

Landscape of Cardiovascular Device Registries in the United States

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Background—Regulators increasingly rely on registries for decision making related to high-risk medical devices in the United States. However, the limited uniform standards for registries may create substantial variability in registry implementation and utility to regulators. We surveyed the current landscape of US cardiovascular device registries and chart the extent of inconsistency in goals, administration, enrollment procedures, and approach to data access.

Methods and Results—A systematic review using Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines identified studies (1995–2017) referencing cardiovascular device registries with a US-based institution. Registries were then evaluated by reviewing associated articles and websites. Extracted data included device type, primary scientific aim(s), funding, stewardship (eg, administration of registry procedures), enrollment procedures, informed consent process, and mechanisms to access data for research. The 138 cardiovascular device registries in the cohort covered devices addressing interventional cardiology (65.9%), arrhythmias (15.2%), heart failure (10.1%), and valvular disease (10.1%). While the majority (55.8%) were industry-funded, stewardship was predominantly overseen by academic centers (74.0%). Most registry participation was voluntary (77.5%), but a substantial minority (19.7%) were required as a condition of device implantation. Informed consent requirements varied widely, with written consent required in only 55.1% of registries. Registry data were primarily accessible only to stewards (84.1%), with 13.8% providing pathways for external applications.

Conclusions—The majority of cardiovascular device registries were funded privately under the auspices of academic institutions, which set the rules for data access. The substantial variation between cardiovascular device registries suggests a role for regulators to further strengthen guidelines to improve quality, consistency, and ethical standards. (*J Am Heart Assoc.* 2019;8:e012756. DOI: 10.1161/JAHA.119.012756.)

Key Words: post-market surveillance • registry • systematic review

Regulatory oversight of innovative high-risk medical devices attempts to clarify the benefit-risk balance of the new technology using detailed premarket safety and effectiveness assessment, as well as continued oversight after approval. In the United States, the Food and Drug

Administration (FDA) is responsible for both premarket and postmarket evaluation of medical devices,¹ but in recent months has taken a number of steps to truncate expectations for preapproval testing.^{2,3} These efforts will necessarily heighten the importance of rigorous postmarket surveillance systems designed to identify emerging safety signals, support comparative effectiveness evaluation, and refine product labeling.

Traditionally, postmarket surveillance of newly approved medical devices has relied heavily on passive collection of adverse events. Recognizing the limitations of this approach, however, the FDA's strategic vision for monitoring high-risk devices increasingly emphasizes the role of medical device registries. A medical device registry is a database that actively collects and maintains information about individual patient exposures to medical devices.^{4,5} In the past decade, the FDA has leveraged its National Medical Device Registry Taskforce as well as the Medical Device Epidemiological Network experts to coordinate stakeholder input on registry objectives and development strategies.^{6–8} Similarly, private initiatives through the Pew Charitable Trusts, Blue Cross Blue Shield Association, and the Brookings Institution have offered

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A version of this analysis was presented as an abstract at the American Heart Association's Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke Scientific Sessions, April 5 to 6, 2019, in Arlington, VA.

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Received March 22, 2019; accepted April 24, 2019.

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Clinical Perspective

What Is New?

- We reviewed the landscape of cardiovascular device registries in the United States and identified substantial variation between cardiovascular device registries according to enrollment and consent procedures, as well as access to data for research.

What Are the Clinical Implications?

- Clinicians and patients making use of high-risk cardiovascular devices rely on high-quality postmarket surveillance to ensure longitudinal safety and effectiveness.
- The substantial variation between cardiovascular device registries suggests a role for regulators to further strengthen guidelines to improve quality, consistency, and ethical standards.

recommendations to anchor a national system for medical device postmarket surveillance on the routine establishment and use of registries.^{9–11}

While these working groups have focused on registry elements such as data quality and common definitions to promote data sharing,¹² other questions remain about the broad characteristics of medical device registries. For example, registry management can be led by professional societies, industry, academic institutions, and partnerships among these groups. These institutions may have different goals for the registries they oversee and varying rules and procedures for accessing registry data. Variations in registry implementation may have important ethical and practical implications for patients. For example, postmarket registries are commonly mandated by the FDA upon approval of novel medical devices. However, obligatory participation by patients as a condition of receiving a device may require heightened attention to informed consent and privacy protections.

