ab OR "Greece".ti,ab OR "Herzegovina".ti,ab OR "Hungary".ti,ab OR "Iceland".ti,ab OR "Ireland".ti,ab OR "Italy".ti,ab OR "Kazakhstan".ti,ab OR "Kosovo".ti,ab OR "Kyrgyzstan".ti,ab OR "Latvia".ti,ab OR "Liechtenstein".ti,ab OR "Lithuania".ti,ab OR "Luxembourg".ti,ab OR "Malta".ti,ab OR "Moldova".ti,ab OR "Monaco".ti,ab OR "Montenegro".ti,ab OR "Netherlands".ti,ab OR "North Macedonia".ti,ab OR "Northern Ireland".ti,ab OR "Norway".ti,ab OR "Poland".ti,ab OR "Portugal".ti,ab OR "Romania".ti,ab OR "Russia".ti,ab OR "San Marino".ti,ab OR "Scotland".ti,ab OR "Serbia".ti,ab OR "Slovakia".ti,ab OR

"Slovenia".ti,ab OR "Spain".ti,ab OR "Sweden".ti,ab OR "Switzerland".ti,ab OR "Turkey".ti,ab OR "Ukraine".ti,ab OR "United Kingdom".ti,ab OR "Uzbekistan".ti,ab OR "Vatican City".ti,ab OR "Wales".ti,ab OR "Albanian".ti,ab OR "Armenian".ti,ab OR "Austrian".ti,ab OR "Belgian".ti,ab OR "Bosnian".ti,ab OR "Bulgarian".ti,ab OR "Croatian".ti,ab OR "Czech".ti,ab OR "Danish".ti,ab OR "British".ti,ab OR "Estonian".ti,ab OR "Finnish".ti,ab OR "French".ti,ab OR "Georgian".ti,ab OR "German".ti,ab OR "Greek".ti,ab OR "Hungarian".ti,ab OR "Icelandic".ti,ab OR "Irish".ti,ab OR "Italian".ti,ab OR "Kosovan".ti,ab OR "Latvian".ti,ab OR "Lithuanian".ti,ab OR "Moldovan".ti,ab OR "Dutch".ti,ab OR "Macedonian".ti,ab OR "Norwegian".ti,ab OR "Polish".ti,ab OR "Romanian".ti,ab OR "Russian".ti,ab OR "Scottish".ti,ab OR "Serbian".ti,ab OR "Slovakian".ti,ab OR "Slovenian".ti,ab OR "Spanish".ti,ab OR "Swedish".ti,ab OR "Swiss".ti,ab OR "Turkish".ti,ab OR "Ukrainian".ti,ab OR "Welsh".ti,ab)) OR ((exp *"cardiac implantable electronic device"/ OR exp *"artificial heart pacemaker"/ OR "pacemaker".ti,ab OR "pacemakers".ti,ab OR exp *"Artificial Heart"/ OR "artificial heart".ti,ab OR "artificial hearts".ti,ab OR exp *"Heart Assist Device"/ OR "Artificial Heart".ti,ab OR "Artificial Ventricle".ti,ab OR "Artificial Ventricles".ti,ab OR "Heart Assist Device".ti,ab OR "Heart Assist Devices".ti,ab OR "Heart Assist Pump".ti,ab OR "Heart Assist Pumps".ti,ab OR "Vascular Assist Device".ti,ab OR "Vascular Assist Devices".ti,ab OR "Ventricle Assist Device".ti,ab OR "Ventricle Assist Devices".ti,ab OR "Ventricular Assist Device".ti,ab OR "Ventricular Assist Devices".ti,ab OR exp *"Heart Valve Prosthesis"/ OR "Heart Valve Prosthesis".ti,ab OR "Heart Valve Prosthesis".ti,ab OR "Cardiac Valve Prosthesis".ti,ab OR "Cardiac Valve Prostheses".ti,ab OR "Heart Prosthesis".ti,ab OR "Heart Prosthesis".ti,ab OR "Cardiac Prosthesis".ti,ab OR "Cardiac Prostheses".ti,ab OR "artificial heart valves".ti,ab OR "artificial heart valve".ti,ab OR "artificial valves".ti,ab OR "artificial valves".ti,ab OR exp *"Implantable Defibrillator"/ OR "Implantable Defibrillator".ti,ab OR "Implantable Defibrillators".ti,ab OR "Implantable Cardioverter Defibrillator".ti,ab OR "Implantable Cardioverter Defibrillators".ti,ab OR exp *"bioresorbable vascular stent"/ OR "bioresorbable vascular scaffold".ti,ab OR "bioresorbable vascular scaffolds".ti,ab OR exp *"transcatheter aortic valve implantation"/ OR "transcatheter aortic valve implantation".ti,ab OR "transcatheter aortic valve implant".ti,ab OR "transcatheter aortic valve implants".ti,ab OR "TAVI".ti,ab OR "transseptal mitral valve-in-ring".ti,ab OR "TMVR".ti,ab OR "LAAOC".ti,ab OR ((exp *"Heart"/ OR "heart".ti,ab OR "cardiac".ti,ab) AND (exp

*"Prosthesis"/ OR "Prostheses".ti,ab OR "Prosthesis".ti,ab OR "Implants".ti,ab OR "Implant".ti,ab OR "replacement".ti,ab OR "replacements".ti,ab))) AND (exp *"Register"/ OR "register".ti OR "registers".ti OR "registry".ti OR "registries".ti OR "register".in OR "registers".in OR "registry".in OR "registries".in) AND (exp "European Union"/ OR "European Union".ti,ab OR "European Community".ti,ab OR "European Coal and Steel Community".ti,ab OR "Common Market".ti,ab OR "EEC".ti,ab OR "European Economic Community".ti,ab OR "European Common Market".ti,ab OR "European Economic Area".ti,ab OR exp "Europe"/ OR "Albania"/ OR "Andorra"/ OR "Armenia"/ OR "Armenia"/ OR "Austria"/ OR "Azerbaijan"/ OR "Republic of Belarus"/ OR "Belgium"/ OR "Bosnia and Herzegovina"/ OR "Bulgaria"/ OR "Croatia"/ OR "Czech Republic"/ OR "Denmark"/ OR "England"/ OR "Estonia"/ OR "Finland"/ OR "France"/ OR "Georgia"/ OR "Germany"/ OR "Gibraltar"/ OR "Greece"/ OR "Hungary"/ OR "Iceland"/ OR "Ireland"/ OR "Italy"/ OR "Kazakhstan"/ OR "Kosovo"/ OR "Kyrgyzstan"/ OR "Latvia"/ OR "Liechtenstein"/ OR "Lithuania"/ OR "Luxembourg"/ OR "Malta"/ OR "Moldova"/ OR "Monaco"/ OR "Montenegro"/ OR "Netherlands"/ OR "Republic of North Macedonia"/ OR "Northern Ireland"/ OR "Norway"/ OR "Poland"/ OR "Portugal"/ OR "Romania"/ OR "Russia"/ OR "San Marino"/ OR "Scotland"/ OR "Serbia"/ OR "Slovakia"/ OR "Slovenia"/ OR "Spain"/ OR "Sweden"/ OR "Switzerland"/ OR "Turkey"/ OR "Ukraine"/ OR "United Kingdom"/ OR "Uzbekistan"/ OR "Vatican City"/ OR "Wales"/ OR "Europe".ti,ab OR "European".ti,ab OR "Albania".ti,ab OR "Andorra".ti,ab OR "Armenia".ti,ab OR "Armenia".ti,ab OR "Austria".ti,ab OR "Azerbaijan".ti,ab OR "Belarus".ti,ab OR "Belgium".ti,ab OR "Bosnia".ti,ab OR "Bulgaria".ti,ab OR "Croatia".ti,ab OR "Czech Republic".ti,ab OR "Denmark".ti,ab OR "England".ti,ab OR "Estonia".ti,ab OR "Finland".ti,ab OR "France".ti,ab OR "Georgia".ti,ab OR "Germany".ti,ab OR "Gibraltar".ti,ab OR "Greece".ti,ab OR "Herzegovina".ti,ab OR "Hungary".ti,ab OR "Iceland".ti,ab OR "Ireland".ti,ab OR "Italy".ti,ab OR "Kazakhstan".ti,ab OR "Kosovo".ti,ab OR "Kyrgyzstan".ti,ab OR "Latvia".ti,ab OR "Liechtenstein".ti,ab OR "Lithuania".ti,ab OR "Luxembourg".ti,ab OR "Malta".ti,ab OR "Moldova".ti,ab OR "Monaco".ti,ab OR "Montenegro".ti,ab OR "Netherlands".ti,ab OR "North Macedonia".ti,ab OR "Northern Ireland".ti,ab OR "Norway".ti,ab OR "Poland".ti,ab OR "Portugal".ti,ab OR "Romania".ti,ab OR "Russia".ti,ab OR "San Marino".ti,ab OR "Scotland".ti,ab OR "Serbia".ti,ab OR "Slovakia".ti,ab OR "Slovenia".ti,ab OR "Spain".ti,ab OR "Sweden".ti,ab OR "Switzerland".ti,ab OR "Turkey".ti,ab OR "Ukraine".ti,ab OR

"United Kingdom".ti,ab OR "Uzbekistan".ti,ab OR "Vatican City".ti,ab OR "Wales".ti,ab OR "Albanian".ti,ab OR "Armenian".ti,ab OR "Austrian".ti,ab OR "Belgian".ti,ab OR "Bosnian".ti,ab OR "Bulgarian".ti,ab OR "Croatian".ti,ab OR "Czech".ti,ab OR "Danish".ti,ab OR "British".ti,ab OR "Estonian".ti,ab OR "Finnish".ti,ab OR "French".ti,ab OR "Georgian".ti,ab OR "German".ti,ab OR "Greek".ti,ab OR "Hungarian".ti,ab OR "Icelandic".ti,ab OR "Irish".ti,ab OR "Italian".ti,ab OR "Kosovan".ti,ab OR "Latvian".ti,ab OR "Lithuanian".ti,ab OR "Moldovan".ti,ab OR "Dutch".ti,ab OR "Macedonian".ti,ab OR "Norwegian".ti,ab OR "Polish".ti,ab OR "Romanian".ti,ab OR "Russian".ti,ab OR "Scottish".ti,ab OR "Serbian".ti,ab OR "Slovakian".ti,ab OR "Slovenian".ti,ab OR "Spanish".ti,ab OR "Swedish".ti,ab OR "Swiss".ti,ab OR "Turkish".ti,ab OR "Ukrainian".ti,ab OR "Welsh".ti,ab))) AND (2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022).yr NOT (conference review or conference abstract).pt

Emcare – Orthopaedic registries

(((exp *"Hip Replacement"/ OR exp *"Hip Prosthesis"/ OR "hip replacement".ti OR "hip replacement*".ti OR "hip arthroplasty".ti OR "hip arthroplast*".ti OR "hip prosthesis".ti OR "hip prosthe*".ti OR "THA".ti OR "THR".ti OR "hip implant".ti OR "hip implants".ti OR exp *"Knee Replacement"/ OR exp *"Knee Prosthesis"/ OR "knee replacement".ti OR "knee replacement*".ti OR "knee arthroplasty".ti OR "knee arthroplast*".ti OR "knee prosthesis".ti OR "knee prosthe*".ti OR "TKA".ti OR "TKR".ti OR "knee implant".ti OR "knee implants".ti OR exp *"Shoulder Replacement"/ OR exp *"Shoulder Prosthesis"/ OR "shoulder replacement".ti OR "shoulder replacement*".ti OR "shoulder arthroplasty".ti OR "shoulder arthroplast*".ti OR "shoulder prosthesis".ti OR "shoulder prosthe*".ti OR "shoulder implant".ti OR "knee implants".ti OR exp *"Ankle Replacement"/ OR "Ankle Prosthesis"/ OR "ankle replacement".ti OR "ankle replacement*".ti OR "ankle arthroplasty".ti OR "ankle arthroplast*".ti OR "ankle prosthesis".ti OR "ankle prosthe*".ti OR "ankle implant".ti OR "ankle implants".ti OR ((exp *"Hip"/ OR "hip".ti OR "hips".ti OR exp *"Knee"/ OR "knee".ti OR "knees".ti OR exp *"Shoulder"/ OR "Shoulder".ti OR "Shoulders".ti OR exp *"Ankle"/ OR "ankle".ti OR "ankles".ti) AND (exp *"Prosthesis"/ OR "Prostheses".ti OR "Prosthesis".ti OR "Implants".ti OR "Implant".ti OR "replacement".ti OR "replacements".ti OR "arthroplasty".ti OR "arthroplast*".ti))) AND (exp "Register"/

OR "register".ti,ab OR "registers".ti,ab OR "registry".ti,ab OR "registries".ti,ab OR "register".in OR "registers".in OR "registry".in OR "registries".in) AND (exp "European Union"/ OR "European Union".ti,ab OR "European Community".ti,ab OR "European Coal and Steel Community".ti,ab OR "Common Market".ti,ab OR "EEC".ti,ab OR "European Economic Community".ti,ab OR "European Common Market".ti,ab OR "European Economic Area".ti,ab OR exp "Europe"/ OR "Albania"/ OR "Andorra"/ OR "Armenia"/ OR "Armenia"/ OR "Austria"/ OR "Azerbaijan"/ OR "Republic of Belarus"/ OR "Belgium"/ OR "Bosnia and Herzegovina"/ OR "Bulgaria"/ OR "Croatia"/ OR "Czech Republic"/ OR "Denmark"/ OR "England"/ OR "Estonia"/ OR "Finland"/ OR "France"/ OR "Georgia"/ OR "Germany"/ OR "Gibraltar"/ OR "Greece"/ OR "Hungary"/ OR "Iceland"/ OR "Ireland"/ OR "Italy"/ OR "Kazakhstan"/ OR "Kosovo"/ OR "Kyrgyzstan"/ OR "Latvia"/ OR "Liechtenstein"/ OR "Lithuania"/ OR "Luxembourg"/ OR "Malta"/ OR "Moldova"/ OR "Monaco"/ OR "Montenegro"/ OR "Netherlands"/ OR "Republic of North Macedonia"/ OR "Northern Ireland"/ OR "Norway"/ OR "Poland"/ OR "Portugal"/ OR "Romania"/ OR "Russia"/ OR "San Marino"/ OR "Scotland"/ OR "Serbia"/ OR "Slovakia"/ OR "Slovenia"/ OR "Spain"/ OR "Sweden"/ OR "Switzerland"/ OR "Turkey"/ OR "Ukraine"/ OR "United Kingdom"/ OR "Uzbekistan"/ OR "Vatican City"/ OR "Wales"/ OR "Europe".ti,ab OR "European".ti,ab OR "Albania".ti,ab OR "Andorra".ti,ab OR "Armenia".ti,ab OR "Armenia".ti,ab OR "Austria".ti,ab OR "Azerbaijan".ti,ab OR "Belarus".ti,ab OR "Belgium".ti,ab OR "Bosnia".ti,ab OR "Bulgaria".ti,ab OR "Croatia".ti,ab OR "Czech Republic".ti,ab OR "Denmark".ti,ab OR "England".ti,ab OR "Estonia".ti,ab OR "Finland".ti,ab OR "France".ti,ab OR "Georgia".ti,ab OR "Germany".ti,ab OR "Gibraltar".ti,ab OR "Greece".ti,ab OR "Herzegovina".ti,ab OR "Hungary".ti,ab OR "Iceland".ti,ab OR "Ireland".ti,ab OR "Italy".ti,ab OR "Kazakhstan".ti,ab OR "Kosovo".ti,ab OR "Kyrgyzstan".ti,ab OR "Latvia".ti,ab OR "Liechtenstein".ti,ab OR "Lithuania".ti,ab OR "Luxembourg".ti,ab OR "Malta".ti,ab OR "Moldova".ti,ab OR "Monaco".ti,ab OR "Montenegro".ti,ab OR "Netherlands".ti,ab OR "North Macedonia".ti,ab OR "Northern Ireland".ti,ab OR "Norway".ti,ab OR "Poland".ti,ab OR "Portugal".ti,ab OR "Romania".ti,ab OR "Russia".ti,ab OR "San Marino".ti,ab OR "Scotland".ti,ab OR "Serbia".ti,ab OR "Slovakia".ti,ab OR "Slovenia".ti,ab OR "Spain".ti,ab OR "Sweden".ti,ab OR "Switzerland".ti,ab OR "Turkey".ti,ab OR "Ukraine".ti,ab OR "United Kingdom".ti,ab OR "Uzbekistan".ti,ab OR "Vatican City".ti,ab OR "Wales".ti,ab OR "Albanian".ti,ab OR "Armenian".ti,ab OR "Austrian".ti,ab OR "Belgian".ti,ab OR

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OR exp "Europe"/ OR "Albania"/ OR "Andorra"/ OR "Armenia"/ OR "Armenia"/ OR "Austria"/ OR "Azerbaijan"/ OR "Republic of Belarus"/ OR "Belgium"/ OR "Bosnia and Herzegovina"/ OR "Bulgaria"/ OR "Croatia"/ OR "Czech Republic"/ OR "Denmark"/ OR "England"/ OR "Estonia"/ OR "Finland"/ OR "France"/ OR "Georgia"/ OR "Germany"/ OR "Gibraltar"/ OR "Greece"/ OR "Hungary"/ OR "Iceland"/ OR "Ireland"/ OR "Italy"/ OR "Kazakhstan"/ OR "Kosovo"/ OR "Kyrgyzstan"/ OR "Latvia"/ OR "Liechtenstein"/ OR "Lithuania"/ OR "Luxembourg"/ OR "Malta"/ OR "Moldova"/ OR "Monaco"/ OR "Montenegro"/ OR "Netherlands"/ OR "Republic of North Macedonia"/ OR "Northern Ireland"/ OR "Norway"/ OR "Poland"/ OR "Portugal"/ OR "Romania"/ OR "Russia"/ OR "San Marino"/ OR "Scotland"/ OR "Serbia"/ OR "Slovakia"/ OR "Slovenia"/ OR "Spain"/ OR "Sweden"/ OR "Switzerland"/ OR "Turkey"/ OR "Ukraine"/ OR "United Kingdom"/ OR "Uzbekistan"/ OR "Vatican City"/ OR "Wales"/ OR "Europe".ti,ab OR "European".ti,ab OR "Albania".ti,ab OR "Andorra".ti,ab OR "Armenia".ti,ab OR "Armenia".ti,ab OR "Austria".ti,ab OR "Azerbaijan".ti,ab OR "Belarus".ti,ab OR "Belgium".ti,ab OR "Bosnia".ti,ab OR "Bulgaria".ti,ab OR "Croatia".ti,ab OR "Czech Republic".ti,ab OR "Denmark".ti,ab OR "England".ti,ab OR "Estonia".ti,ab OR "Finland".ti,ab OR "France".ti,ab OR "Georgia".ti,ab OR "Germany".ti,ab OR "Gibraltar".ti,ab OR "Greece".ti,ab OR "Herzegovina".ti,ab OR "Hungary".ti,ab OR "Iceland".ti,ab OR "Ireland".ti,ab OR "Italy".ti,ab OR "Kazakhstan".ti,ab OR "Kosovo".ti,ab OR "Kyrgyzstan".ti,ab OR "Latvia".ti,ab OR "Liechtenstein".ti,ab OR "Lithuania".ti,ab OR "Luxembourg".ti,ab OR "Malta".ti,ab OR "Moldova".ti,ab OR "Monaco".ti,ab OR "Montenegro".ti,ab OR "Netherlands".ti,ab OR "North Macedonia".ti,ab OR "Northern Ireland".ti,ab OR "Norway".ti,ab OR "Poland".ti,ab OR "Portugal".ti,ab OR "Romania".ti,ab OR "Russia".ti,ab OR "San Marino".ti,ab OR "Scotland".ti,ab OR "Serbia".ti,ab OR "Slovakia".ti,ab OR "Slovenia".ti,ab OR "Spain".ti,ab OR "Sweden".ti,ab OR "Switzerland".ti,ab OR "Turkey".ti,ab OR "Ukraine".ti,ab OR "United Kingdom".ti,ab OR "Uzbekistan".ti,ab OR "Vatican City".ti,ab OR "Wales".ti,ab OR "Albanian".ti,ab OR "Armenian".ti,ab OR "Austrian".ti,ab OR "Belgian".ti,ab OR "Bosnian".ti,ab OR "Bulgarian".ti,ab OR "Croatian".ti,ab OR "Czech".ti,ab OR "Danish".ti,ab OR "British".ti,ab OR "Estonian".ti,ab OR "Finnish".ti,ab OR "French".ti,ab OR "Georgian".ti,ab OR "German".ti,ab OR "Greek".ti,ab OR "Hungarian".ti,ab OR "Icelandic".ti,ab OR "Irish".ti,ab OR "Italian".ti,ab OR "Kosovan".ti,ab OR "Latvian".ti,ab OR "Lithuanian".ti,ab OR "Moldovan".ti,ab OR "Dutch".ti,ab OR

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Emcare – Cardiovascular registries

(((exp *"cardiac implantable electronic device"/ OR exp *"artificial heart pacemaker"/ OR "pacemaker".ti
OR "pacemakers".ti OR exp *"Artificial Heart"/ OR "artificial heart".ti OR "artificial hearts".ti OR exp *"Heart Assist Device"/ OR "Artificial Heart".ti OR "Artificial Ventricle".ti OR "Artificial Ventricles".ti OR "Heart Assist Device".ti OR "Heart Assist Devices".ti OR "Heart Assist Pump".ti OR "Heart Assist Pumps".ti OR "Vascular Assist Device".ti OR "Vascular Assist Devices".ti OR "Ventricle Assist Device".ti OR "Ventricle Assist Devices".ti OR "Ventricular Assist Device".ti OR "Ventricular Assist Devices".ti OR exp *"Heart Valve Prosthesis"/ OR "Heart Valve Prosthesis".ti OR "Heart Valve Prosthesis".ti OR "Cardiac Valve Prosthesis".ti OR "Cardiac Valve Prostheses".ti OR "Heart Prosthesis".ti OR "Heart Prosthesis".ti OR "Cardiac Prosthesis".ti OR "Cardiac Prostheses".ti OR "artificial heart valves".ti OR "artificial heart valve".ti OR "artificial valves".ti OR "artificial valves".ti OR exp *"Implantable Defibrillator"/ OR "Implantable Defibrillator".ti OR "Implantable Defibrillators".ti OR "Implantable Cardioverter Defibrillator".ti OR "Implantable Cardioverter Defibrillators".ti OR exp *"bioresorbable vascular stent"/ OR "bioresorbable vascular scaffold".ti OR "bioresorbable vascular scaffolds".ti OR exp *"transcatheter aortic valve implantation"/ OR "transcatheter aortic valve implantation".ti OR "transcatheter aortic valve implant".ti OR "transcatheter aortic valve implants".ti OR "TAVI".ti OR "transseptal mitral valve-in-ring".ti OR "TMVR".ti OR ("".ti) OR "LAAOC".ti OR ((exp *"Heart"/ OR "heart".ti OR "cardiac".ti) AND (exp *"Prosthesis"/ OR "Prostheses".ti OR "Prosthesis".ti OR "Implants".ti OR "Implant".ti OR "replacement".ti OR "replacements".ti))) AND (exp "Register"/ OR "register".ti,ab OR "registers".ti,ab OR "registry".ti,ab OR "registries".ti,ab OR "register".in OR "registers".in OR "registry".in OR "registries".in) AND (exp "European Union"/ OR "European Union".ti,ab OR "European Community".ti,ab OR "European Coal and Steel Community".ti,ab OR

"Common Market".ti,ab OR "EEC".ti,ab OR "European Economic Community".ti,ab OR "European Common Market".ti,ab OR "European Economic Area".ti,ab OR exp "Europe"/ OR "Albania"/ OR "Andorra"/ OR "Armenia"/ OR "Armenia"/ OR "Austria"/ OR "Azerbaijan"/ OR "Republic of Belarus"/ OR "Belgium"/ OR "Bosnia and Herzegovina"/ OR "Bulgaria"/ OR "Croatia"/ OR "Czech Republic"/ OR "Denmark"/ OR "England"/ OR "Estonia"/ OR "Finland"/ OR "France"/ OR "Georgia"/ OR "Germany"/ OR "Gibraltar"/ OR "Greece"/ OR "Hungary"/ OR "Iceland"/ OR "Ireland"/ OR "Italy"/ OR "Kazakhstan"/ OR "Kosovo"/ OR "Kyrgyzstan"/ OR "Latvia"/ OR "Liechtenstein"/ OR "Lithuania"/ OR "Luxembourg"/ OR "Malta"/ OR "Moldova"/ OR "Monaco"/ OR "Montenegro"/ OR "Netherlands"/ OR "Republic of North Macedonia"/ OR "Northern Ireland"/ OR "Norway"/ OR "Poland"/ OR "Portugal"/ OR "Romania"/ OR "Russia"/ OR "San Marino"/ OR "Scotland"/ OR "Serbia"/ OR "Slovakia"/ OR "Slovenia"/ OR "Spain"/ OR "Sweden"/ OR "Switzerland"/ OR "Turkey"/ OR "Ukraine"/ OR "United Kingdom"/ OR "Uzbekistan"/ OR "Vatican City"/ OR "Wales"/ OR "Europe".ti,ab OR "European".ti,ab OR "Albania".ti,ab OR "Andorra".ti,ab OR "Armenia".ti,ab OR "Armenia".ti,ab OR "Austria".ti,ab OR "Azerbaijan".ti,ab OR "Belarus".ti,ab OR "Belgium".ti,ab OR "Bosnia".ti,ab OR "Bulgaria".ti,ab OR "Croatia".ti,ab OR "Czech Republic".ti,ab OR "Denmark".ti,ab OR "England".ti,ab OR "Estonia".ti,ab OR "Finland".ti,ab OR "France".ti,ab OR "Georgia".ti,ab OR "Germany".ti,ab OR "Gibraltar".ti,ab OR "Greece".ti,ab OR "Herzegovina".ti,ab OR "Hungary".ti,ab OR "Iceland".ti,ab OR "Ireland".ti,ab OR "Italy".ti,ab OR "Kazakhstan".ti,ab OR "Kosovo".ti,ab OR "Kyrgyzstan".ti,ab OR "Latvia".ti,ab OR "Liechtenstein".ti,ab OR "Lithuania".ti,ab OR "Luxembourg".ti,ab OR "Malta".ti,ab OR "Moldova".ti,ab OR "Monaco".ti,ab OR "Montenegro".ti,ab OR "Netherlands".ti,ab OR "North Macedonia".ti,ab OR "Northern Ireland".ti,ab OR "Norway".ti,ab OR "Poland".ti,ab OR "Portugal".ti,ab OR "Romania".ti,ab OR "Russia".ti,ab OR "San Marino".ti,ab OR "Scotland".ti,ab OR "Serbia".ti,ab OR "Slovakia".ti,ab OR "Slovenia".ti,ab OR "Spain".ti,ab OR "Sweden".ti,ab OR "Switzerland".ti,ab OR "Turkey".ti,ab OR "Ukraine".ti,ab OR "United Kingdom".ti,ab OR "Uzbekistan".ti,ab OR "Vatican City".ti,ab OR "Wales".ti,ab OR "Albanian".ti,ab OR "Armenian".ti,ab OR "Austrian".ti,ab OR "Belgian".ti,ab OR "Bosnian".ti,ab OR "Bulgarian".ti,ab OR "Croatian".ti,ab OR "Czech".ti,ab OR "Danish".ti,ab OR "British".ti,ab OR "Estonian".ti,ab OR "Finnish".ti,ab OR "French".ti,ab OR "Georgian".ti,ab OR "German".ti,ab OR "Greek".ti,ab OR "Hungarian".ti,ab OR "Icelandic".ti,ab OR "Irish".ti,ab OR

"Italian".ti,ab OR "Kosovan".ti,ab OR "Latvian".ti,ab OR "Lithuanian".ti,ab OR "Moldovan".ti,ab OR "Dutch".ti,ab OR "Macedonian".ti,ab OR "Norwegian".ti,ab OR "Polish".ti,ab OR "Romanian".ti,ab OR "Russian".ti,ab OR "Scottish".ti,ab OR "Serbian".ti,ab OR "Slovakian".ti,ab OR "Slovenian".ti,ab OR "Spanish".ti,ab OR "Swedish".ti,ab OR "Swiss".ti,ab OR "Turkish".ti,ab OR "Ukrainian".ti,ab OR "Welsh".ti,ab)) OR ((exp *"cardiac implantable electronic device"/ OR exp *"artificial heart pacemaker"/ OR "pacemaker".ti,ab OR "pacemakers".ti,ab OR exp *"Artificial Heart"/ OR "artificial heart".ti,ab OR "artificial hearts".ti,ab OR exp *"Heart Assist Device"/ OR "Artificial Heart".ti,ab OR "Artificial Ventricle".ti,ab OR "Artificial Ventricles".ti,ab OR "Heart Assist Device".ti,ab OR "Heart Assist Devices".ti,ab OR "Heart Assist Pump".ti,ab OR "Heart Assist Pumps".ti,ab OR "Vascular Assist Device".ti,ab OR "Vascular Assist Devices".ti,ab OR "Ventricle Assist Device".ti,ab OR "Ventricle Assist Devices".ti,ab OR "Ventricular Assist Device".ti,ab OR "Ventricular Assist Devices".ti,ab OR exp *"Heart Valve Prosthesis"/ OR "Heart Valve Prosthesis".ti,ab OR "Heart Valve Prosthesis".ti,ab OR "Cardiac Valve Prosthesis".ti,ab OR "Cardiac Valve Prostheses".ti,ab OR "Heart Prosthesis".ti,ab OR "Heart Prosthesis".ti,ab OR "Cardiac Prosthesis".ti,ab OR "Cardiac Prostheses".ti,ab OR "artificial heart valves".ti,ab OR "artificial heart valve".ti,ab OR "artificial valves".ti,ab OR "artificial valves".ti,ab OR exp *"Implantable Defibrillator"/ OR "Implantable Defibrillator".ti,ab OR "Implantable Defibrillators".ti,ab OR "Implantable Cardioverter Defibrillator".ti,ab OR "Implantable Cardioverter Defibrillators".ti,ab OR exp *"bioresorbable vascular stent"/ OR "bioresorbable vascular scaffold".ti,ab OR "bioresorbable vascular scaffolds".ti,ab OR exp *"transcatheter aortic valve implantation"/ OR "transcatheter aortic valve implantation".ti,ab OR "transcatheter aortic valve implant".ti,ab OR "transcatheter aortic valve implants".ti,ab OR "TAVI".ti,ab OR "transseptal mitral valve-in-ring".ti,ab OR "TMVR".ti,ab OR ("".ti,ab) OR "LAAOC".ti,ab OR ((exp *"Heart"/ OR "heart".ti,ab OR "cardiac".ti,ab) AND (exp *"Prosthesis"/ OR "Prostheses".ti,ab OR "Prosthesis".ti,ab OR "Implants".ti,ab OR "Implant".ti,ab OR "replacement".ti,ab OR "replacements".ti,ab))) AND (exp *"Register"/ OR "register".ti OR "registers".ti OR "registry".ti OR "registries".ti OR "register".in OR "registers".in OR "registry".in OR "registries".in) AND (exp "European Union"/ OR "European Union".ti,ab OR "European Community".ti,ab OR "European Coal and Steel Community".ti,ab OR "Common Market".ti,ab OR "EEC".ti,ab OR "European Economic Community".ti,ab OR "European Common Market".ti,ab OR

"European Economic Area".ti,ab OR exp "Europe"/ OR "Albania"/ OR "Andorra"/ OR "Armenia"/ OR "Armenia"/ OR "Austria"/ OR "Azerbaijan"/ OR "Republic of Belarus"/ OR "Belgium"/ OR "Bosnia and Herzegovina"/ OR "Bulgaria"/ OR "Croatia"/ OR "Czech Republic"/ OR "Denmark"/ OR "England"/ OR "Estonia"/ OR "Finland"/ OR "France"/ OR "Georgia"/ OR "Germany"/ OR "Gibraltar"/ OR "Greece"/ OR "Hungary"/ OR "Iceland"/ OR "Ireland"/ OR "Italy"/ OR "Kazakhstan"/ OR "Kosovo"/ OR "Kyrgyzstan"/ OR "Latvia"/ OR "Liechtenstein"/ OR "Lithuania"/ OR "Luxembourg"/ OR "Malta"/ OR "Moldova"/ OR "Monaco"/ OR "Montenegro"/ OR "Netherlands"/ OR "Republic of North Macedonia"/ OR "Northern Ireland"/ OR "Norway"/ OR "Poland"/ OR "Portugal"/ OR "Romania"/ OR "Russia"/ OR "San Marino"/ OR "Scotland"/ OR "Serbia"/ OR "Slovakia"/ OR "Slovenia"/ OR "Spain"/ OR "Sweden"/ OR "Switzerland"/ OR "Turkey"/ OR "Ukraine"/ OR "United Kingdom"/ OR "Uzbekistan"/ OR "Vatican City"/ OR "Wales"/ OR "Europe".ti,ab OR "European".ti,ab OR "Albania".ti,ab OR "Andorra".ti,ab OR "Armenia".ti,ab OR "Armenia".ti,ab OR "Austria".ti,ab OR "Azerbaijan".ti,ab OR "Belarus".ti,ab OR "Belgium".ti,ab OR "Bosnia".ti,ab OR "Bulgaria".ti,ab OR "Croatia".ti,ab OR "Czech Republic".ti,ab OR "Denmark".ti,ab OR "England".ti,ab OR "Estonia".ti,ab OR "Finland".ti,ab OR "France".ti,ab OR "Georgia".ti,ab OR "Germany".ti,ab OR "Gibraltar".ti,ab OR "Greece".ti,ab OR "Herzegovina".ti,ab OR "Hungary".ti,ab OR "Iceland".ti,ab OR "Ireland".ti,ab OR "Italy".ti,ab OR "Kazakhstan".ti,ab OR "Kosovo".ti,ab OR "Kyrgyzstan".ti,ab OR "Latvia".ti,ab OR "Liechtenstein".ti,ab OR "Lithuania".ti,ab OR "Luxembourg".ti,ab OR "Malta".ti,ab OR "Moldova".ti,ab OR "Monaco".ti,ab OR "Montenegro".ti,ab OR "Netherlands".ti,ab OR "North Macedonia".ti,ab OR "Northern Ireland".ti,ab OR "Norway".ti,ab OR "Poland".ti,ab OR "Portugal".ti,ab OR "Romania".ti,ab OR "Russia".ti,ab OR "San Marino".ti,ab OR "Scotland".ti,ab OR "Serbia".ti,ab OR "Slovakia".ti,ab OR "Slovenia".ti,ab OR "Spain".ti,ab OR "Sweden".ti,ab OR "Switzerland".ti,ab OR "Turkey".ti,ab OR "Ukraine".ti,ab OR "United Kingdom".ti,ab OR "Uzbekistan".ti,ab OR "Vatican City".ti,ab OR "Wales".ti,ab OR "Albanian".ti,ab OR "Armenian".ti,ab OR "Austrian".ti,ab OR "Belgian".ti,ab OR "Bosnian".ti,ab OR "Bulgarian".ti,ab OR "Croatian".ti,ab OR "Czech".ti,ab OR "Danish".ti,ab OR "British".ti,ab OR "Estonian".ti,ab OR "Finnish".ti,ab OR "French".ti,ab OR "Georgian".ti,ab OR "German".ti,ab OR "Greek".ti,ab OR "Hungarian".ti,ab OR "Icelandic".ti,ab OR "Irish".ti,ab OR "Italian".ti,ab OR "Kosovan".ti,ab OR "Latvian".ti,ab OR "Lithuanian".ti,ab OR "Moldovan".ti,ab OR "Dutch".ti,ab OR

"Macedonian".ti,ab OR "Norwegian".ti,ab OR "Polish".ti,ab OR "Romanian".ti,ab OR "Russian".ti,ab OR "Scottish".ti,ab OR "Serbian".ti,ab OR "Slovakian".ti,ab OR "Slovenian".ti,ab OR "Spanish".ti,ab OR "Swedish".ti,ab OR "Swiss".ti,ab OR "Turkish".ti,ab OR "Ukrainian".ti,ab OR "Welsh".ti,ab))) AND (2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022).yr

Medline – Orthopaedic registries

(((exp *Arthroplasty, Replacement, Hip/ OR exp *Hip Prosthesis/ OR hip replacement.ti. OR hip replacement*.ti. OR hip arthroplasty.ti. OR hip arthroplast*.ti. OR hip prosthesis.ti. OR hip prosthe*.ti. OR THA.ti. OR THR.ti. OR hip implant.ti. OR hip implants.ti. OR exp *Arthroplasty, Replacement, Knee/ OR exp *Knee Prosthesis/ OR knee replacement.ti. OR knee replacement*.ti. OR knee arthroplasty.ti. OR knee arthroplast*.ti. OR knee prosthesis.ti. OR knee prosthe*.ti. OR TKA.ti. OR TKR.ti. OR knee implant.ti. OR knee implants.ti. OR exp *Arthroplasty, Replacement, Shoulder/ OR exp *Shoulder Prosthesis/ OR shoulder replacement.ti. OR shoulder replacement*.ti. OR shoulder arthroplasty.ti. OR shoulder arthroplast*.ti. OR shoulder prosthesis.ti. OR shoulder prosthe*.ti. OR shoulder implant.ti. OR knee implants.ti. OR exp *Arthroplasty, Replacement, Ankle/ OR exp *Ankle Prosthesis/ OR ankle replacement.ti. OR ankle replacement*.ti. OR ankle arthroplasty.ti. OR ankle arthroplast*.ti. OR ankle prosthesis.ti. OR ankle prosthe*.ti. OR ankle implant.ti. OR ankle implants.ti. OR ((exp *Hip/ OR exp *Hip Joint/ OR hip.ti. OR hips.ti. OR exp *Knee/ OR exp *Knee Joint/ OR knee.ti. OR knees.ti. OR exp *Shoulder/ OR exp *Shoulder Joint/ OR Shoulder.ti. OR Shoulders.ti. OR exp *Ankle/ OR exp *Ankle Joint/ OR ankle.ti. OR ankles.ti.) AND (exp *Prostheses and Implants/ OR Prostheses.ti. OR Prosthesis.ti. OR Implants.ti. OR Implant.ti. OR replacement.ti. OR replacements.ti. OR arthroplasty.ti. OR arthroplast*.ti.))) AND (exp Registries/ OR register.mp. OR registers.mp. OR registry.mp. OR registries.mp. OR register.in OR registers.in OR registry.in OR registries.in) AND (exp European Union/ OR European Union.mp. OR European Community.mp. OR European Coal and Steel Community.mp. OR Common Market.mp. OR EEC.mp. OR European Economic Community.mp. OR European Common Market.mp. OR European Economic Area.mp. OR exp Europe/ OR exp Albania/ OR exp Andorra/ OR exp Armenia/ OR exp Armenia/ OR exp Austria/ OR exp Azerbaijan/ OR exp Republic of Belarus/ OR exp Belgium/ OR exp Bosnia and Herzegovina/ OR exp Bulgaria/ OR exp Croatia/ OR

exp Czech Republic/ OR exp Denmark/ OR exp England/ OR exp Estonia/ OR exp Finland/ OR exp France/ OR exp Georgia/ OR exp Germany/ OR exp Gibraltar/ OR exp Greece/ OR exp Hungary/ OR exp Iceland/ OR exp Ireland/ OR exp Italy/ OR exp Kazakhstan/ OR exp Kosovo/ OR exp Kyrgyzstan/ OR exp Latvia/ OR exp Liechtenstein/ OR exp Lithuania/ OR exp Luxembourg/ OR exp Malta/ OR exp Moldova/ OR exp Monaco/ OR exp Montenegro/ OR exp Netherlands/ OR exp Republic of North Macedonia/ OR exp Northern Ireland/ OR exp Norway/ OR exp Poland/ OR exp Portugal/ OR exp Romania/ OR exp Russia/ OR exp San Marino/ OR exp Scotland/ OR exp Serbia/ OR exp Slovakia/ OR exp Slovenia/ OR exp Spain/ OR exp Sweden/ OR exp Switzerland/ OR exp Turkey/ OR exp Ukraine/ OR exp United Kingdom/ OR exp Uzbekistan/ OR exp Vatican City/ OR exp Wales/ OR Europe.mp. OR European.mp. OR Albania.mp. OR Andorra.mp. OR Armenia.mp. OR Armenia.mp. OR Austria.mp. OR Azerbaijan.mp. OR Belarus.mp. OR Belgium.mp. OR Bosnia.mp. OR Bulgaria.mp. OR Croatia.mp. OR Czech Republic.mp. OR Denmark.mp. OR England.mp. OR Estonia.mp. OR Finland.mp. OR France.mp. OR Georgia.mp. OR Germany.mp. OR Gibraltar.mp. OR Greece.mp. OR Herzegovina.mp. OR Hungary.mp. OR Iceland.mp. OR Ireland.mp. OR Italy.mp. OR Kazakhstan.mp. OR Kosovo.mp. OR Kyrgyzstan.mp. OR Latvia.mp. OR Liechtenstein.mp. OR Lithuania.mp. OR Luxembourg.mp. OR Malta.mp. OR Moldova.mp. OR Monaco.mp. OR Montenegro.mp. OR Netherlands.mp. OR North Macedonia.mp. OR Northern Ireland.mp. OR Norway.mp. OR Poland.mp. OR Portugal.mp. OR Romania.mp. OR Russia.mp. OR San Marino.mp. OR Scotland.mp. OR Serbia.mp. OR Slovakia.mp. OR Slovenia.mp. OR Spain.mp. OR Sweden.mp. OR Switzerland.mp. OR Turkey.mp. OR Ukraine.mp. OR United Kingdom.mp. OR Uzbekistan.mp. OR Vatican City.mp. OR Wales.mp. OR "Albanian".mp OR "Armenian".mp OR "Austrian".mp OR "Belgian".mp OR "Bosnian".mp OR "Bulgarian".mp OR "Croatian".mp OR "Czech".mp OR "Danish".mp OR "British".mp OR "Estonian".mp OR "Finnish".mp OR "French".mp OR "Georgian".mp OR "German".mp OR "Greek".mp OR "Hungarian".mp OR "Icelandic".mp OR "Irish".mp OR "Italian".mp OR "Kosovan".mp OR "Latvian".mp OR "Lithuanian".mp OR "Moldovan".mp OR "Dutch".mp OR "Macedonian".mp OR "Norwegian".mp OR "Polish".mp OR "Romanian".mp OR "Russian".mp OR "Scottish".mp OR "Serbian".mp OR "Slovakian".mp OR "Slovenian".mp OR "Spanish".mp OR "Swedish".mp OR "Swiss".mp OR "Turkish".mp OR "Ukrainian".mp OR "Welsh".mp)) OR ((exp Arthroplasty, Replacement, Hip/ OR exp Hip Prosthesis/ OR

hip replacement.mp. OR hip replacement*.mp. OR hip arthroplasty.mp. OR hip arthroplast*.mp. OR hip prosthesis.mp. OR hip prosthe*.mp. OR THA.mp. OR THR.mp. OR hip implant.mp. OR hip implants.mp. OR exp Arthroplasty, Replacement, Knee/ OR exp Knee Prosthesis/ OR knee replacement.mp. OR knee replacement*.mp. OR knee arthroplasty.mp. OR knee arthroplast*.mp. OR knee prosthesis.mp. OR knee prosthe*.mp. OR TKA.mp. OR TKR.mp. OR knee implant.mp. OR knee implants.mp. OR exp Arthroplasty, Replacement, Shoulder/ OR exp Shoulder Prosthesis/ OR shoulder replacement.mp. OR shoulder replacement*.mp. OR shoulder arthroplasty.mp. OR shoulder arthroplast*.mp. OR shoulder prosthesis.mp. OR shoulder prosthe*.mp. OR shoulder implant.mp. OR knee implants.mp. OR exp Arthroplasty, Replacement, Ankle/ OR exp Ankle Prosthesis/ OR ankle replacement.mp. OR ankle replacement*.mp. OR ankle arthroplasty.mp. OR ankle arthroplast*.mp. OR ankle prosthesis.mp. OR ankle prosthe*.mp. OR ankle implant.mp. OR ankle implants.mp. OR ((exp Hip/ OR exp Hip Joint/ OR hip.mp. OR hips.mp. OR exp Knee/ OR exp Knee Joint/ OR knee.mp. OR knees.mp. OR exp Shoulder/ OR exp Shoulder Joint/ OR Shoulder.mp. OR Shoulders.mp. OR exp Ankle/ OR exp Ankle Joint/ OR ankle.mp. OR ankles.mp.) AND (exp Prostheses and Implants/ OR Prostheses.mp. OR Prosthesis.mp. OR Implants.mp. OR Implant.mp. OR replacement.mp. OR replacements.mp. OR arthroplasty.mp. OR arthroplast*.mp.))) AND (exp *Registries/ OR register.ti. OR registers.ti. OR registry.ti. OR registries.ti. OR register.in OR registers.in OR registry.in OR registries.in) AND (exp European Union/ OR European Union.mp. OR European Community.mp. OR European Coal and Steel Community.mp. OR Common Market.mp. OR EEC.mp. OR European Economic Community.mp. OR European Common Market.mp. OR European Economic Area.mp. OR exp Europe/ OR exp Albania/ OR exp Andorra/ OR exp Armenia/ OR exp Armenia/ OR exp Austria/ OR exp Azerbaijan/ OR exp Republic of Belarus/ OR exp Belgium/ OR exp Bosnia and Herzegovina/ OR exp Bulgaria/ OR exp Croatia/ OR exp Czech Republic/ OR exp Denmark/ OR exp England/ OR exp Estonia/ OR exp Finland/ OR exp France/ OR exp Georgia/ OR exp Germany/ OR exp Gibraltar/ OR exp Greece/ OR exp Hungary/ OR exp Iceland/ OR exp Ireland/ OR exp Italy/ OR exp Kazakhstan/ OR exp Kosovo/ OR exp Kyrgyzstan/ OR exp Latvia/ OR exp Liechtenstein/ OR exp Lithuania/ OR exp Luxembourg/ OR exp Malta/ OR exp Moldova/ OR exp Monaco/ OR exp Montenegro/ OR exp Netherlands/ OR exp Republic of North Macedonia/ OR exp Northern Ireland/ OR exp Norway/ OR exp Poland/ OR exp

Portugal/ OR exp Romania/ OR exp Russia/ OR exp San Marino/ OR exp Scotland/ OR exp Serbia/ OR exp Slovakia/ OR exp Slovenia/ OR exp Spain/ OR exp Sweden/ OR exp Switzerland/ OR exp Turkey/ OR exp Ukraine/ OR exp United Kingdom/ OR exp Uzbekistan/ OR exp Vatican City/ OR exp Wales/ OR Europe.mp. OR European.mp. OR Albania.mp. OR Andorra.mp. OR Armenia.mp. OR Armenia.mp. OR Austria.mp. OR Azerbaijan.mp. OR Belarus.mp. OR Belgium.mp. OR Bosnia.mp. OR Bulgaria.mp. OR Croatia.mp. OR Czech Republic.mp. OR Denmark.mp. OR England.mp. OR Estonia.mp. OR Finland.mp. OR France.mp. OR Georgia.mp. OR Germany.mp. OR Gibraltar.mp. OR Greece.mp. OR Herzegovina.mp. OR Hungary.mp. OR Iceland.mp. OR Ireland.mp. OR Italy.mp. OR Kazakhstan.mp. OR Kosovo.mp. OR Kyrgyzstan.mp. OR Latvia.mp. OR Liechtenstein.mp. OR Lithuania.mp. OR Luxembourg.mp. OR Malta.mp. OR Moldova.mp. OR Monaco.mp. OR Montenegro.mp. OR Netherlands.mp. OR North Macedonia.mp. OR Northern Ireland.mp. OR Norway.mp. OR Poland.mp. OR Portugal.mp. OR Romania.mp. OR Russia.mp. OR San Marino.mp. OR Scotland.mp. OR Serbia.mp. OR Slovakia.mp. OR Slovenia.mp. OR Spain.mp. OR Sweden.mp. OR Switzerland.mp. OR Turkey.mp. OR Ukraine.mp. OR United Kingdom.mp. OR Uzbekistan.mp. OR Vatican City.mp. OR Wales.mp. OR "Albanian".mp OR "Armenian".mp OR "Austrian".mp OR "Belgian".mp OR "Bosnian".mp OR "Bulgarian".mp OR "Croatian".mp OR "Czech".mp OR "Danish".mp OR "British".mp OR "Estonian".mp OR "Finnish".mp OR "French".mp OR "Georgian".mp OR "German".mp OR "Greek".mp OR "Hungarian".mp OR "Icelandic".mp OR "Irish".mp OR "Italian".mp OR "Kosovan".mp OR "Latvian".mp OR "Lithuanian".mp OR "Moldovan".mp OR "Dutch".mp OR "Macedonian".mp OR "Norwegian".mp OR "Polish".mp OR "Romanian".mp OR "Russian".mp OR "Scottish".mp OR "Serbian".mp OR "Slovakian".mp OR "Slovenian".mp OR "Spanish".mp OR "Swedish".mp OR "Swiss".mp OR "Turkish".mp OR "Ukrainian".mp OR "Welsh".mp))) AND (2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022).yr

Medline – Cardiovascular registries

(((exp *Pacemaker, Artificial/ OR pacemaker.ti. OR pacemakers.ti. OR exp *Heart, Artificial/ OR artificial heart.ti. OR artificial hearts.ti. OR exp *Heart-Assist Devices/ OR Artificial Heart .ti. OR Artificial Ventricle.ti. OR Artificial Ventricles.ti. OR Heart Assist Device.ti. OR Heart Assist Devices.ti.

