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ORIGINAL ARTICLE LEARNING HEALTH SYSTEM

Building Real-World Evidence Infrastructure to Improve Health and Healthcare in the United States: Part III—Questions for Translational Science and Action Theory

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ABSTRACT

Background and Objective: Previous work in this series has introduced real-world evidence (RWE), coordinated registry networks (CRNs), and systemic, coordinated, inter-organizational networks (SCIONs) theory. The application of SCIONs theory to CRNs illuminates how their structure and function foster trust and cooperation in a network of organizations to successfully address complex problems in healthcare. This third part in the series asks questions about how SCIONs theory can benefit CRNs and how the experience of CRNs can further develop the SCIONs theory.

Methods: This manuscript analyzes reciprocal relationships related to SCIONs theory and CRN practice, examining how each can be used to benefit the other. While SCIONs theory has not yet formally been used to direct the development of a CRN, future application is proposed. Conversely, we explored how the practical experiences of CRNs can inform and refine our understanding of SCIONs, including identifying areas for theoretical development and through an exploration of the current limitations of CRNs.

Results: The SCIONs theory may usefully direct CRN development in key leadership areas, including increasing human capital, encouraging organizational adaptiveness, expanding institutional capacity, mobilizing political engagement, and generating cooperative behavior. CRNs, guided by SCIONs theory, can offer a pathway towards a more efficient, equitable, and learning-oriented healthcare system. A comprehensive approach proposed for CRNs may facilitate the expansion of the evaluation component in SCIONs theory.

Conclusion and Implications for Translation: CRN program managers should prioritize strategic approaches that foster human capital, organizational adaptability, and institutional capacity. Government agencies may consider investments in CRN as a way to build RWE infrastructure that improves quality and efficiency of healthcare broadly. Public discourse may benefit from a clearer understanding of the role of cooperation in society to address issues that government and markets are not well suited to address. The literature on SCIONs can support the non-profit literature in the way the business literature supports the for-profit sector.

Keywords: Evidence-Based Medicine, Learning Health System, Public Health, Registries

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INTRODUCTION

A Learning Health System (LHS) is a vision for a healthcare system that leverages real-world evidence (RWE) to support public health decision-making, accelerate innovation, improve the quality and safety of care, and managing the health system more efficiently using data. As introduced and discussed extensively in Part I of this series, Real-world data (RWD) refers to the vast amounts of data collected as part of routine clinical care, while RWE is the insights and knowledge generated from the analysis of such data. Coordinated Registry Networks (CRNs) are data driven partnerships that have successfully captured and used RWE. CRNs address the data needs of many stakeholders by curating and linking registries with other data platforms to support the evidentiary needs of the healthcare system, including clinical care, quality improvement (QI), research, and regulatory decision-making. The clinical specialty societies and their members are able to direct the identification of appropriate data elements and frame questions that dynamically address the needs of healthcare.

CRNs have been described in this manuscript as systemic, coordinated, inter-organizational networks (SCIONs), a sociological concept that describes a third coordination mode that successfully addresses complex social problems through collaborative, non-market, and non-state coordination. SCIONs are characterized by their ability to bring together many partners and organizations to achieve common goals and are particularly well-suited to addressing the challenges of building a learning health system.

The prior two papers in this three-part series have explored the history and development of CRNs and the sociological theory of SCIONs (in Part I) and then examined how CRNs embody the characteristics of SCIONs to enhance patient outcomes and achieve public health objectives and illustrated this with a case study of the Vascular Quality Initiative and Vascular Implant Surveillance and Interventional Outcomes Network (VQI/VISION), a mature CRN (in Part II).

METHODS

In this paper, we explore the reciprocal relationship between the SCIONs theory and CRN practice by asking (1) How the SCIONs theory can guide CRN development? (2) How CRN experiences can inform the future development of the SCIONs theory? Also, we present the limitations of CRNs. We argue that the analysis of CRNs can help refine and strengthen the SCIONs theory, providing a grounding in practical experience in healthcare. Lastly, we discuss the translational implications of this analysis for program managers, government agencies, and the public, integrating insights across this three-part series.

