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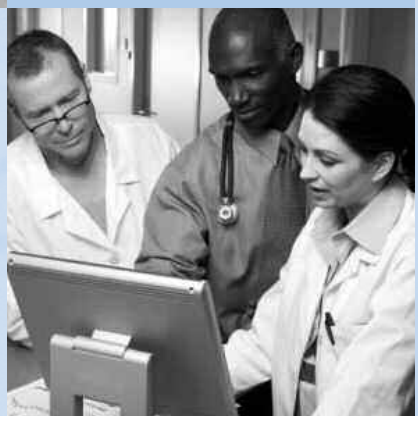
NATIONAL QUALITY FORUM

HEALTH INFORMATION TECHNOLOGY



Health Information Technology Automation of Quality Measurement: Quality Data Set and Data Flow

Foreword

THE LACK OF A SET OF PRECISELY DEFINED, universally adopted, electronic quality measures is an obstacle to automating measurement and comparing quality using electronic health information. The National Quality Forum (NQF) Health Information Technology Expert Panel (HITEP) initially was charged with prioritizing measures used for public reporting; identifying common data types from the subset of highest priority measures to be standardized for automation in electronic health records (EHRs) and health information exchanges; and developing an overarching quality measure development framework to facilitate developing, using, and reporting on quality measures from EHR systems. In its first report, *Recommended Common Data Types and Prioritized Performance Measures for Electronic Healthcare Information Systems,* the panel presented its key recommendations to help provide a common road map for addressing gaps and for moving forward. The first HITEP report led to new feasibility criteria for measure endorsement by NQF.

In this, its second report, *Health Information Technology Automation of Quality Measurement: Quality Data Set and Data Flow,* HITEP addresses the issue that quality measure specifications do not leverage EHR systems because the clinical information required for quality measurement is not adequately captured in EHRs. To resolve these gaps, HITEP drafted a quality data set (QDS) to empower automated, patient-centric, longitudinal quality measurement. This report describes the QDS framework and necessary "connectors" to electronic information called data flow attributes. Using the QDS framework and data flow attributes, HITEP presents two example measures modified from traditional abstraction specifications to electronic clinical information requirements. HITEP also offers six recommendations for further work to enhance the development and use of the QDS and electronic data sources.

NQF thanks HITEP and its workgroups for their work in continuing its efforts to envision the EHR platform required for future automated performance measurement.

Janet M. Corrigan, PhD, MBA
President and Chief Executive Officer

The mission of the National Quality Forum is to improve the quality of American healthcare by setting national priorities and goals for performance improvement, endorsing national consensus standards for measuring and publicly reporting on performance, and promoting the attainment of national goals through education and outreach programs.

This work was conducted under a contract from the Agency for Healthcare Research and Quality (www.ahrq.gov). Additionally, the Health Information Technology Expert Panel would like to acknowledge the federal government for its leadership in funding activities to create and maintain healthcare information standards.

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Executive Summary

THE NATIONAL QUALITY FORUM (NQF), with support from the Agency for Healthcare Research and Quality (AHRQ), established the Health Information Technology Expert Panel (HITEP) to accelerate ongoing efforts defining how health information technology (HIT) can evolve to effectively support performance measurement. As noted in the first HITEP report, *Recommended Common Data Types and Prioritized Performance Measures for Electronic Healthcare Information Systems* (HITEP-I), collecting and reporting accurate, comparative healthcare performance data is complex and largely a time-consuming, manual process. The earlier HITEP report recommended 11 data categories and 39 data types, for a set of 84 high-priority performance measures to enhance capabilities for the electronic capture of data for quality measurement. This information has been incorporated by the Healthcare Information Technology Standards Panel (HITSP) into updates to the Quality Interoperability Specification and the HITSP components to which it refers. HITSP specifically identified an electronic source and a standard code set for each data category and data type in the first HITEP report. Many of these requirements also have been incorporated into certification requirements for electronic health records (EHRs) by the Certification Commission for Health Information Technology (CCHIT).

The first HITEP report led to new feasibility criteria for measure endorsement by NQF. However, quality measure specifications currently do not leverage EHR systems. Many rely heavily on administrative rather than clinical data, and clinical information required for quality measurement is not adequately captured in EHRs. The American Recovery and Reinvestment Act of 2009 and the Health Information Technology for Economic and Clinical Health Act have significantly raised the bar and shortened timelines for implementation by providing funding to support the adoption of qualified EHRs and the alignment of related timelines. The acts specifically define the meaningful use of HIT systems as the use of electronic prescribing (e-prescribing), the electronic exchange of health information to improve the quality of healthcare, such as promoting care coordination, and the submission of information on clinical quality measures.

To resolve the gaps between current quality measurement and EHR reporting capabilities, HITEP reconvened, tasked with drafting a quality data set (QDS) to empower automated, patient-centric, longitudinal quality measurement. Performance assessment requires consistent measurement across conditions, settings, and providers.

Efficient measurement must automatically gather reliable, high-quality, clinical information from numerous electronic sources. Based on the results of an environmental scan, HITEP had a clear mandate that measures must be more clearly and consistently defined, that there needs to be recognition that structured data and the reuse of data elements that exist in EHRs or other electronic formats are essential, and that workflows are complex. It is also clear that the authoritative data that are required to capture the meaning of elements within the measure can be found in specific medical record locations. HITEP therefore created two workgroups—the QDS Workgroup and the Data Flow Workgroup. The QDS Workgroup standardized data elements and developed a framework to consistently use standard code sets and code lists. The Data Flow Workgroup addressed how to determine from its use within the clinical workflow that any given data element is the authoritative source for the information required. The Data Flow Workgroup created a framework of characteristics to represent data used within measures based on their representation within EHRs.

The QDS framework contains three levels of information: standard elements, quality data elements, and data flow attributes. Standard elements represent the atomic unit of data identified by a data element name, a code set, and a code list composed of one or more enumerated values. Examples include diabetes and all pertinent ICD-9-CM codes or diabetes medications and all representative medications coded in the code set RxNorm. Standard data elements can be reused within other quality data elements. Each standard element's category defines the code set that is used. Quality data elements are pieces of information that are used in quality measures to describe part of the clinical care process. Examples include active diabetes diagnosis, diabetes family history, diabetes medication dispensed, and diabetes medication administered. Quality data elements can be reused by other measures, clinical guidelines, and clinical decision support (CDS) developers. The quality data type is a grouping of information that indicates the circumstance of use for any individual standard data type. Examples include active diagnosis, family history of diagnosis, and medication prescribed. Data flow attributes describe the authoritative source for the information that is required to represent any given quality data element. Data flow attributes include the data source, recorder, setting, and health record field. The *source* is the originator of the quality data element and may be an individual or a device. The *recorder* is the individual or device that enters the data element into a health record field and also may be the source of the data, but that is not necessarily true. The *setting* is the physical location where the data element is captured, defining the encounter location where the data are expected to originate. The *health record field* is the location within an electronic record where the data should be found. Detailed examples of each of these elements are provided in this report. A sample measure is used to show how each element of the framework is used to construct the measure.

This report also provides a list of the QDS elements and data flow attributes that HITEP identified. Two example measures also are presented with suggestions to modify them

from the requirement for abstraction to an electronic format. One is based on the ambulatory setting—antiplatelet therapy for coronary artery disease—and the other is inpatient based—venous thromboembolism prophylaxis.

HITEP offers six recommendations for further work to enhance the development and use of the QDS and electronic data sources:

RECOMMENDATION 1: NQF should develop and maintain the QDS with the involvement of all stakeholders. Specific recognized standards and taxonomies should be used. The QDS should be hosted in a publicly available, centrally located, web-based repository such as the United States Health Information Knowledge Base (USHIK) with content (quality measures and definitions) submitted by measure developers. A measure authoring tool should be created to facilitate the development of EHR-ready measures that also can be used as a resource by the stakeholders and through which gaps and feedback can be communicated. Maintenance of the QDS should support the evolving data requirements of meaningful use of EHRs in 2011, 2013, and 2015, as defined by the Health IT Policy Committee and the Health IT Standards Committee.

RECOMMENDATION 2: Develop measures that use the richness of all available electronic data, focusing on clinical, patient-centered outcomes. Quality measures should leverage clinical data captured in the EHR as a byproduct of routine clinical care. Quickly retool and test existing high-priority measures to take advantage of these electronic data and develop standard methods for using the QDS in defining new measures.

RECOMMENDATION 3: Communicate with all stakeholders and seek their buy-in, and educate and train the quality measure supply chain (e.g., study designers, guideline developers, quality measure developers, performance reporting consumers, EHR vendors, and CDS developers) regarding the QDS and its associated authoring tool. Provide resources to measure developers to retool and test high-priority measures specified in the QDS using the full range of available electronic data. Roles, responsibilities, relationships, and opportunities of stakeholders in the quality measure ecosystem should be enumerated (e.g., the Office of the National Coordinator for Health Information Technology, the Health IT Policy and Standards Committees, CCHIT, the Centers for Medicare & Medicaid Services, HITSP, vendors, providers, measure developers, and guideline developers).

RECOMMENDATION 4: Set a timeline for QDS implementation, including demonstrated functionality and workflow assessment, and enumerate the essential activities and stakeholders. Perform comparative testing to assess the validity and reliability of performance measures derived from EHR clinical data.

RECOMMENDATION 5: NQF should move swiftly to incorporate the QDS into the Consensus Development Process. Requesting that measure developers incorporate the QDS model into their measure submissions will ease the process of incorporating endorsed measures into EHR systems.

RECOMMENDATION 6: Future quality measure development should use the National Priorities and Goals as a guide. The QDS maintenance activity should track and assign data quality scores for the data requirements for emerging measures using the QDS.

Although outside of the original scope of work requested by AHRQ, the members of HITEP agreed that it would be timely and appropriate for NQF to offer an approach to the measurement of meaningful use. Next steps included the development and approval of a set of HIT-sensitive criteria that can be used to identify clinical performance measures that highlight the effect of meaningful use of HIT. The HIT-sensitive criteria can be used to emphasize measures that demonstrate the effect of the use of core HIT functions on clinical quality:

- e-prescribing;
- preventive services reminders;
- health information exchange; and
- CDS.

The HIT-sensitive criteria can be used to systematically review the NQF portfolio of endorsed and pipeline measures to identify a starter set of HIT-sensitive measures that focus on meaningful HIT use in topical areas related to the National Priorities and high-impact conditions. Measure developers can work with NQF to further retool HIT-sensitive measures to conform to EHR-based specifications.

Future work includes the ongoing maintenance of the QDS, the maintenance of reusable code lists, and the development of a measure authoring tool to enable more facile incorporation of the QDS into the quality measurement development process. Additionally, further coordination with standard-development organizations and EHR certification bodies is required to encourage increased quality data type migration into EHRs.

The HITEP QDS and data flow frameworks will provide significant advancement in the development of quality measures. They also will provide a glide path for the incorporation of quality data elements more consistently and based on standards into EHR products and implementations. The QDS is not static; rather, the framework creates a dynamic product that will enable versioning, growth, and expansion to enable future needs for measurement, CDS, and guideline implementation.

Health Information Technology Automation of Quality Measurement: Quality Data Set and Data Flow

Introduction

IN 2007, the Agency for Healthcare Research and Quality (AHRQ), at the request of the American Health Information Community (AHIC) Quality Workgroup, contracted with the National Quality Forum (NQF) to engage in an effort to address issues related to whether electronic records can be used to create and aggregate data for quality measurement. For this purpose, NQF established the Health Information Technology Expert Panel (HITEP) to accelerate ongoing efforts defining how health information technology (HIT) can evolve to effectively support performance measurement.[1] As noted in the first HITEP report, *Recommended Common Data Types and Prioritized Performance Measures for Electronic Healthcare Information Systems* (HITEP-I), collecting and reporting accurate, comparative, healthcare performance data is complex and largely a time-consuming, manual process. The vast majority of electronic health information that is readily available for quality measurement remains administrative, claims-based data, which include only limited clinical information. Quality improvement leaders have long recognized that the widespread adoption of HIT will automate and simplify these processes by providing electronic information. Electronic health record (EHR) systems have long been identified as a fundamental HIT tool for collecting high-quality, electronic, clinical information.[2,3,4] The AHIC Quality Workgroup specified the following recommendation: "The National Quality Forum, through its endorsement process, should apply criteria that reinforce the use of standardized data elements in measures to allow quality measures to be embedded in EHRs. The NQF may do so by incorporating such criteria into its endorsement criteria for new measures."

The Health Information Technology for Economic and Clinical Health Act (HITECH) (part of the American Recovery and Reinvestment Act of 2009 [ARRA])[5] has significantly raised the bar and shortened timelines for implementation by providing funding to support the adoption of qualified EHRs and alignment of related timelines. The act specifically addresses three areas of critical importance for quality measurement:

a. using EHR technology in a meaningful manner including electronic prescribing;

b. exchanging health information electronically to improve healthcare quality, with the promotion of care coordination cited as an example; and

c. submitting clinical quality measure-related information in a form and manner specified by the Secretary of the Department of Health and Human Services (DHHS).

Furthermore, the Secretary is tasked with requiring more stringent measures of meaningful use to improve the use of EHRs and healthcare quality over time.

The first HITEP report recommended 11 data categories and 39 data types, for a set of 84 high-priority performance measures to enhance capabilities for the electronic capture of data for quality measurement. This information has been incorporated by the Healthcare Information Technology Standards Panel (HITSP) into updates to the Quality Interoperability Specification and the HITSP components to which it refers.[6] HITSP specifically identified an electronic source and a standard code set for each data category and data type in the HITEP report. Many of these requirements also have been incorporated into certification requirements for EHRs by the Certification Commission for Health Information Technology (CCHIT).[7]

Since the publication of the first HITEP report, challenges remain in connecting the dots between the electronic information and quality measurement. HITEP identified the following gaps in automating quality measurement:

- quality measurement specifications are not designed to leverage EHR systems;
- quality measurement specifications rely heavily on administrative rather than clinical data; and
- clinical information required for quality measurement is not adequately captured in EHRs.

To fill these gaps, HITEP reconvened, tasked with drafting a quality data set (QDS) to empower the development and use of automated, patient-centric, longitudinal quality measures. Performance assessment requires consistent measurement across conditions, settings, and providers. Efficient measurement must automatically gather reliable, high-quality, clinical information from numerous electronic sources. The task included a review of existing data sets, including those used in currently endorsed measures, those developed by the Centers for Medicare & Medicaid Services (CMS) for its CARE[8] tool, those referenced by HITEP in its initial work, and those developed by The Joint Commission for transfers of care. The QDS is intended to include the relevant data captured during inpatient and ambulatory office visits as well as the data required to support transitions of care between settings. HITEP also was tasked to gather, synthesize, and refine clinical workflow maps, focusing on the care processes related to the care that underlies the conditions targeted by the previously prioritized set of measures. The panel was asked to determine mechanisms and opportunities within these workflows for identifying patients who are eligible for inclusion in the measure populations, for gathering performance measurement data, and for providing clinical decision support (CDS) to optimize performance in targeted areas. As noted in the environmental scan referenced below, workflow maps are neither standardized nor consistently used, and workflow varies for many reasons from one organization to another. Therefore, HITEP elected to address how to determine whether any given data element is the authoritative source for the information required. Using authoritative characteristics allows local

processes to capture needed information. Thus, these characteristics are the links that enable clinical workflow based on local infrastructure. This report will describe these characteristics as *data flow.*

The goal of this effort has been to represent quality data requirements (concepts, data types, data elements, and sets of values or codes) unambiguously and specifically. The first step was to begin with data requirements from the stewards of existing NQF-endorsed® measures. For composite and longitudinal measures, the QDS also must include cross-cutting, longitudinal, quality concepts, such as patient preference and functional status, and structural measures that require data from disparate information systems. The structure of the QDS must be simple to understand and sufficiently robust to incorporate information about each element such that it can be reused without ambiguity with respect to meaning. The structure also must include capabilities for versioning and expansion to include future measure data requirements using electronic data across settings.

Standardizing quality measures will help to automate successful measurement. Yet the volume and variety of measures that exist in paper format slow standardization. For example, at the time of this publication, NQF's database contains more than 500 endorsed measures, the CMS Quality Measure Information System contains 362 measures, and the AHRQ National Quality Measures Clearinghouse contains 1,778 measures.

Decomposing a complex problem can provide more feasible solutions. All measures require numerous individual pieces of information to perform a calculation (e.g., "aspirin allergy," "beta blocker prescribed," "diabetes active diagnosis"). However, the process of standardization begins with identifying and standardizing this list of individual quality concepts resulting in the QDS. The AHIC Quality Workgroup recommended further development of quality information categories from HITEP-I into the QDS.

Standardization will help us to speak and understand the same quality language. Currently, those who use quality measurement in their clinical practices are burdened by new or updated measures. Each new measure requires learning a new dialect. With standardization, we can use the same words, just in new sentences.

Although standards enable information sharing, the number of participants and the complexity of information in the quality conversation limit the feasibility of measurement. Electronic clinical information comes from many containers, including EHRs, health information exchanges, personal health records (PHRs), laboratory information systems, and Pharmacy Benefits Managers (PBMs). Although much of the information in these systems is stored in a standard manner, there is significant variability among systems. As a result, quality measures currently cannot communicate directly with all of these electronic containers, resulting in the need for laborious manual abstraction. Although various efforts are under way to further align and share information between containers, AHIC recommended that HITEP

address workflow issues that involve moving the information between the containers and quality measurement. The QDS is the dictionary of quality measure "words." Each measure then will contain the specific connectors to locate the QDS elements within electronic records, depending on the authoritative sources for that measure.

This report is divided into the following sections:

- a description of an environmental scan conducted of HIT within quality measurement;
- information about the structure of the QDS;
- information about quality data types for the QDS;
- information about example measures and their required QDS elements;
- recommendations for data flow structure to enable the QDS;
- recommendations for housing, maintaining, and overseeing the QDS; and
- recommendations for implementing the QDS.

Environmental Scan

NQF contracted with Booz Allen Hamilton (BAH) to conduct an environmental scan of current initiatives that use electronic clinical data in quality measurement and improvement initiatives. The goal of the environmental scan was to characterize current efforts that are using electronic clinical data to measure performance, to identify areas in which electronic data standards for structured clinical data are needed, and to share this information with HITEP to inform its efforts to conceptualize and define the QDS and a workflow framework. BAH used a two-pronged approach to conduct the environmental scan, including conducting a literature review of published data and grey media and collecting primary data through targeted interviews. BAH interviewed staff from 20 organizations, including 9 provider organizations (large and small), 10 collaboratives, and 2 government organizations. An interview guide was used to structure the hour-long interviews.

Most interviewees used the CMS Reporting Hospital Quality Data for Annual Payment (RHQDAPU) measures, the AQA Alliance (AQA) measures, and the Healthcare Effectiveness Data and Information Set (HEDIS) measures. Some organizations modified these widely used measures, especially in the ambulatory setting. Changes included adjustments to denominators to capture information on particular patient populations (e.g., patients over 55 years of age) or to enhance automation. Payers/collaborators altered measures to meet program goals. Composite measures were created from AQA/HEDIS component measures. A few organizations reported developing home-grown measures. One organization (the Indian Health Service) developed measures that can be collected electronically through its systemwide EHR. Significant issues not addressed by existing, nationally recognized measures included particular aspects of care (e.g., safety, mental health, care coordination/transitions of care, care episodes) and efficiency (e.g., patient flow). Areas often reported as missing data included specialty care, because of the use of proprietary registries that are

expensive for organizations to access, and disparities, because data on race and ethnicity are not always captured.

Technical limitations for measure implementation included the lack of measure specifications designed for electronic capture of data. Also, some elements are typically not captured in structured format or by interoperable system components (e.g., imaging studies outside of the provider's electronic network). Reference laboratory data also was challenging without data-sharing agreements being in place. Still other information is generated outside of the healthcare infrastructure, such as cash transactions to purchase over-the-counter medications. Care that takes place in employer-based wellness clinics also was difficult to access.

Resource burdens challenged virtually all stakeholders that have a need to engage in some manual chart abstraction and data collection. Costs associated with electronic data collection also were a burden based on requirements to upgrade EHRs to capture new data elements as specifications are updated or new measures added. Some required external vendors to extract data from EHRs (providers) or to aggregate data from multiple sources (collaboratives).

Workflow maps were viewed as valuable for standardizing the collection of data elements for quality measurement. Although two large provider organizations were beginning to develop such maps, and one organization encouraged individual facilities to document their workflow maps, there was no single standard. Many organizations cited the burden of creating workflows, especially because of individual provider preference. Hence, few organizations had created workflow maps.

There were many sources of data, including electronic and paper-based sources, such as administrative and financial systems, paper charts/medical records, EHRs, and external HIT systems (e.g., laboratory, pharmacy). The inherent nature of some measures (e.g., the CMS RHQDAPU) necessitated manual chart abstraction. In most cases, clinical judgment was seen as necessary based on the measure definitions (e.g., for bloodstream infections, the need to determine the cause of a positive culture). The multiple sources used included clinical data from providers—in both electronic and paper formats—claims data, reference laboratory data, PBMs, and others. Some interviewees had available state registries or other administrative data sources.

Data audit and validation were seen as vital because of the complexity of the measure specifications. Except for the organizations that were able to utilize a common technology platform, auditing and validation were largely manual processes.

The environmental scan identified a number of issues to inform the HITEP effort. Stakeholders recognized the challenges inherent in extracting quality measures from EHRs, such as low EHR adoption, privacy and security issues, the inability to identify patients consistently across care settings, the need for methodologies to attribute patients to providers for purposes of accountability, and the need for agreements to enable data sharing. The respondents recognized the complexity of data capture and use for measurement. Therefore, they recommended prioritizing data categories for standardization to provide basic, high-quality information for measurement, including laboratory data, information about medications,

patient medical and surgical history, immunization data, diagnostic test data, allergy data, information on comorbidities, contraindications, functional status, and biologics (e.g., blood pressure), and information related to the discharge summary. The stakeholders further suggested the standardization of functions within EHRs to enhance interoperability and measurement, including data capture, automated exclusion criteria assessment, time and date stamping, and CDS. Additional standardization work was recommended in the areas of specialty care, continuity of care, episodes of care and longitudinal assessment, chronic conditions, patient satisfaction, disparity assessment, preventive services, children's healthcare needs, behavioral health, and other areas prioritized by the National Priorities Partnership.

Some basic healthcare infrastructure requirements also were identified, specifically the need for a universal patient identifier or standard patient matching algorithms to track a patient across care settings and different electronic data systems, the need for standardized algorithms to attribute patient care to the accountable provider, and the need for expanded querying and extraction capabilities to search and gather large amounts of electronic clinical information. From the standpoint of measurement, respondents preferred a standard specification format designed to be used with clinical HIT systems, population measures such that single patients have less of an impact (e.g., blind patient without eye exam, no pap smear because of hysterectomy), and a standard measure release cycle to help EHR vendors to establish a schedule of upgrades, minimizing the disruption to care delivery that currently occurs given the need for almost continuous EHR maintenance and upgrades.

The CARE tool is being piloted to potentially replace the Minimal Data Set (MDS)[9] and the Outcome and Assessment Information Set (OASIS),[10] but any such implementation is expected in the future and is not currently available. OASIS (home health) and MDS (nursing facilities, skilled nursing facilities, and rehabilitation facilities) are currently the quality measurement and reporting standards for all payers. New versions of OASIS-C and MDSv3 will be released in January 2010 and October 2010, respectively. Federally required patient assessments in nursing facilities and home health agencies do contain data elements used for quality reporting and assessment and, therefore, will use the same QDS elements as quality measures.

In summary, the environmental scan provided a clear message that measures must be more clearly and consistently defined, that having structured data and reusing data elements that exist in EHRs or other electronic formats are essential, and that workflows are complex. It also is clear from the scan that the authoritative data required to capture the meaning of elements within a measure can be found in specific medical record locations. In conclusion, it is important that HITEP standardize data elements, consistently use standard code types and common code sets, and enable the specification of measures with respect to an EHR-specific authoritative source for the information desired.

The full environmental scan report can be found in Appendix C.