OR Heart Assist Pump.ti. OR Heart Assist Pumps.ti. OR Vascular Assist Device.ti. OR Vascular Assist Devices.ti. OR Ventricle Assist Device.ti. OR Ventricle Assist Devices.ti. OR Ventricular Assist Device.ti. OR Ventricular Assist Devices.ti. OR exp *Heart Valve Prosthesis/ OR Heart Valve Prosthesis.ti. OR Heart Valve Prosthesis.ti. OR Cardiac Valve Prosthesis.ti. OR Cardiac Valve Prostheses.ti. OR Heart Prosthesis.ti. OR Heart Prosthesis.ti. OR Cardiac Prosthesis.ti. OR Cardiac Prostheses.ti. OR artificial heart valves.ti. OR artificial heart valve.ti. OR artificial valves.ti. OR artificial valves.ti. OR exp *Defibrillators, Implantable/ OR Implantable Defibrillator.ti. OR Implantable Defibrillators.ti. OR Implantable Cardioverter Defibrillator.ti. OR Implantable Cardioverter Defibrillators.ti. OR bioresorbable vascular scaffold.ti. OR bioresorbable vascular scaffolds.ti. OR transcatheter aortic valve implantation.ti. OR transcatheter aortic valve implant.ti. OR transcatheter aortic valve implants.ti. OR TAVI.ti. OR transseptal mitral valve-in-ring.ti. OR TMVR.ti. OR (percutaneous.ti.
AND left anterior.ti. AND aortic cusp.ti.) OR LAAOC.ti. OR ((exp *Heart/ OR heart.ti. OR cardiac.ti.) AND (exp *Prostheses and Implants/ OR Prostheses.ti. OR Prosthesis.ti. OR Implants.ti. OR Implant.ti. OR replacement.ti. OR replacements.ti.))) AND (exp Registries/ OR register.mp. OR registers.mp. OR registry.mp. OR registries.mp. OR register.in OR registers.in OR registry.in OR registries.in) AND (exp European Union/ OR European Union.mp. OR European Community.mp. OR European Coal and Steel Community.mp. OR Common Market.mp. OR EEC.mp. OR European Economic Community.mp. OR European Common Market.mp. OR European Economic Area.mp. OR exp Europe/ OR exp Albania/ OR exp Andorra/ OR exp Armenia/ OR exp Armenia/ OR exp Austria/ OR exp Azerbaijan/ OR exp Republic of Belarus/ OR exp Belgium/ OR exp Bosnia and Herzegovina/ OR exp Bulgaria/ OR exp Croatia/ OR exp Czech Republic/ OR exp Denmark/ OR exp England/ OR exp Estonia/ OR exp Finland/ OR exp France/ OR exp Georgia/ OR exp Germany/ OR exp Gibraltar/ OR exp Greece/ OR exp Hungary/ OR exp Iceland/ OR exp Ireland/ OR exp Italy/ OR exp Kazakhstan/ OR exp Kosovo/ OR exp Kyrgyzstan/ OR exp Latvia/ OR exp Liechtenstein/ OR exp Lithuania/ OR exp Luxembourg/ OR exp Malta/ OR exp Moldova/ OR exp Monaco/ OR exp Montenegro/ OR exp Netherlands/ OR exp Republic of North Macedonia/ OR exp Northern Ireland/ OR exp Norway/ OR exp Poland/ OR exp Portugal/ OR exp Romania/ OR exp Russia/ OR exp San Marino/ OR exp Scotland/ OR exp Serbia/ OR exp Slovakia/ OR

exp Slovenia/ OR exp Spain/ OR exp Sweden/ OR exp Switzerland/ OR exp Turkey/ OR exp Ukraine/ OR exp United Kingdom/ OR exp Uzbekistan/ OR exp Vatican City/ OR exp Wales/ OR Europe.mp. OR European.mp. OR Albania.mp. OR Andorra.mp. OR Armenia.mp. OR Armenia.mp. OR Austria.mp. OR Azerbaijan.mp. OR Belarus.mp. OR Belgium.mp. OR Bosnia.mp. OR Bulgaria.mp. OR Croatia.mp. OR Czech Republic.mp. OR Denmark.mp. OR England.mp. OR Estonia.mp. OR Finland.mp. OR France.mp. OR Georgia.mp. OR Germany.mp. OR Gibraltar.mp. OR Greece.mp. OR Herzegovina.mp. OR Hungary.mp. OR Iceland.mp. OR Ireland.mp. OR Italy.mp. OR Kazakhstan.mp. OR Kosovo.mp. OR Kyrgyzstan.mp. OR Latvia.mp. OR Liechtenstein.mp. OR Lithuania.mp. OR Luxembourg.mp. OR Malta.mp. OR Moldova.mp. OR Monaco.mp. OR Montenegro.mp. OR Netherlands.mp. OR North Macedonia.mp. OR Northern Ireland.mp. OR Norway.mp. OR Poland.mp. OR Portugal.mp. OR Romania.mp. OR Russia.mp. OR San Marino.mp. OR Scotland.mp. OR Serbia.mp. OR Slovakia.mp. OR Slovenia.mp. OR Spain.mp. OR Sweden.mp. OR Switzerland.mp. OR Turkey.mp. OR Ukraine.mp. OR United Kingdom.mp. OR Uzbekistan.mp. OR Vatican City.mp. OR Wales.mp. OR Albanian.mp. OR Armenian.mp. OR Austrian.mp. OR Belgian.mp. OR Bosnian.mp. OR Bulgarian.mp. OR Croatian.mp. OR Czech.mp. OR Danish.mp. OR British.mp. OR Estonian.mp. OR Finnish.mp. OR French.mp. OR Georgian.mp. OR German.mp. OR Greek.mp. OR Hungarian.mp. OR Icelandic.mp. OR Irish.mp. OR Italian.mp. OR Kosovan.mp. OR Latvian.mp. OR Lithuanian.mp. OR Moldovan.mp. OR Dutch.mp. OR Macedonian.mp. OR Norwegian.mp. OR Polish.mp. OR Romanian.mp. OR Russian.mp. OR Scottish.mp. OR Serbian.mp. OR Slovakian.mp. OR Slovenian.mp. OR Spanish.mp. OR Swedish.mp. OR Swiss.mp. OR Turkish.mp. OR Ukrainian.mp. OR Welsh.mp.)) OR ((exp Pacemaker, Artificial/ OR pacemaker.mp. OR pacemakers.mp. OR exp Heart, Artificial/ OR artificial heart.mp. OR artificial hearts.mp. OR exp Heart-Assist Devices/ OR Artificial Heart .mp. OR Artificial Ventricle.mp. OR Artificial Ventricles.mp. OR Heart Assist Device.mp. OR Heart Assist Devices.mp. OR Heart Assist Pump.mp. OR Heart Assist Pumps.mp. OR Vascular Assist Device.mp. OR Vascular Assist Devices.mp. OR Ventricle Assist Device.mp. OR Ventricle Assist Devices.mp. OR Ventricular Assist Device.mp. OR Ventricular Assist Devices.mp. OR exp Heart Valve Prosthesis/ OR Heart Valve Prosthesis.mp. OR Heart Valve Prosthesis.mp. OR Cardiac Valve Prosthesis.mp. OR Cardiac Valve Prostheses.mp. OR Heart Prosthesis.mp. OR Heart Prosthesis.mp. OR Cardiac Prosthesis.mp. OR Cardiac Prostheses.mp. OR

artificial heart valves.mp. OR artificial heart valve.mp. OR artificial valves.mp. OR artificial valves.mp. OR exp Defibrillators, Implantable/ OR Implantable Defibrillator.mp. OR Implantable Defibrillators.mp. OR Implantable Cardioverter Defibrillator.mp. OR Implantable Cardioverter Defibrillators.mp. OR bioresorbable vascular scaffold.mp. OR bioresorbable vascular scaffolds.mp. OR transcatheter aortic valve implantation.mp. OR transcatheter aortic valve implant.mp. OR transcatheter aortic valve implants.mp. OR TAVI.mp. OR transseptal mitral valve-in-ring.mp. OR TMVR.mp. OR (percutaneous.mp. AND left anterior.mp. AND aortic cusp.mp.) OR LAAOC.mp. OR ((exp Heart/ OR heart.mp. OR cardiac.mp.) AND (exp Prostheses and Implants/ OR Prostheses.mp. OR Prosthesis.mp. OR Implants.mp. OR Implant.mp. OR replacement.mp. OR replacements.mp.))) AND (exp *Registries/ OR register.ti. OR registers.ti. OR registry.ti. OR registries.ti. OR register.in OR registers.in OR registry.in OR registries.in) AND (exp European Union/ OR European Union.mp. OR European Community.mp. OR European Coal and Steel Community.mp. OR Common Market.mp. OR EEC.mp. OR European Economic Community.mp. OR European Common Market.mp. OR European Economic Area.mp. OR exp Europe/ OR exp Albania/ OR exp Andorra/ OR exp Armenia/ OR exp Armenia/ OR exp Austria/ OR exp Azerbaijan/ OR exp Republic of Belarus/ OR exp Belgium/ OR exp Bosnia and Herzegovina/ OR exp Bulgaria/ OR exp Croatia/ OR exp Czech Republic/ OR exp Denmark/ OR exp England/ OR exp Estonia/ OR exp Finland/ OR exp France/ OR exp Georgia/ OR exp Germany/ OR exp Gibraltar/ OR exp Greece/ OR exp Hungary/ OR exp Iceland/ OR exp Ireland/ OR exp Italy/ OR exp Kazakhstan/ OR exp Kosovo/ OR exp Kyrgyzstan/ OR exp Latvia/ OR exp Liechtenstein/ OR exp Lithuania/ OR exp Luxembourg/ OR exp Malta/ OR exp Moldova/ OR exp Monaco/ OR exp Montenegro/ OR exp Netherlands/ OR exp Republic of North Macedonia/ OR exp Northern Ireland/ OR exp Norway/ OR exp Poland/ OR exp Portugal/ OR exp Romania/ OR exp Russia/ OR exp San Marino/ OR exp Scotland/ OR exp Serbia/ OR exp Slovakia/ OR exp Slovenia/ OR exp Spain/ OR exp Sweden/ OR exp Switzerland/ OR exp Turkey/ OR exp Ukraine/ OR exp United Kingdom/ OR exp Uzbekistan/ OR exp Vatican City/ OR exp Wales/ OR Europe.mp. OR European.mp. OR Albania.mp. OR Andorra.mp. OR Armenia.mp. OR Armenia.mp. OR Austria.mp. OR Azerbaijan.mp. OR Belarus.mp. OR Belgium.mp. OR Bosnia.mp. OR Bulgaria.mp. OR Croatia.mp. OR Czech Republic.mp. OR Denmark.mp. OR England.mp. OR Estonia.mp. OR Finland.mp. OR France.mp. OR Georgia.mp. OR

Germany.mp. OR Gibraltar.mp. OR Greece.mp. OR Herzegovina.mp. OR Hungary.mp. OR Iceland.mp. OR Ireland.mp. OR Italy.mp. OR Kazakhstan.mp. OR Kosovo.mp. OR Kyrgyzstan.mp. OR Latvia.mp. OR Liechtenstein.mp. OR Lithuania.mp. OR Luxembourg.mp. OR Malta.mp. OR Moldova.mp. OR Monaco.mp. OR Montenegro.mp. OR Netherlands.mp. OR North Macedonia.mp. OR Northern Ireland.mp. OR Norway.mp. OR Poland.mp. OR Portugal.mp. OR Romania.mp. OR Russia.mp. OR San Marino.mp. OR Scotland.mp. OR Serbia.mp. OR Slovakia.mp. OR Slovenia.mp. OR Spain.mp. OR Sweden.mp. OR Switzerland.mp. OR Turkey.mp. OR Ukraine.mp. OR United Kingdom.mp. OR Uzbekistan.mp. OR Vatican City.mp. OR Wales.mp. OR Albanian.mp. OR Armenian.mp. OR Austrian.mp. OR Belgian.mp. OR Bosnian.mp. OR Bulgarian.mp. OR Croatian.mp. OR Czech.mp. OR Danish.mp. OR British.mp. OR Estonian.mp. OR Finnish.mp. OR French.mp. OR Georgian.mp. OR German.mp. OR Greek.mp. OR Hungarian.mp. OR Icelandic.mp. OR Irish.mp. OR Italian.mp. OR Kosovan.mp. OR Latvian.mp. OR Lithuanian.mp. OR Moldovan.mp. OR Dutch.mp. OR Macedonian.mp. OR Norwegian.mp. OR Polish.mp. OR Romanian.mp. OR Russian.mp. OR Scottish.mp. OR Serbian.mp. OR Slovakian.mp. OR Slovenian.mp. OR Spanish.mp. OR Swedish.mp. OR Swiss.mp. OR Turkish.mp. OR Ukrainian.mp. OR Welsh.mp.))) AND (2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022).yr

PubMed – Orthopaedic registries

((("Arthroplasty, Replacement, Hip"[majr] OR "Hip Prosthesis"[majr] OR "hip replacement"[ti] OR "hip replacement*"[ti] OR "hip arthroplasty"[ti] OR "hip arthroplast*"[ti] OR "hip prosthesis"[ti] OR "hip prosthe*"[ti] OR "THA"[ti] OR "THR"[ti] OR "hip implant"[ti] OR "hip implants"[ti] OR "Arthroplasty, Replacement, Knee"[majr] OR "Knee Prosthesis"[majr] OR "knee replacement"[ti] OR "knee replacement*"[ti] OR "knee arthroplasty"[ti] OR "knee arthroplast*"[ti] OR "knee prosthesis"[ti] OR "knee prosthe*"[ti] OR "TKA"[ti] OR "TKR"[ti] OR "knee implant"[ti] OR "knee implants"[ti] OR "Arthroplasty, Replacement, Shoulder"[majr] OR "Shoulder Prosthesis"[majr] OR "shoulder replacement"[ti] OR "shoulder replacement*"[ti] OR "shoulder arthroplasty"[ti] OR "shoulder arthroplast*"[ti] OR "shoulder prosthesis"[ti] OR "shoulder prosthe*"[ti] OR "shoulder implant"[ti] OR "knee implants"[ti] OR "Arthroplasty, Replacement, Ankle"[majr] OR "Ankle Prosthesis"[majr] OR

"ankle replacement"[ti] OR "ankle replacement*"[ti] OR "ankle arthroplasty"[ti] OR "ankle arthroplast*"[ti] OR "ankle prosthesis"[ti] OR "ankle prosthe*"[ti] OR "ankle implant"[ti] OR "ankle implants"[ti] OR (("Hip"[majr] OR "Hip Joint"[majr] OR "hip"[ti] OR "hips"[ti] OR "Knee"[majr] OR "Knee Joint"[majr] OR "knee"[ti] OR "knees"[ti] OR "Shoulder"[majr] OR "Shoulder Joint"[majr] OR "Shoulder"[ti] OR "Shoulders"[ti] OR "Ankle"[majr] OR "Ankle Joint"[majr] OR "ankle"[ti] OR "ankles"[ti]) AND ("Prostheses and Implants"[majr] OR "Prostheses"[ti] OR "Prosthesis"[ti] OR "Implants"[ti] OR "Implant"[ti] OR "replacement"[ti] OR "replacements"[ti] OR "arthroplasty"[ti] OR "arthroplast*"[ti]))) AND ("Registries"[Mesh] OR "register"[tw] OR "registers"[tw] OR "registry"[tw] OR "registries"[tw] OR "register"[ad] OR "registers"[ad] OR "registry"[ad] OR "registries"[ad]) AND ("European Union"[Mesh] OR "European Union"[tw] OR "European Community"[tw] OR "European Coal and Steel Community"[tw] OR "Common Market"[tw] OR "EEC"[tw] OR "European Economic Community"[tw] OR "European Common Market"[tw] OR "European Economic Area"[tw] OR "Europe"[Mesh] OR "Albania"[mesh] OR "Andorra"[mesh] OR "Armenia"[mesh] OR "Armenia"[mesh] OR "Austria"[mesh] OR "Azerbaijan"[mesh] OR "Republic of Belarus"[mesh] OR "Belgium"[mesh] OR "Bosnia and Herzegovina"[mesh] OR "Bulgaria"[mesh] OR "Croatia"[mesh] OR "Czech Republic"[mesh] OR "Denmark"[mesh] OR "England"[mesh] OR "Estonia"[mesh] OR "Finland"[mesh] OR "France"[mesh] OR "Georgia"[mesh] OR "Germany"[mesh] OR "Gibraltar"[mesh] OR "Greece"[mesh] OR "Hungary"[mesh] OR "Iceland"[mesh] OR "Ireland"[mesh] OR "Italy"[mesh] OR "Kazakhstan"[mesh] OR "Kosovo"[mesh] OR "Kyrgyzstan"[mesh] OR "Latvia"[mesh] OR "Liechtenstein"[mesh] OR "Lithuania"[mesh] OR "Luxembourg"[mesh] OR "Malta"[mesh] OR "Moldova"[mesh] OR "Monaco"[mesh] OR "Montenegro"[mesh] OR "Netherlands"[mesh] OR "Republic of North Macedonia"[mesh] OR "Northern Ireland"[mesh] OR "Norway"[mesh] OR "Poland"[mesh] OR "Portugal"[mesh] OR "Romania"[mesh] OR "Russia"[mesh] OR "San Marino"[mesh] OR "Scotland"[mesh] OR "Serbia"[mesh] OR "Slovakia"[mesh] OR "Slovenia"[mesh] OR "Spain"[mesh] OR "Sweden"[mesh] OR "Switzerland"[mesh] OR "Turkey"[Mesh] OR "Ukraine"[mesh] OR "United Kingdom"[mesh] OR "Uzbekistan"[mesh] OR "Vatican City"[mesh] OR "Wales"[mesh] OR "Europe"[tw] OR "European"[tw] OR "Albania"[tw] OR "Andorra"[tw] OR "Armenia"[tw] OR "Armenia"[tw] OR "Austria"[tw] OR "Azerbaijan"[tw] OR "Belarus"[tw] OR

"Belgium"[tw] OR "Bosnia"[tw] OR "Bulgaria"[tw] OR "Croatia"[tw] OR "Czech Republic"[tw] OR "Denmark"[tw] OR "England"[tw] OR "Estonia"[tw] OR "Finland"[tw] OR "France"[tw] OR "Georgia"[tw] OR "Germany"[tw] OR "Gibraltar"[tw] OR "Greece"[tw] OR "Herzegovina"[tw] OR "Hungary"[tw] OR "Iceland"[tw] OR "Ireland"[tw] OR "Italy"[tw] OR "Kazakhstan"[tw] OR "Kosovo"[tw] OR "Kyrgyzstan"[tw] OR "Latvia"[tw] OR "Liechtenstein"[tw] OR "Lithuania"[tw] OR "Luxembourg"[tw] OR "Malta"[tw] OR "Moldova"[tw] OR "Monaco"[tw] OR "Montenegro"[tw] OR "Netherlands"[tw] OR "North Macedonia"[tw] OR "Northern Ireland"[tw] OR "Norway"[tw] OR "Poland"[tw] OR "Portugal"[tw] OR "Romania"[tw] OR "Russia"[tw] OR "San Marino"[tw] OR "Scotland"[tw] OR "Serbia"[tw] OR "Slovakia"[tw] OR "Slovenia"[tw] OR "Spain"[tw] OR "Sweden"[tw] OR "Switzerland"[tw] OR "Turkey"[tw] OR "Ukraine"[tw] OR "United Kingdom"[tw] OR "Uzbekistan"[tw] OR "Vatican City"[tw] OR "Wales"[tw] OR "Albanian"[tw] OR "Armenian"[tw] OR "Austrian"[tw] OR "Belgian"[tw] OR "Bosnian"[tw] OR "Bulgarian"[tw] OR "Croatian"[tw] OR "Czech"[tw] OR "Danish"[tw] OR "British"[tw] OR "Estonian"[tw] OR "Finnish"[tw] OR "French"[tw] OR "Georgian"[tw] OR "German"[tw] OR "Greek"[tw] OR "Hungarian"[tw] OR "Icelandic"[tw] OR "Irish"[tw] OR "Italian"[tw] OR "Kosovan"[tw] OR "Latvian"[tw] OR "Lithuanian"[tw] OR "Moldovan"[tw] OR "Dutch"[tw] OR "Macedonian"[tw] OR "Norwegian"[tw] OR "Polish"[tw] OR "Romanian"[tw] OR "Russian"[tw] OR "Scottish"[tw] OR "Serbian"[tw] OR "Slovakian"[tw] OR "Slovenian"[tw] OR "Spanish"[tw] OR "Swedish"[tw] OR "Swiss"[tw] OR "Turkish"[tw] OR "Ukrainian"[tw] OR "Welsh"[tw])) OR (("Arthroplasty, Replacement, Hip"[Mesh] OR "Hip Prosthesis"[Mesh] OR "hip replacement"[tw] OR "hip replacement*"[tw] OR "hip arthroplasty"[tw] OR "hip arthroplast*"[tw] OR "hip prosthesis"[tw] OR "hip prosthe*"[tw] OR "THA"[tw] OR "THR"[tw] OR "hip implant"[tw] OR "hip implants"[tw] OR "Arthroplasty, Replacement, Knee"[Mesh] OR "Knee Prosthesis"[Mesh] OR "knee replacement"[tw] OR "knee replacement*"[tw] OR "knee arthroplasty"[tw] OR "knee arthroplast*"[tw] OR "knee prosthesis"[tw] OR "knee prosthe*"[tw] OR "TKA"[tw] OR "TKR"[tw] OR "knee implant"[tw] OR "knee implants"[tw] OR "Arthroplasty, Replacement, Shoulder"[Mesh] OR "Shoulder Prosthesis"[Mesh] OR "shoulder replacement"[tw] OR "shoulder replacement*"[tw] OR "shoulder arthroplasty"[tw] OR "shoulder arthroplast*"[tw] OR "shoulder prosthesis"[tw] OR "shoulder prosthe*"[tw] OR "shoulder implant"[tw] OR "knee implants"[tw] OR

"Arthroplasty, Replacement, Ankle"[Mesh] OR "Ankle Prosthesis"[Mesh] OR "ankle replacement"[tw] OR "ankle replacement*"[tw] OR "ankle arthroplasty"[tw] OR "ankle arthroplast*"[tw] OR "ankle prosthesis"[tw] OR "ankle prosthe*"[tw] OR "ankle implant"[tw] OR "ankle implants"[tw] OR (("Hip"[mesh] OR "Hip Joint"[Mesh] OR "hip"[tw] OR "hips"[tw] OR "Knee"[mesh] OR "Knee Joint"[mesh] OR "knee"[tw] OR "knees"[tw] OR "Shoulder"[Mesh] OR "Shoulder Joint"[Mesh] OR "Shoulder"[tw] OR "Shoulders"[tw] OR "Ankle"[mesh] OR "Ankle Joint"[mesh] OR "ankle"[tw] OR "ankles"[tw]) AND ("Prostheses and Implants"[Mesh] OR "Prostheses"[tw] OR "Prosthesis"[tw] OR "Implants"[tw] OR "Implant"[tw] OR "replacement"[tw] OR "replacements"[tw] OR "arthroplasty"[tw] OR "arthroplast*"[tw]))) AND ("Registries"[majr] OR "register"[ti] OR "registers"[ti] OR "registry"[ti] OR "registries"[ti] OR "register"[ad] OR "registers"[ad] OR "registry"[ad] OR "registries"[ad]) AND ("European Union"[Mesh] OR "European Union"[tw] OR "European Community"[tw] OR "European Coal and Steel Community"[tw] OR "Common Market"[tw] OR "EEC"[tw] OR "European Economic Community"[tw] OR "European Common Market"[tw] OR "European Economic Area"[tw] OR "Europe"[Mesh] OR "Albania"[mesh] OR "Andorra"[mesh] OR "Armenia"[mesh] OR "Armenia"[mesh] OR "Austria"[mesh] OR "Azerbaijan"[mesh] OR "Republic of Belarus"[mesh] OR "Belgium"[mesh] OR "Bosnia and Herzegovina"[mesh] OR "Bulgaria"[mesh] OR "Croatia"[mesh] OR "Czech Republic"[mesh] OR "Denmark"[mesh] OR "England"[mesh] OR "Estonia"[mesh] OR "Finland"[mesh] OR "France"[mesh] OR "Georgia"[mesh] OR "Germany"[mesh] OR "Gibraltar"[mesh] OR "Greece"[mesh] OR "Hungary"[mesh] OR "Iceland"[mesh] OR "Ireland"[mesh] OR "Italy"[mesh] OR "Kazakhstan"[mesh] OR "Kosovo"[mesh] OR "Kyrgyzstan"[mesh] OR "Latvia"[mesh] OR "Liechtenstein"[mesh] OR "Lithuania"[mesh] OR "Luxembourg"[mesh] OR "Malta"[mesh] OR "Moldova"[mesh] OR "Monaco"[mesh] OR "Montenegro"[mesh] OR "Netherlands"[mesh] OR "Republic of North Macedonia"[mesh] OR "Northern Ireland"[mesh] OR "Norway"[mesh] OR "Poland"[mesh] OR "Portugal"[mesh] OR "Romania"[mesh] OR "Russia"[mesh] OR "San Marino"[mesh] OR "Scotland"[mesh] OR "Serbia"[mesh] OR "Slovakia"[mesh] OR "Slovenia"[mesh] OR "Spain"[mesh] OR "Sweden"[mesh] OR "Switzerland"[mesh] OR "Turkey"[Mesh] OR "Ukraine"[mesh] OR "United Kingdom"[mesh] OR "Uzbekistan"[mesh] OR "Vatican City"[mesh] OR "Wales"[mesh] OR "Europe"[tw] OR "European"[tw] OR "Albania"[tw] OR "Andorra"[tw] OR

"Armenia"[tw] OR "Armenia"[tw] OR "Austria"[tw] OR "Azerbaijan"[tw] OR "Belarus"[tw] OR "Belgium"[tw] OR "Bosnia"[tw] OR "Bulgaria"[tw] OR "Croatia"[tw] OR "Czech Republic"[tw] OR "Denmark"[tw] OR "England"[tw] OR "Estonia"[tw] OR "Finland"[tw] OR "France"[tw] OR "Georgia"[tw] OR "Germany"[tw] OR "Gibraltar"[tw] OR "Greece"[tw] OR "Herzegovina"[tw] OR "Hungary"[tw] OR "Iceland"[tw] OR "Ireland"[tw] OR "Italy"[tw] OR "Kazakhstan"[tw] OR "Kosovo"[tw] OR "Kyrgyzstan"[tw] OR "Latvia"[tw] OR "Liechtenstein"[tw] OR "Lithuania"[tw] OR "Luxembourg"[tw] OR "Malta"[tw] OR "Moldova"[tw] OR "Monaco"[tw] OR "Montenegro"[tw] OR "Netherlands"[tw] OR "North Macedonia"[tw] OR "Northern Ireland"[tw] OR "Norway"[tw] OR "Poland"[tw] OR "Portugal"[tw] OR "Romania"[tw] OR "Russia"[tw] OR "San Marino"[tw] OR "Scotland"[tw] OR "Serbia"[tw] OR "Slovakia"[tw] OR "Slovenia"[tw] OR "Spain"[tw] OR "Sweden"[tw] OR "Switzerland"[tw] OR "Turkey"[tw] OR "Ukraine"[tw] OR "United Kingdom"[tw] OR "Uzbekistan"[tw] OR "Vatican City"[tw] OR "Wales"[tw] OR "Albanian"[tw] OR "Armenian"[tw] OR "Austrian"[tw] OR "Belgian"[tw] OR "Bosnian"[tw] OR "Bulgarian"[tw] OR "Croatian"[tw] OR "Czech"[tw] OR "Danish"[tw] OR "British"[tw] OR "Estonian"[tw] OR "Finnish"[tw] OR "French"[tw] OR "Georgian"[tw] OR "German"[tw] OR "Greek"[tw] OR "Hungarian"[tw] OR "Icelandic"[tw] OR "Irish"[tw] OR "Italian"[tw] OR "Kosovan"[tw] OR "Latvian"[tw] OR "Lithuanian"[tw] OR "Moldovan"[tw] OR "Dutch"[tw] OR "Macedonian"[tw] OR "Norwegian"[tw] OR "Polish"[tw] OR "Romanian"[tw] OR "Russian"[tw] OR "Scottish"[tw] OR "Serbian"[tw] OR "Slovakian"[tw] OR "Slovenian"[tw] OR "Spanish"[tw] OR "Swedish"[tw] OR "Swiss"[tw] OR "Turkish"[tw] OR "Ukrainian"[tw] OR "Welsh"[tw]))) AND ("2013/01/01"[PDAT] : "3000/12/31"[PDAT])

PubMed – Cardiovascular registries

((("Pacemaker, Artificial"[majr] OR "pacemaker"[ti] OR "pacemakers"[ti] OR "Heart, Artificial"[majr] OR "artificial heart"[ti] OR "artificial hearts"[ti] OR "Heart-Assist Devices"[majr] OR "Artificial Heart"[ti] OR "Artificial Ventricle"[ti] OR "Artificial Ventricles"[ti] OR "Heart Assist Device"[ti] OR "Heart Assist Devices"[ti] OR "Heart Assist Pump"[ti] OR "Heart Assist Pumps"[ti] OR "Vascular Assist Device"[ti] OR "Vascular Assist Devices"[ti] OR "Ventricle Assist Device"[ti] OR "Ventricle Assist Devices"[ti] OR "Ventricular Assist Device"[ti] OR "Ventricular Assist Devices"[ti] OR "Heart Valve

Prosthesis"[majr] OR "Heart Valve Prosthesis"[ti] OR "Heart Valve Prosthesis"[ti] OR "Cardiac Valve Prosthesis"[ti] OR "Cardiac Valve Prostheses"[ti] OR "Heart Prosthesis"[ti] OR "Heart Prosthesis"[ti] OR "Cardiac Prosthesis"[ti] OR "Cardiac Prostheses"[ti] OR "artificial heart valves"[ti] OR "artificial heart valve"[ti] OR "artificial valves"[ti] OR "artificial valves"[ti] OR "Defibrillators, Implantable"[majr] OR "Implantable Defibrillator"[ti] OR "Implantable Defibrillators"[ti] OR "Implantable Cardioverter Defibrillator"[ti] OR "Implantable Cardioverter Defibrillators"[ti] OR "bioresorbable vascular scaffold"[ti] OR "bioresorbable vascular scaffolds"[ti] OR "transcatheter aortic valve implantation"[ti] OR "transcatheter aortic valve implant"[ti] OR "transcatheter aortic valve implants"[ti] OR "TAVI"[ti] OR "transseptal mitral valve-in-ring"[ti] OR "TMVR"[ti] OR ("percutaneous"[ti] AND "left anterior"[ti] AND "aortic cusp"[ti]) OR "LAAOC"[ti] OR (("Heart"[majr] OR "heart"[ti] OR "cardiac"[ti]) AND ("Prostheses and Implants"[majr] OR "Prostheses"[ti] OR "Prosthesis"[ti] OR "Implants"[ti] OR "Implant"[ti] OR "replacement"[ti] OR "replacements"[ti])) AND ("Registries"[Mesh] OR "register"[tw] OR "registers"[tw] OR "registry"[tw] OR "registries"[tw] OR "register"[ad] OR "registers"[ad] OR "registry"[ad] OR "registries"[ad]) AND ("European Union"[Mesh] OR "European Union"[tw] OR "European Community"[tw] OR "European Coal and Steel Community"[tw] OR "Common Market"[tw] OR "EEC"[tw] OR "European Economic Community"[tw] OR "European Common Market"[tw] OR "European Economic Area"[tw] OR "Europe"[Mesh] OR "Albania"[mesh] OR "Andorra"[mesh] OR "Armenia"[mesh] OR "Armenia"[mesh] OR "Austria"[mesh] OR "Azerbaijan"[mesh] OR "Republic of Belarus"[mesh] OR "Belgium"[mesh] OR "Bosnia and Herzegovina"[mesh] OR "Bulgaria"[mesh] OR "Croatia"[mesh] OR "Czech Republic"[mesh] OR "Denmark"[mesh] OR "England"[mesh] OR "Estonia"[mesh] OR "Finland"[mesh] OR "France"[mesh] OR "Georgia"[mesh] OR "Germany"[mesh] OR "Gibraltar"[mesh] OR "Greece"[mesh] OR "Hungary"[mesh] OR "Iceland"[mesh] OR "Ireland"[mesh] OR "Italy"[mesh] OR "Kazakhstan"[mesh] OR "Kosovo"[mesh] OR "Kyrgyzstan"[mesh] OR "Latvia"[mesh] OR "Liechtenstein"[mesh] OR "Lithuania"[mesh] OR "Luxembourg"[mesh] OR "Malta"[mesh] OR "Moldova"[mesh] OR "Monaco"[mesh] OR "Montenegro"[mesh] OR "Netherlands"[mesh] OR "Republic of North Macedonia"[mesh] OR "Northern Ireland"[mesh] OR "Norway"[mesh] OR "Poland"[mesh] OR "Portugal"[mesh] OR "Romania"[mesh] OR "Russia"[mesh] OR "San Marino"[mesh] OR "Scotland"[mesh] OR "Serbia"[mesh] OR

"Slovakia"[mesh] OR "Slovenia"[mesh] OR "Spain"[mesh] OR "Sweden"[mesh] OR "Switzerland"[mesh] OR "Turkey"[mesh] OR "Ukraine"[mesh] OR "United Kingdom"[mesh] OR "Uzbekistan"[mesh] OR "Vatican City"[mesh] OR "Wales"[mesh] OR "Europe"[tw] OR "European"[tw] OR "Albania"[tw] OR "Andorra"[tw] OR "Armenia"[tw] OR "Armenia"[tw] OR "Austria"[tw] OR "Azerbaijan"[tw] OR "Belarus"[tw] OR "Belgium"[tw] OR "Bosnia"[tw] OR "Bulgaria"[tw] OR "Croatia"[tw] OR "Czech Republic"[tw] OR "Denmark"[tw] OR "England"[tw] OR "Estonia"[tw] OR "Finland"[tw] OR "France"[tw] OR "Georgia"[tw] OR "Germany"[tw] OR "Gibraltar"[tw] OR "Greece"[tw] OR "Herzegovina"[tw] OR "Hungary"[tw] OR "Iceland"[tw] OR "Ireland"[tw] OR "Italy"[tw] OR "Kazakhstan"[tw] OR "Kosovo"[tw] OR "Kyrgyzstan"[tw] OR "Latvia"[tw] OR "Liechtenstein"[tw] OR "Lithuania"[tw] OR "Luxembourg"[tw] OR "Malta"[tw] OR "Moldova"[tw] OR "Monaco"[tw] OR "Montenegro"[tw] OR "Netherlands"[tw] OR "North Macedonia"[tw] OR "Northern Ireland"[tw] OR "Norway"[tw] OR "Poland"[tw] OR "Portugal"[tw] OR "Romania"[tw] OR "Russia"[tw] OR "San Marino"[tw] OR "Scotland"[tw] OR "Serbia"[tw] OR "Slovakia"[tw] OR "Slovenia"[tw] OR "Spain"[tw] OR "Sweden"[tw] OR "Switzerland"[tw] OR "Turkey"[tw] OR "Ukraine"[tw] OR "United Kingdom"[tw] OR "Uzbekistan"[tw] OR "Vatican City"[tw] OR "Wales"[tw] OR "Albanian"[tw] OR "Armenian"[tw] OR "Austrian"[tw] OR "Belgian"[tw] OR "Bosnian"[tw] OR "Bulgarian"[tw] OR "Croatian"[tw] OR "Czech"[tw] OR "Danish"[tw] OR "British"[tw] OR "Estonian"[tw] OR "Finnish"[tw] OR "French"[tw] OR "Georgian"[tw] OR "German"[tw] OR "Greek"[tw] OR "Hungarian"[tw] OR "Icelandic"[tw] OR "Irish"[tw] OR "Italian"[tw] OR "Kosovan"[tw] OR "Latvian"[tw] OR "Lithuanian"[tw] OR "Moldovan"[tw] OR "Dutch"[tw] OR "Macedonian"[tw] OR "Norwegian"[tw] OR "Polish"[tw] OR "Romanian"[tw] OR "Russian"[tw] OR "Scottish"[tw] OR "Serbian"[tw] OR "Slovakian"[tw] OR "Slovenian"[tw] OR "Spanish"[tw] OR "Swedish"[tw] OR "Swiss"[tw] OR "Turkish"[tw] OR "Ukrainian"[tw] OR "Welsh"[tw])) OR (("Pacemaker, Artificial"[Mesh] OR "pacemaker"[tw] OR "pacemakers"[tw] OR "Heart, Artificial"[Mesh] OR "artificial heart"[tw] OR "artificial hearts"[tw] OR "Heart-Assist Devices"[mesh] OR "Artificial Heart"[tw] OR "Artificial Ventricle"[tw] OR "Artificial Ventricles"[tw] OR "Heart Assist Device"[tw] OR "Heart Assist Devices"[tw] OR "Heart Assist Pump"[tw] OR "Heart Assist Pumps"[tw] OR "Vascular Assist Device"[tw] OR "Vascular Assist Devices"[tw] OR "Ventricle Assist Device"[tw] OR "Ventricle Assist

Devices"[tw] OR "Ventricular Assist Device"[tw] OR "Ventricular Assist Devices"[tw] OR "Heart Valve Prosthesis"[Mesh] OR "Heart Valve Prosthesis"[tw] OR "Heart Valve Prosthesis"[tw] OR "Cardiac Valve Prosthesis"[tw] OR "Cardiac Valve Prostheses"[tw] OR "Heart Prosthesis"[tw] OR "Heart Prosthesis"[tw] OR "Cardiac Prosthesis"[tw] OR "Cardiac Prostheses"[tw] OR "artificial heart valves"[tw] OR "artificial heart valve"[tw] OR "artificial valves"[tw] OR "artificial valves"[tw] OR "Defibrillators, Implantable"[Mesh] OR "Implantable Defibrillator"[tw] OR "Implantable Defibrillators"[tw] OR "Implantable Cardioverter Defibrillator"[tw] OR "Implantable Cardioverter Defibrillators"[tw] OR "bioresorbable vascular scaffold"[tw] OR "bioresorbable vascular scaffolds"[tw] OR "transcatheter aortic valve implantation"[tw] OR "transcatheter aortic valve implant"[tw] OR "transcatheter aortic valve implants"[tw] OR "TAVI"[tw] OR "transseptal mitral valve-in-ring"[tw] OR "TMVR"[tw] OR ("percutaneous"[tw] AND "left anterior"[tw] AND "aortic cusp"[tw]) OR "LAAOC"[tw] OR (("Heart"[mesh] OR "heart"[tw] OR "cardiac"[tw]) AND ("Prostheses and Implants"[Mesh] OR "Prostheses"[tw] OR "Prosthesis"[tw] OR "Implants"[tw] OR "Implant"[tw] OR "replacement"[tw] OR "replacements"[tw]))) AND ("Registries"[majr] OR "register"[ti] OR "registers"[ti] OR "registry"[ti] OR "registries"[ti] OR "register"[ad] OR "registers"[ad] OR "registry"[ad] OR "registries"[ad]) AND ("European Union"[Mesh] OR "European Union"[tw] OR "European Community"[tw] OR "European Coal and Steel Community"[tw] OR "Common Market"[tw] OR "EEC"[tw] OR "European Economic Community"[tw] OR "European Common Market"[tw] OR "European Economic Area"[tw] OR "Europe"[Mesh] OR "Albania"[mesh] OR "Andorra"[mesh] OR "Armenia"[mesh] OR "Armenia"[mesh] OR "Austria"[mesh] OR "Azerbaijan"[mesh] OR "Republic of Belarus"[mesh] OR "Belgium"[mesh] OR "Bosnia and Herzegovina"[mesh] OR "Bulgaria"[mesh] OR "Croatia"[mesh] OR "Czech Republic"[mesh] OR "Denmark"[mesh] OR "England"[mesh] OR "Estonia"[mesh] OR "Finland"[mesh] OR "France"[mesh] OR "Georgia"[mesh] OR "Germany"[mesh] OR "Gibraltar"[mesh] OR "Greece"[mesh] OR "Hungary"[mesh] OR "Iceland"[mesh] OR "Ireland"[mesh] OR "Italy"[mesh] OR "Kazakhstan"[mesh] OR "Kosovo"[mesh] OR "Kyrgyzstan"[mesh] OR "Latvia"[mesh] OR "Liechtenstein"[mesh] OR "Lithuania"[mesh] OR "Luxembourg"[mesh] OR "Malta"[mesh] OR "Moldova"[mesh] OR "Monaco"[mesh] OR "Montenegro"[mesh] OR "Netherlands"[mesh] OR "Republic of North Macedonia"[mesh] OR "Northern Ireland"[mesh] OR "Norway"[mesh] OR

"Poland"[mesh] OR "Portugal"[mesh] OR "Romania"[mesh] OR "Russia"[mesh] OR "San Marino"[mesh] OR "Scotland"[mesh] OR "Serbia"[mesh] OR "Slovakia"[mesh] OR "Slovenia"[mesh] OR "Spain"[mesh] OR "Sweden"[mesh] OR "Switzerland"[mesh] OR "Turkey"[mesh] OR "Ukraine"[mesh] OR "United Kingdom"[mesh] OR "Uzbekistan"[mesh] OR "Vatican City"[mesh] OR "Wales"[mesh] OR "Europe"[tw] OR "European"[tw] OR "Albania"[tw] OR "Andorra"[tw] OR "Armenia"[tw] OR "Armenia"[tw] OR "Austria"[tw] OR "Azerbaijan"[tw] OR "Belarus"[tw] OR "Belgium"[tw] OR "Bosnia"[tw] OR "Bulgaria"[tw] OR "Croatia"[tw] OR "Czech Republic"[tw] OR "Denmark"[tw] OR "England"[tw] OR "Estonia"[tw] OR "Finland"[tw] OR "France"[tw] OR "Georgia"[tw] OR "Germany"[tw] OR "Gibraltar"[tw] OR "Greece"[tw] OR "Herzegovina"[tw] OR "Hungary"[tw] OR "Iceland"[tw] OR "Ireland"[tw] OR "Italy"[tw] OR "Kazakhstan"[tw] OR "Kosovo"[tw] OR "Kyrgyzstan"[tw] OR "Latvia"[tw] OR "Liechtenstein"[tw] OR "Lithuania"[tw] OR "Luxemfcrdbourg"[tw] OR "Malta"[tw] OR "Moldova"[tw] OR "Monaco"[tw] OR "Montenegro"[tw] OR "Netherlands"[tw] OR "North Macedonia"[tw] OR "Northern Ireland"[tw] OR "Norway"[tw] OR "Poland"[tw] OR "Portugal"[tw] OR "Romania"[tw] OR "Russia"[tw] OR "San Marino"[tw] OR "Scotland"[tw] OR "Serbia"[tw] OR "Slovakia"[tw] OR "Slovenia"[tw] OR "Spain"[tw] OR "Sweden"[tw] OR "Switzerland"[tw] OR "Turkey"[tw] OR "Ukraine"[tw] OR "United Kingdom"[tw] OR "Uzbekistan"[tw] OR "Vatican City"[tw] OR "Wales"[tw] OR "Albanian"[tw] OR "Armenian"[tw] OR "Austrian"[tw] OR "Belgian"[tw] OR "Bosnian"[tw] OR "Bulgarian"[tw] OR "Croatian"[tw] OR "Czech"[tw] OR "Danish"[tw] OR "British"[tw] OR "Estonian"[tw] OR "Finnish"[tw] OR "French"[tw] OR "Georgian"[tw] OR "German"[tw] OR "Greek"[tw] OR "Hungarian"[tw] OR "Icelandic"[tw] OR "Irish"[tw] OR "Italian"[tw] OR "Kosovan"[tw] OR "Latvian"[tw] OR "Lithuanian"[tw] OR "Moldovan"[tw] OR "Dutch"[tw] OR "Macedonian"[tw] OR "Norwegian"[tw] OR "Polish"[tw] OR "Romanian"[tw] OR "Russian"[tw] OR "Scottish"[tw] OR "Serbian"[tw] OR "Slovakian"[tw] OR "Slovenian"[tw] OR "Spanish"[tw] OR "Swedish"[tw] OR "Swiss"[tw] OR "Turkish"[tw] OR "Ukrainian"[tw] OR "Welsh"[tw]))) AND ("2013/01/01"[PDAT] : "3000/12/31"[PDAT])

Web of Science – Orthopaedic registries

((ti=("Hip Replacement" OR "Hip Prosthesis" OR "hip replacement" OR "hip replacement*" OR "hip

arthroplasty" OR "hip arthroplast*" OR "hip prosthesis" OR "hip prosthe*" OR "THA" OR "THR" OR "hip implant" OR "hip implants" OR "Knee Replacement" OR "Knee Prosthesis" OR "knee replacement" OR "knee replacement*" OR "knee arthroplasty" OR "knee arthroplast*" OR "knee prosthesis" OR "knee prosthe*" OR "TKA" OR "TKR" OR "knee implant" OR "knee implants" OR "Shoulder Replacement" OR "Shoulder Prosthesis" OR "shoulder replacement" OR "shoulder replacement*" OR "shoulder arthroplasty" OR "shoulder arthroplast*" OR "shoulder prosthesis" OR "shoulder prosthe*" OR "shoulder

implant" OR "knee implants" OR "Ankle Replacement" OR "Ankle Prosthesis" OR "ankle replacement" OR "ankle replacement*" OR "ankle arthroplasty" OR "ankle arthroplast*" OR "ankle prosthesis" OR "ankle prosthe*" OR "ankle implant" OR "ankle implants" OR (("Hip" OR "hip" OR "hips" OR "Knee" OR "knee" OR "knees" OR "Shoulder" OR "Shoulder" OR "Shoulders" OR "Ankle" OR "ankle" OR "ankles") AND ("Prosthesis" OR "Prostheses" OR "Prosthesis" OR "Implants" OR "Implant" OR "replacement" OR "replacements" OR "arthroplasty" OR "arthroplast*"))) AND (ts=("Register" OR "register" OR "registers" OR "registry" OR "registries") OR ad=("register" OR "registers" OR "registry" OR "registries")) AND TS=("European Union" OR "European Union" OR "European Community" OR "European Coal and Steel Community" OR "Common Market" OR "EEC" OR "European Economic Community" OR "European Common Market" OR "European Economic Area" OR "Europe" OR "Albania" OR "Andorra" OR "Armenia" OR "Armenia" OR "Austria" OR "Azerbaijan" OR "Republic of Belarus" OR "Belgium" OR "Bosnia and Herzegovina" OR "Bulgaria" OR "Croatia" OR "Czech Republic" OR "Denmark" OR "England" OR "Estonia" OR "Finland" OR "France" OR "Georgia" OR "Germany" OR "Gibraltar" OR "Greece" OR "Hungary" OR "Iceland" OR "Ireland" OR "Italy" OR "Kazakhstan" OR "Kosovo" OR "Kyrgyzstan" OR "Latvia" OR "Liechtenstein" OR "Lithuania" OR "Luxembourg" OR "Malta" OR "Moldova" OR "Monaco" OR "Montenegro" OR "Netherlands" OR "Republic of North Macedonia" OR "Northern Ireland" OR "Norway" OR "Poland" OR "Portugal" OR "Romania" OR "Russia" OR "San Marino" OR "Scotland" OR "Serbia" OR "Slovakia" OR "Slovenia" OR "Spain" OR "Sweden" OR "Switzerland" OR "Turkey" OR "Ukraine" OR "United Kingdom" OR "Uzbekistan" OR "Vatican City" OR "Wales" OR "Albanian" OR "Armenian" OR "Austrian" OR "Belgian" OR "Bosnian" OR "Bulgarian" OR "Croatian" OR "Czech" OR "Danish" OR "British" OR

