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Review

Registries of implantable medical devices in Europe

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ABSTRACT

Background: In early 2012, a number of serious events in the implant area raised public awareness and started a discussion on safety issues and monitoring medical devices in academics and politics. Apparently, there is a lack in the surveillance of medical devices. Therefore, the objective of this work is to detect and classify implant registries in Europe.
Methods and findings: A systematic search of literature was carried out to identify the different types of registries. Furthermore, to characterize the implant registries by different criteria a medical device classification system was established. One hundred and one European registries were found. Most registries exist in the field of cardiac implants and arthroplasty (38 and 29) and their distribution showed variation within Europe. For a lot of implant categories, none or very few registries could be identified. Some countries run more registries than others. There are a lot of differences in aim and structure among the registries.
Conclusion: There is only a limited number of reviews on registries and a centralized monitoring system in Europe is missing. Our results reveal a lack of transparency concerning number, aim, structure and quality of registries. This is crucial, as registries work as early warning systems for identifying and notifying patients at risk.

1. Introduction

1.1. Rationale

During the last few years the medical device industry has greatly improved. Significant progress has been achieved in many areas of the medical device industry, in particular in the fields of miniaturization, computerization and molecularization [1].

However, with the increasing quantity and diversity of medical products the number of related incidents has started to grow, too. By looking at the vigilance and notification reports of the national competent authorities (NCARs) of the European Union it is noticeable that there has been a steady rise from 2007 to 2011/12 in all kinds of medical devices (Fig. 1) [2].

Thus, the following incidents are no individual cases, but just the tip of the iceberg.

A recent example of the growing number of errors especially in the field of implant production is the scandal of the defective breast implants of the French company Poly Implant Prothèse. The company was blamed of selling breast implants filled with low quality silicone to millions of women.

In Europe, any product that has obtained a CE-mark in a European Union (EU) member state can be sold. In case of PIP implants, the company attached a CE-mark to

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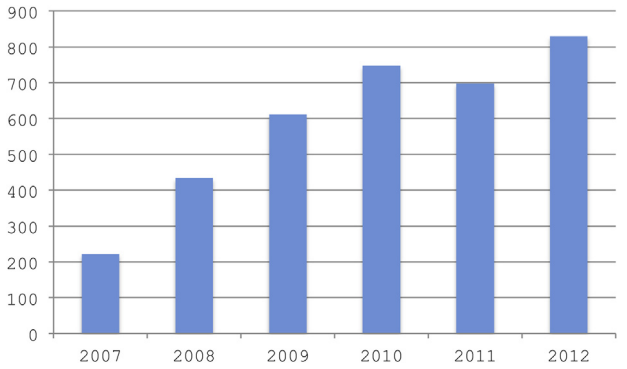

Fig. 1. Number of NCARs exchanged at European level between 2007 and 2012.

their devices suggesting that they meet all the relevant EU regulations [3]. The German notified body TÜV Rheinland was in charge of the conformity assessment of these breast implants that includes checks of safety and the compliance with regulations. The French regulatory authority discovered that the firm was using industrial silicone for their prostheses which was not detected by the responsible notified body [3].

The second incident in the field of medical devices discussed in the press concerns arthroplasty, more precisely "metal on metal" (MoM) hip implants. People from all over the world may have been exposed to dangerously high levels of toxic metals from defective hip implants [4]. The drawback of these prostheses made of two metal layers, cobalt and chromium, is in the release of metal ions by friction of the metal joints. Patients with these implants have to be re-operated more often. According to the British Medical Journal (BMJ) the prostheses came into the market although it is still unclear what impact the metal ions have on the body [5].

1.2. Objectives

In the case of breast implants, there were many difficulties to find out which women have been wearing these implants. Although breast implant registries exist within Europe, not every country has one, these are not mandatory and thus most of the women are not registered. The incident concerning metal-on-metal hip prostheses has shown that in the field of medical devices and in particular in the field of implants, there are plenty of possibilities for patient harm. Therefore, the objective of this study is to reveal the current status of medical device registries for implants in Europe and to classify their structure and characteristics.

2. Methods

2.1. Key questions

This text shows which registries exist for the different types of implants in Europe and in each particular country.

Therefore, the following questions are crucial:

- Which registries exist in Europe?
- In which area do most registries exist?
- For which implant category do most registries exist?
- How can they be classified and categorized?

2.2. Medical device registry classification

The implant registries are classified using different criteria discussed at an intern panel meeting of members of the leading edge cluster Medical Valley European Metropolitan Region Nuremberg. A checklist was developed to characterize the identified registries. The following criteria were chosen.

2.2.1. Basic information

The name of the registry, its topic and its geographical coverage are mentioned. This category also involves the scope of the registry. Registries can exist on local, regional, national, international or EU basis and can obtain data from one hospital or from more centers (Multi-Center). Mentioning a country without any supplements means that this registry has more than one center and works on a national basis. If the registry's scope is different, the variations are clearly stated.

2.2.2. Time

Furthermore, the starting time of the registry and, if available, its duration are presented.

2.2.3. Funding

To value the registry in a correct way it is important to know if it is supported by private or public means or if it is financed independently from industry or by industrial means.

2.2.4. Who uses the information?

There are different stakeholders who can use the results, for example, the industry, health insurances, health care providers, health care authorities or society.

2.2.5. Type of information provided

Registries report different kinds of information that are available for the stakeholders mentioned above. Registries can be used for adverse event reporting, active surveillance of medical products, to discover complications and risks. Information about the quality and stability of implants can

be obtained. Registries can show if implants or prostheses are safe and suitable for patient's use. Some registries provide information about primary surgery and revisions and survival of patients and patient characteristics. Some are used for follow-up and monitoring. Registries are also important for benchmarking and comparison between different registries.

2.2.6. Type of registry

Epidemiologic registries consider all devices that are implanted in a special region and the prevalence of a disease. They can assess if there are any accumulations. The progress of the expansion of a disease can be observed.

Furthermore, there are hospital-based registries that have the aim to improve the quality of treatment.

2.2.7. Access

Sometimes, registries are accessible as open source. Some of the registries release for example an annual report or publish their main results in articles.

2.2.8. Cost-effectiveness

Furthermore, it is interesting whether registries also consider cost-effectiveness of the devices.

Detailed information about open access and reporting of cost-effectiveness is only available in the supplemental material.