Rationale

Quality represents a continuum that comprises structure, process, and outcome, as outlined by Donabedian.[11] For the purpose of measurement, the structure begins with a systematic assessment of the best evidence incorporated within clinical guidelines and algorithms; the process includes incorporation of the evidence within the care model using CDS and evaluation of the effectiveness and efficiency of the processes and the outcomes through quality measurement. The process continues as new evidence is gained through measurement to generate modifications in existing guidelines or new ones. But because the guidelines, CDS, and quality developers arose independently, many of the definitions used by each community are different. Each recognizes the value of consistent and standard elements from which all groups can draw and to which all groups can contribute. This HITEP effort was created to provide a framework for understanding which data are of high quality and to establish a set of high-quality data elements for reuse throughout the entire quality measure supply chain.

The QDS was designed in part to address each of the HITEP-I recommendations.

RECOMMENDATION: *NQF should evaluate the quality of data types used in measure specifications as a criterion in the endorsement of new measures, as well as in the reassessment of measures for continued endorsement.*

Decomposing complex quality measures into individual QDS items allows for evaluation of each item separately. Therefore, the data quality of a measure can be assessed from the data quality of each QDS item in that measure.

RECOMMENDATION: *A coded, interdisciplinary clinical problem list in the EHR should be used in place of billing codes to identify patient conditions, inclusion diagnoses, and exclusion diagnoses for quality measurement. It is further recommended that this problem list be accessible and utilized across care settings (e.g., inpatient, outpatient, long-term care facilities).*

The QDS should be able to meet the immediate needs of existing measures as well as be forward-reaching toward the future of measurement, which includes cross-cutting concepts (e.g., functional status, patient preference) and transition of information sources from billing codes (ICD-9) to clinical problems (SNOMED). Rather than needing to retool all existing measures separately, each item in the QDS (e.g., "diabetes active diagnosis") can be bridged individually.

RECOMMENDATION: *NQF should work with HITSP to develop a "reader's digest" version of a data dictionary for use by measure developers that would contain the HITEP data types and their corresponding HITSP-recommended code sets.*

In the Interoperability Specification for Quality, HITSP recommended standards for describing quality information. However, current measures are written using a combination of plain English and code sets, making it difficult to apply the HITSP recommendations. The QDS is a universal data dictionary for quality measures that can be used in other healthcare applications such as CDS. Once measures use the QDS, HITSP recommendations can be applied to it. This will encourage measure developers to transition information sources from administrative codes to HITSP-recommended codes. Implementing these recommendations is more feasible with individual QDS items than with all measures at once.

RECOMMENDATION: *Medication allergies and side effects should be distinguished from each other and entered using standardized codes.*

Currently, those who develop healthcare software have difficulty translating measure descriptions from paper to the computer. The QDS will define standard concepts for quality measures. This, in turn, will allow software developers to more easily incorporate quality measurement into the software, including features that would enable the software to tell the differences between "allergy" and "side effect" using standard HITSP-recommended codes.

RECOMMENDATION: *Standardized codes for summary impressions of diagnostic test results should be developed, where feasible. Quantitative results, when available, should accompany qualitative results of diagnostic studies.*

Quality measures are specified according to the information that is readily available. Another audience of the QDS is clinicians interpreting diagnostic tests. The QDS will illuminate what diagnostic tests require coded summary impressions.

RECOMMENDATION: *EHR vendors should develop methods of presenting EHR medication data with external medication data from pharmacies and pharmacy networks to help providers assess patients' adherence to medication treatment plans.*

Quality measures using the QDS can describe where the electronic information should be located. As an example, medications may be found in an EHR/PHR or in a pharmacy/pharmacy network directly.

RECOMMENDATION: *Quality and information technology stakeholders should work together to define additional EHR functional requirements that support quality measurement.*

The QDS contains the building blocks of quality measurement, serving as a single converging dictionary for both quality measure developers and information technology programmers. Initial quality functions required by an EHR can begin with the QDS, allowing for innovation by all stakeholders around a common standard.

Goals

The goals of the QDS address HITEP-I recommendations and encourage automating quality measurement using electronic clinical information. The QDS elements can define structural, process, and outcome measures and serve as the variables for risk-adjustment and stratification.

GOAL: *Describe, unambiguously, the clinical information that is needed for all quality measures.*

Quality measures define similar clinical concepts in different ways, challenging the comparability of similar measure conditions from different measure developers. Furthermore, measure definitions can be ambiguous, which is often a reflection of missing or inadequate clinical information at the source. As we move toward the use of electronic clinical information, we have the opportunity to more precisely define the clinical information needed for quality measurement.

GOAL: *Reuse quality information definitions.*

A sustainable quality measurement system must balance the need for a variety of definitions without the burden of programming each new variation. A coordinated approach of first defining existing quality information followed by harmonization of concept definitions will result in the reuse of each definition. This will require that data elements are carefully defined and presented to enable appropriate reuse. Such reuse minimizes rework and allows quality measurements to mature while limiting the burden of having to reprogram each new definition. The QDS framework is intended to represent clinical and administrative information required to calculate quality measures. These elements will be used to construct, with measure-related logic, numerators and denominators. Similarly, they can be used, with care, to construct statements such as those in the CMS MDS, OASIS, the CARE tool, and public health and safety reporting instruments.

GOAL: *Accommodate current and future measure needs.*

The future of quality measurement will be powered by electronic clinical information, allowing real-time feedback to clinicians. As we transition clinically from paper to electronic records, quality measurement must work with the administrative/claims data currently available, even though this arrangement is imperfect. The QDS will serve as the guide for transitioning clinical information to electronic sources. Furthermore, because future measures are expected to track the National Priorities, and future measure endorsement will require the use of the QDS, the content of the QDS will therefore be aligned with the National Priorities.

GOAL: *Bridge the translation gap between quality measure content experts and EHR vendors and implementers.*

Although the underlying clinical information is similar between these stakeholders, the method for describing the same information differs. A common language that both quality measure developers and HIT programmers can speak will facilitate automated measurement using electronic information. This common language must be intuitive to the content of measure developers and relate to the technical requirements of HIT programmers. The QDS is the Rosetta Stone that will translate between the quality and HIT domains.

Workgroups

Quality measurement information can be divided into 1) definitions for clinical information and 2) instructions for locating the information. Because both of these are required to automate quality measurement, HITEP created two workgroups—one for the QDS and one for data flow.

QDS Workgroup

The goal of the QDS Workgroup was to provide a centralized, maintained repository of quality data requirements (concepts, data types, data elements, code sets) and data definitions used by multiple stakeholders to develop, specify, and enable quality measurement. The scope included the following:

- Begin with existing measure data specifications from current measure developers.

- Evaluate the CMS CARE tool and The Joint Commission transfers of care data sets.
- Include cross-cutting, longitudinal, quality concepts such as patient preference and functional status that require data from disparate information systems.
- Structure the QDS to include future measure data requirements using EHR data across care settings.
- Propose a framework that can represent current and future measures.

Data Flow Workgroup

The goal of the Data Flow Workgroup was to identify the most authoritative source for specific quality information required by any measure. The meaning of this quality information may vary depending on its source, how it is acquired, how it is recorded, where it occurred, and in which health record field it is stored. Ideally, guideline, CDS, or quality measure developers should define these attributes to accurately capture the measure's intent. The scope of the Data Flow Workgroup included the following:

- Establish the framework of essential data element attributes to describe the authoritative source of quality information.
- Evaluate the set of quality data elements and create a set of options for these attributes.

The QDS and Data Flow Workgroups worked independently and then joined forces to consolidate their efforts for evaluation by the full HITEP.

Expert Panel Analysis

HITEP initially convened in Washington, DC, on February 24, 2009. The QDS and Data Flow Workgroups (Appendix A) convened twice, on February 25 and April 13, 2009. Co-chairs from the workgroups presented recommendations to HITEP during its second meeting on May 6-7, 2009.

Framework Process

The QDS and Data Flow Workgroups met on February 25, 2009, beginning with a starter set of 10 selected measures that covered inpatient and ambulatory settings, as well as some newer clinically enriched measures to address clinical elements that will be available electronically in the near term. The workgroups identified the types of information required to calculate each measure and the location of that information. These types, or quality data types, are a continuation of the work of HITEP-I. The QDS Workgroup identified the quality data types required for the current measures and for future measures addressing the continuum of care and the National Priorities of the National Priorities Partnership. Additionally, the QDS Workgroup created a framework, or model, to include both the quality data types and the standard code lists that are specified in measures. The Data Flow Workgroup created a framework to describe the origination and location of the information. Through a series of workgroup calls, the QDS Workgroup reviewed additional NQF-endorsed measures using a web-based evaluation system. The frameworks were modified to

better fit the structure of quality measures. The QDS framework, quality data types, data flow framework, and data flow descriptions were finalized at the second meeting on April 13, 2009, and were presented to the full HITEP on May 6-7, 2009. Quality data types were further validated by applying the QDS framework to all NQF-endorsed measures. The purpose of the QDS and data flow is to describe the information required to calculate quality measures. Although other efforts have focused on how to describe a measure algorithm or logic (e.g., *If* A *and not* B *then* C *or* D), the QDS will provide the basic building blocks—the clinical information—needed to complete the algorithm.

Framework Example Measure: Diabetic Control of Hemoglobin A1c

To illustrate the QDS framework, we will follow an example of a simplified measure throughout this report (Box 1). The measure is intended to show the effectiveness of care for patients with diabetes. The basic determinant of the denominator (or population) is patients with an active diagnosis of diabetes. The quality data element, therefore, is active diagnosis of diabetes. This element can be reused by other measures to define a specific population of patients with diabetes. In the example, the active diagnosis is listed as an administrative claim of diabetes. The application of the QDS and data flow frameworks will detail preferred methods and code sets to identify an active diagnosis (or problem) to avoid the need for administrative claims and use of clinical information from the EHR.

Box 1: Example Measure Description*

Percentage of patients with diabetes (either by administrative claim of diabetes or if a diabetic medication has been dispensed) who have had a Hemoglobin A1c laboratory test result < 8 percent within the past year.

(National Committee for Quality Assurance [NCQA], currently under review for endorsement)

*This measure is intended to show the effectiveness of care for patients with diabetes.

The above example requires the following pieces of information:

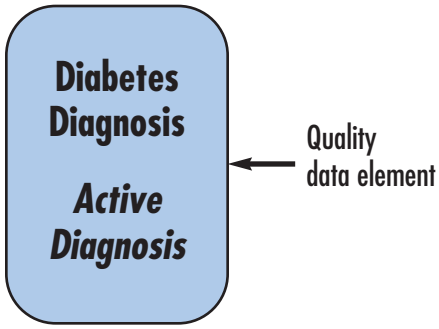
1. an active diagnosis of diabetes;
2. the diabetic medication dispensed; and
3. the hemoglobin A1c laboratory test result (including the date of the result to calculate whether it was performed within the last year).

The QDS framework describes these types of information, generalized for any measure. The data flow framework shows how to locate this information electronically.

Quality Data Element

A quality data element is a single piece of information that is used in quality measures to describe part of the clinical care process, including both a clinical entity and its context of use. In our example, the basic determinant of the denominator, or patient population, is patients with an active diagnosis of diabetes (Figure 1).

Figure 1: Quality Data Element for Active Diagnosis of Diabetes



The quality data element contains both a clinical entity (diabetes diagnosis) and information about how it is used (active). This element may be defined in one measure and reused in additional measures to define a specific population of diabetic patients. This reuse encourages standardization of quality measures, and it reduces computer programming requirements for new measures.

Quality Data Type

Current measure specifications assist abstracters with understanding the components of the quality data element so they can be located within a medical record. Similarly, a computer system needs to understand the components to correctly find the appropriate information. In this example, an active diagnosis is a type of information representing a condition that is currently monitored or tracked or that needs to be factored into the current treatment plan. This data type is the *context of use* for the information required. For example, past history diagnosis, family history diagnosis, or active diagnosis are all data types indicating different contexts for the concept of diagnosis. By applying the context of use, the concept has more specific meaning. HITEP referred to this type of information as a quality data type. These are all contexts of the standard category of diagnosis. The quality data type more clearly identifies the meaning intended in the measure to appropriately locate the intended electronic information. Each quality data type applies a specific use to a data category (Figure 2).

Only three data types are required for this measure. The full list of quality data types for all measures is discussed below in the section "QDS Data Types."

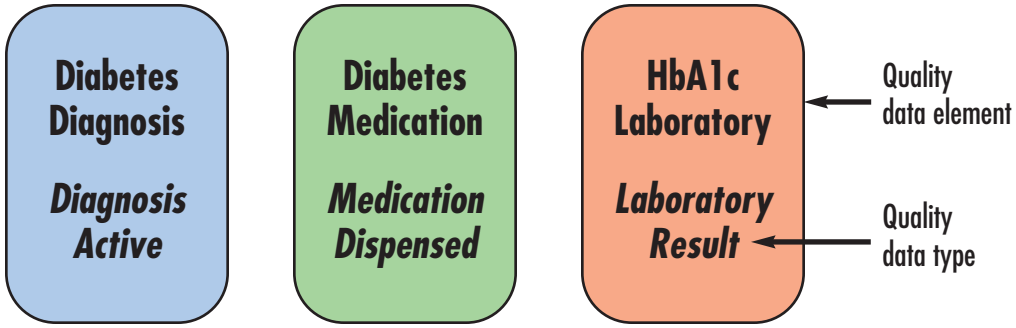
Quality Data Type-Specific Attributes

All quality elements should contain a date and time stamp. Additionally, certain quality data types contain qualifying information or attributes. For example, medication dispensed and medication ordered both contain information about the dose, route, strength, and duration of a medication such as penicillin. A medication allergy, however, would contain information about the allergy type and allergy severity, and more. Because these qualifiers pertain to specific quality data types, they are called quality data type-specific attributes. Similarly, efficiency and cost-related information are necessary data type-specific attributes.

Standard Element

To automatically locate quality data elements within an electronic medical record, information must be described explicitly. Although people

Figure 2: Quality Data Elements and Their Associated Quality Data Types

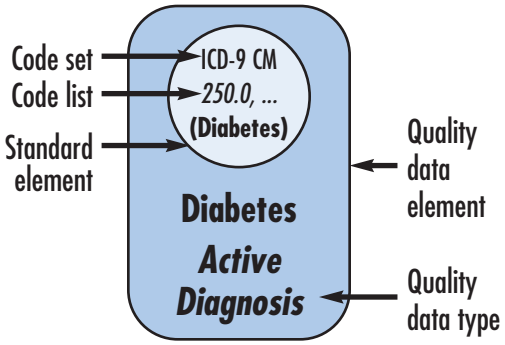


To illustrate different standard categories, the figures use color coding: blue shapes are diagnoses, green shapes are medications, and red shapes are laboratory tests.

easily understand the term "diabetes," computers do not. Therefore, computer code sets (or coding systems) are used to define the clinical information or standard category. In the example measure, the standard category of diagnosis can be defined using the ICD-9-CM code set. Furthermore, measure developers choose a specific code list to define diabetes. These codes are stored in a reusable format called a standard element, which contains a name, a code set, and a code list (e.g., diabetes, ICD-9-CM, 250.xx; see Figure 3). To provide a larger clinical context for measurement, for the future, the code set for problems should reference SNOMED-CT as well, as noted in the first HITEP report.

Different quality data elements will reuse the same code list. For example, the quality data element diabetes family history may reference the same diabetes codes as the diabetes active diagnosis. HITEP defined this standard element

Figure 3: Standard Element (including code set and code list) as Part of the Quality Data Element



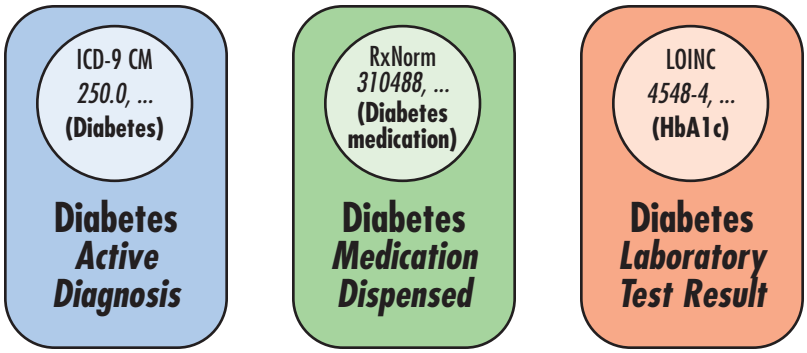
The standard element (light blue circle) has a code set and specific code list and is part of the quality data element. The color of the circle indicates the standard category—in this example, diagnosis.

as a unique concept that can be represented by a numerical value (e.g., a birth date) or a specified list of codes that can be interpreted in an electronic system.[12] Figure 4 demonstrates standard elements for our example measure.

Standard elements may contain a list of codes (e.g., ICD-9-CM codes), words (e.g., drug names), or concepts described at length in measure specifications (e.g., definition of smoking cessation counseling components) to allow an abstracter to determine whether the concept is in the medical record. For the exchange of clinical information among electronic data systems, HITSP has recommended specific code sets for each standard category including problems (SNOMED-CT[13]), medications (RxNorm[14] and NDF-RT[15]), laboratory procedures (LOINC[16]), and others.[17]

The advantage of using standard elements is that a single code list can be reused in many different quality data elements. For example, the standard element in Figure 2 contains approximately 100 different medication codes. Rather than having to redefine that list of codes each time, it is referenced in a new measure; the measure can simply refer to the standard element "diabetes medications." This is akin to referencing a "look-up" spreadsheet or appendix, which is the current practice in many measures involving medication lists. Once defined, this standard element may then be reused in many different clinical contexts as a component of multiple quality data elements. Referring back to our example measure that requires information regarding whether diabetes medications were dispensed, the standard element is diabetes medications, the quality data type is medication dispensed, and the quality data element is diabetes medication dispensed. Another measure may reuse the same standard element of diabetes medications in the context of "was it ordered?" The standard element remains diabetes medications; however, the quality data type would be medication ordered, and the resulting quality data

Figure 4: Quality Data Elements, Quality Data Types, and Standard Elements



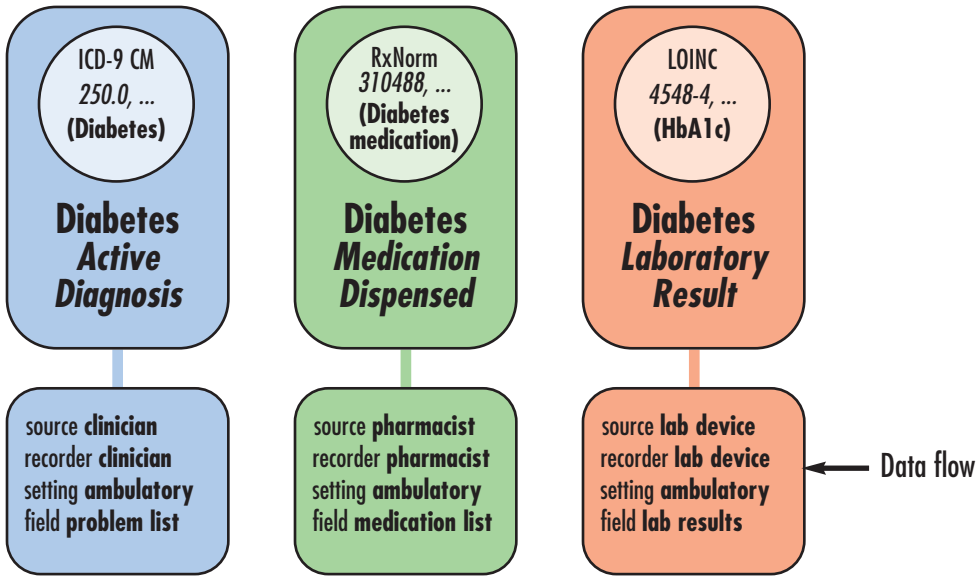
Each quality data element (rounded rectangle) contains a standard element (circle) with a code set (top of circle) and code list (middle of circle) to define the clinical information in a computer-readable format. The color of the circles define the standard categories diagnosis (blue), medication (green), and laboratory test (red).

element would be diabetes medication ordered. Yet a third measure may reuse diabetes medications to exclude a patient from receiving the medication because of an allergy: The standard element remains diabetes medications, the quality data type would be medication allergy, and the quality data element would be diabetes medication allergy.

Quality Data Flow

In the examples above, the computer would know the code list (defined by the standard element) and how it is used (defined by the quality element). However, in order to identify the authoritative source and the appropriate meaning for such information within an individual patient's record, the electronic record requires additional related information, such as where to find information of that type and in that particular clinical context. For example, a diabetes medications order may be found in the medication orders, while diabetes medications allergy will be on the allergy list. Similarly, a clinician's account of an allergy may be found in an EHR allergy list, but a patient's account of an allergy will be found in a PHR allergy list. Quality data flow allows a measure developer to clearly define in the specifications where the quality data should be found to achieve the intended meaning of the measure (Figure 5).

Figure 5: Example Measure Including Quality Data Elements and Data Flow



Each quality data element (rounded rectangle) has associated data flow information (bottom rounded rectangles). These data flow attributes describe where to find the quality data element electronically.

The data flow contains four attributes:

1. **Source -** The source is the originator of the quality data element. The source may be an individual or a device. Some examples of sources are:
   a. The laboratory measurement device when tracking a lab result.
   b. The patient or patient proxy when determining if medication is taken.
   c. An imaging device such as cardiac ultrasound when diagnosing a left ventricular ejection fraction.
2. **Recorder -** The recorder is the individual or device that enters the data element into a health record field. The desired recorder also may be, but is not necessarily, the source of the data.
3. **Setting -** The setting is the physical location where the data element is captured. The setting defines the encounter location where the data are expected to originate.
4. **Health Record Field -** The health record field is the location within an electronic record where the data should be found. As shown in the examples, a problem list may be the preferred and only acceptable field where an active diagnosis of diabetes may be found. A family history may be the preferred health record field for family history of diabetes.

Although a quality data element can be shared by many measures, the data flow attributes should be defined *within* a given measure specification and should be specific to that measure. Enabling the definition of data flow as part of the measure authoring environment helps a measure developer to simplify the measure specification descriptions and to very clearly state the acceptable health record field(s). Specifying the authoritative source of information allows a measure developer to determine how, by whom, and where, within the clinical workflow, a process occurred or an outcome was achieved. To illustrate how the same quality data element can be used in measures, suppose there are two measures for measuring blood pressure management:

1. Blood pressure compliance in the ambulatory setting; and
2. Blood pressure measurement at home.

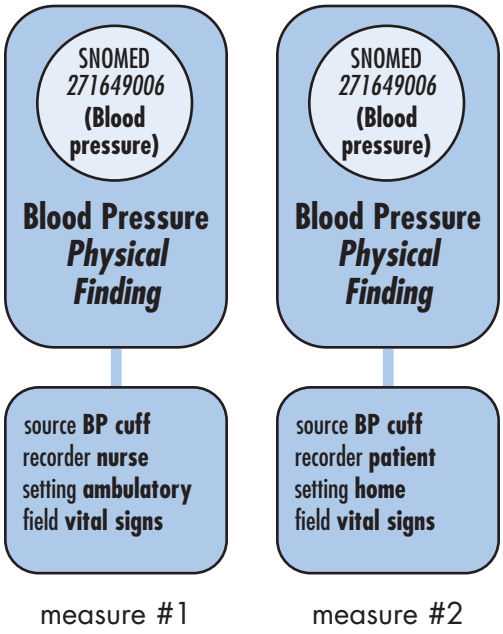
Both will utilize the same quality data element of blood pressure physical finding; however, the data flow attributes can describe different authoritative sources for the same type of information: vital signs taken by a nurse (or physician) in an office practice and recorded in an EHR vital sign field and vital signs taken by a patient or patient proxy in the home setting and recorded in a PHR vital sign field, respectively (Figure 6).

Summary of QDS Framework

The QDS framework contains three levels of information: standard elements, quality data elements, and data flow attributes (Figure 7).

