TO: Pulmonary and Critical Care Steering Committee

FR: Reva Winkler, MD, MPH and Kathryn Streeter, MS

RE: Follow-up of four pulmonary measures

DA: September 26, 2012

On October 3, 2012 the Pulmonary and Critical Care Steering Committee will meet by conference call to revisit four measures from the Pulmonary and Critical Care Project:

1. ***0506 Thirty-day all-cause risk standardized readmission rate following pneumonia hospitalizations***
   1891 Thirty-day all-cause risk standardized readmission rate following COPD hospitalizations

   During the comment period, it was pointed out that the condition-specific readmission measures should be harmonized with the all-condition, all-cause hospital readmission measure endorsed by NQF earlier this year. In response to the comment, CMS/Yale advised NQF that they were working on harmonization of exclusions using a new algorithm for planned readmission for the all readmission measures, including pneumonia and COPD. A report describing revised measure specifications that include the new planned readmission algorithm was submitted to NQF on September 21, 2012 and is attached for your review.

   Additionally, NQF has been asked by CMS to perform *ad hoc* reviews of the same algorithm as it applies to the heart failure, AMI and stroke readmission measures. Other Committees are reviewing those measures in this same timeframe.

   ACTION ITEM:

   - **After review of the new materials and discussion among the Committee, does the Committee wish to maintain their recommendation for endorsement of these two measures as revised to include the algorithm for planned readmissions?**

2. ***1893 Thirty-day all-cause risk standardized mortality rate following COPD hospitalizations***
   This measure was voted on and approved by the NQF membership and presented to the CSAC. Several CSAC members noted that the measure appropriately excludes patients that are enrolled in Medicare hospice programs at any time in the prior 12 months or on the first day of hospitalization. CSAC members questioned whether the exclusion is broad enough sincethe condition of some COPD patients may not be well established in the first 24 hours in order to determine if a hospice or palliative care approach is preferred. . While CSAC members acknowledge that the reason for limiting the exclusion is that enrollment in hospice after the first day may be a result of adverse

events/quality of care problems, there were concerns that the 24 hour window seems quite short for making end of life decisions. The claims-based risk model does not capture patient preferences, such as for end-of-life decisions or potential referrals to palliative care that may be occur following a hospitalization. CSAC members raised concerns that avoidance of appropriate palliative care may be an unintended consequence of this measure. CSAC members noted that this issue is more significant for chronic conditions that deteriorate as a part of the natural disease process such as COPD and heart failure and less so for pneumonia and AMI which are more acute.

Yale/CMS has responded to these concerns in an attached letter which provides analyses of patients referred to hospice in 2008 at admission and discharge and also compares mortality rates using this measure for hospitals with palliative care programs compared to those without palliative care programs.

ACTION ITEM:

- **Because the issue of the hospice exclusion was not specifically discussed by the Steering Committee, the CSAC is asking for input from the Committee on the validity of the measure given concerns with the hospice exclusions.**

  After review of the CSAC questions, the memo and data on hospice/palliative care from Yale and discussion among the Committee, does the Committee wish to maintain their recommendation for endorsement of this measure?

3. 0356: PN3a--Blood Cultures Performed Within 24 Hours Prior to or 24 Hours After Hospital Arrival for Patients Who Were Transferred or Admitted to the ICU Within 24 Hours of Hospital Arrival

After reviewing the comments received on this measure, particularly the lack of support from APIC, SCCM and ACEP, the Committee changed their recommendation of this measures to "do not recommend" (5 YES, 10 NO) primarily for not meeting the evidence criterion. In response to the second vote, the measure developer has offered additional justification for this measure that was not previously presented to the Committee. The co-chairs have agreed that the Committee should consider the new information. Additionally, staff has requested input from the guideline developer, IDSA, as well as offered the three organizations that commented against the measure to expand their rationale for not supporting the measure.

Attached to this document are the following:

- The new information from the measure developer
- The response from IDSA
- The follow-up from SCCM, APIC and ACEP.

The discussion of this measure centers primarily on the evidence to support the process of care, i.e., performing blood cultures on patients admitted to the ICU for pneumonia. NQF's evaluation criteria

detail the expectations for quantity, quality and consistency for the evidence to support the measure focus. The evidence criteria allow for an exception for the evidence criterion (from Table 3):

Potential Exception to Empirical Body of Evidence for Other Types of Measures	**Pass subcriterion 1c:**
If there is no empirical evidence, expert opinion is systematically assessed with agreement that the benefits to patients greatly outweigh potential harms.	Yes, but only if it is judged that potential benefits to patients clearly outweigh potential harms; otherwise, No

ACTION ITEM:

- **After reviewing the attached information and discussion by the Committee, does the Committee wish to maintain its recommendation <u>against</u> endorsement of the measure?**
- **Does the Committee wish to make an exception to the evidence criterion in order to recommend the measure?**

RESPECIFYING THE HOSPITAL 30-DAY PNEUMONIA AND 30-DAY CHRONIC OBSTRUCTIVE PULMONARY DISEASE READMISSION MEASURES BY ADDING A PLANNED READMISSION ALGORITHM

Submitted By Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE)

CMS Contract # HHSM-500-2008-00025I/HHSM-500-T0001, Modification No. 000007

September 21, 2012

Prepared for the Centers for Medicare & Medicaid Services for submission to the National Quality Forum Pulmonary Project

Contents

List of Tables

List of Figures

Background

The Centers for Medicare & Medicaid Services (CMS) has developed hospital risk-standardized readmission measures for pneumonia and chronic obstructive pulmonary disorder (COPD). The pneumonia measure has been approved by the National Quality Forum (NQF), and both measures are currently under review at NQF[1]. CMS has contracted with Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) to update these measures to identify and remove planned readmissions from the measure outcomes. This report describes the changes to each measure for consideration by NQF.

Readmission measures are intended to capture unplanned readmissions that arise from acute clinical events requiring urgent rehospitalization within 30 days of discharge. Higher than expected unplanned readmission rates suggest lower quality of hospital and post-discharge care and are the focus of hospital quality measurement as part of efforts to promote quality improvement. In contrast, planned readmissions are generally not a signal of quality of care. Furthermore, there is concern that including planned readmissions in a readmission measure could create a disincentive to provide appropriate care to patients who are scheduled for elective or necessary procedures unrelated to the prior admissions.

During development of the readmission measures, YNHHSC/CORE clinicians, additional clinical consultants, and technical expert panels identified readmissions for each measure that are typically scheduled as follow-up care within 30 days of discharge. For pneumonia and COPD they concluded that there are no readmissions that are typically scheduled as follow-up care to treat either condition within 30 days of a discharge. However, there has been growing interest in identifying and excluding from this measure planned readmissions for procedures and treatments such as chemotherapy, which are not directly related to the index admission, but were likely planned.

To more broadly identify planned readmissions, CMS contracted with YNHHSC/CORE to develop a planned readmission "algorithm" (a set of criteria) for classifying readmissions as planned using claims data. The algorithm identifies admissions that are typically planned and may occur within 30 days of discharge from the hospital. The planned readmission algorithm was developed for a hospital-wide cohort of patients regardless of the index admission diagnosis. Since it identifies commonly planned readmissions for all types of patients, it is a comprehensive definition of planned readmissions that includes procedures and conditions that are not considered follow-up care for pneumonia or COPD admissions (e.g. elective cholecystectomy). The planned readmission algorithm therefore can be used to enhance the identification of planned readmissions in the readmission measures.

We have updated both readmission measures by applying this planned readmission algorithm. In this report we present: (1) an overview of the planned readmission algorithm; (2) our approach to applying the planned readmission algorithm to each readmission measure; (3) an impact analysis of how this

[1] Measure numbers are: pneumonia – 0506 and COPD - 1891

change in the measure affects the readmissions identified as planned, the rate of planned readmissions, model performance, and the distribution of hospital rates; and (4) a summary of the measure updates.

1. Planned Readmission Algorithm Overview

We based the planned readmission algorithm on three principles:

1. A few specific, limited types of care are always considered planned (obstetrical delivery, transplant surgery, maintenance chemotherapy, rehabilitation);
2. A planned readmission is defined as a non-acute readmission for a scheduled procedure; and
3. Admissions for acute illness or for complications of care are never planned.

Clinicians in our internal working group reviewed the full list of Agency for Healthcare Research and Quality (AHRQ) Procedure Clinical Classification Software (Proc CCS) codes and identified procedure categories that are commonly planned based on these principles. The full preliminary list of planned readmissions and acute diagnoses was posted as part of two public comment periods for the Hospital-Wide All-Cause Unplanned Readmission Measure. The details of the resulting algorithm are presented in Appendix A. In brief, the algorithm uses a flow chart (Figure A 1) and four tables of specific procedure categories and discharge diagnosis categories to classify readmissions as planned or unplanned. Specifically:

1. Table A 1 lists four procedure categories that are always planned regardless of diagnosis;
2. Table A 2 lists four diagnosis categories that are always planned regardless of procedure;
3. Table A 3 presents the list of potentially planned procedure categories (readmissions with these procedures are considered planned if not accompanied by an acute discharge diagnosis); and
4. Table A 4 presents the acute diagnosis categories that disqualify a potentially planned readmission from being considered planned.

2. Applying the Planned Readmission Algorithm

Approach to applying the planned readmission algorithm

Since we developed the planned readmission algorithm in a hospital-wide cohort of patients, our first step in applying it to condition-specific measures was to review the potentially planned procedures in the algorithm (Table A 3) and identify any procedures that should be added or removed to adapt the algorithm for each cohort of patients. Specifically, we took the following steps:

1. We applied the algorithm to each readmission measure, and examined the procedures and associated diagnoses that were identified as being potentially planned.
2. YNHHSC/CORE clinicians reviewed the results for face validity and determined whether any procedures considered planned by the algorithm were likely unplanned among each patient population.

