Dear SVS Colleague:

Comparative effectiveness research has quickly become a key component in our specialty’s pursuit of evidence-based treatment options for every patient, but where to begin?

That is the question that the Clinical and Comparative Effectiveness Research Committee set out to answer. This document is our response — a first-of-its-kind guide for vascular care professionals interested in comparative effectiveness research (CER) as a pathway for mapping treatment strategies, or as a methodology for initiating or enhancing a research plan.

**CER: a pathway for mapping treatment strategies**

Comparative effectiveness research has gained traction under health care reform because it focuses on the intersection of data-driven treatment options, patient quality of life and sustainable care principles, including cost containment considerations. In that context, every vascular surgeon can benefit from understanding CER fundamentals, minimally to:

- Better understand and interpret ongoing research presented in scientific journals and professional meetings;
- Stimulate innovative, evidence-based treatment strategies; and
- Inform conversations with colleagues, oversight committees and executive administrators.

**CER: a methodology for initiating or enhancing a research plan**

The guide is also intended for vascular surgeons whose practices already include or are considering research as a career component. Especially for junior faculty and new investigators seeking to broaden their research, these pages offer a jump-start to:

- Explore the fundamentals of CER and assess its appropriateness for current and upcoming investigations;
- Identify resources to help inform and inspire team members; and
- More easily navigate dataset options.

We appreciate that many of our colleagues generously contributed time and expertise to this effort. Our thanks to everyone on the Research Council and SVS leadership team who offered their guidance and encouragement, and to our fellow SVS members for their ongoing collegiality and support.

Wei Zhou, MD, Chair
Clinical and Comparative Effectiveness Committee
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NATIONWIDE INPATIENT SAMPLE (NIS)  
http://www.hcup-us.ahrq.gov

NIS DATABASE DOCUMENTATION:  
http://www.hcup-us.ahrq.gov/db/nation/nis/nisdbdocumentation.jsp

NIS is an all-payer inpatient database, 20% validated sample yielding national estimates of hospital inpatient stays from AHRQ’s Healthcare Cost and Utilization Project (HCUP).

NIS contains clinical and resource-use information that is included in a typical discharge abstract.

**Strengths** – Inexpensive, large numbers available; epidemiologic and disparities research.

**Weaknesses** – No info on disease severity or anatomy. No longitudinal (post-discharge) data. Difficult to distinguish comorbidity from complication.

**Availability of cost information:** Cost data not available.

**Requirements for data access:** NIS data for years 1988 through 2012 are available for purchase. Individuals required to take online Data Use Agreement Training Course and sign the Data Use Agreement for Nationwide Databases.

**Cost $50 (students) or $350 per year**

**Key publications utilizing dataset:**

Vogel TR et al.  
Carotid artery stenting in the nation: the influence of hospital and physician volume on outcomes.  
Vasc Endovascular Surg 2010; 44(2):89-94

Park BD et al.  

Schermerhorn ML et al  
STATE INPATIENT DATABASE (SID)
STATE AMBULATORY SURGERY DATABASE (SASD)
http://www.hcup-us.ahrq.gov

The same methodology as NIS, however 100% sample from AHRQ's Healthcare Cost and Utilization Project (HCUP).

**Availability of cost information:** Cost data available from selected states.

**Requirements for data access:** Same as National Inpatient Sample (NIS); expensive, varies state by state.

**Key publications utilizing dataset:**

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)
DATA NAVIGATOR
http://dnav.cms.gov
http://www.resdac.org

Medicare and Medicaid beneficiary utilization data.

**Strengths:** Large numbers, longitudinal data (survival, reintervention, readmission), define pre-existing conditions from prior claims, inpatient and outpatient, Part A-hospital codes-ICD9, Part B-physician bill-CPT.

**Weaknesses:** No disease severity, anatomy, hospital coders, missing ages <65, missing HMO and uninsured, expensive, cumbersome (need experienced statisticians).

**Availability of cost information:** Cost data available.

**Requirements for data access:** Non-identifiable data within the public domain available for download at no cost.

Data for purchase: CMS Data files that have been edited and stripped of all information that could be used to identify individuals.

