Leveraging Real World Evidence to Advance Regulation, Care Quality & Efficiency

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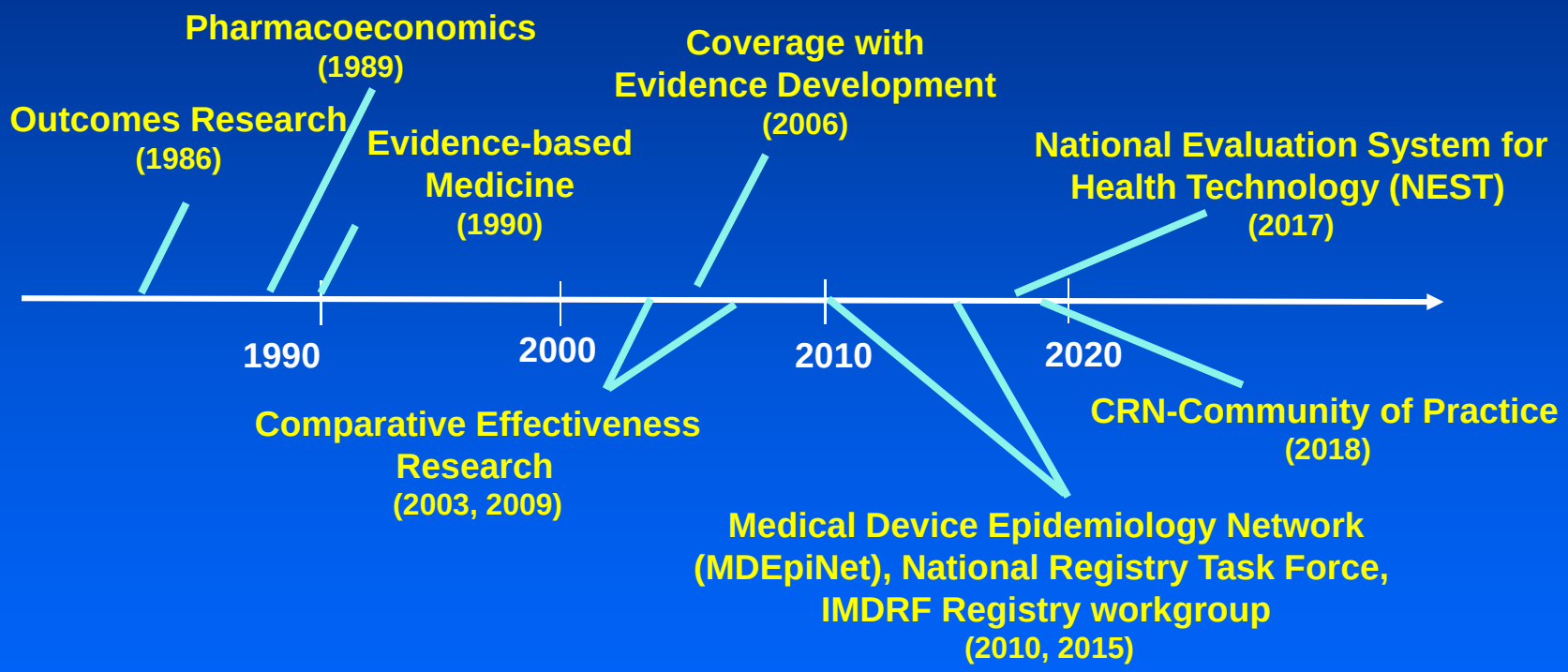
The Origin of Real World Evidence

