

Outcome Measure Framework (OMF) Design Document

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1. INTRODUCTION

1.1. Background

A patient registry is defined as “an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.”¹ Common purposes for patient registries include evaluating the safety, effectiveness, or quality of medical treatments, products, and services, and studying the natural history of diseases. Some registries are developed and maintained solely to assist in care delivery, coordination, and quality improvement, but many serve broader research purposes. Properly designed and conducted, patient registries can provide unique insights into real-world clinical practice, effectiveness, safety, and quality.

Interest in and use of patient registries has increased in recent years. Despite this interest, there is no central database designed specifically to list patient registries. ClinicalTrials.gov is a database and public website that provides information about research studies, but it is designed primarily for providing information about experimental studies, such as randomized trials. Not all data fields in ClinicalTrials.gov are applicable or relevant to patient registries, and some data that would be useful for describing registries are not collected. A database and searchable public website that is designed specifically to provide information about patient registries would support research collaborations, reduce redundancies, encourage the efficient use of resources, and improve transparency in the use of patient registries.

The primary goal of the Registry of Patient Registries (RoPR) project is to engage stakeholders in the design and development of a RoPR database system that is compatible with ClinicalTrials.gov and meets the following objectives:

- 1) Provides a searchable database of existing patient registries in the United States;
- 2) Facilitates the use of common data fields and definitions in similar health conditions to improve opportunities for sharing, comparing, and linkage;
- 3) Provides a public repository of searchable summary results, including results from registries that have not yet been published in the peer-reviewed literature;
- 4) Offers a search tool to locate existing data that researchers can request for use in new studies;
- 5) Serves as a recruitment tool for researchers and patients interested in participating in patient registries.

1.2. Rationale

As noted above, the second objective of the RoPR system is to facilitate the use of common data elements and outcome measures across registries. A major effort in creating any new registry is the development of data elements and definitions. Currently, few standards exist across registries, and substantial effort is duplicated as each registry develops unique data elements and definitions. For example, multiple registries focusing on cardiovascular disease may collect myocardial infarction as a primary outcome, but each may use a slightly different definition of myocardial infarction. Two

registries focusing on cancer may each define “significant disability” differently and use unique validated instruments to measure this outcome. Not only does this represent an inefficient use of resources, but the variations in data elements and definitions make it far more challenging to link and compare data across registries. Standardization of data elements and outcome measures, including both common definitions and common syntax, would result in reduced effort in developing a registry and increased opportunities to link and compare data across registries.

As registries collect a broad range of data for multiple purposes, much work is needed to standardize all data elements for registries. Standardizing outcomes and outcome measures, which represent a subset of registry data elements, would provide substantial benefits by allowing results from individual registries to be compared and aggregated. Within patient registries, the outcomes that are collected and measured vary widely depending on the purpose of the study and may include events, laboratory test results, or patient-reported outcomes. Within this document, the term ‘outcome’ refers to an individual patient-level outcome (e.g., HbA1C > 9.0%), while the term ‘outcome measure’ refers to a population-level outcome (e.g., proportion of patients with HbA1C > 9.0%). Some examples of outcomes and outcome measures that may be used within a patient registry are listed in Table 1.

Table 1: Examples of Outcome Measures

Title	Definition	Type
Response to rituximab treatment	Reduction of ≥ 3 in score on the Safety of Estrogens in Lupus Erythematosus: National Assessment (SELENA) version of the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) ²	Outcome
Significant disability	A score of ≤ 40 on the Short-Form 12 (SF-12) ³	Outcome
Acute myocardial infarction inpatient mortality	Proportion of acute myocardial infarction (AMI) patients who expired during hospital stay ⁴	Outcome Measure
HbA1c in poor control	The percentage of patients 18-75 years of age with diabetes (type 1 or type 2) who had HbA1c in poor control ($>9.0\%$) ⁵	Outcome Measure

An important first step towards standardization is the collation of outcomes and outcome measures already used by registries. Characterizing the range of outcomes and outcome measures currently used within registries will allow for the identification of commonly used items that may become standards for new registries. In areas where there are no commonly used outcomes or outcome measures, characterization will provide the foundation for informed discussions about how to build consensus and move towards standardization.

1.3.Purpose and Objectives of the OMF

The purpose of this project is to design and develop a prototype of an Outcome Measures Framework (OMF). The Outcome Measures Framework (OMF) is being developed as a tool to facilitate the process of collating and characterizing the outcomes and outcome measures currently used in patient registries. The OMF is a mechanism for the collection and display of information on existing outcomes and

outcome measures used in patient registries in a standardized way and that supports searching for those outcomes and outcome measures. Users of the OMF will fall into two major types: those with a registry who are providing information on the data they collect in their registry, and those who are searching for information about how a particular type of outcome or outcome measure is collected within patient registries. The first group of users – registry holders – must be able to enter information into the system easily and efficiently. The second group of users – registry seekers – must be able to find sufficient information on outcomes and outcome measures to identify items for use in their own registry. Meeting the needs for both sets of users is an important consideration in the design of the OMF.

The initial objective of the OMF is to collect sufficient information to characterize the types of outcomes and outcome measures that are currently used in patient registries. The long-term objective of the OMF is to support efforts to standardize outcomes and outcome measures and to facilitate access to that information.

This document describes the proposed design of the OMF and discusses how the OMF could be incorporated into a system such as the RoPR. The design of the OMF will be revised and finalized following the peer review and public comment periods, and this document will be updated accordingly.

2. APPROACH TO DESIGNING THE OMF

2.1. Background Research

Existing systems that collect and present information on data elements, outcomes and outcome measures, and/or quality measures were identified and reviewed, including the Common Data Elements initiative at the National Institute of Neurological Disorders and Stroke,⁶ the United States Health Information Knowledgebase (USHIK),⁷ the Consensus Measures for Phenotypes and eXposures (PhenX) project, the National Quality Measures Clearinghouse (NQMC), and the National Quality Forum (NQF). Of the reviewed systems, the three systems that are most relevant for this project are PhenX, NQMC, and NQF. The most relevant of these examples is the PhenX project. PhenX aims to provide standard measures related to complex diseases, phenotypic traits, and environmental exposures, with the goals of facilitating the linkage of data from multiple studies and helping to integrate genetics and epidemiological research.⁸ Some of the PhenX measures are outcomes that would be suitable for inclusion in the OMF, and the system provides an excellent example of the ‘Toolkit’ approach, in which a user can browse or search for relevant measures and create a selection of measures to place in a bucket for later use.

