commentary

The Coordinated Clinical Studies Network: A Multidisciplinary Alliance to Facilitate Research and Improve Care

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Abstract

The NIH Roadmap is a major effort to reshape the US health research enterprise to accelerate medical discovery and to do so in such a way that actually hastens population health improvement through research. The Roadmap's ultimate goal resonates with the HMO Research Network, a consortium of integrated health care systems that uses its collective scientific capabilities to integrate research, practice, and policy for the improvement of health and health care among diverse populations. (See page 6 for abstracts from the HMO Research Network annual conference.) As such, the HMO Research Network was ideally suited to propose a new consortium project as a part of the NIH Roadmap, the Coordinated Clinical Studies Network (CCSN). The CCSN was funded in 2004 to create a path-breaking research facility that leverages several distinctive features of the HMO Research Network: the multidisciplinary scientific capabilities of its researchers; the ability to rapidly move clinical research findings into care delivery; its large, diverse patient populations; and a commitment to placing its findings in the public domain. Among the goals of the CCSN are to augment the capacity and infrastructure for conducting research, and to use considerable investments in health informatics to improve the scope and efficiency of research data collection. The NIH Roadmap is a revolutionary step toward a new paradigm for research and responds to both a compelling social need and rapid technological advances in biomedicine. The CCSN's participation in the Roadmap Initiative is a unique opportunity for researchers, clinicians, and our patients.

Integrating and Expanding the Research Enterprise

The US national landscape for conducting clinical and health services research is evolving rapidly, due in large part to transformative effort on the part of the National Institutes of Health (NIH), dubbed the NIH Roadmap. The Roadmap is designed to accelerate progress on pressing scientific questions, synergistically leverage the NIH research agenda to address these questions, remove impediments to efficiently conducting research, and facilitate uptake in everyday clinical practice. Roadmap activities are vast initiatives (http://nihroadmap.nih.gov). Each is based in the director's office and administered through a single designated institute. However, each initiative involves all institutes of NIH and importantly, each one is funded from agreed-upon contributions from individual institutes' budgets.

Research Partnerships with Community Partners

An important pillar in the NIH Roadmap is the initiative, "Re-engineering the Clinical Research Enterprise." This endeavor is designed to spur new research partnerships between researchers and community practices that care for large, diverse patient populations.[1] This initiative resonated with the members of the HMO Research Network (HMORN), a consortium of 14 health plans situated across all regions of the US, including six Kaiser Permanente (KP) Regions. All of the HMORN members have formal, recognized research capabilities, and a commitment to using their collective scien-

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tific capabilities to integrate research and practice for the improvement of health and health care. The HMORN has had a significant impact on health care and outcomes[2] and has spawned several externally funded formal research consortia addressing cancer control,[3] pharmacoepidemiology,[4] and vaccine safety,[5] along with numerous more ad hoc multisite research projects.

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Coordinated Clinical Studies Network: An Unparalleled Research Facility

The HMORN received funding for a new consortium, the Coordinated Clinical Studies Network (CCSN), in response to this "Re-engineering" initiative. It is one of 12 contracts awarded by the NIH and is administered through the National Heart, Lung, and Blood Institute (NHLBI). Each of the contracts has the similar objective of streamlining various aspects of the clinical research process, from rapid case identification to project monitoring and protocol preparation. Most of the other contractors are based at academic centers, and draw patients for research trials from the surrounding communities. The HMORN's contract is the only one that draws from a geographically dispersed population base. The members of the CCSN are uniquely positioned within some of the largest and most innovative health plans in the nation—plans that provide care to nearly 13 million individuals in the United States. The HMO-based researchers in this Network have already performed influential studies affecting health care policy, delivery and organization,[6] as well as important trials of disease prevention strategies and surveillance for adverse outcomes.[7]

Key features of the CCSN include the multidisciplinary composition of its multicenter investigator team, including extensive expertise in translational research, and robust clinical information systems that support health care and research. This contract enables us to leverage these features, while also enhancing the research infrastructure at each member site and the Network as a whole. The CCSN aims to function in a bidirectional capacity. Our research can inform practice changes, but changes in practice—such as the introduction of a new drug benefit—can potentially influence research. Thus, the CCSN is committed to transparency, flexibility, innovation, and rapid-cycle discovery.