Data files contain aggregate level information on Medicare beneficiary or provider utilization.

CMS data cost dependent on size of cohort.

**Key publications utilizing dataset:**

Egorova NN et al.
Effect of gender on long-term survival after abdominal aortic aneurysm repair based on results from the Medicare national database.

Greenblatt DY et al.
Causes and implications of readmission after abdominal aortic aneurysm repair.

Goodney PP et al. Relationship between regional spending on vascular care and amputation rate.
JAMA Surgery. 2014;149(1): 34-42

Schermerhorn ML et al.
Endovascular vs. open repair of abdominal aortic aneurysms in the Medicare population.
**VASCULAR QUALITY INITIATIVE (VQI)**
**SOCIETY FOR VASCULAR SURGERY PATIENT SAFETY ORGANIZATION (SVS PSO)**
http://www.vascularqualityinitiative.org

VQI collects perioperative and one-year follow-up data to generate real-time benchmarked reports to assess quality of care and determine best practices in vascular surgery.

**Strengths:** Detailed anatomical/clinical data, large numbers, follow-up 1 year or longer, procedure specific outcomes, designed by vascular surgeons.

**Weaknesses:** No 30-day data, only 50% 1-year follow-up, lack of follow-up beyond 1 year.

**Availability of cost information:** Cost data not available.

**Requirements for data access:** Enrollment required to access data — requires institutional participation.

**Key publications utilizing dataset:**

Aiello FA et al.
Outcomes reported by the Vascular Quality Initiative and the National Surgical Quality Improvement Program are not comparable. J Vasc Surg 2014; 60(1): 152-159

Kalish JA et al.

Lo RC et al.

Woo K et al.

Cronenwett JL et al.
AMERICAN COLLEGE OF SURGEONS
NATIONAL SURGICAL QUALITY IMPROVEMENT PROGRAM (ACS NSQIP)
http://site.acsnsqip.org

ACS NSQIP is a risk-adjusted, outcomes-based program to measure and improve the quality of surgical care.

**Strengths:** Trained nurse reviews op notes, hospital charts, office notes and makes phone calls. 100% 30-day follow-up by chart review or telephone. Readmission (with reason). Large number of cases.

**Weaknesses:** Not all cases captured within a given hospital, follow-up limited to 30-days, no anatomical details, variables not defined by vascular surgeons, no procedure specific outcomes.

**Availability of cost information:** Cost data not available.

**Requirements for data access:** Enrollment required to access data NSQIP data exists for 2005 – 2012.

**Key publications utilizing dataset:**

Curran T et al.
Risk factors and indications for readmission after lower extremity amputation in the American College of Surgeons National Surgical Quality Improvement Program. J Vasc Surg 2014; Published online June 28:1-10

Aiello FA et al.
Outcomes reported by the Vascular Quality Initiative and the National Surgical Quality Improvement Program are not comparable. J Vasc Surg 2014; 60(1): 152-159

Bensley RP et al.
**NSQIP TARGETED**

http://site.acsnsqip.org

Targeted NSQIP now available. Detailed clinical information, procedure specific outcomes.

**Strengths:** Anatomical details, variables defined by vascular surgeons, procedure specific outcomes.

**Weaknesses:** Not all cases captured within a given hospital, follow-up limited to 30-days, less detailed than VQI.

**Availability of cost information:** Cost data not available.

**Requirements for data access:** Data collection from 2011.

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**U.S. DEPARTMENT OF VETERANS AFFAIRS SURGICAL QUALITY IMPROVEMENT PROGRAM (VASQIP)**

U.S. Department of Veterans Affairs
Surgical Quality Improvement Program (VASQIP)
Similar to NSQIP

**Requirements for data access:** Must be a VA practitioner; need approval for access.

**Key publications utilizing dataset:**

Bush et al,

Bush et al.
Performance of endovascular aortic aneurysm repair in high-risk patients: results from the Veterans Affairs National Surgical Quality Improvement Program.
J Vasc Surg 2007; 45:227-235
AMERICAN COLLEGE OF CARDIOLOGY — NATIONAL CARDIOVASCULAR DATA REGISTRY (NCDR)
https://www.ncdr.com/webncdr

NCDR is a cardiovascular data repository (six hospital-based registries and one outpatient registry), providing evidence-based quality improvement solutions for cardiologists and other medical professionals.

