CMSS Presents:

Defining and Creating the Registries of the Future

September 22, 2022
Registry and Research Initiative: Defining and Creating Registries of the Future

CMSS Registry Webinar Series
A clinical registry is a computer database that collects information about your health and the care you receive as a patient. The data in the registry comes from the information your healthcare provider collects while providing your care and is added to information on other patients who are similar to you. It is then used to help improve the quality of your care as well as the care of other patients, now and in the future. This article provides answers to the most common questions patients have about clinical registries.

Types of Registries
- Improvement of patient care.
- Professional education.
- Administrative information.
- Clinical research.

A disease registry is a special database that contains information about people diagnosed with a specific type of disease. Most disease registries are either hospital based or population based.

While clinical trials focus on efficacy—the extent to which medical interventions achieve health improvements under ideal circumstances—registries provide strong evidence for the extent to which medical interventions achieve health improvements in real practice settings.

An organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more.

Database: a collection of information (i.e., data) arranged for ease of search and retrieval of information. Registry: a collection of information or databases whose organizers receive information from multiple sources, maintain the information over time, and control access to the information.

Registries focused on specific diseases or conditions collect information voluntarily from people with those conditions. Clinical trials registries collect basic health information from people who agree to be contacted about participating in future clinical trials or studies.
Why Do We Exist?

Data is Everywhere!

Systematic Health IT is Alive

Is our Purpose Changing?

Where Should we Invest?
Innovative clinical registries
Leveraging federal data standards
Patient-generated data

Multi-stakeholder governance
Data quality
Evolving strategies for sustainability
It’s Time to Reasses
Coordinated Registry Networks (CRNs): Foundational Building Blocks

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Associate Director
Office of Clinical Evidence and Analysis
FDA/CDRH
It Takes a Village!

**Need:** Curated, fit for purpose, interoperable, real-world, longitudinal data, available for decision making, regulatory science and public health

**Journey:** From one-off studies to strategically aligned RWD and registry-embedded studies

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### Key Milestones

- **Need:** Curated, fit for purpose, interoperable, real-world, longitudinal data, available for decision making, regulatory science and public health

- **Journey:** From one-off studies to strategically aligned RWD and registry-embedded studies

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### CRN Maturity Framework**

**FHIR® enabled/FHIR® enhanced**

**UDI:** Precise identification of medical devices and their attributes

**Data collection efficiency:** Structured data capture, mobile apps and automation with interoperability solutions

**Data Quality:** Coverage, completeness of enrollment & records at both baseline and follow-up, and periodic audits

**Engaging patients and incorporation of patient-generated data:** Engage, evaluate preferences and measure general and disease specific PROs

**Governance and Sustainability:** Engage major stakeholders: societies, payers, various states, obtain major & diverse funding

**Healthcare Quality Improvement:** Device technologies require continuous evaluation: Feedback, benchmarking and outlier assessments

**Total Product Life Cycle:** Infrastructure for conducting research and surveillance at different stages of device evaluation. Important role for data linkages

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**Example:** Mature CRN (VQI/VISION)

**CRN Name** | **Clinical Area (current phase)**
---|---
1. Women’s Health Technology Coordinated Registry Network (WHT-CRN) | Women’s Health Women's Health (uterine fibroids, pelvic organ prolapses, stress urinary incontinence, sterilization)
2. Vascular Implants Surveillance and Outcomes Network (VISION-CRN) | Vascular
3. Cardiac Devices Coordinated Registry Network (CD-CRN) | Cardiac
4. Orthopedic Devices Coordinated Registry Network (Ortho-CRN) | Orthopedic
5. Devices Intended for Acute Ischemic Stroke Intervention (DAISI-CRN) | Acute ischemic stroke
6. Venous Access National Guideline & Registry Development Coordinated Registry Network (VANGUARD-CRN) | Venous access
7. Robotic Surgery Coordinated Registry Network (Robotic-CRN) | Robotic surgery
8. Study of Prostate Ablation Evidence Development (SPARED-CRN) | Prostate ablation
9. Temporomandibular Joint Coordinated Registry Network (TMJ-CRN) | Temporomandibular joint
10. National Breast Implants Registry (NBIR) | Breast implants
11. Obesity CRN | Obesity devices
12. End Stage Kidney Disease Coordinated Registry Network (ESKD-CRN) | End stage kidney disease
13. Abdominal Core | Abdominal Core

