

HOW REGISTRIES CAN HELP PERFORMANCE MEASUREMENT IMPROVE CARE



HIGH-VALUE
HEALTH CARE
PROJECT

An initiative of the Quality Alliance Steering Committee

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EXECUTIVE SUMMARY

Improving Care and Advancing Performance Measurement with Registries Data

The Institute of Medicine (IOM) has recommended creating a “Learning Health Care System” that would include the capacity for learning more quickly and effectively from the delivery of health care. An infrastructure capable of supporting rapid learning could meet critical needs for better evidence in, at a minimum, three areas: measuring the quality and cost of health care; comparative clinical effectiveness research; and medical product safety surveillance.

Patient registries — databases of clinical information critical to evaluating care processes and outcomes — can play a vital role in measuring quality and cost. However, as the role of registries is often limited by significant shortcomings in their current design and function, they must be adapted and expanded to meet changing needs.

Several challenges exist in leveraging registries to achieve better performance measurement. The time and expense of linking administrative and clinical data have been questioned because most currently endorsed measures that would use a new, hybrid database require elements from only one of the datasets. There is still a significant lack of measures that require both clinical and administrative data elements.

Several physician groups, integrated delivery systems, and health information exchanges have reported adopting or creating their own internal registries. National (external) registries may have limited use if they cannot interface with

administrative or medication data in the same way internal registries can. Furthermore, while external registries contain information that can lead to improved quality of care, they must be linked to claims data to achieve the breadth of information that internal registries can provide. Allowing this linkage can raise legal concerns related to patient privacy.

Additionally, using registries to advance performance measurement and ultimately improve care will involve finding solutions to what are currently common registry limitations. These include:

- Standardizing data elements and definitions across registries that address the same disease or treatment areas;
- Developing a uniform method of patient identity management;
- Helping registries actively interoperate with electronic health records systems;
- Standardizing methodologies for sampling, data quality assurance, and risk adjustment;
- Standardizing linkage methods;
- Ensuring high provider participation across these programs; and
- Guaranteeing that providers and data users are confident registries are sustainable.

This paper describes short-term solutions for leveraging both administrative and registry data to make additional performance results available, as well as longer-term solutions to further increase the utility of registries for performance measurement and other purposes. While these recommendations are based on experience with cardiovascular disease registries, they can be applied to other clinical areas and are also broadly relevant across the health care system.

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INTRODUCTION

The Institute of Medicine (IOM) has recommended creating a “Learning Health Care System” that would include the capacity for learning more quickly and effectively from the delivery of health care. An infrastructure capable of supporting rapid learning could meet critical needs for better evidence in, at a minimum, three areas: measuring the quality and cost of health care; comparative clinical effectiveness research; and medical product safety surveillance.

In this paper, we focus on the first of those three areas. We examine the critical role that patient registries — databases of clinical and other information, such as patient racial and ethnic identifiers that are critical to evaluating care processes and outcomes — can play in

measuring quality and cost. We find that the role of registries is often limited by significant shortcomings in their current design and function, and they must be adapted and expanded to meet changing needs.

The increasing use of national registry data for provider reimbursement and public reporting will inevitably lead to discussions about their ownership and control. While it is important to determine the direction of data repositories that traditionally have been under the exclusive control of professional organizations, this paper does not take up the broader issue of the role of stakeholders — such as health plans, public and private health care purchasers, and consumers. This issue will arise in the future, however, as the demand increases for the public benefits that registry data provide.

GETTING TO A HIGH-VALUE HEALTH CARE SYSTEM

The High-Value Health Care (HVHC) Project is working to make valid, timely, and consistent information about the quality and cost of health care widely available in the United States. As part of this effort, the Engelberg Center is developing strategies for combining clinical information with administrative data to provide more valid and comprehensive measures of the quality of care. The objectives for these new measures, which would address both internal and external uses of information, include:

- Enhancing the availability and use of performance measures for quality improvement programs, resulting in higher-quality care;
- Fostering development of performance-based financing for individual providers and institutions, providing financial incentives to encourage the best possible care; and
- Improving public transparency about the health care system, not only to allow patients to make better informed decisions about choice of providers or therapies, but also to result in more informed actions by policymakers and regulatory bodies.

HVHC is an initiative of the Quality Alliance Steering Committee (QASC), a collaborative effort aimed at implementing measures to improve the quality and efficiency of health care across the United States. The QASC is comprised of existing and emerging sector-specific quality alliances, as well as leaders among physicians, nurses, hospitals, health insurers, consumers, accrediting agencies and the public sector. Together, these stakeholders are working to ensure that quality measures are constructed and reported in a clear, consistent, and person-focused way to inform consumer and employer decision-making, as well as the efforts of practitioners to improve care that is delivered. QASC will also help coordinate and build the initial components of an infrastructure to collect health care quality and cost data nationwide.

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Clinical data allow precise characterization of a patient's condition and the ability to group patients by the severity of their disease, but these data are not easily accessible and often are too narrowly focused on one disease or procedure to allow for comprehensive, patient-centered performance measurement. While administrative data, usually from insurance claims, are more comprehensive and follow patients over time across care settings and different medical providers, such data lack clinical details like patient risk factors, disease severity, or clinical outcomes. Combining administrative and clinical data allows for more sophisticated and comprehensive performance measurement.

In order to make effective use of both administrative data sources, such as insurance claims, and clinical data housed in registries, the Engelberg Center is piloting feasible short-term approaches for leveraging both data sources to make additional performance results available. In addition, we have identified longer-term solutions to further increase the utility of registries for performance measurement and other purposes. While the recommendations in this paper are based on our experience with cardiovascular disease registries, they can be applied to other clinical areas and are also broadly relevant across the health care system. Additionally, this paper provides the Quality Alliance Steering Committee with recommendations regarding how registries can play an important role in performance measurement and in the evolving national health information technology (IT) infrastructure.

Identifying Short- and Long-Term Solutions

Linking clinical data from registries with claims data can support better coordinated, more patient-centric care, as well as better performance measurement in the short term. This strategy requires the periodic creation of a linked dataset. Since claims and clinical registry data usually do not contain a common,

unique identifier, patients in the two data sets have to be matched based on the probability that the patient identified in a given registry record represents the same patient in a claims database record. One must judge, for example, whether the patient identified in the registry by name, date of birth, medical facility, etc. is the same patient reflected in the claims database with the same or similar name, date of birth, etc. As the accuracy and reliability of data linkage methodologies have improved over time, this short-term strategy of data linkage is increasingly appealing as a support for quality improvement efforts and performance measurement.

The Engelberg Center has been engaged in a series of “proof of concept” activities in the area of data linkage, or integration, and its role in supporting quality improvement and producing more valid and comprehensive performance measures. Activities have included soliciting input from key stakeholders regarding a number of key issues: how useful the measures derived from linked data can be, how feasible it is for others to replicate the data linkage, and whether there is a business case to support the continued financing of this approach.

