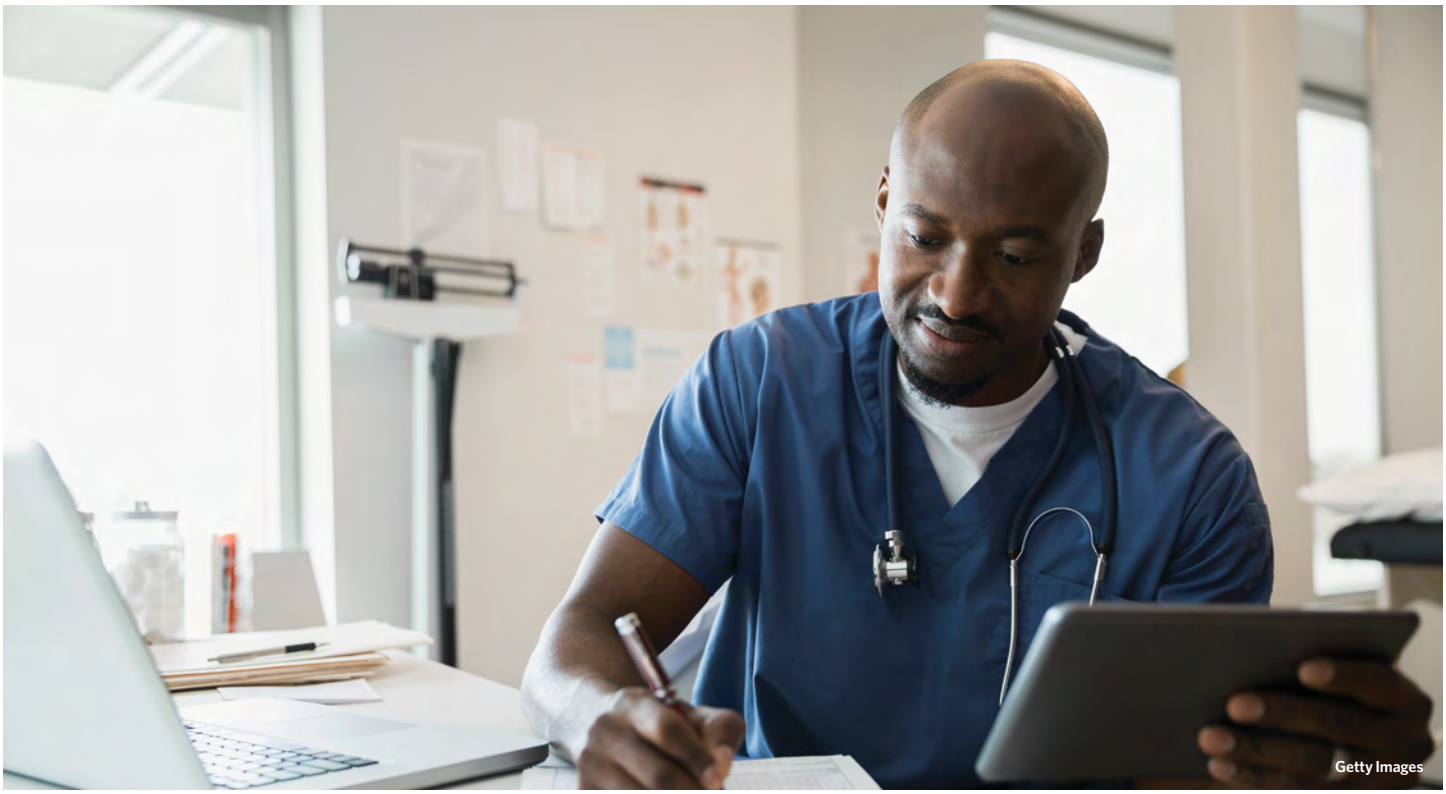

Next Steps to Encourage Adoption of Data Standards for Clinical Registries

This fact sheet was updated Nov. 23, 2016, to correct the affiliations of several experts in the acknowledgments section.

Overview

As hospitals, health plans, and physicians search for ways to cut costs and improve patient care, one of the best tools at their disposal is information housed in clinical data registries. Researchers can use these data to evaluate patient outcomes associated with high-risk procedures, such as hip and knee replacements and stent insertions. And clinicians can use registries to compare patient outcomes with those of their colleagues. These large databases—which are also used to collect data on drugs and medical devices—rely on the capture of specific, well-defined information. However, registries lack harmonized standards to guide this process, limiting how effectively the data can be used for research or to improve performance. For example:

- Much of the clinical information recorded in electronic health record (EHR) systems used in hospitals and doctors' offices exists as text rather than discrete data and cannot be moved easily into registries. To transfer the information, staff members typically must translate a portion of the patient record—a process known as abstraction—and manually enter the required data into the registry.

