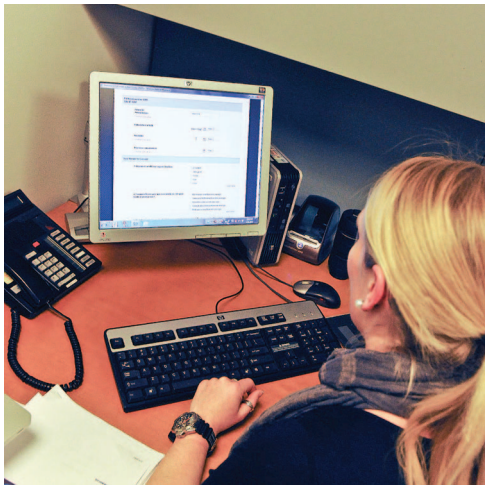
A Public-Private Strategy to Advance the Use of Clinical Registries

WITH an increasing U.S. focus on quality and cost, and the steady maturation of health information technologies, the opportunity to leverage electronic clinical registries to improve outcomes and appropriate utilization of care has never been greater. Two laws passed by the administration of United States President Barack Obama and the United States Congress—the Health Information Technology for Economic and Clinical Health (HITECH) Act provisions of the Recovery Act and the Affordable Care Act—create a new environment in which the use of registries may grow dramatically. This article focuses on the opportunities presented by electronic clinical registries and describes a path through which use of clinical registries may grow.



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The challenge for the United States government, purchasers, payers, and patients is to create an ecosystem in which clinicians are rewarded for participation in registries; participation is easy and inexpensive and registries provide consistent clinical value to participating clinicians. Meeting these challenges would produce a sustainable clinical and business case for registries—and help address the collective action problem that has so far limited their use.

Opportunities Presented by Registries

Well-designed and managed clinical registries provide depth, breadth, and specificity of data that cannot be achieved by administrative claims data alone. Analyses based on clinical data are widely accepted by clinicians and patients, in contrast to those derived solely from administrative data, which are thought to be less reliable and truly representative of clinical care.

Clinical registries provide the optimal foundation upon which to base many important elements of U.S. health reform and to pursue the three-part aim of better care for individuals, better health for populations, and lower cost through improvement. Examples of use include clinician and facility performance assessment; transparency and public reporting; performance-based reimbursement; value-based purchasing; clinical decision support; shared decision-making; development of evidence-based practice guidelines and performance measures; regional and national quality improvement initiatives; comparative effectiveness and cost-effectiveness research; and enhanced postapproval monitoring (*e.g.*, device and drug surveillance).

Registries empower clinicians broadly in quality initiatives through participation in a common platform that defines outcomes measures, analyzes data and facilitates reporting and use of such a report. Experience from the quality measurement field suggests that clinician initiation of and participation in quality reporting helps make improvement programs successful. Successful registries have clearly defined a value proposition for the users to ensure prolonged participation and dedication to valid data capture. Registries can be a key enabler of physician participation and success in quality efforts. The transition to performance-based Maintenance of Certification and Maintenance of Licensure frameworks by the American Board of Medical Specialties and the Federation of State Medical Boards, respectively, are in support of such clinician-led approaches.

Essential Components of Clinical Registries

A core set of relevant data elements necessary for registries should be identified and specified using a common taxonomy. Examples include patient demographic and clinical

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variables before treatment, details of the treatment provided (including appropriateness and adherence to evidence-based processes of care), measures of short and long-term clinical outcomes, measures of patient satisfaction, and patient-reported outcomes.

Harmonization and standardization of data elements should be used to facilitate interoperability and linkages across registries within and across clinical specialties. Ideally, efforts should be made to use open data standards that if broadly adopted, would advance many of these programs into the mainstream of care. It has been suggested that the current U.S. efforts to establish electronic health records standards for interoperability and meaningful use may not yet be taking full advantage of their potential role in facilitating national, regional, and local efforts to accomplish quality improvement through registries.

Data should be submitted to data warehouses and analytical centers with expertise in managing large clinical databases, and frequent audits should be performed to ensure data accuracy and completeness. These include both routine intrinsic data verification (such as screens for missing and out-of-range data) and periodic external audits. Validation of some data elements, such as in-hospital or 30-day mortality outcomes, may be accomplished using linkages to state or national registries (*e.g.*, Social Security Death Master File or National Death Index). There should be standards for acceptable performance on such audits and a corrective action plan when these standards are not met.

Risk models should be developed and implemented for all major outcomes—however difficult and complex the process or appropriately adjusting for risk may be. Providers should accordingly receive frequent and timely risk-adjusted feedback of their performance relative to benchmark populations at state, regional, national, or similar hospital levels.

A Path Forward toward Broader Use of Registries

Although we have defined an "ideal" state for the broad use of clinical registries, we recognize that broad health care industry cooperation will be required to achieve this ideal state. We propose several approaches to broadening use of clinical registries.