3. Our team of clinicians also determined whether any additional procedures not identified as potentially planned by the algorithm should in fact be considered planned for these patient groups.
4. Based on these considerations, we finalized the algorithm for each readmission measure.

3. Impact Analyses

Pneumonia Measure

Based on our review, we updated the pneumonia readmission measure by applying the planned readmission algorithm without any adaptation. In reviewing the planned readmission algorithm for use in the pneumonia readmission measure (**step 2**), our clinicians did not identify any procedure categories that should be removed from the algorithm because they would unlikely be planned in this patient population. Similarly, the clinicians felt that the algorithm captured all appropriate planned readmissions for this measure (**step 3**).

We compared the results of the original, NQF-endorsed and updated pneumonia readmission measures to assess the effect of updating the measure with the planned readmission algorithm.

Data

The measures were applied to admissions during the period between July 2008 to June 2011. There were 1,096,708 index admissions for pneumonia at 4,859 hospitals.

Readmissions identified as planned in the updated measure

The updated measure identified 6,928 planned readmissions. The top 10 procedures among planned readmissions identified by the updated measure are presented in Table 1.

Table 1: Top 10 Planned Procedures among Planned Readmissions Following Pneumonia Discharge

Procedure CCS	Procedure Description	Number of Planned Procedures
47	Diagnostic cardiac catheterization; coronary arteriography	1,129
48	Insertion; revision; replacement; removal of cardiac pacemaker or cardioverter/defibrillator	582
84	Cholecystectomy and common duct exploration	428
67	Other therapeutic procedures; hemic and lymphatic system	310
211	Therapeutic radiology for cancer treatment	298
999	Maintenance Chemotherapy	284
78	Colorectal resection	277
169	Debridement of wound; infection or burn	274
157	Amputation of lower extremity	214
159	Other diagnostic procedures on musculoskeletal system	214

Rate of planned readmissions identified by the original NQF-endorsed and updated measures

Using the original, NQF-endorsed measure, the crude 30-day unplanned readmission rate was 18.5%. The updated measure decreased the number of readmissions counted in the outcome by identifying some readmissions as planned. For the updated measure, the crude 30-day unplanned readmission rate was 17.8%. The updated measure has a planned readmission rate of 0.6% (discrepancy due to rounding).

Comparison of model performance

To assess potential change in model performance, we calculated the c-statistic for the original, NQF-endorsed measure and the updated measure. The c-statistic changed negligibly from 0.631 to 0.634.

We also examined the odds ratios for the risk factors and their 95% confidence intervals (CIs) to determine whether this update substantially changed model variables, which would suggest they should be re-selected. The odds ratios for the original, NQF-endorsed measure and for the updated measure are in Appendix B in Table B.1. The odds ratios are nearly identical, indicating that the risk factors have a similar magnitude of effect regardless of whether or not the planned readmissions are counted in the readmission outcome.

Impact on distribution of RSRRs and relative performance of hospitals

To assess the effect on hospitals' relative performance, we examined the distribution of the Risk-Standardized Readmission Rates (RSRR) in the original, NQF-endorsed measure and the updated measure. The distribution of RSRRs shifted slightly downward from the original, NQF-endorsed measure (Figure 1) for the updated measure (Figure 2). This is expected given that the updated crude 30-day unplanned readmission rate decreased from 18.5% to 17.8%.

We then examined the distribution of the difference in hospitals' RSRR values (RSRR of the original, NQF-endorsed measure subtracted from the RSRR of the updated measure). A narrow distribution would suggest that the relative performance of hospitals is not substantially affected by the change. The median difference in hospital RSRRs was -0.6. All hospitals experienced a decrease in their rate and, for most, the difference was between -1.3 and -0.3 (Figure 3).

Figure 1: Distribution of Hospital RSRRs for the Original, NQF-Endorsed Pneumonia Measure

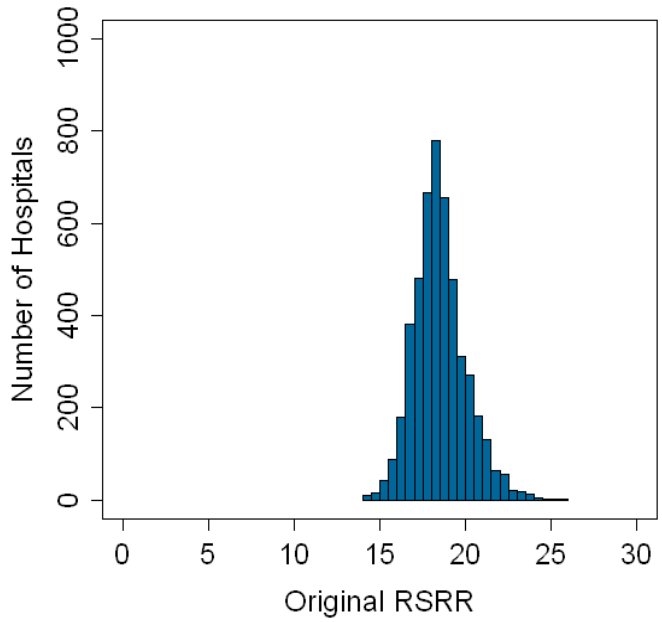


Figure 2: Distribution of Hospital RSRRs for the Updated Pneumonia Measure

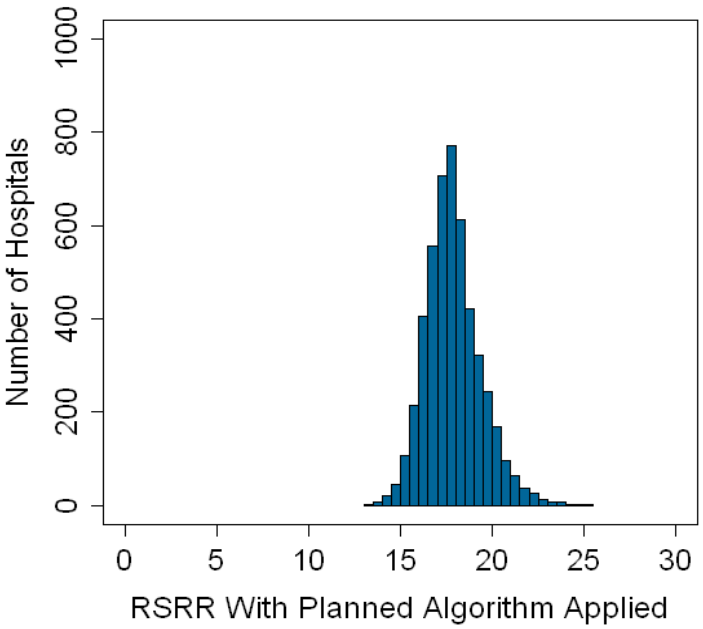
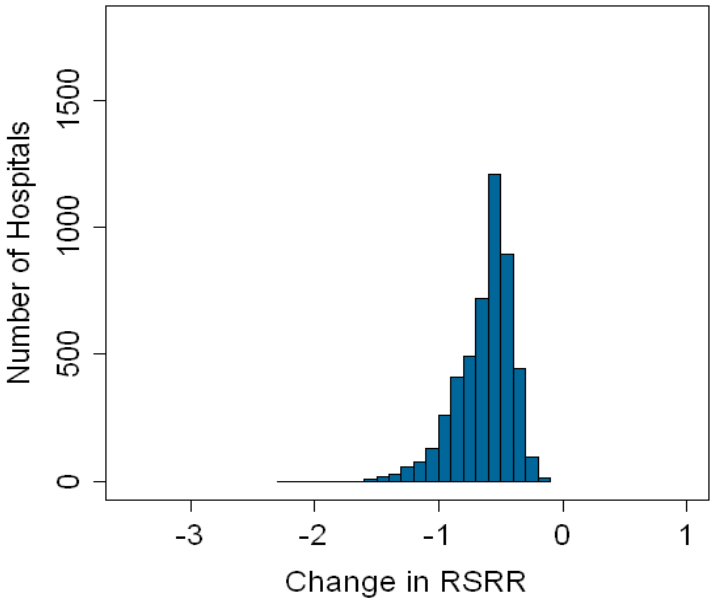


Figure 3: Distribution of Hospitals' Change in RSRR for Pneumonia after Applying the Planned Readmission Algorithm



COPD Measure

Based on our review, we updated the COPD readmission measure by applying the planned readmission algorithm without any adaptation. In reviewing the planned readmission algorithm for use in the COPD readmission measure (**step 2**), our clinicians did not identify any procedure categories that should be removed from the algorithm because they would likely be unplanned in this patient population. Similarly, the clinicians felt that the algorithm captured all appropriate planned readmissions for this measure (**step 3**).

We compared the results of the original, NQF-endorsed and updated readmission measures to assess the effect of updating the measure with the planned readmission algorithm.

Data

The measures were applied to admissions during the 2008 calendar year. There were 352,631 index admissions for COPD at 4,637 hospitals.

Readmissions identified as planned in the updated measure

The updated measure identified 2,219 planned readmissions. The top 10 procedures among planned readmissions identified by the updated measure are presented in Table 2.