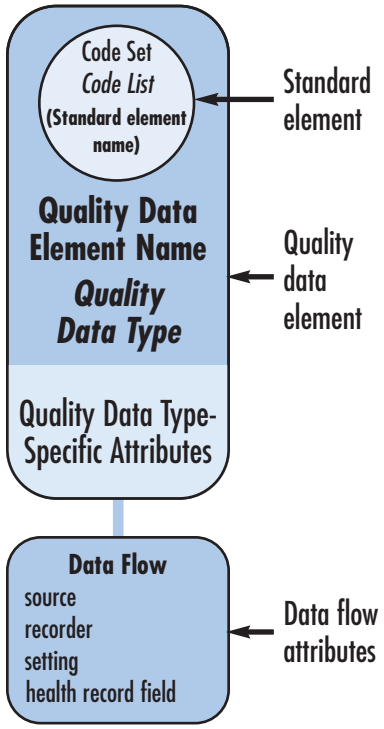
A standard element is an atomic unit of data that is identified by a data element name, a code type, and a code set composed of one or more enumerated values. Examples include diabetes and all pertinent ICD-9-CM codes, or diabetes medications and all representative medications coded in the code type RxNorm. Standard data elements can be reused within other quality data elements.

Figure 6: Example Quality Data Elements with Different Data Flow



Although both measures reuse the same quality data element of blood pressure physical finding, the first measure specifies the recorder as a nurse and the setting as ambulatory; this measure would require looking for the quality data element in the vital sign field of an EHR. The second measure specifies a patient recording at home and therefore requires a search for the vital sign field in a PHR.

Figure 7: Summary Combined QDS and Data Flow Frameworks



A standard category is a class or category of information. Examples include medication, problem, laboratory test, and diagnostic test. Many data type categories contain qualifying information or attributes. As an example, medication has the specific attributes of dose, route, strength, and duration. Allergy, whether referring to medication, environmental, chemical, or other types of information, has specific attributes, including allergy type and allergy severity.

A quality data element is a single piece of information used in quality measures to describe part of the clinical care process. It can be considered the specific instance of use. The quality data element represents the standard data element with its perspective of use. Examples include active diagnosis of diabetes, diabetes family history, and diabetes medication dispensed. Quality data elements can be reused by other measures, clinical guidelines, and CDS developers.

A quality data type is a grouping of information that indicates the circumstance of use for any individual standard data type. Examples include active diagnosis, family history of diagnosis, and medication prescribed. All quality data types should contain a date and time stamp. The quality data types inherit the attributes of the data type categories from which they are developed. Hence, medication administered maintains the medication data type attributes of dose, route, strength, and duration. Medication allergy inherits the allergy data type attributes including allergy type and allergy severity.

Data flow attributes describe the authoritative source for the information that is required to represent the quality data element. The authoritative source, as shown in the examples, will vary with the intended meaning of the performance measure. In the example shown in Figure 5, one measure shows monitoring and compliance with the treatment plan based on the clinician as the authoritative source. The second measure in that example shows patient engagement in care by specifying the patient and a patient-generated finding as the authoritative source. The measure specification, therefore, assigns the data flow attributes to the QDS elements used within the measure.

1. **Source -** The source is the originator of the quality data element. The source may be an individual or a device.
2. **Recorder -** The recorder is the individual or device that enters the data element into a health record field. The desired recorder also may be, but is not necessarily, the source of the data.
3. **Setting -** The setting is the physical location where the data element is captured. The setting defines the encounter location where the data are expected to originate.
4. **Health Record Field -** The health record field is the location within an electronic record where the data should be found. As shown in the examples (Figure 5), a problem list may be the preferred and only acceptable field where an active diagnosis of diabetes may be found. A family history may be the preferred health record field for family history of diabetes.

Evaluation and testing will likely extend the data flow attributes. The alignment of these concepts with existing electronic data transmission standards has started with the creation of a new Health Level 7 (HL7) ballot, eMeasure: Representation of the Health Quality Record Format. Scheduled for ballot as a draft standard for trial use at the HL7 Working Group meeting in Atlanta, Georgia, in September 2009, this new standard coordinates the QDS elements and data flow attributes with information within EHR models. Some elements, such as data sources and recorders, will need to be incorporated within the standards. To avoid complexity where there is no preference for data source or recorder, the attributes should be optional.

The QDS describes the basic information needed to calculate a measure. These quality data elements come together, along with logic, in the details of a measure specification.

Measure Logic

Industry efforts, one of which is the Health Quality Measures Format,[18] have focused on describing the algorithms and logic of measures and created prototype representations for measures. To clearly differentiate the QDS, combination statements and specific values are best managed during the measure authoring environment, adding logic to the quality data element itself. Table 1 provides examples of concepts that may be represented in the measure authoring environment and the specific quality data elements used to represent them.

Table 1: Deconstructing Simple Measure Logic into Individual Quality Data Elements

MEASURE CONCEPT	REQUIRED QUALITY DATA ELEMENTS	RATIONALE
"ACEI or ARB prescribed"	ACEI medication prescribed, ARB medication prescribed	ACEI and ARB are joined together in the measure logic with *or*. This allows reuse of two existing quality data elements.
"HbA1c >9%"	HbA1c laboratory test result	If measures have different thresholds for HbA1c, the QDS should contain the element that represents the result and should allow the measure to calculate the logic of the actual value(s), e.g., > or < a threshold. This method allows other measures to reuse the same QDS concept and, as new evidence is gained, to modify the expected thresholds without changing the quality data element needed to represent the information in the health record.
"ambulates 10 meters"	ambulation distance functional status	Similar to HbA1c, the threshold "10 meters" is best defined in the individual measure.
"improved gas exchange"	oxygen saturation	The measure can calculate the logic of "improvement" from two gas exchange quantitative results during a specified window of time.
"patient age"	birth date patient characteristic, measurement calculation date system characteristic	Patient age is calculated by *measurement calculation date – date of birth.*
"worsening renal failure"	serum creatinine laboratory test results	Worsening renal failure is calculated in the measure logic by a rate of change of creatinine value over time exceeding a threshold set by the measure.

QDS Data Types

A list of QDS data types is presented in Table 2. Full definitions are provided in a glossary (see Appendix B)

Table 2: Standard Categories and QDS Data Types

STANDARD CATEGORIES	QDS DATA TYPES
Care experience	**Patient** care experience **Provider** care experience
Care goal	Care **goal** Care **plan**
Communication	Communication **provider to provider** Communication **to patient** Communication **from patient**
Device	Device **adverse event** Device **applied** Device **intolerance** Device **ordered** Device **offered** Device **declined**
Diagnosis/condition/problem	Diagnosis **active** Diagnosis **family history** Diagnosis **past history** Diagnosis, **risk of** Diagnosis, **factored risk**
Diagnostic study	Diagnostic study **adverse event** Diagnostic study **intolerance** Diagnostic study **order** Diagnostic study **result** Diagnostic study **offered** Diagnostic study **declined**
Encounter	Encounter
Functional status	Functional status
Individual characteristic	**Patient** characteristic **Provider** characteristic
Laboratory test	Laboratory test **performed** Laboratory test **order** Laboratory test **result**

more

Table 2: Standard Categories and QDS Data Types

STANDARD CATEGORIES	QDS DATA TYPES
Laboratory test *(continued)*	Laboratory test **offered** Laboratory test **declined**
Medication	Medication **administered** Medication **adverse event** Medication **allergy** Medication **discontinued** Medication **dispensed** Medication **intolerance** Medication **order** Medication **offered** Medication **declined**
Physical finding	Physical exam finding
Preference	**Patient** preference **Provider** preference
Procedure	Procedure **adverse event** Procedure **history** Procedure **intolerance** Procedure **order** Procedure **result** Procedure **assessment of** Procedure **offered** Procedure **declined** Procedure **performed**
Risk category/assessment	Risk category/assessment
Screening	Screening **result**
Substance	Substance **administered** Substance **adverse event** Substance **allergy** Substance **intolerance** Substance **ordered** Substance **declined**
Symptom	Symptom **active** Symptom **assessed**
System characteristic	System characteristic
Transfer of care	Transfer **from** Transfer **to** Location current

Quality Data Flow Attributes and Associated Choices

Data flow attributes and associated choices are listed in Tables 3 through 6 for 1) sources, 2) recorder, 3) setting, and 4) health record field. These data flow choices were developed from a set of existing measures and expectations for future measures; the list of options will expand as new authoritative sources are identified.

Table 3: Data Flow—Sources

- Any Clinician*
- Care Manager*
- Certified Nurse Assistant (CNA)*
- Certified Nurse Midwife (CNMW)*
- Certified Registered Nurse Anesthetist (CRNA)*
- Clinical Medical Assistant (CMA)*
- Clinical Nurse Specialist (CNS)*
- Clinical Trial Coordinator*
- CPOE
- Electronic Monitoring Device
- EMS Staff*
- Enterostomal Therapist
- e-prescribing
- Family Member*
- Laboratorian/Lab Tech*
- Laboratory Information System
- Laboratory Modality
- Licensed Practice/Vocational Nurse (LP/VN)*
- Manually Operated Device
- Modality Device (Digital x-ray, U/S)*
- Monitoring Device*
- Nurse*
- Nurse Practitioner (NP)*
- Occupational Therapist
- Other Clinician*
- Other Healthcare Team Member*
- Patient*
- Patient Proxy*
- Pharmacist*
- Pharmacy Management System (PhMS)*
- Physical Therapist*
- Physician*
- Physician Assistant*
- Radiologist*
- Radiology Information System
- Registered Nurse (RN)*
- Registration Clerk*
- Specialty Driven Therapist
- Speech/Language Pathology Therapist
- Triage Nurse*
- Ultrasonographer*

Black print = person, Blue print = device/machine,* = also listed as a recorder

Table 4: Data Flow—Recorders

- Any Clinician*
- Care Manager*
- Certified Nurse Assistant (CNA)*
- Certified Nurse Midwife (CNMW)*
- Certified Registered Nurse Anesthetist (CRNA)*
- Clinical Medical Assistant (CMA)*
- Clinical Nurse Specialist (CNS)*
- Clinical Trial Coordinator*
- Dentist
- Dietician
- Electronic Monitoring Device
- EMS Staff*
- Family Member*
- Laboratorian/Lab Tech*
- Licensed Practice/Vocational Nurse (LP/VN)*
- Modality Device (Digital x-ray, U/S)*
- Monitoring Device*
- Nurse*
- Nurse Practitioner (NP)*
- Occupational Therapist
- Operating Room Clerk
- Other Clinician*
- Other Healthcare Team Member*
- Patient*
- Patient Proxy*
- Payer
- Pharmacist*
- Pharmacy Benefit Manager
- Pharmacy Management System (PhMS)*
- Physical Therapist*
- Physician*
- Physician Assistant*
- Protocol
- Provider
- Radiologist*
- Radiology Technician
- Registered Nurse (RN)*
- Registration Clerk*
- Researcher
- Respiratory Therapist
- RxHub/Surescripts
- Student
- Technician
- Triage Nurse*
- Ultrasonographer*
- Unit Clerk

Black print = person, Blue print = device/machine,* = also listed as a source

Table 5: Data Flow—Settings

- Acute Care Facility
- Ambulatory
- Ambulatory Community Based
- Ambulatory Hospital Based
- Ambulatory Surgicenter
- Emergency Department
- EMS Entity
- Home
- Home Care
- Home Hospice
- Hospice/Palliative Care
- Hospital
- Inpatient
- Nursing Home
- Postacute Care
- Skilled Nursing Facility

Table 6: Data Flow—Health Record Fields*

- Administering Agent/Vendor
- ADT
- Advanced Directives
- Allergy List
- Allergy Repository
- Allergy Service
- Ambulatory e-Pharmacy Management System
- Anesthesia Record
- Autopsy Record
- Continuity of Care Record
- Clinical Documentation
- Clinical Note
- Consult Summary Document
- Diagnosis Field/Claims File
- Discharge Summary
- Electronic Record Exam Section
- Electronic Record Vital Signs/ Examination Section
- Emergency Department Clinical Note
- Emergency Department Evaluation Summary
- Emergency Department Notes, Narrative Text or Encoded
- Emergency Management System Form
- E-prescribing
- Imaging Modality (e.g., Ultrasound)
- Immunization Record
- Master Patient Index
- Medical Device
- Medication Administration Record
- Modality (e.g., PACS System)
- Monitoring Device
- Narrative Text Note
- Nursing Documentation
- Nursing Note
- Operating Room Management System
- Operative Report
- Patient Care Task List
- Patient Request
- Pharmacy Information Management System
- Pharmacy Management System (PhMS)
- Plan of Care Actual Outcome
- Plan of Care Diagnosis
- Plan of Care Expected Outcome
- Plan of Care Intervention Delivered
- Plan of Care Planned Intervention
- Problem List
- Protocol
- Radiology Information System
- Registry
- Social History
- Survey Instrument
- Transition Record
- Triage From
- Vital Signs

*From containers such as EHR, PHR, HIE, etc.

Example Measures

Following is an example of two future EHR-derived measures that would use the QDS and data flow elements. Two current measures, one intended for the ambulatory setting and one for the inpatient setting, were selected, and retooling options are discussed to demonstrate how the selection of QDS and data flow elements can modify the process. The first is ambulatory based, seeking the percentage of patients with coronary artery disease (CAD) who were prescribed antiplatelet therapy (Tables 7 and 8). The second seeks to determine the percentage of patients admitted to a hospital who receive prophylaxis for venous thromboembolism (VTE) or documentation regarding why none was given (Table 9).

Example Measure 1: Antiplatelet Therapy for CAD (Ambulatory)

This measure identifies the percentage of patients with CAD who were prescribed antiplatelet therapy.[19]

Table 7: Percentage of Patients with CAD Who Were Prescribed Antiplatelet Therapy

DENOMINATOR	NUMERATOR	EXCLUSION
All patients with CAD and >18 years and encounters with the physician ■ ICD-9-CM codes for CAD *OR* ■ CPT diagnosis codes related to CAD *AND* ■ CPT codes for patient visit ■ Patient's age is >18 years.	Patients prescribed antiplatelet therapy (aspirin, clopidogrel, or combination of aspirin and dipyrimadole) ■ Drug list *OR* ■ CPT-II code: 4011F Oral antiplatelet therapy prescribed.	Documentation of **medical reason(s)** for not prescribing antiplatelet therapy [CPT-II code 4011F-1P]: ■ Active bleeding in the previous six months, which required hospitalization(s) or transfusion(s); *OR* ■ Aspirin/clopidogrel allergy/intolerance (ICD-9-CM exclusion codes); *OR* ■ Other medical reason(s) documented by the practitioner for not prescribing antiplatelet therapy *OR* Documentation of **patient reason(s)** for not prescribing antiplatelet therapy (e.g., economic, social, religious) [CPT-II code 4011F-2P] *OR* Documentation of **system reason(s)** documented by the practitioner for not prescribing antiplatelet therapy [CPT-II code 4011F-3P]

Per Patient: Whether or not patient was prescribed antiplatelet therapy.

Per Patient Population:
Percentage of all patients who were prescribed antiplatelet therapy.
Percentage of patients who were prescribed antiplatelet therapy, with all denominator exclusions applied.

The measure provides access to a set of medications and their respective National Drug Code (NDC)[20] drug names that represent antiplatelet therapy, including aspirin, clopidogrel, and combinations of aspirin and dipyrimadole. Using codes provided for each of the acceptable medications, an EHR or an e-prescribing electronic data stream can identify that a prescription was created for any one of them. However, medications taken over the counter and not part of a prescription, for example, aspirin 81 mg, require specific documentation that the patient was instructed to purchase and take the over-the-counter medication. Aspirin, therefore, will not be in a transaction stream, but it should be on the active medication list.

Example Measure 1: The QDS

A review of this measure for the QDS identified the quality data elements listed below. Today, this measure relies on existing coding systems (e.g., NDC, ICD-9-CM, CPT, CPT Category-II); the latest version does include some SNOMED coding for clinical concepts. It is expected that EHRs will capture all of this information electronically as a byproduct of direct clinical care and transactions. Appropriate coding systems for defining each element will evolve in the future. As clinical data become available for measurement, the requirement for attestation for inclusion or exclusion of quality data elements will be drastically reduced.

- Active diagnosis of CAD,
- Birth date,
- Patient visit,
- Aspirin therapy prescribed,
- Clopidogrel therapy prescribed,
- Dipyrimadole therapy prescribed,
- Past history of active bleeding,
- Antiplatelet therapy allergy or intolerance,
- Medical reasons for exclusion,
- Patient reasons for exclusion,
- System reasons for exclusion.

Example Measure 1: Data Flow

Even though the measure currently uses CPT-II codes to represent physician attestation that antiplatelet therapy was prescribed, entry of aspirin as an active medication on the medication list will ensure that the medication list is more accurate and focused on all medications and over-the-counter agents, and it will also enable more effective monitoring of medication interactions. The data flow category framework established by HITEP allows a measure developer to select detailed elements, following the data workflow, that represent the preferred meaning. In this example, rather than physician attestation that antiplatelet therapy has been prescribed (CPT-II code: 4011F Oral antiplatelet therapy prescribed), a retooled measure may require that the medication "health record field" refers to the medication list. Similarly, a clinician other than a physician may perform medication reconciliation such that the data source remains the patient or patient proxy (perhaps through direct communication with a clinician or electronically through a PHR patient-generated active medication list). These elements are described more clearly in Table 8. Note that some elements, depending on local workflow, may be entered by clinicians other than physicians. Addressing data flow will help to reduce the burden of documenting the specified information for any one individual at all locations.

Table 8: Quality Data Elements and Data Flow Attributes for CAD/Antiplatelet Measure

QUALITY DATA ELEMENT	SOURCE	RECORDER	SETTING	HEALTH RECORD FIELD
Active coronary artery disease diagnosis	Physician	Physician	Ambulatory	Problem list
Birth date	Patient *OR* patient proxy	Clinician, patient, patient proxy	Ambulatory	Demographics
Patient ambulatory encounter	Physician	Physician	Ambulatory	Billing
Aspirin order	Physician	Physician	Ambulatory	Medication list (active)
Clopidogrel order	Physician	Physician	Ambulatory	Medication dispensed*
Dipyrimadole order	Physician	Physician	Ambulatory	Medication dispensed*
Past history active bleeding	Physician, patient, patient proxy	Clinician	Ambulatory	Problem list
Antiplatelet therapy allergy or intolerance	Patient, patient proxy, clinician	Clinician, patient, patient proxy	Ambulatory	Allergy list
Clopidogrel allergy	Patient, patient proxy, clinician	Clinician, patient, patient proxy	Ambulatory	Allergy list
Dipyrimadole allergy	Patient, patient proxy, clinician	Clinician, patient, patient proxy	Ambulatory	Allergy list
Medical reasons for exclusion	Physician	Physician	Ambulatory	Documentation
Patient preference reasons for exclusion	Patient, patient proxy	Clinician	Ambulatory	Documentation
System reasons for exclusion	Healthcare system	Clinician	Ambulatory	Documentation

*Note that in this example data elements used to define this measure are modified to use data elements of higher quality (e.g., use of problem list for diagnosis instead of billing diagnosis). Because each element is defined within a measure based on the expected authoritative source and health record field, specifications can be more simply stated. Measure requirements can also require the use of certified EHR components and functions such that EHRs can be implemented more effectively to use components designed for more effective patient care. Note that in this ambulatory measure example, the "health record field" assignment is different from that suggested in the original measure. The original requirement was that antiplatelet medication is prescribed, and that can be represented as the presence of an order or the presence of the medication on the active medication list. Although not entirely under the control of the ordering physician, the QDS and data flow framework allow a measure to determine a more patient-focused step—that the medication prescription was filled and dispensed. The measure developer determines which elements and data flow objects to select. However, this framework provides measure developers with the ability to raise the bar and to expect greater accountability for assurance of impact for patients and consumers.

Example Measure 2: VTE Prophylaxis (Inpatient)

This measure assesses the number of patients who received VTE prophylaxis or who have documentation regarding why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission.[21] See Table 9.

The measure provides access to a set of drug names that represent VTE prophylaxis, including low dose unfractionated heparin, low molecular weight heparin, fondaparinux, and warfarin. A table of acceptable mechanical interventions for prophylaxis is also provided (venous intermittent compression devices and others). If codes for each of the acceptable medications are provided, an inpatient EHR can identify that one of the required medications has been administered or that a mechanical intervention has been used. Exclusions for medical conditions or procedures that would create a risk for bleeding could also be identified in a relatively straightforward manner using electronic data from a fully implemented EHR. Some of the exclusions, comfort measures only, and clinical trials for treatment of related conditions require standardization efforts for clinical documentation in a paper environment as well as in an electronic care environment. Provider preference is also somewhat vague.

Table 9: VTE Prophylaxis (CMS Measure)

DENOMINATOR	NUMERATOR	EXCLUSION
All patients admitted to the hospital.	Patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given: ▪ the day of or the day after hospital admission ▪ the day of or the day after surgery end date for surgeries that start the day of or the day after hospital admission.	▪ Patients <18 years ▪ Patients who have a length of stay (LOS) <2 days and >120 days ▪ Patients with Comfort Measures Only documented ▪ Patients enrolled in clinical trials ▪ Patients who are direct admits to intensive care unit (ICU), or transferred to ICU the day of or the day after hospital admission with ICU LOS = one day ▪ Patients with ICD-9-CM Principal Diagnosis Code of Mental Disorders or Stroke ▪ Patients with ICD-9-CM Principal or Other Diagnosis Codes of Obstetrics or VTE ▪ Patients with ICD-9-CM Principal Procedure Code of Surgical Care Improvement Project (SCIP) VTE selected surgeries.

Example Measure 2: The QDS

A review of this measure for the QDS identified the following quality data elements:

- Admission to hospital,
- Hospital discharge,
- Low dose unfractionated heparin administered,
- Mechanical VTE prophylaxis completed,
- Low molecular weight heparin administered,
- Fondaparinux administered,
- Warfarin administered,
- Provider reason for not giving VTE prophylaxis,
- Birth date,
- Comfort measure only,
- Clinical trial enrollment,
- Hospital intensive care unit admission,
- Mental disorders active diagnosis,
- Obstetric diagnoses contraindicating VTE prophylaxis,
- VTE active diagnosis,
- Patient reason for not giving VTE prophylaxis, and
- Surgical procedures with risk for VTE.

Example Measure 2: Data Flow

As with the ambulatory example provided earlier, the data flow category framework established by HITEP allows a measure developer to select detailed elements, following the data workflow, that represent the preferred meaning. In this example, the chart abstracter can consult the detailed specification for guidance on which notations (often free text) in the clinical record meet the intent for each data element. Providing more detail on authoritative sources, recorders, settings, and health record fields results in more specific and succinct specifications. These elements are described more clearly in Table 10. Note that some elements, depending on local workflow, may be entered by clinicians other than physicians, except when entry by a physician is required to impart the expected meaning.

As with the ambulatory measure example, this measure is more simply defined by identifying the authoritative sources for each of the data elements required. Measures retooled in this manner will encourage the actual use of EHR components routinely for real-time, direct care to patients. Functional requirements for vendor systems and innovation will focus on components of the EHR that are essential for safe, efficient, and effective care.

Preferred Future State

The QDS framework provides a structure within which to apply quality measure policy recommendations. A few HITEP-I summary recommendations can be achieved as a direct effect of the QDS (Figure 8).