Availability of cost information: Cost data not available.

Requirements for data access: Enrollment required to access data.

Key publications utilizing dataset:

Wimmer NJ et al.
Clinical prediction model suitable for assessing hospital quality for patients undergoing carotid endarterectomy.
J Am Heart Assoc 2014; 3:e000728

Vaitkus PT.
Contemporary carotid stenting: comparative effectiveness research from the NCDR (National Cardiovascular Data Registry)
JACC Cardiovasc Interv 2014; Feb; 7(2):178-9

Longenecker JC et al.
Adherence to ACC/AHA performance measures for myocardial infarction in six Middle-Eastern countries; association with in-hospital mortality and clinical characteristics.
Int J Cardiol 2013; Aug 20; 167(4): 1406-11

Allen DS et al.
Comparison of bleeding complications using arterial closure device versus manual compression by propensity matching in patients undergoing percutaneous coronary intervention.
Am J Cardiol. 2011 Jun 1; 107(11): 1619-23
HEALTH ECONOMIC RESOURCE CENTER US DEPARTMENT OF VETERANS AFFAIRS (HERC)
http://www.herc.research.va.gov/home/default.asp

HERC is a national center that assists VA researchers in assessing the cost-effectiveness of medical care, evaluating the efficiency of VA programs and providers, and conducting high-quality health economics research.

**Availability of cost information:** Cost data available.

**Requirements for data access:** Must be a VA practitioner.

CENTERS FOR DISEASE CONTROL NATIONAL HEALTHCARE SAFETY NETWORK (NHSN)
http://www.herc.research.va.gov/home/default.asp

CDC’s National Healthcare Safety Network is the nation’s most widely used healthcare-associated infection tracking system. NHSN provides facilities, states, regions, and the nation with data to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections.

**Requirements for data access:** Cost data not available.

**Requirements for data access:** Enrollment required to access data.
UNIVERSITY HEALTH CONSORTIUM (UHC)
https://www.uhc.edu/home.htm

UHC is an alliance of 120 academic medical centers and 299 of their affiliated hospitals. UHC databases provide comparative data in clinical, operational, faculty practice management, financial, patient safety, and supply chain areas.

Availability of cost information: Cost data available.

Requirements for data access: Academic medical center enrollment required to access data.

TRUVEN HEALTH ANALYTICS MARKETSCAN RESEARCH DATABASES
http://truvenhealth.com

MarketScan databases include claims data on more than 180 million unique patients since 1995.
Patient-level data (inpatient, outpatient, drug, lab, etc) includes commercial, Medicare supplemental and Medicaid populations.

Requirements for data access: Claims data available.

Requirements for data access: Data available for purchase.

FAIR HEALTH
http://www.fairhealth.org

Collection of private medical and dental claims data and data tools for use by consumers, health plans, policymakers, bill review companies, administrators, healthcare providers, and researchers.

Requirements for data access: Claims data available.

Requirements for data access: Data available for purchase.
ACADEMYHEALTH
http://www.academyhealth.org

AcademyHealth is a national professional organization serving the fields of health services and policy research. Offers programs and services that support the development and use evidence and provides research analysis, facilitation, education and training, strategic planning, and program management.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)
http://www.ahrq.gov

AHRQ provides extensive resources and information on comparative effectiveness research for use by patients, physicians, and policymakers. Website includes health resources, datasets available, grant opportunities.

COCHRANE COLLABORATION
http://www.cochrane.org

Cochrane is a global network of health practitioners, researchers, and patient advocates, making the evidence generated through research useful for informing decisions about health.

Cochrane is a not-for-profit organization with collaborators from over 120 countries who promote evidence-informed health decision-making by producing systematic reviews and other synthesized research evidence.