RESULTS

Can Theory of SCIONs Strengthen CRNs and Improve Healthcare?

Our application of the sociological theory of SCIONs to CRNs is intended to support the direction of their development and to enhance their ability to improve healthcare. This application of SCIONs literature is an example of action theory that intends not only to describe organizations but also contribute to their improvement. To date, the SCIONs theory has not been formally adopted by any CRN, this work being the first time the theory has been applied in this way. We propose as a working hypothesis that the SCIONs theory can help CRN leaders become more self-conscious about management, investment direction, and strategy development, in the way that business literature aids business management and development.

The CRN QI activities have evolved out of previous quality efforts but should not be confined by them. While legacy registries have evolved over decades, the need for further development continues as new opportunities created by technology arise and as new uses of the data develop. Overtreatment is a cause of preventable harm and waste in healthcare that can be addressed with CRN.^[1,2] Just as business literature has proposed conceptual frameworks for the management of inter-organizational innovation,^[3] so can SCIONs literature advance knowledge for the management of CRNs in the not-for-profit sector. “The General Theoretical Framework for Measuring SCION Effectiveness,”^[4] summarizes how SCIONs create value [Figure 1].

Increasing Human Capital

The SCIONs theory has identified the development of human capital as a critical strategy that CRNs use to: (1) facilitate collaboration between clinical centers for the conduct of academic studies; (2) promote best practices that support improved clinical outcomes; (3) train nursing and information technology (IT) staff in data curation; (4) train staff on interpreting quality reports and benchmarking; and (5) share operational information that helps clinical centers increase their efficiency in clinical and data processes.

Recognizing the need for human capital development, professional societies have encouraged healthcare systems to invest in leadership through training programs.^[5] Studies on the development of surgeons and surgical trainees as managers and team members provide a solid evidence base for designing, developing, and implementing leadership initiatives in surgery. Taking into considerations the best practices from these studies may help to ensure that interventions are acceptable to the surgical community and effective in improving surgical leadership. The SCIONs theory



Figure 1: Theoretical framework for measuring effectiveness of SCIONs. This diagram illustrates key factors contributing to SCION effectiveness. SCION: Systemic, coordinated, inter-organizational network.

strengthens the support for human capital development in clinical medicine.

Encouraging Organizational Adaptiveness

The QI objective of CRNs promote organizational adaptiveness. CRNs achieve QI by demonstrating and sharing changes in workflow, staff organization, and specific techniques. Adaptation strives to improve care in the face of changing clinical science and organizational environments, including reimbursement, market changes, and healthcare regulations.

The adaptiveness of CRN is a value created by the standing data platform and clinical specialty-focused partnerships that are ready to respond to new challenges. The response to postmarket challenges of new medical products provides an excellent example. CRNs create value through the readiness and rapidity of the platform, responding to potential problems with new products as they arise, especially compared to the common scenario for products without a CRN.^[6,7] Currently,

important new products without CRNs often have legacy postapproval requirements with small numbers of patients and studies that are frequently abandoned early. When signals emerge, there is typically an uncoordinated effort by many parties with different agendas. New research may necessitate a new request for proposal (RFP), a competitive application process, followed by execution. These studies are years in the making in an era when the cycle of new product development may outstrip the product evaluation process. A CRN is a multi-partner platform in which data collection on new products begins as soon as they are used in practice and captured in electronic health records. The cost and time savings of this approach are well documented.^[8–10] The same CRN platform can study all comers, potentially leading to rapid label expansion and randomized clinical trial proposals.