Table 2: Top 10 Planned Procedures among Planned Readmissions Following COPD Discharge

Procedure CCS	Procedure Description	Number of Planned Procedures
47	Diagnostic cardiac catheterization; coronary arteriography	601
48	Insertion; revision; replacement; removal of cardiac pacemaker or cardioverter/defibrillator	153
84	Cholecystectomy and common duct exploration	132
78	Colorectal resection	91
159	Other diagnostic procedures on musculoskeletal system	79
211	Therapeutic radiology for cancer treatment	75
113	Transurethral resection of prostate (TURP)	69
51	Endarterectomy; vessel of head and neck	57
5	Insertion of catheter or spinal stimulator and injection into spinal canal	54
86	Other hernia repair	53

Rate of planned readmissions identified by original NQF-endorsed and updated measures

Using the original, NQF-endorsed measure, the crude 30-day unplanned readmission rate was 21.9%. The updated measure decreased the number of readmissions counted in the outcome by identifying some readmissions as planned. For the updated measure, the crude 30-day unplanned readmission rate was 21.3%. The revised measure has a planned readmission rate of 0.6%.

Comparison of model performance

To assess potential change in model performance, we calculated the c-statistic for the original, NQF-endorsed measure and the updated measure. The c-statistic changed negligibly from 0.629 to 0.631.

We also examined the odds ratios for the risk factors and their 95% confidence intervals (CIs) to determine whether this update substantially changed model variables, which would suggest they should be re-selected. The odds ratios for the original, NQF-endorsed measure and for the updated measure are in Appendix B in Table B 2. The odds ratios are nearly identical, indicating that the risk factors have a similar magnitude of effect regardless of whether or not the planned readmissions are counted in the readmission outcome.

Impact on distribution of RSRRs and relative performance of hospitals

To assess the effect on hospitals' relative performance, we examined the distribution of the Risk-Standardized Readmission Rates (RSRR) in the original, NQF-endorsed measure and the updated measure. The distribution of RSRRs shifted slightly downward from the original, NQF-endorsed measure (Figure 4) for the updated measure (Figure 5). This is expected given that the updated measured readmission rate decreased from 21.9% to 21.3%.

We then examined the distribution of the difference in hospitals' RSRR values (RSRR of the original, NQF-endorsed measure subtracted from the RSRR of the updated measure). A narrow distribution would suggest that the relative performance of hospitals is not substantially affected by the change. The median difference in hospital RSRRs was -0.6. All hospitals experienced a decrease in their rate and, for most, the difference was between -1.2 and -0.4. (Figure 6)

Figure 4: Distribution of Hospital RSRRs for the Original, NQF-Endorsed COPD Measure

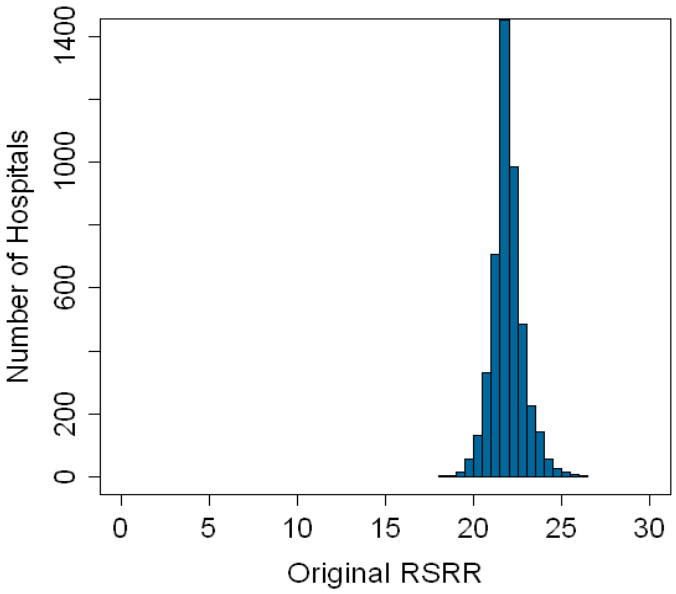


Figure 5: Distribution of Hospital RSRRs for the Updated COPD Measure

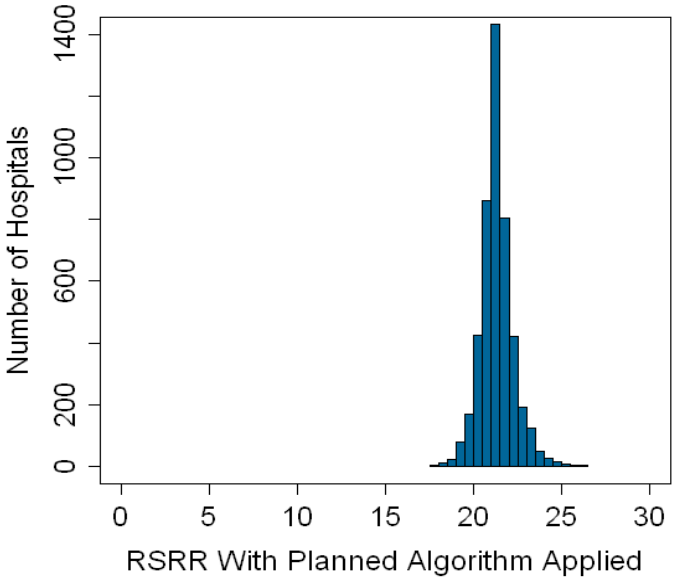
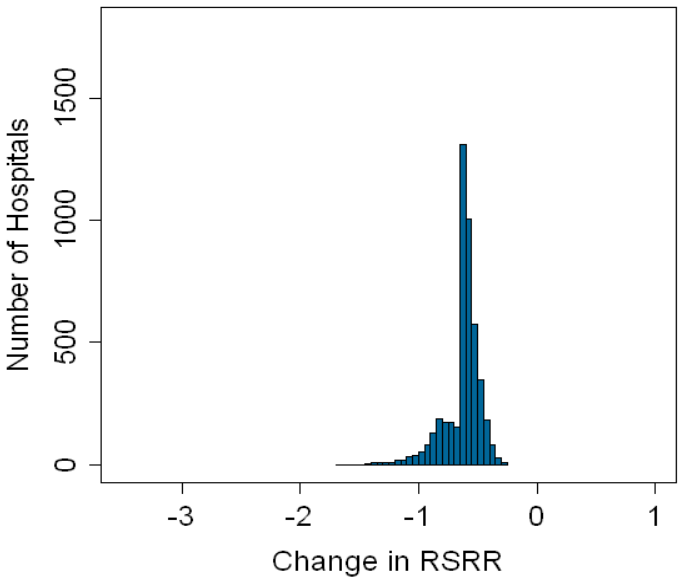


Figure 6: Distribution of Hospitals' Change in RSRR for COPD after Applying the Planned Readmission Algorithm



4. Summary of Measure Updates

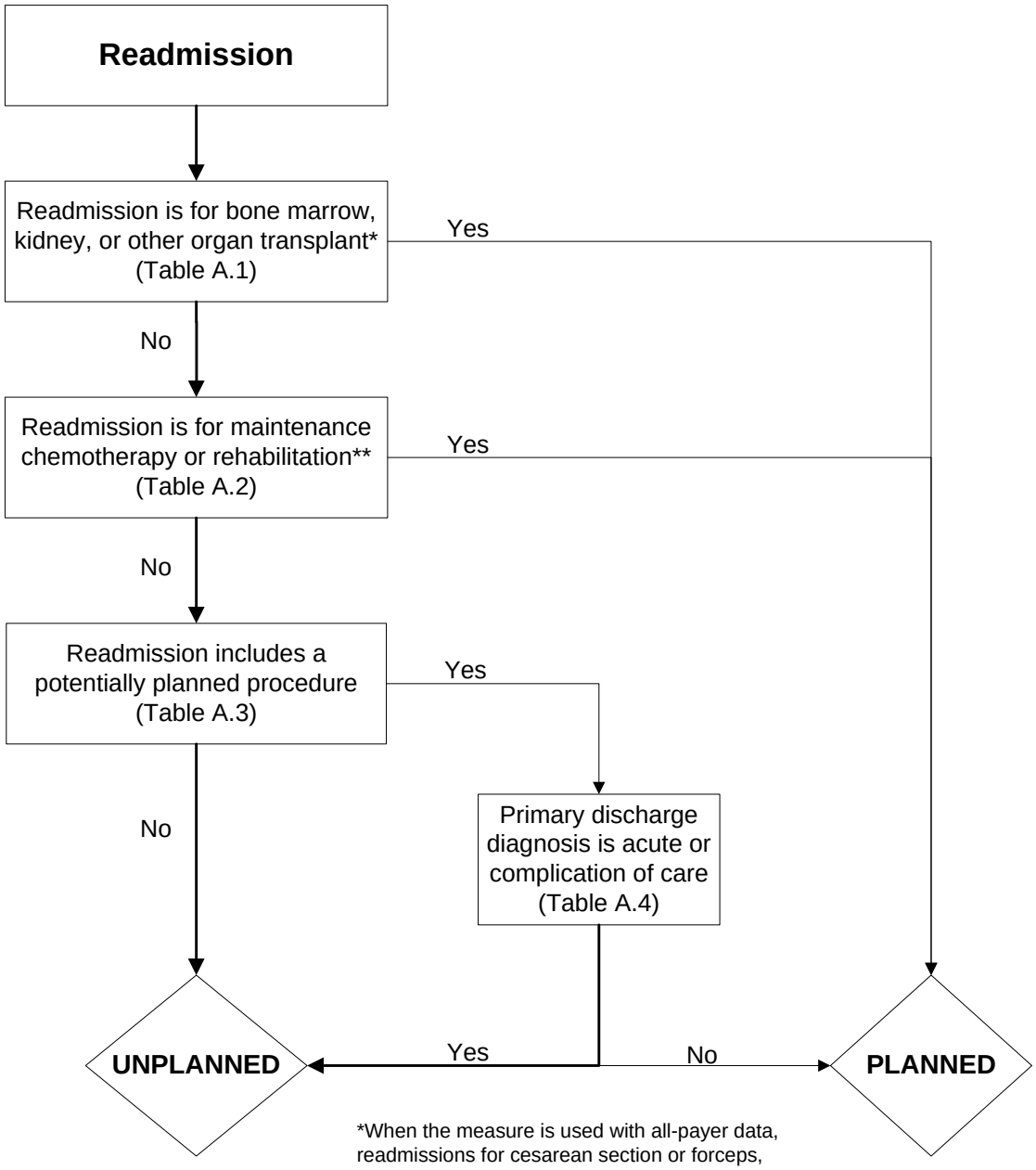
For the pneumonia readmission measure, we applied the planned readmission algorithm without adaptation to the original, NQF-endorsed measure. In the updated measure, the measured crude readmission rate was 17.8%.