However, in some cases, information was not available (n.a.).

2.3. Information sources and search for implant registries

This article is based on a review of publications in different databases such as PubMed, Medline and CRD York of existing implant registries. Furthermore specific websites concerning implant registries were detected. The search was performed during March and April 2012 (01.03.2012–30.04.2012) and December 2012. The intention was to identify all existing registries on implants in Europe and to classify them by different criteria. Therefore, the interest was not on studies performed in cooperation with the registries, but on the discovery of European implant registries.

The integrity of the information was confirmed by using the links to web pages of other registries and technical documents. Additional information was obtained from the European Arthroplasty Register (EAR) where all existing arthroplasty registries within Europe are listed. A single inclusion criterion was used in this paper: implant registries working on a regional or national basis in Europe with focus on the European Economic Area and Switzerland. Specific hospital initiatives not working on a regional or a state basis are not considered in this search except for some cases where other registries could not be found. A further limit searching the Internet was the availability of web pages and information on registries in English or German. Registries with unavailable information in the Internet and other bibliometric sources were excluded.

2.4. Key words

The following key words were used for the search of literature: medical device registry, implant register, implant registry, cardiac device register, arthroplasty, hip, knee, stent, brain stimulation, cochlear implant, as well as country names such as Sweden and Denmark, Europe. It was searched for different types of implant registries: pacemaker, stents, deep brain stimulation, artificial heart, catheter-port, cochlear implant, visual prosthesis (retina implant, cataract register, intraocular lens register), dental implant, drug depot or depot medication, drug implant, bone drug implant, microchip implant, joint replacement, materials used in trauma surgery and neurology (craniofacial prosthesis), penile prosthesis, sphincter prosthesis.

2.5. Search documentation

The tables that show the search results for each database and the selection criteria can be found in the Annex.

The number of exported sources was also documented. The search was performed in the databases PubMed, Medline, CRD York. The internet (Google/Google scholar), web pages of BfArM, BVmed, the European Commission, etc. were handsearched. Articles were rejected if in the respective title or abstract no implant registry or registry name was mentioned. As there were many results for the same registries in some cases, the most current or most significant source was chosen.

3. Results

3.1. Bibliographic research results

Fig. 2 shows the selection process of the literature.

1126 articles were identified. Unrelated articles, duplications and articles where the same registries are mentioned were deleted. 67 Articles about arthroplasty, heart stents and pacemakers, tubes, breast implants, and other kind of implants were selected. 34 articles as results from handsearching were added. 101 articles and sources from handsearching were used in this paper for the systematic review of registries.

To describe the registries' characteristics additional literature was identified.

3.2. Implant registries in the EU

Considering this background, the paper gathers implant registries already existing in Europe. In an implant registry, a systematic collection of information about patients with implants is pictured. Thus, concerned people can be identified in case of emergency.

The existing implant registries of countries in Europe and their characteristics are listed in a table (Table 1). The questions mentioned in the methodology chapter of this article are answered.

The registries identified by literature search show different scope, they are established on national, international, EU, regional or local basis, most of them on national basis.

Table 1
Identified registries and their characteristics.

Registry[I]	Topic	Geographical coverage[II]	Time[III]	Funding	Who uses the information	Information	Type of registry[IV]	Compulsory
Arthroplasty (29)								
The Austrian Arthroplasty Register [51,52]	Arthroplasty	AT[1]	(Pilot 2004) 2007–	Public	N.a.	Adverse events, early warning	H	N.a.
Belgian National Arthroplasty Register* [53]	Arthroplasty	BE[2]	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.
Danish Hip Arthroplasty Register [54]	Arthroplasty	DK[3]	1995–	Public	N.a.	Risk factors, surgical technique, benchmarking	E	N.a.
Catalan Arthroplasty Register [55,56]	Arthroplasty, hip, knee	ES[4]: Catalonia	2004–	Public	Industry, health insurance, society	Stability, quality, population characteristics	H, E	No
Croation Arthroplasty Register* [57]	Arthroplasty	HR[5]	2006–n.a.	N.a.	N.a.	N.a.	N.a.	N.a.
Czech Rep. Arthroplasty Register* [58]	Arthroplasty	CZ[6]	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.
Danish Knee Arthroplasty Register [59]	Arthroplasty, knee	DK	1996–	Public (independent)	Industry, society, health authorities, health care provider	Stability quality, identify predictors of outcome	E	Yes
Dutch Arthroplasty Register (LROI)* [60]	Arthroplasty	NL[7]	2007–	Private (health assurance)	Industry, health insurance, society	Active surveillance, revisions, training	N.a.	N.a.
Finnish National Arthroplasty Register* [61]	Arthroplasty	FI[8]	1980–2011	N.a.	N.a.	N.a.	N.a.	N.a.
French Arthroplasty Register [62]	Arthorplasty	FR[9]	2006–n.a.	Public	N.a.	N.a.	N.a.	N.a.
German Arthroplasty Register (EPRD) [63]	Arthroplasty	DE[10]	2012–(in development)	Private and public funding	Industry, health insurance, society	Quality, revisions	N.a.	N.a.
Hungarian Arthroplasty Register* [64]	Arthroplasty	HU[11]	2007–	N.a.	N.a.	N.a.	N.a.	N.a.
National Joint Registry (NJR) [65,66]	Arthroplasty	UK[12]: England, Wales, Northern Ireland	2002–	Levy raised on the sale of implants	Industry, society, regulatory authorities, health care provider	Safety, adverse events, early warning, stability, revisions, quality, monitoring, surveillance	E	N.a.
Norwegian Arthroplasty Register [67,68]	Arthroplasty	NO[13]	1987–	N.a.	N.a.	Surveillance, adverse events, stability, revisions, quality	E	No
Portuguese National Arthroplasty Register [69,70]	Arthroplasty	PT[14]	2005, active since 2009–	Public and private, mainly national health system	N.a.	Stability, revisions, monitoring	H	N.a.
RIPO – Register for Orthopaedic Prosthetic Implantation [71,72]	Arthroplasty	IT[15]: Emilia-Romagna	Initiated 1990, started in 2000–	Public and private	Society, health care provider, health care authority	Population characteristics, information about first surgery and revisions, benchmarking, providing of information	H	No

Table 1 (*Continued*)

