BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-019039
Article Type:	Research
Date Submitted by the Author:	09-Aug-2017
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Primary Subject Heading:	Cardiovascular medicine
Secondary Subject Heading:	Health services research, Public health, Qualitative research
Keywords:	cardiac implant, high-risk device, implant registry, real-world

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Cardiac implant registries 2006-2016: a systematic review of global practices

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Abstract:

OBJECTIVES: The importance of cardiac implant registry (CIR) for ensuring a long-term follow-up in post-marked surveillance has been recognized and approved, but there is lack of consensus standards on how to establish a CIR. The aim of this study is to investigate the structure and key elements of CIRs in the past decade (2006-2016), and to provide recommendations on "best practice" approaches.

SETTINGS AND PARTICIPANTS: A systematic search on CIR was employed in line with the PRISMA guidelines. The following databases were searched: the PubMed (Medline), ScienceDirect and the Scopus database, EMBASE. After identifying the existed CIR, an inductive approach will be used to explore key elements emerging in the identified registries.

RESULTS: The following 82 registries were identified: 18 ICD registries, 7 CRT registries, 5 pacemaker registries, and 6 Cardiovascular Implantable Electronic Device (CIED) registries which combined ICD, pacemaker and CRT implantation data; as well as 22 coronary stent registries and 24 TAVI registries. While 71 national or local registries are from a single country, 44 are from European countries, and 9 are located in USA. The following criteria have been summarized from the identified registries, including: registry working group, ethic issues, transparency, research objective, inclusion criteria, compulsory participation, endpoint, sample size, data collection basement, data collection methods, data entry, data validation and statistical analysis.

CONCLUSIONS: Registries provide a "real-world" picture for patients, physicians, manufacturers, payers, decision-makers and other stakeholders. CIRs are important for regulatory decisions concerning the safety and therefore approval issues of the medical device; for payers CIRs provide evidence on the medical device benefit and drive the decision whether the product should be reimbursed or not; for hospitals CIRs' data are important for sound procurement decisions, and CIRs also help patients and their physicians to joint decision making which of the products is the most appropriate.

Article summary:

Strengths and limitations of this study

This study summarized the global structure and key elements of the cardiac implant registries, and provided recommendations on how to solve the problems arising from designing and planning a registry. However, this is study is just the first step, more specific information needed to be research in the future.

- This study summarized 82 different cardiac implant registries over the world;
- This study identified 14 key elements of importance;
- This study provided recommendations on how to solve problems raising from planning a cardiac implant registry.

1.1 Rational

Any group of high-risk medical devices, bears the risk of inferior products which can bring harms to patients and can cause additional costs to the healthcare system because the revision procedures are needed, as stated by Labek et al. recently [1]. These high-risk medical devices include joint implants, osteosynthesis devices, breast implants, contact lenses as well as cardiology products [1]. In the field of cardiac implants, a total of 103 cases of cardiac implant adverse events have been reported in the past decade, 34 cases were due to battery problems [2].

To solve the above mentioned problems, technology needs to be constantly improved; setting up a complete post-surveillance system to track patients with cardiac implants is also an option. Compared to clinical studies, registries can be designed to ensure a long-term follow-up in post-marked surveillance [3]. There is a clear demand from political authorities on changing from efficacy studies under ideal circumstance to effectiveness studies in a “real-world” setting for post-marked surveillance. With the aim to raise awareness and bring evidence of the safe and good use of medical devices in the field of healthcare, World Health Organization (WHO) start to collect data of baseline country survey on medical devices from 2009, the updated version was published in 2017 [4]. This baseline country survey on medical devices is designed to establish availability of policies, guidelines, standards, and services for assessment, management and regulation of health technology in Member States. But it also shows a big challenge for each country to provide complete, updated or sufficient data and records on medical devices [4]. Facing these challenges some jurisdictions started to provide frameworks for the documentation and management of medical devices. The U.S. Food and Drug Administration (FDA) Medical Device Epidemiology Network (MDEpiNet) issued “Recommendations for a National Medical Device Evaluation System” aiming to bridge clinical care and research through strategically coordinated registry networks in August 2015 [5]. Moreover, the

European Commission issued in May 2017 the "New Regulation on Medical Devices", which was heavily influenced by the preceding "Poly Implant Prothèse – PIP" scandal in 2012 [6,7].

As high-risk devices, cardiac implants have specific characteristics and thus registries have to reflect their requirements. Cardiac implant registries belong to the group of product registries, which aim to investigate the performance and impact of a product in a "real-world" setting [8]. It is different from the patient registry's objective, which focuses on the severity and duration of the disease [8]. Cardiac implants have different types of products. One specific category is based on using a battery inside called cardiovascular implantable electronic device (CIED) including Implantable Cardioverter Defibrillator (ICD), Pacemaker, and Cardiac Resynchronization Therapy (CRT); the other category does not need a battery to support including Coronary Stents and Transcatheter Aortic Heart Valve Implantation (TAVI). Although there are several cardiac implant registries worldwide [9] , there is still a lack of consensus about standards on how to design a cardiac implant registry.

1.2 Objective

The aim of this study is to investigate the global structure and key elements of the cardiac implant registries, through an overview of existing cardiac implant registries worldwide in the past decade (2006-2016), and to provide recommendations on how to solve the problems arising from designing and planning a registry.

2. Methods

2.1 Search methodology

The search methodology was employed in line with the PRISMA guidelines [10]. The following databases were searched: the PubMed (Medline), the ScienceDirect, the Scopus database and the EMBASE via DIMID. Studies were also identified by scanning articles' reference lists through citation snowballing, as well as grey literature searching. The authors used the PubMed MeSH terms to identify the following search terms: Implantable cardioverter defibrillator registry, ICD registry, Cardiac Resynchronization Therapy registry, CRT registry, and pacemaker registry, coronary stent registry, TAVI registry, transcatheter aortic heart valve registry.

2.2 Study selection

The eligibility criterion for a registry was an existing cardiac implant registry in the past decade (2006-2016). The publications were excluded if they were a single clinical study but with the registry name.

2.3 Data extraction

The potential relevant title and abstract has been reviewed by two independent researchers after removing the duplicated studies. After identifying all the relevant articles, the researchers summarized them based on the same name of the registry. From those articles published by one single registry, the most recent or most significant article regarding the registry design has been chosen. To identify the key elements of registry design, an inductive approach was used [11].

3. Results

3.1 Bibliographic research results

This review identified 1529 studies that were potentially relevant. Of all these studies, 406 originated from the PubMed (Medline) database, 344 from the Scopus database, and 251 from the ScienceDirect, as well as 528 from the EMBASE. After removing duplicates, 414 abstracts have been reviewed independently by two researchers. Among of them, 217 were related to an ICD registry, 13 were a CRT registry, 29 were about a pacemaker registry, 76 were from a coronary stent registry, and 81 were from a TAVI registry. To summarize the cardiac implant registries from the identified articles, 82 registries were achieved, which shows in Figure 1.

Figure 1: PRISMA Flow diagram of study selection

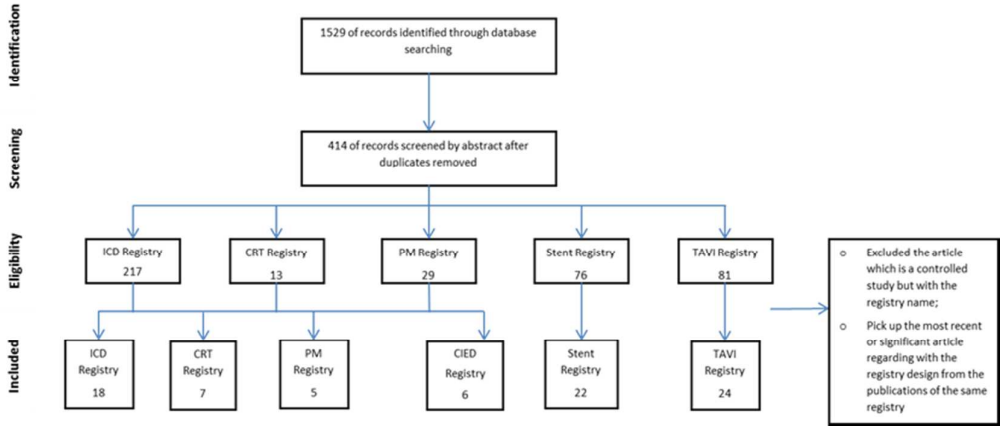
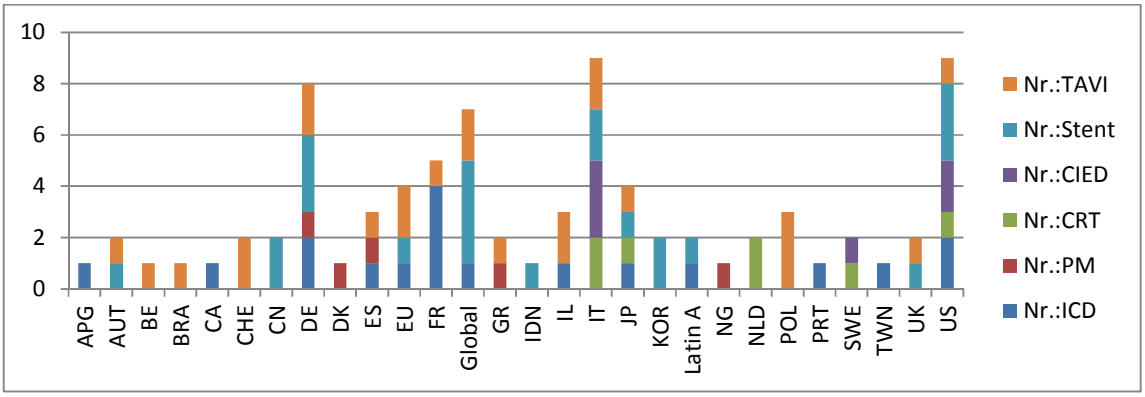


Figure 2 shows the distributions of global cardiac implant registries. Table 1 provides an overview of the identified cardiac registries, among all of 82 identified registries, 35 registries are on-going registries. Specific information about the key elements of registries can be found in Additional file 1.

Figure 2: Location of identified cardiac implant registries



US=United States; CA=Canada; BRA=Brazilian; Latin A=Latin America; AUT=Austria; BE=Belgium; CHE=Swiss; DE=Germany; DK=Denmark; ES=Spain; GR= Grace; IT=Italy; NLD=Nederland; POL=Poland; PRT= Portugal; SWE=Sweden; UK=United Kingdom; EU=European Union; APG= Arab states of the Persian Gulf; CN=China; IDN=India; JP=Japan; KOR=Korea; TWN=Taiwan; NG=Nigeria

3.2 Key elements for designing the cardiac implant registry

An inductive approach was used to collect key elements arising from identified cardiac implant registries. The results were illustrated in following text. Specific information about key elements of registry design can be found in Additional file 1.

3.2.1 Research objective

Most registries were based on a clear research objective. Different kinds of research objectives can be summarized as follows: 24 registries aimed to provide a record of clinical status of the devices; 17 registries investigated safety and performance of the devices, with most of them being stent registries. Moreover, 5 registries examined the frequency of complications and their predictors after implantation; 4 registries predicted all-cause mortality of patients after implantation, most of them are CRT registries; and 10 registries compared the effects of devices from different manufactures or from different procedures, most of them are TAVI registries.

3.2.2 Participant criteria and participant requirement

The inclusion criteria for a registry study are not as strict as those for a clinical study. Only if the registry focuses on a specified group of patients, inclusion criteria will be defined accordingly. Patient inclusion criteria are different from each type of study for an implanted device in the registries. The Stent Registry collected data usually under “all-comers” conditions [12]. Patients are classified based on different categories in the CIED registries: first implantation versus generation replacement and primary prevention versus secondary prevention [13]. The TAVI registries usually need a dedicated heart team to determine participants’ criteria [14].

Based on patients' willingness to participate, it differentiates into volunteer registry and compulsory registry. 5 identified registries are compulsory registries, which have a mandatory requirement for all patients in a defined region with identified implanted device to participant [15-19]. Of all 82 identified registries, 4 registries reported tracking patients with a unique identifier.

3.2.3 Funding

Funding support is crucial for registries. 26 out of all 82 registries are funded by public organizations, which include cardiology societies, foundations or research institutes; 5 are financed by their local or national governments. 17 are funded by manufacturers, and 2 registries are funded by public organizations and manufacturers cooperatively.

3.2.4 Organization

All registries are cooperating with a health department. For a well-designed registry, a steering committee is necessary. The steering committees are responsible for defining the strategies, supervising the annual report, and encouraging health department to participate [20,21]. Most identified registries have not provided a comprehensive description of their steering committee.

3.2.5 Ethic approval

Most registries have been approved by their local ethic committee or health department. The patient's consent is also required in most registries. One exception was found in the Ontario ICD Database, as a "prescribed entity" under Ontario health information privacy legislation, the coordinating center is allowed to collect data on all patients in this registry without informed consent [15].

3.2.6 Research type, data collection basement and sample size

Of all 82 registries identified in our study, 69 registries collected data prospectively, 11 registries conducted a retrospective study, and 2 studies conducted a prospective study also included data retrospectively. A registry can collect data from single center or from multicenter. As shown in Table 1, of all 82 identified registries, 30 are national level multicenter registries, 5 are international level multicenter registries, and 16 are single center registries, the rest are regional multicenter registries.

Unlike a clinical study, a registry study usually does not set a fixed sample size in the registry design phase, they just report the sample size when they publish and analyze the data. Exceptionally, few registries have a target enrollment number like The Gulf ICD Registry [22].

3.2.7 *Clinical endpoint*

Different types of registries have different clinical endpoint definitions. Major endpoints can be categorized as device-related outcomes and clinical outcomes. The TAVI registries defined an endpoint according to recommendations of the Valve Academic Research Consortium (VARC) or VARC-2, which is a standardized endpoint definition for TAVI [23,24]. There is also clinical endpoint for coronary stent trials from Academic Research Consortium (ARC) [25]. However, endpoints for the CIED registry are inconsistently reported.

3.2.8 *Procedures of collecting data*

Data collection: the data has been collected either from medical records or from questionnaires. For the CIED device, data also can be taken from device interrogation. After preparing a questionnaire, there are two ways to fill out the questionnaire: either patients fill out the questionnaires by themselves with a hard copy or via an online system; or medical staffs fill out the questionnaires according to a telephone interview or a face-to-face interview.

Data entry: most registries have a secure, web-based or a computer-based reporting system. For the single center registry, data entry is conducted by a trained nurse or fixed person in the working group. For the multicenter registries, participating centers entry the data into the system directly or send the data to the registry working group.

Data validation: different methods were found to ensure the data accuracy. The registry can check the data randomly, and assess the data by regular review, similar to an annual report. If the registry collects the data from a multicenter, each participating center can confirm the data first, and then an independent working group in the registry can review the data again. In addition, the registry can assess if the data is complete by comparing the registry data with the manufactures' data.

3.2.9 *Public accessibility*

Of all 82 identified cardiac implant registries, 6 registries can be accessed via a web page, along with an annual report. The other 76 registries neither have a web-site available to the public nor an annual report. These registries can be only identified via the publications, these publications provide clinical outcomes but limited information on registry design.

4. Discussion

To the best of our knowledge, our study is the first study to review the existing global cardiac implant registries and their practices as well as experiences. This manuscript introduces the structure and key

elements, which can be seen as the first step of guidance on designing a cardiac implant registry in the future and making them more appropriate for public health decision makers as well as transparent to patients and other stakeholders. This review identified 82 cardiac implant registries from 28 countries or regions in the past decade. From these 82 registries, 9 categories with 16 key elements have been identified and illustrated in detail. The following text illustrates the recommendations and concerns arising from planning and designing a cardiac implant registry.

4.1 Cardiac implant registry's primary focus

The primary focus of cardiac implant registries is on product's safety and effectiveness. As a high-risk medical device registry, the authors summarized the following aspects needed to be noticed in the process of designing a cardiac implant registry.

4.1.1 Volunteer bias

For a medical device registry, two kinds of volunteer bias will potentially occur: organizational level volunteer bias and individual level volunteer bias [15]. Volunteer bias can be defined as the bias that comes from the fact that a particular sample can contain only those participants who are actually willing to participate in the study or experiment [26]. In our case, for a volunteer cardiac implant registry, on the organizational level, centers may not participate for different reasons (low experience in the procedure, not enough staffs, not willing to publish data). On a patient level there might be volunteer bias towards patient groups with a higher level of health awareness and/or higher socio-economic level.

4.1.2 Systematic follow-up for an adverse event reporting system

As a result, adverse event reporting should be considered and discussed as a major focal point when planning a cardiac implant registry. In addition, the registry should be capable of providing systematic follow-up event data. In our study, most of the registries summarized the event data in their publications or annual report.

4.1.3 Rapid tracking of potentially impacted patients

There is clear demand for the registry to take responsibility for tracking patients who have suffered from adverse events. Adverse events here indicate both device-related technique problems such as lead malfunction, and major adverse cardiovascular events (MACE) like atrial fibrillation (AF). When an adverse event occurred, the registry should track the patients who are implanted with such devices and notify them to prevent harm. However, not all registries were capable of tracking

patients. The STS/ACC TVT Registry added a Unique Device Identifier field to allow tracking of specific devices, which are pending implementation of a Unique Device Identifier strategy by the FDA [27].

4.1.4 Product generation and replacement

Being a product which is placed in human body, cardiac implants have their own configurations nature and characteristics. One important area requiring attention is product generation and battery replacement. In this context, battery problems are the most frequent reasons for recalls and replacement of cardiac implants [2,28]. Secondly, device technologies change more rapidly within a shorter time span compared to drug products [29]. This rapid change demands that researchers record the product brand and specifications model within registries. Implantation devices and their providers should be described in the registry and considered when analyzing data.

4.2 Public accessibility

The release of a free annual report and the accessibility on a web site are the most significant strategies for disseminating registries' results [30]. However, the result from our study demonstrated that there is still room for improvement. 74 (90.2%) registries can be only identified through their publications.

Data accessibility does not mean open access to the entire patient's data. Data accessibility is a way to give patients the opportunity to access information directly relevant to their condition. Since the cardiac implant registry aims to prevent adverse events, accessibility and transparency is vital to both researchers and the public. Many registries are only accessible to the sponsoring organizations. To improve public health and patient care; registry findings should be available and accessible for all stakeholders [31].

4.3 Funding source

Funding sources and complying with the funders' purpose highlight two issues which need to be considered. Where does the funding come from? Are the funding sources capable of covering all expenditures? Stable funding source can guarantee financial support and eliminate the risk of the registry failing. Potential funding sources for registries are recommended by the "Agency for Healthcare Research and Quality (AHRQ)", which includes federal agencies such as government and other national governmental organizations, professional associations for instance patient groups, cardiology associations, product manufacturers such as companies or the pharmaceutical industry, as well as non-profit, private foundations and funders [32].

4.4 Limitation

The main limitation of this study is that the authors are only available to search in English, German and Chinese. Although the authors have done a global database search, grey search and hand search, however, it is difficult to assess whether all cardiac implant registries have been identified.

5. Conclusion

The importance of cardiac implants registries has been recognized and approved, but there is lack of consensus standards on how to establish a cardiac implant registry. Registries provide a “real-world” picture for patients, physicians, manufacturers, payers, decision-makers and other stakeholders. In this context, medical device registries are important for regulatory decisions, concerning the safety and therefore approval issues of the medical device. For payers medical device registries provide evidence on the benefit of the medical device and drive the decision whether the product should be reimbursed or not. For hospitals medical device registries’ data are important for sound procurement decisions, and last - and of paramount importance- medical device registries help patients and their physicians to make joint decision on which product is the most appropriate.

6. Funding

The research is supported by the German Federal Ministry of Education and Research (BMBF), project grant no. 13EX1013B, as part of the National Leading-Edge Cluster Medical Technologies ‘Medical Valley EMN’. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed. No writing assistance was utilized in the production of this manuscript.

The present work was performed in (partial) fulfillment of the requirements for obtaining the degree “Dr. rer. biol. hum.” at the Medical Faculty of Friedrich-Alexander University of Erlangen-Nürnberg.

7. Competing interests statement

No, there are no competing interests.

8. Contributor ship statement

Mr. Peter L. Kolominsky-Rabas provided substantial contributions to conception and design; Ms. Shixuan Zhang drafted the articles with acquisition of data, analysis and interpretation of data; Mr. Sebastian Gaiser revised the manuscript critically for important intellectual content; Mr. Peter L.

Kolominsky-Rabas made the final approval of the version to be published. The guarantor is Mr. Peter L. Kolominsky-Rabas.

9. Data sharing statement

Not applicable in this manuscript.