To help understand the clinical and ethical challenges that may arise from greater regulatory and clinical reliance on medical device registries, we surveyed the current landscape of cardiovascular registries. We focused on registries' funding and stewardship, enrollment mechanisms, informed consent procedures, and access to data.

Methods

Consistent with the American Heart Association's journal policy, the data that support the findings of this study are available from the corresponding author upon reasonable request.

Database and Search Terms

We first conducted a systematic review following Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines to identify published studies using data from cardiovascular device registries based in the United States. We searched MEDLINE using the terms "cardiology," "registry," and "equipment and supplies" as medical subject heading and free text queries. The search was limited to publications in the English language (1995–2017) for which full text was available.

Inclusion Criteria

From this search, we extracted the title and abstract of publications with a reference to a single-center, multicenter, or international registry with at least 1 participating US-based institution. Device registries were defined as prospective, observational databases specifically designed to collect information on individual patient exposures and outcomes related to a medical device. Articles describing only retrospective data collection were excluded, as were studies based entirely on administrative data sets collected for nonresearch purposes (eg, billing claims). Editorials and commentaries were excluded.

After this screen, full-text articles were reviewed and articles pertaining to noncardiovascular devices were excluded. Redundant references to the same registry were also removed.

Registry Analysis

Each cardiovascular device registry was then evaluated by accessing its associated publication and (when available) registry website.

We assessed the dates of inception and, for registries that closed, the date of termination. The primary scientific aims for each registry were identified and categorized as relating to 1 of 4 nonmutually exclusive categories: safety, effectiveness, comparative effectiveness (eg, between device types), or epidemiology (eg, a focus on the utilization, patient characteristics, and/or facility experiences with the use of a new device). The study population was characterized as primarily pertaining to interventional cardiology (eg, coronary stents, peripheral stents); arrhythmias (eg, atrial fibrillation treatment), valvular heart disease (eg, surgical or percutaneous heart valves), heart failure (eg, ventricular assist devices), or other. Additionally, we noted whether children (patients younger than 18 years) were eligible for inclusion in the registry.

Funding and stewardship for each registry were defined as public, private, professional society, academic institutions, or

a combination of these. Private funding sources included corporations and industry members.

For each registry, we identified the enrollment mechanism, noting whether patients were registered voluntarily, automatically without knowledge, or as a condition of receiving the device at issue, or unknown. We extracted the procedures for informed consent, including whether written or verbal consent was obtained or if no consent process was specified.

Last, we examined the procedures by which access to data were controlled, characterizing registry data as publicly available, available only to registry stewards, or available through an investigator-initiated proposal process.

For registries with missing data, authors of its associated publications were contacted by email to answer remaining queries.

Descriptive statistics were calculated using RStudio software version 0.98.945 (R Foundation).

Results

Among the 1565 studies under initial consideration, 166 identified cardiac device registries, and after excluding 28 duplicates, the final cohort consisted of 138 registries described in published studies (Figure 1).

As shown in the Table, a small percentage of registries (4.3%) began collecting data before 1990, while 17.4% began from 1990 to 1999. The majority (64.5%) of published registries began patient enrollment between 2000 and 2010, while another 12.3% began enrolling patients after 2010. Registries varied in the length of enrollment period, with many registries continuing to enroll patients currently. Among the studies with a defined end point for data collection, 50.0% lasted 1 to 5 years, 18.1% lasted 5 to 10 years, and 3.6% lasted >10 years (Figure 2).