Table 10: Quality Data Elements and Data Flow Attributes for VTE Prophylaxis Measure

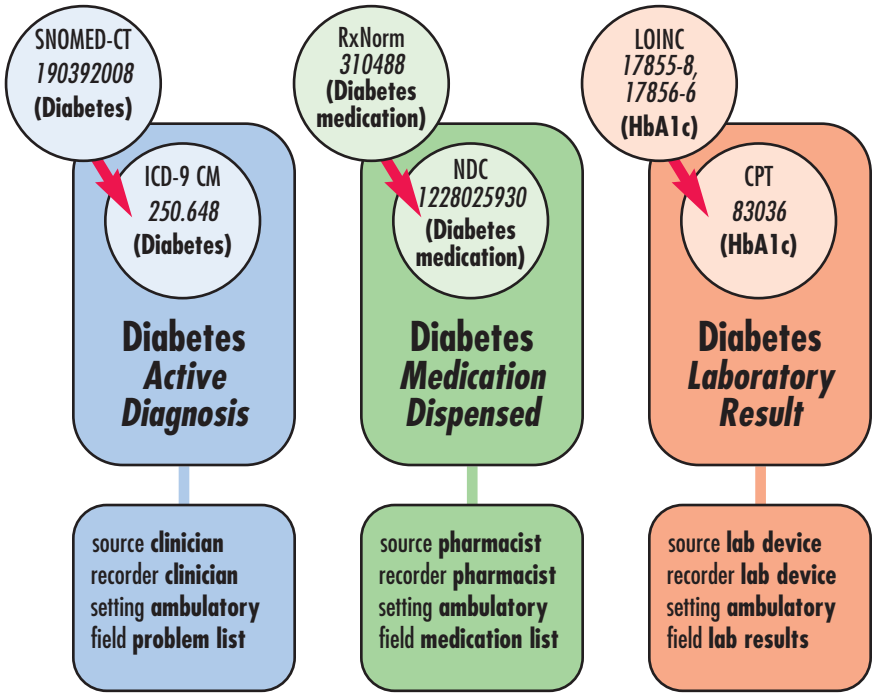
QUALITY DATA ELEMENT	SOURCE	RECORDER	SETTING	HEALTH RECORD FIELD
Admission to hospital	Physician	Clinician	Inpatient	Admission, discharge, transfer
Hospital discharge	Physician	Clinician	Inpatient	Admission, discharge, transfer
Low dose unfractionated heparin administered	Nurse	Nurse	Inpatient	Medication Administration record
Mechanical VTE prophylaxis completed	Nurse	Nurse	Inpatient	Nursing intervention documentation
Low molecular weight heparin administered	Nurse	Nurse	Inpatient	Medication Administration record
Fondaparinux administered	Nurse	Nurse	Inpatient	Medication Administration record
Warfarin administered	Nurse	Nurse	Inpatient	Medication Administration record
Provider reason for not giving VTE prophylaxis	Physician	Physician	Inpatient	Medication list, problem list
Birth date	Patient, patient proxy	Clinician, registration clerk	Inpatient	Patient demographics
Comfort measure only	Physician, midlevel practitioner	Physician	Inpatient	Order
Clinical trial	Physician, midlevel practitioner	Physician, midlevel practitioner	Inpatient	Registry, pharmacy management system
Hospital ICU admission	Physician	Clinician	Inpatient	Admission, discharge, transfer
Mental disorders active diagnosis	Physician	Physician	Inpatient	Problem list
Obstetric diagnoses contraindicating VTE prophylaxis	Physician	Physician	Inpatient	Problem list

more

Table 10: Quality Data Elements and Data Flow Attributes for VTE Prophylaxis Measure

QUALITY DATA ELEMENT	SOURCE	RECORDER	SETTING	HEALTH RECORD FIELD
VTE active diagnosis	Physician	Physician	Inpatient	Problem list
Patient preference for not giving VTE prophylaxis	Patient	Clinician	Inpatient	Medication list, problem list
Surgical procedures performed with risk for VTE	Physician	Physician	Inpatient	Procedures performed

Figure 8: Transition to Preferred Code Sets



Using the standard element framework of the QDS, code lists can be migrated to preferred code sets.

1. **Evaluate the quality of data types as the criterion for measure endorsement.** If quality measures utilize the QDS, the data types are explicitly defined by the measure developer.
2. **Use coded, interdisciplinary clinical problem lists in place of billing codes.** To achieve this, two changes must occur. First, the data flow must specify the field as "problem list" rather than as "billing." However, this would not solve the problem entirely, because some EHRs use billing codes in the problem list as well. Therefore, the code set that is used to describe diagnoses must change from ICD-9-CM to SNOMED-CT, as recommended by HITSP. Figure 8 demonstrates replacing an existing standard element using ICD-9-CM with SNOMED-CT or ICD-10. This change would require evidence of equivalency between the two standard elements, or the measure may evaluate different populations.
3. **Utilize HITEP data types and HITSP-recommended code sets.** Figure 8 also demonstrates transitioning code sets from NDC to RxNorm (for medications) and from CPT to LOINC (for laboratory tests).
4. **Distinguish allergies and side effects from each other.** The QDS contains a data type for "medication allergy" but does not have a data type for "medication side effect."

We will need a path to transition from existing measure specifications, code sets, and information locations. Not only does the QDS provide the framework to represent the current information required for quality measurement, but it also indicates specific leverage points for transition: HITSP-recommended standard element code sets and code lists, as well as preferred data flow EHR fields. This transition does not imply simply replacing administrative data with clinical information from EHRs; rather, it utilizes information from the complete, rich, clinically relevant sources of data. Measurement of efficiency will require an integrated system combining claims and clinical information. Clinical information alone will not be sufficient. Conversely, the use of administrative codes exclusively may be problematic. For example, inpatient pediatric intensive care services include bedside pulmonary function testing; the latter is not assigned a separate CPT code when provided as part of critical care services.[22] If a billing transaction inadvertently lists the procedure with an additional charge, separate reporting of this service could be seen as abuse or fraud. Hence, data about the frequency of bedside pulmonary function use cannot be retrieved from billing transactions for patients with inpatient pediatric intensive care services. The use of clinical terms provides greater flexibility for quality elements. Maintaining currency with administrative code sets is also essential (ICD-9-CM to ICD-10, as an example).

The QDS will allow clinical information systems to include the standardization of information incrementally, limiting the cost of otherwise "big bang" efforts. By maintaining data consistency with respect to coding and clinical context, such implementation of the QDS should lower the time and cost of EHR implementations as compared to the current state.

Expert Panel Recommendations

RECOMMENDATION 1: NQF should develop and maintain the QDS with the involvement of all stakeholders. Specific recognized standards and taxonomies should be used. The QDS should be hosted in a publicly available, centrally located, web-based repository such as the United States Health Information Knowledge Base (USHIK)[23] with content (quality measures and definitions) submitted by measure developers. A measure authoring tool should be created to facilitate the development of EHR-ready measures that can also be used as a resource by the stakeholders and as a conduit for reporting gaps and gathering feedback. Maintenance of the QDS should support the evolving data requirements of meaningful use of EHRs in 2011, 2013, and 2015, as defined by the Health IT Policy Committee[24] and the Health IT Standards[25] Committee.

RECOMMENDATION 2: Develop measures that use the richness of all available electronic data, focusing on clinical, patient-centered outcomes. Quality measures should leverage clinical data captured in the EHR as a byproduct of routine clinical care. Quickly retool and test existing high-priority measures to take advantage of these electronic data and develop standard methods for using the QDS in defining new measures.

RECOMMENDATION 3: Communicate with all stakeholders and seek their buy-in, and educate and train the quality measure supply chain (e.g., study designers, guideline developers, quality measure developers, performance reporting consumers, EHR vendors, and CDS developers) regarding the QDS and its associated authoring tool. Provide resources to measure developers to retool and test high-priority measures specified in the QDS using the full range of available electronic data. Roles, responsibilities, relationships, and opportunities of stakeholders in the quality measure ecosystem should be enumerated (e.g., the Office of the National Coordinator for Health Information Technology [ONC],[26] the Health IT Policy and Standards Committees, CCHIT,[27] CMS, HITSP,[28] vendors, providers, measure developers, and guideline developers).

RECOMMENDATION 4: Set a timeline for QDS implementation, including demonstrated functionality and workflow assessment, and enumerate the essential activities and stakeholders. Perform comparative testing to assess the validity and reliability of performance measures derived from EHR clinical data.

RECOMMENDATION 5: NQF should move swiftly to incorporate the QDS into the Consensus Development Process. Requesting that measure developers incorporate the QDS model into their measure submissions will ease the process of incorporating endorsed measures into EHR systems.

RECOMMENDATION 6: Future quality measure development should use the National Priorities and Goals as a guide. The QDS maintenance activity should track and assign data quality scores for the data requirements for emerging measures using the QDS.

Considerations for Meaningful Use

Although outside the scope of work requested by AHRQ, HITEP agreed that it would be timely and appropriate for NQF to offer an approach to the measurement of "meaningful use." In the next six to eight months, NQF should endorse a starter set of EHR-based performance measures that reflect effective or "meaningful" use of HIT functions for measurement and improvement. The effort requires the following steps:

- Develop and approve a set of HIT-sensitive criteria that can be used to identify clinical performance measures that highlight the effect of meaningful use of HIT.
- Use the HIT-sensitive criteria to systematically review the NQF portfolio of endorsed/pipeline measures to identify a starter set of HIT-sensitive measures that highlight meaningful HIT use in topical areas related to the National Priorities and high-impact conditions.
- Encourage measure developers to work with NQF to further retool HIT-sensitive measures to conform to EHR-based specifications.

NQF has effectively utilized this approach in the disparities arena. To address measures that are especially sensitive to disparities in care, NQF has identified a set of primary and secondary criteria used to identify and endorse a set of measures that are sensitive to the potential effects of disparities on quality of care. The HIT-sensitive criteria can be used to highlight measures that demonstrate the effect of the use of core HIT functions on clinical quality:

- e-prescribing,
- preventive services reminders,
- health information exchange, and
- CDS.

The criteria for prioritizing measures for retooling are as follows:

- Is the measure related to a National Priority or a high-impact condition? Does it explicitly impact value/cost?
- Does the measure effectively leverage HIT?
- Does the measure reflect a more credible representation of quality?
- Is the measure sensitive to effective coordination of care or data sharing across sites, providers, and patients?
- Does the measure reflect the use of innovative, patient-centered data sources (bidirectional)?

HIT-sensitive criteria may include the following:

- **Does the measure depend on the presence of an EHR and its effective use?**

  In order to efficiently report on the measure and demonstrate good results, the organization would need to have implemented a capable EHR, and the clinicians would need to be using it effectively.

- **Does the measure reflect the use of innovative, patient-centered data sources?**

  Examples:

  1. The measure includes an assessment of patient home monitoring (e.g., blood glucose monitoring).
  2. The measure includes patient-reported health status (e.g., completion of PHQ-9 depression screening tool by patients).

- **Is the measure sensitive to effective coordination of care or data sharing across sites and providers?**

  Examples:

  1. Coordination of care examples: Measures include information that would need to be shared across sites (e.g., medication reconciliation) and information related to coordination between clinicians (e.g., timely receipt of consult notes).
  2. Data-sharing example: Percent of surgical site infections (SSIs) occurring within 30 days after operative procedure if no implant is left in place. This includes the capacity to capture infection information from ambulatory care to calculate an accurate SSI rate.

With more than 500 measures in the NQF portfolio, available measures could be deemed "HIT sensitive." The HIT-sensitive starter set should be comprehensive and should apply across healthcare settings. These measures will require the inclusion of key clinical data that are available only in EHR systems (e.g., data from problem list and medication lists) and that encourage the use of essential components of the EHR.

Future Work

Maintenance of the QDS

The QDS contains quality data elements for measurement use. As measures are created and continually updated, the QDS will need to reflect these changes. HITEP recommended that maintenance of the QDS content should occur every six months. As part of the NQF measure maintenance policy, updated measures shall include specifications using the QDS. In the near term, measure developers should classify data requirements using the framework of the QDS. To facilitate this process, NQF is developing a web-based measure authoring tool that will allow measure developers to choose elements from the QDS for each measure. A shared authoring tool also will allow measure developers to share quality data elements used in other measures and by other measure developers. Although this first compilation of the QDS was completed by NQF, as measures are created and updated, QDS content generation will be defined by the content experts—measure developers. NQF will serve as the convener of the QDS and will work to encourage the development and maintenance of high-quality data elements and to minimize the duplication of similar data elements. HITEP has acknowledged that NQF should oversee this reconciliation of quality data elements. These processes and policies are forthcoming.

The QDS will be used to standardize data requirements of quality measures. It also can be used to empower CDS and public health applications. Therefore, the QDS should be considered a public good. HITEP recommended that NQF store the QDS and share it with the general public. The standard elements used by the QDS also will be defined using the measure authoring tool.

Maintenance of Standard Code Sets

Standard elements are best housed in a code set repository so the elements also may be reused for routine clinical information system implementations, for guideline compliance, and for CDS functions.

As each set of terms or codes (herein titled "code set" and used synonymously with "value set," or a set of specific values or codes) is created, measure developers will establish expert panels to represent the specific intent of the data element for consistency in performance reporting. Thus, for reuse, the specific meaning must be represented in the title and the purpose of the code set. A consortium of multiple research and public health stakeholders met in Salt Lake City, Utah, on March 11-12, 2007, to establish international guidelines for representing code sets.[29] The guidelines included specific core requirements in addition to the actual codes used (Table 11).

In many respects, the QDS uses a high-impact subset of code sets for the implementation of clinical systems to commonly identify problems, medication lists, allergies, and other significant data types identified in this HITEP report consistently across electronic health systems. Impacting the implementation of clinical systems prospectively will enable more facile incorporation of performance monitoring, measurement, and CDS.

A code set repository, or registry, is required that contains the standard elements from which new quality data elements can be selected. Some of these elements will be represented in more than one code type because, in the near term, certain code systems will be commonly used in electronic transactions. Alternate code system sets are required to enable transition to future use (e.g., ICD-9-CM to ICD-10) and also to enable transition to preferred code systems to provide more clinical context (e.g., SNOMED-CT). The examples provided include SNOMED and ICD-9-CM. CMS has indicated that there will be movement from ICD-9 to ICD-10 by 2013. Administrative and clinical data are required to maintain consistency with global public health efforts that rely on ICD-10. Harmonization between SNOMED and ICD-10 is required to allow the appropriate management of code sets in the implementation and operation of EHRs.

Using an example of an active diagnosis of diabetes, a number of options follow:

- diabetes <all> by ICD-9
- diabetes <all> by SNOMED
- diabetes <all> by ICD-10
- diabetes type 1 by ICD-9
- diabetes type 1 by SNOMED
- diabetes type 1 by ICD-10
- diabetes type 2 by ICD-9
- diabetes type 2 by SNOMED
- diabetes type 2 by ICD-10

These differences are more easily displayed by listing the standard element and providing links to each of the related code sets:

- diabetes <all> ICD-9 SNOMED ICD-10
- diabetes type 1 ICD-9 SNOMED ICD-10
- diabetes type 2 ICD-9 SNOMED ICD-10

Measure Authoring Tool

A near-term future step in this process is to develop a measure authoring tool to allow measure developers to select quality data elements, apply mathematical operators and logic, and create a computer-readable measure specification. As noted in earlier discussions, some concepts are most effectively handled as

Table 11: Core Requirements to Define Code Sets

CODE SET CHARACTERISTIC	DESCRIPTION
Code set identifier	A common identifier registered with an appropriate standard organization for common electronic record usage (e.g., HL7 or ISO or ANSI).
Code set name	Name for the code set. A standard naming convention will be helpful.
Code set definition	Brief description about the concepts in the code set (code set members) as well as the general purpose of the code set. Example: All antiplatelet medications used as secondary prevention to decrease the risk of acute myocardial infarction in patients with coronary artery disease. The description clarifies the intended use such that reuse will be encouraged only if the same meaning is intended.
Code system information	The code system used for building the code set and the code system version used for building the value set.
Code set type	Static (all codes are specified, or enumerated) or Dynamic (based on criteria, e.g., identifying only the medication class Angiotensin Converting Enzyme Inhibitors, which changes as medications are approved or removed from the market).
Code set version	Reference to the edition of the code set, potentially represented as a date (YYYYMMDD).
Code set status	Active (current), Inactive (retired).
Date revised	Date of the current version (revision) of the code set.
Date created	Generally refers to the published date for the first version of a code set.
Code set effective date	The code set may be based on a coding system that is updated annually (such as ICD-9). A code set based on the next update of the coding system would have an effective date after publication of the coding system with time for implementers to be ready.
Code set expiry date	When the code set or coding system on which it is based will no longer be active (expires).

part of the measure specification within this future measure authoring tool. Logic, ranges, and concept pairing are expected to occur using such a tool by incorporating existing quality data types within logical expressions. Furthermore, the authoring tool will address interdependencies between data elements such as relative setting and timing of events.

Quality Data Type Migration to EHRs

"Care goal," for example, is a common element used within nursing plans of care in various care settings.[30] Such goals as "ambulation x meters," "improved gas exchange," or "patient understanding of disease-specific education" can be discretely defined as functional status, physical finding, and communication in the current model, respectively.

A future action also will require enhancing some of the concepts in the EHR Functional Model and creating new concepts and/or a Quality Profile in HL7 that represents the appropriate concepts as requirements in EHRs. It is expected that HITSP and the Health IT Standards Committee will identify standards for interoperability to allow data entered once, in EHRs, to flow, as appropriate, to registries and other receivers of data.

Related Topics

The process of public comment resulted in the emergence of issues related to quality measures and the data they contain that must be addressed but that are outside the scope of HITEP:

1. Privacy regulations have the potential to prohibit clinical data element collection by external parties such as payers who now rely on claims information for measurement. To avoid dual reporting (claims data to third parties and clinical information for internal reporting and analysis), clarification of access issues to EHR data elements should be addressed at the same pace as data elements and code sets are specified.
2. Intellectual property concerns for registries and other data repositories, as well as for risk-adjustment algorithms, must be addressed within the infrastructure of managing the QDS and measures.
3. Concurrent with efforts to enhance clinical data coding and standardization in EHRs, ONC and the Health IT Policy and Standards Committees should address the alignment of federal and state administrative data systems. Without alignment, serious disruption to national and state measurement of quality, safety, and efficiency could result.
4. Migration of code sets requires an understanding of the relationships between various code sets. For example, a chain of rules and relationships exist between CPT and ICD-9-CM, but these rules are expressed in various locations—indexes, notes, chapter beginnings, and more. Without the rules, miscoding can occur. CPT or ICD-9-CM code selections are different from LOINC or NDC code selections, because the latter code sets are more precise and unambiguous.

Notes

1 NQF, *Recommended Common Data Types and Prioritized Performance Measures for Electronic Healthcare Information Systems,* Washington, DC: NQF; 2008.

2 NQF, *Information Technology and Healthcare Quality: A National Summit.* Washington, DC: NQF; 2003.

3 Institute of Medicine, *Fostering Rapid Advances in Health Care: Learning from System Demonstrations,* Washington, DC: National Academies Press; 2002.

4 National Committee on Vital and Health Statistics, *Information for Health: A Strategy for Building the National Health Information Infrastructure.* Washington, DC: Department of Health and Human Services; 2001. Available at http://aspe.hhs.gov/sp/NHII/Documents/NHIIReport2001/default.htm. Last accessed June 2009.

5 U.S. Congress, American Recovery and Reinvestment Act of 2009, February 17, 2009. Available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1enr.pdf. Last accessed June 2009.

6 HITSP is a cooperative partnership between the public and private sectors for the purpose of achieving a widely accepted set of performance standards to enable widespread inter-operability among healthcare software applications. HITSP Interoperability Specifications for Quality, "IS 06." Available at http://sp.org. Last accessed June 2009.

7 CCHIT was created by the DHHS Office of the National Coordinator for Health Information Technology to oversee private sector certification of HIT products.

8 The Continuity Assessment Record and Evaluation (CARE) tool is for use at acute care hospital discharge and at postacute care admission and discharge to measure the health and functional status of Medicare acute discharges and measure changes in severity and other outcomes for Medicare postacute care patients. Information is available at www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/PACPR_RTI_CMS_PAC_PRD_Overview.pdf. Last accessed July 2009.

9 The MDS is a potentially powerful tool for implementing standardized assessment and for facilitating care management in nursing homes for Medicare patients. Available at www.cms.hhs.gov/Nursinghomequalityinits/25_NHQIMDS30.asp. Last accessed July 2009.

10 The instrument/data collection tool used to collect and report performance data by home health agencies is called the Outcome and Assessment Information Set (OASIS). Available at www.cms.hhs.gov/HomeHealthQualityInits/01_Overview.asp#TopOfPage. Last accessed July 2009.

11 Donabedian A, Evaluating the quality of medical care, *Milbank Mem Fund Q,* 1966;44(1):166-203.

12 The EHR Functional Model Glossary (2009) defines a code set as "Under HIPAA, this is any set of codes used to encode data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes. This includes both the codes and their descriptions. HIPAA requires every provider who does business electronically to use the same health care transactions, code sets, and identifiers. Code sets are the codes used to identify specific diagnosis and clinical procedures on claims and encounter forms." The glossary provides the following references: http://aspe.hhs.gov/admnsimp/faqcode.htm and www.cms.hhs.gov/TransactionCodeSetsStands/. Last accessed July 2009.

13 SNOMED CT (Systematized Nomenclature of Medicine-Clinical Terms) is a comprehensive clinical terminology, originally created by the College of American Pathologists (www.cap.org). As of April 2007, it is owned, maintained, and distributed by the International Health Terminology Standards Development Organisation (www.ihtsdo.org), a not-for-profit association in Denmark. More information is available at www.nlm.nih.gov/research/umls/Snomed/snomed_main.html. Last accessed June 2009.

14 RxNorm provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software, including those of First Databank, Micromedex, MediSpan, Gold Standard Alchemy, and Multum. By providing links between these vocabularies, RxNorm can mediate messages between systems not using the same software and vocabulary. More information is available at www.nlm.nih.gov/research/umls/rxnorm. Last accessed June 2009.

15 The National Drug File-Reference Terminology (NDF-RT) is produced by the U.S. Department of Veterans Affairs, Veterans Health Administration (VHA). NDF-RT is an extension of the VHA National Drug File (NDF). It organizes the drug list into a formal representation. NDF-RT is used for modeling drug characteristics including ingredients, chemical structure, dose form, physiologic effect, mechanism of action, pharmacokinetics, and related diseases. More information is available at www.nlm.nih.gov/research/umls/sourcereleasedocs/2008AB/NDFRT/. Last accessed June 2009.

16 The purpose of LOINC (Logical Observation Identifiers Names and Codes) is to facilitate the exchange and pooling of clinical results for clinical care, outcomes management, and research by providing a set of universal codes and names to identify laboratory and other clinical observations. The Regenstrief Institute, Inc., an internationally renowned healthcare and informatics research organization (www.regenstrief.org), maintains the LOINC database and supporting documentation and the RELMA (Regenstrief LOINC Mapping Assistant) mapping program. More information is available at http://loinc.org. Last accessed June 2009.

17 The HITSP Clinical Document and Message Terminology Component defines the vocabularies and terminologies utilized by HITSP specifications for Clinical Documents and Messages used to support the interoperable transmission of information. More information is available at http://hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=80. Last accessed June 2009.

18 The Health Quality Measures Format is the product of the Collaborative for Performance Measure Integration with EHR Systems, cosponsored by the American Medical Association, the National Committee for Quality Assurance, and the Electronic Health Record Association, a group of stakeholders in the physician performance measurement and quality improvement arena that has a shared goal to provide the industry with workable recommendations for performance measure use. More information is available at www.ama-assn.org/ama1/pub/upload/mm/370/collaborative-hqmf-0409.pdf. Last accessed August 2009.

19 American College of Cardiology, American Heart Association, and Physician Consortium for Performance Improvement, *Clinical Performance Measures: Chronic Stable Coronary Artery Disease, Tools Developed by Physicians for Physicians;* 2005. Available at www.ama-assn.org/ama1/pub/upload/mm/370/cadminisetjune06.pdf. Last accessed June 2009.

20 Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which is a universal product identifier for human drugs, maintained by the Food and Drug Administration. Available at www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm. Last accessed July 2009.

21 The Joint Commission, *Venous Thromboembolism (VTE) Core Measure Set, VTE-1: Venous Thromboembolism Prophylaxis.* Available at www.jointcommission.org/PerformanceMeasurement/PerformanceMeasurement/VTE.htm. Last accessed June 2009.

22 American Medical Association, Evaluation and Management/Other Evaluation and Management Services, in CPT 2009, p. 34.

23 The United States Health Information Knowledgebase is a metadata registry of healthcare-related data standards funded and directed by AHRQ with management support provided in partnership with CMS. Available at http://ushik.ahrq.gov/registry/index.html?Referer=Index. Last accessed July 2009.

24 The Health IT Policy Committee, a U.S. federal advisory committee, will make recommendations to the National Coordinator for Health Information Technology on a policy framework for the development and adoption of a nationwide health information infrastructure, including standards for the exchange of patient medical information. ARRA provides that the committee shall at least make recommendations on standards, implementation specifications, and certifications criteria in eight specific areas. Information is available at http://healthit.hhs.gov/portal/server.pt?open=512&objID=1269&parentname=CommunityPage&parentid=4&mode=2&in_hi_userid=10741&cached=true. Last accessed July 2009.