It has long been recognized that much of medical practice in the United States is self-regulated.^[11] Clinical societies have played an important role in quality improvement and monitoring through the use of their registries. To address the dynamic nature of healthcare, CRNs may be

able to service other professional societies in this way. For CRNs to continue their success and adapt to changing circumstances, it is important to implement new methods and understand the practice in facilities that are not currently using CRN processes. SCION processes create momentum for change: gap analysis (comparing performance to goals), understanding why some facilities have adopted evidence-based medicine while others have not, and goal setting by communities of practitioners. CRNs can implement these strategies from the SCIONs literature.

Expanding Institutional Capacity

The expansion of institutional capacity within the broader network of partners promotes CRN growth and sustainability. Expanding institutional capacity for government agencies, patient groups, and industry to be better able to work with CRNs as partners is critical. To date, collaborations between government agencies and CRNs have been sporadic and focused in limited areas. The expansion of government agency capacity may allow for the ability to work with an independent network coordinating organization (NCO). Government agencies such as the Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS) have final authority when setting and enforcing certain standards (e.g., patient safety or quality of evidence) but can work with independent NCOs in mutually beneficial ways. Government engagement can improve CRNs' sustainability by providing technical advice and process evaluation.

Moreover, all professional societies may not be ready for CRN development and may need expansion of their own institutional capacity to manage this operation. Typically, professional societies spin-off registry management into subsidiary or related organizations, a development that also requires institutional capacity.

Mobilizing Partners Engagement

Partners engagement will be needed to build the type of national RWE infrastructure envisioned here. While a group of CRNs covering most of medical practice can be considered the core of this infrastructure, there are many other components of national data infrastructure that needs further development for a fully functional network. Those include an all-payer claims database (APCD) for patients under 65; modernization of the National Death Index for easier data linkage; improvement of cancer registries to provide more granular data as outcomes and as cohorts for linkage; improving the semantic interoperability of laboratory data; and continuing linkage of CMS data; etc. The data linkage methods of CRNs can then be deployed with these national data resources to expand the utility of RWE.

Currently, a comprehensive dataset for medical claims through CMS is available only for people 65 and older, patients on renal dialysis, and people with disabilities. A multi-stakeholder national coalition has been established to promote the provision of a national APCD for people under 65 years of age. This national coalition, which CRNs have joined, has produced a strategic plan and passed initial legislation.^[12] A similar effort is underway to improve access to mortality data for linkage. This same sort of stakeholder mobilization is critical to building each of the components of a national RWE infrastructure.^[13]

More broadly, professional societies and their registries are central to the development and evolution of evidence-based medicine, which has potential medical, political, and even legal ramifications. By actively engaging in outreach and lobbying, the professional associations can counterbalance the efforts to rationalize healthcare and ensure that the expertise and autonomy of healthcare professionals are respected while promoting high-quality, patient-centered care.^[14] The role of health professionals promoting medical practice based on evidence will necessitate more, not less, negotiations of this kind. As health systems negotiate to control the costs of highly effective but expensive drugs, doctors who rely on evidence-based medicine are likely to push back, advocating for the use of these treatments despite their high costs.

Generating Cooperative Behavior

The QI strategy used by CRNs fosters cooperative behavior in a competitive environment. Competition for excellence drives institutions and individual clinicians to compare outcomes with peers and engage in the development of data standards and methods of comparison.

The NCO manages competition to a productive end, promoting cooperative behavior by monitoring care and sharing innovations. The collaborative tone of the NCO staff is critical, and successful cooperation provides feedback to improve the staff's ability to encourage cooperation. Replicating the CRN model in additional clinical specialties would increase cooperative behavior to foster broader healthcare improvements in the United States. The SCIONs theory endorses this cooperative behavior, highlighting its potential in healthcare. For example, NicaSalud, a notable SCION of non-governmental organizations that emerged in northern Nicaragua's mountainous region following the devastating impact of Hurricane Mitch, was extensively researched by Hage and colleagues. This inter-organizational network focused on implementing initiatives that promoted safe motherhood and child survival in local communities.^[4]

Can the CRN Experience Contribute to SCIONs Theory?