The aims of each registry were determined as primarily addressing safety (51.4%), effectiveness (62.3%), comparative effectiveness (15.9%), or epidemiology (16.7%). The most common devices targeted were coronary and carotid stents (interventional cardiology, 65.9%) and treatments for arrhythmias (15.2%, such as implantable cardioverter-defibrillator [ICD] implantation and catheter ablation for atrial fibrillation). An additional 10% focused on heart failure and valvular heart disease (e.g. left ventricular assist devices and transcatheter heart valve devices).

Pediatric patients were included in 10.1% of the registries. This subset included some registries specifically addressing pediatric populations, such as the Cryocath International Patient Registry for patients younger than 18 years undergoing catheter-based ablation for arrhythmias, the National Registry for AED Use in Sports to capture high school students with ICDs, and the Congenital Cardiac Catheterization Project on

Outcomes Registry for pediatric patients undergoing congenital heart surgeries. The remaining registries covered both pediatric and adult patients, including the Texas Heart Institute Research Database, Mid-Atlantic Group of Interventional Cardiology Registry, and the Extracorporeal Life Support Organization Registry.

Funding was categorized as being public (13.0%), private and nonacademic (55.8%), academic (23.2%), derived from a professional society (13.8%), or unknown (2.2%). By contrast, academic institutions were charged with stewardship of the data in 74.0%, while only 12.3% of registries were stewarded by private institutions, 10.1% by professional societies, and 3.6% by public institutions (Figure 3). For example, the Angio-Seal Evolution Device Registry, a multicenter registry of patients undergoing interventional or diagnostic procedures by femoral access with use of the Angio-Seal device, received funding from St. Jude Medical, but was stewarded by Wake Forest University Health Sciences. Similarly, the Computer-Based Endoluminal Graft Repair Registry was sponsored by Medtronic, although the data stewards were investigators at St. Mary's Duluth Clinic Regional Heart Center.

By contrast, the Society of Thoracic Surgeons Interagency Registry for Mechanically Assisted Circulatory Support for adult and pediatric patients receiving mechanical circulatory support was developed as a combined effort between the National Heart, Lung, and Blood Institute, the FDA, and the Centers for Medicare & Medicaid Services and remains based at the University of Alabama at Birmingham with funding support from participating sites and device manufacturers.

Enrollment, Consent, and Access

Patients were enrolled into the registries via 2 primary mechanisms: (1) voluntary enrollment at the discretion of providers (77.5%) or (2) obligatory enrollment on the condition of receiving a device within a participating health insurance system (eg, Kaiser Permanente, Blue Cross Blue Shield of Michigan, Medicare) (20.3%). For example, in 2006, the Kaiser Permanente National Implant Registry began enrolling all patients who received a cardiovascular implant device (eg, pacemaker, ICD, valve, or stent) in a registry integrated with the electronic medical record. Similarly, the Pediatric Interagency Registry for Mechanical Circulatory Support collects pertinent patient information and outcome measures for all pediatric patients who undergo treatment with mechanical circulatory support devices. The National Cardiovascular Data Registry for Implantable Cardioverter-Defibrillators (2006–2018) required that hospitals contribute to the registry as a condition of coverage for ICDs for primary prevention in Medicare beneficiaries. By contrast, other registries are