Based on the content of those discussions and the Engelberg Center's work with cardiovascular disease registry owners, we make recommendations in each of the following areas:

- The lack of nationally-endorsed performance measures that take full advantage of linked administrative/clinical data;
- Growing challenges to participation in specialty society-based national registry programs from provider-based “home-grown” registries;
- Impediments to data linkage posed by differing interpretations of the Health Insurance Portability and Accountability Act (HIPAA); and
- Use of registries to assess racial and ethnic disparities in access to and quality of care.

The paper concludes by addressing challenges and opportunities for long-term efforts to create ideal registries that also meet evolving performance measurement needs. While current options are limited to probabilistic matching of large databases, more long-term strategies will be available in the future to accomplish the same objectives of quality improvement and performance measurement through the integration of clinical and administrative data. One such cost-effective solution will be real-time data acquisition from the patient encounter. For example, when a patient receives treatment, various combinations of administrative and clinical data elements would be transmitted concurrently to payers, registries, and other authorized repositories as appropriate. This strategy supplies information to a registry in a manner timely enough to support and improve patient care — through decision support tools, improved care coordination, etc. It also allows all data elements to be used in determining the numerators and denominators for quality measures, while still residing behind the firewalls of data repositories — such as the claims databases of health insurance plans. This solution helps to eliminate HIPAA-related issues regarding patient privacy, as well as problems in linking patient records through probabilistic linkage.

As we look toward a future in which electronic health records (EHR) are ubiquitous, registries will continue to play a critical role, as performance measurement often will require organizing particular data elements from the vast amount of information contained in an EHR system.

WHAT ARE REGISTRIES?

The Agency for Healthcare Research and Quality's (AHRQ) handbook, "Registries for Evaluating Patient Outcomes: A User's Guide," defines patient registries as a collection of uniform data (clinical and other) used to evaluate outcomes in specific populations for scientific, clinical or policy purposes.¹

Registries collect data on populations defined by clinical conditions or diseases, procedures or treatment, or resource use. For example, the Society of Thoracic Surgeons (STS) National Database collects data on patients who undergo all forms of thoracic surgery, including coronary artery bypass graft (CABG) surgery. In addition, registries can support a number of important functions at the individual patient, care team, and organization levels, including:

- Collecting and storing data on a patient's diagnosis and treatment that can be analyzed and referred to as needed;
- Generating outputs that facilitate care delivery and coordination at the individual patient level, such as decision support, patient reports, reminders, notifications, lists for proactive care, and educational content;
- Providing tools to assist with population management, quality improvement, and quality reporting – for example, risk adjustment, trend analysis, population views, benchmarks, and quality report transmissions; and
- Supporting essential research applications such as comparative effectiveness studies.

Current Registries Vary Significantly

Not all of these functions are currently performed by all registries, and some could be performed through other data sources, such as EHRs, that may eventually become the primary source of data for registry functions. This variation is driven by several factors, including technical

limitations. All registries collect and clean data to some extent, and many provide population-based reports to their participants, although this practice can vary significantly.

A major area of differentiation is the degree to which registries provide care delivery and coordination functions at the individual patient level. Not surprisingly, an important determinant of whether patient care/coordination functions will be implemented is where in the patient-clinician workflow the data are actually collected, analyzed, and reported. To be useful for individual care purposes, registries need to have data available for processing and a means to deliver information to the provider team close in time to the care episode. For example, the American Heart Association's (AHA) Get With The Guidelines program, the American College of Cardiology's (ACC) CathPCI registry, and the STS CABG database provide quality measurement and improvement tools to participants. However, because data are collected through third-party systems that periodically upload data to a central repository, these registries do not provide the same patient-specific information at the point of care – unless the third party system chooses to implement algorithms based on the data collected.

Registries are not only a mechanism to collect quality and performance data, but in several cases they are associated with progressive performance improvement by their participants. Of particular interest are those registries that use reporting and other tools for rapid cycle quality improvement. In a randomized study of "low-intensity" continuous quality improvement interventions conducted within the 359 institutions in the STS database network, Ferguson et al. demonstrated a significant difference in improvement for sites receiving additional continuous quality improvement support including reporting.²

Several large, national studies^{3,4,5} have demonstrated how providers have significantly impacted their performance through

participation in a national registry. In a head-to-head study that used hospital data from Hospital Compare, an online database created by the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS), 223 hospitals using the AHA Get With The Guidelines (GWTG)-Coronary Artery Disease (CAD) registry fared significantly better in measures of guideline compliance than 3,407 non-GWTG-CAD hospitals.⁶ The availability of both guidelines information and real-time data for rapid cycle quality improvement through the

registry itself was thought to be an important reason for the difference in results.

Registries in cardiovascular disease originate from a number of different sources, including professional societies, national voluntary health agencies, hybrid payer/provider entities, integrated delivery systems, regions/communities, and government entities. Some coordination of registry development occurs across several organizations — such as harmonizing definitions between ACC and STS registries — although these efforts remain limited.

Learning from Experience

Piloting efforts to link registry and claims data to calculate performance measures

The Engelberg Center has been piloting a short-term strategy for better performance measurement. This effort has involved linking clinical data from registries with claims data to create a hybrid database that can be used to calculate more valid and comprehensive measures of the quality and cost of medical care. The projects use claims data to look forward and backward in time from a particular cardiovascular procedure. This approach provides useful information for improving quality and care coordination by allowing us to understand long-term outcomes more broadly and essential components of care in greater depth. Also, both projects support longer-term goals of improving the specificity and clinical relevance of the measures to be included in quality reports.

Two examples of Engelberg Center projects are:

- With the American College of Cardiology (ACC) and UnitedHealthcare, linking the ACC's catheterization/percutaneous coronary intervention (cath/PCI) registry with UnitedHealthcare claims. This project applies quality measures to linked data to assess care that occurs after the patient's catheterization. For example, to determine: Did the patient need a transfusion before discharge? Did the patient need a non-invasive stress test within six months after PCI?
- With the Society of Thoracic Surgeons (STS) and WellPoint, linking the STS coronary artery bypass graft registry with WellPoint claims to assess care after open-heart surgery. For example, to determine: Had the patient suffered a prior heart attack while on beta-blocker medication? Did the patient remain on lipid-lowering drugs for six months after surgery?

HOW CAN REGISTRIES IMPROVE IN THE SHORT TERM?

Linking Registries with Administrative Claims for Better Performance Measurement: Current Impediments and Recommendations to Overcome Them

Data integration involves linking clinical data from sources like registries (information that is clinically detailed but limited in both time period and scope) with administrative data such as insurance claims, which include entire periods of coverage for the insured across different providers and care settings but contain limited clinical detail. The Engelberg Center's recent experiences with a short-term strategy for better performance measurement highlight several challenges in pursuing this approach. These are described below, along with recommended solutions for registry owners, policymakers, and others.