An appraisal of the experience of CRNs presented in this three-part series may influence the further development of the theory of SCIONs.^[15,16] The evaluation of CRNs in this manuscript identifies three approaches to the evaluation of the success of networked organizations: radical innovation as an evaluation criterion following Mote, Jordan, and Hage,^[17] the framework for measuring value created by the CRN,^[10] and the CRN Maturity Framework,^[18] which focuses on domains of organizational strength. These approaches offer overlapping and unique perspectives. For example, the sustainability of an organization does not always lead to radical innovation, and organizational maturity may not result in value creation or radical innovation. Advanced program evaluation theory brings radical innovation, value creation, and organizational maturity into a single framework.^[19] The future development of SCIONs theory may be built upon this synthesis, establishing a comprehensive framework for evaluating CRNs that integrates considerations of value and maturity, performance, and structural integrity.

Another area of development for the SCIONs theory might be the exploration of how SCIONs in different areas might work together. As observed previously in this manuscript, professional associations alone are not well positioned to affect the risk factor behavior and social determinants of health. Social science can usefully analyze how professional and community-based organizations addressing social determinants of health and health behavior might collaborate to address these underlying factors. Current plans to develop a CRN to improve obstetrical care in the US^[20] should be extended to partner with efforts to change social determinants of infant mortality (health behaviors such as smoking, nutrition, and prenatal care utilization)^[21] in communities, following the example of the successful SCION (NicaSalud) that has been developed in Nicaragua, as described in Part I.

DISCUSSION

Limitations of CRNs: A Step Towards Translation

Identifying the current limitations of CRNs is an initial step toward the translation of the ideas proposed here into developed solutions. The first set of limitations proposed here relates to the level of maturity attained by a CRN, the markers that include the level of participation by clinicians, the capacity to address social determinants of health and patient engagement.

As CRNs are voluntary, the level of participation in a CRN can vary widely, from nearly 100% to 1% of clinical practices in a particular specialty. In general, wider participation

increases the potential for improving the quality of care nationwide. However, lower levels of participation can accomplish some of the CRN objectives. For example, the US National Hernia Registry covers only 1% of procedures nationwide, but the procedure is so common that the CRN generates sufficient data for product evaluation and QI among participating clinical units.^[22] National improvement in the quality of hernia surgery will probably not advance with the current low levels of participation in this QI program. Government-required participation in registries has been used successfully in some cases for promoting participation and could be used as a way to improve care nationally.^[23]

Another indicator of maturity is the CRNs' ability to address the social determinants of health.^[24] A focus solely on improving healthcare quality cannot resolve systemic problems such as fragmentation of care, structural racism,^[25] lack of health insurance, poor access to care, and discriminatory policies of specific healthcare organizations. CRN QI efforts have been able to find ways to improve quality and efficiency of healthcare for its member organizations and may help identify the need for institutional policy change. Differences in health outcomes may persist due to social determinants of health that are more difficult for CRNs to address, including lifestyle and risk factor behavior. A SCION that works within communities (like NicaSalud referred to here) to address underlying factors might, in the future, evolve as part of or in partnership with a CRN.

CRNs have implemented patient engagement, a critical feature of CRN maturity, with varying degrees of success.^[26] Factors influencing the development of patient organizations include the nature of particular diseases and funding requirements.^[27] Patient advocacy groups have been successful for those with serious chronic diseases, such as acquired immunodeficiency syndrome and sickle cell disease, and in the case of some rare diseases. For example, the American Society of Hematology Research Collaboration and their CRN have strong patient engagement and ongoing consultation with people with sickle cell disease.^[28] The serious and chronic nature of the disease may be a factor in this success. "Individualization" of patients,^[29] the increasing tendency to act autonomously as opposed to according to a group logic, is a limiting factor to patient participation. As patient organizations receive funds from pharmaceutical companies,^[30] identification of non-commercial support for patient organizations would ideally be an agenda item for CRNs.

