Clinical registries play an important role in measuring healthcare delivery and supporting quality improvement for individuals with cardiovascular disease and stroke. Well-designed clinical registry programs provide important mechanisms to monitor patterns of care, evaluate healthcare effectiveness and safety, and improve clinical outcomes. The use of clinical registries is likely to grow given the increasing focus on measuring and improving healthcare delivery and patient outcomes by stakeholders in both the private and public sectors.

The American Heart Association (AHA) has a longstanding commitment to promoting the innovative and effective use of clinical registries. The importance of clinical registries was highlighted recently in an AHA Scientific Statement on “Essential Features of a Surveillance System to Support the Prevention and Management of Heart Disease and Stroke” in the United States. This policy statement expands on the previous scientific statement by providing recommendations to policy makers and the healthcare community for expansion of the applications of existing and future clinical registries.

The term “clinical registry” is defined here as an observational database of a clinical condition, procedure, therapy, or population in which there are often no registry-mandated approaches to therapy and relatively few inclusion or exclusion criteria. The focus of clinical registries is to capture data that reflect “real-world” clinical practice in large patient populations. The data from clinical registries do not replace the need for traditional randomized controlled trials. Rather, registries and trials are complementary approaches, each with unique advantages and imperfections. Clinical registries do not solely contain claims or administrative data yet may be linked to such data sources.

There are at least 3 classifications of clinical registries based on the patient population, including procedure/therapy/encounter-based, disease-based, and population-based registries. Registries also can be classified from a functional perspective, such as whether the registry is used to conduct clinical research, to perform quality measurement, or to provide feedback to clinicians for quality improvement. Such uses are not mutually exclusive. Although clinical registries...

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can be either prospective or retrospective in design, this policy statement focuses on prospective clinical registries.

The potential uses of clinical registries have captured the attention of policy makers at the federal level. This has resulted in changes in the substance and scope of roles that clinical registries play within the US health system. Some examples include the use of registries to support safety and comparative effectiveness research of marketed drugs, devices, or treatment strategies; to gather data on new therapies granted provisional coverage by Medicare under Medicare’s coverage with evidence development initiative; or to assess the reliability and validity of potential performance measures for use by public payers, private payers, and accreditation organizations. Clinical registries are developed and operated by many types of entities, including researchers, research consortiums, nonprofit organizations, government agencies (eg, the National Institutes of Health), and industry.

Clinical registries also provide the opportunity to identify and evaluate healthcare disparities within a broad patient population in community practice outside of the structured research protocol setting. This promotes the ability to examine important issues involving patient access and outcomes in subpopulations, including racial and ethnic minorities, women, the elderly, individuals with multiple comorbidities, and individuals with congenital heart conditions.

The potential value derived from investing resources in clinical registry development is demonstrated by national cardiovascular disease and stroke registries that have matured over the past decade. Prominent examples include the AHA’s Get With The Guidelines (GWTG) registries for coronary artery disease (GWTG-CAD), heart failure (GWTG-CHF), stroke (GWTG-Stroke), and outpatient care (GWTG-Outpatient); the Interagency Registry for Mechanically Assisted Circulatory Support; the Centers for Disease Control and Prevention’s Paul Coverdell National Acute Stroke Registry; the AHA’s National Registry of Cardiopulmonary Resuscitation; the Society of Thoracic Surgeons National Database, which includes the Society of Thoracic Surgeons Adult Cardiac Surgery Database; the American College of Cardiology Foundation National Cardiovascular Data Registry (NCDR) programs, including the ICD Registry for implantable cardiac defibrillators; the Carotid Artery Revascularization and Endarctectomy Registry; the CathPCI Registry for diagnostic cardiac catheterizations and percutaneous coronary interventions; the Practice Innovation and Clinical Excellence (PINNACLE) registry for quantifying and improving the quality of outpatient care; and the ACTION Registry–GWTG for acute myocardial infarction.

**Considerations in Establishing Clinical Registries and Interpreting Registry Data**

Many of the opportunities and challenges associated with clinical registry implementation arise from the fact that clinical registries typically serve multiple functions. Examples include public health surveillance, quality improvement, evaluation of temporal trends in care and outcomes, monitoring for drug or device safety and efficacy (including post-marketing surveillance), evaluation of access to medically necessary care (including underuse, overuse, and misuse), and the assessment of clinical effectiveness, cost-effectiveness, and value.

Clinical registries must be designed with sufficient safeguards, rigor, and transparency to ensure that the primary functions of the registry are well served. Regardless of the purpose, data collection must be of high quality to avoid erroneous conclusions. Examples of threats to a registry’s validity include selected and incomplete patient sampling, ambiguous data definitions, and high rates of missing data. Many of these considerations have been described extensively in a comprehensive guidance document published by the Agency for Healthcare Research and Quality (AHRQ) in 2007, which will be updated in the near future. Although it is not within the scope of the present policy statement to reiterate these practices, the AHRQ-published document provides important guidance about registry planning, registry design, data elements and sources, data quality procedures, and the uses of registries. Additional information is provided in the Appendix.

