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Maturity framework and select approaches for developing Coordinated Registry Networks (CRNs): Medical Device Epidemiology Network (MDEpiNet) supplement

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Real-world evidence (RWE) is a robust and pragmatic solution for evaluating many priority medical devices and health technologies for regulatory and clinical decision-making. RWE not only complements evidence provided by clinical trials but also independently informs decision-making when it is fit for purpose of timely evaluation of devices.[1] Within various data sources for generating RWE, registries often form the core for the evaluation of specific procedures and related devices.[2] With this focus, Medical Device Epidemiology Network (MDEpiNet) Coordinated registry networks (CRNs) were developed to advance the use of the RWE in medical device evaluations.[3] CRNs include not only data but also a learning community of healthcare stakeholders such as clinicians, industry, patient groups, payers, academia and regulators. CRNs create good value for stakeholders when conducting timely and efficient device performance evaluations when compared with traditional clinical research.[4 5] CRNs often build from quality improvement registries,[6] product-specific registries established by clinicians, regulators and payors,[7] or major integrated delivery organisations[8] based on clinical or device research needs of these organisations (figure 1).

In this supplement, we describe major examples of CRN initiation, advancement, and maturation with the help of strategic and systematic stakeholder alignment. First, we describe the CRN maturity framework with seven attributes that define the registry's path to success. Then, we describe current developments in select clinical settings of CRNs.

THE FRAMEWORK OF CRN MATURATION

The maturity framework presented in this supplement is an innovative and practical guide for clinicians and researchers interested in developing robust CRNs and advancing global capability. It was proposed by MDEpiNet Coordinating Center at Weill Cornell Medicine based on decade-long experience with registries and regulators and key collaborator input. The collaborators were engaged over 2 years to define technical areas related to the development and activities of CRNs, using a formal Delphi consensus method.[9] The need for a maturity framework was recognised for effective registry creation and data collection because there is an immense burden of cost, time and accuracy in collecting device data. CRN maturity framework has a systematic approach to important attributes of success such as patient engagement, data quality, efficiency, accuracy as well as ability to maintain the infrastructure comprehensively and sustainably for regulatory decision-making. The maturity framework[10] describes these attributes as seven domains (figure 2). The goal of the framework is for registry leaders to prioritise making required investments in each area of maturity to create value for relevant stakeholders.

STAKEHOLDER ALIGNMENT APPROACH FOR DEVELOPING AND ADVANCING CRNS

The next six papers in this supplement summarise the collaborative work of MDEpiNet in the past several years that helped select CRNs to develop data capacity and infrastructure.[11–16] CRNs were tailored to the clinical context as well as the available resources to provide an efficient platform for device performance evaluation. The stakeholder alignment provided registry leaders early insights into the potential challenges

