Highlights From The First Decade

10th MDEpiNet Annual Meeting

Addressing Challenges in National and Global Health Technology Research and Surveillance

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MDEpiNetPPPMDEpiNetPPP

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Acronym	Definition
AAA	Abdominal Aortic Aneurysm
ACC	American College of Cardiology
ACOG	American College of Obstetricians and Gynecologists
AHA	American Heart Association
AHRQ	Agency for Healthcare Research and Quality
AHS	Americas Hernia Society
AHSQC	Americas Hernia Society Quality Collaborative
AJRR	American Joint Replacement Registry
ALCL	Anaplastic Large Cell Lymphoma
AQUIRE	AUGS Urogynecology Quality Registry
ASN	American Society of Nephrology
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ASPS	American Society of Plastic Surgeons
AUGS	American Urogynecologic Socirty
BIA-ALCL	Breast Implant Associated - Anaplastic Large Cell Lymphoma
BUILD	Building UDI into Longitudinal Data for Medical Device Evaluation
Cath-PCI	Catheterization and/or Percutaneous Coronary Intervention
CBRI	Claims Based Research Initiative
CDC	Center for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CDRN	Clinical Data Research Network
CEA	Carotid Endarterectomy
CIED	Cardiac Implantable Electronic Devices
CKD	Chronic Kidney Disease
CMS	Centers for Medicare and Medicaid Services
CNS	Congress of Neurological Surgeons
COP	Community of Practice
CRC	Colon and Rectal Cancer
CRN	Coordinated Registry Network
CROWNWeb	Consolidated Renal Operations in a Web-Enabled Network
DAISI	Devices Used for Acute Ischemic Stroke Intervention
DELTA	Data Extraction and Longitudinal Trend Analysis
DGHD	Danish Groin Hernia Database
DUA	Data Use Agreement
ECMO	Electrocorporeal Membrane Oxygenation
EHR	Electronic Health Record
EOC	Executive Operations Committee
ESRD	End-Stage Renal Disease
EuraHS	European Registry of Abdominal Wall Hernias
EVAR	Endovascular Aneurysm Repair
FDA	Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources

Acronym	Definition
FORCE-TJR	Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement
GUDID	Global Unique Device Identification Database
HHS	Department of Health and Human Services
HIFU	High-Intensity Focused Ultrasound
HIVE	High-performance Integrated Virtual Environment
HL7	Health Level Seven
ICD	International Classification of Diseases
ICD	Implantable Cardiac Defibrillator
ICD-Pieces	Improving Chronic Disease Management with Pieces
ICOR	International Consortium of Orthopedic Registries
ICVR	International Consortium of Vascular Registries
IMDRF	International Medical Device Regulators' Forum
IRB	Institutional Review Board
ISAR	International Society of Arthroplasty Registries
KECC	Kidney Epidemiology and Cost Center
KHI	Kidney Health Initiative
LOINC	Logical Observation Identifiers Names and Codes
MAUDE	Manufacturer and Use Facility Device Experience
MDEpiNet	Medical Device Epidemiology Network
MDIC	Medical Device Innovation Consortium
MOU	Memorandum of Understanding
NBIR	National Breast Implant Registry
NCDR	National Cardiovascular Data Registry
NCD	National Coverage Determination
NCD	National Cardiovascular Data
NCI	National Cancer Institute
NEST	National Evaluation System for health Technology
NESTcc	National Evaluation System for health Technology Coordinating Center
NIH	National Institutes of Health
NLM	National Library of Medicine
NYC-CDRN	New York City Clinical Data Research Network
oAAA	Open Abdominal Aortic Aneurysm
ONC	Office of the National Coordinator for Health Information Technology
OPC	Objective Performance Criteria
OPG	Objective Performance Goals
PAD	Peripheral Artery Disease
PASSION	Predictable And Sustainable Implementation Of National
PCOR	Patient Centered Outcomes Research
PCORTF	Patient Centered Outcomes Research Trust Fund
PICC	Peripherally Inserted Central Catheter
POP	Pelvic Organ Prolapse
PROFILE	Patient Registry and Outcomes For breast Implants and ALCL Etiology and Epidemiology

Acronym	Definition
PSF	Plastic Surgery Foundation
PSO	Patient Safety Organization
rAAA	Ruptured Abdominal Aortic Aneurysm
RAPID	Registry Assessment of Peripheral Interventional Devices
ROI	Return on Investment
RRT	Renal Replacement Therapy
RWD	Real World Data
RWE	Real World Evidence
SAVR	Surgical Aortic Valve Replacement
SGHR	Swedish Groin Hernia Database
SMART	Specific, Measurable, Achievable, Results-Oriented, Time Bound
SNOMED-CT	Systematized Nomenclature of Medicine
SOC	Scientific Oversight Committee
SPARCS	Statewide Planning and Research Cooperative System
SPARED	Study of Prostate Ablation Energy Devices
STS	Society of Thoracic Surgeons
SUI	Stress Urinary Incontinence
SVS	Society for Vascular Surgery
TAVR	Transcatheter Aortic Valve Replacement
TEVAR	Thoracic Endovascular Aortic Repair
THA	Total Hip Arthroplasty
TJRR	Total Join Replacement Registry
TKA	Total Knee Arthroplasty
TMD	Temporomandibular Disorders
TMJ	Temporomandibular Joint
TPLC	Total Product Life Cycle
TVT	Transcatheter Valve Therapy
UCSF	University of California, San Francisco
UDI	Unique Device Identifier
UF	Uterine Fibroids
ULTRA	Uterine Leiomyoma Treatment with Radiofrequency Ablation
USRDS	United States Renal Data System
VANGUARD	Venous Access National Guideline and Registry Development
VISION	Vascular Implant Surveillance and Interventional Outcomes Network
VQI	Vascular Quality Initiative

HIGHLIGHTS FROM THE FIRST DECADE

Highlights From the First Decade

INTRODUCTION

The Medical Device Epidemiology Network (MDEpiNet) is a global Public-Private Partnership that brings together leadership, expertise, and resources from health care professionals, industry, patient groups, payers, academia, and government to advance a national patient-centered medical device evaluation and surveillance system.

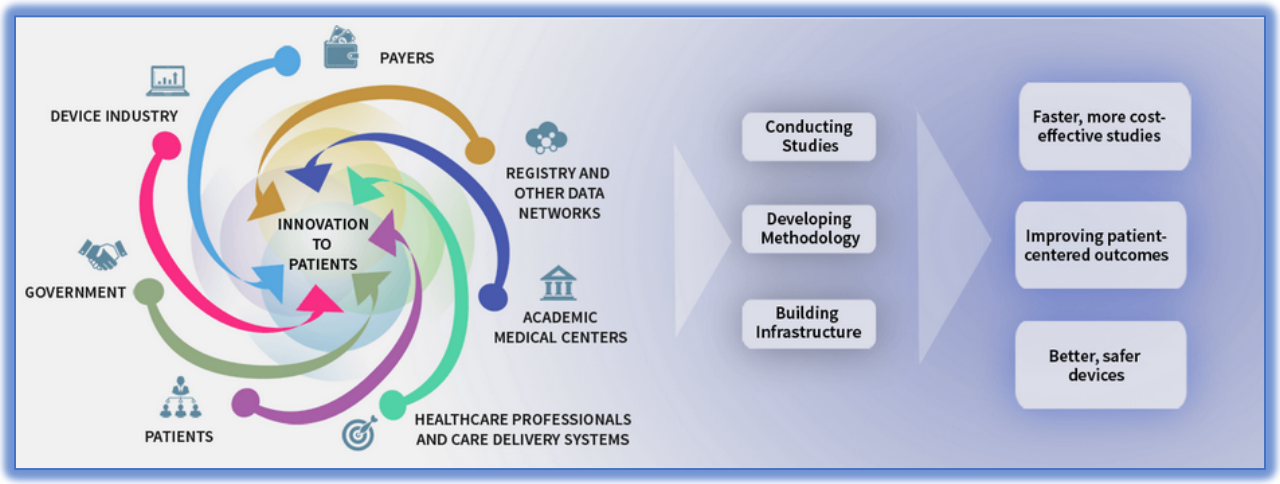
Since its establishment in 2010, MDEpiNet has worked to build a global real-world evidence (RWE) collaborative for health technologies. The MDEpiNet Coordinating Center at Weill Cornell Medicine supports MDEpiNet operations under a cooperative agreement with the US Food and Drug Administration (FDA), and the Center for Devices and Radiological Health (CDRH).

Vision:

MDEpiNet is a global leader in the development of innovative approaches for robust, relevant, and reliable evidence generation throughout the medical device lifecycle.

Mission:

MDEpiNet's mission is to develop and test novel methods, infrastructure, and partnerships for the creation of re-useable real-world data resources and support device evaluation by multiple stakeholders.



MDEpiNet's objectives are to:

- Build strategically Coordinated Registry Networks to advance the collection and use of real-world data
- Develop methodologies to support RWE
- Conduct studies to better understand how devices perform in the real world
- Collaborate with the National Evaluation System for health Technology Coordinating Center (NESTcc) to provide CRN evidence to the NEST

MDEpiNet Coordinating Registry Network (CRN)

CRN is a key MDEpiNet strategy to bring together real-world data from a variety of sources to address the needs of device evaluation for multiple stakeholders. The CRN approach circumvents the limitations of traditional registries and data repositories by building linked data systems from multiple sources.

MDEpiNet broadly defines CRNs based on the International Medical Device Regulators' Forum (IMDRF) definition of registry system as follows: 'Registries are organized systems with a primary aim to increase the knowledge of medical devices contributing to improve the quality of patient care that continuously collect relevant data, evaluate meaningful outcomes, and comprehensively cover the population defined by exposure to particular device(s) at a reasonably generalizable scale (e.g. international, national, regional, and health system)'. CRNs leverage national investments in various real-world data sources to create robust medical device ecosystems in multiple clinical areas.

MDEpiNet CRN Community of Practice

Since 2017, MDEpiNet has been developing Community of Practice (COP) for CRNs to speed the development and maturity of the networks. CRN COP is facilitated and supported by the MDEpiNet Coordinating Center at Weill Cornell Medicine, which is establishing working groups charged with advancing multiple maturity domains through developmental work and implementation. The COP ensures that each CRN focuses on broad and balanced stakeholder participation which leads to strong stakeholder engagement and sustainability. Within the community, the CRN leaders are able to leverage medical device ecosystem stakeholders currently engaged with the MDEpiNet.

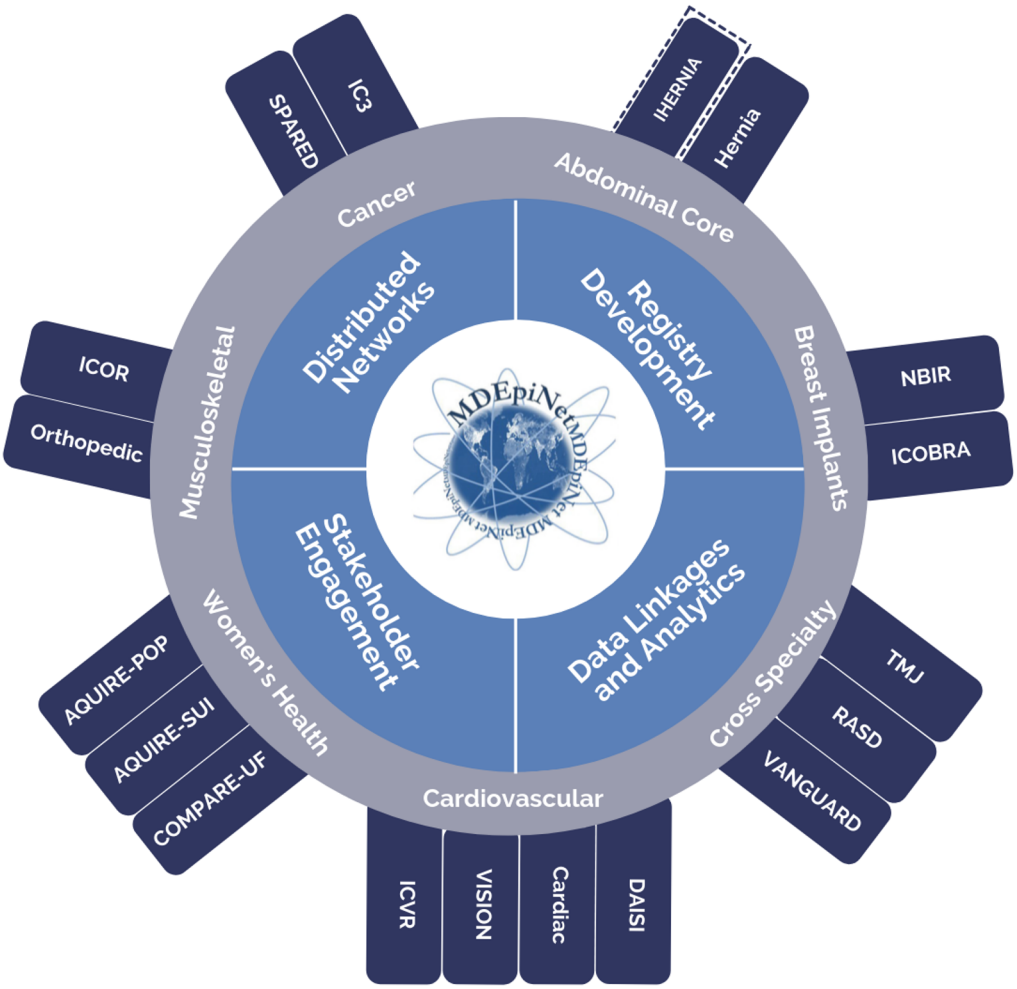
COP's main goal is to promote CRN development as a robust source of evidence for device evaluation and serve as a foundational component of NEST.

Objectives include:

- Development of a repository of materials, tools, and best practices to support the maturity of the CRNs in Device Identification, Quality Improvement/Beneficial Change, Total Product Life Cycle (TPLC), Efficiency, Data Quality, and Governance.
- Development of a CRN assessment tool to evaluate CRN maturity, determine the specific needs of each CRN, and guide the curation of resources to best meet needs - such as a maturity model that can be useful to understand the level of development of each CRN to help plan further development.
- Development of individual CRN-led interdisciplinary tactical teams that directly support CRNs in creating developmental plans and help CRNs track their progress.
- Development of recommendations to the NESTcc on the needs for future infrastructure and methodological development for CRNs.

The NESTcc and MDEpiNet communities recognize the value that CRNs contribute as a real-world data source, and thus, endorse MDEpiNet in its efforts to create a COP. Currently, there are fourteen CRNs operating or under development (see table below).

AREA OF STUDY	COORDINATED REGISTRY NETWORK NAME	EXAMPLE DEVICES EVALUATED
CARDIOVASCULAR	Vascular Implants Surveillance and Outcomes Network (VISION-CRN) and International Consortium of Vascular Devices (ICVR)	Endovascular Aneurysm Repair (EVAR) Carotid Stents Peripheral Stents Peripheral Artery Dilation Balloons Thoracic Endovascular Aortic Repair (TEVAR)
CARDIOVASCULAR	Cardiac Devices Coordinated Registry Network (Cardiac-CRN)	Transcatheter Aortic Valve Replacement (TAVR) Bioprosthetic and Mechanical Valves Intraaortic Balloon Pumps (IABP) Extracorporeal Membrane Oxygenation (ECMO)
WOMEN'S HEALTH	Women's Health Technology Coordinated Registry Network (WHT-CRN) -**A**UGS Urogynecology **Qu**ality **Re**gistry- Pelvic Organ Prolapse (AQUIRE-POP) - **A**UGS Urogynecology **Qu**ality **Re**gistry - Stress Urinary Incontinence (AQUIRE-SUI) -**C**omparing **O**ptions for **M**anagement: **Pa**tient-centered **Re**sults for **U**terine **F**ibroids (COMPARE-UF)	Mesh for Pelvic Organ Prolapse Sterilization Devices (e.g. Essure) Uterine Fibroids Treatment Devices (e.g. Ultrasound Ablation) Synthetic Mid-Urethral Slings
MUSCULOSKELETAL	Orthopedic Devices Coordinated Registry Network (Ortho-CRN) and International Consortium of Orthopedics Registries (ICOR)	Knee, Hip, Shoulder Replacement implants. Spinal Fusion Devices
CANCER	International Cooperative Colorectal Cancer (IC3)	Staplers Endoluminal Stabilization Devices Endoluminal Energy Delivery Devices
CANCER	Study of Prostate Ablation Evidence Development (SPARED-CRN)	Cryoablation Focal Laser Ablation High Intensity Focused Ultrasound Robotic Devices
ABDOMINAL CORE	Abdominal Core Health Coordinated Registry Network (ACH-CRN)	Meshes Fixation Devices Adhesives
BREAST IMPLANTS	National Breast Implants Registry (NBIR) and International Collaboration of Breast Registry Activities (ICOBRA)	Saline-Filled and Silicone-Filled
CROSS SPECIALTY	Venous Access National Guideline & Registry Development Coordinated Registry Network (VANGUARD-CRN)	Venous Access Catheters and Technologies
CROSS SPECIALTY	Robotic Surgery Coordinated Registry Network (RASD-CRN)	Various Surgical Robots
CROSS SPECIALTY	End-Stage Renal Disease Coordinated Registry Network (ESRD-CRN)	New Technologies for Dialysis
CROSS SPECIALTY	Temporo-mandibular Joint Coordinated Registry Network (TMJ-CRN)	Various Joint Fixation Devices



MDEpiNet national and international CRNs and their areas of study

MDEPINET CRN SUMMARIES

1. ABDOMINAL CORE HEALTH CRN

I. Background

Tens of millions of hernia operations are performed worldwide every year to improve patients' abdominal core health[1]. Many products (e.g., meshes, fixation devices, and adhesives) are used in the care of these patients. These products and techniques are designed to last decades but their real-world durability requires large-scale research. Comprehensive surveillance of these products will help address effectiveness and safety in the general population and subpopulations. To address these needs, the Americas Hernia Society Quality Collaborative (AHSQC) was established in 2013. Surgeons in private practice and academic settings created the registry to maximize quality and value of hernia patient care.

The AHSQC mission is to utilize the concepts of continuous quality improvement through patient-centered data collection, ongoing performance feedback to clinicians, and improvement based on analysis of collected data and collaborative learning. In 2018, the AHSQC partnered with MDEpiNet to establish a CRN capable of addressing key questions through research and surveillance of techniques and devices. The AHSQC has taken the lead on the Abdominal Core Health CRN, with aims to fill the knowledge gap related to post market surveillance system in the US and plans to expand globally in partnership with international registries.

II. Objectives

The CRN was initiated with two main objectives. Its first objective is to establish a CRN capable of addressing clinical questions and long-term surveillance of techniques and devices important to the maintenance of abdominal core health. The CRN's second objective is to harmonize the collection of abdominal core health data by identifying and maintaining the common key variables important to patients and patient outcomes.

III. Partnership Structure

The CRN is guided by the AHSQC Foundation, with input from its collaboration partners, including its Executive Council and MDEpiNet leadership. The CRN is supported by several collaborating agencies, foundations, and hospital organizations involved in managing abdominal wall hernia disease.
In addition to MDEpiNet, lead agencies supporting the CRN and the AHSQC include: the Cleveland Clinic Foundation (AHSQC Center of Innovation), The Ohio State University Wexner Medical Center (AHSQC Data Coordination Center), Vanderbilt University Medical Center, and Weill Cornell Medicine (MDEpiNet Coordinating Center). CRN leadership includes Benjamin Poulose (Ohio State and AHSQC) AHSQC, Michael Rosen (Cleveland Clinic and AHSQC), Danica Marinac-Dabic (U.S. FDA), and Art Sedrakyan (Weill Cornell Medicine).

Existing agreements
MDEpiNet Coordinating Center has an existing Data Use Agreement (DUA) with the AHSQC and collaborates with the lead institutions for data analytics. The AHSQC has agreements with

each of its analytic sites including the Cleveland Clinic Foundation, Ohio State University Wexner Medical Center, and Vanderbilt University Medical Center.

International efforts relevant to the CRN

International efforts relevant to the Abdominal Core CRN include several registries with representatives from France Club Hernie, Denmark (Danish Groin Hernia Database (DGHD), Belgium (EuraHS), Spain (Registro Español de Eventraciones), Germany/Austria/Switzerland (Herniamed), and Sweden (Swedish Hernia Registry (SGHR)[2]. In 1992, prospective data collection on hernia surgeries began with the SGHR. Then in 1998, the DGHD was established which and later expanded to include ventral hernias in 2007 (DGHD). These registries were followed by the German Herniamed Registry in 2009; the French Club Hernie in 2011; EuraHS as well as the Spanish Registro Español de Eventraciones in 2012; and the AHSQC Registry in 2013.

IV. Data Infrastructure

Patient population

The AHSQC registry includes patients aged 18 years and older who have had an inguinal or ventral hernia repair operation including umbilical, epigastric, Spiegelian, lumbar, incisional, and parastomal hernias, at a US-based hospital, academic health center, or surgery center. The registry collects demographics and pre-operative, intra-operative, post-operative, and long-term clinical data. As of September 2019, the AHSQC registry includes 54,129 patients treated by 354 participating surgeons in academic and private practice locations across the United States with long term follow up data as long as 5 years for cases conducted early in the registry's history.

Data sources

Aside from registry data, current data sources for linkage include New York State all payer data from the Statewide Planning and Research Cooperative System (SPARCS) as well as Medicare l data. The AHSQC facilitates data management through its web-based proprietary data platform. A main goal of the AHSQC and Abdominal Core Health CRN is to merge data sources to create an effective model for answering critical clinical questions and enabling post-market surveillance.

V. Current Projects and Plans

There are two major ongoing projects for Abdominal Core CRN that include 1) collection of patient perspective reported outcomes for short and long term follow up and, 2) conducting data linkages with the New York State and Medicare claims data.

Patient reported outcome (PRO): The AHSQC plans to develop a questionnaire that is valid for addressing long-term catastrophic mesh related complications. The plan is to decouple the assessment of highly impactful patient events (that patients are very likely to recall) from a clinical visit with a provider to enhance the efficiency of surveillance.

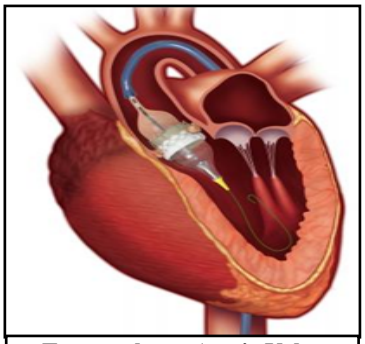
In this effort, the CRN prioritizes the evaluation of outcomes such as readmission, reoperation, surgical site infection, and mesh-related complications, developing PROs sensitive to long-term, low rate, serious complications after hernia repair, and developing a common set of core variables in concert with international partners.

Data linkage projects: The project focus is an assessment of medical device performance through the linkage of AHSQC registry data to claims data. A pilot study was initiated in 2019 to link AHSQC registry data with New York State discharge claims and examine data completeness as well as the potential to determine short and long-term outcomes following ventral hernia repair. After the pilot study is completed and evaluated, the analytic center will link Center for Medicare and Medcaid Services (CMS) claims data to the registry. The CRN anticipates the completion of the first linkage project in January 2020.