Systemic Limitations Related to CRN Partners

A second set of limitations relates to the nature of relations between governments and industry with CRNs. Discussed here are the government's capacity to engage with CRNs, the sustainability of CRNs, and medical product innovation.

Government Capacity to Engage in CRNs

CRNs have developed in the US, where government agencies do not play a large role in the direct provision of healthcare.^[31] Regulation of quality of care is diffuse in US healthcare, creating a niche for CRNs. In contrast, state intervention in healthcare in countries that are members of the Organization for Economic Cooperation and Development has provided regulatory oversight of quality of care and supported robust national registries.^[31] In most advanced economies, professional associations are integrated into national health systems, and physicians may be government employees. Physicians in European countries, for example, are intimately involved in all levels of work on national registries.^[32]

Despite the potential of CRN to fill a critical information gap by creating data to better manage healthcare in the US, the government agencies often address data problems independently, as directed by their highly specific legal authorities. This narrow focus hinders collaboration between federal agencies for the development of CRNs, even though mature CRNs could benefit all agencies.

Challenges to the Sustainability of CRNs

However, many CRNs face limitations rooted in current technologies used for data collection. Current-generation electronic health records (EHR) and related systems still have serious limitations that necessitate costly and time-consuming data curation to transform them into useful RWE. This burden discourages voluntary participation of clinical systems in QI activities,^[33] and may limit participation by clinical practices with small margins and low volume of particular types of care.

Advocates for the democratization of health data^[34,35] as a solution to these problems encounter an already well-established market around RWD.^[36,37] The place of the CRNs in that marketplace depends on their ability to produce highly curated data supporting multiple uses with a sustainable ecosystem approach. The sustainability model of the CRN, rooted in unique collaborative mechanisms, allows CRNs to operate where market forces are not favorable (i.e., below the profit margins demanded by markets) through the unique set of relationships facilitated by the professional societies and described by the SCIONs theory.

Another dimension of sustainability depends on the willingness of the medical product industry and other potential partners to participate in shared data activities. The competitive nature of companies creates resistance to using shared CRN information, even with policies that protect company privacy and intellectual property specified by the CRN. CRNs have demonstrated the ability to provide “better, faster, cheaper” evidence for the medical product industry.^[10]

However, these incentives may not be enough for companies that prefer to control data exclusively. There have been multiple successful examples of government encouragement of industry investments in CRN. The use of CRNs has proven successful in the past for pharmaceutical companies to access accelerated pathways to market and secure coverage for payment of their products.^[38]

Medical Product Innovation and CRNs

Hage, Valadez, and Hadden, in their recent book, have made the case for cooperation to accelerate innovation, drawing on successful initiatives like SEMATECH, a US consortium of semiconductor manufacturers that accelerated the development of new technologies and processes.^[4] Developments in the medical device area point in a similar direction. IDEAL-D is a framework for medical device development; it offers a balanced approach, mitigating risks in first-in-human translational studies while promoting rapid translation of new devices into clinical practice.^[39]

Globally, national registries have guided the procurement of quality medical products to control healthcare costs.^[40] Application to the US context is more complex, despite the possibility that data can be aggregated to address cost and quality of care. While CRNs have accelerated the innovation of some medical products, global market forces and their relationship with regulators primarily shape medical product innovation and favor follow-on products over genuinely innovative solutions.^[41] Moreover, incentives for healthcare delivery organizations are generally misaligned, rewarding production rather than efficiency; those organizations rarely conduct studies of cost and quality, except in specific instances.^[42]

Role of Coordination and Networks of CRNs

The limitations detailed here may be addressed in part via coordination between various CRNs that are innovating and learning from each other. Shared obstacles, such as the burden of curation of data, could be addressed via systematic sharing of experience across CRN.^[43] Currently, however, there is no funded organization that supports CRN development across specialties, facilitates studies to improve registry performance, or otherwise addresses the shared needs of the CRNs as a community. The current level of coordination between CRNs is best described as a learning community with information sharing, joint projects, and partner mobilization, as presented in this article. A network of CRNs could be used to promote learning from more mature registries and emerging literature on how registries may be improved and more effectively coordinate partner engagement.