"Estonian" OR "Finnish" OR "French" OR "Georgian" OR "German" OR "Greek" OR "Hungarian" OR "Icelandic" OR "Irish" OR "Italian" OR "Kosovan" OR "Latvian" OR "Lithuanian" OR "Moldovan" OR "Dutch" OR "Macedonian" OR "Norwegian" OR "Polish" OR "Romanian" OR "Russian" OR "Scottish" OR "Serbian" OR "Slovakian" OR "Slovenian" OR "Spanish" OR "Swedish" OR "Swiss" OR "Turkish" OR "Ukrainian" OR "Welsh")) OR (ts=("Hip Replacement" OR "Hip Prosthesis" OR "hip replacement" OR "hip replacement*" OR "hip arthroplasty" OR "hip arthroplast*" OR "hip prosthesis" OR "hip prosthe*" OR "THA" OR "THR" OR "hip implant" OR "hip implants" OR "Knee Replacement" OR "Knee Prosthesis" OR "knee replacement" OR "knee replacement*" OR "knee arthroplasty" OR "knee arthroplast*" OR "knee prosthesis" OR "knee prosthe*" OR "TKA" OR "TKR" OR "knee implant" OR "knee implants" OR "Shoulder Replacement" OR "Shoulder Prosthesis" OR "shoulder replacement" OR "shoulder replacement*" OR "shoulder arthroplasty" OR "shoulder arthroplast*" OR "shoulder prosthesis" OR "shoulder prosthe*" OR "shoulder implant" OR "knee implants" OR "Ankle Replacement" OR "Ankle Prosthesis" OR "ankle replacement" OR "ankle replacement*" OR "ankle arthroplasty" OR "ankle arthroplast*" OR "ankle prosthesis" OR "ankle prosthe*" OR "ankle implant" OR "ankle implants" OR (("Hip" OR "hip" OR "hips" OR "Knee" OR "knee" OR "knees" OR "Shoulder" OR "Shoulder" OR "Shoulders" OR "Ankle" OR "ankle" OR "ankles") AND ("Prosthesis" OR "Prostheses" OR "Prosthesis" OR "Implants" OR "Implant" OR "replacement" OR "replacements" OR "arthroplasty" OR "arthroplast*"))) AND ti=("Register" OR "register" OR "registers" OR "registry" OR "registries" OR "register" OR "registers" OR "registry" OR "registries") AND ts=("European Union" OR "European Union" OR "European Community" OR "European Coal and Steel Community" OR "Common Market" OR "EEC" OR "European Economic Community" OR "European Common Market" OR "European Economic Area" OR "Europe" OR "Albania" OR "Andorra" OR "Armenia" OR "Armenia" OR "Austria" OR "Azerbaijan" OR "Republic of Belarus" OR "Belgium" OR "Bosnia and Herzegovina" OR "Bulgaria" OR "Croatia" OR "Czech Republic" OR "Denmark" OR "England" OR "Estonia" OR "Finland" OR "France" OR "Georgia" OR "Germany" OR "Gibraltar" OR "Greece" OR "Hungary" OR "Iceland" OR "Ireland" OR "Italy" OR "Kazakhstan" OR "Kosovo" OR "Kyrgyzstan" OR "Latvia" OR "Liechtenstein" OR "Lithuania" OR "Luxembourg" OR "Malta" OR "Moldova" OR "Monaco" OR "Montenegro" OR "Netherlands" OR "Republic of North Macedonia" OR "Northern

Ireland" OR "Norway" OR "Poland" OR "Portugal" OR "Romania" OR "Russia" OR "San Marino" OR "Scotland" OR "Serbia" OR "Slovakia" OR "Slovenia" OR "Spain" OR "Sweden" OR "Switzerland" OR "Turkey" OR "Ukraine" OR "United Kingdom" OR "Uzbekistan" OR "Vatican City" OR "Wales" OR "Albanian" OR "Armenian" OR "Austrian" OR "Belgian" OR "Bosnian" OR "Bulgarian" OR "Croatian" OR "Czech" OR "Danish" OR "British" OR "Estonian" OR "Finnish" OR "French" OR "Georgian" OR "German" OR "Greek" OR "Hungarian" OR "Icelandic" OR "Irish" OR "Italian" OR "Kosovan" OR "Latvian" OR "Lithuanian" OR "Moldovan" OR "Dutch" OR "Macedonian" OR "Norwegian" OR "Polish" OR "Romanian" OR "Russian" OR "Scottish" OR "Serbian" OR "Slovakian" OR "Slovenian" OR "Spanish" OR "Swedish" OR "Swiss" OR "Turkish" OR "Ukrainian" OR "Welsh"))) AND py=(2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022) NOT dt=(meeting abstract)

Web of Science – Cardiovascular registries

((ti=("cardiac implantable electronic device" OR "artificial heart pacemaker" OR "pacemaker" OR "pacemakers" OR "Artificial Heart" OR "artificial heart" OR "artificial hearts" OR "Heart Assist Device" OR "Artificial Heart" OR "Artificial Ventricle" OR "Artificial Ventricles" OR "Heart Assist Device" OR "Heart Assist Devices" OR "Heart Assist Pump" OR "Heart Assist Pumps" OR "Vascular Assist Device" OR "Vascular Assist Devices" OR "Ventricle Assist Device" OR "Ventricle Assist Devices" OR "Ventricular Assist Device" OR "Ventricular Assist Devices" OR "Heart Valve Prosthesis" OR "Heart Valve Prosthesis" OR "Heart Valve Prosthesis" OR "Cardiac Valve Prosthesis" OR "Cardiac Valve Prostheses" OR "Heart Prosthesis" OR "Heart Prosthesis" OR "Cardiac Prosthesis" OR "Cardiac Prostheses" OR "artificial heart valves" OR "artificial heart valve" OR "artificial valves" OR "artificial valves" OR "Implantable Defibrillator" OR "Implantable Defibrillator" OR "Implantable Defibrillators" OR "Implantable Cardioverter Defibrillator" OR "Implantable Cardioverter Defibrillators" OR "bioresorbable vascular stent" OR "bioresorbable vascular scaffold" OR "bioresorbable vascular scaffolds" OR "transcatheter aortic valve implantation" OR "transcatheter aortic valve implantation" OR "transcatheter aortic valve implant" OR "transcatheter aortic valve implants" OR "TAVI" OR "transseptal mitral valve-in-ring" OR "TMVR" OR "LAAOC" OR (("Heart" OR "heart" OR "cardiac") AND

("Prosthesis" OR "Prostheses" OR "Prosthesis" OR "Implants" OR "Implant" OR "replacement" OR "replacements"))) AND (ts=("Register" OR "register" OR "registers" OR "registry" OR "registries") OR ad=("register" OR "registers" OR "registry" OR "registries")) AND TS=("European Union" OR "European Union" OR "European Community" OR "European Coal and Steel Community" OR "Common Market" OR "EEC" OR "European Economic Community" OR "European Common Market" OR "European Economic Area" OR "Europe" OR "Albania" OR "Andorra" OR "Armenia" OR "Armenia" OR "Austria" OR "Azerbaijan" OR "Republic of Belarus" OR "Belgium" OR "Bosnia and Herzegovina" OR "Bulgaria" OR "Croatia" OR "Czech Republic" OR "Denmark" OR "England" OR "Estonia" OR "Finland" OR "France" OR "Georgia" OR "Germany" OR "Gibraltar" OR "Greece" OR "Hungary" OR "Iceland" OR "Ireland" OR "Italy" OR "Kazakhstan" OR "Kosovo" OR "Kyrgyzstan" OR "Latvia" OR "Liechtenstein" OR "Lithuania" OR "Luxembourg" OR "Malta" OR "Moldova" OR "Monaco" OR "Montenegro" OR "Netherlands" OR "Republic of North Macedonia" OR "Northern Ireland" OR "Norway" OR "Poland" OR "Portugal" OR "Romania" OR "Russia" OR "San Marino" OR "Scotland" OR "Serbia" OR "Slovakia" OR "Slovenia" OR "Spain" OR "Sweden" OR "Switzerland" OR "Turkey" OR "Ukraine" OR "United Kingdom" OR "Uzbekistan" OR "Vatican City" OR "Wales" OR "Albanian" OR "Armenian" OR "Austrian" OR "Belgian" OR "Bosnian" OR "Bulgarian" OR "Croatian" OR "Czech" OR "Danish" OR "British" OR "Estonian" OR "Finnish" OR "French" OR "Georgian" OR "German" OR "Greek" OR "Hungarian" OR "Icelandic" OR "Irish" OR "Italian" OR "Kosovan" OR "Latvian" OR "Lithuanian" OR "Moldovan" OR "Dutch" OR "Macedonian" OR "Norwegian" OR "Polish" OR "Romanian" OR "Russian" OR "Scottish" OR "Serbian" OR "Slovakian" OR "Slovenian" OR "Spanish" OR "Swedish" OR "Swiss" OR "Turkish" OR "Ukrainian" OR "Welsh")) OR (ts=("cardiac implantable electronic device" OR "artificial heart pacemaker" OR "pacemaker" OR "pacemakers" OR "Artificial Heart" OR "artificial heart" OR "artificial hearts" OR "Heart Assist Device" OR "Artificial Heart" OR "Artificial Ventricle" OR "Artificial Ventricles" OR "Heart Assist Device" OR "Heart Assist Devices" OR "Heart Assist Pump" OR "Heart Assist Pumps" OR "Vascular Assist Device" OR "Vascular Assist Devices" OR "Ventricle Assist Device" OR "Ventricle Assist Devices" OR "Ventricular Assist Device" OR "Ventricular Assist Devices" OR "Heart Valve Prosthesis" OR "Heart Valve Prosthesis" OR "Heart Valve Prosthesis" OR "Cardiac Valve Prosthesis" OR "Cardiac Valve Prostheses" OR "Heart

Prosthesis" OR "Heart Prosthesis" OR "Cardiac Prosthesis" OR "Cardiac Prostheses" OR "artificial heart valves" OR "artificial heart valve" OR "artificial valves" OR "artificial valves" OR "Implantable Defibrillator" OR "Implantable Defibrillator" OR "Implantable Defibrillators" OR "Implantable Cardioverter Defibrillator" OR "Implantable Cardioverter Defibrillators" OR "bioresorbable vascular stent" OR "bioresorbable vascular scaffold" OR "bioresorbable vascular scaffolds" OR "transcatheter aortic valve implantation" OR "transcatheter aortic valve implantation" OR "transcatheter aortic valve implant" OR "transcatheter aortic valve implants" OR "TAVI" OR "transseptal mitral valve-in-ring" OR "TMVR" OR "LAAOC" OR (("Heart" OR "heart" OR "cardiac") NEAR/4 ("Prosthesis" OR "Prostheses" OR "Prosthesis" OR "Implants" OR "Implant" OR "replacement" OR "replacements"))) AND ti=("Register" OR "register" OR "registers" OR "registry" OR "registries" OR "register" OR "registers" OR "registry" OR "registries") AND ts=("European Union" OR "European Union" OR "European Community" OR "European Coal and Steel Community" OR "Common Market" OR "EEC" OR "European Economic Community" OR "European Common Market" OR "European Economic Area" OR "Europe" OR "Albania" OR "Andorra" OR "Armenia" OR "Armenia" OR "Austria" OR "Azerbaijan" OR "Republic of Belarus" OR "Belgium" OR "Bosnia and Herzegovina" OR "Bulgaria" OR "Croatia" OR "Czech Republic" OR "Denmark" OR "England" OR "Estonia" OR "Finland" OR "France" OR "Georgia" OR "Germany" OR "Gibraltar" OR "Greece" OR "Hungary" OR "Iceland" OR "Ireland" OR "Italy" OR "Kazakhstan" OR "Kosovo" OR "Kyrgyzstan" OR "Latvia" OR "Liechtenstein" OR "Lithuania" OR "Luxembourg" OR "Malta" OR "Moldova" OR "Monaco" OR "Montenegro" OR "Netherlands" OR "Republic of North Macedonia" OR "Northern Ireland" OR "Norway" OR "Poland" OR "Portugal" OR "Romania" OR "Russia" OR "San Marino" OR "Scotland" OR "Serbia" OR "Slovakia" OR "Slovenia" OR "Spain" OR "Sweden" OR "Switzerland" OR "Turkey" OR "Ukraine" OR "United Kingdom" OR "Uzbekistan" OR "Vatican City" OR "Wales" OR "Albanian" OR "Armenian" OR "Austrian" OR "Belgian" OR "Bosnian" OR "Bulgarian" OR "Croatian" OR "Czech" OR "Danish" OR "British" OR "Estonian" OR "Finnish" OR "French" OR "Georgian" OR "German" OR "Greek" OR "Hungarian" OR "Icelandic" OR "Irish" OR "Italian" OR "Kosovan" OR "Latvian" OR "Lithuanian" OR "Moldovan" OR "Dutch" OR "Macedonian" OR "Norwegian" OR "Polish" OR "Romanian" OR "Russian" OR "Scottish" OR "Serbian" OR "Slovakian" OR "Slovenian" OR "Spanish" OR "Swedish" OR "Swiss" OR "Turkish"

OR "Ukrainian" OR "Welsh"))) AND py=(2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022) NOT dt=(meeting abstract)

Google Scholar – Orthopaedic registries

allintitle: "Hip"|"Knee"|"Shoulder"|"Ankle" "Prosthesis"|"Implant"|"replacement"|"arthroplasty" "Register"|"registers"|"registry"|"registries" -"american" -"australian" -"canadian"

Google Scholar – Cardiovascular Registries

allintitle: "Heart"|"cardiac" "Prosthesis"|"Implant"|"replacement" "Register"|"registers"|"registry"|"registries" -"american" -"australian" -"canadian"

allintitle: "cardiac implant"|"pacemaker"|"Artificial Heart"|"Implantable Defibrillator" "Register"|"registers"|"registry"|"registries" -"american" -"australian" -"canadian"

allintitle: "TAVI"|"TMVR"|"LAAOC" "Register"|"registers"|"registry"|"registries" -"american" -"australian" -"canadian"

Publication date limit: (2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022)

Supplementary Table 1A: Cardiovascular registries – Domain Identification

Table S1A: Cardiovascular registries – Domain 'Identification'				
	Country	**Design**	**Website**	**Initial motivation / goal**
Cardiovascular registries – combined				
British Cardiovascular Intervention Society	The UK	National	https://www.bcis.org.uk/	To promote education, training and research in cardiovascular intervention and develops and upholds clinical and professional standards[1]
East Denmark Heart Registry	Denmark	National	N/R	N/R
German Society for Thoracic and Cardiovascular Surgery	Germany	National	https://www.dgthg.de/	To promote the science and further development of therapies in the field of thoracic, cardiac, and vascular surgery[465]
Polish National Database of Cardiac Surgery Procedures	Poland	National	https://krok.csioz.gov.pl/krok/	N/R
Portuguese National Registry of Intervention Cardiology	Portugal	National	https://www.apic.pt/	To study, investigate and promote other scientific activities within the scope of medical, surgical, technological, and organizational aspects of cardiovascular intervention[466]
Spanish Cardiac Catheterization and Coronary Intervention Registry	Spain	National	N/R	To report the activity recorded in interventional cardiology laboratories in Spain[7]
Western Denmark Heart Registry	Denmark	Regional	N/R	To promote clinical and health services research on use of cardiovascular procedures and their outcomes[8]
Cardiovascular registries – stents				
Polish National Percutaneous Coronary Intervention Registry	Poland	National	https://www.orpki.cm-uj.krakow.pl/	N/R
Swedish Coronary Angiography and Angioplasty Registry	Sweden	National	https://www.ucr.uu.se/swedeheart/start-scaar/	To collect relevant information regarding disease severity, medical and medical-technical treatment from the time of intervention on all performed coronary angiograms and PCI treatments[9]
Cardiovascular registries – valves				
Quality Assurance Registry on Aortic Valve Replacement	Germany	National	N/R	N/R
Austrian-TAVI Registry	Austria	National	https://www.tavi.at/	N/R
Belgian TAVI Registry	Belgium	National	N/R	N/R
Czech TAVI Registry	Czechia	National	N/R	To investigate 1) the clinical impact of the relative high rate of paravalvular leaks, and 2) the function of implanted valves in real long-term follow-up exceeding 5 years[194]
FinnValve Registry	Finland	National	N/R	N/R
FRANCE-TAVI Registry	France	National	N/R	To identify all patients with a change of valves implanted catheter meets the selection criteria of the technical accepting the scheduled evaluations in the context of this disease and who have agreed to participate in the study[477]
German Aortic Valve Registry	Germany	National	https://www.aortenklappenregister.de/	1) to present the structure, process, and result quality of the various techniques of aortic valve therapy; 2) to determine criteria for indications (e.g. through scoring systems); 3) to record quality and safety of specific medical devices; 4) to assess the quality of care of participating centres with the aim to improve healthcare quality, and 5) to evaluate health economical statuses of treatments[478]
Polish Registry of Transcatheter Aortic Valve Implantation	Poland	National	N/R	1) to monitor TAVI indications and procedural strategy; 2) to supervise adherence to the guidelines and compliance with indications/contraindications to TAVI; 3) to assess objectively and non-commercially peri-procedural device success; 4) to monitor and improve safety, quality and efficacy of treatment; 5) to assess early- and long-term results of this novel method of treatment in order to develop the most optimal therapeutic follow-up strategy, and 6) to monitor and evaluate cost-effectiveness of TAVI in Poland[16]
Spanish Registry of Heart Valves Repair	Spain	National	N/R	N/R
Swedish Transcatheter Cardiac Intervention Registry	Sweden	National	https://www.ucr.uu.se/swedeheart/start-swentry/	To evaluate the new method for aortic valve intervention both with regard to acute results and long-term follow-up[479]
Swiss TAVI Registry	Switzerland	National	https://www.swisstavi.ch/	To assess the clinical outcomes of consecutive patients undergoing TAVI in Switzerland[252]

Supplementary Table 2A: Cardiovascular registries – Domain Maturity

Table S2A: Cardiovascular registries – Domain 'Maturity'			
	Starting year	First annual report (publishing year)	Most recent/last annual report (publishing year)
Cardiovascular registries – combined			
British Cardiovascular Intervention Society	1988[1]	1991[1]	2020, data till 2020[1]
East Denmark Heart Registry	2005[2]	N/R	N/R
German Society for Thoracic and Cardiovascular Surgery	1978[3]	1989[3]	2021, data till 2020[4]
Polish National Database of Cardiac Surgery Procedures	2006[5]	N/R	N/R
Portuguese National Registry of Intervention Cardiology	2002[6]	N/R	N/R
Spanish Cardiac Catheterization and Coronary Intervention Registry	1990[7]	1990[7]	2020, data till 2019[7]
Western Denmark Heart Registry	1999[8]	N/R	N/R
Cardiovascular registries – stents			
Polish National Percutaneous Coronary Intervention Registry	N/R	N/R	N/R
Swedish Coronary Angiography and Angioplasty Registry	1998[9]	2007[10]	2021, data till 2020[9, 10]
Cardiovascular registries – valves			
Quality Assurance Registry on Aortic Valve Replacement	N/R	N/R	N/R
Austrian-TAVI Registry	2011[11]	N/R	N/R
Belgian TAVI Registry	2007[12]	N/R	N/R
Czech TAVI Registry	2009[13]	N/R	N/R
FinnValve Registry	N/R	N/R	N/R
FRANCE-TAVI Registry	2013[14]	N/R	N/R
German Aortic Valve Registry	2010[15]	N/R	N/R
Polish Registry of Transcatheter Aortic Valve Implantation	2013[16]	N/R	N/R
Spanish Registry of Heart Valves Repair	N/R	2013[17]	2019, data till 2017[18]
Swedish Transcatheter Cardiac Intervention Registry	2010[19]	2010[10]	2021, data till 2020[10]
Swiss TAVI Registry	2011[20]	N/R	N/R

Supplementary Table 3A: Cardiovascular registries – Domain Governance

Table S3A: Cardiovascular registries – Domain 'Governance'					
	Mandatory	Patients' consent	Funding	Who can access the data and see results?	Privacy regulation for patients identifiable information
Cardiovascular registries – combined					
British Cardiovascular Intervention Society	N/R	N/R	Public[21]	N/R	N/R
East Denmark Heart Registry	Yes[22]	N/R	N/R	N/R	N/R
German Society for Thoracic and Cardiovascular Surgery	No[3]	N/R	N/R	N/R	N/R
Polish National Database of Cardiac Surgery Procedures	Yes[5]	Not required[5]	Public[5]	N/R	N/R
Portuguese National Registry of Intervention Cardiology	No[6]	Required[23]	N/R	N/R	N/R
Spanish Cardiac Catheterization and Coronary Intervention Registry	No[7]	N/R	N/R	N/R	N/R
Western Denmark Heart Registry	Yes[22]	Not required[24]	Public[25]	N/R	Serial numbers are generated when uploading data[8]
Cardiovascular registries – stents					
Polish National Percutaneous Coronary Intervention Registry	N/R	N/R	N/R	N/R	N/R
Swedish Coronary Angiography and Angioplasty Registry	Yes[26]	Not required[26]	Public[27]	N/R	Unique personal ID number[28]
Cardiovascular registries – valves					
Quality Assurance Registry on Aortic Valve Replacement	Yes[29]	N/R	N/R	N/R	N/R
Austrian-TAVI Registry	N/R	Required[11]	N/R	N/R	N/R
Belgian TAVI Registry	N/R	N/R	N/R	N/R	N/R
Czech TAVI Registry	N/R	Not required[13]	N/R	N/R	All data are anonymous[13]
FinnValve Registry	N/R	Not required[30]	N/R	N/R	N/R
FRANCE-TAVI Registry	No[14]	Required[14]	Private[14]	N/R	N/R
German Aortic Valve Registry	No[31]	Required[32]	Private[15]	N/R	All data are anonymous[33]
Polish Registry of Transcatheter Aortic Valve Implantation	Yes[16]	Required[16]	Public[34]	Limited to authorized representatives of TAVI-centers[16]	N/R
Spanish Registry of Heart Valves Repair	No[35]	N/R	N/R	N/R	N/R
Swedish Transcatheter Cardiac Intervention Registry	Yes[26]	Not required[26]	Public[27]	N/R	Unique personal ID number[36]
Swiss TAVI Registry	Yes[9]	Required[20]	Private[20]	N/R	N/R

Supplementary Table 4A: Cardiovascular registries – Domain Coverage, design & organisation

Table S4A: Cardiovascular registries – Domain 'Coverage, design & organisation'

	No. of hospitals (% of coverage)	Number of patients/ procedures (total)	Number of patients/ procedures (selected)	Annual number of patients/ procedures (last year)	Data capture and collection	Access to registry for users/members	Type of information provided, for whom and at which level	Data linkage with other sources
Cardiovascular registries – combined								
British Cardiovascular Intervention Society	Minimal 118 (exact number unknown) (N/R)[1]	28,622 TAVI procedures (2007-2020)[1]	N/A	6,076 TAVI procedures and 100,112 PCI procedures (2019)[1]	Web-based[1]	Through website[1]	Hospital- and surgeon-level[1]	National health service[37]
East Denmark Heart Registry	N/R (N/R)	N/R	3 studies (range: 944-50,460)[2, 38, 39]	N/R	Web-based[25]	Through website[25]	N/R	N/R
German Society for Thoracic and Cardiovascular Surgery	78 (N/R)[3]	N/R	N/A	35,469 valves (2020)[40]	Web-based[41]	N/R	N/R	N/R
Polish National Database of Cardiac Surgery Procedures	37 (100%)[5]	N/R	15 studies (range: 3,057-188,972)[5, 42-55]	N/R	Web-based[56]	N/R	N/R	National health fund (health insurance institution)[53]
Portuguese National Registry of Intervention Cardiology	25 (N/R)[57]	73,977 PCI (2010-2015)[58]	N/A	13,891 PCI (2015)[58]	Web-based[6]	N/R	N/R	N/R
Spanish Cardiac Catheterization and Coronary Intervention Registry	123 (97.6%)[59]	N/R	N/A	4,692 valves and 92,771 stents (2020)[59]	Web-based[60]	N/R	N/R	N/R
Western Denmark Heart Registry	13 (100%)[8]	N/R	74 studies (range: 68-1,200,472)[8, 24, 25, 61-131]	N/R	Web-based[8]	Through website[8]	Hospital- and medical device-level[8]	National patient register[130]
Cardiovascular registries – stents								
Polish National Percutaneous Coronary Intervention Registry	161 (28.2%)[132]	N/R	46 studies (range: 591 - 1,436,546)[133-178]	N/R	Web-based[166]	N/R	N/R	N/R
Swedish Coronary Angiography and Angioplasty Registry	29 (N/R)[179]	380,220 (2007-2020)[180]	N/A	24,657 PCI patients (2020)[180]	Web-based[9]	Through website[9]	Hospital- and medical device-level[10]	National patient register[28]
Cardiovascular registries – valves								
Quality Assurance Registry on Aortic Valve Replacement	95 (N/R)[181]	N/R	4 studies (range: 6,972-120,280)[29, 182-184]	N/R	Web-based[29]	N/R	N/R	N/R
Austrian-TAVI Registry	11 (100%)[11]	N/R	2 studies (range: 959-1,822)[11, 185]	N/R	Web-based[185]	Through website[185]	N/R	N/R
Belgian TAVI Registry	23 (N/R)[12]	N/R	3 studies (range: 328-861)[12, 186, 187]	N/R	Web-based[188]	N/R	N/R	N/R
Czech TAVI Registry	N/R	N/R	6 studies (range: 58-1,532)[13, 189-194]	N/R	Web-based[194]	N/R	N/R	N/R
FinnValve Registry	5 (100%)[195, 196]	6,463 (2008-2017)[30]	N/R	N/R	Web-based[197]	N/R	N/R	National Statistical Institution[195], Finnish Population Register Centre[197], Finnish National Institute for Health and Welfare[197]
FRANCE-TAVI Registry	50 (N/R)[198]	N/R	27 studies (range: 287-30,913)[14, 198-223]	N/R	Web-based[14]	N/R	N/R	N/R
German Aortic Valve Registry	92 (N/R)[15]	N/R	23 studies (range: 1,118-142,435)[15, 31-33, 224-242]	N/R	Web-based[33]	Through website[33]	Hospital- and medical device-level[33]	German external quality assurance plan[33]

Polish Registry of Transcatheter Aortic Valve Implantation	21 (N/R)[16]	N/R	11 studies (range: 19-5,043)[16, 34, 243-251]	N/R	Web-based[16]	N/R	N/R	Civil registries[248]
Spanish Registry of Heart Valves Repair	27 (N/R)[18]	N/R	N/R	1,607 mitral valve, 4,289 aortic valve, and 98 tricuspid valve replacements (2017)[18]	Web-based[18]	N/R	N/R	N/R
Swedish Transcatheter Cardiac Intervention Registry	8 (N/R)[10]	N/R	N/A	1,299 TAVI procedures (2020)[10]	Web-based[19]	Through website[19]	Hospital- and medical device-level[10]	National patient register[36]
Swiss TAVI Registry	16 (N/R)[252]	N/R	40 studies (range: 113-9,478)[20, 253-291]	N/R	Web-based[282]	Through website[282]	N/R	N/R

Supplementary Table 5A: Cardiovascular registries – Manufacturers mentioned in annual reports, peer-reviewed publications & websites

Table S5A: Cardiovascular registries – Manufacturers mentioned in annual reports, peer-reviewed publications & websites	
Stents	**Valves**
Abbott Laboratories[110, 292-307]	Abbott Laboratories[5, 15, 30, 38, 42, 59, 185, 197, 228, 231, 259, 260, 263, 266, 267, 278, 282, 285, 286, 288, 308]
B. Braun[298, 301, 303-305]	Baxter International[5]
Biosensors International[292, 299, 301, 302]	Biosensors International[59, 253]
Biotronik AG[292-294, 299, 301, 302]	Boston Scientific[15, 38, 59, 185, 228, 250, 253, 258-260, 262, 263, 265-267, 274, 278, 281, 282, 285-288, 290, 308-311]
Boston Scientific[104, 110, 117, 119, 292-299, 301-304, 306, 307, 312, 313]	CryoLife[5, 42]
CID S.p.A[298, 304]	Edwards Lifesciences[5, 11, 12, 14, 15, 24, 30-32, 34, 38, 42, 59, 185, 186, 189, 191, 197, 199-202, 204-212, 214, 216-220, 223, 228-231, 233, 237, 243, 245, 246, 251, 253-255, 258-267, 271, 272, 274, 278, 282, 285-290, 308-311]
Cordis[71, 104, 110, 117, 119, 295-298, 301, 303-307, 312, 313]	JenaValve[15, 32, 228, 253, 282, 285, 286]
LivaNova[303, 305]	Labcor[5, 42, 228]
Medtronic[71, 110, 292-299, 301-307, 312]	LivaNova[5, 15, 30, 31, 42, 228, 231]
Terumo Corporation[292-294, 299, 301, 302]	Medtronic[2, 5, 11, 12, 14, 15, 20, 30-32, 34, 38, 42, 59, 185, 186, 189, 199-202, 204-212, 214, 216-220, 223, 228-231, 233, 237, 245, 246, 251, 253-255, 258-260, 262-267, 271, 272, 274, 278, 282, 285-290, 308-311]
	Meril Life[59]

Supplementary Table 6A: Cardiovascular registries – Domain data quality & completeness

Table S6A: Cardiovascular registries – Domain 'Data quality & completeness'				
	Quality assurance system defined/quality check of data	Missing data for patients' characteristics	Methods for handling missing data	Data completeness on patient/ procedure-level
Cardiovascular registries – combined				
British Cardiovascular Intervention Society	Data platform has error checking for range and consistency and a validation cycle provides every operator to read their report so that corrections can be made prior to data publication[37]	N/R	In case of a completeness of <95% of a specific variable; the risk adjusted outcomes are considered to be inadequate[314]	N/R
East Denmark Heart Registry	N/R	N/R	N/R	N/R
German Society for Thoracic and Cardiovascular Surgery	After entering the data, it will be checked for completeness[3]	N/R	N/R	N/R
Polish National Database of Cardiac Surgery Procedures	N/R	N/R	N/R	N/R
Portuguese National Registry of Intervention Cardiology	N/R	N/R	N/R	N/R
Spanish Cardiac Catheterization and Coronary Intervention Registry	The steering committee and the working group perform data cleaning[60]	N/R	N/R	N/R
Western Denmark Heart Registry	Systematic validation procedures and random spot checks after data entry and variable levels are restricted within pre-specified limits[8]	N/R	N/R	N/R
Cardiovascular registries – stents				
Polish National Percutaneous Coronary Intervention Registry	N/R	N/R	N/R	N/R
Swedish Coronary Angiography and Angioplasty Registry	Data platform has error checking for range and consistency, definitions are displayed on screen when data is entered, data entered in the registry of 20 hospitals will be annually compared information in the patients' records from 30- 40 randomly chosen patients in each hospital and the majority of variables are mandatory[315]	N/R	N/R	N/R
Cardiovascular registries – valves				
Quality Assurance Registry on Aortic Valve Replacement	Controlled by validated system[29]	N/R	N/R	N/R
Austrian-TAVI Registry	N/R	N/R	N/R	N/R
Belgian TAVI Registry	N/R	N/R	N/R	N/R
Czech TAVI Registry	N/R	N/R	N/R	N/R
FinnValve Registry	Robust checking of completeness and data quality[310]	N/R	N/R	N/R
FRANCE-TAVI Registry	Regular data checks, data platform has error checking for range and consistency[14]	N/R	N/R	N/R
German Aortic Valve Registry	Data completeness is verified by an electronic tool which analyses reimbursement, data validity is monitored by a multistage plausibility check combined with an on-site data verification on a randomly selected 3% of the samples[33]	N/R	N/R	N/R
Polish Registry of Transcatheter Aortic Valve Implantation	Credibility and completeness of data will be verified through internal and external regular audits[16]	N/R	N/R	N/R
Spanish Registry of Heart Valves Repair	N/R	N/R	N/R	N/R
Swedish Transcatheter Cardiac Intervention Registry	N/R	N/R	N/R	N/R
Swiss TAVI Registry	The Clinical Trials Unit of Bern performs data monitoring (e.g., completeness of data and plausibility checks)[286]	N/R	N/R	N/R

Supplementary Table 7A: Cardiovascular registries – Outcomes reported, definition & duration of follow-up

Table S7A: Cardiovascular registries – Outcomes reported, definition & duration of follow-up			
	Mortality	**MACE**	**Other**
Cardiovascular registries – combined			
British Cardiovascular Intervention Society	In-hospital[316-326]; 5-day[327]; 1-week[307]; 10-day[324, 327]; 15-day[327]; 20-day[324, 327]; 25-day[327]; 1-month[307, 318, 320, 323-336]; 100-day[324]; 6-month[307, 323, 330]; 200-day[324]; 10-month[324]; 1-year[307, 318, 322-325, 328, 330-332, 334, 337, 338]; 500-day[307]; 2-year[322, 337]; 1000-day[307]; 3-year[322, 323, 334, 337]; 4-year[322, 337]; 1500-day[307]; 5-year[322, 334]; 2000-day[307]; 6-year[319]; 2500-day[307].	In-hospital (including death, myocardial infarction, and re-intervention[320, 339]); In-hospital (including death, myocardial infarction, and revascularization[331]); In-hospital (including death, emergency coronary artery bypass grafting, myocardial infarction, and re-intervention[334]); In-hospital (unspecified[340])	Access site complication[331], aortic dissection[319, 323], arterial complication[326], bleeding[307, 317, 318, 321, 324-326, 331, 334, 339-341], blood transfusion[307, 318, 321, 330], cardiac complication[325], cardiogenic shock[317], cardioversion[319, 330], complication (unspecified)[325, 326], coronary dissection[307, 323], coronary complication[318, 322], coronary perforation[307, 323, 330], CVA[319, 321, 323, 326], ECMO usage[317], heart failure[317, 341], ICU stay (length)[317], in-hospital stay (length)[317, 321, 323, 339, 341], myocardial infarction[307, 316-319, 321-324, 326, 332, 341], no flow[307, 319, 323], pacemaker implantation[309], pericardial tamponade[323, 330], procedural success[318, 323, 337, 341], rehospitalization[341], re-intervention[318, 319, 322-324, 326, 330], renal failure[307, 323, 330], revascularization[307, 341], side branch occlusion[307, 319, 323, 330], slow flow[307, 319, 323], stent thrombosis[317, 341], stroke[307, 317, 322, 324, 325, 332, 341], vascular complication[322, 323, 325, 339]
East Denmark Heart Registry	1-month[2]; 1-year[2, 38]; 2-year[38]; 3-year[38]; 4-year[38]; 5-year[38, 39]; 6-year[38]; 7-year[38]; 8-year[38]; 9-year[38].	N/R	In-hospital stay (length)[2], myocardial infarction[39], revascularization[39], vascular complication[2]
German Society for Thoracic	In-hospital[3, 41, 342-379]	N/R	Complication (unspecified)[380], infection[381], re-intervention[378, 379]
and Cardiovascular Surgery			
Polish National Database of Cardiac Surgery Procedures	In-hospital[5, 42-44, 49, 50, 53]; Early (<24hr) post-operative[45, 48, 52, 53]; 10-day[50]; 20-day[50]; 1-month[45, 48, 50, 52, 54]; 1-year[43-45, 48, 49, 52-54]; 2-year[43-45, 48-50, 52-54]; 3-year[44, 45, 48, 49, 52-54]; 4-year[43-45, 48-50, 52-54]; 5-year[45, 48, 49, 52-54]; 6-year[43, 45, 48-50, 52-54]; 7-year[45, 48, 49, 52-54]; 8-year[43, 45, 48-50, 52-54]; 9-year[45, 48, 49, 52-54]; 10-year[43, 45, 48-50, 52-55]; 11-year[45, 48, 49, 52-54]; 12-year[45, 48-50, 52, 53]; 13-year[52].	N/R	Cardiogenic shock[53], ECMO usage[45, 48, 50, 52], gastro-intestinal complication[44, 45, 48-50, 52, 53], ICU readmission[49], ICU stay (length)[5, 42, 45, 48, 50, 52, 53], infection[45, 48-50, 52, 53], in-hospital stay (length)[5, 42], left ventricular support[43, 45, 49], multi-organ failure[45, 48, 50, 52, 53], myocardial infarction[43, 45, 49, 50, 52, 53], neurological complication[44, 45, 48-50, 52, 53], pacemaker implantation[48, 50, 52], pericardial tamponade[45, 49, 50, 52, 53], pulmonary embolism[45], re-intervention[43, 45, 49, 50, 52, 53], renal failure[43-45, 48-50, 52, 53], respiratory failure[44, 45, 49, 50, 52, 53]
Portuguese National Registry of Intervention Cardiology	N/R	N/R	N/R
Spanish Cardiac Catheterization and Coronary Intervention Registry	In-hospital[382]; 6-month[383].	N/R	In-hospital stay (length)[382], mitral regurgitation[382], procedural success[382]
Western Denmark Heart Registry	In-hospital[24, 76, 82, 111, 123]; 10-day[74]; 20-day[74]; 1-month[8, 24, 63, 67, 69, 70, 74, 76, 79, 82, 84, 86, 88, 95, 96, 101, 103, 110, 122, 126, 127, 130]; 4-month[82]; 6-month[67, 71, 86, 93, 122, 127];	2-year (including death, myocardial infarction, and revascularization[115]; 3-year (including cardiovascular-related death, myocardial infarction, revascularization, and stent thrombosis[100]);	Allergic reaction[8], arrhythmia[8, 79, 84, 127], atrial fibrillation[73, 107, 118, 129], bleeding[8, 25, 79, 86, 111, 121, 123, 128], blood transfusion[63, 102, 107, 118, 121], contrast-fluid reaction[79], EuroSCORE[124], infection[8, 25, 96, 102, 123], ICU stay (length)[8, 25, 67, 86, 96, 123, 125], in-hospital stay (length)[67, 79, 86, 96, 102, 109, 125], limb amputation[106], malignancy[108], myocardial infarction[8, 25, 61-63, 65, 67, 69, 71, 74, 77, 80, 81, 84, 86, 88-90, 92, 98, 100, 101, 105, 110, 117, 120, 122, 123, 128, 130], obstructive coronary artery disease[65], pericardial tamponade[86, 121], peripheral artery disease[106], rehospitalization[83, 102, 109], re-intervention[8, 24, 25, 61, 63, 67, 79, 86, 113, 121, 122], renal

	1-year[8, 24, 92, 93, 95-98, 101-103, 117, 126, 127]; 15-month[117]; 18-month[71, 101]; 2-year[62, 69, 71, 72, 76, 78, 93, 98, 102, 103, 126]; 30-month[24]; 3-year[72, 92, 93, 97, 102-104]; 4-year[72, 93, 103]; 5-year[24, 66, 72, 80, 93, 103, 127]; 6-year[93]; 7-year[93, 105]; 90-month[24]; 9-year[89]; 10-year[24, 90, 120, 127]; 11-year[77, 99]; 150-month[24, 128]; 15-year[24].	3-year (including death, myocardial infarction, revascularization, and stroke[102]); 5-year (including cardiovascular-related death, cardiac arrest, myocardial infarction, and revascularization[66]); 5-year (including cardiovascular-related death, myocardial infarction, and stroke[80]); 5-year (unspecified[85])	failure[25, 63, 67, 84, 86, 88, 96, 102, 116, 127, 128], revascularization[62, 69, 71, 75, 77, 87, 91, 92, 97, 98, 100-102, 119, 127], stent failure[97], stent restenosis[71, 91], stent thrombosis[62, 69, 71, 91, 92, 97, 98, 100, 101, 104, 111, 117, 126], stroke[8, 25, 61, 63, 67, 81, 84, 86, 88-90, 102, 112, 120, 122, 123, 127], TIA[8, 112]
Cardiovascular registries – stents			
Polish National Percutaneous Coronary Intervention Registry	Procedural[135, 137-140, 147, 149, 153, 154, 158, 159, 161, 162, 165-170, 174, 175]; In-hospital[141, 142, 150]; 5-day[150]; 10-day[150]; 15-day[150, 155]; 20-day[150]; 25-day[150]; 1-month[141, 150, 155, 157]; 45-day[155]; 2-month[155, 157]; 75-day[155]; 3-month[155, 157]; 4-month[157]; 5-month[157]; 6-month[142, 150, 155, 157]; 7-month[157]; 8-month[157]; 9-month[157]; 10-month[157]; 11-month[157]; 1-year[141, 142, 150, 155-157, 172, 176, 178];	Procedural (including death, myocardial infarction, and stroke[138, 161]); 1-year (including death, myocardial infarction, revascularization, and urgent PCI/CABG[156]); 3-year (unspecified[141, 150]); 3-year (including cardiac arrest, death, rehospitalization for heart failure, myocardial infarction, and stroke[142]); 3-year (including cardiac arrest, death, myocardial infarction, and stroke[155])	Allergic reaction[133-136, 138, 143, 144, 146-148, 151, 159, 161, 162, 165-167, 170, 175], angiographic findings[136, 144, 146-148, 153, 156, 161, 162, 168, 172, 178], bleeding[133-136, 138-140, 143, 144, 148, 149, 151, 161, 162, 167, 168, 170, 174, 175], cardiac arrest[140, 142-144, 148], complication (unspecified)[146, 175], coronary dissection[133, 134, 136, 138, 143, 144, 146, 147, 151, 154, 161, 166-168, 170, 175], coronary perforation[135, 136, 138-140, 143, 146, 148, 149, 154, 162, 164-166, 168, 170, 175], heart failure[142, 155], in-hospital stay (length)[142], myocardial infarction[138, 139, 142-144, 146, 151, 155, 156, 159, 161, 162, 165-168, 170, 172, 176, 178], no-reflow[133-135, 138-140, 143, 144, 146-148, 151, 153, 154, 159, 161, 162, 164-168, 170, 174, 175], rehospitalization[142, 155], re-intervention[142, 155, 156, 172, 176, 178], restenosis[144, 146, 162, 176], revascularization[156, 172, 178], stent thrombosis[146, 156, 162, 172, 176, 178], stroke[133, 134, 136, 138, 140, 142-144, 146, 151, 152, 154, 155, 159, 161, 162, 165-168, 170, 175], vessel perforation[147]

	13-month[157]; 14-month[157]; 15-month[157]; 16-month[157]; 17-month[157]; 18-month[142, 150, 155, 157]; 19-month[157]; 20-month[157]; 21-month[157]; 22-month[157]; 23-month[157]; 2-year[142, 150, 155, 157]; 30-month[142, 150, 155]; 3-year[141, 142, 150, 155].		
Swedish Coronary Angiography and Angioplasty Registry	Procedural[384, 385]; In-hospital[385-391]; 1-day[392, 393]; 3-day[393]; 5-day[391, 393, 394]; 1-week[392, 393, 395]; 10-day[315, 391, 396-400]; 15-day[391]; 20-day[315, 391, 394, 396-400]; 25-day[391, 394]; 1-month[302, 304, 315, 330, 388, 390-392, 394, 396-421]; 2-month[292, 411, 422, 423]; 50-day[424]; 3-month[293, 294, 415, 425, 426]; 100-day[315, 406, 407, 424]; 4-month[292, 411, 422, 423]; 5-month[424]; 6-month[292-294, 298, 301, 302, 330, 388, 411, 415, 422, 423, 425-430]; 200-day[315, 406, 407, 424]; 8-month[292, 411, 422, 423]; 250-day[424]; 9-month[293, 294, 415, 425, 426]; 10-month[292, 315, 406, 407, 411, 422-424]; 1-year[292-294, 297-302, 304, 312, 315, 330, 385, 388, 389, 391, 392, 400, 403-407, 409, 410, 414, 415, 418, 420-422, 424-449];	1-year (including death, myocardial infarction, re-intervention, restenosis, and revascularization[421]); 4-year (including death, myocardial infarction, and revascularization[448])	Allergic reaction[385, 390], anaphylactic reaction[384], anemia[454], arrhythmia[330, 385, 390], bleeding[384, 385, 399, 400, 403, 405-408, 413, 418-420, 425, 443, 454, 455], bradycardia[387], cardiogenic shock[398, 400, 413, 414], cerebrovascular event[454], complication (unspecified)[384-386, 390, 391, 408, 414, 455, 456], coronary flow reserve[457], coronary occlusion[390], coronary perforation[330, 385, 390, 391], gastro-intestinal bleeding[454], heart failure[394, 400, 406, 416, 426, 434, 435, 441, 443, 447, 449], hemodynamic complication[385, 390, 414], in-hospital stay (length)[394], in-stent thrombosis[292-294, 297-302, 304, 306, 313, 315, 385, 391, 394, 402, 403, 405, 407, 411, 413, 414, 418, 420-423, 436, 441, 445, 447, 448, 458], intra-aortic balloon pump therapy[414], myocardial infarction[292-294, 299-303, 312, 384, 385, 389, 391, 399, 401, 406, 407, 410, 411, 421, 422, 424, 425, 427, 428, 430, 433, 435, 437, 441, 443, 447-450, 452, 459], neurological complication[315, 385, 390, 394, 413, 414, 418, 455], left ventricular ejection fraction[394], left ventricular dysfunction[411], pericardial tamponade[330, 384, 385, 390, 391, 411], procedural success[315, 384, 392, 409, 444], pseudoaneurysm[385], rehospitalization[391, 394, 416, 421, 426, 443, 450, 460], re-intervention[299, 330, 384, 385, 390, 391, 393, 403, 412, 421, 424, 447], renal failure[330, 384, 385, 447, 460], restenosis[292-294, 296-299, 301-303, 312, 385, 391, 414, 421-423, 429, 430, 433, 436, 445, 447, 448, 461], re-restenosis[295], resuscitation[389], revascularization[294, 385, 391, 394, 411, 414, 421, 422, 426, 433, 435, 441, 448, 452], side branch occlusion[330, 385, 391], stent loss[385, 390], stent thrombosis[292-294, 297-302, 304-306, 313, 315, 385, 391, 394, 402, 403, 405, 407, 411, 413, 414, 418, 420-423, 436, 441, 445, 447, 448, 458], stroke[315, 384, 394, 399, 401, 406, 411, 412, 416, 435, 443, 447, 449, 452], TIA[412], vascular complication[385, 390], ventricular fibrillation[387], ventricular tachycardia[387]

