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Building Real-World Evidence Infrastructure to Improve Health and Healthcare in the United States: Part I—Coordinated Registry Networks and Systemic Coordinated Inter-Organizational Networks

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ABSTRACT

Background and Objective: Over the past decade substantial government and market-driven efforts focused on the use of real-world evidence (RWE) to improve healthcare decision-making. A successful strategy has been mounted by specialty societies and their registries that have created RWE through a model known as the Coordinated Registry Network (CRN), which has accelerated innovation, improved care quality, addressed the safety and efficacy of medical products, and supported medical research. This three-part manuscript works to understand how the CRNs have succeeded by applying organizational sociology and the theory of Systemic Coordinated Inter-Organizational Networks (SCIONs).

Methods: We describe CRNs as organizations that evolved from the traditional registries of clinical specialty societies. We present the SCIONs theory, a network of organizations that deploy a coordination strategy based on trust and cooperation to solve complex problems. By applying sociological concepts, we identified key characteristics and functions that can inform the development of CRNs, providing practical guidance for their implementation.

Results: Our analysis reveals that CRNs offer a unique mode of coordination that can address complex healthcare challenges, leveraging traditional market and government efforts. CRNs can support the vision of a learning health system and evidence-based medicine by harnessing the power of RWE, transforming, and improving healthcare delivery.

Conclusion and Implications for Translation: CRNs have the potential to transform evidence generation in healthcare by curating and integrating multiple data sources that can address the data needs of multiple CRN partners. This American solution to the provision of evidence for supporting decision-making in healthcare builds on professional society relationships; the CRN model has demonstrated success in large national registries and warrants expansion to other specialty areas. By understanding the organizational sociology of CRNs, we can unlock their full potential to drive innovation, efficiency, and quality improvement in healthcare.

Keywords: Evidence-Based Medicine, Learning Health System, Public Reporting of Healthcare Data, Quality Improvement, Quality of Healthcare, Registries, Social Theory

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INTRODUCTION

Real-world data (RWD) collected as part of routine clinical care can play a critical role in generating real-world evidence (RWE) and enhancing decision-making across the healthcare ecosystem. In the United States (U.S.), successful large-scale coordinated registry networks (CRNs) have demonstrated significant value within the unique structure of the U.S. healthcare system and, if expanded, could help address longstanding challenges related to the quality and use of RWD in healthcare.^[1,2,3] This three-part manuscript applies organizational sociology and systemic coordinated inter-organizational networks (SCIONs) theory^[4] to understand how CRNs work and have succeeded.

The CRNs are data-driven strategic partnerships that differ from other RWE efforts in many ways. They build on clinical registries of professional societies by linking them to other data platforms to meet the many needs for evidence in the learning health system (LHS),^[5] such as for clinical care support, quality improvement, research, and making regulatory decisions.^[6–8] CRNs have overcome impediments to the production of RWE through the unique set of relations described for curation that is done in the context of clinical care. CRNs successfully curate data out of clinics by maintaining access to the detailed context of care that is necessary for accurate coding and interpretation of data describing patient care. CRNs also link registries to complementary data sources—including medical claims, vital records, and patient/app-generated data—they provide data on patients over time and more granular RWE. Clinicians and their professional societies provide the timely selection of appropriate data elements and direct analysis addressing the needs of clinical care in a changing environment. Studies have documented that CRNs outperform legacy sources of evidence in terms of efficiency (faster data collection at lower costs) and usefulness.^[3,9,10] The term “registry” is a legacy term that may not accurately convey the more encompassing concept of CRN.

Hage, Valadez, and Hadden (2024),^[4] who originated the SCIONs theory, describe it as a third coordination mode that successfully addresses difficult social problems where the two long-standing societal coordination modes, market competition and state coordination,^[11] have not.

CRNs have succeeded, as this third mode, whereas other models have not, after a decade of intense investment in health information technology (IT) by the private sector and in government. Billions of annual venture capital over past years^[12] have not solved the problems of RWE described here. Government investments (Sentinel,^[13] COVID-related^[14]) have had limited success, foundering on inability to produce sufficient granular data. The model used by industry and government, which involves curating data after it has been

aggregated, severs the connection to the original source of the data, making it difficult to establish a clear source of truth. Furthermore, this method also disrupts the relationships between data creators, experts, and innovators, hindering the ability to tap into the collective experience and knowledge of a large network. This, in turn, slows down the dissemination of innovative solutions, ultimately hindering progress in addressing complex health issues. In addition, the repetitive curation of health data for single-purpose studies by multiple entities is not sustainable. Our manuscript describes how CRNs operate under the coordination of clinical specialty societies as a collaborative model in clinical practice.

