PUBLIC COMMENT SUMMARY REPORT

Project Title:

Claims-Only Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure and Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors

Dates:

The Call for Public Comment ran from January 29, 2018 and closed on February 27, 2018.
The Public Comment Summary was made on February 27, 2018.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with *Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE)* to develop a hospital-level outcome performance measure of all-cause mortality across a broad mix of medical and surgical patients admitted to the hospital. The intent is to create a measure that can be used to assess hospital-level performance for Medicare fee-for-service (FFS) patients. The overarching purpose of the project is to develop a measure that can be used to enhance the quality of care provided to Medicare beneficiaries. The contract name is *Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospital and Eligible Clinicians, Option Year 4*. The contract number is HHSM-500-2013-13018I Task Order HHSM-500-T0001. As part of its measure development process, CMS has requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project. Specifically, in a staged approach to measure development, CMS sought public input on the measure specifications of two hospital-level measures of hospital-wide mortality (HWM), including the measure concept, measure cohort, measure outcome, and approach to risk adjustment through a public comment period from November to December 2016.

At that time, several commenters supported the concept and use of a HWM measure to evaluate hospital quality and drive quality improvement. The majority of the Technical Expert Panel (TEP) also agreed with the cohort definition. Concerns included the adequacy of claims-based risk adjustment and/or assessment of disease severity, correct attribution of mortality across surgical patients, and handling of hospice patients. A few commenters were concerned about the burden of additional measures on hospitals, or that an all-condition, all-procedure, all-cause mortality measure would not be as actionable or useful by hospitals as the condition-specific measures. We made several updates to the measure specifications based on the feedback we received, as summarized in the Claims-only and Hybrid HWM methodology reports. We will try to incorporate stakeholder input as we consider the feedback from this most recent public comment period from January and February 2018.

Project Objectives:

The primary goal is to develop two hospital-level measures of hospital-wide mortality, one calculated using only data from Medicare FFS claims and a second that uses clinical data from the electronic health record to enhance the risk adjustment model. Both measures allow CMS to assess a broad range of hospitals' performance while ensuring hospitals and patients have access to meaningful information to enable quality improvement and evaluate hospital quality.

Information About the Comments Received:

Public comments were solicited by:

- Email notifications to CMS listserv groups;
- Email notifications to CORE listserv groups;
- Email notification to the hospital-wide mortality quality measure development Technical Expert Panel (TEP), Technical Work Group, and Patient and Family Caregiver Work Group;
- Person & Family Engagement Network; and
- Web posts on the CMS Public Comment website.

Nine response letters were received, including four patients and patient advocates. We have categorized these comments into topics and summarized them within each topic, along with our response, in the subsequent sections of this report.

Stakeholder Comments and Responses—General and Specific Measure Development Topics

Summary of General Comments

Several commenters supported the use of a hospital-wide mortality measure and mortality rates to evaluate hospital quality and drive quality improvement. Two commenters also supported the cohort, inclusions, and exclusions as proposed.

Response:
Thank you for your support for the use of a hospital-wide mortality measure to evaluate hospital quality and drive quality improvement.

Two commenters expressed concern about whether a 30-day measurement period is attributable to the hospital stay. One commenter inquired about the evidence behind choosing a 30-day measurement period.

Response:
Thank you for your comment. The 30-day time period for assessment of mortality following hospitalization aligns with CMS's condition- and procedure-specific mortality outcome measures currently publicly reported on *Hospital Compare*. The 30-day time frame is also supported by the input we have received from clinical experts, empiric analyses performed during the development of this measure, and the published literature.

From a clinical perspective, adverse events that occur within the immediate post-discharge timeframe are often attributable to the hospital stay. For example, a patient released from the hospital may experience dizziness while driving, from medication or anesthesia administered during the hospital stay, and experience a fatal car accident. Also, adverse events that occur 30 days post-discharge can be attributed to the hospital. For example, a patient given a diuretic at discharge may become dehydrated, leading to kidney failure and death. However, input we received from clinical experts suggested deaths beyond 30 days are seldom attributed to care received during the hospitalization and are more commonly attributed to underlying health or care received in other settings.

From an empirical data analysis perspective, during measure development we reviewed survival curves (for Medicare beneficiaries 65 years and older) up to 90 days following admission to evaluate the appropriateness of the 30-day time frame across the HWM cohort. We found that 30 days post-admission was the most appropriate time frame to capture most post-hospitalization deaths.

Finally, we also examined the published literature and found that older adults are more vulnerable to adverse health outcomes within 30 days of a hospital admission and that mortality can be influenced by hospital care and the early transition to the outpatient setting during this time.[1,2] Based on the evidence discussed above, we feel confident that a 30-day measurement period is the most appropriate period to measure mortality in a hospital setting.

Two commenters did not think that a hospital-wide mortality measure is sensitive enough to accurately capture hospital quality. They noted that there are few performance outliers identified and questioned whether this measure would provide actionable information to inform quality improvement for hospitals or meaningful information to patients about the quality of hospitals.

Response:
Thank you for your comments. Should CMS include these measures in public reporting, consistent with other measures, hospitals would receive confidential, patient-level data for quality improvement, allowing for thorough investigation of patient scenarios that resulted in mortality. In addition, similar to CMS's Hospital-Wide Readmission measure, confidential data and mortality results may be provided to all hospitals for each of the service-line divisions, allowing hospitals to identify service lines with greater mortality and target them for improvement.

Additionally, using 95% confidence interval (uncertainty) estimates to categorize hospital outliers is conservative by design. The distribution and mortality rates themselves, however, do convey meaningful variation. We found that the overall hospital risk-standardized mortality rates ranged from 4.8% to 9.3% with a median risk-standardized mortality rate of 7.6%. This variation provides a quality signal and we believe reporting hospital mortality scores will improve transparency and promote quality improvement. This measure identified 2.6% of hospitals as outliers, which is consistent with other CMS condition- and procedure-specific measures that display a range of 2.5% - 11.2% of hospitals as outliers.

Finally, CMS is not wedded to the same approach for reporting results for all measures. There are many options we are considering, to communicate meaningful variation in performance and optimize the usefulness of this measure for the public.