	14-month[292]; 15-month[293, 294]; 16-month[292]; 18-month[292-294, 298, 301, 388, 427, 430]; 20-month[292]; 21-month[293, 294]; 22-month[292]; 2-year[292-294, 297-299, 301, 304, 312, 385, 388, 391, 392, 400, 412, 414, 418, 421, 423, 427, 428, 431, 432, 435, 436, 438-441, 444, 446-451]; 730-day[438]; 30-month[301, 388, 427, 430, 452]; 3-year[297, 299, 301, 304, 385, 388, 391, 392, 400, 410, 412, 414, 416, 418, 421, 427, 428, 430-432, 434-436, 438, 439, 441, 444-449, 451]; 42-month[388, 430]; 4-year[297, 299, 385, 391, 400, 414, 418, 421, 423, 428, 430-432, 435, 438-441, 444, 446-449, 451, 453]; 1460-day[438]; 5-year[297, 299, 385, 391, 400, 406, 414, 418, 421, 428, 432, 435, 438, 439, 441, 444, 446, 447, 449, 451]; 66-month[432]; 6-year[299, 385, 391, 414, 418, 421, 423, 438-441, 443, 444, 446, 451]; 2195-day[438]; 7-year[299, 385, 391, 414, 418, 421, 438, 439, 446]; 8-year[299, 385, 391, 414, 418, 421, 423, 438-440, 446, 451]; 2920-day[438]; 9-year[299, 385, 391, 418, 421, 438, 439]; 10-year[299, 313, 385, 391, 418, 421, 423, 438-440, 451]; 11-year[385, 391, 421]; 12-year[421]; 21-year[442].		
Cardiovascular registries – valves			
Quality Assurance Registry on Aortic Valve Replacement	In-hospital[29, 182-184]; 1-month[184].	N/R	Aortic regurgitation[183], cerebrovascular event[29], complication (unspecified)[183, 184], delirium[182], in-hospital stay (length)[29, 182, 184], low cardiac output[29], myocardial infarction[29, 183], neurological complication[183], pacemaker implantation[182, 184], renal failure[29, 182, 184], resuscitation[29], stroke[182], TIA[182], vascular complication[183, 184]
Austrian TAVI Registry	1-month[11, 185]; 6-month[185]; 1-year[11, 185];	N/R	Complication (unspecified)[11], echographic findings[11], procedural success[11], quality-of-life[11], rehospitalization[11]

	18-month[185]; 2-year[185]; 30-month[185]; 3-year[185].		
Belgian TAVI Registry	Procedural [186]; 1-month[12, 186]; 3-month[12]; 6-month[12, 186]; 1-year[12, 186]; 18-month[12]; 2-year[12, 187]; 30-month[12]; 3-year[12].	30-day (including death, myocardial infarction, pacemaker implantation, stroke, and TIA[12]); Unknown (including pacemaker implantation, renal failure, and stroke[187])	Echographic findings[186], pacemaker implantation[186], procedural success[12, 186], renal failure[186, 187], stroke[186], TIA[186], valve migration[12]
Czech TAVI Registry	5-day[462]; 10-day[462]; 15-day[462]; 20-day[462]; 25-day[462]; 1-month [462].	N/R	Aortic regurgitation[13, 462], bleeding[462], cerebrovascular event[462], complication (unspecified)[191], coronary obstruction[462], in-hospital stay (length)[191], mitral regurgitation[462], NYHA classification[462], procedural success[462], rehospitalization[191]
FinnValve Registry	1-month[196, 308, 311]; 1-year[30, 195-197, 308, 310, 311]; 2-year[30, 195-197, 308, 310, 311]; 3-year[30, 195, 197, 308, 310, 311]; 4-year[30, 195, 197, 310, 311]; 5-year[30, 195, 197, 311]; 6-year[30, 195, 197]; 7-year[195, 197]; 8-year[30]; 10-year[30].	N/R	Aortic annulus rupture[196], aortic dissection[196, 308], aortic peak gradient[30], atrial fibrillation[30, 196, 308, 310, 311], bleeding[30, 196, 308, 310, 311], blood transfusion[196, 308, 310, 311], coronary occlusion[196, 308], ECMO usage[196], ICU stay (length)[30], in-hospital stay (length)[30, 196, 308, 311], infection[30, 197, 308, 310], intra-aortic balloon pump therapy[196], pacemaker implantation[30, 196, 308], paravalvular regurgitation[196, 308], re-intervention[30, 196, 197, 308, 310, 311], renal failure[30, 196, 308, 310, 311], revascularization[308], stroke[30, 196, 308, 310, 311], vascular complication[196, 308, 310]
FRANCE TAVI Registry	Procedural[210]; In-hospital[198, 200, 203, 211, 218]; 1-month[198, 199, 201, 202, 204, 205, 207, 209, 210, 212-214, 216, 218-220]; 2-month[216]; 3-month[200, 216]; 100-day[205, 214, 219]; 4-month[202, 210, 216]; 5-month[216]; 6-month[200, 201, 204, 205, 216, 220];	N/R	Acute coronary syndrome[222], acute occlusion (unspecified artery/vessel)[219], annulus rupture[14, 198, 204, 209, 211, 217], aortic dissection[14, 198, 211, 217], aortic regurgitation[201, 204, 205, 207, 212, 219, 220, 223], atrial fibrillation[214], blood transfusion[213], bleeding[198, 200-205, 207, 209, 213, 214, 216, 219, 220, 222, 223], echographic findings[14, 200, 208, 217], heart failure[201, 208], hemorrhagic shock[198], ICU stay (length)[204, 205, 207, 209, 213, 214, 219], infection[198, 199, 203, 223], in-hospital stay (length)[199, 204, 205, 207, 209, 211, 213, 214, 217, 219, 220], left ventricular ejection fraction[212], life threatening event[205, 214], mitral regurgitation[204, 205, 207, 219], myocardial infarction[14, 198-205, 207, 209, 214, 219, 220], NYHA classification[202, 216], pacemaker implantation[14, 198-201, 203-205, 207, 209, 211, 214, 217, 219, 220, 223], pericardial tamponade[14, 198, 204, 205, 207, 209, 211, 214, 217], peri-

	200-day[205, 214, 219]; 7-month[216]; 8-month[202, 210, 216]; 9-month[200, 213, 216]; 10-month[205, 214, 216, 219]; 11-month[216]; 1-year[200-205, 207, 209, 210, 212, 214-217, 219, 220]; 400-day[205, 214, 219]; 18-month[200, 212]; 2-year[200, 203, 215, 217]; 3-year[203, 215, 217]; 4-year[208, 217]; 5-year[217].		procedural complication (unspecified)[203, 223], procedural success[14, 199, 201, 204, 205, 207, 209-214, 218-220], pulmonary embolism[14, 198, 211], rehospitalization[199, 202], re-intervention[198, 200, 201, 204, 205, 207, 209, 214, 219], renal failure[14, 198, 201-205, 207, 209, 211, 213, 214, 219], stroke[14, 198-205, 207-209, 211, 213, 214, 216, 217, 219, 222], valve dysfunction[201, 202], valve migration[14, 198, 199, 211, 217, 220], vascular complication[198-205, 207, 209, 213, 214, 219, 220]
German Aortic Valve Registry	In-hospital[15, 31, 32, 224, 225, 228, 230-233, 235-237, 241]; 5-day[240]; 10-day[240]; 15-day[232, 240]; 20-day[240]; 25-day[240]; 1-month[32, 224, 228, 229, 232, 234, 238-240]; 2-month[224, 228, 229, 232, 240]; 3-month[230]; 4-month[224, 228, 229, 232, 234, 240]; 6-month[32, 224, 225, 228-230, 232, 238, 240]; 8-month[224, 228, 229, 232, 234, 240]; 9-month[230]; 10-month[224, 228, 229, 240]; 1-year[15, 32, 224, 225, 228-232, 234, 238-240]; 2-year[15]; 3-year[15]; 4-year[15]; 5-year[15].	1-year (including death, myocardial infarction, and stroke[32])	Aortic dissection[233], aortic regurgitation[31, 228, 230, 231, 233, 234, 237, 239-241], atrial fibrillation[31, 225, 228, 230, 231, 235, 240, 241], bleeding[32, 228, 230, 231, 233, 236, 241], blood transfusion[31, 234, 235, 237, 240], cerebrovascular event[237], conversion sternotomy[224, 230, 237], coronary occlusion[237], delirium[239], device malposition[224], echographic findings[236, 241], EQ-5D-3L scores[235], ICD implantation[32, 225, 231, 235, 236], ICU stay (length)[224, 225, 228, 231, 234-236, 241], infection[231, 234, 239, 241], in-hospital stay (length)[31, 224, 225, 228, 231, 235, 236, 240, 241], left ventricular decompensation[230, 237, 239], low cardiac output[32, 224, 231], mechanical ventilation (duration)[237], myocardial infarction[15, 31, 32, 224, 225, 228, 230, 231, 233-236, 238-240], NYHA classification[225, 231, 238], pacemaker implantation[15, 31, 32, 224, 225, 228, 230, 231, 233, 235-241], pericardial tamponade[231, 233, 237, 239, 240], procedural success[224, 230, 234], rehospitalization[225, 230, 231, 235], re-intervention[31, 32, 225, 233, 235-238, 241], renal failure[15, 31, 32, 224, 225, 228, 231, 233-237, 239, 241], respiratory failure[224, 239], resuscitation[32, 224], sepsis[230, 236, 239, 241], stroke[15, 31, 32, 224, 225, 228, 230, 231, 233-236, 238-241], thromboembolic event[230, 237], TIA[225, 228, 231, 235, 240, 241], vascular complication[32, 224, 228, 230, 231, 233, 234, 237, 239, 240]
Polish Registry of Transcatheter Aortic Valve Implantation	In-hospital[34, 243, 251]; 1-month[248, 250, 251]; 50-day[251]; 100-day[251]; 5-month[251]; 6-month[246]; 200-day[251];	30-day (including cardiovascular-related death, myocardial infarction, and stroke[249])	Bleeding[34, 244], mitral regurgitation[251], myocardial infarction[34], NYHA classification[243], paravalvular leakage[246], procedural success[34, 243, 250], quality of life[245], thromboembolic event[34], vascular access site complication[247], vascular complication[34]

	250-day[251]; 10-month[251]; 350-day[251]; 400-day[251]; 15-month[251]; 500-day[251]; 550-day[251].		
Spanish Registry of Heart Valves Repair	N/R	N/R	N/R
Swedish Transcatheter Cardiac Intervention Registry	In-hospital[36]; 1-month[28]; 6-month[36]; 1-year[28, 36]; 2-year[28, 36]; 3-year[28, 36]; 4-year[28, 36]; 5-year[28, 36]; 6-year[28, 36]; 7-year[28]; 8-year[28, 36].	N/R	In-hospital stay (length)[36], pacemaker implantation[36], re-intervention[36], stroke[28, 36]
Swiss TAVI Registry	Procedural[253, 274]; In-hospital[289]; 5-day[255, 270, 282, 284]; 10-day[255, 268, 270, 282, 284]; 15-day[255, 270, 282, 284]; 20-day[255, 268, 270, 282, 284]; 25-day[255, 270, 282, 284]; 1-month[20, 253, 255-258, 260, 262-266, 268-270, 272, 274, 275, 278, 280-282, 284-287, 291]; 2-month[256-259, 262, 263, 266, 267, 269, 274, 275, 280, 283, 285-287, 291]; 3-month[253, 256-259, 262, 263, 266, 267, 269, 275, 278, 280, 283, 285, 286, 291]; 100-day[268]; 4-month[256-259, 262, 263, 266, 267, 269, 274, 275, 278, 280, 283, 285-287, 291]; 5-month[253, 256-259, 262, 263, 266, 267, 269, 275, 278, 280, 283, 285, 286, 291];	1-year (including cardiovascular-related death, myocardial infarction, and stroke[257])	Access site complication[20, 253, 255, 257, 258, 264, 272], annulus rupture[263, 266], aortic dissection[289], aortic regurgitation[20, 253, 263, 266, 272, 282, 290], aortic rupture[289], arrhythmia[260], atrial fibrillation[290], bleeding[20, 253, 255-257, 259, 260, 263-267, 272, 274, 278, 281, 282, 284-287, 290, 291], blood transfusion[253, 259], central venous pressure[276], cerebrovascular event[253, 259, 262, 267, 291], coronary occlusion[263, 266, 284, 289], effective orifice area[260], ICU stay (length)[253, 259, 282, 286, 289], in-hospital stay (length)[253, 257, 259, 281, 282, 285, 286, 289, 290], left bundle branch block[284], left ventricular function[281, 287], leg ischemia[289], mitral regurgitation[287], myocardial infarction[20, 253, 255-260, 262, 264, 266, 267, 271, 272, 274, 278, 282, 285-287, 291], NYHA classification[265, 275, 280], pacemaker implantation[20, 253, 259, 263-266, 272, 281, 282, 284-286, 289, 290], pericardial tamponade[263, 266, 284, 289], procedural success[263, 274], rehospitalization[265, 279], re-intervention[20, 260, 263, 264, 285, 289], renal failure[20, 253-255, 258, 260, 263, 264, 266, 267, 272, 278, 282, 285-287, 289], stroke[20, 253, 256-260, 263-266, 269, 271, 272, 274, 278, 281, 282, 285-287, 289, 291], TIA[256, 260, 271, 272, 274, 282, 285-287, 291], transvalvular gradient[260, 281], transvalvular pressure[288], valve dislocation[266, 284], valve dysfunction[265], valve migration[263, 289], valvular leakage[289], vascular complication[20, 263, 265, 266, 274, 281, 282, 284-287, 289]

	6-month[256-259, 262-264, 266, 267, 269, 274, 275, 278, 280, 281, 283, 285-287, 291]; 200-day[268]; 7-month[253, 256-259, 262, 263, 266, 267, 269, 275, 278, 280, 283, 285, 286, 291]; 8-month[256-259, 262, 263, 266, 267, 269, 274, 275, 278, 280, 283, 285-287, 291]; 9-month[253, 256-259, 262, 263, 266, 267, 269, 275, 278, 280, 283, 285, 286, 291]; 10-month[256-259, 262, 263, 266-269, 274, 275, 278, 280, 283, 285-287, 291]; 11-month[253, 256-259, 262, 263, 266, 269, 275, 278, 280, 283, 285, 286, 291]; 1-year[253, 256-259, 262-269, 271, 272, 274-276, 278, 280, 281, 283, 285-287, 290, 291]; 14-month[274, 287]; 16-month[274, 287]; 18-month[264, 274, 287]; 20-month[274, 287]; 22-month[274, 287]; 2-year[264, 271, 272, 274, 277, 287]; 3-year[271, 272]; 4-year[271, 272]; 5-year[271, 272];		

Supplementary Table 8A: Cardiovascular registries – Domain Safety & performance

Table S8A: Cardiovascular registries – Domain 'Safety & performance'

	Frequency of feedback	Level of feedback provided	Feedback (time period)	Outlier reports/procedures	Accessibility of results	Definition of outlier	Number of outliers identified
Cardiovascular registries – combined							
British Cardiovascular Intervention Society	Annually[1]	Hospital level[314]	N/R	Call to treatment time, door to treatment time, adverse outcome (CVA/needing emergency cardiac surgery), survival (only individual hospitals)[314]	Publicly available, and individual hospitals (survival data)[314]	Funnel plots using 3SD and 2SD (call to treatment, door to treatment, and survival)[314]	N/R
East Denmark Heart Registry	N/R	N/R	N/R	N/R	N/R	N/R	N/R
German Society for Thoracic and Cardiovascular Surgery	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Polish National Database of Cardiac Surgery Procedures	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Portuguese National Registry of Intervention Cardiology	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Spanish Cardiac Catheterization and Coronary Intervention Registry	Annually[463]	N/R	N/R	N/R	N/R	N/R	N/R
Western Denmark Heart Registry	Annually and quarterly[25]	N/R	N/R	N/R	N/R	N/R	N/R
Cardiovascular registries – stents							
Polish National Percutaneous Coronary Intervention Registry	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Swedish Coronary Angiography and Angioplasty Registry	Annually[10]	Hospital- and medical device-level[10, 464]	30-day (hospital level) and 1-year (medical device level)[10, 464]	N/R (30-day mortality after PCI in STEMI patients per hospital including mean and 95% and waiting time per hospital are reported (statistical testing unknown), stent thrombosis and restenosis in most used stents are reported (statistical testing unknown)[10, 464]	Publicly available[10, 464]	N/R	N/R
Cardiovascular registries – valves							
Quality Assurance Registry on Aortic Valve Replacement	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Austrian-TAVI Registry	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Belgian TAVI Registry	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Czech TAVI Registry	N/R	N/R	N/R	N/R	N/R	N/R	N/R
FinnValve Registry	N/R	N/R	N/R	N/R	N/R	N/R	N/R
FRANCE-TAVI Registry	N/R	N/R	N/R	N/R	N/R	N/R	N/R
German Aortic Valve Registry	Annually[33]	Hospital level[33]	N/R	N/R (Individual hospitals' results are compared with the entire registry data; statistical testing unknown)[33]	Individual hospitals[33]	N/R	N/R
Polish Registry of Transcatheter Aortic Valve Implantation	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Spanish Registry of Heart Valves Repair	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Swedish Transcatheter Cardiac Intervention Registry	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Swiss TAVI Registry	N/R	N/R	N/R	N/R	N/R	N/R	N/R

Supplementary Table 1B: Orthopaedic registries – Domain Identification

Table S1B: Orthopaedic registries – Domain 'Identification'				
	Country	Design	Website	Initial motivation / goal
Orthopaedic arthroplasty registries – combined				
Croatian Register of endoprothesis	Croatia	National	N/R	N/R
German Arthroplasty Register	Germany	National	https://www.eprd.de/de/	To create a robust framework for the assessment of hip and knee arthroplasties[45]
Finnish Arthroplasty Register	Finland	National	https://www.thl.fi/far/	To study and ensure the quality of prostheses for the safety of patients[81]
Irish National Orthopaedic Register	Ireland	National	https://www.noca.ie/audits/irish-national-orthopaedic-register/	1) to improve the quality of services and care provided to patients having joint replacement surgery, and 2) to monitor the safety of implants and support hospitals should an implant recall occur[4]
Lithuanian Arthroplasty Register	Lithuania	National	https://lsed.lt/	N/R
Dutch Arthroplasty Register	The Netherlands	National	https://www.lroi.nl/	To provide insight into and feedback on the results of arthroplasties in the Netherlands and the related orthopaedic Care[82]
Hungarian Arthroplasty Register	Hungary	National	https://www.ortopedtarsasag.hu/	To collect the quality indicators of domestic hip and knee prosthesis implants with a user-friendly, internet-based system that provides real-time data processing[7]
Norwegian Arthroplasty Register	Norway	National	https://nrlweb.ihelse.net/	1) to prevent the use of poor prostheses in patients, and 2) to provide an overview of the products and surgical procedures in use at any time and the patient groups who need arthroplasty[8]
Nordic Arthroplasty Register Association	Denmark, Finland, Norway, Sweden	Multi-country	N/R	To improve the quality of research and understanding of the clinical course of patients undergoing joint replacement surgery and thereby improve the results after joint replacement surgery[83]
National Joint Registry for England, Wales, Northern Ireland, the Isle of Man, and the States of Guernsey	England, Wales, Northern Ireland, the Isle of Man, and the states of Guernsey	Multi-country	https://www.njrcentre.org.uk/	To record patient information and provide data on: the performance and longevity of replacement joint implants; the surgical outcomes for the hospitals where these operations are carried out; and on the performance outcomes of the surgeons who conduct the procedures[56]
Belgian National Arthroplasty Register	Belgium	National	https://www.ehealth.fgov.be/nl/egezondheid/beroepsbeoefenaars-in-de-gezondheidszorg/qermidorthopride/	1) to collect data to enable professionals to examine the quality of care during hip prosthesis placement; 2) to provide information about the type of prostheses placed on a patient when he or she comes for a consultation, so that accessories can be appropriately ordered if necessary, and 3) to determine the lifespan of the prostheses[84]
Catalan Arthroplasty Register	Catalonia (Spain)	Regional	N/R	To assess the clinical effectiveness of hip and knee arthroplasties in Catalonia[13]
National Arthroplasty Registry of Slovenia	Slovenia	National	https://www.ob-valdoltra.si/	To support quality and safe health care for the patients, as well as to improve the orthopaedic profession[34]
Italian Arthroplasty Registry	Italy	National	https://riap.iss.it/riap/	To monitor the long-term effectiveness of hip, knee, shoulder and ankle prostheses (measured as implant survival), and support regions and hospitals when recall of patients is needed because of problems reported on specific implants[36]
Emilia-Romagna Region Arthroplasty Register	Emilia-Romagna (Italy)	Regional	https://www.ior.it/en/curarsi-al-rizzoli/register-orthopaedic-prosthetic-implants/	1) to determine the demographic characteristics and the diagnostic categories of patients who have undergone replacement surgery; 2) to gather detailed information on the use of the different prostheses used in primary and revision surgery; 3) to assess the effectiveness of the different types of prostheses; 4) supply orthopaedic surgeons with a very useful tool to give the patient timely information; 5) to collaborate in post-marketing surveillance, allowing surgeons to easily identify patients implanted with a recalled implant; 6) compare the regional situation with other national and international situations; 7) to inform the Regional Orthopaedic Commission about those implants that show an abnormal failure rate, and 8) to answer questions coming from the Regional Orthopaedic Commission or from other National or European Institutions[63]
Romanian National Arthroplasty Register	Romania	National	https://www.rne.ro/	To keep track of the revision surgery, in order to compare the quality of different types of endoprosthesis, cement and surgical techniques to detect low quality implants as soon as possible, by comparing the results of different medical devices and treatments used[77]
Portuguese National Arthroplasty Register	Portugal	National	https://www.rpa.spot.pt/	To investigate what kind of arthroplasty is better than the rest, or what are the best joint pairs[85]

Scottish Arthroplasty Project Joint Registry	Scotland	National	https://www.arthro.scot.nhs.uk/	To encourage continual improvement in the quality of care provided to joint replacement surgery (arthroplasty) patients[20]
Slovakian National Arthroplasty Register	Slovakia	National	https://sar.mfn.sk/	1) to provide an epidemiological analysis of performed artificial joint replacements; 2) to identify risk factors of primary and revision implantations that result in arthroplasty failure, taking into account the age and gender of the patient, the type of implant and the method of its fixation, the surgical procedure used; 3) to reduce the number of revision operations by analyzing and eliminating risk factors; 4) to create a standard algorithm for regular checks of patients with an artificial joint replacement, thereby eliminating the occurrence of large-scale destruction during the release of the endoprosthesis, and 5) to improve the quality of patient care after joint replacement[86]
Swiss Arthroplasty Register	Switzerland	National	https://www.siris-implant.ch/	To improve quality in implant medicine by means of a continuous learning process based on systematically collected data[22]
Orthopaedic arthroplasty registries – hips				
Czech Republic Arthroplasty Register	Czechia	National	https://www.ksrzis.cz/	To register data on treatment with the use of an endoprosthesis and specific information specifying this treatment in more detail[87]
French Arthroplasty Register	France	National	https://www.sofcot.fr/	1) to promote and develop knowledge of French orthopaedic and trauma surgery; 2) to strengthen the links between orthopaedic and trauma surgeons in order to facilitate exchanges and to be able to reach consensus beneficial to the development of the specialty; 3) to foster relationships with other disciplines and countries concerned with the musculoskeletal system; 4) 4o organize any international, European, national or local scientific event related to its purpose, and 5) 5o coordinate the monitoring of the evolution of the specialty's practices and its environment[24]
Danish Hip Arthroplasty Register	Denmark	National	https://www.dhr.dk/	To continuously monitor and improve the quality of treatment of primary and revision THA in Denmark[88]
Swedish Hip Arthroplasty Register	Sweden	National	https://shpr.registercentrum.se/	To analyze the entire process surrounding hip replacement surgery – that is, to identify predictors of both good and poor outcomes in a multidimensional and individual-based manner[89]
Orthopaedic arthroplasty registries – knees				
Danish Knee Arthroplasty Register	Denmark	National	https://www.danishhealthdata.com/find-health-data/Dansk-Knaealloplastik-Register/	1) to examine the epidemiology of knee replacement procedures in Denmark, and 2) to monitor and facilitate continuous improvement of knee replacement surgery outcomes on both local and national levels[44]
Swedish Knee Arthroplasty Register	Sweden	National	https://www.myknee.se/	To collect, analyze, and render information that could warn against suboptimal techniques and implants[72]

Supplementary Table 2B: Orthopaedic registries – Domain Maturity

Table S2B: Orthopaedic registries – Domain 'Maturity'			
	Starting year	**First annual report (publishing year)**	**Most recent/last annual report (publishing year)**
Orthopaedic arthroplasty registries – combined			
Croatian Register of endoprothesis	2006[1]	N/R	N/R
German Arthroplasty Register	2012[2]	2019[2]	2020, data till 2019[2]
Finnish Arthroplasty Register	1980[3]	1997[3]	Only updates on website[3]
Irish National Orthopaedic Register	2014[4]	2020[4]	2021, data till 2020[4]
Lithuanian Arthroplasty Register	2010[5]	N/R	N/R
Dutch Arthroplasty Register	2007[6]	2016[6]	2021, data till 2020[6]
Hungarian Arthroplasty Register	2007[7]	N/R	N/R
Norwegian Arthroplasty Register	1987[8]	1999[8]	2021, data till 2020[8]
Nordic Arthroplasty Register Association	2007[9]	N/R	N/R
National Joint Registry for England, Wales, Northern Ireland, the Isle of Man, and the States of Guernsey	2002[10]	2004[10]	2021, data till 2020[10]
Belgian National Arthroplasty Register	2009[11]	2011[11]	2019, data till 2018[11]
Catalan Arthroplasty Register	2005[12]	N/R	2017, data till 2014[13]
National Arthroplasty Registry of Slovenia	2019[14]	2019[14]	2021, data till 2020[14]
Italian Arthroplasty Registry	2006[15]	2014[15]	2020, data till 2019[15]
Emilia-Romagna Region Arthroplasty Register	2000[16]	2001[16]	2020, data till 2018[16]
Romanian National Arthroplasty Register	2001[17]	2010[17]	Data till 2011 but nowadays updates on website[17]
Portuguese National Arthroplasty Register	2009[18]	2010[18]	Data till 2013[18]
Scottish Arthroplasty Project Joint Registry	1996[19]	2002[20]	2021, data till 2020[20]
Slovakian National Arthroplasty Register	2003[21]	2003[21]	2013, data till 2011[21]
Swiss Arthroplasty Register	2012[22]	2015[22]	2020, data till 2019[22]
Orthopaedic arthroplasty registries – hips			
Czech Republic Arthroplasty Register	2003[23]	N/R	N/R
French Arthroplasty Register	2006[24]	2014[24]	2020, data till 2019[24]
Danish Hip Arthroplasty Register	1995[25]	2004[25]	2020, data till 2019[25]
Swedish Hip Arthroplasty Register	1979[26]	2002[27]	2020, data till 2019[26]
Orthopaedic arthroplasty registries – knees			
Danish Knee Arthroplasty Register	1997[28]	N/R	N/R
Swedish Knee Arthroplasty Register	1975[29]	1999[29]	2020 data till 2019[29]

Supplementary Table 3B: Orthopaedic registries – Domain Governance

Table S3B: Orthopaedic registries – Domain 'Governance'

	Mandatory	Patients' consent	Funding	Who can access the data and see results?	Privacy regulation for patients identifiable information
Orthopaedic arthroplasty registries – combined					
Croatian Register of endoprothesis	N/R	N/R	N/R	N/R	N/R
German Arthroplasty Register	No[30]	Required[2]	Private and public[2]	N/R	N/R
Finnish Arthroplasty Register	Yes[31]	N/R	Public[3]	N/R	N/R
Irish National Orthopaedic Register	N/R	Required[4]	Private[4]	Only hospitals' own data are accessible[4]	N/R
Lithuanian Arthroplasty Register	No[32]	N/R	N/R	N/R	N/R
Dutch Arthroplasty Register	Yes[6]	Not required[6]	Private[6]	N/R	Privacy at hospital level[6]
Hungarian Arthroplasty Register	N/R	N/R	N/R	Only orthopaedic departments' own data are accessible[7]	N/R
Norwegian Arthroplasty Register	Yes[8]	Required[8]	N/R	N/R	No privacy at hospital level[33]
Nordic Arthroplasty Register Association	N/R	N/R	N/R	N/R	Personal identification number is deleted[9]
National Joint Registry for England, Wales, Northern Ireland, the Isle of Man, and the States of Guernsey	Yes[10]	Required[10]	N/R	Patients personal data is only available for treating surgeons[10]	No privacy at hospital- and surgeon-level[10]
Belgian National Arthroplasty Register	Yes[11]	N/R	N/R	N/R	N/R
Catalan Arthroplasty Register	No[12]	N/R	N/R	N/R	N/R
National Arthroplasty Registry of Slovenia	N/R	N/R	Private and public[34]	N/R	N/R
Italian Arthroplasty Registry	No[15]	Required[35]	Public[15]	N/R	Before data are transmitted, a pseudonym is assigned to every patient[36]
Emilia-Romagna Region Arthroplasty Register	Yes[37]	N/R	N/R	N/R	N/R
Romanian National Arthroplasty Register	Yes[17]	N/R	N/R	N/R	N/R
Portuguese National Arthroplasty Register	No[38]	N/R	N/R	N/R	N/R
Scottish Arthroplasty Project Joint Registry	N/R	N/R	N/R	N/R	N/R
Slovakian National Arthroplasty Register	Yes[21]	N/R	N/R	N/R	N/R
Swiss Arthroplasty Register	Yes[22]	Required[22]	N/R	N/R	Patient personal data and clinical data are stored separately[39]
Orthopaedic arthroplasty registries – hips					
Czech Republic Arthroplasty Register	N/R	N/R	Public[23]	N/R	N/R
French Arthroplasty Register	No[40]	N/R	N/R	N/R	N/R
Danish Hip Arthroplasty Register	Yes[25]	N/R	Public[25]	N/R	N/R
Swedish Hip Arthroplasty Register	No[41]	Not required[26]	Private and public[26]	Data is only available for Swedish hip arthroplasty register researches[42]	N/R
Orthopaedic arthroplasty registries – knees					
Danish Knee Arthroplasty Register	Yes[43]	Not required[44]	N/R	N/R	N/R
Swedish Knee Arthroplasty Register	No[29]	N/R	Private and public[29]	N/R	N/R

Supplementary Table 4B: Orthopaedic registries – Domain Coverage, Design & Organisation

Table S4B: Orthopaedic registries – Domain 'Coverage, design & organisation'

	No. of hospitals (% of coverage)	Number of patients/procedures (total)	Annual number of patients/procedures (last year)	Data capture and collection	Access to registry for users/members	Type of information provided, for whom and at which level	Data linkage with other sources
Orthopaedic arthroplasty registries – combined							
Croatian Register of endoprothesis	N/R	N/R	N/R	N/R	N/R	N/R	N/R
German Arthroplasty Register	723 (N/R)[2]	1,381,355 hip and knee arthroplasties (2012-2019)[45]	157,681 primary hip arthroplasties and 124,677 primary knee arthroplasties (2019)[45]	Web-based and barcode scanning[30, 46]	N/R	Medical device level[45]	Health insurers[2]
Finnish Arthroplasty Register	36 (N/R)[3]	229,172 primary THA and 247,068 primary knee arthroplasties (1980-2021)[3]	1,920 primary THA and 2,596 primary knee arthroplasties (2021)[3]	Web-based and barcode scanning[47]	N/R	Hospital- and medical device-level[3]	N/R
Irish National Orthopaedic Register	7 (58.3%)[48]	3,344 primary hip arthroplasties and 2,677 primary knee arthroplasties (2014-2019)[48]	1,013 primary hip arthroplasties and 781 primary knee arthroplasties (2019)[48]	Web-based and barcode scanning[48]	N/R	N/R	National database on discharges from acute public hospitals[48]
Lithuanian Arthroplasty Register	24 (100%)[49]	N/R	N/R	Web-based[32]	N/R	N/R	Implant usage database[32]
Dutch Arthroplasty Register	89 (100%)[50, 51]	353,668 primary THA and 287,777 primary TKA (2007-2020)[6]	27,205 primary THA and 19,615 primary TKA (2020)[6]	Web-based or by paper and barcode scanning[6]	Through website[6]	Hospital- and medical device-level (hospital level not public available)[6, 51]	Hospitals information systems and the Dutch national insurance database[52]
Hungarian Arthroplasty Register	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Norwegian Arthroplasty Register	70 (hip arthroplasties)[53] and 82 (knee arthroplasties)[54] (100%, 2000)[55]	218,445 primary hip arthroplasties (excluded hemi prosthesis for hip fractures; 1987-2020) and 102,649 primary knee arthroplasties (1994-2020)[33]	8,538 primary hip arthroplasties (excluded hemi prosthesis for hip fractures) and 6,587 primary knee arthroplasties (2020)[33]	N/R	N/R	Hospital- and medical device-level[33]	National patient register[33]
Nordic Arthroplasty Register Association	N/R	N/R	N/R	N/R	N/R	N/R	N/R

National Joint Registry for England, Wales, Northern Ireland, the Isle of Man, and the States of Guernsey	433 (N/R)[10]	1,251,164 primary hip arthroplasties and 1,357,077 primary knee arthroplasties (2003-2020)[56]	54,858 primary hip arthroplasties and 50,904 primary knee arthroplasties (2020)[56]	Web-based[10]	Through website[10]	Hospital-, medical device-, and surgeon-level[10]	Hospital episode statistics[56]
Belgian National Arthroplasty Register	N/R	102,665 primary THA and 97,138 primary TKA (2009-2018)[57]	24,704 primary THA and 22,027 primary TKA (2018)[57]	Web-based[58]	Through website[58]	N/R	N/R
Catalan Arthroplasty Register	52 (94.5%)[59]	46,488 primary hip arthroplasties and 60,192 primary knee arthroplasties (2005-2014)[13]	11,038 primary hip arthroplasties and 12,798 primary knee arthroplasties (2014)[13]	Web-based[12]	N/R	N/R	Central register of insured persons, minimum basic data set at hospital discharge, and prosthesis catalogue[13]
National Arthroplasty Registry of Slovenia	N/R	N/R	3,075 primary THA and 2,192 primary TKA (2020)[60, 61]	Web-based and barcode scanning[34]	N/R	Hospital-, medical device-, and surgeon-level[60, 61]	N/R
Italian Arthroplasty Registry	277 (35%)[36]	N/R	27,329 primary THA and 27,588 primary TKA (2018)[62]	Web-based[35]	N/R	N/R	Hospital discharge databases[35]
Emilia-Romagna Region Arthroplasty Register	63 (N/R)[63]	120,408 primary THA and 102,786 primary knee arthroplasties (2000-2018)[63]	8,533 primary THA and 7,881 primary knee arthroplasties (2018)[63]	Data is provided in paper forms, but transferred by registry staff to an electronically database[63]	Through website[63]	Medical device level[63]	Hospitals discharge databases[63]
Romanian National Arthroplasty Register	125 (N/R)[17]	117,923 primary THA and 43,208 primary TKA (2001-2021)[17]	7,016 primary THA and 4,009 primary TKA (2021)[17]	Web-based or by paper and barcode scanning[64]	N/R	N/R	N/R
Portuguese National Arthroplasty Register	141 (N/R)[18]	20,860 primary hip arthroplasties and 20,110 primary knee arthroplasties (2009-2013)[38]	4,440 primary hip arthroplasties and 4,234 primary knee arthroplasties (2013)[38]	N/R	N/R	Hospital- and medical device-level[38]	N/R
Scottish Arthroplasty Project Joint Registry	16 (N/R)[20]	132,180 primary hip arthroplasties and 123,246 primary knee arthroplasties (2001-2020)[20]	4,034 primary hip arthroplasties and 3,199 primary knee arthroplasties (2020)[20]	N/R	N/R	N/R	N/R
Slovakian National Arthroplasty Register	40 (hip arthroplasties) and 31 (knee arthroplasties) (N/R)[65]	45,350 primary THA and 36,943 primary TKA (2003-2020)[90]	5,347 primary THA and 3,754 primary TKA (2020)[90]	N/R	N/R	Hospital- and medical device-level[65]	N/R
Swiss Arthroplasty Register	186 (100%)[39]	134,673 primary THA and 102,638 primary TKA (2012-2019)[39]	19,897 primary THA and 15,378 primary TKA (2019)[39]	Web-based or by paper and barcode scanning[39]	N/R	Medical device level[39]	The federal office of public health and implant sales[39]
Orthopaedic arthroplasty registries – hips							
Czech Republic Arthroplasty Register	72 (N/R)[23]	101,734 primary hip arthroplasties (2003-2012)[23]	N/R	N/R	N/R	Medical device-level[23]	N/R
French Arthroplasty Register	N/R	52,391 primary hip arthroplasties (2006-2021)[66]	3,146 primary hip arthroplasties (september 2020-september 2021)[66]	N/R	N/R	N/R	N/R
Danish Hip Arthroplasty Register	47 (N/R)[67]	191,946 primary THA (1995-2019)[67]	11,193 primary THA (2019)[67]	Web-based or by paper[25]	N/R	Hospital- and medical device-level[67]	All the Danish medical databases and the administrative registers[68]
Swedish Hip Arthroplasty Register	75 (N/R)[26, 69]	306,075 primary THA (2000-2019)[26, 69]	19,942 primary THA (2019)[26, 69]	Web-based[26, 69]	N/R	Hospital- and medical device-level[26, 69]	National patient register[41]
Orthopaedic arthroplasty registries – knees							
Danish Knee Arthroplasty Register	57 (95%)[44]	141,085 primary knee arthroplasties (1997-2019)[70]	10,184 primary knee arthroplasties (2019)[70]	Web-based[44]	N/R	Hospital level[71]	National patient register[70]
Swedish Knee Arthroplasty Register	72 (100%)[72]	302,589 primary knee arthroplasties (1975-2019)[72]	16,929 primary knee arthroplasties (2019)[72]	Paper forms, expect for PROMs (web-based)[72]	N/R	Hospital- and medical device-level[72]	National patient register[72]

Supplementary Table 5B: Orthopaedic registries – Manufacturers mentioned in annual reports, peer-reviewed publications & websites

Table S5B: Orthopaedic registries – Manufacturers mentioned in annual reports, peer-reviewed publications & websites	
Hip arthroplasties	**Knee arthroplasties**
aap Implantate AG[77]	Adler Ortho[63]
Adler Ortho[13, 33, 63, 77]	Aesculap AG[45, 48, 65]
Aesculap AG[13, 23, 45, 77]	Amplitude[39, 63]
Amplitude[51, 63, 67, 79]	Anika[48]
Anika[79]	Arthrex[39, 51, 63]
Argomedical[77]	B. Braun[38, 39, 56, 63]
AristoTech Industries GmbH[49]	CERAVER[63, 65]
ARTIQO[45]	Citieffe[63]
ASCO Medical[77]	Corin[39, 45, 51, 56, 63]
Aston-Med[79]	DEDIENNE Sante[63]
ASTON-SEM[38, 79]	DePuy Synthes[3, 13, 38, 39, 45, 48, 51, 56, 63, 65]
Atesos Medical AG[45]	Endoplant GmbH[65]
Auxein Medical[77]	Endoplus Orthopedics[63]
B. Braun[38, 39, 65, 67, 79]	Exactech[13, 38, 51, 56, 63]
Biotechni[33, 77]	Finceramica[63]
Citieffe[63]	Groupe Lepine[13]
Corin[13, 26, 45, 56, 79]	Implantcast GmbH[45, 56]
DEDIENNE Sante[79]	Lafitt[38]
DePuy Synthes[3, 13, 26, 33, 38, 39, 45, 48, 51, 56, 63, 65, 67, 77, 79]	LimaCorporate[38, 39, 45, 51, 63, 65]
Endoplant GmbH[63]	Mathys Ltd Bettlach[39, 45, 51, 63, 65]
Endoplus Orthopedics[63]	MatOrtho Limited[33, 51, 56]
Evolutis[33, 38, 79]	MBA[38]
FH Orthopedics[38, 79]	Medacta International[39, 45, 56]
Finsbury Orthopaedics[63]	MEDIN[65]
FOURNITURES HOSPITALIERES[77]	MicroPort Orthopedics[13, 39, 45, 56]
Groupe Lepine[33, 38, 49, 63, 77, 79]	OHST[45]
Gruppo Bioimpianti[63, 77]	Permedica S.p.A.[63]
Hipokrat[77]	SAMO[63]
Implantcast GmbH[33, 45, 51, 63]	SERF[65]
ImplanTec[39]	Smith+Nephew[13, 38, 39, 45, 48, 51, 56, 63]
IMPOL[38]	Speetec Implantate GmbH[45]

Joint Medica[33]	STRYKER[3, 13, 38, 39, 45, 48, 51, 56, 63, 65]
JRI Orthopaedics[13, 33, 56]	Surgival[13]
Lafitt[38]	Symbios[63]
LimaCorporate[33, 38, 39, 48, 51, 63, 65, 67, 79]	Waldemar LINK[13, 38, 39, 45, 56, 63, 65]
Mathys Ltd Bettlach[39, 45, 51, 63, 79]	Wright Medical UK[38, 63]
MatOrtho Limited[13, 26]	Zimmer Biomet[3, 13, 38, 39, 45, 48, 51, 56, 63, 65]
MBA[38]	
Medacta International[38, 39, 45, 48, 63, 79]	
Medcomtech[38]	
MEDIN[23]	
Merete GmbH[38]	
MicroPort Orthopedics[13, 33, 45, 56, 79]	
Narang Medical Limited[77]	
Permedica S.p.A.[38, 63, 77]	
Peter Brehm[38, 45]	
Plus Orthopedics[39]	
Protetim[77]	
REDA Instrumente GmbH[77]	
SAMO[38, 63]	
SERF[13, 48, 63, 65, 67, 79]	
Shakti Orthopaedic[77]	
Signature Orthopaedics[65]	
Smith+Nephew[3, 13, 26, 33, 38, 39, 45, 48, 51, 56, 63, 67, 77, 79]	
STRYKER[3, 13, 26, 33, 38, 39, 45, 48, 49, 51, 56, 63, 65, 67, 77, 79]	
Surgival[63, 77]	
Symbios[39, 45, 63, 79]	
TIPMED[77]	
TST Medical Devices[77]	
V2-EVREN[77]	
Waldemar LINK[3, 13, 26, 33, 45, 51, 63, 65, 67, 77]	
Wright Medical UK[38, 63]	
Zimmer Biomet[3, 13, 23, 26, 33, 38, 39, 45, 48, 51, 56, 63, 65, 67, 77, 79]	

Supplementary Table 6B: Orthopaedic registries – Domain Data quality & completeness

Table S6B: Orthopaedic registries – Domain 'Data quality & completeness'

	Quality assurance system defined/quality check of data	Missing data for patients' characteristics	Methods for handling missing data	Data completeness on patients/procedure-level
Orthopaedic arthroplasty registries – combined				
Croatian Register of endoprothesis	N/R	N/R	N/R	N/R
German Arthroplasty Register	The registry thoroughly reviews incoming data sets to identify inconsistencies[45]	N/R	N/R	70% hip and knee arthroplasties combined (2019)[45]
Finnish Arthroplasty Register	Annual database check (comparing data with the nationwide hospital discharge registry)[73]	7% ASA score and 12% BMI (hip arthroplasties 2014-2021)[3]	N/R	95% primary hip arthroplasties and 95% primary knee arthroplasties (2021)[3]
Irish National Orthopaedic Register	N/R	N/R	N/R	19% hip arthroplasties and 24% knee arthroplasties (2018)[48]
Lithuanian Arthroplasty Register	N/R	N/R	N/R	86% primary THA (2011-2013)[32] and 95% primary TKA (2016)[74]
Dutch Arthroplasty Register	Annual database check, automatic implant library (if the entered product does not correspond with the current target joint, a warning message on display will appear)[51]	Ranging 0.0-4.6% for hip arthroplasties and 0.0-2.1% for knee arthroplasties (2020)[51]	N/R	96.5% hip arthroplasties and 99.2% for knee arthroplasties (2020)[51]
Hungarian Arthroplasty Register	N/R	N/R	N/R	N/R
Norwegian Arthroplasty Register	N/R	N/R	N/R	97,5% primary hip arthroplasties and 97,6% primary knee arthroplasties (2017)[33]
Nordic Arthroplasty Register Association	N/R	N/R	N/R	N/R
National Joint Registry for England, Wales, Northern Ireland, the Isle of Man, and the States of Guernsey	Monthly or quarterly data quality checks (not further specified)[56]	N/R	Missing data is considered as missing completely at random (not further specified)[56]	97,6% primary hip arthroplasties and 98,5% for primary knee arthroplasties (2018)[56]
Belgian National Arthroplasty Register	N/R	N/R	N/R	N/R
Catalan Arthroplasty Register	Data quality check twice a year (not further specified)[12]	N/R	N/R	69,4% primary hip arthroplasties and 69,6% primary knee arthroplasties (2014)[75]
National Arthroplasty Registry of Slovenia	Data quality checks are often performed (not further specified)[34]	N/R	N/R	93% hip arthroplasties and 99,4% knee arthroplasties (2020)[60, 61]
Italian Arthroplasty Registry	Syntactic and semantic data quality checks first on procedure and then on device data[62]	Records not passing quality checks[62];	Records not passing quality checks are not	65,8% hip arthroplasties and 63,7% knee arthroplasties (2018)[62]

		Procedures: hip (3.8%), knee (3.7%) Devices: hip (7.3%), knee (6.0%)	included in the analyses[62]	
Emilia-Romagna Region Arthroplasty Register	Checking data on coverage & correct classification of implanted components, matching towards regional databases, and continuous check of data entry[37]	N/R	N/R	96% of hip, knee and shoulder arthroplasties (2018)[63]
Romanian National Arthroplasty Register	N/R	N/R	N/R	N/R
Portuguese National Arthroplasty Register	N/R	N/R	N/R	N/R
Scottish Arthroplasty Project Joint Registry	N/R	N/R	N/R	N/R
Slovakian National Arthroplasty Register	N/R	N/R	N/R	N/R
Swiss Arthroplasty Register	The plausibility of the data is checked as closely as possible at the time it is entered in order to obtain "valid values" for each data record using an automatically analysis script, and if necessary the user will be contacted to correct the data[22]	11% ASA score and 15% BMI for hip arthroplasties and 10% ASA score and 15% BMI for knee arthroplasties (2019)[39]	N/R	91,7% primary THA (for all reasons excluding trauma) and 94,1% primary knee arthroplasties (for all reasons excluding trauma) (2018)[39]
Orthopaedic arthroplasty registries – hips				
Czech Republic Arthroplasty Register	N/R	N/R	N/R	N/R
French Arthroplasty Register	N/R	N/R	N/R	N/R
Danish Hip Arthroplasty Register	N/R	8% ASA score and 11% BMI (2020)[67]	N/R	96,5% primary THA (2019)[67]
Swedish Hip Arthroplasty Register	During registration there are compulsory entries that cannot be left blank if the data is to be saved, the web input module comes with automatically generated controls, control reports are automatically generated if operation-data for one or more variables is missing or if the data is inconsistent, then the hospital in question is contacted and corrects the data itself or a medical record is sent to the register for follow-up, contact secretaries and doctors receive a balancing report twice per year in order to be able to check that the reported operations balances with the real production unit is requested to control its register-balance with the local patient administrative system[26]	0.4% ASA score, 0.7% BMI, 0.1% fixation method, 0.2% articulation (2018)[26]	N/R	98% hip arthroplasties (2018)[26]
Orthopaedic arthroplasty registries – knees				
Danish Knee Arthroplasty Register	Checked every 3 months (comparing data with the national patient registry), the entered data are regularly subject to missing value control for all variables included in the dataset, checks for coding errors are continuously performed for several of the most important variables (e.g., date of surgery and implant design)[44]	N/R	Missing procedures will be sent every 3 months to each orthopaedic department and request for data entry[44]	98-99% primary knee arthroplasties (2019)[76]
Swedish Knee Arthroplasty Register	Randomly selected hospitals with >50 annual procedures are asked to produce patient records for 25 primary knee arthroplasties and these will be compared to data which is entered in the register. Staff from the Swedish Knee Arthroplasty Register are visiting hospitals to gather patient data and will compared to data entered in the register[72]	Reported in most variables (ranging 0.0-5.1%)[72]	N/R	97,1% knee arthroplasties (2018)[72]