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**Linkage Breadth:**

- 88% of all EVAR patients
- 93% of all AAA patients

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*Recommendations for a National Medical Device Evaluation System Strategically Coordinated Registry Networks to Bridge Clinical Care and Research (accessed at: https://www.fda.gov/media/93140/download)

Registries and CRNs: Intersections of FDA, MDEpiNet and NEST

THE VISION FOR NATIONAL SYSTEM LAUNCHED
FDA 4-day Public Meeting
Day 1. Launch of FDA strategy
Day 2. MDEpiNet Annual Mtg.
Days 3-4. Registries

Develop and test drive novel methods and scientific infrastructure for device evidence generation synthesis and appraisal nationally and internationally

MDEpiNet Launch
International Registry Consortia (e.g. ICOR)

Reports:
- Planning Board
- MDEpiNet Registry Task Force
- IMDRF

NEST Data Collaborators Network
NEST Data Collaborators Network

ICVR

Tools for assessing the Usability of Registries for Regulatory Decision Making, March 2018

CRN Collaborative Learning Communities
CRN Collaborative Learning Communities


MDEpiNet Methodology Center at Harvard
MDEpiNet Science and Infrastructure Center at Cornell
CRNs - Key Concepts

Embedded in routine practice (better, faster, cheaper)

Strategically coordinated/harmonized within the ecosystem
- Clinical core data sets (including PRO where possible)
- Informatics solutions (including UDI, SDC)
- Sustainability (value propositions, ROI, maturity models)

Network
- Term was “Coined” for registries - but applies beyond

Include national and international/global opportunities
Coordinated Registry Networks (CRNs)

CRNs are the real-world data sources encompassing strategically partnered electronic health information systems serving one or more clinical area (e.g. orthopedic, vascular, abdominal hernia etc.)

The CRNs build on the national/regional registry(ies), strategically harmonize data elements and link data to comparable data across the systems (e.g. EHR, administrative claims, patient generated data etc.)

Complementary clinical conditions areas can be harmonized via family of CRNs (e.g. WHT-CRN harmonizes registries in fibroid, SUI, POP)

CRNs from diverse clinical areas are further strategically aligned though CRN Learning Community, established and coordinated by the MDEpiNet via grant from FDA
Strategically Coordinated Registry Networks (CRN) Principles:

- Link complementary sustainable registries/e-repositories (Professional society registries, EHRs, Claims data)
- TPLC as a true continuum of structured “real world” evidence
- “Dual purpose” existing site-base work flow
CRNs Build on International Models and Standards

“Organized system with a primary aim to increase the knowledge on medical devices contributing to improve the quality of patient care that continuously collects relevant data, evaluates meaningful outcomes and comprehensively covers the population defined by exposure to particular device(s) at a reasonably generalizable scale (e.g. international, national, regional, and health system”).

Partnership between the FDA and Office of the Assistant Secretary for Planning and Evaluation (ASPE)


https://www.mdepinet.net/coordinated-registry-networks
Framework of Maturity of CRNs and Registries
7 Key Domains and 5 Levels of Maturity

**UDI:**
Precise identification of medical devices and their attributes

**Data Collection Efficiency:**
Structured data capture, mobile apps and automation with interoperability solutions

**Data Quality:**
Coverage, completeness of enrollment & records at both baseline and follow-up, and periodic audits

**Total Product Life Cycle:**
Infrastructure for conducting research and surveillance at different stages of device evaluation. Important role for data linkages

**Governance and Sustainability:**
Engage major stakeholders: societies, payers, various states. Obtain major & diverse funding

**Healthcare Quality Improvement:**
Device technologies require continuous evaluation: Feedback, benchmarking and outlier assessments

**Engaging patients and incorporation of patient generated data:**
Engage, evaluate preferences and measure general and disease specific PROs

**Example: Optimized Data Collection Efficiency**
Technologies are in place (e.g. structured data extraction from EHRs/ mobile apps for all core minimum data elements, and there is a full adoption and integration of data and terminology standards (assumes complete interoperability)