Countries with highly developed registries have managed their health systems more efficiently and produced better health outcomes.^[15] In the United States, successful, large-scale CRNs demonstrated the value to the distinct structure of US healthcare and if scaled may help address some of the longstanding issues related to quality and use of RWD in our healthcare ecosystem.

This Part I of the three-part argument sets out the concepts of CRN and SCION. In Part II, the SCIONs theory is applied to CRN practice, and an extended case study is offered; the Vascular Quality Initiative is described using the concepts of SCIONs theory. Part III evaluated the utility of SCIONs theory for CRN development, and the contribution to the SCIONs theory by this review of CRNs is considered.

METHODS

The framework of action theory^[16] is sociology’s approach to providing practical solutions to real-world problems. By applying the insights of organizational sociology, we aim to enhance CRN development and create a foundation for the subsequent sections of this article. This approach also serves as a bridge to evaluating the effectiveness of CRNs and further refining the theory of SCIONs. Moving from this theoretical foundation, we turn our attention to the practical building blocks of RWE and the development of LHSs.

RESULTS

Building Blocks of RWE

Evidence-based medicine (EBM) was a concept born during the rise of biomedical informatics, with the increasing conduct of clinical trials and an explosion of published information about healthcare in the decades preceding public access to the internet. The growing awareness of problems in healthcare quality and inconsistent adoption of EBM led to the vision of a national LHS.^[17] In 2007, a seminal report by the Institute of Medicine (IOM) described LHS as a “system designed to generate and apply the best evidence for the collaborative healthcare choices of each patient

and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in healthcare.”^[18] Later iterations of the LHS vision incorporated additional proposed roles including^[19] addressing rising US healthcare costs, which continue to outpace those of other highly developed economies.^[20,21]

The IOM’s vision for the LHS^[19,22] included the collection of RWD as part of routine clinical care and its transformation into RWE^[23] for a wide variety of uses. The promotion of RWE aimed to bridge the gap between clinical research and clinical medicine, as data collection within the same settings was leading to redundancy and fragmentation instead of shared solutions.^[24] RWE has accelerated the pace of EBM, driving innovation and transforming healthcare on a large scale.^[25] In the US, national professional societies and their academic medical center partners have leveraged RWE to create clinical registries that not only inform evidence-based interventions but also facilitate their widespread adoption across various healthcare settings nationwide.^[26]

To realize the vision of the LHS, the RWE infrastructure would be capable of overcoming current limitations, as well as including “messy data”^[27] problem, which medical informatics literature calls “lack of semantic interoperability.” In addition the RWE infrastructure would enable tracking cohorts longitudinally to understand outcomes and adverse events related to intervention.

The next section describes how CRNs have overcome these roadblocks to the transformation of RWD into RWE and how they have successfully accelerated innovation in healthcare.

CRNS: A UNIQUE SET OF ORGANIZATIONAL RELATIONSHIPS

CRNs are data-driven networks that stimulate and coordinate innovations across various clinical settings, supporting clinical improvements based on evidence developed in clinical practice.^[28] CRNs evolved out of traditional registries of clinical specialty societies, which have been part of healthcare since the early 20th century.^[29] Most CRNs began as quality improvement programs and have expanded to include a range of evidence-based initiatives [Figure 1]. CRNs have evolved into robust and sustainable infrastructure that supports and informs regulatory decision-making, addressing overtreatment, innovation in medical processes and products, and research on patient-centered outcomes.^[3,10,30–45] Potential future applications include pandemic preparedness, medical product price negotiations, and determination of payment for care services.^[42]

Over the years, some of these registries have transformed into large, sophisticated CRNs, supported by numerous information technology contractors.^[46] The operations on these data sources in participating clinics involve extraction,^[47]

curation,^[48] standardization,^[49] interoperability,^[50] and harmonization^[49]—prespecified processes essential to ensure integration into a multipurpose, accessible data source. Although CRNs were initially established in the surgical and procedure specialties, they are currently being developed or planned in most clinical specialty areas.