2. CARDIAC CRN

I. Background

Over 25% of all deaths in the US are attributed to cardiovascular disease[3]. Cardiovascular interventions are the most common procedures worldwide and often involve the use of implantable devices. Among these procedures, the treatment of aortic stenosis can be performed using surgical or transcatheter interventions. In the US, more than a million such procedures have been captured in the Society of Thoracic Surgeons (STS) and Transcatheter Valve Therapy (TVT) registries over the past decade**.** With the recent growth of transcatheter aortic valve replacement (TAVR), it is important to compare the long-term safety and effectiveness of transcatheter vs. surgical valve implants.



Transcatheter Aortic Valve Replacement

FDA approved the first TAVR device in 2011 for patients who were considered at extremely high risk or inoperable through traditional surgeries [4]. Since then TAVR has been approved for patients considered to be at high, intermediate, and low risk for surgery[4]. With the expansion of TAVR to younger and lower risk patients, there are increasing needs to investigate the long-term durability of TAVR valves[4]. Under this scientific premise, the conversation to establish a Cardiac CRN and engage stakeholders from multiple areas began. The envisioned Cardiac CRN would bring together registries and claims data enabling comparative studies with longitudinal follow-ups. As a step toward building the infrastructure and foundation for the CRN, claims-based studies are conducted to investigate relevant topics. In addition, international efforts for collaboration have been initiated to conduct multi-country or multi-region studies.

II. Objectives

The current objective of the Cardiac CRN is to investigate the short and long-term safety and effectiveness of cardiac valve devices utilizing existing data infrastructures and/or a combination of them. These research aims will provide the evidence needed for clinical and regulatory decision making and timely issuance of societal treatment guidelines supported by data. A secondary objective of CRN is evaluation of percutaneous mechanical cardiac support devices.

III. Partnership Structure

Cardiac CRN is a collaborative effort that involves partners from private and public agencies such as the FDA, CMS, and New York State Department of Health; academic partners include Weill Cornell Medicine and University of California San Francisco (UCSF) and industry collaborators include Abiomed. Cardiac CRN leads include Kathleen Hewitt (American College of Cardiology), John Laschinger (Gore Vascular), Joseph Bavaria (University of Pennsylvania), Ralph Brindis (American College of Cardiology), Vinod Thourani (Piedmont Heart Institute).

Existing agreements
Memorandums of understanding (MOU) have been signed between the MDEpiNet Coordinating Center and CRN leadership to join the CRN COP.

IV. Data Infrastructure

Patient population
Cardiac CRN initiative focuses on patients who are 18 years or older with clinical conditions such as aortic valve replacement and cardiac support services such as percutaneous mechanical cardiac support, balloon pumps, and ECMO.

Data sources
The Cardiac CRN data sources include EHRs, administrative claims, and registry data. The following registry data are proposed for data partners for the CRN:

Proposed data partners	*Description*
Databases	
Adult Cardiac Surgery Database	Database for adult cardiac surgery that was launched in 1989 and contains more than 6.5 million cardiac surgery procedure records and nearly 3,800 participating physicians
General Thoracic Surgery Database	Largest North American clinical database on thoracic surgery that contains more than 556,000 general thoracic surgery procedure records and more than 1,000 participating surgeons
Congenital Heart Surgery Database	Largest North American clinical database in North America on congenital cardiac malformations that contains more than 475,000 congenital heart surgery procedure records and more than 1,000 participating physicians
STS/ACC TVT Registry	Registry on clinical data related to TAVR and transcatheter mitral valve repair (TMVR)

V. Current Projects and Plans

Cardiac CRN's current research projects include valve replacement safety and outcome studies, mechanical cardiac support devices investigating patient morbidities, and coronary bypass grafting studies using the STS registry.

Valve replacement safety and volume outcomes: This study used national and regional claims databases to evaluate the impact of annual and 5-year cumulative volume of surgeons on the short-term outcomes after aortic valve replacement and mitral valve replacement. This study utilized New York State discharge data between 2000 and 2016 and determined mortality, major events, and 30-day readmission following valve replacement.

Another study is focusing on the impact of physician characteristics on the short-term outcome following TAVR procedures using New York State discharge data with linkage to physician data. The New York State discharge data is also used to examine the use pattern of other cardiac procedures, including percutaneous coronary intervention, pacemaker and defibrillator implantation, among patients undergoing TAVR procedures, compared with those undergoing Surgical Aortic Valve Replacement (SAVR) procedures.

Assessment of trends of mechanical cardiac support devices: This study aims to determine the use of mechanical cardiac support devices and patient morbidities. This study uses Nationwide Inpatient Sample and assesses the recent trends of device adoption as well as patient morbidity

profiles and healthcare costs related to the devices. A collaborative initiative was formed with Abiomed, Inc. to assess the feasibility of linking clinical study data and CMS claims data. The investigated cohort was a clinical trial of mechanical cardiac support devices use among percutaneous coronary interventions' patients. The pilot effort will investigate the linkage efficiency between clinical study data and claims database.

Coronary bypass grafting study (CABG): This study compares the incidence of deep sternal wound infections following CABG procedures using bilateral internal thoracic arteries (BITA) graft and non-BITA graft using the STS adult cardiac surgery database. Subgroup analysis is also planned among patients who are obese, patients with diabetes, and patients with chronic lung disease.

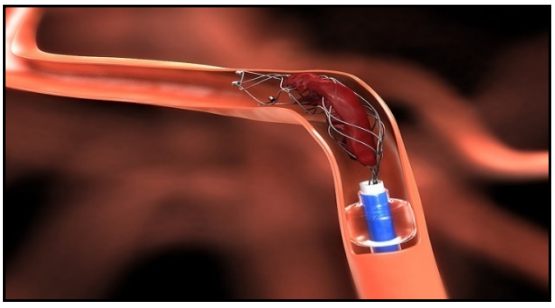
Methodological projects: Currently, Cardiac CRN plans to engage stakeholders to firmly establish the CRN, continuously conduct TAVR/SAVR comparative long-term studies, and develop data linkage and statistical methodologies for CRN studies and/or claims and registry-based studies.

On an international level, methodological work is planned to harmonize data analyses using administrative data. Regional databases from New York State and Ontario will be used to evaluate use of TAVR and short-term outcomes after the procedure. New York State and Ontario regional data will also help evaluate adoption of TAVR and short-term outcomes after TAVR procedures in these two regions.

3. DEVICES USED FOR ACUTE ISCHEMIC STROKE INTERVENTION (DAISI) CRN

I. Background

Every year, approximately 795,000 Americans suffer a new or recurrent stroke and nearly 140,000 people die from strokes of which 87% are ischemic [5]. Stroke is a leading cause of disability and treatment costs exceed 70 billion in the USA. Endovascular mechanical stroke thrombectomy is one of the few devices approved for specific indication of stroke treatment and only limited real-world data is available to study device specific performance. Ccomplexity of the neurovasculature makes it challenging for industry and the FDA to conduct clinical studies for these devices. However, the FDA is committed to supporting the sustainable generation and use of robust RWE in the course of clinical care by patients, providers, and payers, for the purpose of enhancing regulatory and other decision-making.



Thrombectomy

The network for Devices used for Acute Ischemic Stroke Intervention (DAISI) was developed with a focus on acute ischemic stroke that allows the capture of data from actual patient encounters with medical devices and was launched by the FDA on November 9, 2017. Since its initiation, DAISI has held annual meetings to finalize common data elements, imaging data elements in neurothrombectomy trials to assess revascularization, and capabilities of imaging. The focus of the meetings has also been in aligning methodology and infrastructure in considering the recommendations of registry owners and the FDA, finalizing data use models of inflow and access to data from the CRN, and initiating the DUAs for industry trials and society registries to advance the development of the DAISI CRN.

II. Objectives

The objectives of DAISI are to establish a nationwide and international CRN using RWE and develop methodology and infrastructure to support the CRN. DAISI CRN will provide support to establish evidence needed for clinical and regulatory decision-making, building from existing data infrastructure. Through the CRN, real-world practice data and evidence will be accumulated with the potential for post-market device surveillance, expanded indications, and future prospective trials for pre-market approvals.

III. Partnership Structure

DAISI CRN is a collaborative effort initiated by FDA and facilitated by the MDEpiNet Coordinating Center with partners from professional medical societies, neurointerventional device companies, and various government agencies.

The DAISI CRN is led by three clinical co-chairs: Adnan Siddiqui (University of Buffalo), Sameer Ansari (Northwestern), and David Liebeskind (UCLA). The FDA representation is led by Avena Russell and Carlos Pena. The governance council includes stakeholders who coordinate, plan, implement, and execute critical infrastructure controls by providing oversight of the CRN. This includes assisting with development, implementation and sustainability plans. The Governance Council includes members from the FDA, physician specialty societies, industry, MDEpiNet Coordinating Center, and other non-voting participants. The DAISI oversight and data use committees are to be identified to ensure no head-to-head comparisons of competitor devices, including by researchers.

Existing agreements

DAISI CRN is governed by specific DUAs between M2S, MDEpiNet Coordinating Center at Weill Cornell Medicine, participating registries, and participating medical device companies. The professional medical society-supported registry data are stored on a secure server at M2S. CMS DUA is established to conduct for data linkages. Projects are approved by the DAISI Governance Council. All three DAISI CRN co-chairs have an established MOU with the MDEpiNet Coordinating Center to join the CRN COP and are members of the MDEpiNet Executive Operations Committee (EOC).

IV. Data Infrastructure

Patient population

Initial focus of DAISI CRN includes patients with acute ischemic stroke who underwent endovascular mechanical stroke thrombectomy for basilar artery occlusions. Data from professional medical societies' registries and industry sponsored registries are considered for the initial data capture, as well as data from clinical trials including high quality prospective data.

Data sources

Professional medical societies such as the American Association of Neurological Surgeons, Society of Neurointernational Surgery and Society of Vascular and Interventional Neurology are working towards one combined registry for endovascular neurosurgeons, interventional neuroradiologists, interventional neurologists, among others and are in the process of combining data elements with a single vendor partner for data collection (M2S). The data elements come from NeuroVascular Quality Initiative, Quality outcome Database, Get with the Guidelines-Stroke Database, Paul Coverdell National Acute Stroke Registry, Interventional Stroke Therapy Outcomes Registry, and StrokeNet. The American Heart Association (AHA) also plans to contribute to DAISI CRN data infrastructure.

Industry Data: Industry partners, including Cerenovus (J&J), Medtronic, Penumbra, and Stryker Neurovascular, contribute to this CRN. The industry partners provide data on the following

devices: Solitaire (stent retriever), Trevo (stent retriever), Embotrap (stent retriever), and Penumbra Aspiration System (aspiration device).

V. Current Projects and Plans

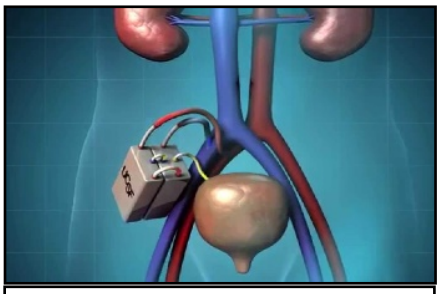
***Basilar artery occlusions (BAO) pilot study*:** The current project of DAISI CRN is to evaluate the safety and efficacy of FDA-approved thrombectomy devices in the real world setting of posterior circulation stroke secondary to BAO. The data can be used to support a regulatory application to expand FDA labeling of stent retriever and/or aspiration thrombectomy devices for this indication.

This project is based on the retrospective collection of data from the DAISI CRN collaboration and will be conducted using the MDEpiNet infrastructure. Initial data capture will be limited to industry-sponsored registries and clinical trials with higher quality due to prospective data entry and adjudicated outcomes in comparison to self-reporting physician/society registries. For this project, DUA with industry partners have been initiated. Primary clinical outcome measures are planned to be captured accurately with modified Rankin Scale (mRS) at 90 days and secondary procedural and safety outcomes have been defined analogous to the previous stroke intervention trials. Common data elements are also approved for the project.

4. END STAGE RENAL DISEASES (ESRD) CRN

I. Background

Kidney disease is the ninth leading cause of death in the US with more than 726,000 people living with end-stage renal disease (ESRD) [6]. Annually, about $114 billion of Medicare funding is spent to care for ESRD patients but there is a major variation in outcomes. Based on the 2018 annual data report from the United States Renal Data System (USRDS), the adjusted mortality rate for ESRD overall was 134 per 1,000 patient-years and 164 per 1,000 patient-years for dialysis patients[7]. Given the critical state of care for Americans with kidney disease, there are various national efforts set forth to improve care for patients with kidney disease and reduce healthcare costs, among which is the ESRD Network Program organized by CMS to promote quality and cost-effective healthcare in kidney disease[8]. CMS maintains the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb), assisted by ESRD networks for data quality. This data is used for both payment for performance programs and quality improvement activities. All regional networks receive CROWNWeb Data from the central ESRD National Coordination center[9].



New Technologies for ESRD Treatment

There are various other programs that collect data in ESRD. The University of Michigan runs the Kidney Epidemiology and Cost Center (KECC), which supports many CMS and Center for Medicare & Medicaid Innovation programs for ESRD data collection and analysis[10]. The U.S. Chronic Kidney Disease Surveillance System is a collaborative effort among KECC, the Centers for Disease Control and Prevention (CDC), and UCSF. Moreover, Veterans Affairs (VA) maintains several ESRD programs through coordination with CMS and the University of Michigan[11]. In addition, a proposal was set forth for a national registry of patients requiring vascular access and other resources relating to renal replacement therapy (RRT). A comprehensive ESRD-CRN would further enable examination of more clinical and broader research questions to improve patients' quality of care and outcomes.

II. Objectives

The objective of the ESRD CRN is to establish an infrastructure to capture RWE of patients' interactions with medical devices. The Kidney Health Initiative (KHI), a public-private partnership between the FDA and American Society of Nephrology (ASN) has developed a Technology Roadmap that defines the priorities and opportunities for innovative RRT. The Kidney Innovation Accelerator (KidneyX), a public-private partnership between the US Department of Health and HHS and the ASN through its prize programs provides the funding mechanism for innovative RRT. Through these collaborative efforts, ESRD CRN aims to ensure the engagement of a variety of key stakeholders including patients in the healthcare ecosystem and a commitment to platform sustainability over time.

III. Partnerships Structure

The ESRD CRN is a collaborative effort that engages organizations such as the ASN, through its public-private partnerships, KHI and KidneyX, FDA, CMS, and Weill Cornell Medicine. The CRN leverages relationships and contacts with industry, patients, and professional medical societies, both in the U.S. and abroad. Patient organizations will be an important part of the collaboration.

Existing agreements

The MDEpiNet Coordinating Center is in the process of establishing MOUs with all participating partners. After the ESRD CRN membership is finalized, MOUs will be finalized with CRN's leadership.

IV. Data Infrastructure

Patient population

The patient population for this CRN includes individuals with ESRD.

Data sources

ESRD CRN data sources include claims and administrative data, as well as registry and other data sources. One of the potential data sources for the CRN is the USRDS, which is funded by the National Institute of Diabetes and Digestive and Kidney Diseases and currently housed by the Chronic Disease Research Group in Minneapolis [12]. This national data system collects, analyzes, and disseminates information on chronic kidney disease (CKD) and ESRD. USRDS produces comprehensive annual reports on dialysis and CKD-related metrics for researchers, regulators, and clinicians. The USRDS works collaboratively with CMS and the United Network for Organ Sharing.

Furthermore, dialysis organizations have a network of multisite electronic medical record (EMR) data. Three large dialysis EMRs, which include DaVita, Fresenius Medical Care, and Dialysis Clinic, Inc., encompass 80% of US dialysis patients, while 14 smaller EMRs comprise the rest of the market. These independent dialysis organizations' data are consolidated though the National Renal Administrators Association health information exchange.

Existing core data sets for chronic kidney disease include the following: (1) Standardized Outcomes in Nephrology, which is an international initiative that aims to establish core outcomes in CKD[13]; (2) the International Consortium for Health Outcomes Measurement Standard Set for CKD, which are recommendations established by a group of physicians, measurement experts, and patients[14]; and (3) the European Association of Rehabilitation in CKD recommendations on measurement and interpretation of physical function[15].

V. Current Projects and Plans

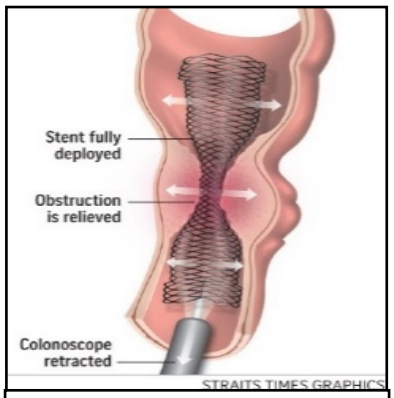
Patient Preference Information Pilot Study: This effort aims to develop innovative methodology for patient engagement and input to build a patient-centered CRN. Specifically, a pilot study will be conducted that develops and incorporates patient preference information data into a core data elements set for ESRD. As one of the prime uses of the data and evidence generated by the CRN is for regulatory decision making, it is vital that PPI regarding benefit/risk trade-offs is captured as valid scientific evidence that can be used by regulators as well as payers, providers, and patients. The CRN platform will capture and expand capacity to identify outcomes most important to patients and aid in the design of clinical trials to reduce the time and cost of execution. Data developed from rapid-cycle clinical trials and linked to sources of real-world data will generate evidence for a variety of decision-making and improve patient care.

Collaboration with KHI: The ESRD prioritizes collaborating with KHI to ensure the engagement of a variety of key stakeholders including patients in the healthcare ecosystem and a commitment to platform sustainability over time. The KHI developed a "Technology Roadmap for Innovative Approaches to RRT,"[16] which defines the priorities and opportunities for innovative RRT and allocates 2019-2022 for the establishment of the ESRD CRN.

5. INTERNATIONAL COOPERATIVE OF COLORECTAL CANCER (IC3) CRN

I. Background

Colon and rectal cancers (CRCs) are the third leading cause of cancer-related deaths in the United States and the third most common cancer in men and in women[17]. Worldwide, more than a million cases are diagnosed each year. Although these cancers have historically been common in western countries, they now are increasing rapidly in Asia and the Middle East. The recent rapid increase in rates of CRC in patients under 50 years of age is also alarming. With advancement in communication platforms, data sharing networks and advanced analytics now available, it is possible to study international patterns of cancer occurrence and treatment. Using multinational resources, superfast computing, artificial intelligence (AI), and a dedicated team of professionals with expert skills and intimate patient contact, the disease outcomes can be improved in treatment and care of CRC patients.



Stent and Colonoscopy used in Colorectal Cancer Procedures

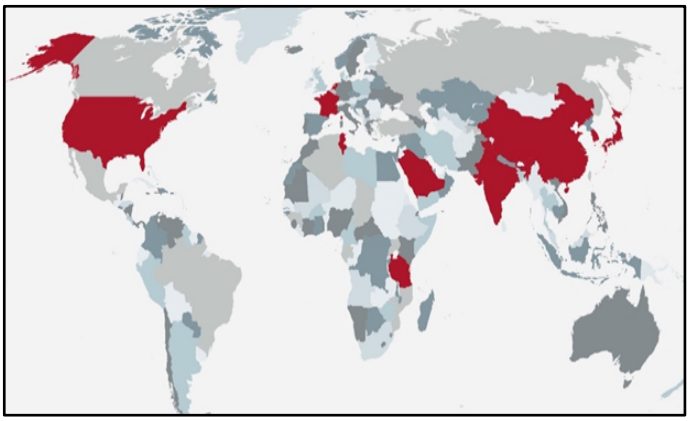
With this in mind, an international team of healthcare professionals formed a study group in 2016, dedicated to examining colon cancer on a global scale. The International Cooperative of Colorectal Cancer (IC3) pursues improvements in the prevention, treatment, and cure of colon and rectal cancers by studying the similarities and differences in therapies around the world and aims to lower health care costs in colorectal cancer therapies. Collaborators at Weill Cornell Medicine and MDEpiNet Coordinating Center are leading this effort to bring talents from multiple disciplines together. Since its founding, the IC3 collaborative has grown in number of researchers, nations, and continents represented. Currently, the IC3 team include participants from specialty hospitals in China, France, India, Japan, the Netherlands, Saudi Arabia, South Korea, Tanzania, Tunisia and the United States that form a consortium for multicenter prospective observational study comparing oncologic and clinical outcomes in surgery for colon cancer.

II. Objectives

The main objective of IC3 is to investigate and compare outcomes of cancer and use of technology in existing databases from each participating country. The secondary objective is to initiate primary data collection from leading institutions within each country to evaluate the devices, treatment methods, and outcomes. The third objective is to plan basic science research as well as cost-analysis studies that have the potential to improve outcomes and advance towards a cure for colon and rectal cancer.

III. Partnerships structure

The IC3 is an international collaborative that partners with the MDEpiNet Coordinating Center. IC3 is led by Jeffrey W. Milsom (Weill Cornell Medicine) with input from Art Sedrakyan and his team from the MDEpiNet Coordinating Center.



The IC3 collaborators represent countries from global chapters that are listed below:

Country	*Beijing*
China	Beijing Friendship Hospital and West China Hospital
Japan	NTT Medical Center Tokyo, Oita University, Osaka University, Saitama University, Shimane Prefectural Hospital, Keio Hospital
Tanzania	Benjamin Mkapa Hospital
India	Columbia Asia Hospitals Bangalore
The Netherlands	Erasmus University Medical Center
Saudi Arabia	King Faisal Specialist Hospital & Research Centre and King Saud University Medical Center
South Korea	Korea University Anam Hospital
France	Timone Hospital
Tunisia	University Hospital Farhet Hached
The United States	Weill Cornell Medicine and New York Presbyterian

Existing Agreements

MDEpiNet Coordinating Center and IC3 have subcontract agreements with all entities under the protocol titled "Multicenter Prospective Observational Study Comparing Oncologic and Clinical Outcomes in Surgery for Colon Cancer in Specialty Hospitals".

IV. Data Infrastructure

Patient population

The patient population includes colorectal cancers patients from various countries around the world, including China, India, Tanzania, Japan, Tunisia, France, The Netherlands, Saudi Arabia, and South Korea.

Data sources

IC3 utilizes EHRs and registry data for its research projects, including records from its international partners like Japanese Society for Cancer of the Colon and Rectum (JSCCR) and the aforementioned hospital systems. Data-sharing agreements are underway for countries such as Korea University Anam Hospital and NIIT Medical Center in Tokyo.

V. Current Projects and Plans

IC3's main ongoing studies include evaluating survival following CRC surgery in the US and Japan. The first three studies evaluated the 5-year survival after CRC surgery using US SEER cancer registry and Japanese registry data. US-based claims analysis was performed to evaluate

the use and outcomes of bowel stenting in colorectal cancer patients as palliative treatment and as a bridge to surgery.

IC3's current plan is to expand data infrastructure and data-sharing platforms internationally, using Research Electronic Data Capture (REDCap) or High-Performance Integrated Virtual environment (HIVE) for data capture. A meeting was held in May 2019 that trained coordinators and surgeons to use the REDCap app. The priority is to finalize REDCap data collection forms and finalize data sharing agreements.

The IC3 team is working to advance the international efforts and explore funding opportunities. The Cornell team is planning to run a survey among partner institutions to collect background information on colorectal cancer treatment in order to create an information sheet to be used for potential fundraising for IC3.