For the COPD readmission measure, we also applied the planned readmission algorithm without adaptation to the original, NQF-endorsed measure. In the updated measure, the measured crude readmission rate was 21.3%.

Using the planned readmission algorithm improves the way the readmission measures identify planned readmissions. These measure updates further strengthen the measures' validity and minimizes any incentive on the part of hospitals to postpone appropriate care for patients who are scheduled for elective or necessary procedures.

Appendix A

Figure A 1: Planned Readmission Algorithm



*When the measure is used with all-payer data, readmissions for cesarean section or forceps, vacuum, or breech delivery are considered planned

**When the measure is used with all-payer data, readmissions for forceps or normal delivery are considered planned

Planned Readmission Algorithm

1. There are several procedures (Table A.1) and diagnoses (Table A.2) for which readmissions are always considered planned

Table A 1: Procedure Categories that are Always Planned regardless of Diagnosis

Procedure CCS[2]	Description
64	Bone marrow transplant
105	Kidney transplant
134	Cesarean section[3]
135	Forceps; vacuum; and breech delivery[3]
176	Other organ transplantation

Table A 2: Diagnosis Categories that are Always Planned regardless of Procedure

Diagnosis CCS[2]	Description
45	Maintenance chemotherapy
194	Forceps delivery[3]
196	Normal pregnancy and/or delivery[3]
254	Rehabilitation

[2] CCS: Clinical Classification Software, developed by the Agency for Healthcare Research and Quality (AHRQ). The software creates clinically-coherent, mutually-exclusive condition categories (diagnosis groups) and procedure categories.

[3] CCS to be included only in all-payer settings, not intended for inclusion in CMS' claims-based readmission measures for Medicare fee-for-service beneficiaries aged 65+ years

2. Readmissions that include any typically scheduled or elective procedures are considered planned *if the readmission is not for an acute diagnosis*

    - The algorithm identifies a finite list of typically scheduled or elective procedures

    - The list includes 60 AHRQ procedure categories from among 231 AHRQ procedure categories, plus 11 individual ICD-9 procedure codes (Table A.3)
        Examples: total hip replacement; hernia repair

    - Readmissions with these specific procedures are considered planned unless the readmission diagnosis is acute
        - Example: hip replacement is considered unplanned if hip fracture is the discharge diagnosis

3. Readmissions for acute diagnoses or complications of care are not considered planned

    - The algorithm identifies a finite list of acute diagnoses (Table A.4)

    - The list includes 99 diagnosis groups from among 285 AHRQ condition categories, plus 4 groupings of individual ICD-9 diagnosis codes that represent cardiac diagnoses that would not be associated with a planned readmission
        - Examples: sepsis, acute myocardial infarction, fracture, ischemic stroke, pneumonia

    - No readmissions with these specific discharge diagnoses are considered planned (unless a procedure always considered planned, such as transplant or obstetrical delivery, occurred)

Table A 3: List of Potentially Planned Procedure Categories

Procedure CCS[4]	Description
3	Laminectomy; excision intervertebral disc
5	Insertion of catheter or spinal stimulator and injection into spinal
9	Other OR therapeutic nervous system procedures
10	Thyroidectomy; partial or complete
12	Other therapeutic endocrine procedures
33	Other OR therapeutic procedures on nose; mouth and pharynx
36	Lobectomy or pneumonectomy
38	Other diagnostic procedures on lung and bronchus
40	Other diagnostic procedures of respiratory tract and mediastinum
43	Heart valve procedures
44	Coronary artery bypass graft (CABG)
45	Percutaneous transluminal coronary angioplasty (PTCA)
47	Diagnostic cardiac catheterization; coronary arteriography
48	Insertion; revision; replacement; removal of cardiac pacemaker or cardioverter/defibrillator
49	Other OR heart procedures
51	Endarterectomy; vessel of head and neck
52	Aortic resection; replacement or anastomosis
53	Varicose vein stripping; lower limb
55	Peripheral vascular bypass
56	Other vascular bypass and shunt; not heart
59	Other OR procedures on vessels of head and neck
62	Other diagnostic cardiovascular procedures
66	Procedures on spleen
67	Other therapeutic procedures; hemic and lymphatic system
74	Gastrectomy; partial and total
78	Colorectal resection
79	Local excision of large intestine lesion (not endoscopic)
84	Cholecystectomy and common duct exploration
85	Inguinal and femoral hernia repair
86	Other hernia repair
99	Other OR gastrointestinal therapeutic procedures
104	Nephrectomy; partial or complete
106	Genitourinary incontinence procedures
107	Extracorporeal lithotripsy; urinary
109	Procedures on the urethra
112	Other OR therapeutic procedures of urinary tract
113	Transurethral resection of prostate (TURP)

[4] CCS: Clinical Classification Software, developed by the Agency for Healthcare Research and Quality (AHRQ). The software creates clinically-coherent, mutually-exclusive condition categories (diagnosis groups) and procedure categories.

Procedure CCS[4]	Description
114	Open prostatectomy
119	Oophorectomy; unilateral and bilateral
120	Other operations on ovary
124	Hysterectomy; abdominal and vaginal
129	Repair of cystocele and rectocele; obliteration of vaginal vault
132	Other OR therapeutic procedures; female organs
142	Partial excision bone
152	Arthroplasty knee
153	Hip replacement; total and partial
154	Arthroplasty other than hip or knee
157	Amputation of lower extremity
158	Spinal fusion
159	Other diagnostic procedures on musculoskeletal system
166	Lumpectomy; quadrantectomy of breast
167	Mastectomy
169	Debridement of wound; infection or burn
172	Skin graft
211	Therapeutic radiology for cancer treatment
ICD-9 Codes	**Description**
30.1, 30.29, 30.3, 30.4, 31.74, 34.6	Laryngectomy, revision of tracheostomy, scarification of pleura (from Proc CCS 42- Other OR Rx procedures on respiratory system and mediastinum)
38.18	Endarterectomy leg vessel (from Proc CCS 60- Embolectomy and endarterectomy of lower limbs)
55.03, 55.04	Percutaneous nephrostomy with and without fragmentation (from Proc CCS 103- Nephrotomy and nephrostomy)
94.26, 94.27	Electroshock therapy (from Proc CCS 218- Psychological and psychiatric evaluation and therapy)

Table A 4: Acute Diagnosis Categories that Disqualify a Readmission from Being Considered Planned

Diagnosis CCS[5]	Description
1	Tuberculosis
2	Septicemia (except in labor)
3	Bacterial infection; unspecified site
4	Mycoses
5	HIV infection
7	Viral infection
8	Other infections; including parasitic
9	Sexually transmitted infections (not HIV or hepatitis)
54	Gout and other crystal arthropathies
55	Fluid and electrolyte disorders
60	Acute posthemorrhagic anemia
61	Sickle cell anemia
63	Diseases of white blood cells
76	Meningitis (except that caused by tuberculosis or sexually transmitted disease)
77	Encephalitis (except that caused by tuberculosis or sexually transmitted disease)
78	Other CNS infection and poliomyelitis
82	Paralysis
83	Epilepsy; convulsions
84	Headache; including migraine
85	Coma; stupor; and brain damage
87	Retinal detachments; defects; vascular occlusion; and retinopathy
89	Blindness and vision defects
90	Inflammation; infection of eye (except that caused by tuberculosis or sexually transmitted disease)
91	Other eye disorders
92	Otitis media and related conditions
93	Conditions associated with dizziness or vertigo
100	Acute myocardial infarction
102	Nonspecific chest pain
104	Other and ill-defined heart disease
107	Cardiac arrest and ventricular fibrillation
109	Acute cerebrovascular disease
112	Transient cerebral ischemia
116	Aortic and peripheral arterial embolism or thrombosis
118	Phlebitis; thrombophlebitis and thromboembolism
120	Hemorrhoids
122	Pneumonia (except that caused by TB or sexually transmitted disease)
123	Influenza

[5] CCS: Clinical Classification Software, developed by the Agency for Healthcare Research and Quality (AHRQ). The software creates clinically-coherent, mutually-exclusive condition categories (diagnosis groups) and procedure categories.