The National Medical Device Registry Taskforce^[2] first used the term CRN for clinical registries that strategically linked data from a variety of sources, traditionally limited to 30-day follow-up. A CRN links many RWD sources (e.g., medical claims data, electronic health records, and patient-generated health information). They also bring together legacy registries, combine related specialty areas, or facilitate regional efforts to improve coverage in a larger CRN.

A maturity model^[28] supports the development of CRN capacity by providing a continuum for CRN evaluation. Mature CRNs are associated with professional societies such as the American College of Cardiology, the Society of Thoracic Surgeons, the Society for Vascular Surgery, the American College of Surgeons, and the American Academy of Orthopedic Surgeons, among others.^[51]

Various medical specialties are increasingly using CRNs to drive technology-driven practices, improve patient outcomes, and advance medical research. The Intelligent Research in Sight registry^[52] supports technology-driven practices in ophthalmology. The American Heart Association/American Stroke Association has built a suite of programs collectively called “Get with the Guidelines” that use a registry of multiple diseases.^[53] The I-SPY program,^[54] which can be considered a CRN, is a network of oncology practices aggregating data from an adaptive phase 2 platform trial that integrates continuous improvement of medical science and quality of care for the treatment of breast cancer. The National Institute of Dental and Craniofacial Research developed the Temporomandibular Joint Implant Registry and Repository, a patient-led CRN, to address temporomandibular joint disorders treated by multiple clinical specialties.^[55,56] Also, the Cystic Fibrosis Foundation Patient Registry^[57] addresses a rare condition. These last two mentioned are patient-led registries offering a different model for conditions for which professional societies have difficulties.

CRN is not the branding for specific organizations but rather a concept describing advanced clinical registries that use similar strategies to solve problems. CRNs that bring together data in primary care^[58] and community health centers^[59] are also being established. The evaluation of COVID-19 vaccines^[60] using linked claims from the Centers for Medicare and Medicaid Services (CMS) for individuals across time has important similarities and could be considered a CRN.

The CRN’s unique organizational relationships explain how they have overcome the challenges posed by “missing” and “messy” data, which plague RWE. As a novel coordination

mechanism, CRNs effectively prespecify data by collaborating directly with clinicians at specific care sites, who possess the comprehensive contextual knowledge necessary to overcome these challenges. Clinical societies also provide a forum in which essential data elements are identified and modes of standardizing coding are promoted. Consultation with the people who create and collect the data is also essential to ensure the continued utility of data as clinical practice evolves. Commercial aggregators that separate data from the context of the collection cannot replicate the relationships that underpin the CRN's success in data curation. Data aggregated but cut off from the context of clinical care cannot be adequately curated.^[61–64] Another challenge pertains to the missingness of data in numerous digitalized sources. For example, in cardiology, almost 25% of the data collected in the National Cardiovascular Disease Registry is not found in the electronic health records. Currently, missing data is addressed via manual curation, leveraging a high level of knowledge of clinical context.

The linkage of data to enrich registries and provide longitudinality has been another hallmark of CRNs. Cohorts of RWE typically lack follow-up data because patients in the United States move between providers over time, making it difficult to follow these patients longitudinally. The study of the progression of disease and the safety and efficacy of treatment has successfully been addressed by data linkage.^[60–65] The linkage of registries to CMS claims data has provided this longitudinality for CRNs.^[66] Methods are well developed to maintain the confidentiality and security of the records.^[67]

The sustainability of the CRNs also stems from the unique set of relationships between participating clinics and many partners using the data. Each partner in the network can contribute to and benefit from the CRN in unique ways.^[18] Despite the intensive labor and high cost of data curation, CRNs efficiently distribute costs among partners by collecting and curating data once and utilizing it across multiple partners. Researchers have documented CRN-generated RWE as “better, faster, and cheaper” than evidence from the types of studies traditionally used to evaluate medical products, owing to the unique relationships involved.^[7,8,32,34,68] The achievements of CRN in enhancing the quality of care represent a radical innovation, given as a technical definition by the sociological theory below. The CRN's quality improvement functions are well documented while contrasted to programs that seek quality improvement through traditional, top-down process management, such as audit and feedback programs for medical professionals, which have shown little impact on the quality of care.^[69–71]