6. NATIONAL BREAST IMPLANTS REGISTRY (NBIR) CRN

I. Background

More than 300,000 breast implant surgeries including augmentation and other reconstructive procedures are conducted annually in the US[18]. Given recent concerns related to these devices there is a need to evaluate these technologies and improve quality of care for patients that undergo breast implant procedures. To address these gaps, the NBIR was developed as a collaboration of FDA, The Plastic Surgery Foundation (PSF), The American Society of Plastic Surgeons (ASPS), as well as patients and breast implant device manufacturers. The NBIR database is a prospective, opt-out, non-interventional, population-based, outcomes and safety surveillance registry and quality improvement initiative. It collects data at the time of operation and any subsequent reoperations for all US patients receiving breast implants. Collecting this information will allow the NBIR, plastic surgeons, and breast implant manufacturers to identify trends and other helpful safety information.

Silicone Filled Breasts Implants

The NBIR is a quality improvement initiative and safety surveillance registry that collects clinical, procedural and outcomes data at the time of operation and any subsequent reoperations for all US patients receiving breast implants. NBIR collaborates with breast implant manufacturers that can use the registry to further investigate the device safety and improvement. The manufacturers can use the registry for Device Tracking purposes required by the FDA. Additional aims of the NBIR include serving as a potential infrastructure for post-market studies. NBIR data can be used to study trends related to all breast implant procedures.

II. Objectives

The main objectives of the NBIR are to strengthen the national infrastructure for post-market surveillance of breast implants and communicate timely, accurate, systematic, and prioritized assessments of breast implants throughout their marketed life. The NBIR is aiming to 1) leverage high-quality, standardized and structured data; 2) identify potential safety signals in near real-time from a variety of privacy-protected data sources; 3) reduce the burdens and costs of medical device post-market surveillance; and 4) facilitate the clearance and approval of new devices, or new uses of existing devices. Additional aims of the NBIR include serving as a potential infrastructure for post-market studies; as well as providing an infrastructure for device manufacturers to facilitate the post-implant component of their device tracking data collection.

III. Partnership Structure

NBIR CRN has partners from government agencies such as the FDA, professional societies like the ASPS, The PSF, and MDEpiNet, as well as the device manufacturers and industry partners, Allergan, Sientra, and Mentor, and patient groups.

NBIR CRN is led by Andrea Pusic (Harvard Medical School) who also co-chairs the NBIR Steering Committee with Charles Verheyden (Baylor Scott & White Health). The NBIR Steering Committee is responsible for developing and implementing the strategic goals of the NBIR and is the governing body that oversees registry operations, including the successful implementation, monitoring, and management of resources and activities.

IV. Data Infrastructure

Patient population

The NBIR patient population includes patients who have had breast implant procedures in the US. There are thousands of patients already registered with the registry.

Data sources

Electronic Case Report Form (eCRF): The NBIR Data is collected at two key clinical points: 1) Initial Implant Procedure and, 2) Any subsequent Reoperation. It also collects other information about the patient and patient procedure, including their contact information for manufacturer follow-up related to device tracking, information about their medical history, their breast implant operation and the implant itself, and any complications that may have occurred from the patient's breast implant operation.

NBIR Barcode Scanning App: Another source of data is the NBIR Barcode Scanning App, which can be used to assist NBIR participants with the data entry of implanted device-specific data elements. The app scans and decodes both Linear and 2D breast implant device barcodes and pushes the data contained within the barcode to the NBIR directly from FDA's Global Unique Device Identification Database (GUDID). Electronic data captures with bar code scanning to help decrease burden and improve data quality. More information on how to use the app can be found in the following link: https://www.thepsf.org/documents/Research/Registries/NBIR/how-to-use-the-nbir-barcode-scanner.pdf.

PROFILE Registry: The Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma etiology and Epidemiology (PROFILE) is based on scientific reports of possible association between Anaplastic Large Cell Lymphoma (ALCL) and breast implants. ASPS/PSF and FDA have collaborated to conduct research and launch the PROFILE to increase the scientific data on ALCL in women with breast implants. The primary goal of this registry is to better understand the role of the breast implants in the etiology of primary ALCL in women with breast

implants. It can also help identifypotential risk factors and criteria detection and management of this disease. Additionally, the confirmed cases in the registry of primary ALCL in women with breast implants will be available for analytical epidemiological studies.

Just as NBIR, the PROFILE Registry captures data necessary to describe patient demographic characteristics and other medical history, implant procedure information, characteristics of the implant, clinical presentation, pathologic findings, and clinical course, treatment and treatment outcomes of patients with primary Breast Implant Associated ALCL.

V. Current Projects and Plans

In October 2018, the NBIR was launched broadly for use by everyone who performs breast implant procedures in the US. One-year post-launch, the NBIR now has over 500 sites registered to participate and over 4800 patient visits. An annual report summarizing key findings from year one of registry operations is currently underway. As of July 1, 2019, the NBIR can be used as an infrastructure for device tracking. Through this mechanism, we can increase registry participation among surgeons and minimize duplicate data entry in the operating room. The NBIR Steering Committee continues to strategize methods to increase participation and case capture.

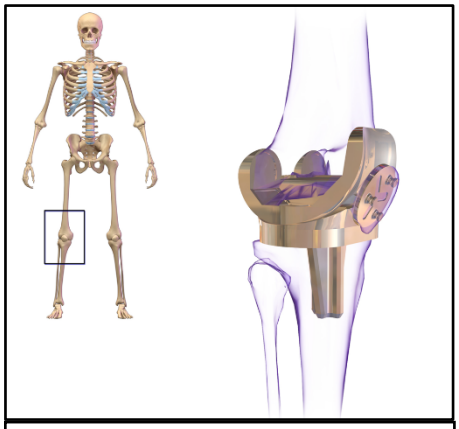
ASPS/PSF is in the process of developing a breast implant symptom severity scale to examine common signs and symptoms that patients receiving breast implants may encounter. Upon completion of a Delphi Panel to identify these common symptoms, we will pilot the inclusion of PRO measurement tools for these symptoms within the NBIR. We will identify 10-20 high performing NBIR sites and invite them to participate. Upon completion of the pilot, which we anticipate could take between 12-18 months, we will broadly open up PROs within the NBIR.

International effort: The International Collaboration of Breast Registry Activities (ICOBRA) CRN based in Australia aims to encourage a collaborative approach to sharing registry science and registry data, and support emerging and existing breast device registries to enhance their effectiveness. The US was an inaugural signatory and there are now over 20 signatories. International collaboration including data points from six countries: Australia, Austria, The Netherlands, Sweden, United Kingdom, and United States as well as close partnership with the Australian Breast Device Registry helps identify data sources for this effort. Some of the benefits of a collaborative approach are a standardized minimum dataset, amplified dataset, facilitated data linkage and data comparison, enabled development of evidence-based international early warning systems.

7. ORTHOPEDICS CRN

I. Background

Total joint replacement is the fastest growing elective device-based surgery with over 1.2 million hip and knee replacements performed annually in the US[19]. With the aging of the baby boomer generation, higher rates of osteoarthritis diagnoses, innovative treatment options, and the growing demand for improved mobility and quality of life, volumes of procedure are projected to reach 3 million annually in the next two decades[20]. The performance of thousands of hip and knee devices is the most critical device safety issue in the US today. There is an increased need of network to maintain resources and address the safety and effectiveness of new devices that enter routine usage, as major evidence gaps in device performance exist as well as a need for novel partnership that can build a national infrastructure to fill the gaps in evidence.



Total Knee Replacement

Building from the major successes of the International Consortium of Orthopedic Registries (ICOR), the Orthopedics (Ortho) CRN aims to bring together national registries in the US in a systematic way and obtain longer, more complete patient follow-up via data linkages. Ortho CRN utilizes multiple data networks, allowing researchers to conduct comparative effectiveness studies within a short period after the devices' market entry. Linkages between registries and state/national claims datasets will also significantly benefit registry efforts, including validation of complications, increased follow-up rate, ability for risk adjustment, and increased information about patient characteristics. This in turn allows the network of registries to contribute to hospitals by providing more detailed, useful reports.

II. Objectives

The objective of the Ortho CRN is to share knowledge about best practices for data collection, linkages with claims and other data systems, analytics, and dissemination, which in turn allows registries to better serve as a high-quality data source utilized for research and the generation of useful reports. The major goals are to develop a framework for a US total joint replacement registries' collaboration to conduct signal detection and confirmatory studies using existing US registry data; to collaborate with international registries to investigate device signals and conduct comparative effectiveness research; to provide a platform for collaborative post-market surveillance of implants in the US.; and to facilitate tracking of implants for optimal regulatory process.

III. Partnership Structure

The Ortho CRN is made possible by the collaboration and partnership between the MDEpiNet Coordinating Center, the FDA, and representatives of orthopedic registries such as the American Joint Replacement Registry (AJRR), Kaiser Permanente's (KP) Total Joint Replacement Registry

(TJRR), the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR) registry and hospital for Special Surgery (HSS) registry, and The Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI).
The CRN has a Steering Committee/Working Group that consists of representatives from the FDA, regsitries and relevant organizations.

Ortho CRN is led and supported by the team of collaborators that include Liz Paxton (KP), Raquel Peat (FDA), Art Sedrakyan (Weill Cornell Medicine) and Danica Marniac-Dabic (FDA).

International effort: Globally, the International Consortium of Orthopedic Registries (ICOR) worked to bring together global partners to facilitate this registry. More information about ICOR can be found in the *next section*.

Existing agreements
The Ortho CRN leads have established MOUs with the MDEpiNet Coordinating Center to join the CRN COP and are members of the MDEpiNet EOC.

IV. Data Infrastructure

Patient population
Currently the CRN is focusing on all patients undergoing hip and knee surgery. Starting in 2010 the CRN also focused on patients undergoing shoulder and spine surgery in the US.

Data sources
Kaiser Permanente (KP) has several inter-regional implant registries that capture patient demographics, implant characteristics, surgical techniques, and outcomes, including a variety of orthopedic devices/surgeries such as total knee/hip, anterior cruciate ligament (ACL), spine, shoulder, and hip fracture. The device registries were developed to address recall situations, disseminate best practices, identify patients at risk for failure and assess clinical effectiveness of total joint replacement implants. In addition to the inter-regional implant registries, KP also has the world's largest private sector EHRs, KP HealthConnect®. Interconnection of all patient encounters within the EHR allows extraction of laboratory, procedural, diagnostic, pharmacy, and hospital encounters for all members in every patient care setting across KP's regions. These data supplement inter-regional implant registries and provide a foundation for longitudinal assessment of medical devices.

AJRR captures hip and knee arthroplasty procedures from multiple sites across the US. Patients are followed up between 270 and 365 days after the procedure. AJRR reports that 1,735,066 hip and knee replacement procedures that enrolled from 1,312 participating sites with 9,172 surgeons with all 50 US States represented. The registry conducts linkages with Medicare to obtain revision rates and other relevant outcomes.

MARCQI started in 2012 as a major statewide quality improvement initiative to improve the care of hip and knee joint replacement surgery procedures. Since 2012, more than 70,000 hip replacements and over 130,000 knee replacements have been included in the registry and almost all hospitals and surgeons in Michigan participate in the registry. The registry is funded by Blue Cross and Blue Shield of Michigan and Blue Care Network, which enables longitudinal assessment of revisions and other endpoints.

FORCE-TJR registry, created and managed by University of Massachusetts Medical School's Department of Orthopedics, collects, and analyzes comprehensive post-TJR data on more than 24,000 patients treated by a diverse and representative group of surgeons and hospitals in 24 states (urban and rural, academic and community hospitals, low and high-volume practices) to date. Patient enrollment is ongoing and exceeded 35,000 in 2015. Uniquely, patients consent to (a) complete annual patient-reported outcomes (pain and function) and (b) report adverse events and surgical revisions at intervals for years into the future. A secure web-based data collection platform is used for direct data submission from patients and clinicians. Longitudinal data is complete with at least 85% follow-up for patient-reported outcomes.

V. Current Projects and Plans

ORTHO CRN's are currently invested in several research and projects including the objective performance criteria development (OPC) project, spine and shoulder project, and several linkage projects that are described below:

OPC development project: The OPC development for hip and knee replacements project is led by the Ortho CRN team from MDEpiNet, FDA, and KP to expand the capacity of the CRN to produce reliable and relevant evidence, and align with international partnerships. The aim is to develop OPC measures for major outcomes following primary hip and knee replacements, utilizing RWE, including registries and claims data within the Ortho CRN network and literature review. The project primarily focuses on 2-year endpoints of all-cause and cause-specific revisions as well as disease specific and general health PROs. Benchmarking methods and literature review are planned to be used to develop OPCs. The project aims to explore the feasibility to use real-world data sources to scientifically develop OPC that could be utilized in pre-market IDE clinical studies. This project will help FDA, device innovators and manufacturers to adopt least burdensome approach for evidence generation and reduce the costs of clinical trials. For many 510K devices, OPCs will encourage evidence-based competition among manufacturers.

Spine and shoulder projects: The CRN focuses on the evaluation of several orthopedic conditions and treatments including pediatric spinal disorders, adult spinal disorders, shoulder and elbow surgery, osseointegrated prosthesis for amputees, and foot and ankle surgery. Currently 1-year data for shoulder surgery has been assessed, the elbow surgery evaluation has begun, and preliminary results have been generated in the evaluation of rotator cuffs.

Data linkage projects: Ortho CRN has completed linkages between registries and state/national claims datasets to significantly advance registry efforts, including validation of complications, increased follow-up rate, ability for risk adjustment, and increased information about patient characteristics. Currently four registries are partners in this national effort and havecreated core minimum data for harmonization of analytic process and conducted linking clinical registry

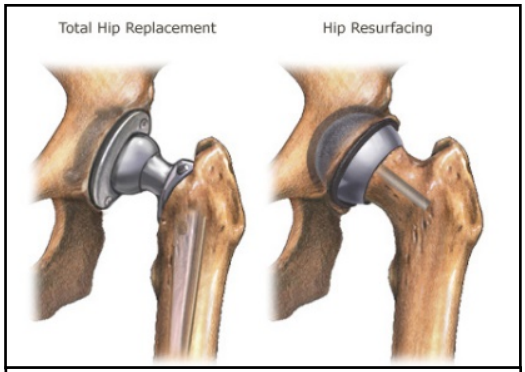
information from diverse registries in the orthopedic setting. AJRR is currently leading the linkages of CMS data and third-party payer claims.

The completed claims data linkage demonstration projects highlight the importance of linking registries and other existing administrative data to provide necessary infrastructure in the US for medical device evaluation. This work serves as the foundation for future clinical studies to general US evidence and provides a mechanism for surveillance within the US. The Ortho CRN also leverages the supplementary device attribute database developed by its international chapter ICOR.

8. THE INTERNATIONAL CONSORTIUM OF ORTHOPEDIC REGISTRIES (ICOR) CRN

I. Background

The ICOR (http://www.icor-initiative.org/) is a worldwide initiative that has enabled collaboration of orthopedics registries. There are more than 10 million patients enrolled in these registries worldwide that capture all implantable devices on the market. Various stakeholder come together to build this consortium to collaborate and focus on understanding the variability in outcomes of total hip arthroplasty (THA) and total knee arthroplasty (TKA) devices. National and international orthopedics registries that are at various stages of development participate in building this comprehensive network that helps utilize the international data sources and methods for post-market evaluations and surveillance of orthopedic devices. This initiative has built methodological infrastructure to evaluate orthopedic implant safety and effectiveness and assist participating organizations with the creation of a learning network.



Hip Replacement Devices

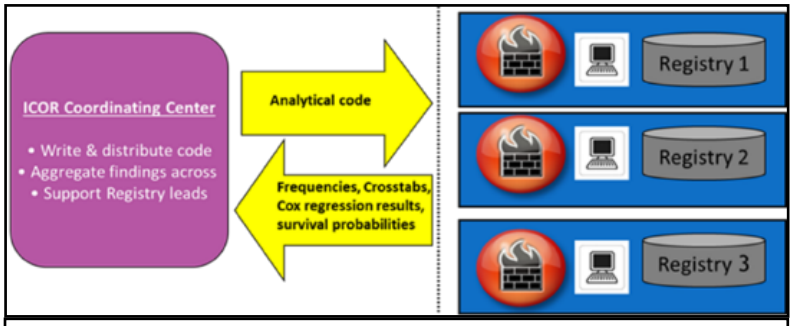
ICOR was launched in 2011 with an inaugural conference that was held on May 9-10 at the headquarters of the FDA in Silver Spring, MD. The conference attendees included 73 stakeholders from 29 orthopedic joint registries (total joint arthroplasty) representing 14 nations as well as non-registry stakeholders representing industry. Attendees also included Agency for Healthcare Research and Quality (AHRQ), National Institute of Health (NIH), CMS, academia, device regulatory agencies, device cataloguing experts, insurers and payers. Since then, ICOR has expanded internationally to facilitate and enhance inter-registry collaboration through supportive infrastructure and the development of a distributed data network that uses innovative approaches to analyze the data.

II. Objectives

The major objectives of ICOR have been developing priorities that reflect the consensus of different stakeholders, addressing the impact of rapid innovations in devices, filling in the gaps in device identification (in the absence of unique identifiers), using a systematic approach to medical device research, addressing large evidence gaps on new and evolving devices as well as the high cost of trials in both the pre-market and post-market area, as well as understanding individual device performance. The ICOR aimed to leverage resources and expertise from multiple stakeholders toward the development and application of innovative methods to address methodological gaps in studying orthopedic devices.

ICOR has been hugely successful and has achieved all its objectives. As a pioneering effort in a space of international collaborations, ICOR enabled more than 30 primary investigations that

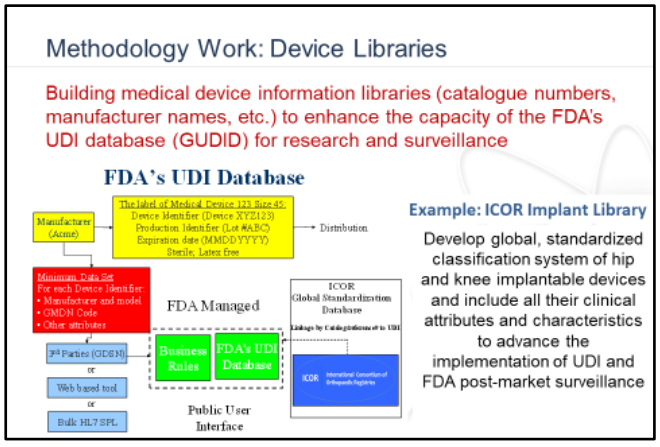
addressed the most urgent issues in orthopedics such as performance of metal on metal implants, various bearings, and new technologies. ICOR developed an innovative distributed data network model to study the performance of devices and advanced the methodological approaches to analysis of registry data. Examples include:



Ortho CRN's distributed data network to perform effectiveness studies

1. International comparative evaluation of knee replacement with fixed vs mobile non-posterior stabilized implants.
2. International comparative evaluation of knee replacement with fixed vs mobile posterior stabilized implants.
3. International comparative evaluation of fixed cruciate retaining versus fixed posterior cruciate substituting total knee replacement.
4. Evaluation of head size on outcomes of hip replacement in a combined analysis of six international registries focusing on metal on highly cross-linked polyethylene bearings.
5. Comparative Effectiveness of Ceramic on Ceramic Implants in Stemmed Hip Replacement: Multinational Study of Six International Registries.
6. Distributed analysis of hip implants using six national and regional registries comparing metal on metal to metal on highly cross-linked polyethylene bearings in uncemented THA in young patients.
7. THA risk of revision: Metal on conventional versus metal on crosslinked results from six international registries.
8. Multinational Comprehensive Evaluation of Fixation Method Used in Hip Replacement: Interaction with Age in Context.

Another important objective and achievement of ICOR was the development of internationally harmonized *Implant Library for Orthopedic Implants.* The creation of an orthopedic implant library and relevant nomenclature for device attributes and characteristics is the critical link with clinical and research community interested in devices from post-market surveillance and research perspectives when using registries. In orthopedics, large registries or networks of registries capture device information on a very detailed level and can become particularly important for active surveillance and post-market evaluation. The registries can also provide denominator data for specific devices implants and facilitate comparative studies.



This is especially the case in settings where participation with the registry is mandatory or the registries have over 90% coverage of the exposed population.

The FDA UDI rule mandates that manufacturers must label medical devices with an UDI identifier to populate the GUDID, a public hub of standardized UDI data intended to integrate with billing, inventory, and electronic surveillance. The ICOR implant library of clinical attributes and characteristics is as an adjunct database to GUDID. The ICOR library facilitated standardized processes that enabled the development of a universal implant library that all registries could use for consistency of reporting and enhanced inter-registry collaboration.

III. Partnership Structure

The ICOR brought together global partners and helped launch the US chapter (ICOR-USA) that is now developing a US national device surveillance network in the orthopedic device space.

Existing agreements

Many international registries have established MOUs with the MDEpiNet Coordinating Center and are members of MDEpiNet International Committee.

IV. Data Infrastructure

Patient population

ICOR CRN's patient population came from participating countries and registries listed below in Table 1.

Data sources

The ICOR uses registry data from and collaborates closely with the International Society of Arthroplasty Registries (ISAR); the list of registries maintained by the ISAR can be found below:

Table 1. List of international ISAR registries

Country	*Registry*
USA	Kaiser Permanente National Total Joint Registry, AJRR, FORCE-TJR
	The Study Group - University of Arizona, Mayo Clinic Total Joint Registry, Michigan Arthroplasty Registry Collaboration Quality Institute, Hospital for Special Surgery Quality Institute, Harris Joint Registry
Canada	Canadian Joint Replacement Registry
Ireland	Irish National Orthopaedic Register
United Kingdom	Scottish Arthroplasty Project, National Arthroplasty Registry of the Malawi Ortho Association and National Joint Registry
The Netherlands	Dutch Arthroplasty Registry
Portugal	Portuguese Arthroplasty Register
Spain	Catalan Arthroplasty Register - Registre d'Artrplàsties de Catalunya
Switzerland	Geneva Arthroplasty Registry and Swiss National Joint Registry
Italy	Register of Orthopaedic Implants and Italian Arthroplasty Registry
Germany	EPRD Deutsche Endoprothesenregister gGmbH (German Arthroplasty Register)
Denmark	Danish Knee Arthroplasty Register
Norway	The Norwegian Arthroplasty Register
Sweden	Swedish Hip Arthroplasty Register and Swedish Knee Arthroplasty
Slovakia	Slovak Arthroplasty Register
Lithuania	Lithuanian Arthroplasty Register
Romania	Romanian Arthroplasty Register
Egypt	Egyptian Community Arthroplasty Register
Iran	Iranian Joint Registry
Pakistan	Pakistan National Joint Registry
India	Indian Society of Hip & knee Surgeons
Japan	Japanese Arthroplasty Register
Australia	Australian Orthopaedic Association National Joint Replacement Registry
New Zealand	The New Zealand Joint Registry

V. Current Projects and Plans

The current focus of the ICOR CRN is to facilitate the ICOR-USA (Ortho-CRN) project development focusing on OPC for hip and knee replacement devices. The project will have global implications and will also lead to future projects such as objective performance goals (OPG) development for shoulder and spine devices.

9. ROBOTIC ASSISTED SURGICAL DEVICES (RASD) CRN

I. Background

Use of robotic systems for minimally invasive surgery has rapidly increased during the last decade. Intuitive surgical reports indicate that over a million robotic procedures are performed in the United States across various surgical specialties[21]. A robotic surgery registry is being developed to systematically collect device-related and process-related real-time data. The U.S. FDA/CDRH has identified this as a priority area for evidence development and helped develop a collaborative effort. Development of this registry has a potential to support pre-market regulatory decision-making, to streamline the development of innovative products in patient care, as well to establish monitoring and safety innovation of RASD.