In this policy statement, the AHA provides guidance to policy makers and the healthcare community on navigating the challenges inherent in establishing and maintaining existing and future clinical registries. Emphasis is placed on the opportunities and challenges associated with cardiovascular disease and stroke, including short- and long-term prevention, diagnosis, treatment, and rehabilitation of individuals with these diseases. The discussion and recommendations are divided into the following 5 categories:

- Ensuring high quality data
- Linking clinical registries with supplemental data
- Integrating clinical registries with electronic health records
- Safeguarding privacy while reducing barriers to healthcare improvement
- Securing adequate funding and developing business models to initiate and sustain clinical registries

**Ensuring High-Quality Data**

Because the usefulness of any clinical registry depends directly on the quality of the data it collects, ongoing quality-monitoring procedures that characterize data validity and reliability and improve and maintain data quality are critical. Limitations in the quality of the data collection markedly undermine the potential uses and applications of a registry.

A particularly important aspect of data quality is the degree to which the population targeted by the registry is accurately represented. Regardless of the use of a registry, an understanding of the composition of the population is important. The quality of the registry depends on consistent adherence to the explicit inclusion, exclusion, and sampling rules of the registry. For example, a registry may establish inclusion and exclusion criteria, but individual sites may apply these rules inconsistently. Registries need to assess and disclose the level of adherence to the intended entry criteria. To the extent possible, comparisons of the included and excluded populations with data sources common to both populations can be useful in gauging representativeness.
Gauging the representativeness of clinical registry data is also critical in ongoing efforts to identify and address disparities in our healthcare system. Clinical registries can and should play a central role in both the inclusion of adequate numbers of patients who traditionally have been underrepresented in the scientific literature (including racial and ethnic minorities, women, the elderly, and socioeconomically disadvantaged individuals) and the capture of meaningful data for these subpopulations of patients. If necessary, oversampling can be performed to ensure adequate numbers of traditionally underrepresented populations. To ensure data quality, clinical registries can also play a leadership role in the collection of data on sex, race, ethnicity, language, and other important indicators using standardized definitions for such data.

Data completeness is another important component of registry quality. Incomplete medical record documentation of key elements (eg, medical history, laboratory data, differential diagnosis) is common in both hospital and ambulatory settings. Data completeness also may be a function of the extent to which collection is integrated with clinical care, the training and consistency of those who enter data, and the extent to which data elements are required. Case completeness issues may arise from errors made when records are reviewed manually or when automated coding efforts are undermined by changing data definitions within electronic medical records. In a particularly egregious example, an analysis of 78 practices participating in a disease registry demonstrated 100-fold differences in the rates for recording relevant data, including missing diagnostic codes in patients who received treatment and infrequently recorded data related to the primary purpose of the registry. Missing data are a particular challenge because one cannot assume that data are missing randomly. Efforts to handle missing data statistically are complex and cannot specifically address data not missing at random. The approach of removing cases from an analysis for missing data elements may result in bias or decreased generalizability of findings. For these reasons, efforts to minimize missing data are critical to minimizing bias.

Even when skilled abstractors are instructed effectively on data collection, source documents may be absent, incomplete, or contradictory because of the large number of healthcare providers involved in documentation and inconsistencies in recording. There are numerous other sources of abstraction errors, including failure to meet the expectation of consecutive case inclusion, inconsistent coding, lack of common data elements or inappropriate application of definitions, ambiguous data definitions, poor layout of data collection forms, use of nonvalidated scales (ie, those that have not undergone psychometric testing for validity and reliability), haphazard adjudication of complex data, and insufficient systems for follow-up data collection.

Many of these threats to data quality, including variability in case completeness and data accuracy, may be overcome with careful registry planning and design, training of personnel, and mechanisms to assess and improve data quality. In 1 study, case completeness and data accuracy improved with interventions to ensure adequate training of staff, use of supplementary source reporting, conformity with published standards such as those developed by the AHA and American College of Cardiology Foundation, and achievement of national certification. Additional methods for ensuring data accuracy and consistency include the use of site visits, chart reviews, clarifications of all discrepancies, core laboratories, and critical events committees. Such steps help ensure uniformity in definitions and high-quality data, although these safeguards may be cost prohibitive, especially in the case of registries for large patient populations.

When data definitions are not explicit or response options do not encompass the entire spectrum of potential choices, variability in data interpretation is more likely to occur. Paper data collection systems that require secondary electronic data entry are predisposed to data entry errors that may be avoided with a direct electronic data collection system that automatically performs checks for consistency, plausible value ranges, and missing values. Nonetheless, errors also occur in systems with direct data entry. Explicit, comprehensive, and interpretable data standards; primary electronic data entry; and automated data integrity assessment are all likely to enhance the quality of registry data.

Over the past decade, some large clinical registries published reports that addressed data quality and variability. However, because there are no standard requirements for such reporting, there is possibly unrecognized bias within other registries that could undermine the reliability, credibility, and representativeness of registry reports.

