Maturity Model for Medical Device Registries and Coordinated Registry Networks (CRNs)

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Coordinated Registry Networks (CRNs)

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

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

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

CRNs from diverse clinical areas are further strategically aligned though CRN Learning Community, established and coordinated by the MDEpiNet via grant from FDA

Office of the Assistant Secretary for Planning and Evaluation (ASPE). Developing a Strategically Coordinated Registry Network (CRN) for Women's Health Technologies. https://aspe.hhs.gov/developing-strategically-coordinated-registry-network-crn-womens-health-technology.

Office of the Assistant Secretary for Planning and Evaluation (ASPE). Bridging the PCOR Infrastructure and Technology Innovation through Coordinated Registry Networks (CRN) Community of Practice. https://aspe.hhs.gov/bridging-pcor-infrastructure-and-technology-innovation-through-coordinated-registry-networks-crn-community-practice

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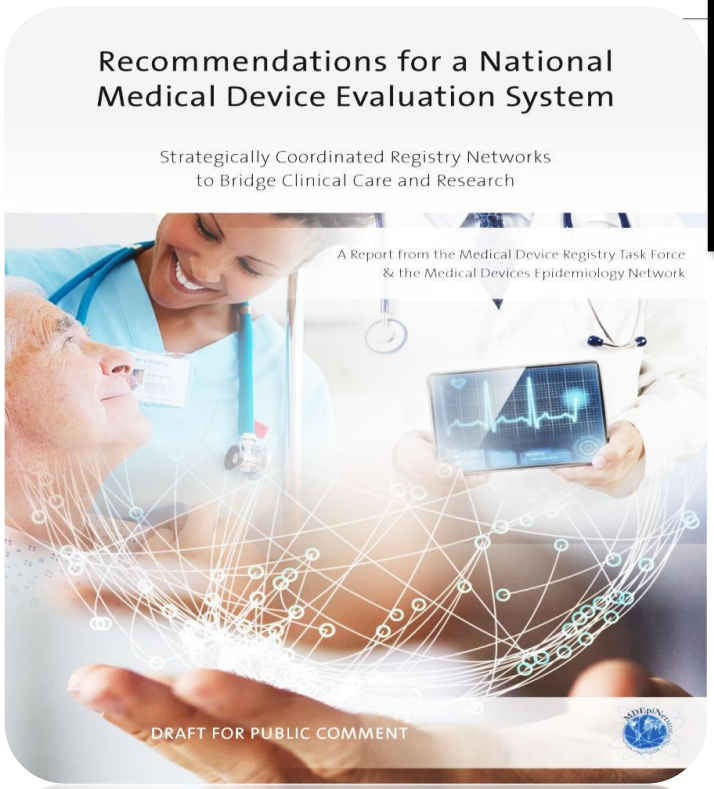
Birth of the CRN Concept



BRIDGING UNMET CLINICAL CARE AND CLINICAL RESEARCH NEEDS WITH STRATEGICALLY COORDINATED REGISTRY NETWORKS

Report from the National Medical Device Registry Task Force & The Medical Devices Epidemiology Network

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VIEWPOINT

Bridging Unmet Medical Device Ecosystem Needs With Strategically Coordinated Registries Networks

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In June 2014, the Medical Device Epidemiology Network (MDEpiNet) Public Private Partnership,[1] on behalf of the US Food and Drug Administration Center for Devices and Radiologic Health (CDRH), convened the Medical Device Registries Task Force (MDRTF) (see eAppendix in the Supplement). The task force was launched to address the CDRH's commitments[2,3] to strengthen the medical device postmarket surveillance system using existing resources and under current authorities and to develop an integrated system that efficiently and effectively achieves its basic functions, from timely identification of postmarket signals to facilitating premarket device clearance and approval.