Robotic Devices Used in Surgical Procedures

A landmark RASD Registry consensus conference was convened by the Institute of Surgical Excellence (ISE) in September 2016, which brought together 44 key opinion leaders through a public – private partnership to determine the minimal data set that would be needed for a RASD Registry. The participants included robotic surgery experts, registry experts, government representatives, and society representatives. Through the consensus conference discussions and two additional post-conference Delphi surveys completed by meeting participants, a minimal intraoperative and operative room staff experience data set was agreed upon that will be included in the RASD Registry. In an update meeting in 2019, it was agreed upon to utilize procedures related to gynecologic cancers in the pilot study since there is some controversy regarding the efficacy of minimally invasive procedures for the treatment of these cancers.

II. Objectives

The RASD CRN's main objective is to design, develop, and successfully implement a real-world data robotic surgery data registry that systematically collects in near real-time device-related and process-related data, is interoperable with clinical databases, and utilizes those data to improve device safety, surgeon/team performance, and public health. To further this mission, the CRN aims to conduct a six-month pilot study in three to six hospitals to test the RASD registry data set, optimize the efficiency of collecting the data, and refine data security measures. Findings from the pilot study will be incorporated into the data collection workflow and the development of a national RASD registry that is anticipated to be completed and ready for rollout in the second quarter of 2021.

III. Partnership Structure

RASD CRN is a collaborative effort of ISE with MDEpiNet Coordinating Center at Weill Cornell Medicine and FDA. It is led by ISE with data vendor partners such as Medstreaming/M2S.

ISE is a 501(c) (3) non-profit organization dedicated to improving surgical care and patient outcomes with a mission to support the implementation of safer solutions to complex surgical interventions and emerging technologies. ISE utilizes a systems-based approach to bring together key stakeholders to identify issues, set goals, facilitate collaboration, and develop education and training tools to assess and fill gaps in creating a change in informing healthcare consumers. ISE's leadership includes Jeffrey Levy, Martin Martino, Nazema Siddiqui, John Porterfield, Carla Pugh, and Dimitrios Stefanidis. ISE also has an advisory board consisting of medical experts in the fields of Cardiology, Cardiothoracic, Colorectal, Neurosurgery, Neonatology, Ob/Gyn, Orthopedics, Pediatrics, Urology, and Vascular medicine. The advisory board also includes experts in non-profit organizations and law.

The registry network is supported by Jeffery Levy (ISE), Binita Ashar (FDA), Danica Marinac-Dabic(FDA), Jay Redan (University of Central Florida) and Art Sedrakyan (Weill Cornell Medicine).

Existing agreements
There is an established MOU between MDEpiNet Coordinating Center and the CRN led by ISE. There is also an established MOU between ISE and the Society of Robotic Surgery (SRS).

IV. Data Infrastructure

Patient population
RASD CRN is in the development stage and aims to collaborate with academic centers and hospitals as well as public private partners across the US to capture patient populations of various demographics and backgrounds. The patient population to be captured in the pilot study include those undergoing hysterectomy, radical hysterectomy, lymph node resection, and oophorectomy. This patient population will be expanded with the roll out of a national RASD registry following the pilot RASD registry to also include prostectomy, nephrectomy, cystectomy, colorectal resection, and lobectomy.

Data sources
The data sources for the registry are EHRs, RASD data output, claims and other registry data.

V. Current Projects and Plans

RASD CRN is working towards identifying relevant clinical data elements, establishing core-minimum dataset for women's health pilot RASD registry in cervical, uterine and ovarian cancer. For this initiative, ISE plans to develop society partnerships based on the current partnership with the SRS for registry participation and dissemination. Anticipated society partners for the pilot study are women's health societies such as the American College of Obstetricians and

Gynecologists (ACOG), Society of Gynecologic Oncology, and the American Association of Gynecologic Laparoscopists.

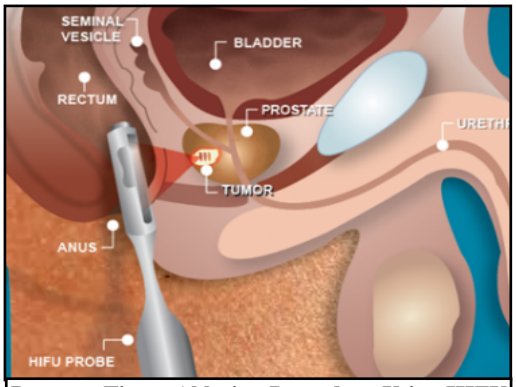
The CRN is finalizing contractual agreements with technology/industry partners to develop and manage the registry, as well as expanding the steering committee to include all major stakeholders. It is also working on finalizing hospital systems to participate in a pilot study. RASD CRN is also exploring fundraising opportunities from its partners and RASD manufacturers. The CRN's goal is to conduct the pilot studies in 2020 and disseminate the results with plans to pilot and roll out the national registry by 2021.

Claims based robotics research projects are focusing on evaluations of the adoption and comparative effectiveness. Prostatectomy, thoracic and colo-rectal surgery outcomes studies have been completed. There is ongoing study to determine outcomes after robot-assisted versus open cystectomy for bladder cancer.

10. STUDY OF PROSTATE ABLATION RELATED ENERGY DEVICES (SPARED) CRN

I. Background

Prostate cancer is the most commonly diagnosed solid tumor in US men with estimated 174,650 new cases in 2019 and estimated deaths 31,620.[22] Men diagnosed with prostate cancer have multiple options when choosing treatment, including radiation therapy, radical prostatectomy, active surveillance, and partial gland ablation (focal therapy). In contrast to traditional whole gland treatments such as radiation therapy and surgery, which have long-term data available to guide patient and clinician decision-making, focal therapy is a newer treatment with an absence of long-term data. The rapid adoption of novel but unproven technologies for prostate ablation has created the need to monitor the safety and effectiveness in the post-market arena. Following the recent approval of high-intensity focused ultrasound (HIFU) for ablation of prostate tissue, it is expected that more companies with novel technologies will apply for FDA clearance/approval.



Prostate Tissue Ablation Procedure Using HIFU Probe

In light of the ever-expanding options to treat prostate cancer, the MDEpiNet Coordinating Center at Weill Cornell Medicine, in collaboration with a multi-disciplinary group of stakeholders, has initiated theSPARED CRN. This effort will collect clinical information regarding patient and treatment characteristics as well as outcomes following prostate ablation. Armed with data from SPARED, clinicians will be better equipped to help inform men with prostate cancer regarding the pros and cons of focal therapy. In addition, industry will be better-informed regarding opportunities for technology improvement, and payers will be armed with effectiveness data for decisions regarding coverage of novel technologies.

II. Objectives

The overarching objective of SPARED CRN is to create a comprehensive clinical database to facilitate patient-centered research for existing and emerging focal therapy technologies. The acquisition of nationally representative treatment characteristics and clinical outcomes for prostate ablation technologies will serve to guide clinical decision and policy making in the absence of randomized clinical trials. The incorporation of the unique device identifier for medical devices in the SPARED registry will aid to identify and address device-related safety issues. This registry is a multi-institutional effort to prospectively obtain real-world clinical data on prostate-sparing ablative devices including HIFU, cryotherapy, focal laser ablation, irreversible electroporation, photodynamic therapy, and future technologies.

III. Partnerships Structure

The SPARED registry is an effort facilitated by the MDEpiNet Coordinating Center at Weill Cornell Medicine in collaboration with a multi-disciplinary group of stakeholders. Collaborators include Weill Cornell Medicine, Johns Hopkins University, Memorial Sloan Kettering, University of California (Los Angeles, San Diego, San Francisco, and Irvine), Columbia University, MD Anderson, Stanford University, University of Chicago, University of Michigan, University of Texas Medical Branch, three community sites within Healthtronics/cryo on-line database (COLD) registry, as well as other investigators, academics, vendors and industry partners.

SPARED CRN committees include the Clinical Informatics and Partnership & Sustainability committees to schedule meetings, define group deliverables, and propose milestones and timelines. SPARED CRN also has a publications committee to review requests for de-identified or limited datasets from the SPARED registry.

SPARED CRN leadership includes Charles Viviano (FDA), Jim Hu (Weill Cornell Medicine) Danica Marinac-Dabic (FDA), Art Sedrakyan (Weill Cornell Medicine), Benjamin Fisher (FDA), Michael Gorin (Johns Hopkins), and Fernando Bianco (Urological Research Network).

Existing agreements

All participating CRNs have established MOUs with the MDEpiNet Coordinating Center to join the CRN COP and are members of the MDEpiNet EOC. SPARED is coordinated out of the James Buchanan Brady Urological Institute at Johns Hopkins University School of Medicine (Principal Investigator: Michael Gorin). Data collection for inclusion in the SPARED Registry was previously approved by the Johns Hopkins Institutional Review Board (IRB). All participating sites have obtained local IRB approval and patients have signed informed consent allowing for data collection and related analyses

IV. Data Infrastructure

Patient population

SPARED CRN has an estimated 1,000 patients in its various institutional registries that are transitioning to single data platform and expanding data collection efforts.

Data sources

Medical records are reviewed for demographics, cancer stage and grade, details of treatment, oncologic follow-up (i.e. subsequent biopsies, PSA values, surveillance imaging, additional treatments, etc.), quality of life assessments, and the occurrence of complications.

V. Current Projects and Plans

SPARED CRN's ongoing project includes active surveillance and comparative evaluation of new technologies in urological oncology using free-text electronic health record data. The project aims to develop research infrastructure to ascertain critically necessary data elements to support device evaluation in urological device use for prostate cancer care and apply natural language processing (NLP) to extract information from clinical reports in a large-scale, multi-institutional database of EHR. The relevant FDA Strategic Priorities of this project is to develop methods and tools to improve and streamline clinical and post-market evaluation of FDA-regulated products. This project will enable impactful, timely, patient-centered active surveillance and comparative device studies in urological oncology for new device-based technologies leveraging the integrated EHRs data from multiple care providers.

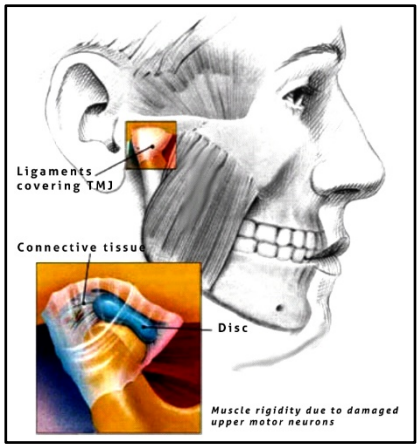
Other projects and plans for the CRN include planning for REDCap data collection at an early stage in the TPLC of these medical devices in the clinical setting. The REDCap data collection site has been built and is hosted at Johns Hopkins Medical Institute. Patient enrollment and data collection will begin at multiple sites and progress will be assessed in late 2019. The established registry will focus on OPC/OPG as a platform to guide the creation of single arm studies within the SPARED CRN.

CRN's accomplishments include core minimum data of the requisite clinical and treatment-related characteristics that were established after four rounds of the Delphi process using validated quality of life instruments and involving urologists, industry leadership, patient advocacy groups, and members of the FDA; manuscript preparation is currently underway.

11. TEMPOROMANDIBULAR JOINT (TMJ) CRN

I. Background

Temporomandibular disorders (TMD) are common disabling conditions and from 6% to 12% of the population is estimated to experience clinical symptoms[23]. The treatments include many devices that have limited evidence of safety and effectiveness and little comparative data is available. Data on long-term outcomes is particularly limited, leading to use of trial-and-error approach in treating patients. As a result, some patients develop serious conditions including worsened chronic pain, facial paralysis, disfigurement, infection, device migration within the skull, reduced jaw mobility, increased opioid use and dependence, increased suicidality, and other serious adverse events.



There is an urgent need to understand factors that lead to patients' experiences of success or failure for all TMD treatments, especially those that are irreversible such as temporomandibular joint implants, and, to share these with health care professionals and regulators for informed decision-making. The TMJ CRN was initiated by MDEpiNet to address these issues. The project aims to ultimately inform the development of scientificallyrobust, comprehensive treatment guidelines to enhance outcomes of TMD treatments based upon knowledge of a patient's overall phenotype, disease progression, and treatment trajectory, while also improving the lives of patients suffering from TMD.

II. Objectives

The main objective of the TMJ CRN is to develop a standardized data infrastructure for capturing patient-generated data, physician experience, and other healthcare ecosystem data necessary to better understand the disparate treatment pathways and outcomes that patients experience. Another goal is to change clinical trial conduct to incorporate patient preference and real-world experience into FDA-regulated and public health trials, beginning with medical devices. The CRN also aims to provide a roadmap for the development of precision medicine algorithms that predict individual outcomes from TMJ therapies, and develop evidence-based protocols, guidelines, and best practices for inclusion in professional health care curriculums.

III. Partnership Structure

The TMJ-CRN consists of a partnership between the FDA/CDRH, The TMJ Association, AHRQ, Device Manufacturers, FDA/CDER, FDA/OWH, TMJ Patients, Weill Cornell Medicine, and the National Institute of Dental and Craniofacial Research. The TMJ Patient-Led Round Table is

supported by a number of agencies including MDEpiNet, The TMJ Association, TMJ Patients, the FDA, National Institute of Dental and Craniofacial Research, FDA/OWH, American Association of Oral and Maxillofacial Surgeons, American Society of Temporomandibular Joint Surgeons, Zimmer Biomet, TMJ Concepts, clinicians, scientists, advocacy organizations, and other experts, all under the auspices of MDEpiNet. The Steering Committee consists of the participating organization listed above.

Four Working Groups have been established focusing on:

- TMJ Patients: Natural History and Assessment of Biomarkers Associated with Outcomes in TMJ Implant Patients
- PRO Evaluation
- Physician and Patient Education/Patient-Centered Treatment
- Data Collection and Analysis

Existing agreements

MDEpiNet Coordinating Center established MOU with the CRN's Leads, including with Terrie Cowley (TMJ Association).

IV. Data Infrastructure

Patient population

The patient population for this CRN includes individuals diagnosed with or receiving treatment for TMJ disorders.

Data sources

The development of a TMJ specific registry is underway. Registries of common overlapping conditions are identified and will be linked and used to perform research evaluating TMJ-related procedures. Examples of common overlapping conditions and registries include the Get with the Guidelines Registry from the AHA for stroke, the Multiple Sclerosis Registry for multiple sclerosis, and the Kaiser Permanent Spine Registry Database for functional disorders of the upper cervical spine. Claims data analyses can also help address specific issues related to reoperations after implant use.

V. Current Projects and Plans

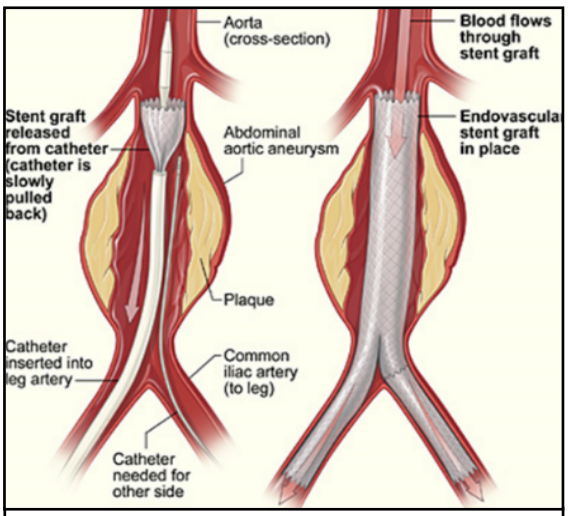
Current projects for TMJ CRN include the development of a minimum core dataset through the Delphi method and focus on pilot studies to test the data collection methods. The developed minimum core data set of elements will be vetted by the multi-stakeholder community via formal consensus building. The core dataset elements will include a data dictionary with permissible values sets, adherence to international standards, and capture by the NLM's repository of common data elements. The development of the minimum core dataset is anticipated to take approximately

4 to 6 months. The Delphi process will require approximately 2 to 4 additional months. All pilots are anticipated to be completed within a 3-year timeframe. Following the completion of these projects, a report evaluating these processes will be generated and submitted for publication. The CRN is also planning exploratory claims data analyses and protocol is in development as well.

12. VASCULAR IMPLANT SURVEILLANCE AND INTERVENTIONAL OUTCOMES NETWORK (VISION) CRN

I. Background

Vascular disease is common and has significant impact on quality on life and life expectancy**.** Each year, over 200,000 people are diagnosed with abdominal aortic aneurysms (AAA), 700,000 people with carotid artery disease, and more than 10 million with peripheral arterial disease in the US [24]. More than 600,000 patients undergo high risk vascular procedures annually to treat aortic aneurysms, carotid stenosis, and peripheral vascular disease. With an aging population, vascular surgery is projected to have the highest increase in healthcare demand [25].



Endovascular Stent Graft

The VISION project builds on the Vascular Quality Initiative (VQI) formed in 2010 by Society for Vascular Surgery Patient Safety Organization (SVS-PSO). The VQI is an AHRQ-listed PSO consisting of regional groups of physicians, data managers and quality assurance professionals who collect and exchange data on vascular procedures for the purpose of improving patient care. The VQI has more than 600 participating centers across the United States and Canada and contains greater than 600,000 records, with 8,000 new records entered each month. VISION aims to advance the maturation of the registry by development of CRN via linkages to other data sources and the application of novel methodologies for evidence generation, synthesis and appraisal, with the ultimate goal of improving the quality, safety, effectiveness and cost of vascular healthcare.

II. Objectives

The main objective of the VISION CRN is to facilitate low-cost, high value RWE research through the creation of a national repository of linked clinical-claims analytic datasets. The second objective is to measure the safety and effectiveness of vascular devices, including predictor derivation and comparative effectiveness, the impact of provider characteristics on device outcomes, health disparities related to device use and outcomes, and the impact of medical practice guidelines and healthcare policies.

III. Partnership Structure

VISION is a partnership between the SVS-PSO and MDEpiNet. Other partners include Abbott Vascular, Gore, BARD, BTG, Cook Medical, Medtronic, Boston Scientific, GETINGE, the FDA, and Weill Cornell Medicine.

The core team is led by Phil Goodney (SVS-PSO) and Art Sedrakyan (Weill Cornell Medicine) who are responsible for updating linkages, generating Medicare-derived outcomes, performing quality assurance checks of matched datasets, and day-to-day operations.

A VISION Steering Committee with representatives from the VQI, medical device industry, and the FDA sets the strategies and priorities of the organization. The VISION Steering Committee is composed of an Executive Council, a Data Core, Research and Publications Council and five procedure-specific device councils. The Steering Committee was formed in 2019 and meets monthly.

Existing agreements

Use of VISION data is governed by specific DUAs between CMS, Weill Cornell Medicine, and the SVS-PSO. Data are kept on a secure server at the MDEpiNet Coordinating Center. Projects are approved by the VQI Research Advisory Committee, VISION Research and Publications Council and the FDA Research Involving Human Subjects Committee. In addition, VISION CRN established MOUs with the MDEpiNet Coordinating Center to join the CRN COP and is a member of the MDEpiNet EOC.

International effort

The International Consortium of Vascular Registries (ICVR) is a global effort related to the VISION CRN but is a separate CRN (*see ICVR description in the next section*). The ICVR leverages existing national registries, VQI, and collaborates with Vascunet, a sub-committee of the European Society of Vascular Surgery. Several steering committee members on VISION also represent ICVR, such as Drs. Adam Beck and Daniel Bertges.

IV. Data Infrastructure

Patient population

VISION covers 605,322 patients captured by the VQI registry from over 600 academic and community hospitals across the United States and Canada. The patients present within the VQI registry underwent one or more of the following procedures: carotid endarterectomy (CEA), carotid artery stenting, infrainguinal and suprainguinal bypass, open infrarenal abdominal aortic aneurysm repair, endovascular infrarenal abdominal aortic aneurysm repair, thoracic endovascular aortic repair, and peripheral vascular intervention of aortoiliac and lower extremity arterial disease.

Data sources

The VQI is a mature registry, governed by the SVS-PSO. The dataset collects information concerning the patient (i.e., demographics, anatomic, and pathology data) and clinical data (i.e., comorbidities, device type, lesion length, procedure type). The VQI has different procedure registries (see table) and has an average of one year of follow-up time after procedures.

VQI Dataset	Years Captured	Devices Captured
VQI Quality	2002-current	Al vascular devices
VQI- AAA	2002- current	All AAA endoprostheses
VQI- Thoracic Aortic Aneurysm	2010- current	All thoracic aortic endoprostheses
VQI- Lower Extremity PAD	2008- current	Bypass devices, PAD (Peripheral Artery Disease) stents, balloon catheters, related devices
VQI- Carotid Artery Stents	2002- current	Carotid stents, catheters and related devices
VQI- Cardio-thoracic	1995 –current	Endoprostheses
VQI- Dialysis	2010 - current	Dialysis-related devices

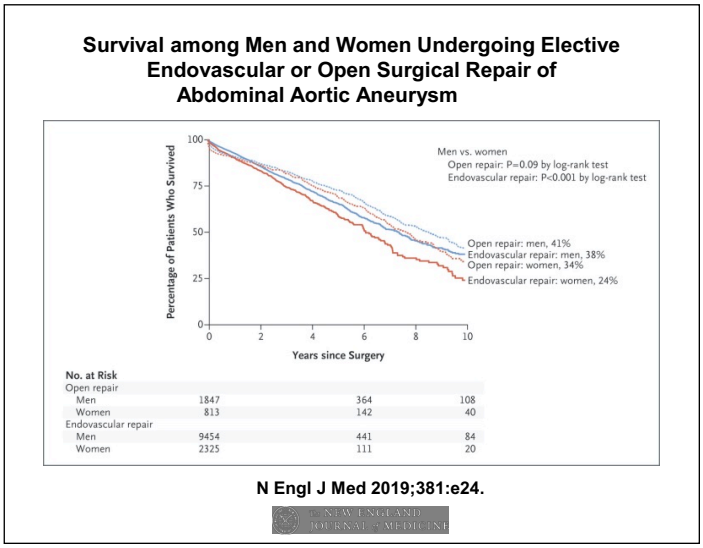
The registry is continuously linked to CMS claims, the primary health insurance provider to individuals above the age of 65 in the US. Furthermore, within the VISION environment, the VQI registry has also been linked to two additional longitudinal datasets: the New York SPARCS dataset and the New York City Clinical Data Research Network (NYC-CDRN) dataset. VQI-CDRN linkage was conducted for New York City hospitals that participated in VQI. NYC-CDRN data contains patient clinical information as well as lab and prescription data. Linkage rates between VQI and CDRN varied by health systems, ranging from 60% to 94%.

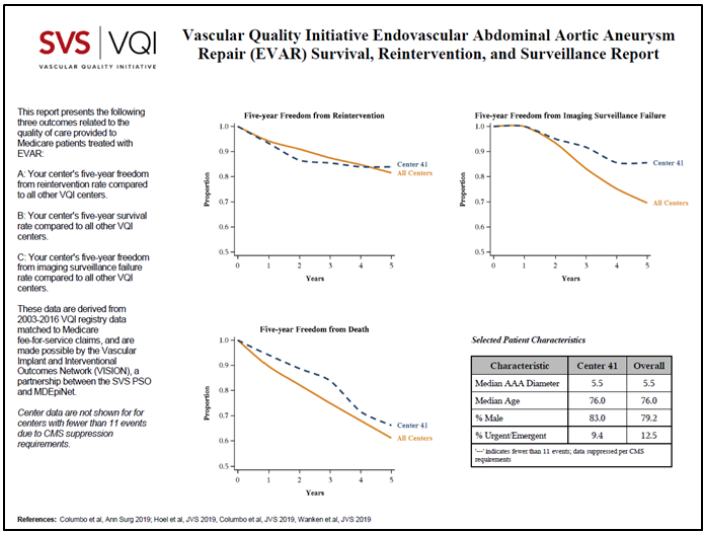
V. Current Projects and Plans

VISION CRN's current priorities focus on completing three main activities: (1) Continuously linking registries and claims, (2) Conducting research examining the long-term effectiveness of vascular procedures, and (3) Generating feedback reports for VQI members and hospitals.