Some registries have reported good interrater reliability between registry and medical records data. However, even when overall agreement for a particular measure of quality may be at least moderate (ie, $\kappa$-scores $\geq 0.60$), there may be some data fields with poor reliability. For example, in an acute stroke registry with good overall interrater reliability for quality of care metrics, several individual data fields demonstrated poor reliability, including stroke onset time, stroke team consultation, time to initial brain imaging, and discharge destination. Recommendations to improve data recording of symptom onset time may improve the quality of this traditionally poorly recorded variable. Furthermore, one would expect greater variability for data that reflect a subjective measure than for data on objective measures.

Thus, although an individual report from clinical registry data may provide only an overall $\kappa$-value that summarizes all performance measures, publication of a detailed audit of registry data that specifies the major fields used in the analysis is necessary to substantiate clinical registry quality and to identify areas for improvement in data quality. Information about the accuracy of specific data fields is necessary to improve the quality of submitted data, as well as the registry's overall quality.

Furthermore, because of their observational nature, the data generated by clinical registries must be interpreted with an understanding of the limitations that arise from treatment selection bias when alternative forms of therapy are compared (such as in the case of comparative effectiveness research). Advanced statistical methods often can help diminish the adverse effects of treatment selection bias, and
sensitivity analyses may be useful. However, in many cases, there are no statistical techniques that completely eliminate treatment selection bias, and no statistical technique can account for confounders that either are not measured or are measured inadequately in the data collected for the registry.

Publications are available that provide an overview of steps used in database audits,\(^2\) and other reports provide methods used in quality control and statistical analysis; however, there are no written standards that have been described and evaluated to determine the effectiveness of attempts to ensure registry quality. Furthermore, the minimum acceptable standard of clinical registry data quality (overall and individual data fields) has not been specified beyond a requirement for statistical agreement between data abstracted manually from patient medical records and registry data.

Linking Clinical Registries With Supplemental Data

The value of linking population-based clinical registries with supplemental data is substantial, and such linking contributes to a wide range of important functions, including public health surveillance, clinical research, quality improvement, and monitoring of patient safety. The linking of clinical registry data to other data sources allows researchers to leverage existing data to create a linked clinical-longitudinal database that capitalizes on the strengths of both types of data sources. This is increasingly important at a time when there is otherwise little infrastructure to answer important safety, clinical efficacy, comparative effectiveness, and other clinical questions for large cardiovascular and stroke patient populations in real-world clinical settings. The linking of clinical registries with supplemental data also provides the potential ability to examine outcomes for smaller subpopulations, including assessment of disparities for racial and ethnic minorities and other groups that may otherwise be underrepresented.

The linking of clinical registry data with claims data for longitudinal follow-up has many advantages over direct longitudinal clinical follow-up. Obtaining data on clinical events such as hospitalization and vital statistics from existing claims sources is far more efficient and may be more complete than direct data collection.\(^1\) Longitudinal data on hundreds of thousands of patients can be linked and analyzed in a highly efficient fashion.\(^2\) To the extent that the process can be based on anonymous identifiers, a data linkage system would likely be more complete than a system that requires hospitals and patients to opt-in for collection of longitudinal follow-up data.\(^2\) The resulting linked database would not be subject to participation-based selection biases that have posed challenges for other registries or data sets that require informed consent or that have lost patients to follow-up.\(^2\) Potential limitations of such administrative databases are significant and include the general absence of clinical data (eg, blood pressures) or patient-centered assessments (eg, symptoms, health status, psychosocial status, quality of life) and the systematic exclusion of those who are not insured by the plan that administers the data source, thus systematically excluding individuals without formal access to care.

A particular challenge in data linkage is the availability of unique direct patient identifiers (eg, Social Security numbers).\(^1\) Without such direct identifiers, it may still be possible through matching algorithms to create a high-quality link between inpatient clinical registry data and claims data (so-called probabilistic matching).\(^1\) A number of studies have validated the use of indirect identifiers to link healthcare databases (eg, a combination of data elements such as date of birth, sex, and date of healthcare encounter). It is essential to ensure there is adequate privacy and security protection for personal health information when data sets are linked, because the reidentification of previously deidentified records has occurred.\(^2\)

Methods have been developed to identify records from clinical registries by use of Medicare inpatient claims data through indirect identifiers (eg, admission date, discharge date, patient age, date of birth).\(^1\) This method takes advantage of the hospital clustering observed in each database by demonstrating that different combinations of indirect identifiers within hospitals yield a large proportion of unique patient records.\(^1\) This high level of uniqueness allows linking without advance knowledge of the provider number of each registry hospital.\(^1\) Once such records have been linked to a data source that includes a patient identifier, additional identified data sets can then be linked as well.

However, such linkages through probabilistic matching inevitably result in the loss of some of the sample because of the inability to match individuals in both data sources. In addition, the use of indirect identifiers to link databases may result in some proportion of erroneous links, although it is unlikely that incorrect links would introduce a large amount of systematic bias such biases are difficult to assess.\(^1\) Further investigations of these biases by comparison of the results obtained by direct linkage with those in the same data sets using indirect linkages will be useful in further delineating the potential limitations of the indirect approach.