Both the NQMC and the NQF provide information on quality measures, rather than outcome measures. The NQMC is a database of evidence-based health care quality measures and measure sets.⁹ Sponsored by the Agency for Healthcare Research and Quality (AHRQ), the system aims to provide detailed information on quality measures to a broad set of stakeholders to support dissemination, implementation, and use of these measures. While the system focuses on quality measures rather than outcomes, it contains many similar features to the proposed OMF, such as search and compare tools

and detailed measure summaries. In particular, the NQMC provides relevant examples of archived entries, topics for browsing, and a measure compare tool. The NQF is a nonprofit organization focused on improving the quality of health care by building consensus on national quality improvement priorities, endorsing national consensus standards for quality measures, and publically reporting on performance.¹⁰ The organization manages a directory of NQF-endorsed standards, which provides relevant examples of displaying search results and browsing options. All three systems provided useful examples of how to display individual measures and what information should be included for each measure.

In addition to the review of existing system, illustrative examples of outcomes and outcome measures that are currently used by patient registries were assembled. The examples cover multiple disease areas, such as diabetes, myocardial infarction, and heart failure, and outcome types, such as laboratory tests, events, and patient-reported outcomes. Forty-three examples were assembled, and ten illustrative examples are presented in Appendix A. The examples were used to explore the complexities around displaying and searching for measures within the OMF.

2.2.Stakeholder Activities

Five stakeholder meetings were held in the first quarter of 2011 to collect information on how outcome measures are collected currently in existing patient registries and to learn about how stakeholders would like to see information on outcome measures presented within the RoPR or another similar system. Registry sponsors, clinicians, and clinical researchers were invited to participate in the meetings, which were organized around the following AHRQ priority condition areas:

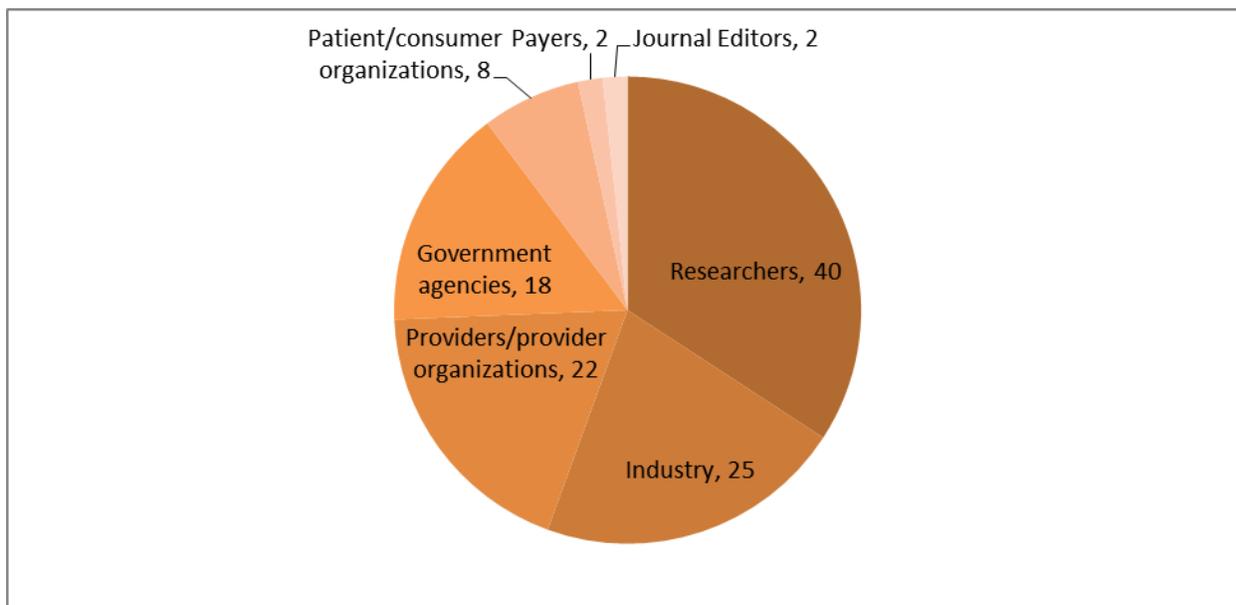
- Cardiovascular disease, including stroke and hypertension
- Diabetes mellitus
- Obesity
- Cancer
- Infectious diseases including HIV/AIDS
- Peptic ulcer disease and dyspepsia
- Pulmonary disease/asthma
- Arthritis and non-traumatic joint disorders
- Depression and other mental health disorders
- Developmental delays, attention-deficit hyperactivity disorder, and autism
- Functional limitations and disability

A final meeting was held in April of 2011 to discuss the preliminary design of the OMF. Stakeholders at this final meeting represented health care provider organizations, professional societies, academia, research and consulting organizations, government agencies, patient/consumer organizations, and pharmaceutical companies. In total, 117 stakeholders participated in the series of meetings, as depicted in Figure 1.

Stakeholders provided valuable input regarding what outcome measures they currently collect, how they would like to search for outcome measures within the RoPR, what type of information they would

be willing to provide on outcomes when entering a registry into the RoPR, and what type of information they would like to find in the OMF. In particular, the stakeholder discussions shaped the plans described here for displaying information within the OMF, collecting and sharing information on the data elements that comprise an outcome or outcome measure, and entering and updating content within the OMF.

Figure 1: Stakeholders Participating in Project Meetings, by Type



2.3.Future Stakeholder Activities

Stakeholder input will continue to be valuable in refining and improving the OMF requirements and design. Stakeholder feedback will be collected on the proposed design described here through public comments, and the design will be revised accordingly. Additional stakeholder feedback on the revised design will be collected through user acceptance testing activities in the next phase of this project.

3. DESIGN AND IMPLEMENTATION CONSIDERATIONS

The background research and stakeholder activities identified several major issues that must be taken into account in the OMF design and related implementation and maintenance plans. These issues are discussed below.

3.1.Significant Variation

Outcomes and outcome measures vary significantly in type, complexity, and definition. These variations introduce several challenges that must be considered in the design of the OMF. In particular, the issues of variation in type of information to be displayed, variation in definitions for the same concept, and variation in timeframe must be considered.

3.1.1. Variation in Type of Information to be Displayed

As noted above, outcomes and outcome measures encompass multiple types of data, including laboratory tests, patient-reported outcomes, events, and derived (i.e., calculated) measures. Depending on the type of data, different information must be presented within the OMF. For example, at the most basic level, an outcome collected in a registry may be “HbA1c control (<8.0%).”¹¹ To provide useful information for users searching for an outcome, the OMF would need to collect and display a small amount of information on this outcome, such as the title and the source. A more complex example is a patient-reported outcome, such as “Significant disability,” which is defined as a score of ≤ 40 on the Short-Form 12 (SF-12).¹² To display this example, the OMF would need to include, at minimum, the title, the definition, and the source. Events that are collected as outcomes, such as myocardial infarction, are similar, in that the title, definition, and source must be displayed. Some events may also require the use of subterms to provide further clarity to users searching for an outcome.