Registry[I]	Topic	Geographical coverage[II]	Time[III]	Funding	Who uses the information	Information	Type of registry[IV]	Compulsory
ROLP – Arthroplasty Register of Lombardy* [73]	Arthroplasty	IT: Lombardy	2003–	N.a.	N.a.	N.a.	N.a.	N.a.
Romanian Arthroplasty Register [74]	Arthroplasty	RO[16]	2001–	N.a.	N.a.	Adverse events, surveillance, early warning, stability, revisions, quality	H	Yes
The Scottish Arthroplasty Project [75,76]	Arthroplasty	UK: Scotland	2001–	Public	No inf	Adverse events, surveillance, revisions, quality	N.a.	N.a.
Slovakian National Arthroplasty Register [77,78]	Arthroplasty	SK[17]	2003–	N.a.	N.a.	Stability, revisions, quality, risk factors	E	No
Slovenian Arthroplasty Register (RES) [79]	Arthroplasty	SI[18]	2009–n.a.	N.a.	N.a.	Survival rate, stability, revisions, quality	H, E	N.a.
Swedish Knee Arthroplasty Register [80,81]	Arthroplasty	SE[19]	1975–	Public	Society	Adverse events, surveillance, survival, stability, revisions, quality, implementation of better implants and methods	E	No
Swedish Hip Arthroplasty Register [82,83]	Arthroplasty	SE	1979–	Public	Society	Stability, revisions, quality, complications	E	N.a.
Swiss Arthroplasty Register [84]	Arthroplasty	CH[20]	N.a.	Public and private, levy raised on the sale of implants	Industry, health insurance, society	Adverse events, surveillance, safety, revision, quality, benchmarking	E, H	No
Valdoltra Arthroplasty Register [85]	Arthroplasty	SI: Valdoltra Orthopedic Speciality Hospital	2002–2011	N.a.	N.a.	Stability, revisions	H	N.a.
Scottish Shoulder Arthroplasty Register [86]	Arthroplasty	UK: Scotland	1996–n.a.	N.a.	N.a.	Benchmarking, stability, revisions, to assess contemporary practice, risk factors, outcome	H	No
Swedish Ancle Arthroplasty Register* [87]	Arthroplasty, ankle	SE	Initiated in 1993 started 1997	N.a.	N.a.	N.a.	N.a.	N.a.
SWISSspine Registry [88,89]	Spine	CH	2005–n.a.	Public	Industry, health insurance, society, Swiss federal office of health	Generation of evidence, reimbursement	N.a.	Yes
North West Arthroplasty Register [90]	Arthroplasty	UK: North West region of England	1991–	N.a.	N.a.	Stability, revisions	H	N.a.

Cardiac devices (38)								
The registry of the European Working Group on Cardiac Pacing (EWGCP) [6]	Pacemaker	Europe	N.a.	Public	N.a.	N.a.	N.a.	N.a.
EURID the European registry for implantable cardioverter defibrillators [91]	Implantable cardioverter defibrillators (ICDs)	Started in DE, AT, BE, HR, CZ, HU, IT, LT[21], PL[22], SK, SI, SE, CH	1993–n.a.	Private	Industry, society	Quality of life	E	N.a.
The European Pacemaker Register [91]	Pacemaker	AT, BE, BG[23], HR, CZ, DK, FR, DE, GR[24], HU, IT, NL, NO, PL, PT, RO, SI, ES, SE, CH, UK, HR, BA[25], RS[26], ME[27], MK[28]	Established more than 25 years ago	N.a.	N.a.	N.a.	N.a.	N.a.
The Global Registry of Acute Coronary Events (GRACE) [92]	Acute coronary syndromes	North America, South America, Europe, Asia, Australia, New Zealand	1999–	Private	Industry, health insurance, society	Track outcomes of patients presenting with acute coronary syndromes, including myocardial infarction or unstable angina	E	N.a.
Pacemaker-, ICD- und Loop-Recorder-Register [93]	Pacemaker, ICD, loop recorder	AT	1980–	N.a.	N.a.	Medical device vigilance, product performance and life cycle, quality assurance	N.a.	N.a.
Adult heart surgery registry [94]	Heart surgery	AT	N.a.	N.a.	N.a.	Comparison of treatment results in the different centers	N.a.	N.a.
The Danish National Patient Register [7,95]	Information on all patients in Danish hospitals	DK	1977–	Public	Health insurance, society	Monitoring, basis for the payment of public as well as private hospitals	H	Yes
The western Denmark Heart Registry [7]	Clinical database within a population-based health care system	DK	1999–n.a.	The participating centers own the WDHR and finance its operation through annual membership fees set according to hospital size	N.a.	Quality	H	N.a.
The Danish Pacemaker Register [96]	Pacemaker	DK	1982–n.a.	Self- owned and independent institution	N.a.	Quality, risks	N.a.	N.a.

Table 1 (*Continued*)

Registry[I]	Topic	Geographical coverage[II]	Time[III]	Funding	Who uses the information	Information	Type of registry[IV]	Compulsory
Patient analysis and tracking system (PATS)-registry [97]	PCI Register	DK: Rigshospitalet (RH)	N.a.	N.a.	N.a.	N.a.	H	N.a.
The Danish ICD Register [91]	ICD	DK	1997–n.a.	N.a.	N.a.	N.a.	H	N.a.
Stidefix national registry [98]	ICD implantation	FR	2005–n.a.	Public	Society, Health authorities	Population characteristics, revision, stability, information, factors that might be responsible for regional differences	H, E	Yes
Database of the obligatory external quality control program of the Institute of Quality Assurance Hessen [99]	Pacemaker implantation	DE	2003–2006	N.a.	N.a.	Complications, Quality	H	Yes
The Aortic Stent Register [100]	Stents	DE	2008–	Private (Sponsor: Stiftung Institut für Herzinfarkt-forschung)	N.a.	Follow-up, Complications, operational risk, technical enforcement, results of intervention, hospital lethality, medication at discharge	E, H	N.a.
German Pacemaker Register [101]	Pacemaker	DE	1982–	N.a.	Health care provider	Quality, surveillance	N.a.	Yes
Prospective Prevention of Sudden Cardiac Death II (PreSCD II) registry [102]	Defibrillator	DE	2002–2005	N.a.	N.a.	To investigate the clinical practice of IC therapy, survival	N.a.	N.a.
DES.de Register [103]	Drug eluting stents (DES)	DE	2005–2009	Private (manu-facturers)	Industry and manufacturers	Indications, complications, benchmarking for quality assurance	H	N.a.
German mitral valve registry [103]	Mitral valve	DE	2010–2013	N.a.	N.a.	Indications, patient characteristics, treatment outcome	N.a.	N.a.
German TAVI (Transcatheter Aortic Valve Intervention) Register [103]	TAVI	DE	2009–	Public/Private, independent	Health care provider	Indication, complication, safety, effectiveness, benchmarking	H	N.a.
German PCI register [103]	PCI	DE	2008–	Public/independent	Health care provider, society, health authorities	Indications, complications, benchmarking	H	N.a.
German LASER Register [103]	Stents	DE	2008–	N.a.	N.a.	Treatment, cardiac event rates, complications, benchmarking	H	N.a.
German Cypher Register [103]	Cypher stent	DE	2002–2005	Private	Manufacturers, health care provider	Indications, complications, benchmarking	H	N.a.
German carotid artery stent registry [103]	Stents	DE	2011–	Private	Industry, health care provider	Follow-up, indication, treatment, complications, benchmarking	H	N.a.