Mature CRNs Have Transformed Healthcare

This manuscript emphasizes the structure and function of CRNs as organizations, but it is their success in addressing

the most difficult problems in US healthcare that draw our interest. The highly mature CRNs are improving healthcare at scale. The National Cardiovascular Disease Registry (NCDR) is a suite of registries developing over a 35-year history that has had a major impact on healthcare in the US and globally. It brings together two major specialty societies, the American College of Cardiology and the Society for Thoracic Surgery. Almost all cardiac catheterization labs currently participate. The NCDR is part of a global growth of registries to improve health.^[72]

The NCDR has had a major impact on the care of cardiovascular disease and the healthcare industry more broadly. NCDR has helped create a culture of accountability and continuous improvement among healthcare professionals and hospitals.^[73] Improving the quality of care through the use of the large databases of NCDR has improved the safety and quality of cardiovascular care. NCDR has supported research leading to innovation, including, as a prominent example, the development of procedures for aortic valve replacement in older patients, the data being used to support Food and Drug Administration (FDA) approval and the CMS payment.^[74] Finally, health policy has been informed by these national registries,^[75] including the promotion of active surveillance to decrease the time required to discover problems (e.g., adverse events with cardiac devices).^[76] Part II of this manuscript provides a case study of how a professional society and its CRN have transformed vascular surgery and references successes in other specialty areas. There is a growing consensus that these registries can increase their utility in the future through planned improvement.^[77]

The CRNs' unique relationships can be better understood by applying a theoretical formulation from SCIONs theory.

SCIONS

Sociologist Jerald Hage and colleagues have proposed the theory of SCIONs, which are collaborative networks of organizations united by a shared societal goal. SCIONs manifest as alternative organizational structures that address societal problems where market forces and governmental efforts have not succeeded.^[4] According to Hage and colleagues, SCIONs offer two key advantages, that is, their source of value, that make them a viable alternative: Firstly, the varied change strategies within SCIONs enable rapid organizational adaptation and flexibility. Secondly, continuous coordination in SCIONs fosters collaboration and effectiveness, leading to impactful institutional change.^[4] The limitations of government and market-driven forces are well understood, including challenges such as vested interests, sunk costs, previous organizational success, and single-loop thinking (evaluating the implementation of a strategy without evaluating the strategies themselves as a second loop).^[16] “Bounded rationality” renders organizational change difficult, even when individuals in an organization understand the obstacles.^[78] A distinction between

individual learning and organizational learning has led to the search for new organizational structures that address social problems that current institutions are unable to resolve. For a deeper understanding of CRNs as a prime example of SCIONs, we refer the reader to Hage, Valadez, and Hadden (2024).^[4] This work explores the capabilities and limitations of market forces and government in detail, characterizes SCIONs, and explains why SCIONs can succeed where business and government cannot.

The characteristics of SCIONs, their coordination mechanism, and performance evaluation criteria are listed in Table 1 and described below.

Characteristics of SCIONs

Systemic. The “systemic” characteristic of SCIONs entails assembling a variety of organizations to engage in decentralized decision-making, ensuring representation from all facets of a particular system working towards a common objective. Each organization may have distinct goals and expertise, but what unites them is a shared system output that they all value.

Organizational. Different types of organizational networks can be ranked based on the nature of their relationships.^[4] At one level, organizations may begin to share information to further their own ends. This may start with personal relationships between members of different organizations, as in interest groups,^[79,80] but these become organizational ties when they move beyond personal ties.^[79,81] Organizations may also move on from information sharing to the joint solving of common problems and, at another level, to the coordination of services, joint training, and capacity building. It is these ties that define a network. The SCION is at the top of this ranking, needing relationships among organizations pursuing shared goals and collectively producing solutions; each organization contributes, but no one organization dominates.

Coordination. Coordination is another defining characteristic of SCIONs. An autonomous coordinating unit with specialized resources enables purposeful coordination of network activities. These units, called network coordinating organizations (NCOs), serve as a platform for resolving different perspectives and building positive relationships among the organizations that participate in the network. The NCO's independent nature is critical to a unique and continuous coordination mechanism that is absent in market or state models.^[4]

Typically, NCOs are organized as 501(c)(3) non-profit organizations. A board comprising representatives from the network's member organizations governs the NCO, while a Chief Executive Officer (CEO) who is not from one of the member organizations manages its operations. Resources of NCOs include dedicated staff with expertise and experience providing technical support regarding the issues that SCIONs address. To provide technical assistance across the

Table 1: SCIONs criteria: characteristics, coordination mechanisms, and performance evaluation.