The most complex example in terms of the information displayed is a derived measure. Derived measures are calculated based on data collected within the registry. An example of a derived measure is “Acute myocardial infarction inpatient mortality,” which is defined as the percentage of acute myocardial infarction (AMI) patients who expired during hospital stay.¹³ In addition to the title, definition, and source, the information displayed for this example must include detailed information on how the measure is calculated, such as the inclusion and exclusion criteria for the measure and the specification of the numerator and denominator. A derived measure is generally based on a patient-level outcome – AMI in this example. The patient-level outcome should be defined in the derived measure definition; in some cases, the definition is included as part of the inclusion criteria or in the specification of the numerator. The OMF could provide the ability to define the patient-level outcome as one entry and link that entry to the derived measure that is based on the patient-level outcome.

3.1.2. Variation in Definitions for the Same Concept

A second area of complexity is the lack of consistent definitions for the same concept. As noted above, many registries collect similar data in different ways. While a major goal of the OMF is to standardize definitions for the same concept across registries, characterization of the outcomes and outcome measures currently used by registries is an important first step. To accomplish this first step, however, the OMF must display information on different definitions for the same concept in a logical, understandable way. Definitions vary in three major ways: 1) different wording for the same concept; 2) different definitions for the same concept; and 3) varying levels of detail such that it is not possible to determine if the definitions are equivalent.

In the first scenario, the definitions may be worded differently, but they refer to the same concept. These are considered clinically equivalent definitions. For example, an important outcome measure in diabetes care is management of HbA1c. Two registries may both collect information on this measure, but may use different wording for the concept, as seen in Table 2 below. In the table, Example 1 and Example 2 are considered clinically equivalent definitions. Both definitions may be entered into the OMF as valid examples of how HbA1c Management is collected as an outcome measure within patient registries. However, users of the OMF may find it confusing to review multiple definitions of HbA1c Management that are clinically equivalent. Therefore, the OMF should identify these clinically

equivalent definitions in such a way that the user knows that both definitions exist in the OMF and is aware that these definitions are equivalent.

Table 2: Management of HbA1c Definitions

No.	Title	Definition
1	HbA1c Management: Poor Control ¹⁴	The percentage of patients 18-75 years of age with diabetes (type 1 or type 2) who had HbA1c in poor control (>9.0%).
2	Diabetes: HbA1c Poor Control ¹⁵	The percentage of patients 18-75 years of age with diabetes (type 1 or type 2) who had HbA1c >9.0%.

Table 3: Myocardial Infarction Definitions

No.	Title	Definition
1	Acute myocardial infarction ¹⁶	Includes: myocardial infarction specified as acute or with a stated duration of 4 weeks (28 days) or less from onset. Excludes: (1) certain current complications following acute myocardial infarction; (2) (I23.-) myocardial infarction: old (I25.2), specified as chronic or with a stated duration of more than 4 weeks (more than 28 days) from onset (I25.8); subsequent (I22.-); and (3) postmyocardial infarction syndrome (I24.1).
2	Myocardial infarction ¹⁷	<p>Criteria for acute, evolving or recent Myocardial Infarction (MI). Either one of the following criteria satisfies the diagnosis for an acute, evolving or recent MI:</p> <ol style="list-style-type: none"> (1) Typical rise and gradual fall (troponin) or more rapid rise and fall (creatinine kinase-MB fraction [CK-MB]) of biochemical markers of myocardial necrosis with at least one of the following: <ol style="list-style-type: none"> (a) ischemic symptoms; (b) development of pathologic Q waves on the electrocardiogram (ECG); (c) ECG changes indicative of ischemia (ST segment elevation or depression); or (d) coronary artery intervention (e.g., coronary angioplasty). (2) Pathologic findings of an acute MI. <p>Criteria for established MI. Any one of the following criteria satisfies the diagnosis for established MI:</p> <ol style="list-style-type: none"> (1) Development of new pathologic Q waves on serial ECGs. The patient may or may not remember previous symptoms. Biochemical markers of myocardial necrosis may have normalized, depending on the length of time that has passed since the infarct developed. 1) (2) Pathologic findings of a healed or healing MI.

No.	Title	Definition
3	Myocardial Infarction ¹⁸	<p>Criteria for Acute Myocardial Infarction. The term myocardial infarction should be used when there is evidence of myocardial necrosis in a clinical setting consistent with myocardial ischaemia. Under these conditions any one of the following criteria meets the diagnosis for myocardial infarction:</p> <ol style="list-style-type: none"> (1) Detection of rise and/or fall of cardiac biomarkers (preferably troponin) with at least one value above the 99th percentile of the upper reference limit (URL) together with evidence of myocardial ischaemia with at least one of the following: <ol style="list-style-type: none"> (a) Symptoms of ischaemia; (b) Electrocardiogram (ECG) changes indicative of new ischaemia (new ST-T changes or new left bundle branch block [LBBB]); (c) Development of pathological Q waves in the ECG; (d) Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality. (2) Sudden, unexpected cardiac death, involving cardiac arrest, often with symptoms suggestive of myocardial ischaemia, and accompanied by presumably new ST elevation, or new LBBB, and/or evidence of fresh thrombus by coronary angiography and/or at autopsy, but death occurring before blood samples could be obtained, or at a time before the appearance of cardiac biomarkers in the blood. (3) For percutaneous coronary interventions (PCI) in patients with normal baseline troponin values, elevations of cardiac biomarkers above the 99th percentile URL are indicative of peri-procedural myocardial necrosis. By convention, increases of biomarkers greater than 3 x 99th percentile URL have been designated as defining PCI-related myocardial infarction. A subtype related to a documented stent thrombosis is recognized. (4) For coronary artery bypass grafting (CABG) in patients with normal baseline troponin values, elevations of cardiac biomarkers above the 99th percentile URL are indicative of peri-procedural myocardial necrosis. By convention, increases of biomarkers greater than 5 x 99th percentile URL plus either new pathological Q waves or new LBBB, or angiographically documented new graft or native coronary artery occlusion, or imaging evidence of new loss of viable myocardium have been designated as defining CABG-related myocardial infarction. (5) Pathological findings of an acute myocardial infarction.