10. Reference

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Table 1 an overview of cardiac implant registries in the last decade In Multicenter=International level multicenter; N Multicenter=National level multicenter

Topic	Registry Name	Geography Coverage	Time	Research Type	Data Collection Basement
ICD Registry	NCDR ICD Registry	US	04.2006-	Prospective	N Multicenter
	Multicenter Pediatric ICD Registry	US	03.1992-03.2004	Retrospective	Multicenter
	The Ontario ICD Database	CA	02.2007-08.2009	Prospective	Multicenter
	The Medtronic ICD Registry	Latin A	01.2005-08.2007	Retrospective	Multicenter
	ICD-registry Ludwigshafen	DE	1992-05.2008	Prospective	Single center
	The German DEVICE registry	DE	03.2007-04.2010	Prospective	Multicenter
	Spanish ICD Registry	ES	2005-	Prospective	N Multicenter
	French OPERA registry	FR	05.2002-09.2008	Prospective	Single center
	Stidefix Registry	FR	03.2007-	Prospective	Multicenter
	The LEADER registry	FR	N.a.	Prospective	Multicenter
	National Registry on Cardiac Electrophysiology	PRT	N.a.	Prospective	N Multicenter
	EFFORTLESS S-ICD Registry	EU&NZ	06.2009-	P&R	In Multicenter
	The European LQTS ICD Registry	Global	2002-	P&R	In Multicenter
	The Israeli ICD Registry	IL	07.2010-	Prospective	Multicenter
	The Japanese Cardiac Device Treatment Registry	JP	08.2006-	Prospective	Multicenter
	The Gulf ICD Registry	AGR	10.2011-07.2016	Prospective	In Multicenter
	ICD registry in Taiwan	TWN	1998-2009	Retrospective	Multicenter
	A Multicenter French Registry	FR	2002-2012	Retrospective	Multicenter
Pacemaker Registry	German Pacemaker Registry	DE	1982-	Prospective	N Multicenter
	Danish Pacemaker Register	DK	01.1982-	Prospective	N Multicenter
	Spanish Pacemaker Registry	ES	1997-	Prospective	N Multicenter
	Single Academic Pacemaker Center	GR	01.1989-06.2006	Retrospective	Single center
	Nigeria Pacemaker Registry	NGA	01.2008-	Prospective	Single center
CRT Registry	The CRT RENEWAL	US	N.a.	Prospective	Multicenter
	Single center registry on prognosis in CRT	NLD	N.a.	Prospective	Single center
	The InSync/InSync ICD Italian Registry	IT	1999-	Prospective	Multicenter
	Single center CRT registry	SWE	1998-2008	Retrospective	Single center
	J-CRT	JP	04.2006-03.2009	Prospective	Multicenter
	The Contak Italian Registry	IT	2004-2007	Prospective	Multicenter
	A prospective CRT registry	NL	2005-2009	Prospective	Single center
CIED Registry	The REPLACE Registry	US	07.2007-06.2009	Prospective	Multicenter
	The HomeGuide Registry	IT	N.a.	Prospective	Multicenter
	Registry of Emilia Romagna on Arrhythmia Interventions	IT	07.2005-	Prospective	Multicenter
	Italy PM and ICD Registry	IT	2001-	Prospective	N Multicenter
	Swedish PM and ICD Registry	SWE	PM: 1989- ICD: 2004-	Prospective	N Multicenter
	The Kaiser Permanente-Cardiac Device Registry	US	01.2007-12.2013	Prospective	Multicenter
Stent Registry	Guthrie Health Off-label Stent (GHOST) Registry	US	07.2001-12.2007	Prospective	Single center
	The prairie "real world" stent registry	US	05.2003-07.2007	Retrospective	Single center
	HMORN-Stent Registry	US	2004-2007	Prospective	Multicenter
	POLAR Registry	Latin A	11.2008-07.2010	Prospective	Multicenter
	AUTAX (Austrian Multivessel TAXUS-Stent) registry	AUT	06.2004-	Prospective	Multicenter
	the Leipzig SUPERA Popliteal Artery Stent Registry	DE	01.2008-04.2010	Retrospective	Single center
	German Cypher Stent Registry	DE	04.2002-	Prospective	N Multicenter
	German DES.DE Registry	DE	10.2005-10-2006	Prospective	N Multicenter
	WAR-STENT registry	IT	11.2008-06.2010	Prospective	Multicenter
	The Tacrolimus-Eluting STent (TEST) registry	IT	02.2005-08.2005	Prospective	Single center
	Artery Angioplasty-Stent Registry III	UK	2005-2008	Prospective	Multicenter
	The Frontier stent registry	EU	05.2002-10.2002	Prospective	Multicenter
	The China CYPHER Select registry	CN	07.2004-08.2005	Prospective	Multicenter
	A novel computer based stent registry	IDN	01.2002-12.2011	Retrospective	Single center
	The j-Cypher Registry	JP	08.2004-11.2006	Prospective	Multicenter
	the DATE registry	KOR	12.2006-03.2008	Prospective	Multicenter
	FOCUS registry	Asia	03.2009-02.2010	Prospective	Multicenter
	The 'all comer' Coroflex Please drug-eluting stent registry in Europe and Asia	EU&ASIA	09.2006-02.2008	Prospective	Multicenter
	DESERT (international Drug-Eluting Stent Event Registry of Thrombosis)	Global	04.2003-	Retrospective	Multicenter
	The TIMI 38 Coronary Stent Registry (CSR)	Global	07.2007-07.2009	Prospective	Multicenter
	E-Five Registry	Global	10.2005-	Prospective	Multicenter
	The Korean Multicenter Drug-Eluting Stent Registry	Korea	N.a.	Prospective	Multicenter
TAVI Registry	The STS/ACC TVT Registry	US	05.2012-	Prospective	N Multicenter
	Brazilian TAVI Registry	BR	01.2008-12.2012	Prospective	Multicenter
	The Austrian TAVI Registry	AUT	01.2011-	Prospective	N Multicenter
	The Belgian TAVI Registry	BE	N.a.	Prospective	N Multicenter
	The Swiss TAVI registry	CHE	2011-	Prospective	N Multicenter
	The Bern TAVI Registry	CHE	08.2007-04.2012	Prospective	Single center
	The Aachen TAVI registry	DE	01.2008-	Prospective	Single center
	The German TAVI Registry	DE	01.2009-	Prospective	N Multicenter
	FRANCE 2 Registry	FR	2010-	Prospective	N Multicenter
	The ATHENS TAVR Registry	GR	10.2009-09.2011	Prospective	Multicenter
	The POL-TAVI registry	POL	2013-	Prospective	N Multicenter
	OBSERVANT TAVI Registry	IT	12.2010-	Prospective	Multicenter
	The UK TAVI registry	UK	2008-	Prospective	N Multicenter
	The Ibero-American TAVI registry	The Ibero-A	12.2007-05.2012	Prospective	In Multicenter

	The multi-centre European PARTNER TAVI study	EU	N.a.	Prospective	In Multicenter
	Rabin Medical Center TAVR registry	IL	11.2009-08.2013	Prospective	Single center
	The Optimized CathEter vAlvular iNtervention (OCEAN-TAVI) registry	JP	10.2013-12.2014	Prospective	Multicenter
	A large multicenter TAVI registry	Israel	2008-2014	Retrospective	Multicenter
	the Italian CoreValve registry	IT	2007-	Prospective	Multicenter
	A Multicenter Spanish Registry	ES	2014-	Prospective	Multicenter
	A Poland single-center registry	PL	2008-2014	Prospective	Single center
	The Transcatheter Valve Treatment Sentinel Pilot Registry	EU	01.2011-05.2012	Prospective	Multicenter
	The ROUTE registry	PL	05.2013-06.2014	Prospective	Multicenter
	SAPIEN XT Aortic Bioprosthesis Multi-Region Outcome Registry	International	07.2010-11.2011	Prospective	Multicenter

474

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

Topic	Registry Name	Geography coverage	Time	Research objectives	Participant criteria	Endpoint	Research type	Data collection basement	Initiator or funding	Registry working group	Ethic committee approval	Informed consent	Compulsory
ICD Registry	NCDR ICD Registry [1]	US	04.2006-	To provide important insights into clinical and procedural characteristics of patients receiving an ICD in US	N.a.	N.a.	Prospective	Multicenter	American College of Cardiology Foundation and the Heart Rhythm Society	Working group	N.a.	N.a.	No
	Multicenter Pediatric ICD Registry [2]	US	03.1992-03.2004	To examine a current-era cohort using a long-term multicenter retrospective approach to identify a large group of pediatric and CHD patients with ICDs.	Yes	N.a.	Retrospective	Multicenter	N.a.	N.a.	Local review board	N.a.	No
	The Ontario ICD Database [3]	CA	02.2007-08.2009	To examine the frequency of complications and their predictors.	N.a.	N.a.	Prospective	Multicenter	Ontario Ministry of Health and Long-term care	Local electrophysiologist and a trained research coordinator	N.a.	No	Yes
	The Medtronic ICD Registry [4]	Latin A	01.2005-08.2007	To summarize experience in patients with Chagas' disease and life-threatening ventricular arrhythmias implanted with ICDs and to classify the type of spontaneous ventricular tachyarrhythmia presented and the respective therapy provided by the device.	N.a.	Multiple shocks or adverse event	Retrospective	Multicenter	Medtronic Inc. Latin America Operations	N.a.	Local ethics committee	Yes	No
	ICD-registry Ludwigshafen [5]	DE	1992-05.2008	N.a.	N.a.	N.a.	Prospective	Single center	N.a.	N.a.	N.a.	Yes	No
	The German DEVICE registry [6]	DE	03.2007-04.2010	To gather information on overall mortality, re-hospitalization, early and late clinical and device complications, heart failure development, incidence of ICD shock delivery, change of medication and necessary device upgrading procedures.	Only data on new implants	N.a.	Prospective	Multicenter	Institut für Herzinfarktforschung	DEVICE registry office	N.a.	Yes	No
	Spanish ICD Registry [7]	ES	2005-	To determine how ICDs are currently used in Spain.	N.a.	N.a.	Prospective	N Multicenter	Spanish Society of Cardiology	Working group on ICDs	N.a.	N.a.	No
	French OPERA registry [8]	FR	05.2002-09.2008	To study the determinants of FAT and FIT therapies delivered by single-, dual-, and triple-chamber ICD	Yes	N.a.	Prospective	Single center	Guidant/Boston Scientific	N.a.	Approved by CNIL	Yes	No
	Stidefix Registry [9]	FR	03.2007-	To respond to the legal mandate of the French health authorities requiring the enrolment of all new ICD implants in a national registry by the medical centres, to create a database enabling analysis of the French practices in the area of cardiac pacing and defibrillation, and to provide a computer-based tool to the implanting centres for managing implantations.	Yes	N.a.	Prospective	Multicenter	Biotronik France, Boston Scientific France, Medtronic France, Saint Jude Medical France, and Sorin Group France	N.a.	N.a.	Yes	No
	The LEADER registry [10]	FR	N.a.	To determine the DT procedures used in everyday practice, to compare the characteristics of patients with or without DT, and to compare severe adverse events in these two populations during implantation and follow-up.	Yes	N.a.	Prospective	Multicenter	Boston Scientific Corporation, Guidant France SAS	N.a.	Approved by the French Ministry of Scientific Research and the French Privacy Authority	Yes	No
	National Registry on Cardiac Electrophysiology [11]	PRT	N.a.	To provide an overall picture of the situation in Portugal with regard to the number of participating centers and their volume of activity and the number and type of procedures performed, as well as development over time.	N.a.	N.a.	Prospective	N Multicenter	Portuguese Association of Arrhythmology, Pacing and Electrophysiology (APAPE) and the Portuguese Institute of Cardiac Rhythm (IPRC)	N.a.	N.a.	N.a.	No
	EFFORTLESS S-ICD Registry [12]	EU&NZ	06.2009-	To document clinical, system, and patient related outcome data from S-ICD patients implanted since the commercial release of the S-ICD.	Yes	N.a.	P&R	In Multicenter	Cameron Health	N.a.	N.a.	Yes	No
	The European LQTS ICD Registry [13]	Global	2002-	To assess the current indications to implant according to clinical history, response to previous therapy, and specific genotype and to evaluate the	Yes	N.a.	P&R	In Multicenter	Medtronic Bakken Research Center in the Netherlands and Boston	Working Group	Local institutional review boards	Yes	No

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

				clinical course after ICD implantation.					Scientific				
	The Israeli ICD Registry [14]	IL	07.2010-	N.a.	N.a.	All-cause mortality. VT/VF, HF, ATP or shock	Prospective	Multicenter	N.a.	Working Group	Ethics committee of each participating institution	Yes	Yes
	The Japanese Cardiac Device Treatment Registry [15]	JP	08.2006-	To record current clinical situation of cardiac implantable defibrillator devices.	N.a.	N.a.	Prospective	Multicenter	The Japanese Heart Rhythm Society	JHRS office	Each institution	Yes	N.a.
	The Gulf ICD Registry [16]	AGR	10.2011-07.2016	To describe the characteristics and the outcomes of patients receiving ICDs in the Arab Gulf region.	A new ICD implant	All-cause mortality, adverse event	Prospective	Multicenter	Conducted under the auspices of the Gulf Heart Association, Gulf Heart Rhythm Society, and Saudi Heart Rhythm Society. Funded by Medtronic Inc. and Boston Scientific, Inc	N.a.	Per local ethics regulations	Yes	N.a.
	ICD registry in Taiwan [17]	TWN	1998-2009	To investigate the long-term prognosis and the predictors of mortalities among ICD recipients in Taiwan.	N.a.	The occurrence of all-cause mortality	Retrospective	Multicenter	N.a.	N.a.	Approved by the institutional review board	N.a.	No
	A Multicenter French Registry [18]	FR	2002-2012	To determine the proportion of female ICD recipients, and differences in terms of characteristics at implant and outcomes in women compared to men.	At least 18 years old at the time of ICD implantation, first implantation	Appropriate therapies, early complications, inappropriate shocks, overall and specific mortalities.	Retrospective	Multicenter	Public sources	Steering Committee:	By the French data protection committee	Yes	No
Pacemaker Registry	German Pacemaker Registry [19]	DE	1982-	N.a.	N.a.	N.a.	Prospective	Multicenter	N.a.	N.a.	N.a.	N.a.	No
	Danish Pacemaker Register[20]	DK	01.1982-	To record all implantations and removals of PPM and PM-leads.	N.a.	N.a.	Prospective	N Multicenter	N.a.	N.a.	N.a.	N.a.	Yes
	Spanish Pacemaker Registry [21]	ES	1997-	To report most relevant characteristic in Spain.	N.a.	N.a.	Prospective	N Multicenter	Spanish Society of Cardiology	Working group	N.a.	N.a.	No
	Single Academic Pacemaker Center [22]	GR	01.1989-06.2006	To evaluate changes in indications for pacing and pacing modes.	N.a.	N.a.	Retrospective	Single center	N.a.	N.a.	N.a.	N.a.	No
	Nigeria Pacemaker Registry [23]	NGA	01.2008-	N.a.	N.a.	N.a.	Prospective	Single center	N.a.	N.a.	Ethics committee	Yes	No
CRT Registry	The CRT RENEWAL [24]	US	N.a.	To predict all-cause mortality as a means to help better manage this group of patients.	Specific device	N.a.	Prospective	Multicenter	Boston Scientific CRM	N.a.	Local institutional review boards	Yes	No
	Single center registry on prognosis in CRT [25]	NLD	N.a.	To better understand survival benefit in patients treated with CRT.	Yes	N.a.	Prospective	Single center	N.a.	N.a.	N.a.	N.a.	No
	The InSync/InSync ICD Italian Registry [26]	IT	1999-	To evaluate the effectiveness of CRT alone or in combination with an ICD (CRT-D).	Yes	All-cause mortality	Prospective	Multicenter	N.a.	N.a.	By ethics committees of each participating center	Yes	No
	Single center CRT registry [27]	SWE	1998-2008	N.a.	Yes	N.a.	Retrospective	Single center	The Stockholm County Council	N.a.	Approved by the local ethics committee	N.a.	No
	J-CRT [28]	JP	04.2006-03.2009	To identify both ability of echocardiographic parameters to detect CRT volume responders and relation of these parameters with clinical outcomes.	Yes	Death; adverse event	Prospective	Multicenter	N.a.	J-CRT committee, 2-day workshop training	each institution	Yes	No

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

	The Contak Italian Registry [29]	IT	2004-2007	To compare the long-term prognosis of patients who received CRT-D or CRT-P according to class IA recommendations of the European Society of Cardiology (ESC).	Yes	Death	Prospective	Multicenter	N.a.	N.a.	Approved by the Local Ethics Committees	Yes	No
	A prospective CRT registry [30]	NL	2005-2009	To assess the independent predictive value of apical rocking on long-term clinical outcomes in a large study population.	CRT-D	MACE	Prospective	Single center	N.a.	N.a.	the institutional review board	N.a.	No
CIED Registry	The REPLACE Registry [31]	US	07.2007-06.2009	Risk related to generator replacements with lead generator.	Yes	6 months	Prospective	Multicenter	Funded by BIOTRONIK	The REPLACE Registry Steering Committee, Clinical Events committee, Novella Clinical	Each institution	Yes	No
	The HomeGuide Registry [32]	IT	N.a.	To provide an organizational model for implementing remote monitoring of CIEDs in daily clinical practices.	N.a.	N.a.	Prospective	Multicenter	Biotronik Italia	Steering committee	An institutional review board	Yes	No
	Registry of Emilia Romagna on Arrhythmia Interventions [33]	IT	07.2005-	To collect clinical and implant data for all cardiac devices implanted in the Emilia-Romagna region.	N.a.	N.a.	Prospective	Multicenter	The regional health care and social agency of Emilia-Romagna	N.a.	Each institution	Yes	No
	Italy PM and ICD Registry [34]	IT	2001-	To evaluate the effects in clinical practice of the major guidelines.	N.a.	N.a.	Prospective	Multicenter	Italian Society of Arrhythmology and Cardic Pacing (AIAIC)	N.a.	N.a.	N.a.	No
	Swedish PM and ICD Registry [35]	SWE	PM: 1989- ICD: 2004-	To provide a real time picture of the use of CIED in clinical practice.	N.a.	N.a.	Prospective	N Multicenter	Swedish Heart Lung-Foundation & Stockholm County council	Registry Administers	Each institution	N.a.	Yes
	The Kaiser Permanente-Cardiac Device Registry [36]	US	01.2007-12.2013	To describe key elements, clinical outcomes, and potential uses of the Kaiser Permanente-Cardiac Device Registry	N.a.	N.a.	Prospective	Multicenter	N.a.	N.a.	N.a.	Yes	Yes
Stent Registry	Guthrie Health Off-label Stent (GHOST) Registry [37]	US	07.2001-12.2007	To compare long-term safety and effectiveness of DES versus BMS in patients undergoing PCI for NSTEMI.	Yes	MACE	Prospective	Single center	The Guthrie Health Foundation	N.a.	N.a.	N.a.	No
	The prairie "real world" stent registry [38]	US	05.2003-07.2007	To compare long-term mortality for DES versus BMS in patients with SVG disease from our large "real world" cohort of stent patients	Yes	All-cause mortality, MACE	Retrospective	Single center	N.a.	N.a.	N.a.	N.a.	No
	HMORN-Stent Registry [39]	US	2004-2007	All patients who underwent PCI with a DES	N.a.	N.a.	Prospective	Multicenter	N.a.	N.a.	N.a.	N.a.	No
	POLAR Registry [40]	Latin A	11.2008-07.2010	To clinically evaluate the Promus stent in patients in clinical practice.	No	N.a.	Prospective	Multicenter	Boston Scientific	The Cardiovascular Research Centre	Ethics Committees approval	Yes	No
	AUTAX (Austrian Multivessel TAXUS-Stent) registry [41]	AUT	06.2004-	To evaluate patients with multivessel CAD with/without previous PCI or concomitant cardiac surgery with possible complete revascularization by PCI, and treated solely with multiple TAXUS Express stent implantation in a "real world" setting, and to report the short, medium, and long term angiographic and clinical outcomes	No	N.a.	Prospective	Multicenter	N.a.	N.a.	Austrian Society of Cardiology and the institutional review committees approval	Yes	No
	the Leipzig SUPERA Popliteal Artery Stent Registry [42]	DE	01.2008-04.2010	To evaluate the efficacy and integrity of this new nitional stent system in complex popliteal artery obstructions, implementing a clinically established systematic follow-up regime with stent fracture screening and evaluation for restenosis.	No	N.a.	Retrospective	Single center	N.a.	N.a.	N.a.	Yes	No
	German Cypher Stent Registry [43]	DE	04.2002-	To determine the safety, effectiveness and 6-month and long term follow-up data of the SES in clinical practice and factors associated with clinical events as well as the need for TVR during follow-up.	No	N.a.	Prospective	Multicenter	DGK;DNK;ALKK, Cordis Corporation, J&J	Steering committee	N.a.	Yes	No