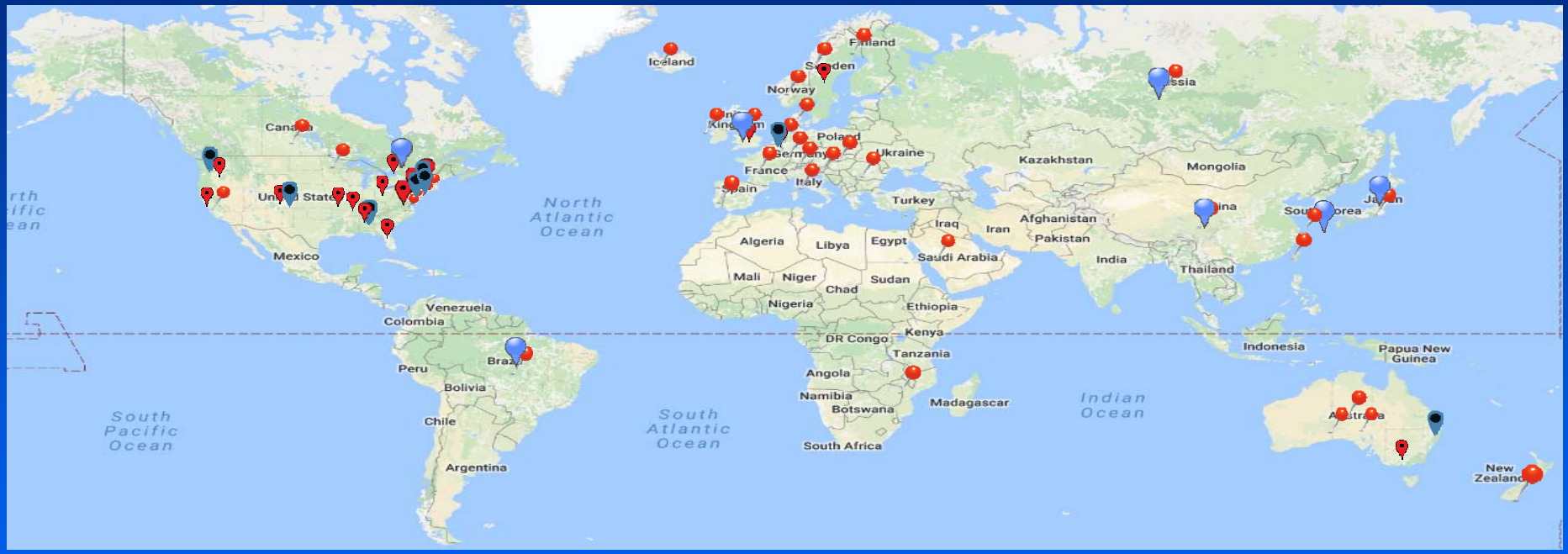
- Donabedian used concept of **Quality**
  - Structure
  - Process
  - Outcomes
- The IOM used the issue of "**patient safety**"
  - Underuse
  - Overuse
  - Misuse

(Donabedian A: Evaluating the quality of medical care. Milbank Q 1966;44:166-203)

Real World Evidence (RWE): Grounded in Epidemiology, EBM & Health Services Research



Global MDEpiNet



Existing MDEpiNet Chapter

Future MDEpiNet Chapter

Academic Centers

Data Sources

JVS Journal of Vascular Surgery
Official Publication of the Society for Vascular Surgery

Short-term and long-term results of endovascular and open repair of abdominal aortic aneurysms in Germany

Christian-Alexander Behrendt, MD, Art Sedrakyan, MD, PhD, Henrik Christian Rieß, MD, Franziska Heidemann, MD, Tilo Kölbel, MD, Jörg Petersen, Eike Sebastian Debus, MD

Abstract | Full Text | Images | References

Abstract

Background

Endovascular aortic repair (EVAR) has emerged as a standard of care for abdominal aortic aneurysm (AAA) repair. However, real-world evidence to compare this technology to open aortic repair (OAR) is limited. Major gaps exist related to long-term outcomes of therapies worldwide.