Device Register Phase I/Phase II [104]	ICD	DE	2007, 2011	N.a.	N.a.	Revisions, telemetry	N.a.	N.a.
Italian ICD Register [105]	ICD implant	IT	N.a.	N.a.	N.a.	N.a.	H	N.a.
Registro Regionale di Aritmologia Interventistica [106]	All cardiac devices implanted in the Emilia Romagna region	IT: Emilia-Romagna	2005–	N.a.	Society, health care provider	Observe current clinical practice, collecting clinical and implant data for all cardiac devices implanted	H	N.a.
Sicilian Drug-eluting Stent Registry [107]	DES	IT: Sicilia	2004–2005	N.a.	N.a.	N.a.	N.a.	N.a.
Swedish Catheter Ablation Registry [108]	Catheter ablation	SE	2004–2007	Public, independent	Society, health care provider, health authorities	Complications, the registry contains data from ablations performed. Demographic data, diagnosis, procedure data, catheter data, primary success according to the operator	H, E	No
Swedish Pacemaker Registry [91]	Pacemaker	SE	1989–n.a.	N.a.	N.a.	Stability, revision	H	N.a.
Spanish Implantable Cardioverter-Defibrillator (ICD) Registry [109]	ICD	ES	1996–n.a.	N.a.	N.a.	Indications, patient characteristics, implantation parameters, types of device and programming, complications	N.a.	N.a.
Spanish Pacemaker Registry [110]	Pacemaker	ES	1994–n.a	N.a.	N.a.	N.a.	N.a.	No
Spanish Catheter Ablation Registry [111]	Catheter ablation	ES	2002–n.a.	Public	N.a.	Treatment of cardiac arrhythmias	N.a.	No
ESTROFA-2 (Estudio Español Sobre Trombosis de Stents Farmacoactivos de Segunda Generacion-2) [112]	Second generation DES	ES	N.a.	Public	N.a.	To assess DES thrombosis incidence in real practice	E	N.a.
UK Heart Valve Registry [113]	Heart valve	UK	1986–	N.a.	N.a.	Reoperation and survival statistics for individual patients but no follow-up on valve-related events	N.a.	N.a.
Implantable Cardiac Defibrillator Database [114]	ICD	UK, IE[29]	1989–	Public	N.a.	Complications	N.a.	N.a.
National Pacemaker Database [114]	Pacemaker	UK, IE	1977–	N.a.	N.a.	Complications, to investigate the reliability of early pacing units	N.a.	N.a.
Thoracic Stent Registry [114]	Thoracic stent	UK	N.a.	N.a.	N.a.	All endovascular procedures for thoracic aortic dissections or aneurysms are included	N.a.	N.a.

Table 1 (*Continued*)

Registry[I]	Topic	Geographical coverage[II]	Time[III]	Funding	Who uses the information	Information	Type of registry[IV]	Compulsory
UK Cardiac Surgical Register [114]	Cardiac surgery	UK	1977–	N.a.	N.a.	Annual cardiac surgical activity and mortality data from each NHS cardiothoracic surgical unit	E, H	N.a.
General implant registries (2)								
The Austrian Medical Device Register [12]	Medical devices	AT	2002–n.a.	N.a.	Society	Product registration	N.a.	Yes
Implant Allergy Registry [13]	Allergy against nickl, chrome	DE	2002–2007	Public and private	N.a.	N.a.	N.a.	N.a.
Breast implants (9)								
International Breast Implant Registry [115]	Breast implant	TR[30]	2002–	N.a.	Industry, manufacturer, society, health care provider, health care authorities	Safety, survival, complications, risks, quality long-term outcomes	E	No
Danish Registry for Plastic Surgery of the Breast [116]	Breast implant	DK	1999–	Private and public	N.a.	Quality, complications, surgical results, surveillance, follow-up	E	No
Danish Breast Cancer Cooperative Group register [117]	Breast cancer	DK	1977–n.a.	N.a.	N.a.	Complications, revisions, implant displacement, scar revision, implant rapture, guidelines for treatment	E, H	N.a.
Danish National Registry of Patients [118]	Patient registry	DK	1977–n.a.	N.a.	N.a.	All women who underwent breast reduction surgery at public hospitals	N.a.	N.a.
DGGG Registry [119]	Breast implant	DE	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.
Swedish national implant registry/Swedish national inpatient registry [120]	Inpatients	SE	1964	Public and private	N.a.	Follow-up, to examine the relation between connective tissue disease and related conditions and breast implants	N.a.	N.a.
Swedish hospital discharge register [121]	Hospital discharge	SE	1964, having complete nationwide coverage since 1987–n.a.	N.a.	N.a.	All instances of in-hospital care are recorded	N.a.	N.a.n
Breast Cancer Register of the Stockholm-Gotland health-care region [122]	N.a.	SE: Stockholm – Gotland	1990–2004	N.a.	N.a.	N.a.	H	N.a.
UK National Breast Implant Registry UKBIR [14]	Breast implants	UK	1993–	Public	Research	Stability, first surgery, revisions, benefits and problems, research projects, adverse incidents, breast implant usage	N.a.	No
Cochlear implants (3)								
Swiss Cochlear Implant Register (CI-Database) [15]	Cochlear implant	CH	1992–	N.a.	N.a.	Stability, revisions, demographic aspects	E, H	N.a.