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

	German DES.DE Registry [44]	DE	10.2005-10-2006	To compare the effects of PES, SES and BMSs in a "real-world" setting	Yes	N.a.	Prospective	Multicenter	DGK;DNK;ALKK	Steering committee	N.a.	Yes	No
	WAR-STENT registry [45]	IT	11.2008-06.2010	To investigate the contemporary management of patients on warfarin undergoing PCI-S, and to determine the incidence of adverse events in a real-world setting.	No	N.a.	Prospective	Multicenter	N.a.	N.a.	Ethic committee	Yes	No
	The Tacrolimus-Eluting STent (TEST) registry [46]	IT	02.2005-08.2005	To investigate the safety and efficacy of this particular TES in an unselected population of patients, without the restrictive clinical or angiographic criteria applicable to previous trials.	Yes	MACE	Prospective	Single center	N.a.	N.a.	N.a.	N.a.	No
	Artery Angioplasty-Stent Registry III [47]	UK	2005-2008	To set standards of practice of interventional radiologists carrying out iliac interventional procedures.	No	N.a.	Prospective	Multicenter	BSIR	Working group	N.a.	N.a.	No
	The Frontier stent registry [48]	EU	05.2002-10.2002	To investigate the safety and performance of this device for the treatment of de novo or restenotic bifurcation lesions.	Yes	MACE	Prospective	Multicenter	Guidant Corp	The data and safety monitoring board and clinical events committee	N.a.	N.a.	No
	The China CYPHER Select registry [49]	CN	07.2004-08.2005	To evaluate the safety and efficacy or the CYPHER Select SES	No	MACE, cardiac death, nonfatal MI, TLR	Prospective	Multicenter	Chinese Society of Cardiology	Data coordinating center and core laboratory	N.a.	Yes	No
	A novel computer based stent registry [50]	IDN	01.2002-12.2011	To evaluate the feasibility of a computer based stent registry with patient directed automated information system to prevent retained double J stents.	No	N.a.	Retrospective	Single center	N.a.	N.a.	N.a.	N.a.	No
	The j-Cypher Registry [51]	JP	08.2004-11.2006	To investigate the safety of DES	N.a.	Death	Prospective	Multicenter	Cordis Cardiology Japan and J&J	Data management center	N.a.	Yes	No
	the DATE registry [52]	KR	12.2006-03.2008	To determine the feasibility of 3-month dual antiplatelet therapy after ZES implantation in relatively low risk patients with coronary artery disease.	Yes	Death	Prospective	Multicenter	IN-SUNG Foundation	Steering committee	Institutional review board	Yes	No
	FOCUS registry [53]	Asia	03.2009-02.2010	To evaluate the safety and efficacy of a second-generation cobalt-chromium sirolimus-eluting stent in routine treatment of patients with coronary artery disease.	Yes	MACE	Prospective	Multicenter	MicroPort Medical	An independent clinical research organization	ethics committees	Yes	No
	The 'all comer' Coroflex Please drug-eluting stent registry in Europe and Asia [54]	EU&ASIA	09.2006-02.2008	To further document the safety and efficacy of the Coroflex Please paclitaxel-eluting stent.	Yes	MACE	Prospective	Multicenter	N.a.	Data management group	N.a.	N.a.	No
	DESERT (international Drug-Eluting Stent Event Registry of Thrombosis) [55]	Global	04.2003-	To identify clinical, procedural, and angiographic correlates of late/very late DES thrombosis as well as to determine the clinical outcomes of these events.	Yes	N.a.	Retrospective	Multicenter	N.a.	N.a.	N.a.	N.a.	No
	The TIMI 38 Coronary Stent Registry (CSR) [56]	Global	07.2007-07.2009	To investigate the DAPT after ACS.	Yes	MACE	Prospective	Multicenter	Daiichi Sankyo Co, Ltd, and Eli Lilly and Co.	N.a.	N.a.	N.a.	No
	E-Five Registry [57]	Global	10.2005-	To documentation of the safety and clinical performance of the Endeavor ZES in real-world and to assess the event rate	Yes	MACE	Prospective	Multicenter	Medtronic Vascular	N.a.	Local ethics committees	Yes	No
	The Korean Multicenter Drug-Eluting Stent Registry [58]	Korea	N.a.	For second-generation biocompatible or biodegradablepolymer coated DES	Stent	Stent-oriented outcomes (target lesion failure [TLF]) and patient-oriented composite outcomes (POCO)	Prospective	Multicenter	N.a.	N.a.	The ethics committee at each participating center	Yes	No
TAVI Registry	The STS/ACC TVT Registry [59]	US	05.2012-	to measure and improve quality of care and patient outcomes in clinical practice and to have a pivotal role in the scientific evidence and surveillance for medical devices	N.a.	N.a.	Prospective	N Multicenter	The Society of Thoracic Surgeons and the American College of Cardiology	The steering committee	N.a.	N.a.	No

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

Brazilian TAVI Registry [60]	BR	01.2008-12.2012	To identify the clinical and procedural variables related to PPM implantation after TAVI.	N.a.	N.a.	Prospective	Multicenter	Brazilian society of interventional cardiology	N.a.	N.a.	Yes	No
The Austrian TAVI Registry [61]	AUT	01.2011-	To monitor TAVI procedures	N.a.	from VARC	Prospective	Multicenter	Austrian Society of Cardiology, Committee on Interventional Cardiology	N.a.	The institutional Review Board of the Medical University Graz	Yes	No
The Belgian TAVI Registry [62]	BE	N.a.	To include and follow-up all consecutive Belgian TAVI procedures.	TAVI was considered by the heart team	N.a.	Prospective	Multicenter	N.a.	No core laboratory	Approved by the institutional Ethics Committee	N.a.	Yes
The Swiss TAVI registry [63]	CHE	2011-	To assess the safety and efficacy of unselected and consecutive TAVI procedures in Switzerland.	N.a.	from VARC	Prospective	Multicenter	Swiss Heart Foundation, manufactures, the Swiss Working Group of Interventional Cardiology and Acute Coronary Syndromes	Under the lead of Swiss Cardiovascular Center Bern	N.a.	Yes	Yes
The Bern TAVI Registry [64]	CHE	08.2007-04.2012	N.a.	N.a.	from VARC	Prospective	Single center	N.a.	N.a.	The local ethics committee	Yes	No
The Aachen TAVI registry [65]	DE	01.2008-	To evaluate the clinical pre-interventional predictors, including aortic valve calcification severity, of 3-year outcome and mortality in a real-world population treated with TAVI.	Yes	N.a.	Prospective	Single center	N.a.	N.a.	N.a.	N.a.	No
The German TAVI Registry [66]	DE	01.2009-	N.a.	N.a.	N.a.	Prospective	Multicenter	N.a.	N.a.	Yes	No	N.a.
FRANCE 2 Registry [67]	FR	2010-	To analyze patient characteristics and clinical outcome of performing TAVI.	By a dedicated heart team	Incidence of AKI (acute kidney injury)	Prospective	Multicenter	N.a.	Scientific committee	N.a.	N.a.	No
The ATHENS TAVR Registry [68]	GR	10.2009-09.2011	To evaluate the procedural, echocardiographic and 30-day clinical outcomes of patients undergoing transfemoral implantation of the newer generation valves in the "real world"; 2) to compare the procedural, echocardiographic and 30 day clinical outcomes of the nonrandomized use of the two available valve types.	Under a systematic workup protocol	from VARC	Prospective	Multicenter	N.a.	N.a.	Each participating centre	Yes	No
The POL-TAVI registry [69]	POL	2013-	To assess the incidence of moderate-to-severe PVL after TAVI.	Yes	N.a.	Prospective	N Multicenter	N.a.	N.a.	N.a.	N.a.	Yes
OBSERVANT TAVI Registry [70]	IT	12.2010-	To evaluate and compare short-, medium-, and long-term outcomes in patients undergoing SAVR or TAVI, in terms of both survival and major adverse cardiac and cerebrovascular events, to build a new pre-procedure risk score, specific for the elderly population, and to define specific "indication criteria" to guarantee appropriate patient selection for SAVR or TAVI	Yes	All-cause mortality, MACCE	Prospective	Multicenter	N.a.	Steering group	N.a.	N.a.	No
The UK TAVI registry [71]	UK	2008-	To create a comprehensive record of all TAVI procedures in UK	N.a.	N.a.	Prospective	Multicenter	NICOR	DMG; The clinical Research Group and the Dataset Group	N.a.	N.a.	No
The Ibero-American TAVI registry [72]	The Ibero-A	12.2007-05.2012	To find out the indications, early results and survival of TAVI patients	Yes	N.a.	Prospective	Multicenter	Medtronic	The CoreValve Registry committee from ES and PRT	N.a.	Yes	No
The multi-centre European PARTNER TAVI study [73]	EU	N.a.	To prospectively establish the role of both TF and TA in the high-risk population	Yes	Death, haemodynamic	Prospective	Multicenter	N.a.	N.a.	Ethics committee approval at each center	Yes	No
Rabin Medical	IL	11.2009-	To report our initial long-term clinical experience	N.a.	N.a.	Prospective	Single center	N.a.	N.a.	N.a.	N.a.	No

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

	Center TAVR registry [74]		08.2013	with TAVI for "all comer" patients with severe symptomatic AS using currently approved devices.									
	The Optimized CathEter vAlvular iNtervention (OCEAN-TAVI) registry [75]	JP	10.2013-12.2014	To evaluate all patients received a Sapien XT bioprosthesis (Edwards Lifesciences, Irvine, CA, USA) via either transfemoral (TF) or transapical approach (TA).	N.a.	VARC-2	Prospective	Multicenter	N.a.	N.a.	N.a.	Yes	No
	A large multicenter TAVI registry [76]	Israel	2008-2014	To evaluate TAVI temporal trends in a large multicenter Israeli registry	STS-PROM	VARC-2	Retrospective	Multicenter	N.a.	3 centers	N.a.	N.a.	No
	the Italian CoreValve registry [77]	IT	2007-	Describing and improving the use of implantable devices in Italian clinical practice which has already been described elsewhere	N.a.	VARC	Prospective	Multicenter	Medtronic Italy	N.a.	N.a.	N.a.	No
	A Multicenter Spanish Registry [78]	ES	2014-	To assess, in patients with severe AS, the determinants of management and prognosis	Not previous AS intervention	N.a.	Prospective	Multicenter	N.a.	N.a.	By the Ethics Committee	Yes	No
	A Poland single-center registry [79]	PL	2008-2014	To evaluate early- and mid-term clinical outcomes after TAVI in a single-center setting	N.a.	VARC	Prospective	Single center	Fund	A multidisciplinary heart team	By the institutional Ethical Board	N.a.	No
	The Transcatheter Valve Treatment Sentinel Pilot Registry [80]	EU	01.2011-05.2012	To assess and identify predictors of in-hospital outcome and complications of contemporary TAVI practice	No	VARC	Prospective	Multicenter	European Society of Cardiology	The relevant Working Groups and Associations	By the TCVT Registry Executive Committee	Yes	No
	The ROUTE registry [81]	PL	05.2013-06.2014	To determine the feasibility of using Tao access for TAVI procedures employing the Edwards SAPIEN transcatheter heart valve.	TAo	VARC-2	Prospective	Multicenter	N.a.	A cardiac surgeon, an interventional cardiologist, and a cardiologist	N.a.	N.a.	No
	SAPIEN XT Aortic Bioprosthesis Multi-Region Outcome Registry [82]	International	07.2010-11.2011	To evaluate the epidemiology, predictors, and prognostic implications of AF, either pre-existing or new onset, in TAVR patients	SAPIEN XT valve only	VARC	Prospective	Multicenter	Edwards Lifesciences	The local heart team	The local regulatory authorities	Yes	No

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

Topic	Registry Name	Data collection	Data entry	Data validation	Statistical analysis	Data information	Device type	Procedure type	Follow-up	Website	Patients tracked	Sample size	Limitation
ICD Registry	NCDR ICD Registry [1]	Data collection version	NCDR Web site and personnel	He rigorous Data Quality Reporting (DQR) process ensure data accuracy, monthly site manager meetings, online dashboard	Yes	130 data elements	Single-or dual-chamber ICDs, CRT-D	Implantations and replacement	N.a.	Yes, annual report	N.a.	Most centers	N.a.
	Multicenter Pediatric ICD Registry [2]	Medical records	N.a.	N.a.	Yes	Demographic information, implant electrical parameters, appropriate and inappropriate shock data, and complications	N.a.	N.a.	N.a.	No	No	4 centers, 443 patients	Practice variation between centers; variation between operators in implantation techniques, variances in case mix, ages, and complexity of CHD, follow-up data insufficient
	The Ontario ICD Database [3]	Local electrophysiologist and a trained research coordinator	Into a web-sited registry	Continually assessed by regular review and correspondence with study sties, automated range checks, notification of uncoded data elements, and ongoing random site audits.	Yes	Patient characteristics, indication for the defibrillator, LVEF and implant-related data	ICD, CRT-D, lead	Implantations and generator replacements	Follow-up data is availabe	N.a.	Yes, unique encrypted card number	N.a.	The role of trainee, the location of the procedure, and the number of years in practice of the operator is not available in the registry.
	The Medtronic ICD Registry [4]	Medical records	N.a.	N.a.	Yes	Demographic data, ECG, two-dimensional echocardiogram, and concomitant treatment were reported in all patients	Single-or dual-chamber ICDs, CRT-D	Implantations and replacement	Mean follow-up was 12 months	No	No	507 patients	Possible bias in patient selection, only focused on Medtronic ICDs, the mean follow-up was short.
	ICD-registry Ludwigshafen [5]	N.a.	N.a.	N.a.	Yes	Patient characteristics and ICD shock therapy	ICD	Implantations and generator replacements	Every 3 month, median 3 year	No	No	1411 patients	N.a.
	The German DEVICE registry [6]	Telephone interview, a standard questionnaire	N.a.	N.a.	Yes	Age, gender, underlying heart disease, LVEF, NYHA class, co-morbidities, and medication, type of device and implantation procedure	ICD, CRT-D	Implantations and generator replacements	One-year follow up data	No	No	44 centers, 2812 patients	Long-term development of LV function is missing; no standardized questionnaires were used to analyze the potential change of the quality of life of enrolled patients within 1 year after device implantation.
	Spanish ICD Registry [7]	Data collection form was filled out by each implant team and sent to SEC	Members of the SEC entered data into registry	Data were cleaned by a SEC computer specialist and a member of the WG-ICD.	Yes	Indications, clinical characteristics of the patients, implant parameters, types of device, device programming, and complications	Single-or dual-chamber ICDs, CRT-D	Implantations and replacement	N.a.	Yes, annual report	N.a.	About 85%	N.a.
	French OPERA registry [8]	By the sponsor and an external org	N.a.	N.a.	Yes	The time between device programming and-	ICD, CRT-D	Implantations and generator replacements	3, 6, 12, 18, 24 months after enrolled	N.a.	N.a.	636 patients	Insufficient sample size
	Stidefix Registry [9]	Enrolled online	N.a.	N.a.	Yes	Medical information, indications for ICD implantation, and type of device implanted, and distinguishes first implants from device replacements	Single-dual chamber ICD, and CRT-D	Implantations and generator replacements	N.a.	No	No	66 ceners	N.a.
	The LEADER registry [10]	Data collection at the time of hospital discharge	N.a.	N.a.	Yes	Procedural characteristics, device implantation-related adverse events and device programming	ICD, lead, CRT-D	Implantations and replacement	Followed up at 3-6 months and at 12 months after the implantation	No	No	42 centers	Not consecutive, data were collected on paper and some missing data could not be obtained despite extensive repeated requests to the invetigators.
	National Registry on Cardiac Electrophysiology [11]	Personal contact with the heads of the pacing and electrophysiology laboratories and forms were sent via Email	N.a.	N.a.	Yes	The number and type of diagnostic electrophysiologic studies (EPS) and ablation procedures performed, types of arrhythmia treated by ablation and number and type of ICDs implanted or replaced,	ICD & BiV ICD	Implantations and replacement	N.a.	Yes, annual report	N.a.	18 centers	Lack of an online platform that would facilitate data collection and analysis.

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

						including biventricular cardiac resynchronization device (BiV ICDs)							
	EFFORTLESS S-ICD Registry [12]	Patients reported outcome	N.a.	N.a.	Yes	Adverse events, spontaneous arrhythmia episodes, and programming changes	N.a.	N.a.	60 months follow-up, first year record	N.a.	N.a.	472	N.a.
	The European LQTS ICD Registry [13]	Prespecified questionnaire	N.a.	N.a.	Yes	Demographics, genotype, personal and family clinical history, ECG measurements, treatment, response to therapy both before and after the ICD implantation, technical and functional characteristics of the devices, delivered therapies, revisions, and device-related complications.	ICDs	Implantations and replacement	Mean observation time for 4.6+3.2 years	No	No	233 patients	Potential time-dependent differences relative to the patients' baseline characteristics or the technical features of devices due to long term, possibly skewed the results due to multicenter nature of the study
	The Israeli ICD Registry [14]	Data were collected at the time of any initial device implantation and upgrade	Entered into a secure, web-based electronic case report form	Assessed by regular review and correspondence, completeness of implantation data was assessed by comparing the registry data with the number of devices provided by the manufacturers	Yes	Demographic and clinical characteristics, indication for defibrillator implantation, comorbidities, laboratory and echocardiographic data, previous medical treatments, device manufacturer, device and lead model, pacing and sensing parameters	ICDs, CRT-D	Implantations and replacement	Annual basis	No	No	07.2010-06.2012: 2811 patients	N.a.
	The Japanese Cardiac Device Treatment Registry [15]	Medical staff record a hard copy data sheet	JHRS office assess to JID-CAD website, and input patient data	N.a.	Yes	Implantation information, patient characteristics and pharmacologic treatment at the time of the implantation	ICD, CRT-D, CRT-P	First and replacements	Every 6 month within 2 years	N.a.	N.a.	60 centers, target population is 800	N.a.
	The Gulf ICD Registry [16]	Data collected on paper Case-report form (CRF)	Enter online using a web-based, custom designed, and password-protected electronic data capture portal.	N.a.	Yes	Baseline demographics, admission characteristics, medical history and risk factors, diagnostic procedures, ICD implant procedure characteristics, ICD programing, adverse events, discharge characteristics, discharge medications.	ICD	First implant	Follow-up schedule will be at the discretion of the implanting physician, which is typically every 3 or 4 months	N.a.	N.a.	1500	Risk to lost follow-up
	ICD registry in Taiwan [17]	N.a.	N.a.	N.a.	Yes	Patient data, including baseline characteristics, clinical comorbidities, primary cardiac diagnosis, the use of anti-arrhythmia drugs and LVEF were registered and collected from 3 sites	ICD	generator replacements	Every 3 months to evaluate	No	No	3 centers, 238 patients	Retrospective study character, Insufficient sample size
	A Multicenter French Registry [18]	Medical record	Co-investigators in charge of the data collection and analysis at each medical center	Data storage, quality control, and statistical analyses by three institutes.	Yes	Comorbidities, the type of ICDs	ICD	First	4-6 months	No	No	5539 patients	Retrospective nature of the registry led to information bias; no central adjudication for classification of appropriate and inappropriate therapies was used.
Pacemaker Registry	German Pacemaker Registry [19]	N.a.	N.a.	N.a.	N.a.	N.a.	Pacemaker	First and replacements	N.a.	Yes	N.a.	N.a.	N.a.
	Danish Pacemaker Register[20]	N.a.	N.a.	N.a.	N.a.	N.a.	Pacemaker	Implantations and generator replacements	N.a.	Yes	N.a.	All 14 centers	N.a.
	Spanish Pacemaker	European Pacemaker Patient Identification	Using specific software by 2 nurses trained in	Refine the data which transferred from the EPPIC	Yes	Age, sex, codes for symptoms, causes, indications, pacing modes,	Pacemaker, CRT-P	Implantations and generator	In 2013, some	Yes, Annual	Yes	About 35%	N.a.

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

	Registry [21]	Card (EPPIC), information from PM suppliers	the monitoring of pacing devices			implantations and extractions of leads and generators		replacements	included in home monitoring/follow-up groups	report, data sent to EUCOMED			
	Single Academic Pacemaker Center [22]	Clinic's archive	Transfer to electronic database	N.a.	Yes	all implants, first or replacements of permanent pacemakers	Pacemaker	First and replacements	N.a.	No	No	2180 patients	No follow-up data are available
	Nigeria Pacemaker Registry [23]	Data storage covers the fields recommended by the European pacemaker patient identification codes	A Microsoft access database	N.a.	Yes	Patients data, implant data and complications	Pacemaker	First and replacements	Median 26 months	No	No	2008-2012 51 patients	N.a.
CRT Registry	The CRT RENEWAL [24]	Data collected at each visit; Minnesota Living with Heart Failure quality of life questionnaire	N.a.	N.a.	Yes	Minnesota Living with Heart Failure QOL Questionnaire, Heart rate variability measures and activity log data	CRT	N.a.	2 weeks, 3, 6, 12 months post-implant visits	No	No	1206 patients from 107 centers	Patients dropped out of the study, lost to follow-up
	Single center registry on prognosis in CRT [25]	Data collected by chart review, device interrogation and telephone contact	N.a.	N.a.	Yes	N.a.	CRT	N.a.	Median 25+19 months	No	No	716 patients	N.a.
	The InSync/InSync ICD Italian Registry [26]	N.a.	N.a.	All examinations of a subject were always made by the same physician, who had a specific competence in assessing the effects of CRT	Yes	Demographic, history, and clinical variables as baseline, complications	CRT, CRT-D	First and replacements	1, 3, 6 months and every 6 months thereafter	No	No	117 Italian center	Potential bias in patient selection as well as lack of control group and patient blinding.
	Single center CRT registry [27]	Medical records	Entered into a database	N.a.	Yes	Medical records	CRT	N.a.	N.a.	No	No	627 patients	Retrospective study character and lack of a suitable control group
	J-CRT [28]	Doppler 1w, 6m, 12m after CRT	N.a.	N.a.	Yes	N.a.	CRT	Initially implantation	At least 6 months	N.a.	N.a.	225 patients from 18 centers	Data variability among the institutions
	The Contak Italian Registry [29]	N.a.	N.a.	N.a.	Yes	Baseline evaluation,	CRT	N.a.	Regular clinical visits	N.a.	N.a.	658 patients	Small population, not randomized
	A prospective CRT registry [30]	Patients with CRT-D	N.a.	N.a.	Yes	Baseline characteristics, ECG, procedural data	CRT-D	N.a.	A median of 5.2 years	N.a.	N.a.	295 patients	Technical limitations
CIED Registry	The REPLACE Registry [31]	A secure electronic data management system	Novella Clinical	Review medical record, reported events adjusted by Clinical Events Committee	Yes	Clinical data, complications, patient medical complaints	ICD and pacemaker generator replacement, including CRT-P and CRT-D	For generator replacement	A wound examination, a 3-month clinic or tele query, a final 6-month clinic visit	No	N.a.	Fixed sample size, 1750 patients, 72 institutions	Low precision because of not representative, no data beyond 6 months, not capture infrequent events
	The HomeGuide Registry [32]	Remote monitoring was accomplished with the Biotronik HM system based on ultra-low power daily or event-triggered transmissions in the MICS	From the implanted device to a mobile patient unit, forwarding data via GSM with GPRS protocol to a Service center with encrypted access	N.a.	Yes	N.a.	CIED	For generator replacement	At post-implanted discharge, at 1 month and then once in year	No	No	75 sites, 1650 patients	N.a.
	Registry of Emilia Romagna on Arrhythmia Interventions [33]	Data collected in each institution	N.a.	N.a.	Yes	Clinical characteristics, characteristics of implanted devices	CIED	First and replacements	N.a.	N.a.	N.a.	24 centers	N.a.
	Italy PM and ICD Registry [34]	EURID/Eucomed implant form, retrieved from mail	N.a.	Data checked on the day entry, and annual report review	Yes	EURID/Eucomed items	CIED	First and replacements	N.a.	Yes	Yes	N.a.	N.a.