1. Lack of Nationally-Endorsed Measures for Linked Registry and Claims Data

The time and expense of linking administrative and clinical data for more valid and comprehensive performance measurement has been questioned because most currently endorsed measures that would use a new, hybrid database require elements from only one of the datasets. Although more than 70 “clinically-enriched” measures have been endorsed or are pending endorsement by the National Quality Forum, there is still a significant lack of measures that require both clinical and administrative data elements. In large part this is because technical challenges — including coding systems, data submission practices and patient and provider identifiers — hinder more rapid development and implementation of such measures. It will be important to address such issues in order for data linkage to find a sustainable business case; also necessary will be more nationally-endorsed measures that require linked data and prove useful to providers, patients, health plans, and purchasers.

Current quality and cost measures for cardiovascular care are often derived from only one source of readily available data and usually focus on the technical process of care. These measures, based on insurance claims, address the issue of whether or not the appropriate procedures were followed for certain patients. However, the simplicity of the data source can often lead to a measure that lacks the precision necessary for further analysis and interpretation.

Interviews conducted in early 2009 with key quality leaders and clinical experts in cardiovascular care consistently found that patient care after an inpatient stay is poorly measured. While follow-up care and care coordination for up to 90 days post-discharge are key to overall care quality, these components of the care process are reflected in very few existing measures.

Respondents also observed that existing measures do not support the goal of a more patient-centered care system. Very few measures directly address issues most important to patients — including access, outcomes, and quality of life or health status. In addition, they raised questions regarding both patient and clinician confidence in the measures themselves. General unease regarding sources of the measures and also about the proprietary nature or transparency of some measures presents a significant challenge to the development of more meaningful, consumer-friendly performance information.

Current data also do not adequately support robust cost-of-care measurement for a number of reasons:

- Current cost-of-care measures, typically based on claims data, may be subject to the common limitations of claims data with respect to accuracy and completeness — exclusion of out-of-pocket expenses, services provided under benefit “carve-outs”, etc.
- Ideal cost-of-care measures would identify clinically homogeneous patient cohorts and measure the costs of care associated with

treating those patients. Administrative data alone cannot identify clinically homogenous patient populations for certain conditions because of their inability to measure underlying clinical variability among patients. For example, among patients diagnosed with breast cancer, clinical stage information is critical for cohort identification since costs of care can vary significantly from Stage I patients to Stage II, III, or IV patients. Or, in the case of patients with acute myocardial infarction (AMI), administrative data cannot distinguish the ST segment elevation myocardial infarction (STEMI) patients requiring a specific type of intervention from non-STEMI events. This is very important in predicting the costs associated with a patient's care.

- Most cost-of-care measures rely on a risk adjustment model to account for the effect a patient's co-morbid conditions have on the costs of care for the condition of interest. For example, to measure the costs of care associated with treating a patient's coronary artery disease, risk adjustment would typically account for whether or not a patient also has congestive heart failure (CHF), which can be indicated by the presence of CHF diagnosis codes in claims data. However, many risk adjustment models could be improved by accounting for the severity of these co-morbid conditions. For example, the seriousness of the patient's co-morbid CHF could be gauged using other clinical information like the patient's left ventricular ejection fraction. The availability of this kind of information about a wide range of clinical conditions could make the measure's risk adjustment model significantly more accurate than using claims data alone.
- Some cost-of-care measures are calculated on a per-capita basis (all costs for care over a time period, typically one year) while other cost-of-care measures consider only condition-related resource use. While attributing cost to an individual illness is

challenging for any patient with multiple conditions, the lack of clinical information in claims makes it particularly difficult to determine whether a treatment was more directly related to the condition of interest or to another of the patient's co-morbid conditions. For example, whether lipid-lowering medications are related to diabetes or to hypertension in a patient with both conditions.

A hybrid database that includes both claims and clinical data would provide distinct advantages by addressing the shortcomings of using either type of data alone:

- **Improve Precision.** Linked data could be used to broaden, narrow, or subdivide the measured population to make the target population more homogeneous or to determine with certainty whether a particular procedure or therapy is relevant to a given measure. In the context of appropriateness-of-care measures, linked data can better identify patients for whom a particular elective procedure may not have been advised appropriately or other patients for whom a particular procedure should have been advised. Clinical registry data could be used in conjunction with claims to more effectively risk-adjust measures and address a principal objection among physicians who say that measures of cost and efficiency do not effectively account for variation in patient morbidity or relative risk. Claims have the advantage of including services delivered across many different care settings and allowing us to look forward and backward in time from a registry-based procedure.
- **Facilitate Quality Improvement Efforts.** Performance measures built on linked data would permit adjustments for patient treatment adherence and provide the comprehensive data necessary to provide actionable steps for improving quality. Those measures and the data systems to report them could be leveraged secondarily

— not only to reform incentives inherent in current provider reimbursement systems, but also to align them more closely with the goals of providing higher-quality care. Such examples could be through pay-for-performance arrangements or the formation of accountable care organizations.

- **Support Patient-Centered Care.** Integrating administrative and clinical registry data would permit development of measures of utilization and variation in resource use as well as measures of outcomes and provider performance. These measures would take into account information going both downstream (follow-up procedures and evaluations) and upstream (pre-procedure diagnostics) in order to provide a more complete picture of care at the patient level.

Recommendations: Nationally-Endorsed Measures

1. Measure developers and the National Quality Forum (NQF) should focus on and receive more support for the identification and endorsement of performance measures relying on combined sources (e.g, clinical registry data combined with physician, hospital, and pharmacy claims, laboratory data, etc.).
2. AHRQ and/or CMS should establish funding mechanisms for measure development using hybrid (linked) databases.
3. Existing national registry programs should develop flexible data infrastructures to prepare them to accommodate — in a cost-effective, provider-friendly and real-time environment — data inputs from multiple sources that may be required for the next generation of performance measures.

2. “Home-Grown” Registries and National Registry Programs

A number of physician groups, integrated delivery systems (IDS), and health information

exchanges (HIE) have reported adopting or creating registries for chronic diseases including coronary artery disease. Some of the larger IDS and physician groups report developing registries that interface with their practice management systems, EHR systems, and network labs. Others have worked with commercial vendors to specify and purchase registry “add-ons” that interface with a multitude of data sources.

For providers, these registries support clinical practice by collecting, aggregating, and integrating clinical, administrative, and patient demographic data. Depending on the provider organization, these processes support reporting that can be used in patient management, quality improvement, and/or performance assessments. Aggregated data in registries have been used to identify patients who are non-adherent to evidence-based disease management protocols. Examples include patients whose lab values are in poor control, who are missing lab results, or who have not been seen during recommended follow-up intervals.