Characteristics of SCIONs	
Systemic	Pursuing a common socially valued goal
Organizations	A network of organizations Non-governmental, but also potentially private or government
Coordination	An autonomous coordinating organization Decentralized decision-making, supportive supervision, information sharing, Network Coordinating Organization (NCO)
Technical staff	Knowledgeable Technical assistance, diffusing innovations
SCIONs coordination mechanisms**	
Allocating	Various resources, funds, equipment, appropriate skills, and technologies
Controlling	Activities of the organizations in the network; Limiting the number of members and requiring reports from them: Forcing organizations to leave the network due to poor performance: Supportive supervision of member organizations' activities
Stimulating Cooperation	Achieve common goals, sharing of information between members about tactics, exchanging funds between members, starting sub-networks in different regions or around specialized problems to do joint planning interventions
Performance evaluation criteria	
Learning	Increase organizational capacity Improved knowledge of environment, system
Innovation	New strategies and tactics Faster diffusion of new technology
Adaptation	Problem solving Coping with change
**Adapted from Table 1.3 coordination mechanisms. SCIONs: Systemic coordinated inter-organizational networks.	

numerous units of the network, the staff are expected to also possess the ability to collaborate with various organizations and individuals. As opposed to rule-driven government organizations, NCOs work through support, supervision, and information sharing.^[4]

An independent CEO leads the NCO, using charm, charisma, or diplomacy to unite partners in a network.^[82] The inter-organizational component denotes that at least three organizations are brought together around shared goals. The networks are voluntary and based on the utility of each unit. A SCION decentralizes decision-making, functioning as a cooperative structure where network members share decision-making.

Technical Staff. Unlike the hierarchical staffing model of government bureaucracies, which emphasizes top-down communication,^[83] the technical staff of a SCION NCO works collaboratively with and complements the staff of the organizations in the network. Supportive supervision promotes organizational learning and builds trust (social capital) that enhances the ongoing work. The technical specialties depend on the inter-organizational network's specific goals.

Coordination Mechanisms

Coordination mechanisms, a second set of criteria for a SCION, provide the distinct advantage that allows them to succeed where other types of organizations have not. This section describes how coordination occurs and how it differs from similar mechanisms in markets and government. The mechanisms of coordination are the allocation of resources, control of specified activities, and stimulation of cooperation between units in the network.^[4]

Allocation of Resources. Markets allocate resources via price mechanisms, which are known to be slow. NCOs can act comparatively quickly. SCIONs can rapidly introduce new skills and technologies relevant to the inter-organizational network to start the process of organizational learning. In contrast, companies in the marketplace are slow to share innovation. The spread of new skills and technologies within market-driven organizations can be slow, as companies tend to be risk-averse. Governments use rule-driven coordination, also characterized by slow speed.^[4]

Control of Specified Activities. While NCOs act as gatekeepers in some respects, they primarily act through supportive supervision rather than the tight supervision and control found in government bureaucracies. The technical staff of the NCO assists units in solving problems, complementing, and guiding the technical staff of member organizations. Supportive supervision of SCIONs is distinctive and helps create organizational learning. The development of social capital, specifically in the form of trust, is critical during the later stages of the development process.^[4]

Stimulation of Cooperation Between Units of Work. The promotion of cooperation, the most distinctive form of coordination of SCIONs, is characterized by three small c's: an independent CEO, competent technical staff, and their use of charm, charisma, or diplomacy.^[4]

A SCION NCO executive director has independence from the units that constitute the network and is not a CEO of participating member organizations. This independence allows avoidance of divided loyalties between managing the network organization and managing other entities (a firm, public agency, or a specific organization in a network). The CEO of an NCO provides checks and balances, allowing for concentration on the goals.

The second critical coordination component is a competent technical staff with expertise in specialties and skills needed to build human capital in the inter-organizational network. Which competencies are most critical depends on an inter-organizational network's goals.