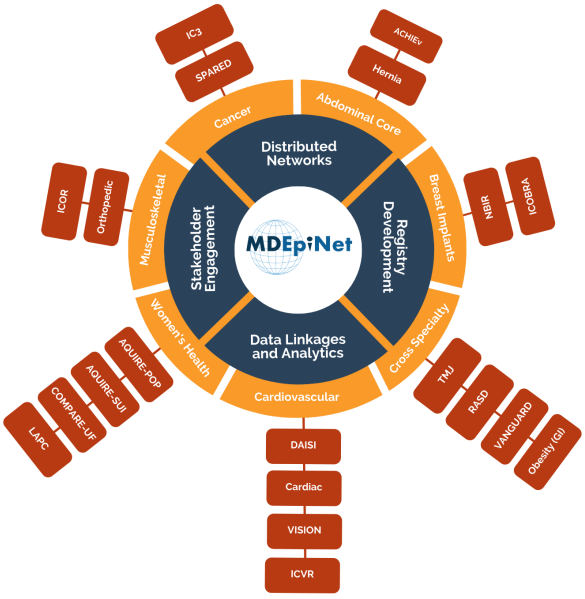

Figure 1 MDEpiNet's Strategically Coordinated Registry Networks in various clinical areas. ACH, Abdominal Core Health; ACHIEv, Abdominal Core Health International Evaluations; ACQUIRE; The American Urogynecologic Society (AUGS) Community for Quality Improvement Using Real-world Evidence; POP, Pelvic Organ Prolapse and SUI, Stress Urinary Incontinence; COMPARE-UF, Comparing Options for Management: Patient-centred Results for Uterine Fibroids; DAISI, Devices used for Acute Ischemic Stroke Intervention; ESRD, End-Stage Renal Disease; ICOR, International Consortium of Orthopedic Registries; ICVR, International Consortium of Vascular Registries; ICOBRA, International Consortium of Breast Registry Activities; LAPC, Long-acting and Permanent Contraception; NBIR, National Breast Implants Registry; Ortho, Orthopedic Devices; RASD, Robotic-Assisted Surgery Devices; SPARED, Study of Prostate Ablation Evidence Development; TMJ, Temporo-mandibular Joint; VANGUARD, Venous Access National Guideline & Registry Development; VISION, Vascular Implants Surveillance, and Outcomes Network.

Figure 2 Domains of maturity for coordinated registry networks.

and paths for the successful development of CRN. Stakeholders often met in person to identify the barriers, challenges, and potential solutions towards registry initiation. The CRNs established core data elements, conducted pilot studies, and major investigations when reaching maturity.

The select CRNs covered in this supplement are as follows:

Orthopedics CRN, launched in 2017, is a mature CRN that promotes novel device research methods, infrastructure, and partnerships with a systematic collaboration of national orthopaedic registries like Kaiser Permanente, Michigan Arthroplasty Registry, and the FORCE-TJR registry, as well as the International Consortium of Orthopedic Registries (ICOR). It consists of the major health system and federal and state-funded efforts, capturing long-term events enabling complete follow-up for surveillance and research.[8 17] This national network has established a platform for high-quality data sources for comparative effectiveness research and enhanced the overall regulatory process through active surveillance with advanced methodologies in signal detection, implant tracking, gender studies, and objective performance criteria in hip and knee arthroplasty.[11]

Devices in Acute Ischemic Stroke Intervention (DAISI) CRN, established in 2017, is enhancing regulatory and clinical decision-making to support the development of innovative and safe neurovascular devices. DAISI successfully identified its core data elements with the help of a multistakeholder committee of 15 experts and multiple data sources such as the National Cardiovascular Data Registry-Peripheral Vascular Intervention registry, American Heart Association, NeuroVascular Quality Initiative, National Acute Stroke Registry, Interventional Stroke Therapy Outcomes Registry, and StrokeNet. By majority voting method, the council identified a set of 234 core data elements, which consists of patient demographics, medical history, preprocedural, procedure, and post-procedural information, imaging data, and follow-up outcomes.[12] A pilot study on basilar artery occlusions is ongoing using the core data elements.

Obesity Devices (GI) CRN, inaugurated in 2016, is at an early stage of building capacity for data quality, registry participation, and efficient data collection and sharing in obesity devices. CRN stakeholders including patients convened a forum and three workgroups: patient-reported outcomes, clinical registries, and informatics to develop core data elements for research and surveillance of endoscopic obesity and metabolic devices. The data sources for establishing core data elements included existing literature, case report forms, and instruments from the American College of Surgeons Metabolic and Bariatric Surgery Accreditation and Quality Improvement registry. Using a majority voting method, core data elements were identified with relevant device characteristics, clinical information, and outcomes important for safety and effectiveness evaluations.[13]

Women's health technologies (WHT) CRN, launched in 2017, has successfully developed the capacity in evaluating surgical devices used in women's reproductive health. The CRN has established core data elements in pelvic organ prolapse (POP), uterine fibroids (UF), and long-acting and permanent contraception with the help of collaborations with national registries like The American Urogynecologic Society Community for Quality Improvement Using Real-world Evidence (ACQUIRE) and Comparing Options for Management: Patient-centred Results of UF (COMPARE-UF). Delphi consensus method was used by the three clinical working groups to gather experts' agreement on the compatibility of the technologies with the data elements initially proposed. The three papers by Baird *et al* describe the established core data elements in POP, UF, and contraception.[14–16] It is a crucial milestone towards advancing the CRN's capacity to evaluate the safety and effectiveness of these technologies.

The successful establishment of these CRNs and the creation of a framework of maturity were made possible by the systematic collaborative approach of the CRN learning community. MDEpiNet's public–private partnership with over a decade of continuous effort and investment has helped nurture this community with access to national and international registries.

Overall, CRNs have developed a very promising capacity for benchmarking and quality assurance for interventional procedures and contribute to specialty societies as well as to manufacturers to evaluate devices and meet regulatory requirements.

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