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

	Swedish PM and ICD Registry [35]	EURID implant forms	Participating centers using direct data entry on the website	Regularly checked for internal consistencies by the Registry administer, and online statistics are updated on a daily basis.	Yes	Patients demographics, clinical indications, aetiology, complications, fluoroscopy time, surgical time, technical information on generators and leads, survival data	PM, ICD, CRT, CRT-P, CRT-D	First and replacements	1 year to see complications	Yes, annual report	Yes	44 centers, covering almost 100%, 121744 PM and 10503 ICD	NYHA class, left ventricular ejection fraction, and phrenic nerve stimulation are not available, CRT could therefore not be assessed.
	The Kaiser Permanente-Cardiac Device Registry [36]	Data source: device manufacturers, Paceart, and Apollo Data Repository.	All data were recorded and transferred to a centralized data repository for data management, validation, and reporting.	Automated, ongoing quality control procedures were carried out to flag patient and device data anomalies that were adjudicated using the EMR by clinical content experts.	Yes	Device characteristics, patient demographics, clinical indications for implant, procedural details, and postoperative outcomes	CIED	First and replacements	4 months follow-up	Yes	Yes	385 medical facilities	The KP-CDR does not track certain data on time variant and CIED-specific variables, is limited on the number of variables and detail of procedures captured in order to minimize data collection burden and ensure high quality.
Stent Registry	Guthrie Health Off-label Stent (GHOST) Registry [37]	A nurse performed data collection, medical records, telephone	Entered into an Excel spreadsheet and utilized for outcomes analysis	Exclusion patients make selection bias	Yes	Baseline clinical and angiographic characteristics, laboratory values, and in-hospital outcomes.	N.a.	N.a.	At least 5 years or occurrence of MACE	No	No	07.2001-12.2007: 896 PAT	Exclusion crieteria
	The prairie "real world" stent registry [38]	Procedure and in-hospital outcome data were obtained from NCDR Registry	Telephone	N.a.	Yes	Patient characteristics, MACE	DES, BMS	N.a.	6 M, 1 year, annually thereafter	No	No	379 PAT	Retrospective and not randomized control
	HMORN-Stent Registry [39]	N.a.	N.a.	N.a.	Yes	Clinical characteristics	N.a.	N.a.	N.a.	No	No	3 sites, 7689 PAT	N.a.
	POLAR Registry [40]	Latin A	11.2008-07.2010	To clinically evaluate the Promus stent in patients in clinical practice.	No	N.a.	Prospective	Multicenter	Boston Scientific	The Cardiovascular Research Centre	Ethics Committees approval	Yes	
	AUTAX (Austrian Multivessel TAXUS-Stent) registry [41]	N.a.	N.a.	N.a.	Yes	Patient characteristics, angiographic findings, procedural characteristics	TAXUS	N.a.	2 years	No	No	9 Centers	N.a.
	the Leipzig SUPERA Popliteal Artery Stent Registry [42]	Medical records	N.a.	N.a.	Yes	Patient characteristics, angiographic findings, procedural characteristics	SUPERA	N.a.	6, 12 M	No	No	101 patients	Further evidence needed to confirm these first encouraging results.
	German Cypher Stent Registry [43]	Case report forms were collected via the internet	N.a.	A query management was established for missing or implausible data	Yes	Patient characteristics, angiographic findings, interventional characteristics, clinical events	N.a.	N.a.	Up to 5 years	No	No	04.2002-09.2005: 5946 PAT	No reliable data during follow-up, no external outcome data validation
	German DES.DE Registry [44]	Internet platform	N.a.	N.a.	Yes	Baseline clinical and angiographic characteristics and certain procedural and clinical in-hospital events	Taxus and Cypher	N.a.	3, 6, 9, 12 M	No	No	From 10.2005-10.2006, 6384 patients at 98 sites	Low rates of enrollment and under-reporting of event
	WAR-STENT registry [45]	N.a.	N.a.	N.a.	Yes	Baseline characteristics, procedural characteristics, in-hospital events, prescriptions at discharge	N.a.	N.a.	12 M	No	No	411 patients from 37 centers	Small size is the main limitation
	The Tacrolimus-Eluting STent (TEST) registry [46]	Taken from centralized information database of the center, hospital records, telephone contacts	N.a.	N.a.	Yes	Patient characteristics, angiographic findings, procedural characteristics; in-hospital and long-term outcome	N.a.	N.a.	6, 9 M	No	No	140 PAT	N.a.
	Artery Angioplasty-Stent Registry III [47]	Online 3-page sheet	Website, Access, Excel Crystal Reports XI for business objects	N.a.	Yes	Complications	N.a.	N.a.	No	No	No	37 centers	No long-term follow-up

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

			software										
	The Frontier stent registry [48]	N.a.	N.a.	N.a.	Yes	Patient characteristics, procedural characteristics; MACE	N.a.	N.a.	180 days	No	No	130 PAT	Larger in profile, less flexible
	The China CYPHER Select registry [49]	Internet base, through phone call or visit	All data were submitted to a data-coordinating center and core laboratory via internet	Audit check was undertaken for all patients to assess data entry accuracy	Yes	Patient characteristics, MACE, the QCA measurements	SES	N.a.	6, 12 M	No	No	20 Center 1189 PAT	Different from "all comers" registry, patients selection bias may exist
	A novel computer based stent registry [50]	Computer-based, hospital information system	N.a.	N.a.	Yes	N.a.	N.a.	N.a.	N.a.	No	No	21 Cases	N.a.
	The j-Cypher Registry [51]	N.a.	Data entry	N.a.	Yes	Patient characteristics, procedural characteristics	N.a.	N.a.	5 years	No	No	37 centers	Patients participating in the registry were not fully monitored.
	the DATE registry [52]	A dedicated web-based case report form, medical record, telephone contact	N.a.	All outcome data were confirmed by source documentation collected from each participating center and were reviewed by an independent clinical event adjudication committee	Yes	Patient characteristics, procedural characteristics; Clinical outcome	ZES	N.a.	1, 3, 6, 12 M	No	No	17 centers 851 PAT	Sample size small, specific to one DES type
	FOCUS registry [53]	Via electronic data capture using web-based case report forms	Data management	N.a.	Yes	Lesion and procedural characteristics, clinical outcomes	N.a.	N.a.	30D, 6, 12, 24, 36 M	No	No	83 Center50 84 PAT	N.a.
	The 'all comer' Coroflex Please drug-eluting stent registry in Europe and Asia [54]	Paper hard copies and entry into database	Database	Accuracy of data	Yes	Patient characteristics, procedural characteristics; MACE	N.a.	N.a.	10.5+3.8 M	No	No	29 centers, 1230 PAT	A less stringent control of data collection and study monitoring
	DESERT (international Drug-Eluting Stent Event Registry of Thrombosis) [55]	N.a.	N.a.	N.a.	Yes	Patient characteristics, procedural characteristics	N.a.	N.a.	N.a.	No	No	984 patients from 21 sites	Case-control study cannot provide direct insight in to the incidence
	The TIMI 38 Coronary Stent Registry (CSR) [56]	N.a.	N.a.	N.a.	Yes	Patient characteristics, procedural characteristics	N.a.	N.a.	6-15 M	No	No	38 sites 20 countries; 2110 patients	N.a.
	E-Five Registry [57]	N.a.	N.a.	N.a.	Yes	Patient characteristics, angiographic and procedural characteristACics; Adverse Events	Promus	N.a.	1, 6, 12, 24 M	No	No	40 centers 1121 PAT	Bias in participants selection
	The Korean Multicenter Drug-Eluting Stent Registry [58]	A Web-based reporting system	N.a.	For any clinical event, all relevant medical records were reviewed and adjudicated by an external clinical event adjudication committee.	Yes	Demographics, Coexisting condition, Cardiac risk factors, Clinical Indication of PCI	Stent	N.a.	35 months	N.a.	N.a.	12,426 patients	Possibility of unmeasured confounders
TAVI Registry	The STS/ACC TVT Registry [59]	Electronic data support	N.a.	Data quality checks have been implemented at the National Cardiovascular Data Registry data warehouse and Duke Clinical Research Institute to optimize data completeness and accuracy.	Yes	Patient demographics, comorbidities, functional status, quality-of-life indexes, and procedural details and outcomes	N.a.	N.a.	Yearly follow-up	Yes, annual report	Yes	N.a.	N.a.
	Brazilian TAVI Registry [60]	N.a.	N.a.	N.a.	Yes	N.a.	TAVI	CoreValve and Sapien procedure	N.a.	No	No	18 centers 418 patient	N.a.
	The Austrian TAVI Registry [61]	N.a.	Accessible on the internet and allows an easy assessment of	N.a.	Yes	Demography, baseline characteristics including comorbidities, STS Score,	TAVI	CoreValve and Sapien procedure	1, 3, 6, 12, 24 and 36 month,	No	No	11 centers	A number of TAVI cases in Austria implanted by surgical centers are not included.

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

			patient data and procedures			EuroSCORE, QoL			median follow-up was 182 days				
	The Belgian TAVI Registry [62]	Collected and recorded at site	N.a.	Data pooling and statistical analysis were performed at the University	Yes	Patient characteristics, procedural characteristics and outcomes, causes of procedural mortality,	TAVI	CoreValve and Edwards procedure	1, 6, 12 months	No	No	15 centers	No centers performing both procedures, the number of patients is limited, no central core laboratory monitoring all events.
	The Swiss TAVI registry [63]	Standardized case-report forms from web-based database, follow-up data based on phone calls or clinical visit by each center	An independent monitor and statistician was performed to verify completeness and accuracy of data entry at each site	No on-site monitoring or patient data validation was performed	Yes	Baseline, procedural and in-hospital characteristics, follow-up data	TAVI	5 kinds of devices	30 days, 12 months, 3 and 5 years	No	N.a.	All centers	Clinical practice and expertise might be different in centers
	The Bern TAVI Registry [64]	By either clinical in-hospital visits or a standardized telephone interview.	Data were entered into a dedicated Web-based database, held at an academic clinical trials unit	All suspected events were presented to a dedicated clinical event committee consisting of cardiologists and cardiac surgeons	Yes	Baseline clinical and procedural characteristics as well as follow-up data.	TAVI	N.a.	After discharge, adverse events were assessed through active follow-up at 30 days and 12 months	N.a.	N.a.	N.a.	N.a.
	The Aachen TAVI registry [65]	Dedicated database, follow-up by visit or by telephone	N.a.	N.a.	Yes	Baseline clinical, laboratory, echocardiographic, DSCT as well as procedural data and clinical follow-up data	TAVI	N.a.	1 monthe, 1 year, 2 and 3 year	No	No	01.2008-08.2012: 367 TAVI procedures	N.a.
	The German TAVI Registry [66]	N.a.	N.a.	N.a.	Yes	Patient characteristics, outcome up to 30 days post procedure, preprocedural imaging	TAVI	CoreValve and Edwards procedure	N.a.	No	No	22 centers	Limited number of evaluated variables,
	FRANCE 2 Registry [67]	N.a.	N.a.	N.a.	Yes	Patient characteristics, procedural characteristics and outcomes, causes of procedural mortality,	TAVI	CoreValve and Edwards procedure	Mean 245 days	No	No	34 centers	Long term follow up is needed
	The ATHENS TAVR Registry [68]	Baseline and follow-up clinical and echocardiography data were prospectively gathered in each participating centre.	N.a.	N.a.	Yes	Baseline and follow-up clinical and echocardiography data	TAVI	N.a.	N.a.	No	No	4 centers 126 patients	N.a.
	The POL-TAVI registry [69]	Data was submitted by 20 centers	N.a.	N.a.	Yes	Baseline patient demographic, clinical and echocardiographic variables	TAVI	N.a.	After 6 month	No	No	381 Patients	Data was submitted by 20 centers performing TAVI procedures with different grade of completeness. Data submission was not monitored.
	OBSERVANT TAVI Registry [70]	A unique database for contemporary data collection	Online data entry on a password protected website.	A process of assessment of data completeness and robusness	Yes	Demographic characteristics, health status prior to intervention, comorbidities and complete information on the type of intervention	TAVI	N.a.	30-days follow-up	No	No	101 centers	The incompleteness of the monitoring process
	The UK TAVI registry [71]	95 variables	Data entry is performed by clinical staff and data clerks; A web browser based data entry	No external validation, range checks are applied to appropriate fields	Yes	Patient demographic features, indications, procedural details and outcomes up to the time of hospital discharge	TAVI	N.a.	1-3 years followed up	Yes	Yes, NHS number provides a unique identifier for any person	All centers	Lack of data validation, apart from life status, later clinical and quality-of-life follow-up.

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

											registered with the NHS in England and Wales		
	The Ibero-American TAVI registry [72]	Online-form	An online-form for data entry	N.a.	Yes	Baseline, procedural, complications	TAVI	CoreValve	Median 238 days	No	No	42 centers	Incomplete data
	The multi-centre European PARTNER TAVI study [73]	QoL questionnairs	N.a.	N.a.	Yes	Baseline, procedural, follow-up data	TAVI	N.a.	30 days, 6 months, and 1 year	No	No	N.a.	Sample size too small
	Rabin Medical Center TAVR registry [74]	Data were collected before TAVR, during hospitalization, and postoperatively at 30 days, 6, 12 months, and yearly after.	All collected data were registered in an electronic database.	N.a.	Yes	Demographic, clinical, and laboratory data	TAVI	N.a.	Postoperatively at 30 days, 6, 12 months, and yearly after.	No	No	319 patients	N.a.
	The Optimized CathEter vAlvular iNtervention (OCEAN-TAVI) registry [75]	N.a.	N.a.	N.a.	Yes	VARC-2	TAVI	TA, TF	N.a.	N.a.	N.a.	4 centers	No long-term outcomes.
	A large multicenter TAVI registry [76]	Prespecified clinical and laboratory data	N.a.	N.a.	Yes	VARC-2	TAVI	transfemoral,transapical, transaxillary, or direct aortic access routes		N.a.	N.a.	3 centers	No cause-and-effect suppositions
	The Italian CoreValve registry [77]	Self-report	Yes	Posteriori	Yes	VARC	TAVI	TF	13 months	N.a.	N.a.	7 centers	Not randomized
	A Multicenter Spanish Registry [78]	Clinical data and ECG data	N.a.	N.a.	Yes	Clinical and echocardiographic parameters, Charlson co-morbidity index,17 EuroSCORE II,18 and hospital characteristics	TAVI	N.a.	1 Year	N.a.	N.a.	726 patients	Not randomized; small sample size
	A Poland single-center registry [79]	N.a.	N.a.	N.a.	Yes	VARC	TAVI	TA, TF	At discharge, 30 days, 6 months and 12 months	N.a.	N.a.	101 patients	Small sample size
	The Transcatheter Valve Treatment Sentinel Pilot Registry [80]	From national registries	Data entered into a web-based case record form (CRF) or transferred from compatible national registries	Yes	Yes	VARC	TAVI	TA, TF	N.a.	N.a.	N.a.	4,571 patients from 137 centers in 10 EU countries	The absence of a centralised analysis process and independent adjudication
	The ROUTE registry [81]	N.a.	N.a.	N.a.	Yes	VARC-2	TAVI	Tao	30-day	N.a.	N.a.	32 patients	Small sample size
	SAPIEN XT Aortic Bioprosthesis Multi-Region Outcome Registry [82]	An independent clinical events committee adjudicated all adverse events	All data were entered in the electronic data capturing system and monitored	N.a.	Yes	VARC	SAPIEN XT valve	N.a.	2 years	N.a.	N.a.	99 sites in 17 countries	Pre- and post-TAVR echocardiographic evaluations were site reported and not reviewed by an independent core laboratory.

Supplementary Table 1 criteria of all 82 identified cardiac implant registries

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1#
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2#
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3#
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4#
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/a
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4#
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4#
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	4#
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5#
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5#
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5#
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5#
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	5#
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	5#

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	5#
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/a
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	5#
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6#
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	6#
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	6#
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	6-8#
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	6#
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	8-9#
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	10#
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	10#
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	10#

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BMJ Open

Cardiac implant registries 2006-2016: a systematic review and summary of global experiences

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-019039.R1
Article Type:	Research
Date Submitted by the Author:	10-Jan-2018
Complete List of Authors:	Zhang, Shixuan; Friedrich-Alexander-University of Erlangen-Nürnberg, Interdisciplinary Centre for Health Technology Assessment (HTA) and Public Health (IZPH) Gaiser, Sebastian; St. Jude Medical, Coordination Center BVBA Kolominsky-Rabas, Peter; Friedrich-Alexander-University of Erlangen-Nürnberg, Interdisciplinary Centre for Health Technology Assessment (HTA) and Public Health (IZPH)
Primary Subject Heading:	Cardiovascular medicine
Secondary Subject Heading:	Health services research, Public health, Qualitative research
Keywords:	cardiac implant, high-risk device, implant registry, real-world

Cardiac implant registries 2006-2016: a systematic review and summary of global experiences

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Cardiac implant registries 2006-2016: a systematic review and summary of global experiences

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Abstract:

OBJECTIVES: The importance of cardiac implant registry (CIR) for ensuring a long-term follow-up in post-market surveillance has been recognized and approved, but there is lack of consensus standards on how to establish a CIR. The aim of this study is to investigate the structure and key elements of CIRs in the past decade (2006-2016), and to provide recommendations on "best practice" approaches.

SETTINGS AND PARTICIPANTS: A systematic search on CIR was employed in line with the PRISMA guidelines. The following databases were searched: the PubMed (Medline), ScienceDirect and the Scopus database, EMBASE. After identifying the existing CIRs, an aggregative approach will be used to explore key elements emerging in the identified registries.

RESULTS: The following 82 registries were identified: 18 ICD registries, 7 CRT registries, 5 pacemaker registries, and 6 Cardiovascular Implantable Electronic Device (CIED) registries which combined ICD, pacemaker and CRT implantation data; as well as 22 coronary stent registries and 24 TAVI registries. While 71 national or local registries are from a single country, 44 are from European countries, and 9 are located in USA. The following criteria have been summarized from the identified registries, including: registry working group, ethic issues, transparency, research objective, inclusion criteria, compulsory participation, endpoint, sample size, data collection basement, data collection methods, data entry, data validation and statistical analysis.

CONCLUSIONS: Registries provide a "real-world" picture for patients, physicians, manufacturers, payers, decision-makers and other stakeholders. CIRs are important for regulatory decisions concerning the safety and therefore approval issues of the medical device; for payers CIRs provide evidence on the medical device benefit and drive the decision whether the product should be reimbursed or not; for hospitals CIRs' data are important for sound procurement decisions, and CIRs also help patients and their physicians to joint decision making which of the products is the most appropriate.

Article summary:

Strengths and limitations of this study

- This study is the first review summarizing global practice experience of the structure and key elements of the cardiac implant registries.
- Strength of the study is the identification of 14 key elements for designing and planning a cardiac implant registry, based on the experiences from 82 different registries.
- General limitation of a systematic review is due to the language limits, not all of the registries have been included in the review, which might cause missing data.

1.1 Rational

Any group of high-risk medical devices, bears the risk of inferior products which can bring harms to patients and can cause additional costs to the healthcare system because the revision procedures are needed, as stated by Labek et al. recently [1]. These high-risk medical devices include joint implants, osteosynthesis devices, breast implants, contact lenses as well as cardiology products [1]. In the field of cardiac implants, a total of 103 cases of cardiac implant adverse events have been reported in the past decade, 34 cases were due to battery problems [2].

To solve the above mentioned problems, technology needs to be constantly improved; setting up a complete post-surveillance system to track patients with cardiac implants is also an option. Compared to clinical studies, registries can be designed to ensure a long-term follow-up in post-market surveillance [3]. There is a clear demand from political authorities on changing from efficacy studies under ideal circumstance to effectiveness studies in a “real-world” setting for post-market surveillance. With the aim to raise awareness and bring evidence of the safe and good use of medical devices in the field of healthcare, World Health Organization (WHO) started to collect data of baseline country survey on medical devices from 2009, the updated version was published in 2017 [4]. This baseline country survey on medical devices is designed to establish availability of policies, guidelines, standards, and services for assessment, management and regulation of health technology in Member States. But it also shows a big challenge for each country to provide complete, updated or sufficient data and records on medical devices [4]. Facing these challenges some jurisdictions started to provide frameworks for the documentation and management of medical devices. The U.S. Food and Drug Administration (FDA) Medical Device Epidemiology Network (MDEpiNet) issued “Recommendations for a National Medical Device Evaluation System” aiming to bridge clinical care and research through strategically coordinated registry networks in August 2015 [5]. Moreover, the European Commission issued in May 2017 the “New Regulation on Medical Devices”, which was heavily influenced by the preceding “Poly Implant Prothèse – PIP” scandal in 2012 [6, 7].