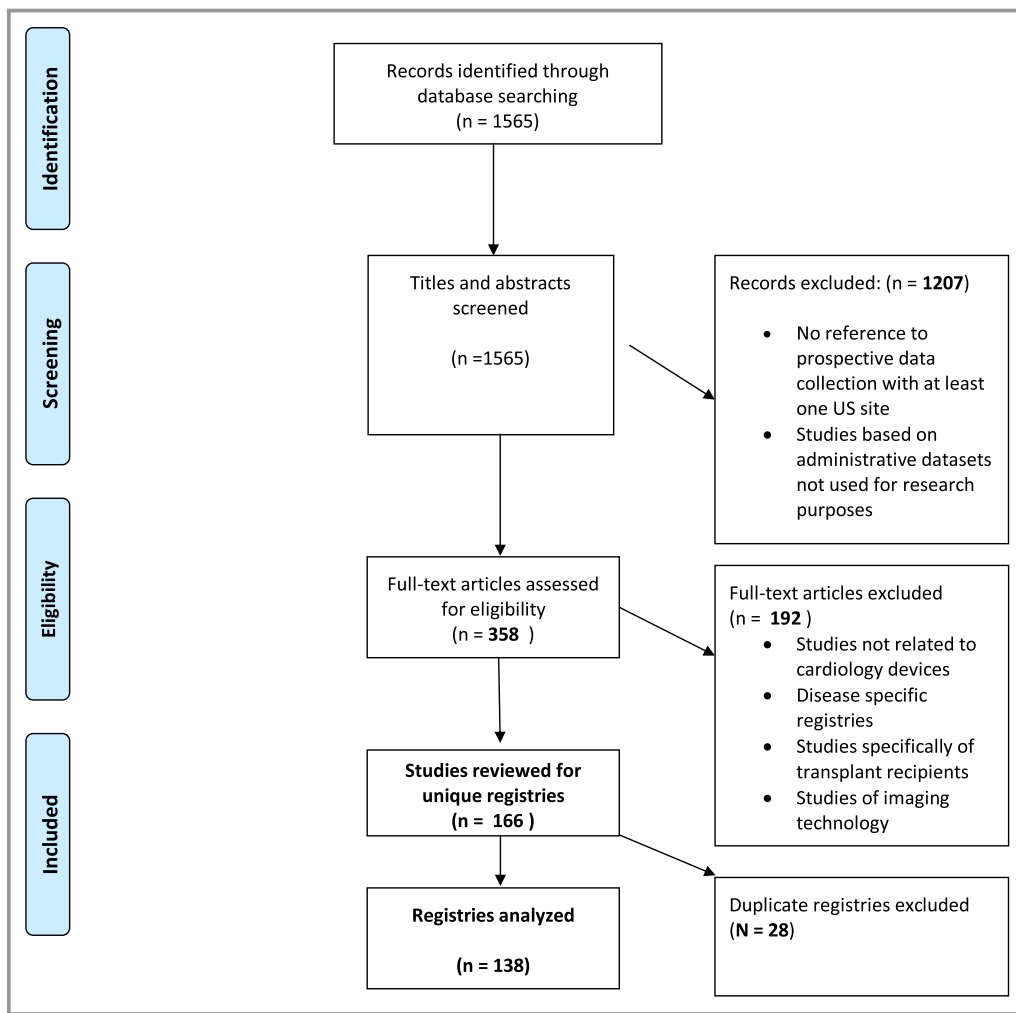


Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) diagram for registry inclusion demonstrating search strategy for published articles from which cardiovascular device registries were identified for qualitative analysis.

designed such that participating centers may choose whether to submit data, including the TAXUS Peri-Approval Registry: A Multi-Center Safety Surveillance Program for patients receiving the Boston Scientific TAXUS stent or the Antithrombotic Strategy Variability In Atrial Fibrillation and Obstructive Coronary Disease Revascularized With PCI Registry for patients with nonvalvular atrial fibrillation undergoing percutaneous coronary intervention.

Requirement of informed consent also differed by registry, with 15.2% of registries waiving the need for verbal or written informed consent, 55.1% requiring written informed consent, and 23.9% mandating that the institutional review boards of participating institutions determine whether informed consent was necessary. For example, the Endovascular Valve Edge-to-Edge Repair Study II High-Risk Registry enrolled patients treated with the MitraClip device and required specific written consent before enrollment in the study. In the Antiarrhythmics

versus Implantable Defibrillators Registry, consent procedures depended on local institutional review boards, with verbal rather than written consent allowed at a majority of sites. By contrast, the Blue Cross Blue Shield of Michigan Cardiovascular Consortium Percutaneous Coronary Intervention Quality Improvement Initiative Registry required no verbal or written consent for inclusion.