In the second scenario, the definitions may have the same title and refer to the same concept, but the definitions are substantively different. In Table 3, Example 2 and Example 3 are both examples of how myocardial infarction may be collected as an outcome within a patient registry. However, the definitions are not clinically equivalent. Example 2 encompasses acute and established myocardial infarctions, while Example 3 refers only to acute events. Within the OMF, these need to be presented as

distinct entries, so that the user can understand that both of these examples may be used to collect myocardial infarction in a patient registry, but they are not clinically equivalent.

Lastly, in the third scenario, definitions for the same concept may vary in the level of detail provided. In Table 3, Example 1 provides less detail than Examples 2 and 3. This makes it more difficult to assess clinical equivalency, since the definitions must be equivalent in both directions. In other words, if one item is a broad definition and a second item describes a subset of that broad definition, the definitions are not equivalent.

An additional question related to this complexity is how the determination of clinical equivalency will be made. This issue is discussed further in the Maintenance section below.

3.1.3. Variation in Timeframe

In addition to variations in definition, outcomes and outcome measures may vary in the timeframe of interest. For example, the readmission rate for heart failure patients may be an outcome of interest for two registries. Both registries may use the same definition of heart failure, but one registry may collect readmissions within 45 days of the initial hospitalization, while the other registry collects readmissions within 30 days of the initial hospitalization. This type of variation in timeframe is common with outcomes and outcome measures, which are often collected for a specified follow-up period or measured over time (e.g., change in blood pressure from baseline to 60 days). Through discussions with stakeholders and clinical experts, it was determined that outcomes and outcome measures that are identical with the exception of the timing of their collection or calculation are clinically equivalent. However, these discussions also revealed that there is interest in understanding what timeframe registries are using when collecting a specific outcome or outcome measure. Therefore, the OMF needs to collect information on the outcome or outcome measure that is used by the registry and the specific timeframe of collection.

3.2. Controlled Process

During the stakeholder meetings, participants provided examples of outcomes and outcome measures that they currently use in their registries. The examples exhibited the wide variations in definition discussed above. Due to these variations, many systems that collect this type of information do so using 'free text' data entry. Users enter the information they feel is relevant for their outcomes and/or outcome measures into the system. As a result, entries have varying levels of detail, and it is difficult for users to understand whether registries are collecting the same outcomes or outcome measures. These types of entries may contain other variations, such as inconsistent use of acronyms or a lack of clarity around their intended meaning. Stakeholders discussed these issues in the series of meetings and indicated that it would be preferable to select from an existing list of outcomes and outcome measures that contained sufficient detail for them to make relevant selections. Therefore, the OMF is envisioned as a curated library, rather than a library of non-administered user-entered information. The OMF will need to use a controlled process for collecting new data and reviewing the data for completeness and clinical equivalency before updating the OMF. This process is discussed further in the Maintenance section below.

3.3.OMF Inclusion and Exclusion Criteria

Because the OMF will use a controlled process for collecting and entering new content, clear inclusion criteria for the OMF are needed. Submitted outcomes and outcome measures should be reviewed against the inclusion and exclusion criteria and for completeness before being added to the dataset. As currently envisioned, the OMF will include any outcome or outcome measure that is or was used by a patient registry and is submitted with all required information. The OMF focuses specifically on outcomes, rather than all data collected by a registry. Data elements that do not represent outcomes will be excluded, as will measures that focus on quality of care rather than patient outcomes. To be considered complete, an outcome must include the following data: Source, Source version/date, Title, Subterms (if applicable), Definition, Reference, and Keywords. In addition to these seven items, a complete outcome measure must include the Denominator, Numerator, and Exclusion Criteria. Outcomes and outcome measures that are published in multiple places (e.g., the NQMC) may be listed in the OMF. In these cases, the original source of the measure should be cited.

3.4.Minimizing Burden for Registry Holders

A major consideration of the design for the OMF has been actual usage of the system by registry holders and those seeking to start a new registry. The OMF needs to be expandable so that it may eventually include outcomes and outcome measures from more than the priority condition areas and from a broad group of registries. It must also ensure that the additional content does not overwhelm the users or make the burden of selecting relevant outcomes and outcome measures too high for actual use. The realities of usage must be balanced with a purely theoretically constructed system. In particular, the stakeholder discussions identified an issue with collecting and presenting all relevant data elements for an outcome or outcome measure. Outcomes and outcome measures can be broken down into separate data elements, each of which could be defined and described within the OMF. For example, the outcome measure '30 day readmission for heart failure' could be broken down into individual data elements: 'date of hospitalization,' 'date of readmission,' and 'heart failure.' However, the burden of selection of this level of detail becomes overwhelming for the user, and, based on stakeholder feedback, this level of detail is not included in the proposed OMF. Options to filter or browse the OMF content would help to reduce the burden of selecting relevant items from the OMF. Filters could limit the content displayed by disease/condition area (e.g., cardiovascular disease, oncology) or by type of outcome or outcome measure (e.g., laboratory result, patient-reported outcome measure). These features would provide flexibility for users to search for content in different ways.

3.5.Maintenance and Governance of the OMF

As a curated system, the OMF will require dedicated maintenance resources to review and add new entries to the OMF and update or archive existing entries as needed. When reviewing new entries, maintenance personnel will need to consider the relevancy of the entry for the OMF (e.g., is it an outcome or outcome measures? Is it used by a patient registry?), the completeness of the entry (are all relevant data included?), and the equivalency of the entry to other entries in the OMF. The last step is the most complex and will require personnel with clinical expertise to compare the submitted entry to data already existing in the OMF. This step may be time consuming and will require highly knowledgeable resources. If the entry is determined to meet the inclusion requirements and is unique

(i.e., not clinically equivalent, as defined in Section 3.1.2.), the OMF staff will add it to the OMF system. Incomplete entries will need to be returned to the submitter for further information. Clinically equivalent entries will need to be appended to the equivalent definition and designated as equivalent, as shown in the 'Proposed OMF Design' section. In addition to adding new content, maintenance staff for the OMF must manage existing content. For example, a widely used definition of an outcome may be revised. In this scenario, since users may have selected the existing definition and the new definition may not be clinically equivalent, the OMF staff would need to treat the revised definition as a new entry and compare it to the existing definition. The definitions may be distinct, in which case both may remain in the OMF.

An additional maintenance consideration relates to the long-term supportability of the framework. The framework is intended to be used in other systems, such as the RoPR. The RoPR may subscribe to the OMF, in which case it receives all updates. An update schedule and versioning plan will need to be developed to support clear communication with the RoPR or other systems.