As high-risk devices, cardiac implants have specific characteristics and thus registries have to reflect their requirements. Cardiac implant registries belong to the group of product registries, which aim to investigate the performance and impact of a product in a "real-world" setting [8]. It is different from the patient registry's objective, which focuses on the severity and duration of the disease [8]. Cardiac implants have different types of products. One specific category is based on using a battery inside called cardiovascular implantable electronic device (CIED) including Implantable Cardioverter Defibrillator (ICD), Pacemaker, and Cardiac Resynchronization Therapy (CRT); the other category does not need a battery to support including Coronary Stents and Transcatheter Aortic Heart Valve Implantation (TAVI). Although there are several cardiac implant registries worldwide [9, 10], there is still a lack of consensus about standards on how to design a cardiac implant registry. What elements should be included to design a cardiac implant registry? For different type of cardiac implant registry, what should be noticed when performing each element? Questions like these to design a cardiac implant registry need to be answered.

1.2 Objective

The aim of this study is to investigate the global structure and key elements of the cardiac implant registries, through an overview of existing cardiac implant registries worldwide in the past decade (2006-2016), and to provide recommendations on how to solve the problems arising from designing and planning a registry.

2. Methods

2.1 Search methodology

The search was performed for articles published between 01 January 2006 and 31 December 2016 in English. The following databases were searched: the PubMed (Medline), the ScienceDirect, the Scopus database and the EMBASE via DIMID. After performing the search, citation snowballing was used to make sure that all relevant literature was found. Finally, grey literature searching has been used to search the website of cardiac implant registry according to a practical tool for searching health-related grey literature published by Canada's Health Technology Assessment (HTA) Agency CADTH, and recommended by University of York [11]. National and international HTA web sites, clinical practice guideline producers, drug and device regulatory agencies are main grey literature source in this review. The search term regarding the name of different cardiac implants combined with registry were used as followings: Implantable cardioverter defibrillator registry, ICD registry, Cardiac Resynchronization Therapy registry, CRT registry, and pacemaker registry, coronary stent registry, TAVI registry, transcatheter aortic heart valve registry. The search was limited to titles,

abstracts in each addressed database. The full electronic search strategy for each database can be found in the online supplementary additional file 1. The review process followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [12].

2.2 Study selection

The titles and abstracts of all retrieved articles were reviewed by two researchers (SZH & PKO) independently after removing the duplicated studies. If two researchers had discrepancies, the article was discussed within an internal panel of members of the leading edge cluster Medical Valley. After identifying all the relevant articles, the researchers summarized them based on the same name of the registry. From those articles published by one single registry, the most recent or most significant article regarding the registry design has been chosen. The quality of observational studies included in our review was appraised by Newcastle-Ottawa Scale (selection, comparability, and outcome) criteria [13]. According to the criteria described by Niederlaender et al. 2017 [14], articles are included in the review if they precisely describe the design process of a cardiac implant registry. The publications were excluded if they were a single clinical study but with the registry name. Inclusion criteria and exclusion criteria for this review were listed in Table 1.

2.3 Data extraction

To identify the key elements of registry design, the researchers aggregated findings which are relevant to the design of a cardiac implant registry from each identified publication, based on 'Aggregative approaches to synthesis' described by Gough et al., 2013 [15]. The researchers took each element from identified articles which are relevant to the design of a cardiac implant registry. The quality of key elements was assessed based on the criteria described by Niederlaender et al., 2017 [14]. This step has been done by two researchers (SZH & PKO) independently. We assessed the possibility of publication bias both visually and formally to check if the publication contains description of each element for designing a cardiac implant registry.

3. Results

3.1 Bibliographic research results

This review identified 1529 studies that were potentially relevant. Of all these studies, 406 originated from the PubMed (Medline) database, 344 from the Scopus database, and 251 from the ScienceDirect, as well as 528 from the EMBASE. After removing duplicates, 624 abstracts have been reviewed by two researchers independently. 438 articles have been put into full text review afterwards. 416 articles were actually relevant and then included in the review. Among of them, 217 were related to an ICD registry, 13 were a CRT registry, 29 were about a pacemaker registry, 76 were

from a coronary stent registry, and 81 were from a TAVI registry. To summarize the cardiac implant registries from the identified articles, 82 registries were achieved, which shows in Figure 1. Detailed information of full electronic search strategy for each database can be found in online supplementary additional file 1.

Figure 1: PRISMA Flow diagram of study selection

Figure 2 shows the distributions of global cardiac implant registries. Table 2 provides an overview of the identified cardiac registries, among all of 82 identified registries, 35 registries are on-going registries. Specific information about the key elements of registries can be found in online supplementary additional file 2.

Figure 2: Location of identified cardiac implant registries

3.2 Key elements for designing the cardiac implant registry

A systematic 'Aggregative approaches to synthesis' described by Gough et al., 2013 was used to collect key elements arising from identified cardiac implant registries. The results were illustrated in following text. Specific information about key elements of registry design can be found in online supplementary additional file 2.

3.2.1 Research objective

Most registries were based on a clear research objective. Different kinds of research objectives can be summarized as follows: 24 registries aimed to provide a record of clinical status of the devices; 17 registries investigated safety and performance of the devices, with most of them being stent registries. Moreover, 5 registries examined the frequency of complications and their predictors after implantation; 4 registries predicted all-cause mortality of patients after implantation, most of them are CRT registries; and 10 registries compared the effects of devices from different manufactures or from different procedures, most of them are TAVI registries.

3.2.2 Participant criteria and participant requirement

The inclusion criteria for a registry study are not as strict as those for a clinical study. Only if the registry focuses on a specified group of patients, inclusion criteria will be defined accordingly. Patient inclusion criteria are different from each type of study for an implanted device in the registries. The Stent Registry collected data usually under "all-comers" conditions [16]. Patients are classified based on different categories in the CIED registries: first implantation versus generation replacement and

primary prevention versus secondary prevention [17]. The TAVI registries usually need a dedicated heart team to determine participants' criteria [18].

Based on patients' willingness to participate, it differentiates into volunteer registry and compulsory registry. 5 identified registries are compulsory registries, which have a mandatory requirement for all patients in a defined region with identified implanted device to participant [19-23]. Of all 82 identified registries, 4 registries reported tracking patients with a unique identifier.

3.2.3 Funding

Funding support is crucial for registries. 26 out of all 82 registries are funded by public organizations, which include cardiology societies, foundations or research institutes; 5 are financed by their local or national governments. 17 are funded by manufacturers, and 2 registries are funded by public organizations and manufacturers cooperatively.

3.2.4 Organization

All registries are cooperating with a health department. For a well-designed registry, a steering committee is necessary. The steering committees are responsible for defining the strategies, supervising the annual report, and encouraging health department to participate [24, 25]. Most identified registries have not provided a comprehensive description of their steering committee.

3.2.5 Ethic approval

Most registries have been approved by their local ethic committee or health department. The patient's consent is also required in most registries. One exception was found in the Ontario ICD Database, as a "prescribed entity" under Ontario health information privacy legislation, the coordinating center is allowed to collect data on all patients in this registry without informed consent [19].

3.2.6 Research type, data collection basement and sample size

Of all 82 registries identified in our study, 69 registries collected data prospectively, 11 registries conducted a retrospective study, and 2 studies conducted a prospective study also included data retrospectively. A registry can collect data from single center or from multicenter. As shown in Table 2, of all 82 identified registries, 30 are national level multicenter registries, 5 are international level multicenter registries, and 16 are single center registries, the rest are regional multicenter registries.

Unlike a clinical study, a registry study usually does not set a fixed sample size in the registry design phase, they just report the sample size when they publish and analyze the data. Exceptionally, few registries have a target enrollment number like the Gulf ICD Registry [26].

3.2.7 Clinical endpoint

Different types of registries have different clinical endpoint definitions. Major endpoints can be categorized as device-related outcomes and clinical outcomes. The TAVI registries defined an endpoint according to recommendations of the Valve Academic Research Consortium (VARC) or VARC-2, which is a standardized endpoint definition for TAVI [27, 28]. There is also clinical endpoint for coronary stent trials from Academic Research Consortium (ARC) [29]. However, endpoints for the CIED registry are inconsistently reported.

3.2.8 Procedures of collecting data

Data collection: the data has been collected either from medical records or from questionnaires. For the CIED device, transmitters are able to interrogate to most of the devices, and then download data from the device, which also can support data collection and data entry. After preparing a questionnaire, there are two ways to fill out the questionnaire: either patients fill out the questionnaires by themselves with a hard copy or via an online system; or medical staffs fill out the questionnaires according to a telephone interview or a face-to-face interview.

Data entry: most registries have a secure, web-based or a computer-based reporting system. For the single center registry, data entry is conducted by a trained nurse or fixed person in the working group. For the multicenter registries, participating centers entry the data into the system directly or send the data to the registry working group.

Data validation: different methods have been found to ensure the data accuracy. The registry can check the data randomly, and assess the data by regular review, similar to an annual report. If the registry collects the data from a multicenter, each participating center can confirm the data first, and then an independent working group in the registry can review the data again. In addition, the registry can assess if the data is complete by comparing the registry data with the manufactures' data.

3.2.9 Public accessibility

Of all 82 identified cardiac implant registries, 6 registries can be accessed via a web page, along with an annual report. The other 76 registries neither have a web-site available to the public nor an

annual report. These registries can be only identified via the publications, these publications provide clinical outcomes but limited information on registry design.

4. Discussion

To the best of our knowledge, our study is the first study to review the existing global cardiac implant registries and their practices as well as experiences. This manuscript introduces the structure and key elements, which can be seen as the first step of guidance on designing a cardiac implant registry in the future and making them more appropriate for public health decision makers as well as transparent to patients and other stakeholders. This review identified 82 cardiac implant registries from 28 countries or regions in the past decade. From these 82 registries, 9 categories with 14 key elements have been identified and illustrated in detail. The following text illustrates the recommendations and concerns arising from planning and designing a cardiac implant registry.

4.1 Cardiac implant registry's primary focus

The primary focus of cardiac implant registries is product's safety and effectiveness. As a high-risk medical device registry, the authors summarized the following aspects needed to be noticed in the process of designing a cardiac implant registry.

4.1.1 Volunteer bias

For a medical device registry, two kinds of volunteer bias will potentially occur: organizational level volunteer bias and individual level volunteer bias [19]. Volunteer bias can be defined as the bias that comes from the fact that a particular sample can contain only those participants who are actually willing to participate in the study or experiment [30]. In our case, for a volunteer cardiac implant registry, on the organizational level, centers may not participate for different reasons (low experience in the procedure, not enough staffs, not willing to publish data). On a patient level there might be volunteer bias towards patient groups with a higher level of health awareness and/or higher socio-economic level. To avoid volunteer bias, registries can learn from compulsory registries. Of all identified registries, 5 registries are compulsory registries, which were not subject to volunteer bias and were able to study all patients. For example, the Ontario Database was mandated by the administrator of health care services in Ontario [19], and participation from all ICD implanting centers was required. In addition, the Swiss TAVI registry has stated that consecutive patient enrolment was mandatory [23].

4.1.2 *Systematic follow-up for an adverse event reporting system*

Adverse event reporting should be considered and discussed as a major focal point when planning a cardiac implant registry. In addition, the registry should be capable of providing systematic follow-up event data. In our study, most of the registries summarized the event data in their publications or annual report.

4.1.3 *Rapid tracking of potentially impacted patients*

There is clear demand for the registry to take responsibility for tracking patients who have suffered from adverse events. Adverse events here indicate both device-related technique problems such as lead malfunction, and major adverse cardiovascular events (MACE) like atrial fibrillation (AF). When an adverse event occurred, the registry should track the patients who are implanted with such devices and notify them to prevent harm. However, not all registries were capable of tracking patients. The STS/ACC TVT Registry added a Unique Device Identifier field to allow tracking of specific devices, which are pending implementation of a Unique Device Identifier strategy by the FDA [31]. This example of a patient tracking strategy and usage is close to the authors' recommendation. Political authorities began to set up a device identification system to track the patients affected. The FDA issued the complete Global Unique Device Identification Database (GUDID) on 26 June 2014 [32]. The European Commission released a recommendation for a common framework for a UDI system of medical devices in the European Union on 05 April 2013 after the first announcement in the United States [33].

4.1.4 *Product generation and replacement*

Being a product which is placed in human body, cardiac implants have their own configurations nature and characteristics. One important area requiring attention is product generation and battery replacement. In this context, battery problems are the most frequent reasons for recalls and replacement of cardiac implants [34, 35]. Secondly, device technologies change more rapidly within a shorter time span compared to drug products [36]. This rapid change demands that researchers record the product brand and specifications model within registries. Implantation devices and their providers should be described in the registry and considered when analyzing data.

4.2 Public accessibility

The release of a free annual report and the accessibility on a web site are the most significant strategies for disseminating registries' results [37]. However, the result from our study demonstrated that there is still room for improvement. 74 (90.2%) registries can be only identified through their publications.

Data accessibility does not mean open access to the entire patient's data. Data accessibility is a way to give patients the opportunity to access information directly relevant to their condition. Since the cardiac implant registry aims to prevent adverse events, accessibility and transparency is vital to both researchers and the public. Many registries are only accessible to the sponsoring organizations. To improve public health and patient care; registry findings should be available and accessible for all stakeholders [38]. In an ideal setting, the communication between patients and physicians should be based on registry data. Therefore a personalized treatment can be delivered.

Publication is a way to show the study outcome from the registry, however, the public can only find limit information about registry design. Registries in principle are a new scientific entity as stated by Labek et al. 2016 [1]; there is a need from the research side for standardization for creation of a cardiac implant registry. If each registry describes their registry design and shares their experience with other researchers, it will improve the development of the registry study. One example of this would be sharing the requirements of randomized clinical trials (RCTs): "all RCTs are needed to provide a protocol describing the rational, methods, proposed analysis plan and organizational details [39]. "

4.3 Funding source

Funding sources and complying with the funders' purpose highlight two issues which need to be considered. Where does the funding come from? Are the funding sources capable of covering all expenditures? Stable funding source can guarantee financial support and eliminate the risk of the registry failing. Potential funding sources for registries are recommended by the "Agency for Healthcare Research and Quality (AHRQ)", which includes federal agencies such as government and other national governmental organizations, professional associations for instance patient groups, cardiology associations, product manufacturers such as companies or the pharmaceutical industry, as well as non-profit, private foundations and funders [40].

4.4 Limitation

The main limitation of this study is that the authors are only available to search in English, so other existing and well-developed cardiac implant registries have not been included in this review. Although the authors have done a global database search, grey search and hand search, however, it is difficult to assess whether all cardiac implant registries have been identified.

5. Conclusion

The importance of cardiac implants registries has been recognized and approved, but there is lack of consensus standards on how to establish a cardiac implant registry. Registries provide a "real-world" picture for patients, physicians, manufacturers, payers, decision-makers and other stakeholders. In this context, medical device registries are important for regulatory decisions, concerning the safety and therefore approval issues of the medical device. For payers medical device registries provide evidence on the benefit of the medical device and drive the decision whether the product should be reimbursed or not. For hospitals medical device registries' data are important for sound procurement decisions, and last - and of paramount importance- medical device registries help patients and their physicians to make joint decision on which product is the most appropriate.

6. Funding

The research is supported by the German Federal Ministry of Education and Research (BMBF), project grant no. 13EX1013B, as part of the National Leading-Edge Cluster Medical Technologies 'Medical Valley EMN'. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed. No writing assistance was utilized in the production of this manuscript.

The present work was performed in (partial) fulfillment of the requirements for obtaining the degree "Dr. rer. biol. hum." at the Medical Faculty of Friedrich-Alexander University of Erlangen-Nürnberg.

7. Competing interests statement

No, there are no competing interests.

8. Contributor ship statement

Mr. Peter L. Kolominsky-Rabas provided substantial contributions to conception and design; Ms. Shixuan Zhang drafted the articles with acquisition of data, analysis and interpretation of data; Mr. Sebastian Gaiser revised the manuscript critically for important intellectual content; Mr. Peter L. Kolominsky-Rabas made the final approval of the version to be published. The guarantor is Mr. Peter L. Kolominsky-Rabas.

9. Data sharing statement

Not applicable in this manuscript.

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Table 1 Inclusion criteria and exclusion criteria

Inclusion criteria	Exclusion criteria
• Cardiac implant registry; • Published from January 2006 to December 2016; • Peer-reviewed publications; • English language.	• Review, abstract, conference notice; • Clinical studies; • No complete description of registry design; • Not for cardiac implant registry.

Table 2 an overview of cardiac implant registries in the last decade In Multicenter=International level multicenter; N Multicenter=National level multicenter

Topic	Registry Name	Geography Coverage	Time	Research Type	Data Collection Basement
ICD Registry	NCDR ICD Registry	US	04.2006-	Prospective	N Multicenter
	Multicenter Pediatric ICD Registry	US	03.1992-03.2004	Retrospective	Multicenter
	The Ontario ICD Database	CA	02.2007-08.2009	Prospective	Multicenter
	The Medtronic ICD Registry	Latin A	01.2005-08.2007	Retrospective	Multicenter
	ICD-registry Ludwigshafen	DE	1992-05.2008	Prospective	Single center
	The German DEVICE registry	DE	03.2007-04.2010	Prospective	Multicenter
	Spanish ICD Registry	ES	2005-	Prospective	N Multicenter
	French OPERA registry	FR	05.2002-09.2008	Prospective	Single center
	Stidefix Registry	FR	03.2007-	Prospective	Multicenter
	The LEADER registry	FR	N.a.	Prospective	Multicenter
	National Registry on Cardiac Electrophysiology	PRT	N.a.	Prospective	N Multicenter
	EFFORTLESS S-ICD Registry	EU&NZ	06.2009-	P&R	In Multicenter
	The European LQTS ICD Registry	Global	2002-	P&R	In Multicenter
	The Israeli ICD Registry	IL	07.2010-	Prospective	Multicenter
	The Japanese Cardiac Device Treatment Registry	JP	08.2006-	Prospective	Multicenter
	The Gulf ICD Registry	AGR	10.2011-07.2016	Prospective	In Multicenter
	ICD registry in Taiwan	TWN	1998-2009	Retrospective	Multicenter
	A Multicenter French Registry	FR	2002-2012	Retrospective	Multicenter
Pacemaker Registry	German Pacemaker Registry	DE	1982-	Prospective	N Multicenter
	Danish Pacemaker Register	DK	01.1982-	Prospective	N Multicenter
	Spanish Pacemaker Registry	ES	1997-	Prospective	N Multicenter
	Single Academic Pacemaker Center	GR	01.1989-06.2006	Retrospective	Single center
	Nigeria Pacemaker Registry	NGA	01.2008-	Prospective	Single center
CRT Registry	The CRT RENEWAL	US	N.a.	Prospective	Multicenter
	Single center registry on prognosis in CRT	NLD	N.a.	Prospective	Single center
	The InSync/InSync ICD Italian Registry	IT	1999-	Prospective	Multicenter
	Single center CRT registry	SWE	1998-2008	Retrospective	Single center
	J-CRT	JP	04.2006-03.2009	Prospective	Multicenter
	The Contak Italian Registry	IT	2004-2007	Prospective	Multicenter
	A prospective CRT registry	NL	2005-2009	Prospective	Single center
CIED Registry	The REPLACE Registry	US	07.2007-06.2009	Prospective	Multicenter
	The HomeGuide Registry	IT	N.a.	Prospective	Multicenter
	Registry of Emilia Romagna on Arrhythmia Interventions	IT	07.2005-	Prospective	Multicenter
	Italy PM and ICD Registry	IT	2001-	Prospective	N Multicenter
	Swedish PM and ICD Registry	SWE	PM: 1989- ICD: 2004-	Prospective	N Multicenter
	The Kaiser Permanente-Cardiac Device Registry	US	01.2007-12.2013	Prospective	Multicenter
Stent Registry	Guthrie Health Off-label Stent (GHOST) Registry	US	07.2001-12.2007	Prospective	Single center
	The prairie "real world" stent registry	US	05.2003-07.2007	Retrospective	Single center
	HMORN-Stent Registry	US	2004-2007	Prospective	Multicenter
	POLAR Registry	Latin A	11.2008-07.2010	Prospective	Multicenter
	AUTAX (Austrian Multivessel TAXUS-Stent) registry	AUT	06.2004-	Prospective	Multicenter
	the Leipzig SUPERA Popliteal Artery Stent Registry	DE	01.2008-04.2010	Retrospective	Single center
	German Cypher Stent Registry	DE	04.2002-	Prospective	N Multicenter
	German DES.DE Registry	DE	10.2005-10-2006	Prospective	N Multicenter
	WAR-STENT registry	IT	11.2008-06.2010	Prospective	Multicenter
	The Tacrolimus-Eluting STent (TEST) registry	IT	02.2005-08.2005	Prospective	Single center
	Artery Angioplasty-Stent Registry III	UK	2005-2008	Prospective	Multicenter
	The Frontier stent registry	EU	05.2002-10.2002	Prospective	Multicenter
	The China CYPHER Select registry	CN	07.2004-08.2005	Prospective	Multicenter
	A novel computer based stent registry	IDN	01.2002-12.2011	Retrospective	Single center
	The j-Cypher Registry	JP	08.2004-11.2006	Prospective	Multicenter
	the DATE registry	KOR	12.2006-03.2008	Prospective	Multicenter
	FOCUS registry	Asia	03.2009-02.2010	Prospective	Multicenter
	The 'all comer' Coroflex Please drug-eluting stent registry in Europe and Asia	EU&ASIA	09.2006-02.2008	Prospective	Multicenter
	DESERT (international Drug-Eluting Stent Event Registry of Thrombosis)	Global	04.2003-	Retrospective	Multicenter
	The TIMI 38 Coronary Stent Registry (CSR)	Global	07.2007-07.2009	Prospective	Multicenter
	E-Five Registry	Global	10.2005-	Prospective	Multicenter
	The Korean Multicenter Drug-Eluting Stent Registry	Korea	N.a.	Prospective	Multicenter
TAVI Registry	The STS/ACC TVT Registry	US	05.2012-	Prospective	N Multicenter
	Brazilian TAVI Registry	BR	01.2008-12.2012	Prospective	Multicenter
	The Austrian TAVI Registry	AUT	01.2011-	Prospective	N Multicenter
	The Belgian TAVI Registry	BE	N.a.	Prospective	N Multicenter
	The Swiss TAVI registry	CHE	2011-	Prospective	N Multicenter
	The Bern TAVI Registry	CHE	08.2007-04.2012	Prospective	Single center
	The Aachen TAVI registry	DE	01.2008-	Prospective	Single center
	The German TAVI Registry	DE	01.2009-	Prospective	N Multicenter
	FRANCE 2 Registry	FR	2010-	Prospective	N Multicenter
	The ATHENS TAVR Registry	GR	10.2009-09.2011	Prospective	Multicenter
	The POL-TAVI registry	POL	2013-	Prospective	N Multicenter
	OBSERVANT TAVI Registry	IT	12.2010-	Prospective	Multicenter
	The UK TAVI registry	UK	2008-	Prospective	N Multicenter
	The Ibero-American TAVI registry	The Ibero-A	12.2007-05.2012	Prospective	In Multicenter