Finally, registries were analyzed to determine data accessibility, with the majority (84.1%) of studies providing access only to stewards, while 13.8% were open for outside data use proposals. Several of the large, national databases, including the Peripheral Vascular Intervention Registry, stewarded by the National Cardiovascular Device Registry and American College of Cardiology, allow access to registry data by external research groups via application. Single site registries, including the University of California Stent Thrombosis Registry and the Prairie Heart “Real-World”

Table. Characteristics of Cardiac Device Registries, 1995–2017

Descriptor	Total (N=138), No. (%)
Device type	
Arrhythmia	21 (15.2)
Interventional cardiology	91 (65.9)
Heart failure	14 (10.1)
Valvular	14 (10.1)
Pediatric patients included	14 (10.1)
Registry goals	
Safety	71 (51.4)
Effectiveness	86 (62.3)
Comparative effectiveness	22 (15.9)
Epidemiology	23 (16.7)
Enrollment	
Voluntary	107 (77.5)
Condition of receiving device	28 (20.3)
Unknown	3 (2.2)
Consent process	
None	21 (15.2)
Written	76 (55.1)
Waiver governed by individual institutional review board	33 (23.9)
Unknown	8 (5.8)
Funding	
Public	18 (13.0)
Private	77 (55.8)
Professional society	19 (13.8)
Academic	32 (23.2)
Unknown	3 (2.2)
Stewardship	
Public	5 (3.6)
Private	17 (12.3)
Professional society	14 (10.1)
Academic	102 (74.0)
Access to data	
Registry stewards only	116 (84.1)
Outside proposals by application	19 (13.8)
Unknown	3 (2.2)

Percentages by category may not sum to 100%, as registries may meet criteria for ≥ 1 subcategory.

Stent Registry, less frequently provide a publicly available mechanism through which external researchers may access data.

Discussion

The structure and administration of cardiovascular device registries in the United States shows that the majority of such registries we identified are funded privately under the auspices of academic institutions, which set the rules for data access. There is substantial variation between cardiovascular device registries according to enrollment and consent procedures, indicating a role for regulators to strengthen guidelines to improve quality, consistency, and ethical standards.

High-risk medical devices pose challenges for premarket testing compared with drugs or biologic agents. These include the permanence of many implants, practical limitations to blinding, mechanistic complexity, procedural learning curves, and interoperator and intraoperator technical variability—all factors that are largely irrelevant for drugs. Even devices subjected to rigorous premarket trials will benefit from prospective, focused data collection to characterize their postmarket experience.¹³ Unlike drugs, devices also undergo continuous incremental advancement that may include manufacturing or design changes that heighten the importance of postmarket surveillance.¹⁴ Medical device registries seek to overcome the many limitations of passive adverse event collection, including underreporting and data inconsistency, without incurring prohibitive costs. Accordingly, well-designed registries have helped refine clinical guidance and labeling for devices such as transcatheter aortic valves, left ventricular assist devices, and vascular closure devices.^{15–17} These and other successful registries support the FDA's vision for establishing a national system of active surveillance that leverages registries.

However, while the FDA or other regulators such as the Centers for Medicare and Medicaid Services can mandate registry creation and establish some parameters for their scientific aims, the majority of registries appear to be funded privately and run cooperatively by academic institutions and industry. This may pose potential challenges for harmonizing the goals of regulatory bodies with those of registry stewards. For example, the National Cardiovascular Data Registry for Implantable Cardioverter-Defibrillators to date has collected data on over 1 million device implants, with data managed primarily by the American College of Cardiology. This registry has been used successfully to describe implantation trends, health services use, and survival trends among device recipients. However, despite its size and useful data linkages (eg, to Medicare claims), the ICD registry has not been used for comparative effectiveness research of pivotal clinical and economic importance, such as identifying differences in device performance (battery life and lead failure rates) between manufacturers. Indeed, despite the enormous impact of ICD lead failure on patient care, amplified by high-profile recalls that affected hundreds of thousands of patients, the