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Level 1. Early Learner
Level 2. Making progress
Level 3. Defined path to success
Level 4. Well managed
Level 5. Optimized

* Paper accepted for publication in BMJ-SIT, expected April, 2022
Example: Data Collection Efficiency Domain

• Extent to which the registry is embedded in the healthcare quality improvement system so that data collection occurs as part of care delivery

Level 1. Early Learner

Heavy burden with ad hoc data elements on a project basis but without an agreement on clinically relevant minimum core data elements

Level 2. Making progress

Level 3. Defined Path to Success

Level 4. Well-Managed

Technologies are in place (e.g. structured data extraction from EHRs/mobile apps for all core minimum data elements, and there is a full adoption and integration of data and terminology standards (assumes complete interoperability)

Level 5. Optimized
Example of a Mature CRN

CRNs typically include data from national registry, claims data, EHRs, PGHD.

In the case of VISION, the CRN also includes the (NY-SPARCS and CA-OSHPD), PCORNet, and clinical trial data tailored for multiple uses.

Linkages: 2002 – 2019
Up to 15 years of follow up – Mean 3-4 years
415,616 patients captured in current linkage efforts
14,000 patients captured in current validation efforts

Amputation laterality (Yale, Dartmouth, ~4,000 patients, ongoing)
Stroke after carotid revascularization (multisite, ~10,000 patients, initial stages)
Thoracic reinterventions after TEVAR (planning stages)

Linkage Breadth:
88% of all EVAR patients
93% of all AAA patients

30 publications / 6 validation studies in high impact journals

880 clinical sites
3000 providers
> 200 types of devices
## US CRN Learning Community

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<thead>
<tr>
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**Crosspollination areas:** clinical, data science, epidemiology/statistics, digital tools, blockchain, imaging, international

**16 tools shared and applied:** (a) harmonization efforts in CRN architecture and data exchange (logic model for clinical work flow), (2) methods (validation, data linkages, outcomes studies, ROI, ML/AI), (3) mobile apps (patient and provider-based) and others.
Registries Without Borders: International Consortium of Vascular Registries (ICVR)

- Launched in November 2014
- Supported by the MDEpiNet Analytic Center at Weill Cornell Medicine and High Performance Integrated Virtual Environment (HIVE) – under grant from FDA
- Represents a collaboration of 28 reginal and national registries:
  - FDA and Vascular Device Manufacturers are at the table
- Embraced the CRN concept
- Rich portfolio of harmonization, validation and outcomes studies
- Collaborative study under way for labeling change in rAAA space

International Consortium of Vascular Registries
Spring Meeting (Hybrid)
Granada, Spain
Thursday May 19, 2022
CRNs: Pragmatic Advantages & Efficiencies

- Registries and Beyond!
- Existing systems participating in CRNs:
  - Minimize re-engineering (cost, time to implement)
  - Leverage established clinical work flow
  - Established governance & sustainability
- Strategic data sharing across participating CRN systems:
  - Flexibility in design: accommodate emerging e-systems
  - Customizable across device, stakeholder and other diversity
  - Builds architectural consistency (use/re-use of structured data sets & data sharing solutions across device areas)
CRNs are Already Producing the Regulatory Grade Evidence

- Used for postmarket surveillance, mandated post-approval studies, labeling expansions
- ROI Studies documented up to 550% Return on Investment


PMID: 32051216; PMCID: PMC8740525.
Registries and CRNs to Advance Evaluation of Technologies

Art Sedrakyan, MD, PhD
Professor, Weill Cornell Medicine,
New York Presbyterian Hospital
Director of Institute For Technologies and Interventional care
Director, MDEpiNet Coordinating & Science Infrastructure Center
Co-Chair, IDEAL Collaboration
Co-Editor-In-Chief, BMJ Surgery Innovations & Technologies
CRNs leverage all RWD to Enrich the Registry

CRN is a data and partnership network to achieve the regulatory, clinical and scientific vision of generating RWE for evaluation of technologies and address limitations of any single registry.