Methods

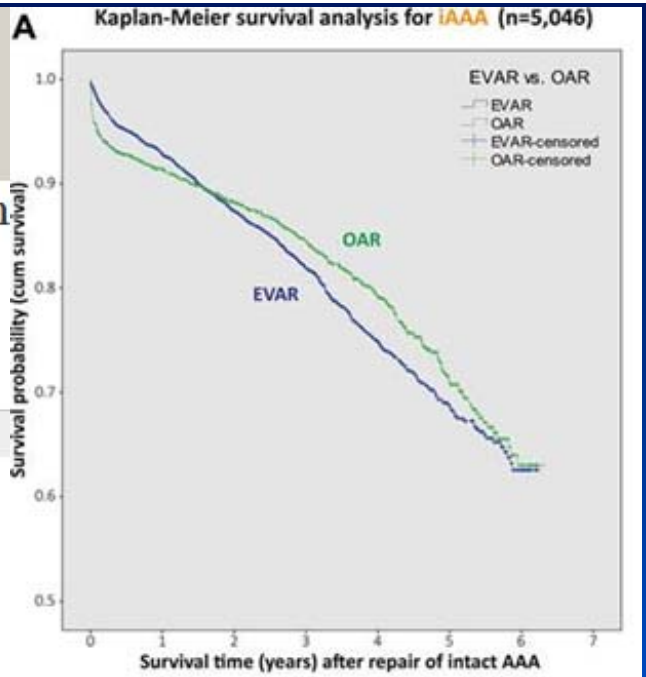
Health insurance claims data of Germany's third largest insurance provider, DAK-Gesundheit, were used to determine outcomes after interventions for intact AAA (iAAA) and ruptured AAA (rAAA). The study included patients operated on between October 2008 and April 2015.

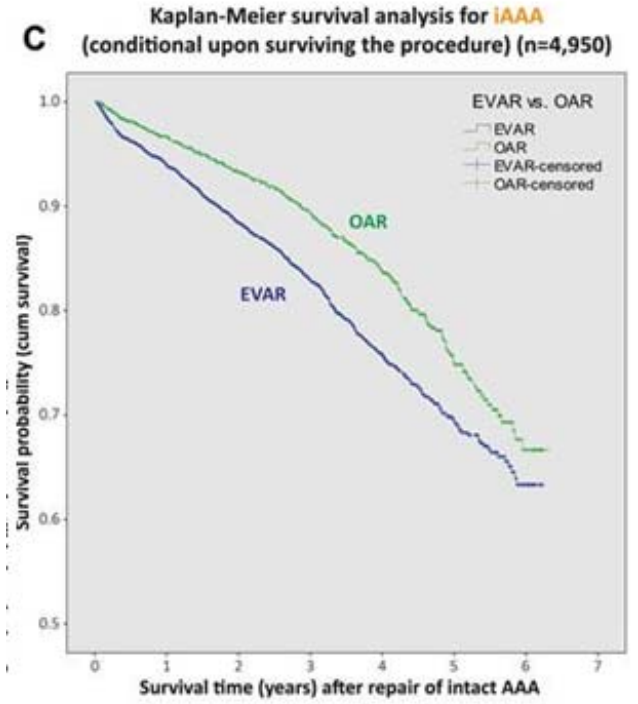
Results

Included were 5509 patients (3627 EVAR and 1859 OAR). Median follow-up was 2.44 years (range, 0-6.46 years). The in-hospital mortality was lower after EVAR compared with OAR for both iAAA (1.2% vs 5.4%) and rAAA (26.1% vs 42%; $P < .001$). Postoperative length of stay and occurrence of complications were also lower after EVAR. The in-hospital mortality benefits of EVAR were most prominent in octogenarians (iAAA: EVAR, 2.2%; OAR, 18.2%; rAAA: EVAR, 34.4%; OAR, 62.3%; $P < .001$). However, the early survival benefit after EVAR reversed at ~1.5 years, and Cox proportional hazard models revealed no differences in overall survival between EVAR and OAR. Landmark analysis focusing on patients surviving the procedure has shown lower survival in patients with EVAR.

Conclusions

In this largest European investigation to date using health insurance claims data, we found that in-hospital outcomes in Germany favor EVAR, which is comparable to findings reported in the United States and the United Kingdom. Trends toward lower long-term survival after EVAR after discharge are important and require future research and reflection.