One commenter felt that the measure exhibited face validity.

Response:
Thank you for your support.

One commenter was concerned about the understanding and contributions to measure development of the patient and family caregiver work group with specific concern about the complexity of the statistical risk models used in this measure.

Response:
Thank you for your comments. We engaged with several stakeholder groups throughout the development process for both the claims-only HWM measure and the hybrid HWM measure. We elicited feedback on the measure concept, outcome, cohort, risk model variables, and how to develop and report measure results in a meaningful way for patients, family caregivers, and providers. These engagements have included two advisory groups in the form of a Technical Work Group and a Patient and Family Caregiver Work Group. We also convened a national Technical Expert Panel (TEP) consisting of a diverse set of stakeholders, including providers and patients.

While the measure results are intended for all audiences, the complex methodology is necessary to ensure that we are capturing the correct outcome while properly risk adjusting. We committed to bringing all major pieces of measure development and reevaluation to the Patient & Family Caregiver Work group, despite the technical nature of the project, by clearly explaining analytic findings and project tradeoffs. While creating materials for the public, we attempted to balance technical information, for complete transparency about measure specifications, statistical results about hospital performance, and plain-language explanations suitable for all audiences. To do this, we worked with experts experienced with communicating technical information to consumers and the public to create an overview document that summarized the measure purpose and public comment components.

One commenter supported the divisions as proposed.

Response:
Thank you for your support.

One commenter suggested providing hospitals with tools to prevent mortality instead of measuring mortality after death has already occurred.

Response:
Thank you for your comment. We believe that the hospital-wide mortality measure, the overall score, as well as the division-level results, can provide actionable information to hospitals to support important quality improvements. Hospitals will receive detailed patient-level data along with their hospital-wide mortality performance scores, and this patient-level detail can help the hospital decide where to focus its quality improvement efforts.

One commenter was concerned that a measure of hospital-wide mortality is a poor indicator of quality for patients at the end-of-life.[3]

Response:
Thank you for your comment. We are committed to examining and avoiding unintended consequences in relation to patient goals, and we agree that mortality is not an appropriate assessment of quality for patients who have elected to receive only comfort care and are at the end of life.

During measure development, we sought to identify and exclude cases in which survival was not a goal of the care the hospital was providing. We did this by excluding patients who had enrolled in hospice within the past 12 months of the index hospitalization, or within two days after admission to the hospital. We feel that most patients who have prior enrollment in hospice, do not have the same goals of care as those who were not enrolled. Additionally, based on feedback from stakeholders and experts we consulted during measure development, it is likely that for most patients and/or families who had the discussion and agreed to enroll in hospice within two days of admission, survival is not likely the primary goal due to a condition that was present on admission and therefore, mortality should not be used as a marker of quality care. However, we recognize that there is no single, correct approach to identifying patients at the end of life and the use of hospice enrollment may not be adequate to differentiate patients who have a goal of survival from those who do not. We are also aware that this approach does not exclude all patients at the end-of-life from the measure cohort and might inadvertently exclude some patients for whom mortality is an appropriate signal of quality. However, we feel it accurately identifies most patients and errs on the side of protecting a patient's choice to defer aggressive treatment at the end of life.

Two commenters expressed concern over the reliability of both measures.

Response:
Thank you for your comments. These measures show high measure score (or test-retest) reliability, meaning that each hospital's measure score is similar when recalculated with different sets of patients. To determine measure score reliability, we calculate the measure scores (risk-standardized mortality rates) using two distinct sets of patients that are created by randomly selecting patients and placing them into two different datasets (the "development" and "validation" samples). The measure scores calculated from these two datasets were compared using the intraclass correlation coefficient (ICC), a statistic that evaluates how similar or correlated the results are. The ICC between the development and validation sample was 0.83 for the composite score for the claims-only measure and 0.84 for the hybrid measure, both considered "high" measure score reliability. Furthermore, test-retest reliability is a conservative measure of measure score reliability.

One commenter expressed concern that the measure does not adjust for social risk factors and that no analysis of their impact on the measures was provided.

Response:
Thank you for your comment. As part of our preparation to submit this measure to the National Quality Forum (NQF) for endorsement, we will conduct measure testing that includes assessing the impact of social risk factors on measure results. For all measures seeking NQF endorsement, NQF requires developers to present the results of analyses examining the impact of social risk factors on the measure outcome, as well as the degree to which any association is occurring at the patient-level or hospital-

level. The relevant NQF committees will examine the evidence and determine whether the measure is suitable for endorsement with or without adjustment for social risk factors. This analysis and any changes to the measure will occur before the measure is implemented. Additionally, CMS continuously monitors the impact of social risk factors on hospitals' performance on the measures currently in federal programs.

Mortality Outcome

One commenter did not agree with the assertion in the report that avoiding mortality is a primary goal or intended outcome for hospital stays. The commenter thought that the primary goal for most patients is to make a full recovery and to receive the best treatment possible.

Response:
Thank you for your comment. We agree that the goal for all patients should be to receive optimal care within the hospital and to make a full recovery, and that there is a need for more measures focused on these outcomes. We also believe that most patients have the expectation that they will survive a hospitalization and the immediate post-hospitalization period and that their life will not be shortened by a preventable error or complication caused by poor quality of care. In this way, we believe that survival is also an important and fundamental goal for most patients and, therefore, an important focus of quality measures.

The hospital-wide mortality measure was developed to broadly measure quality of care across hospitals, including the quality of care in smaller volume hospitals. Mortality is an important health outcome that is meaningful to patients and providers, and updated estimates suggest that more than 400,000 patients die each year from preventable harm in hospitals.[4]

Two commenters expressed their opinion that resources (time and money) might be better spent on upstream improvement efforts. One commenter felt that a focus on promoting wellness and preventing mortality was preferable to a measure that assesses a hospital's performance on deaths that have already occurred. This commenter suggested that there should be a greater focus on developing measures that assess how well the healthcare system promotes safety, good health, and wellness rather than mortality. The commenter stated that this measure is intended to impact hospitals reimbursement taking into account mortality rates and expressed a preference for greater resources being spent on interventions to improve patients' safety and wellness. Another commenter felt that the measure would focus improvement efforts on a narrow population of very sick patients and that money and effort may be better invested in reducing complications that are more common.