25 The Health IT Standards Committee is a U.S. federal advisory committee charged with making recommendations to the National Coordinator for Health Information Technology on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information. At first, the Health IT Standards Committee will focus on the policies developed by the Health IT Policy Committee's initial eight areas. Within 90 days of the signing of ARRA, the Health IT Standards Committee must develop a schedule for the assessment of policy recommendations developed by the Health IT Policy Committee, to be updated annually. In developing, harmonizing, or recognizing standards and

implementation specifications, the standards committee also will provide for the testing of the standards and specifications by the National Institute for Standards and Technology. Information is available at http://healthit.hhs.gov/portal/server.pt?open=512&objID=1271&parentname=CommunityPage&parentid=1&mode=2&in_hi_userid=10741&cached=true. Last accessed July 2009.

26 ONC is at the forefront of the Administration's HIT efforts and is a resource for all health system constituencies with an interest in the advancement and broad adoption of a nationwide HIE to improve healthcare. ONC is organizationally located within the Office of the Secretary of the U.S. Department of Health and Human Services. Information is available at http://healthit.hhs.gov/portal/server.pt?open=512&objID=1200&parentname=CommunityPage&parentid=1&mode=2&in_hi_userid=10741&cached=true. Last accessed July 2009.

27 Founded in 2004, and certifying electronic health records (EHRs) since 2006, the commission established the first comprehensive, practical definition of what capabilities were needed in these systems. The certification criteria were developed through a voluntary, consensus-based process engaging diverse stakeholders, and the Certification Commission was officially recognized by the federal government as a certifying body. Information is available at http://healthit.hhs.gov/portal/server.pt?open=512&objID=1200&parentname=CommunityPage&parentid=1&mode=2&in_hi_userid=10741&cached=true. Last accessed January 2009.

28 HITSP is a cooperative partnership between the public and private sectors. The panel was formed for the purpose of harmonizing and integrating standards that will meet clinical and business needs for sharing information among organizations and systems. Information is available at http://sp.org. Last accessed July 2009.

29 Consortium: The Centers for Disease Control and Prevention Public Health Information Network, HL7, LexGrid, UK Cancer Grid, U.S. National Cancer Institute, entitled the *Value Set Consortium. Summary of Value Set Consortium Minutes;* 2007. Available at www.termcorps.com/documents/value-set-summit-minutes-2007-03.doc. Last accessed June 2009.

30 Goals are common within care plan phases and often must be met in order to move a patient from one phase of a care plan to another. For example, for a patient to move from the post-operative recovery room to a surgical floor bed, certain vital signs must be stable. Whether these goals are considered met or not met may depend on clinician judgment. Parameters shall be set using QDS elements in decision support rules. A typical goal is expressed as an observation scheduled for some time in the future with a particular value in the observation value field. For example, a rule may state that the observation of a heart rate between 60 and 100 beats per minute be present at the time of discharge from recovery. A care plan may identify this heart rate as a goal for 30 minutes after entry to the recovery unit (adapted from HL7 Care Provision Model). Additionally, the EHR Functional Model direct care elements DC2.2, DC2.2.1.1, and DC2.2.1.2 refer to patient management using plans of care (HL7 EHR Workgroup Electronic Health Record – System Functional Model, Release 1.1, January 2009, Chapter Three: Direct Care Functions).

Appendix A
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Appendix B
Glossary

STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
care experience	patient care experience	Care experience is measured most often with a validated survey tool. The most common tool is the Consumer Assessment of Healthcare Providers and Systems (CAHPS®; details are available at www.cahps.ahrq.gov/default.asp).	The EHR Functional Model does not provide support for determination of patient care experience.
	provider care experience	Provider care experience gauges provider satisfaction with key processes in the healthcare delivery system. The Medicare Contractor Provider Satisfaction Survey (MCPSS) is designed to garner quantifiable data on provider satisfaction with the performance of Medicare fee-for-service contractors.[a] Most care experience surveys are local. Provider care experience is a factor in provider turnover.	The EHR Functional Model does not provide support for determination of provider care experience.
care goal	care goal	A goal is a defined target or measure to be achieved in the process of patient care. A typical goal is expressed as an observation scheduled for some time in the future with a particular value.	HL7 Care Provision Model
	care plan	The plan of care (care plan) is the structure that is used by all stakeholders, including the patient, to define the management actions for the various conditions, problems, or issues identified for the target of the plan. It is the structure through which the goals and care planning actions and processes can be organized, planned, communicated, and checked for completion.	HL7 Care Provision Model
communication	communication from patient	Receive response from a patient with respect to any aspect of the care provided.	EHR Functional Model DC.3.2 (Support Clinical Communication) LTC-NH EHR-S FP: DC.1.1.4 DC.1.5.1
	communication provider to provider	The provision of any communication from one clinician to another regarding findings, assessments, plans of care, consultative advice, instructions, educational resources, and more.	EHR Functional Model DC.3.2 (Support Clinical Communication) LTC-NH EHR-S FP: DC.1.1.4 DC.1.5.1

[a] Medicare Contractor Provider Satisfaction Survey (MCPSS). Information is available at **www.cms.hhs.gov/MCPSS/**.

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
communication *(continued)*	communication to patient	Providing any communication to the patient, for example, results, findings, plans for care, medical advice, instructions, educational resources, appointments, results, and more.	EHR Functional Model partially supports communication to the patient by: DC.3.2 (Support Clinical Communication) DC.1.6.2 (Manage Patient Specific Care Plan) DC.3.2.4 (Patient, Family, and Care Giver Education) DC.1.9 (Generate and Record Patient-Specific Instructions) DC.2.3.2 (Support for Medication and Immunization Administration) LTC-NH EHR-S FP: DC.1.1.4 DC.1.5.1
condition/diagnosis/problem		A problem, diagnosis, or condition is a scientific interpretation of result, assessment, and treatment response data that persists over time and tends to require intervention or management. It is used to guide planning, implementation, treatment, and evaluation. A problem or condition includes, but is not limited to, chronic conditions, diagnoses, symptoms, functional limitations, or visit- or stay-specific conditions.	EHR Functional Model DC.2.1.3 (Support for Identification of Potential Problems and Trend) DC.1.4.3 (Manage Problem List)
	diagnosis, active	A problem, diagnosis, or condition that is currently monitored or tracked or that is a factor that must be considered as part of the treatment plan in progress.	EHR Functional Model Glossary: Problem List DC.2.1.3 (Support for Identification of Potential Problems and Trend) DC.1.4.3 (Manage Problem List)
	diagnosis, factored risk	Potential for the development of problems or conditions determined by specific factors defined within the measure by the measure developer. Most often, these risks can be defined as a composite of several QDS elements that, based on evidence, in combination represent a risk of a specific condition or negative outcome.	The EHR Functional Model provides some support for assessment but no direct discussion of factored risk. DC.2.1.2 (Support for Patient Context-Driven Assessments) DC.2.1.3 (Support for Identification of Potential Problems and Trends)
	diagnosis, family history	Problems, conditions, and diagnoses existing currently or in the past for a patient's family members.	Problems, conditions, and diagnoses existing currently or in the past for a patient's family members.

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
condition/diagnosis/problem *(continued)*	diagnosis past history	Problems, conditions, and diagnoses that have occurred in the past for the patient under treatment.	Problems, conditions, and diagnoses that have occurred in the past for the patient under treatment. See ***www.bradenscale.com/.***
	diagnosis, risk of	Potential for the development of problems or conditions determined by a risk calculator scale. Examples: Braden Score for Predicting Pressure Sore Risk,* Morse Fall Risk Scale, Pneumonia Severity Index** * *Available at* ***www.bradenscale.com/.*** ** *Available at* ***htpda.ahrq.gov/clinic/psi/psicalc.asp.***	The EHR Functional Model provides some support for assessment but no direct discussion of risk calculators. DC.2.1.2 (Support for Patient Context Driven Assessments) DC.2.1.3 (Support for Identification of Potential Problems and Trends)
device		Device has been defined by the Food and Drug Administration (FDA), Department of Health and Human Services. Available at ***www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm.*** A device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." This definition provides a clear distinction between a medical device and other FDA-regulated products such as drugs. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug.	

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
device *(continued)*	device adverse event	In the instance of a quality measure, a device adverse event is an unexpected or dangerous reaction to a device. Serious adverse events are those that are fatal, life-threatening, permanently/significantly disabling, those that require or prolong hospitalization, and those that require intervention to prevent permanent impairment or damage. A time/date stamp is required, as are notations indicating whether item is patient reported and/or provider verified.	EHR Functional Model DC.1.4.1 (Manage Allergy, Intolerance, and Adverse Reaction List)
	device applied	Indication that equipment designed to treat, monitor, or diagnose a patient's status is in use. An example in a venous thromboembolism measure is that an antithrombotic device has been placed on the patient's legs to prevent thromboembolism.	DC.2.4.2 (Support for Non-medication Ordering) supports the ordering of a device, but no clear reference is identified to represent documentation that a device is in use.
	device declined	Equipment designed to treat, monitor, or diagnose a patient's status has been declined by the patient.	Some of the concepts are addressed in the following EHR Functional Profile sections. Patient refusal of a procedure, intervention, service, or treatment is not clearly defined in the EHR Functional Model. Related sections: DC.2.2.4 (Support Self Care) DC.1.3.1 (Manage Patient and Family Preferences) DC.1.3.3 (Manage Consents and Authorizations) DC.2.3.1.2 (Support for Patient Specific Dosing and Warnings) DC.1.3.2 (Manage Patient Advance Directives)
	device intolerance	Device intolerance is a reaction in specific patients representing a low threshold to the normal actions of a device. Side effects experienced do not represent adverse events or allergies. A time/date stamp is required, as are notations indicating whether the item is patient reported and/or provider verified.	EHR Functional Model DC.1.4.1 (Manage Allergy, Intolerance, and Adverse Reaction List)
	device offered	Equipment designed to treat, monitor, or diagnose a patient's status is offered to the patient.	EHR Functional Model DC.2.4.2 (Support for Non-medication Ordering) although "offered is not specified."

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
device *(continued)*	device order	Equipment designed to treat, monitor, or diagnose a patient's status is ordered.	EHR Functional Model DC.2.4.2 (Support for Non-medication Ordering)
diagnostic study	diagnostic study adverse event	In the instance of a quality measure, a diagnostic study adverse event is an unexpected or dangerous reaction to a diagnostic study. Serious adverse events are those that are fatal, life-threatening, permanently/significantly disabling, those that require or prolong hospitalization, and those that lead to congenital anomaly or require intervention to prevent permanent impairment or damage. A time/date stamp is required, as are notations indicating whether item is patient reported and/or provider verified.	EHR Functional Model DC.1.4.1 (Manage Allergy, Intolerance, and Adverse Reaction List)
	diagnostic study declined	A diagnostic study has been declined by the patient or the patient proxy.	Some of the concepts are addressed in the following EHR Functional Model sections. Patient refusal of a procedure, intervention, service, or treatment is not clearly defined in the EHR Functional Model. Related sections: DC.2.2.4 (Support Self Care) DC.1.3.1 (Manage Patient and Family Preferences) DC.1.3.3 (Manage Consents and Authorizations) DC.2.3.1.2 (Support for Patient Specific Dosing and Warnings) DC.1.3.2 (Manage Patient Advance Directives)
	diagnostic study intolerance	Diagnostic study intolerance is a reaction in specific patients representing a low threshold to the normal reported or expected reactions of the study. Side effects experienced do not represent adverse events or allergies. A time/date stamp is required, as are notations indicating whether the item is patient reported and/or provider verified.	EHR Functional Model DC.1.4.1 (Manage Allergy, Intolerance, and Adverse Reaction List)
	diagnostic study offered	An offer or suggestion to a patient for a diagnostic study. Diagnostic studies are those that are not performed in the clinical laboratory. Such studies include but are not limited to imaging studies, cardiology studies (electrocardiogram, treadmill stress testing), pulmonary function testing, vascular laboratory testing, and others.	The EHR Functional Model does not have a clear representation for diagnostic study offered.

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
diagnostic study *(continued)*	diagnostic study order	A request by a physician or appropriately licensed care provider to an appropriate provider or facility to perform a diagnostic study on a patient. The request may be in the form of a consultation or a direct order to the facility or organization that performs the diagnostic study. Diagnostic studies are those that are not performed in the clinical laboratory. Such studies include but are not limited to imaging studies, cardiology studies (electrocardiogram, treadmill stress testing), pulmonary function testing, vascular laboratory testing, and others.	The EHR Functional Model provides support for nonmedication ordering including supplies such as: ❙ 4x4s and ACE bandages; ❙ nonmedical devices such as TTY phones for the hearing impaired; ❙ groups of supplies or kits common to an organization;· simple durable medical equipment ❙ simple durable medical equipment (DME) such as crutches or walkers; ❙ complex DME such as wheelchairs and hospital beds; and ❙ therapies and other services that may require a referral and/or an authorization for insurance coverage. It is not clear that procedures as defined are covered in this EHR FM section. DC.2.4.2 (Support for Non-Medication Ordering)
	diagnostic study result	The result, described in concepts or numerical values of a diagnostic on a patient. Diagnostic studies are those that are not performed in the clinical laboratory. Such studies include but are not limited to imaging studies, cardiology studies (electrocardiogram, treadmill stress testing), pulmonary function testing, vascular laboratory testing, and others.	The EHR Functional Model provides support for diagnostic study result management in the following sections: DC.2.4.3 (Support for Result Interpretation) DC.1.1.3.1 (Capture Data and Documentation from External Clinical Sources)
encounter	encounter	A patient encounter represents an interaction between a healthcare provider and a patient, such as a face-to-face or otherwise billable visit for any form of diagnostic treatment and/or therapeutic event.	EHR Functional Model S.3.1 (Encounter/Episode of Care Management) S.3.1.2 (Encounter Specific Functionality) S.3.1.5 (Other Encounter and Episode of Care Support)
	encounter location	Each encounter has an associated location where it occurred. The encounter location is the patient's locality at the time of measurement.	The EHR Functional Model has components that refer to some of the concepts required by the "location" data element, but "received from" and "transferred/ sent to" concepts are not specifically identified. S.1.4.2 (Patient's Location Within a Facility)

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
functional status	functional status	The capacity to engage in activities of daily living and social role activities.	LTC-NH EHR-S FP: DC.1.1.4 DC.1.5.1
individual characteristic	patient characteristics	Specific information about the patient, including demographics	EHR Functional Model DC.1.1.2 (Manage Patient Demographics) S.1.4.1 (Patient Demographics)
	provider characteristics	Specific information about the clinician provider or the facility caring for the patient.	EHR Functional Model S.1.3 (Provider Information) S.1.3.4 (Provider's Location(s) or Office(s)) S.1.3.5 (Team/Group of Providers Registry or Directory)
laboratory test	laboratory test declined	A study in the clinical laboratory (traditionally including chemistry, hematology, microbiology, serology, urinalysis, blood bank departments) has been declined by the patient or the patient proxy. Depending on the point in the clinical workflow desired by the measure, various options are provided—offered, declined, ordered, performed, and resulted.	Some of the concepts are addressed in the following EHR Functional Model sections. Patient refusal of a procedure, intervention, service, or treatment is not clearly defined in the EHR Functional Model. Related sections: DC.2.2.4 (Support Self Care) DC.1.3.1 (Manage Patient and Family Preferences) DC.1.3.3 (Manage Consents and Authorizations) DC.2.3.1.2 (Support for Patient Specific Dosing and Warnings) DC.1.3.2 (Manage Patient Advance Directives)
	laboratory test offered	A study in the clinical laboratory (traditionally including chemistry, hematology, microbiology, serology, urinalysis, blood bank departments) has been offered to the patient or patient proxy. Depending on the point in the clinical workflow desired by the measure, various options are provided—offered, declined, ordered, performed, and resulted.	EHR Functional Model includes: **Glossary** Active Order: Active – In a state of action Order – Request for a certain procedure to be performed. DC.2.4.2 (Support for Non-medication Ordering: Statement) DC.1.1.3.1 (Capture Data and Documentation from External Clinical Source) DC.2.4.3 (Support for Result Interpretation) DC.1.8.3 (Manage Results)

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
laboratory test *(continued)*	laboratory test order	A study in the clinical laboratory (traditionally including chemistry, hematology, microbiology, serology, urinalysis, blood bank departments) has been ordered. Depending on the point in the clinical workflow desired by the measure, various options are provided—offered, declined, ordered, performed, and resulted.	EHR Functional Model includes: **Glossary** Active Order: Active – In a state of action Order – Request for a certain procedure to be performed. DC.2.4.2 (Support for Non-medication Ordering: Statement) DC.1.1.3.1 (Capture Data and Documentation from External Clinical Source) DC.2.4.3 (Support for Result Interpretation) DC.1.8.3 (Manage Results)
	laboratory test performed	A study in the clinical laboratory (traditionally including chemistry, hematology, microbiology, serology, urinalysis, blood bank departments) has been completed. Depending on the point in the clinical workflow desired by the measure, various options are provided—offered, declined, ordered, performed, and resulted.	EHR Functional Model includes: **Glossary** Active Order: Active – In a state of action Order – Request for a certain procedure to be performed DC.2.4.2 (Support for Non-medication Ordering: Statement) DC.1.1.3.1 (Capture Data and Documentation from External Clinical Source) DC.2.4.3 (Support for Result Interpretation) DC.1.8.3 (Manage Results)

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
laboratory test *(continued)*	laboratory test result	The result of a study in the clinical laboratory (traditionally including chemistry, hematology, microbiology, serology, urinalysis, blood bank departments). Depending on the point in the clinical workflow desired by the measure, various options are provided—offered, declined, ordered, performed, and resulted.	EHR Functional Model includes: **Glossary** Active Order: Active – In a state of action Order – Request for a certain procedure to be performed. DC.2.4.2 (Support for Non-medication Ordering: Statement) DC.1.1.3.1 (Capture Data and Documentation from External Clinical Source) DC.2.4.3 (Support for Result Interpretation) DC.1.8.3 (Manage Results)
medication	medication administered	A record by the care provider that a medication actually was administered and whether or not this fact conforms to the order. Appropriate time stamps for all medication administration are generated.	EHR Functional Model DC.1.8.1 (Manage Medication Administration)
	medication adverse event	In the instance of a quality measure, a medication adverse event is an unexpected or dangerous reaction to a medication. Serious adverse events are those that are fatal, life-threatening, permanently/significantly disabling, those that require or prolong hospitalization, and those that lead to congenital anomaly or that require intervention to prevent permanent impairment or damage. A time/date stamp is required as are notations indicating whether an item is patient reported and/or provider verified.	EHR Functional Model DC.1.4.1 (Manage Allergy, Intolerance, and Adverse Reaction List)
	medication allergy	A medication allergy is an immunologically mediated reaction that exhibits specificity and recurrence on re-exposure to the offending drug. A time/date stamp is required as are notations indicating whether the item is patient reported and/or provider verified.	EHR Functional Model DC.1.4.1 (Manage Allergy, Intolerance, and Adverse Reaction List)

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
medication *(continued)*	medication declined	A medication has been declined by the patient or patient proxy.	Some of the concepts are addressed in the following EHR Functional Profile sections. Patient refusal of a procedure, intervention, service, or treatment is not clearly defined in the EHR Functional Model. Related sections: DC.2.2.4 (Support Self Care) DC.1.3.1 (Manage Patient and Family Preferences) DC.1.3.3 (Manage Consents and Authorizations) DC.2.3.1.2 (Support for Patient Specific Dosing and Warnings) DC.1.3.2 (Manage Patient Advance Directives)
	medication discontinued	A record by the care provider that a medication has been purposely stopped (or discontinued). Medications may be discontinued based on an order by a physician (usually an inpatient practice), notification to a patient to stop taking a medication (ambulatory), or notification from a patient to a care provider that the patient has independently stopped taking the drug. Appropriate time stamps for all medication discontinuations are generated.	The EHR Functional Model has some components of this definition in the following actions. Further analysis is required. DC.1.7.1 (Manage Medication Orders) DC.1.4.2 (Manage Medication List) DC.1.8.1 (Manage Medication Administration)
	medication dispensed	A medication prescription is filled by a pharmacy, and the medication has been provided to the patient or patient proxy. In the ambulatory setting, medications are primarily taken directly by patients and administration is not directly observed by a clinician. Hence, dispensed is the closest health provider documentation of medication compliance. In settings where patients attest to taking medications in electronic format (perhaps a personal health record), patient attestation of "medication taken" may be available.	The EHR Functional Model has concepts with respect to medication ordering, management, and administration. Dispensed (or taken by the patient in the context of ambulatory personal health record patient attestation) is not specifically identified. DC.1.7.1 (Manage Medication Orders) DC.1.4.2 (Manage Medication List) DC.1.8.1 (Manage Medication Administration)
	medication intolerance	Medication intolerance is a reaction in specific patients representing a low threshold to the normal pharmacological action of a drug. Side effects experienced do not represent adverse events or allergies. A time/date stamp is required as are notations indicating whether the item is patient reported and/or provider verified.	EHR Functional Model DC.1.4.1 (Manage Allergy, Intolerance, and Adverse Reaction List)

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
medication *(continued)*	medication offered	A specific medication has been offered to the patient or patient proxy.	The EHR Functional Model has concepts with respect to medication ordering, management, and listing. Offered is not specifically identified. DC.1.7.1 (Manage Medication Orders) DC.1.4.2 (Manage Medication List)
	medication order	A request by a physician or appropriately licensed care provider to a pharmacy to provide medication to a patient. The request is in the form of prescriptions or other medication orders with sufficient detail for correct filling and administration.	EHR Functional Model DC.1.7.1 (Manage Medication Orders)
physical finding	physical exam finding	A physical examination is the evaluation of the patient's body to determine its state of health. The techniques of inspection include palpation (feeling with the hands and/or fingers), percussion (tapping with the fingers), auscultation (listening), and smell. Measurements may include vital signs (blood pressure, pulse, respirations) as well as other clinical measures (such as expiratory flow rate, size of lesion).	The EHR Functional Profile provides some direction for management of physical examination findings. Further evaluation is required. DC.1.8.4 (Manage Patient Clinical Measurements) DC.1.8.5 (Manage Clinical Documents and Notes)
preference	patient preference	Healthcare treatment choices influenced by but not limited to language, religious, or cultural preferences selected by the patient and family.	Some of the concepts are addressed in the following EHR Functional Model sections. Patient refusal of a procedure, intervention, service, or treatment is not clearly defined in the EHR Functional Model. Related sections: DC.2.2.4 (Support Self Care) DC.1.3.1 (Manage Patient and Family Preferences) DC.1.3.3 (Manage Consents and Authorizations) DC.2.3.1.2 (Support for Patient Specific Dosing and Warnings) DC.1.3.2 (Manage Patient Advance Directives)
	provider preference	Healthcare treatment choices by the care provider based on knowledge of the patient's clinical status and findings. Synonymous with "medical reason" for inclusion or exclusion of a patient in a measure population.	Not covered in the EHR Functional Profile.