University Hospital Cochlear Implant program [16]	Cochlear implant	IT: University Hospital of Ferrara	N.a.	N.a.	N.a.	Complications	N.a.	N.a.
European Association of Cochlear Implant Users [17]	Cochlear implant	Europe	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.
Pumps (4)								
Community and Academic Practice Patient Registry [21]	Continuous glucose sensor-augmented insulin pump therapy	Central and Eastern European or Mediterranean countries	N.a.	Private	Health care provider, clinicians	Population characteristics, to assess the impact of the insulin pump therapy on treatment practices in patients with diabetes	N.a.	N.a.
Czech national register of patients [19]	Insulin pump therapy	CZ	N.a.	N.a.	N.a.	Safety and effectiveness, treatment indications, adverse events, safety, survival	N.a.	N.a.
The EVADIAC registry (EVAluation dans le Diabète des Implants Actifs) [18]	Insulin pump	FR	1990–n.a.	N.a.	Research, society, clinicians	to monitor the safety of the technique, assess the quality of the diabetes treatment by active implants	N.a.	N.a.
Yorkshire Children diabetes register [20]	Insulin pump	UK: Yorkshire	1973–n.a.	Public	Society, health authorities, health care provider, health services	Safety, survival, mortality, patterns, trends, cause of diabetes in children, demography, research	E	No
Tubes (3)								
The Norwegian CP register, Norwegian Cerebral Palsy Registry (CPRN), The Cerebral Palsy Follow-up Program (CPOP) [25]	Tubes, geriatrics	NO	Data collection started in 2003–n.a., 2006–n.a.	N.a.	N.a.	To estimate the prevalence of feeding and nutritional problems in children with cerebral palsy (CP) in Norway	E	No
Spanish enteral nutrition register [23]	Tubes	ES	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.
German Gemidas Database [24]	Tubes	DE	2003–2006	Member contribution, independent	Health insurance, society, health care provider, health authorities	Geriatric treatment, patient characteristics, PEG tubes, mortality	E, H	No
Colorectal stents (1)								
International Colorectal Stent Register [26]	Colorectal stent	UK, IE	N.a.	Private and public	N.a.	To collect individual patient records and track these procedures as a bridge to surgery and for palliative care	N.a.	N.a.
Ophthalmological activities (6)								
Swedish National Cataract Register [27]	Retina implants	SE	1992–	Public	N.a.	To determine the preoperative or postoperative patient-related factors, quality, assurance and improvement, unusual outcomes	E, H	N.a.

Table 1 (*Continued*)

Registry[I]	Topic	Geographical coverage[II]	Time[III]	Funding	Who uses the information	Information	Type of registry[IV]	Compulsory
The Pediatric Cataract Register – PECARE Sweden/PECARE Denmark [123]	Retina implants	SE, DK	N.a.	N.a.	N.a.	To evaluate newborn eye-screening strategies for early detection of pediatric cataracts, registry for all pediatric cataract surgery in Sweden and other participating nations, quality assurance, unexpected outcomes	N.a.	N.a.
Swedish Cornea Transplant Register [124]	Corneal transplant	SE	1996–	N.a.	N.a.	Reason for transplantation, monitoring of outcomes, adverse events, national basis for audit of individual corneal transplant units in Sweden	N.a.	N.a.
Retinitis Pigmentosa Register [125]	Retina implant	DK: National Eye Clinic	1993–n.a.	N.a.	N.a.	N.a.	N.a.	N.a.
The Swedish Retinal Detachment Register [126]	Retina implant	SE	N.a.	N.a.	N.a.	Epidemiological and clinical studies on RD	E, H	No
The Netherlands Intraocular Implant Club (NIOIC) [127]	Intraocular implant	NL	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.
Brain stimulation and shunts (2)								
Brain stimulation Tübingen [28]	Brain stimulation	DE: Tübingen	N.a.	Private and public	N.a.	Safety, survival	E, H	N.a.
UK Hydrocephalus Shunt Registry [29]	Shunts	UK, IE	1995–	N.a.	N.a.	Stability, revisions, complications, performance of different shunts, mortality	H, E	N.a.
Sacral neuromodulation (3)								
The French national Register for sacral neuromodulation* [30]	Neuromodulation	FR	2003–2009	N.a.	N.a.	To analyze current practice patterns and evaluate effectiveness, adverse events	N.a.	N.a.
Sacral neuromodulation registry Switzerland [31]	Sacral neuro-modulation	CH	2000–n.a.	N.a.	N.a.	Adverse events, efficacy, safety, implantation techniques and characteristics, follow up, management	N.a.	N.a.
The prospective Italian Register of spinal cord stimulation (SCS) [32]	Sacral neuro-modulation	IT	1998–2001	Private	Industry	To evaluate the immediate and long-term clinical outcome	N.a.	N.a.
Dental implants (1)								
Smile Dental Implant Registry [33]	Dental implants	UK	N.a.	Public, independent	N.a.	Stability, revisions, complications, monitoring	N.a.	N.a.

[I]Registry: * = Information was not available in English or German. [II]Geographical coverage: [1]AT = Austria, [2]BE = Belgium, [3]DK = Denmark, [4]ES = Spain, [5]HR = Croatia, [6]CZ = Czech Republic, [7]NL = Netherlands, [8]FI = Finland, [9]FR = France, [10]DE = Germany, [11]HU = Hungary, [12]UK = United Kingdom, [13]NO = Norway, [14]PT = Portugal, [15]IT = Italy, [16]RO = Romania, [17]SK = Slovakia, [18]SI = Slovenia, [19]SE = Sweden, [20]CH = Switzerland, [21]LT = Lithuania, [22]PL = Poland, [23]BG = Bulgaria, [24]GR = Greece, [25]BA = Bosnia and Herzegovina, [26]RS = Serbia, [27]ME = Montenegro, [28]MK = Macedonia,[29]IE = Ireland, [30]TR = Turkey. [III]Time: – = the registry is still running. [IV]Type of registry: E = epidemiologic, H = hospital-based. N.a. = not available.