Supplementary Table 7B: Orthopaedic registries – Outcomes reported, definition & follow-up

Table S7B: Orthopaedic registries – Outcomes reported, definition & duration of follow-up

	Revision	Reasons for revision (hip)	Reasons for revision (knee)	PROMs	Other
Orthopaedic arthroplasty registries – combined					
Croatian Register of endo prothesis	N/R	N/R	N/R	N/R	N/R
German Arthroplasty Register	Cumulative revisions[45]; 6-month[45]; 1-year[45]; 18-month[45]; 2-year[45]; 30-month[45]; 3-year[45]; 42-month[45]; 4-year[45]; 54-month[45]; 5-year[45].	Infection, loosening (cup/stem/cup & stem), osteolysis with fixed component (cup/stem/cup & stem), periprosthetic fracture, dislocation, wear, component failure, malalignment, progression of arthrosis, condition after removal, and 'other'[45]	Infection, loosening (femoral component/tibial tray/patellar component/several components), osteolysis with fixed component (femoral component/tibial tray/patellar component/several components), periprosthetic fracture, ligament instability, wear, component failure, malalignment, restricted mobility, progression of arthrosis, condition after removal, and 'other'[45]	N/R	N/R
Finnish Arthroplasty Register	Revision risks[3]; 1-year[3]; 3-year[3]; 5-year[3]; 7-year[3]; 10-year[3]; 15-year[3]; 20-year[3]; 25-year[3].	Acute femoral neck fracture, adverse reaction to metal debris, aseptic loosening of the acetabular component, aseptic loosening of the femoral component, acetabular osteolysis, avascular necrosis of femoral head, breakage of the acetabular component, breakage of the femoral head, breakage of the liner, breakage of the modular neck, breakage of the stem, correction of leg length discrepancy, developmental dysplasia of the hip, dislocation, failed osteosynthesis (pertrochanteric femoral fracture), femoral osteolysis, infection, inflammatory psoriatic arthritis, lack of osseointegration (cup), lack of osseointegration (stem), malposition of the acetabular component, malposition of the femoral component, metastasis, other disease, other inflammatory disease, periprosthetic acetabular fracture, periprosthetic femoral fracture, posttraumatic secondary OA, primary OA, trunnion problem, unspecific pain, unusual noise of implant, and 'other'[3]	Primary OA, acute fracture (femur), aseptic loosening of femoral component, aseptic loosening of patellar component, aseptic loosening of tibial component, breakage of femoral component, breakage of insert, breakage of patellar component, breakage of tibial component, dislocation of insert, failed osteosynthesis (tibia), femoral osteolysis, infection, instability of PF joint, instability of TF joint, malposition of femur component, malposition of patellar component, malposition of tibia component, other disease, periprosthetic femoral fracture, periprosthetic patellar fracture, periprosthetic tibial fracture, status post septic arthritis, stiffness, tibial osteolysis, unspecific pain, wear of insert, wound necrosis, and 'other'[3]	N/R	N/R
Irish National Orthopaedic Register	Revision rates[48]; <1 year[48].	Aseptic loosening, component failure, infection, instability, pain of unknown origin, periprosthetic fracture, and 'other'[48]	Aseptic loosening femur, aseptic loosening tibia, infection, instability, malalignment, pain of unknown origin, and 'other'[48]	EQ-5D-5L hip/knee, Oxford Hip Score, and Oxford Knee Score[48]; Pre-operatively[48]; 6-month post-operatively[48]; 2-year post-operatively[48]; 5-year post-operatively)[48].	Cardiopulmonary complications within 30-days of hip/knee surgery, dislocation within 30-days of hip surgery, infections within 30-days of hip/knee surgery, instability within 30-days of knee surgery, mortality within 30-days of hip/knee surgery, periprosthetic fracture within 30-days of hip/knee surgery, thromboembolic events within 90-days of hip/knee surgery, wound hematoma within 30-days of hip/knee surgery[48]
Lithuanian Arthroplasty Register	N/R	N/R	N/R	N/R	N/R
Dutch Arthroplasty Register	Cumulative revision percentages[6]; 1-year[6]; 3-year[6]; 5-year[6]; 7-year[6]; 10-year[6]; 12-year[6].	Dislocation, girdlestone situation, infection, inlay wear, loosening of acetabular component, loosening of femur component, peri-articular ossification, peri-prosthetic fracture, symptomatic MoM bearing, and 'other'[6]	Arthrofibrosis, infection, insert wear, instability, loosening of femur component, loosening of patella component, loosening of tibia component, malalignment, patellar dislocation, patellar pain, periprosthetic fracture, progression of OA, revision after knee removal, and 'other'[6]	Anchor question: daily functioning hip/knee, anchor question: pain knee, NRS rest scores hip/knee, NRS activity scores hip/knee, NRS satisfaction scores knee, EQ-5D index scores hip/knee, EQ-5D thermometer scores hip/knee, HOOS-PS scores hip, Oxford hip scores, Oxford knee scores, KOOS-PS scores knee[6]; Pre-operatively[6];	Re-revision hip (dislocation/infection/inlay wear/loosening of acetabulum component/loosening of femur component/peri-articular ossification/peri-prosthetic fracture/symptomatic MoM bearing/other), re-revision knee (arthrofibrosis/infection/insert wear/instability/loosening of femur component/loosening of patella component/loosening of tibia component/malalignment/patellar dislocation/patellar pain/periprosthetic fracture/progression OA/other)[6]

				3-month post-operatively[6]; 1-year post-operatively[6].	
Hungarian Arthroplasty Register	N/R	N/R	N/R	N/R	N/R
Norwegian Arthroplasty Register	Revision rates[33]; Unknown FU.	Deep infection, dislocation, gluteal failure, implant failure, loosening of acetabular component, loosening of femoral component, osteolysis acetabular (no loosening), osteolysis femur (no loosening), pain, periprosthetic fracture, polyethylene wear, previous girdlestone, and 'other'[33]	Deep infection, defect polyethylene, dislocation (no patella), dislocation of patella, fracture near implant, instability, loose distal component, loose patella component, loose proximal component, malalignment, pain, and 'other'[33]	EQ-5D scores hip/knee, HOOS scores hip, KOOS scores knee[33]; Pre-operatively[33]; 1-year post-operatively[33].	Per-operative complications hip (not specified), peri-operative complications knee (administrative failure/anesthesia problems/avulsion fractures/blood torniquet failing/failure of instruments/fracture/ligament rupture/patella tendon rupture/problem difficulty due to anatomy/rupture of damage MCL/technical problem with cement/tendon injury/violation of sterility tourines/other)[33]
Nordic Arthroplasty Register Association	N/R	N/R	N/R	N/R	N/R
National Joint Registry for England, Wales, Northern Ireland, the Isle of Man, and the States of Guernsey	Cumulative revisions[56]; 1-year[56]; 2-year[56]; 3-year[56]; 4-year[56]; 5-year[56]; 6-year[56]; 7-year[56]; 8-year[56]; 9-year (only knees)[56]; 10-year[56]; 11-year (only knees)[56]; 12-year[56]; 13-year[56]; 14-year (only knees)[56]; 15-year[56];	Adverse reaction to particulate debris, aseptic loosening, dislocation & subluxation, head of socket size mismatch, implant fracture, infection, lysis, malalignment, pain, and periprosthetic fracture[56]	Aseptic loosening or lysis, dislocation & subluxation, implant wear, infection, instability, malalignment, pain, and 'other'[56]	N/R	30-days, 90-days, 1-year, 5-years, 10-years, 15-years mortality hip/knee, 17-years mortality hip, re-revisions hip (adverse reaction to particulate debris/aseptic loosening/dislocation & subluxation/head of socket size mismatch/implant fracture/infection/lysis/malalignment/pain/periprosthetic fracture), re-revision knee (aseptic loosening or lysis/dislocation & subluxation/implant wear/infection/instability/malalignment/pain/periprosthetic fracture/progressive arthritis/stiffness/other)[56]
	16-year[56]; 17-year[56].				
Belgian National Arthroplasty Register	Revision rates[57]; 1-year[57]; 2-year[57]; 3-year[57]; 4-year[57]; 5-year[57]; 6-year[57]; 7-year[57]; 8-year[57]; 9-year[57]; 10-year (only hips)[57].	Aseptic loosening, infection, instability, pain, periprosthetic fracture, wear, and 'other'[57]	Aseptic loosening, implant failure, infection, instability, malalignment, pain, periprosthetic fracture, progressive OS in nonreplaced component, stiffness, wear of polyethylene component, and 'other'[57]	N/R	90-days mortality hip/knee[57]
Catalan Arthroplasty Register	Cumulative revision rates[75]; 1-month[75]; 3-month[75]; 1-year[75]; 3-year[75]; 5-year[75]; 7-year[75]; 9-year[75].	Infection, mechanical complications, and 'other'[75]	Infection, mechanical complications, and 'other'[75]	N/R	N/R
National Arthroplasty Registry of Slovenia	Revision rates[60, 61]; Unknown FU.	Chronic infection, condition after girdlestone, dislocation, early infection, implant broken, loosening, metallosis, NP, osteolysis, pain, paraarticular ossification, periprosthetic fracture of acetabulum, periprosthetic fracture of femur, wear of inlay, and 'other'[60]	2-stage revision, chronic infection (>3 months), early infection (<3 months), femoral component loosening, implant broken, inequality, instability, instability of cruciate ligaments, instability of lateral ligaments, malimplantation, non-diagnosis, necrosis, OA of other component, pain, patellar dislocation, periprosthetic fracture, poor ROM, tibial component removal, total prosthesis loosening, and 'other'[61]	N/R	N/R

Italian Arthroplasty Registry	Revision rates[62]; Unknown FU.	Aseptic loosening (cup), aseptic loosening (stem), aseptic loosening (total), disease progression, implant fracture, infection, lysis, pain, periprosthetic fracture, previous prosthesis removal, prosthesis dislocation, wear, and 'other'[62]	Aseptic loosening of femur, aseptic loosening of patella, aseptic loosening of several components, aseptic loosening of tibia, disease progression, dislocation, fractured spacer, implant fracture, infection, instability, pain, periprosthetic fracture, stiffness, wear, and 'other'[62]	N/R	Discharge destination hip/knee (deceased/discharge against medical advice/discharge to a nursing home/discharge to a residential health care/discharge to hospital at home/ordinary discharge/transfer in the same hospital/transfer to an acute admission unit of a different hospital/transfer to an inpatient rehabilitation hospital)[62]
Emilia Romagna Region Arthroplasty Register	Revision rates[63]; 5-year[63]; 10-year[63] 15-year[63]; 18-year (only hips)[63].	Acetabulum fracture, aseptic loosening (cup), aseptic loosening (stem), aseptic loosening (total), bone fracture, heterotopic bone, metallosis, pain without loosening, poly wear, primary instability, prosthesis breakage, prosthesis dislocation, septic loosening, trauma, two steps prosthesis removal, and 'other'[63]	Aseptic loosening of femoral component, aseptic loosening of tibial component, breakage prosthesis, insert wear, instability, pain without loosening, periprosthetic bone fracture, progression of disease, prosthesis dislocation, septic loosening, stiffness, total aseptic loosening, trauma, two steps prosthesis removal, and 'other'[63]	N/R	Deaths during hospitalization hip/knee, deaths within 90-days after procedure hip, intra-operative complications hip (acetabulum fracture/anesthesiologic/calcar fracture/diaphysis fracture/greater trochanter fracture/hemorragia/instability/other), intra-operative complications knee (anesthesiologic/femoral fracture/hemorragia/ligament lesion/rupture patellar tendon/tibial fracture/tibial tuberosity fracture/vascular lesion/other), post-operative complications hip/knee (early infection/deep venous thrombosis), re-revision hip (aseptic loosening (cup)/aseptic loosening (stem)/breakage prosthesis/global aseptic loosening/pain without loosening/periprosthetic bone fracture/poly wear/primary instability/recurrent prosthesis dislocation/septic loosening/unknown/other)[63]
Romanian National Arthroplasty Register	Revision rates[77]; 1-year (only hips)[77]; 2-year (only hips)[77]; 3-year (only hips)[77]; 4-year (only hips)[77]; 5-year (only hips)[77]; 6-year (only hips)[77]; 7-year (only hips)[77]; 8-year (only hips)[77]; 9-year (only hips)[77]; 10-year (only hips)[77].	Acetabular loosening, acetabular osteolysis, acetabular protrusion, broken implant, cotiloiditis, early infection, femoral osteolysis, late infection, luxation, paraarticular ossification, periprosthetic fracture, wear, and 'other'[77]	N/R	N/R	90-days and 1-year mortality after primary hip procedure[77]
Portuguese National Arthroplasty Register	Number of revisions[38]; Unknown FU.	Aseptic loosening, deficient implantation stem, dislocation, dissociation, fracture implant, infection, osteolysis stem, pain, PE wear, and 'other'[38]	Aseptic loosening, deficient implantation, fracture of the implant, infection, luxation, osteolysis, pain, polyethylene wear, and periprosthetic fracture[38]	N/R	N/R
Scottish Arthroplasty Project Joint Registry	Revision rates[20]; Unknown FU.	N/R	N/R	N/R	Acute renal failure/acute myocardial infarction/CVA/ within 30-days after hip/knee procedure, mortality/deep venous thrombosis/pulmonary embolism within 90-days after hip/knee procedure, dislocation/infection withing 1-year after hip/knee procedure[20]
Slovakian National Arthroplasty Register	Cumulative revision risks[65]; 1-month[65]; 3-month[65]; 1-year[65]; 2-year[65]; 3-year[65]; 4-year[65]; 5-year[65]; 6-year[65]; 7-year (only hips)[65]; 8-year (only hips)[65]; 9-year (only hips)[65].	Acetabular protrusis, aseptic loosening of acetabular component, aseptic loosening of both components, aseptic loosening of femur component, big bone defect of acetabulum, big bone defect of femur, chronic infection, early infection, fracture of implant, girdlestone to THA, luxation, osteolysis of acetabulum, osteolysis of femur, paraarticular ossifications, periprosthetic fracture, polyethylene wear, spacer to THA, and 'other'[65]	Aseptic loosening of femoral component, aseptic loosening of patellar component, aseptic loosening of tibial component, chronic infection, collateral ligament instability, early infection, fracture of the implant, instability of PCL, knee pain without loosening, luxation, malposition, patellar luxation, patellar pain, PE wear, periprosthetic fracture, spacer to TKA, stiffness, and 'other'[65]	N/R	N/R
Swiss Arthroplasty Register	Cumulative revision rates[78]; 1-year[78]; 2-year[78]; 3-year[78]; 4-year[78]; 5-year[78]; 6-year[78]; 7-year[78].	Acetabular osteolysis, acetabular protrusion, blood ion level, dislocation, femoral osteolysis, impingement, implant breakage, infection, loosening acetabular component, loosening femoral component, metallosis, periprosthetic fracture, position orientation of stem, position orientation of the cup, squeaking, status after spacer, trochanter pathology, wear, and 'other'[78]	Component malposition femur, component malposition tibia, femorotibial instability, infection, joint stiffness or arthrofibrosis, loosening femur, loosening patella, loosening tibia, pain, patella problems, patellar instability, periprosthetic fracture femur, periprosthetic fracture patella, periprosthetic fracture tibia, sizing femoral component, sizing tibial component, wear of inlay, and 'other'[78]	N/R	30-days, 90-days, 1-year, 2-years, 3-years, 4-years, 5-years, and 6-years mortality after hip procedure[78]
Orthopaedic arthroplasty registries – hips					

Czech Republic Arthroplasty Register	N/R	N/R	N/A	N/R	N/R
French Arthroplasty Register	Cumulative revision risks & revision rate per 100 observed component years[79]; 1-year[79]; 2-year[79]; 3-year[79]; 4-year[79]; 5-year[79]; 6-year[79].	Aseptic loosening, calcifications, deep acute infection, dislocation, head and neck resection, implant fracture, pain, peri-operative fracture, periprosthetic fracture, removal of material, septic loosening due to chronic infection, wear and/or osteolysis, and 'other'[79]	N/A	N/R	N/R
Danish Hip Arthroplasty Register	Revision rate per 100 observed component years[67]; Up to 25-year[67].	Aseptic loosening acetabular component, aseptic loosening femoral component, aseptic loosening of femoral & acetabular component, component failure, dislocation, femoral fracture, infection, osteolysis without loosening, pain, PE wear without loosening, and 'other'[67]	N/A	N/R	5-years mortality after primary THA, 5-years mortality after primary THA due to OA, blood transfusion within 7-days after primary THA due to OA, rehospitalization after primary THA due to OA, rehospitalization after primary THA due to fracture, reprocedures within 1-year after primary THA due to infection, reprocedures within 2-years after primary THA, reprocedures within 2-years after primary THA due to OA, reprocedures within 2-years after primary THA due to fracture, re-revision (aseptic loosening (all)/component failure/dislocation/femoral fracture/infection/osteolysis without loosening/pain/Polyethylene wear without loosening/'other')[67]
Swedish Hip Arthroplasty Register	Survival rates[26]; 2-year[26]; 5-year[26]; <10-year[26]; 10-15year[26].	Dislocation, implant fracture, infection, instability, loosening, periprosthetic fracture, and 'other'[26]	N/A	Pre-operatively, 1-year, 6-years, and 10-years post-operatively (EQ VAS/EQ-5D-5L index/pain VAS/satisfaction VAS)[26]	2nd and 3rd revision (dislocation/extraction without registered insertion (yet)/infection/loosening/periprosthetic fracture/other), 9-years patient survival, 30-days and 90-days mortality after hip procedure, adverse events within 30- and 90-days after hip procedure (i.e., all kinds of readmissions that can be assumed to have a connection with the operation that has been carried out, divided into: cardiovascular/medical/surgical complications), reoperation in 1st/2nd/3rd year after hip procedure (allergy/ALVAL and/or pseudotumor/bleeding, hematoma/cup and/or liner wear/cyst and/or bursa/delayed fracture healing/difference in bone length/dislocation
					and/or instability/dislocation/fracture of spacer/faulty inserted implant/fracture acetabulum/fracture femur/fracture under resurfacing prosthesis/heightened metal ion concentrations/heterotopic bone formation/implant rupture inclusive plate rupture/inadequate cementation/loose piece of cement/infection/loose implant part/loosening/malignant or benign tumor/material left behind (not cement)/nerve or vascular injury/osteolysis acetabulum and/or femur/per operative fracture (previous op.)/trochanteric problems, limb/unclear pain/wound complication (rupture, granuloma)/other)[26]
Orthopaedic arthroplasty registries – knees					
Danish Knee Arthroplasty Register	N/R	N/A	N/R	N/R	N/R
Swedish Knee Arthroplasty Register	Cumulative revision rates[72]; Up to 10-years[72].	N/A	Fracture, infection, instability, loosening, patella, progress, wear, and 'other'[72]	Pre-operatively and 1 year post-operatively (EQ5D/EQ-VAS/KOOS/OMERACT-OARSI/VAS-knee pain/VAS-satisfaction with the surgery)[72]	Adverse events within 90-days after primary knee replacement (adverse surgical events/all/cardiovascular events/death within 90-days/other)[72]

Supplementary Table 8B: Orthopaedic registries – Domain Safety & performance

Table S8B: Orthopaedic registries – Domain 'Safety & performance'							
	Frequency of feedback	Level of feedback provided	Feedback (time period)	Outlier reports/procedures	Accessibility of results	Definition of outlier	Number of outliers identified
Orthopaedic arthroplasty registries – combined							
Croatian Register of endoprothesis	N/R	N/R	N/R	N/R	N/R	N/R	N/R
German Arthroplasty Register	Annually[45]	Medical device level[45]	1-, 2-, 3-, 4-, 5-years[45]	N/R (revisions per implant are reported; statistical testing unknown)[45]	Publicly available[45]	N/R	N/R
Finnish Arthroplasty Register	Annually[3]	Hospital- and medical device level[3]	1-, 3-, 5-years (hospital level) and 1-, 3-, 5-, 7-, 10 years (medical device level)[3]	N/R (revisions per implant and hospital are reported; statistical testing unknown)[3]	Publicly available[3]	N/R	N/R
Irish National Orthopaedic Register	Annually and quarterly[48]	N/R	N/R	N/R	N/R	N/R	N/R
Lithuanian Arthroplasty Register	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Dutch Arthroplasty Register	Annually[51]	Hospital- and medical device/ level[51]	1- and 5-years[51]	Revision outlier procedures for hospitals and implants[6, 51]	Members and individual hospitals[6]	N/R	N/R
Hungarian Arthroplasty Register	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Norwegian Arthroplasty Register	Annually[33]	Hospital- and medical device level[33]	10-years (hospital level) and 3- and 10-years (medical device level)[33]	N/R (durability of replacements per hip implant and percentage non-revised standard hip patients per hospital are reported; statistical testing unknown)[33]	Publicly available[33]	N/R	N/R
Nordic Arthroplasty Register Association	N/R	N/R	N/R	N/R	N/R	N/R	N/R
National Joint Registry for England, Wales, Northern Ireland, the Isle of Man, and the States of Guernsey	Annually[56]	Hospital-, medical device-, and surgeon-level[56]	Medical devices: 1-, 3-, 5-, 10-, 15-, 17 years[56], Hospitals and surgeons: 1- and 3-year[90]	Revision outlier performances for hospitals, implants, and surgeons[90]	Publicly available[56, 90]	- Hospitals: outside the range based on the expected range of performance for hospitals[90] - Implants: having a more than twice prothesis time incident rate when compared to the group, allowing for confidence intervals[90] - Surgeon: Outside 99.8% control limits of funnel plot (analysing 90-day mortality following THA and TKA)[90]	Hospitals performing both THA and TKA: - 201 positive outlier hospitals and 7 negative outlier hospitals on compliance; - 218 positive outlier hospitals and 6 negative outlier hospitals on revision compliance; - 257 positive outlier hospitals and 38 negative outlier hospitals on consent; - 319 positive outlier hospitals and 8 negative outlier hospitals on valid NHS number; - 198 positive outlier hospitals and 79 negative outlier hospitals on time taken to enter data[90] Hospitals performing THA: - 7 positive outlier hospitals on compliance; - 6 positive outlier hospitals on revision compliance; - 5 positive outlier hospitals and 3 negative outlier hospitals on consent; - 5 positive outlier hospitals and 2 negative outlier hospitals on valid NHS number; - 3 positive outlier hospitals and 3 negative outlier hospitals on time taken to enter data[90]

							Hospitals performing TKA: - 2 positive outlier hospitals on compliance; - 2 positive outlier hospitals on revision compliance; - 1 negative outlier hospital on consent; - 1 positive outlier hospitals on valid NHS number; - 1 positive outlier hospitals and 1 negative outlier hospital on time taken to enter data[90] - 31 component combinations (THA); 12 THA cups; 13 THA stems, and 17 TKA implants - No outlier surgeons identified[90]
Belgian National Arthroplasty Register	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Catalan Arthroplasty Register	N/R	N/R	N/R	N/R	N/R	N/R	N/R
National Arthroplasty Registry of Slovenia	Annually[60, 61]	Medical device level[60, 61]	N/R	N/R (revisions per implant are reported; only numbers are shown, no statistical testing)[60, 61]	Publicly available[60, 61]	N/R	N/R
Italian Arthroplasty Registry	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Emilia-Romagna Region Arthroplasty Register	Annually[63]	Medical device level[63]	5-years[63]	N/R (revisions per implant are reported; statistical testing unknown)[63]	Publicly available[63]	N/R	N/R
Romanian National Arthroplasty Register	N/R	Hospital- and medical device level[77]	2-, 5- and 10-years (hospital level) and range ±8- to 13-years (medical device level)[77]	N/R (implant survival & reoperations per hospital and implant are reported; statistical testing unknown)[77]	Publicly available[77]	N/R	N/R
Portuguese National Arthroplasty Register	N/R	Hospital level[38]	N/R	N/R (list of hospitals in which revisions were performed; statistical testing unknown)[38]	Publicly available[38]	N/R	N/R
Scottish Arthroplasty Project Joint Registry	Annually[20]	Hospital level[80]	30- and 90 days, 1-, 3-, and 5 years[80]	Hospitals between 2-3SD are alerted to their position and advised to investigate this internally, hospitals that have exceeded >3 SD above the mean are alerted as well and required to conduct investigations on this issue[80]	N/R	2-3SD above the mean and >3SD above the mean[80]	2 hospitals (hip AMI within 30-days), 1 hospital (hip ARF within 30-days), 2 hospitals (hip CVA within 30-days), 2 hospitals (hip infection within 1 year), 2 hospitals (hip mortality within 90-days), 2 hospitals (hip revision within 1-year), 1 hospital (hip revision within 5-years), 3 hospitals (knee ARF within 30-days), 1 hospital (knee infection within 1-year), 2 hospitals (knee mortality within 90-days), 1 hospital (knee revision within 1-year), 2 hospitals (knee revision within 5-years)[80]
Slovakian National Arthroplasty Register	N/R	Hospital- and medical device level[65]	N/R	Revisions per implant are reported including relative risks on revision; RR >5% are marked in orange and >10% are marked in red, revisions per hospital are reported[65]	Publicly available[65]	RR >5% and RR >10%[65]	49 component combinations (THA) of which 20 uncemented, 13 cemented, 8 hybrids, and 8 reverse hybrids[65]
Swiss Arthroplasty Register	Annually and quarterly[22]	Medical device level[39]	2-years[39]	Revision per implant are reported outlier status is set at	Publicly available[39]	Revision rates of more than twice	12 component combinations (THA) of which 9 uncemented, 3

				more than twice than the relevant group average[39]		compared to the relevant group[39]	hybrids, and 3 TKA implants (all component fixations)[39]
Orthopaedic arthroplasty registries – hips							
Czech Republic Arthroplasty Register	N/R	N/R	N/R	N/R	N/R	N/R	N/R
French Arthroplasty Register	Annually[79]	Medical device level[79]	N/R	Revision rate per 100 observed component years per implants are reported, implants >1.3 revision rate per 100 observed component years are considered to raise concern[79]	Publicly available[79]	Revision rates of >1.3 per 100 observed component years[79]	3 cups (THA); 1 uncemented cup; 1 cemented cup; 1 double mobility cup uncemented, and 2 uncemented stems (THA)[79]
Danish Hip Arthroplasty Register	Annually[25]	Hospital level[67]	7-days, 2- and 5-years[67]	Blood transfusion rates within 7-days after primary THA due to OA & rehospitalization after primary THA & rehospitalization after primary THA due to OA & rehospitalization after primary THA due to fracture & reprocedures within 2-years after primary THA & reprocedures within 2-years after primary THA due to OA & reprocedures within 2-years after primary THA due to fracture & 5-years mortality after primary THA & 5-years mortality after primary THA due to OA per hospital are reported (funnel plots)[67]	Publicly available[67]	Outside 95% control limits of funnel plot[67]	2 hospitals (rehospitalization after primary THA), 3 hospitals (rehospitalization after primary THA due to fracture), 4 hospitals (reprocedures within 2-years after primary THA), 3 hospitals (reprocedures within 2-years after primary THA due to OA), 4 hospitals (5-years mortality after primary THA), 3 hospitals (5 years mortality after primary THA due to OA)[67]
Swedish Hip Arthroplasty Register	Annually[26]	Hospital-, medical device- and surgeon level[26]	90-days and 2-years (surgeon level), 2-, 5-, 10-years (hospital level) and <2-, 2-, and 5-years (medical device level)[26]	Revision outlier procedures for surgeons (e.g., above the 95% CI for adverse events within 90-days & reoperations within 2-years after hip procedure), 30-days adverse events, 90-days adverse events, 5- and 10-years implant survival per hospital (95% CI interval for each hospital above the average 30- and 90-days adverse events rates and survival rate), N/R (reoperations within 2-years after primary procedure per hospital are reported; statistical testing unknown), revision on 10-year survival (based on log-rank tests with significance set at p<0,0005 compared with control group)[26]	Publicly available as well as individual reports to hospitals[26]	Above the 95% CI for adverse events within 90-days & reoperations within 2-years after hip procedure based on the average during that period (surgeon level) and 95% CI per hospital above the average 5- and 10-years survival rates[26]	1 surgeon for reoperations within 2-years (data 2016), 8 hospitals on 5-years implant survival, 7 hospitals on 10-years implant survival, 14 hospitals on 30-days adverse events (elective patients), 16 hospitals on 90-days adverse events (elective patients), 5 hospitals on 30-days adverse events (standard patients), 6 hospitals on 90-days adverse events (standard patients), 5 hospitals on 30-days adverse events (fracture patients), 2 hospitals on 90-days adverse events (fracture patients), 7 hospitals on 30-days adverse events (after first reoperation), 6 hospitals on 90-days adverse events (after first operation), 4 hospitals on 30-days adverse events (second or later operation), 2 hospitals on 90-days adverse events (second or later operation), 6 hospitals on 30-days adverse events (after first revision), 6 hospitals on 90-days adverse events (after first revision), 3 hospitals on 30-days adverse events (after second or later revision), 3 hospitals on 90-days adverse events (after second or later revision), 7 THA cups, and 1 THA stem[26]
Danish Knee Arthroplasty Register	N/R	N/R	N/R	N/R	N/R	N/R	N/R

Swedish Knee Arthroplasty Register	Annually[72]	Hospital- and medical device level[72]	90-days (hospital level), N/R (medical device level)[72]	N/R (all events/adverse surgical events/cardiovascular events/death/other events within 90-days per hospital (risk/1000) are reported; statistical testing unknown), risk of revision per implant are reported (marked in red with higher risk ratio, based on risk of revision (RR); the PFC-Sigma MBT implant is used as reference), relative risk of revision per hospital are reported (marked in red with higher risk ratio; statistical testing unknown)[72]	Publicly available as well as individual reports to hospitals[72]	N/R	3 TKA implants (general risk of revision), 4 TKA implants (risk of revision when infection is not considered to be a revision), 10 hospitals (relative risk of revision), 9 hospitals (relative risk of revision when infection is not considered to be a revision)[72]

A.2 Appendix 2: Paper published in J Bone Joint Surg Am

Validating Orthopaedic Data Evaluation Panel (ODEP) ratings across 9 orthopaedic registries: total hip implants with an ODEP Rating perform better than those without an ODEP Rating (J Bone Joint Surg Am 2024, Epub May 31. doi: 10.2106/JBJS.23.00793)

Introduction

In the United States of America, medical devices are regulated by the Food and Drug Administration.[1] In the European Union (EU), medical devices are regulated according the Medical Device Regulation (MDR), aiming to provide "a robust, transparent, predictable, and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation".[2, 3] To ensure patient safety, the MDR requires manufacturers to monitor their implants' performances, e.g. total hip (TH) and total knee (TK) implants, by benchmarking ("a systematic process of determining whether an implant meets specified performance levels").[4, 5] Several methods for benchmarking TH- and TK-implants are used, e.g. comparing implants to: i) the best-performing implant; ii) the average performance of comparable implants, and iii) absolute thresholds by using objective-performance-criteria (OPC).[6-15]

The Orthopaedic Data Evaluation Panel (ODEP) rating is an example of OPC used to promote evidence-based selection of implants by assigning a rating to implants presenting evidence of meeting survivorship criteria.(10) ODEP-ratings are available for: i) TH-components (cups/stems); ii) TK-implants (tibial-femoral combinations); iii) unicondylar knee implants; iv) shoulder components (glenoid/stems); v) reverse shoulder implants; vi) total elbow implants, and vii) spine implants (cervical discs). The ODEP benchmarks implants based on revision data from observational studies (e.g. single-centre studies, manufacturers in-house sources or registry data). Thus, not all ODEP-ratings are based on registry data. The submitted data is supplied by manufacturers using standardised ODEP-submission forms.(16) Not all implants on the market are submitted to ODEP as data submission is voluntary, but surgeons and hospitals are encouraged to use ODEP-rated implants. As different data sources can be used by manufacturers to submit their application for an ODEP-rating, these data may not be representative of daily-clinical practice. Therefore, before submission, manufacturers have to declare that "the clinical data submitted is representative of all studies that have been conducted in relation to it". The ODEP-rating includes a number (years of evidence) and a letter (strength of evidence). The latter denotes performance of implants based on OPC at specific timepoints (3/5/7/10/13/15-years), i.e. minimum number of centers and surgeons, size of the cohort, patients at risk, and the maximum revision rate. Implants can be rated as A* (highest), A (lower), B (where usage is limited but the implant is extremely important or for new implants introduced in a limited manner), starting from 3-years of evidence. Implants not meeting ODEPs' benchmark-criteria (Table 1) are not rated. Although originally focused on the United Kingdom (UK), the ODEP-rating is increasingly used internationally for quality assessment of

implants.(17-19) In the Dutch Arthroplasty Register, 100% of all TH-cups and -stems and 92% of all TK-implants used in 2019 were assigned an ODEP-rating. In the UK, comparable numbers were reported in 2018.(18, 20) Although increasingly used, external validation of ODEP-ratings across multiple registries has never been undertaken.

We therefore aimed to assess across multiple registries whether: 1) Higher (A*) ODEP-rated TH- and TK-implants have lower cumulative revision risks (CRR) than lower (A) ODEP-rated implants; and 2) the extent to which A*-rated implants would receive the A*-rating based on pooled registries CRR. Since the maximum revision rate for A*-rated implants is lower than for A-rated implants, we hypothesised that A*-rated implants have lower CRR across registries than A-rated implants. Furthermore, we expected the majority – rather than all – of A*-rated implants to be A*-rated based on the pooled registries CRR, as revision risks are also influenced by e.g. surgeon factors potentially affecting implant performances.

Table 1. ODEP-benchmark-criteria for TH- and TK-implants

TH-implant – ODEP criteria A* ratings	**3A***	**5A***	**7A***	**10A***	**13A***	**15A***
Minimum number of centres outside development centre(s)	3	3	3	3	3	3
Minimum number of surgeons outside of development centre(s)	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	150	225	300	400	400	400
Maximum revision rate[†]	3.0%	3.5%	4.0%	5.0%	6.5%	8.0%
TH-implant – ODEP criteria A ratings	**3A**	**5A**	**7A**	**10A**	**13A**	**15A**
Minimum number of centres and surgeons	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	72	66	60	51	42	40
Maximum revision rate[†]	5.0%	5.5%	6.0%	7.0%	8.5%	10.0%
TH-implant – ODEP criteria B ratings	**3B**	**5B**	**7B**	**10B**	**13B**	**15B**
Minimum number of centres and surgeons	1	1	1	1	1	1
Minimum total cohort	100	100	100	100	100	100
Minimum at risk at benchmark time	40	40	40	40	40	40
Maximum value of 95% lower confidence limit for revision rate	3.0%	3.5%	4.0%	5.0%	6.5%	8.0%
TK-implant – ODEP criteria A* ratings	**3A***	**5A***	**7A***	**10A***	**13A***	**15A***

Minimum number of centres outside development centre(s)	3	3	3	3	3	3
Minimum number of surgeons outside of development centre(s)	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	150	225	300	400	400	400
Maximum revision rate[†]	3.5%	4.0%	4.5%	5.0%	6.0%	6.5%
TK-implant – ODEP criteria A ratings	**3A**	**5A**	**7A**	**10A**	**13A**	**15A**
Minimum number of centres and surgeons	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	66	60	55	51	51	45
Maximum revision rate[†]	5.5%	6.0%	6.5%	7.0%	8.0%	8.5%
TK-implant – ODEP criteria B ratings	**3B**	**5B**	**7B**	**10B**	**13B**	**15B**
Minimum number of centres and surgeons	1	1	1	1	1	1
Minimum total cohort	100	100	100	100	100	100
Minimum at risk at benchmark time	66	60	55	51	45	42
Maximum value of 95% lower confidence limit for revision rate	3.5%	4.0%	4.5%	5.0%	6.0%	6.5%
TH- and TK-implant – ODEP criteria pre-entry A*	Product launched under Beyond Compliance					
TH- and TK-implant – ODEP criteria pre-entry A	Product details supplied to ODEP					

[†]The upper 95% confidence interval for KM revision rate (1-Survival) must be lower than the specified level

Material and Methods

The ODEP-rating

The data submitted to ODEP is evaluated by a voluntary independent panel of orthopaedic-experts. To prevent camouflage (i.e. the performance of a specific implant design variant concealed because different variants exist under the same implant name)(21), the ODEP-panel reviews implants at the product-code-level(21) (Table 1(10)). After being assigned an ODEP-rating, manufacturers have to resubmit new evidence at every ODEP-milestone to prevent their implants from being lapsed, which not all manufacturers may do.(10) ODEP usually only lapse an ODEP-rating after a “grace” period of one-year before the ODEP-rating is removed. Implants not meeting the benchmark-criteria do not receive an ODEP-rating.

Matching registry data to ODEP-ratings

European registries were identified using a systematic review supplemented by non-European registries as listed on the website of the Australian Registry.(22, 23) Registries were included if they reported implant-specific CRR including standard error (SE) or 95% confidence interval (95%CI) to allow pooling data, and if they were "active" ("publishing ≥1 annual report/paper containing registries' data, during or later than 2018"(23)). CRR was defined as the number of patients who needed to undergo a revision up to a certain timepoint as a proportion of the total number of patients at risk after a primary procedure.

The following registry data were extracted for TH-components (cups and stems), TH-implants (cup-stem combinations) and TK-implants (tibial-femoral combinations): name, manufacturer, fixation, number of implants, and CRR with SE and/or 95%CI. If only the 95%CI was provided, the SE was calculated by subtracting the upper- and lower-95%CI and dividing this by 3,92.(24)

Implants in registry data were identified, based on implant name, as having received an ODEP-rating or not (Figures 1-2). ODEP-matched implants with a B-rating were excluded because they are assigned for implants with limited usage.

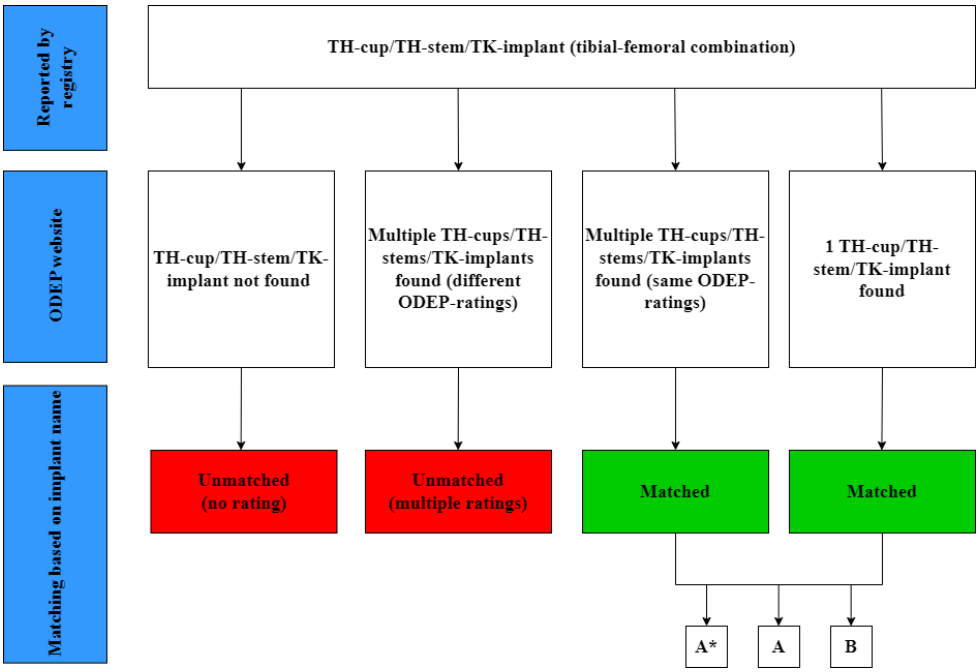

Figure 1: Flowchart showing the matching process for TH-components and TK-implants

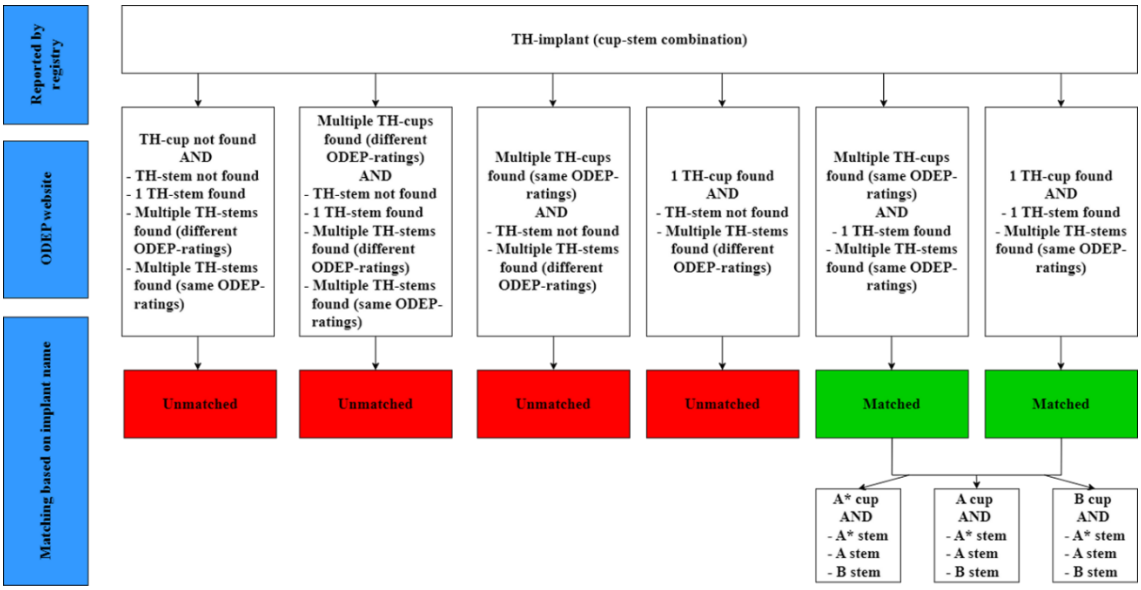

Figure 2: Flowchart showing the matching process for TH-implants

Data analysis

Before comparing CRR differences between higher- and lower-rated implants, we assessed whether ODEP-rated implants are a selection of implants. We therefore evaluated whether ODEP-matched implants differed from unmatched implants without and with multiple ODEP-ratings (red boxes; Figures 1-2) regarding CRR, using independent t-tests.

Within ODEP-matched implants, random effects models were used to calculate the pooled registries CRR (3/5/10-year) for A*- and A-rated implants, including the DerSimonian-Laird estimator to consider the heterogeneity between implant designs.(25) ODEP-ratings (A*/A) was included as a factor to test for group differences. This analysis was done separately for TH-components and TK-implants. For TH-implants, comparable random effects models were used but then comparing A*A*- with AA-hip-stem-combinations. The I2 was used to estimate the extent of heterogeneity in the pooled registries CRR, which was considered low (25%), moderate (50%), or high (75%).(26, 27) Exploring reasons for observed heterogeneities, the same analyses were conducted separately by fixation of each TH-component and TK- and TH-implants and for TH-implants also whether components were from the same/different manufacturer.

To answer the second research question, random effects models were used to calculate the pooled CRR (3/5/10-year) with 95%CI for each TH-component across all registries in which it was reported. These pooled registries CRR were then compared with ODEP-benchmark-criteria (Table 1) to assess if the TH-component met the A*-criteria. We then calculated the percentage of A*-rated TH-components that would receive an A*-rating based on the pooled registries CRR, and similarly for A-rated TH-components. Considering that implants' performances may differ across registries, we also

examined the median (range) number of registries in which each TH-component would be assigned an A*-rating and also how many TH-components would consistently get an A*-rating in all registries in which it was reported.

Metafor Package in R-statics (version:4.1.2) was used for analyses. Significance was set at p-value<0,05.

Results

Nine registries were included (Figure 3) of which the latest annual reports (data until 12/2019) of eight registries were used(18, 28-34) and up-to-date (until 03/2021) registry-website data of one registry(35). Mean patient/procedure-level completeness of the included registries was 87.3% (range:40%(28)-99%(18)).

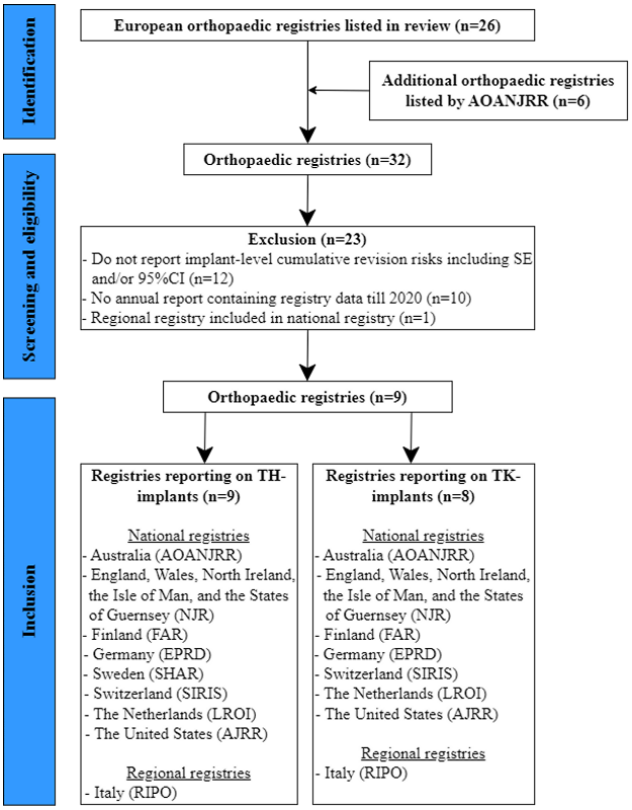

Figure 3: Flowchart of included registries

Nine registries reported on 583 unique TH-cups (2,615,890 implants), 618 TH-stems (2,567,442 implants), and eight registries on 634 TH-implants (2,266,864 implants) and 508 TK-implants (2,940,899 implants) (Supplementary Tables 1-4). 313 (54%) cups, 356 (58%) stems, 218 (34%) TH-implants, and 68 (13%) TK-implants reported by registries were matched to ODEP-ratings. Percentages of ODEP-matching

varied widely between registries: ranging 35-69% (cups), 46-80% (stems), 22-55% (TH-implants) and 6-20% (TK-implants). For unmatched implants due to multiple ODEP-ratings, the median number of possible ODEP-ratings was: 2 (range:2-6) for cups, 2 (range:2-8) for stems, and 4 (range:2-48) for TK-implants (data not shown). Since only 13% of TK-implants were matched, they were not further analysed. The main reason for failure to match is that the granularity with which ODEP-ratings are applied to a TK-implant is much more detailed than most registry reports of a TK-implant.

ODEP-matched versus ODEP-unmatched TH-implants

ODEP-matched cups and stems had significantly lower 5- and 10-year (cups also 3-year) CRR than unmatched cups and stems without an ODEP-rating, but had comparable CRR compared to unmatched cups and stems with multiple ODEP-ratings (Table 2). ODEP-matched TH-implants had significantly lower CRR at all follow-up points compared with ODEP-unmatched TH-implants (Table 3).