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
procedure	procedure adverse event	In the instance of a quality measure, a procedure adverse event is an unexpected or dangerous reaction to a procedure. Serious adverse events are those that are fatal, life-threatening, permanently/significantly disabling, those that require or prolong hospitalization, and those that require intervention to prevent permanent impairment or damage. A time/date stamp is required, as are notations indicating whether an item is patient reported and/or provider verified.	EHR Functional Model DC.1.4.1 (Manage Allergy, Intolerance, and Adverse Reaction List)
	procedure declined	A procedure has been declined by the patient or patient proxy.	Some of the concepts are addressed in the following EHR Functional Model sections. Patient refusal of a procedure, intervention, service, or treatment is not clearly defined in the EHR Functional Model. Related sections: DC.2.2.4 (Support Self Care) DC.1.3.1 (Manage Patient and Family Preferences) DC.1.3.3 (Manage Consents and Authorizations) DC.2.3.1.2 (Support for Patient Specific Dosing and Warnings) DC.1.3.2 (Manage Patient Advance Directives)
	procedure history	A procedure has been completed in the past and includes a time/date stamp. Chargeable versus nonchargeable.	The EHR Functional Model somewhat covers this topic, but not completely: DC.1.1.3.1 (Capture Data and Documentation from External Clinical Sources Statement) DC.1.8.3 (Manage Results)
	procedure intolerance	Procedure intolerance is a reaction in specific patients representing a low threshold to the normal effects of a procedure. Side effects experienced do not represent adverse events or allergies. A time/date stamp is required, as are notations indicating whether the item is patient reported and/or provider verified.	EHR Functional Model DC.1.4.1 (Manage Allergy, Intolerance, and Adverse Reaction List)

more

STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
procedure *(continued)*	procedure offered	A procedure is suggested or recommended to a patient.	The EHR Functional Model does not have a clear representation for the concept "procedure offered."
	procedure order	A request by a physician or appropriately licensed care provider to an appropriate provider or facility to perform a procedure on a patient. The request may be in the form of a consultation or a direct order to the facility or organization that performs the procedure.	The EHR Functional Model provides support for nonmedication ordering including supplies such as: ▌ 4x4s and ACE bandages; ▌ nonmedical devices such as TTY phones for the hearing impaired; ▌ groups of supplies or kits common to an organization; ▌ simple durable medical equipment (DME) such as crutches or walkers; ▌ complex DME such as wheelchairs and hospital beds; and ▌ therapies and other services that may require a referral and/or an authorization for insurance coverage. It is not clear that procedures as defined are covered in this EHR Functional Model section. DC.2.4.2 (Support for Non-Medication Ordering)
	procedure performed	A procedure has been completed. Depending on the point in the clinical workflow desired by the measure, various options are provided—offered, declined, ordered, performed, and resulted. Procedures also include patient care processes provided directly to a patient by a care provider to assist or direct a patient with activity or to apply single use or durable medical equipment. Examples include assisted ambulation, behavioral interventions (e.g., counseling provided), dressing changes, placement of antithrombotic devices, and insertion or removal of intravascular access. Some of these procedures are not reimbursed.	The EHR Functional Model provides support for procedure result management in the following sections: DC.2.4.3 (Support for Result Interpretation) DC.1.1.3.1 (Capture Data and Documentation from External Clinical Sources)

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
procedure *(continued)*	procedure result	Procedure results are the findings identified as a result of the procedure. The result of a surgical procedure documents the actual procedure performed and the findings of the procedure. These findings are usually present in the operative note (e.g., lymph node dissection with 15 lymph nodes obtained for biopsy). The procedure result is distinct from the pathology report, which is a laboratory result data type that could state 2 of 15 nodes positive for malignancy. It is also distinct from clinical outcome, which could use various data types (e.g., patient characteristic "alive" at 18 months postoperatively, or functional status data type required preoperatively and at 6, 12, and 18 months postoperatively).	The EHR Functional Model provides support for procedure result management in the following sections: DC.2.4.3 (Support for Result Interpretation) DC.1.1.3.1 (Capture Data and Documentation from External Clinical Sources)
risk category/assessment	risk category/assessment	Risk category assessments include tools and calculators that suggest vulnerabilities for any given patient. Distinct from functional status, risk categorization uses findings, observations, results, and sometimes judgments and patient-generated information for use within clinical care algorithms, clinical decision support, and severity analysis.	The EHR Functional Model does not have a direct corollary to risk category/assessment. Included are DC.2.6.1 Support for Epidemiological Investigations of Clinical Health within a Population
substance	substance administered	A record by the care provider that a food or other substance actually was given to the patient and whether or not this fact conforms to the order. Appropriate time stamps for all medication administration are generated.	EHR Functional Model DC.1.7.2.1 (Capture and Track Patient Care Orders)
	substance adverse event	In the instance of a quality measure, a substance adverse event is an unexpected or dangerous reaction to a substance (e.g., food, environmental agent). Serious adverse events are those that are fatal, life-threatening, permanently/significantly disabling, those that require or prolong hospitalization, and those that lead to congenital anomaly or require intervention to prevent permanent impairment or damage. A time/date stamp is required, as are notations indicating whether the item is patient reported and/or provider verified.	EHR Functional Model DC.1.4.1 (Manage Allergy, Intolerance, and Adverse Reaction List) DC.2.3.1.2 (Support for Drug Interaction Checking)
	substance allergy	A substance allergy is an immunologically mediated reaction that exhibits specificity and recurrence on re-exposure to the offending substance. A time/date stamp is required, as are notations indicating whether the item is patient reported and/or provider verified.	EHR Functional Model DC.1.4.1 (Manage Allergy, Intolerance, and Adverse Reaction List)

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
substance *(continued)*	substance declined	A substance has been declined by the patient or patient proxy.	Some of the concepts are addressed in the following EHR Functional Model sections. Patient refusal of a procedure, intervention, service, or treatment is not clearly defined in the EHR Functional Model. Related sections: DC.2.2.4 (Support Self Care) DC.1.3.1 (Manage Patient and Family Preferences) DC.1.3.3 (Manage Consents and Authorizations) DC.2.3.1.2 (Support for Patient Specific Dosing and Warnings) DC.1.3.2 (Manage Patient Advance Directives)
	substance intolerance	Substance intolerance is a reaction in specific patients representing a low threshold to the normal effects of a substance. Side effects experienced do not represent adverse events or allergies. A time/date stamp is required, as are notations indicating whether the item is patient reported and/or provider verified.	EHR Functional Model DC.1.4.1 (Manage Allergy, Intolerance, and Adverse Reaction List) DC.2.3.1.2 (Support for Drug Interaction Checking)
	substance ordered	A request by a physician or appropriately licensed care provider to provide food or other substance to a patient.	EHR Functional Model DC.1.7.2.1 (Capture and Track Patient Care Orders)
symptom	symptom active	A symptom is an indication that a person has a condition or disease. Some examples are headache, fever, fatigue, nausea, vomiting, and pain. [Source: UMLS] Also, subjective evidence of disease perceived by the patient. [Source: NCI] As an example to differentiate symptom from finding—the patient's subjective symptom of fever is distinguished from the temperature (a finding), which has a temperature measuring device as a source and the device itself (electronically) or an individual (healthcare provider, patient, etc.) as the recorder.	The EHR Functional Model does not directly address symptoms. DC.1.2 (Manage Patient History) has reference to history but does not directly state symptoms. Assessments that may include symptom identification include: DC.2.1.1 (Support for Standard Assessment) DC.2.1.2 (Support for Patient Context-Driven Assessments) DC.2.1.3 (Support for Identification of Potential Problems and Trends)

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STANDARD ELEMENT	QUALITY DATA ELEMENT	HITEP DEFINITION	EHR FUNCTIONAL MODEL/HL7 REFERENCE
symptom *(continued)*	symptom assessed	A symptom is an indication that a person has a condition or disease. Some examples are headache, fever, fatigue, nausea, vomiting, and pain. [Source: UMLS] Also, subjective evidence of disease perceived by the patient. [Source: NCI] As an example to differentiate symptom from finding—the patient's subjective symptom of fever is distinguished from the temperature (a finding), which has a temperature measuring device as a source and the device itself (electronically) or an individual (healthcare provider, patient, etc.) as the recorder. Assessment is part of the care provider activity during the current encounter.	The EHR Functional Model does not directly address symptoms. DC.1.2 (Manage Patient History) has reference to history but does not directly state symptoms. Assessments that may include symptom identification include: DC.2.1.1 (Support for Standard Assessment) DC.2.1.2 (Support for Patient Context-Driven Assessments) DC.2.1.3 (Support for Identification of Potential Problems and Trends)
system characteristic	system characteristic	The structural configuration of an organization, for example, nursing staff ratios, availability of durable medical equipment, health information technology structures (e.g., e-prescribing), and invasive procedure capabilities.	The EHR Functional Model addresses nurse staffing but not all system characteristics. S.3.6 Acuity and Severity: Statement
transfer of care	transfer from	The setting from which a patient is received (e.g., home, acute care hospital, skilled nursing) to the current location.	The EHR Functional Model has components that refer to some of the concepts required by the "location" data element, but "received from" and "transferred/ sent to" concepts are not specifically identified. S.1.4.2 (Patient's Location Within a Facility)
	transfer to	The setting to which a patient is released (e.g., home, acute care hospital, skilled nursing, rehab) from the current location.	The EHR Functional Model has components that refer to some of the concepts required by the "location" data element, but "received from" and "transferred/ sent to" concepts are not specifically identified. S.1.4.2 (Patient's Location Within a Facility)

Appendix C
Using Electronic Data to Inform Quality Improvement: An Environmental Scan of Current Initiatives

Using Electronic Data to Inform Quality Improvement: An Environmental Scan of Current Initiatives

A Report for the National Quality Forum

Booz Allen Hamilton

February 2, 2009

This paper has been edited for minimal stylistic consistency. The content and accuracy of the paper are the responsibility of the author, not the National Quality Forum.

Table of Contents

I. Introduction

Many healthcare policy and industry leaders view interoperable health information technology (health IT) as a critical tool to facilitate improvement of care delivered in the United States.[1] Specifically, interoperable health IT has been promoted as being able to:

- facilitate collection of data for quality improvement initiatives and public health disease surveillance;
- facilitate coordination of care across healthcare institutions, thus reducing duplication of services, decreasing the likelihood of adverse events, and improving the quality of care;
- automate and streamline clinical workflow, closing loops in communication that can result in delays or gaps in care; and
- aid provider decision-making capability through the use of evidence-based clinical decision support.[2]

Electronic health records (EHRs) in particular are seen as an important health IT tool that can enable the efficient collection and exchange of clinical data to inform quality improvement. However, widespread adoption of current commercially available EHRs will not, in and of itself, provide the data needed to support healthcare quality measurement. Quality measures and EHRs must co-evolve to support quality improvement and automated measurement.

The challenges to using EHRs to support quality begin with data capture. Data required for today's quality measures are often captured in unstructured fields or in free text. EHR architectures, which are designed primarily to support care, are often suboptimized for population analysis. Additionally, while numerous interoperability standards have been harmonized to support information sharing, the standardization of data for quality measurement is in its early stages.

In an effort to improve the ability of EHRs to support quality measurement and improvement efforts, the Agency for Healthcare Research and Quality (AHRQ) contracted with the National Quality Forum (NQF) in 2007 to convene the Health Information Technology Expert Panel (HITEP). AHRQ charged the HITEP (referred to in this report as the HITEP 1) with identifying and recommending a set of common data elements for standardization to enable automation of a prioritized set of Ambulatory Quality Alliance (AQA) and Hospital Quality Alliance (HQA) measures through EHRs and Health Information Exchanges (HIEs). The HITEP 1 provided the Health Information Technology Standards Panel (HITSP) with a listing of common data elements used across a prioritized set of measures for them to identify standards for how these data elements could be expressed. In addition, the HITEP 1 developed a set of recommendations that outlined specific actions that could be taken to improve the ability of the quality measurement and health IT enterprise to support quality improvement. These recommendations targeted key audiences including HITSP and the standards development organizations with which it works, the Certification Commission for Health Information Technology (CCHIT), EHR vendors, measure developers, and NQF.[3]

AHRQ has now contracted with NQF to re-convene the HITEP and build upon its earlier efforts. Specifically, AHRQ has charged the second HITEP with defining a draft "quality data set" (QDS) that could be used nationwide to support automated, patient-centric, and longitudinal quality measurement. The QDS was conceived based on a recommendation from the American Health Information Community (AHIC) Quality Workgroup. The AHIC Quality Workgroup's recommendation states:

> The QDS refers to a minimum set of data elements or types of data elements that can be used as the basis for developing harmonized and machine-computable quality measures. More specifically, the QDS will serve as the basis for prioritizing data elements for inclusion in EHRs and other health IT systems and for prioritizing the development of standards for interoperability, data export, and data storage and for prioritizing related certification criteria.[4]

In addition, AHRQ charged the HITEP with gathering, synthesizing, and refining clinical workflow maps and identifying opportunities within these workflows to apply patient inclusion criteria in measure populations, gather performance measurement data, and provide clinical decision support. The goal of this effort is to determine how best to gather data as a seamless part of care delivery, to facilitate improved quality measurement and reporting, and drive improved care outcomes.[5]

NQF contracted with Booz Allen Hamilton (Booz Allen) to conduct an environmental scan of current initiatives that use electronic clinical data in quality measurement and improvement initiatives. The goal of this environmental scan is to characterize current efforts, identify areas in which the electronic data standards for structured clinical data are needed, and share this information with the HITEP to inform its efforts to conceptualize and define the QDS.

The remainder of this report is organized as follows:

- **Section II: Methodology** describes Booz Allen's methods for conducting the environmental scan, which included a literature review and targeted stakeholder interviews.
- **Section III: Findings by Key Topic Area** groups the research from the literature review and the data captured from the stakeholder interviews into three topic areas: an overview of organizations that are contributing to the transformation of the quality measurement and improvement enterprise and its movement towards use of electronic data sources; the current landscape of quality measurement; and a description of current approaches for quality measurement and improvement based on information supplied by the interviewees.
- **Section IV: Recommendations to the HITEP** discusses the recommendations received from the targeted stakeholder interviews. The responses have been categorized into technical, policy, and business recommendations.

II. Methodology

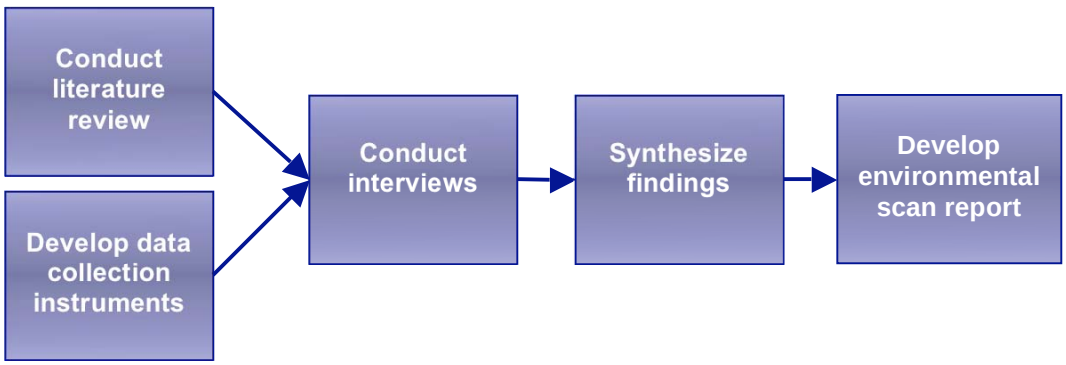
Booz Allen used a two-pronged approach to conduct the environmental scan. This approach consisted of:

- A ***literature review*** of published data and current initiatives that describe how electronic clinical data are being used to inform quality improvement initiatives and where data standards for structured clinical data are needed.
- Primary data collection through ***targeted interviews*** of organizations that are using and exchanging electronic data to inform their quality improvement efforts.

Booz Allen anticipated that there would be limited insights gathered from the literature review, since few studies target the specific areas of interest to NQF and the HITEP. The literature review did, however, illuminate initiatives that are aggregating electronic clinical and administrative data and fed the list of potential stakeholders to be interviewed. As there is a wealth of anecdotal learning that could inform the NQF HITEP efforts, Booz Allen interviewed 20 key stakeholders from relevant pilots, HIE initiatives, and provider groups to help inform NQF's understanding of barriers and enablers to interoperability, integration of data from multiple sources, and areas in which standardized electronic clinical data could be used to help advance quality of care. The stakeholder organizations varied by size, region of country, and maturity of health IT implementation.

Figure 1 depicts the steps conducted to develop the Environmental Scan Report. Additional details on the approach used to carry out each step are described below.

Figure 1. Environmental Scan Methodology



Conduct literature review: Booz Allen conducted a literature review of published reports, studies, and publicly available information. The review focused on the successes that have been achieved and the barriers that have been faced in efforts to combine electronic clinical and administrative data from multiple sources for quality improvement purposes and to identify the organizations undertaking such efforts. A primary Google search was conducted on each of the following: "Better Quality Information to Improve Care for Medicare Beneficiaries (BQI) Pilots," "Nationwide Health Information Network (NHIN) Trial

Implementation Sites," "Regional Health Information Organizations (RHIOs)," and "Health Information Exchanges (HIEs)."

The literature review also included the identification of articles, reports, and other relevant documentation through structured Internet searches using search engines such as PubMed, Biomed Central, and Google. In addition, Booz Allen reviewed information from the websites of key players in the health IT and quality arena including (but not limited to) AHRQ, the Centers for Medicare and Medicaid Services (CMS), NQF, the U.S. Department of Health and Human Services (HHS), the Indian Health Service (IHS), AHIC, Geisinger Health System, Intermountain Healthcare, Partners HealthCare, and Blue Cross Blue Shield (BCBS). Examples of keywords used to search these databases can be seen in the box below. In addition, searches on specific programs were also conducted. Booz Allen also examined the citations from relevant articles to obtain additional articles for review.

Representative Literature Review Search Terms	
• EHR, clinical research • Collaborative, performance measure(s) • EHR, quality measure(s)/performance measure(s), barrier(s) • EHR, quality measure(s)/performance measure(s), success(es) • EHR, quality measure(s)/performance measure(s) • Clinically enriched claims data • Interoperability standards, health IT, quality • Health IT standards	• Health Information Exchange • Health IT, EHR • Health IT, quality measurement/ performance measurement • EHR, quality measurement/performance measurement • Performance measure using EHR • Using electronic health records to collect patient-specific performance measures • Clinical workflow, EHR • Clinical workflow, quality measurement/ performance measurement

Develop data collection instruments: To ensure a systematic approach to primary data collection, Booz Allen developed interview guides to facilitate the interviews. One instrument was developed to collect information from collaborative entities such HIEs, employer-sponsored collaborations, and the BQI and NHIN grantees. A separate instrument was developed to collect data from provider groups, such as physicians, hospitals, and healthcare systems. In order to adhere to Office of Management and Budget (OMB) regulations requiring that government-sponsored data collection efforts limit the burden of data collection on the general public to no more than nine entities without OMB clearance, Booz Allen conducted interviews with nine nongovernmental entities for each of these two primary data collection efforts described above. A full list of interviewed stakeholders is included in Appendix A: Interviewed Stakeholders.

It is Booz Allen's practice to use such guides to facilitate discussion during the course of an interview with the understanding that each interviewee will bring unique perspectives and insights, and therefore some questions may not be appropriate for each individual interviewee. The guides were informed by the findings from the literature review and from our historical expertise in the areas of quality measurement reporting and health IT interoperability. Topics in the interview guide included:

- general characteristics of quality measurement and improvement initiatives in which the organization participates;
- data categories collected and their respective sources;
- data shared across settings to facilitate continuity of care and quality measurement;
- challenges and gaps in capturing or aggregating standardized data through EHRs or other clinical health IT systems; and
- recommendations for improving the standardization of the clinical data collected and for improving how health IT could be enhanced as a data source to support quality measurement and improvement.

Conduct interviews: Booz Allen identified the organizations to be interviewed through the literature review and in collaboration with NQF. Booz Allen and NQF identified specific stakeholder groups to include in the interview group to ensure multiple perspectives were adequately represented. With a maximum of 20 interviews possible, Booz Allen and NQF then prioritized stakeholders within these groups who are innovators and have experience in the use of electronic data for quality measurement.

Stakeholder discussions were structured as 45- to 60-minute conference calls conducted by a two-person team. At NQF's request, Booz Allen asked during each interview for key pieces of documentation that would facilitate the HITEP's efforts to conceptualize a QDS and begin its assessment of clinical workflow maps. The documentation requested included:

- Data dictionaries, data maps, or other relevant documentation that outlined how electronic (clinical) data were mapped to the measures that a given organization was collecting. NQF deemed that this information would be useful for the HITEP to consider when making determinations regarding what data elements or data types to focus on for inclusion in the QDS.
- Clinical workflow maps for the HITEP to analyze to determine mechanisms and opportunities within the workflows for identifying patients who are eligible for inclusion in the measure populations, for gathering performance measurement data, and for providing clinical decision support to optimize performance in targeted areas.

Materials that were received served to augment Booz Allen's understanding of the topics described above and were provided to the HITEP to support its own analyses.

Synthesize findings: Booz Allen synthesized the findings from the literature review and stakeholder interviews and reviewed the resulting data to identify key themes as they relate to data collection, measurement, the use of electronic data, and the challenges associated with capturing or aggregating standardized data through EHRs or other clinical health IT systems. Additionally, interviewee recommendations related to standardization were categorized into technical, business, and policy recommendations. To the extent possible, the recommendations were then ordered, within their respective categories, by the number of times they were recommended to help the HITEP in its assessment of the recommendations.

As previously mentioned, the literature review was limited in its ability to provide insights for the targeted areas, so the interviews provided significant input into this report. However, it is important to note that the interviewed stakeholders do not constitute a representative sample of the healthcare industry, and their responses cannot be extrapolated to represent organizations beyond the interview sample.

Develop environmental scan report. The findings were then populated into a draft report that was provided to NQF for its review. Based on this review, Booz Allen made modifications to the document and submitted a final draft to NQF prior to the HITEP kick-off meeting in February 2009.

III. Findings by Key Topic Areas

As mentioned in the introduction, the goals of this environmental scan are to characterize current initiatives that are using electronic clinical data in quality measurement and improvement; identify areas in which electronic data standards for structured clinical data are needed; and share this information with the HITEP to inform their efforts to conceptualize and define the QDS. The section below outlines findings from the environmental scan by key topic areas, including:

A. Initiatives to transform the quality measurement and improvement enterprise using electronic data sources.

B. The current landscape of quality measurement.

C. Approaches to quality measurement and improvement using electronic clinical data, including a discussion of its impact on clinical workflow, health information exchange to facilitate continuity of care, and key challenges.

A. Initiatives to Transform the Quality Measurement and Improvement Enterprise

There are a number of initiatives in place today that are working to drive quality and health IT interoperability initiatives that are relevant to the HITEP's efforts. They can be categorized, as seen in the boxes below, into two distinct groups:

- **enabling organizations** that are focused on developing and/or implementing the processes and/or technical frameworks for exchanging electronic data; and
- **implementing organizations** that are exchanging clinical data electronically for quality improvement.

Relevant Initiatives Driving Quality and Health IT Interoperability Activities

Enabling Organizations	Implementing Organizations

• Agency for Healthcare Research and Quality
• Centers for Medicare and Medicaid Services
• Certification Commission for Healthcare Information
• Healthcare Information Technology Standards Panel
• High-Value Health Care Project
• Integrating the Healthcare Enterprise
• National Committee on Vital and Health Statistics
• National eHealth Collaborative
• Quality Collaboratives
  - Alliance for Pediatric Quality
  - Collaborative for Performance Measure Integration with EHR Systems
	• Better Quality Information to Improve Care for Medicare Beneficiaries Pilots
	• HIEs
	• National Health Information Network
	• Private Sector Efforts
	  - Health Plans
	  - Providers
	  - Provider Organizations

1. ENABLING ORGANIZATIONS

The enabling organizations described below each play a critical role in creating and strengthening the infrastructure through which standardized electronic data can be captured and used to inform quality measurement and improvement. They span the public and private sectors and also include public-private collaboratives.

The Agency for Healthcare Research and Quality is the lead federal agency charged with improving the quality, safety, efficiency, and effectiveness of healthcare, which includes health IT. In an effort to support and stimulate investment in health IT, AHRQ has made more than $260 million in grants and contracts to organizations in 41 states, with a special focus on rural and underserved areas. Through these efforts, along with others, AHRQ and its partners seek to identify health IT adoption and implementation challenges and subsequent tools needed to support hospitals and clinicians in their adoption and implementation of health IT.[6]

The Centers for Medicare and Medicaid Services facilitates performance measurement and quality improvement through its voluntary reporting programs, such as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) and Physician Quality Reporting Initiative (PQRI). CMS is also engaged in a pilot demonstration to standardize the assessment of the quality and efficiency of care for post-acute care (PAC) settings. The pilot uses an electronic, standardized patient assessment instrument called the Continuity Assessment Record and Evaluation (CARE) tool. The benefit of the web-based technology is that it will allow for future modifications of the data sets it collects to reflect the latest evidence-based medicine. The CARE tool was informed by providers and health services and information technology experts and is intended to replace current Medicare assessment forms, including the OASIS, Minimum Data Set (MDS), and Inpatient Rehabilitation Facility Patient Assessment Instrument (IRFPAI) tools.[7]

The Certification Commission for Healthcare Information Technology is a recognized certification body for EHRs that aims to accelerate the adoption of robust health IT by facilitating interoperability between EHRs, HIEs, and other entities; to make patient records portable; and to facilitate quality measurement and improvement. CCHIT

helps to drive standards compliance into health IT products and to accelerate adoption of those products by providers through its certification process.[8]

The Healthcare Information Technology Standards Panel was formed for the purpose of harmonizing and integrating standards that meet clinical needs for sharing information among organizations and systems. Specifically, HITSP works with standards development organizations to identify and/or harmonize Interoperability Specifications, suites of documents that define selected standards and provide implementation-level guidance to satisfy the requirements imposed by a given AHIC Use Case.[9] On January 21, 2009, the Secretary of HHS formally recognized three of these interoperability standards related to EHR, personal health records, and electronic quality monitoring.[10] These standards are now part of the mandatory requirements for federal agencies to adhere to when implementing health IT systems. In addition, HITSP standards are used as the basis for NHIN grantee pilot testing of the AHIC use cases. CCHIT also incorporates selected interoperability specifications into its own certification programming for commercial EHR products.