The OMF should be governed by stakeholders with clinical expertise, experience in registry design and conduct, and information technology system design. The governing body for the OMF will be responsible for ensuring that the content of the OMF remains relevant and useful to registry holders and registry seekers and maintaining the balance between the need for complete information and the burden on users. The governing body will also be responsible for promoting the objectives of the OMF and disseminating information about its purpose and use to encourage submission of outcomes and outcome measures; the issues related to submission are discussed further in the "Strengths and Limitations" section below. Policies and procedures for determining clinical equivalency, identifying the dominant entry when clinically equivalent entries exist, displaying equivalent outcomes and outcome measures, and updating and archiving content should be developed for the OMF. The governing body of the OMF will manage the release of updates to the OMF and should give priority to users' interests when contemplating changes or revisions to the OMF.

4. PROPOSED OMF DESIGN

The proposed design for the OMF must meet the basic requirements of providing a tool for the collection and display of information on outcomes and outcome measures used in patient registries. The OMF must support searching for and comparison of identified outcomes and outcome measures. In addition, the OMF must take into account the major issues noted above, such as variation in content, clinically equivalent outcomes and outcome measures, and burden of use. Easing the burden of use for registry holders is a major priority of the OMF. While it is possible to create a theoretically sound framework to catalogue outcome measures, the framework will not be used in a third-party system such as the RoPR, where participation is voluntary, if the burden of use is too high.

The proposed OMF provides a construct for storing and displaying multiple types of outcomes and outcome measures. All items in the OMF include a title, source, and definition. Data that are categorized as 'outcomes' are also able to include subterms and references. Data that are categorized

as ‘outcome measures’ are able to display information on numerators, denominators, and inclusion/exclusion criteria, as well as subterms and references. Users of the OMF are able to search for an outcome or outcome measure using various search tools. Search results are displayed in a summary view, and users then have the option to select a single outcome or outcome measure for a more in-depth review or select multiple entries to compare. The in-depth view displays all information on the outcome or outcome measure contained in the OMF.

The following mock-ups display the potential implementation of the OMF within a system such as the RoPR. They display sample content that a user might see when listing a registry in the RoPR and choosing what outcomes and outcome measures are collected within that registry. The ‘Add’ buttons throughout the mockups would be used by RoPR registrants to select the outcomes or outcome measures that they collect within their registries. The workflow presented in these mock-ups is as follows: 1) the user searches for outcomes and outcome measures related to myocardial infarction; 2) the search results are displayed, and the user selects five entries to compare (Figure 2); 3) the user reviews the selected entries on the Compare page (Figure 3); 4) the user views the complete record for one outcome entry and one outcome measure entry (Figures 5 and 6); and 5) the user adds four items to their registry and indicates the timeframe of interest for each item (Figures 7 and 8).

As shown in Figure 2 below, ‘myocardial infarction’ may be included in the title of an outcome or outcome measure within the OMF, or it may be a phrase related to the content comprising a complete OMF entry. The summary view displayed here is an example of the shortened content set that is accessible immediately after searching. From here, a user could choose to compare selections to see more information.

Figure 2: Searching within the OMF

<input type="text" value="myocardial infarction"/> <input type="button" value="SEARCH"/>					
OMF ID #	Title	Type	Source	Version or access date	Compare
100	Myocardial Infarction	Outcome	Joint European Society of Cardiology (ESC)/American College of Cardiology Foundation (ACCF)/American Heart Association (AHA)/ World Heart Federation (WHF) Task Force for the Redefinition of Myocardial Infarction.	2007	<input type="checkbox"/>
151	Myocardial Infarction	Outcome	The Joint European Society of Cardiology/American College of Cardiology Committee for the redefinition of myocardial infarction	Multiple	<input checked="" type="checkbox"/>
187	Myocardial Infarction	Outcome	Medical Subject Headings (MeSH)	2012	<input type="checkbox"/>
201	Myocardial Infarction	Outcome	National Cancer Institute (NCI)'s Common Terminology Criteria for Adverse Events (CTCAE)	Multiple	<input checked="" type="checkbox"/>
1882	Acute Myocardial Infarction (AMI) Mortality Rate	Outcome Measure	Agency for Healthcare Research and Quality	4.3	<input checked="" type="checkbox"/>
236	Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute myocardial infarction (AMI) hospitalization.	Outcome Measure	Centers for Medicare and Medicaid Services	4.0	<input checked="" type="checkbox"/>
739	Percutaneous Coronary Intervention (PCI) Risk Adjusted Mortality	Outcome Measure	American College of Cardiology Foundation	4 January 2012	<input checked="" type="checkbox"/>

In Figure 3, the user has selected several entries to compare. The Compare page shows the user information on each selected measure. While not shown in the mock-up below, the Numerator, Exclusion Criteria, Keyword, and Reference fields are also visible on the Compare page.

Figure 3: Comparing Entries within the OMF

Compare					
	<input type="button" value="ADD"/>	<input type="button" value="ADD"/>	<input type="button" value="ADD"/>	<input type="button" value="ADD"/>	<input type="button" value="ADD"/>
Type	Outcome	Outcome	Outcome Measure	Outcome Measure	Outcome Measure
OMF ID #	151	201	1882	236	739
Title	Myocardial Infarction	Myocardial Infarction	Acute Myocardial Infarction (AMI) Mortality Rate	Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute myocardial infarction (AMI) hospitalization.	Percutaneous Coronary Intervention (PCI) Risk Adjusted Mortality
Source	The Joint European Society of Cardiology/ American College of Cardiology Committee for the redefinition of myocardial infarction; 1 additional clinically equivalent outcome(s)	National Cancer Institute (NCI)'s Common Terminology Criteria for Adverse Events (CTCAE); 2 additional clinically equivalent outcome(s)	Agency for Healthcare Research and Quality	Centers for Medicare and Medicaid Services	American College of Cardiology Foundation
Version	Multiple	Multiple	4.3	4.0	4 January 2012
Subterms	(1) Acute, evolving or recent myocardial infarction (MI) (2) Established MI	None			
Definition	Criteria for acute, evolving or recent Myocardial Infarction (MI) Either one of the following criteria satisfies the diagnosis for an acute, evolving or recent MI: (1) Typical rise and gradual fall (troponin) or more rapid rise and fall (creatinine kinase-MB fraction [CK-MB]) of biochemical markers of myocardial... more	A disorder characterized by gross necrosis of the myocardium; this is due to an interruption of blood supply to the area.	Not available	The measure estimates a hospital-level risk-standardized mortality rate (RSMR) for patients discharged from the hospital with a principal diagnosis of AMI.	Not available
Denominator			All discharges, age 18 years and older, with a principal diagnosis code of	The target population for this measure includes admissions for Medicare FFS	1. Data submissions that passed the data quality completeness

The display of outcomes or outcome measures that have clinically equivalent definitions from multiple sources is a challenge in the Compare view. Displaying separate entries for all clinically equivalent definitions would create visual clutter and may be confusing to users. In Figure 3, the first two entries have clinically equivalent definitions, and text is used to indicate the number of additional clinically

equivalent measures. The measure displayed here is the dominant measure, which appears in search results and when browsing. The clinically equivalent measures are displayed on the full record for the outcome or outcome measure (see Figure 5 below). As noted in the Governance section, the procedures for identifying the dominant entry when clinically equivalent entries exist should be clearly defined and transparent. An alternative approach to displaying entries with clinically equivalent sources within the Compare view is shown in Figure 4 below.