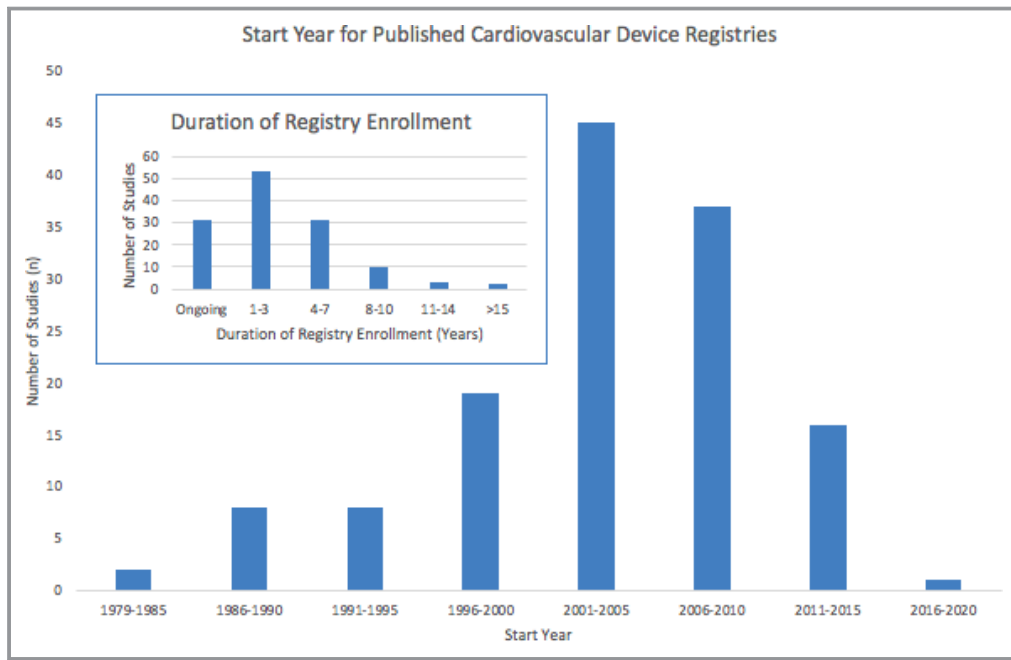


Figure 2. Enrollment in cardiovascular device registries.

largest meta-analysis of ICD lead performance included <50 000 patients¹⁸—less than any single year of the ICD registry’s experience.¹⁹ This example illustrates the way in which even large and successful registries may not be easily tailored to scientific questions that were not explicitly embedded in their design.

Since such issues are likely to be prevalent given the heterogeneous registry landscape that we observed, the government could take a more active role in setting guidelines for registry development. For example, while not all device registries will likely influence future regulatory decision making, those for which that role is anticipated should

consider whether brand-specific comparisons should be embedded prospectively as analytic goals. At the same time, registry design should account for the need for such comparisons—given the significant potential economic stakes for funding partners—to capture sufficient clinical detail to support adequate methods for control of confounding, reducing the likelihood of spurious findings.