The High-Value Health Care Project (HVHC), conducted by the Brookings Institution Engelberg Center for Health Care Reform, promotes widespread use of valid quality and cost measures to improve medical care and facilitate more informed decisions by patients. HVHC is funded by the Robert Wood Johnson Foundation. HVHC also supports the Quality Alliance Steering Committee (QASC). Through HVHC, the Brookings Institution is working with the QASC to identify the necessary steps to achieve QASC's strategic plan, or "roadmap," to help drive the nation towards development of "nationally consistent performance results." More specifically, the Brookings Institution is identifying methods to aggregate and integrate healthcare data, to measure costs and efficiency of high-priority clinical conditions, and to collect disparity data to improve care for all racial and ethnic groups.[11]

Integrating the Healthcare Enterprise (IHE) coordinates the use and drives the adoption of established standards such as Digital Imaging and Communications in Medicine (DICOM) and Health Level 7 (HL7) to address specific clinical needs. IHE intends to bring together health IT stakeholders to implement standards for efficient patient information exchange by creating an interoperability framework. In order to drive the adoption of standards, IHE developed Integration Profiles that detail how the standards are to be implemented and utilized to enhance interoperability.[12,13]

The National Committee on Vital and Health Statistics (NCVHS) serves as the statutory public advisory body to the Secretary of HHS in the areas of health data and statistics. NCVHS has implemented a subcommittee on quality to better understand the emerging data needs for measuring and tracking population health. In an effort to provide recommendations, NCVHS plans to determine the applicability, use, and limitations of health IT tools as methods for capturing population health information. They will also assess current and proposed certification standards for taxonomy, standards, and privacy and security concerns for health IT.[14]

The National eHealth Collaborative (NeHC), previously known as the successor to AHIC, will continue the work of AHIC, specifically the prioritization of areas to develop interoperability standards for health IT. In addition, it is anticipated that NeHC will also lead the creation and promote the use of secure interoperable nationwide health

information systems to advance the public's interest in health and the quality, safety, efficiency, and accessibility of healthcare information.[15]

Quality Collaboratives that comprise experts across the healthcare industry have come together to help improve specific aspects of healthcare delivery including quality measurement and reporting. The Hospital Quality Alliance (HQA) brings together hospital groups, consumer organizations, provider groups, oversight organizations, government representatives, and employer groups to collaborate on how to make information about hospital performance available to consumers as well as providers in order to improve care. The Ambulatory Care Quality Alliance, a similar consensus-based effort related to physician performance, renamed itself the AQA after expanding its scope to encompass all aspects of physician care. Both alliances seek to create an aligned, orderly, and strategic approach to performance measurement through recommending measures for national adoption.

Two additional examples relevant to the HITEP's charge are the Alliance for Pediatric Quality and the Collaborative for Performance Measure Integration with EHR Systems (Collaborative).

The Alliance for Pediatric Quality supported the Quality Reporting Document Architecture (QRDA), which is focused on developing electronic data standards for exchange of patient-level quality measurement data between healthcare information systems. The initiative mapped selected existing measures to the HL7 Clinical Document Architecture, which is an open data standard that can be implemented in centralized and distributed systems irrespective of underlying application, communications platform, or architecture. QRDA will improve the ability to report based directly on clinical findings as well as on administrative data for current and emerging measures. The Alliance has identified next steps for consideration, including specification and profile development, pilot implementation and testing, and communication, education, and coordination.[16]

The Collaborative is co-sponsored by the American Medical Association, the Electronic Health Record Association, and the National Committee for Quality Assurance (NCQA). The Collaborative was formed to improve the accurate translation of measures and to promote quality through the integration of performance measures into EHR systems. The Collaborative recently developed a prototype XML format using standardized language, thus allowing more consistent EHR measure specifications for EHR systems vendors to incorporate standards for measurement-related data within their products. The XML schemas focused on the Physician Consortium for Performance Improvement and NCQA measures. Further testing of these schemas will be conducted in 2009.[17]

2. IMPLEMENTING ORGANIZATIONS

Despite insufficient standards and interoperability requirements and policies to help structure and facilitate exchange of information for quality measurement and improvement purposes, there are leaders in the field of quality measurement who are collecting electronic clinical data and/or a combination of electronic and manually collected clinical data for quality improvement purposes.

Better Quality Information to Improve Care for Medicare Beneficiaries (BQI) Pilots were launched by CMS in six communities. The BQIs tested methods to aggregate Medicare claims data with data from commercial health plans and, in some cases, clinical

data, in order to calculate and report quality measures for physician groups. The six communities implemented different processes to aggregate data for performance measurement reporting. The results from the project will be used to guide future efforts for aggregating Medicare claims data with data from other payers to produce quality measure results that provide a more comprehensive picture of the quality of services being provided to Medicare beneficiaries. The BQI pilot concluded in 2008,[18] although many of the BQI organizations continue to serve HIE functions within their communities.

HIE initiatives are building relationships, infrastructure, and capacity to move clinical information electronically between disparate healthcare information systems. HIEs serve to facilitate access to and retrieval of clinical data to provide safer, more timely, efficient, effective, equitable and patient-centered care. Formal organizations have emerged to support the HIE functions. These organizations, such as RHIOs, oversee HIEs within a defined geographic area for participating stakeholders for the purpose of improving health and healthcare delivery in that community. Additional organizations support this goal of the implementation and use of both health IT and health information exchange, including national organizations such as the Office of the National Coordinator (ONC) within HHS, private-public partnerships such as Connecting Communities for Better Health Program conducted by the eHealth Initiative Foundation, and philanthropic initiatives such as the Markle Foundation's Connecting for Health initiative.[19]

The National Health Information Network (NHIN) operates under oversight from ONC. NHIN, and is currently in its pilot phase. It seeks to provide a secure, nationwide, interoperable health information infrastructure. Often referred to as a "network of networks," NHIN is intended to connect all healthcare stakeholders, allow the exchange of patient-level information, facilitate clinical decisionmaking, and support the delivery of appropriate, evidence-based medical care through a three-phased approach.[20] This approach includes:

1) Prototype architectures that fed the design and standards development processes related to the NHIN Trial Implementations *(completed).*[21]

2) Trial implementations that will operate as the NHIN Cooperative to implement and test the NHIN specifications and securely exchange patient data, including the 2007 Quality Use Case, and demonstrate their connectivity to other networks *(in process).*[22]

3) Production that will allow a phased approach to move NHIN toward production *(scheduled to begin in 2009).*[23]

Health Plans are uniquely positioned to promote quality because of their ability to collect, aggregate, and report on claims data across the continuum of care and to influence their providers to augment claims data with clinical data through the use of incentive-based programs. Health plans such as Anthem BCBS, which received the 2008 John M. Eisenberg Patient Safety and Quality Award for its Hospital Incentive Program and Quality Physician Performance Program, are rewarding hospitals and physicians for practicing evidence-based medicine and implementing other nationally recognized best practices.[24]

Healthcare Providers and Provider Organizations include individual physicians and clinicians as well as the provider practices, hospitals, and health systems in which they provide care. Together, these groups are the focal point of most quality improvement efforts. Innovative and leading-edge providers and provider organizations are leveraging

their clinical data to drive internal quality improvements through health IT, including measuring clinical trends, identifying gaps in care, and giving providers, researchers, and patients access to the collected information.

B. Current Landscape of Quality Measurement

Over the last 15 years, the healthcare industry has developed metrics to assess performance for three primary purposes: internal improvement, public reporting, and value-based reimbursement. The sources for these measures vary and have changed over time. Initial quality measures relied heavily on administrative data from provider billing systems and payer claims systems. These data had the advantage of being readily available and standardized, and measures based on them could often be calculated automatically with little if any human intervention. As quality measurement increasingly became a tool for benchmarking providers and even reimbursement, however, the imprecision of administrative data became a concern. Studies found that using ICD-9 billing codes to identify patient populations and specific interventions was significantly less accurate than relying on clinical data recorded during the care process.[25] Measures used for quality reporting began to shift toward using clinical data. While measures based on clinical data were more likely to be accepted by clinicians, extracting the necessary data elements presented additional issues. Precision—most frequently reflected in detailed exclusion criteria to define the measure denominators—translated into a heavy burden of manual chart abstraction. To date, EHRs have not made a significant dent in this burden. In recent years, there has even been a slight shift back to using administrative data: Eleven of the 13 new inpatient hospital measures implemented by CMS for FY 2009, for example, use administrative data.

As the HITEP seeks to conceptualize a QDS for which interoperability standards should be prioritized, it will be useful to understand the measures that organizations are currently using and how they are (or are not) using administrative sources as well as EHRs and other health IT tools to collect and report them.

The following section presents a discussion of which measure sets are being used, how organizations are altering widely used measures to meet their measurement goals, and types of care organizations would like to measure but cannot. As with other sections of this report, the information presented is intended to provide a window into what is happening in the real world environment, but because of the relatively small number of organizations interviewed, is not a scientific sample of the entire universe of organizations undertaking measurement activities.

1. CURRENT REPORTING REQUIREMENTS

Healthcare quality measurement in the United States began as a decentralized endeavor, with providers and payers developing their own measures for internal improvement and reporting purposes. In the 1990s, however, national healthcare organizations began to define the measurement landscape. In 1992, NCQA took responsibility for the Healthcare Effectiveness Data and Information Set (HEDIS), an effort by employers and health plans to develop a common ambulatory care measure set for the managed care population. NCQA expanded HEDIS to accommodate additional measures and domains of care and in 1999 incorporated it into the NCQA managed care accreditation process. Today, NCQA accredits health plans and measures performance using a set of over 60 standards spanning across 40 conditions and areas of care. The majority of NCQA measures can be

calculated solely from claims data, but a few widely used measures, such as the diabetes measures, require clinical values that are not available in claims.

A similar process occurred for the inpatient community. The Joint Commission, known at the time as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), released its ORYX program in the mid-1990s in an effort to incorporate objective measurement of care processes into the hospital accreditation process. Under the initial ORYX program, hospitals were required to demonstrate that they measured their care processes against an external reference database. In 2002, JCAHO further standardized this initiative by establishing core measures in four clinical areas and requiring the use of a subset of these measures as a prerequisite for accreditation. These core measures, which were based on measures developed by CMS for use by its Quality Improvement Organization program, have since expanded to include eight domains of care. The heavy reliance of these measures on clinical data translates into a high reliance on chart abstraction in order to calculate the measures.

Responding to dictates in the Medicare Modernization Act of 2003 to increase the transparency of healthcare, CMS further reinforced the use of the core measure set in 2004, when it tied reporting of a "starter" set of 10 core measures to receipt of a hospital's full Medicare market basket update. This connection of quality reporting to payment in effect ensured that virtually all acute care hospitals in the United States would report on a common measure set. Public reporting of hospital performance on CMS' Hospital Compare website has served only to heighten the centrality of these measures, which now include 43 process and outcome measures as well as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAPHS) patient experience of care survey.[26]

CMS has also initiated an ambulatory care quality reporting program. The PQRI, now entering its third year, offers incentive payments to providers (currently two percentage points) who report on quality measures for a minimum percentage of their patients. The 2009 PQRI consists of 153 quality measures and 7 measures groups.[27] Participating providers can choose from a wide array of performance measures in primary and specialty care, some of which overlap with HEDIS and AQA measures. Reporting can occur via claims or, for some measures, via registries that CMS approves for this purpose. In addition, in 2009, CMS is piloting the use of EHR-based reporting for 11 measures.

Other national organizations have contributed measure sets that are widely used in the field. The Society of Thoracic Surgeons National Database, developed in the early 1990s, is now used by over 85 percent of cardiac surgeons nationwide,[28] and the American College of Cardiology's National Cardiovascular Data Registry offers standardized measures for both facility-based and office care. Submission to these registries is primarily a manual process that relies on chart abstraction.

New Directions in Measurement. The nationally oriented initiatives highlighted above have offered evidence-based, tested process and outcome measures with high reliability and validity for particular sectors of the healthcare community. As attention shifts to the need to provide patient-centered care across care settings, however, a new paradigm of measurement needs to be developed. Several nascent efforts to measure care across settings are worth noting. CMS' CARE tool, described earlier, seeks to use a common tool with common measures across post-acute care settings to support continuity of care.

NQF's project "Measurement Framework: Evaluating Efficiency Across Patient-Focused Episodes of Care" has developed a conceptual model that can catalyze the development of measures across care settings.

As the number of available measures continues to multiply, and reporting mandates continue to increase, there is a concern that the costly and labor-intensive nature of current measurement activities is not sufficiently advancing the state of healthcare delivery in the United States. The National Priorities Partnership, an initiative sponsored by NQF, seeks to define "high-leverage" areas that, with the appropriate focused measurement resources, are most likely to demonstrate improvements in care delivery. Through a collaborative process involving 28 national organizations, the National Priorities Partnership will work toward setting a consensus-based set of priority measurement areas for the nation.

2. USE OF MEASURES TODAY

The 20 organizations that Booz Allen interviewed present a useful snapshot of how provider groups, health plans, employer initiatives, and other collaborative groups are utilizing measures to achieve quality improvement goals. These organizations have taken advantage of the emergence of the widely accepted, evidence-based process and outcomes measures for ambulatory care as well as inpatient and outpatient facility-based care that are discussed above. The publicly reported measures contained within the HEDIS, AQA, HQA, Joint Commission, and CMS measure sets offer a ready-made set of tested measures that increasingly cover a large spectrum of care provided.

Measure sets used. Organizations interested in assessing inpatient performance used the measures under CMS' RHQDAPU program as the basis for their quality reporting and improvement activities. As one health plan stated, "we use what hospitals already report on." Several nonprovider organizations with easy access to claims data supplemented these measures with claims-based reporting (e.g., CABG mortality; AHRQ Patient Safety Indicators).

Interviewees focused on ambulatory care similarly relied on the widely used AQA and/or HEDIS measures, but were more likely to report that they "tweaked" the measures to suit internal needs. For example, one collaborative and former BQI site created composite measures on diabetes, ischemic heart disease, and vascular disease, relying on HEDIS measures for the child measures. Another collaborative, in an effort to make the measures more acceptable to providers, refined the denominators of HEDIS/AQA measures to ensure the population was more narrowly focused on a provider's "current" pool of patients. IHS altered denominators to narrow the measures to particular age ranges or gender to better focus its internal reporting on specific populations. A health plan changed the timing of data collection of HEDIS diabetes measures, preferring to measure concurrently rather than retrospectively.

A few organizations created their own "home-grown" measures. For example, two inpatient provider organizations reported developing measures for internal improvement that focused on particular "hot button" issues such as safety and door-to-drug times for which no existing measures were suitable. IHS has created its own measures to meet several different government reporting requirements for federally sponsored healthcare programs. When widely used measures that mapped to IHS goals required chart abstraction or simply were not available, it developed alternative measures that could be

collected via the fields available in the Resource and Patient Management System, its EHR. A statewide collaborative created its own depression measures that capture data longitudinally from point of onset through the first year of treatment to see if patients improve over a baseline PHQ-9 score.

Data Types/Categories Used. HITEP 1 defined data categories and types necessary to measure a priority set of HQA and AQA measures. Booz Allen sought to determine through its interviews and through examining supplemental data provided by some respondents how the data being collected by the 20 interviewees compared to the common data categories and types in the HITEP I report. Since the organizations interviewed by Booz Allen used the same HQA and AQA measures that HITEP had initially prioritized, it was not surprising that the categories and types of data they reported using in quality measurement activities tied closely to the list in the first HITEP report. Whether the interviewee was part of a provider organization with direct access to many of the data types necessary to calculate quality measures or a collaborative that had to obtain data from providers, payers, and other sources, the respondents reported using the same types of data. Diagnosis, diagnostic study (order and result), medication order and order filled, procedure, and vital signs (i.e., blood pressure) were frequently used. The organizations also collected data on the providers and payers, date of service, and patient demographic information. The measure specifications and data dictionaries supplied by some of the interviewees and provided to NQF as a supplement to this report offer more detailed information on measure types as well as which standardized codes are used to capture them.

3. MEASUREMENT GAPS

Stakeholders interviewed were also asked whether there were aspects of clinical care they would like to measure but were unable to measure. In their responses, the interviewees listed not only domains they would like to measure, but types of data they would like to collect but could not currently access.

The most frequently mentioned domains for which the respondents would like to measure performance were specialty care and continuity of care across settings, especially post-discharge. Both collaboratives and providers expressed interest in measuring each of these areas. Reasons that specialty care was not currently being measured included cost and limited availability both of the data and of adequate measures. Similarly, the lack of existing measures of care coordination/transitions across settings was a barrier to measurement in that area. Another related area respondents indicated they would like to measure but was currently unable to were episodes of care. The desire to conduct longitudinal assessments was mentioned several times by respondents.

Other areas cited by more than one respondent included measuring efficiency (e.g., patient flow), mentioned by three inpatient providers, and pediatric care. Several interviewees said they would like to delve more deeply into issues around disparities in care, but were hampered by a lack of racial and ethnic data. Behavioral health, cancer staging, obesity, hypertension, and filled prescriptions were also mentioned.

Certain barriers to measurement were mentioned more frequently by particular types of interviewees. Collaboratives, which almost exclusively rely on other organizations to provide data to them, often cited cost as a barrier to additional measurement. For example, one collaborative that wished to measure specialty care noted that some of the

data it would need to measure was currently available via registries, but that the specialty societies charged too much for access to the information. Another mentioned the same barrier for laboratory data—while hospitals that were part of the collaborative provided their in-house laboratory data to the collaborative, the collaborative needed to pay for access to reference laboratory data. A third collaborative mentioned cost in general as a barrier to all the areas this organization would like to measure. In contrast, cost was less frequently mentioned as a barrier by provider organizations, which were more apt to cite the lack of adequate measures as a reason they were not conducting certain measurement activities.

The absence of an available electronic record of a transaction was another barrier mentioned. Three examples were provided: patients paying cash for generic drugs rather than using their prescription plans, patients taking over-the-counter medications, and patients receiving care at employer-based clinics. In all situations, no claim is filed and no other electronic record is available, making it difficult to collect data about what occurred during the transaction.

C. Current Approaches for Quality Measurement and Improvement

Current efforts to collect data for quality measurement and improvement purposes follow a common process that typically includes the following key activities: data collection, aggregation and measure calculation, and audit and validation of results. However, the use of health IT as a data source for quality measurement and improvement initiatives has introduced critical points of variation in how these activities are carried out. In addition, differences in the organizational constructs used to exchange health information for quality measurement and improvement purposes also result in variation in how these activities are conducted. Understanding the current approaches to quality measurement and improvement along with the challenges faced in carrying out these activities will provide useful context to the HITEP as it deliberates on how to conceptualize the QDS.

The following section presents an overview of the quality measurement and reporting activities described by interviewed stakeholders, including a discussion of the impact the quality measurement and reporting process and health IT have on clinical workflow. In addition, it describes the input received from interviewees regarding the exchange of clinical information among providers and across care settings to facilitate continuity of care, when such exchange occurs. Finally, a summary of the challenges associated with the use of electronic clinical data for quality improvement as articulated by the interviewed stakeholders is also provided. As noted previously, findings should not be considered representative of the universe of organizations undertaking measurement. They do, however, provide useful insight into the issues being faced by stakeholders involved in measurement activities that use electronic data.

1. OVERVIEW OF THE QUALITY MEASUREMENT AND IMPROVEMENT PROCESS

Data Collection. The sources of clinical data (e.g., EHR, paper chart, other clinical health IT systems) used to inform quality measures varied depending on the infrastructure and resources available to the interviewed organizations. Data sources for the measures collected by the providers interviewed included information from internal administrative and financial systems, paper charts/medical records, EHRs, and other clinical health IT systems. In some cases, data from laboratory systems, pharmacy systems, and radiology results were integrated with the provider organization's health IT systems. This integration usually occurred in the large health systems and integrated delivery systems where such

services are part of the organization. In situations in which the laboratories were independent entities, data were sometimes sent to the provider in paper or electronic format but were not necessarily integrated into their health IT systems. Whether or not data are sent to the provider in these cases depended on the data sharing arrangements in place between the provider and the external entity. For collaboratives, data collection was dictated by the partnerships in place with local organizations, to include hospitals, providers, health plans, and, in a few cases, local laboratories and pharmacies.

While infrastructure and resources dictated which data sources are used to support care delivery and quality measurement, the nature of the measures themselves also influenced data sources used and data collection processes. For example, all providers/integrated systems interviewed that included inpatient facilities submitted data for the CMS RHQDAPU program. By necessity, these measures require manual data collection. As several provider organizations interviewed pointed out, it is impossible to collect via EHRs all the data necessary to populate CMS' RHQDAPU measures. Even interviewees that had developed their own EHRs could not achieve 100 percent electronic collection. They were able to populate between 70 percent and 85 percent of the RHQDAPU measure data automatically, but still had to supplement the electronic data with data obtained through manual chart abstraction. One organization cited the specific timing requirements inherent to the RHQDAPU measures as the kind of data element that could not be collected electronically. An example of ambulatory measures dictating which data sources were used was raised by an integrated health system that reported on childhood immunizations and lead exposure assessments. In both cases, the system had to integrate administrative data from statewide registries with its internal EHR data in order to report on these measures.

There were also instances in which providers did not rely solely on electronic data because they felt clinical judgment was necessary. An example raised was bloodstream infections. Even though electronic data might indicate that an infection was present, there still needed to be clinician review to determine the cause of the positive culture.

Finally, there were also business reasons providers could not rely solely on EHRs as sources for quality measurement. While most of the providers reported having some laboratory data integrated into their EHR, and several also had integrated radiology or pharmacy information, they at times had to incorporate ancillary data from a provider that did not integrate with their system. For example, one small provider interviewed was part of a larger physician group that used a common EHR, but the local hospital where they admitted most of their patients was not part of their integrated system. All relevant information from this hospital was scanned into its EHR and had to be extracted manually for quality improvement and reporting purposes.

Aggregation and Measure Calculation. The majority of interviewed stakeholders who took part in data aggregation and measure calculation activities indicated that even with the use of electronic data, significant manual effort was required to ensure data were aggregated and measures were calculated properly. Mapping electronic health IT system data fields to quality measures is an important part of this process and one that happened with varying degrees of sophistication across the interviewed stakeholders. One collaborative respondent indicated that it provided measure specifications to its providers and then actively worked with them to ensure they were using the appropriate fields from which to pull data to inform their quality measures. The collaborative noted that the process was not formalized, and it did not have documentation of its system to measure

mapping, but that it utilized a dedicated staff person to review the submitted data and work with its provider organizations to ensure the data that were submitted were appropriate for the measure. Another collaborative indicated that it had developed detailed data maps and worked with its providers to ensure they were followed.

For multistakeholder collaboratives, aggregation was a particular challenge because the providers submitting data were not all using the same vendor products for their clinical health IT systems. Ensuring that all provider organizations were submitting appropriate data and that the data could be aggregated across these organizations required significant effort. Two collaboratives used a vendor to perform this service and indicated that the vendor had developed very detailed data maps that allowed them to perform this activity. Two other collaboratives dealt with this issue by asking participating provider organizations to submit data via an online portal. While this method helped with data standardization, it also required manual data entry to submit the data on the part of the providers. Two collaboratives indicated that they also accepted paper-based data faxed by providers who lacked clinical health IT systems or who lacked the resources to extract the data from their clinical health IT systems, which added to the complexity and level of effort required to aggregate the data. Only one collaborative indicated that it had succeeded in collecting all the necessary data from EHRs and was able to automatically extract the data and enter it into its clinical data repository. This collaborative followed a deliberate strategy of standardizing the EHRs used in the communities it serviced, and then working with the EHR vendors to customize the tools to meet reporting needs. A few collaboratives also collected data from health plans and/or laboratories in the communities they served. While the data collected from health plans were claims data, collaboratives faced significant challenges with ensuring that patients, providers, and facilities were matched appropriately.