Algorithms to define variables, yearly linkages, and ICD9 to ICD10 mapping are current projects supporting the continuous generation of linked registry-claims dataset. Each year, linking algorithms are reviewed, updated and refined for the identification of late events in Medicare

claims. Long-term outcomes such as reinterventions and imaging follow-ups are derived from linked claims to create a consolidated data repository that will enable specific research projects. These data allow unique insights into the long-term outcomes of vascular care, such as gender-based disparities, as outlined in the New England Journal of Medicine (Ramkumar et al 2019, 381:e284) (Figure).





The major research projects currently conducted by VISION are 1) AAA device outcomes (open and EVAR) 2) Carotid stenting and operations outcomes 3) TEVAR outcomes 4) PVI outcomes and objective performance development in collaboration with 'Registry Assessment of Peripheral Interventional Devices' (RAPID) project. The projects include evaluation of late rupture following EVAR, comparison of atherectomy, evaluations of open compared to endovascular aneurysm repair, and examining survival of devices by manufacturer. Feedback reports such as SRS (Figure), inform VQI Sites and industry stakeholders on key performance indicators to help improve the care provided to patients with vascular disease.

Our priorities in future years will focus on gender-based disparities in long-term vascular outcomes, as well as examining outcomes following paclitaxel coated balloon angioplasty and stenting of superficial femoral and popliteal artery. The first stage of the project, which is underway, is to evaluate intermediate-term mortality following these procedures using registry data. Following this, the VISION CRN will be used to evaluate longer-term outcomes for treatments received by patients with vascular disease.

13. THE INTERNATIONAL CONSORTIUM OF VASCULAR REGISTRIES (ICVR)

I. Background

In November 2014, the MDEpiNet Coordinating Center, in collaboration with the SVS/VQI and the European Society of Vascular Surgery VASCUNET registry launched the ICVR to build an innovative international network dedicated to vascular surgery and device outcomes. The ICVR has direct data sharing from multiple national registries and distributed systems for research and surveillance, initially focusing on high priority questions related to the variation in device use and patient selection. The ICVR has access to data for hundreds of thousands of procedures performed to treat abdominal, carotid and lower limb arterial disease with both open and endovascular repairs. Since 2014, the representatives of 13 registries have developed a governance structure for data sharing and have held bi-annual meetings (alternating between US and Europe) to launch investigations.

The international sharing of experience in quality improvement, desire to improve vascular care, and evaluation of device performance are three main motivators that have led to enthusiastic participation of national registries and clinician leaders. Importantly, most vascular devices are approved earlier in Europe than in the US, but the US population provides a larger cohort for device evaluation. Combining data from multiple registries accelerates the ability to detect device safety signals and benefits patients worldwide. The ICVR collaborative infrastructure will help adapt these methods to study vascular devices. The ICVR hosts forums for discussion including workshops and conferences. The ICVR members participate in scientific workshops and conferences intended to bring together external parties with relevant expertise to define evidence gaps and questions, datasets, and best practices.

II. Objectives

The major objective of the ICVR is to provide a collaborative platform through which registries and other stakeholders around the world can share data to improve vascular health care. The ICVR focuses on the development and testing of innovative methodological approaches. Examples include the use of directly linked (with de-identification) versus distributed network analyses, propensity scores, instrumental variables, inverse probability weighting, doubly robust estimation, registry-based randomized control trials, and other epidemiological methods which show great potential for use in medical device research. Other focuses of the ICVR include safety studies, surveillance, and comparative outcome evaluation. The ICVR research and surveillance studies aim to inform stakeholders about real-world outcomes of devices including advantages and disadvantages of different surgical techniques, devices and patient/pathology selection for treatment.

III. Partnership Structure

Member organizations of the ICVR include MDEpiNet, SVS-VQI, and Vascunet (HUSvasc, Swedvasc, UK National Vascular Registry, GermanVasc, NORKAR, Australasian Vascular

Audit, Isvasc, Swissvasc, Hungarian Vascular Registry, Italian Vascular and Endovascular Registry, Karbase, Dutch Surgical Aneurysm Audit).

The ICVR Leadership Board was established during the first meeting on November 17, 2014. The current European Chair of the ICVR is Maarit Venermo (Helsinki University) and the current US Chair is Adam Beck (University of Alabama at Birmingham); the past European Chair was Martin Bjorck (Uppsala University Hospital) and the past US Chair was Jack Cronenwett (Dartmouth). In addition to the leadership board, the ICVR maintains advisors from the US FDA and input from stakeholder manufacturer representatives, such as Medtronic, Cook Medical, Gore, Endologix, and Terumo.

Existing agreements

The ICVR maintains MOU with MDEpiNet Coordinating Center to advance the development of the CRN and COP. MDEpiNet also has agreement with the VQI and sepaare agreement with VASCUNET.

IV. Data Infrastructure

Patient population

The ICVR maintains a registry database of roughly 226,135 patients, including 47,263 CEA patients and 178,872 EVAR patients.

Data sources

In order to create this collaborative platform, the ICVR is leveraging existing national registries, including the SVS/VQI, and has a history of collaboration in VASCUNET, a sub-committee of the European Society of Vascular Surgery which aims to increase the knowledge and understanding of vascular disease and to promote excellence in vascular surgery by means of international vascular audits. Additionally, the ICVR contains registry data from Australia, Denmark, Finland, France, Hungary, Iceland, Malta, New Zealand, Sweden, Switzerland, Germany, Norway, and the US.

V. Current Projects and Plans

Ongoing ICVR projects include:

International variation in device use: Projects have been completed for AAA devices and carotid devices. There are plans to also study new technologies and approaches, including an analysis of outcome variation of carotid endarterectomy based on carotid patch type and outcomes of peripheral intervention with the use of drug-eluting/coated devices (i.e. balloons and stents).

Volume outcomes study: The first phase of the current project evaluating volume-outcome relationship in AAA procedures has been completed. The second phase is specifically focused on the volume threshold for mortality after intact open AAA repair. Other ongoing projects include the analysis of the variation in outcome by country for intact AAA repair.

Ruptured abdominal aortic aneurysms (rAAA) study: A prospective study utilizing the registry network to evaluate EVAR device for ruptured abdominal aortic aneurysms (rAAA) is being planned. This study will enroll rAAA patients from participating registries undergoing EVAR comparing the short-term performance based on mortality to that of patients undergoing open treatment.

Global Harmonization of Registry Infrastructure: The ICVR's current plans include continued global harmonization of registry infrastructure and the definition of items that will overcome limitations related to single country investigations and enhance the development of RWE. The ICVR completed the Delphi study for peripheral arterial revascularization which included 25 international vascular registry experts to achieve a consensus recommendation for a minimum core data set and an optimum data set for this patient population.

Miscellaneous projects: Other tasks include updates to the implementation of the new European Union medical device regulation changes, registry quality improvement initiative, and the plan for High-performance Integrated Virtual Environment (HIVE) for data sharing to address EU General Data Protection Regulation requirements.

14. VENOUS ACCESS NATIONAL GUIDELINE AND REGISTRY DEVELOPMENT (VANGUARD) CRN

I. Background

Central venous access is a life-preserving intervention for millions of Americans each year.
A considerable proportion of important data in the venous access domain is not captured in the EHR. At least half of venous access care is delivered outside the ICU (where most data is collected) and outside the hospital. Patients and families often feel that their voice is not heard or respected regarding chronic central venous access health care decisions, even though access is often a life-preserving intervention and their complications may be life-ending events. Overall, added costs for all catheter-related complications may exceed tens of billions. With this in mind, MDEpiNet collaborative project has been initiated to develop a patient-facing portal to obtain patientgenerated health data, especially to flag sentinel events, to facilitate patient access to health information for relevant available evidence, and to encourage patient participation and decision making.

The VANGUARD CRN initiative provides a comprehensive, stakeholder-driven environment to define, gather, synthesize, and distribute information related to patients who require chronic central venous access. As a smart think-tank workgroup, VANGUARD was adopted by MDEpiNet in 2015 as one of several related initiatives to develop a national pathway to evaluation of medical device safety and effectiveness. VANGUARD is collaborating with Webshield and MDEpiNet on a Demonstration Project that aims to develop a CRN infrastructure and shared services of value across the CRN COP, focusing on globally selected applied-use cases to focus on ubiquitous problems with solutions that help high-need, high-cost patients. Each Demonstration Project component will share several features: they will demonstrate secure and interoperable exchange of high-value health information, they will be achievable with improved outcomes, decreased costs, and less workflow burden for clinicians and other participants, they will improve data quality in line with federal requirements for sensitive and regulated data, and they will be translatable and scalable across the COP. It is the intent of this project to develop shared services that can be easily adopted by existing CRNs and for other healthcare ecosystem participants.

II. Objectives

The goal of the VANGUARD initiative is the development of a prototypical fully-realized coordinated central venous access registry network with broad stakeholder support and participation that is relevant to the clinical, economic and quality of life concerns of the patient populations at risk and responsive to fundamental mandates. It is intended to lower the threshold for fostering innovation; protect health and welfare; provide safe and effective therapy and devices; and reduce the cost of quality healthcare delivery. The mission of the VANGUARD initiative is to leverage multidisciplinary, multi-institutional evidence to improve the quality of care and reduce the costs and complications of care related to central venous access. Therefore, it is developing a national CRN which integrates with other electronic data sources for relevant populations, centered on patient outcomes throughout the venous life cycle, to provide a nexus for collegial action including research, quality assurance, regulation, certification, policy development, guidelines and standards.

III. Partnership Structure

VANGUARD CRN is a collaborative MDEpiNet effort initiated by FDA with partners including The Office of the National Coordinator for Health Information Technology (ONC), NLM, NCI Center for Biomedical Informatics & Information Tech, HL-7 Vocabulary Group, AHRQ, catheter manufacturers, health information technology vendors, clinical content experts, and additional potential stakeholder collaborators. The original VANGUARD Advisory Board organized through the MDEpiNet Coordinating Center with Duke Clinical Research Institute has now evolved to a Stakeholder Advisory Panel with logistical support through MDEpiNet leadership at FDA.

Existing agreements

VANGUARD has established an MOU with the MDEpiNet Coordinating Center to join the CRN COP.

IV. Data Infrastructure

Patient population

The patient population includes adult and pediatric patients and often high-need, high-cost patient populations who require chronic central venous access as well as those who require chronic vascular access. These venous access devices include central venous lines, PICCs, Ports and Pumps. The procedures involving central venous access devices fall into five categories: insertion (placement of catheter through a newly established venous access); repair (fixing device without replacement of either catheter or port/pump, other than pharmacologic or mechanical correction of intra-catheter or peri-catheter occlusion); partial replacement of only the catheter component associated with a port/pump device, but not entire device; complete replacement of entire device via same venous access site (complete exchange); and removal of entire device.

Data sources

Data sources for VANGUARD will include claims and administrative data, as well as registry and other data from various partners. VANGUARD is working with MyLink.com (currently installed in over 25,000 clinics nationally), a service free to patients, to develop partnerships with patient and family organizations like the Oley Foundation (22,000 members concerned with chronic nutritional support) and other similar agencies (e.g., chronic kidney disease patient support), and health IT firms like Cognitive Medical Systems and Mitre Corp. (Patient Toolkit) to enable patients to obtain all their health records and store them in one place, to authorize exchange of their health data with authorized users, to electively participate in research, and to obtain educational materials, guidelines and standards relevant to their healthcare needs.

V. Current Projects and Plans

Interoperable Coordinated Registry Architecture for Networked Enterprises (iCRANE): iCRANE plans to employ a service-oriented architecture to provide a transparent, platform-independent workflow and registry interface including improved efficiency in patient- and device-tracking and standardization, automated and secure retrieval and distribution of data and images, compliance and tracking for documentation, billing, and communication, and decision support for clinician and patient engagement, as well as for public health and patient safety surveillance, quality improvement, and clinical research.

Semantically interoperable vocabulary: VANGUARD has an approved Project Scope Statement co-sponsored by HL7 Clinical Interoperability Council and the HL7 Clinical Interoperable Modeling Initiative. Interoperable core common data elements have been established. A need for domain-specific interoperable terminology is anticipated by ONC in the US Core Data for Interoperability standard as part of the Cures Act. Employing software from HL7, Mitre and Logica (formerly HSPC), health IT professionals, subject matter experts and other domain-specific stakeholders, core domain-specific clinical data models, FHIR profiles, implementation guides, data dictionaries, SNOMED-CT, LOINC and other standard coding and other documentation will be produced. Targeted terminology will be constrained by necessary and sufficient requirements for planned critical studies. The first phase of this project is targeted for completion by September 2020. Interoperable data elements will also permit automated extraction of other critical events that are captured by the EHR, such as catheter infection and venous thrombosis, with greater validity and precision.

Integrated Medical Management and Educational Gateway (iMMEG): High level EHR "gateway" tool at decision-points of care SOA platform services: The project aims to develop an interactive visual map as an integral CRN component designed as both a source and target for secure interoperable data exchange and data aggregation across patients, devices, systems, and events. It will be integrated with a back-end database and structured reports, decision support and patient engagement systems and with CRN enterprise architecture. As part of continuing care documentation this visual interface will travel with the patient. It will provide an "alert" level source of actionable data for quality, safety, coordination, and research functions wherever the patient may be; from home to healthcare institution to the scene of a disaster. It will serve as a single locus for relevant domain-specific critical clinical events and outcomes.

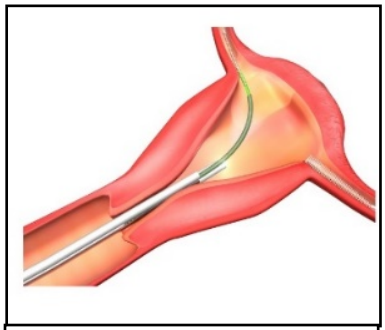
Pilot registry of venous access: VANGUARD pilot registry project is validating the relationship of central venous structures with visible 'anchor' structures such as the spine and the tracheal carina as part of the foundational work in this domain. This allows reliable description of the position of a catheter tip within the venous system. Pilot research is being developed to correlate catheter tip position and complications in high-risk populations, such as ports in oncology patients, hemodialysis catheters in renal failure patients and central access in high-risk pediatric patients.

VANGUARD and UDI: VANGUARD is creating a ripe platform for testing and development of UDI and other EHR tools on compelling implantable medical device problems associated with high volume, high cost and high morbidity events, with rich opportunities for collaboration and convergence on success with other SMART Think Tank initiatives.

15. WOMEN'S HEALTH TECHNOLOGIES (WHT) CRN

I. Background

There is a growing demand for evidence to evaluate the performance of women's health devices related to sterilization, uterine fibroids (UF), pelvic organ prolapse (POP), and stress urinary incontinence (SUI), and to produce evidence that better reflects the patient experience during routine care. Registries can help meet this demand by collecting data on real-world patient care and the specific devices used for that care. However, registries can be expensive to maintain if they are not efficiently designed. Collecting long-term outcome data is also challenging and requires major investments. While each medical condition and relevant registry is unique, in most instances, these multiple registries collect the same demographic and comorbidity information but are not working together to gain efficiencies.



Sterilization Device

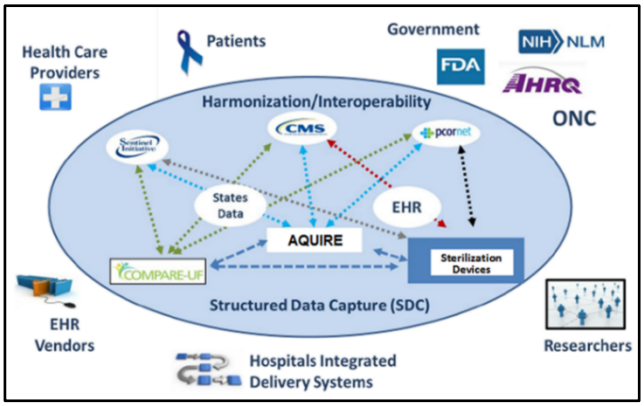
With this initiative to invest in infrastructure development to address the challenges in women's health, MDEpiNet has created a WHT-CRN. This CRN illustrates the strength of big data to address specific questions and advances the registry model to use tools such as structured data capture and HL7 FHIR to efficiently extract, standardize and exchange data across multiple real-world data sources. The CRN concept was originally developed by the National Medical Device Registry Task Force and defined as "strategically partnered electronic health information systems that support 1) the implementation of structured device identifiers, core minimum data elements and definitions and 2) the ability to share complementary data across information systems." The WHT-CRN aims to demonstrate the application of this vision in the clinical context of specific devices used in clinical areas unique to women.

II. Objectives

The primary objective of the WHT-CRN is to develop tools to facilitate data collection within the existing and new registries by leveraging efficient clinical data capture mechanisms, taking advantage of relevant claims and EHRs data sources and creating patient-facing applications for capturing patient-reported outcomes. The secondary objective is to demonstrate that data in the CRN can be used to evaluate the effectiveness and safety of various device and non-device treatment options; provide a framework for the conducting of clinical studies within CRN, including industry-sponsored studies required to fulfill the FDA's request for pre-market and post-market regulatory activities; enable more effective assessment of surgeon and patient outcomes related to device technology use as part of quality improvement activities (including for CMS purposes); and create collaborative opportunities for new and existing registries related to women's health technologies to work with each other and link to other major data sources and networks.

III. Partnership Structure

WHT-CRN is a major MDEpiNet collaborative effort with a major grant to MDEpiNet Coordinating Center at Weill Cornel Medicine. It is governed by FDA and partners such as ONC, NLM, The Assistant Secretary for Planning and Evaluation (ASPE), ACOG, American Urogynecologic Society (AUGS), Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, AHRQ, and Patient Community (e.g., Fibroids Foundation, APOPS, Voices for PFD, etc.). The governing bodies responsible for advancing the WHT-CRN effort include: WHT-CRN leadership committee; WHT-CRN coordinating center; WHT-CRN clinical working groups; patient partners; informatics working group; funding partners (non-FDA); industry; payers; and professional societies.



Existing agreements

All WHT-CRN co-chairs have established an MOU with the MDEpiNet Coordinating Center to join the CRN COP and are members of the EOC. Use of WHT-CRN data will be governed by specific DUAs between Weill Cornell Medicine, participating registries, and participating medical device companies.

IV. Data Infrastructure

Patient population

The patient population in WHT-CRN includes patients in four major clinical areas of women's health – POP, SUI, UF and Sterilization/LARC. Aside from growing registries, there were approximately 560,000 elderly women who underwent POP and SUI sling procedures between 2008 and 2016, in Medicare claims data. These data are comprised of both facility and physician billings. NY State discharge database research shows that approximately 50,000 women underwent sterilization between 2005 and 2016, approximately 85,000 women underwent POP and SUI sling procedures between 2008 and 2016, and approximately 220,000 women underwent UF treatment between 2007 and 2016.

Data sources

UF - Registry, claims and patient generated data: For registry data, the WHT-CRN is collaborating with COMPARE-UF, a nationwide registry of women with uterine fibroids that hopes to answer questions about the outcomes of different treatment options. For claims data, members of the WHT-CRN Uterine Fibroids working group have performed several claims-based research studies to evaluate devices used for uterine fibroids. The primary procedures evaluated among women with uterine fibroids within claims thus far are endometrial ablation, myomectomy, hysterectomy, and uterine artery embolization. For patient-generated data, recommendations from Patient Reported Outcome Measures (PROMs) have been evaluated for patients with uterine

fibroids. These include the UFS-QOL (UF Symptom and Quality of Life Questionnaire), the SF-36 (MOS 36-item Short Form Health Survey), and the EQ-5D (European Quality of Life Instrument).

SUI – Registry, claims and patient generated data: For registry data, the WHT-CRN is funding the AUGS Urogynecology Quality Registry (AQUIRE), which is a national urogynecology-focused registry open to all physicians and designed to measure and report healthcare quality and patient outcomes. The WHT-CRN activities have worked to establish two new modules within AQUIRE: one for SUI and one for POP. The SUI surgery module is currently enrolling patients and is planning to recruit 2000 patients. For claims data, New York State data have been the primary claims data source utilized to evaluate a number of effectiveness and safety concerns associated with medical devices indicated for the treatment of SUI. For patient-generated data, there are several SUI instruments/questionnaires, including a 6-week follow-up and a 1-year follow-up, that are included in the SUI module. ICIQ is a validated questionnaire that is used as a part of the 1-year follow-up. These questionnaires have two versions, one for mesh patients and the other for non-mesh patients. Additionally, the WHT-CRN is working on the development of a patient-facing mobile app to assist patients in submitting PROs.

POP – Delphi method: The POP working group used the Delphi method to create a core minimum dataset to evaluate the safety and efficacy of devices used for POP procedures. Current work focuses on identifying PROs of POP surgery, which were not included in the original set of data elements from the Delphi process. With WCM coordinating center facilitation, AUGS is collaborating with ONC as a pilot of the IG for the WHT-CRN, using the POP data elements as test CRN instruments to be published on the FHIR server and FHIR app. After the pilot, the planned version 2 of the POP registry will include PROs as identified by our patient group as well as collecting unique device identifiers and validating that data against the AccessGUDID database. In terms of patient-generated data, the current instruments/ questionnaires used to evaluate POP include: PFDI-20, Patient Global Impression of Improvement (PGI-I), Pelvic Floor Impact Questionnaire (PFIQ-7), the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12), the International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF), and PROMIS Global Health Questionnaire.

Sterilization/LARC – Delphi method: The Sterilization/LARC working group used the Delphi method to create a core minimum dataset to collect data to evaluate the safety and efficacy of devices used for sterilization and LARC procedures. The process of creating a registry for this condition is under discussion with relevant stakeholders. Members of the WHT-CRN Sterilization/LARC working group have performed extensive claims-based research studies to evaluate devices used for sterilization procedures. After successful claims data analyses conducted by our team the Essure device was taken out of the market and the current focus for this working group is on LARC. The group plans to use MDEpiNet HIVE for data implementation and pilot testing.

V. Current Projects and Plans

The WHT-CRN is conducting pilots to test the WHT-CRN infrastructure for the following clinical areas: UF, SUI, and POP.

The Uterine Fibroids pilot is being conducted by the UCSF, led by Dr. Vanessa Jacoby, who is collaborating with other appropriate UF stakeholders. UCSF is currently conducting a nationwide study for women who would like to share their experience with radiofrequency ablation (Acessa^{TM}) to treat uterine fibroids (the ULTRA study). The study team will pilot the UF core minimum dataset within the ULTRA study. The data points will be structured to serve as a template for a case report form in the research environment (e.g. post-market surveillance) and/or to embed within the electronic health record for use in a general clinical care workflow. The study sponsor, Acessa Health, has agreed to collaborate with this project to allow the new data elements to be piloted in the ULTRA study.