Response:
Thank you for your comments. We agree that we should continue to develop measures focused on patient safety (complications), prevention of disease and death, as well as greater wellness among Medicare beneficiaries and all patients in the healthcare system. However, we also believe that by assessing mortality, we create transparency for hospitals and the public about this important outcome. Mortality following an acute illness is often preventable. There is evidence that hospitals can successfully improve patient safety and prevent complications of care, thereby reducing their patients' risk of death in the hospital and in the immediate post-discharge period.

Hospital-wide mortality fits under just one of CMS's six priority areas for quality measurement ("Promote Effective Prevention & Treatment"). CMS focuses on other aspects of health through its measurement efforts, including a focus on complications through the priority area "Making Care Safer by Reducing Harm Caused in the Delivery of Care" and a focus on wellness through the priority area "Work with Communities to Promote Best Practices of Healthy Living."

Surgical and Non-Surgical Admissions

One commenter was unclear how the measure defines surgical versus non-surgical procedures and which surgical procedures are included in the measure. This commenter specifically referenced inpatient versus outpatient procedures.

Response:
Thank you for your comment. This is a hospital-wide measure that only includes inpatient admissions, and patients are sorted into surgical vs non-surgical divisions based on inpatient procedures.

To identify patients as surgical or non-surgical, admissions were first screened for the presence of an eligible surgical procedure category. These were defined as "major surgical procedures," representing procedures for which a patient is likely to be cared for primarily by a surgical service and identified using the approach used by CMS's Hospital-Wide Readmission (HWR) measure to identify surgical admissions. Admissions with any "major surgical procedures" were assigned to a surgical division, regardless of the principal discharge diagnosis code for the admission. All remaining admissions were assigned to service-line divisions based on the principal discharge condition category.

As mentioned above, the hospital-wide mortality measure uses the same definition of "major surgical procedures" as the HWR measure, which assigns patients to a surgical cohort if the patient underwent a surgical procedure as defined by a standardized list of procedures that are considered "surgical." We have slightly modified this list, to exclude, for example, minor procedures (such as a biopsy), that are unlikely to be cared for by a surgical team.

Two commenters expressed concern about risk adjustment. One wondered how the measure accounts for various mortality risks associated with different procedures performed in the hospital. The other commenter noted that the measure includes a broad range of conditions and procedures associated with widely varying mortality risk.

Response:
Thank you for your comments. We agree that one of the key challenges to developing a hospital-wide mortality measure is to adequately account for the differing risk of mortality for the different populations of patients admitted to the hospitals and to adequately adjust for these differences when comparing hospitals' performance.

We addressed risk adjustment in several ways. First, since the risk of death differs between surgical and non-surgical patients, we separated patients who had surgery from patients who did not. We then further divided the surgical and non-surgical groups into a total of 13 service-line divisions (Surgical divisions: General, Orthopedics, Cardiac, Cancer, and Neurosurgery; Non-surgical divisions: Cardiac, Infectious Disease, Pulmonary, Gastrointestinal, Renal, Orthopedic, Neurology, and Cancer). The surgical divisions were created by combining clinically related groups of procedures, considering the risk of death and the reason for admission (the principal discharge diagnosis) during the combination step. For

the non-surgical division, we categorized patients based on medical conditions that would typically be cared for by the same group of clinicians, as well ask the risk of death.

To further account for differences in risk among patients, we adjust for both patient-level factors (the medical condition of the patient when admitted to the hospital, accounted for by adjusting for illnesses and diagnoses the patient has when admitted) and hospital service mix differences (the types of conditions/procedures cared for by the hospital, accounted for by the reason the patient was hospitalized). Each of the 13 service-line divisions is risk-adjusted independent of the others, which helps account for differences in the mortality risks of procedures in the separate divisions.

The work described above was done with the careful and systematic input of clinicians. In addition, the steps described above were presented to CORE's patient and clinician workgroups and our Technical Expert Panel, all of whom generally supported the approach.

Summary of Comments on Reporting the Measure

Four commenters provided input related to reporting the measure. Specifically, they suggested:

- Adding more description and qualitative details to help patients understand how a hospital is performing.
- Providing more granular information by reporting outcomes for specific procedures or reporting hospital-level results by division.
- Regularly updating performance on measures and providing them to CMS patients and the public.
- Representing results in a more patient-friendly way by reporting the hospital-level results in comparison to the national average at the hospital and division level or by giving hospitals a grade (A, B, C, etc.).
- Requiring hospitals to present their own scores to their patients as well as scores of hospitals in the area.
- Presenting this information to patients to help them make the best decisions about their care in any medical situation.
- Providing hospitals with adequate time to review the measure before the results are publicly reported.
- Reporting results in a more hospital- and patient-friendly way than it is presented in the methodology report.
- Avoiding reporting results by expanding the confidence interval to 90% instead of the standard 95% confidence interval to increase the number of outliers.
- Exploring the idea of reporting the probability that a hospital is statistically different than average with the stipulation that it is proven helpful and understandable to patients and their families.

Response:
Thank you for your comments and suggestions. Should CMS consider the HWM measures for public reporting, these ideas about how to make the measures useable and understandable for patients will be very helpful. Please note that in preparation for public reporting of measures, CORE will engage with our Persons and Family Engagement Network to receive input into communication strategies. We appreciate your thoughtful input and extensive and specific suggestions, which we will take note of for future development of this measure.

One commenter inquired how this measure will be used in relation to the condition- and procedure-specific measures already reported.

Response:
Thank you for your comment. Existing CMS condition- and procedure-specific mortality measures currently included in the Hospital Inpatient Quality Reporting and the Hospital Value-Based Purchasing Programs have a narrow focus, only capturing specific patient populations, while the HWM measures will capture most Medicare Fee-For Service (FFS) beneficiaries over 65 years old admitted to acute care hospitals. The HWM measures are not currently publicly reported or included in any CMS payment programs. CMS will announce any future intentions to implement the measures, and for which programs, through the regulatory or rulemaking process. Since the measures include service-line divisions, CMS may, in the future, consider the feasibility of reporting additional, more granular information for each division in addition to the overall hospital-wide mortality rate.