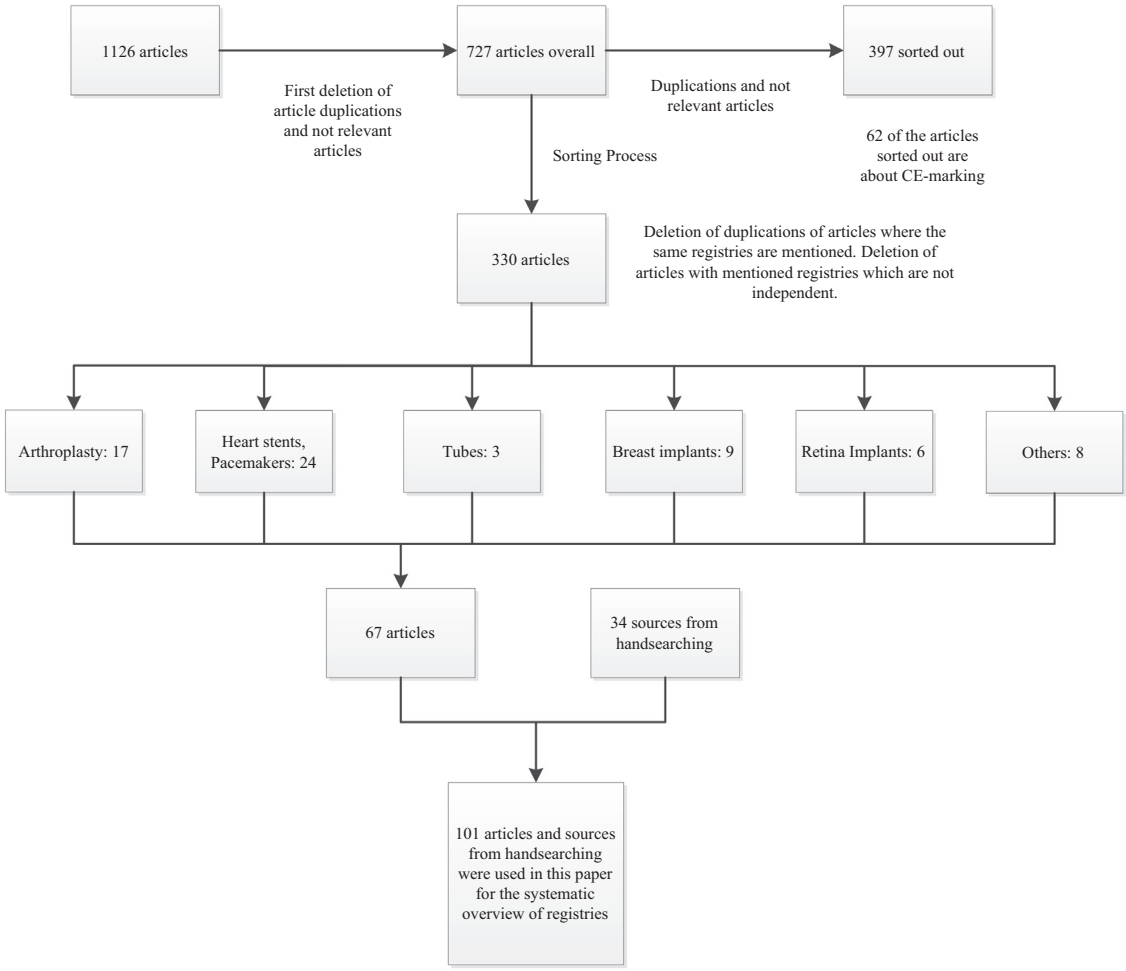

Fig. 2. Bibliographic research results.

The table shows that most registries exist in the field of cardiac implants and arthroplasty (29). 38 registries in the field of cardiac devices are included in this outline, 12 of them located in Germany. There are a lot of sections where no or only one to three registries could be identified. Furthermore, it is interesting to see in which area most registries exist. In some countries, many registries could be identified, in other ones less or even no registry.

3.2.1. Which registries do exist in Europe?

3.2.1.1. Pacemakers and heart stents. In the field of cardiology, in addition to real implant registries, for example pacemakers and stents, there are ongoing implant trial registries or disease related registries, too. There are European organizations, such as the registry of the European Working Group on Cardiac Pacing (EWGCP) and the Implantable Cardiac Device (ICD) and Pacemaker (PM) Register of the European Society of Cardiology [6]. Furthermore, there are trial registries or disease specific registries, for example the Western Denmark Heart Registry, where the focus is on diseases and the different procedures are listed with regard to the use of an implant [7]. Some countries run more than one registry.

3.2.1.2. Arthroplasty. It can be noticed that there is a real arthroplasty registry for nearly all the European countries. There are mainly registries about knee or hip arthroplasty, in the majority of cases in Northern European countries, such as Sweden or Denmark. Furthermore, there are some Arthroplasty registry associations, for example the European Arthroplasty Register (EAR), the International Society of Arthroplasty Registers (ISAR), the Nordic Arhtroplasty Register Association (NARA), and the European Federation of National Associations of orthopedics and Traumatology-Arthropasty Registers [8–11].

Registries were found in other areas, too. The search was performed in the field of brain stimulation, catheter, pumps, cochlear implant, retina implant, dental implant, breast implant, drug depot, surgery, penile prosthesis and sphincter prosthesis. However, in many cases, it was difficult or impossible to find any registry.

General implant registries, such as the Austrian medical device registry and the Implant Allergy Registry, concern more than one implant type [12,13].

3.2.1.3. Breast implants. In addition to special breast implant registries, for example like the UK National Breast

Implant registry, there are several patient registries or registries by cancer institutes, which document the use of an implant, too [14].

3.2.1.4. Cochlear implants. In the case of cochlear implants, a Swiss registry, an Italian cochlear implant program of a university and a European Association of Cochlear Implant Users could be found [15–17]. The website of this organization serves as an information platform for patients, too.

3.2.1.5. Pumps. In the field of pump registries, in France, the Czech Republic, the UK and Central and Eastern European or Mediterranean countries, only patient registries could be found that included insulin pumps [18–21]. The Insulin Pump Service is supplied by the NHS [22], but, because it is no real registry, it is not listed in the table.

3.2.1.6. Tubes. The search was also performed for tubes or nutrition tubes. A Spanish registry about home enteral nutrition could be found [23]. Furthermore, in the German Gemidas database of a geriatric hospital, patients with placement of a percutaneous endoscopic gastrostomy (PEG) are listed [24]. The Norwegian Cerebral Palsy (CP) Register is a disease specific registry where patients who get artificial nutrition are listed, too [25]. However, the focus is not on the nutrition tube.