The SUI pilot will support the implementation and refinement of specifications in the WHT-CRN Implementation Guide (IG) in a test environment, production environment (e.g. clinical or provider setting) and/or manufacturing setting. The purpose of the pilot is to test the CRN capabilities mapped to specific actors and interactions of the technical specifications of the CRN IG, including the underlying standards and common clinical data sets that are being developed as part of this project for collecting and sharing women's health data. Currently, AUGS is working with ONC to stand up a FHIR server and FHIR app. The AUGS-SUI clinical team is finalizing the data elements for terminology in preparation for storing in the instrument repository. AQUIRE gets information from AccessGUDID based on UDI. The new module will continue this functionality.

The POP pilot will support the implementation and refinement of specifications in the WHT-CRN Implementation Guide (IG) in a test environment, production environment (e.g. clinical or provider setting) and/or manufacturing setting. The purpose of the pilot is to test the CRN capabilities mapped to specific actors and interactions of the technical specifications of the CRN IG, including the underlying standards and common clinical data sets that are being developed as part of this project for collecting and sharing women's health data. The POP pilot is working to stand up a FHIR server on MDEpiNet HIVE platform, replicate/customize the FHIR app for POP, test/make available on mobile and connected devices, work with clinical team to determine/refine/finalize the data elements for terminology in preparation for storing in the instrument repository (for other conditions), gather clinician feedback on app design and usability, and update and refine app based on feedback.

There are also ongoing projects using claims database. We have recently examined the long-term reoperation after sterilization procedures using New York State data. A similar project to examine long-term outcomes following POP procedures is being carried out. For SUI sling, a project is being conducted to identify predictors of long-term reoperations and erosion diagnosis after initial sling procedures. The predictor analysis is utilizing both traditional predictive modeling and machine learning techniques to identify predictors of long-term outcomes.

MDEpiNet Programs

MDEpiNet Programs

The MDEpiNet Programs are responsible for facilitating the learning in the specific program areas such as:

(1) Methodology advancement
(2) UDI adoption within the health care system
(3) Clinical trials embedded in the routine clinical care
(4) Clinical trials embedded in international registries
(5) Automated surveillance – DELTA
(6) New Program: University of California San Francisco Outcomes Program

These programs work closely with the Coordinating Center to advance the MDEpiNet efforts and research projects.

1. METHODOLOGY

Lead Investigator: Sharon Lise-Normand; Lead Institution: Harvard Medical School

The Methodology team is leading the development of advanced statistical and epidemiological methods to improve the understanding of safety and effectiveness of FDA-regulated medical devices. The team is comprised of methodological investigators from Harvard Medical School, Harvard School of Public Health, clinical investigators from Brigham and Women's Hospital, investigators from Weill Cornell Medicine and Duke University.

The Methodology program was established in January 2012 and is focusing on statistical methods for inferring device safety and effectiveness based on heterogeneous high-dimensional observational data sources and piloting the implementation of unique device identifiers within the hospital system.

The expert team is developing a comprehensive set of methodological approaches for the continuous evaluation of pre-market and post-market active surveillance through evidence synthesis of large clinical and administrative databases, including billing claims data; clinical data found in international, national and state registries; and electronic medical record data.

2. UDI ADOPTION WITHIN HEALTH CARE SYSTEM

BUILDING UDI INTO LONGITUDINAL DATA FOR MEDICAL DEVICE EVALUATION (BUILD)

Lead Investigator: Joseph Drozda; Lead Institution: Mercy Hospital System

UDIs are unique identifiers for a medical device that are required on the device label and packaging of both human and machine-readable forms. These are required on the medical devices that are intended for more than one use and intended to be reprocessed before each use. The U.S. FDA mandated the UDI system in September 2013.

The BUILD Initiative supports MDEpiNet by developing the infrastructure and methodology for robust post-market surveillance, research, and innovation through a system of automated capture of clinical data from EHRs and UDI associated device data, all of which are linked to national registries. The focus of the BUILD initiative is to:

- Implement an UDI system at the point of clinical care and leverage UDI to connect data sources
- Access the global unique device identification database)
- Move information on devices to clinicians for patient care,
- Allow researchers to assess device effectiveness and safety
- Support device innovation across the device product life cycle

The BUILD Initiative has three complementary components:

- Extension of the UDI Implementation Pilot: The Mercy Health coronary stent UDI demonstration project was extended to production status at two additional health systems, Geisinger and Intermountain Healthcare.
- Medical Device Data Capture and Exchange: Leading Practices and Future Directions*:* Leadership interviews were performed in hospital systems that have implemented UDI for implantable devices to rigorously assess leading practices and gaps; a multi-stakeholder consortium of hospital system and manufacturer leaders in UDI was formed (BUILD Consortium); a BUILD website was created and maintained for education and information sharing.
- Electrophysiology structured reporting Providing UDI for Leads and devices using industry Standards to EHRs and CVIS systems:The use and utility of UDI across multiple dimensions of health care (including patient engagement) will be demonstrated for cardiac implantable electronic devices (CIED) such as pacemakers, cardioverter defibrillators, and CIED leads.

3. Clinical Trials Embedded in the Routine Clinical Care

Registry Assessment of Peripheral Interventional Devices (RAPID)

Lead Investigator: Mitchell Krucoff; Lead Institution: Duke University

RAPID focuses on a pre-competitive, stakeholder ecosystem approach to enhanced TPLC evaluation of devices for peripheral vascular intervention. This system was developed by the Predictable And Sustainable Implementation Of National (PASSION) Registries for Cardiovascular Devices program of MDEpiNet. RAPID is currently a formally designated NESTcc Demonstration Program coordinated by the Duke Clinical Research Institute.

RAPID Phase I originated the construct of the "minimum core data structure" for PAD device evaluation, as a re-usable model across NEST-based CRNs supporting efficient systems interoperability. For the Phase I use case in PAD, data elements from pivotal trial and professional society case report forms were leveraged as a starting point to develop and publish in the public domain the core minimum set of data elements to support evaluation of devices used to treat PAD. In parallel, efforts to promote the adoption of GUDID were initiated in the peripheral vascular community. RAPID Phase I was not only completed ahead of schedule, but through this inclusive,

productive collaborative effort, good faith and trusting relationships were built between stakeholders throughout the peripheral device ecosystem.

RAPID Phase II developed the most contemporary OPG for devices used in the SFA and femoral-popliteal anatomy available in the PAD literature. The timeline for completion of this OPG was dramatically accelerated and facilitated by the "rapid" implementation of the Phase I minimum core data elements by the VQI registry. This achievement by our professional society partners thus provided the real-world data utilized to update OPC for PAD devices. Results of the Superficial Femoral Artery-Popliteal EvidencE Development OPG were shared in the RAPID stakeholder meeting at the FDA on March 20, 2019 [26]. These results have currently been submitted for peer review.

RAPID Phase III Pathways was launched in June of 2019 following the FDA's Special Advisory Panel on the mortality/safety signal concerns following PAD intervention with devices delivering paclitaxel. Pathways is intended to leverage the immediate challenges of questions surrounding the paclitaxel mortality signal discernment as a use case promoting improvements to the evaluation of all PAD devices throughout their lifecycle. RAPID Pathways will provide a neutral ground to foster frank dialogue among stakeholders already engaged in these issues, and to promote pragmatic, collaborative, pre-competitive approaches with well-defined deliverables and timelines serving these objectives.

Pathways is structured to combine leadership from regulatory, industry, clinical and professional society stakeholders in multiple areas of key expertise, including clinical data content, clinical data structure, biostatistics, patient preference science, as well as to host currently active studies examining data from industry, professional societies, claims, third party payers, the VA Medical Centers, and international sources.

Pathways will develop a 'lean' case report form and explore other opportunities to support future device trials using lessons learned from the PTX experience. RAPID Pathways will focus on the goal of "better, faster, cheaper" PAD device evaluation.

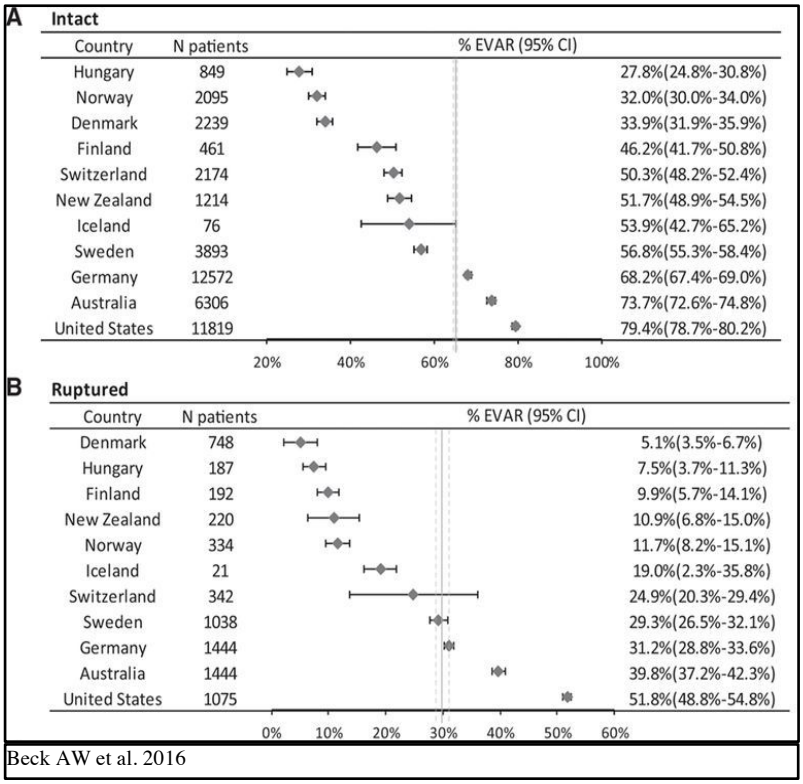
4. CLINICAL TRIALS NESTED UNDER THE INTERNATIONAL VASCULAR REGISTRIES

Lead Investigator: Adam Beck; Lead Institution: University of Alabama at Birmingham (UAB)

EVAR in the treatment of ruptured abdominal aortic aneurysms (rAAA) is an MDEpiNet Coordinating Center -supported clinical trial project nested under the ICVR. UAB has been established as an MDEpiNet collaborator for this and future projects.

The aim of this project is to evaluate the safety and effectiveness of EVAR devices used to treat rAAA (compared to open rAAA repair) by international evaluation in the existing ICVR registries. The project is intended to provide manufacturers of currently approved EVAR devices (Cook, Endologix, Gore, Medtronic) with real-world data allowing them to understand better how their devices perform in the setting of ruptured aneurysm.

As EVAR is now the primary treatment for AAA (Figure)[27], there is increasing importance to evaluate these parameters from a surgical quality and outcome perspective. Additionally, these data could be used as support for a regulatory application to modify the labeling of the endovascular grafts evaluated in this study with respect to rAAA.



Beck AW et al. 2016

The central purpose of this project is to evaluate in-hospital mortality after EVAR for rAAA in a multinational registry collaboration using mortality associated with standard open repair to establish performance goals. Given that untreated rAAA carries a mortality approaching 100%, the project will focus specifically on survival to discharge. Further, the long-term safety and effectiveness of these EVAR devices has been extensively studied and established for elective AAA repair. The major endpoint for this project is improving initial survival based on the improvement of outcomes after rAAA repair.

This figure (*Beck AW et al. 2019*) demonstrates the modality of repair for intact (A) and ruptured (B) aneurysms internationally[27]. EVAR has become the dominant method of repair for elective aneurysms internationally. In the United States, the proportion of ruptured aneurysms treated with EVAR exceeds 50%, despite a lack of formal evaluation in this clinical setting.

5. AUTOMATED SURVEILLANCE

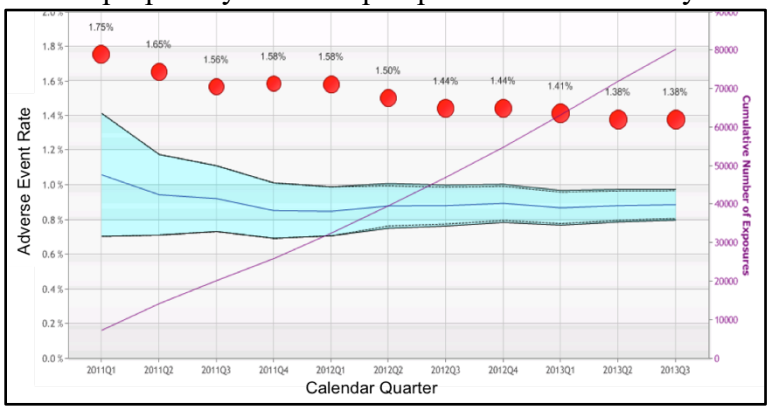
DATA EXTRACTION AND LONGITUDINAL TREND ANALYSIS (DELTA)

Lead Investigator: Fred Resnic; Lead Institution: Lahey Hospital and Medical Center

The DELTA System is designed to provide near real-time active safety surveillance of clinical EHRs or clinical registry data during the course of evaluating a marketed medical device, medication, or therapeutic intervention. The DELTA projects are a part of the MDEpiNet programs supported by FDA/CDRH research grants and private philanthropies and led by Frederic Resnic at Lahey Hospital and Medical Center with Michael Matheny from Vanderbilt University, and Sharon-Lise Normand from Harvard Medical School.

DELTA features flexible alerting mechanisms that can trigger notification when an observed event rate exceeds boundaries of risk-adjusted expectations for the event of interest, permitting analysts to monitor large numbers of simultaneous, prospective active surveillance studies. The DELTA Surveillance propensity matching is uniquely suited to comparative safety analyses. It is statistically robust, easy to interpret and explain, and is conducive to post-hoc analysis for signal exploration. In a pragmatic and scalable approach, DELTA is validated in central data model and distributed models. The system has been validated in multiple medical device and medication safety surveillance domains and numerous data source environments from single hospital EHR systems, statewide clinical registries, national clinical registries, and distributed hospital networks. Fully open-source version (version 3.61) was released for academic and public health applications, including validated methods using the linked analytic engine Observational Cohort Event and Analysis Notification System and propensity matched prospective survival analysis.

This is a typical cumulative adverse event-monitoring chart (figure) with the red circles indicate a higher than expected adverse event rate for the studied medical device as compared with prospectively identified, propensity-matched control, population who received an alternative device.



Recent DELTA implementation projects include active surveillance of several National Cardiovascular Data (NCD) Registries. A CathPCI DELTA pilot study used an integrated clinical-data surveillance system to conduct a prospective, propensity-matched analysis of the safety of the Mynx vascular-closure device, as compared with alternative approved vascular-closure devices, with data from the CathPCI Registry of the NCD Registry[28]. The primary outcome was any vascular complication - a composite of access-site bleeding, access-site hematoma, retroperitoneal bleeding, or any vascular complication requiring intervention. The study concluded that a strategy of prospective, active surveillance of a clinical registry rapidly identified potential safety signals among recipients of an implantable vascular-closure device, with initial alerts occurring within the first 12 months of monitoring. Following that, the team published the prospective, active safety surveillance of national clinical registries and concluded feasibility to provide near-real-time safety assessments of new medical devices[29].

The current DELTA implementation pilot project is studying Implantable Cardiac Defibrillator (ICD) with a goal to validate DELTA propensity matched survival methods applied to the four most commonly used ICD leads in a prospective study to monitor the failure rate of four contemporary ICD leads.

6. NEW PROGRAM: UNIVERSITY OF CALIFORNIA SAN FRANCISCO OUTCOMES PROGRAM

Lead Institution: UCSF; Lead Investigators: Rita Redberg, Julie Ann Sosa, and Vanessa Jacoby (ULTRA)

Cardiac projects

UCSF and MDEpiNet Coordinating Center are collaborating to study the adoption pattern of cardiac surgical procedures (e.g. TAVR), percutaneous coronary interventions, pacemaker, and defibrillator implantations. The New York State discharge data is used for the projects and California all-payer data will be acquired.

Piloting Women's Health Registries in EHRs – the ULTRA Study at UCSF:

ULTRA study is a pilot study for Uterine Fibroid led by Dr. Vanessa Jacoby (https://fibroids.ucsf.edu/). This collaborative effort aims to help patients and doctors understand how the treatment changes fibroid symptoms, affects fertility and pregnancy, and impacts the need for additional fibroid treatment in the future.

In a post-market observational cohort study, ULTRA assesses safety and effectiveness of women undergoing Acessa™ treatment. The project recruits women through voluntary referrals from clinicians and engaged clinical sites in a multicenter study. UCSF follows up for 3 years after surgery. The outcomes of the study are operative morbidity, change in fibroid, treatment failure, and pregnancy outcomes. The patient population is queried every 6 months with questionnaires to collect PRO, and medical records are obtained for follow-up imaging. ULTRA collaborates with COMPARE-UF for harmonization of outcome assessments (CRFs and questionnaires) as well as WHT-CRN for opportunities to pilot new data elements in an ongoing post-market device study.

The collaborators created a core minimum data set for surgeries and procedures to treat uterine fibroids with a focus on the use of medical devices during these procedures. The minimum data set draws from data collected at the time of surgery (i.e. intraoperative outcomes and events). These data points are structured to serve as a template for a case report form in the research environment (e.g. post-market surveillance) and/or to embed within the electronic health record for use in a general clinical care workflow.

MDEpiNet Governance and Coordinating Center

MDEpiNet Governance and Coordinating Center

1. MDEpiNet Executive Operations Committee

The EOC is the central operations leadership committee for MDEpiNet. This committee is tasked with operations aligned with strategic direction provided through interaction with the national evaluation system for medical devices. The EOC reviews and approves projects, reviews progress from Committees and Learning Hubs and reviews, approves formal communications from MDEpiNet and advises on stakeholder engagement and sustainability opportunities. MDEpiNet Coordinating Center supports and facilitates the tasks carried out by the EOC.

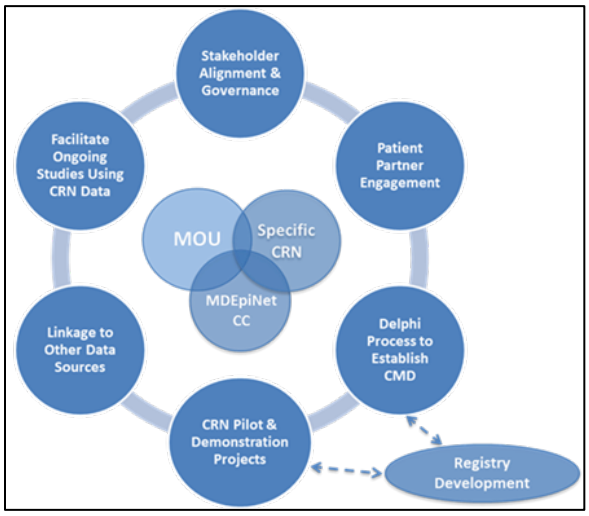
2. MDEpiNet Scientific Oversight Committee

The Scientific Oversight Committee (SOC) offers scientific and strategic advice reviews to members of MDEpiNet upon request as part of the process to be considered an MDEpiNet project. The SOC facilitates, provides guidance and oversight, and evaluates the progress of the individual working groups; it is responsible for considering key aspects of the working group implementation plans, including but not limited to:
(1) alignment of objectives with the MDEpiNet mission;
(2) implementation plans; and
(3) proposed deliverables.
SOC membership includes a broad range of individuals, representing the scientific community (from academia and industry) and regulatory agencies (US and International). The SOC reports directly to the EOC. MDEpiNet Coordinating Center supports and facilitates the tasks carried out by the SOC.

3. THE MDEPINET COORDINATING CENTER

The MDEpiNet Coordinating Center advances the infrastructure and frameworks for medical device innovation and evaluation. Several FDA white papers guide the overall approach of the Center, including the following:

1. *Strengthening Our National System for Medical Device Post-Market Surveillance Update and Next Steps* [30]
2. *Strengthening Patient Care: Building an Effective National Medical Device Surveillance System* [31]



The Center collaborates with partners and creates forums for discussion to bring external stakeholders together with relevant data owners and experts to share best practices and build collaborations. The Center conducts comparative outcomes studies and applies the results to informing clinical and regulatory decision-making. The Center is responsible for the advancement of novel infrastructure approaches and partnerships including strategically CRNsand international registry consortiums, and the coordination of all MDEpiNet governance committees and project development activities, in the following ways:

I. STAKEHOLDER ALIGNMENT AND GOVERNANCE

MDEpiNet Coordinating Center supports stakeholder alignment and governance by identifying important stakeholders for each CRN and facilitating communications and meetings among parties. The Center helps establish a CRN governance structure, including a steering committee and various subcommittees; holds think tank meetings with stakeholders and manages annual meetings at the FDA; and coordinating periodic conference calls as well as providing regular management support. The Center manages various committees and stakeholder participation in executive operations, scientific oversight, development of international chapters, and manuscript and publications. The Center engages providers and clinicians, health system executives, device industry, policy makers, researchers, community boards, as well as patient advocates and organizations including patient partners.

Patient Partners: MDEpiNet Coordinating Center actively helps to facilitate patient engagement efforts. Patients are an important part of MDEpiNet and a critical voice on many of its projects. Patient partners work alongside clinicians, researchers, device manufacturers, the FDA, and other federal agency staff to develop and improve real-world data collection and analyses in a variety of clinical areas. They bring the knowledge, experience and perspective of the patient community to MDEpiNet projects, advice to working groups on the needs and interests of the patient community and help develop the real-world data infrastructure that collects and communicates clinical evidence and outcomes that are of interest to patients.

The MDEpiNet Coordinating Center has implemented two different models for engaging patients:

Model 1 – patient partner recruitment by specific clinical areas

This effort engages patients in clinical areas of various CRNs. In this model, patients are recruited by each clinical working group through website announcements and an application process, are selected based on their interests, motivation, and experience being a patient or a caregiver in a specific clinical domain. *Example:* WHT pilot projects engaged patients in clinical areas such as SUI, UF, POP, and LARC/sterilization. Patient partners participate in an orientation to become familiarized with the project and activities; attend monthly meetings and calls with clinical working groups of their interest; provid feedback to the development of core minimum datasets to ensure that the registries collect patient-reported data; and are essential participants in answering research questions of fundamental interest to the patient community.