The third component, which can be challenging to measure and difficult to locate in leadership, is charisma, charm, and diplomacy. Charisma and charm make people want to follow leaders and promote comfortable working relations. A leader of an NCO can use diplomacy to win over people who may initially be suspicious or hold different opinions.^[4]

Performance Evaluation Criteria

Performance evaluation guides SCIONs in measuring the effectiveness of units within the network and as a whole. Goal attainment, gap analysis, and feedback are critical services that a network-coordinating organization provides to the network in order to facilitate social integration, an increase in social capital, decreased costs, and increased benefits to network members.^[4]

The SCIONs must be able to create "radical change" within organizations. Radical change is defined as changes in strategies, multiple tactics, organization restructuring, or the introduction of new technologies, products, or services that go beyond incremental changes. The amount of organizational change is relative to the existing patterns of behavior and the stock of organizational knowledge. If a business, public agency, or non-governmental organization judges its strategy change sufficiently, it may be considered radical; however, structural change is by definition radical.^[4]

These aspects of institutional change have to be measured using clear evaluation frameworks that prioritize effectiveness and goal attainment. Social integration and social capital are two examples of process measures. Outcomes such as decreased costs and increased benefits ideally would be measurable. The NCO typically works with organizations across the network to coordinate measurement of performance, conduct gap analysis, and provide feedback. Internally generated inventions or the identification and addressing of performance gaps can achieve change.^[4]

Identifying performance gaps leads to network members questioning their strategies and tactics. The diversity of organizations within a SCION allows for information sharing, the generation of new ideas, and the testing and refinement of multiple strategies, all of which lead to faster and more radical organizational change for members.^[84] NCOs promote sharing and cooperation, which generate learning, increase organizational capacity, and improve knowledge of the environment and systems. Through innovation, the NCO fosters new strategies and tactics to enhance outcomes by measurement and information sharing. It also accelerates the diffusion of innovation throughout the network.

SCIONs promote three types of radical organizational change: learning, innovation, and adaptation.^[4] First, learning increases organizational capacity and improves knowledge of the environment and systems developed outside of the network to be incorporated and diffused through the network, where they are further evaluated. Second, innovations are the new strategies and tactics developed within the network that improve outcomes. New products, and services, or at least incremental improvements in them, serve as indicators of organizational innovation. Finally, adaptation, which is a component of organizational learning, involves implementing new organizational procedures or technology to address challenges faced by network partners. An organization's adaptiveness, derived from the study of business administration, identifies the organization's response to changes in the environment. Hage, Valadez, and Hadden argue that SCIONs increase the probability of the recognition of problems and their solutions.^[4]

DISCUSSION

This paper presents the CRN as a successful strategy for building an RWE infrastructure that supports the evidentiary needs for health and healthcare. The emergence of CRNs can be traced back to a broader historical context of the need for EBM and the vision for an LHS that can provide evidence for a variety of needs, utilizing data collected during clinical practice. CRNs have evolved out of clinical specialty society registries, linking with other data resources to cater to a variety of needs. Research has shown that this model yields evidence that is both more valuable (allowing for the study of heterogeneity of effect with large sample sizes) and efficient (requiring less money and time) than previous studies. The specific types of cooperation-based relationships between clinics and other partners in the network described by SCIONs theory and observed for CRNs in the next part of this three-part series enable CRNs to create value.

This work also presents the SCIONs, theory to illuminate an emerging organizational type that has successfully resolved problems where business and government approaches have not. In Part II of this series, we apply the theory of SCIONs to CRNs, including a review of a specific CRN experience and an extended case study on, the Vascular Quality Initiative (VQI)/Vascular Implant Surveillance and Interventional Outcomes Network (VISION). Part III looks at how organizational sociology can be used to figure out how the CRN model can grow in more clinical areas. It also talks about the other things that an emerging RWE national infrastructure will need and what the problems with CRNs are.