Diagnosis CCS[5]	Description
124	Acute and chronic tonsillitis
125	Acute bronchitis
126	Other upper respiratory infections
127	Chronic obstructive pulmonary disease and bronchiectasis
128	Asthma
130	Pleurisy; pneumothorax; pulmonary collapse
131	Respiratory failure; insufficiency; arrest (adult)
135	Intestinal infection
137	Diseases of mouth; excluding dental
139	Gastroduodenal ulcer (except hemorrhage)
140	Gastritis and duodenitis
142	Appendicitis and other appendiceal conditions
145	Intestinal obstruction without hernia
146	Diverticulosis and diverticulitis
148	Peritonitis and intestinal abscess
153	Gastrointestinal hemorrhage
154	Noninfectious gastroenteritis
157	Acute and unspecified renal failure
159	Urinary tract infections
165	Inflammatory conditions of male genital organs
168	Inflammatory diseases of female pelvic organs
169	Debridement of wound; infection or burn
172	Ovarian cyst
197	Skin and subcutaneous tissue infections
198	Other inflammatory condition of skin
225	Joint disorders and dislocations; trauma-related
226	Fracture of neck of femur (hip)
227	Spinal cord injury
228	Skull and face fractures
229	Fracture of upper limb
230	Fracture of lower limb
232	Sprains and strains
233	Intracranial injury
234	Crushing injury or internal injury
235	Open wounds of head; neck; and trunk
237	Complication of device; implant or graft
238	Complications of surgical procedures or medical care
239	Superficial injury; contusion
240	Burns
241	Poisoning by psychotropic agents
242	Poisoning by other medications and drugs

Diagnosis CCS[5]	Description
243	Poisoning by nonmedicinal substances
244	Other injuries and conditions due to external causes
245	Syncope
246	Fever of unknown origin
247	Lymphadenitis
249	Shock
250	Nausea and vomiting
251	Abdominal pain
252	Malaise and fatigue
253	Allergic reactions
259	Residual codes; unclassified
650	Adjustment disorders
651	Anxiety disorders
652	Attention-deficit, conduct, and disruptive behavior disorders
653	Delirium, dementia, and amnestic and other cognitive disorders
656	Impluse control disorders, NEC
658	Personality disorders
660	Alcohol-related disorders
661	Substance-related disorders
662	Suicide and intentional self-inflicted injury
663	Screening and history of mental health and substance abuse codes
670	Miscellaneous disorders
ICD-9 codes	**Description**
Acute ICD-9 codes within Dx CCS 97: Peri-; endo-; and myocarditis; cardiomyopathy	
03282	Diphtheritic myocarditis
03640	Meningococcal carditis nos
03641	Meningococcal pericarditis
03642	Meningococcal endocarditis
03643	Meningococcal myocarditis
07420	Coxsackie carditis nos
07421	Coxsackie pericarditis
07422	Coxsackie endocarditis
07423	Coxsackie myocarditis
11281	Candidal endocarditis
11503	Histoplasma capsulatum pericarditis
11504	Histoplasma capssulatum endocarditis
11513	Histoplasma duboisii pericarditis
11514	Histoplasma duboisii endocarditis
11593	Histoplasmosis pericarditis
11594	Histoplasmosis endocarditis
1303	Toxoplasma myocarditis
3910	Acute rheumatic pericarditis

Diagnosis CCS[5]	Description
3911	Acute rheumatic endocarditis
3912	Acute rheumatic myocarditis
3918	Acute rheumatic heart disease nec
3919	Acute rheumatic heart disease nos
3920	Rheumatic chorea w heart involvement
3980	Rheumatic myocarditis
39890	Rheumatic heart disease nos
39899	Rheumatic heart disease nec
4200	Acute pericarditis in other disease
42090	Acute pericarditis nos
42091	Acute idiopath pericarditis
42099	Acute pericarditis nec
4210	Acute/subacute bacterial endocarditis
4211	Acute endocarditis in other diseases
4219	Acute/subacute endocarditis nos
4220	Acute myocarditis in other diseases
42290	Acute myocarditis nos
42291	Idiopathic myocarditis
42292	Septic myocarditis
42293	Toxic myocarditis
42299	Acute myocarditis nec
4230	Hemopericardium
4231	Adhesive pericarditis
4232	Constrictive pericarditis
4233	Cardiac tamponade
4290	Myocarditis nos
Acute ICD-9 codes within Dx CCS 105: Conduction disorders	
4260	Atrioventricular block complete
42610	Atrioventricular block nos
42611	Atrioventricular block-1st degree
42612	Atrioventricular block-mobitz ii
42613	Atrioventricular block-2nd degree nec
4262	Left bundle branch hemiblock
4263	Left bundle branch block nec
4264	Right bundle branch block
42650	Bundle branch block nos
42651	Right bundle branch block/left posterior fascicular block
42652	Right bundle branch block/left ant fascicular block
42653	Bilateral bundle branch block nec
42654	Trifascicular block
4266	Other heart block
4267	Anomalous atrioventricular excitation
42681	Lown-ganong-levine syndrome

Diagnosis CCS[5]	Description
42682	Long qt syndrome
4269	Conduction disorder nos
Acute ICD-9 codes within Dx CCS 106: Dysrhythmia	
4272	Paroxysmal tachycardia nos
7850	Tachycardia nos
42789	Cardiac dysrhythmias nec
4279	Cardiac dysrhythmia nos
42769	Premature beats nec
Acute ICD-9 codes within Dx CCS 108: Congestive heart failure; nonhypertensive	
39891	Rheumatic heart failure
4280	Congestive heart failure
4281	Left heart failure
42820	Unspecified systolic heart failure
42821	Acute systolic heart failure
42823	Acute on chronic systolic heart failure
42830	Unspecified diastolic heart failure
42831	Acute diastolic heart failure
42833	Acute on chronic diastolic heart failure
42840	Unpec combined syst & dias heart failure
42841	Acute combined systolic & diastolic heart failure
42843	Acute on chronic combined systolic & diastolic heart failure
4289	Heart failure nos

Appendix B

Table B 1: Pneumonia Measure Odds Ratios and 95% Confidence Intervals

Pneumonia Effect	NQF Endorsed Measure OR (Lower CI - Upper CI)	Updated Measure OR (Lower CI - Upper CI)	diff
Demographic			
Age-65 (years above 65, continuous)	1.00 (1.00-1.00)	1.00 (1.00-1.00)	0.00
Male	1.07 (1.06-1.08)	1.07 (1.05-1.08)	0.00
Comorbidity			
History of CABG	0.88 (0.86-0.90)	0.89 (0.87-0.91)	-0.01
History of infection (CC 1, 3-6)	1.04 (1.03-1.05)	1.05 (1.04-1.06)	-0.01
Septicemia/shock (CC 2)	1.07 (1.05-1.09)	1.06 (1.04-1.08)	0.01
Metastatic cancer or acute leukemia (CC 7)	1.21 (1.18-1.24)	1.21 (1.18-1.24)	0.00
Lung or other server cancers (CC 8)	1.20 (1.18-1.22)	1.20 (1.17-1.23)	0.01
Other major cancer (CC 9-10)	1.02 (1.01-1.01)	1.01 (0.99-1.02)	0.01
Diabetes mellitus (DM) or DM complications (CC 15-20, 119-120)	1.08 (1.07-1.09)	1.08 (1.07-1.10)	0.00
Protein-calorie malnutrition (CC 21)	1.16 (1.15-1.18)	1.17 (1.15-1.19)	-0.01
Disorders of fluid, electrolyte, acid-base (CC 22-23)	1.16 (1.15-1.17)	1.16 (1.15-1.18)	0.00
Other gastrointestinal disorders (CC 36)	1.03 (1.02-1.05)	1.03 (1.02-1.05)	0.00
Severe hematological disorders (CC 44)	1.21 (1.18-1.23)	1.20 (1.18-1.23)	0.01
Iron deficiency or other anemias and blood disease (CC 47)	1.12 (1.11-1.14)	1.13 (1.12-1.14)	-0.01
Dementia or other specified brain disorders (CC 49-50)	1.01 (1.00-1.02)	1.02 (1.01-1.03)	-0.01
Drug/alcohol abuse/dependence/psychosis (CC 51-53)	1.08 (1.07-1.10)	1.09 (1.07-1.10)	-0.01
Major psychiatric disorders (CC 54-56)	1.04 (1.03-1.06)	1.05 (1.04-1.07)	-0.01
Other psychiatric disorders (CC 60)	1.09 (1.08-1.11)	1.10 (1.08-1.12)	-0.01
Hemiplegia, paraplegia, paralysis, functional disability (CC 67-69, 100-102, 177, 178)	1.08 (1.06-1.10)	1.08 (1.06-1.10)	0.00
Cardio-respiratory failure or shock (CC 79)	1.15 (1.13-1.16)	1.17 (1.15-1.18)	-0.02
Congestive heart failure (CC 80)	1.19 (1.17-1.20)	1.19 (1.17-1.20)	0.00
Acute coronary syndrome (CC 81-82)	1.10 (1.08-1.12)	1.09 (1.07-1.11)	0.01
Coronary atherosclerosis or angina (CC 83-84)	1.06 (1.05-1.07)	1.05 (1.04-1.06)	0.01
Valvular or rheumatic heart disease (CC 86)	1.07 (1.06-1.08)	1.06 (1.05-1.08)	0.01
Specified Arrhythmias (CC 92-93)	1.10 (1.09-1.11)	1.09 (1.08-1.10)	0.01
Stroke (CC 95-96)	1.06 (1.05-1.07)	1.06 (1.04-1.07)	0.00
Vascular or circulatory disease (CC 104-106)	1.06 (1.05-1.07)	1.06 (1.05-1.07)	-0.01
Chronic obstructive pulmonary disease (CC 108)	1.18 (1.16-1.19)	1.19 (1.18-1.21)	-0.01
Fibrosis of lung or other chronic lung disorders (CC 109)	1.09 (1.07-1.10)	1.09 (1.07-1.10)	0.00
Asthma (CC 110)	0.98 (0.97-1.00)	0.98 (0.97-1.00)	0.00
Pneumonia (CC 111-113)	1.06 (1.05-1.07)	1.07 (1.05-1.08)	-0.01
Pleural effusion/pneumothorax (CC 114)	1.12 (1.10-1.13)	1.12 (1.10-1.13)	0.00
Other lung disorder (CC 115)	1.03 (1.02-1.04)	1.03 (1.02-1.04)	0.00
End stage renal disease or dialysis (CC 129-130)	1.20 (1.17-1.23)	1.21 (1.17-1.24)	-0.01