- **CRNs: Continuous Real-World Evidence**

  "Organized system that continuously and consistently collects relevant data in conjunction with routine clinical care, evaluates meaningful outcomes and comprehensively covers the population defined by exposure to particular device(s) at a reasonable generalizable scale (e.g., international, national, regional, and health system) with a primary aim to improve the quality of patient care." - International Medical Device Regulatory Forum

<table>
<thead>
<tr>
<th>CRN</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Device data: the registry contains sufficient information to uniquely identify the device. Ideally, the unique device identifier would be included, but when unavailable, the registry would include a combination of identifiers (catalogue number, manufacturer, description).</td>
</tr>
<tr>
<td>2</td>
<td>Quality improvement system: is part of a healthcare delivery improvement system or evolving into one as device technologies are diffused into practice and need continuing evaluation (including outlier identification).</td>
</tr>
<tr>
<td>3</td>
<td>Beneficial change: has established mechanisms to bring about beneficial change in healthcare delivery through stakeholder participation, ownership, and integration into the relevant healthcare systems.</td>
</tr>
<tr>
<td>4</td>
<td>Efficiency: the registry is embedded in the healthcare delivery system so that data collection occurs as part of care delivery (i.e., not overly burdensome, not highly complicated, not overly costly) and integrated with workflow of clinical teams.</td>
</tr>
<tr>
<td>5</td>
<td>Actionable data: the registry provides actionable information in a relevant and timely manner to decision makers.</td>
</tr>
<tr>
<td>6</td>
<td>Transparency: the governance structure, data access, and analytical processes of the registry are transparent.</td>
</tr>
<tr>
<td>7</td>
<td>Linkability: information in the registry can be linked with other data sources for enhancement, including adequate follow-up achievement.</td>
</tr>
<tr>
<td>8</td>
<td>Total device lifecycle: the registry can serve as infrastructure for seamless integration of evidence throughout the device lifecycle.</td>
</tr>
</tbody>
</table>
Our Current Data Contributing to CRNs

- Clinical Data (Various clinical cohorts, IPD meta-analysis)
- Registries (conducting data linkages with registries and claims data e.g. Medicare)
- Public and Private Payer Data (state longitudinal discharge datasets, Private insurers)
- Social Determinants (Various state and national data linkages)
- Medicare Data (100% Medicare data on hospitalizations, Part B and carrier data for many clinical cohorts)
- EHRs (Collaboration with PCORI CDRNs and Informatics groups)
- Patient Reported / Generated Data (Developing mobile apps and collecting PROs)
Key Areas of Focus to Get Good ROI

- Data linkages
- Mobile apps
- Clinician practice help
- Analytics
Index Exposure

Registry data

1 mo 1 yr 2 yrs 3 yrs 4 yrs 5 yrs

Centralized Follow-up

Administrative Data (Medicare, commercial claims, All-payer State)
Mobile apps: Colorectal CRN

Patients are the key partners and work collaboratively with Doctors
Registry Data Systems: Value for Clinicians

HIVE image fusion & data collection

INPUT

- doctor surveys
- patient surveys
- web-app
- Imaging hardware exported images
- CT imaging, MRI, Ultrasound
- Endoscopic imaging
- GPS markers

HIVE honeycomb DB
- HIVE honeycomb DB
- data validation & standardization engine

DATA PROCESSING

- Wireframe triangulation
- Reconstruction of opacity 3D model
- 2D images, 3D wireframe templates

OUTPUT

- 3D interactive model
- Annotations
- 3D mapped observed image sections
- 3D interactive model
- VR model mapping
- AI/object annotation
- Image fusion

- VR dashboard

Surgical annotation on 3D model

Annotations

3D interactive model
Example OPCs and OPGs Developed by MDEpiNet

- The freedom from Target Lesion Revascularization (TLR) OPGs at one year in the popliteal artery were 81.3% (PTA), 81.3% (stenting), 80.2% (atherectomy), and 81.1% (any treatments).

- Revision rates after hip and Knee Surgery at two years were 2.1% and 1.7% respectively. Disease specific and general PRO measure based estimates also calculated.
Robotic-Assisted Surgical Devices

Women’s Health Technologies (WHT-CRN)

Vascular Implant Surveillance and Interventional Outcomes Network (VISION)

Orthopedic Devices

Study of Prostate Ablation Related Energy Devices (SPARED)

National Breast Implant Registry (NBIR)

Venous Access: National Guideline & Registry Development (VANGUARD)

Temporomandibular Joint (TMJ)

Devices used for Acute Ischemic Stroke Intervention (DAISI)

Cardiac Device

Abdominal Core

null

null

null
Please Send Your Best (And Good) Studies!

https://sit.bmj.com/pages/authors/
Thank You!