Although the use of supplemental data for longitudinal follow-up or evaluation of other vital information has several advantages, it also has important limitations. For example, Medicare claims exist only for patients ≥65 years of age and patients with other qualified coverage in this fee-for-service sector.\(^1\) State-level all-payer claims files, Medicaid data, and major private insurer databases provide alternatives for linking patients ≥65 years of age. Specific data sources that could prove useful include the American Medical Association’s Physician Masterfile, the Social Security Death Index, and the US Census. However, each of these data sources covers only select groups of patients. The assembly of a data set with complete follow-up in all patients would require the integration of multiple sources of supplemental data.

Data linkages between clinical registries and longitudinal claims databases provide opportunities to assess outcomes such as mortality, readmission, and subsequent procedures. Likewise, outpatient, community, and prehospital clinical registry data linked to hospital data can facilitate evaluation of in-hospital diagnostic studies, treatments, procedures, and hospital-based quality measures. Such linked data sets may allow researchers to answer questions about long-term safety and efficacy of treatments and about the relative importance.
of prehospital, hospital, and outpatient processes for patient outcomes.

A number of important issues must be considered in the interpretation of the findings from data sets composed of registry data linked with supplemental sources. The linked database will be limited by the biases contained in all of the component sources. There are potential selection biases inherent in clinical registries, unless consecutive patients are enrolled and the participating centers are representative of the nation as a whole. This may limit inferences that can be made about incidence of the disease state, cardiovascular events, or procedures and the patient population in general.

Biases can also be introduced when dealing with missing data or missing links. Methods are available for imputing missing data, but more work is needed to develop and evaluate methods that address the special case of missing data in linked data sets from multiple sources. If linkage is available only in a certain subgroup of the patients enrolled in the clinical registry, this can introduce a population-selection bias not previously present in the clinical registry.

Although the voluntary, nonrandom participation associated with clinical registries linked to supplemental data does not necessarily limit generalizability, the representativeness of the clinical registry linked to supplemental data must be established on a case-by-case basis. In evaluation of linked data sets, factors to consider include the completeness and accuracy of the linkages; the completeness, quality, and accuracy of the parent clinical registries; and the completeness, quality, and accuracy of the linkage data set. Rigorous standards need to be developed for the selection, evaluation, and interpretation of linkage data sets.

**Integrating Clinical Registries With Electronic Health Records**

The electronic health record (EHR) systematically collects health information about individual patients. Because it uses a digital format, an EHR can track patients across the continuum of care and collect data for national clinical registries to promote the study of practices and methods for improving health care for various populations.

There are multiple potential benefits of integrating EHRs with clinical registries. First, clinical registries can help define data collection within EHRs that is meaningful, accurate, and actionable. More specifically, registries can guide the specification of which data are critical to capture in EHR formats (e.g., categorical rather than narrative text) to directly support evaluation of care delivery and patient outcomes. The specification of data includes data elements and data definitions, as well as specification of data collection (e.g., ranges) to enhance accurate and standardized data collection.

Second, registries can serve a critical role with regard to the benchmarking of and feedback on care and patient outcomes based on data obtained from EHRs. A primary role of national clinical registry programs, such as GWTG and the NCDR, is to assess quality of care and provide benchmark reports to registry participants. Only with such benchmarking can providers, practices, and hospitals know where they may have gaps in care delivery compared with others, which permits tracking in relation to the nation over time. Finally, the transfer of data from EHRs to registries integrates data collection into clinical care, which reduces the time needed for data collection and potentially increases the reliability and completeness of data elements.

Investigators and their institutions using EHRs that supply data to national clinical registries should adhere to the data specification, evaluation, benchmarking, recognition, and reporting standards developed by national clinical registries. There are multiple reasons why participation in national clinical registries is superior to having EHRs act independently. Given the number of EHR vendors and the customization of EHR interfaces within vendors, existing data structures are highly heterogeneous, which limits the validity of comparisons between EHRs. Furthermore, because of their commercial interests, EHR vendors typically strive to differentiate their products rather than seek compatibility with others. Collection of data according to the specifications of national clinical registries ensures comparable, valid data.

There is also a risk that EHRs will not keep pace with current clinical practice guidelines or newly evolving evidence in cardiovascular practice. National clinical registries such as GWTG and the NCDR are tied directly to the clinical practice guidelines and performance measures of the American College of Cardiology Foundation/AHA, and therefore, they more efficiently reflect current best practices in data specification and evaluation. EHR vendors are also unable to provide representative regional and national benchmarking of care, another major strength of national clinical registries. Furthermore, there is significant concern about heterogeneity and proliferation of “quality of care” evaluations and metrics if these are developed by EHR vendors rather than by professional societies and their national clinical registries that evaluate and report only validated, approved quality metrics.