Pneumonia Effect	NQF Endorsed Measure OR (Lower CI - Upper CI)	Updated Measure OR (Lower CI - Upper CI)	diff
Renal failure (CC 131)	1.16 (1.15-1.17)	1.17 (1.16-1.19)	-0.01
Urinary tract Infection (CC 135)	1.06 (1.04-1.07)	1.06 (1.04-1.07)	0.00
Other urinary tract disorders (CC 136)	1.03 (1.02-1.04)	1.04 (1.02-1.05)	-0.01
Decubitus ulcer or chronic skin ulcer (CC 148-149)	1.11 (1.09-1.12)	1.09 (1.08-1.11)	0.01
Vertebral fractures (CC 157)	1.10 (1.08-1.12)	1.09 (1.07-1.11)	0.01
Other injuries (CC 162)	1.05 (1.04-1.07)	1.05 (1.04-1.06)	0.00

Table B 2: COPD Measure Odds Ratios and 95% Confidence Intervals

COPD Effect	Originally Submitted Measure OR (Lower CI - Upper CI)	Updated Measure OR (Lower CI - Upper CI)	diff
Demographics			
Age-65 (continuous)	1.00 (1.00 - 1.00)	1.00 (1.00 - 1.00)	0.00
Cardiovascular/Respiratory			
Sleep Apnea (ICD-9 codes: 327.20, 327.21, 327.23, 327.27, 327.29, 780.51, 780.53, 780.57)	1.01 (0.98 - 1.03)	1.00 (0.98 - 1.03)	0.01
History of Mechanical Ventilation (ICD-9 codes: 93.90, 96.70, 96.71, 96.72)	1.14 (1.10 - 1.17)	1.13 (1.09 - 1.16)	0.01
Respirator Dependence/Respiratory Failure (CC 77-78)	1.10 (1.03 - 1.17)	1.11 (1.04 - 1.18)	-0.01
Cardio-Respiratory Failure and Shock (CC 79)	1.22 (1.19 - 1.24)	1.20 (1.18 - 1.23)	0.02
Congestive Heart Failure (CC 80)	1.23 (1.21 - 1.26)	1.23 (1.21 - 1.25)	0.00
Chronic Atherosclerosis (CC 83-84)	1.09 (1.07 - 1.11)	1.10 (1.08 - 1.12)	-0.01
Arrhythmias (CC 92-93)	1.14 (1.12 - 1.17)	1.15 (1.13 - 1.17)	-0.01
Other and Unspecified Heart Disease (CC 94)	1.07 (1.05 - 1.10)	1.07 (1.05 - 1.09)	0.00
Vascular or Circulatory Disease (CC 104-106)	1.09 (1.07 - 1.11)	1.09 (1.07 - 1.11)	0.00
Fibrosis of Lung and Other Chronic Lung Disorder (CC 109)	1.09 (1.07 - 1.12)	1.09 (1.07 - 1.12)	0.00
Pneumonia (CC 111-113)	1.10 (1.09 - 1.12)	1.10 (1.08 - 1.12)	0.00
Comorbidities			
History of Infection (CC 1, 3-6)	1.07 (1.05 - 1.09)	1.07 (1.05 - 1.09)	0.00
Metastatic Cancer and Acute Leukemia (CC 7)	1.19 (1.13 - 1.25)	1.20 (1.14 - 1.27)	-0.01
Lung, Upper Digestive Tract, and Other Severe Cancers (CC 8)	1.17 (1.13 - 1.21)	1.18 (1.14 - 1.22)	-0.01
Lymphatic, Head and Neck, Brain, and Other Major Cancers; Breast, Prostate, Colorectal and Other Cancers and Tumors; Other Respiratory and Heart Neoplasms (CC 9-11)	1.03 (1.01 - 1.06)	1.04 (1.02 - 1.07)	-0.01
Other Digestive and Urinary Neoplasms(CC 12)	0.98 (0.95 - 1.01)	0.98 (0.95 - 1.01)	0.00
Diabetes Mellitus (DM) or DM Complications (CC 15-20, 119-120)	1.07 (1.05 - 1.09)	1.07 (1.05 - 1.09)	0.00
Protein-calorie Malnutrition (CC 21)	1.16 (1.13 - 1.20)	1.15 (1.12 - 1.18)	0.01
Disorders of Fluid/Electrolyte/Acid-Base (CC 22-23)	1.16 (1.14 - 1.18)	1.15 (1.13 - 1.18)	0.01
Other Endocrine/Metabolic/Nutritional Disorders (CC 24)	0.92 (0.90 - 0.94)	0.92 (0.91 - 0.94)	0.00
Pancreatic Disease (CC 32)	1.13 (1.09 - 1.17)	1.12 (1.08 - 1.16)	0.01
Peptic Ulcer, Hemorrhage, Other Specified Gastrointestinal Disorders (CC 34)	1.08 (1.05 - 1.11)	1.08 (1.06 - 1.11)	0.00
Other Gastrointestinal Disorders (CC 36)	1.06 (1.05 - 1.08)	1.07 (1.05 - 1.09)	-0.01
Severe Hematological Disorders (CC44)	1.15 (1.09 - 1.21)	1.14 (1.09 - 1.21)	0.01
Iron Deficiency and Other/Unspecified Anemias and Blood Disease (CC 47)	1.13 (1.11 - 1.15)	1.13 (1.11 - 1.15)	0.00
Dementia and Senility (CC 49-50)	0.99 (0.97 - 1.02)	0.99 (0.97 - 1.01)	0.00
Drug/Alcohol Induced Dependence/Psychosis (CC 51-52)	1.14 (1.10 - 1.19)	1.14 (1.09 - 1.18)	0.00
Major Psychiatric Disorders (CC 54-56)	1.06 (1.04 - 1.09)	1.06 (1.04 - 1.09)	0.00
Depression (CC 58)	1.05 (1.03 - 1.07)	1.05 (1.02 - 1.07)	0.00
Anxiety Disorders (CC 59)	1.14 (1.09 - 1.19)	1.13 (1.09 - 1.18)	0.01
Other Psychiatric Disorders (CC 60)	1.13 (1.11 - 1.16)	1.13 (1.11 - 1.15)	0.00
Quadriplegia, Paraplegia, Functional Disability (CC 67-69, 100-102, 177-178)	1.06 (1.02 - 1.09)	1.06 (1.02 - 1.10)	0.00
Polyneuropathy (CC 71)	1.11 (1.07 - 1.14)	1.10 (1.07 - 1.14)	0.01
Acute Coronary Syndrome (CC 81-82)	1.09 (1.06-1.12)	1.10 (1.07 - 1.13)	-0.01

COPD Effect	Originally Submitted Measure OR (Lower CI - Upper CI)	Updated Measure OR (Lower CI - Upper CI)	diff
Hypertensive Heart and Renal Disease or Encephalopathy (CC 89)	1.12 (1.09 - 1.16)	1.12 (1.09 - 1.15)	0.00
Stroke (CC 95-96)	1.03 (1.00 - 1.07)	1.03 (1.00 - 1.07)	0.00
Renal Failure (CC 131)	1.10 (1.07 - 1.13)	1.10 (1.07 - 1.13)	0.00
Decubitus Ulcer or Chronic Skin Ulcer (CC 148-149)	1.05 (1.02 - 1.09)	1.06 (1.03 - 1.09)	-0.01
Cellulitis, Local Skin Infection (CC 152)	1.06 (1.04 - 1.09)	1.06 (1.03 - 1.09)	0.00
Vertebral Fractures (CC 157)	1.17 (1.13 - 1.21)	1.17 (1.13 - 1.21)	0.00

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September 21, 2012

Kathryn Streeter
Project Manager, Performance Measures
National Quality Forum
1030 15th Street, NW, Suite 800
Washington, DC 20005

Dear Ms. Streeter,

This letter responds to an item flagged by National Quality Forum's (NQF's) Consensus Standards Approval Committee (CSAC) regarding the Centers for Medicare & Medicaid Services' (CMS's) mortality measure for chronic obstructive pulmonary disease (COPD) patients (NQF# 1893). Specifically, the committee asked the Pulmonary and Critical Care Steering Committee to further consider whether patient preferences for end-of-life care in lieu of life-sustaining care are adequately accounted for in the measure. As the measure developer, we are responding to that concern by reviewing the rationale for the measure's approach and providing additional analysis to inform the Steering Committee's discussion.

Approach to Hospice Patients

The COPD mortality measure is designed to capture patients who, on admission, have the goal of survival. Toward that end, the CMS/Yale-CORE COPD mortality measure excludes patients enrolled in Medicare hospice on admission. The measure does not exclude patients (other than those who had been enrolled in hospice prior to admission) who are discharged to hospice or who have a palliative care consultation (as identified by a v66.7 claims code encounter for palliative care) during their hospital stay. We have limited the exclusion to those enrolled at admission because the decision to transition to hospice care during the course of an admission may be due in part to the consequences of poor quality care. In addition, we have not used the v66.7 code because it is a general code for palliative care services and does not necessarily indicate that a patient has transitioned to comfort measures only. This approach is also used in the three related CMS publicly-reported and NQF-endorsed mortality measures for acute myocardial infarction, heart failure, and pneumonia.

The CSAC is concerned that this approach may put providers of high-quality end-of-life care at a disadvantage. The Committee suggested that this issue may be of greater concern for COPD than for other patient cohorts given the clinical course of COPD. NQF has asked CMS/Yale-CORE to provide additional information to further inform the discussion of how best to identify and exclude from the measure patients who do not have survival as their goal.