Email: ars2013@med.cornell.edu

http://mdepinet.net/
The ASH Research Collaborative Data Hub

William Wood, MD, MPH
Chair, ASH RC Data Hub Oversight Group
The Data Hub:
Capturing Real-World Data to Generate Real-World Evidence for Hematology

People Living with Hematologic Conditions

Real-World Data
- Electronic health records
- Electronic case report forms/NLP for clinical information maintained outside structured EHR fields
- Patient-reported outcomes
- Patient-generated health data
- Claims data
- Other population data

OMOP FHIR

Multi-Stakeholder
- Patients and community members
- Clinicians
- Clinical care sites
- Researchers
- Quality improvement specialists
- Federal entities

Research
- Contemporaneous control groups
- Post market surveillance
- Academic research
- Cohort identification

Enhance Clinical Care
- Access site-specific outcomes
- Exchange best practices
Data Submission and Validation

Phase 1
- Local Research Data
- Flat File Export
- Pre-Populated eCRF
- Participating site validates pre-populated EHR data and completes missing data

Phase 2
- EHR Data
- OMOP or FHIR format
- Data Hub
Data Quality

✓ Accuracy
✓ Completeness
✓ Conformance
✓ Plausibility
✓ Reproducibility
✓ Provenance
Data Hub Fit for Use for FDA Regulated Research

- RCTs clinical outcomes
- External control arms
- Observational studies to support an efficacy supplement
- Fulfill post-marketing requirement/commitment
ePhenotyping

Rule-Based
Value Set
Business Logic

Model-Based
Machine Learning / AI

Validating ePhenotyping
Explicit
Reproducible
Valid
Summary Metrics

The counts represent all SCD data in the Data Hub as of your most recent data submission. The percentages represent the changes in the counts since your previous data submission.

Previous submission: May 04, 2022
Most recent submission: July 07, 2022

- Participants: 418 (39.33%)
- Encounters: 1,980 (560%)
- Providers: 8 (60%)

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<th>Metric</th>
<th>Current Value</th>
<th>% Change</th>
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<tr>
<td>Average Participants per Provider</td>
<td>52.25</td>
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<td>Maximum Participants per Provider</td>
<td>339</td>
<td>160.77%</td>
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<td>Minimum Participants per Provider</td>
<td>5</td>
<td>-82.14%</td>
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<td>Office Encounters</td>
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<td>Inpatient Admissions</td>
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Sample Data
### Data Quality Report

#### Sample Data

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Data Hub-powered SCD Learning Community

1. Multi-stakeholder teams
2. Common goals and select improvement areas
3. Change package
4. Measure change

Data Hub
Federal Collaborations

- HHS Office of Minority Health
- NHLBI
- FDA
Real-World Evidence Initiative

- Engage stakeholders
- Support the development of the ASH RC's Data Hub
- Explore methods for “Accelerating Innovations for Sickle Cell Disease with Real-World Evidence”
Results and Recommendations

Four Topic Areas:
1. Data Fit for Use
2. Data Access and Use
3. Data Sources, Including Patient Experience Data
4. Sustainability
Public Comment
Open Now!

Comments due no later than October 15, 2022 and can be submitted here.

Draft recommendations
The Vascular Quality Initiative – Vascular Implant Surveillance and Interventional Outcomes Network (VQI-VISION): Building Infrastructure For Success

Philip Goodney, MD and Kayla Moore, MS
On behalf of the VQI VISION Steering Committee

SVS | VQI
In collaboration with NCDR®
Disclosures

• FDA U01FD005478 (Sedrakyan = PI)
• NIA U01AG046830 (Skinner = PI)
• PCORI ME-1503-28261 (O’Malley = PI)
• NEST-CC Pilot Award (Sedrakyan = PI)
• AHA SFRN (Creager / Goodney = Project PI)
• SVS-PSO / Society for Vascular Surgery
• AHRQ R21 HS021581 (Goodney = PI)
Goals

• Outline the VQI-VISION coordinated registry network

• Share Key Findings from VQI-VISION, and VISION Infrastructure

• Describe what is next for VQI-VISION
Goals

• Review data shared at FDA panel in November outlining the role of device type in long-term EVAR outcomes.