Unfortunately, the adoption of EHRs has been slow. In a recent survey of 3049 hospitals in the United States, 1.5% had comprehensive systems, whereas an additional 7.6% had basic systems that included clinical documentation and test results. Office-based practices have somewhat better adoption of EHRs. In a 2009 survey, the National Center for Health Care Statistics found that 20.5% of office practices in the United States had a basic system that included patient demographics, clinical notes, prescription orders, and laboratory and imaging results. An additional 6.3% had fully functional systems that included medical history, electronic ordering and prescribing, drug interactions, and decision support for guideline-based interventions. One interesting option for the establishment of EHRs is to make use of the public domain software developed and used by the Veterans Health Administration for its system. This system has provided the basis for a number of valuable database studies. The limited adoption of EHRs in both the ambulatory and inpatient setting is another important barrier to the systematic collection of clinical data for robust registries.

The benefit of EHRs will only be achieved through a standardized method of collecting and reporting the data to registries. There are a variety of factors that can help foster success in this area. The American Recovery and Reinvestment Act of 2009, and in particular the Health Information...
Technology for Economic and Clinical Health Act that Congress included within American Recovery and Reinvestment Act, has a key goal of driving greater and quicker adoption of EHRs through financial incentives for physicians and hospitals. The Health Information Technology for Economic and Clinical Health Act provides a total of $23 billion for health information technology, which includes payments to healthcare providers who adopt EHRs in a manner consistent with published “meaningful use” requirements.\(^4,35\)

The widespread adoption of EHRs should provide access to unprecedented amounts of clinical data. These data will need to be aggregated through registries to allow for study of the most effective practices and the implementation of evidence-based medicine. Although the integration of EHRs is essential, as well as optimal, to ensure robust and accurate outcome registries, there are several barriers to achieving this goal. In addition to the barrier created by low adoption rates, there are also 2 other important barriers: interoperability issues and privacy.

Interoperability in EHRs has been defined as “the ability of two or more systems or components to exchange information and to use the information that has been exchanged.”\(^4,36\) The degree of interoperability ranges from advanced (in which the receiving computer can understand and act on the data) to minimal (in which the information can only be viewed, such as in a PDF format). Because EHR vendors operate in competitive markets, vendors attempt to differentiate their products from their competitors. Although this approach may have commercial benefits, it limits interoperability among EHRs and their functionality within national registries.

The robustness of an EHR, as well as the degree of participation in clinical registries, relies on the ability to move data with minimal effort and on the information being in a format that is useful for subsequent analysis. For this to happen, several principles must be met. First, the data must be “computable electronic data,” which means “electronically entered data that can be computed by other systems.”\(^4,36\) For example, electronic transmission of a PDF form would not be usable without significant manipulation. Second, the data definitions must be consistent across operating systems. For example, if the measure of left ventricular ejection fraction were “LVEF” in 1 system, this would not be interpretable if the receiving system only recognized the label “ejection fraction.”

Among the most critical functions of EHRs is the capture of clinical data to support feedback on care quality to the clinicians using them. Ensuring the seamless transfer of data from EHRs to national clinical registries can support feedback on care quality to the clinicians using them. The primitive focus is quality assessment or improvement.\(^4,37–45\) As articulated by the Institute of Medicine in 2009, these concerns often stifle innovations to improve public health, even when the risk to individual patients is minimal or absent.\(^44\) A notable example is the highly publicized temporary suspension by the Office for Human Research Protections of a successful and innovative quality assurance initiative designed to reduce central line infections in intensive care units.\(^46\) The Office for Human Research Protections stated that although HIPAA regulations “do not apply when institutions are only implementing practices to improve the quality of care…, if institutions are planning research activities examining the effectiveness of interventions to improve the quality of care, then the regulatory protections are important” and do apply.\(^46–48\)

Safeguarding Privacy While Reducing Barriers to Healthcare Improvement

Although the regulations that govern privacy in health care are essential to protect the fundamental rights of patients, recently there has been increasing concern about the appropriate balance between patient protection and advancement of the public health. Current regulations arise primarily from 2 sources. The Common Rule, which has been applied to all federally funded research since 1991, is applied by many institutions to all research. The Common Rule describes the conditions under which institutional review board (IRB) review and approval are required, the degree of review required, and the requirements for patient informed consent, including conditions in which the informed consent may be waived.

The Privacy and Security Rule, initially published in 2000 as part of the Health Insurance Portability and Accountability Act (HIPAA), applies to all research, whether federally funded or not. This rule establishes requirements about the release of protected health information with and without patient authorization. In contrast to the Common Rule, the Privacy and Security Rule specifically addresses the responsibilities of “covered entities” that have access to or distribute protected health information.

The Privacy Rule severely restricts the circumstances under which individually identifiable health information may be disclosed, although it also describes specific types of activities for which disclosure of protected health information is permitted without authorization, including the provision of “treatment,” “payment,” and “health care operations.”\(^37\) Although certain types of mixed activities involving aspects of research, quality assessment, and performance improvement may be possible without patient authorization under HIPAA, the regulations are ambiguous, and interpretations are often inconsistent. Moreover, penalties for noncompliance are severe. Thus, many covered entities believe that the safest and most conservative approach is to apply research protections even to mixed activities that clearly promote the public welfare.