Table 2: Cumulative revision risks ODEP-matched *versus* ODEP-unmatched implants

	Matched implants		Unmatched implants – multiple ODEP-ratings		Matched *versus* unmatched implants – multiple ODEP-ratings	Unmatched implants – no ODEP-rating		Matched *versus* unmatched implants – no ODEP-rating
	Revision risk	n	Revision risk	n	Mean difference (95% CI)	Revision risk	n	Mean difference (95% CI)
Cups – 3-year	2.6%	1,270,520	2.5%	645,191	0.1% (-0.25;0.39)	3.2%	379,345	**-0.6% (-0.32;-0.94)***
Cups – 5-year	3.1%	1,406,957	3.2%	631,813	-0.1% (-0.49;0.30)	5.1%	370,942	**-2.0% (-1.37;-2.58)****
Cups – 10-year	5.6%	944,820	5.4%	506,671	0.2% (-0.79;1.11)	11.8%	196,116	**-6.3% (-4.43;-8.09)*****
Stems – 3-year	2.7%	1,423,161	2.7%	165,456	0.0% (-0.47;0.46)	2.9%	692,944	-0.2% (-0.09;0.46)
Stems – 5-year	3.4%	1,418,673	3.4%	162,655	0.0% (-0.82;0.82)	4.2%	675,774	**-0.7% (-0.16;-1.30)***
Stems – 10-year	6.7%	1,004,520	5.7%	112,264	1.0% (-1.73;3.80)	8.8%	606,571	**-2.0% (-0.33;-3.74)****

*= p-value=<0.001; **= p-value=<0.001; ***= p-value=<0.001; *= p-value=0.013; **= p-value=0.019; *= p-value=0.042

Table 3: Cumulative revision risks ODEP-matched *versus* ODEP-unmatched TH-implants

	Matched implants		Unmatched implants		Matched *versus* unmatched implants
	Revision risk	n	Revision risk	n	Mean difference (95% CI)
TH-implants – 3-year	2.6%	799,382	2.9%	1,405,493	**-0.3% (-0.08;-0.58)***
TH-implants – 5-year	3.0%	793,761	4.0%	1,365,984	**-1.0% (-0.47;-1.52)****
TH-implants – 10-year	5.2%	503,730	8.6%	1,006,928	**-3.4% (-1.66;-5.08)*****

*= p-value=0.010; **= p-value=<0.001; ***= p-value=<0.001

A*-rated versus A-rated TH-implants

No overall differences in CRR were found between A*- and A-rated TH-implants (Tables 4-5). Moderate to high (range:67-95%) heterogeneity was found reflecting between-implant variation in CRR (Tables 4-5). Exploring this heterogeneity, analyses were repeated by fixation which again showed no significant differences in 3/5/10-year CRR for all analysed groups; moderate to high heterogeneity remained (data not shown). Within the same manufacturer TH-implants, A*A*-implants had significantly lower 3- and 5-year CRR than AA-implants. Within different manufacturer TH-implants, no significant differences were found (data not shown).

Table 4: Cumulative revision risks A*- *versus* A-rated TH-components (cups and stems)

	A* components			A components			A* *versus* A components	
	Revision risk	n	Registries included, n	Revision risk	n	Registries included, n	Mean difference (95% CI)	I^2
Cups – 3-year	2.3%	1,058,495	7	2.6%	153,979	5	-0.3% (-0.71;1.19)	78%
Cups – 5-year	2.6%	1,302,734	9	3.0%	180,830	7	-0.4% (-0.78;1.34)	86%
Cups – 10-year	4.5%	1,030,923	6	6.2%	137,499	5	-1.7% (-0.49;3.55)	90%
Stems – 3-year	2.3%	1,098,938	7	2.3%	288,025	7	-0.1% (-0.74;0.60)	67%
Stems – 5-year	3.0%	1,109,707	8	3.2%	311,695	8	-0.1% (-0.81;0.76)	70%
Stems – 10-year	5.5%	1,001,275	6	6.9%	170,134	5	-1.5% (-2.08;4.63)	95%

Table 5: Cumulative revision risks higher- *versus* lower-rated TH-implants

	A*A* implants			AA implants			A* cup + A stem implants			A cup + A* stem implants			A*A* *versus* AA implants	
	Revision risk	n	Registries included, n	Revision risk	n	Registries included, n	Revision risk	n	Registries included, n	Revision risk	n	Registries included, n	Mean difference (95% CI)	I^2
3-year	2.1%	448,940	7	3.7%	16,066	4	2.5%	191,696	7	2.2%	86,761	5	-1.6% (-0.03;2.25)	76%
5-year	2.7%	452,788	8	4.1%	17,121	5	3.0%	211,212	8	2.6%	87,954	6	-1.4% (-0.10;2.25)	73%
10-year	5.2%	351,180	5	7.7%	14,891	4	4.7%	116,519	4	4.6%	83,244	5	-2.5% (-1.47;3.22)	82%

ODEP-ratings based on pooled registries CRR

From all ODEP-matched A*-rated cups and stems, 39% cups and 42% stems would also get an A*-rating based on the pooled registries CRR at 3-year, 44% cups and 35% stems at 5-year, and 30% cups and 5% stems at 10-year (Table 6, Supplementary Figures 1-2 for implant-level results). Analysing cups and stems reported by ≥2 registries, resulted in similar percentages at 3- and 5-year, but lower percentages at 10-year (Table 6). Cups and stems qualifying for an A*-rating based on the pooled registries CRR, would get an A*-rating in a median of 1 registry at all follow-up points (range:0-4 (cups) and 0-6 (stems)) (Supplementary Table 5, Supplementary Figures 1-2). Three cups and stems would consistently get an A*-rating in all registries at 3-year, 4 cups and 2 stems at 5-year, and 3 cups and 0 stems at 10-year (Supplementary Tables 5-6).

From all ODEP-matched A-rated cups and stems, 24% cups and 31% stems would get an A*-rating based on the pooled registries CRR at 3-year, 24% cups and 32% stems at 5-year, and 22% cups and 23% stems at 10-year (Table 6, Supplementary Figures 3-4). Analysing A-rated cups and stems reported by ≥2 registries, these percentages were: 27% cups and 30% stems (3-year), 18% cups and 25% stems (5-year), and 33% cups and 40% stems (10-year) (Table 6). Cups qualifying for an A*-rating based on the pooled registries CRR, would get an A*-rating in a median of 0 registries at all follow-up points (range:0-5) (Supplementary Table 7). For stems these were: a median of 1 registry (range:0-2) at 3-year, 1 registry (range:0-2) at 5-year, and 0 registries (range:0-1) at 10-year (Supplementary Table 8). Zero cups and 1 stem would consistently receive an A*-rating in all registries at 3-year, 1 cup and 2 stems at 5-year, and no cup or stem at 10-year (Supplementary Tables 7-8).

Table 6: A*- and A-rated TH-components (cups and stems) reaching the A*-OPC based on pooled cumulative revision risks

	Unique type of components, n		Components reaching the A* benchmark, n (% of unique type of components)	
	All components	Components used in ≥2 registries	All Components	Components used in ≥2 registries
A* cups – 3-year	33	23	13 (39)	9 (39)
A* cups – 5-year	36	25	16 (44)	11 (44)
A* cups – 10-year	30	18	9 (30)	4 (22)
A* stems – 3-year	33	25	14 (42)	12 (48)
A* stems – 5-year	31	24	11 (35)	8 (33)
A* stems – 10-year	20	14	1 (5)	-
A cups – 3-year	17	11	4 (24)	3 (27)
A cups – 5-year	17	11	4 (24)	2 (18)
A cups – 10-year	9	3	2 (22)	1 (33)
A stems – 3-year	29	10	9 (31)	3 (30)
A stems – 5-year	28	12	9 (32)	3 (25)
A stems – 10-year	13	5	3 (23)	2 (40)

Discussion

This multi-registry study showed that ODEP-matched TH-implants had significantly lower CRR than unmatched TH-implants without an ODEP-rating. Within matched TH-implants, higher ODEP-rated implants did not differ in CRR than lower ODEP-rated implants. TK-implants were not analysed as only 13% of TK-implants reported by registries were matched to an ODEP-rating. Only 39% of A*-rated cups and 42% of A*-rated stems would be assigned the A*-rating based on the pooled registries CRR at 3-year, but also 24% of A-rated cups and 31% A-rated stems (with similar or lower percentages at longer follow-up) and assigned ODEP-ratings varied across registries. The latter implies that assigned ODEP-ratings do not necessarily apply to TH-implants' performances in other countries and therefore registries should first validate ODEP-ratings using country-specific data to better guide implant selection in their country.

In principle, OPC like ODEP can be helpful for stakeholders to: i) monitor implants' performances; ii) stimulate continuous evaluation of implants which may result in a higher ODEP-rating and prevent losing an ODEP-rating when no data are provided two-years (3/5/13-year ODEP-ratings) or three-years (7/10/15-year ODEP-ratings) after an ODEP-rating has been assigned, and iii) use ODEP-ratings to guide implant selection. ODEP aims to "promote evidence-based selection of implants so that patients receive the very best and safest implants".(36) Our study showed that ODEP-matched TH-implants had better performance than unmatched TH-implants without an ODEP-rating, suggesting that ODEP achieves this aim by encouraging surgeons and hospitals to use ODEP-rated implants.

Previous studies benchmarked against a predefined-benchmark created by a quality institute, others used relative-benchmarks such as the performance not being worse than the – at that time – best-performing implant or against the average performance of similar implants.(6, 11-15) Using a relative-benchmark means that whether implants are considered to have outlier performances depends on the performance of the comparator. As implants' performances can change over time, the comparators' performance may also change. So, even if an implant continues to have the same performance over time, that implant could become an outlier if the comparator improves. This differs from using absolute-benchmarks e.g. ODEP-ratings, where the OPC is predefined based on what is

considered to be an acceptable level of implants' performance, making interpretations and assessments of implants' performances more straight-forward.(10) However, absolute-benchmarks need to be updated over time (e.g. the ODEP-rating originally had a 10-year benchmark threshold of <10%(10)), so it has to be considered whether the OPC are still acceptable.

A prerequisite for assigning ODEP-ratings is that manufacturers declare that the voluntarily submitted data – which may be based on various data sources – are representative for the performance of these implants in daily-clinical practice.(10) Our study tested the external validity of the ODEP-rating across multiple registries, and showed that about 40% of A*-rated cups and stems would receive this ODEP-rating based on the pooled registries CRR but also about a quarter of A-rated cups and stems, with the rating inconsistent across registries. Reasons for this inconsistency may be due to differences between registries in case-mix, revision indications, smaller 95%CI due to pooling data resulting in meeting the OPC, or camouflage.(21) Another explanation, particularly for implants used for decades and knowing that implants' performances have improved over time, may be that CRR apply to patients operated in a different period. For some registries the 10-year CRR of implants may include patients operated in the previous century, whereas for newer registries it would include patients operated more recently. This highlights the importance of including patients from the same period when combining data across multiple registries. Nonetheless, if well-established implants continue to be used to the same extent, the impact of patients operated long ago on the reported revision estimates will likely be small. The inconsistency also underscores the importance of transparent reporting on what submitted data sources ODEP-ratings are based as this would also allow validation whether the data is indeed representative as claimed by manufacturers.

Some study limitations should be noted. First, there may be selection bias as some implants could not be matched – due to multiple ODEP-ratings – and thus excluded. However, ODEP-matched TH-implants had similar CRR than unmatched TH-implants with multiple ODEP-ratings, making selection bias unlikely. The matching-problem is due to insufficient details on implants reported by registries, resulting in a large number of compatible construct combinations within one implant name ("camouflage").(21) To solve this matching-problem –, most prominently in TK-implants – , registries should register implants' product-codes, which is already done by few registries.(37) Second, some registries may not include all patients or revisions which may influence the CRR. The Swedish Hip Arthroplasty Register, for example, likely underestimates revisions as they exclude revisions due to infection, thus the actual implant-level CRR are higher than reported.(32) For TH-implants commonly used in this registry, these underestimated CRR may result in an A*-rating being assigned, whereas it might have been an A-rating when including all revisions. Similarly, the American Joint Replacement Registry only includes >65 years-old osteoarthritis patients which may again result in underestimated CRR as literature generally shows lower CRR among older patients.(28, 38) Third, registries were mainly excluded for analysis because they did not publish CRR with SE or 95%CI, making data comparison and pooling impossible. This highlights the importance of international agreement across registries on definitions, reporting detail (e.g. product-codes), and methodologies to enable data pooling.(23) Fourth, we evaluated the performance

of A* and A hip-stem-combinations to give insight into possible performance differences, but ODEP has never rated the combinations, only hip components separately. This is aligned with clinical practice where clinicians mix-and-match cups and stems from different manufacturers, often with excellent results. This may be a potential reason for some of the mismatch between the pooled CRR and the "construct" ODEP-ratings generated. Lastly, we only analysed 3/5/10-year CRR, because they were – besides the 1-year CRR – the most frequently reported timepoint, with each registry contributing at least two timepoints. 1-year CRR were not analysed as these are not used for ODEP-ratings, where the 3-year rating is the first.

In conclusion, clinicians should be encouraged to use implants with a rating such as ODEP as these have better CRR than unrated implants. A minority of A*-rated cups and stems would be eligible for an A*-rating based on the pooled registries CRR and assigned ODEP-ratings varying across registries, indicating that implants' performances vary across countries. Therefore, registries should first validate ODEP-ratings to better guide implant selection in their country and preferable at the product-code-level to prevent camouflage. Making data submission mandatory, including the data source, removing the grace period before the ODEP-rating is lost and using revision data from at least two regional/national/multi-country registries with >95% implant-level completeness(23, 39) would strengthen the ODEP-benchmarks.

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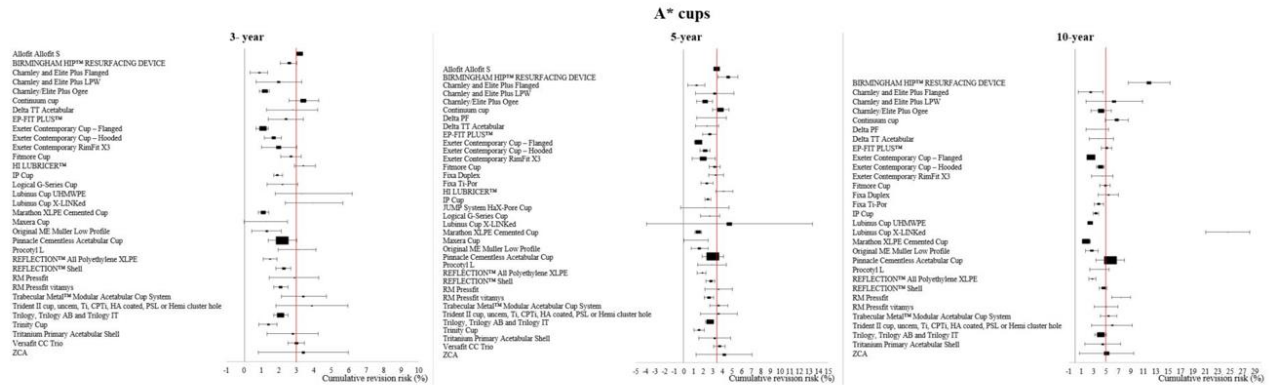
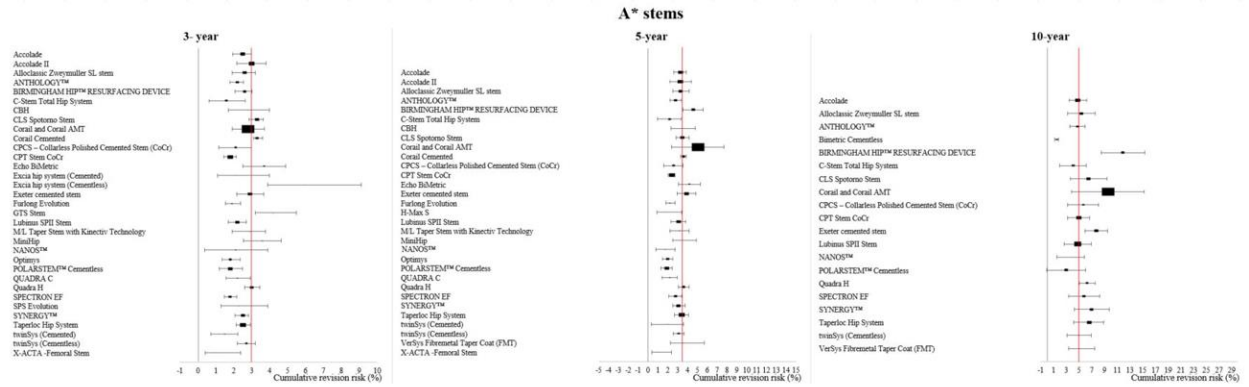
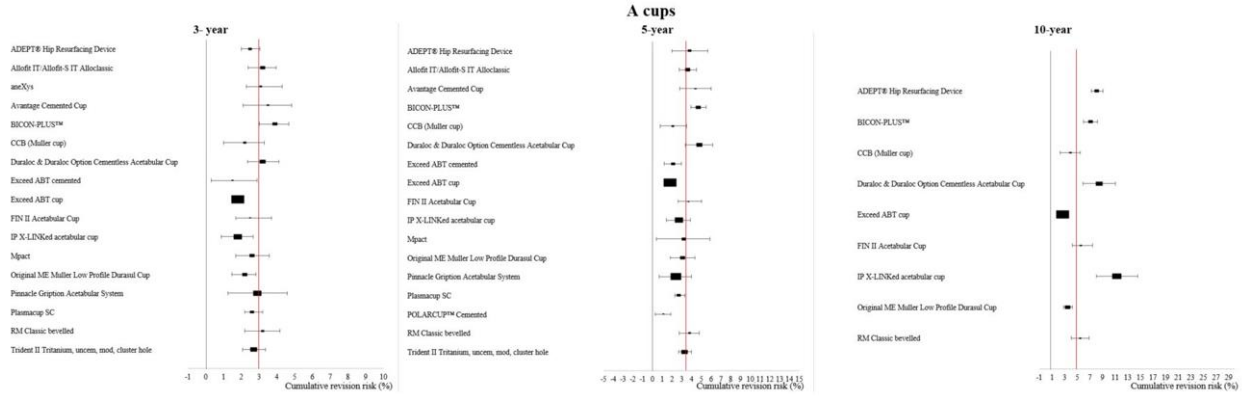


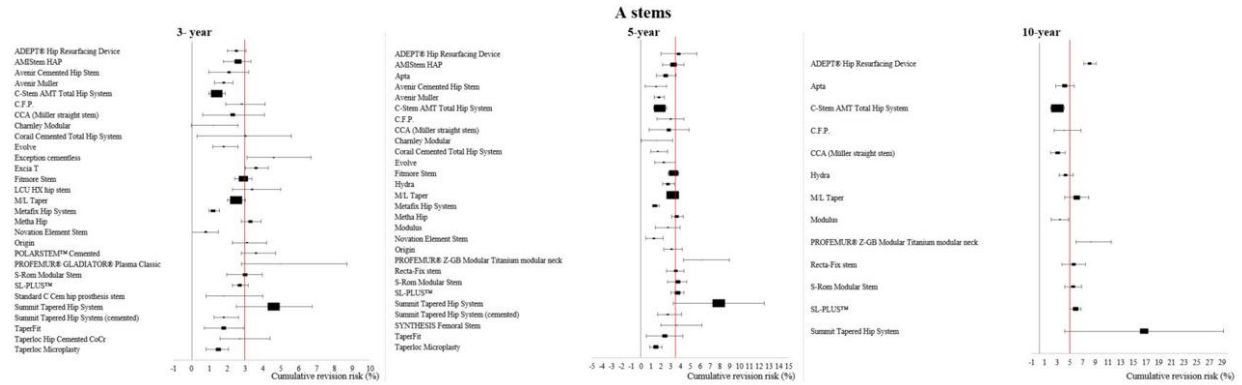
Supplementary Figure 1: Forest plots of A*-rated cups in nine registries with cumulative revision risks (3/5/10 year) with the red line indicating the A*-OPC



Supplementary Figure 2: Forest plots of A*-rated stems in nine registries with cumulative revision risks (3/5/10 year) with the red line indicating the A*-OPC



Supplementary Figure 3: Forest plots of A-rated cups in nine registries with cumulative revision risks (3/5/10 year) with the red line indicating the A*-OPC



Supplementary Figure 4: Forest plots of A-rated stems in nine registries with cumulative revision risks (3/5/10 year) with the red line indicating the A*-OPC

Supplementary Table 1: Implant demographics of TH-cups

	AJRR	AOANJRR	EPRD	FAR	LROI	NJR	RIPO	SHAR	SIRIS
Unique type of cups used, n	20 (243,980)	138 (422,351)	56 (242,941)	123 (177,972)	74 (219,875)	64 (921,900)	62 (55,284)	26 (261,959)	20 (69,628)
Match with ODEP, n (% of total unique cups)	7 (35)	59 (43)	30 (54)	53 (43)	49 (66)	44 (69)	41 (66)	18 (69)	12 (60)
A-rating*	5 (72)	41 (70)	16 (53)	36 (68)	23 (47)	37 (84)	29 (71)	11 (61)	12 (100)
A-rating	-	12 (20)	9 (30)	10 (19)	17 (35)	5 (9)	3 (7)	7 (39)	-
B-rating	1 (14)	-	-	-	-	-	-	-	-
Lapsed, pre-entry or withdrawn rating	1 (14)	6 (10)	5 (17)	7 (13)	9 (18)	2 (5)	9 (22)	-	-
Multiple ODEP-ratings, n (% of total unique cups)	2 (10)	47 (34)	3 (5)	10 (8)	15 (20)	6 (9)	6 (10)	4 (15)	7 (35)
No ODEP-rating, n (% of total unique cups)	11 (55)	32 (23)	23 (41)	60 (49)	10 (14)	14 (22)	15 (24)	4 (15)	1 (5)
Total number of ODEP-matched cups used	123,149	104,829	138,066	84,725	114,457	670,600	39,750	237,252	37,563
Mean cumulative revision risk									
ODEP-matched and ODEP-unmatched cups – 3-year	1.8%	2.7%	3.4%	3.5%	2.3%	1.7%	-	-	2.4%
ODEP-matched and ODEP-unmatched cups – 5-year	2.2%	3.6%	3.8%	5.4%	2.9%	2.7%	3.5%	1.2%	2.9%
ODEP-matched and ODEP-unmatched cups – 10-year	-	6.8%	-	11.6%	4.5%	5.2%	5.2%	1.9%	-
ODEP-matched cups – 3-year	1.8%	2.6%	3.5%	3.5%	2.3%	1.4%	-	-	2.5%
ODEP-matched cups – 5-year	2.1%	3.3%	3.5%	4.9%	2.9%	1.9%	2.7%	1.0%	3.1%
ODEP-matched cups – 10-year	-	5.7%	-	9.0%	4.3%	3.4%	4.7%	1.9%	-
Unmatched cups (no rating and multiple ODEP-ratings) – 3-year	1.8%	2.8%	3.2%	3.6%	2.4%	2.4%	-	-	2.4%
Unmatched cups (no rating and multiple ODEP-ratings) – 5-year	2.2%	3.9%	4.1%	5.8%	3.0%	4.5%	5.1%	2.2%	2.6%
Unmatched cups (no rating and multiple ODEP-ratings) – 10-year	-	7.5%	-	13.3%	4.8%	9.1%	6.2%	1.9%	-
Unmatched cups (no ODEP-rating) – 3-year	1.9%	3.5%	3.3%	3.6%	2.3%	2.8%	-	-	1.6%
Unmatched cups (no ODEP-rating) – 5-year	2.2%	5.2%	4.1%	5.9%	2.9%	5.5%	5.9%	2.2%	1.6%
Unmatched cups (no ODEP-rating) – 10-year	-	11.1%	-	14.1%	5.2%	10.9%	6.4%	2.3%	-
Unmatched cups (multiple ODEP-ratings) – 3-year	1.7%	2.3%	3.2%	3.8%	2.5%	1.7%	-	-	2.5%
Unmatched cups (multiple ODEP-ratings) – 5-year	2.5%	3.0%	-	5.2%	3.1%	2.1%	3.0%	-	2.8%
Unmatched cups (multiple ODEP-ratings) – 10-year	-	5.4%	-	8.8%	4.6%	3.3%	5.9%	1.7%	-

Supplementary Table 2: Implant demographics of TH-stems

	AJRR	AOANJRR	EPRD	FAR	LROI	NJR	RIPO	SHAR	SIRIS
Unique type of stems used, n	38 (233,779)	138 (422,351)	82 (240,645)	123 (177,972)	74 (219,875)	64 (921,900)	62 (55,284)	17 (226,008)	20 (69,628)
Match with ODEP, n (% of total unique stems)	25 (66)	77 (56)	38 (46)	59 (48)	59 (80)	36 (56)	37 (60)	12 (71)	13 (65)
A-rating*	11 (44)	55 (71)	18 (47)	44 (75)	45 (76)	24 (67)	17 (36)	10 (83)	7 (54)
A-rating	13 (52)	21 (27)	17 (45)	15 (25)	5 (8)	11 (31)	18 (49)	2 (17)	5 (38)
B-rating	1 (4)	-	1 (3)	-	-	-	2 (5)	-	-
Lapsed, pre-entry, or withdrawn rating	-	1 (1)	2 (5)	-	9 (15)	1 (3)	-	-	1 (8)
Multiple ODEP-ratings, n (% of total unique stems)	1 (3)	17 (12)	5 (6)	8 (7)	8 (11)	5 (8)	5 (8)	1 (6)	4 (20)
No ODEP-ratings, n (% of total unique stems)	12 (32)	44 (32)	39 (48)	56 (46)	7 (10)	23 (36)	20 (32)	4 (24)	3 (15)
Total number of ODEP-matched stems used	211,185	230,752	148,846	106,275	189,679	481,828	36,074	166,977	56,600
Mean cumulative revision risk									
ODEP-matched and ODEP-unmatched stems – 3-year	1.8%	2.7%	3.4%	3.5%	2.3%	1.7%	-	-	2.4%
ODEP-matched and ODEP-unmatched stems – 5-year	2.2%	3.6%	3.7%	5.4%	2.9%	2.7%	3.5%	0.6%	2.9%
ODEP-matched and ODEP-unmatched stems – 10-year	-	6.8%	-	11.6%	4.5%	5.2%	5.2%	2.1%	-
ODEP-matched stems – 3-year	1.7%	2.8%	3.3%	3.7%	2.2%	1.7%	-	-	2.4%
ODEP-matched stems – 5-year	2.1%	3.8%	3.6%	5.1%	2.7%	2.7%	3.0%	0.6%	2.9%
ODEP-matched stems – 10-year	-	8.0%	-	9.6%	4.2%	5.3%	5.2%	1.9%	-
Unmatched stems (no ODEP-rating and multiple ODEP-ratings) – 3-year	2.1%	2.6%	3.5%	3.4%	2.8%	1.7%	-	-	2.5%
Unmatched stems (no ODEP-rating and multiple ODEP-ratings) – 5-year	2.4%	3.4%	3.7%	5.6%	3.5%	2.7%	4.3%	-	3.0%
Unmatched stems (no ODEP-rating and multiple ODEP-ratings) – 10-year	-	5.5%	-	13.2%	5.4%	5.1%	5.2%	2.4%	-
Unmatched stems (no ODEP-rating) – 3-year	2.1%	2.6%	3.6%	3.4%	2.6%	1.8%	-	-	2.1%
Unmatched stems (no ODEP-rating) – 5-year	2.3%	3.3%	3.5%	5.8%	3.4%	2.9%	4.7%	-	2.5%
Unmatched stems (no ODEP-rating) – 10-year	-	5.3%	-	13.4%	5.8%	5.6%	5.2%	2.5%	-
Unmatched stems (multiple ODEP-ratings) – 3-year	2.2%	2.8%	3.1%	2.8%	3.0%	1.3%	-	-	2.8%
Unmatched stems (multiple ODEP-ratings) – 5-year	2.6%	3.6%	4.6%	4.4%	3.7%	1.8%	2.5%	-	3.3%
Unmatched stems (multiple ODEP-ratings) – 10-year	-	6.2%	-	10.0%	4.9%	3.2%	5.1%	1.9%	-

Supplementary Table 3: Implant demographics of TH-implants (cup-stem combination)

	AJRR	AOANJRR	EPRD	FAR	LROI	NJR	RIPO	SIRIS
Unique type of implants used, n	33 (200,068)	138 (422,351)	120 (199,786)	123 (177,972)	74 (219,875)	64 (921,900)	62 (55,284)	20 (69,628)
Match with ODEP, n (% of total unique implants)	14 (42)	35 (25)	41 (34)	27 (22)	41 (55)	26 (41)	26 (42)	8 (40)
A cup + A* stem*	3 (21)	15 (43)	22 (54)	11 (41)	16 (39)	12 (46)	8 (31)	5 (63)
A cup + A stem*	9 (64)	7 (20)	9 (22)	7 (26)	3 (7)	10 (38)	10 (38)	2 (25)
A cup + B stem*	1 (7)	-	-	-	-	-	-	-
A cup + withdrawn, pre-entry or lapsed stem*	-	-	-	-	-	-	-	1 (13)
A cup + A stem*	-	7 (20)	7 (17)	4 (15)	8 (20)	3 (12)	1 (4)	-
A cup + A stem	-	2 (6)	2 (5)	2 (7)	2 (5)	-	2 (8)	-
A cup + B stem	-	-	-	-	-	-	-	-
A cup + withdrawn, pre-entry or lapsed stem	-	-	-	-	3 (7)	-	-	-
B cup + A stem*	-	-	-	-	-	-	-	-
B cup + A stem	-	-	-	-	-	-	-	-
B cup + B stem	-	-	-	-	-	-	-	-
B cup + withdrawn, pre-entry or lapsed stem	-	-	-	-	-	-	-	-
Withdrawn, pre-entry or lapsed cup + A stem*	1 (7)	2 (6)	1 (2)	1 (4)	5 (12)	-	2 (8)	-
Withdrawn, pre-entry or lapsed cup + A stem	-	1 (3)	-	2 (7)	-	-	2 (8)	-
Withdrawn, pre-entry or lapsed cup + B stem	-	-	-	-	-	-	1 (4)	-
Withdrawn, pre-entry or lapsed cup + withdrawn, pre-entry or lapsed stem	-	1 (3)	-	-	4 (10)	1 (4)	-	-
No match with ODEP, n (% of total unique implants)	19 (58)	103 (75)	79 (66)	96 (78)	33 (45)	38 (59)	36 (58)	12 (60)
Total number of ODEP matched implants used	104,372	59,178	77,529	53,772	93,399	382,197	29,933	32,833
Mean cumulative revision risk								
ODEP-matched and ODEP-unmatched implants – 3-year	1.9%	2.7%	3.3%	3.5%	2.3%	1.7%	-	2.4%
ODEP-matched and ODEP-unmatched implants – 5-year	2.2%	3.6%	3.3%	5.4%	2.9%	2.7%	3.5%	2.9%
ODEP-matched and ODEP-unmatched implants – 10-year	-	6.8%	-	11.6%	4.5%	5.2%	5.2%	-
ODEP-matched implants – 3-year	1.8%	2.6%	3.1%	3.7%	2.1%	1.5%	-	2.6%
ODEP-matched implants – 5-year	2.2%	3.3%	3.2%	4.9%	2.7%	1.9%	2.8%	3.2%
ODEP-matched implants – 10-year	-	5.8%	-	8.0%	4.2%	3.4%	4.7%	-
ODEP-unmatched implants – 3-year	1.9%	2.8%	3.3%	3.5%	2.5%	1.9%	-	2.4%
ODEP-unmatched implants – 5-year	2.2%	3.7%	3.5%	5.5%	3.2%	3.2%	4.1%	2.7%
ODEP-unmatched implants – 10-year	-	7.1%	-	12.5%	4.8%	6.3%	5.6%	-

Supplementary Table 4: Implant demographics of TK-implants (tibial-femoral combination)

	AJRR	AOANJRR	EPRD	FAR	LROI	NJR	RIPO	SIRIS
Unique type of implants used, n	32 (400,870)	154 (697,265)	88 (186,867)	47 (223,009)	36 (229,612)	96 (1,076,263)	45 (50,602)	10 (76,411)
Match with ODEP, n (% of total unique implants)	2 (6)	20 (13)	13 (15)	4 (9)	3 (8)	16 (17)	8 (18)	2 (20)
A-rating*	1 (50)	3 (15)	7 (54)	-	1 (33)	4 (25)	3 (38)	1 (50)
A-rating	-	8 (40)	6 (46)	3 (75)	1 (33)	8 (50)	3 (38)	1 (50)
B-rating	-	-	-	1 (25)	-	2 (13)	-	-
Lapsed, pre-entry or withdrawn rating	1 (50)	9 (45)	-	-	1 (33)	2 (13)	2 (25)	-
Multiple ODEP-ratings, n (% of total unique implants)	22 (69)	69 (45)	48 (55)	14 (30)	24 (67)	34 (35)	18 (40)	8 (80)
No ODEP-ratings, n (% of total unique implants)	8 (25)	65 (42)	27 (31)	29 (62)	9 (25)	46 (48)	19 (42)	-
Total number of ODEP-matched implants used	24,131	57,339	31,208	14,099	3,997	103,112	10,255	12,876
Mean cumulative revision risk								
ODEP-matched and ODEP-unmatched implants – 3-year	1.4%	3.0%	3.5%	4.1%	4.0%	2.0%	-	4.4%
ODEP-matched and ODEP-unmatched implants – 5-year	1.8%	3.9%	3.6%	5.6%	5.3%	2.8%	3.6%	5.7%
ODEP-matched and ODEP-unmatched implants – 10-year	-	5.7%	-	9.4%	7.2%	4.5%	4.7%	-
ODEP-matched implants – 3-year	1.5%	3.2%	4.2%	4.5%	3.7%	1.9%	-	4.4%
ODEP-matched implants – 5-year	1.9%	4.3%	4.4%	5.8%	4.8%	2.6%	3.5%	5.6%
ODEP-matched implants – 10-year	-	5.8%	-	10.0%	6.3%	5.1%	5.5%	-
ODEP-unmatched implants (no ODEP-rating and multiple ODEP-ratings) – 3-year	1.4%	2.9%	3.4%	4.1%	4.0%	2.0%	-	4.4%
ODEP-unmatched implants (no ODEP-rating and multiple ODEP-ratings) – 5-year	1.8%	3.8%	3.5%	5.6%	5.3%	2.8%	3.6%	5.8%
ODEP-unmatched implants (no ODEP-rating and multiple ODEP-ratings) – 10-year	-	5.7%	-	9.4%	7.4%	4.4%	4.6%	-
ODEP-unmatched implants (no ODEP-rating) – 3-year	1.6%	3.0%	3.6%	4.6%	4.3%	2.1%	-	-
ODEP-unmatched implants (no ODEP-rating) – 5-year	2.1%	4.0%	4.0%	6.5%	5.5%	3.0%	3.8%	-
ODEP-unmatched implants (no ODEP-rating) – 10-year	-	5.9%	-	11.7%	8.0%	4.5%	5.2%	-
ODEP-unmatched implants (multiple ODEP-ratings) – 3-year	1.3%	2.8%	3.2%	3.2%	3.9%	1.8%	-	4.4%
ODEP-unmatched implants (multiple ODEP-ratings) – 5-year	1.7%	3.6%	3.3%	3.7%	5.2%	2.6%	3.4%	5.8%
ODEP-unmatched implants (multiple ODEP-ratings) – 10-year	-	5.5%	-	4.7%	7.1%	4.3%	4.1%	-

Supplementary Table 5: A*-rated cups reaching the A*-OPC based on pooled cumulative revision risks

ODEP name	3-year		ODEP-rating		5-year		ODEP-rating		10-year		ODEP-rating	
	Pooled revision risk (95% CI)	Used cups, n	Pooled	A* in registry	Pooled revision risk (95% CI)	Used cups, n	Pooled	A* in registry	Pooled revision risk (95% CI)	Used cups, n	Pooled	A* in registry
Allofit Allofit S	3.2% (3.10;3.30)	78,570	A	0/1	3.4% (3.20;3.60)	78,570	A	0/1	-	-	-	-
BIRMINGHAM HIP™ RESURFACING DEVICE	2.6% (2.08;3.01)	26,435	A	1/3	4.6% (3.55;5.61)	26,510	A	0/4	11.9% (8.56;15.33)	26,435	A	0/3
Charnley and Elite Plus Flanged	0.9% (0.34;1.35)	9,806	A*	1/1	1.3% (0.39;2.19)	9,806	A*	1/1	2.5% (0.49;4.55)	9,806	A*	1/1
Charnley and Elite Plus LPW	2.0% (0.69;3.32)	18,968	A	1/2	3.2% (1.18;5.20)	18,968	A	1/2	6.3% (1.79;10.89)	18,968	A	1/2
Charnley/Elite Plus Ogee	1.2% (0.89;1.46)	54,218	A*	1/3	2.2% (1.33;2.97)	54,218	A*	1/3	4.2% (2.56;5.85)	54,218	A	1/3
Continuum cup	3.4% (2.60;4.29)	62,397	A	3/5	3.8% (2.99;4.66)	70,922	A	4/7	6.7% (4.89;8.56)	20,195	A	0/2
Delta PF	-	-	-	-	2.4% (1.30;4.40)	429	A	0/1	3.1% (1.80;5.40)	429	A	0/1
Delta TT Acetabular	2.8% (1.29;4.23)	2,396	A	0/1	2.4% (1.19;3.62)	4,230	A	1/3	3.8% (2.30;6.20)	502	A	0/1
EP-FIT PLUS™	2.4% (1.40;3.39)	13,560	A	1/4	2.7% (1.94;3.44)	18,001	A*	1/5	5.1% (4.25;5.91)	11,948	A	0/4
Exeter Contemporary Cup – Flanged	1.1% (0.71;1.40)	93,872	A*	2/2	1.5% (1.08;1.84)	93,872	A*	2/2	2.6% (2.07;3.09)	93,872	A*	2/2
Exeter Contemporary Cup – Hooded	1.7% (1.17;2.13)	31,773	A*	2/2	2.2% (1.66;2.70)	31,773	A*	2/2	4.1% (3.50;4.69)	38,442	A*	2/3
Exeter Contemporary RimFit X3	2.0% (1.02;3.02)	45,008	A	2/4	2.0% (0.84;3.25)	79,804	A*	3/5	4.4% (2.70;6.10)	643	A	0/1
Fitmore Cup	2.7% (2.11;3.28)	15,151	A	0/4	3.2% (2.61;3.75)	16,453	A	0/4	4.9% (4.02;5.69)	8,309	A	0/3
Fixa Duplex	-	-	-	-	3.3% (2.57;4.11)	5,012	A	0/1	5.4% (3.71;6.98)	5,012	A	0/1
Fixa Ti-Por	-	-	-	-	2.4% (1.79;3.01)	13,390	A*	1/1	3.8% (3.10;4.57)	11,476	A*	1/1
HI LUBRICER™	3.4% (2.90;4.10)	4,106	A	0/1	4.1% (3.30;5.10)	4,106	A	0/1	-	-	-	-
IP Cup	1.9% (1.70;2.20)	12,470	A*	1/1	2.5% (2.20;2.80)	12,470	A*	1/1	3.4% (2.90;3.80)	12,470	A*	1/1
JUMP System HaX-Pore Cup	-	-	-	-	2.2% (-0.37;4.70)	1,497	A	0/1	-	-	-	-
Logical G-Series Cup	2.2% (1.32;3.08)	3,703	A	0/1	2.7% (1.73;3.71)	3,171	A	0/1	-	-	-	-

Lubinus Cup UHMWPE	3.3% (1.80;6.20)	349	A	0/1	-	-	-	-	2.4% (2.20;2.60)	37,995	A*	1/1
Lubinus Cup X-LINKed	4.0% (2.35;5.68)	1,419	A	0/2	4.7% (-3.89;13.36)	53,059	A	1/2	24.7% (21.10;28.20)	653	A	0/1
Marathon XLPE Cemented Cup	1.1% (0.81;1.42)	46,192	A*	2/4	1.5% (1.14;1.83)	46,192	A*	2/4	1.8% (1.11;2.48)	76,569	A*	2/2
Maxera Cup	1.3% (0.00;2.50)	322	A*	1/1	1.3% (0.00;2.50)	322	A*	1/1	-	-	-	-
Original ME Muller Low Profile	1.3% (0.46;2.13)	14,261	A*	2/2	1.6% (0.75;2.54)	14,261	A*	2/2	2.7% (1.68;3.74)	14,261	A*	2/2
Pinnacle Cementless Acetabular Cup	2.2% (1.38;3.04)	284,211	A	2/3	3.0% (1.89;4.10)	284,211	A	2/3	5.7% (3.38;8.00)	200,119	A	1/2
Procotyl L	3.1% (1.97;4.14)	2,088	A	0/3	2.9% (1.44;4.38)	1,392	A	0/2	4.0% (2.40;5.50)	684	A	0/1
REFLECTION™ All Polyethylene XLPE	1.5% (1.10;1.90)	4,634	A*	1/1	1.9% (1.40;2.30)	4,634	A*	1/1	2.8% (2.20;3.40)	4,634	A*	1/1
REFLECTION™ Shell	2.3% (1.84;2.69)	23,232	A*	1/4	2.8% (2.31;3.21)	22,419	A*	1/3	4.6% (3.92;5.17)	20,478	A	0/3
RM Pressfit	2.9% (1.46;4.29)	5,808	A	1/3	3.6% (2.19;5.03)	4,787	A	1/2	7.4% (5.94;8.93)	1,259	A	0/2
RM Pressfit vitamys	2.1% (1.70;2.53)	25,064	A*	2/3	2.6% (2.13;3.08)	25,064	A*	1/3	5.0% (3.10;6.90)	3,277	A	0/1
Trabecular Metal™ Modular Acetabular Cup System	3.4% (2.14;4.73)	12,542	A	2/6	3.6% (2.69;4.58)	11,617	A	2/5	5.4% (4.06;6.76)	7,161	A	1/4
Trident II cup, uncem, Ti, CPTi, HA coated, PSL or Hemi cluster hole	3.9% (1.82;5.94)	6,329	A	0/1	3.6% (1.70;5.57)	7,735	A	0/2	6.0% (2.68;9.24)	7,395	A	0/2
Trilogy, Trilogy AB and Trilogy IT	2.1% (1.69;2.52)	89,122	A*	2/6	2.7% (2.23;3.11)	90,369	A*	3/8	4.2% (3.23;5.09)	73,282	A	2/6
Trinity Cup	1.4% (0.87;1.90)	13,274	A*	1/2	1.6% (1.02;2.14)	13,274	A*	2/2	-	-	-	-
Tritanium Primary Acetabular Shell	2.8% (1.32;4.25)	10,986	A	1/3	3.2% (1.57;4.87)	10,530	A	2/3	4.5% (1.60;7.32)	9,366	A	1/2
Versafit CC Trio	3.0% (2.53;3.48)	23,039	A	0/2	3.7% (3.06;4.27)	17,333	A	0/2	-	-	-	-
ZCA	3.4% (0.84;5.97)	21,186	A	1/3	4.2% (1.25;7.11)	21,186	A	1/3	5.1% (0.72;9.47)	43,024	A	2/3

Supplementary Table 6: A*-rated stems reaching the A*-OPC based on pooled cumulative revision risks

ODEP name	3-year				5-year				10-year			
			ODEP-rating				ODEP-rating				ODEP-rating	
	Pooled revision risk (95% CI)	Used stems, n	Poole d	A* in registry	Pooled revision risk (95% CI)	Used stems, n	Poole d	A* in registry	Pooled revision risk (95% CI)	Used stems, n	Poole d	A* in registry
Accolade	2.5% (1.94;2.99)	55,048	A*	2/5	3.3% (2.61;3.90)	55,048	A	2/5	4.8% (3.48;6.19)	50,031	A	2/5
Accolade II	3.0% (2.16;3.81)	72,999	A	3/6	3.3% (2.24;4.37)	66,331	A	2/6	-	-	-	-
Alloclassic Zweymuller SL stem	2.6% (1.93;3.21)	38,018	A	1/3	3.3% (2.48;4.16)	38,018	A	0/3	5.4% (3.21;7.59)	29,263	A	0/2
ANTHOLOGY™	2.2% (1.79;2.56)	27,630	A*	3/5	2.8% (2.21;3.36)	27,630	A*	3/5	4.8% (3.58;5.97)	16,842	A	2/4
Bimetric Cementless	-	-	-	-	-	-	-	-	1.5% (1.20;1.80)	10,812	A*	1/1
BIRMINGHAM HIP™ RESURFACING DEVICE	2.6% (2.08;3.01)	26,435	A	1/3	4.6% (3.55;5.61)	26,510	A	0/4	11.9% (8.56;15.33)	26,435	A	0/3
C-Stem Total Hip System	1.6% (0.64;2.64)	16,989	A*	1/2	2.2% (0.94;3.38)	16,989	A*	1/2	4.1% (1.96;6.16)	16,989	A	1/2
CBH	2.8% (1.69;3.99)	1,136	A	0/1	3.6% (2.32;4.78)	1,136	A	0/1	-	-	-	-
CLS Spotorno Stem	3.3% (2.87;3.65)	34,199	A	0/4	3.5% (2.86;4.18)	37,232	A	0/5	6.5% (3.62;9.45)	34,639	A	1/5
Corail and Corail AMT	2.8% (1.91;3.70)	342,817	A	3/6	5.1% (2.42;7.73)	342,268	A	3/7	9.6% (3.82;15.30)	329,665	A	2/6
Corail Cemented	3.3% (3.10;3.60)	28,363	A	0/1	3.6% (3.30;3.90)	28,363	A	0/1	-	-	-	-
CPCS – Collarless Polished Cemented Stem (CoCr)	2.1% (1.17;3.00)	14,388	A	1/2	2.6% (1.57;3.53)	14,388	A	1/2	5.7% (3.24;8.12)	10,450	A	0/1
CPT Stem CoCr	1.8% (1.44;2.12)	68,132	A*	1/2	2.4% (2.05;2.72)	68,132	A*	2/2	5.0% (3.25;6.66)	58,740	A	1/3
Echo BiMetric	3.7% (2.51;4.91)	6,132	A	1/2	4.2% (3.06;5.33)	6,132	A	1/2	-	-	-	-
Excia hip system (Cemented)	2.1% (1.10;4.00)	542	A	0/1	-	-	-	-	-	-	-	-
Excia hip system (Cementless)	6.0% (3.90;9.10)	389	A	0/1	-	-	-	-	-	-	-	-
Exeter cemented stem	2.9% (2.16;3.69)	41,926	A	2/4	3.9% (2.97;4.87)	41,926	A	2/4	7.7% (5.92;9.54)	37,024	A	0/3
Furlong Evolution	1.9% (1.54;2.38)	4,702	A*	1/1	2.2% (1.80;2.75)	4,702	A*	1/1	-	-	-	-
GTS Stem	4.2% (3.20;5.50)	1,428	A	0/1	-	-	-	-	-	-	-	-
H-Max S	-	-	-	-	1.8% (0.90;3.40)	696	A*	1/1	-	-	-	-

Lubinus SPII Stem	2.2% (1.68;2.71)	43,257	A*	1/3	3.1% (2.33;3.83)	43,257	A	0/3	4.8% (2.70;6.89)	109,467	A	1/3
M/L Taper Stem with Kinectiv Technology	2.9% (1.93;3.78)	3,155	A	0/2	3.2% (2.22;4.14)	3,155	A	0/2	-	-	-	-
MiniHip	3.6% (2.55;4.65)	2,552	A	0/2	3.5% (2.50;4.90)	1,052	A	0/1	-	-	-	-
NANOS™	2.1% (0.37;3.90)	3,930	A	1/2	1.8% (0.79;2.71)	1,325	A*	1/2	3.0% (1.50;5.90)	307	A	0/1
Optimys	1.8% (1.35;2.34)	20,517	A*	3/3	2.0% (1.49;2.51)	20,517	A*	3/3	-	-	-	-
POLARSTEM™ Cementless	1.8% (1.20;2.47)	51,159	A*	6/6	1.9% (1.33;2.44)	53,335	A*	6/7	3.0% (-0.08;6.09)	27,100	A	1/2
QUADRA C	2.2% (1.56;2.93)	4,838	A*	1/3	2.2% (1.40;2.96)	3,873	A*	0/2	-	-	-	-
Quadra H	3.0% (2.60;3.46)	31,105	A	0/3	3.6% (3.06;4.16)	25,791	A	0/2	6.3% (5.05;7.55)	16,593	A	0/1
SPECTRON EF	1.8% (1.48;2.17)	22,864	A*	3/3	2.8% (2.09;3.41)	22,864	A*	2/3	5.8% (3.35;8.24)	22,365	A	1/3
SPS Evolution	2.3% (1.30;3.90)	594	A	0/1	-	-	-	-	-	-	-	-
SYNERGY™	2.5% (2.07;2.84)	38,635	A*	2/5	3.1% (2.51;3.75)	39,172	A	3/6	7.0% (4.25;9.76)	28,981	A	0/5
Taperloc Hip System	2.5% (2.14;2.93)	79,366	A*	3/5	3.4% (2.69;4.08)	81,399	A	3/6	6.6% (4.22;8.87)	41,305	A	2/5
twinSys (Cemented)	1.5% (0.73;2.24)	2,431	A*	2/3	2.0% (0.33;3.58)	1,294	A	1/2	-	-	-	-
twinSys (Cementless)	2.7% (2.21;3.22)	13,223	A	0/4	3.1% (2.56;3.66)	13,223	A	0/4	5.0% (3.10;6.90)	3,277	A	0/1
VerSys Fibremetal Taper Coat (FMT)	-	-	-	-	3.6% (2.30;5.70)	505	A	0/1	5.1% (3.40;7.50)	505	A	0/1
X-ACTA -Femoral Stem	1.0% (0.40;2.40)	582	A*	1/1	1.0% (0.40;2.40)	582	A*	1/1	-	-	-	-