- Even when clinical information is recorded as structured data in an EHR, the specific elements used in a given registry could be different. For example, EHRs are required to record smoking status—using codes showing whether a patient is a current or former smoker—but registries may require information about whether the patient has smoked within the past year.[1] Thus, the structured smoking status data in the electronic record would be insufficient for registry use.
- Different registries may use varying definitions of key clinical concepts, such as heavy bleeding or myocardial infarction. This makes the abstraction more difficult because clinical staff must know the specific definition that applies to each registry.

Abstracting information from EHRs requires providers who work with multiple registries—often operated by different clinical societies—to invest substantial resources in order to submit data. The fact that registries use different standards also makes it difficult to compare findings and aggregate data. These challenges in collecting, recording, and moving patient data can be addressed through wider adoption of data standards, which are collections of data elements, definitions, and formats used to describe the same clinical concept (such as a diagnosis or laboratory value).

Hospital Impact Due to Lack of Data Standards

Mercy, a health care system based in St. Louis, reports to eight cardiac data registries, including several within the National Cardiovascular Data Registry, and to the Society of Thoracic Surgeons' Adult Cardiac Surgery Database. To meet reporting requirements, the system employs 15 highly skilled registered nurses to perform quality review and manual data abstraction from patient charts. The administrative director of Mercy's cardiac catheterization laboratories estimates that the annual cost for participating in and supporting registries is over $1 million.

In June, The Pew Charitable Trusts, an independent nonprofit research and public policy organization, and PCPI, a national nonprofit working to improve patient health outcomes, gathered experts from organizations that manage registries ("registry stewards"), federal government officials, standards development groups, and health information technology software vendors. Together, they identified barriers to more widespread use of data standards and outlined ways to encourage their adoption.

The experts identified four issues that need to be addressed to facilitate adoption of data standards:

- Registry stewards should develop a unifying roadmap of specific actions and policy changes needed to drive development and adoption of data standards.
- Registry stewards should actively participate in the standards development process to ensure that their needs are met.
- Stakeholders should help develop a resource center so they can share best practices, provide training on using data standards, and educate registry stewards on the impact of federal regulations.
- The federal government should use appropriate regulatory tools to encourage the use of data standards.

Problem 1: Registry stewards lack effective coordination.

Registry stewards are aware of the benefits of adopting data standards but have yet to agree on a path to achieve this goal. Voluntary organizations such as the PCPI's National Quality Registry Network have laid the groundwork by educating specialists in a wide range of clinical areas and producing documents explaining how federal regulations apply to registries.[2] With more federal interest now in using registries to evaluate the quality of American health care, the time is right for registry stewards to advance the adoption of common data standards.

Solution

In order to make progress toward this goal, registry stewards should create and implement a roadmap to resolve any remaining barriers. This would involve bringing together registry stewards across many clinical areas to:

- Clearly articulate the value they see in the use of data standards.
- Discuss how to set up and maintain a centralized resource community to share learning.
- Explain funding needs and priorities.
- Describe actions that registry stewards need to take in collaboration with other stakeholders, including the federal government and standards development organizations.
- Identify policy changes needed to spur the adoption of data standards.
- Lay out a timeline for progress.

Problem 2: Existing data standards do not meet the needs of registries, and most stewards have not participated in national standards development processes.

Many of the experts said existing data standards do not meet their needs. For example, a registry may want to collect information about blood pressure using Logical Observation Identifiers Names and Codes (LOINC), a standard terminology used to electronically transfer laboratory and clinical observations, but there are over 130 codes for blood pressure in LOINC.[3] This common occurrence creates problems when EHRs and registries use different codes. This means that in order to send information about blood pressure from an EHR to the registry, data elements must be individually paired between the two systems and manipulated to ensure that transmission can occur. To add to this challenge, some registries require more granularity than others. For example, a registry focused on congestive heart failure may need to know only whether a patient is diabetic and whether he or she is being treated with insulin, while a registry focused on diabetes would require much more detailed information, such as whether the patient has Type 1 or Type 2 diabetes and what type of insulin was being used.[4]

To address these problems, registry stewards have traditionally defined data elements specific to the needs of their individual registry. Naturally, that led to the use of data definitions that are not standardized. However, even when registry stewards work together to develop consensus on specific data elements within a clinical specialty, adoption and use have been limited. For example, the American College of Cardiology and the American Heart Association have created and published data standards for several cardiovascular domains, but they have yet to be widely adopted—even within the registries maintained by those organizations.[5]

Solution

To address these challenges, standards development organizations (such as the International Health Terminology Standards Development Organisation and the Regenstrief Institute) should collaborate with

registry stewards to ensure that new standards created for specific clinical specialties meet their needs. Standards development organizations rely heavily on volunteers from other organizations to do their work, and registry stewards to date have not actively participated in this process. Stewards should increase their involvement in standards development processes so they can help inform discussions on which elements should be used to encode information within their database systems and which transmission standards could provide easier exchange of electronic data. Standards development organizations should also proactively reach out to registry stewards and invite them to participate in relevant discussions.