INSTITUTE OF MEDICINE (IOM)
http://iom.edu

IOM is an independent, nonprofit organization that works outside of government to provide advice to decision makers and the public. IOM asks and answers the nation’s most pressing questions about health and health care to help those in government and the private sector make informed health decisions. Many studies the IOM undertakes begin as specific mandates from Congress and others are requested by federal agencies and independent organizations.
ORGANIZATIONS AND RESOURCES FOR RESEARCHERS

INTERNATIONAL CONSORTIUM FOR HEALTH OUTCOMES RESEARCH (IC Hom)
http://www.ichom.org

ICHOM is a not-for-profit organization with the purpose to transform health care systems worldwide by measuring and reporting patient outcomes in a standardized way.

INTERNATIONAL SOCIETY FOR PHARMA COECONOMICS AND OUTCOMES RESEARCH (ISPOR)
http://ispor.org

ISPOR promotes the science of health economics and outcomes research and facilitates the translation of this research into useful information for health care decision makers.

ISPOR provides opportunities for education and produces publications and tools for outcomes research practice and health policy issues.

NATIONAL QUALITY FORUM (NQF)
http://www.qualityforum.org/Home.aspx

NQF reviews, endorses, and recommends use of standardized healthcare performance measures. Performance measures are tools used to evaluate how well healthcare services are being delivered.

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI)
http://www.pcori.org

PCORI is authorized by Congress to conduct research to provide information about the best available evidence to help patients and their health care providers make informed decisions. PCORI supports research intended to give patients a better understanding of the prevention, treatment and care options available, and the science that supports those options.
ORGANIZATIONS AND RESOURCES
FOR RESEARCHERS

RESEARCH DATA ASSISTANCE CENTER (RESDAC)
http://www.resdac.org

Provides technical assistance and workshops to researchers using Medicare and/or Medicaid data.

SOCIETY FOR MEDICAL DECISION MAKING (SMDM)
http://www.smdm.org

SMDM is an organization that provides a scholarly forum for researchers, clinicians, educators, managers and policy makers from a variety of backgrounds and academic disciplines. SMDM offers educational programs, networking opportunities, publications, and awards for leadership in medical decision making.

SURGICAL OUTCOMES CLUB
http://www.surgicaloutcomesclub.com

Consortium of surgeons and scientists interested in advancing health services and outcomes research in surgery. SOC members may attend virtual didactic sessions to receive updates in research, share progress, and set the stage for future collaborations and opportunities. SOC offers annual scientific session to members during ACS Clinical Congress.


PRINCIPLES AND METHODS OF COMPARATIVE EFFECTIVENESS RESEARCH (CER)
http://ctsa-cermethodscourse.org

**Audience:** Junior faculty, clinical fellows, postdoctoral fellows, and graduate students.

Free online course provides an introduction to CER and methods for conducting CER and covers four areas of research methodology:

- Design and Analysis of Randomized Clinical Trials
- Design and Analysis of Observational Studies and Large Datasets
- Research Synthesis, Systematic reviews, and Meta-analysis
- Economic Evaluations, Modeling, and Health Policy

HEALTH ECONOMICS RESOURCE CENTER (HERC)
http://www.herc.research.va.gov/training/default.asp

Free health economics cyber seminars about cost data and economic research. The seminars feature presentations on health economics, health services, and implementation topics via conference calls with interactive, web-based slide presentations.

The Cost-Effectiveness Analysis Course and Econometrics Course describe methods of economic evaluation of health care with special reference to VA datasets. Topics include cost measurement (direct measurement, fee schedules, cost regressions), VA and non-VA cost and utilization data sources (OPC/PTF, DSS, CDR, pharmacy data, and more), methods of economic evaluation (managerial studies and the standard CEA reference case), modeling and measurement of health care outcomes, and patient utilities.

ACS OUTCOMES RESEARCH COURSE
http://www.facs.org/cqi/src/outcomes-research.html

Course is designed for clinical and health services researchers with varying degrees of experience in the field. Participants select modules appropriate to their skill level and interest. Surgeons new to the field will be able to focus on didactics and skills-based labs in managing, analyzing, and interpreting large datasets. Meanwhile, surgeons with more established research agendas will be able to present their research to experts for critique and advice. Participants will also be exposed to scientific and practical aspects of ongoing surgical outcomes research of leaders in the field.