Cross-sector and Intrasector Alignment

Private sector and government initiatives should be aligned to promote use of clinical registries. Equally important, however, is greater alignment across federal agencies and also among individual actors in different parts of the private sector (*i.e.*, health plans, physician groups, *etc.*).

Incentives, Penalties, and Requirements

The business model upon which existing registries have been built is not scalable. Most of these developed gradually over years to decades, and initially they were not economically self-sustaining.

The urgency of health reform precludes the use of this more gradual, haphazard paradigm for registry development, and the economics of health care makes it improbable that many providers will embrace the registry concept unless there are clearly defined incentives, penalties, or regulatory requirements.

Accordingly, some have suggested that the federal government should provide inducements both for broader participation in existing registries and for the creation of new registries in areas where they do not currently exist.

Federal support and encouragement could include regulatory requirements for participation (*i.e.*, conditions for participation), financial incentives for development and implementation of registries that meet specific criteria, reimbursement incentives for providers that participate in such registries (especially if they agree to publicly report), and additional rewards for top performers identified by quality assessment programs based on such registries. The HITECH Act's Medicare and Medicaid Incentive program, which rewards physicians with up to $63,750 in incentive payments for demonstrating "meaningful use" of electronic health records—with the definition of "meaningful use" determined by an evolving set of federal regulations—could be structured to offer proper incentives for registry participation, and to ensure reporting to certified entities that use a common reporting standard and platform.

Facilitate Expeditious, Standardized, Cost-effective Registry Development

A public-private partnership of the federal government, payers, medical specialty societies and other clinical registry developers, and data warehouses/analytical centers could provide standardized, "off-the shelf" technical and implementation templates to organizations desiring to develop new clinical registries. This approach would reduce the entry barriers that currently discourage such development and would facilitate more rapid and widespread adoption of the clinical registry paradigm.

Broaden the Registry Perspective through Linkages

Current clinical registries often focus on isolated conditions or procedures. To achieve a more holistic approach to broad disease categories, efforts should be made to link related clinical registries together. These may further be linked to administrative data sources to obtain important information not typically found in clinical registries, including long-term medication compliance, readmissions, reinterventions, deaths, and cumulative resource utilization. All such linkage ought to occur, of course, with full attention to appropriate protection of patients' privacy rights.

Develop Standardized Definitions

Widespread implementation of such linkages would require several preliminary steps. First, stakeholders must collaborate to develop a nationally standardized lexicon that harmonizes

common data element definitions across databases. This essential component of interoperability is currently being addressed by a number of entities but needs central coordination and oversight, and any effort to advance registries should be fully aligned with these ongoing efforts.

Clarify Privacy Regulations

There exists a need to clarify the existing ambiguity in privacy regulations as they apply to data collected to assess and improve quality. Although current regulations do permit release of personal health information without authorization for "healthcare operations," which include quality assurance and quality improvement, this has often been interpreted as a use of data that directly benefits the specific patients whose personal health information is being released. However, the optimal use of such data frequently entails the creation of "generalizable knowledge" that benefits the health of entire populations, which then may place such activities into the category of research.

Methods have been developed for collecting data primarily for quality assurance and quality improvement purposes, linking to other relevant data sources, and subsequently stripping such data of personal health information before performing any analyses that may lead to "generalizable knowledge."

However, some providers and Institutional Review Boards remain uncertain regarding the regulations. Further clarity from the federal government would be useful to achieve the optimal balance between the critical goals of protecting individual patient privacy while at the same time advancing the healthcare of populations.

Continuous Linkages to Facilitate Research

The Centers for Medicare and Medicaid Services and the Agency for Health Care Quality and Research could consider modifying the way in which quality-oriented clinical registries access federal databases. Rather than the existing "one-off" approach that requires separate requests and reimbursement for each specific use, consideration should be given to long-term linkages that could be used for a variety of qualified quality improvement. This would create a "research engine" based on both clinical and administrative data that could be used to answer quickly and cost-effectively a variety of questions of interest to the healthcare community and the federal government.

Some have suggested that a government entity or private sector organization would be required to ensure that a registry effort is successfully launched, effectively managed, and widely adopted. A lead organization could coordinate efforts across regions and specialties and align individual registries with national priorities and standards. A credible national lead organization could create a platform for capturing and integrating required data at scale and facilitating national and eventual international comparisons. This lead organization should have sufficiently broad organizational scope to enable coverage of the broadest population of patients.

Conclusion

The late social scientist Mancur Olson elaborated the term "collective action problem" to describe situations in which many would stand to benefit from a certain action, which, however, has an associated cost that makes it implausible that any one individual would undertake it. Clinical registries are emerging from the realm of collective action problems and entering a realm in which a collaborative multistakeholder effort will decisively expand their use to advance the U.S. healthcare system's three-part aim of better health, better care, and lower cost through improvement.

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