Problem 3: It is expensive for registries to develop, use, and steward data standards.

Participating in the process to create new standards can be a lengthy and costly undertaking for registry stewards and other stakeholders. Once standards have been created, wide adoption can often be a challenge. Even when data standards exist, many stewards still choose to develop new ones for a variety of reasons. Input from the meeting suggests that many registry stewards are not aware of resources such as the National Library of Medicine's Common Data Elements Repository and Value Set Authority Center, which hold information on existing data standards that could be adopted. Implementation challenges could also hold registry stewards back from switching to a different standard.

When making the transition to a different standard, registry stewards need to map their existing data elements to the new ones in order to retain the conceptual relationships and meanings needed for consistency. This process is often time-consuming and expensive, because there can be hundreds of fields in each registry to convert, requiring extensive training for partner health care organizations and clinical staff. Registry stewards often do not have the capability to engage in this process. For example, one expert representing a large registry would like to conduct pilot projects exploring how to adapt its legacy systems to use a different data standard and to develop methodologies that could be shared with others. However, a lack of funding has made it difficult to take on such a large project. Standards adoption only benefits the registry community if many organizations move forward together, but the incentive to act first—or alone—is low.

Solution

The experts recommended that registry stewards, providers, payers, vendors, and the federal government jointly fund a resource center to share knowledge and support the dissemination of best practices. This center should involve federal agencies, such as the Agency for Healthcare Research and Quality and the National Library of Medicine, and private sector organizations that have spearheaded efforts to represent and share health information, such as the Healthcare Services Platform Consortium and the Clinical Information Modeling Initiative. These organizations can help educate registry stewards about available data standards that may meet their needs, provide training on their use, and develop methodologies and tools to help reduce costs and the burden of adopting existing data standards. The center could also fund pilot projects aimed at expanding knowledge on how to implement data standards.

Registry stewards, vendors, and other parts of the U.S. health care system would benefit from the creation of this resource center. In particular, stewards could identify existing standards that would suit their needs and provide more robust and reliable clinical information, which researchers at hospitals and health plans can use to find ways to cut costs and improve patient care. And vendors that develop software that hospitals use to report to registries could learn ways to design their products in a manner that reduces the burdens associated with manually abstracting clinical data.

Problem 4: Efforts by the federal government to increase the interoperability of health information technology systems have not focused on registries.

The $30 billion Medicare and Medicaid EHR Incentive Programs have encouraged hospitals and clinicians to adopt EHRs but have not ensured that data could be extracted from these systems and used for other purposes, including research by registries.[6] Overall, there have been few efforts by the federal government to drive the adoption of specific data standards in a way that would facilitate the exchange of clinical data between EHRs and registries. The Office of the National Coordinator for Health Information Technology (ONC) has set some requirements for the exchange of limited data sets from EHRs, but vendors have flexibility in how they meet the requirements. Moreover, the rules do not apply to the vast majority of clinical data elements.[7] While ONC does not have direct regulatory authority over registries, current regulations on EHRs do not sufficiently encourage the use of standards to exchange the granular clinical data that registries need.

Solution

The experts gathered by Pew and PCPI agreed that the federal government should not choose the data standards that registry stewards should use, because the regulatory process simply will not keep up with the pace of innovation, and extensive working knowledge of the clinical environment is required in order to identify a suitable standard. However, the government should use its regulatory authority to encourage the private sector to develop and adopt common data standards.

For example, under the new Merit-Based Incentive Payment System, providers may submit annual quality reports to the Centers for Medicare & Medicaid Services (CMS) through certified registries.[8] CMS could require the registries that apply for certification to use a set of common standards agreed to through a consensus-based process involving ONC, registry stewards, health information technology vendors, providers, and standards development organizations.

Many federal agencies would benefit from increased harmonization of data standards. For example, the Food and Drug Administration requires the use of electronic standards developed by the Clinical Data Interchange Standards Consortium when data from clinical trials are submitted as part of new drug applications.[9] Other agencies, such as the National Institutes of Health and the Centers for Disease Control and Prevention, could also encourage the adoption of data standards as part of their conditions for grant funding.

Conclusion

As the federal government and private health plans increasingly focus on improving the quality and value of health care, clinical data registries are poised to play an even bigger role in meeting this aim. Registry stewards should continue to work with hospitals and other stakeholders to develop and adopt harmonized data standards that meet their needs. The solutions outlined in this document provide a starting point for greater collaboration among registry stewards, standards development organizations, providers, clinicians, payers, and the federal government.

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Endnotes

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