In response, we have sought to better describe the implications of the measure's approach. Specifically, we have assessed:

- The proportion of patients identified as "hospice" patients by each of 3 potential indicators of hospice use in claims data -- enrollment in Medicare hospice on admission, discharge to hospice, and the V66.7 code;

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- The overlap in the patient populations identified by these methods;
- Crude mortality rates among patients meeting each criteria;
- Variation across hospitals in the percent of patients discharged to hospice;
- Variation in the percent of patients with a v66.7 code; and
- The distribution of risk-standardized mortality rates (RSMRs) across hospitals with and without palliative care programs.

Results

- Among COPD patients in the measure cohort in 2008, 2% were enrolled in Medicare hospice on admission, 3% were discharged to hospice, and 0.5% had a v66.7 code (Table 1).
- As expected, patients with any of the three indicators of palliative care had higher mortality rates (Table 1).
- There was limited overlap among patients identified with each approach (Figure 1); for example, only 18% of patients discharged to hospice were enrolled in Medicare hospice prior to or on the first day of admission.
- The rate of discharge to hospice and v66.7 code use varied across hospitals (Table 2). The median percent of patients discharged to hospice (among hospitals with >25 cases) was 1.8 (range 0-14.8). The median percent of patients with a v66.7 code was 0 (range 0-15.2).
- Hospitals with and without palliative care programs as indicated in the FY 2008 data from the American Hospital Association perform similarly on the measure (Table 2 and Figure 2).

Discussion and Recommednation

The assumption of the measure is that for the vast majority of patients the goal of the hospitalization is survival. Nevertheless, we attempt to identify and remove from the measure patients who are admitted to the hospital for comfort measures only. Identifying these patients is complicated even with the best possible data. Patient preferences are not always known at admission, may take time to evolve, and may be influenced by the patient's clinical trajectory. Once a patient is admitted and receiving care, it is possible that a decision to choose comfort measures only will be driven in part by the patient's having received less than optimal care. Hence, in constructing the measure exclusion for hospice patients, we limited the measure to those patients who choose comfort care early in or prior to their hospital stay. These considerations are not unique to COPD, and have informed the approach we have developed in previously NQF-endorsed mortality measures for pneumonia and heart failure.

Expanding the exclusion using other available indicators is problematic. Using discharge to hospice or the v66.7 code to exclude patients' could improve the measure score of hospitals that have higher rates of hospice use simply because they provide poor quality care. Moreover, these services are provided quite variably across hospital, possibly because of differences in local practice patterns and/or differences in the availability of hospice services. As a result, the effect on risk-standardized rates may vary independent of quality. Finally, using these indicators would potentially create an incentive to provide palliative care services to exclude patients from measurement; while we don't expect providers to consider quality metric criteria when making clinical decisions, we try not to create incentives for them to do so.

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We do not have any evidence that 30-day mortality rates for COPD or other common conditions are biased by their failure to exclude all hospice patients. Our analysis of palliative care and non-palliative care hospitals is reassuring, as both groups perform similarly on the measure. Given these considerations and findings, we recommend continuing with the current approach to the hospice exclusion used in the NQF-endorsed mortality measures and the proposed COPD measure (excluding patients enrolled in Medicare hospice prior to or on the first day of admission).

Sincerely,

Elizabeth Drye, MD, SM
Director, Quality Measurement

cc: CMS

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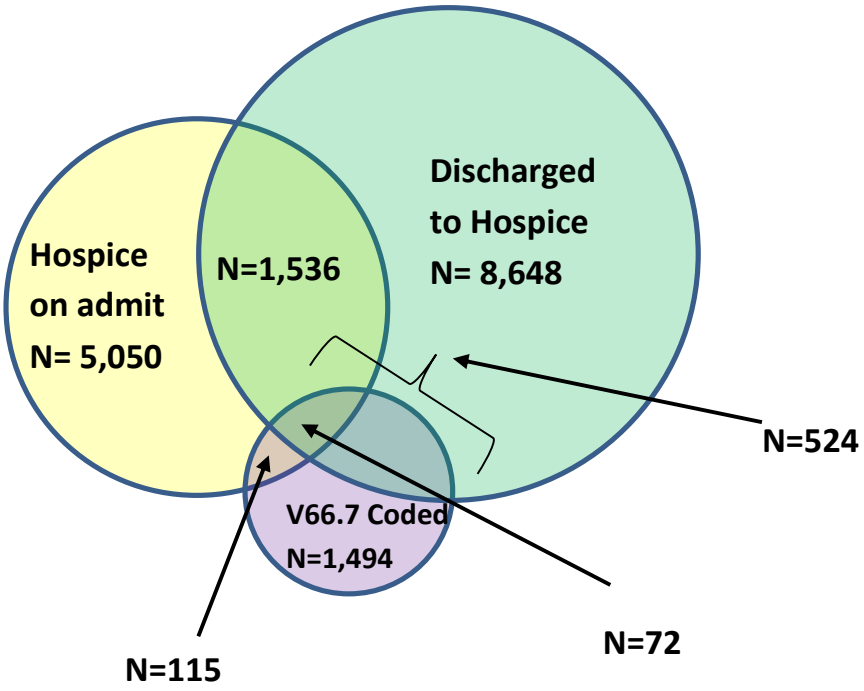
Table 1. Occurrence of Three Indicators Among COPD Patients

	All Patients (304,731)	Hospice on Admission (5,050)	Hospice on Discharge (8,648)	V66.7 (1,494)
% of cohort	100	2	3	0.5
% In-hospital deaths	4	7	2	51
% 30-day deaths	9	20	56	76
% of all 30-day deaths	-	4	18	4

Figure 1. Overlap Across Patients of Hospice Use Indicators



Overlaps	N
Hospice on Admit AND Discharge to Hospice	1,536
Hospice on Admit AND V66.7 Coded	115
V66.7 Coded AND Discharge to Hospice	524
All Three	72

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Table 2. RSMRs for Palliative Care and non-Palliative Care Hospitals

Description	Palliative Care Hospital			
	No		Yes	
	Volume	RSMR	Volume	RSMR
N	2540		1266	
100% Max	368	0.1371	773	0.1279
99%	255	0.1093	379	0.1165
95%	162	0.0999	262	0.1041
90%	129	0.0961	211	0.0998
75% Q3	74	0.0898	139	0.0924
50% Median	32	0.0851	81	0.0859
25% Q1	13	0.0816	38	0.0803
10%	6	0.0777	17	0.0752
5%	3	0.0750	8	0.0719
1%	1	0.0684	2	0.0649
0% Min	1	0.0540	1	0.0544

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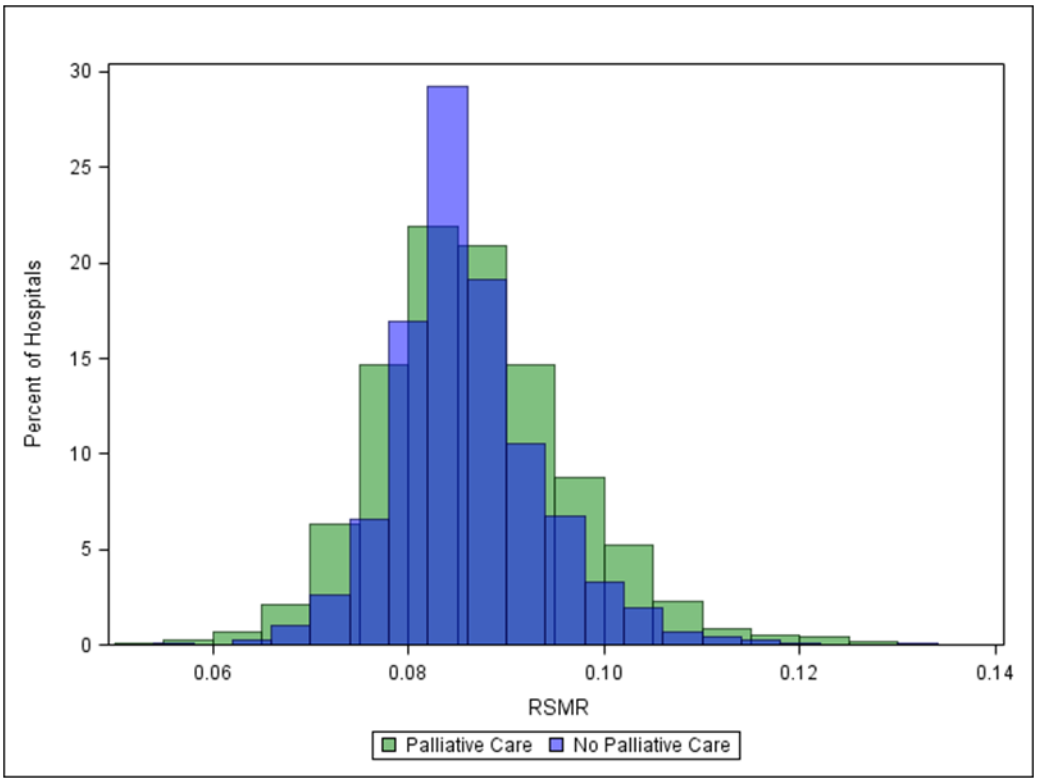
Figure 2. Overlap of RSMRs for Palliative Care and non-Palliative Care Hospitals



TO: Reva Winkler, MD, MPH

FROM: Dale Bratzler, DO

RE: Measure PN-3a

First, I want to point out that we have supported evaluation of the evidence and usefulness of pneumonia performance measures for many years – including the blood culture measures. They have been modified substantially since first implemented in 1999. For example, based on some of our observations from the national pneumonia performance measures, we had abandoned the recommendation to complete blood cultures in all hospitalized pneumonia patients in 2004. In a 2006 Letter to the Editor, I noted the following[i]:

Since inception of the National Pneumonia Project, the performance measures to promote improved quality of care for pneumonia have undergone numerous revisions. All measures are reviewed quarterly by a panel of clinical experts in the management of pneumonia, along with staff of the Joint Commission on Accreditation of Healthcare Organizations and the Centers for Medicare & Medicaid Services (CMS). The measures are subject to review by the National Quality Forum. The panel has discussed the possible unintended consequences of using performance measures designed for quality improvement for accountability purposes (eg, public report cards and pay-for-performance) and the potential impact of the pneumonia measures on the triage of patients in the emergency department (ED). Those discussions are helping to shape future policy around implementation of the Project. Recognizing the importance of input from emergency physicians, the panel has asked CMS to invite the American College of Emergency Physicians to appoint a representative to participate in project leadership.