A provider can also access a registry to review patients’ records, including individual patient and lab values. Registries can be used to generate monthly reports to give feedback to both providers and patients, and the information would be used to provide targeted intervention to patients — such as recruiting high-risk patients for more aggressive disease management programs.

These registries also provide an array of functions to support payers’ need for timely information. For payers, registries may be used as a tool to generate automatic reports of provider performance. The reports, which can provide a snapshot of and serve as the basis for determining incentive payments, are more accurate and comprehensive when the registries are populated with both clinical and claims data.

Kaiser Permanente (KP) is one organization that uses both external registries and their own internal, “home-grown” systems. Because

of KP's robust EHR system, internal registries provide more timely information, making it more actionable for internal applications such as planning, business decision-making, developing risk calculators for physician decision support tools, and tracking patients for "care gaps." Physicians can receive instant feedback and have immediate access to data for research, and as a result are more willing to support and participate in the registries. KP leaders feel that this sort of immediate feedback is key to garnering physician support and changing physician behavior.

KP also participates in some overlapping external registries (for the same conditions), primarily to provide the organization with benchmarking data. Furthermore, these external registries may be able to support the organization in other ways such as submitting data to the CMS Physician Quality Reporting Initiative (PQRI), Bridges to Excellence, and other payer-sponsored incentive programs. For organizations such as KP, external registries may have limited use if they cannot interface with KP administrative or medication data in the same way internal registries can.

In addition, the nature of KP's integrated system and registries allows internal users to look at long-term outcomes for some patients. For example, researchers can view data on heart disease patients who received medical treatment, then catheterization and stent placement, and finally a CABG procedure. This is currently not possible with external registries, not only because of the separation of care components in different registries, but also sometimes due to different standards for coding, definitions, or data submission.

Recommendations: "Home-Grown" Registries

1. National registry owners should engage provider organizations that are developing their own internal registries to better understand the evolving needs — such as functionalities and ease of use as part of routine care — that are the impetus for registry development.

- a. National registries should re-orient data output and input systems to facilitate the more transactional or on-demand functionalities providers are seeking, as well as develop longer-term monitoring functions for quality improvement and outcomes measurement.
 - b. Among the functionalities national registries should seek to integrate into their data reporting outputs are decision-support, links to practice management systems, and public reporting.
2. Over time, if the growth of internal registries for on-demand functions increases, national registry programs might re-evaluate their futures in the clinical world. For example, their niche could be providing national benchmarks, standards, and best practices for registries rather than more detailed QI information; diffusing evidence-based practice guidelines; and supporting registry programs for relatively low-volume services that make sense only when aggregated nationally.

3. Effects of the HIPAA Privacy Rule

While clinical registries contain information that can lead to improved quality of care, allowing access to this information can raise legal concerns related to patient privacy. Privacy regulations under HIPAA, or the Privacy Rule,⁷ govern how health plans and other entities⁸ may use and disclose protected health information (PHI).

The Privacy Rule requires that PHI not be used or disclosed without an individual's authorization, unless that use or disclosure is specifically permitted under the rule. Health plans that disclose PHI to "business associates" — for example, to a claims processing service or data analysis company — must have a written agreement with that associate containing a

number of specific provisions for safeguarding the information. Specific restrictions are often placed on the organizations both giving and receiving the information. Safeguarding PHI requires understanding these restrictions, which may or may not allow the linkage of PHI to claims data for quality improvement activities.

In the Privacy Rule, a distinction also is drawn between use of PHI to improve a health plan or provider's own health care operations — this is allowed as long as proper safeguards are taken — and using it for broader research purposes, such as studying quality improvement initiatives for the industry at large. Although the Privacy Rule defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge,”⁹ the line between quality improvement and research can sometimes be hard to determine. However, it is an important distinction, because in many cases explicit permission must be obtained from patients to use their information for research, and there is currently no uniform mechanism for this.

While there may be policy implications that argue for allowing for quality improvement-related research to be done through a broader approval process under the Privacy Rule, the entity responsible for enforcing the Privacy Rule — the HHS Office for Civil Rights (OCR) — has not provided such leeway at this point. This lack of clarity may discourage providers from disclosing PHI to registries.

Currently, the Privacy Rule provides for a number of ways by which a registry can use or disclose PHI for research in addition to obtaining individual patient consent. These include the following:

- **De-identified Information.** One approach, and the most conservative, is for the registry to de-identify the PHI before using or disclosing the information for research purposes. Once de-identified, the information, by definition, is no longer PHI, and no longer subject to the Privacy Rule.

- **Limited Data Set.** A health plan can use or disclose a limited data set for research purposes. Therefore, some entities maintaining clinical registries enter into a specific data use agreement with the health plan, in addition to the basic business associate agreement, permitting use or disclosure of the information for research purposes. Provided that the registry complies with the data use agreement, this approach likely complies with the Privacy Rule and does not violate the terms of the agreements between the parties.
- **IRB Waiver of Authorization.** A health plan is permitted to use or disclose PHI for research purposes if it obtains appropriate documentation of an institutional review board's waiver of the authorization requirement. The Privacy Rule does not contain a specific provision to allow a business associate to use or disclose PHI for research purposes with an IRB waiver of authorization. Permitting the IRB waiver to include business associates — a decision also under the purview of OCR — could result in a compliant approach that does not entail removing certain identifiers to create a limited data set or de-identifying data, a task that can be extraordinarily time consuming and costly.

There is some debate about whether or how the Privacy Rule allows PHI to be linked to claims data in order to further analyze the data. If the purpose of such a linkage is to obtain knowledge that can be generalized, the use or disclosure likely would be considered research under the Privacy Rule. Still, it is less clear whether the information would also be useful in promoting quality of care for the patients involved themselves.

Lack of clarity around the permissibility of linking clinical registry data with claims data using probabilistic matching has resulted in a number of varying interpretations of the Privacy Rule, as follows:

- Data linkage is not permitted, even if using a limited data set and creating a data use agreement, because the probabilistic matching re-identifies the limited data set. As a result, the use and disclosure actually involves PHI and thus, violates the data use agreement.
- Provided that the data linkage involves only the use or disclosure of a limited data set, that use or disclosure is consistent with the data use agreement. (Proponents of this position recognize that it walks a fine line because of the potential for the probabilistic matching to re-identify the information, depending on the contents of the limited data set.)
- Linking PHI with claims is acceptable with an IRB waiver of authorization that permits research, provided that the PHI is not merged to create a separate database.

The need to obtain institutional review board (IRB) approval and/or patient consent can often stop data linkage initiatives before they begin. While many registries may be exempt from IRB review under the Common Rule, this is not universally true, and different institutions may interpret the rules differently. A recent IOM report recommended clarifications in both HIPAA and IRB issues related to research and registries, as well as significant HIPAA modifications to better support a learning healthcare environment.¹⁰

Recommendations: HIPAA

1. The federal government should pursue a policy of public education regarding what is and is not acceptable under HIPAA. This should include clearer guidance from OCR on when it is permissible under the Privacy Rule to link clinical registries with claims data and/or any business associate or data use agreements between the parties — such as for comparative effectiveness research or in the release of summary information like quality measure numerators and denominators.