Our review also suggests an opportunity for guidance on enrollment and consent for medical device registries. The Medical Device Registry Task Force noted, “because traditional registries often collect information that is stored and may be accessed at a later time for purposes not defined at the time of

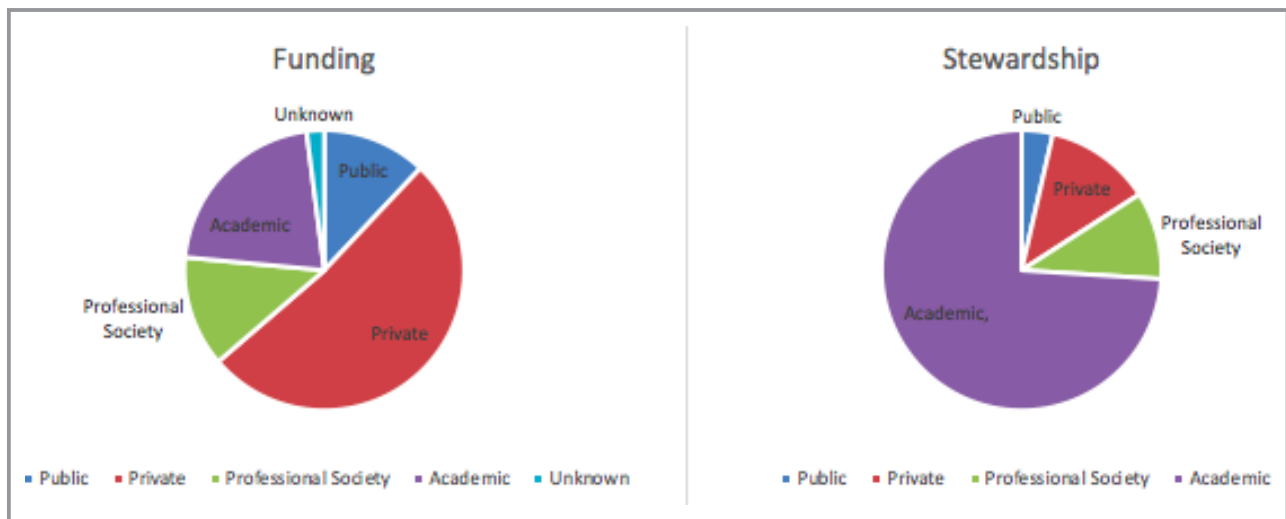


Figure 3. Funding vs stewardship of cardiac device registries.

collection, a lack of clarity exists regarding appropriate research protections generally and informed consent procedures specifically.²⁰ Obtaining informed consent increases costs and administrative burden on registry stewards, and may limit the generalizability and statistical power of registry findings if a substantial proportion of patients decline to participate. However, consent may also enrich registries by permitting direct links to patients' protected health information and providing more flexibility around future use that may not be possible under a consent waiver.

Under current guidelines, consent for research can generally be waived in select circumstances, including research that poses no more than minimal risk to participants, that does not affect the rights or welfare of participants, that would be significantly hindered if informed consent were required, and on the condition that the researchers will provide relevant information to participants after conclusion of the study.²¹ This framework is typically applied to studies such as retrospective chart reviews and studies without the use of identifiable protected health information. But these waivers of consent face several practical and ethical challenges when applied to registries, particularly given the fraying plausibility of completely deidentifying participants.^{22,23} Waiver of consent may also be particularly problematic in registries for which participation is mandatory as a condition of receiving the device. Again, the ICD registry provides an example: From 2006 to 2018, enrollment of Medicare beneficiaries receiving an ICD for primary prevention of sudden cardiac death was mandatory as a condition of reimbursement, and there was no mechanism for patients to provide consent or to opt out of any aspect of the registry, and no standardized information provided to participants. However, these data contain protected health information and have been linked to Medicare claims and other data sources such as the Boston Scientific ALTITUDE registry. This seems to challenge the most fundamental requirements in the Code of Federal Regulations for a waiver—that the research not contain identifiable personalized health information which could be released to a third party and that the research not pose more than minimal risk to participants.²¹

At a minimum, patients entered into registries without their consent should be provided information about the registry, its stewardship, goals, information on privacy protection, and mechanisms for contacting registry leadership with concerns. Another approach that may balance patient autonomy with larger registry goals would be to require mechanisms for patients to opt out, either entirely or for aspects of a given registry that may require inclusion of protected health information. For example, a registry study looking at institutional and provider volumes for a novel transcatheter valve procedure would be able to characterize several aspects of these cases—numbers of patients treated over time, routes

of vascular access—with limited or no protected health data obtained. More longitudinal outcomes studies leveraging links to insurance claims will necessarily require more individual identifiers.