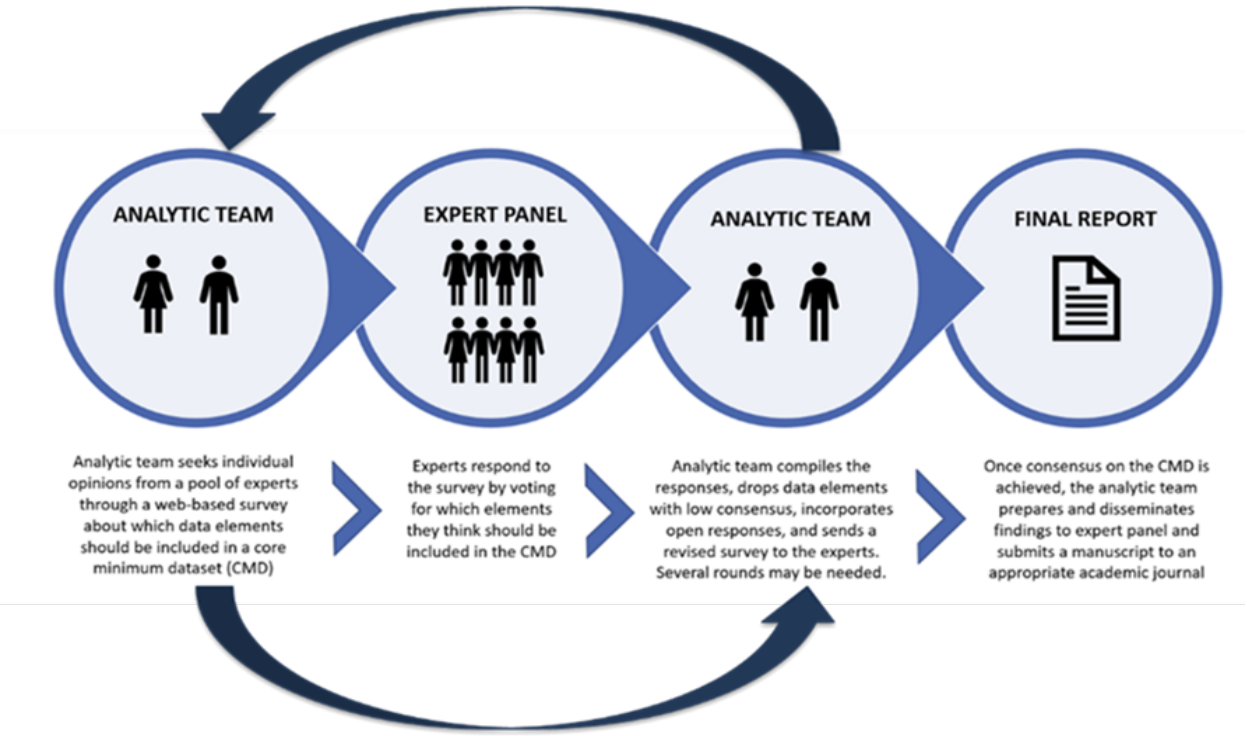
Model 2 – patient led roundtable with major stakeholders

This effort primarily engages patients in round-table meetings that bring patients together with agencies such as NIH, academics, device manufacturers and others to assess the current state of evidence relating to their field of medical devices. *Example*: TMJ piloted the model in TMJ replacement devices. Patients share their stories and concerns about the urgent need for interdisciplinary research and a paradigm shift in TMJ treatment; participate as Steering Committee members, working group co-chairs, working group participants, and co-investigators in the project; identify gaps and next steps to support working groups and establish a roadmap to achieve high-quality real-world data. They also highlight patients' needs as they too often continue to receive less than adequate guidance and treatment and suffer physically, socially, and economically.

II. Delphi Processes To Establish Core Minimum Data

The Coordinating Center supports the CRNs by convening stakeholders and leading a Delphi process to facilitate consensus on important aspects of registry advancement, such as the development of a core minimum dataset. Undergoing a Delphi process is a preferred method for reaching concordance about a core minimum dataset as there are many challenges to the traditional consensus panel approaches, such as the impact of a single person with a strong personality or the lack of anonymity, which may introduce bias. As a result, the Delphi process was developed to achieve consensus while minimizing bias inherent in group dynamics and face-to-face responses.

The below figure shows the working process of the Delphi method:



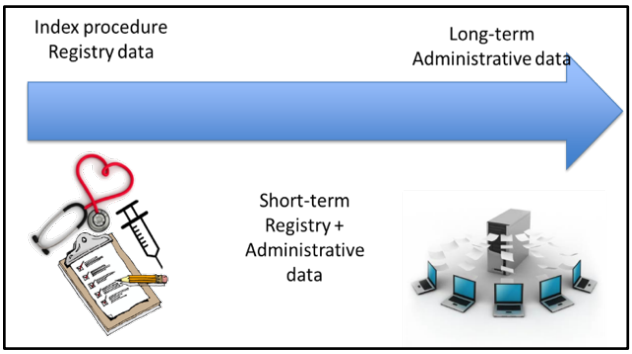
During a Delphi process, the first series of questionnaires are sent to the panel and answered by each expert anonymously and individually. From the questionnaires, experts have an opportunity to introduce new options and suggestions between rounds. Results are analyzed to identify responses with strong consensus (e.g. >50%). Data elements that lack consensus are automatically dropped (<50%) This process is repeated 2-3 times until a group consensus is reached.

MDEpiNet utilizes this process in various CRN efforts like NBIR, RASD, SPARED, TMJ, ICVR, and WHT. The WHT-CRN's clinical working groups (sterilization/long acting reversible contraceptives, pelvic organ prolapse, and uterine fibroids) have made substantial progress to include additional stakeholders (e.g., patient partners) by using the Delphi method to create core minimum datasets from the initial list of clinical elements identified.

III. Methodology Support for Registry Development

MDEpiNet Coordinating Center provides registry development support for pilot projects and ongoing studies using CRN data. The Center facilitates subcontracting and legal support including DUAs, data purchase, hosting, and access. The Center plays a crucial role in the methodology and analytics (e.g. data management and cleaning), statistical analysis, dataset linkage, OPC analysis, and others discussed further below.

Data Linkages



One of the main MDEpiNet methodological advancements has been to conduct linkages between registry data and routinely available data sources (e.g. claims and administrative data). The Center has been successfully developing and refining anonymous linkage algorithms to harness data resources including registries, claims data, and EHRs. Data linkage with indirect identifiers is reliable with high sensitivity and accuracy. It is the most cost-effective way to obtain long-term outcomes and has positive implications for long-term device surveillance. CRNs are currently supported for data linkage between registries and Medicare claims data; three-way linkage between registry, Medicare, and clinical data; linkage between registry and statewide discharge data; and linkage between registry and CDRN data.

Device Libraries

The Center is also building medical device information libraries, which include information like catalogue numbers and manufacturer names, to promote UDI for medical devices and enhance the capacity of the FDA's GUDID for research and surveillance.
ICOR, again, has a great example of a device library – see *ICOR CRN section for more details*. The ICOR implant library is supported by the Coordinating Center to develop a global, standardized classification system of hip and knee implantable devices, and includes all their clinical attributes and characteristics to advance the implementation of UDI and FDA post-market surveillance.

Distributed Analysis for International Registries

The Center has developed methodologies that have enabled the distributed analysis of international data. One great example of this work is in the ICOR in which data is being collected from over 30 registries across the world that can be used to conduct more large-scale studies. In this approach, a standardized data extraction is implemented by ICOR and distributed to participating registries. Each registry then completes the analyses of their own registry and completely de-identified data summaries are sent back to the coordinating center. Data are then combined using multivariable hierarchical models to evaluate comparative outcomes of devices regarding the main patient-centered outcomes (e.g. revision surgery after initial device implantation).

Natural Language Processing

Another important initiative of the Center is to develop natural language processing methods to extract information from text data. Ongoing work includes the development of methods to extract patient and device events and other information from device adverse event reports in the FDA Manufacturer and Use Facility Device Experience (MAUDE) database. These events and information can then be used to analyze patient and device events related to reintervention and patterns in adverse event reporting.

OPC Analysis

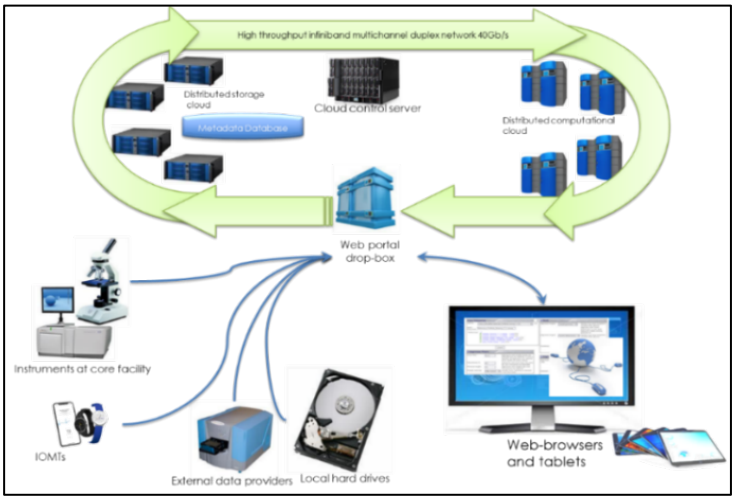
The Center is also developing OPC to leverage routinely available electronic, discharge and claims data to advance national post-market surveillance. An OPC is a target performance that was derived from historical data from clinical studies and/or registries, which may be used to compare safety or effectiveness endpoints for medical devices. OPCs can be utilized in pre-market and post-market clinical studies, such as single-arm trials, to improve the assessment of new and existing devices when having a control group is not feasible. OPCs may also be used toward evidence for labeling change of existing devices. OPC methodology has been used to evaluate the clinical performance of prosthetic heart valves and in other settings. The Center is currently working with Orthopedics CRN in developing OPC for outcomes following hip and knee replacements.

IV. MDEpiNet - High-Performance Integrated Virtual environment (HIVE)

MDEpiNet- HIVE is a technology that provides a secure healthcare biomedical data archival ecosystem. MDEpiNet- HIVE maintains a standardization and harmonization framework, high performance analytics, and an integrator platform. Dr. Vahan Simonyan is the lead instructor of HIVE efforts.

The recent implementation of HIVE hardware and software at the FDA presents a great opportunity for exploring new ways of analyzing vast amounts of data and deriving evidence that is more comprehensive to characterize a medical product.

HIVE is a distributed storage and computation environment and a multicomponent cloud infrastructure, which provides secure web access for authorized users to deposit, retrieve, annotate, and compute on biomedical big data. Importantly, it also allows users to analyze the outcomes using web interface visual environments appropriately built in collaboration with internal and external end users.



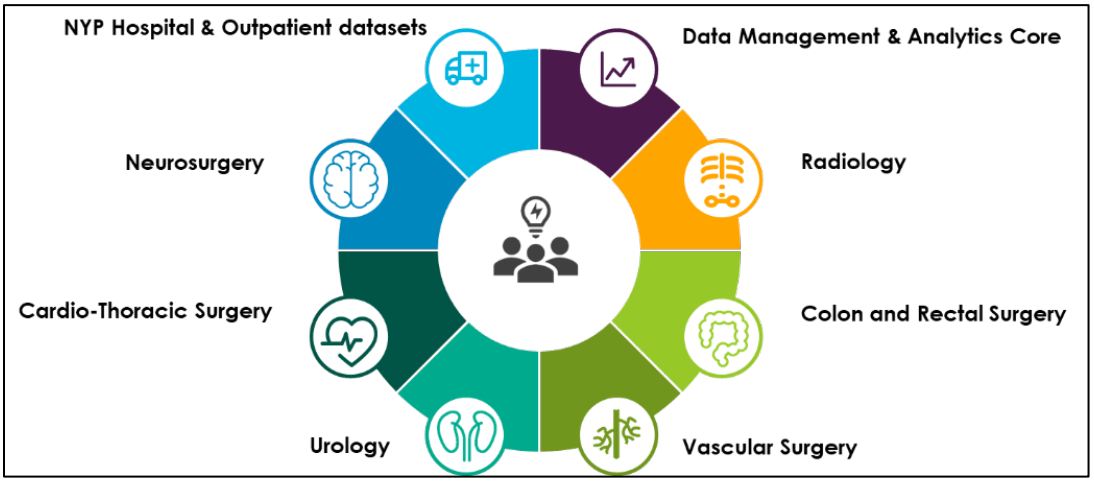
In addition to the initial HIVE applications to next generation sequencing, the current universe of HIVE projects covers tailor-made applications involving dimensionality analysis, federated and integrated data mapping, modeling and simulations that are applicable to basic research, biostatistics, epidemiology, clinical studies, post-market evaluation, manufacturing consistency, environmental metagenomics, outbreak detection, etc.

MDEpiNet Coordinating Center currently supports various HIVE pilot projects in women's health technologies and cancer settings. Patient and physician registry platforms are being developed as well as infrastructure for hosting registry and claims data and conducting data linkages that are distributed and centralized to support national and international collaborations.

Pilot approaches are set to develop a customized FHIR app for projects such as POP and SUI. These are being tested on mobile and connected devices through work with clinical teams to finalize the data elements for terminology and refine the app with feedback on usability.

V. MDEpiNet and Weill Cornell Medicine Claims Based Research Initiative (CBRI)

The Center coordinates research within this program to evaluate current and innovative devices and device-based interventions in medicine. Collaborating with clinical departments at Weill Cornell Medicine, the project aims to provide information and evidence for physicians and patients to facilitate informed clinical decision-making. The scope of the CBRI initiative includes the evaluation of device or procedure safety and efficacy and assessment of the impact of provider characteristics on patient and device outcomes. The program has access to a number of datasets including Medicare, New York State comprehensive discharge data, SEER-Medicare data for various cancer surgeries, and National Surgical Quality Improvement Program data, as well as international registry data for various surgical procedures. The program has expanded with the formal development of the Institute for Health Technologies and Interventions at Weill Cornell Medicine, which collaborates with various clinical departments, depicted below:



Major research areas:

- Research in radiology focuses on procedures and devices used in interventional radiology. These procedures and devices, such as liver tumor ablation, kidney tumor ablation, and inferior vena cava, may be used for cancer and non-cancer treatment.
- Research in colorectal surgery focuses on interventions and devices related to the treatment of colorectal cancer and benign conditions with a major focus on assessing safety, efficacy, and effectiveness of these technologies and interventions using big data and primary clinical data sources.
- Research in vascular surgery focuses on both traditional open and minimally invasive procedures in cardiovascular practice, and patient-centered surgical outcomes and provider

level factors in the areas of valve replacement or repairAAA, peripheral vascular disease, carotid stenosis, and cerebral aneurysm.

- Research in urology focuses on interventions and devices related to treatment of urologic cancers and benign urologic diseases, and comparative studies and patient-centered approaches that are used to assess the safety and efficacy of urologic procedures.
- Research in cardio-thoracic surgery is conducted on various topics including pulmonary resection, treatment of lung cancer, cardiac valve replacement or repair etc.
- Research in neurosurgery focuses on interventions and devices related to the treatment of brain tumors.

MDEpiNet's International Chapters

MDEpiNet's International Chapters

MDEpiNet has been championing international collaborations since our launch in 2010. The International Registry Consortia is one of the founding pillars of the MDEpiNet infrastructure with major successes of the ICVR and ICOR initiatives. In the past two years, MDEpiNet' s multi-stakeholder focused international chapters are a driving and unifying force for building the global device research discipline.

Australia Chapter

The Australia chapter was founded at the University of New South Wales Big Data Centre in January 2018. This chapter focuses on engaging regulators, major payers, and manufacturers to develop data infrastructure and implement unique device identifiers. A primary goal has been to highlight the role of RWE in active surveillance of health technologies by engaging registries and administrative databases. The chapter also plans to work with the leaders from the IMDRF that focus on big data to start a dialogue about application of the administrative data in regulatory science.

Developing Japan Chapter

MDEpiNet organized a real- world evidence workshop and summit in Japan for clinicians and regulators in January 2019 to discuss the launch of the Japan Chapter at the National Center for Global Health and Medicine, one of three major clinical and research centers in Japan that receives government funding for research. The chapter will have access to insurance claims data in Japan to develop its data model. Collaborations with novel partners like the national surgical registry of Japan are lined up for infrastructure development. Major meetings are planned for winter 2019 to kick start the developmental work.

Developing German Chapter

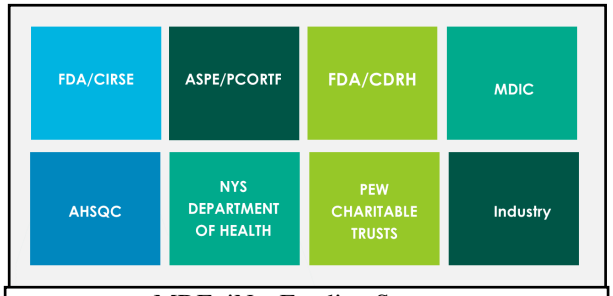
MDEpiNet German Chapter has been launched at the University Medical Center Hamburg-Eppendorf Research Group in collaboration with GermanVasc (https://germanvasc.de/) at the University of Hamburg, Germany. A nationwide Summit on RWE in cardiovascular medicine is planned for November 1, 2019 to advance the network. The GermanVasc group is well experienced in the scientific utilization of health insurance claims and registry data and is involved in national and international collaborations in cardiovascular medicine. Various public and private stakeholders and representatives from different medical specialties are invited to join the multidisciplinary task force further developing the MDEpiNet German Chapter.

MDEpiNet Sustainability / Funding

MDEpiNet Sustainability / Funding

Broad Range of Funding Sources

A broad range of private and public donors as well as non-profit governmental organizations support MDEpiNet collaborative efforts. They include the FDA Cardiovascular and Interventional Radiological Society of Europe (CIRSE); Office of the Assistant Secretary for Planning and Evaluation (ASPE); CDRH; Medical Device Innovation Consortium (MDIC); AHSQC; Patient Centered Outcomes Research Trust Fund (PCORTF); NY State Department of Health; the Pew Charitable Trusts; and various industry collaborators.



MDEpiNet Funding Sources

Broad Range of Stakeholders

MDEpiNet has a broad and diverse stakeholder engagement from public and private sectors that are showcased below:

Return on Investment

MDEpiNet is also committed to the promotion of RWE to reduce costs and time associated with evidence addition as well as overcoming the limitations of traditional tools and methods. MDEpiNet has been focused on documenting a clear method to demonstrate the value of CRNs and the public health benefits created by CRNs. Return on investment (ROI) studies using TVT CRN as a case study found ROI investments from registry-generated evidence to be greater than 550% [32]. Future ROI studies on vascular devices and abdominal core health devices are planned to enable greater discussion of the drivers of ROI and time savers.

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Image Source

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APPENDIX I - MDEPINET EXPERTS AND AFFILIATES

APPENDIX I - MDEpiNet Experts and Affiliates

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Benz, Heather	U.S. Food & Drug Administration
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Berliner, Elise	Agency for Healthcare Research and Quality
Berman, Scott	Tucson Vascular Surgery
Bertges, Daniel	University of Vermont
Bianco, Fernando	Urological Research Network Corp
Biggs, David	Cook Medical
Björck, Martin	Uppsala University Hospital

Name	Affiliation
Black, Dennis	Beckton-Dickinson
Bloss, Roberta	Gore
Bosco Lindi, John	Benjamin Mkapa Hospital
Bosela, Carrie	Vascular Quality Initiative
Boure, Ludovic	Medtronic
Boyle, Denea	Novant Health
Boyle, Jon	University of Cambridge
Bradley, Cate	University of Iowa
Bragg, Maria	Medtronic
Bragg, Maria	Medtronic
Braun, John	Mass General Hospital
Breiter, David	Medtronic
Brindis, Ralph	American College of Cardiology
Brinza, Diane	Coloplast
Brooke, Benjamin	University of Utah
Brooks, Claudette	U.S. Food & Drug Administration
Brown, Angela	Empowering Actions
Brown, Jennifer	Cook Medical
Broyles, Susan	U.S. Food & Drug Administration
Brush, Jenny	Office of the National Coordinator
Budtz Lilly, Jacob	Aarhus University
Burstin, Helen	Council of Medical Specialty Societies
Burtnyk, Mathieu	Profound Medical
Cahill, Patrick	Children's Hospital of Philadelphia
Calip, Evelyn	Torrance Memorial Medical Center
Campbell, Joanna	Allergan
Campion, Thomas	Weill Cornell Medicine
Canos, Daniel	U.S. Food & Drug Administration
Capatch, Kevin	Geisinger
Carmel, Maude	Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction
Carney, Patricia	Bayer
Carol, Mark	Sonacare Medical
Carty, Kelly	Allergan
Cassar, Kevin	Unversity of Malta
Cavanaugh, Ken	U.S. Food and Drug Administration
Chamblee, Sherri	Industry partner
Chandika, Alphonce	Benjamin Mkapa Hospital
Chang, Cynthia	U.S. Food & Drug Administration
Charalel, Resmi	Weill Cornell Medicine
Chen, David	Fox Chase Cancer Center
Cheng, Hong	U.S. Food & Drug Administration
Cher, Michael	Med Wayne
Chetta, Joshua	U.S. Food & Drug Administration
Chin, Joseph	Centers for Medicare & Medicaid Services
Chinn, Douglas	Chinn & Chinn Urology Associates
Chouinard, Scott	Medtronic
Chudnoff, Scott	Stamford Health
Chughtai, Bilal	Weill Cornell Medicine
Ci, Shufang	U.S. Food & Drug Administration
Claffey, Mairsil	Cerenovus Neuravi
Clarke, Harry	Medical University of South Carolina
Coelho, Don	BD-Bard
Coffelt, Cheryl	Baxter
Cohen, Andrea	Weill Cornell Medicine
Colden, Kelly	U.S. Food & Drug Administration
Cole, Curtis	Weill Cornell Medicine
Connor, Richard	Medtronic
Cope, Richard	Boston Applied Analytics
Cornelison, Terri	U.S. Food & Drug Administration
Cowley, Terrie	TMJ Association
Cronenwett, Jack	Dartmouth-Hitchcock

Name	Affiliation
Cronin, Heather	Medtronic
Crothall, Katherine	Aspire Bariatrics Inc
Crowley, Jay	USDM Life Sciences
Cunkelman, Jacqueline	U.S. Food & Drug Administration
Curet, Myriam	Intuitive Surgical
Currigan, Sean	American College of Obstetricians and Gynecologists
Dalsing, Michael	Indiana University
Dameral, Erin	Halt Medical
Darbouze, Farrah	Office of National Coordinator
Dave, Trushna	New York Presbyterian
Davis, Daniel	Penumbra
De Martino, Randall	Mayo Clinic
Debus, Sebastian	University Heart Center Hamburg-Eppendorf
Demarin, Melissa	WL Gore
Devlin, Vincent	U.S. Food & Drug Administration
Dhruva, Sanket	University of California, San Francisco
DiFabio, Vincent	American Society of Temporomandibular Surgeons
Dineen, Martin	Advanced Urology Institute
Dixon, Chris	University of Texas Health Tyler
Douthard, Regine	National Institute of Health
Downing, Denise	Association of periOperative Registered Nurses
Doyle, Lea	Bolton Medical
Dressler, Jeff	Abbott Laboratories
Drozda, Joseph	Mercy Health System
Du, Tony	U.S. Food & Drug Administration
Dudley, Curtis	Mercy Health System
Dumont, Douglas	U.S. Food & Drug Administration
Dunkel, Jeff	Titan Spine
Dunstan, Shelby	Americas Hernia Society Quality Collaborative
Durack, Jeremy	Memorial Sloan Kettering
Dutcher, Sarah	U.S. Food & Drug Administration
Eaton-Jankov, Laura	Apollo Endosurgery
Eberts, John	HealthTronics
Edhale, Behfar	Memorial Sloan Kettering Cancer Center
Eggener, Scott	University of Chicago
Eldrup, Nikolaj	Aarhus University Hospital
Eldrup-Jorgensen, Jens	MaineHealth
Eloff, Benjamin	U.S. Food & Drug Administration
Embert, Hugo	EDAP-USA
Erekson, Elisabeth	Dartmouth-Hitchcock
Etoh, Tsuyoshi	Oita University Hospital
Eydelman, Malvina	U.S. Food & Drug Administration
Faris, Owen	U.S. Food & Drug Administration
Federici, Tara	AdvaMed
Fisher, Benjamin	U.S. Food & Drug Administration
FIsher, Deborah	Duke University
Fitridge, Rob	University of Adelaide
Fletcher, Christian	Terumo
Fleurence, Rachael	National Evaluation System for health Technology
Flynn, Michael	University of Massachusetts
Foley, Jack	University of Maryland
Forsberg, Jonathan	Johns Hopkins University
Fortier, Brian	Aorta Medical
Franklin, Patricia	University of Massachusetts
Furnes, Ove	Haukeland University Hospital
Gamble, Ginger	Yale University
Garcia, Marcus	Hologic
Garcia, Stephanie	U.S. Department of Health and Human Services
Gardner, Donna	VP, Boston Scientific
Garellick, Goran	University of Gothenburg
Gaudino, Mario	Weill Cornell Medicine