2. End users of linked datasets should collaborate in development of a number of important and illustrative “straw-man” scenarios, designed to be representative of questions commonly asked by the end users’ legal counsels, which could be submitted to OCR. The agency could then publicly respond to these in an effort to provide guidance as to whether or not particular situations violate HIPAA.
3. Depending on the interpretations of the law offered by OCR, Congress should act to revise HIPAA in such a way that it permits the linking of datasets as part of research activities designed to support quality improvement, provided reasonable precautions are taken to ensure patient privacy is preserved.

4. Addressing Disparities: Collecting Race, Ethnicity, and Language Data

Disparities in quality of care based on race or ethnicity are well documented. For example, African-American men are 73 percent less likely than white men to receive an implantable cardioverter-defibrillator, a life-saving technology for those with the highest risk for sudden cardiac death.¹¹ African Americans are also less likely to use revascularization procedures and even when clinically indicated, they are more likely not to receive the procedure.¹²

Health care disparities have been found in other minority populations as well. The 2009 National Health Disparities Report found that the proportion of hospital patients with heart failure who received the recommended hospital care was lower for Hispanics and American Indians/Alaskan Natives than for whites.¹³

In order to more fully document, assess, and improve disparities in care, the IOM has called for increased efforts among health care organizations to acquire and report race and ethnicity data. Currently, 22 states require that hospitals report race and ethnicity data.¹⁴ But

unlike state requirements for hospitals, only two states, California and Massachusetts, passed legislation requiring health plans to collect and/or report such data.^{15,16} Hospitals and community health centers have had higher response rates, but health plans have been limited in their ability to acquire directly-collected race and ethnicity identifiers from members. In addition, even when such data are acquired they are often stored in warehouses that are incompatible with data sources containing performance information. Also, stratifying administrative data by race, ethnicity or language categories further limits the analyses that can be conducted, since the sample sizes in each category become too small to allow for appropriate comparisons and statistical power. These limitations make identifying disparities and determining strategies to reduce them extremely challenging.

The use of registry data can help address health care disparities in a number of ways, including:

- Using registries as a clinically rich source of standardized data across geographically diverse service-provider settings. One major challenge to understanding health care disparities over geographically diverse populations is an inability to compare patients of varying racial and ethnic backgrounds because data are collected in a multitude of ways and with differing categories. Registries may be one way to acquire standardized race/ethnicity data from patients, which can be compared across geographic locations.
- Integrating indirectly estimated and directly collected race/ethnicity data to assess population-level health care equity. The Engelberg Center and The RAND Corporation have engaged a multi-state pilot to evaluate the feasibility of health plans using RAND's indirect estimation algorithm to determine race/ethnicity composition among members where directly collected data are unavailable. This pilot also will evaluate the feasibility of integrating directly collected and indirectly

estimated data to assess population-level disparities.

- Using race/ethnicity data to improve equitable cardiac care. Perhaps the greatest contribution registries will have in the effort to eliminate health care disparities is in their ability to proactively engage patients in their own care with decision support tools and educational materials. Further, patient reports and other tools offered to providers — and perhaps to payers — that highlight areas of disparities will be essential in advancing culturally appropriate care for all patients.

Recommendations: Addressing Disparities

1. Users of registry data should leverage non-clinical data elements, such as race, ethnicity, and language (REL) data, to further inform quality improvement and research activities, such as reduction of care disparities.
2. The IOM recently developed recommendations for advancing standard race/ethnicity categories across health care sectors. Such standardization is imperative to the development of comparable disparity information from variable data sources.
3. To the extent a registry's REL data are limited or the registry does not have such data elements, efforts should be made to link the registry's data to REL data from one or more other sources. The registry also should encourage participating providers to submit this information directly in the future.
4. Earlier, we recommended that registries should increase and augment their current functionalities to be more appealing to providers and provider groups going forward. Registries also should ensure these additional functionalities can be used to support aspects of the care process that can address disparities, including cultural competency support for providers and a variety of languages in patient support decision tools.

LONG-TERM STRATEGIES: WHAT MAKES AN “IDEAL” REGISTRY?

Long-term strategies to support patient care and performance measurement — whether real-time clinical data acquisition from the point-of-care or queries made through EHR systems — will eliminate the need for large-scale data linkage projects, but not for the clinical data that reside in registries. Even when linkage to registries is no longer an issue, registry owners and users will face general challenges in making these sources of clinical data more useful. If we create a new registry today taking into account current and future needs, how should it be designed in the context of the “ideal” registry for the future?

Regarding the recently released interim final rule for meaningful use of EHR technology by the HHS Office of the National Coordinator (ONC), the functionalities of an ideal registry can further enhance or supplement EHR systems, and therefore help eligible providers and facilities meet such requirements. For example, the meaningful use incentive program requires reporting of performance metrics and other structural indicators to illustrate “meaningful use” of health information technology to improve care coordination and improve population health. The ability to aggregate data from multiple data sources in a registry, such as EHRs, that can be queried by chronic disease population, by provider, and by patient affords the user an enhanced functional capacity to sufficiently address meaningful use priority areas. For additional details on how an ideal registry supports priority areas of meaningful use, see Appendix 1.

Few registries today have all of the characteristics of an ideal registry. A review of cardiovascular registries, for example, identifies many strengths and limitations. Some registries collect highly uniform data that can be used for risk adjustment, but have limited follow-up for long-term outcomes. Many are used in hospitals with EHR systems, but are generally

Features of an Ideal Registry

The ideal registry can facilitate the exchange and use of health information for direct patient care and performance measurement and reporting. It collects uniform data on risk factors, treatments, and outcomes at key points for a particular disease or treatment. It obtains the data from multiple sources and across care settings. It leverages health information technology systems through interoperability, and other data sets through linkage.

The ideal registry uses standardized methods to assure that the patients sampled are representative of the care provided; that the data collected are of sufficiently high quality to be used for decision-making and payment; and, that the information collected is comparable across providers. Such a registry provides feedback at the patient and population levels, guides quality improvement, supports comparative effectiveness research, and can facilitate quality reporting to third parties. Importantly, an ideal registry will have a high level of participation by providers and patients and have a long-term, sustainable business model.

not interoperable with those systems on a real-time basis. Examples provided in Table 1 vary in levels of provider participation, use of nationally-standardized data sets, quality assurance methods, and many other ideal characteristics.