Thus, concerns surrounding HIPAA and the Privacy Rule include not only traditional clinical research activities but also the application of research regulations to activities for which the primary focus is quality assessment or improvement.\(^37–45\) As articulated by the Institute of Medicine in 2009, these concerns often stifle innovations to improve public health, even when the risk to individual patients is minimal or absent. A notable example is the highly publicized temporary suspension by the Office for Human Research Protections at the Department of Health and Human Services of a successful and innovative quality assurance initiative designed to reduce central line infections in intensive care units.\(^46\) The Office for Human Research Protections stated that although HIPAA regulations “do not apply when institutions are only implementing practices to improve the quality of care…, if institutions are planning research activities examining the effectiveness of interventions to improve the quality of care, then the regulatory protections are important” and do apply.\(^46–48\)
Both existing and expanded uses of clinical registries raise similar concerns. For example, although most clinical registries are founded with the objectives of facilitating quality assurance and performance improvement, registries often are also ultimately used to develop generalizable knowledge. Questions remain whether such “mixed” activities are still considered quality assurance initiatives and at what point such activities fall under the regulations that govern human subject research. These concerns are heightened when such registries collect identifiable health-care information such as name, address, and Social Security number, which are important to facilitate linkages with other clinical or administrative databases.

As methods for promoting security improve, the issue of whether and how to implement some form of a national personal identifier warrants attention. For example, to maintain confidentiality, unique patient identifiers could be created via a 1-way hash function that uses pieces of information entered at each encounter (birth date, sex, first name, mother’s maiden name) to create a unique identifier remote from this information.

As noted previously, clinical registries linked with external data sources have the potential to drive guidelines, change the course of appropriateness criteria, and ultimately produce policy to reduce the overall cost of health care. The development of consistent, easily applicable standards that assure the protection of patients’ privacy while simultaneously enabling analyses of clinical care and outcomes to support future quality improvement must be a high priority for the entire healthcare and research community. However, the healthcare community does not have the authority to change the regulations that limit the potential utility of registries. Ultimately, legislators must work with the healthcare community and patients to effect the changes necessary to enhance the value of registries while maintaining adequate protection for patient privacy.

Securing Adequate Funding and Developing Business Models to Initiate and Sustain Clinical Registries

Although data derived from clinical registries can provide remarkable value for research and quality improvement, the activities associated with the design, collection, analysis, and dissemination of such data are time-consuming, resource intensive, and costly. As a result, funding and sustainable business models are among the most significant challenges facing the expanded use of clinical registries.

Many of the potential advantages of using clinical registries, including the achievement of improvements in health-care quality and outcomes, benefit the health system as a whole. Given the limitations in allocating financial gain to individual stakeholders, it is challenging to allocate the costs of registries to specific constituencies. As such, registries are an investment in the infrastructure of healthcare delivery and require innovative and visionary leadership to support the vital role that they play in improving healthcare quality.

To address the funding challenge, innovative business strategies are necessary. As with any business model, sustainability requires a careful balancing of costs and revenue. The costs associated with initiating and operating a clinical registry include database planning, design, upkeep, data cleaning and management, data auditing, quality assurance, data analysis, and reporting.

Although costs can be constrained by carefully narrowing the scope of a registry to maintain focus on a well-circumscribed aspect of health care, successful data collection and feedback often stimulate expansion. Numerous references have been developed to assist in the design of clinical registries, thus minimizing wasted resources.

Beyond the costs of a registry’s infrastructure, individual registry participants also must dedicate significant resources to the identification of eligible patients and the extraction of high-quality data. The costs imposed on participants must be considered carefully in the design and implementation of clinical registries.

An important mechanism for reducing costs involves optimization of the efficiency of data input and use within the work flow of patient care. The identification of ways to minimize the administrative burdens associated with the input and collection of data remains a critical issue. For example, the costs of data entry increase significantly when the same data must be entered ≥2 times for use both in delivering health care and in participating in a clinical registry. To the extent that the data elements can be acquired through EHRs or abstracted automatically from other data entry procedures, such as the hemodynamic monitoring systems of cardiac catheterization laboratories, efficient data entry and improved accuracy of data collection can be achieved.

At this time, there remain obstacles in most settings to the seamless incorporation of data collection into the work flow of patient care; however, the collection of registry data by point-to-point computing is an unsustainable, nonscalable approach in the long term. As we face an important transitional period, it remains critical to explore how best to make changes to registry design and operation to continue integrating data collection within the daily work flow of delivering patient care. Nonetheless, even with efficient design, registries are expensive, and the full scope of resources required is often underappreciated.

In addition to minimizing expenses, registry developers should carefully consider potential revenue streams to support their efforts. One strategy for stimulating revenues from registries is to define the value of registries for specific components of the healthcare system, thereby demonstrating to those entities that their financial support is cost-effective. For example, if guidelines derived from clinical registry data achieved meaningful improvements in care and outcomes, payers (including employers, private health insurance companies, public health insurance programs, and consumers) might benefit financially by paying less for maintaining the health of their covered population. Yet building sufficient evidence to support these “savings” and convincing payers, who are typically striving to minimize their costs, to invest in a registry is challenging. In some cases, however, a payer may seek to quantify the processes of care as part of a “pay-for-performance” system to encourage providers to use evidence-based care in treating patients. If the registry can acquire the requisite data for such programs, payers could
reduce the substantial costs associated with collecting these data with an investment in a registry. An advantage of this strategy is the greater objectivity of a registry and the reduction in potential complaints against a payer’s approach to assessing performance. This assumes, however, that the registry is designed and governed to avoid real or perceived conflicts between the output of the registry and the interests of the payer.