Name	Affiliation
Gawrit, Nicholas	HEARTBASE
Gebben, David	U.S. Food & Drug Administration
George, Arvin	University of Michigan
Gibeily, George	U.S. Food & Drug Administration
Gibson, John	The MITRE Corporation
Girardi, Leonard	Weill Cornell Medicine
Given, Robert	Urology of Virginia
Glorioso-Rivera, Raquel	King Faisal Specialist Hospital & Research Centre
Glover, William	Novant Health UVA Health System
Glusenkamp, Nathan	American Joint Replacement Registry
Goddard, Carol	Americas Hernia Society Quality Collaborative
Goldestein, Jeffrey	Bayer
Gomelsky, Alex	Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction
Gonzales, Oscar	Biomet Microfixation
Goodney, Philip	Dartmouth-Hitchcock
Gordillo, Gayle	Indiana University Health
Gordon Cockburn, Myles	University of Southern California
Gorin, Michael	Johns Hopkins Medicine
Graham, Jove	Geisinger
Graves, Stephen	Australian Joint Replacement Registry
Greenberg, Jerry	El Dorado Urology
Grima, Matthew	Mater Dei Hospital
Grotemeyer, Dirk	Heinrich-Heine-University Hospital
Guiahi, Maryam	University of Colorado, Denver
Guo, Jianan	West China Hospital
Gurm, Hitinder	University of Michigan
Guss, Daniel	Harvard University
Haas, Kara	Johnson &Johnson
Hadlock, Melanie	Bard Peripheral Vascular
Hahn Kim, Seon	Korea University Anam Hospital
Hale, Douglas	Indiana University / Methodist Hospital
Hall, Leslie Kelly	Healthwise
Hallstrom, Brian	University of Michigan
Hammontree, Lee	Urology Centers of Alabama
Hanna, Sylvia	Allergan
Harbaugh, Robert	Penn State Health
Harkness, Donald	Stryker Neurovascular
Harris, Ray	Kidney Health Initiative
Harrison, Sebron	Weill Cornell Medicine
Hasegawa, Hirotoshi	Keio University
Hata, Taishi	Osaka University
Heath, Anne	Duke University
Heimer, Dawn	BD-Bard
Heise, Theodore	MED Institute
Heller, Georg	Kantonsspital Chur
Helwig, Amy	Agency for Healthcare Research and Quality
Herrmann, Robert	U.S. Food & Drug Administration/CDRH
Hewitt, Kathleen	American College of Cardiology
Hiatt, Jo Carol	Kaiser Permanente
Hiratsuka, Takahiro	Oita University Hospital
Hodde, Jason	Cook Biotech
Hodshon, Beth	Yale University
Hoel, Andrew	Northwestern Medicine
Hope, William	New Hanover Regional Medical Center
Hopper, Ingrid	Monash University
Hu, Jim	Weill Cornell Medicine
Hu, Ning	U.S. Food & Drug Administration
Huff, Stan	Intermountain
Hughes, Richard	University of Michigan
Huppert, Jill	Agency for Healthcare Research and Quality
Hysell, Kay	Mayo Clinic

Name	Affiliation
Ibrahim, Said	Weill Cornell Medicine
Illoh, Onyekachukwu	U.S. Food & Drug Administration
Inomata, Masafumi	Oita University Hospital
Irony, Telba	U.S. Food & Drug Administration
Isaacson, Keith	Newton-Wellesley Hospital
Isaia, Cristina	Gore
Ivanova-Trencheva, Koiana	Weill Cornell Medicine
Iverson, Sharon	Coloplast
Jacoby, Vanessa	University of California, San Francisco
Jalbert, Jessica	Weill Cornell Medicine
Jamshidi, Roxanne	George Washington University
Jan deBorst, Gert	University Medical Center Utrecht
Janis, Scott	National Institute of Health
Jayawardena, Gayathri	Office of the National Coordinator
Jenkins, Majorie	U.S. Food & Drug Administration
Jones, Schulyer	Duke University
Jorm, Louisa	University of New South Wales
Jung, Mary	U.S. Food & Drug Administration
Kanazawa, Akiyoshi	Shimane Prefectural Central Hospital
Kashanian, James	Weill Cornell Medicine
Kato, Masaaki	Osaka Prefectural Hospital
Kaushal, Rainu	Weill Cornell Medicine
Keller, James	Cooper Surgical
Kemp, Laura	Halt Medical
Kennedy, Kelley	Medtronic
Kerrigan, Betti	ARMUS Corporation
Kessler, Larry	University of Washington
Kim, Hyung	Cedars Sinai Medical Center
Klos, Katherine	Holy Cross Hospital
Kobashi, Kathleen	Virginia Mason Medical Center
Komori, Kimihiro	Nagoya University Hospital, JSVS
Kondo, Hiroka	Saitama University Medical Center
Kong, David	Duke University
Kono, Yohei	Weill Cornell Medicine
Korz, Dorian	U.S. Food & Drug Administration
Kottke, Melissa	Emory University
Kowalczyk, Keith	Georgetown
Koyama, Yukinori	Shimane Prefectural Central Hospital
Kraiss, Larry	University of Utah
Krause, David	U.S. Food & Drug Administration
Krucoff, Mitchell	Duke University Medical Center
Kuhne, JoAnn	Sientra
Kusiak, John	National Institute of Dental and Craniofacial Research
Kwolek, Chris	Massachusetts General Hospital
La, Chicuong	Focal healthcare
Labek, Gerold	University of Innsbruck
Lane, David	WL Gore
Lang, Lisa	National Library of Medicine
Lange, J.F.	Erasmus University Medical Center
Larson, Noelle	Mayo Clinic
Laschinger, John	U.S. Food & Drug Administration
Lattmann, Thomas	Kantonsspital Winterthu
Laughlin-Tommaso, Shannon	Mayo Clinic
Laviana, Aaron	Vanderbilt
Laxdal, Elin	Haukeland University Hospital
Lee, Angie	U.S. Food & Drug Administration
Lee, Joyce	U.S. Food & Drug Administration
Lemack, Gary	Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction
Lerman, Melvyn	Dallas Medical Specialists
Leroy, Antoine	KOELIS
Levie, Mark	Albert Einstein College of Medicine

Name	Affiliation
Levy, Barbara	American College of Obstetricians and Gynecologists
Levy, David	Cleveland Clinic
Levy, Jeffrey	Case Network
Lewallen, David	American Joint Replacement Registry
Liebeskind, David	University of California, Los Angeles
Lin, Asiyah	U.S. Food & Drug Administration
Lonner, Baron	Scoliosis and Spine Associates
Lopez Espada, Cristina	University of Granada
Lottes, Aaron	Cook Medical
Loyo-Berrios, Nilsa	U.S. Food & Drug Administration
Lupinetti, Patrick	First Databank
Lystig, Ted	Medtronic
Macarios, Dave	Allergan
Mack, Christina	IQVIA
Mack, Michael	Baylor University
Maisel, William	U.S. Food & Drug Administration
Malchau, Henrik	Massachusetts General Hospital
Malone, Misti	U.S. Food and Drug Administration
Mani, Kevin	Uppsala University
Mao, Jialin	Weill Cornell Medicine
Marinac-Dabic, Danica	U.S. Food & Drug Administration
Marks, Leonard	University of California, Los Angeles
Marks, Michelle	Setting Scoliosis Straight
Marler, John	Food and Drug Administration
Marsh, Erica	University of Michigan
Marsolo, Keith	Duke University
Martino, Martin	Lehigh Valley Health Network
Marx, Robert	Hospital for Special Surgery
Master, Sundeep	Intuitive Surgical
Matheny, Michael	Vanderbilt
Maughan, Tom	DePuySynthes
Maxwell, Larry	Inova Health Systems
McClure, Timothy	Weill Cornell Medicine
McComb, Jan	Minerva Surgical
McLaren, Alexander	Medicines and Healthcare Products Regulatory Agency
Medina, Mike	Zimmer Tether
Mege, Diane	Timone Hospital
Mehendale, Shilpa	Intuitive Surgical
Mehran, Roxana	Mount Sinai Hospital
Mek, Oki	U.S. Department of Health and Human Services
Melkerson, Mark	U.S. Food & Drug Administration
Meltzer, Andrew	Weill Cornell Medicine
Menyhei, Gabor	University of Pécs
Miller, Lisa	U.S. Food & Drug Administration
Millin, Courtney	U.S. Food & Drug Administration
Milsom, Jeffrey	Weill Cornell Medicine
Minaei, Behnaz	U.S. Food & Drug Administration
Mitchell, Kristi	Avalere
Mitchell-Magaldi, Donna	BD-Bard
Mizushima, Tsunekazu	Osaka University
Moalli, Pamela	American Urogynecologic Society
Mokni, Moncef	University Hospital Farhet Hached
Momose, Kota	Weill Cornell Medicine
Montgomery, Jeffrey	University of Michigan
Morabito, Julia	U.S. Food & Drug Administration
Morales, Pablo	U.S. Food & Drug Administration
Morcos, Manal	Bayer
Mori, Masaki	Osaka University
Morioka, Michina	Shimane Prefectural Central Hospital
Morrissey, Kevin	Weill Cornell Medicine
Moulakakis, Konstaninos	Rutgers University

Name	Affiliation
Mraz, Paul	ApiFix
Muhlestein, Brent	Intermountain Healthcare
Mullen, Erin	American Society of Plastic Surgeons
Myers, Evan	Duke University
Nakajima, Kentaro	NTT Medical Center Tokyo
Nakajima, Kiyokazu	Osaka University
Namba, Robert	Kaiser Permanente
Nandakumar, Govind	Columbia Asia Hospitals Bangalore
Natarajan, Shyam	Avenda Health
Navarro, Ron	Kaiser Permanente
Ness, Gregory	U.S. Food & Drug Administration
Nguyen, Hao	University of California, San Francisco
Nichol, Graham	University of Washington
Nicholson, Wanda	University of North Carolina
Nielsen, Joseph	U.S. Food & Drug Administration
Nitti, Victor	Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction
Nolan, Brian	Maine Medical Center
Normand, Sharon-Lise	Harvard Medical School
Nowell, Benjamin	Global Healthy Living Foundation
O'Boyle, Amy	American Urogynecologic Society
Ocke Reis, Paulo	Federal Fluminense University
Oduyebo, Titilope	Centers for Disease Control and Prevention
Ohno-Machado, Lucila	University of California, San Diego
Ohtsu, Hiroshi	National Center for Global Health and Medicine
Ojeda, Lahila	Centers for Medicare & Medicaid Services
Olson, Molly	Weill Cornell Medicine
O'Neill, Allison	U.S. Food & Drug Administration
Osborne, Nicholas	University of Michigan
Padmanabhan, Priya	Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction
Palmer, Sarah	Duke University
Panox, Elizabeth	U.S. Food & Drug Administration
Pappas, Gregory	U.S. Food & Drug Administration
Paraiso, Marie	Cleveland Clinic
Parkinson, Rosalind	Parkinson Logistics Associates LLC
Parsons, J. Kellogg	University of California, San Diego
Patel, Bakul	U.S. Food & Drug Administration
Paul, Subroto	Weill Cornell Medicine
Paxton, Liz	Kaiser Permanente
Peat, Raquel	U.S. Food & Drug Administration
Pena, Carlos	U.S. Food & Drug Administration
Perry, Robert	Department of Defense
Persenaire, Maarten	TelaBio
Philips, Bart	Medtronic
Philips, James	Franciscan Missionaries Of Our Lady Health System
Pisters, Louis	MD Anderson
Polascik, Thomas	Duke University
Porter, Martyn	Wrightington Hospital
Posthuma Batalden, Rebecca	American Urogynecologic Society
Poulose, Benjamin	Ohio State University
Prabhu, Ajita	Cleveland Clinic
Price, Veronica	U.S. Food & Drug Administration
Priester, Alan	University of California, Los Angeles
Prieto-Alhambra, Dani	University of Oxford
Prillinger, Julie	Abbott Laboratories
Pulliam, Samantha	University of North Carolina School of Medicine
Pullin, Brian	U.S. Food and Drug Administration
Pusic, Andrea	Harvard Medical School
Rabben, Toril	Oslo University Hospital
Rafiqi , Abdullah	Office of the National Coordinator
Raine, June	Medicines and Healthcare products Regulatory Agency
Ramakrishna, Rohan	Weill Cornell Medicine

Name	Affiliation
Rardin, Charley	Brown University
Raska, Melanie	Boston Scientific
Reardon, Michele	TMJ Patient Advocate
Redan, Jay	AdventHealth
Reed, Terrie	Reed McCullough, LLC
Resnic, Frederic	Lahey Hospital
Retherford, Katie	CR Bard
Rewcastle, John	Steba Biotech and USC
Reynolds, Stuart	American Urogynecologic Society
Richter, Holly	University of Alabama
Rieser, CJ	University of Virginia, MITRE
Ritchey, Mary Beth	RTI Health Solutions
Roan, Rachael	National Library of Medicine
Robbins, Susan	Lahey Hospital
Roberts, Jason	U.S. Food & Drug Administration
Robertson, Cary	Duke University Medical Center
Robison, Katina	Women and Infants Hospital in Rhode Island
Romanowski, Christine	Johnson & Johnson/Ethicon
Romero, Lucas	Weill Cornell Medicine
Rosen, Mike	Cleveland Clinic
Rosinia, Kristina	American Joint Replacement Registry
Ross, Jeff	MicroMatrix
Ross, Joseph	Yale University
Rothstein, Zach	AdvaMed
Rovner, Eric	Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction
Ruckle, Herbert	Loma Linda University Health
Rush, Scott	Terumo
Saad, Ahmed	MedStreaming LLC
Sagliocca, Franco	Mount Sinai Health System
Samdani, Amer	Shriners Hospital For Children
Sangha, Roopina	Henry Ford Health System
Santiago-Lastra, Yahir	Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction
Sase, Kazuhiro	Juntendo University
Scali, Salvatore	University of Florida Health
Schermerhorn, Marc	Harvard Medical School
Scherr, Douglas	Weill Cornell Medicine
Schiller, Mike	Matrix IT
Schleckser, Patricia	Johnson & Johnson/Ethicon
Schlegel, Peter	Weill Cornell Medicine
Schmidt, Lisa	TMJ Patient Advocate
Schmitz, Niels-Derrek	Johnson & Johnson/Ethicon
Schneider, Darren	Weill Cornell Medicine
Schwartzman, Harriet	Americas Hernia Society Quality Collaborative
Sedrakyan, Art	Weill Cornell Medicine
Segars, James	Johns Hopkins University
Seger, Rian	BD-Bard
Selander, Kristine	Francis Medical
Serrano, Katrina	National Institute of Health
Setacci, Carlo	University Hospital of Siena
Settembre, Nicla	University of Helsinki
Sewell, Catherine	U.S. Food & Drug Administration
Shaffer, William	American Academy of Orthopaedic Surgeons
Shahriary, Melanie	American Heart Association
Sharma, Sam	Weill Cornell Medicine
Sharp, Howard	University of Utah
Shaya, Fadia	Institute for Clinical and Translational Research, University of Maryland
Sheldon, Murray	U.S. Food & Drug Administration
Shrader, Patricia	Medtronic
Shuren, Jeffrey	U.S. Food & Drug Administration
Siddiqui, Adnan	University of Buffalo
Siddiqui, Mohummad	University of Maryland

Name	Affiliation
Sigvant, Birgitta	Uppsala University
Silvestri, Angela	Stryker
Simanowith, Michael	American College of Cardiology
Simoes, Tiessa	Medtronic
Simons, Jessica	University of Massachusetts
Simonyan, Vahan	WHISE/Emblema
Singh, Goldy	Profound Medical
Sinohara, Katsuto	University of California, San Francisco
Skapik, Julia	Cognitive Medicine
Skau, Colleen	American Urogynecologic Society
Skolasky, Richard	Johns Hopkins University
Slotwiner, David	Weill Cornell Medical College - New York Presbyterian Hospital
Smale, Josh	CR Bard
Smith, Elizabeth	Acell
Smith, Scott	Office of the Assistant Secretary for Planning and Evaluation
Snyder, Brian	Harvard University
Somerman, Martha	National Institute of Health
Sommers, Katie	American Society of Plastic Surgeons
Sonn, Geoff	Stanford School of Medicine
Spies, Jim	Georgetown University
Sponseller, Paul	Johns Hopkins University
Steger, Brad	Zimmer Biomet
Steliac, Marta	U.S. Food & Drug Administration
Stewart, Elizabeth	Mayo Clinic
Stewart, Thomas	Vanderbilt University
Stiles, Brendon	Weill Cornell Medicine
Stimpson, Susan	Novant Health, Inc.
Su, Bowdoin	Allergan
Suarez-Mier, Gabriela	U.S. Food & Drug Administration
Sui, Xiufen	Centers for Medicare & Medicaid Services
Svetlikov, Alexei	Sokolov Clinical Hospital
Szeberin, Zoltan	Semmelweis University
Taira, Itsuki	Shimane Prefectural Central Hospital
Talenfeld, Adam	Weill Cornell Medicine
Taylor, Anna	U.S. Food & Drug Administration
Tcheng, James	Duke University
Tcheng, Jimmy	Duke University
Teng, Xiao	West China Hospital, Sichuan University
Thatcher, Robert	4C Medical Technologies
Thompson, Kweli	Medtronic
Thompson, Matt	Endologix
Thomson, Ian	University of Otago
Thourani, Vinod	MedStar Health
Tomes, Madris	Device Events
Tong, Liyue	Epidemiologist at U.S. Food & Drug Administration
Tonohira, Yuko	Weill Cornell Medicine
Toor, Sadaf	U.S. Food & Drug Administration
Tornetta, Paul	Boston Medical Center
Torosyan, Yelizaveta	U.S. Food & Drug Administration
Trinh, Quoc-Dien	Brigham and Women's Hospital
Tsuruta, Masashi	Keio University
Tucker, Keith	Orthopaedic Data Evaluation Panel
Ulisney, Karen	U.S. Food & Drug Administration
Unger, Julie	U.S. Food & Drug Administration
Uppuluri, Nagesh	Medtronic
van de Graaf, Floyd	Erasmus University Medical Center
Van Velthoven, Roland	Bordet Cancer Institute, Brussels
Varosy, Paul	Department of Veterans Affairs
Vega, Dora	U.S. Food & Drug Administration
Velezis, Marti	U.S. Food & Drug Administration
Vemulapalli, Sreekanth	Duke University Medical Center

Name	Affiliation
Venable, Sateria	Fibroid Foundation
Venermo, Maarit	Helsinki University Central Hospital
Verheyden, Charles	Baylor Scott & White Cosmetic Surgery Center
Vitale, Michael	Columbia University
Viviano, Charles	U.S. Food & Drug Administration
Voorhorst, Paul	Johnson & Johnson
Wadzinski, Jim	Society for Vascular Surgeons
Wang, Grace	University of Pennsylvania
Wang, Ziqiang	West China Hospital, Sichuan University
Ward, John	MD Anderson
Warner, Lizette	Philips
Weber, Stephen	U.S. Food & Drug Administration
Wei, Mingtian	West China Hospital, Sichuan University
West, Melissa	Kidney Health Initiative
White, Roseann	your3rdopinion
Whiteman, Maura	Centers for Disease Control and Prevention
Wiedmeier, Kirk	Duke University
Wigger, Pius	Kantonsspital Winterthur
Wilgus, Rebecca	Duke University
Williams, Erin	The MITRE Corporation
Williams, Mary	Duke University
Williams, Scott	Cook Medical
Willis, Debi	MyLinks
Willson, Elizabeth	Society of Interventional Radiology
Wilson, Natalia	Arizona State University
Wilson, Ricki	Vizient
Winchester, Kendra	BD-Bard
Wirtshafter, Amery	Urological Consultants of Florida
Wise, Heather	TMJ Concepts
Wisman, Craig	BD-Bard
Wittebols, Kristel	Medtronic
Woodle, Carole	U.S. Department of Veterans Affairs
Wysock, James	New York University
Yakushiji, Hiromi	Oita University Hospital
Yamaguchi, Shigeki	Saitama University Medical Center
Yanagisawa, Kiminori	Osaka University
Yang, Wen	West China Hospital, Sichuan University
Yao, Hong-wei	Beijing Friendship Hospital
Yeo, Heather	Weill Cornell Medicine
Yesha, Yelena	University of Maryland, Baltimore County
Yoon, Sung	U.S. Food & Drug Administration
Young, Melissa	Boston Scientific
Zhang, Ke	M2S Inc.
Zhang, Shumin	Johnson & Johnson
Zheng, Xiaolin	U.S. Food and Drug Administration
Zhou, Qi	BCBS Maine
Zinnert, Michelle	American Urogynecologic Society
Zuckerman, Diana	National Center for Health Research
Zusterzeel, Robbert	National Evaluation System for health Technology Coordinating Center

APPENDIX II - MDEPINET LIST OF SELECTED PUBLICATIONS

APPENDIX II – MDEpiNet List of Selected Publications

1. Columbo JA, Martinez-Camblor P, O'Malley AJ, Suckow BD, Hoel AW, Stone DH, Schanzer A, Schermerhorn ML, Sedrakyan A, Goodney PP; Society for Vascular Surgery's Vascular Quality Initiative. Long-term Reintervention After Endovascular Abdominal Aortic Aneurysm Repair. Ann Surg. 2019 Jul 8. doi:10.1097/SLA.0000000000003446. [Epub ahead of print] PubMed PMID: 31290764.
2. Gross MD, Sedrakyan A, Bianco FJ, Carroll PR, Daskivich TJ, Eggener SE, Ehdaie B, Fisher B, Gorin MA, Hunt B, Jiang H, Klein EA, Marinac-Dabic D, Montgomery JS, Polascik TJ, Priester AM, Rastinehad AR, Viviano CJ, Wysock JS, Hu JC. Study of Prostate Ablation Related Energy Devices (SPARED) Collaboration: Patient Selection for Partial Gland Ablation in Men with Localized Prostate Cancer. *J Urol*. 2019 May 30:101097JU0000000000000357. doi: 10.1097/JU.0000000000000357.
3. Mao J, Guiahi M, Chudnoff S, Schlegel P, Pfeifer S, Sedrakyan A. Seven-Year Outcomes After Hysteroscopic and Laparoscopic Sterilizations. *Obstet Gynecol.* 2019 Feb;133(2):323-331. doi: 10.1097/AOG.0000000000003092.
4. Rieß HC, Debus ES, Schwaneberg T, Sedrakyan A, Kölbel T, Tsilimparis N, Larena-Avellaneda A, Behrendt CA. Gender disparities in fenestrated and branched endovascular aortic repair. *Eur J Cardiothorac Surg.* 2019 Feb 1;55(2):338-344. Doi: 10.1093/ejcts/ezy249.
5. Baskin KM, Mermel LA, Saad TF, Journeycake JM, Schaefer CM, Modi BP, Vrazas JI, Gore B, Drews BB, Doellman D, Kocoshis SA, Abu-Elmagd KM, Towbin RB; Venous Access: National Guideline and Registry Development (VANGUARD) Initiative Affected Persons Advisory Panel. Evidence-Based Strategies and Recommendations for Preservation of Central Venous Access in Children. JPEN J Parenter Enteral Nutr. 2019 Apr 21. doi: 10.1002/jpen.1591. [Epub ahead of print]
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