

SPECIAL COLLECTION

SPECIAL COLLECTION TRANSLATIONAL PUBLIC HEALTH

Introduction to Special Collection: Building the Real-World Evidence Infrastructure to Accelerate Innovation and Improve Outcomes in Healthcare

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It is my honor to join the editorial leadership of the *International Journal of Translational Medical Research and Public Health* (IJTMRPH). I am excited about the opportunity to grow this emerging scholarly journal and rally the community of researchers interested in translating research into policy and practice. In this theme issue of IJTMRPH, we introduce a special collection of articles on building the real-world evidence (RWE) infrastructure to accelerate innovation and improve outcomes in healthcare. RWE falls squarely within the scope of IJTMRPH—to advance the translation and application of research into practice for improved health outcomes.^[1] Article types include original articles, systematic reviews with or without meta-analysis, narrative reviews, viewpoints or perspectives, field reports, letters to the editor, etc.

This special collection sets out how far we have come toward establishing a learning health system and provides direction for future development of how data collected as part of routine clinical care (real-world data) can be used to address the many complex problems facing healthcare.^[2] The nation needs infrastructure that accelerates innovation to improve the quality and efficiency of care, promotes a range of research needs, and supports regulatory decision-making. While many components of the national RWE infrastructure are developing, there is still a lack of clarity regarding what works and what parts are lagging. The translational lens provided by this journal provides the context in which science can take its practical form. The three-part article that is the centerpiece of this theme issue, drawing from sociology, calls this translational mission “action theory.”

The first article of this theme issue was provided by a patient advocate who calls for a national RWE infrastructure that can address the needs of patients in the rapidly changing regulatory environment in the United States (US).^[3] While faster access to new medical products is critical, historic weaknesses in the post-market product evaluation have led to avoidable hardship and damage. Terrie Cowley founded and led the Temporomandibular Joint Association, a patient-led organization devoted to the improvement of the care of a complex and poorly understood condition. Terrie, herself a patient, suffered from the inadequacy of the procedures and products that were available when she was first treated, which post-market evaluation has been poorly equipped to address. This issue is dedicated to Terrie in recognition of a lifetime of work in memoriam, Terrie having passed away after writing the piece.

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A three-part article, “*Real-World Evidence Infrastructure to Improve Health and Healthcare*,” provides the centerpiece of the theme issue. The first article documents the development of a successful model for national RWE infrastructure, the Coordinated Registry Network (CRN), and proposes a sociological theory, Systemic Coordinated Interorganizational Network (SCION), that can be used to guide future development.^[4] Part two article applies the SCION theoretical formulation to CRNs and a case study of a CRN working in vascular surgery.^[5] The third part questions the translation of this body of knowledge, and sociological action theory is proposed to chart a course for future research and practice.^[6] SCIONs, as an emerging type of organization, different from market-driven organizations and government, are proposed as a model for RWE infrastructure development. The translational insights provided in this theme issue and by future submissions called for in this introduction will create a literature to guide the development of the non-governmental organization (NGO) sector in ways that the business literature guides private enterprises.

Market forces are well-suited for addressing some needs of society, but not all. The same can be said of the government. This theme issue introduces a third mode of social coordination, a unique set of organizational structures and functions that solve complex problems where other approaches have not. Business organizations are driven by market forces. Government bureaucracies are rule-driven. SCIONs, as the third way to address complex health issues, produce value through the cooperation of networks of organizations they bring together, as NGOs.

What may seem controversial about this work to some readers is the notion that cooperation rather than competition is a viable form of societal coordination. While some streams of thought suggest that the only solution to societal problems is capitalism, SCIONs are not ideological or political solutions in nature. Instead, we draw from the social science literature documenting cooperation between organizations that successfully solve some complex problems that market forces and bureaucracies cannot, and that certain forms of NGOs are better suited to deploy cooperation. The striving of physicians for excellence, though competitive in character, has, for a very long time, focused on improving outcomes for all patients through sharing knowledge. Some sectors operate better through cooperation, and most of the evidence points to the fact that healthcare delivery is one of those sectors.

We propose the CRN as an example of a SCION that is a uniquely American solution to the complex problems facing healthcare that market-driven and bureaucratic organizations have not been able to solve. National registries have been a critical component of European and other countries supplying the data needs for management

of national health systems. CRNs can be viewed as the US counterpart, providing similar solutions within the distinct constellation of US institutions. After over a decade of heavy investment from the government and the private sector, RWE has fallen short of the vision for which it was originally proposed; however, the urgency to create data to better manage healthcare in the US has never been more acute. The CRNs connected to other health data infrastructure, including vital records, an all-payer claims database, and other data resources, have succeeded at scale in a few clinical areas and provide a direction for further development.

The special collection goes on to provide additional examples of building the national RWE infrastructure. While most CRNs have been established by societies and their registries, a CRN that is managed by patient themselves, working with clinicians, to address the needs of temporomandibular joint disorder (TMD) patients is evolving. TMD is treated by several clinical specialties in medicine, surgery, and dentistry. A patient advocacy group has taken leadership with the support of the National Institutes of Health to build a CRN that would bring together the multiple clinical areas to build the science needed to improve the care of TMD. The commentary by Laura Elisabeth Gressler, distinguished member of the faculty of College of Pharmacy at the University of Arkansas for Medical Sciences and former fellow of the FDA, in this issue reports of progress toward establishing that CRN.^[7]

The special collection rounds off with a book review of the “*Saving Societies From Within: Innovation and Equity Through Inter-Organizational Networks*” by Hage which the three-part study derives its theoretical context from Michael Quinn Patton, the first author on this review, is a distinguished evaluation scientist renowned for his innovative contributions to the field of program evaluation. His book, *Utilization-Focused Evaluation*, is in its fifth edition.^[8] He received a Lazarsfeld Award for lifetime contributions to evaluation theory.

We hope that this special collection of the IJTMRPH stimulates translational scholarship that will promote building a national RWE infrastructure and evaluate that process so that continuous improvement follows.

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COMPLIANCE WITH ETHICAL STANDARDS

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Special Collection

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