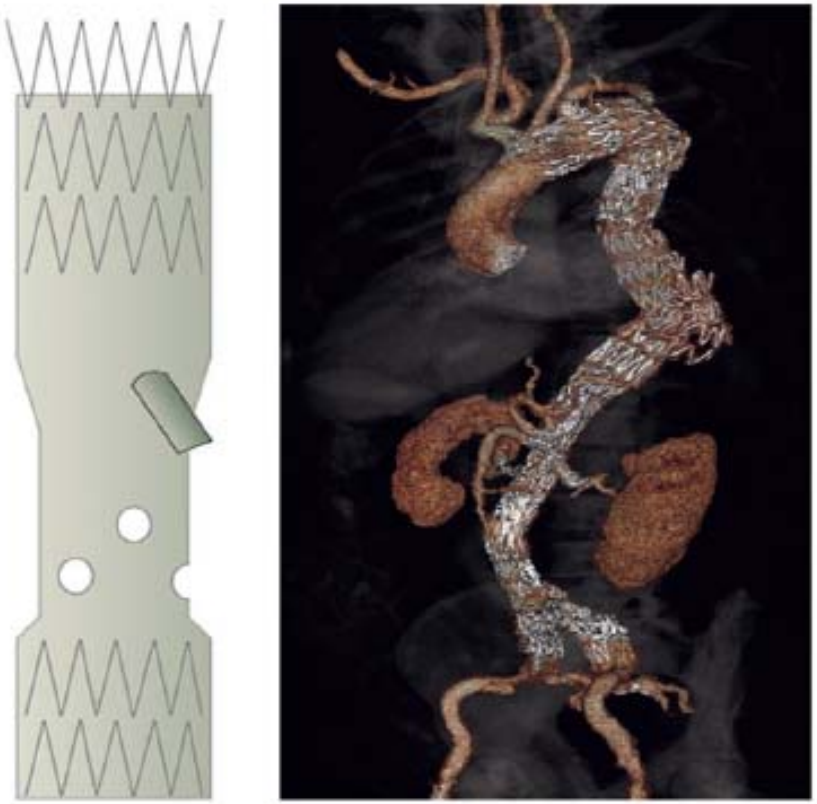




EUROPEAN JOURNAL OF
CARDIO-THORACIC SURGERY

Gender disparities in fenestrated and branched endovascular aortic repair

Henrik Christian Rieß[a], Eike Sebastian Debus[a], Thea Schwaneberg[a], Art Sedrakyan[b], Tilo Kölbel[a], Nikolaos Tsilimparis[a], Axel Larena-Avellaneda[a] and Christian-Alexander Behrendt[a,*]



Outcomes by Gender

Table 2: Perioperative outcomes following fenestrated or branched endovascular aortic repair

	Fenestrated or branched endovascular aortic repair			
	Female	Male	*P*-value	Relative risk (95% CI)
Number of patients	163	796		
In-hospital mortality	17 (10.4)	29 (3.6)	**<0.001**	2.86 (1.61–5.08)
30-Day mortality	20 (12.3)	43 (5.4)	**0.002**	2.27 (1.37–3.76)
90-Day mortality	23 (14.1)	57 (7.2)	**0.006**	1.97 (1.25–3.10)
Acute respiratory insufficiency	21 (12.9)	75 (9.4)	0.23	1.37 (0.87–2.15)
Acute renal failure	20 (12.3)	57 (7.2)	**0.042**	1.71 (1.06–2.77)
Acute myocardial infarction	6 (3.7)	17 (2.1)	0.37	1.72 (0.69–4.30)
Stroke or TIA	4 (2.5)	7 (0.9)	0.19	2.79 (0.83–9.42)
Paraplegia	10 (6.1)	18 (2.3)	**0.015**	2.71 (1.28–5.77)
Pneumonia	8 (4.9)	28 (3.5)	0.53	1.40 (0.65–3.01)
Acute bowel ischaemia	5 (3.1)	11 (1.4)	0.23	2.22 (0.78–6.30)
Acute limb ischaemia	10 (6.1)	28 (3.5)	0.18	1.74 (0.86–3.52)
Lower extremity amputation	1 (0.6)	2 (0.3)	1	2.44 (0.22–26.77)
Bleeding or anaemia requiring blood transfusion	63 (38.7)	175 (22.0)	**<0.001**	1.76 (1.39–2.22)
Sepsis or SIRS	5 (3.1)	12 (1.5)	0.29	2.03 (0.73–5.70)
Gastric ulcer	0 (0.0)	11 (1.4)	0.27	0 (0)
Transfer to another hospital	9 (5.5)	26 (3.3)	0.24	1.69 (0.81–3.54)
Discharged to rehab or nursery	6 (3.7)	24 (3.0)	0.84	1.22 (0.51–2.94)
Length of total hospital stay in days, median (IQR)	12 (8–21.5)	9 (7–16)	**0.003**	NA
Postoperative hospital stay in days, median (IQR)	9 (6–15)	7 (5–11)	**0.001**	NA
Aneurysm-related hospital readmissions	2 (1.2)	17 (2.1)	0.65	0.57 (0.13–2.46)
Aneurysm-related reoperations	137 (84.0)	590 (74.1)	**0.009**	1.13 (1.05–1.23)

Values reported in total numbers and % unless otherwise indicated. Significant *P*-values are marked in bold.