CONCLUSION AND IMPLICATIONS FOR TRANSLATION

The translation of the findings of this work should be evaluated by how the implementation of these insights can be useful to program managers, government agencies, and the public.

Translation/Utility for Program Managers

The findings of this manuscript on CRNs and SCIONs are valuable for program managers as they provide strategic perspectives for the development of programs for CRNs and their clinical and other partners. Those approaches to program management include: (1) increasing the human capital; (2) encouraging organizational adaptiveness; (3) expanding institutional capacity; (4) mobilizing partner engagement; and (5) generating cooperative behavior. A more formal CRN Learning Communities are critical to the future of CRNs because it can increase learning and cooperation sharing between CRNs, increasing their value. A forum, or possibly a future higher-level SCION, that brings together CRNs is another direction for program managers to consider. A thorough ongoing evaluation of CRN on how registries can be more efficient and effective may come out of such an engagement; the future of how CRN are structured and function should be chartered with that sort of view. The future role for mature CRN includes monitoring the time from the identification of Evidence-based Medicine (EBM) interventions and implementations in clinical settings. An ongoing effort to decrease the time from bench to bedside would ideally become a core function of CRNs. More broadly SCION literature would support decision making in the private sector. Organizational sociology has become a critical component of business schools and has supported the business literature guiding decision making. A similar role can be envisioned for literature on SCION theory supporting the non-profit sector. This is an excellent example of how action theory in sociology and translational science come together.

Translation/Utility for Government Agencies

Translation of this work could potentially lead to (1) more systematic evaluations of CRNs, (2) increasing collaboration among all partners, and (3) coordinated national strategy to build the LHS using RWE. Over the past decade, substantial investment in RWE infrastructure has provided new approaches to building the LHS. The translation of this work could lead to coordination of future investments within a national strategy informed by lessons learned over the past decade. CRNs cannot meet all needs in healthcare but can go a long way towards supporting a learning health system.

Translation/Utility for the Public

Government and industry have experimented with and invested in RWE infrastructure for a decade, yielding workable models for improving the quality and efficiency of healthcare. Our evaluation of CRNs and, more broadly, SCIONs theory demonstrates that cooperation can operate effectively in various settings and at large scale. The success of mature CRNs operating in the US, if replicated in other areas of healthcare, could radically improve quality, outcomes, and efficiency in the country. Another accomplishment of the SCIONs theory may be helping society see beyond the discourse focusing on and promote the collaboration across the ecosystem.

Key Messages

1) The sociological theory of systemic, coordinated, inter-organizational networks (SCIONs) can be applied to support and develop coordinated registry networks (CRNs): The assessment of SCIONs has identified features that predict their success, including the need for an independent network coordinating organization (NCO). Lessons learned about the structure and function of other SCIONs in other sectors and CRNs will contribute to their success and development in other areas of healthcare. 2) The converse is also true; CRNs enhance understanding of SCIONs: Understanding how CRNs operate will advance knowledge of SCIONs. Recognizing CRNs as examples of SCIONs demonstrates the broad applicability of the SCIONs theory and highlights how different problems might be resolved by creating a SCION. 3) Limitations of CRNs: CRNs cannot resolve all healthcare issues, especially those rooted in social determinants of health. Reliance on voluntary participation by doctors and institutions poses challenges for the sustainability of CRNs. Without dedicated funding, CRNs will struggle to become established and mature.

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COMPLIANCE WITH ETHICAL STANDARDS

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