In addition, most registries have focused on high-volume, adult hospital admission diagnoses or procedures. With some important exceptions, registries do not typically collect information on less common diseases, or even common cardiovascular disease as managed by primary care clinicians. While some national organizations have launched or are planning to launch ambulatory-based registries — such as the ACC PINNACLE Program and AHA

Table 1. Examples of cardiovascular disease registries and their relative strengths and limitations

Sponsoring Organization	Clinical Condition	Registry Type	Example of Strength	Example of Limitation
Professional society (e.g. ACC, STS)	Acute Coronary Syndrome	Hospitalization	Collects uniform data	Limited patient follow-up
	Cardiovascular Surgery	Procedure & Hospitalization	Risk Adjusted	Administrative burden of collecting a large volume of data
Voluntary Membership Organization (e.g. AHA)	Stroke	Hospitalization	High participation	Not yet interoperable with EHR systems
Integrated delivery system (e.g. Maine Medical Center)	Heart disease and diabetes	Disease	Extensive care delivery and care coordination functionalities	Cannot provide external benchmarks
Individual hospital (St. Elizabeth's Hospital)	Heart Failure	Disease	Large percentage of patients enrolled	Non-standardized data collected
Regional/Community (Wisconsin)	Pediatric CV abnormalities	Disease	Data from doctors and patients Representative sampling	Limited quality assurance, low participation
Government agency (e.g. MA Dept. of Public Health)	Stroke	Hospitalization	Mandated participation	No risk adjustment

GWTG-Outpatient — few cardiovascular disease registries currently exist in the ambulatory area, and those that do have limited participation. Long-term follow-up is generally limited in many of the large, professional society-driven registries. However, there is growing experience with linking these registries to administrative datasets to obtain longer-term outcomes.^{17,18,19}

Building ideal registries will involve finding solutions to what are currently common limitations:

Data elements and definitions should be standardized across relevant conditions.

Current lack of standardization makes it difficult to link data or to compare results across registries. Developing common, core data standards that can be applied consistently is the clear solution. Although this is slowly occurring for some conditions, efforts could be significantly accelerated in cardiovascular disease if stakeholders moved more aggressively towards developing core datasets through multi-stakeholder consortia for each

condition. A major comparative effectiveness research (CER) initiative — the ACC and STS Collaboration on the Comparative Effectiveness of Revascularization Strategies (ASCERT), which looks at the comparative effectiveness of treatments for stable coronary artery disease — is moving forward even without current consensus on data strategies across registries, and will provide technical solutions to address a number of these registry data issues.

A uniform method of patient identity management is needed.

Since different care settings and different databases collect data on patients with their own identifiers, standardizing those identifiers is necessary to link data either longitudinally in the same database from different care settings or between databases. Currently there is no standard, accepted way for health care entities to securely and smoothly share a patient identifier or pseudonym between them, such as when a patient receives care at both a hospital and an independent physician office practice. Methods for secure patient identity management exist (e.g., PIX²⁰) but have not been widely tested or deployed across registries. Testing such methods in broader pilots could both standardize the methods and encourage implementation, thereby helping to bridge the critical divide in how data can be collected across care settings.

It may also be possible to link records without reliable unique identifiers — an important development since the nation is unlikely to get a single unique patient identifier in the near future. Some current technologies, such as “blindfolded” record linkage based on cryptologic techniques, show promise in enhancing the probability of successful record matches without compromising the privacy of patient demographic data.

Registries should be able to actively interoperate with EHR systems.

EHR usage is increasing due in part to the \$19 billion in incentive payments for adoption under

the American Recovery and Reinvestment Act of 2009 (ARRA). However, investment in health IT will not by itself create more willingness among providers to enter their information into more than one electronic system, such as both EHRs and registries. For this reason, a number of groups — including the Clinical Data Interchange Standards Consortium (CDISC), Integrating the Healthcare Enterprise (IHE), and the Healthcare Information and Management Systems Society (HIMSS) — are supporting the concept of functional interoperability between EHRs and registries. In particular, these groups are promoting a kind of interoperability that supports key functionalities typically offered by one system or the other and can be achieved in the near-term. Also, much more effective movement and communication of data between EHRs and registries could occur if existing open standards are broadly adopted. To date, these standards have been widely tested by many of the larger EHR system vendors²¹ and endorsed by the EHR vendors association,²² but have not been broadly adopted.

Part of the reason for this may be the lack of a clear business case to implement open standards for EHRs and facilitate their use. Furthermore, if these standards are not implemented with provider control of the configuration process — allowing them to choose which diagnosis codes trigger notification of a registry to appear in the system — it is unlikely that even deployment of the standards will result in widespread use, as customization by the EHR vendor would be required. Current discussions regarding definitions of “meaningful use” under ARRA provide a unique opportunity to directly influence adoption of open standards as part of the “certification” process, and to do so in a manner that allows simple configurations to be done by the provider. Pilot programs can further demonstrate how these standards can be easily implemented, as well as produce actual improvements in care based on data exchange.

Methodologies for sampling, data quality assurance, and risk adjustment should be standardized.

While many registries seek to collect data on all patients, it is unknown how many hospitals or practices comply with this requirement. Few perform audits of screening logs or provide sampling algorithms to assist high-volume centers in lowering the significant costs of data collection. With respect to data quality assurance, defined data elements and automated error checking are relatively standard, but beyond that, there is a tremendous range in procedures — from relatively expensive on-site data audits to monitoring to nothing at all. The impact of such variation is unknown, but it is difficult to compare or combine data sets or know the accuracy of the observations in a data set without standardization of methods. One potential solution is to seek a list of standard requirements for registries that will participate in performance measurement. This should be achieved through stakeholder and expert collaboratives. The goal of such meetings would be to define minimal quality assurance requirements for national performance measurement participation with an emphasis on practical, clinically important issues and feasibility — as detailed standards may not be needed for every lab test, but rather just the important ones for a particular disease. Once registries meet minimal standards, the bar can be raised periodically through similar meetings every few years.

Linkage methods should be standardized.

While linkage of data is now possible, the full value of data linkage will only be realized with adequate standardization. Standardization is necessary both so that registry developers know what elements to include in their data sets for future linkage and so that reasonably high matching levels are routinely achieved.

Several cardiovascular disease registries have been early adopters of probabilistic and deterministic methods to link their registry data to other data sources containing outcomes

information, such as Medicare and Medicaid. This has been particularly important since many of these registries are limited in their ability to collect long-term outcomes data.

Both statistical and legal issues are associated with such linkage efforts for performance measurement. First, statistical methods have advanced beyond the legal framework, creating uncertainty about whether the extensive linkage activities envisioned for performance measurement could create privacy law violations. Clarification of legal safe harbors is needed from HHS, specifically with respect to avoiding unintended re-identification of patients. Second, for linked outcomes to be used for performance measurement, the accuracy of the linkage needs to be sufficiently high to allow use of the information at the accountable care organization or provider level. This requires both standardization of matching approaches to improve accuracy and a clear understanding of the limitations of such approaches for linked data sets for the specific purpose of performance measurement. Seeking standardization of linkage approaches through pilots and expert reviews and obtaining clarification of privacy issues affected by such linkage from HHS would greatly facilitate these efforts — unless the linkages took place within a secure data system with only summary information reported out.