• Summarize FDA’s guidance for next steps

• Outline the Long term EVAR Assessment and Follow up (LEAF) System, our multi-stakeholder plan to meet FDA’s goals for long-term post-EVAR surveillance
The Vascular Implant Surveillance and Interventional Outcomes (VISION) Coordinated Registry Network: An effort to advance evidence evaluation for vascular devices

Greg Tsougranas, BS,a,b,c Jens Eldrup-Jorgensen, MD,d Daniel Bertges, MD,e Marc Schermerhorn, MD,f Pablo Morales, MD,g Scott Williams, MS, RAC,h Roberta Bloss, MS,i Jessica Simons, MD, MPH,j Sarah E. Deery, MD, MPH,k Salvatore Scali, MD,l Graham Roche-Nagle, MD, MBA, ME,m Leila Mureebe, MD, MPH, MMC,n Matthew Mell, MD,o Mahmoud Malas, MD, MHS,p Brian Pullin, MS,q David H. Stone, MD, MS,a,b Misti Malone, PhD,q Adam W. Beck, MD, s Grace Wang, MD, MS,t Danica Marinac-Dabic, MD, PhD, v Art Sedrakyan, MD, PhD, w and Philip P. Goodney, MD, MS, a,b Lebanon and Hanover, NH; White River Junction and Burlington, Vt; Portland, Me; Boston, Mass; Rockville, Md; Bloomington, Ind; Flagstaff, Ariz; Gainesville, Fl; Toronto, Ontario, Canada; Durham, NC; Davis, San Diego, Calif; Birmingham, Ala; Philadelphia, Pa; New York, NY
How this works....

Start With VQI Data

- Mr. Jones (name, SS#)
- Clinical Factors (comorbidities)
- Implant Data (Graft XYZ)
- Surgical Details (how it was placed)
  - Surgeon Details
  - Hospital Information
  - Short term complications

Data Linkages to Medicare Claims

The Dartmouth Institute

Measure Long-Term Events:

- Survival
- Effectiveness of the Procedure
- Long-Term Device Failures/Revisions
- Cost
Our “VISION” for the Data In VISION:

Accurately Measure Long-Term Post-Surgical Outcomes:

• Survival
• Reintervention
• Need for further procedures
generalizable, real-world effectiveness research
Long-term Reintervention After Endovascular Aneurysm Repair

Jesse A. Columbo, MD, MS, †‖§ Pablo Martinez-Cambor, PhD,†‖§ Bjoern D. Suckow, MD, MS, † Andrew W. Hoel, MD, † David H. Scherer, MD, †‖§ Marc L. Schermerhorn, MD, †‖§ Art Sedrakyan, MD, PhD, †‖§ and Philip P. Goodney, MD, MS, †‖§‖§ The Vascular Implant Surveillance and Interventional Outcomes Network (VQI-VISION) links short-term details in VQI data to long-term outcome assessment using Medicare claims.

A comparison of reintervention rates after endovascular aneurysm repair between the Vascular Quality Initiative registry, Medicare claims, and chart review

Jesse A. Columbo, MD, a,b,c,d,e Ravinder Kang, MD, MS, a,b,c,d,e Andrew W. Hoel, MD, f Jeanwan Kang, MD, a,d Kathleen A. Leinweber, BA, d Karissa S. Tauber, BA, d Regis Hila, BA, d Niveditta Ramkumar, MPH, a Art Sedrakyan, MD, PhD, a and Philip P. Goodney, MD, MS, a,c,d,e Lebanon and Hanover, NH; White River Junction, VT; Chicago, IL; and New York, NY

Characterization of Endovascular Abdominal Aortic Aneurysm Repair Surveillance in the Vascular Quality Initiative

Zachary J. Wanken, MD Spencer W. Trooboff, MD, MBA

Each year in the United States, >30,000 patients undergo endovascular abdominal aortic aneurysm repair (EVAR).1 Guidelines from the Society for Vascular Surgery and American College of Cardiology Foundation/American Heart Association/American Association for Vascular Surgery recommend surveillance of patients who have undergone EVAR.2,3 The Vascular Quality Initiative (VQI) is the largest surveillance program that now supports long-term outcome assessment, including reintervention rates, after EVAR.4,5 The VQI-VISION links short-term details in VQI data to long-term outcome assessment using Medicare claims.