Many aspects of the research implementation process could benefit from more systematic approaches. For better or worse, a hallmark of research is the regular refinement and even re-creation of approaches to measuring or intervening in the context of a newly funded study. Successive studies build on their predecessors, which is certainly important for replicating important findings or enhancing our understanding of research results, but this may come at the cost of efficiency. Therefore, a primary aim of the CCSN is to promulgate standards and common approaches to many of the tasks in the cycle of research, from participant recruitment to data aggregation. Ultimately, the infrastructure improvements envisioned as the backbone of the CCSN will result in a research facility with the capability to conduct research more efficiently and cost-effectively.

Sustainable Infrastructure for Research

As a contractor to the NIH, we are obliged to deliver on a promised set of tasks and utilities. In spite of the short three-year duration of the contract, however, we anticipate that the research infrastructure that results from the CCSN deliverables will be sustained long after the contract ends.

Data Resources

Building on the successful work of the HMORN's Cancer Research Network (CRN) and the HMO Centers for Education and Research in Therapeutics (CERT), the CCSN will leverage the HMOs' mature and comprehensive automated health care data systems by building an information technology infrastructure that addresses four mainstay issues in clinical research: feasibility of the scientific question; rapid case ascertainment; data collection and monitoring; and surveillance mechanisms to facilitate translation of results into clinical practice. Working with the informatics community to promote shared data standards and interoperable systems is an overarching priority of the "Re-engineering the Clinical Research Enterprise" initiative, and the CCSN's companion contracts also address this. The benefits of having standardized data resources available to HMO researchers and clinicians are manifold. For example, as treatment advances occur, such as the recent advent of vinorelbine plus cisplatin as adjuvant therapy for non-small cell lung cancer, we can observe the uptake of these treatments in our health systems. This provides a window to understanding the levers that impact treatment decisions, the changing costs of care, and observation of any adverse consequences of new therapies. Similarly, our health systems are well positioned to study the impact of changes to cost structures or screening guidelines.

Research Review and Implementation

Protection of human subjects is a fundamental element of research, but one that can be time consuming in the context of multicenter studies.[8] The CCSN will seek to reduce

the administrative burden of research review by creating a repository of Institutional Review Board (IRB) application materials and related compliance procedures by site, and recommended approaches to navigating review procedures. Future plans include consideration of the creation of a common IRB review platform, modeled after the National Cancer Institute's Centralized IRB initiative.[9]

Standardizing approaches to recruitment and data collection across multiple sites can be onerous, since collaborators may all approach a multisite study with different ideas for the study design. The HMORN has vast experience with recruiting and retaining a wide array of different study populations for multisite studies. The CCSN will help organize, share, and expand this knowledge by creating an organized repository of protocols and practices for data collection methods, and accompanying training materials. These utilities will result in efficiencies and cost savings.

Clinical Trial Initiation and Management

Collectively, the above resources will enable the CCSN to create a sophisticated coordination structure for clinical trials. The utilities will be augmented by streamlined tools for budget development and closeout of projects. Already, we are seeking opportunities to test the approaches planned as part of the CCSN, in either a simulated trial, or a bona fide study. A companion substudy is identifying potential barriers to HMO participation in cardiovascular clinical trials. This substudy builds on recent work that assessed barriers to HMO participation in cancer clinical trials.[10]

Fulfilling the Promise of the CCSN

At any given time, researchers across the HMO Research Network are engaged in hundreds of research studies at various stages of completion. As noted by Tunis,[11] it is inefficient to recreate networks of investigators, coordinators, data collection systems, patient tracking systems and quality control mechanisms for each and every new study. The success of the CCSN and its companion contractors will be measured by the extent to which its utilities are used by researchers and clinicians to improve health outcomes. The NIH Roadmap vigorously advocates that research teams become more interdisciplinary and more community based. From inception, our community orientation and involvement of multiple disciplines have been integral components of the HMO Research Network, and by extension, the CCSN. We believe that the placement of our research centers in health systems is critical to integrating our findings into clinical care. We work in teams—our researchers practice in our health care systems, providing clear insight into the mechanisms of dissemination and translation that will take the real-world environment into account. By combining this insight with the CCSN's thoughtfully constructed research utilities, everyone stands to gain—researchers, practitioners, and especially patients. ❖

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