CI: confidence interval; IQR: interquartile range; NA: not applicable; SD: standard deviation; SIRS: systemic inflammatory response syndrome; TIA: transient ischaemic attack.

Table 3: Logistic regression results for in-hospital mortality for fenestrated or branched aortic repair by different risk factors

Variables	Fenestrated or branched endovascular aortic repair		
	Odds ratio	95% CI	*P*-value
Older age of the patients (increase by 1 year)	1.057	1.013–1.105	**0.012**
Female gender (vs male)	3.206	1.664–6.015	**<0.001**
Van Walraven comorbidity score (increase by one point)	1.062	1.024–1.101	**0.001**

Public-Private-Partnership

- Over 130 partners
- Over 100 registries
- Over 750 clinical experts
- Over 100 methodologists
- National and State claims data
- International claims and EHRs
- Integrated Health Care Delivery Systems (e.g. Kaiser)
- Major Collaboration with funders and data owners

Original Article

Research Synthesis Methods

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(wileyonlinelibrary.com) DOI: 10.1002/jrsm.1159

Meta-analysis of survival curve data using distributed health data networks: application to hip arthroplasty studies of the International Consortium of Orthopaedic Registries

Guy Cafri, [a,b] * Samprit Banerjee, [c] Art Sedrakyan, [c] Liz Paxton, [a]

RESEARCH

OPEN ACCESS

Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study

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ABSTRACT

OBJECTIVE

To compare the safety and efficacy of hysteroscopic sterilization with the "Essure" device with laparoscopic sterilization in a large, all-inclusive, state cohort.

DESIGN

Population based cohort study.

higher risk of unintended pregnancy (odds ratio 0.84 (95% CI 0.63 to 1.12)) but was associated with a substantially increased risk of reoperation (odds ratio 10.16 (7.47 to 13.81)) compared with laparoscopic sterilization.

CONCLUSIONS

Patients undergoing hysteroscopic sterilization have a similar risk of unintended pregnancy but a more than

RESEARCH

thebmj

Use and risks of surgical mesh for pelvic organ prolapse surgery in women in New York state: population based cohort study

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[2]Patient-Centered Comparative Effectiveness Program and MDEpiNet Science and Infrastructure Centre, Department of Healthcare Policy and Research at Weill Cornell Medical College and New York-Presbyterian, New York, NY 10065, USA

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Additional material is published online only. To view please visit

ABSTRACT

OBJECTIVE

To assess the use of mesh in pelvic organ prolapse surgery, and compare short term outcomes between procedures using and not using mesh.

DESIGN

All inclusive, population based cohort study.

SETTING

Statewide surgical care captured in the New York Statewide Planning and Research Cooperative System.

PARTICIPANTS

Women who underwent prolapse repair procedures in New York state from 2008 to 2011.

MAIN OUTCOMES MEASURES

within 90 days (mesh 7.5% *v* no mesh 5.6%, risk ratio 1.33 (95% confidence interval 1.18 to 1.51)), compared with those who received surgery without mesh. In subgroup analyses based on age, mesh use was associated with an increased risk of reintervention within one year in patients under age 65 years, and increased risk of urinary retention in patients aged 65 years and over.

CONCLUSIONS

Despite multiple warnings released by the US Food and Drug Administration since 2008, use of mesh in pelvic organ prolapse surgery continues to grow. In this statewide comprehensive study, mesh procedures were associated with an increased risk of reinterventions within one year and urinary retention after surgery.

