Venous disease patient registries available in the United States

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ABSTRACT

Patient registries are beneficial in that they allow the collection of prospective data focused on a specific medical issue. These registries give providers a "real-world" view of patient outcomes. Many medical disciplines have a long history of developing and using patient registries; the first patient registry for chronic venous disease in the United States was launched in 2011, fairly recently in comparison. Registries included in this review were identified by surveying members of major academic societies that focus on the care of chronic venous disease and by searching MEDLINE and Embase databases using Ovid interface. Medical directors of four of the five databases available in the United States completed a standard questionnaire, and the answers served as the basis for this review. This review is not a comparison of registries; it does, however, describe the common and unique features of four venous registries currently available in the United States with the purpose of increasing awareness of and fostering participation in these registries. (J Vasc Surg: Venous and Lym Dis 2017;■:1-8.)

Practicing evidence-based medicine implies that patient management decisions are guided by evidence. Treatment outcomes are benchmarked against expectations that are based on either scientific evidence or known outcomes in similar cases managed in accordance with local standards of care. Such high standards frequently conflict with a lack of evidence support for real-world clinical needs. Expert consensus statements and "best practice" guidelines can temporarily resolve these conflicts.[1-3] However, these documents usually do not influence health care policy or practice patterns.[3,4] Ultimately, sufficient evidence needs to be generated to define evidence-based standards of care.

Although randomized clinical trials (RCTs) and the meta-analyses of them represent a desirable level of evidence,[5] they are not always practical or feasible, and they are not free from controversy.[6,7]

In the absence of RCTs, observational studies may provide a sufficient level of evidence for practice. These studies should be based on uniformly and systematically collected data from a large representative sample of the population of clinical interest. The instrument that meets this criterion for data collection is defined as a patient registry.[8] Patient registries allow prospective data collection to be focused on a specific issue (condition, treatment, or utilization) and can be designed to facilitate high participation rates and significant volumes of data collection in a short time with reasonable cost. Participation in the registry reduces variability of care and in some cases reduces the cost of care by increasing the patient's adherence to more cost-effective treatment.[9] Moreover, patient registries often more accurately depict the real-world outcomes of patients instead of the highly selected and curated sample within an RCT.

Despite a high prevalence of chronic venous disease (CVD), few large controlled clinical studies have been done, so the level of existing evidence is low to moderate at best.[10,11] Patient registries for CVD may provide valuable information in answering some of the most important questions related to the care of these patients. A registry's data can help describe the natural history and scope of the disease, determine clinical and cost effectiveness of treatment options, assess safety of new treatments, and measure or improve quality of care.[12] In addition, venous registries will define standard metrics for use in the diagnosis and severity of disease. By uncovering practice patterns for venous disease diagnosis and treatment across the United States and across varied specialties, a registry enables the assessment of functional outcomes and comparative analyses of different clinical approaches to venous disease management. This will make it a powerful tool for identifying science-based best practices, developing treatment guidelines, modifying public policy with evidence, and redirecting health care resources.

Several registries focused on venous diseases are available in the United States. However, because these instruments have been developed very recently, one of the many barriers to achieving sufficient participation remains the awareness and understanding of each of the registries (Table I).

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The purpose of this review was to describe venous disease patient registries available in the United States.

METHODS

Registries were identified by surveying members of the major academic societies focused on the care of CVD (American Venous Forum [AVF], American College of Phlebology [ACP], Society for Vascular Surgery [SVS], and Society of Interventional Radiology) at their annual meetings and by searching MEDLINE and Embase databases using Ovid interface including free text and medical subject terms from 2015 to December 2016. The medical directors of four of the five identified registries agreed to participate in writing this manuscript. The Society of Interventional Radiology registry has been under development up to the time of submission of this manuscript and was not included.

A standard questionnaire was sent to all medical directors, and the answers served as the basis for this review. Each of the registries was responsible for the accuracy of the description of the corresponding registry and provided approval of the final manuscript.

The purpose of this review was to provide the readers of the *Journal* with a qualitative description of the key elements of each of the registries and to encourage their participation in the registry that best serves their needs. It was not the authors' intention to compare one registry with another or to describe any advantages or disadvantages of each of the registries.

RESULTS

The results are summarized in Table II.

Vascular Quality Initiative (VQI). At the time of this review, the VQI had two venous modules: the Varicose Vein Registry (VQI VVR) and the inferior vena cava filter registry. Both of these registries represent collaboration between the AVF and the SVS Patient Safety Organization.

The registries were designed with the intent to analyze procedural and follow-up data, to benchmark outcomes for continuous improvement, to reduce costs and improve outcomes by developing best practices, and to provide the metrics for meeting Intersocietal Accreditation Commission certification for vein centers and board certification for physicians.

A volunteer committee composed of the SVS and AVF members is responsible for identifying opportunities of each registry for improvement, such as determining critical adverse outcomes, nonessential variables for each registry, and error trapping variable combinations. The committee also designates long-term follow-up required fields and identifies two or three quality improvement projects that may lead to best practice recommendations for each registry. Because the VQI is recognized by the Centers for Medicare and Medicaid Services (CMS) as a Qualified Clinical Data Registry, the committee is able to report quality measure data to CMS and in collaboration with the SVS to evaluate and develop quality measures for the Physician Quality Reporting System.

The VQI is a distributed network of regional groups that uses a cloud-based system to collect and to analyze data. It includes a web-based data registry with real-time reporting.

Only patients with Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) class C2 to C6 venous disease who are undergoing an invasive treatment are captured

Table I. Barriers to achieving sufficient participation in patient clinical registries

Practice-based concerns	
Staffing requirements	• Manual data entry ~½-2 FTE
Workflow concerns	• Duplicate entry unless unique automated system • Health-related quality of life queries (in office vs portal)
Registry license fees	• Registration fees • Annual fees • Interface fees
EMR vendor fees	• EMR system • Custom template development consistent with registry requirements • Interface build vs script to pull data
Practical concerns	
Capital equipment expenditure	• Hardware and software • Cloud-based vs off-site server backup
EMR-registry interoperability is cumbersome	• EMR ability to dump clean data • Vendor appreciation of the purpose
Lack of tangible incentive	• No formal incentive for participation despite potential benefits

Provider misperceptions	• "My data won't add much to the story."
	  ○ This misses the power in numbers.
	• "Patients don't want to complete more forms."
	  ○ HRQL is critical in identifying the degree of benefit of any treatment.

EMR, Electronic medical record; *FTE,* full-time equivalent; *HRQL,* health-related quality of life.