One commenter suggested a change in the titles of the measures to make them more descriptive, searchable, and patient-friendly.

Response:
Thank you for your comment. We appreciate the suggestion to help make the measures we develop for CMS more accessible to patients. We use a similar naming convention for all the measures we develop to aid in the understanding of differences between measures. For example, we previously developed a Hospital-Wide Readmission measure for CMS, so naming these new measures "Hospital-Wide Mortality" highlights the similarities and differences between these two measures. We agree that it is important to make CMS measures accessible and useful to patients and appreciate your input. If CMS decides to implement the measure, we will continue to seek input from patients and caregivers on the measure.

One commenter requested clarity on whether the measure will report the results of each division.

Response:
Thank you for your comment. These measures are not currently publicly reported or included in any CMS programs. Should CMS implement these measures for public reporting or payment determination programs, CMS will determine if division-level information will be publicly available, or only privately reported to hospitals along with patient-level data.

Summary of Comments on the use of Electronic Health Record (EHR) data (Hybrid HWM measure)

Many Commenters expressed a preference for the use of EHR data for measure risk adjustment. Specifically, commenters expressed:

- Concern that using claims data in this measure focuses too much on the payment of the hospital.
- Concern that claims data is not an easy metric to aid hospitals in improving their mortality outcomes.
- A suggestion for incorporating even more data into this measure including data from other providers who treat the patient following discharge from the hospital.

Response:
Thank you for your comments. Administrative claims data is routinely submitted by hospitals for quality measurement and is frequently audited by CMS. This allows for relatively accurate data and patient history while preventing undue burden on providers to submit de novo data collection.

We believe that a measure that uses EHR data will more thoroughly capture patient risk and measure hospitals in an equitable way. The data elements currently included in the Hybrid HWM risk adjustment models are elements routinely collected for every patient and therefore available consistently across hospitals in EHR systems. This serves to balance the benefits of using clinical data with minimizing any burden on hospitals and healthcare providers to collect the data.

CMS is incorporating clinical EHR data into outcome measures, in response to hospital feedback. Using this data allows for more specific risk adjustment that accounts for patients' clinical status at the start of an inpatient encounter. We agree that using EHR data relies on the accuracy of the data itself. Extensive testing was conducted on each EHR data element, which showed high feasibility and validity for all data elements used in the hybrid HWM risk model. Validity was assessed by comparing the EHR-extracted variable to the patient's chart.

In addition, for claims-based outcome measures (procedure-specific mortality and readmission measures) previously developed by CORE for CMS, we have shown that measure scores calculated from data derived from medical records correlate highly with measure scores calculated with claims.[5,6,7,8,9,10] These studies are seen as a firm validation of the use of claims for outcomes such as mortality.

Finally, for other quality improvement measures we have developed for CMS that are currently in public reporting, hospitals receive Hospital-Specific Reports that provide patient-level data. If this measure is implemented by CMS, hospitals would receive these reports which, paired with division-level scores, would aid the hospital in focusing their quality improvement efforts.

One commenter was concerned about the applicability of the EHR variables included in the hybrid HWM measure. Specifically, commenters:

- Expressed a desire for greater specificity of the units of measurement for the platelet and white blood cell count (WBC) data elements.
- Requested clarity about whether weight and temperature are to be reported in Fahrenheit or Celsius and in pounds or kilograms respectively.
- Expressed concern that the feasibility of the EHR data was only assessed in a single health system representing a single application of the Epic EHR.

Response:
Thank you for your comments. In the future, we will clarify that the unit of measurement for platelet and WBC is "k/mcL" in our technical documents. For the temperature and weight data elements, we are not limiting the units that hospitals can submit their data in. Hospitals should submit data in whatever unit the data is stored in, to reduce burden, and report what unit was used when they submit the data. Standardization of units will be done by CMS during measure score calculations.

Although the feasibility and data element validity for the EHR data elements used in the hybrid hospital-wide mortality measure was initially established in a single health system using an Epic EHR, we have previously demonstrated the feasibility and data element validity of these data elements in five health systems using four different EHR systems.

Many commenters were concerned that the hybrid HWM measure was tested using only 22 hospitals within the same health system and using the same EHR system. One commenter suggested testing the measure in a larger group of hospitals or using a pilot period prior to mandatory public reporting.

Response:
Thank you for your comments. The Hybrid Hospital-Wide Readmission (HWR) measure, which uses a nearly identical set of EHR data elements, is currently implemented as a voluntary measure in the Hospital Inpatient Reporting Program. CMS is actively compiling stakeholder feedback on the electronic specifications for the EHR data elements, their extraction, and on data submission processes. Because this measure uses a nearly identical set of data elements, we believe that the experience gained through voluntary reporting of the hybrid HWR measure will ease implementation of this measure. CMS is considering options for the implementation of the hospital-wide mortality measures and will announce their intentions in future regulations or rulemaking.

Overall Analysis of the Comments and Preliminary Recommendations

We appreciate the submitted comments, summarized above. We aim to develop two measures of hospital-wide mortality that provide a broad view of the quality of care across hospitals, including smaller volume hospitals. This measure intends to facilitate quality improvement, provide more transparent information for the public, and allow policymakers to monitor a very important outcome. We are keenly aware of the possibility of unintended consequences, such as incentives to keep end of life care patients alive longer than they want, and the measures' design attempts to minimize these possibilities as much as possible. Also, this measure uses data elements already captured by hospitals, minimally increasing effort for the hospital. We hope that measuring hospital-wide mortality will incentivize hospitals to integrate programs that improve patient care and prevent mortality. We will continue to evaluate the measures' development in alignment with these goals.