CONCLUSION AND IMPLICATIONS FOR TRANSLATION

The application of SCIONs theory advances the CRN literature by highlighting the distinct nature of relationships

that enable them to succeed in areas where other organizational relationships have failed. Professional societies, with their registries driving change, have succeeded in improving the quality of healthcare, accelerating innovation, and controlling costs in the US in a few areas. More generally, market forces have not succeeded in addressing these ongoing challenges in US healthcare after decades of attempts.^[85] European and other countries have developed national, government-sponsored registries that have played a critical role in producing better outcomes at a lower cost.^[86] One may compare the utility of the CRN to the European national health registries; however, the distinctive characteristics of US healthcare have led to the development of CRNs that effectively tackle these issues, albeit in limited specialty areas currently. The implication of this work for translation is to understand how organizations based on cooperation have succeeded and how the model can be spread to other specialty areas in the United States as a unique American solution.

Leveraging action theory that is fundamental to the SCION literature, this paper bridges Parts II and III of this paper series, making arguments for the application of institutional sociology to the development of quality improvement and health information systems, i.e., RWE and CRNs. Hage, Valadez, and Hadden^[4] have observed that SCIONs theory is useful for describing concrete interventions that have been successful. They provide an extended study of NicaSalud, a SCION that has decreased infant and maternal mortality in Nicaragua. "Evaluations of SCIONs in different settings will consolidate [the SCIONs] theory that has been advanced here as well as solving some of the most vexing problems facing the world today." That is, the development of SCIONs theory should aid in the development of solutions for complex societal problems that the government and industry have yet to address. The SCIONs theory provides a service, similar to the business literature that supports the development of for-profit operations.

Action theory is also well-suited as a bridge for the translation of medical, public, and population health research into policy and practical actions that improve the health and well-being of populations.^[87] Action theory in sociological analysis, when applied to the problems addressed in this paper, provides implications for program managers, government agencies, and the public^[16] as a translation of medical science and public health into practice. Action theory works in the same way, pushing sociology to ensure theoretical formulations are useful for social change and, reflexively, to improve them, translating findings into better theories.

In the associated papers, the translation of the findings of this three-part series is discussed using action theory. In Part II, the theory of SCIONs is applied to CRN activities, demonstrating how a highly functional CRN can create value by improving evidence generation. This enhanced evidence

Current and Future Uses of CRNs	
Quality Improvement & Assessment	- Clinical quality improvement/assurance guided by CRN [13-30] - Driving clinical standardization of care across diverse care facilities and assessment of training programs [31-34] - Addressing overtreatment [35-39] - Understanding of obstacles to care [40]
Public Health Preparedness	- Improve health outcomes of all groups [41] - Pandemic preparedness ** [42]
Clinical Trials and Regulatory Science	- Embedding in Randomized Clinical Trials in CRN [43-45] - Build on current use of registries to determine payment for services ** [43] - Safety and efficacy of medical products including post-approval studies, signal detection, compliance studies, and modifications of labels [46-50-55]
Coverage and Payment	- Supporting national coverage decisions [43] - Build on current use of registries to determine payment for services ** [43] - Include consideration of benefit of use of CRN data to medical product manufacturers as consideration in product price negotiations ** [43]

** Indicates proposed uses in the future

Figure 1: The applications of CRNs in healthcare span quality improvement, public health preparedness, clinical trials and regulatory science, and coverage and payment. While CRNs are already being utilized for various purposes, potential future applications (indicated by **) can further leverage CRN capabilities in addressing evolving healthcare challenges.

generation, in turn, supports quality improvement and efficiency in healthcare. In Part III, the application of SCIONs theory for program managers, government agencies, and the public is specifically evaluated. Finally, we also address the reflexive aspect of action theory by answering questions about how the study of CRNs may contribute to the further development of SCIONs theory.

Key Messages

1) Real-world evidence (RWE) can enhance the quality of health and healthcare: Doctors are using everyday patient care information to find new ways to improve treatments, keep people healthy, and improve healthcare efficiency. 2) Sharing data is key: By securely linking different types of health information (e.g., medical records, insurance claims, vital records, and even patient-generated data), researchers can learn how healthcare works in the real world. 3) Registries are powerful tools: Coordinated Registry Networks (CRNs) are like super-powered data hubs. They can gather information from many places, clean it up, link it, and use it to answer questions about disease, treatment efficacy, and healthcare quality. 4) SCIONs theory provides a service to the non-profit sector in the way that the business literature supports business.

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expertise in technology and strategic thinking revolutionized healthcare delivery and management. His dedication and knowledge helped make this manuscript possible.

COMPLIANCE WITH ETHICAL STANDARDS

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