In some cases, payers have invested significant resources in registry projects. Minnesota Community Measurement and the Michigan BMC2 consortium (Blue Cross Blue Shield of Michigan Cardiovascular Consortium) are examples of state-wide registry efforts focused on quality of care that are sponsored by private payer organizations. Unfortunately, although payers often stand to gain the most from the implementation of registries, such examples of payer-based programs are relatively rare.

An additional potential revenue stream to help support clinical registries may come from the device and pharmaceutical industry’s need to fund large observational real-world phase 4 studies to support new products. This is a common requirement for approval by the US Food and Drug Administration. The use of registries to support these efforts can benefit both the registry and industry, but firewalls must be erected to preserve the integrity and purpose of the registry. The National Institutes of Health model, in which external sponsors may support a registry as long as there is no direct access to the data by the sponsors, is a potential strategy.

An emerging opportunity for registries may lie in the growth of comparative effectiveness research. The US Congress recently enacted provisions that will continue large-scale public funding of comparative effectiveness research as part of the healthcare reform legislation. Both the National Heart, Lung, and Blood Institute and the AHRQ have solicited applications for funding for comparative effectiveness research and for the infrastructure to support such investigation. As a result, clinical registries (a foundation for such research) can be supported in part by the per capita payment that will be contributed by public and private health insurance programs. This could serve as a model for further efforts to fund clinical registry activities.

Moreover, a market for the support of personalized medicine is likely to emerge. An important product of registries and comparative effectiveness research is the creation of prediction models that can estimate the benefits of alternative treatments in patients with specific clinical profiles. As this paradigm evolves, registry owners may be able to license their models to those entities that translate this evidence-based paradigm of health care to clinical practice and obtain a royalty stream from the eventual sale and use of these models.

Many of the positive benefits of clinical registry development result in “public good” that has the potential to improve citizens’ lives. Government policy makers have a unique role to play in fostering these initiatives. Such support may take the form of funding to develop and sustain clinical registries and financial incentives for providers to participate in important clinical registries.

Although registries have the potential to create new opportunities to improve the quality and efficiency of care, registries also present challenges that result from potential conflicts of interest and concerns about protecting patient privacy. Registries are created and used by a wide variety of stakeholders within the healthcare delivery system, each of which has unique and different interests. The societal value of a clinical registry is enhanced whenever the financial viability of the registry is balanced with the ethical duty to objectively collect, analyze, and report high-quality data.

**Recommendations**

To promote the appropriate use of clinical registries in the interest of improving patient care, the AHA presents the following recommendations.

**Ensuring High-Quality Data**

1. Regular auditing and reporting of the quality of clinical registry data should be conducted with approaches advocated by the AHRQ and in a transparent manner.
2. Registry managers must continually strive to improve and verify data quality, because the value of the data collected by a clinical registry is proportional to the completeness and accuracy of the data.
3. Data quality reports from clinical registries should be made public so that the results can be interpreted properly, including information on the systems and processes used to ensure the sample population is representative and the data collected are complete, accurate, and reliable.
4. When results are reported that are based on data from a clinical registry, details related to the quality of the data including the design, sampling strategy (consecutive or other), and potential enrollment biases, should be explicitly noted. The variables included in the minimum data set should be reported, as well as whether definitions, values, and qualifiers were clearly stated, reflecting evidence of adherence to robust scientific principles.
5. Future guidance regarding the standards and processes for assessing the quality and limitations of the data produced by clinical registries is required. Such guidance should apply to both the initiation and ongoing operations of clinical registries.
6. Clinical registries should be used to obtain high-quality data and to examine important issues involving patient access and outcomes in vulnerable subpopulations, including the collection of nonclinical data elements such as race, ethnicity, and language. Standard definitions and categories for race, ethnicity, and language should be adopted to ensure comparable disparity information from variable data sources.
7. Registries should generate reports on disparity-related data elements related to key registry themes and include disparity-related data to provide healthcare professionals with information on the quality of care provided compared with other practices/institutions/peers at the state, regional, and national levels.
Linking Clinical Registries With Supplemental Data

1. Policy makers should promote the linkage of clinical registries to supplemental data. These efforts will require resources, which should be provided by federal, state, and private sector sources.
2. Research should be supported to assess alternative approaches to the linkage of clinical registries and identify the most accurate and efficient methods of linkage.
3. Programs engaging in linkage of clinical registries with supplemental data should promote linkages and interoperability among clinical registries, health information technology systems, and databases with administrative claims, laboratory data, imaging data, and patient outcomes.
4. Resources devoted to promoting comparative effectiveness research should be used to support the infrastructure needed to link clinical registries with supplemental data. National standards for linking and interpreting linked data should be developed.
5. If a registry does not collect race, ethnicity, and language data elements, or if such registry data are limited, efforts should be made to link the registry to these types of data from other sources.