References

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Public Comment Verbatim Report

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations /Actions Taken
2/1/18	Hospital-Wide Mortality	Greetings, I have reviewed the materials posted on the website re the two proposed measures of Hospital Wide Mortality - the Claims Only measure and the Hybrid measure. It would appear that neither one will totally measure the mortality risk as desired, that there are reliability issues w/ each. I am part of the Patient and Family group that was involved in the development of the measures. I tend to lean to the Hybrid model for the reason that it includes more clinical information and, therefore, may prove to be more accurate in documenting the various components of the patients' diagnoses and complications. I realize that there are limitations to that measure, but I think the addition of clinical risk variables is important. Thank you.	Sandra Geisinger, Patient and Family Advisor for CapitalCare Medical Group	Member of the Person & Family Caregiver Group	See Stakeholder Comments and Responses
2/19/18	Hospital-Wide Mortality	Hello, this is my public comment for Project Title: Claims-Only Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure, and Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Contract number: HHSM-500-2013-13018I Task Order HHSM-500-T0001. My name is Jody Yarborough, I am a patient family partner at Stanford Healthcare, participating in the CORE project. I can be reached at XXXXX@XXX.XXX or XXX-XXX-XXXX. Question 1: Do I have input on the service line division structure of the measure. No, overall I think the 13 service lines identified are appropriate. However, in reading through the literature, I did not see a definition of what "surgical" vs. "non-surgical" is. It seems to me, that more and more "procedures" that in my opinion are invasive are being considered more and more as "non-surgical". For example, implanting monitoring probes in the brain for Parkinson's or other neuro issue is done on an "outpatient" basis. Also many orthopedic orthoscopic procedures that are considered "minimally invasive". How are	Jody Yarborough, Patient Family Partner at Stanford Healthcare	Patient/ Family Advocate	See Stakeholder Comments and Responses

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations /Actions Taken
2/19/18	Hospital-Wide Mortality	*(continued from previous page)* these procedures being captured in your service line divisions? As we are told when we are consenting for a procedure, we are told there is always a risk. Are these "risks" being captured in the mortality calculations of this study? Question 2: Do you have input on the measure testing approach? No. I think the authors did a good job of taking a lot of complex information and data, and applying mathematical algorithms that can provide the most objective and fair analysis. This I think will provide a level of credibility that hospitals will most likely embrace and use as a tool to improve lower their rates of mortality. Question 3: Do you have input in the hospital measure results? No. Question 4: Do you have input on how the measure results might be presented to the public? With as many qualitative descriptors to make the quantitative data palatable. Many members of the public will not have any reference point for statistical averages independently presented. I know it gets hard because you don't want to provide inaccurate data, but just saying that "hospital x has a 12% lower risk of mortality" doesn't mean much on its own for a patient trying to understand the quality of care at an institution they are about to hand their life over to. Question 5: How could CMS present supplemental hospital performance information in public reporting, such as service-line division-level results, to create a more meaningful and usable measure? By doing just that. Providing contextual information specific to the delivery of care. i.e. expected outcomes/ experiences/risks of a knee replacement vs. open heart surgery. Question 6; How could CMS report more information about hospitals in a No Different From National Average group (defined using 95% confidence intervals) to help clinicians and patients use the measure results to improve patient care and make informed choices? Without going against its stated goal of not making more reporting burden for patients, physicians, and other clinicians, I think the hybrid methodology of combining both claims data AND medical record data is the best. Here's why. Although not desired, as a patient, I know many times I	Jody Yarborough, Patient Family Partner at Stanford Healthcare	Patient/ Family Advocate	See Stakeholder Comments and Responses

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations /Actions Taken
2/19/18	Hospital-Wide Mortality	*(continued from previous page)* have an inaccurate claim made to CMS or an inaccurate information put in my medical chart. This can either happen intentionally to ease a billing issue, or, because of poor patient/doctor communication. Results are only as good as the data they are being extracted from. The more CMS can do, even if after the fact, to accurately capture the true mortality causes for a patient, the more accurate hospitals can be evaluated for their current state, as well as future improvement initiatives. Overall I highly applaud this effort. A close family friend of mine was admitted for a knee replacement with no admitting pre-existing conditions or risk factors, (they had had several joint replacements prior without incident) and died 24 hours post op. I contribute to this effort in their memory. The examination of hospital-wide mortality, while a large and complex undertaking, I feel is crucially important to improving the overall state of our healthcare system. Lastly, once rules are in place and new measures adopted, the results of the examination data at specific routine intervals needs to be robustly communicated to CMS patients and the larger public. The more informed and empowered patients can be, the better. Thank you for your time in reading. It is an honor to contribute. Sincerely, Jody Yarborough	Jody Yarborough, Patient Family Partner at Stanford Healthcare	Patient/ Family Advocate	See Stakeholder Comments and Responses
2/26/18	Hospital-Wide Mortality	To whom it may concern, Thank you for the opportunity to weigh in on this very important topic. After reading both the claims-based data and the hybrid model as proposed rules for CMS to measure hospital wide mortality, I would like to submit comments from a patient perspective. These proposed rules are two very serious, focused, well-thought out, well-executed strategies. I would like to focus on the overall thrust and comparison of the two measures. I thought these do an outstanding job in defining the samples (including inclusions and exclusions)—as health care can be so complex when looking at any one individual case. And the final 13 Service Line Divisions make a lot of intuitive sense to me (and provide, at least me, with	Andrea Baer, Director of Patient Advocacy and Program Management of Mended Heats and Mended Little Hearts	Patient/ Patient Advocate	See Stakeholder Comments and Responses

