

# A multiregional registry experience using an electronic medical record to optimize data capture for longitudinal outcomes in endovascular abdominal aortic aneurysm repair

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**Objective:** Registries have been proven useful to assess clinical outcomes, but data entry and personnel expenses are challenging. We developed a registry to track patients undergoing endovascular aortic aneurysm repair (EVAR) in an integrated health care system, leveraging an electronic medical record (EMR) to evaluate clinical practices, device performance, surgical complications, and medium-term outcomes. This study describes the registry design, data collection, outcomes validation, and ongoing surveillance, highlighting the unique integration with the EMR.

**Methods:** EVARs in six geographic regions of Kaiser Permanente were entered in the registry. Cases were imported using a screening algorithm of inpatient codes applied to the EMR. Standard note templates containing data fields were used for surgeons to enter preoperative, postoperative, and operative data as part of normal workflows in the operating room and clinics. Clinical content experts reviewed cases and entered any missing data of operative details. Patient comorbidities, aneurysm characteristics, implant details, and surgical outcomes were captured. Patients entered in the registry are followed up for life, and all relevant events are captured.

**Results:** Between January 2010 and June 2013, 2112 procedures were entered in the registry. Surgeon compliance with data entry ranges from 60% to 90% by region but has steadily increased over time. Mean aneurysm size was 5.9 cm (standard deviation, 1.3). Most patients were male (84%), were hypertensive (69%), or had a smoking history (79%). The overall reintervention rate was 10.8%: conversion to open repair (0.9%), EVAR revision (2.6%), other surgical intervention (7.3%). Of the reinterventions, 27% were for endoleaks (I, 34.3%; II, 56.9%; III, 8.8%; IV and V, 0.0%), 10.5% were due to graft malfunction, 3.4% were due to infection, and 2.3% were due to rupture.

**Conclusions:** Leveraging an EMR provides a robust platform for monitoring short-term and midterm outcomes after abdominal aortic aneurysm repair. Use of standardized templates in the EMR allows data entry as part of normal workflow, improving compliance, accuracy, and data capture using limited but expert personnel. Assessment of patient demographics, device performance, practice variation, and postoperative outcomes benefits clinical decision-making by providing complete and adjudicated event reporting. The findings from this large, community-based EVAR registry augment other studies limited to perioperative and short-term outcomes or small patient cohorts. (*J Vasc Surg* 2015;61:1160-7.)

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Abdominal aortic aneurysms (AAAs) are associated with high morbidity and mortality, contributing to approximately 10,000 deaths per year in the United States.<sup>1</sup> Since Parodi's initial report, endovascular aortic aneurysm repair (EVAR) has become the standard of care for infrarenal AAA for most surgeons.<sup>2,3</sup>

Coincident with this transition to endovascular AAA repair, follow-up care and monitoring of endovascular grafts have posed unique challenges for vascular surgeons and health care systems. Although EVAR reduces perioperative morbidity and mortality associated with AAA repair, surveillance for intermediate- and long-term complications (including thrombosis, endoleak, migration, and delayed rupture) is essential and can be problematic.<sup>4-6</sup> Historically, follow-up of patients has been the responsibility of the primary surgeon. However, patient relocation, failure to return for follow-up, and loss of or changes in health insurance coverage limit the effectiveness of this approach.

In addition, information about the endovascular procedures themselves and outcomes have not always been properly recorded or tracked, even in academic medical centers and by health care organizations. Linked registries (eg, the California Office of Statewide Health Planning and Development hospital registry cross-referenced to the National Death Index) have the potential of creating a mechanism for long-term tracking across hospitals and care systems, although those types of registries are largely limited to administrative patient discharge data and therefore lack the option to prospectively choose data of importance.<sup>7</sup> Although these databases are useful in retrospective reviews,<sup>8</sup> they have not been particularly valuable in tracking longer term outcomes.