The NEW ENGLAND JOURNAL of MEDICINE

INAL ARTICLE

gistry-Based Prospective, Active Surveillance of Medical-vice Safety

ric S. Resnic, M.D., Arjun Majithia, M.D., Danica Marinac-Dabic, M.D., Ph.D., Susan Robbins, B.S., Henry aganda, M.D., Kathleen Hewitt, M.S.N., Angelo Ponirakis, Ph.D., Nilsa Loyo-Berrios, Ph.D., Issam Moussa, M.D., h Drozda, M.D., Sharon-Lise Normand, Ph.D., and Michael E. Matheny, M.D., M.P.H.

gl J Med 2017; 376:526-535 | February 9, 2017 | DOI: 10.1056/NEJMoa1516333

ORIGINAL RESEARCH ARTICLE

Variations in Abdominal Aortic Aneurysm Care: A Report From t International Consortium of Vascular Registries

Adam W. Beck, Art Sedrakyan, Jialin Mao, Maarit Venermo, Rumi Faizer, Sebastian Debus, Christian-Alexander Behrendt, Salvatore Sca Martin Altreuther, Marc Schermerhorn, Barry Beiles, Zoltan Szeberin, Nikolaj Eldrup, Gudmundur Danielsson, Ian Thomson, Pius Wigge Martin Björck, Jack L. Cronenwett, Kevin Mani

and On behalf of the International Consortium of Vascular Registries

JAMA Surgery

New Online Issues

Failures of Sacral Neuromodulation for Incontinence

Bilal Chughtai, MD[1]; Dominique Thomas, BS[1]; Tianyi Sun, MS[2]; et al

» Author Affiliations | Article Information

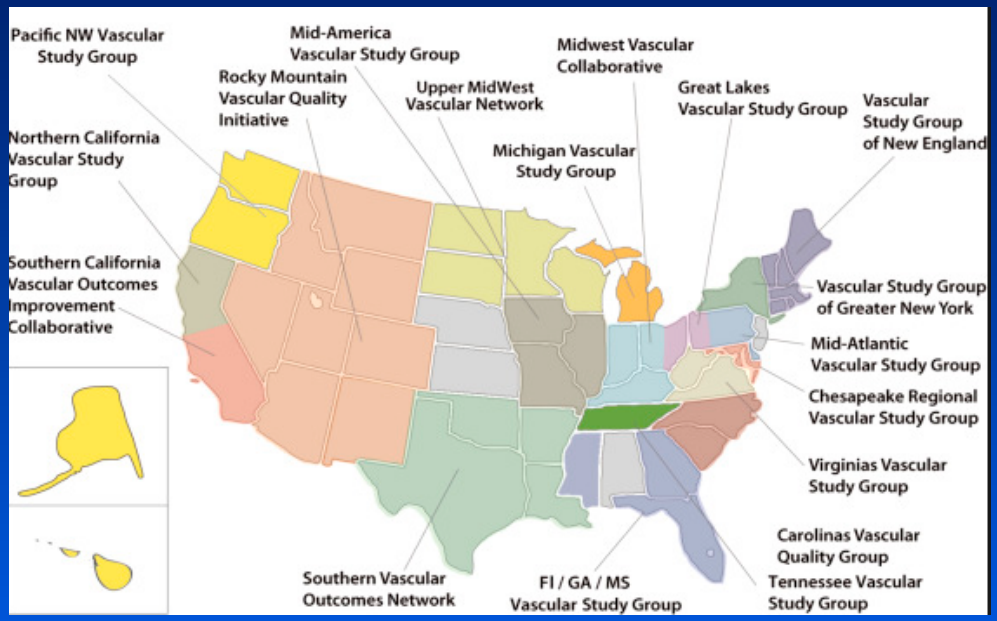
JAMA Surg. Published online February 14, 2018. doi:10.1001/jamasurg.2017.6093

Circulation

Example Recognotion/Impact

- NEST partner for all CRN/registry related work
- Impact on regulatory decisions worldwide (example MoM, mesh
- Significant contributions to:
  - IMDRF General Principles documents (published)
  - IMDRF Registry Assessment tool for regulatory decision making (new)
- Innovative Methodologies for TPLC Evaluation
- Over $30M in funding and continuous leveraged projects
- Over 300 manuscripts published in the past 5 years

RWE: Registries
Technology Registry Definition



"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 Technology at a reasonably generalizable scale (e.g. international, national, regional, and health system)' with a primary aim to improve the quality of patient care"