Figure 4: Alternate Display of Clinically Equivalent Entries

Source	The Joint European Society of Cardiology/ American College of Cardiology Committee for the redefinition of myocardial infarction	National Cancer Institute (NCI)'s Common Terminology Criteria for Adverse Events (CTCAE)	Agency for Healthcare Research and Quality	Centers for Medicare and Medicaid Services	American College of Cardiology Foundation
Additional Clinically Equivalent Sources in OMF?	Y (1)	Y (2)	N	N	N
Version	Multiple	Multiple	4.3	4.0	4 January 2012

From the Compare view, the user could select individual outcomes or outcome measures to review in detail. Clicking on an individual entry brings the user to the complete record of the OMF entry. The complete record displays all information in the OMF for the outcome or outcome measure. Figure 5 shows a complete record for an outcome entry, while Figure 6 shows a complete record for an outcome measure entry.

The complete record view also shows full details on the clinically equivalent entries. There is no limit to the number of clinically equivalent entries that could be listed for a given entry. Based on stakeholder feedback, it has been noted that separate listings for all clinically equivalent entries would clutter the initial search results unnecessarily and increase the burden on users to sift through equivalent content before identifying what outcomes or outcome measures are collected within their registry. The designation of clinical equivalency will be determined when content is added to the OMF, as discussed above. Figure 5 provides an example of how clinically equivalent entries would appear in the OMF. While not shown in Figure 6, clinically equivalent entries would appear in the same manner for outcome measures.

As noted above, once users identify the relevant entry for their registry, they could select the “Add” button to add the entry to their registry profile within the RoPR system. Users who are searching for entries to facilitate building a new registry could find sufficient information on the complete record page to determine if the outcome or outcome measure is relevant for their registry and use the references to find more information, if needed, to incorporate the outcome into their registry.

Figure 5: Complete Record for an Outcome Entry

Outcome Mock-up ADD

OMF ID #	151
Title	Myocardial Infarction
Source	The Joint European Society of Cardiology/American College of Cardiology Committee for the redefinition of myocardial infarction
Version	2000
Subterms	(1) Acute, evolving or recent myocardial infarction (MI) (2) Established MI
Definition	<p>Criteria for acute, evolving or recent Myocardial Infarction (MI) Either one of the following criteria satisfies the diagnosis for an acute, evolving or recent MI: (1) Typical rise and gradual fall (troponin) or more rapid rise and fall (creatin kinase-MB fraction [CK-MB]) of biochemical markers of myocardial necrosis with at least one of the following: (a) ischemic symptoms; (b) development of pathologic Q waves on the electrocardiogram (ECG); (c) ECG changes indicative of ischemia (ST segment elevation or depression); or (d) coronary artery intervention (e.g., coronary angioplasty). (2) Pathologic findings of an acute MI.</p> <p>Criteria for established MI Any one of the following criteria satisfies the diagnosis for established MI: (1) Development of new pathologic Q waves on serial ECGs. The patient may or may not remember previous symptoms. Biochemical markers of myocardial necrosis may have normalized, depending on the length of time that has passed since the infarct developed. (2) Pathologic findings of a healed or healing MI.</p>
Reference	Myocardial infarction redefined—a consensus document of The Joint European Society of Cardiology/American College of Cardiology Committee for the redefinition of myocardial infarction. Eur Heart J. 2000 Sep;21(18):1502-13.
Keywords	Acute myocardial infarction AMI Myocardial infarction Myocardial Infarct MI Heart attack Coronary thrombosis Myocardial necrosis Myocardial ischemia Ischemia Ischemic symptoms Cardiac arrest American College of Cardiology ACC European Society of Cardiology ESC Established myocardial infarction Established MI

Equivalent Outcomes

Title	Myocardial Infarction
Source	Consensus Measures for Phenotypes and eXposures (PhenX)
Version	5.0
Reference	RTI International. Consensus Measures for Phenotypes and eXposures (PhenX). Myocardial Infarction. http://www.phenxtoolkit.org - February 24 2012, Ver 5.0.

Figure 6: Complete Record for an Outcome Measure Entry

Outcome Measure Mock-up

ADD

OMF ID #	1882
Title	Acute Myocardial Infarction (AMI) Mortality Rate
Source	Agency for Healthcare Research and Quality
Version	4.3
Definition	Not available
Denominator	All discharges, age 18 years and older, with a principal diagnosis code of AMI.
Numerator	Number of deaths (DISP=20) among cases meeting the inclusion and exclusion rules for the denominator.
Exclusion Criteria	<ul style="list-style-type: none"> • transferring to another short-term hospital (DISP=2) • MDC 14 (pregnancy, childbirth, and puerperium) • with missing discharge disposition (DISP=missing), gender (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing) or principal diagnosis (DX1=missing)
Reference	Agency for Healthcare Research and Quality. Inpatient Quality Indicators #15. Technical Specifications. Acute Myocardial Infarction (AMI) Mortality Rate. Available at: http://www.qualityindicators.ahrq.gov/Downloads/Software/SAS/V43/TechnicalSpecifications/IQI%2015%20Acute%20Myocardial%20Infarction%20(AMI)%20Mortality%20Rate.pdf . Last accessed on 23 February 2012.
Keywords	Acute myocardial infarction AMI Myocardial infarction Myocardial Infarct MI Heart attack Coronary thrombosis Myocardial necrosis Myocardial ischemia Ischemia Ischemic symptoms Cardiac arrest In-patient mortality Inpatient mortality Mortality Death Expired In-hospital death In-hospital mortality Agency for Healthcare Research and Quality AHRQ

As discussed in the previous section, some outcomes and outcome measures require the entry of a timeframe of collection or calculation. In Figure 7, the user has added four items to their registry profile in RoPR. The user now has the ability to specify the timeframe of collection or calculation for each outcome or outcome measure. A default timeframe selection would be available to users of the RoPR, or users could select another timeframe. If the available options do not sufficiently describe the timeframe used in their registry, users could enter free-text information. The list of proposed timeframes available for selection in the drop-down list is presented in Figure 8.