In addition to their value in patient care, outcome data are useful to compare procedures, costs, and devices over time. Numerous large administrative and multi-institutional databases exist that can be used to perform this comparative effectiveness research for vascular surgery. These vary and include the Nationwide Inpatient Sample (NIS), University Hospital Consortium, National Surgical Quality Improvement Program (NSQIP), Veterans Affairs National Surgical Quality Improvement Project, and Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI).<sup>7-9</sup> Each of these has advantages and disadvantages. For example, whereas the NIS has large numbers, it consists entirely of International Classification of Diseases, Ninth Revision (ICD-9) administrative coding and in fact represents only a small percentage of all Medicare admissions per year. NSQIP is a short-term outcomes quality improvement database championed by the American College of Surgeons that has been used extensively for outcomes research; it has excellent periprocedural data but samples only a fraction of the total cases for an institution and is limited to 30-day follow-up. Projects conducted under VQI acquire a large quantity of data, but data entry is labor-intensive and expensive, and outcomes are limited to 1 year.

Financial data are also challenging to obtain from the aforementioned databases. A reduced length of stay associated with increased EVAR utilization would be expected to reduce overall hospital costs; however, these are often offset by procedural and surveillance expenses. The literature remains conflicted as to whether these advantages translate to true cost savings.<sup>10</sup> Some databases, such as University Hospital Consortium, include procedural and billing data but require a subscription and contain no clinical data to include in the analysis. This inability to track EVAR costs (ie, secondary interventions, ongoing surveillance, and longer term readmissions) is a limitation of all the existing quality improvement databases and is particularly difficult to address without the ability to observe patients longitudinally.

Kaiser Permanente (KP) is a large health care organization caring for >9 million individuals in the United States. In 2001, KP established an orthopedic implant registry to track patients with total joint implants, to observe trends in clinical practice patterns, to measure outcomes, and to identify patients in the event of a product recall.<sup>11</sup> This registry is highly successful and internationally recognized, and

it has subsequently been expanded to include cardiology (2006) and vascular endograft implants (2011). KP also uniquely installed a systemwide electronic medical record (EMR) in 2005-2006 previously shown to be valuable in AAA screening.<sup>12</sup>

The Kaiser Permanente Endovascular Stent Graft Registry (KPSGR) was developed to create a prospectively entered registry using the EMR, optimizing the ability to track device utilization and to appraise short- and long-term EVAR outcomes. The underlying premise was that a successful registry should be inexpensive to operate, be user-friendly, and ensure a high level of compliance with data entry. Personnel supporting the KPSGR are clinical project managers, systems administrator, and database manager, most of whom are assigned part-time to this project. The registry allows comprehensive access to data to perform not only internal quality review but also comparative effectiveness research, a stated priority for the SVS.<sup>13</sup>

The purpose of this manuscript was to describe the construct of the registry, mechanisms of data capture, validation (review for data integrity and outcomes), and how the registry supports ongoing surveillance of KP members who have undergone EVAR. We additionally demonstrate some of the early data available from the registry.

## METHODS

Patients with endovascular repair of AAA between January 1, 2010, and June 30, 2013, were entered in the registry and prospectively observed until December 31, 2013. Procedures for endovascular repair of AAA were screened with use of ICD-9 codes recorded in the EMR (Fig 1). Primary EVAR, revision EVAR, and EVAR after an open surgical repair were included for patients with AAA, stenosis, or dissection. Endovascular repair of thoracic, iliac, or subclavian aneurysms was excluded. Automated data extraction from the EMR into the registry database occurs for each consecutive EVAR, including patient demographics (age, gender, race), comorbidities, diagnosis, procedure, and hospital stay data. Each implant is entered into the EMR through barcode scanning of its catalog number and is mapped to a comprehensive device directory in the registry to identify manufacturer, model, and size. All data are transmitted through an internal, secure server and stored in a password-protected centralized data repository for data management, validation, and reporting. Data are de-identified before analysis (Fig 2).

The KPSGR was designed to extract data from the EMR with the intent of minimizing need for manual data collection. More than 700 new cases are entered annually and >2000 are in ongoing surveillance. Personnel support multiple registries, but the KPSGR itself requires a total of 1.5 full-time equivalents, 0.5 for chart review and 1.0 for data abstraction, project management, and analytical/research support. This supports >80 vascular surgeons performing EVAR in >30 hospitals serving a population of >9 million patients. The use of a custom-designed data entry template at point of care and established external definitions for procedures and outcomes (eg, ICD-9 diagnostic

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