	The multi-centre European PARTNER TAVI study	EU	N.a.	Prospective	In Multicenter
	Rabin Medical Center TAVR registry	IL	11.2009-08.2013	Prospective	Single center
	The Optimized CathEter vAlvular iNtervention (OCEAN-TAVI) registry	JP	10.2013-12.2014	Prospective	Multicenter
	A large multicenter TAVI registry	Israel	2008-2014	Retrospective	Multicenter
	the Italian CoreValve registry	IT	2007-	Prospective	Multicenter
	A Multicenter Spanish Registry	ES	2014-	Prospective	Multicenter
	A Poland single-center registry	PL	2008-2014	Prospective	Single center
	The Transcatheter Valve Treatment Sentinel Pilot Registry	EU	01.2011-05.2012	Prospective	Multicenter
	The ROUTE registry	PL	05.2013-06.2014	Prospective	Multicenter
	SAPIEN XT Aortic Bioprosthesis Multi-Region Outcome Registry	International	07.2010-11.2011	Prospective	Multicenter

529

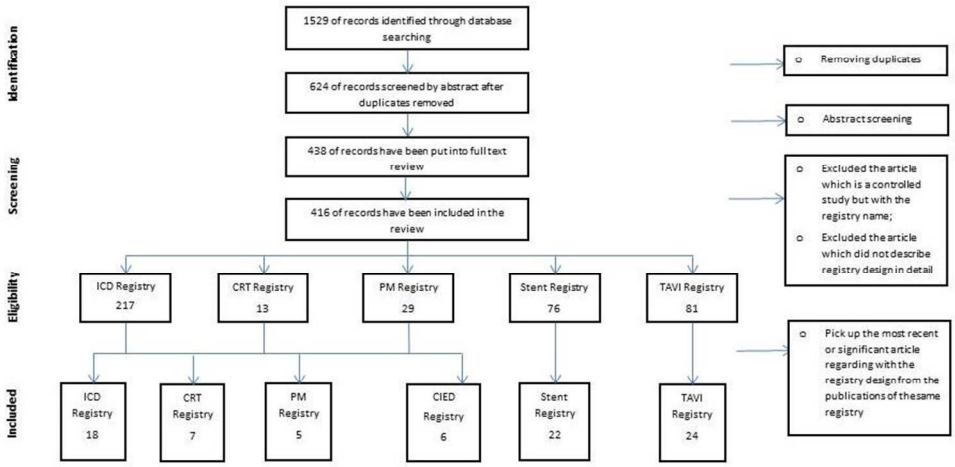

Figure 1: PRISMA Flow diagram of study selection

79x42mm (300 x 300 DPI)

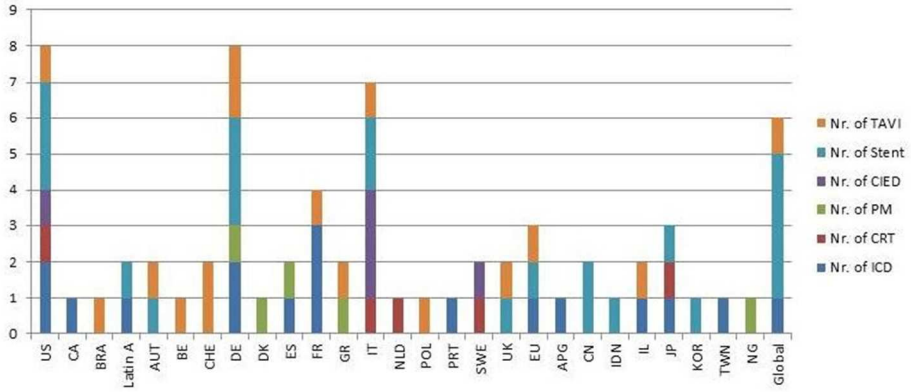

Figure 2: Location of identified cardiac implant registries
US=United States; CA=Canada; BRA=Brazilian; Latin A=Latin America; AUT=Austria; BE=Belgium; CHE=Swiss; DE=Germany; DK=Denmark; ES=Spain; GR= Grace; IT=Italy; NLD=Nederland; POL=Poland; PRT= Portugal; SWE=Sweden; UK=United Kingdom; EU=European Union; APG= Arab states of the Persian Gulf; CN=China; IDN=India; JP=Japan; KOR=Korea; TWN=Taiwan; NG=Nigeria

70x30mm (300 x 300 DPI)

Supplementary additional file 1 full electronic search strategy

Database		Search strategy
PubMed (Medline)	1	"Implantable cardioverter defibrillator registry"[Title/Abstract]
01 January 2006 to 31 December 2016	2	"ICD registry"[Title/Abstract]
	3	"Cardiac Resynchronization Therapy Registry"[Title/Abstract]
	4	"CRT registry"[Title/Abstract]
	5	("Cardiac Resynchronization Therapy"[Title/Abstract]) AND registry[Title/Abstract]
	6	“pacemaker registry”[Title/Abstract]
	7	“stent registry”[Title/Abstract]
	8	“tavi registry”[Title/Abstract]
	9	"Transcatheter aortic valve implantation registry"[Title/Abstract]
Total number of articles		406
Potentially relevant (after screening titles and abstracts)		254
Actually relevant (after screening abstracts and full text articles)		250

Database		Search strategy
Scopus	1	TITLE-ABS-KEY ("Implantable cardioverter defibrillator registry") AND PUBYEAR > 2005 AND PUBYEAR < 2017
	2	TITLE-ABS-KEY ("ICD Registry") AND PUBYEAR > 2005 AND PUBYEAR < 2017
01 January 2006 to 31 December 2016	3	TITLE-ABS-KEY ("Cardiac Resynchronization Therapy Registry") AND PUBYEAR > 2005 AND PUBYEAR < 2017
	4	TITLE-ABS-KEY ("CRT Registry") AND PUBYEAR > 2005 AND PUBYEAR < 2017
	5	TITLE-ABS-KEY ("pacemaker registry") AND PUBYEAR > 2005 AND PUBYEAR < 2017
	6	TITLE-ABS-KEY ("stent registry") AND PUBYEAR > 2005 AND PUBYEAR < 2017
	7	TITLE-ABS-KEY ("tavi registry") AND PUBYEAR > 2005 AND PUBYEAR < 2017
	8	TITLE-ABS-KEY ("Transcatheter aortic valve implantation registry") AND PUBYEAR > 2005 AND PUBYEAR < 2017
Total number of articles		344
After removing duplicates		117
Potentially relevant (after screening titles and abstracts)		117
Actually relevant (after screening abstracts and full text articles)		105

Database		Search strategy
ScienceDirect	1	Pub-date > 2005 and pub-date < 2017 and TITLE-ABSTR-KEY(“Implantable cardioverter defibrillator registry”)
01 January 2006 to 31 December 2016	2	Pub-date > 2005 and pub-date < 2017 and TITLE-ABSTR-KEY("ICD registry")
	3	Pub-date < 2017 and TITLE-ABSTR-KEY("Cardiac Resynchronization Therapy Registry")
	4	Pub-date > 2005 and pub-date < 2017 and TITLE-ABSTR-KEY("CRT registry")
	5	Pub-date > 2005 and pub-date < 2017 and TITLE-ABSTR-KEY("Pacemaker registry")
	6	Pub-date > 2005 and pub-date < 2017 and TITLE-ABSTR-KEY(“stent registry”).
	7	Pub-date > 2005 and pub-date < 2017 and TITLE-ABSTR-KEY(“tavi registry”)
	8	Pub-date > 2005 and pub-date < 2017 and TITLE-ABSTR-KEY("Transcatheter aortic valve implantation registry") Search strategy
Total number of articles		251
After removing duplicates		74
Potentially relevant (after screening titles and abstracts)		50
Actually relevant (after screening abstracts and full text articles)		44

Pub-date=Publication date; ABSTR=Abstract; KEY=Key words

Database		Search strategy
EMBASE via DIMID	1	(TI="Implantable cardioverter defibrillator" AND TI=registry) AND PY=2006 to 2016 AND LA=ENGLISH
01 January 2006 to 31 December 2016	2	(TI=ICD AND TI=Registry) AND PY=2006 to 2016 AND LA=ENGLISH
	3	(TI="Cardiac Resynchronization Therapy" AND TI=registry) AND PY=2006 to 2016 AND LA=ENGLISH
	4	(TI=pacemaker AND TI=registry) AND PY=2006 to 2016 AND LA=ENGLISH
	5	TI="stent registry" AND PY=2006 to 2016 AND LA=ENGLISH
	6	TI=("Transcatheter Aortic Valve Implantation" AND TI=registry) AND PY=2006 to 2016 AND LA=ENGLISH
	7	TI="TAVI Registry" AND PY=2006 to 2016 AND LA=ENGLISH
Total number of articles		528
After removing duplicates		27
Potentially relevant (after screening titles and abstracts)		17
Actually relevant (after screening abstracts and full text articles)		17

TI=Title; PY=Publication year; LA=Language

Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

Topic	Registry Name	Geography coverage	Time	Research objectives	Participant criteria	Endpoint	Research type	Data collection basement	Initiator or funding	Registry working group	Ethic committee approval	Informed consent	Compulsory
ICD Registry	NCDR ICD Registry [1]	US	04.2006-	To provide important insights into clinical and procedural characteristics of patients receiving an ICD in US	N.a.	N.a.	Prospective	Multicenter	American College of Cardiology Foundation and the Heart Rhythm Society	Working group	N.a.	N.a.	No
	Multicenter Pediatric ICD Registry [2]	US	03.1992-03.2004	To examine a current-era cohort using a long-term multicenter retrospective approach to identify a large group of pediatric and CHD patients with ICDs.	Yes	N.a.	Retrospective	Multicenter	N.a.	N.a.	Local review board	N.a.	No
	The Ontario ICD Database [3]	CA	02.2007-08.2009	To examine the frequency of complications and their predictors.	N.a.	N.a.	Prospective	Multicenter	Ontario Ministry of Health and Long-term care	Local electrophysiologist and a trained research coordinator	N.a.	No	Yes
	The Medtronic ICD Registry [4]	Latin A	01.2005-08.2007	To summarize experience in patients with Chagas' disease and life-threatening ventricular arrhythmias implanted with ICDs and to classify the type of spontaneous ventricular tachyarrhythmia presented and the respective therapy provided by the device.	N.a.	Multiple shocks or adverse event	Retrospective	Multicenter	Medtronic Inc. Latin America Operation	N.a.	Local ethics committee	Yes	No
	ICD-registry Ludwigshafen [5]	DE	1992-05.2008	N.a.	N.a.	N.a.	Prospective	Single center	N.a.	N.a.	N.a.	Yes	No
	The German DEVICE registry [6]	DE	03.2007-04.2010	To gather information on overall mortality, re-hospitalization, early and late clinical and device complications, heart failure development, incidence of ICD shock delivery, change of medication and necessary device upgrading procedures.	Only data on new implants	N.a.	Prospective	Multicenter	Institut für Herzinfarktforschung	DEVICE registry office	N.a.	Yes	No
	Spanish ICD Registry [7]	ES	2005-	To determine how ICDs are currently used in Spain.	N.a.	N.a.	Prospective	N Multicenter	Spanish Society of Cardiology	Working group on ICDs	N.a.	N.a.	No
	French OPERA registry [8]	FR	05.2002-09.2008	To study the determinants of FAT and FIT therapies delivered by single-, dual-, and triple-chamber ICD	Yes	N.a.	Prospective	Single center	Guidant/Boston Scientific	N.a.	Approved by CNIL	Yes	No
	Stidefix Registry [9]	FR	03.2007-	To respond to the legal mandate of the French health authorities requiring the enrolment of all new ICD implants in a national registry by the medical centres, to create a database enabling analysis of the French practices in the area of cardiac pacing and defibrillation, and to provide a computer-based tool to the implanting centres for managing implantations.	Yes	N.a.	Prospective	Multicenter	Biotronik France, Boston Scientific France, Medtronic France, Saint Jude Medical France and Sorin Group France	N.a.	N.a.	Yes	No
	The LEADER registry [10]	FR	N.a.	To determine the DT procedures used in everyday practice, to compare the characteristics of patients with or without DT, and to compare severe adverse events in these two populations during implantation and follow-up.	Yes	N.a.	Prospective	Multicenter	Boston Scientific Corporation, Guidant France SAS	N.a.	Approved by the French Ministry of Scientific Research and the French Privacy Authority	Yes	No
	National Registry on Cardiac Electrophysiology [11]	PRT	N.a.	To provide an overall picture of the situation in Portugal with regard to the number of participating centers and their volume of activity and the number and type of procedures performed, as well as development over time.	N.a.	N.a.	Prospective	N Multicenter	Portuguese Association of Arrhythmology, Pacing and Electrophysiology (APAPE) and the Portuguese Institute of Cardiac Rhythm (IPC)	N.a.	N.a.	N.a.	No
	EFFORTLESS S-ICD Registry [12]	EU&NZ	06.2009-	To document clinical, system, and patient related outcome data from S-ICD patients implanted since the commercial release of the S-ICD.	Yes	N.a.	P&R	In Multicenter	Cameron Health	N.a.	N.a.	Yes	No
	The European LQTS ICD Registry [13]	Global	2002-	To assess the current indications to implant according to clinical history, response to previous therapy, and specific genotype and to evaluate the clinical course after ICD implantation.	Yes	N.a.	P&R	In Multicenter	Medtronic Bakken Research Center in the Netherlands and Boston Scientific	Working Group	Local institutional review boards	Yes	No

Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

	The Israeli ICD Registry [14]	IL	07.2010-	N.a.	N.a.	All-cause mortality. VT/VF, HF, ATP or shock	Prospective	Multicenter	N.a.	Working Group	Ethics committee of each participating institution	Yes	Yes
	The Japanese Cardiac Device Treatment Registry [15]	JP	08.2006-	To record current clinical situation of cardiac implantable defibrillator devices.	N.a.	N.a.	Prospective	Multicenter	The Japanese Heart Rhythm Society	JHRS office	Each institution	Yes	N.a.
	The Gulf ICD Registry [16]	AGR	10.2011-07.2016	To describe the characteristics and the outcomes of patients receiving ICDs in the Arab Gulf region.	A new ICD implant	All-cause mortality, adverse event	Prospective	Multicenter	Conducted under the auspices of the Gulf Heart Association, Gulf Heart Rhythm Society, and Saudi Heart Rhythm Society. Funded by Medtronic Inc. and Boston Scientific,	N.a.	Per local ethics regulations	Yes	N.a.
	ICD registry in Taiwan [17]	TWN	1998-2009	To investigate the long-term prognosis and the predictors of mortalities among ICD recipients in Taiwan.	N.a.	The occurrence of all-cause mortality	Retrospective	Multicenter	N.a.	N.a.	Approved by the institutional review board	N.a.	No
	A Multicenter French Registry [18]	FR	2002-2012	To determine the proportion of female ICD recipients, and differences in terms of characteristics at implant and outcomes in women compared to men.	At least 18 years old at the time of ICD implantation, first implantation	Appropriate therapies, early complications, inappropriate shocks, overall and specific mortalities.	Retrospective	Multicenter	Public sources	Steering Committee:	By the French data protection committee	Yes	No
Pacemaker Registry	German Pacemaker Registry [19]	DE	1982-	N.a.	N.a.	N.a.	Prospective	Multicenter	N.a.	N.a.	N.a.	N.a.	No
	Danish Pacemaker Register[20]	DK	01.1982-	To record all implantations and removals of PPM and PM-leads.	N.a.	N.a.	Prospective	N Multicenter	N.a.	N.a.	N.a.	N.a.	Yes
	Spanish Pacemaker Registry [21]	ES	1997-	To report most relevant characteristic in Spain.	N.a.	N.a.	Prospective	N Multicenter	Spanish Society of Cardiology	Working group	N.a.	N.a.	No
	Single Academic Pacemaker Center [22]	GR	01.1989-06.2006	To evaluate changes in indications for pacing and pacing modes.	N.a.	N.a.	Retrospective	Single center	N.a.	N.a.	N.a.	N.a.	No
	Nigeria Pacemaker Registry [23]	NGA	01.2008-	N.a.	N.a.	N.a.	Prospective	Single center	N.a.	N.a.	Ethics committee	Yes	No
CRT Registry	The CRT RENEWAL [24]	US	N.a.	To predict all-cause mortality as a means to help better manage this group of patients.	Specific device	N.a.	Prospective	Multicenter	Boston Scientific CRM	N.a.	Local institutional review boards	Yes	No
	Single center registry on prognosis in CRT [25]	NLD	N.a.	To better understand survival benefit in patients treated with CRT.	Yes	N.a.	Prospective	Single center	N.a.	N.a.	N.a.	N.a.	No
	The InSync/InSync ICD Italian Registry [26]	IT	1999-	To evaluate the effectiveness of CRT alone or in combination with an ICD (CRT-D).	Yes	All-cause mortality	Prospective	Multicenter	N.a.	N.a.	By ethics committees of each participating center	Yes	No
	Single center CRT registry [27]	SWE	1998-2008	N.a.	Yes	N.a.	Retrospective	Single center	The Stockholm County Council	N.a.	Approved by the local ethics committee	N.a.	No
	J-CRT [28]	JP	04.2006-03.2009	To identify both ability of echocardiographic parameters to detect CRT volume responders and relation of these parameters with clinical outcomes.	Yes	Death; adverse event	Prospective	Multicenter	N.a.	J-CRT committee, 2-day workshop training	each institution	Yes	No
	The Contak Italian Registry [29]	IT	2004-2007	To compare the long-term prognosis of patients who received CRT-D or CRT-P according to class IA	Yes	Death	Prospective	Multicenter	N.a.	N.a.	Approved by the Local Ethics	Yes	No

Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

				recommendations of the European Society of Cardiology (ESC).							Committees		
	A prospective CRT registry [30]	NL	2005-2009	To assess the independent predictive value of apical rocking on long-term clinical outcomes in a large study population.	CRT-D	MACE	Prospective	Single center	N.a.	N.a.	the institutional review board	N.a.	No
CIED Registry	The REPLACE Registry [31]	US	07.2007-06.2009	Risk related to generator replacements with lead generator.	Yes	6 months	Prospective	Multicenter	Funded by BIOTRONIK	The REPLACE Registry Steering Committee, Clinical Events committee, Novella Clinical	Each institution	Yes	No
	The HomeGuide Registry [32]	IT	N.a.	To provide an organizational model for implementing remote monitoring of CIEDs in daily clinical practices.	N.a.	N.a.	Prospective	Multicenter	Biotronik Italia	Steering committee	An institutional review board	Yes	No
	Registry of Emilia Romagna on Arrhythmia Interventions [33]	IT	07.2005-	To collect clinical and implant data for all cardiac devices implanted in the Emilia-Romagna region.	N.a.	N.a.	Prospective	Multicenter	The regional health care and social agency of Emilia-Romagna	N.a.	Each institution	Yes	No
	Italy PM and ICD Registry [34]	IT	2001-	To evaluate the effects in clinical practice of the major guidelines.	N.a.	N.a.	Prospective	Multicenter	Italian Society of Arrhythmology and Cardic Pacing (AIAC)	N.a.	N.a.	N.a.	No
	Swedish PM and ICD Registry [35]	SWE	PM: 1989- ICD: 2004-	To provide a real time picture of the use of CIED in clinical practice.	N.a.	N.a.	Prospective	N Multicenter	Swedish Heart Lung Foundation & Stockholm County council	Registry Administers	Each institution	N.a.	Yes
	The Kaiser Permanente-Cardiac Device Registry [36]	US	01.2007-12.2013	To describe key elements, clinical outcomes, and potential uses of the Kaiser Permanente-Cardiac Device Registry	N.a.	N.a.	Prospective	Multicenter	N.a.	N.a.	N.a.	Yes	Yes
Stent Registry	Guthrie Health Off-label Stent (GHOST) Registry [37]	US	07.2001-12.2007	To compare long-term safety and effectiveness of DES versus BMS in patients undergoing PCI for NSTEMI.	Yes	MACE	Prospective	Single center	The Guthrie Health Foundation	N.a.	N.a.	N.a.	No
	The prairie "real world" stent registry [38]	US	05.2003-07.2007	To compare long-term mortality for DES versus BMS in patients with SVG disease from our large “real world” cohort of stent patients	Yes	All-cause mortality, MACE	Retrospective	Single center	N.a.	N.a.	N.a.	N.a.	No
	HMORN-Stent Registry [39]	US	2004-2007	All patients who underwent PCI with a DES	N.a.	N.a.	Prospective	Multicenter	N.a.	N.a.	N.a.	N.a.	No
	POLAR Registry [40]	Latin A	11.2008-07.2010	To clinically evaluate the Promus stent in patients in clinical practice.	No	N.a.	Prospective	Multicenter	Boston Scientific	The Cardiovascular Research Centre	Ethics Committees approval	Yes	No
	AUTAX (Austrian Multivessel TAXUS-Stent) registry [41]	AUT	06.2004-	To evaluate patients with multivessel CAD with/without previous PCI or concomitant cardiac surgery with possible complete revascularization by PCI, and treated solely with multiple TAXUS Express stent implantation in a “real world” setting, and to report the short, medium, and long term angiographic and clinical outcomes	No	N.a.	Prospective	Multicenter	N.a.	N.a.	Austrian Society of Cardiology and the institutional review committees approval	Yes	No
	the Leipzig SUPERA Popliteal Artery Stent Registry [42]	DE	01.2008-04.2010	To evaluate the efficacy and integrity of this new nitional stent system in complex popliteal artery obstructions, implementing a clinically established systematic follow-up regime with stent fracture screening and evaluation for restenosis.	No	N.a.	Retrospective	Single center	N.a.	N.a.	N.a.	Yes	No
	German Cypher Stent Registry [43]	DE	04.2002-	To determine the safety, effectiveness and 6-month and long term follow-up data of the SES in clinical practice and factors associated with clinical events as well as the need for TVR during follow-up.	No	N.a.	Prospective	Multicenter	DGK;DNK;ALKK, Cordis Corporation, J&J	Steering committee	N.a.	Yes	No
	German DES.DE Registry [44]	DE	10.2005-10-2006	To compare the effects of PES, SES and BMSs in a “real-world” setting	Yes	N.a.	Prospective	Multicenter	DGK;DNK;ALKK	Steering committee	N.a.	Yes	No
	WAR-STENT registry [45]	IT	11.2008-06.2010	To investigate the contemporary management of patients on warfarin undergoing PCI-S, and to	No	N.a.	Prospective	Multicenter	N.a.	N.a.	Ethic committee	Yes	No

Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

				determine the incidence of adverse events in a real-world setting.									
	The Tacrolimus-Eluting STent (TEST) registry [46]	IT	02.2005-08.2005	To investigate the safety and efficacy of this particular TES in an unselected population of patients, without the restrictive clinical or angiographic criteria applicable to previous trials.	Yes	MACE	Prospective	Single center	N.a.	N.a.	N.a.	N.a.	No
	Artery Angioplasty-Stent Registry III [47]	UK	2005-2008	To set standards of practice of interventional radiologists carrying out iliac interventional procedures.	No	N.a.	Prospective	Multicenter	BSIR	Working group	N.a.	N.a.	No
	The Frontier stent registry [48]	EU	05.2002-10.2002	To investigate the safety and performance of this device for the treatment of de novo or restenotic bifurcation lesions.	Yes	MACE	Prospective	Multicenter	Guidant Corp	The data and safety monitoring board and clinical events committee	N.a.	N.a.	No
	The China CYPHER Select registry [49]	CN	07.2004-08.2005	To evaluate the safety and efficacy or the CYPHER Select SES	No	MACE, cardiac death, nonfatal MI, TLR	Prospective	Multicenter	Chinese Society of Cardiology	Data coordinating center and core laboratory	N.a.	Yes	No
	A novel computer based stent registry [50]	IDN	01.2002-12.2011	To evaluate the feasibility of a computer based stent registry with patient directed automated information system to prevent retained double J stents.	No	N.a.	Retrospective	Single center	N.a.	N.a.	N.a.	N.a.	No
	The j-Cypher Registry [51]	JP	08.2004-11.2006	To investigate the safety of DES	N.a.	Death	Prospective	Multicenter	Cordis Cardiology Japan and J&J	Data management center	N.a.	Yes	No
	the DATE registry [52]	KR	12.2006-03.2008	To determine the feasibility of 3-month dual antiplatelet therapy after ZES implantation in relatively low risk patients with coronary artery disease.	Yes	Death	Prospective	Multicenter	IN-SUNG Foundation	Steering committee	Institutional review board	Yes	No
	FOCUS registry [53]	Asia	03.2009-02.2010	To evaluate the safety and efficacy of a second-generation cobalt-chromium sirolimus-eluting stent in routine treatment of patients with coronary artery disease.	Yes	MACE	Prospective	Multicenter	MicroPort Medical	An independent clinical research organization	ethics committees	Yes	No
	The 'all comer' Coroflex Please drug-eluting stent registry in Europe and Asia [54]	EU&ASIA	09.2006-02.2008	To further document the safety and efficacy of the Coroflex Please paclitaxel-eluting stent.	Yes	MACE	Prospective	Multicenter	N.a.	Data management group	N.a.	N.a.	No
	DESERT (international Drug-Eluting Stent Event Registry of Thrombosis) [55]	Global	04.2003-	To identify clinical, procedural, and angiographic correlates of late/very late DES thrombosis as well as to determine the clinical outcomes of these events.	Yes	N.a.	Retrospective	Multicenter	N.a.	N.a.	N.a.	N.a.	No
	The TIMI 38 Coronary Stent Registry (CSR) [56]	Global	07.2007-07.2009	To investigate the DAPT after ACS.	Yes	MACE	Prospective	Multicenter	Daiichi Sankyo Co. Ltd, and Eli Lilly and Co	N.a.	N.a.	N.a.	No
	E-Five Registry [57]	Global	10.2005-	To documentation of the safety and clinical performance of the Endeavor ZES in real-world and to assess the event rate	Yes	MACE	Prospective	Multicenter	Medtronic Vascular	N.a.	Local ethics committees	Yes	No
	The Korean Multicenter Drug-Eluting Stent Registry [58]	Korea	N.a.	For second-generation biocompatible or biodegradablepolymer coated DES	Stent	Stent-oriented outcomes (target lesion failure [TLF]) and patient-oriented composite outcomes (POCO)	Prospective	Multicenter	N.a.	N.a.	The ethics committee at each participating center	Yes	No
TAVI Registry	The STS/ACC TVT Registry [59]	US	05.2012-	to measure and improve quality of care and patient outcomes in clinical practice and to have a pivotal role in the scientific evidence and surveillance for medical devices	N.a.	N.a.	Prospective	N Multicenter	The Society of Thoracic Surgeons and the American College of Cardiology	The steering committee	N.a.	N.a.	No
	Brazilian TAVI Registry [60]	BR	01.2008-12.2012	To identify the clinical and procedural variables related to PPM implantation after TAVI.	N.a.	N.a.	Prospective	Multicenter	Brazilian society of interventional cardiology	N.a.	N.a.	Yes	No
	The Austrian TAVI	AUT	01.2011-	To monitor TAVI procedures	N.a.	from VARC	Prospective	Multicenter	Austrian Society of	N.a.	The	Yes	No

Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

	Registry [61]								Cardiology, Committee on Interventional Cardiology		institutional Review Board of the Medical University Graz		
	The Belgian TAVI Registry [62]	BE	N.a.	To include and follow-up all consecutive Belgian TAVI procedures.	TAVI was considered by the heart team	N.a.	Prospective	Multicenter	N.a.	No core laboratory	Approved by the institutional Ethics Committee	N.a.	Yes
	The Swiss TAVI registry [63]	CHE	2011-	To assess the safety and efficacy of unselected and consecutive TAVI procedures in Switzerland.	N.a.	from VARC	Prospective	Multicenter	Swiss Heart Foundation, manufactures, the Swiss Working Group of Interventional Cardiology and Acute Coronary Syndrome	Under the lead of Swiss Cardiovascular Center Bern	N.a.	Yes	Yes
	The Bern TAVI Registry [64]	CHE	08.2007-04.2012	N.a.	N.a.	from VARC	Prospective	Single center	N.a.	N.a.	The local ethics committee	Yes	No
	The Aachen TAVI registry [65]	DE	01.2008-	To evaluate the clinical pre-interventional predictors, including aortic valve calcification severity, of 3-year outcome and mortality in a real-world population treated with TAVI.	Yes	N.a.	Prospective	Single center	N.a.	N.a.	N.a.	N.a.	No
	The German TAVI Registry [66]	DE	01.2009-	N.a.	N.a.	N.a.	Prospective	Multicenter	N.a.	N.a.	Yes	No	N.a.
	FRANCE 2 Registry [67]	FR	2010-	To analyze patient characteristics and clinical outcome of performing TAVI.	By a dedicated heart team	Incidence of AKI (acute kidney injury)	Prospective	Multicenter	N.a.	Scientific committee	N.a.	N.a.	No
	The ATHENS TAVR Registry [68]	GR	10.2009-09.2011	To evaluate the procedural, echocardiographic and 30-day clinical outcomes of patients undergoing transfemoral implantation of the newer generation valves in the "real world"; 2) to compare the procedural, echocardiographic and 30 day clinical outcomes of the nonrandomized use of the two available valve types.	Under a systematic workup protocol	from VARC	Prospective	Multicenter	N.a.	N.a.	Each participating centre	Yes	No
	The POL-TAVI registry [69]	POL	2013-	To assess the incidence of moderate-to-severe PVL after TAVI.	Yes	N.a.	Prospective	N Multicenter	N.a.	N.a.	N.a.	N.a.	Yes
	OBSERVANT TAVI Registry [70]	IT	12.2010-	To evaluate and compare short-, medium-, and long-term outcomes in patients undergoing SAVR or TAVI, in terms of both survival and major adverse cardiac and cerebrovascular events, to build a new pre-procedure risk score, specific for the elderly population, and to define specific "indication criteria" to guarantee appropriate patient selection for SAVR or TAVI	Yes	All-cause mortality, MACCE	Prospective	Multicenter	N.a.	Steering group	N.a.	N.a.	No
	The UK TAVI registry [71]	UK	2008-	To create a comprehensive record of all TAVI procedures in UK	N.a.	N.a.	Prospective	Multicenter	NICOR	DMG; The clinical Research Group and the Dataset Group	N.a.	N.a.	No
	The Ibero-American TAVI registry [72]	The Ibero-A	12.2007-05.2012	To find out the indications, early results and survival of TAVI patients	Yes	N.a.	Prospective	Multicenter	Medtronic	The CoreValve Registry committee from ES and PRT	N.a.	Yes	No
	The multi-centre European PARTNER TAVI study [73]	EU	N.a.	To prospectively establish the role of both TF and TA in the high-risk population	Yes	Death, haemodynamic	Prospective	Multicenter	N.a.	N.a.	Ethics committee approval at each center	Yes	No
	Rabin Medical Center TAVR registry [74]	IL	11.2009-08.2013	To report our initial long-term clinical experience with TAVI for "all comer" patients with severe symptomatic AS using currently approved devices.	N.a.	N.a.	Prospective	Single center	N.a.	N.a.	N.a.	N.a.	No
	The Optimized CathEter vAlvular iNtervention	JP	10.2013-12.2014	To evaluate all patients received a Sapien XT bioprosthesis (Edwards Lifesciences, Irvine, CA, USA) via either transfemoral (TF) or transapical	N.a.	VARC-2	Prospective	Multicenter	N.a.	N.a.	N.a.	Yes	No

Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

	(OCEAN-TAVI) registry [75]			approach (TA).									
	A large multicenter TAVI registry [76]	Israel	2008-2014	To evaluate TAVI temporal trends in a large multicenter Israeli registry	STS-PROM	VARC-2	Retrospective	Multicenter	N.a.	3 centers	N.a.	N.a.	No
	the Italian CoreValve registry [77]	IT	2007-	Describing and improving the use of implantable devices in Italian clinical practice which has already been described elsewhere	N.a.	VARC	Prospective	Multicenter	Medtronic Italy	N.a.	N.a.	N.a.	No
	A Multicenter Spanish Registry [78]	ES	2014-	To assess, in patients with severe AS, the determinants of management and prognosis	Not previous AS intervention	N.a.	Prospective	Multicenter	N.a.	N.a.	By the Ethics Committee	Yes	No
	A Poland single-center registry [79]	PL	2008-2014	To evaluate early- and mid-term clinical outcomes after TAVI in a single-center setting	N.a.	VARC	Prospective	Single center	Fund	A multidisciplinary heart team	By the institutional Ethical Board	N.a.	No
	The Transcatheter Valve Treatment Sentinel Pilot Registry [80]	EU	01.2011-05.2012	To assess and identify predictors of in-hospital outcome and complications of contemporary TAVI practice	No	VARC	Prospective	Multicenter	European Society of Cardiology	The relevant Working Groups and Associations	By the TCVT Registry Executive Committee	Yes	No
	The ROUTE registry [81]	PL	05.2013-06.2014	To determine the feasibility of using Tao access for TAVI procedures employing the Edwards SAPIEN transcatheter heart valve.	TAo	VARC-2	Prospective	Multicenter	N.a.	A cardiac surgeon, an interventional cardiologist, and a cardiologist	N.a.	N.a.	No
	SAPIEN XT Aortic Bioprosthesis Multi-Region Outcome Registry [82]	Internatio nal	07.2010-11.2011	To evaluate the epidemiology, predictors, and prognostic implications of AF, either pre-existing or new onset, in TAVR patients	SAPIEN XT valve only	VARC	Prospective	Multicenter	Edwards Lifesciences	The local heart team	The local regulatory authorities	Yes	No

Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

Topic	Registry Name	Data collection	Data entry	Data validation	Statistical analysis	Data information	Device type	Procedure type	Follow-up	Website	Patients tracked	Sample size	Limitation
ICD Registry	NCDR ICD Registry [1]	Data collection version	NCDR Web site and personnel	He rigorous Data Quality Reporting (DQR) process ensure data accuracy, monthly site manager meetings, online dashboard	Yes	130 data elements	Single-or dual-chamber ICDs, CRT-D	Implantations and replacement	N.a.	Yes, annual report	N.a.	Most centers	N.a.
	Multicenter Pediatric ICD Registry [2]	Medical records	N.a.	N.a.	Yes	Demographic information, implant electrical parameters, appropriate and inappropriate shock data, and complications	N.a.	N.a.	N.a.	No	No	4 centers, 443 patients	Practice variation between centers; variation between operators in implantation techniques, variances in case mix, ages, and complexity of CHD, follow-up data insufficient
	The Ontario ICD Database [3]	Local electrophysiologist and a trained research coordinator	Into a web-sited registry	Continually assessed by regular review and correspondence with study sties, automated range checks, notification of uncoded data elements, and ongoing random site audits.	Yes	Patient characteristics, indication for the defibrillator, LVEF and implant-related data	ICD, CRT-D, lead	Implantations and generator replacements	Follow-up data is available	N.a.	Yes, unique encrypted card number	N.a.	The role of trainee, the location of the procedure, and the number of years in practice of the operator is not available in the registry.
	The Medtronic ICD Registry [4]	Medical records	N.a.	N.a.	Yes	Demographic data, ECG, two-dimensional echocardiogram, and concomitant treatment were reported in all patients	Single-or dual-chamber ICDs, CRT-D	Implantations and replacement	Median follow-up was 12 months	No	No	507 patients	Possible bias in patient selection, only focused on Medtronic ICDs, the mean follow-up was short.
	ICD-registry Ludwigshafen [5]	N.a.	N.a.	N.a.	Yes	Patient characteristics and ICD shock therapy	ICD	Implantations and generator replacements	Every 3 months, median 3 years	No	No	1411 patients	N.a.
	The German DEVICE registry [6]	Telephone interview, a standard questionnaire	N.a.	N.a.	Yes	Age, gender, underlying heart disease, LVEF, NYHA class, co-morbidities, and medication, type of device and implantation procedure	ICD, CRT-D	Implantations and generator replacements	One-year follow up data	No	No	44 centers, 2812 patients	Long-term development of LV function is missing; no standardized questionnaires were used to analyze the potential change of the quality of life of enrolled patients within 1 year after device implantation.
	Spanish ICD Registry [7]	Data collection form was filled out by each implant team and sent to SEC	Members of the SEC entered data into registry	Data were cleaned by a SEC computer specialist and a member of the WG-ICD.	Yes	Indications, clinical characteristics of the patients, implant parameters, types of device, device programming, and complications	Single-or dual-chamber ICDs, CRT-D	Implantations and replacement	N.a.	Yes, annual report	N.a.	About 85%	N.a.
	French OPERA registry [8]	By the sponsor and an external org	N.a.	N.a.	Yes	The time between device programming and-	ICD, CRT-D	Implantations and generator replacements	3, 6, 12, 18, 24 months after enrolled	N.a.	N.a.	636 patients	Insufficient sample size
	Stidefix Registry [9]	Enrolled online	N.a.	N.a.	Yes	Medical information, indications for ICD implantation, and type of device implanted, and distinguishes first implants from device replacements	Single-dual chamber ICD, and CRT-D	Implantations and generator replacements	N.a.	No	No	66 ceners	N.a.
	The LEADER registry [10]	Data collection at the time of hospital discharge	N.a.	N.a.	Yes	Procedural characteristics, device implantation-related adverse events and device programming	ICD, lead, CRT-D	Implantations and replacement	Followed up at 6 months and at 12 months after the implantation	No	No	42 centers	Not consecutive, data were collected on paper and some missing data could not be obtained despite extensive repeated requests to the invetigators.
	National Registry on Cardiac Electrophysiology [11]	Personal contact with the heads of the pacing and electrophysiology laboratories and forms were sent via Email	N.a.	N.a.	Yes	The number and type of diagnostic electrophysiologic studies (EPS) and ablation procedures performed, types of arrhythmia treated by ablation and number and type of ICDs implanted or replaced, including biventricular cardiac	ICD & BiV ICD	Implantations and replacement	N.a.	Yes, annual report	N.a.	18 centers	Lack of an online platform that would facilitate data collection and analysis.

Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

						resynchronization device (BiV ICDs)							
	EFFORTLESS S-ICD Registry [12]	Patients reported outcome	N.a.	N.a.	Yes	Adverse events, spontaneous arrhythmia episodes, and programming changes	N.a.	N.a.	60 months follow-up, first year record	N.a.	N.a.	472	N.a.
	The European LQTS ICD Registry [13]	Prespecified questionnaire	N.a.	N.a.	Yes	Demographics, genotype, personal and family clinical history, ECG measurements, treatment, response to therapy both before and after the ICD implantation, technical and functional characteristics of the devices, delivered therapies, revisions, and device-related complications.	ICDs	Implantations and replacement	Mean observation time for 4.6±3.2 years	No	No	233 patients	Potential time-dependent differences relative to the patients' baseline characteristics or the technical features of devices due to long term, possibly skewed the results due to multicenter nature of the study
	The Israeli ICD Registry [14]	Data were collected at the time of any initial device implantation and upgrade	Entered into a secure, web-based electronic case report form	Assessed by regular review and correspondence, completeness of implantation data was assessed by comparing the registry data with the number of devices provided by the manufacturers	Yes	Demographic and clinical characteristics, indication for defibrillator implantation, comorbidities, laboratory and echocardiographic data, previous medical treatments, device manufacturer, device and lead model, pacing and sensing parameters	ICDs, CRT-D	Implantations and replacement	Annual basis	No	No	07.2010-06.2012: 2811 patients	N.a.
	The Japanese Cardiac Device Treatment Registry [15]	Medical staff record a hard copy data sheet	JHRS office assess to JID-CAD website, and input patient data	N.a.	Yes	Implantation information, patient characteristics and pharmacologic treatment at the time of the implantation	ICD, CRT-D, CRT-P	First and replacements	Every 6 months with 2 years	N.a.	N.a.	60 centers, target population is 800	N.a.
	The Gulf ICD Registry [16]	Data collected on paper Case-report form (CRF)	Enter online using a web-based, custom designed, and password-protected electronic data capture portal.	N.a.	Yes	Baseline demographics, admission characteristics, medical history and risk factors, diagnostic procedures, ICD implant procedure characteristics, ICD programing, adverse events, discharge characteristics, discharge medications.	ICD	First implant	Follow-up schedule will be at the discretion of the implanting physician, which is typically every 3 or 4 months	N.a.	N.a.	1500	Risk to lost follow-up
	ICD registry in Taiwan [17]	N.a.	N.a.	N.a.	Yes	Patient data, including baseline characteristics, clinical comorbidities, primary cardiac diagnosis, the use of anti-arrhythmia drugs and LVEF were registered and collected from 3 sites	ICD	generator replacements	Every 3 months to evaluate	No	No	3 centers, 238 patients	Retrospective study character, Insufficient sample size
	A Multicenter French Registry [18]	Medical record	Co-investigators in charge of the data collection and analysis at each medical center	Data storage, quality control, and statistical analyses by three institutes.	Yes	Comorbidities, the type of ICDs	ICD	First	4-6 months	No	No	5539 patients	Retrospective nature of the registry led to information bias; no central adjudication for classification of appropriate and inappropriate therapies was used.
Pacemaker Registry	German Pacemaker Registry [19]	N.a.	N.a.	N.a.	N.a.	N.a.	Pacemaker	First and replacements	N.a.	Yes	N.a.	N.a.	N.a.
	Danish Pacemaker Register[20]	N.a.	N.a.	N.a.	N.a.	N.a.	Pacemaker	Implantations and generator replacements	N.a.	Yes	N.a.	All 14 centers	N.a.
	Spanish Pacemaker Registry [21]	European Pacemaker Patient Identification Card (EPPIC), information from PM	Using specific software by 2 nurses trained in the monitoring of pacing devices	Refine the data which transferred from the EPPIC	Yes	Age, sex, codes for symptoms, causes, indications, pacing modes, implantations and extractions of leads and generators	Pacemaker, CRT-P	Implantations and generator replacements	In 2013, some included in hom	Yes, Annual report, data sent to	Yes	About 35%	N.a.

Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

		suppliers							monitoring/follow-up groups	EUCOMED			
	Single Academic Pacemaker Center [22]	Clinic's archive	Transfer to electronic database	N.a.	Yes	all implants, first or replacements of permanent pacemakers	Pacemaker	First and replacements	N.a.	No	No	2180 patients	No follow-up data are available
	Nigeria Pacemaker Registry [23]	Data storage covers the fields recommended by the European pacemaker patient identification codes	A Microsoft access database	N.a.	Yes	Patients data, implant data and complications	Pacemaker	First and replacements	Median 26 months	No	No	2008-2012 51 patients	N.a.
CRT Registry	The CRT RENEWAL [24]	Data collected at each visit; Minnesota Living with Heart Failure quality of life questionnaire	N.a.	N.a.	Yes	Minnesota Living with Heart Failure QOL Questionnaire, Heart rate variability measures and activity log data	CRT	N.a.	2 weeks, 3, 6, 12 months post-implant visits	No	No	1206 patients from 107 centers	Patients dropped out of the study, lost to follow-up
	Single center registry on prognosis in CRT [25]	Data collected by chart review, device interrogation and telephone contact	N.a.	N.a.	Yes	N.a.	CRT	N.a.	Median 25-29 months	No	No	716 patients	N.a.
	The InSync/InSync ICD Italian Registry [26]	N.a.	N.a.	All examinations of a subject were always made by the same physician, who had a specific competence in assessing the effects of CRT	Yes	Demographic, history, and clinical variables as baseline, complications	CRT, CRT-D	First and replacements	1, 3, 6 months and every 6 months thereafter	No	No	117 Italian center	Potential bias in patient selection as well as lack of control group and patient blinding.
	Single center CRT registry [27]	Medical records	Entered into a database	N.a.	Yes	Medical records	CRT	N.a.	N.a.	No	No	627 patients	Retrospective study character and lack of a suitable control group
	J-CRT [28]	Doppler 1w, 6m, 12m after CRT	N.a.	N.a.	Yes	N.a.	CRT	Initially implantation	At least 6 months	N.a.	N.a.	225 patients from 18 centers	Data variability among the institutions
	The Contak Italian Registry [29]	N.a.	N.a.	N.a.	Yes	Baseline evaluation,	CRT	N.a.	Regular clinical visits	N.a.	N.a.	658 patients	Small population, not randomized
	A prospective CRT registry [30]	Patients with CRT-D	N.a.	N.a.	Yes	Baseline characteristics, ECG, procedural data	CRT-D	N.a.	A median of 5.2 years	N.a.	N.a.	295 patients	Technical limitations
CIED Registry	The REPLACE Registry [31]	A secure electronic data management system	Novella Clinical	Review medical record, reported events adjusted by Clinical Events Committee	Yes	Clinical data, complications, patient medical complaints	ICD and pacemaker generator replacement, including CRT-P and CRT-D	For generator replacement	A wound examination, a 30-month clinic or telequery, a final 6-month clinic visit	No	N.a.	Fixed sample size, 1750 patients, 72 institutions	Low precision because of not representative, no data beyond 6 months, not capture infrequent events
	The HomeGuide Registry [32]	Remote monitoring was accomplished with the Biotronik HM system based on ultra-low power daily or event-triggered transmissions in the MICS	From the implanted device to a mobile patient unit, forwarding data via GSM with GPRS protocol to a Service center with encrypted access	N.a.	Yes	N.a.	CIED	For generator replacement	At post-implanted discharge, at 1 month and then once in year	No	No	75 sites, 1650 patients	N.a.
	Registry of Emilia Romagna on Arrhythmia Interventions [33]	Data collected in each institution	N.a.	N.a.	Yes	Clinical characteristics, characteristics of implanted devices	CIED	First and replacements	N.a.	N.a.	N.a.	24 centers	N.a.
	Italy PM and ICD Registry [34]	EURID/Eucomed implant form, retrieved from mail	N.a.	Data checked on the day entry, and annual report review	Yes	EURID/Eucomed items	CIED	First and replacements	N.a.	Yes	Yes	N.a.	N.a.
	Swedish PM and ICD Registry [35]	EURID implant forms	Participating centers using direct data entry on the website	Regularly checked for internal consistencies by the Registry administer, and online	Yes	Patients demographics, clinical indications, aetiology, complications, fluoroscopy time,	PM, ICD, CRT, CRT-P, CRT-D	First and replacements	1 year to see complications	Yes, annual report	Yes	44 centers, covering	NYHA class, left ventricular ejection fraction, and phrenic nerve stimulation

Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

				statistics are updated on a daily basis.		surgical time, technical information on generators and leads, survival data						almost 100%, 121744 PM and 10503 ICD	are not available, CRT could therefore not be assessed.
	The Kaiser Permanente-Cardiac Device Registry [36]	Data source: device manufacturers, Paceart, and Apollo Data Repository.	All data were recorded and transferred to a centralized data repository for data management, validation, and reporting.	Automated, ongoing quality control procedures were carried out to flag patient and device data anomalies that were adjudicated using the EMR by clinical content experts.	Yes	Device characteristics, patient demographics, clinical indications for implant, procedural details, and postoperative outcomes	CIED	First and replacements	4 months follow-up	Yes	Yes	385 medical facilities	The KP-CDR does not track certain data on time variant and CIED-specific variables, is limited on the number of variables and detail of procedures captured in order to minimize data collection burden and ensure high quality.
Stent Registry	Guthrie Health Off-label Stent (GHOST) Registry [37]	A nurse performed data collection, medical records, telephone	Entered into an Excel spreadsheet and utilized for outcomes analysis	Exclusion patients make selection bias	Yes	Baseline clinical and angiographic characteristics, laboratory values, and in-hospital outcomes.	N.a.	N.a.	At least 5 years or occurrence of MACE	No	No	07.2001-12.2007: 896 PAT	Exclusion crieteria
	The prairie "real world" stent registry [38]	Procedure and in-hospital outcome data were obtained from NCDR Registry	Telephone	N.a.	Yes	Patient characteristics, MACE	DES, BMS	N.a.	6 M, 1 year, annually thereafter	No	No	379 PAT	Retrospective and not randomized control
	HMORN-Stent Registry [39]	N.a.	N.a.	N.a.	Yes	Clinical characteristics	N.a.	N.a.	N.a.	No	No	3 sites, 7689 PAT	N.a.
	POLAR Registry [40]	Latin A	11.2008-07.2010	To clinically evaluate the Promus stent in patients in clinical practice.	No	N.a.	Prospective	Multicenter	Boston Scientific	The Cardiovascular Research Centre	Ethics Committees approval	Yes	
	AUTAX (Austrian Multivessel TAXUS-Stent) registry [41]	N.a.	N.a.	N.a.	Yes	Patient characteristics, angiographic findings, procedural characteristics	TAXUS	N.a.	2 years	No	No	9 Centers	N.a.
	the Leipzig SUPERA Popliteal Artery Stent Registry [42]	Medical records	N.a.	N.a.	Yes	Patient characteristics, angiographic findings, procedural characteristics	SUPERA	N.a.	6, 12 M	No	No	101 patients	Further evidence needed to confirm these first encouraging results.
	German Cypher Stent Registry [43]	Case report forms were collected via the internet	N.a.	A query management was established for missing or implausible data	Yes	Patient characteristics, angiographic findings, interventional characteristics, clinical events	N.a.	N.a.	Up to 5 years	No	No	04.2002-09.2005: 5946 PAT	No reliable data during follow-up, no external outcome data validation
	German DES.DE Registry [44]	Internet platform	N.a.	N.a.	Yes	Baseline clinical and angiographic characteristics and certain procedural and clinical in-hospital events	Taxus and Cypher	N.a.	3, 6, 12 M	No	No	From 10.2005-10.2006, 6384 patients at 98 sites	Low rates of enrollment and under-reporting of event
	WAR-STENT registry [45]	N.a.	N.a.	N.a.	Yes	Baseline characteristics, procedural characteristics, in-hospital events, prescriptions at discharge	N.a.	N.a.	12 M	No	No	411 patients from 37 centers	Small size is the main limitation
	The Tacrolimus-Eluting STent (TEST) registry [46]	Taken from centralized information database of the center, hospital records, telephone contacts	N.a.	N.a.	Yes	Patient characteristics, angiographic findings, procedural characteristics; in-hospital and long-term outcome	N.a.	N.a.	6, 12 M	No	No	140 PAT	N.a.
	Artery Angioplasty-Stent Registry III [47]	Online 3-page sheet	Website, Access, Excel Crystal Reports XI for business objects software	N.a.	Yes	Complications	N.a.	N.a.	No	No	No	37 centers	No long-term follow-up
	The Frontier stent registry [48]	N.a.	N.a.	N.a.	Yes	Patient characteristics, procedural characteristics; MACE	N.a.	N.a.	180 days	No	No	130 PAT	Larger in profile, less flexible
	The China CYPHER	Internet base, through	All data were submitted	Audit check was undertaken	Yes	Patient characteristics, MACE, the	SES	N.a.	6, 12 M	No	No	20 Center	Different from “all comers”

Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

	Select registry [49]	phone call or visit	to a data-coordinating center and core laboratory via internet	for all patients to assess data entry accuracy		QCA measurements						1189 PAT	registry, patients selection bias may exist
	A novel computer based stent registry [50]	Computer-based, hospital information system	N.a.	N.a.	Yes	N.a.	N.a.	N.a.	N.a.	No	No	21 Cases	N.a.
	The j-Cypher Registry [51]	N.a.	Data entry	N.a.	Yes	Patient characteristics, procedural characteristics	N.a.	N.a.	5 years	No	No	37 centers	Patients participating in the registry were not fully monitored.
	the DATE registry [52]	A dedicated web-based case report form, medical record, telephone contact	N.a.	All outcome data were confirmed by source documentation collected from each participating center and were reviewed by an independent clinical event adjudication committee	Yes	Patient characteristics, procedural characteristics; Clinical outcome	ZES	N.a.	1, 3, 6, 12 M	No	No	17 centers 851 PAT	Sample size small, specific to one DES type
	FOCUS registry [53]	Via electronic data capture using web-based case report forms	Data management	N.a.	Yes	Lesion and procedural characteristics, clinical outcomes	N.a.	N.a.	30D, 6, 12, 24, 36 M	No	No	83 Center50 84 PAT	N.a.
	The 'all comer' Coroflex Please drug-eluting stent registry in Europe and Asia [54]	Paper hard copies and entry into database	Database	Accuracy of data	Yes	Patient characteristics, procedural characteristics; MACE	N.a.	N.a.	10.6, 23.8 M	No	No	29 centers, 1230 PAT	A less stringent control of data collection and study monitoring
	DESERT (international Drug-Eluting Stent Event Registry of Thrombosis) [55]	N.a.	N.a.	N.a.	Yes	Patient characteristics, procedural characteristics	N.a.	N.a.	N.a.	No	No	984 patients from 21 sites	Case-control study cannot provide direct insight in to the incidence
	The TIMI 38 Coronary Stent Registry (CSR) [56]	N.a.	N.a.	N.a.	Yes	Patient characteristics, procedural characteristics	N.a.	N.a.	6-12 M	No	No	38 sites 20 countries; 2110 patients	N.a.
	E-Five Registry [57]	N.a.	N.a.	N.a.	Yes	Patient characteristics, angiographic and procedural characteristACics; Adverse Events	Promus	N.a.	1, 6, 12, 24 M	No	No	40 centers 1121 PAT	Bias in participants selection
	The Korean Multicenter Drug-Eluting Stent Registry [58]	A Web-based reporting system	N.a.	For any clinical event, all relevant medical records were reviewed and adjudicated by an external clinical event adjudication committee.	Yes	Demographics, Coexisting condition, Cardiac risk factors, Clinical Indication of PCI	Stent	N.a.	35 months	N.a.	N.a.	12,426 patients	Possibility of unmeasured confounders
TAVI Registry	The STS/ACC TVT Registry [59]	Electronic data support	N.a.	Data quality checks have been implemented at the National Cardiovascular Data Registry data warehouse and Duke Clinical Research Institute to optimize data completeness and accuracy.	Yes	Patient demographics, comorbidities, functional status, quality-of-life indexes, and procedural details and outcomes	N.a.	N.a.	Yearly follow-up	Yes, annual report	Yes	N.a.	N.a.
	Brazilian TAVI Registry [60]	N.a.	N.a.	N.a.	Yes	N.a.	TAVI	CoreValve and Sapien procedure	N.a.	No	No	18 centers 418 patient	N.a.
	The Austrian TAVI Registry [61]	N.a.	Accessible on the internet and allows an easy assessment of patient data and procedures	N.a.	Yes	Demography, baseline characteristics including comorbidities, STS Score, EuroSCORE, QoL	TAVI	CoreValve and Sapien procedure	1, 3, 6, 12, 24 and 36 month, median follow-up was 382 days	No	No	11 centers	A number of TAVI cases in Austria implanted by surgical centers are not included.
	The Belgian TAVI	Collected and recorded	N.a.	Data pooling and statistical	Yes	Patient characteristics, procedural	TAVI	CoreValve and	1, 12	No	No	15	No centers performing both

Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

	Registry [62]	at site		analysis were performed at the University		characteristics and outcomes, causes of procedural mortality,		Edwards procedure	months			centers	procedures, the number of patients is limited, no central core laboratory monitoring all events.
	The Swiss TAVI registry [63]	Standardized case-report forms from web-based database, follow-up data based on phone calls or clinical visit by each center	An independent monitor and statistician was performed to verify completeness and accuracy of data entry at each site	No on-site monitoring or patient data validation was performed	Yes	Baseline, procedural and in-hospital characteristics, follow-up data	TAVI	5 kinds of devices	30 days, 12 months, 3 and 5 years	No	N.a.	All centers	Clinical practice and expertise might be different in centers
	The Bern TAVI Registry [64]	By either clinical in-hospital visits or a standardized telephone interview.	Data were entered into a dedicated Web-based database, held at an academic clinical trials unit	All suspected events were presented to a dedicated clinical event committee consisting of cardiologists and cardiac surgeons	Yes	Baseline clinical and procedural characteristics as well as follow-up data.	TAVI	N.a.	After discharge, adverse events were assessed through active follow-up at 30 days and 12 months	N.a.	N.a.	N.a.	N.a.
	The Aachen TAVI registry [65]	Dedicated database, follow-up by visit or by telephone	N.a.	N.a.	Yes	Baseline clinical, laboratory, echocardiographic, DSCT as well as procedural data and clinical follow-up data	TAVI	N.a.	1 monthe, 1 year, 2 and 3 year	No	No	01.2008-08.2012: 367 TAVI procedures	N.a.
	The German TAVI Registry [66]	N.a.	N.a.	N.a.	Yes	Patient characteristics, outcome up to 30 days post procedure, preprocedural imaging	TAVI	CoreValve and Edwards procedure	N.a.	No	No	22 centers	Limited number of evaluated variables,
	FRANCE 2 Registry [67]	N.a.	N.a.	N.a.	Yes	Patient characteristics, procedural characteristics and outcomes, causes of procedural mortality,	TAVI	CoreValve and Edwards procedure	Mean 245 days	No	No	34 centers	Long term follow up is needed
	The ATHENS TAVR Registry [68]	Baseline and follow-up clinical and echocardiography data were prospectively gathered in each participating centre.	N.a.	N.a.	Yes	Baseline and follow-up clinical and echocardiography data	TAVI	N.a.	N.a.	No	No	4 centers 126 patients	N.a.
	The POL-TAVI registry [69]	Data was submitted by 20 centers	N.a.	N.a.	Yes	Baseline patient demographic, clinical and echocardiographic variables	TAVI	N.a.	After 6 month	No	No	381 Patients	Data was submitted by 20 centers performing TAVI procedures with different grade of completeness. Data submission was not monitored.
	OBSERVANT TAVI Registry [70]	A unique database for contemporary data collection	Online data entry on a password protected website.	A process of assessment of data completeness and robusness	Yes	Demographic characteristics, health status prior to intervention, comorbidities and complete information on the type of intervention	TAVI	N.a.	30 days follow-up	No	No	101 centers	The incompleteness of the monitoring process
	The UK TAVI registry [71]	95 variables	Data entry is performed by clinical staff and data clerks; A web browser based data entry	No external validation, range checks are applied to appropriate fields	Yes	Patient demographic features, indications, procedural details and outcomes up to the time of hospital discharge	TAVI	N.a.	1-3 years followed up	Yes	Yes, NHS number provides a unique identifier for any person registered with the NHS in England and	All centers	Lack of data validation, apart from life status, later clinical and quality-of-life follow-up.

Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

											Wales		
	The Ibero-American TAVI registry [72]	Online-form	An online-form for data entry	N.a.	Yes	Baseline, procedural, complications	TAVI	CoreValve	Median 238 days	No	No	42 centers	Incomplete data
	The multi-centre European PARTNER TAVI study [73]	QoL questionnairs	N.a.	N.a.	Yes	Baseline, procedural, follow-up data	TAVI	N.a.	30 days, 6 months, and 1 year	No	No	N.a.	Sample size too small
	Rabin Medical Center TAVR registry [74]	Data were collected before TAVR, during hospitalization, and postoperatively at 30 days, 6, 12 months, and yearly after.	All collected data were registered in an electronic database.	N.a.	Yes	Demographic, clinical, and laboratory data	TAVI	N.a.	Postoperatively at 30 days, 6, 12 months, and yearly after.	No	No	319 patients	N.a.
	The Optimized CathEter vAlvular iNtervention (OCEAN-TAVI) registry [75]	N.a.	N.a.	N.a.	Yes	VARC-2	TAVI	TA, TF	N.a.	N.a.	N.a.	4 centers	No long-term outcomes.
	A large multicenter TAVI registry [76]	Prespecified clinical and laboratory data	N.a.	N.a.	Yes	VARC-2	TAVI	transfemoral,transapical, transaxillary, or direct aortic access routes		N.a.	N.a.	3 centers	No cause-and-effect suppositions
	The Italian CoreValve registry [77]	Self-report	Yes	Posteriori	Yes	VARC	TAVI	TF	13 months	N.a.	N.a.	7 centers	Not randomized
	A Multicenter Spanish Registry [78]	Clinical data and ECG data	N.a.	N.a.	Yes	Clinical and echocardiographic parameters, Charlson co-morbidity index,17 EuroSCORE II,18 and hospital characteristics	TAVI	N.a.	1 Y	N.a.	N.a.	726 patients	Not randomized; small sample size
	A Poland single-center registry [79]	N.a.	N.a.	N.a.	Yes	VARC	TAVI	TA, TF	At discharge, 30 days, 6 months and 12 months	N.a.	N.a.	101 patients	Small sample size
	The Transcatheter Valve Treatment Sentinel Pilot Registry [80]	From national registries	Data entered into a web-based case record form (CRF) or transferred from compatible national registries	Yes	Yes	VARC	TAVI	TA, TF	N.a.	N.a.	N.a.	4,571 patients from 137 centers in 10 EU countries	The absence of a centralised analysis process and independent adjudication
	The ROUTE registry [81]	N.a.	N.a.	N.a.	Yes	VARC-2	TAVI	Tao	30-day	N.a.	N.a.	32 patients	Small sample size
	SAPIEN XT Aortic Bioprosthesis Multi-Region Outcome Registry [82]	An independent clinical events committee adjudicated all adverse events	All data were entered in the electronic data capturing system and monitored	N.a.	Yes	VARC	SAPIEN XT valve	N.a.	2 years	N.a.	N.a.	99 sites in 17 countries	Pre- and post-TAVR echocardiographic evaluations were site reported and not reviewed by an independent core laboratory.

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Supplementary additional file 2 criteria of all 82 identified cardiac implant registries

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1#
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2#
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3#
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4#
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/a
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4#
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4#
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5#
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5#
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5#
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5#
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5#
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	5#
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	5#

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	5#
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/a
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	5#
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6#
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	6#
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	6#
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	7-9#
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	6#
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	9-12#
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	12#
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	12#
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	12#

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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