For aggregation that occurred within large health systems or integrated delivery systems, aggregation of data to calculate measures was less burdensome primarily due to the fact that a common technology platform was used across facilities and data were simply being submitted to a parent organization.

Audit and validation of results. A critical step in calculating measures was auditing the data. Interviewed stakeholders indicated that audit processes were used to ensure data accuracy, to ensure completeness of data, and to ensure numerator and denominator calculations were accurate. Even with the use of electronic data, this step was necessary due to the complexity of measure specifications. Audit and validation were burdensome and time consuming for the interviewees since they are largely manual processes.

2. QUALITY MEASUREMENT AND CLINICAL WORKFLOW

The impact of quality measurement and reporting activities on provider institutions and, more specifically, on clinical workflow is an issue of concern for the healthcare industry. Research indicates that the administrative burden on hospitals and providers to report on quality metrics is significant and continues to grow as reporting requirements and quality improvement initiatives expand.

EHRs and other clinical health IT systems have helped reduce the burden of clinical data collection on nursing and support staff and have also helped to eliminate redundancies in data collection tasks.[29] However, studies have also shown that even where EHRs have been implemented, some degree of manual chart review is still necessary to ensure

accurate quality reporting.[30] These findings were echoed by the stakeholders interviewed as part of the environmental scan, who indicated manual chart reviews and/or detailed review or audit of submitted data were needed to ensure appropriate calculation of the numerator and denominator for quality measures and to ensure that exclusion criteria were properly taken into account.

While it has been widely recognized that implementation of an EHR can have positive impact on the efficiency with which clinical workflow is conducted,[31] both anecdotal evidence from the interviews and literature suggest that EHRs and other health IT systems are not developed with quality reporting requirements in mind.[32] Typical problems include difficulty in identifying the best methods to record needed data through the EHR and variations in recording practices across providers.[33] Interviewed stakeholders cited both of these as major issues when considering clinical workflow within their own organizations. These issues, in turn, lead to the need for the manual review discussed above to support quality measurement. Some interviewed organizations indicated that they relied on vendors to provide data extraction services. Others have worked with their vendors to establish quality measurement and reporting modules that sit on top of their EHRs. Providers indicated that ability to query the EHR using variables of interest to them was a much-needed feature that would greatly facilitate quality measurement and reporting initiatives.

Training, user preferences, support from organizational leaders, and the extent to which clinical workflow was taken into account when planning the integration of the EHR into routine use are all seen as critical variables to successful EHR implementation.[34] However, all but two of the interviewed provider organizations indicated they do not have formal clinical workflow documentation, even though many articulated the importance of workflow assessment in implementing their own EHRs. Two large health systems indicated that they were beginning to develop clinical workflows for their system because they realize the inherent value of the workflows, though no substantial progress had been made to share with the HITEP.

3. HEALTH INFORMATION EXCHANGE TO FACILITATE CARE COORDINATION

ONC defines health information exchange as “the electronic movement of health-related information among organizations according to nationally recognized standards.” ONC goes on to describe health information exchange as supporting several primary functions including quality improvement and facilitation of coordinated care.[35]

All of the stakeholders interviewed indicated they are exchanging clinical data electronically to support the collection and reporting of quality measures and use of that information to inform organizationally driven improvement efforts. However, only a subset of the interviewed stakeholders is exchanging clinical health information to facilitate care coordination. Those stakeholders that are exchanging data for this purpose have one key factor in common: the use of a common interoperable technology platform that allows providers across facilities and care settings to access patient data.

A common technology platform typically means that the exchange of health information happens under the umbrella of a common parent organization, such as within a large integrated delivery system or health system. Interviewed stakeholders that represented such organizations indicated that electronic information sharing was limited to those facilities that were part of their network. However, being part of this type of organizational

entity does not guarantee that a common technology platform exists. For instance, one health system indicated it is still working to migrate some of its facilities from existing legacy systems to its chosen administrative and clinical health IT systems. In addition, due to the incremental nature of EHR implementation across networks of providers and institutions, different facilities are using one of two different EHR products. The health system was able to address this limitation by creating an interface between the two EHR systems that allows data sharing between them. Another large health system indicated that health information exchange across its network of facilities still occurs via telephone call, fax, or sharing of paper documentation because of its use of different clinical health IT systems that are not interoperable. This health system did indicate that it is working towards implementing a common EHR technology across its network of facilities.

Interviewed stakeholders indicated that when a common technology is in place to allow an HIE to facilitate continuity of care, providers have access to clinically relevant information related to patients under their care, including common allergy lists, medication lists, and problem lists. However, interviewees also indicated that reconciliation and review processes required an active effort on the part of physicians to review these lists.

The multistakeholder collaboratives that were interviewed as part of the environmental scan typically did not facilitate data sharing across their provider institutions. Instead, they provided reports back to the providers that were part of their collaborative on their performance.

4. CHALLENGES

As part of the interview process, stakeholders were asked to describe the challenges faced in capturing and/or aggregating standardized clinical data through EHRs or other clinical health IT systems to support their quality measurement and improvement activities. The answers spanned multiple areas and have been grouped to describe technical challenges (e.g., lack of standards, measure specifications), policy challenges (e.g., privacy and security), and business-related challenges (e.g., costs, resources). A summary of these challenges is presented below. Further discussion of these issues as they relate to recommendations made by the interviewed organizations is presented in Section IV.

Technical Challenges. The technical challenges identified by interviewees spanned limitations in quality measures that impacted their ability to populate metrics using EHR data to deficiencies within EHR and clinical health IT systems themselves (see the box below). The overarching impact of these issues was an increase in the manual burden to report on quality measures and limitations on the quality assessments that could be made. Understanding these challenges can provide the HITEP with useful insights regarding hurdles that must be overcome related to health information exchange and quality measurement and improvement using clinical electronic data.

Technical Challenges
• Measure specifications are not structured in a way that they can be easily translated into electronic reporting requirements. • Identifying inclusions and exclusions and constructing measure numerators and denominators when using EHR data are difficult. For example: – Considerable manual effort is required to ensure adherence to complex and changing exclusion criteria because EHRs are not structured to capture exclusion criteria the way that measures specify them. – EHRs typically do not record time of data collection, thus making it difficult to report on measures that include a timing component. • Lack of structured fields makes it difficult to capture important patient data, including surgical and medical history. • Having incomplete data complicates verification that measures are accurately reflecting performance. It is difficult for collaboratives in particular to know if they are receiving complete data from all participating provider groups. Collaboratives also often lack important administrative data on certain segments of their community's population. (Also noted as a business challenge.) • Inability to consistently and accurately identify patients and to match patients to providers limits ability to support care across care settings and to assess episodes. (Also noted as a policy issue.) • Disparate clinical health IT systems (and in some cases manual charts) cause challenges for data aggregation due to differences in EHR architecture and how data are structured. • Inability to map laboratory data from private laboratory companies to quality measures due to their use of proprietary code sets and lack of enforceable content standards for laboratory data limits the ability to use laboratory data in quality measurement and improvement initiatives. • Difficulty in querying and extracting data from EHRs using variables that could be used for quality improvement limits the ability to measure quality, analyze information, and make improvements in care delivery • Lag between care delivery and quality/performance reporting due to the time required to collect data, develop measures, audit the data, and develop reports is significant and can reduce the ability to act on the performance reports in a meaningful way.

Policy Challenges. The policy challenges identified by interviewees described barriers to both quality measurement and health information exchange using EHRs that transcended the fields of quality measurement and health IT. These challenges are listed in the box below. While these barriers may not be within the scope of the HITEP to address, they provide useful context regarding what implementing organizations face today.

Policy Challenges
• Low EHR adoption in some communities necessitates continued reliance on claims-driven quality measures and also complicates the ability to develop aggregate metrics using clinical data. • Privacy and security issues impede information exchange across organizational boundaries. • Inability to consistently and accurately identify patients and to match patients to providers limits ability to support care across care settings and to assess episodes. (Also noted as a technical issue.)

Business-Related Challenges. The business-related challenges articulated by the interviewees, provided in the following box, focus primarily on the burden and costs of quality reporting. In addition, the inability to access and utilize information across organizational boundaries was another theme that emerged from the articulated challenges. Similar to the policy challenges just described, while these barriers may not be within the scope of the HITEP to address, they provide useful context regarding the issues that interoperable health IT and standardization of electronic clinical data can help to address.

Business-Related Challenges

- Manual burden of data collection for quality measurement, even with the use of EHRs (e.g., use of structured data fields as opposed to free text data fields), can be a drain on resources and reduce clinical staff ability to spend time on care delivery and requires an assessment of the tradeoff between improved ability to analyze clinical data and reductions in clinical workflow efficiency.
- Inability to exchange data across care settings limits access to the most up-to-date and accurate information about a patient, thereby restricting the ability to deliver optimal care. Stakeholders specifically referenced the lack of information about care received in nonintegrated facilities as a challenge.
- Substantial costs associated with modifications to health IT systems and with utilizing vendors to extract data and assist with data collection, aggregation, and measure calculation limit some organizations' ability to participate in multiple quality initiatives.
- Increased costs associated with accessing laboratory data from private laboratory companies hamper the ability to include laboratory data in quality measurement.
- Incomplete data make it difficult to report on quality measures and to ensure measures are accurately reflecting performance. Collaboratives, in particular, find it is difficult to know if they are receiving complete data from all participating provider groups. They may also lack important administrative data on certain segments of the community population. (Also noted as a technical challenge.)
- Limited resources to support quality measurement and improvement hinder the ability to pursue quality measurement initiatives that could help improve care delivery. Specifically referenced limitations include:
  - Burden of manual chart review/analysis and audit/validation to ensure correct measure construction and to take into account complex exclusion and inclusion criteria.
  - Burden of constructing measures using aggregated data across organizations, which requires complex data mapping.

IV. Recommendations to HITEP Priorities for Structured Clinical Data

Organizations that are currently collecting and exchanging data to measure performance have unique insights into the kinds of changes that could be made to measures, tools, and the overall infrastructure in order to improve the quality measurement enterprise. As part of the interviews with stakeholders, Booz Allen asked what data categories, types, or elements respondents would prioritize for better standardization to improve their ability to measure and improve quality. In addition, Booz Allen asked for their recommendations on how health IT could be enhanced as a data source to support quality measurement and improvement. The recommendations provided can directly inform the HITEP's efforts to

conceptualize a QDS for which interoperability standards should be prioritized. In addition, these recommendations can help the HITEP better understand changes that need to be made in the overall quality measurement environment to support automated quality measurement and reporting.

Not surprisingly, the interviewees' responses reflected the challenges and gaps described in the previous section, as well as the interviewees' enumeration of areas they would like to measure but are not currently able to measure. Their recommendations have been categorized below into technical recommendations (e.g., standards for laboratory values), policy recommendations (e.g., privacy and security issues), and business recommendations (e.g., to promote investment in interoperable EHRs). To facilitate review of this information, the responses have been *ordered* within each of these categories according to the number of times they were recommended by the interviewed organizations.

1. TECHNICAL RECOMMENDATIONS

The technical recommendations received from the interviewed stakeholders crossed many different topic areas (see the boxes below). To facilitate NQF and the HITEP's review, the responses have been grouped into two categories:

- Recommendations for areas in which standardized data elements (for values and/or interoperability) are needed to support information exchange for quality measurement and continuity of care. Many of the providers described specific categories of data that should be better standardized. Others described clinical domains or care settings that should be better standardized or for which standardized measures needed to be created.
- Recommendations for enhancements to EHR functionality to better support information exchange for quality measurement and continuity of care.

Technical Recommendations
Standards to Support Quality Measurement and Continuity of Care
Standardization of specific categories of data • Laboratory data, including laboratory orders and laboratory results • Medications/prescription data, including standardized nomenclature, and information on both prescriptions and fills • Patient medical and surgical history • Immunization data • Diagnostic test data • Allergy data • Comorbidities • Contraindications • Information on functional status

Technical Recommendations
Specific domain or clinical care settings that require standardization
• Specialty care*
• Continuity of care*
• Episodes of care*/longitudinal assessment
• Chronic care conditions
• Patient satisfaction*
• Disparity assessment (e.g., race, ethnicity)*
• Preventive services
• Pediatric care
• Behavioral health
• Clinical decision support
• Areas prioritized by the NQF National Priorities Partnership initiative

* *Denotes areas for which the interviewed stakeholder indicated that measures also need to be created.*

Standardization of Specific Categories of Data. Interviewed stakeholders recommended that several data categories should be standardized, both to expand the types of data available electronically to conduct quality assessment as well as to improve the quality of that data. In many cases, identifying interoperability standards and standards for values will also help to reduce the manual analysis that goes into identifying measure inclusions and exclusions.

The majority of interviewees cited the need for standardization of laboratory and medication/prescription data. For example, one collaborative reported that a laboratory responsible for approximately 50 percent of its patient population used proprietary codes for its laboratory data. As the interviewee noted "because there is no requirement for laboratories to use Logical Observation Identifiers Names and Codes (LOINC), they don't." Another collaborative cited the difficulty in standardizing the laboratory data because it is "such a decentralized industry." The need for standards related to medication nomenclature was referenced several times by interviewees despite the existence of the National Drug Code, which was described as "over-specific" by one interviewed stakeholder and not necessarily usable for quality assessment purposes.

Five organizations mentioned the need to standardize data capture for medical and surgical history in order to get a more comprehensive view of the patient. One of the organizations cited the example of a patient fall. Knowing that a patient had a fall in the past would be a crucial piece of information for a clinician, yet that fact would not be captured in most EHRs if it were not the reason for the patient's visit.

In an effort to support continuity of care, immunizations, prescriptions, diagnostic tests and their respective values, and allergies and contraindications were also mentioned by interviewees as areas that required further standardization.

Specific Domain or Clinical Care Settings that Require Standardization. Interviewed stakeholders cited several domain areas and clinical care settings for which standardization could facilitate quality assessment. In some cases, noted by an asterisk in the

previous table, the stakeholders also referenced the need for standardized measures in these same areas.

Standardization of data to support assessment of disparities in care was recommended twice by organizations that wanted to look at trended data to determine whether different care regimens would benefit patients of specific races or ethnicities. In addition, one organization recommended that the HITEP begin its efforts by focusing on the measurement areas defined by the NQF Priorities Partnership initiative.

Technical Recommendations
Enhancements to Existing EHRs
• Standardized data capture • Automated exclusion criteria assessment and numerator/denominator calculation • Patient identifier • Algorithms to match patients with their providers • Timestamps • Clinical decision support • Expanded query capabilities • Data export/extraction

Interviewed stakeholders made several recommendations regarding enhancements to EHRs that could facilitate use of information for quality measurement and reporting and to facilitate continuity of care. These recommendations encompassed both standard-ization of data capture as well as additional or expanded functionality.

Standardization of data capture was an issue raised by many stakeholders. Many interviewees were frustrated with trying to extract specific information from unstructured narrative, such as patient histories or progress notes. Four interviewed stakeholders specifically recommended the use of structured data fields for areas such as medical/surgical histories. Of course, the existence of structured data fields alone was not always a guarantee that providers would use them. One interviewee pointed out the importance of integrating data collection into clinical workflow so that the use of structured data fields was less of a burden to providers.

One provider took the issue of standardizing data capture a step further and recommended development of a framework for data collection that would cover both data capture as well as standards related to the values and nomenclature (discussed in *Standards to Support Quality Measurement and Continuity of Care,* above) used to document information in the EHR.

As referenced above in the section S*tandards to Support Quality Measurement and Continuity of Care,* interviewed stakeholders recommended several categories of data for which interoperability standards and standards for values would help to reduce the manual burden of assessing inclusions and exclusions to construct measure numerators and denominators. Related to these recommendations, several stakeholders also recommended standardization of the mechanisms for capturing data within an EHR for inclusion and exclusion criteria. One organization gave the following example regarding the capturing data regarding smoking status: “If you ask the patients if they smoke and

the patient quit six months ago, the patient will reply no. If you ask if the patient smoked in the past year, they will respond yes." These two different questions would elicit different responses from the same patient, which would in turn impact the denominator of related measures (such as the RHQDAPU measures requiring smoking cessation counseling) and result in inaccurate reporting. Standardizing how fields are constructed and displayed within an EHR will improve the ability to correctly establish numerators and denominators for quality measures.

In addition, two additional interviewees specifically recommended that EHRs add in functionality to enable automated assessment of inclusion and exclusion criteria. These two organizations cited the need to reduce manual burden on staff to manually review the data.

The majority of interviews identified the need for a unique patient identifier that could be used across EHR systems, and several recommended establishment of such an identifier. Two providers made this recommendation specifically in relation to facilitating data aggregation and to supporting longitudinal quality measurement and improvement, which also requires the ability to do patient-provider record matching. Four collaboratives that made this recommendation cited the need to enable patient and provider record matching to track physician-level performance as well as to facilitate continuity of care. One collaborative provided several examples as to how a patient identifier would be useful in different settings to facilitate improved care delivery:

- Breast Cancer Screening: A patient may have an exclusion in her history that would require the universal patient identifier in order to track the procedure (mastectomy, bilateral or unilateral).
- Colorectal Cancer Screening: A patient may have an exclusion in his/her history that would require the universal patient identifier in order to track the procedure (total colectomy). Also, the colorectal cancer screening measures often require a historical view into a patient's history to collect information on flexible sigmoidoscopy, colonoscopy, and even double contrast barium enema.
- Diabetes Eye Exam: If a patient seeks care from an outside source, a Walmart or another nonhealthcare institution, for example, aggregation of data would require a universal patient identifier in order to record that a patient has had the required service.
- Pharmacy Data Dependent Measures: If a measure would require a prescription fill, a universal patient identifier to follow the data back from the pharmacy claim to the provider would be necessary.

Building on the need for a universal patient identifier, four collaboratives recommended having the capability to match patients with their providers through the development of algorithms. Identifying and using such algorithms in conjunction with a universal identifier or even an organizational-level identifier would facilitate the ability to track patients across the continuum of care and measure performance longitudinally.

Two interviewees recommended that EHR functionality should be expanded to include a record of "when" in time important events, such as procedures, tests, and other aspects of medical and surgical history, occurred. One interviewee noted that the lack of a "time stamp" limits the ability to report electronically on Hospital Compare quality measures that

have a timing component. Another provider noted that a time stamp could help ensure the most up-to-date information regarding a patient is captured within the EHR. It could also help to prompt providers to ask for information if the record is out of date.

Several organizations recommended that standardized clinical decision support functionality needed to be embedded into EHRs to support care delivery. Clinical decision support holds the promise of facilitating consistent delivery of evidence-based care but could also help to facilitate quality assessment as well. Four interviewees recommended the addition of prompts to ensure information related to measure inclusion and exclusion criteria were collected only when it was appropriate to do so. Development of such functionality builds on the concept of automated inclusion and exclusion criteria referenced earlier.

Several stakeholders recommended that better querying and extraction functionality be developed within EHRs to allow EHR users themselves to extract data at both the patient and population levels. They specifically noted that it was important to query all of the data available within the EHR using data elements/variables of interest, not just those used for quality measurement.

2. POLICY RECOMMENDATIONS

Policy Recommendations
• Need a better methodology to match patients and providers.
• Need a common patient identifier that can be used across settings.
• Need to address privacy and security issues to facilitate information sharing.

Each of the recommendations grouped under the heading of "policy recommendations" in the box above has both a technical and a policy component. The recommendations have been included here to reflect the fact that technical solutions alone will not resolve the issues they are raising–each has a strong policy component that must be addressed.

Several interviewed organizations referenced the issue of patient and provider record matching and recommended it as an area for which improved methods were needed. One stakeholder specifically suggested a national patient identifier to track patients. This stakeholder referenced the benefits such an identifier could make, including facilitating the ability to track patients across the continuum of care, develop episode of care groupings, and track costs and outcomes over time.

Another stakeholder referenced the need to address the "delicate balance" between sharing information and protecting patient privacy and recommended this issue as a critical area for which controls needed to be established, especially as we move into a future with increased health information exchange.

3. BUSINESS-RELATED RECOMMENDATIONS

Business-Related Recommendations
• Need for the measure developers to create better-defined specifications that can be used with clinical health IT systems. • Need for more flexible EHRs that can be easily modified or open source health IT software. • Need to establish a measure release cycle.

Business-related recommendations appear in the box above. Five interviewees cited the need for clearer, better-defined measure specifications. They cited the complexity of exclusion criteria and denominator calculations as being too difficult to code into their systems. One hospital system stated that to calculate the denominator of "any process measure, the inclusion, exclusion, and population definition specifications are often so complicated that it still requires manual clinical judgment to make a determination." Clearer, standardized specifications that can be translated to clinical health IT requirements will facilitate more accurate reporting as the risk of misinterpretation and inaccurate documentation decreases, and will also decrease the burden on the providers to collect data and calculate measures."

Not only are the measure specifications complex, they also change frequently, creating additional problems for organizations attempting to develop quality measures electronically. As one interviewee noted, "what gets included and excluded is complex and keeps changing." A few providers highlighted the costs associated with requesting modifications to their EHRs and health IT systems to better support quality measurement, especially in the face of continually evolving measure specifications and reporting requirements. One stakeholder referenced the costliness of an add-on module to support quality measurement and reporting and noted that it was not a luxury all provider organizations could afford to purchase. Others referenced the level of effort associated with building the programming to extract data from their EHRs and analyze that data. Stakeholders that opted to have a vendor perform such activities also incurred additional expenses as specifications and/or reporting requirements evolved. One stakeholder made the recommendation that the industry needed to move towards use of open source software to facilitate the ease with which providers could make modifications and improvements to their EHRs.

Another interviewee recommended that a regular measure specification modification/ measure release cycle would be welcome. Defined release dates would allow vendors to establish their own regular cycles for making upgrades to their EHRs. Establishing such a cycle would also help to minimize disruption to care delivery due to continuous EHR maintenance and upgrades as well as form changes in clinical documentation requirements.

V. Conclusion

Performance measurement is an important element of improving the quality of care provided in the United States. At the present time, however, measurement poses a significant burden in data collection, measure calculation, and reporting for the organizations involved. Required data elements are not uniformly available electronically, methods of capturing information may not have the precision necessary to define conditions accurately, and measure specifications and reporting requirements change frequently, all leading to extensive manual effort and/or cost outlays in order to measure quality. As this report has documented, organizations forego measuring certain aspects of performance because the burden of doing so is too great.

The current HITEP is poised to make a significant contribution to easing this measurement burden through developing a common quality measurement data set that could be collected electronically. This environmental scan can help the HITEP understand the real-world environment in which providers and collaboratives are operating today, including the often very basic challenges they face, the pressing needs that they have, and their perspective on how quality measurement can be enhanced electronically to improve the delivery of care. Participants in the this study were passionate about the ways that measurement can directly improve care delivery, and their insights can inform the HITEP as it embarks upon its creation of the QDS.

Appendix A: Interviewed Stakeholders

Collaboratives

- Anthem Blue Cross Blue Shield Virginia
- Arizona State University Center Health Information and Research
- Blue Cross Blue Shield Illinois*
- California Hospital Assessment and Reporting Taskforce Initiative
- California Cooperative Healthcare Reporting Initiative
- Indiana Health Information Exchange
- Massachusetts eHealth Collaborative
- Minnesota Community Measurement
- MedAllies (New York eHealth Collaborative Grantee)
- Pacific Business Group on Health
- Wisconsin Collaborative for Healthcare Quality

Providers

- Brigham and Women's Hospital
- Cincinnati Children's Hospital Medical Center
- Citizens Memorial Healthcare
- HealthPartners
- Hospital Corporation of America
- Lehigh Valley Physician Group
- Partners HealthCare
- Partners Community Healthcare
- Charles River Medical Associates

Government

- Centers for Medicare and Medicaid Services
- Indian Health Service

** The interview guide was not used for the discussion.*

Appendix B: Endnotes

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