Integrating Clinical Registries With Electronic Health Records

1. Policy makers should ensure that governmental entities continue to provide significant positive incentives for the adoption of EHRs. These incentives should be made available to an even broader spectrum of practitioners than currently allowed.
2. The Secretary of Health and Human Services should ensure that EHRs collect sufficient patient information to permit clinical registries to assess quality of care and to provide feedback to healthcare providers and systems on performance.
3. EHRs should facilitate the uploading of data in a digital format that allows clinical registries to use the information effectively. If EHRs are used for the collection of requisite data elements, then tools should be implemented with the EHR to minimize missing data.
4. Policy makers should create requirements and incentives for EHRs to be designed in such a way that standardized data are easily shared with and transferred to clinical registries. The uploading of data should meet the standard for interaction with health information exchanges.

Safeguarding Privacy While Reducing Barriers to Healthcare Improvement

1. Congress should amend HIPAA to modify the Privacy Rule in a manner that is consistent with the recommendations of the Institute of Medicine’s 2009 report, Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research. Within this report, the Institute of Medicine’s Committee on Health Research and the Privacy of Health Information concluded that the HIPAA Privacy Rule creates impediments for important health research and does not adequately protect patient privacy.
2. Regulatory guidance for researchers that outlines the patient privacy protections for each category of registry should be provided. Policy makers should develop better guidance regarding the conditions in which informed consent may be waived, reconciling the regulations for quality assessment and research functions.
3. Policy makers should pilot test streamlined approaches to IRB review of clinical registries to be used in lieu of, rather than in addition to, full independent review by each local IRB. Such efforts should address the inefficiencies that occur today in practice because local IRBs often remain hesitant under the current regulations to adopt the findings of other IRBs without conducting a full independent review. Options to explore include (1) national IRB reciprocity for common registry projects (ie, 1 institution conducts full board review, with expedited review by IRBs at collaborating sites) and (2) regional “umbrella” IRBs that could be established for large common registries that involve a state or region.
4. Policy makers should implement a national personal identifier. To maintain confidentiality, this unique patient identifier could be created via a 1-way hash function that uses pieces of information entered at each encounter (birth date, sex, first name, mother’s maiden name) to create a unique identifier remote from this information. The personal information entered and used to create the patient identifier at each visit should not be stored.

Securing Adequate Funding and Developing Business Models to Initiate and Sustain Clinical Registries

1. Governmental entities and private payers should financially support clinical registries as a means to promote efficient and high-quality care. Savings that result from the avoidance of independent data collection for pay-for-performance systems can offset the costs of supporting registries. As the payers for healthcare services, these stakeholders share directly in the financial and societal benefits that arise from clinical registries.
2. Device and pharmaceutical companies should leverage clinical registry data to support postmarket evaluation of products’ effectiveness, safety, and cost-effectiveness for the regulatory approval process.
3. Clinical registries should be designed and executed by independent entities, with full transparency of the funding and support of clinical registries.
4. To minimize costs and use resources efficiently, data collection for clinical registries should be limited to only essential items needed to fulfill the purpose of the registry. Whenever possible, data entry should arise as a “by-product” of the process of providing clinical care, ideally through the careful construction of data elements within EHRs.
5. Grant support to leverage clinical registries as the infrastructure for comparative effectiveness research should be pursued.

Clinical registries hold great promise to address many of the challenges facing the US healthcare system. To promote the best interests of patients and guide effective policy decisions, a number of areas require significant focus, including the pursuit of practices that help ensure high-quality data and transparency regarding the strengths and weaknesses of the data generated by individual registries. Tremendous opportunities will result from the integration of clinical registries with EHR systems and the linking of clinical registries with administrative databases and other clinical registries. However, significant challenges remain regarding how to ensure that adequate funding is provided for the development and ongoing implementation of such registries. Policy makers must act quickly to update the rules governing privacy to promote meaningful protections for patients without creating unnecessary burdens on the development of clinical registries. The AHA provides the recommendations described above with the goal of helping to address these issues as a means toward improving quality of care and patient outcomes.

Appendix

A guidance document on registries published by the Agency for Healthcare Research and Quality in 2010, *Registries for Evaluating Patient Outcomes: A User’s Guide,* provides a discussion and tabular listing of best practices for clinical registries. The reader may find the following tables from this document particularly interesting:

- Table 2: Overview of Registry Purposes (page 54)
- Table 20: Research Quality—Basic Elements of Good Practice for Establishing and Operating Registries (pages 310 and 311)
- Table 21: Research Quality—Potential Enhancements to Good Practice for Establishing and Operating Registries (pages 311 and 312)
- Table 22: Evidence Quality—Indicators of Good Evidence Quality for Registries (page 313)
- Table 23: Evidence Quality—Indicators of Enhanced Good Evidence Quality for Registries (page 314)

These tables are available online at http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=531 (accessed September 27, 2010).

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