Figure 7: Identifying Timeframes for Selected Outcomes and Outcome Measures

Selected Outcomes & Outcome Measures						
REGISTRY is COMPLETE						
OMF ID #	Title	Type	Source	Version or access date	Remove	Outcome / Outcome Measure Timeframe (select primary time period from dropdown, or enter free text)
100	Myocardial Infarction	Outcome	Joint European Society of Cardiology (ESC)/ American College of Cardiology Foundation (ACCF)/ American Heart Association (AHA)/ World Heart Federation (WHF) Task Force for the Redefinition of Myocardial Infarction.	2007	<input type="checkbox"/>	enrollment/event date only <input type="text" value="enter text..."/>
1882	Acute Myocardial Infarction Mortality Rate	Outcome Measure	Agency for Healthcare Research and Quality	4.3	<input type="checkbox"/>	Other Assessed at 1 year, 2 years, and 3 years post enrollment
236	Heart Failure 30-day Mortality	Outcome Measure	Centers for Medicare and Medicaid Services	4.0	<input type="checkbox"/>	1 month post enrollment/event date <input type="text" value="enter text..."/>
739	Percutaneous coronary intervention mortality (risk-adjusted)	Outcome Measure	American College of Cardiology	4 January 2012	<input type="checkbox"/>	Full Registry Duration <input type="text" value="enter text..."/>

Figure 8: Identifying Timeframes for Selected Outcomes and Outcome Measures



5. STRENGTHS AND LIMITATIONS OF THE OMF DESIGN

The proposed design of the OMF presented here has several strengths. First, the proposed design is flexible and expandable. These are important attributes, as the OMF will need to collect and display a large number of heterogeneous outcomes and outcome measures. Flexibility is particularly critical to accommodate the variations in types of data and level of detail seen in the examples in Appendix A. The flexible design also allows for the presentation of clinically equivalent entries in a consistent way.

Second, the proposed design simplifies searching for entries by including comprehensive lists of keywords for each entry. Users who enter a keyword into the search field will see all of the entries with that keyword in their search results, which facilitates searching for measures using synonyms. For example, a search for “heart attack” will return entries for acute myocardial infarction, as “heart attack” is a keyword for these entries. The keyword function also supports searching for clinically equivalent measures. As an example, the Consensus Measures for Phenotypes and eXposures (PhenX) definition of myocardial infarction is clinically equivalent to the definition of the Joint European Society of Cardiology/American College of Cardiology Committee. The Joint European Society definition is the dominant definition that appears in search results, while the PhenX definition appears as a clinically equivalent definition. However, users who search for “Consensus Measures for Phenotypes and eXposures” or for “PhenX” will find the Joint European Society definition and the clinically equivalent PhenX definition because these terms are included as keywords.

Finally, an important strength of the proposed design is its ease of use. A registry holder who is entering a registry into the RoPR system can search for and select the outcomes and outcome measures used in

the registry with relatively few steps. The level of complexity in the proposed workflow aligns with what stakeholders suggested would be feasible within a voluntary system, such as the RoPR.

The proposed design does have some limitations. First, the individual data elements that comprise an outcome or outcome measure are not collected and displayed in the OMF. For example, the outcome measure '30 day readmission for heart failure' could be broken down into 'date of hospitalization,' 'date of readmission,' and 'heart failure.' Each of these individual data elements could be defined within the OMF, and registry holders selecting this outcome measure could specify how they collect each component of the measure (e.g., how is date of hospitalization defined and collected? How is date of readmission defined and collected? How is heart failure defined?). This level of detail was not included in the proposed OMF design due to stakeholder concerns that the burden of entry would be too high for a voluntary system. However, it is possible that two registries that appear to collect the same measure based on the OMF data may define the measure differently. In the '30 day readmission for heart failure' example, the registries may define heart failure differently. Alternately, they may define 'readmission' differently, with one registry only counting patients who are readmitted for heart failure, while another includes all readmissions for any reason in the measure. These variations may not be apparent based on the level of detail collected and displayed in the OMF. The issue of including the individual data elements may need to be reassessed after a pilot period of data collection through the OMF. The pilot period would provide both information on burden of entry for registry holders and usefulness of the data for those searching for outcomes and outcome measures.

A second limitation relates to the use of a curated system. The variations in definitions and the discussions with stakeholders led to the decision to create a curated system to ensure that content is entered consistently and that clinically equivalent items are identified as such. While this approach has advantages in terms of the quality of the content, there are also disadvantages related to the timeliness of updates to the system and the required amount of resources. Submitted entries for the OMF will need to be reviewed against the inclusion criteria and for completeness, as well as for clinical equivalency. As a result, the process of adding an entry to the OMF may take some time. Users who do not find their outcome or outcome measure within the existing OMF content set and who submit it for consideration would need to go back into the RoPR system to select their entry once it is available. Some users may not take the time to do this or may find this extra step too burdensome. While reviewing the submitted entries against the inclusion criteria and for completeness will be relatively straightforward, determining clinical equivalency requires time and expertise. Both levels of review – and particularly clinical equivalency – will increase the costs of maintaining and updating the OMF. In addition, outcomes and outcome measures contained within the OMF may be revised, and resources will be needed to ensure that information presented in the OMF remains accurate and current.

6. NEXT STEPS FOR THE OMF

The goal of this project is to design and develop a prototype of the OMF. While designing the OMF, some issues were encountered that were beyond the scope of this project. In particular, two issues that must be tackled prior to a full-scale implementation of the OMF are the process for soliciting outcome

and outcome measure submissions and the process for determining clinically equivalent entries and selecting a dominant entry. Once the OMF design has been finalized following public comment, the OMF will be populated with a starter set of content comprised of outcomes and outcome measures that are publically available and may be used within patient registries. However, additional content will need to be solicited from registry holders. The OMF will need a plan for disseminating information about the project and encouraging registry holders to submit information on their outcomes and outcome measures. Strategies for incentivizing registry holders to share this information will be needed. The OMF will also need an interface to accept and review these submissions. Second, once the OMF receives submitted measures, the governing body will need to develop a clear and transparent approach to determining if entries are clinically equivalent and selecting the dominant measure.