IMDRF Registry Task Force

Key Registry Attributes

- **TECHNOLOGY:** The registry contains sufficient information to uniquely identify the technology.
- **QUALITY IMPROVEMENT SYSTEM**: The registry is part of a health care delivery quality improvement system or evolving into one as device technologies are diffused into practice and need continuing evaluation (including outlier identification).
- **BENEFICIAL CHANGE**: The registry has established mechanisms to bring about beneficial change in health care delivery through stakeholder participation, ownership and integration into the relevant health care systems.
- **EFFICIENCY:** The registry is embedded in the health care delivery system so that data collection occurs as part of care delivery (i.e., not overly burdensome, not highly complicated, not overly costly, etc.) and integrated with work flow of clinical teams.
- **ACTIONABLE DATA**: The registry provides actionable information in a relevant and timely manner to decision makers.
- **TRANPARENCY**: The governance structure, data access, and analytical processes of the registry are transparent
- **LINKABILITY:** Information in the registry can be linked with other data sources for enhancement including adequate follow up achievement.
- **TECHNOLOGY LIFE-CYCLE**: The registry can serve as infrastructure for seamless integration of evidence throughout the technology life cycle.

Real World Evidence (RWE): Coordinated Registry Network (CRN)

CRNs are focused on leveraging national investments in registries and other relevant data systems to help NEST create '*National Medical Device Evaluation System on a fairly immediate basis, greatly minimizing the cost or development resources needed*'

We integrate relevant data such as:

- **Major 'Quality and safety' registries**
- **Federal payer claims**
- **Commercial claims**
- **Electronic health data**
- **All payer databases**

Strategically Coordinated Registries Network (CRNs)

National

- Orthopedics CRN (AKA ICOR-USA)
- Vascular CRN – VISION
- Neurology CRN – DAISI
- Prostate Cancer-SPARED CRN
- Robotic Surgery CRN
- Plastic Surgery – NBIR/PROFILE
- Women's Health Technologies CRN– COMPARE-UF, NPFD, Sterilization Devices

International

- International Consortium Orthopedics Registries (ICOR)
- International Consortium Vascular Registries (ICVR)
- International Consortium of Colorectal Registries (IC3)
- International Collaboration of Breast Registries Activities (I-COBRA)

Five Levels of Maturity (CRNs)

Level	Description
Level 1 Early Learner	• CRN is capturing device information with at least CPT or ICD-9/10 Codes • No linkages done, no outlier assessment, no feedback to clinicians, no nested clinical studies • Core minimum data being established • Single center • No funding, or pilot funding
Level 2 Making Progress*	• CRN is capturing device information preferably at least with manufacturer names but CPT/ICD-9/10 codes appropriate sometimes • No linkages done, limited outlier assessment, limited feedback to clinicians, no nested clinical studies • Core Minimum data established • Focus on large patient population with < 80% completeness of both cases and records • Fully transparent, short term grant funding (<5 year grant)
Level 3 Defined Path to Success	• CRN is capturing device information with at least manufacturer names • No routine linkages (some experience), no routine outlier assessment, limited feedback to clinicians, plans 1+ nested clinical study for regulatory purposes • Manual data entry is often used which might be burdensome • Large patient population with > 80% completeness OR Regionally or Nationally representative with 50-80% completeness of both cases and records • Fully transparent, at least one major long term grant funding (5+ year grant)
Level 4 Well-Managed	• CRN is capturing device information with UDI or Catalogue Numbers • Linkages done almost routinely, routine outlier assessment, adequate feedback to clinicians, at least one clinical study experience for regulatory purposes • Minimally burdensome and steps towards automation of data capture • Regionally or Nationally representative with > 80% completeness of both cases and records • Fully transparent, hosted by a major professional society or health system, not fully sustainable funding
Level 5 Optimized	• CRN is capturing device information with UDI or Catalogue Numbers • Routine feedback to clinicians, Doing linkage routinely, doing routine outlier assessment, multiple nested clinical studies for regulatory purposes • At least a process started for automation and overall minimum burden if manual data entry • Regionally or nationally representative with > 80% completeness of both cases and records • Fully transparent, hosted by a major professional society or health system with funding beyond industry

* Once level two is reached, can be considered a device registry

Thank You!

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http://mdepinet.org/