Registries that include unique device identifiers will also necessarily heighten privacy concerns, as simplifying linkage of devices to patient records is one of the primary motivations supporting that initiative.^{24,25} Indeed, soliciting consent may actually improve registries' ability to answer complicated comparative effectiveness questions by facilitating data linkages across insurance carriers or allowing for investigators to contact patients directly. Engaging patients in this way may also heighten awareness of the importance of registries by calling attention to the evidence gaps remaining for specific devices at the time of FDA approval. At the same time, creating useful linkages to medical records and administrative claims will depend on the reliability of those data sources, the presence and strength of auditing procedures, and the more general complexity of leveraging disparate data sources collected for reasons other than the primary study goals of interest.

This report also focuses attention on the mechanisms by which the public can access registry data. Fewer than 15% of the device registries included in this analysis allowed external access to data via a publicly available application process, with the remainder of the registries maintaining proprietary data available only to the stewards. Limited access to registry data raises the question of whether raw data or findings should be required to be released at regular intervals in order to prioritize detection of adverse patient safety outcomes, particularly within registries that receive public funding. Data sharing in clinical trial contexts has received heightened scrutiny,^{26,27} with a recent study of clinical trial participants noting general willingness to make data available to outside investigators alongside concerns about privacy and data security.²⁸ However, this survey focused on patients who provided consent, and whether participants in registries have similar perspectives on data access and privacy protection remains unknown. This suggests that the FDA and others establishing registries for postmarket surveillance should incorporate guidance on data access, while also supporting research to understand the views of registry participants.

Study Limitations

Our analysis includes certain limitations. Our review covered a large time period in part to allow for a time delay between data collection and eventual publication. However, this also aligns with changes in policy and regulatory emphasis on registry development, which may have led to changes in registry design over time. Most importantly, our approach to identifying cardiovascular device registries depended sequentially on a publication emerging from that data set, and that

our search strategy would identify the study. It is likely that many smaller-scale, single-institution or manufacturer-controlled registries were not captured by this approach. However, such registries may be less likely to influence regulatory decision making or influence clinical practice. It is also likely that our search strategy did not capture all registries that would be eligible for analysis, and it is difficult in the abstract to assess the ways in which those missing studies might bias our findings. Similarly, several important populations of cardiovascular patients are relatively under-represented in our sample, including those with peripheral vascular disorders and aortic disease. Among identified registries, their characteristics were identified through a mix of article methods review and external searches, which may mistakenly characterize specific data elements.

Indeed, whether and with what outcomes publications emerge at all from registries remain uncertain. Analyses that are either unsuccessful because of poor enrollment or changes in stewards' priorities may never generate publications. Others may contain useful data but will avoid peer review if the findings are perceived to be "negative" by study stewards or be subject to publication bias and declined by journals. Future research might investigate whether characteristics of registries such as financial sponsorship influence these outcomes. Similarly, while we assessed in a broad sense the financial backing of registries themselves, our data sources did not allow for a more detailed analysis of potential conflicts of interest among principal investigators or (for relevant registries) institutions involved in running particular studies.

Conclusions

Clinicians and patients making use of high-risk cardiovascular devices rely on high-quality postmarket surveillance to ensure longitudinal safety and effectiveness. Future registry development should include clear guidelines on enrollment and consent procedures and access to data research. These guidelines must balance regulatory and clinical utility, practicality of implementation, and ethical standards for human subjects research.

Disclosures

Dr Kramer is supported by the Greenwall Faculty Scholars Program in Bioethics. The remaining authors have no disclosures to report.

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