Additional issues that may need to be considered include measures that are not publically available and the expansion of the initial content set beyond the priority conditions. Some registries consider their outcome measures proprietary and only share the measure definitions with participants. The OMF may need to consider ways to encourage these registries to share information on their measures publically. In addition, the OMF will eventually need to expand to include disease areas outside the priority condition areas noted above. A re-evaluation of the data collected and displayed within the OMF should be completed after a pilot period of full-scale use. The inclusion of a broader range of entries may identify the need for additional data elements. As information from the OMF becomes available in the RoPR system, registry seekers (users who search for registries within the RoPR) may begin searching for registries based on the specific outcomes or outcome measures that the registry collects. For example, a researcher who is seeking a registry to combine with an existing data source may only be interested in registries that collect myocardial infarction using a specific definition. These new users of the OMF content may also identify data elements that should be added or entered by registry holders.

7. CONCLUSIONS

In summary, the OMF is intended to collect and display information on outcomes and outcome measures used in patient registries, with the goals of characterizing what registries currently collect and supporting long-term efforts to standardize outcome measures. The OMF design proposed here provides a flexible, expandable approach to collecting and displaying this information in way that minimizes user burden and is suitable for inclusion in a system such as the RoPR. In addition, the proposed design addresses many of the complexities around collecting and displaying outcomes and outcome measures identified through discussions with stakeholders and noted here. While this design has many strengths, it may be improved through pilot testing prior to full-scale implementation.

Within the RoPR, the OMF will provide a tool for collecting and displaying information on outcomes and outcome measures in a standard format. The OMF will need to be populated with a starter set of content and then expanded as contributors submit additional outcomes and outcome measures for inclusion. Registry holders who enter a registry in the RoPR can then indicate which outcomes or outcome measures they collect. The collection of this information in a standard format will support efforts to describe the fragmented landscape of outcomes and outcome measures used within patient

registries. The data collected through the OMF can then be used to identify disease areas where some consistent measures are already being used in similar registries. These areas may be targeted for initial efforts to move towards standardization of outcome measures. Other disease areas that require more substantial, long-term efforts to develop and promote the use of standard outcomes and outcome measures may also be identified through these data. Overall, the data collected through the OMF will enable future projects to accurately characterize the current use of outcomes and outcome measures within registries and to develop informed, feasible approaches to standardization.

Appendix A. Examples of Outcomes and Outcome Measures

Table 4: Examples of Outcomes and Outcome Measures

Type of Entry	Source	Title	Sub-terms	Definition	Denominator	Numerator	Exclusion Criteria
Outcome	National Committee for Quality Assurance	HbA1c in poor control ¹⁹	None	HbA1c of >9.0% for patients 18-75 years of age with diabetes (Type 1 or Type 2)	N/A	N/A	N/A
Outcome	National Committee for Quality Assurance	HbA1c control (<8.0%) ²⁰	None	HbA1c of < 8.0% for patients 18 - 75 years of age with diabetes (Type 1 & Type 2)	N/A	N/A	N/A
Outcome	National Committee for Quality Assurance	HbA1c < 7.0% (controlled) ²¹	None	HbA1c of < 7.0% for patients 18 - 64 years of age with diabetes mellitus (Type 1 & Type 2)	N/A	N/A	N/A
Outcome Measure	National Committee for Quality Assurance	Comprehensive Diabetes Care: HbA1c control (<8.0%) ²²	None	The percentage of members 18 - 75 years of age with diabetes (type 1 and type 2) who had HbA1c control (<8.0%).	Members 18 - 75 years of ages with diabetes.	HbA1c level is <8.0% during the measurement year.	Members with a diagnosis of polycystic ovaries who did not have any face-to-face encounters with a diagnosis of diabetes, in any setting, during the measurement year or the year prior to the measurement year. Diagnosis can occur at any time in the member's history, but must have occurred by December 31 of the measurement year.

Type of Entry	Source	Title	Sub-terms	Definition	Denominator	Numerator	Exclusion Criteria
Outcome	French Autoimmunity and Rituximab (AIR) Registry	Response to rituximab treatment, as measured by the SELENA-SLEDAI ²³	None	Reduction of ≥ 3 in score on the Safety of Estrogens in Lupus Erythematosus: National Assessment (SELENA) version of the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI)	N/A	N/A	N/A
Outcome	Endometriosis Patient Registry	Average health status, as measured by the SF-12 ²⁴	None	A score of ≥ 50 on the Short-Form 12 (SF-12)	N/A	N/A	N/A
Outcome	Endometriosis Patient Registry	Significant disability, as measured by the SF-12 ²⁵	None	A score of ≤ 40 on the Short-Form 12 (SF-12)	N/A	N/A	N/A
Outcome Measure	Agency for Healthcare Research and Quality	Congestive Heart Failure (CHF) Mortality Rate	None	None provided.	All discharges, age 18 years and older, with a principal diagnosis code of CHF.	Number of deaths (DISP=20) among cases meeting the inclusion and exclusion rules for the denominator.	-Transferring to another short-term hospital (DISP=2) -MDC 14 (pregnancy, childbirth, and puerperium) -With missing discharge disposition (DISP=missing), gender (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing) or principal diagnosis (DX1=missing)

Type of Entry	Source	Title	Sub-terms	Definition	Denominator	Numerator	Exclusion Criteria
Outcome Measure	Joint Commission	Acute myocardial infarction (AMI) inpatient mortality	None	Acute myocardial infarction (AMI) patients who expired during hospital stay	Discharges with an ICD-9-CM Principal Diagnosis Code for AMI	Inpatient mortality of AMI patients	<ul style="list-style-type: none"> • Patients less than 18 years of age • Patients who have a Length of Stay greater than 120 days • Patients with Comfort Measures Only documented • Patients enrolled in clinical trials • Patients received as a transfer from an inpatient or outpatient department of another hospital • Patients discharged to another hospital • Patients discharged to home for hospice care • Patients discharged to a health care facility for hospice care

Type of Entry	Source	Title	Sub-terms	Definition	Denominator	Numerator	Exclusion Criteria
Outcome Measure	United HealthCare	Risk-Adjusted 30-Day All-Cause Readmission Rate ²⁶	None	Estimates a hospital 30-day risk-adjusted readmission rate by measuring percentage of acute inpatient hospitalizations during the measurement period that were followed by an acute readmission for any diagnosis from any hospital within 30 days.	Total inpatient discharges from acute care hospitals with discharge dates during the measurement period.	The number of acute inpatient stays that are admitted within 30 days of a prior acute discharge	Denominator – Index Discharges: – Patient discharged deceased – Same day transfers – Discharges without a valid patient identifier or hospital identifier – Discharges with discharge date missing or invalid – Discharges for Mental Health and/or Substance Numerator - Readmissions: – Patient discharged deceased – Same day transfers – Discharges without a valid patient identifier or hospital identifier – Discharges with discharge date missing or invalid – Discharges for Mental Health and/or Substance

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