3.2.1.7. Other stents. In addition to cardiac stents, there are also stents in other areas. The International Colorectal stent Registry is supplied by The Association of Coloproctology of Great Britain and Ireland. This registry reports the use of colonic stents for the treatment of lower bowel obstruction due to colonic malignancies [26].

3.2.1.8. Ophthalmological activities. Registries for retina implants could hardly be identified, because there are mostly ongoing trials or smaller hospital based and disease-related registries. The National Cataract Register, for example, was already established in 1992 and the goal was to monitor the effects of introducing a maximum waiting time guarantee in Sweden for patients awaiting cataract surgery [27].

3.2.1.9. Brain stimulation/shunts. Only two registries concerning brain stimulation and shunts were found, first an ongoing clinical trial from Germany and second the UK Hydrocephalus Shunt registry. The UK Shunt Registry contains data on over 55,000 CSF shunt-related procedures, the data includes patient age, diagnosis and the number of revisions a patient has had [28,29].

3.2.1.10. Sacral neuromodulation. In the field of sacral neuromodulation, three registries could be identified. However, these registries are product-related to the InterStim® Therapy (Medtronic, Minneapolis, MN, USA) [30–32].

3.2.1.11. Drug depots. No registry exists for drug depots in Europe.

3.2.1.12. Dental implants. The Smile Implant Registry is an independent registry endorsed by national and international dental associations that collects important data on dental implant procedures [33].

There were no results for implant registries of RFID implants, skull prostheses, craniofacial prostheses, port catheters or microchip implants.

3.2.2. How can registries be classified?

As specified in Section 2, the registries are classified by several criteria.

The registries are funded in different ways, some of them by public means or independent agencies, others by manufacturers or private companies. The funding has also an impact on the use of registries. If the industry of medical devices is involved and supports a registry, they can often use the results for their purposes. A registry funded by public means often has the aim to get an overview on the epidemiology and spread of the device in the population of a country. Furthermore, the type of a registry – epidemiologic or hospital based – has an impact on the information provided. Some registries list risk factors, information about the device and the surgical technique, stability and quality and report adverse events and complications. Epidemiologic registries aim to get an overview on the diffusion of the disease and population characteristics. However, information about registries measuring cost-effectiveness was difficult to obtain and was rarely mentioned. Nearly all registries identified have no open access to their databases. However, some of them release a report or publish their results in scientific articles. In many cases, the involved study centers can obtain data in more detail. Sometimes it is mandatory for hospitals to participate in registries, other registries are voluntarily conducted.

Table 1 provides detailed information about all registries identified.

4. Discussion

The aim of this study was to detect existing implant registries in Europe and classify them by different criteria. There is evidence that registries are considered to have positive effects on patient safety, quality and cost-effectiveness of care as well as on research [34]. However, our results demonstrate that there is a lot of potential for improvement. The latest incidents imply a lack of registry availability.

4.1. Implant registries in Europe

As shown in the results section, there are some registries for implant types in almost every European country, but for some others none can be found. However, there are only a few countries that run more than one to three different types of registries. Especially the Northern European countries, Sweden and Denmark, and the UK and Germany are represented much more frequently than other countries.

The biggest number of implant registries in Europe can be identified in the field of cardiologic implants. They

also exist in many different countries. However, there are differences in the structure and dimension of the registries. Some registries are established on national level, some are only related to special regions.

Many registries exist in the field of arthroplasty. The first registries were developed in Sweden (1975–1979) and in Finland (1980), they hold a pioneering role [35]. The Swedish registry was built to learn more about severe complications of total hip replacement and to improve the results [36]. Thus, the development of this registry shows that over the years, the revision rate in Sweden has been decreasing continuously which shows the success of a well-structured registry.

Further examples for implant groups with a bigger number of existing registries are breast implants, implants in the field of ophthalmological activities and cochlear implants. Nine registries concern breast implants. However, as the latest incidents show, only very few registries in few countries have been established.

Research for the existence of an overview of all existing implantable medical device registries showed, that some information for patient registries in general is available. The ISPOR Patient Registry Special Interest Group shows in its survey what kinds of registries exist and if they are disease-related, country-related or product-related [37].

4.2. Implant registry structure

The benefit of an implant registry depends on its content and quality. In case of wrong documentation, the registry is useless. In the field of medical devices, some guidelines for the design and structure of a registry exist as well as for patient registries in general. For the development of a registry, a lot of requirements have to be considered. Thus, the purpose of the registry has to be communicated, the research question has to be defined and it has to be determined if a registry is an appropriate method to reach the goals. Furthermore, the stakeholders and the target population have to be identified and the funding has to be planned [38]. Ethics, data ownership and privacy are important topics that have to be discussed. Registries must have strict rules for warnings, because a statistically significant difference alone does not necessarily imply any clinical significance and therefore cannot be used as guidance for an early warning to the other registries. The clinical relevance has to be taken into consideration, too [39].

Special data, that have to be collected in the registries, differ between the various registry types. Apparently, there are no further data requirements specified for implant registries in general. To follow up on the previous example of the arthroplasty registries, the structure of it is usually built as follows: the type of hospital, type of operating theater and the surgeon and assistant profile are documented as well as the surgical technique, procedure characteristics, prosthesis/implant characteristics and information about the patient and the outcome [35]. Most guidelines comply with the essential subjects: prosthesis details, patient details, surgery details and hospital details [39]. The value of a registry is important for patient's safety. Therefore, a medical device classification checklist is used to classify the registries found. This checklist contains the most important set to assess the quality of a registry. The table containing the results of the registry check-up shows differences in the documentation of the registries, they also differ in their ambitions. That is why the context in which a registry is built has to be considered in the analysis. A registry developed for the comparison of different devices or surgical techniques has a value that differs from that of an epidemiologic registry.

However, some of the registries found have deficiencies in structure and content, as they, for example, do not conduct a follow up or raise only limited data. Another shortcoming is that there is a lack of transparency. A lot of registries do not publish any information about their structure and content. There is heterogeneity among registries covering the same clinical or device areas. Large national databases provide more information – for example on their Internet presences – and in more detail than smaller registry studies. In these cases, it turned out to be very difficult to get any information about the goals and structure of the registry and in some cases no information could be obtained. Open access to databases is hardly possible.