Supplementary Table 7: A-rated cups reaching the A*-OPC based on pooled cumulative revision risks

ODEP name	3-year		ODEP-rating		5-year		ODEP-rating		10-year		ODEP-rating	
	Pooled revision risk (95% CI)	Used cups, n	Pooled	A* in registry	Pooled revision risk (95% CI)	Used cups, n	Pooled	A* in registry	Pooled revision risk (95% CI)	Used cups, n	Pooled	A* in registry
ADEPT® Hip Resurfacing Device	2.5% (2.01;3.04)	3,691	A	1/0	3.8% (1.98;5.68)	3,812	A	0/2	8.1% (7.23;9.13)	3,691	A	0/1
Allofit IT/Allofit-S IT Alloclassic	3.2% (2.38;3.95)	7,713	A	0/2	3.6% (2.74;4.54)	7,713	A	0/2	-	-	-	-
aneXys	3.1% (2.30;4.30)	1,687	A	0/1	-	-	-	-	-	-	-	-
Avantage Cemented Cup	3.5% (2.10;4.84)	1,705	A	0/2	4.4% (2.78;5.98)	1,008	A	0/1	-	-	-	-
BICON-PLUS™	3.9% (3.02;4.69)	6,075	A	0/2	4.7% (3.94;5.51)	7,009	A	0/3	7.1% (5.98;8.22)	4,621	A (0)	0/2
CCB (Muller cup)	2.2% (1.01;3.29)	2,753	A	1/2	2.1% (0.77;3.51)	2,132	A	0/1	3.9% (2.30;5.50)	1,429	A	0/1
Duraloc & Duraloc Option	3.2% (2.34;4.11)	10,389	A	1/4	4.8% (3.36;6.15)	9,305	A	1/3	8.5% (5.90;11.09)	9,305	A (0)	0/3
Cementless Acetabular Cup												
Exceed ABT cemented	1.5% (0.30;2.90)	1,188	A*	1/1	2.1% (1.17;2.99)	5,031	A*	2/5	-	-	-	-
Exceed ABT cup	1.8% (1.46;2.13)	45,661	A*	3/4	1.8% (1.35;2.30)	48,430	A*	5/5	2.7% (2.12;3.18)	34,942	A* (3)	3/4
FIN II Acetabular Cup	2.5% (1.70;3.70)	1,009	A	0/1	3.7% (2.60;5.00)	1,009	A	0/1	5.6% (4.20;7.40)	1,009	A	0/1
IP X-LINKed acetabular cup	1.8% (0.89;2.66)	17,962	A*	1/2	2.7% (1.40;3.91)	20,753	A	2/3	11.3% (8.01;14.64)	17,151	A	0/1
Mpact	2.6% (1.69;3.59)	6,836	A	0/1	3.2% (0.42;5.91)	5,671	A	0/1	-	-	-	-
Original ME Muller Low Profile Durasul Cup	2.2% (1.46;2.84)	7,563	A*	1/2	3.1% (1.80;4.35)	7,064	A	1/2	3.5% (2.80;4.20)	6,832	A*	1/1
Pinnacle Gription Acetabular System	2.9% (1.27;4.60)	19,077	A	1/2	2.4% (0.71;4.02)	33,524	A	2/3	-	-	-	-
Plasmacup SC	2.6% (2.20;3.20)	4,701	A	0/1	2.7% (2.30;3.30)	4,701	A*	1/1	-	-	-	-
POLARCUP™ Cemented	-	-	-	-	1.1% (0.30;1.90)	912	A*	1/1	-	-	-	-

RM Classic bevelled	3.2% (2.21;4.17)	2,706	A	0/2	3.8% (2.73;4.82)	2,706	A	0/2	5.5% (4.10;6.90)	1,169	A	0/1
Trident II Tritanium, uncem, mod, cluster hole	2.7% (2.06;3.35)	13,223	A	1/2	3.3% (2.66;4.02)	11,427	A	0/2	-	-	-	-

Supplementary Table 8: A-rated stems reaching the A*-OPC based on pooled cumulative revision risks

ODEP name	3-year				5-year				10-year			
			ODEP-rating				ODEP-rating				ODEP-rating	
	Pooled revision risk (95% CI)	Used stems, n	Poole d	A* in registry	Pooled revision risk (95% CI)	Used stems, n	Poole d	A* in registry	Pooled revision risk (95% CI)	Used stems, n	Poole d	A* in registry
ADEPT® Hip Resurfacing Device	2.5% (2.01;3.04)	3,691	A	0/1	3.8% (1.98;5.68)	3,812	A	0/2	8.1% (7.23;9.13)	3,691	A	0/1
AMIStem HAP	2.6% (1.78;3.34)	15,508	A	1/4	3.3% (2.17;4.36)	14,474	A	1/4	-	-	-	-
Apta	-	-	-	-	2.5% (1.53;3.56)	7,487	A	0/1	4.2% (2.76;5.69)	7,487	A	0/1
Avenir Cemented Hip Stem	2.1% (0.97;3.19)	2,798	A	1/3	1.5% (0.39;2.59)	1,188	A*	2/2	-	-	-	-
Avenir Muller	1.8% (1.29;2.32)	2,882	A*	1/1	1.8% (1.29;2.32)	2,882	A*	1/1	-	-	-	-
C-Stem AMT Total Hip System	1.4% (0.98;1.88)	42,745	A*	1/3	1.9% (1.24;2.57)	42,338	A*	1/2	3.0% (1.97;4.12)	41,776	A*	1/2
C.F.P.	2.8% (1.90;4.10)	1,029	A	0/1	3.0% (1.61;4.35)	1,432	A	0/2	4.1% (2.50;6.80)	403	A	0/1
CCA (Müller straight stem)	2.3% (0.61;4.08)	6,447	A	1/3	2.8% (0.79;4.85)	6,447	A	1/3	3.1% (1.94;4.27)	5,268	A*	1/2
Charnley Modular	1.2% (0.00;2.60)	255	A*	1/1	1.6% (0.00;3.20)	255	A*	1/1	-	-	-	-
Corail Cemented Total Hip System	3.0% (0.32;5.60)	1,651	A	1/2	1.7% (1.00;2.70)	915	A*	1/1	-	-	-	-
Evolve	1.8% (1.20;2.60)	1,580	A*	1/1	2.3% (1.40;3.50)	1,580	A	1/1	-	-	-	-
Exception cementless	4.6% (3.10;6.70)	993	A	0/1	-	-	-	-	-	-	-	-
Excia T	3.6% (3.00;4.30)	3,764	A	0/1	-	-	-	-	-	-	-	-
Fitmore Stem	2.9% (2.41;3.40)	25,771	A	0/3	3.3% (2.76;3.81)	25,771	A	0/3	-	-	-	-
Hydra	-	-	-	-	2.7% (2.20;3.40)	4,003	A*	1/1	4.3% (3.30;5.50)	4,003	A	0/1
LCU HX hip stem	3.4% (2.30;5.00)	1,827	A	0/1	-	-	-	-	-	-	-	-
M/L Taper	2.5% (2.00;3.00)	49,047	A	2/6	3.2% (2.68;3.78)	48,175	A	2/6	6.1% (4.22;8.03)	11,702	A	0/2
Metafix Hip System	1.2% (0.97;1.56)	6,277	A*	1/1	1.4% (1.13;1.84)	6,277	A*	1/1	-	-	-	-
Metha Hip	3.3% (2.80;3.90)	5,213	A	0/1	3.6% (3.10;4.30)	5,213	A	0/1	-	-	-	-
Modulus	-	-	-	-	2.7% (1.45;3.94)	931	A	0/1	3.4% (2.08;4.79)	931	A*	1/1
Novation Element Stem	0.8% (0.04;1.51)	2,154	A*	1/1	1.3% (0.45;2.22)	2,154	A*	1/1	-	-	-	-

Origin	3.1% (2.30;4.20)	1,591	A	0/1	3.1% (2.30;4.20)	1,591	A	0/1	-	-	-	-
POLARSTEM™ Cemented	3.6% (2.80;4.70)	1,740	A	0/1	-	-	-	-	-	-	-	-
PROFEMUR® GLADIATOR® Plasma Classic	5.0% (2.80;8.70)	369	A	0/1	-	-	-	-	-	-	-	-
PROFEMUR® Z-GB Modular Titanium modular neck	-	-	-	-	6.2% (4.30;9.00)	421	A	0/1	8.3% (6.00;11.50)	421	A	0/1
Recta-Fix stem	-	-	-	-	3.5% (2.59;4.35)	4,497	A	0/1	5.6% (3.73;7.45)	4,497	A	0/1
S-Rom Modular Stem	3.0% (1.96;3.96)	7,757	A	0/1	3.7% (2.67;4.66)	7,757	A	0/1	5.5% (4.19;6.88)	4,154	A	0/1
SL-PLUS™	2.7% (2.28;3.16)	5,448	A	0/1	3.7% (3.05;4.33)	9,132	A	0/2	5.9% (4.96;6.73)	8,674	A	0/2
Standard C Cem hip prosthesis stem	1.8% (0.80;4.00)	426	A	0/1	-	-	-	-	-	-	-	-
Summit Tapered Hip System	4.6% (2.51;6.74)	48,863	A	1/3	7.9% (3.24;12.50)	49,397	A	1/4	16.7% (4.22;29.26)	18,631	A	1/3
Summit Tapered Hip System (cemented)	1.8% (1.24;2.63)	1,614	A*	1/1	2.7% (1.64;4.10)	1,614	A	0/1	-	-	-	-
SYNTHESIS Femoral Stem	-	-	-	-	3.6% (2.00;6.20)	617	A	0/1	-	-	-	-
TaperFit	1.8% (0.73;2.92)	8,172	A*	1/2	2.4% (0.53;4.25)	8,172	A	1/2	-	-	-	-
Taperloc Hip Cemented CoCr	2.7% (1.60;4.40)	734	A	0/1	-	-	-	-	-	-	-	-
Taperloc Microplasty	1.5% (0.82;2.08)	8,425	A*	2/2	1.5% (0.84;2.12)	8,425	A*	2/2	-	-	-	-

A.3 Appendix 3: Paper submitted to Acta Orthopaedica, revisions requested

Comparing safety notices and registry outlier data on total knee implants – A Coordinating Research and Evidence for Medical Devices (CORE-MD) study

Introduction

According to the Food and Drug (FDA) and the European (EU) Medical Device Regulation, all medical devices have to be subject to post-market surveillance (PMS) in which manufacturers have to collect performance data of their medical devices(2). Once collected, these data need to be analysed by the manufacturer to evaluate if any corrective or preventive actions are needed. If action from the manufacturer is required, a field safety notice (SN) must be released. SNs can be published on websites of manufacturers or national competent authorities. From a safety perspective, arthroplasty implants are interesting to analyse, specifically total hip (TH) and total knee (TK) implants, as they are the most commonly used arthroplasty implants. In this study, TK-implants were analysed since only one manufacturer is involved in its' design whereas multiple manufacturers can be involved in TH-implants ("mix and match")(5).

An exemplary case related to SNs for TK-implants is represented by Optetrak (Exactech). In 2021, Exactech released a SN including a recall of specific Optetrak tibial components following a packaging defect that resulted in these components failing earlier than expected(6). In 2022, Exactech expanded the recall to include all Optetrak tibial components. At the time of the last recall, a large number of components (more than 400,000 globally) had already been sold and potentially used in patients(6). However, prior to these recalls, in 2018, the FDA released a SN stating that the Optetrak "potentially have non-conforming internal threads" and the TK-implant was therefore under investigation by the manufacturer(8). In addition, two peer-reviewed studies demonstrated poor implant performance before the recalls; poor patient satisfaction scores(7,9), abnormal clinical and radiographic results, and high 3-year revision rates(9). Despite several warnings have been released before the recall, the Optetrak continued to be implanted.

SNs are relevant not only for competent authorities, but also for clinicians as they could be used for implant selection. SNs can be issued for a wide variety of issues (e.g. from packaging to material integrity) and therefore they do not have to indicate a problem with the performance of a particular TK-implant. On the other hand, several arthroplasty registries have procedures in place to identify TK-implants with outlier performance, of which the outlier status relies solely on the risk of revision(10). Hence, as these outliers are guaranteed to have performance issues it is expected that these TK-outliers will be reflected in SNs. Whereas registries outlier data solely rely on revision data, SNs may also include problems based on other outcomes, e.g. poor patient satisfaction scores as for the Optetrak, which will be reported to their clinicians earlier than revisions, meaning that these signals could be detected earlier. In addition, SNs can be released based on data other than registry data, e.g. peer-reviewed

publications. Hence, it is unknown to what extent registry outlier data and SNs would signal the same or different TK-implants.

Therefore, the present study aimed to analyse if discrepancies exist between the TK-implants subject to SNs and the TK-outliers identified by registries, and to explore possible reasons for these differences.

Materials and Methods

Design and setting

This study will compare publicly available SNs for TK-implants, published by national competent authorities across 13 countries, with TK-outliers reported by registries.

Identification of Safety Notices

The Coordinating Research and Evidence for Medical Devices (CORE-MD) PMS tool[11] was used to identify TK-implants with publicly released SNs on the websites of competent authorities in the following countries: Australia, Czechia, Denmark, France, Germany, Greece, Ireland, Italy, Portugal, Spain, Sweden, the United States of America (USA), and the Netherlands.

Details of the applied methodology in the CORE-MD PMS tool have been published previously[11,12]. Briefly, the web scraper tool screens the website of each competent authority to collect SNs.

To only include SNs for TK-implants currently on the market, a list of all TK-implants from the latest annual reports from the following registries was constructed: American Joint Replacement Registry (AJRR)(14), Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)(15), Dutch Arthroplasty Register (LROI)(16), Emilia-Romagna Register (R.I.P.O.)(17), German Arthroplasty Registry (EPRD)(18), Swiss National Hip & Knee Joint Registry (SIRIS)(19), the National Joint Registry for England, Wales, Northern Ireland, the Isle of Man and Guernsey (NJR)(20). Also, up-to-date registry-website data from the Finnish Arthroplasty Register (FAR) was included.

The brand name of each TK-implant on this list was used as input for the CORE-MD PMS tool, so that all their associated SNs would be extracted for further analysis. Based on the extended SN text, the adverse event described was linked to an International Medical Device Regulators Forum (IMDRF) medical device problem code(21). These IMDRF-codes have a hierarchical alphanumerical coding structure, including a letter (i.e. referring to the Annex; A in our case) followed by numerical codes at different levels of detail(21,22). Level 1 terms were used in this study, describing 27 different problems (Table 1). This linking-process was conducted independently by two researchers (LH and YR): possible discrepancies in coding were resolved by discussion.

Table 1: List of the 27 IMDRF MD problem codes and relevant description[14]

IMDRF code	IMDRF description of medical device problem
A01 – Patient Device Interaction Problem	Problem related to the interaction between the patient and the device.
A02 – Manufacturing, Packaging or Shipping Problem	Problem associated with any deviations from the documented specifications of the device that relate to nonconformity during manufacture to the design of an item or to specified manufacturing, packaging or shipping processes (out of box problem).
A03 – Chemical Problem	Problem associated with any from the documented specifications of the device that relate to any chemical characterization, i.e. element, compound, or mixture.
A04 – Material Integrity Problem	Problem associated with any deviations from the documented specifications of the device that relate to the limited durability of all material used to construct device.
A05 – Mechanical Problem	Problems associated with mechanical actions or defects, including moving parts or subassemblies, etc.
A06 – Optical Problem	Problem associated with transmission of visible light affecting the quality of the image transmitted or otherwise affecting the intended application of the visible light path.
A07 – Electrical /Electronic Property Problem	Problem associated with the function of the electrical circuitry of the device.
A08 – Calibration Problem	Problem associated with the operation of the device, related to its accuracy, and associated with the calibration of the device.
A09 – Output Problem	Problem associated with any deviation from the documented specifications of the device that relate to the end result, data, or test results provided by the device.
A10 – Temperature Problem	Problem associated with the device producing unintended temperatures.
A11 – Computer Software Problem	Problem associated with written programs, codes, and/or software system that affects device performance or communication with another device.
A12 – Connection Problem	Problem associated with linking of the device and/or the functional units set up to provide means for a transfer of liquid, gas, electricity or data.

	A13 – Communication or Transmission Problem		Problem associated with the device sending or receiving signals or data. This includes transmission among internal components of the device to which the device is intended to communicate.	
	A14 – Infusion or Flow Problem		Problem associated with the device failing to deliver or draw liquids or gases as intended (e.g. delivering drugs at incorrect rate, problems with drawing fluid from a system). This includes vacuum collection devices and manual or mechanical pumps.	
	A15 – Activation, Positioning or Separation Problem		Problem associated with any deviations from the documented specifications of the device that relate to the sequence of events for activation, positioning or separation of device. Note: Deployment is synonymous with activation.	
	A16 – Protective Measures Problem		Problem associated with any deviations from the documented specifications of the device that relate to the implemented and inherited design features specific to devices used for reducing risks to patient or caregiver or maintaining risks within specified levels.	
	A17 – Compatibility Problem		Problem associated with compatibility between device, patients or substances (medication, body fluid, etc.)	
	A18 – Contamination /Decontamination Problem		Problem associated with the presence of any unexpected foreign substance found in the device, on its surface or in the package materials, which may affect performance or intended use of the device, or problem that compromise effective decontamination of the device.	
	A19 – Environmental Compatibility Problem		Problem associated with the surrounding conditions in which the device is being used such as temperature, noise, lighting, ventilation, or other external factors such as power supply.	
	A20 – Installation-Related Problem		Problem associated with unsatisfactory installation, configuration, and/or setup of a specific device.	
	A21 – Labelling, Instructions for Use or Training Problem		Problem associated with device markings/labelling, instructions for use, training and maintenance documentation or guidelines.	
	A22 – Human-Device Interface Problem		Problem associated with an act or omission of an act that has a different result than that intended by the manufacturer or expected by the operator.	
	A23 – Use of Device Problem		Problem associated with failure to process, service, or operate the device according to the manufacturer's recommendations or recognized best practices.	

	A24 – Adverse Event Without Identified Device or Use Problem		An adverse event (e.g. patient harm) appears to have occurred, but there does not appear to have been a problem with the device or the way it was used.	
	A25 – No Apparent Adverse Event		A report has been received but the description provided does not appear to relate to an adverse event. This code allows a report to be recorded for administration purposes, even if it doesn't meet the requirements for adverse event reporting.	
	A26 – Insufficient Information		An adverse event appears to have occurred but there is not yet enough information available to classify the device problem.	
	A27 – Appropriate Term/Code Not Available		The device problem is not adequately described by any other term. Note: this code must not be used unless there is no other feasible code. The preferred term should be documented when submitting an adverse event report. This information will be used to determine if a new term should be added to the code table.	

Registries reporting TK-outliers

Outlier TK-implants currently on the market were identified by EU registries publicly reporting on TK-outliers, as found in a systematic review(23), and non-EU registries as listed on the website of the AOANJRR(24). All registries' annual reports and websites were screened, and any reported TK-outlier was extracted. For all extracted outliers, it was assessed whether they were reported in the latest annual reports and up-to-date website, representing TK-implants currently on the market in these registries. If the outlier was not reported in the latest available registry data (i.e. not implanted in the past year in the included registries), the outlier was an off-market implant and excluded from further analysis. For all outliers, the year of first identification and its' cumulative revision risks (1/5/10-years), including standard error (SE) and/or 95% confidence interval (CI), were extracted. In case only the 95%CI was provided, the SE was calculated by subtracting the upper- and lower-95%CI and dividing it by 3,92(25).

Analysis

First, the overlap between TK-implants with SNs and outliers was determined by comparing the brand name reported in both SNs and registry data. Three groups were characterised: i) TK-implants with SNs but not identified as an outlier ("SN only"); ii) TK-implants with SNs and identified as an outlier ("both"); iii) TK-implants without SNs and identified as an outlier ("outlier only"). The percentage of TK-implants in each of these groups was related to the number of unique TK-implants identified by both SNs and registry data.

Second, to prevent camouflage (i.e. multiple compatible construct combinations existing within one implant brand name(26)), the overlap between TK-implants with SNs and outliers across different variants under the same brand name was analysed. Three variants were considered: i) fixation (e.g. cemented *versus* uncemented); ii) stability (e.g. cruciate retaining *versus* hinged), and iii) mobility (e.g. fixed *versus* mobile).

Third, to explore possible reasons for not signaling the same TK-implants we examined; i) differences in the frequency of IMDRF-codes (Table 1) between the three groups, and ii) whether the "SN only" group had lower cumulative revision risks (and thus seemingly better performance) than the "both" (SN and outlier) group, which might indicate they were not yet signalled as outliers. Random effects models were used to calculate the pooled registries cumulative revision risks (1/5/10-year) for the "SN only" group, as well as for the "both" group.

Metafor Package in R-statistics (version:4.1.2) was used for analyses.

Results

TK-implants with SNs

The CORE-MD PMS tool included a total of 104,638 SN retrieved from 13 competent authorities (Table 2) of which 1,327 SN were considered relevant as they matched with a specific TK-implant included in the list of TK-implants reported in the latest registry data. For the selected 1,327 SNs, 540 SNs were excluded because they were not related to a TK-implant (i.e. associated with surgical protocols) thus resulting in 787 SNs included for further analysis (Figure 1). These 787 SNs were relevant to 38 unique TK-implants brand names. Figure 2 shows the distribution of these SNs among the brand names and originating country, highlighting that the majority was associated with the Nexgen (Zimmer Biomet) (n=243, 31%) and SNs mainly originated from the USA (Figure 2).

Table 2: Countries included in the CORE-MD PMS tool

Country	Last update date	Safety notices (n)	Safety notices selected (n)	Safety notices on TK-implants (n)
Australia (SARA)	31/05/2023	7,208	53	29
Czechia	30/03/2023	3,135	15	7
Denmark	30/03/2023	4,652	22	11
France	12/04/2023	1,474	20	8
Germany	30/03/2023	14,544	192	87

	Greece		13/04/2023		885		5		3	
	Ireland		31/03/2023		7,096		63		27	
	Italy		29/03/2023		8,713		92		51	
	Portugal		13/04/2023		67		0		0	
	Spain		12/04/2023		3,593		25		10	
	Sweden		12/04/2023		679		2		2	
	The Netherlands		31/03/2023		3,830		35		12	
	The USA (Medical Device Recall Database)		01/04/2023		48,762		803		540	
	Total amount				104,638		1,327		787	

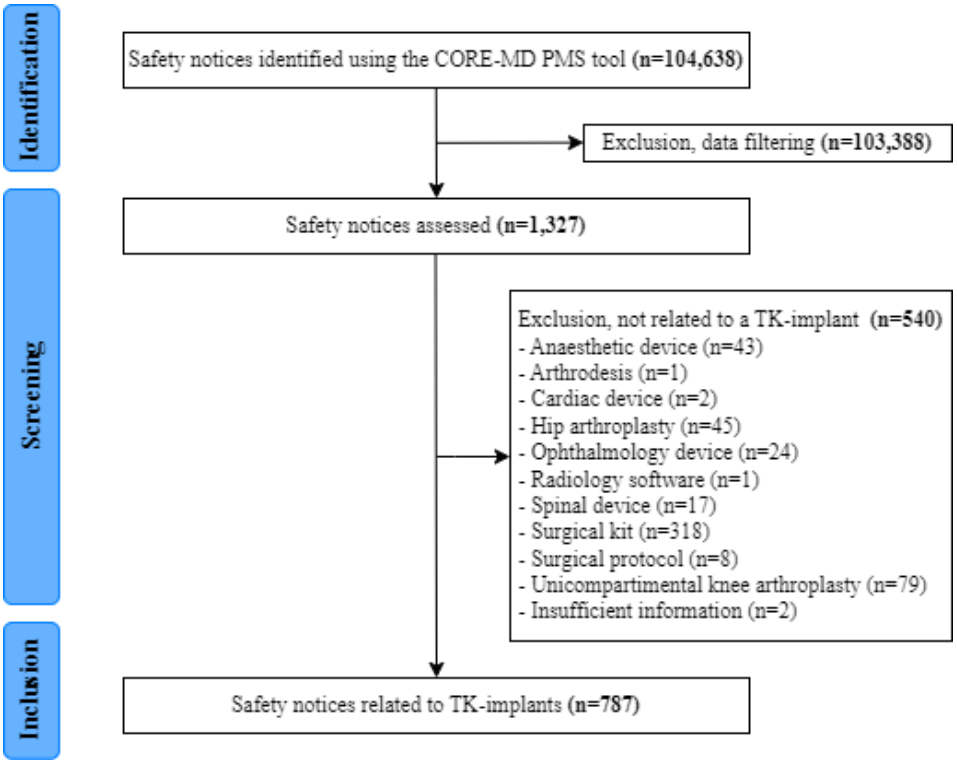


Figure 1: Flowchart showing the selection process of TK-implants with safety notices

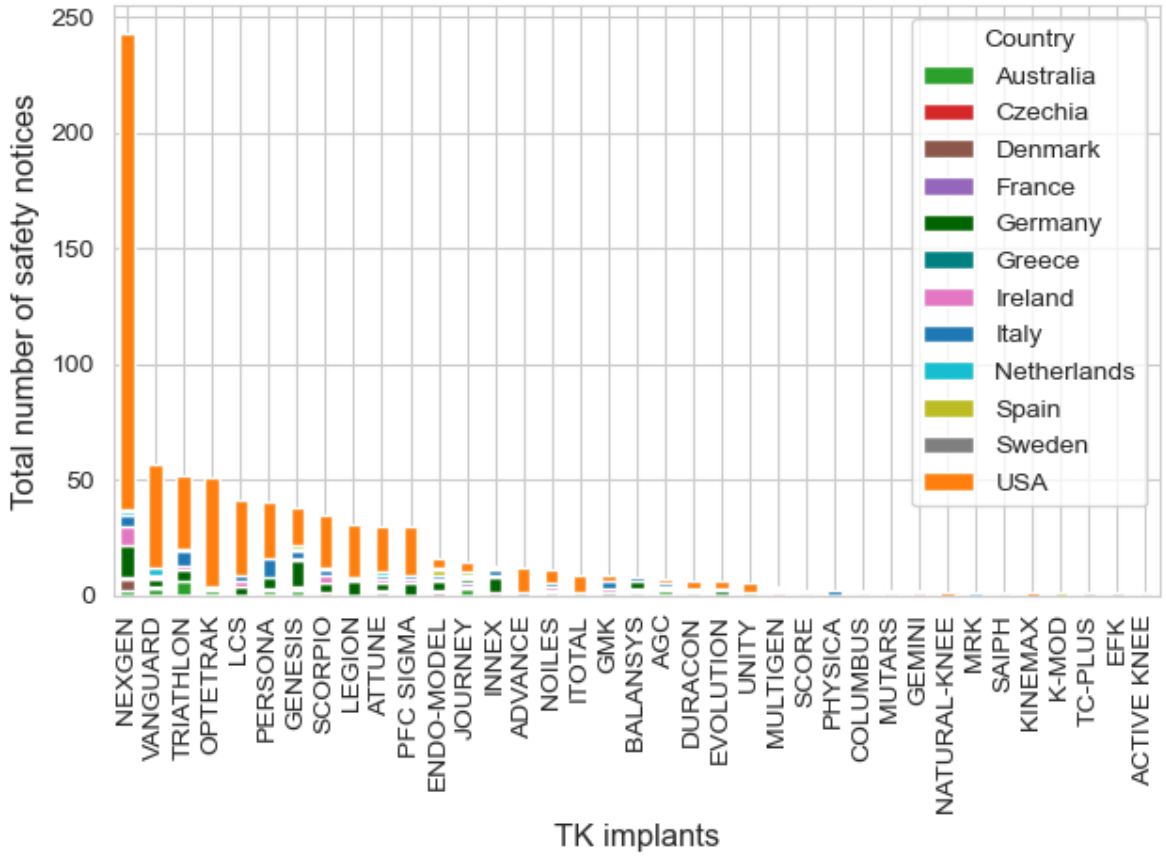


Figure 2a: TK-implants with the number of SNs by country

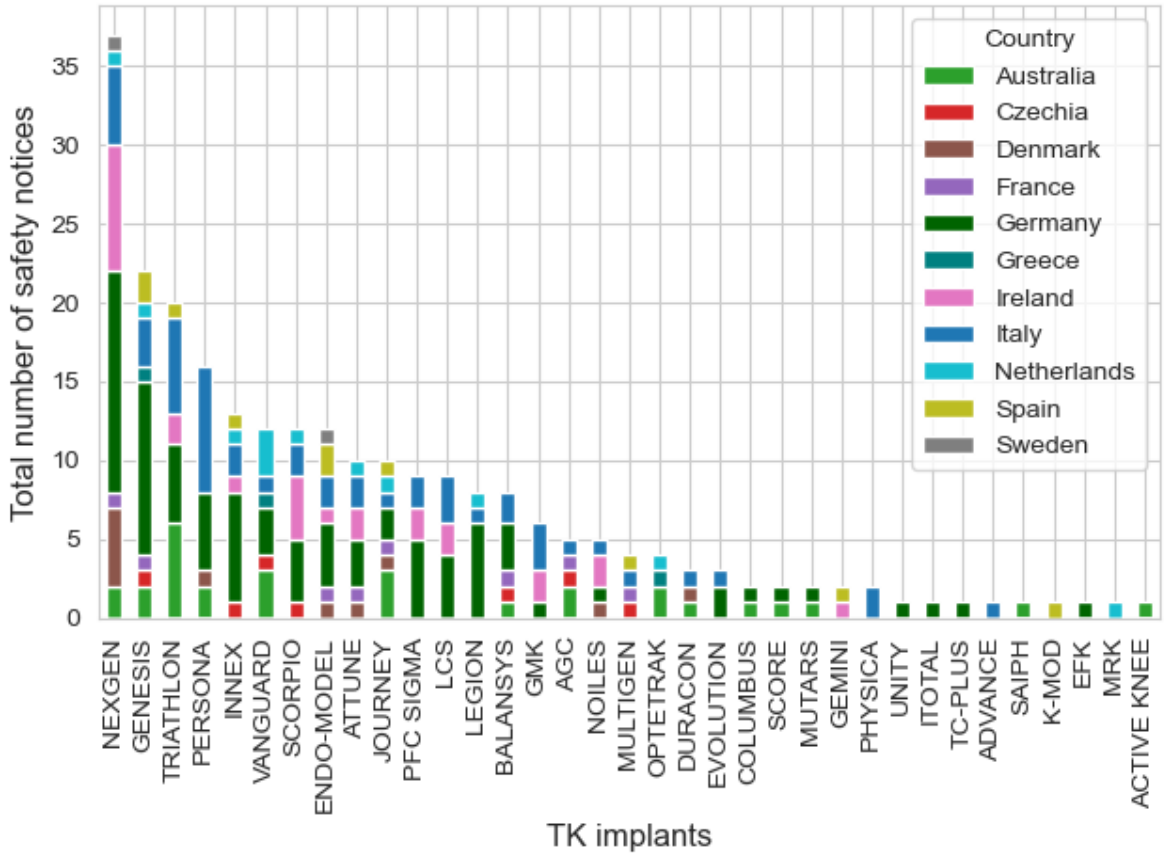


Figure 2b: TK-implants with the number of SNs by country (excluding the USA)

Outlier TK-implants

Four national registries (AOANJRR, NJR, Swedish Arthroplasty Register (SAR) and the SIRIS) reported outliers. After removing duplicate brand names (i.e. the same brand name was mentioned in more than one annual report, or multiple times across registries) and off-market outliers, 35 unique outlier brand names were included for further analysis (Table 3).

Table 3: Outlier TK-implants currently used on the market

Outlier TK-implant	Outlier Reported	Number of implants implanted (n)	Identified by the CORE-MD PMS tool (Number of SNs)
ACS	AOANJRR, NJR	2,900	No
Active Knee	AOANJRR	7,215	Yes (n=1)
Advance	AOANJRR	1,009	Yes (n=12)
AGC Anatomic	AOANJRR, SKAR	Unknown (AOANJRR: 203)	Yes (n=7)
Apex Knee	AOANJRR	513	No
Attune	AOANJRR	854	Yes (n=30)
Columbus	AOANJRR	6,334	Yes (n=2)
Duracon	SKAR	Unknown	Yes (n=6)
E.Motion	AOANJRR, NJR, SIRIS	Unknown (AOANJRR: 1,014, NJR: 339)	No
Endo-Model	NJR	309	Yes (n=16)
Gemini	AOANJRR	21	Yes (n=2)
Genesis	AOANJRR, NJR, SKAR	Unknown (AOANJRR: 826 and NJR: 9,190)	Yes (n=38)
Journey	AOANJRR, NJR, SIRIS, SKAR	Unknown (AOANJRR: 3,033, NJR: 1,714)	Yes (n=14)
Kinemax	SKAR	Unknown	Yes (n=1)
LCS	AOANJRR, NJR	5,729	Yes (n=41)
Legion	AOANJRR, SKAR	Unknown (AOANJRR: 1,017)	Yes (n=31)
Maxim	AOANJRR	413	No
METS Smiles	NJR	954	Yes (n=1)
Miller-Galante	SKAR	Unknown	No
Mutars	AOANJRR	357	Yes (n=2)
Nexgen	AOANJRR, SKAR	Unknown (AOANJRR: 2,110)	Yes (n=243)
Noiles	NJR	594	Yes (n=11)
Optetrak	AOANJRR, NJR	4,098	Yes (n=51)
Origin	NJR	Unknown	No
Persona	SKAR	Unknown	Yes (n=40)
PFC Sigma	AOANJRR, SKAR	Unknown (AOANJRR: 316)	Yes (n=30)
Physica	SIRIS	Unknown	Yes (n=2)
Profix	AOANJRR, SKAR	Unknown (AOANJRR: 1,895)	No
Rotaglide Plus	AOANJRR	631	No
Score	AOANJRR	4,686	Yes (n=2)

	Scorpio		AOANJRR		1,172		Yes (n=35)
	TC-plus		AOANJRR		63		Yes (n=1)
	Trekking		AOANJRR		1,263		No
	Triathlon		SKAR		Unknown		Yes (n=52)
	Vanguard		AOANJRR, SKAR		Unknown (AOANJRR: 6,225)		Yes (n=57)

Overlap in outliers and TK-implants with SNs

Combining the brand names of the 38 TK-implants identified by SN with the 35 outliers resulted in 47 unique TK-implant brand names (Figure 3), of which 26 (55%) were in the "both" group, 12 (26%) in the "SN only" group, and 9 (19%) in the "outlier only" group (Table 4).

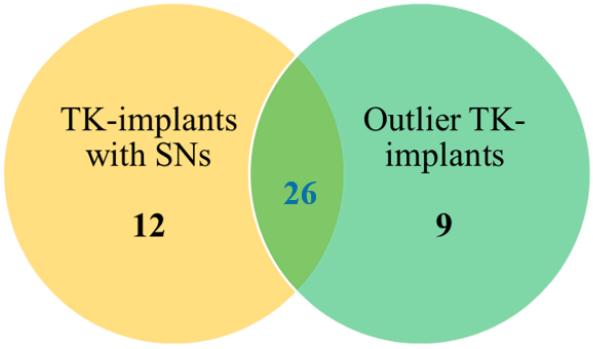


Figure 3: Overlap in SNs and registries signaling the same TK-implants

Considering the 26 TK-implants in the "both" group, 7 (27%) TK-implants did not have any information in the SN about their fixation, 9 (35%) had no information about their stability and 15 (57%) none about their mobility, which would be needed to determine whether the exact same TK-implant was concerned (White colour, Table 5). Focusing on specific variants to prevent camouflage, 5 out of 26 (19%) cemented and 6 (23%) uncemented TK-implants had the same fixation (Green colour, Table 5). Two out of 26 (8%) cruciate retaining, 2 (8%) hinged and 9 (35%) posterior stabilised TK-implants had the same stability. One (4%) fixed, 1 (4%) mobile and 5 (19%) rotating TK-implants had the same mobility. However, 14 out of 26 (54%) cemented and 3 (12%) uncemented TK-implants did not correspond to the same TK-implant based on fixation (Red colour, Table 5).

Six out of 26 (23%) cruciate retaining, 2 (8%) hinged and 7 (27%) posterior stabilised TK-implants did not correspond to the same TK-implant based on stability and 3 (12%) fixed, 5 (19%) mobile and 2 (8%) rotating TK-implants did not correspond to the same TK-implant on mobility.

Table 4: TK_implants brand names with at least one SN

Implant name	Date first safety notice	Identified as outlier	Date first identified as outlier and registry reporting the outlier	Cumulative revision (95% CI)		
				1-year	5-year	10-year
Active knee	21 October 2016	Yes	2016 (AOANJRR)	1.1 (0.9;1.4)[¥]	5.0 (4.6;5.6)[¥]	8.8 (8.1;9.5)[¥]
Advance	11 July 2016	Yes	2013 (AOANJRR)	2.0 (1.3;3.1)[¥]	6.4 (5.0;8.2)[¥]	8.1 (6.4;10.2)[¥]
AGC Anatomic	21 July 2015	Yes	2014 (SKAR)	-	-	-
Attune	29 June 2015	Yes	2023 (AOANJRR)	1.8 (1.0;3.0)[¥]	-	-
Balansys	29 January 2014	No	-	0.9 (0,5;1.2)[~§¥¶]	3.1 (2.3;3.9)[~§¥¶]	5.1 (2.2;8.1)[~¥]
Columbus	17 January 2008	Yes	2009 (AOANJRR)	1.2 (0.9;1.5)[¥]	4.4 (3.7;5.3)[¥]	7.3 (6.0;8.8)[¥]
Duracon	20 September 2007	Yes	2004 (SKAR)	-	-	-
EFK	15 April 2014	No	-	0.6 (0.1;1.2)[¶]	1.7 (0.5;3.0)[¶]	-
Endo-Model	16 April 2012	Yes	2019 (NJR)	1.3 (0.8;2.2)[†]	4.8 (3.7;6.3)[†]	7.0 (5.3;9.2)[†]
Evolution	17 February 2015	No	-	0.7 (0.3;1.1)[¥†¶•]	2.8 (2.1;3.5)[¥†•]	-
Gemini	7 September 2010	Yes	2007 (AOANJRR)	9.5 (2.5;33.0)[¥]	23.8 (10.7;48.1)[¥]	23.8 (10.7;48.1)[¥]
Genesis	9 May 2006	Yes	2004 (AOANJRR), 2018 (SKAR), 2021 (NJR)	1.0 (0.7;1.3)[¥†]	3.6 (3.2;4.1)[¥†]	5.6 (4.8;6.3)[¥†]
GMK Sphere	3 July 2017	No	-	1.1 (0.9;1.4)[¥†§¶•]	3.7 (2.9;4.5)[¥†§•]	4.3 (2.4;6.1)[¥]
Innex	25 July 2005	No	-	0.9 (0.5;1.3)[~§¶]	2.8 (2.0;3.6)[~§¶]	3.5 (2.4;4.6)[~]
iTotal	23 July 2012	No	-	0.4 (0.2;0.9)[§]	3.5 (2.5;5.0)[§]	-
Journey	3 January 2014	Yes	2009 (AOANJRR), 2018 (SKAR), 2022 (SIRIS), 2020 (NJR)	1.6 (0.1;3.1)[¥†§]	6.3 (1.8;10.8)[¥†§]	11.0 (9.9;12.2)[¥]
Kinemax	14 May 2015	Yes	2006 (SKAR)	-	-	-
K-mod	19 May 2021	No	-	-	-	-
LCS	2 December 2005	Yes	2012 (AOANJRR), 2021 (NJR)	0.9 (0.2;1.6)[¥†]	5.6 (1.8;9.5)[¥†]	7.7 (2.5;12.8)[¥†]
Legion	22 Augustus 2009	Yes	2017 (AOANJRR), 2019 (SKAR)	3.3 (2.3;4.6)[¥]	6.3 (4.8;8.3)[¥]	9.9 (7.5;13.0)[¥]
METS Smiles	17 Augustus 2016	Yes	2021 (NJR)	-	-	-
MRK	31 December 2021	No	-	0.3 (0.0;0.6)[¥†~]	1.8 (1.2;2.3)[¥†~]	3.1 (1.6;4.6)[¥†]
Multigen	12 May 2021	No	-	-	-	-
Mutars	3 April 2013	Yes	2023 (AOANJRR)	6.5 (4.2;9.9)[¥]	-	-
Natural-knee	7 November 2019	No	-	0.4 (0.2;0.7)[¥~¶•]	1.7 (1.2;2.1)[¥~¶•]	3.2 (2.4;3.9)[¥~]

Nexgen	13 September 2004	Yes	2018 (AOANJRR), 2002 (SKAR)	2.4 (1.9;3.2)[¥]	5.0 (4.2;6.1)[¥]	6.9 (5.1;9.2)[¥]
Noiles	2 March 2014	Yes	2018 (NJR)	-	-	-
Optetrak	1 June 2006	Yes	2007 (AOANJRR)	1.0 (0.0;2.1)[¥]	10.3 (4.1;16.4)[¥]	13.7 (7.0;20.4)[¥]
Persona	21 November 2012	Yes	2021 (SKAR)	-	-	-
PFC Sigma	2 December 2005	Yes	2018 (AOANJRR), 2013 (SKAR)	2.2 (1.1;4.6)[¥]	7.1 (4.7;10.5)[¥]	7.4 (5.0;10.9)[¥]
Physica	18 April 2019	Yes	2019 (SIRIS)	1.7 (1.3;2.3)[§]	6.8 (5.9;7.9)[§]	-
Saiph	25 March 2022	No	-	0,6 (0,3;1,0)[†]	1,4 (0,9;2,0)[†]	-
Score	4 October 2019	Yes	2013 (AOANJRR)	1.5 (0.8;2.2)[¥]	6.5 (5.5;7.6)[¥]	11.1 (9.3;12.8)[¥]
Scorpio	26 August 2005	Yes	2014 (AOANJRR)	1.2 (0.7;2.0)[¥]	6.1 (4.9;7.7)[¥]	7.4 (6.0;9.2)[¥]
TC-plus	10 June 2008	Yes	2008 (AOANJRR)	1.6 (0.2;10.7)[¥]	8.4 (3.6;19.1)[¥]	14.4 (7.4;26.9)[¥]
Triathlon	7 February 2007	Yes	2021 (SKAR)	-	-	-
Unity	30 September 2021	No	-	0.4 (-0.1;0.9)[¥†¶]	1.5 (0.7;2.3)[†¶]	-
Vanguard	17 October 2016	Yes	2012 (AOANJRR), 2013 (SKAR)	1.9 (1.2;2.6)[¥]	5.9 (4.7;7.1)[¥]	8.2 (6.8;9.5)[¥]

[¥]= based on revision risks as reported by the AOANJRR; [†]= based on revision risks as reported by the NJR; [T]= based on revision risks as reported by the R.I.P.O.; [~]= based on revision risks as reported by the LROI; [§]= based on revision risks as reported by the SIRIS; [¶]= based on revision risks as reported by the EPRD; [*]= based on revision risks as reported by the AJRR.

Table 5: Overlap of TK-implants in the "both" group based on fixation, mobility, and stability

	Fixation		Stability			Mobility		
Implant name	**Cemented**	**Uncemented**	**Cruciate retaining**	**Hinged**	**Posterior stabilised**	**Fixed**	**Mobile**	**Rotating**
Active knee								
Advance								
AGC Anatomic								
Attune								
Columbus								
Duracon								
Endo-Model								
Gemini								
Genesis								
Journey								
Kinemax								
LCS								
Legion								
METS Smiles								

Mutars								
Nexgen								
Noiles								
Optetrak								
Persona								
PFC Sigma								
Physica								
Score								
Scorpio								
TC-plus								
Triathlon								
Vanguard								

White: TK-implants without any information reported in the safety notice (SN) on specific fixation/stability/mobility methods. Green: TK-implants with information in the SN about its' fixation, stability, or mobility, thus overlapping with an outlier implant based on its' implant characteristic (fixation/stability/mobility). Red: TK-implants with information in the SN about its' fixation, stability, or mobility method but without overlapping with an outlier implant based on its' implant characteristics (fixation/stability/mobility).

Revision rates and implant problems

The pooled median 1-, 5-, and 10-year cumulative revision risks for the "both" group were 1.6% (range:0.9-9.5), 6.3 (range:3.6-23.8), and 8.1% (range:5.6-23.8), respectively, compared with 0.7% (range:0.3-1.2), 2.8% (range:1.4-4.0), and 3.9% (range:3.1-5.1), for the "SN only" group.

For the 26 implants in the "both" group, 728 SNs were issued with the most frequently reported problem related to "A02-Manufacturing, Packaging or Shipping" (43%), followed by "A23-Use of Device" (16%) (Figure 4a). The most frequent type of problem found was similar for the 12 TK-implants in the "SN only" group (n= 59 SNs): "A02-Manufacturing, Packaging or Shipping" (44%) (Figure 4b). By looking at differences between the two groups, for SNs related to the "both" group, problems relevant to "A05-Mechanical Problem" (6%) and "A17-Compatibility Problem" (8%), respectively, were also reported (Figure 4a). These problems were not encountered for the "SN only" group.