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2/26/18	Hospital-Wide Mortality	*(continued from previous page)* a high degree of face validity). As a patient, if I have a preference in measures of hospital/care effectiveness, I always want as much information to be taken into account as possible. Which means I would really want to see scores based on the hybrid method. If I were evaluating outcomes as a doctor or hospital, I also think I would want the most information possible when considering effectiveness, and why the scores are what they are, and what we must improve in the care of our patients (and as a corollary, improve our score in service line areas). And presenting this data, and the measures developed, and the use of the c-statistic to doctors and hospitals shouldn't be a problem (and if they can't understand it, I want to know because I don't want to be a patient there!) But the real basis of the issue, regardless whether claims-only, or hybrid method, is how do you present this to the public, and share with patients/family/ care-givers to help them make informed decisions. I am sure that very few patients would want to know the statistical development of the measure, or of the service line divisions—only how does this hospital compare with a national average and/or with other area hospital in the service division I'm about to be serviced by! My sense is that to make this usable you might have to convert the c-statistic into something more intuitive—like alphanumeric grades (A, B, C+, D, etc.) or perhaps into a simple scale of 1 to 10 using whole numbers only. I think there would be statistical ways to define and do that without losing too much exactness/granularity of detail. I don't think most patients/families are really interested in too much granularity. And note, even if presenting the information as a grade for example, that's for the patient's benefit toward understanding—you still need to present the exact c-statistics for presentation to hospitals and doctors. Another issue in presenting these scores to patients is how to ensure that whatever the scoring/reporting system used, the patient is actually presented that information by the hospital—and to ensure that not just that hospital's "grade" is presented, but other nearby hospitals' grades. Even if CMS has those scores online, I don't think many people would take the time to go and look and compare. And of course, from a patient's perspective—a lot depends on whether	Andrea Baer, Director of Patient Advocacy and Program Management of Mended Heats and Mended Little Hearts	Patient/ Patient Advocate	See Stakeholder Comments and Responses

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2/26/18	Hospital-Wide Mortality	*(continued from previous page)* you're admitted via a visit to an emergency room, or if you have time to research and consider. From my personal *(*perspective, if I'm needing another major cardiac procedure—I will take the time to do comparison "shopping", or at least check to see if my usual hospital of preference is continuing to do okay in this area. But if I'm in the back of an ambulance, if the closest hospital has a grade of C- or D or worse, I don't care, just get me there ASAP! If I'm in my home area where I know my local hospitals, I might say take me to X rather than Y if time is about the same—but if I'm out on vacation or business somewhere, I am not going to say, take me to the nearest hospital that has a cardiac c-stat of 0.85 or better. Overall the measures developed here are much more useful to doctors and hospitals, than to patients—and much easier to present to doctors and hospitals. In the paper, you reference the issue of how to make providers more proactive in improving care. If the average for local hospitals in any one service area is B+ and we're a B+, so why improve. Section 5.7 (starting on page 55) of the claims-only document does a good job of addressing this dilemma—although doesn't have a definitive answer any more than I have one! I think the idea of reporting the probability of any one hospital be statistically different from average is a great idea, and needs to be developed. It may not mean much to patients, but doctors and hospitals understand 'statistically' better/worse. In the hybrid method development, they use claims data from only 22 hospitals—a relatively small Number, although it encompasses a ton of patient data. But on page 15, when they comment on the 22 hospitals using the Epic system for tracking/reporting—and then say," we can make the reasoned inference that these data are representative", I just don't know about that. My statistical sense is that you have to prove that to me. Reasoned inferences are usually fine, but can also be very wrong. I understand that gathering more data from more hospitals (and cleaning, standardizing, etc. that data) would be a major undertaking—but until then, while I like the hybrid version better overall, I don't think I	Andrea Baer, Director of Patient Advocacy and Program Management of Mended Heats and Mended Little Hearts	Patient/ Patient Advocate	See Stakeholder Comments and Responses

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2/26/18	Hospital-Wide Mortality	*(continued from previous page)* would want to rely on it given the base "reasoned inference" And I think they know that—because even on page 41 of the hybrid document they reference the small Number of 22 preventing them from doing split-sample reliability testing. I believe the hybrid measurement is better, and that it's worth doing the extra research/testing using data from more than 22 hospitals to ensure it is reliable and valid. Sincerely, Andrea Baer	Andrea Baer, Director of Patient Advocacy and Program Management of Mended Heats and Mended Little Hearts	Patient/ Patient Advocate	See Stakeholder Comments and Responses
2/20/18	Hospital-Wide Mortality	The following are my comments on the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors. My comments are limited to specific technical issues regarding the use of EHR data. 1. If I read the paper correctly, the test data set was obtained from 22 hospitals in the KPNC system. All of these hospitals use the same version and installation of the Epic HER. As such they won't reflect the variation in data that might be found in other EHRs and even in other installations of Epic. I assume you are aware of this situation, but I did not see it mentioned in the discussion. 2. On page 33, the units of platelets is listed as "count". I think the correct unit here is thousands of cells per microliter, or k/mcL. The same units should be used for WBC count. 3. Of course, in many hospitals, patient weight is measured in kilograms, and patient temperature is measured in degrees centigrade. It is likely that all KPNC hospitals use the same units. Since on page 32 you state that a usable data element is "Captured using the same units of measurement across the country", it's not clear if you are allowing for this variation. Thanks for opening this up to comment!	Howard Bregman, MD, MS FAAP, Director, Clinical Informatics at Epic	Vendor	See Stakeholder Comments and Responses

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations /Actions Taken
2/23/18	Hospital-Wide Mortality	Dear Dr. Peter, Thank you for the opportunity to comment on the draft Claims-Only and Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measures. These comments are submitted on behalf of the American Academy of Neurology (AAN). The AAN is an association of more than 32,000 neurologists and neuroscience professionals, and has previously expressed concerns regarding use of the existing stroke mortality measures. The AAN believes the measures have face validity, and favor the enhancements to the adjustment procedures using EHR data. It is not clear if the divisional measures will be reported separately or not, and the AAN would encourage clarity on this. The AAN favors use of an overall mortality measure compared with existing stroke measures. "However, mortality is a poor quality measure for the majority of patients with multiple chronic diseases who are near the end of their life, and may be engaged in preference-sensitive decisions that result in an earlier (or less delayed) death." Holloway and Quill. Mortality as a measure of quality: implications for palliative and end-of-life care. JAMA 2007; 298(7):802-804. Please let me know if you have any questions or concerns.	Amy Bennett, Manager, Quality Improvement American Academy of Neurology	Physician Organization	See Stakeholder Comments and Responses
2/27/18	Hospital-Wide Mortality	We are submitting the following comment on behalf of the Surgical Outcomes and Quality Improvement Center (SOQIC) at Northwestern Medicine. Best, KB 1. Relating to the issue of identification of few outliers. Comment: The inability of the HWM measure to identify outliers does not necessarily "give the illusion that everyone was doing okay." Rather, the inability of the HWM measure to identify outliers suggests that HWM is not a sensitive quality measure. It begs the question: who is the marginal patient for which a unit change in "quality" results in a life versus death? It is not the average patient. The mortality (or survival) of the average patient is generally robust to small-to-moderate variations in quality. It is the fragile patient for which a small variation in quality will translate into large differences in the odds of death. One can think about the problem as one of treatment heterogeneity, in which quality of care is the "treatment" and death is the outcome. The patient population as defined in the HWM	Karl Bilimoria, MD MS, Director of Surgical Outcomes and Quality Improvement Center (SOQIC) at Northwestern Medicine	Quality Improvement	See Stakeholder Comments and Responses