The study involved 14,439 patients who underwent elective repair (endovascular or open) of abdominal aortic aneurysm within the Vascular Quality Initiative.1,4

![Figure 1: Survival among Men and Women Undergoing Elective Endovascular or Open Surgical Repair of Abdominal Aortic Aneurysm.](image)
Medicare Linkages in VQI VISION

Extend Long Term Outcome Assessment
The Vascular Implant Surveillance and Interventional Outcomes Network (VQI-VISION) links short-term details in VQI data to long-term outcome assessment using Medicare claims.


Accurately Measure Long-Term Post-EVAR Outcomes:
• Survival
• Reintervention
• Late AAA rupture

SVS VQI Vascular Implant Surveillance and Interventional Outcomes Network (VISION)

Overview
The SVS VQI Vascular Implant Surveillance and Interventional Outcomes Network (VISION) is a partnership between the SVS VQI and MDEpiNet that directly supports the mission of the SVS VQI to improve the quality, safety, effectiveness and cost of vascular healthcare by collecting and exchanging information. VISION links SVS VQI registry data to Medicare claims to generate novel registry-claims linked datasets. The datasets combine the clinical detail from the SVS VQI with long-term outcome variables derived from Medicare claims. VISION data is used to generate center-specific feedback reports called, Survival, Reintervention and Surveillance (SRS) and to analyze device performance and long-term outcomes of vascular surgical techniques. Use of the data is governed by a Data Use Agreement (DUA) between Weill Cornell Medical College and the Center for Medicaid and Medicare Services (CMS).

Dataset Description
Medicare-Match data are available for EVAR, OAAA, PVI, TEVAR, CAS, INFRA and SUPRA datasets. For each dataset, the following SVS VQI-Medicare derived outcomes are available:
1. Death
2. Procedure-specific adverse outcome (stroke, aortic rupture, amputation)
3. Reintervention (targeted vascular procedures)
Medicare Linkages in VQI-VISION

Extend Long Term Outcome Assessment


Accurately Measure Long-Term Post-EVAR Outcomes:
• Survival
• Reintervention
• Late AAA rupture

vqi.org/data-analysis/vision
Key Issue

Device-Specific Late Reintervention After EVAR

Role of Real-World Evidence
FDA Executive Summary

Circulatory System Devices Panel Meeting

November 3, 2021

General Issues Panel

Real World Surveillance of AAA Endovascular Stent Grafts
Reintervention, By Device Type (VQI/VISION)  
(In Press, BMJ)

**Figure 1.A:** Long-term rate of reintervention across the different device manufacturer types.
Signals Detected In LEAF Could Prompt Clinical Review in VQI, Imaging Evaluation, and Further Data collection

Signal Detection in LEAF

Secondary data elements (imaging, chart review)
Signals Detected In LEAF Could Prompt Clinical Review in VQI, Imaging Evaluation, and Further Data collection

How Does VQI-VISION Create and Curate Date For Surveillance?

Signal Detection in LEAF

Secondary data elements (imaging, chart review)
2 opposing forces

Data as Community Resource

Data Security
2 opposing forces

VISION as a Community Resource

• VISION is a community dedicated to generating RWE to improve the quality and effectiveness of vascular care

• All members provide data to the PSO and data is made available to the community for the purposes of improving vascular care

• VQI has a process in place for data usage in which members to submit proposals to a Research Advisory Council.

• Once approved by the RAC, investigators receive a blinded dataset which they can use to conduct their analyses.

Rules Governing use of CMS Data

• Data must remain on secure HIPAA/FISMA compliant server

• Access is restricted to individuals named on the DUA

• No individual level data can be removed from the server

• Only aggregate/de-identified data (tables, figures) can be removed from the server.