Another problem concerns the obligation to participate in the registries. Participation in a registry can be compulsory or voluntary. In the latter case, some centers may not enter the registry. However, if the participation is mandatory, data might be transferred incompletely and biased, thus their use is hardly possible.

It is important for the quality of the registries, that more registries report epidemiologic data, too, because in this way, the impact of a device on the patients' health and safety can be shown. Scandinavian registries, for example, demonstrate that constant reporting for more than 20 years has been useful, because there is a noticeable decrease in revision surgeries.

However, only few registries outline that they report cost-effectiveness data, too. In this case, there is much room for improvement. Information about cost-effectiveness would be very important for nearly all stakeholders, such as manufacturers and health assurances, health care providers and health authorities. Decisions by policy makers or hospital managers have to be related to profound data that include cost-effectiveness of an intervention or device, too.

4.3. The impact of registries on policy-making

Registries are "prospective observational [studies] of subjects, with certain shared characteristics, that [collect] ongoing and supporting data over time on well-defined outcomes of interest for analysis and reporting" [40]. They can continuously inform policy makers about failures of innovation, side effects, cost-effectiveness of an intervention and can identify high-risk patients [40]. The establishment of registries has an enormous impact on decision-making. Registries serve to inform decision makers in the health care system about the quality and safety of devices and underlying surgical procedures as well as about the durability of the components used [41]. They support decision makers and health care providers in choosing treatment options and can monitor changes in practice of surgery and the impact on outcomes. Furthermore,

registries can be used for benchmarking purposes [42,43]. Decision makers and health care providers can improve their performances by regarding the evidence generated by a registry and, thus, they have the possibility to reduce the economic burden caused by revision surgeries [44]. In summary, registries have a number of benefits: they are important for the epidemiologic analysis of a population; they serve as warning tools for adverse effects and are used for quality assurance. With the help of registries, it is possible to identify the best clinical practices and to improve outcomes and quality of care.

However, some problematic aspects can occur. The establishment of a registry often causes an extra workload for the institutions. Furthermore, some physicians fear that their work may be controlled. The industry may see disadvantages in registries because in this way, a ranking of performances of different implants is easily possible.

That is why it is important to consider which goals shall be achieved by evaluating registry data and how those data evaluations are handled. There is a difference if the results developed by a registry are supposed to be actively used for health care policy decision-making or if the influence on politics is unintended. It has to be stated how and to what extent the evaluations can be included in a decision-making process and which stakeholders are affected. The possible consequences of a decision based on registry data have to be outlined. Beside the positive impact of registries on public health – cost savings, prostheses withdrawn from the market [45] – there may be some negative impacts, too. It has to be considered that unsuspected costs can occur. That is why a strategy should be developed for each registry to deal with these problems depending on the local health care conditions.

A further aspect of major importance is the ownership of registries. Many registries are supported by the industry and thus, there may be a lack of credibility and policy-makers and researchers may doubt the results. The perspective chosen for analysis is an important issue regarding the potential usefulness of a registry. Is the end-user a manufacturer or a policy-maker?

The FDA has identified the tremendous potential for evaluating devices by combining information between and within registries [46].

Currently, there is an intensive discussion in Europe about the use and relevance of registries.

In a recently published article by Black and Tan the use of national clinical databases for informing and evaluating health care policies is analyzed and specific examples of this topic in the UK are identified. The authors outline that there are different possibilities for decision makers to use registry data, for example, they can either make use of the data itself or of research based on the database [47].

Despite all these advantages mentioned above, Black and Tan identified a lack of interest of custodians as well as of policy makers in maintaining and using registries and databases. That is why decision-makers should minimize the legal restrictions on data use and improve the quality of databases because registries and databases constitute a valuable resource for monitoring and evaluating devices [47].

4.4. Regulation of medical devices

Since 2012, the medical device directives have been under revision. “Both the Council and the European Parliament have pointed to the necessity to adapt the medical device legislation to the needs of tomorrow with the aim to achieve a suitable, robust, transparent and sustainable regulatory framework” [48]. In order to ensure that these devices serve the needs of European citizens and to enhance their safety, the European Commission proposed two regulations which are fit for purpose, more transparent and better adapted to scientific and technological progress.

The Scope of EU legislation will be wider and clearer and will also contain regulation for implants with esthetic purposes or medical software. There will be a stronger supervision of notified bodies by national authorities. Notified bodies gain more power, for example unannounced factory inspections will be possible. Databases on medical devices will be extended providing comprehensive and public information on products. Patients and other stakeholders will have the possibility to have access to key data. “A Unique Device Identification system will be introduced to enhance post-market safety of medical devices, to help to reduce medical errors and to fight against counterfeiting”. Furthermore, there will be stricter requirements for clinical evidence [49].

Although this European Commission proposal for a regulation of medical devices contains a number of significant improvements, it is not clear whether these steps are sufficient enough to ensure high levels of protection of human health and safety and improvement of the current regulations. The current system of notified bodies, so far, has been proven insufficient. An example of this is the insufficient regulation of medical devices when it comes to CE-Marking, as revealed by the BMJ [50]. That is why a centralized approval of medium and high risk devices and in vitro diagnostic devices is needed by a new public body. Furthermore, there are no compulsory requirements for assessment of the devices and conducting clinical trials. Registries could be used to gain a lot of data and information about devices.

5. Conclusions

Registries are a cornerstone of the regulatory process of medical devices and in this context a major tool for decision-makers and managers. This becomes obvious given the loopholes and the lack of its enforcement that have steadily been reported over the last five years. They can also be regarded as an overriding tool when it comes to curbing the soaring incidence of adverse events associated particularly with cardiac devices and prostheses implants.

The results show that there are only a limited number of reviews on registries. A centralized monitoring system in Europe is still missing. However, the European Commission reacted on the breast implant scandal and released a revision of the device directives. This is a first step toward a transparent and a qualitative regulation. However, our results reveal a lack of transparency concerning number, aim, structure and quality of registries. This is crucial, as registries work as an early warning system for

identifying and notifying patients at risk. Registries of medical implants should provide the basic data needed to evaluate and compare the quality of implants, to enable early detection of serial defects, to assess short- and long-term reactions and complications. Registries can shorten the time lapse before any health hazard is perceived.

Conflict of interest statement

There are no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.healthpol.2013.08.008.

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