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2/27/18	Hospital-Wide Mortality	*(continued from previous page)* measure is broad and diverse – it includes low risk patients undergoing low-risk procedures for whom differences in quality are unlikely to generate large differences in the odds of death (although differences of quality may be associated with larger differences in some other outcome). It also includes some higher-risk patients for whom differences in quality may generate larger differences in the odds of death vs. survival. Either find a quality metric that will be more sensitive to variations in quality for the average patient, or refine the HWM measure so that it only includes the "marginal" patient population with respect to mortality and quality of care. Finding few outliers is less indicative that "most" hospitals are doing okay, and more indicative that for "most patients," survival is robust to all but the most egregious departures in quality of care. HWM may not be sensitive enough to most quality improvement efforts to be a useful to providers as a guide for quality improvement. Again, because the survival of most patients is likely to be robust to all but the most egregious departures in quality of care, investments in quality improvement to reduce HWM may not be allocatively efficient if it improves survival for a small fraction of patients. The money and effort may be better invested to reduce complications that have a higher incidence rate. We strongly discourage manipulating the confidence interval to artificially inflate the number of outliers detected. The 95% confidence interval corresponds to selecting alpha=0.05 or a 5% probability of making a Type I error. A Type I error is a failure to accept the null hypothesis when the null hypothesis is true – i.e., a Type I error is a false-positive. By using a 90% confidence interval to identify more hospitals in the tails of the distribution, you are essentially raising the probability of making a Type 1 error from 5% to 10%. Thus, while you will identify greater numbers of hospitals at the tails of the distribution, you will increase the probability that you are mislabeling hospitals as "worse than average" or "better than average" when they may actually be no different from average. You will not	Karl Bilimoria, MD MS, Director of Surgical Outcomes and Quality Improvement Center (SOQIC) at Northwestern Medicine	Quality Improvement	See Stakeholder Comments and Responses

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2/27/18	Hospital-Wide Mortality	*(continued from previous page)* identify true outliers, you will only generate an illusion of identifying more outliers. Moreover, there will be non-trivial policy and equity implications of identifying more outliers that may actually false-positives. 2. Relating to the combined administrative/clinic data measure Comment: The administrative + clinical data measure relied on a non-representative sample of hospitals that came from a large system. Hospitals in other systems and certainly hospitals not in large systems are likely to have less capacity for adapting their EHR systems to accommodate data collection for an admin + clinical measure. Much more testing is needed before this measure is ready for widespread use.	Karl Bilimoria, MD MS, Director of Surgical Outcomes and Quality Improvement Center at Northwestern Medicine	Quality Improvement	See Stakeholder Comments and Responses
2/27/18	Hospital-Wide Mortality	Dear CORE team: UnityPoint Health ("UPH") appreciates the opportunity to provide comments on the proposed Claims-Only Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure, and Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors. UPH is one of the nation's most integrated healthcare systems – the 13th largest non-profit healthcare system and the fourth largest nondenominational healthcare system. Through more than 30,000 employees and our relationships with more than 290 physician clinics, 32 hospitals in metropolitan and rural communities and home care services throughout our 9 regions, UPH provides care throughout Iowa, western Illinois and southern Wisconsin. On an annual basis, UPH hospitals, clinics and home health provides a full range of coordinated care to patients and families through more than 6.2 million patient visits. In addition, UnityPoint Accountable Care (UAC) is the largest Next Generation ACO. The quality performance under the Next Generation ACO model continues to improve year after year. In 2016, we achieved the 70th percentile for all metrics except for one measure that achieved the 50th percentile benchmark. Overall, UPH has embraced quality and transparency through internal publishing of provider level data	Cathy Simmons, J.D., M.P.P., Executive Director, Regulatory Affairs Government & External Affairs at UnityPoint Health; and Jordan Russell, MPA, CPHQ, Director, Quality Clinical Analytics at UnityPoint Health	Health System	See Stakeholder Comments and Responses

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations /Actions Taken
2/27/18	Hospital-Wide Mortality	*(continued from previous page)* and therefore understands the importance of ensuring that data is timely and accurate. We consistently use data to identify areas of opportunity and drive improvement and appreciate that measure development involves both claims-based and EHR-based measures. We respectfully offer the following comments limited to public reporting of these measures. **Do you have input on how the measure results might be presented to the public?** Our comments relate to the timing for public reporting, not whether or how the information should be reported. While we support quality transparency and encourage beneficiaries and the public to become more engaged in healthcare decisions, we want to assure that measures are accurate, reliable and can be easily understood before public reporting occurs. For the proposed measures, we encourage a larger pilot of the eCQM measures prior to public reporting. Once this occurs, we also urge that a sufficient timeframe for hospitals to preview the data prior to public reporting be instituted. We appreciate the opportunity to provide comments.	Cathy Simmons, J.D., M.P.P., Executive Director, Regulatory Affairs Government & External Affairs at UnityPoint Health; and Jordan Russell, MPA, CPHQ, Director, Quality Clinical Analytics at UnityPoint Health	Health System	See Stakeholder Comments and Responses
2/27/18	Hospital-Wide Mortality	Dear Administrator Verma: The Federation of American Hospitals (FAH) appreciates the opportunity to comment on the Claims only Hospital-wide (All-Condition, All-Procedure) Risk-standardized Mortality and the Hybrid Hospital-wide (All-Condition, All-Procedure) Risk-standardized Mortality with Electronic Health Record Extracted Risk Factors measures. FAH agrees that hospitals should measure and track mortality rates for quality improvement purposes but any measure that is proposed for accountability uses should be evidence-based and demonstrated to be reliable and valid. As we noted during the previous comment period in late 2016, we do not believe that the rationale for this measure provides sufficient evidence that a death in the 30	Claudia A. Salzberg, PhD	Hospital Association	See Stakeholder Comments and Responses