• Output is reviewed by IT security team prior to transfer to ensure suppression requirements are applied (no cell sizes less than 11)

• In addition, CMS requires that each DUA be project-specific and tied to a single funding source
Process for using VQI VISION data

1. Obtain VQI/RAC approval
2. VISION Priorities Committee conducts secondary screening to ensure:
   - Clarity/feasibility of research question
   - Clear need for Medicare data
   - Falls within scope of DUA
3. VISION Analytic Team requests research memorandum
4. VISION Analytic Team works with investigators to refine analytic plan and conduct analyses
5. Aggregate tables and figures are shared for dissemination of findings

https://www.vqi.org/data-analysis/vision
What’s Next: VQI-VISION and Kaiser Collaboratively Built LEAF for Long-Term EVAR Surveillance

“Device Dashboards” can serve as a near real-time national signal-detection system

Key Advantage: Similar outcomes measured and reported across devices, easing comparison, interpretation and benchmarking

30+ Member Steering Committee includes representatives from industry, FDA, and multidisciplinary vascular societies
Phase 1
- Analyses of 2003-2018 data (current CMS DUA)
- Deliverable: Device-Specific SRS Report (2018 data)
- Timeline: 4-8 weeks from start date

DONE 11/2021

Phase 2
- Analyses of 2003-2019 data (linkages and late-outcomes updated under current CMS DUA)
- Deliverable: Device Specific SRS Report (2019 data)
- Timeline: 2-5 months from start date

DONE 6/2022

Phase 3
- New VRDC DUA- Analyses of most recent available data (2003 - present)
- Deliverable: Device-Specific SRS Report (up to present year)
- Timeline: 12 – 18 months from start date

Phase 4
- Phase 4a: Vascular Research Collaborative (VRC) – Led Chart Review:
  - VQI Centers to collect additional reporting via additional existing CRF
  - Deliverable: Additional CRF collected for device-specific analyses as prompted by Phases 1-3
  - Timeline 6-12 months from start date

- Phase 4b: Vascular Research Collaborative (VRC) – Led Chart Review and Imaging Upload and Review:
  - VQI Centers to collect additional images for Core Lab review for relevant questions
  - Deliverable: Additional imaging and clinical data collected and reviewed as prompted by Phases 1-3
  - Timeline 12-18 months from start date
## Preliminary Collaboration and Planning

<table>
<thead>
<tr>
<th>Preliminary Work</th>
<th>SVS</th>
<th>VQI</th>
<th>KAISER PERMANENTE®</th>
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<td>Conference calls, planning, review</td>
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<td>Mock Report Generation</td>
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Efficiency: LEAF Reports Are Built on Existing VQI Survival, Reintervention, and Surveillance Reports

Vascular Quality Initiative Endovascular Abdominal Aortic Aneurysm Repair (EVAR) Survival, Reintervention, and Surveillance Report

This report presents the following three outcomes related to the quality of care provided to Medicare patients treated with EVAR:

A: Your center’s five-year freedom from reintervention rate compared to all other VQI centers.

B: Your center’s five-year survival rate compared to all other VQI centers.

C: Your center’s five-year freedom from imaging surveillance failure rate compared to all other VQI centers.

These data are derived from 2003-2016 VQI registry data matched to Medicare fee-for-service claims, and are made possible by the Vascular Implant and Interventional Outcomes Network (VISION), a partnership between the SVS PSO and MDEpNet.

Center data are not shown for centers with fewer than 11 events due to CMS suppression requirements.

Selected Patient Characteristics

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<th>Characteristic</th>
<th>Center 4</th>
<th>Overall</th>
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<td>Median AAA Diameter</td>
<td>5.7</td>
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<td>Median Age</td>
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<tr>
<td>% Male</td>
<td>75.8</td>
<td>79.2</td>
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<tr>
<td>% Urgent/Endovaginot</td>
<td>9.9</td>
<td>12.5</td>
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Summary

• Outline the VQI-VISION coordinated registry network
  • *Seminal publication for device surveillance using linked datasets*

• Share Key Findings from VQI-VISION, and VISION Infrastructure
  • *Linkage to registries are an important element*

• Describe what is next for VQI-VISION
  • *Industry partnership and reporting for sustainability and impact*