Provider participation should be consistently high across these programs.

Use of registries for performance measurement will be limited without high levels of participation by providers, since performance measurement is based on relative comparisons between providers or organizations rather than on absolute results. A provider's decision to participate in a particular registry is invariably based on an assessment that the burdens — in this case, the costs and efforts of data collection and submission — are less than the perceived benefits.

A review of existing registries emphasizes that, in many respects, registry participation is linked to economic importance. Participation is highest in registries where it is related to licensure or access to patients — for example, the Primary Stroke Service registry in Massachusetts that requires participation for ambulance diversion to the participating facility, or the ACC CathPCI registry that has mandated participation in several states including Massachusetts and Virginia. Mandates and patient access are closely followed in terms of their ability to encourage provider participation by qualification for payments, such as the ACC ICD Registry, which is part of the CMS Coverage with Evidence Development program. Intermediate in participation are those registries that offer recognition or certification, like the GWTG recognition awards that are published in U.S. News and World Report. Those registries whose sole reward is quality improvement can be highly successful, but participation in those programs is generally less than registries in the other categories. Finally, registries developed primarily for research or for the public good without economic rewards generally have low participation rates.

In addition, future registries will have to keep the cost of participation low by automatically providing registry functions automatically as part of providers' routine electronic clinical management systems. Registries that do not build such functionalities into these existing systems, thus avoiding extra work for the provider, will not be sustainable.

To overcome these issues, it will be important to identify and support initiatives that can make participation more automated from the provider's standpoint and also link participation both to sufficient economic incentives and to clinical benefits for the provider and patients. This will be particularly important among some provider communities when data housed in registries are used in preparing reports on quality and cost that become publicly available. Such reports should be as representative of the population being assessed as possible to enhance their validity.

Therefore, some additional incentives might be required to ensure high participation in registries that provide data for public reporting.

Providers and users of data should be confident that registries are sustainable.

Finally, in order to rely on registries for performance measurement, both providers and users of performance measurement data must have faith that the registries to which they submit data will be sustained over time. Current registry business models for operating registries vary. The registries discussed above are based on a number of models, including organizational investment, external or industry sponsorship, user fees, data sales, and combinations of different models. Many other registries rely on short-term funding sources such as grants. If operating costs were to increase significantly, such as if a registry were required to add new standard quality assurance practices, some registries might not be able to survive financially.

Potential solutions for this issue include advocating for models that provide sufficient incentives for participation so that high-quality registries with sustainable business models emerge. While this sounds difficult, one current example of a performance measurement program using registry reporting is the PQRI registry program. The emerging PQRI Registry Reporting model is highly inclusive, and any registry may self-nominate. It then must meet specified criteria for methodology, follow technical requirements for data transmission, and agree to potential audits. Through this inclusive model, CMS has accepted different measure sets for more than 70 registries in just two years, including ACC-NCDR, STS, and AHA GWTG.

The key advantage to this type of model for organizations that develop registries is that it will provide a new set of incentives for providers to participate in their registries. This sort of "automatic" reporting system — in contrast to the manual, claims-based alternative like PQRI — aligns the incentive of lower provider participation cost with support for a more

sustainable business model for registries. The system's timeliness and multiple functionalities also better support improvements in patient care using the information. Some might argue that it would be advantageous for a single specialty society, for example, to be the national provider of performance measurement data; however, that would likely be difficult to achieve and might even be undesirable. The model described here maintains the independence of the cardiovascular organization's registry goals and, to the extent that performance measurement data requirements diverge from the goals of the organization's registry or the interests of its participants, the registry can opt to be the data provider only for the measures of its choosing.

CONCLUSION

Registries can play an important role in better health care performance measurement. To achieve this, clinical data from registries must be integrated with claims data to create a hybrid database that can be used to improve care and, in turn, calculate more valid and comprehensive measures of the quality and cost of medical care.

However, while clinical data from registries are very detailed, they are usually focused on one event — a procedure or a hospital stay, for example — and don’t include information on what happened to the patient before or after that event. Claims data, on the other hand, include care delivered over time by many different providers in any setting, but do not contain the clinical detail needed to characterize the patient’s condition or to adequately assess their care. One could therefore describe registry data as “an inch wide and mile deep,” and claims data as “a mile wide and an inch deep.” Linking these data sources can overcome the shortcomings of each to produce information that is both comprehensive and clinically detailed.

Most of the registries discussed in this paper were created as feedback programs to serve retrospective quality improvement activities. For example, physicians or institutions voluntarily subscribe, and the registry programs provide both periodic analysis of subscriber results

plus benchmarking to peers elsewhere. Levels of participation among eligible physicians/institutions vary, as does the use of the data once they are analyzed and fed back to subscribers.

Currently, applications for registry data have expanded to include not only linkage to other databases, but also support a number of other applications, as outlined in Table 2.

In order to accommodate the needs of the data users who will define the changing landscape of applications for clinical registries, current registry owners should also pursue two overarching strategies:

- **Multi-stakeholder planning to take advantage of current and emerging opportunities.** Engage large provider groups that have developed their own registries in efforts to assess: 1) where existing national registry programs can provide services more rapidly in the care process to serve needs within these organizations; and, 2) where they can enhance complementary services that provider organizations cannot generate themselves, such as external benchmarking.
- **Break down the silos that prevent registries within the same clinical area from achieving their potential.** Accelerate efforts to “harmonize” registries within clinical areas, such as cardiovascular disease. For example, a heart disease patient being

Table 2. Expanded Use for Registry Data

Types of Applications	Examples
Support for care delivery	Appointment/reminder systems, EHRs
Data for reimbursement arrangements	Quality measures that trigger bonus payments
Clinical comparative effectiveness research	Linking registries to administrative data and to other registries across the continuum of care for a particular condition

medically managed who has a diagnostic catheterization, or stenting, and then a CABG would appear in three different registries — an AHA registry for medical management, ACC registry for catheterization/stenting, and STS registry for CABG. Although data definitions are becoming more standard, these registries do not “talk” to one another. This does not provide strong enough support for medical practice, nor does it promote a patient-centered “learning health care system” in which data better informs services provided to patients.

As a catalyst to support these strategies, federal payment policies can substantially accelerate the efforts of registry owners — if those policies align around paying for better-documented results for patients based on better-integrated data supporting patient care.

Indeed, patient registries hold enormous potential as powerful tools to help measure, manage, and improve care. For registries to fulfill their potential, stakeholders must work together to overcome the current limitations in function and flexibility. The strategies and recommendations outlined in this paper — and summarized in Appendices 2 and 3 — provide a starting point for the short- and long-term activities that can help create a system of registries that support both good health and good health care.