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations /Actions Taken
2/27/18	Hospital-Wide Mortality	*(continued from previous page)* days following an inpatient admission is a predictor of the quality of care provided by a hospital and may well be due to other factors outside of a hospital's control. The articles and research cited to demonstrate the importance and underlying evidence to support the measure continue to be solely focused on inpatient mortality. The FAH does not believe that adequate justification has been made for these measures. It was FAH's understanding that while the developer did not believe that social risk factors should be included in the risk model, testing would be completed to determine whether adjustment of these risk factors was warranted. Regrettably, it appears that this testing was not done. FAH believes that some clinical diagnoses and outcomes will be impacted more significantly by social risk factors (e.g., availability of services such as pharmacies and transportation). Measures must be specified to ensure that they produce results that are reliable and valid and enable fair comparisons. By not examining whether any one of these community-level factors should be included, there is increased risk that a hospital's true performance will be misrepresented and could provide inaccurate information to patients and their families. FAH strongly urges CMS to complete additional testing to determine whether social risk factors should be included. FAH also questions the usefulness of either measure given the limited variation in performance scores with only six hospitals identified as statistically worse than the national average and the majority of the hospitals (92.4%) were no different than the national average. We do not believe that these measures provide any new information that would be useful to hospitals and patients. The proposed approach to report the probability that a hospital is statistically different than average is potentially worth exploring but examples on how this information would be displayed and whether it would be understandable to a patient and their family or useful to a hospital for quality improvement must be examined further prior to its implementation. It is also not clear how these measures will be used along with the condition-	Claudia A. Salzberg, PhD	Hospital Association	See Stakeholder Comments and Responses

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2/27/18	Hospital-Wide Mortality	*(continued from previous page)* specific mortality measures and additional information on this question is needed. FAH has several concerns related to the lack of evidence to support the measures' focus, lack of testing for social risk factors in the risk adjustment approach, and limited usefulness of the results for quality improvement and accountability purposes. As a result, FAH strongly urges CMS to complete additional testing to address many of these questions and concerns prior to implementation of either measure in a federal program. The FAH appreciates the opportunity to comment on these quality measures. We look forward to continued partnership with the CMS as we strive for a continuously improving health care system.	Claudia A. Salzberg, PhD	Hospital Association	See Stakeholder Comments and Responses
2/28/18	Hospital-Wide Mortality	Titles should also be posted in plain English to allow patients to better understand project from beginning. Looking at cmit.cms.gov web site, a search using key terms in measure title returns nearly 2000 results. How can one person comment publicly on the impact and relevance of one additional measure? The 2018 Meaningful Measure efforts have a lot of work to do.By comparing how many patients die within a hospital or shortly after leaving the hospital, we can help hospitals see whether and how they can improve care of their patients. There is no accounting for any treatments or interventions outside of hospital after discharge. Service line groupings are related to care before discharge, not after, which can be critical in cause of death. Why 30 days. Why not 15 or 45 days any evidence basis or arbitrary? Why are there not efforts to find what works (appreciative inquiry) and send out that data/tool kits rather than report irreversible (death) failures after the fact? Improvement in critical processes need to be captured before people die. We need to measure and report effective safety actions taken before death rather than after. Scores for patients that die inside a hospital focus on the institution and do not reflect whatever safety issues were not addressed by clinician prior to hospitalization, even when looking at EHRs. Such indirect measure does not link cause and effect (for example, a missed	Mary Schramke, Person & Family Engagement Network Member	Patient/ Patient Advocate	See Stakeholder Comments and Responses

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2/28/18	Hospital-Wide Mortality	*(continued from previous page)* diagnosis by doctor in a clinic setting that results in patient being hospitalized). Mapping what happens to patient inside hospital is institution-centered view, not patient centered view (entire patient journey mapping required, not hospital efforts in isolation). Claims only data takes "how does institution get paid" perspective. Measures need to tale a "how does patient get healthy faster with lowest dose of drugs (addiction risk reduction), given other medical conditions present (life and wellness- based rather than money-based). Claims data are not easily shared and integrated into medical practice that can be used in patient -clinician decision making for long term wellness. It's a data dead end that cannot easily promote mindful wellness decision making between clinician and patient. EHR data is a good start vs claims data alone, but data from all providers to help patient recover (pharmacy, physical therapy, mental health, home care support, etc.) are needed to understand mortality cause and effect for patient centered outcome to be informative for patients and their families. We engaged with several stakeholder groups throughout the development process of both the claims-only HWM measure and the hybrid HWM measure. We elicited feedback on how to develop and report measure results in a meaningful way for patients, family caregivers, and providers. Mortality is an important outcome that is meaningful to patients and providers. The vast majority of patients admitted to the hospital have survival as a primary goal. I disagree with primary goal. For me and my family our goal it is to have the care and treatment in a hospital that forms the foundation for full recovery, including a plan to continue appropriate treatment in a safe and effective setting, not just getting out alive. Capturing monetary savings for preventable mortality events is challenging, as patients who die may incur fewer expenses than those who survive. Emphasis needs to shift away from money not spent on dead people, rather productivity lost by not keeping citizens healthy. The performance metric, risk-standardized mortality rates (RSMR), are derived from the combined results of multiple	Mary Schramke, Person & Family Engagement Network Member	Patient/ Patient Advocate	See Stakeholder Comments and Responses

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations /Actions Taken
2/28/18	Hospital-Wide Mortality	*(continued from previous page)* statistical models built for groups of admissions that are clinically related and share similar risk profiles. This report reflects specifications that have been developed with close input from patients, caregivers, clinicians and methodological experts. I am wondering how informed the input from patients and caregivers would be on this sort of complex statistical model, particularly finding patients and caregivers that have a multiple (often chronic) condition mix that fits the models being used.	Mary Schramke, Person & Family Engagement Network Member	Patient/ Patient Advocate	See Stakeholder Comments and Responses