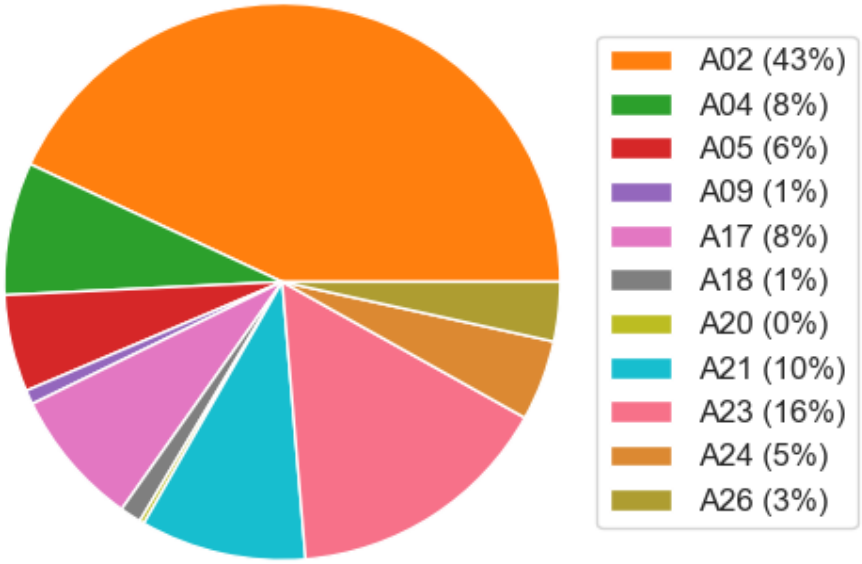


Figure 4a: IMDRF-codes for the 26 overlapping on TK-implants ("both" group) (IMDRF-codes including their description are listed in Table 1)

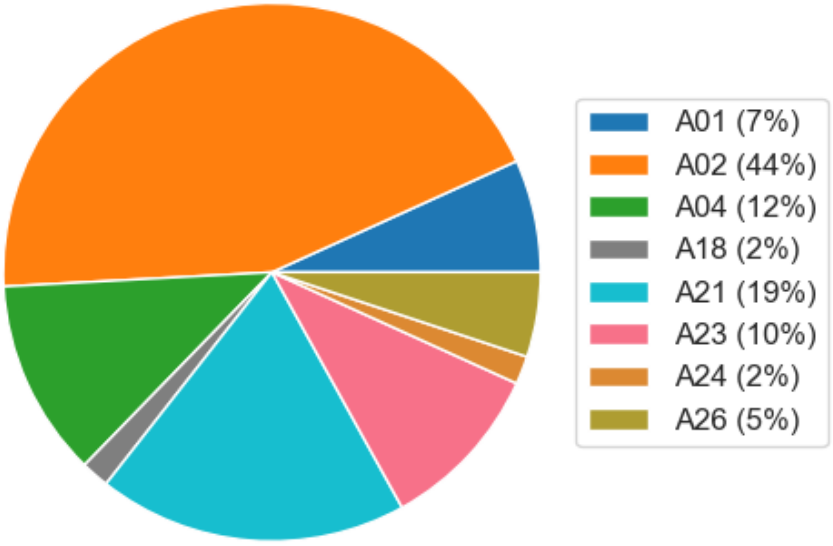


Figure 4b: IMDRF-codes for the TK-implants with SNs but not identified as outliers ("SN only" group) (IMDRF-codes including their description are listed in Table 1)

Discussion

Using the PMS tool, a multi-country analysis of the content of SNs was performed and compared to TK-outliers. Approximately half (45%) of outliers were not associated with publicly released SNs on the websites of national competent authorities. Implant problems were identified by SNs that did not manifest in an outlier status. Finally, TK-implants with both a SN and an outlier status had higher cumulative revision risks (1/5/10-year) than TK-implants with SNs only.

A recent review that assessed the current state of medical device safety signal detection, stated that a global dataset of medical device should be created using automatic reports from national/regional databases(7). In the absence of such a global dataset, the CORE-MD PMS tool was recently developed(9-11). However, our results indicate that creating a global dataset of SNs might still not identify a quarter of TK-implants with statistically-relevant poor performances (i.e. TK-outliers). Additionally, having SNs published, by itself does not constitute a sufficient and necessary condition for being identified a posteriori as outlier (the "SN only" group). However, implementing SNs as an add-on in registries may reduce potential adverse events like poor implant performance in patients. In addition, SNs related to IMDRF-codes "A05-Mechanical Problem" and "A17-Compatibility Problem" were only found in the "both" group and not encountered for the "SN only" group. This observation, once confirmed in future studies, could result in a helpful indication to highlight a higher risk for a certain TK-implant in case the malfunction reported in the SN is associated with these IMDRF-codes.

SN text does not typically include information relevant to identify specific TK-implants such as fixation, stability and mobility. This causes camouflage (i.e. multiple implant variants exist under the same implant name)(26) which makes it difficult or even impossible to link the correct TK-implants with SNs, and more generally to combine data from different data sources. This information is however tremendously important to take action. For example, if a SN only describes the name and manufacturer, then it is hard to tell which variant should be taken off the market (if needed) or that it concerns all variants. Registries also often only report TK-implants' brand name without reporting more detailed information (e.g. fixation, stabilisation and mobility) to identify which specific implant is concerned. In addition, product codes and unique device identifiers (UDIs) were also not reported in SNs or by registries, except for the American medical device recall database. Hence, we recommend minimal reporting requirements for manufacturers for SNs and also for registries to report outliers, including: full brand name, fixation, mobility, stability(28) and product codes or UDIs.

Orthopaedic registries currently only identify TK-outliers based on revision risks(23), which may take several years (at least one) before sufficient numbers are available to detect performance problems. Using revision risk may seem a relatively straightforward endpoint (the occurrence of "revision"), but both surgeon-, implant-, and patient-factors determine whether an implant is revised and between-registry variation exist regarding definitions and reasons of revision(29). Some SNs may be released based on clinical performance issues by a specific TK-implant(30). However, as demonstrated by the Optetrak, SNs can be released for several reasons and also on a case-by-case analysis (i.e. no

minimum number of implants at risk is required), meaning that SNs might provide the first signal of a possible performance problem. Hence, registries could use such a signal indicated by SNs, to analyse specific TK-implants with released SNs, so that they can observe potential adverse trends in performance earlier.

Our study is the first to assess the extent to which SNs and outlier performance in registry data are signaling the same or different TK-implants. Some study limitations should be noted. First, the CORE-MD PMS tool searched for SNs published by competent authorities, whereas manufacturers can also publish SNs on their own websites. Accordingly, we may have missed some SNs and thereby underestimated the number of TK-outliers with SNs. Second, both outliers and TK-implants not identified as an outlier had similar distribution by type of IMDRF-problem, suggesting that the IMDRF-code may not be sufficient to distinguish TK-implants with SNs and TK-implants with outlier performance. However, only the Level 1 IMDRF-problem terms were used due to the large number of SNs to be manually classified, so it might be possible to detect differences in distribution when Level 2 or 3 problem terms were used. Third, other factors such as surgeon- or hospital- performances are known to influence revisions which might skew the revision risks data. However as we used data from nine registries consisting of a large amount of TK-implants the impact of this on our results is likely to be small. Finally, our analysis does not exclude possible duplicates that are the same SNs published in different countries or for different models/lots within the country. This is because different countries use diverse formats and criteria to issue SNs: some countries issue separate SNs for each model (e.g. the USA), while others publish only one SNs with multiple models. Moreover, the aim of this study is to compare both data sources (SNs and outlier data) with each other, so excluding duplicate SNs would not have resulted in different study findings.

Conclusion

Publicly available SNs issued by manufacturers and published by competent national authorities did not address about a quarter of the outlier TK-implants identified by registries, but these SN also pointed to implants not (yet) identified by registries as outliers. This study highlights the potential of adopting a multifaceted approach, integrating various real-world data sources and methods to combine information to enhance medical device safety signal detection which would be beneficial for manufacturers, clinicians as well as competent authorities.

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A.4 Appendix 4: Paper submitted to Int J Technol Assess Health Care

Consensus recommendations to assess the quality and analysis of registry data for (post)market surveillance of medical devices

Background

Post-market surveillance is one of the crucial elements for assuring the safety and performance of medical devices. The European Medical Device Regulation (MDR) requires manufacturers to plan and conduct post-market surveillance of their medical devices (see Article eighty-three of (EU) 2017/745) (1), including the collection of real-world outcomes for patients receiving a specific medical device in clinical practice. For post-market surveillance, different data sources can be used including medical device registries (2). Notified bodies assess whether manufacturers plan and conduct post-market surveillance in a correct manner. Whereas setting up a post-market surveillance system for their device(s) is an activity carried out by manufacturers and assessing whether manufacturers plan and conduct it in a correct manner is an activity of notified bodies, market surveillance covers the activities conducted by regulators to ensure the safety and performance of medical devices placed on the market.

The systematic collection of real-world data using appropriately designed medical device registries contributes to (post)market surveillance as required by the MDR. Registries include all patients receiving a specific medical device in a geographically defined region, rather than selected patient groups (3). Registries also have the ability to capture infrequent adverse events due to the longer duration of follow-up and the large sample size. Moreover, by employing continuous benchmarking they can detect devices with outlier performance (1,3-5). There is, however, heterogeneity between registries in the definitions and methods that are employed to collect the data, in the outcomes that are included, and in publicly reporting relevant structural and methodological variables which might influence the quality of the collected data (3). As a result, although tools and regulatory guidelines exist to assess the quality of registry data (6,7), it is difficult to judge their regulatory utility. The heterogeneity also makes it difficult to combine high-quality data from multiple registries for timely detection of safety concerns for specific medical devices. International regulators have produced guidance on usability and methodological principles (8,9) and the Food and Drug Administration (FDA) indicated relevance and reliability as the key factors to assess real-world data (10). What is lacking however is more prescriptive and detailed guidance on which items should be considered by regulators, notified bodies and manufacturers to assess the quality and analysis of registry data. Agreeing upon a minimum dataset of items that medical device registries should publicly report would assist manufacturers in their selection of data to be used for post-market surveillance, and allow regulators to determine whether the data may be reliable for the evaluation of medical device safety and performance during market surveillance.

The aim of this study therefore was to achieve consensus across all stakeholders on a minimum dataset of items that is necessary to judge: i) the quality of registry data, and ii) the quality of analysis of medical device safety and performance, for evaluation during (post)market surveillance.

Methods

Study design

A three-round Delphi method, consisting of two online surveys and one online consensus meeting (Figure 1) was used to achieve consensus amongst experts in the evaluation of medical device safety and performance. The Delphi method is a validated method that can be used to transform individual opinions into group consensus (11).

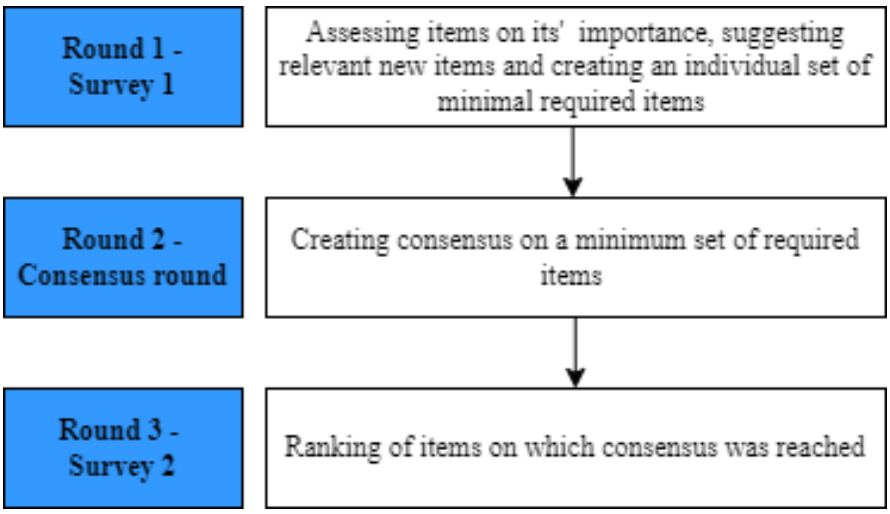

Figure 1: Flowchart showing the consensus-process

In round one, participants were asked to select items from an initial set of twenty-seven items identified through literature review and expert advice (3). Of the twenty-seven items, seventeen related to the quality of registry data and ten concerned the quality of analysis of medical device safety and performance (Table 1). The set of initial items was listed in an online survey and participants were asked to indicate using a Likert scale whether each item was: i) not important, ii) somewhat important, or iii) very important. All items rated as "somewhat important" and "very important" were fed into the second step, as the starting point for participants to create their own minimum dataset. For each item, participants were asked if the item was "required" or "not required" in the minimum dataset. In the third step, participants could suggest new items that they considered necessary. The first author (LH) extracted all newly suggested items and harmonised similar items with different wording between participants.

Items concerning quality of registry data	Items concerning analysis of medical device performances
1. Initial motivation/goal to set up the registry	1. Methods for handling missing data described (e.g. missing procedures will be sent every 3 months to each hospital department and request for data entry/missing data is considered as missing completely at random)
2. Design (e.g. regional/national/multi-country)	2. Time period in which devices were implanted
3. Starting year (year of first patient/procedure included)	3. Minimum number of patients/procedures at risk required for analysis of performance
4. Mandatory (mandatory for surgeons/hospitals to submit data to the registry; yes/no)	4. Minimum number of hospitals in which the device is used required for analysis of performance
5. Patients' consent (patients' consent required before entering their data to the registry; required/not required)	5. Minimum number of surgeons using the device required for analysis of performance
6. Funding (public/private/both)	6. Minimum follow-up duration required for analysis of performance
7. Who can access the data and see results? (e.g. public access/only to members)	7. Approach to analyse performance (e.g. assessing superiority/non inferiority in a relative benchmark/using an absolute benchmark defined by objective performance criteria)
8. Privacy regulation for patients' identifiable information (privacy regulation reported as implemented: yes/no? And if yes: how?)	8. Adequate analysis to adjust for confounding (by indication) (e.g. propensity scores)
9. Data capture and collection method (e.g. electronic/manual/barcodes-industry/surgeon-reported)	9. Definition of outcome analysed
10. Method of access to registry for users/members (e.g. dashboard/real-time/secure server)	10. Definition of outlier performance
11. Level of information provided (data is reported at hospital-/medical device-/surgeon-level)	
12. Data linkage with other sources (e.g. registry data is linked to hospital statistics/manufacturer vigilance data/national competent authority on medical devices)	
13. Quality assurance system defined/quality check of data (e.g. data verification)	
14. Missing data for patients' characteristics reported (%) (e.g. BMI/ASA classification/gender)	
15. Completeness of procedures: number of procedures captured in registries relative to total number of procedures (%)	
16. Coverage: number of participating hospitals relative to the total number of eligible hospitals (%)	
17. Registry collects Unique Device Identifier (UDI)	

Table 1: Initial items concerning quality of registry data (17 items) and concerning analysis of medical device performances (10 items)

As input for the online consensus meeting (round two), LH calculated for each the percentage of experts who had included this item in their minimum dataset; those selected by at least 70 percent of all participants were defined as indicating consensus (12). By email, each participant then received a report detailing which items had reached consensus, together with their individual dataset with information on how often the remaining items (i.e. items not reaching consensus) appeared in the datasets across all participants. During the online consensus meeting, LH first presented the items on which consensus was reached. All remaining items that were included at least once in an individual dataset as well as newly suggested items were then discussed. The discussion was chaired by PMvdM. After initial discussion on a specific item, a poll was created with the following question: "Is this item needed in addition to those items already selected in the minimum dataset?" with two possible answers: i) "yes, it is required" and ii) "no, it is not required". As before, consensus was defined as ≥70 percent of participants voting for the item be included in the dataset (12). If <70 percent of the participants considered that the item was required, the item was discussed until consensus was reached to either include or exclude the item from the dataset. Participants also had the option to rephrase items on which no consensus was reached,

followed by a poll of the rephrased question. This resulted in a final minimum dataset across all participants.

In round three (survey two), participants were asked to rank the items on which consensus had been achieved. A total of 100 points had to be allocated across all items related to the quality of registry data, and another total of 100 points across all items concerning the quality of analysis of medical device safety and performance. More points reflected greater importance. This method was used as it forces participants to choose between the items rather than merely rating all items as very important, since there is evidence that other rating scales (such as visual analogue scores) have limited capacity to differentiate between items (13). Having an average rank for each item may subsequently guide regulators, notified bodies and manufacturers how much weight they should place on an item, as in practice a registry may score poorly on one item but higher on another.

Survey development

The two online surveys were developed by LH using Sawtooth (Sun Valley, Idaho, the United States of America (USA)) and survey links were distributed via e-mail. Both surveys were first piloted by seven PhD students to ensure clear comprehensibility and reliability of the questions. The students provided comments which resulted in several (small) adjustments, and both adjusted surveys were tested again by the group of PhD students.

Expert panel recruitment

A total of 101 European experts, divided into four groups of stakeholders, were invited to participate in our Delphi panel: i) thirty regulators and notified body representatives, ii) twenty-eight healthcare professionals particularly from the orthopaedic and cardiovascular field as together they represent the majority of high-risk medical devices (14), iii) twenty-four experts involved in (national) registries, and iv) nineteen methodological experts (e.g. on analysis of medical device safety and performance). The aim was to include at least ten participants per stakeholder group to ensure sufficient sample size and distribution across groups. Experts had two weeks to complete each survey. If experts did not complete the survey within this timeframe, LH sent a reminder to those who had not yet responded to give them another opportunity to complete the survey within two weeks. If they did not respond to the first survey after four weeks, they were considered non-respondents and excluded from further participation. If participants completed the first survey but did not participate in the consensus round (round two), their input in the first survey was still used in the consensus round to calculate the percentage consensus. These participants were also invited to participate in round three (the second survey).

Data analysis

Descriptive statistics were used to report the response rates in all three rounds; the response rate for round one was calculated as the percentage of participants filling in the first survey relative to all invited

experts. Response rates for round two and three were calculated as the percentage of those participating in round one. For each of the twenty-seven items, the percentage of participants voting "required" was calculated in round one. For round three (survey two), the total sum of points and the mean number of points assigned to each item were calculated. For each item, we calculated their relative weight (i.e. importance) by dividing the mean number of points assigned to that item by the number of expected points if all items had equal weight (i.e. 100 / total number of items to be ranked).

For each participant filling in the online surveys, the time to complete the survey was extracted. Consequently, the median time to complete the online surveys was calculated, together with the corresponding inter quartile range (IQR).

Analyses were performed using Microsoft Excel (Redmond, USA).

Results

Of the 101 experts invited for the Delphi Panel, 51 experts (50 percent) completed round one (survey one), of whom 30 (59 percent) participated in the consensus meeting (round two) and 38 (75 percent) completed round three (survey two) (Supplementary Table 1). The median time to complete the first survey was 8 minutes (IQR: 6 to 19 minutes) and for the second survey 7 minutes (IQR: 5 to 11 minutes).

Round one – selecting an individual minimum dataset

Consensus was achieved on ten of the seventeen (59 percent) data quality items and eight of the ten (80 percent) items concerning the quality of analysis of medical device safety and performance (Supplementary Figure 1A). The top three data quality items most frequently selected in individual minimum datasets were: i) the completeness of procedures (96 percent); ii) the level of information provided (92 percent), and iii) the quality assurance system defined/quality check of data (90 percent). For items concerning the quality of analysis of medical device safety and performance, the top three were: i) the definition of outcome analysed (98 percent); ii) the time period in which devices were implanted (94 percent), and iii) the approach to analyse performance (92 percent) (Supplementary Figure 1B). A total of eleven new data quality items and one quality of analysis item were suggested (Supplementary Table 2).

Round two – creating consensus on a minimum dataset

During the online consensus meeting, the remaining seven data quality items were discussed (Supplementary Figure 1A). During the discussion, two items (items number seven and ten from Table 1) were combined into one item "reporting on procedures how to apply for data, who can access and use the data" which resulted in consensus (100 percent of participants voted for inclusion, Supplementary Figure 2A). In addition, item number five from Table 1 on patients' consent was rephrased for better interpretation into "reporting how patient consent is managed and for which purposes" which then

resulted in consensus (86 percent of participants voted for inclusion in the minimum dataset, Supplementary Figure 2A).

Of the eleven newly suggested data quality items, only three items were discussed because none of the participants felt that any of the other eight items added sufficiently to the minimum dataset. The three items that were discussed were: i) "clearly defined patient inclusion/exclusion criteria"; ii) "important confounders/risk factors/exposures, with potential impact on outcome have been identified and recorded", and iii) "reporting how validation of the standard is achieved". Only the first item on patient selection reached consensus (76 percent of participants voted for inclusion, Supplementary Figure 2B). In total, participants voted on nine data quality items of which five items were included in the minimum dataset (Supplementary Figure 2B).

For items concerning the quality of analysis of medical device safety and performance, two remaining items (Supplementary Figure 1B) and one newly suggested item were discussed but none of these was included in the minimum dataset (Supplementary Figure 2B).

Combining the findings of Delphi rounds one and two, Table 2 shows the minimum dataset upon which consensus was achieved, which includes fifteen items concerning quality of registry data and eight items concerning the analysis.

Items concerning quality of registry data	Items concerning analysis of medical device performances
1. Design (e.g. regional/national/multi-country)	1. Methods for handling missing data described (e.g. missing procedures will be sent every 3 months to each hospital department and request for data entry/missing data is considered as missing completely at random)
2. Mandatory (mandatory for surgeons/hospitals to submit data to the registry; yes/no)	2. Time period in which devices were implanted
3. Reporting how patient consent is managed and for which purposes	3. Minimum number of patients/procedures at risk required for analysis of performance
4. Funding (e.g. public/private/both)	4. Minimum follow-up duration required for analysis of performance
5. Reporting on procedures how to apply for data, who can access and use the data	5. Approach to analyse performance (e.g. assessing superiority/non-inferiority in a relative benchmark/using an absolute benchmark defined by objective performance criteria)
6. Privacy regulation for patients' identifiable information (privacy regulation reported as implemented: yes/no? And if yes: how?)	6. Adequate analysis to adjust for confounding (by indication) (e.g. propensity scores)
7. Data capture and collection method (e.g. electronic/manual/barcodes-industry/surgeon-reported)	7. Definition of outcome analysed
8. Level of information provided (e.g. data is reported at hospital-/medical device-/surgeon-level)	8. Definition of outlier performance
9. Data linkage with other sources (e.g. registry data is linked to hospital statistics/manufacturer vigilance data/national competent authority on medical devices)	
10. Quality assurance system defined/quality check of data (e.g. data verification)	
11. Reporting missing data for all patients' characteristics in registry (%) (e.g. age/gender/BMI/ASA classification)	
12. Completeness of procedures: number of procedures captured in registries relative to total number of procedures (%)	
13. Coverage: number of participating hospitals relative to the total number of eligible hospitals (%)	
14. Collecting Unique Device Identifier (UDI)	
15. Reporting on patient inclusion/exclusion criteria (i.e. patient selection)	

Table 2: Items included in the minimum required dataset

Round three – ranking items included in the minimum dataset

Given that fifteen data quality items were selected, the number of expected points assigned if all items were equally important was 6,67. Of all data quality items, the item "completeness of procedures" was deemed most important for reporting, with a total sum of 421 points assigned across participants (mean per participant 11,1 with standard deviation (SD)=10,3), resulting in a relative weight of 1,66 (Supplementary Figure 3A). The item "reporting missing data for all patients' characteristics in registry (%)" was the second most important, with a total of 334 points (mean 8,8 (SD=4,4) relative weight 1,32). The item with the lowest number of points assigned was: "privacy regulation for patients' identifiable information" with 146 (mean 3,8 (SD=3,0) relative weight 0,58).

As eight data analysis items were selected, the number of expected points assigned if all items were equally important was 12,5. Most points were assigned to "definition of outcome analysed" with a total of 580 (mean 15,3 points (SD=6,1) and relative weight 1,23) followed by "minimum number of patients/procedures at risk required for analysis of performance" (534 points; mean 14,1 (SD=7,2) and relative weight 1,13) (Supplementary Figure 3B). The lowest number of points was assigned to the item "definition of outlier performance" with 420 (mean 11,1 points (SD=5,3) with a relative weight of 0,88).

Discussion

This Delphi study, utilising a large panel of European experts involved in the evaluation of medical devices, achieved consensus on a minimum dataset of fifteen items concerning quality of registry data and eight items concerning the quality of analysis of medical device safety and performance. Of all items included in the dataset, "completeness of procedures" and "definition of outcome analysed" were deemed most important for data quality and quality of analysis respectively. Publicly reporting by registries of this minimum dataset consisting of twenty-three items will allow regulators, notified bodies and manufacturers to better judge the utility of registry data for evaluation of medical devices during (post)market surveillance.

This is the first study to create a minimum required dataset consisting of items on structural and methodological characteristics of registries that are important to judge the quality of the data. Previous initiatives have focused on achieving common definitions and outcomes across registries to increase uniformity of the data collected (6,15-18). The International Medical Device Regulators Forum (IMDRF) has produced guidance on assessing the usability of registries and methodological principles for performing clinical evaluation and signal detection using registry data (8,9) and other reports emphasized the importance of data completeness and accuracy (19,20), to which our minimum dataset adds more detail. Compared with the FDA guidance (10), several items are similar, such as common data capture, data verification procedures and data completeness. Our minimum dataset includes additional items such as reporting on the funding source and the definition of outlier performance. Achieving consensus on items for registries to report in order to judge the quality of registry data and analysis of medical device safety and performance is an important first step. Our minimum dataset does not make clear what

constitutes sufficient quality data, particularly when good scores on some items are combined with worse scores on others. The ranking provided in the current study may guide regulators, notified bodies and manufacturers on which quality items should be assigned most weight.

Decision framework to assess the safety and performance of medical devices

The aforementioned FDA guidance document states that the two key factors for assessing real-world data are "relevance" and "reliability" (10). Under the key factor "relevance" it is listed that: i) “real-world data should contain sufficient detail to capture the use of medical devices, exposure, and the outcomes of interest in an appropriate population”; ii) “the use of a specific medical device in a real-world population should be representative as captured within the data source, and is generalizable to the relevant population being evaluated”, and iii) “available data elements should be able to address the question at hand when valid and appropriate methods are used”. "Reliability" covers various aspects of data collection (e.g. common definitions and a relevant time window) but also data quality such as adherence to verification procedures.

The National Institute for Health and Care Excellence (NICE) framework in the United Kingdom is not exclusively designed for regulatory decision-making nor does it solely concentrate on medical devices (19). Instead, it encompasses a broader spectrum of real-world data sources, including medical device registries, to support those developing evidence to inform NICE guidance. The framework highlights that real-world data should be “of good provenance, relevant and of sufficient quality to answer the research question”, and that evidence should be generated in a transparent way while using “analytical methods that minimize risk of bias and characterize uncertainty”. Under data provenance, they consider knowledge about the purpose and methods of data collection to be important, as well as data coverage and governance. Relevance focuses on generalizable and robust results, where completeness and accuracy are key factors considered for data quality.

In both frameworks, rather general descriptions are given with some examples, they also indicate that other factors may be considered, and that contextual factors may determine the acceptability of the evidence (e.g. high-quality evidence may be more challenging to generate for rare diseases and devices). Thus both frameworks do not specify a minimum dataset of what registries should report to allow regulators and manufacturers to assess the safety and performance of medical devices. We therefore mapped the items on which consensus was achieved in the current Delphi study, to the more generic principles and domains found in these two national frameworks. This resulted in a decision framework that may assist regulators when assessing the safety and performance of medical devices for market surveillance as well as manufacturers when using registry data for post-market surveillance (Figure 2).

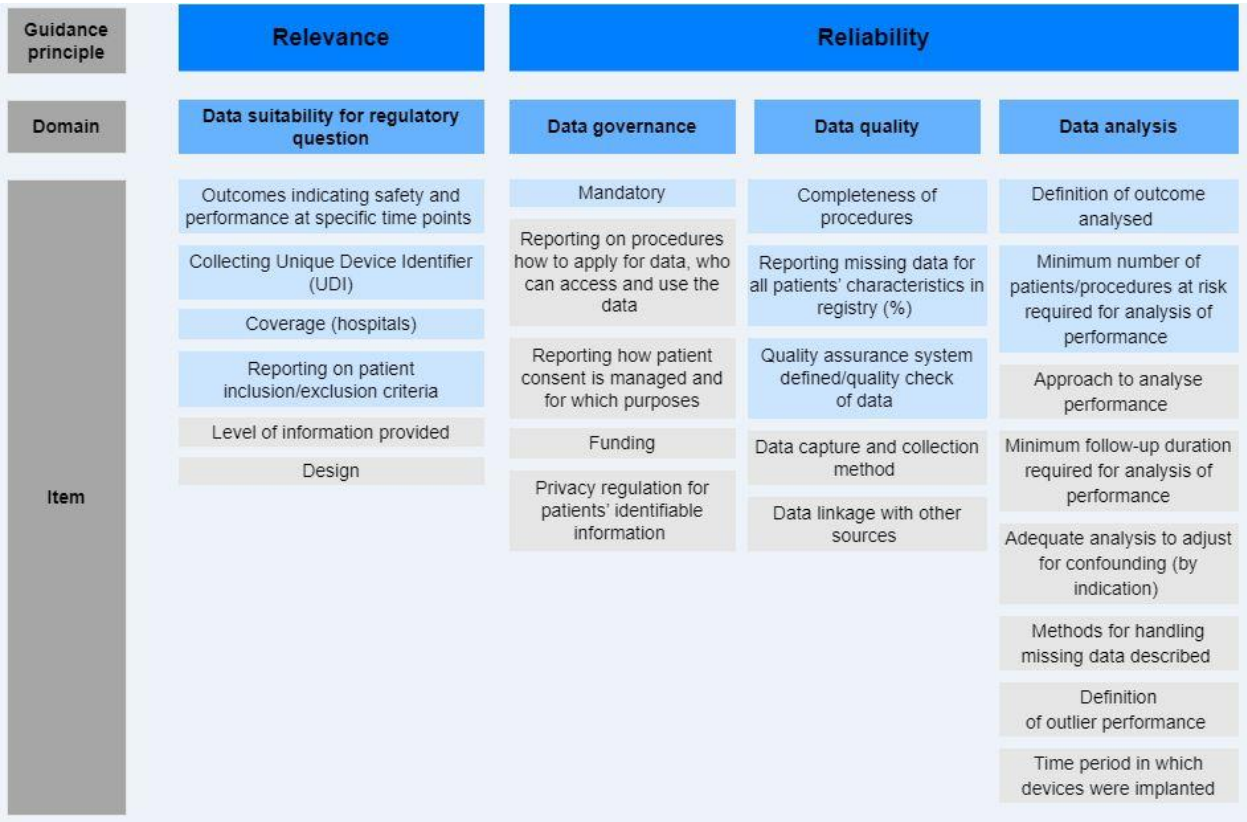

Figure 2: Decision framework to assess safety and performance of medical devices (the items listed in light grey scoring lower than expected and the items listed in light blue higher than expected, based on their relative weight)

The framework uses relevance and reliability as the guiding principles, consistent with previous FDA guidance. Within these principles, we distinguished four domains: data suitability (six items), data governance (five items), data quality (five items) and data analysis (eight items). The outcome of interest at specific time-points was added because of the large heterogeneity found in a previous systematic review in outcomes and time-points captured by registries, and because of the lack of clarity which of these outcomes could be included to calculate the benefit-risk ratio for the intended purpose of a particular medical device (3). If all these factors are explored and found to indicate good quality data and analysis, particularly for the items deemed most important (indicated in blue), then such real-world evidence can be considered trustworthy.

Strengths and study limitations

Our study comprised a large representation of European experts involved in the evaluation of medical devices and the management of national registries. It included good representation across multiple groups of stakeholders. Our results are therefore likely to reflect the opinion of other European experts

in the field of regulatory evaluation of medical devices. Nonetheless, some study limitations should be noted. First, we only included experts proposed from the professional network of the Coordinating Research and Evidence for Medical Devices (CORE-MD) research group, which consisted solely of European experts. Hence, the recommendations drawn from our study may not be generalisable to non-European countries. A broader inclusion of non-European experts may increase the external validity of the minimum dataset. Second, there might be selection bias as only 51 percent of the invited experts participated in round one, with fewer participants in the last two rounds. These response rates are lower than the Delphi Panel guidelines (12). We believe that the response rates did not relate to the length of the surveys, as they were relatively short (median times to complete the surveys were less than 8 minutes). Despite the relatively low response rates, our Delphi Panel is still in line with sample size recommendation for a Delphi Panel, namely: as small as three members or as large as eighty, whereby a sample of approximately fifteen participants is recommended (12,21,22). Importantly, there was a balanced participation by all stakeholder groups in all rounds. Third, no manufacturers were invited to participate in our Delphi, as they are not included in the CORE-MD network and may be influenced by other (commercial) incentives. Last, the time to respond in the Delphi round one and three (survey one and two, respectively) was limited, namely four weeks. However, as three-quarters (thirty-nine out of fifty-two) of the respondents in round one (survey one) also completed the second survey, the effect of this time limit seems to be negligible.

Perspective and future research

The items listed in our proposed dataset are relatively easy to report publicly, as most medical device registries will include these items already. The practical implementation of the minimum required dataset has not been tested, so both its usefulness and effectiveness is currently unknown, indicating that further research is needed to evaluate the experience with the proposed minimum dataset. Further research can determine the thresholds to be used to indicate sufficient quality data, for each item as well as for combinations, given that registries could score "sufficient" on one item, but "insufficient" on another.

Our aim is that the proposed minimum dataset will be implemented by registries, not only for the benefit of regulators, notified bodies and manufacturers, but also to improve data comparison and interoperability between registries. Combining data from medical device registries is crucial to detect any safety and performance concerns related to medical devices as early as possible, in order to prevent patient harm, which will only be achieved if the data are of sufficient quality.

Conclusions

Registries reporting publicly on the proposed fifteen items regarding the quality of registry data and the eight items concerning the quality of analysis will allow regulators, notified bodies and manufacturers to better judge the utility of registry data for evaluation of medical devices during (post)market

surveillance.

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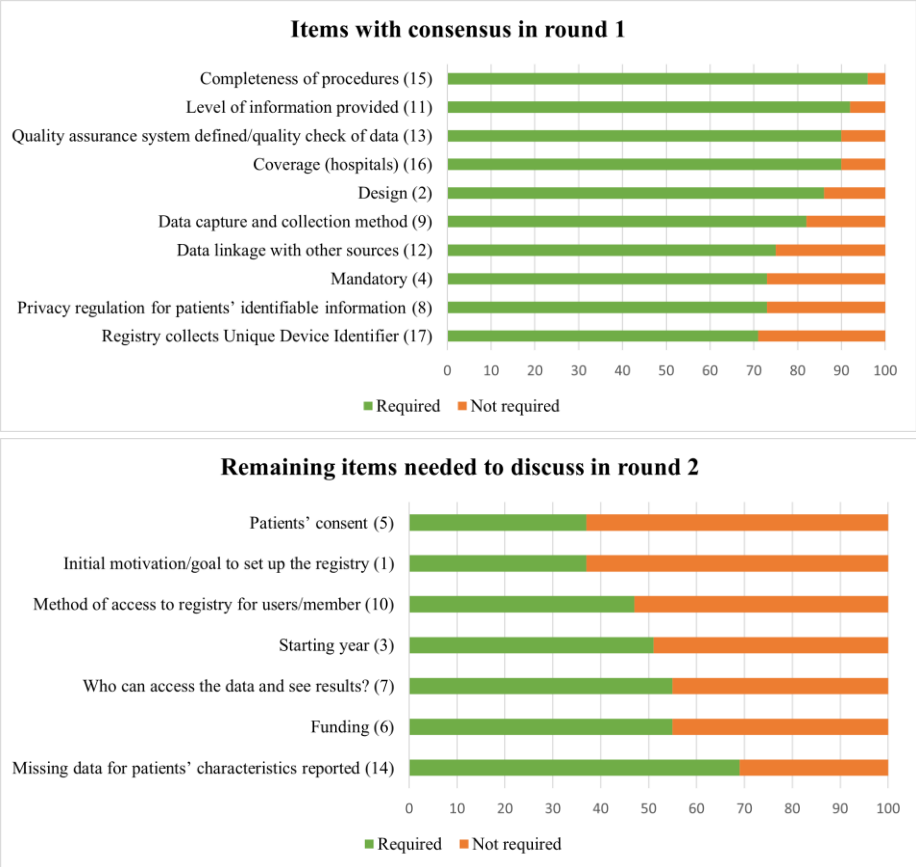
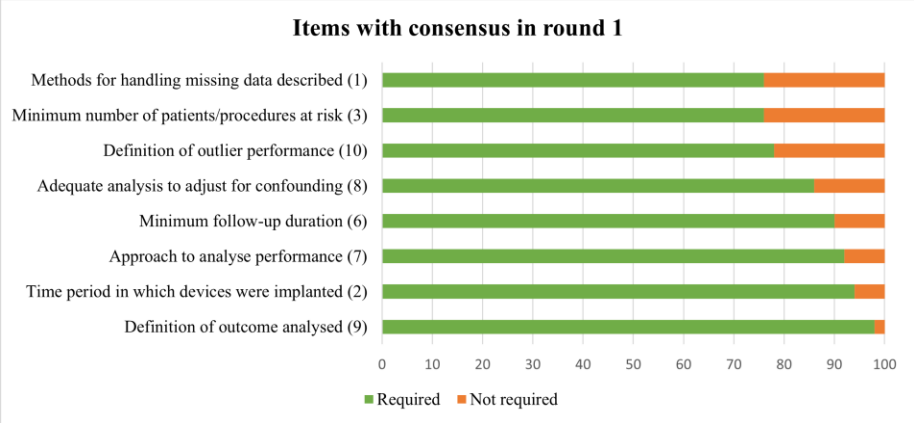
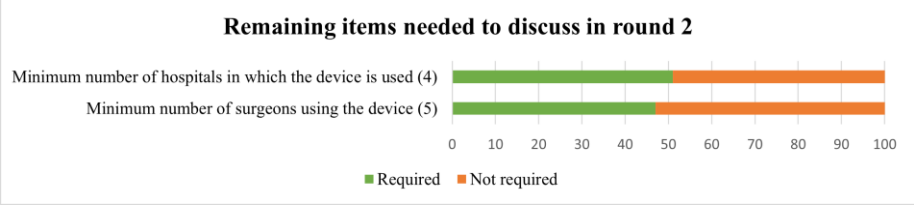
	Delphi round one (survey one)				Delphi round two (consensus-round)				Delphi round three (survey two)		
	Experts invited (n)	Participants (n)	Response rate (%)		Experts invited (n)	Participants (n)	Response rate (%)		Experts invited (n)	Participants (n)	Response rate (%)
Healthcare professionals	28	17	60.7		17	9	52.9		17	14	82.4
Methodological experts	19	9	47.4		9	5	55.6		9	9	100
Registry experts	24	10	41.7		10	6	60.0		10	8	80.0
Regulators and notified body representatives	30	15	50.0		15	10	66.7		15	7	46.7

Supplementary Table 1: Participants and response rates for each Delphi round



Supplementary Figure 1A: Frequency by which items concerning quality of registry data were selected in individual minimum datasets (the number listed behind the item corresponding with the item number as listed in the initial set of items (Table 1))

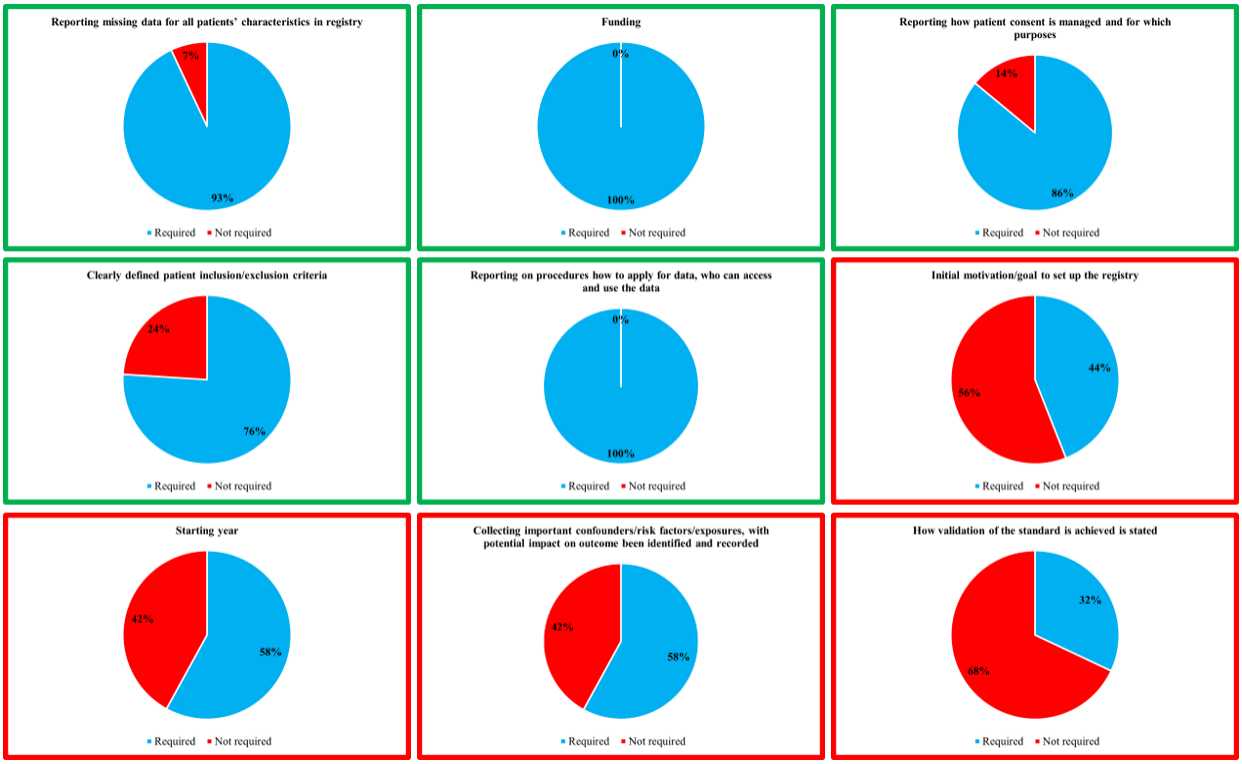




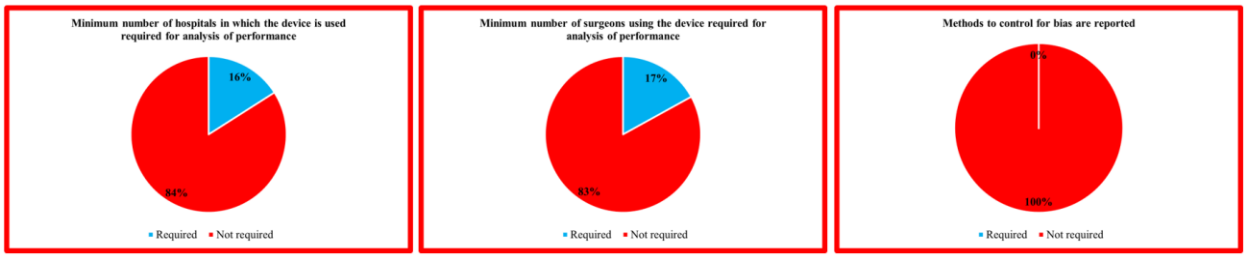
Supplementary Figure 1B: Frequency by which items concerning the quality of analysis of medical device safety and performance were selected in the individual minimum datasets (the number listed behind the item corresponding with the item number as listed in the initial set of items (Table 1))

Newly suggested items concerning the quality of registry data
Type of registry (intervention registry or disease registry)
Objective and research question clearly identified
Clearly defined patient inclusion/exclusion criteria
Including a broad range of patients, to facilitate sub-group analysis
Collecting important confounders/risk factors/exposures, with potential impact on outcome been identified and recorded
Collection of information regarding medication
Set up clear predefined pass/fail criteria (i.e. which outcome value is favourable and which is unfavourable)
The registry foresee to report safety events in line with applicable regulatory requirements
The maturity of the medical device class in relation to the technology development
Collecting surgical techniques- technology assistance during surgery
How validation of the standard (e.g. financial data from the hospitals, nationally collected routine admin data) is achieved is stated (e.g. so that the user can understand whether a claim of e.g. '100% compliance' is likely to be valid)
Newly suggested items concerning the quality of analysis of medical device safety and performance
Methods to control for bias are reported

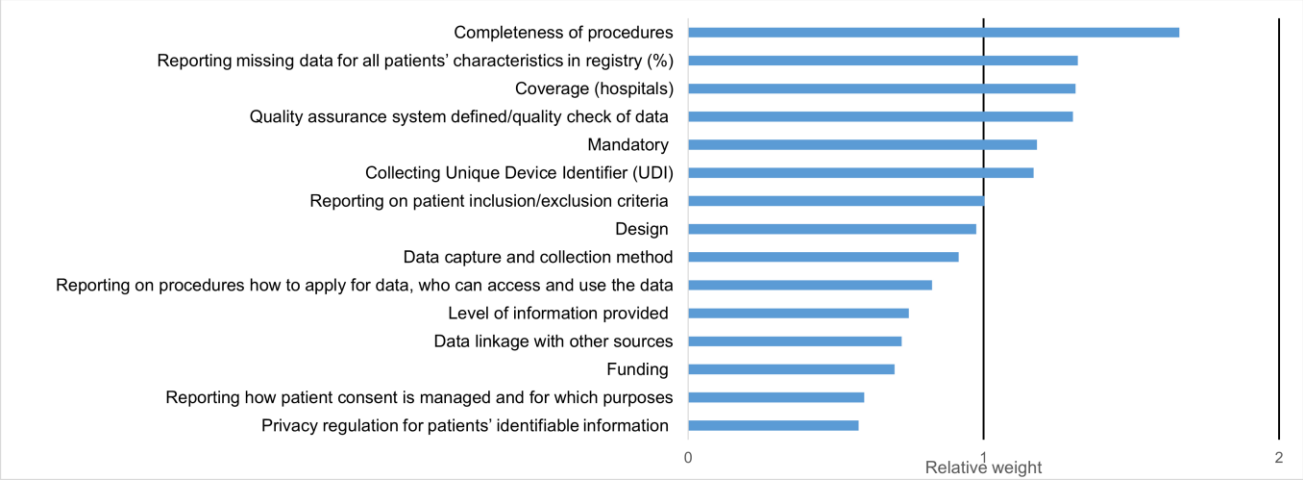
Supplementary Table 2: Newly suggested items in round one



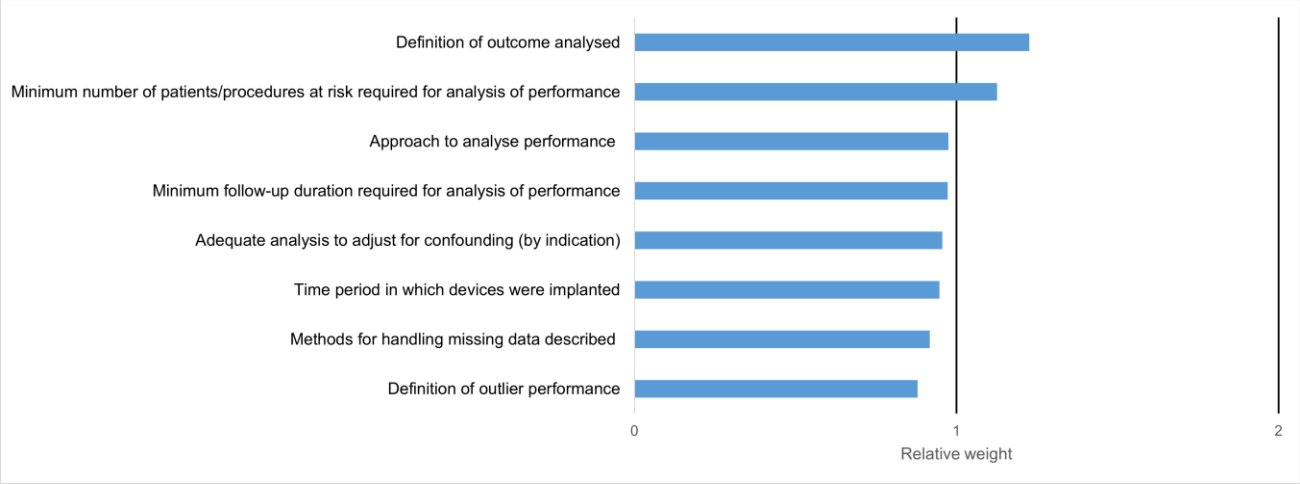
Supplementary Figure 2A: Results from the consensus meeting (round two) – quality of registry data items with no consensus in round one to be included (green box) or excluded (red box) to the minimum dataset, with voting percentages for each item



Supplementary Figure 2B: Results from the consensus meeting (round two) – quality of analysis items with no consensus in round one to be included (green box) or excluded (red box) to the minimum dataset, with voting percentages for each item



Supplementary Figure 3A: Ranking of importance of selected items in the minimum dataset – items related to quality of registry data



Supplementary Figure 3B: Ranking of importance of selected items in the minimum dataset – items related to quality of analysis

CORE-MD

CORE-MD, Coordinating Research and Evidence for Medical Devices, aims to translate expert scientific and clinical evidence on study designs for evaluating high-risk medical devices into advice for EU regulators.

For more information, visit: www.core-md.eu

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