Appendix 1. Meaningful Use Activities

Health Policy Priorities (Meaningful Uses)					
Key Registry Functionalities for QI ²³	Improve quality, safety, efficiency, and reduce health disparities	Engage patients and families	Improve care coordination	Improve population and public health	Ensure adequate privacy and security protections for personal health information
Enroll representative patients, providers, settings	√	√	√	√	
Use standardized data elements and definitions	√		√	√	
Allow rapid changes to be made in response to changing knowledge					
Assure quality of procedures and data					
Have sufficient follow-up to obtain relevant outcomes			√		
Protect privacy and confidentiality					√
Integrate and leverage existing data systems to reduce burden			√		
Provide education/decision support where feasible	√				
Provide real-time or rapid feedback/reports (to improve care and care coordination), including nationally endorsed measures <ul style="list-style-type: none"> - Apply appropriate risk adjustment - Provide relevant benchmarks - Provide reports appropriate for different levels of users (e.g. doctor, hospital, health system) 	√		√	√	

APPENDIX 2

Short-Term Recommendations

	Issue	Recommendation
1	Implement Nationally-Endorsed Measures Based on Linked Administrative/Claims Data	<p>1. NQF should maintain a focus on the endorsement of performance measures relying in part on clinical registry data (in addition to physician, hospital and pharmacy claims, laboratory data, etc.) and should include among their measure evaluation criteria the assurance that the most appropriate data sources have been brought to bear in each measure’s calculation. For example, if a measure could be calculated more appropriately using linked data rather than administrative or clinical data alone, that should count against the measure in the endorsement process if its proposed source is either clinical or administrative data alone.</p> <p>2. The Agency for Healthcare Research and Quality (AHRQ) and/or CMS should establish funding mechanisms for measure development using hybrid (linked) databases; and</p> <p>3. Existing national registry programs should develop flexible data infrastructure to prepare them to accommodate the next generation of performance measures using data elements from multiple sources, particularly EMRs + claims.</p>
2	Deploy “Home-Grown” Registry Functionalities in National Registry Programs	<p>1. National registry owners should engage provider organizations that are developing their own internal registries, to better understand the evolving needs, with respect to functionalities and ease of use, that are the impetus for development of new registries internally.</p> <p>a. National registries should re-orient their data output systems to facilitate the more transactional or on-demand functionalities providers are seeking, as well as developing longer-term monitoring functions for quality improvement and outcomes measurement.</p> <p>b. Among the functionalities national registries should seek to integrate into their data reporting outputs are decision support, links to practice management systems, and public reporting.</p> <p>2. National registry programs should re-evaluate their futures in a clinical world where their niche might be providing national benchmarks (rather than more detailed QI information), diffusing evidence-based practice guidelines, and supporting registry programs for relatively low-volume services (e.g., pediatric neurosurgery) that make sense only when aggregated nationally.</p>

<p>3</p>	<p>Clarify Applications of the HIPAA Privacy Rule to Data Linkage Activities</p>	<p>1.The federal government should pursue a policy of public education regarding what is and is not acceptable under HIPAA.</p> <p>2. End users of linked datasets should collaborate in development of a number of important and illustrative “straw man” scenarios, designed to be representative of questions commonly asked by the end users’ legal counsels, which could be submitted to HHS-OCR. The agency could then publicly respond to these in an effort to provide guidance as to whether or not particular situations violate HIPAA.</p> <p>3. Depending on the interpretations of the law offered by HHS-OCR, Congress should act to revise HIPAA in such a way that it permits the linking of datasets as part of research activities designed to support quality improvement, provided reasonable precautions are taken to ensure patient privacy is preserved.</p>
<p>4</p>	<p>Leverage Race, Ethnicity, and Language Data Collected in Registries to Assess Disparities</p>	<p>1. Users of registry data should leverage non-clinical data elements, such as race, ethnicity, and language (REL) data, to further inform quality improvement and research activities, such as reduction of care disparities.</p> <p>2. The IOM recently developed recommendations for advancing standard race/ethnicity categories across health care sectors. Such standardization is imperative to the development of comparable disparity information from variable data sources.</p> <p>3. To the extent a registry’s REL data are limited or the registry does not have such data elements, efforts should be made to link the registry’s data to REL data from one or more other sources. The registry also should encourage participating providers to submit this information directly in the future.</p> <p>4. Registries should ensure that augmentations to their current functionalities can be used to address disparities, including cultural competency support for providers and a variety of languages in patient decision support tools.</p>

APPENDIX 3

Long-Term Recommendations

VISION: National registries contain consistent summary information derived from comprehensive electronic data to support patient care in near-real time.

	Issue	Recommendation
1	Standardize data elements and definitions across most conditions	Efforts to developing common, core datasets could be significantly accelerated through multi-stakeholder consortia for each cardiovascular condition.
2	Develop a uniform method of patient identity management	Since different care settings and different databases collect data on patients with their own identifiers, standardizing those identifiers is necessary to link data either longitudinally in the same database from different care settings or between databases.
3	Allow registries to actively interoperate with electronic health records systems	While it may be difficult or impossible to achieve full interoperability between EHRs and registries for many years, a concept of functional interoperability (what can be achieved today and is sufficient to get the job done) is emerging from groups like Clinical Data Interchange Standards Consortium (CDISC), Integrating the Healthcare Enterprise (IHE), and the Healthcare Information and Management Systems Society (HIMSS). Pilot programs can further demonstrate how these standards can be easily implemented.
4	Standardize current methodologies for data quality assurance, and risk adjustment	One potential solution is to seek a list of standard requirements for registries that will participate in performance measurement. This can be achieved through end-user, stakeholder, and expert collaboratives. Once registries meet minimal standards, the bar can be raised periodically through similar meetings every few years.

<p>5</p>	<p>Standardize linkage methods</p>	<p>This requires both standardization of matching approaches to improve accuracy and a clear understanding of the limitations of such approaches for linked data sets for the specific purpose of performance measurement. Seeking standardization of linkage approaches through pilots and expert reviews, and obtaining clarification of privacy issues affected by such linkage from HHS would greatly facilitate these efforts.</p>
<p>6</p>	<p>Encourage uniformly high participation by providers across registry programs</p>	<p>Identify and support initiatives that can link participation to sufficient economic incentives, as well as lowering the cost of participation. This will be particularly important when the clinical data in registries are used in preparing reports on quality, cost, etc. that become publicly available. Not only can public reporting be a disincentive for providers to participate in registries, but public reports should be as representative of the population being assessed as possible to enhance their validity. Therefore, some additional incentive might be required to ensure high participation in registries that provide data for public reporting.</p>
<p>7</p>	<p>Create sustainable business models for registry programs</p>	<p>Potential solutions include advocating for models that provide sufficient incentives for participation so that high-quality registries with sustainable business models emerge.</p>

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