The MDRTF included broad stakeholder representation and was mandated to examine the objectives and logistics of leveraging existing electronic registries and information repositories in support of a national system. This work was done in parallel with efforts at the Engelberg Center at the Brookings Institution, which in 2015 reported recommendations from their planning board for a "national medical device surveillance system." These recommendations depicted a system that "supports optimal patient care by leveraging the experiences of pa-

The MDRTF recognized that most existing registries, electronic health records (EHRs), and data sources do not contain all the elements necessary for device evaluations, including device and procedural details, patient descriptors, or long-term outcomes. However, the MDRTF recognized that such limitations could be mitigated through interoperability solutions that strategically link complementary registries and data sources to produce networks for which the data composite could support robust device evaluation. The MDRTF termed this structure the strategically *coordinated registries network*, or CRN—with the recognition that many key elements in such networks (such as EHRs, administrative claims data, or mobile device outputs) are not registries per se. The MDRTF recommends strategic CRNs as the foundational architectural construct for the national system that will augment national registry development and unique device identifier implementation rather than replace them.

The proposed CRN structure could provide novel, important attributes to the national system. Creation of CRNs could encourage efficient "dual-purpose" leveraging of existing registries, EHRs, administrative data resources, and lessons learned from existing linked-registry models such

Strategically Coordinated Registry Networks (CRN) Principles:

- **Link complementary sustainable registries/e-repositories (Professional society registries, EHRs, Claims data, PCORI- CDRNs)**
- **TPLC approach as a true continuum leveraging "real world" evidence**
- **"Dual purpose" existing national, regional or other large scale efforts**

https://www.fda.gov/media/93140/download;
Krucoff MW, Sedrakyan A, Normand SL. Bridging Unmet Medical Device Ecosystem Needs With Strategically Coordinated Registries Networks. JAMA. 2015 Oct 27;314(16):1691-2.

CRNs Build on International Models and Standards

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

http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-160930-principles-system-registries.pdf

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

Office of the Assistant Secretary for Planning and Evaluation (ASPE). Developing a Strategically Coordinated Registry Network (CRN) for Women's Health Technologies. https://aspe.hhs.gov/developing-strategically-coordinated-registry-network-crn-womens-health-technology.

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https://www.mdepinet.net/coordinated-registry-networks

Framework of Maturity of CRNs and Registries
7 Key Domains and 5 Levels of Maturity

***UDI*:**

Precise identification of medical devices and their attributes

***Data Collection Efficiency*:**

Structured data capture, mobile apps and automation with interoperability solutions

***Data Quality*:**

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

***Total Product Life Cycle*:**

Infrastructure for conducting research and surveillance at different stages of device evaluation. Important role for data linkages

***Governance and Sustainability*:**

Engage major stakeholders: societies, payers, various states. Obtain major & diverse funding

***Healthcare Quality Improvement*:**

Device technologies require continuous evaluation: Feedback, benchmarking and outlier assessments

Engaging patients and incorporation of patient generated data:

Engage, evaluate preferences and measure general and disease specific PROs

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

Example: Optimized Data Collection Efficiency

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

* Paper accepted for publication in BMJ-SIT, expected April, 2022

Example: Data Collection Efficiency Domain

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

Level 1. Early Learner

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

Level 2. Making progress

Level 3. Defined Path to Success

Level 4. Well-Managed

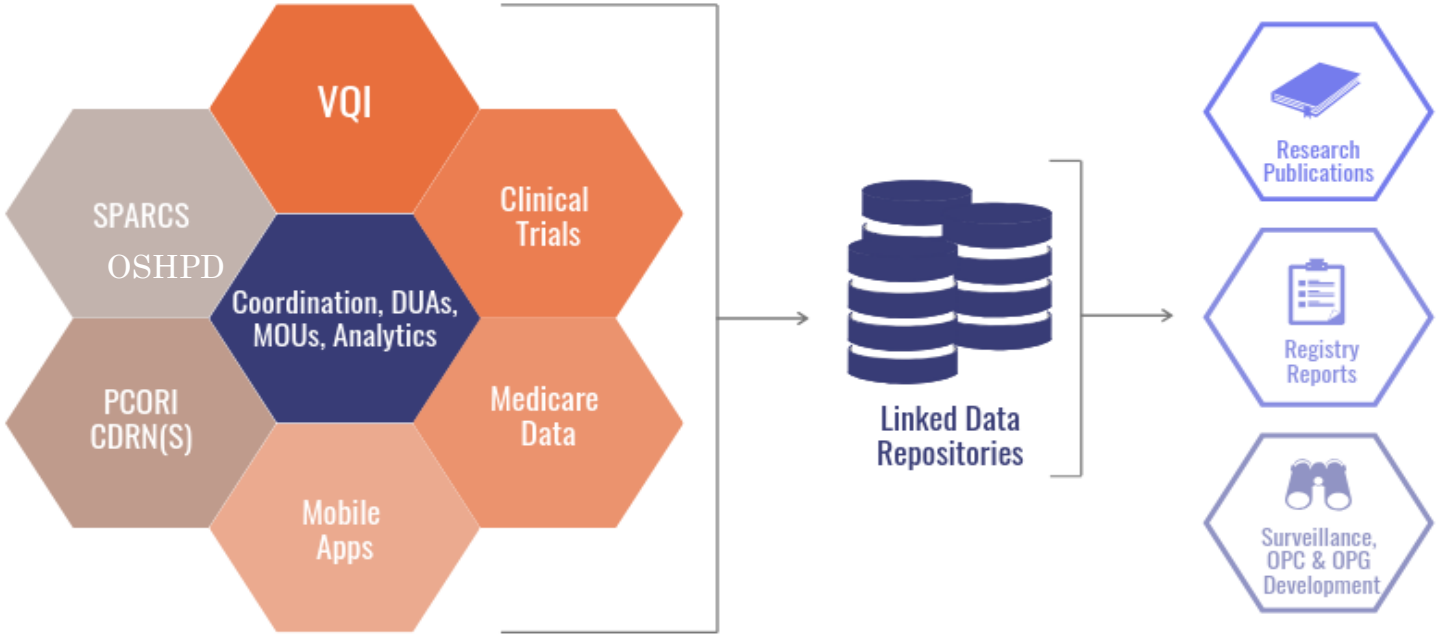
Level 5. Optimized

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

Example of a Mature CRN

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

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



Total Procedures Captured (as of 1/1/2022)	905,355
Peripheral Vascular Intervention	305,540
Carotid Endarterectomy	168,754
Infra-Inguinal Bypass	71,889
Endovascular AAA Repair	69,508
Hemodialysis Access	68,362
Carotid Artery Stent	67,413
Varicose Vein	50,909
Supra-Inguinal Bypass	23,214
Thoracic and Complex EVAR	23,450
Lower Extremity Amputations	23,300
IVC Filter	16,715
Open AAA Repair	15,861
Vascular Medicine Consult	376
Venous Stent	64

30 publications /
6 validation studies in high impact journals

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

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

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

880 clinical sites
3000 providers
> 200 types of devices

US CRN Learning Community

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

- **Crosspollination areas**: clinical, data science, epidemiology/statistics, digital tools, blockchain, imaging, international
- **16 tools shared and applied** : (a) harmonization efforts in CRN architecture and data exchange (logic model for clinical work flow), (2) methods (validation, data linkages, outcomes studies, ROI, ML/AI), (3) mobile apps (patient and provider-based) and others

Example: International Consortium of Vascular Registries (ICVR)

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

CRNs are Already Producing the Regulatory Grade Evidence

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

a. Pappas G, Berlin J, Avila-Tang E, et al. Determining value of Coordinated Registry Networks (CRNs): a case of transcatheter valve therapies **BMJ Surgery, Interventions, & Health Technologies** 2019;1:e000003. doi: 10.1136/bmjsit-2019-000003
b. Cronenwett JL, Avila-Tang E, Beck AW, Bertges D, Eldrup-Jorgensen J, Resnic FS, Radoja N, Sedrakyan A, Schick A, Smale J, Bloss RA, Phillips P, Hasenbank M, Wang S, Marinac-Dabic D, Pappas G. Use of data from the Vascular Quality Initiative registry to support regulatory decisions yielded a high return on investment. **BMJ Surg Interv Health Technol**. 2020 Oct 30;2(1):e000039. doi: 10.1136/bmjsit-2020-000039. PMID: 35051256; PMCID: PMC8749325.

Any Questions?

THANK YOU!

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