Using data from the National Pneumonia Project, Metersky et al demonstrated that the yield of blood cultures was increased in patients with certain predictors of bacteremia and that the yield of blood cultures was reduced by half in those patients who had received prior antibiotics. That study also raised concerns about the impact of false-positive blood cultures. On the basis of this and other studies, along with review of published guidelines, the panel recommended in late 2004 that the performance measures for blood cultures be modified as follows: 1) the proportion of patients admitted to the ICU within 24 hours of hospital arrival because of pneumonia who have a blood culture obtained within 24 hours of arrival (effective July 2005); and 2) the proportion of patients who have a blood culture drawn in the ED who have the culture drawn prior to antibiotic administration (effective January 2006). A case is only eligible for the first measure if the admission to the ICU is because of pneumonia (ie, not for an incidental condition)…… …These revisions are consistent with the updated British Thoracic Society guidelines which state, "blood cultures are recommended for all patients with severe CAP (community-acquired pneumonia) and most other patients admitted with CAP, preferably before antibiotic therapy is commenced," and consistent with the suggestions of Moran and Abrahamian to target patients with more severe illness.

As revised, the blood culture measures are consistent with the current best available evidence and guideline recommendations. The revised measures limit performance expectations to those patients most likely to have a true-positive blood culture, and to those, which in the clinical opinion of the ED physician, are most likely to benefit from a blood culture.

I would also note that recommendations for blood cultures found in current guidelines for management of community-acquired pneumonia (CAP) are based in part on the very large observational study[ii] in which we evaluated the impact of blood cultures in patients with CAP. To date, this is one of the largest cohort studies of blood cultures in CAP patients and many other observational studies that have been published are limited in power by very small sample sizes. In our study of more than 25,000 CAP patients who had blood cultures performed (more than 1800 positive cultures) we found that some patient characteristics predicted higher rates of bacteremia with identified pathogens (not contaminants):

Independent Predictors of Bacteremia in Community-Acquired Pneumonia Patients[ii]		
Characteristic	**Derivation Cohort**	**Validation Cohort**
	OR (95% CI)	**OR (95% CI)**
Prior Antibiotics	0.5 (0.5 – 0.6)	0.5 (0.5 – 0.6)
Comorbidities		
Liver disease	2.3 (1.6 – 3.4)	1.4 (1.0 – 2.2)
Vital Signs		
Systolic blood pressure <90 mm Hg	1.7 (1.3 – 2.3)	1.8 (1.4 – 2.3)
Temperature <35 C ° or ≥40 C°	1.9 (1.4 – 2.6)	1.5 (1.1 – 2.1)
Pulse ≥125/min	1.9 (1.6 – 2.3)	1.7 (1.4 – 2.0)
Laboratory and radiographic data		
Blood urea nitrogen ≥ 30 mg/dl (11 mmol/liter)	2.0 (1.8 – 2.3)	2.2 (1.9 – 2.5)
Sodium <130 mmol/liter	1.6 (1.3 – 2.1)	1.8 (1.4 – 2.2)
WBC<5,000/mm^3 or >20,000/mm^3	1.7 (1.4 – 2.0)	1.9 (1.6 – 2.2)

In this study, we also found that patients who had more than two predictors of bacteremia (liver disease, abnormal vital signs, or abnormal laboratory) had a rate of positive blood culture that ranged from 14-16%, irrespective of prior antibiotic treatment.

In our discussions with our technical expert panel, which includes a number of authors of currently published CAP guidelines, we have noted the lack of randomized trials evaluating the impact of blood cultures in CAP patients. We do not anticipate large scale trials in the future and are thus relatively limited to those observational studies that are published.

Second, I think it is important again to note the very limited denominator population for which the blood culture measure under discussion applies: *patients admitted to the ICU within 24*

hours of hospital arrival <u>because of pneumonia</u>. Patients who have CAP who are admitted to an ICU bed for other reasons not related to pneumonia are not included in the denominator for this measure. The most common pneumonia-related reasons for admission to the ICU are sepsis or respiratory failure.

NQF Request: To provide the Committee with as complete information as possible, could you provide a complete summary of the evidence, including evidence for alternative outcomes and antibiotic stewardship? One of your technical panel members referred to a specific study – are there others? If the research is limited, you may provide the reasons that you are holding providers accountable for the process of care even though the evidence is limited. The Committee is allowed to make an exception to the empirical evidence if there is an exceptional and compelling rationale.

1. **Do blood cultures provide any benefit in patients with a diagnosis of pneumonia?** There is limited evidence that blood cultures do help ICU patients, and if positive, may provide information that is important for patient management. While no study has shown that blood cultures decrease mortality or alter therapy for the subset of noncritical patients without underlying morbidities, it is reasonable to target patients with more severe illness for 2 reasons: the incidence of bacteremia is higher in ICU-admitted CAP patients,[ii, iii] and they have more to lose if empiric therapy is inappropriate. As noted in the IDSA/ATS guidelines, the only randomized controlled trial of diagnostic strategy in CAP (that included blood cultures) demonstrated no statistically significant differences in mortality rate or length of stay between patients receiving pathogen-directed therapy and patients receiving empirical therapy. However, pathogen-directed therapy was associated with lower mortality among the small number of patients admitted to the ICU.[iv] The value of blood cultures (yield of pathogens) and the likelihood of blood cultures changing antibiotic therapy increase with the severity of CAP.[v]
2. **Are there unintended consequences of not doing blood cultures even when the patient has already had antibiotics?** In guidelines for treatment of community-acquired pneumonia, blood cultures are optional for all hospitalized patients with CAP but should be performed selectively in patients with risk factors that predict a higher yield from the culture. The yield for positive blood culture results is halved by prior antibiotic therapy based on a very large observational study evaluating the results of blood cultures in pneumonia patients.[ii] Ideally, samples for blood culture should be obtained before antibiotic administration, however as noted before, when multiple risk factors for bacteremia are present, blood culture results after initiation of antibiotic therapy are still positive in up to 15% of cases. Unintended consequences of not performing blood cultures in ICU-admitted CAP patients include inability to provide pathogen-directed therapy when cultures are positive, and inability to restrict antibiotic spectrum when appropriate (antibiotic stewardship).
3. **Are there populations of patients with pneumonia for which cultures are warranted?** In 2004, we identified cohorts of CAP patients who were more likely to have a positive blood culture. The strongest indication for blood cultures was in patients with severe CAP. Patients with severe CAP are more likely to be infected with pathogens other than *S.*

pneumoniae, including *S. aureus, P. aeruginosa,* and other gram-negative bacilli.[vi] Many of the factors predictive of positive blood culture results overlap with risk factors for severe CAP as described in Metersky et al[ii] Therefore, blood cultures were recommended for all patients with severe CAP in the 2007 update of the IDSA/ATS guidelines[vi] for treatment of CAP because of the higher yield, the greater possibility of the presence of pathogens not covered by the usual empirical antibiotic therapy, and the increased potential to affect antibiotic management.

4. **What about blood cultures to promote antibiotic stewardship?** Desire for pathogen-directed therapy is considered a standard for managing important infectious diseases. Justification is based in large part on avoiding antibiotic abuse, which is an inevitable consequence of the empiric choices based on the IDSA/ATS guidelines for management of community-acquired pneumonia.[vii] Two of the agents often implicated in cases of *C. difficile* disease are ceftriaxone and fluoroquinolones – both often used for empiric management of pneumonia based on published guidelines. As one of our technical experts on CAP treatment noted, he is now spending a large part of his time doing antimicrobial stewardship and can provide pathogen-directed therapy with much greater confidence with the information obtained from blood cultures. For many patients, the positive blood culture was the only test that provided a pathogen with sensitivity that allowed for streamlining of antimicrobial therapy. In several cases that presented with presumed CAP, his team has diagnosed Staphylococcus bacteremia/endocarditis in cases that would have been missed (or diagnosis much delayed) without blood cultures.

   In a recent single-institution study of an antibiotic stewardship intervention on antibiotic management of CAP, Avdic et al[viii] described a reduction in antibiotic use that was based on pathogen-directed treatment.

5. **What about use of rapid PCR-based tests to diagnosis the etiology of pneumonia?** The present tests for rapid diagnosis of pneumonia etiology are based on an early assessment of diagnostic specimens (often blood cultures) which have DNA from offending pathogens present. Often these tests are done on culture specimens (such as blood cultures) to detect early growth of organisms. With the exception of MRSA, those rapid PCR-based tests are currently unable to provide susceptibility data. In a recent review, Bartlett summarized current limitations of available molecular diagnostics including: "(1) cost, (2) lack of adequate specimens from the respiratory tract in many patients, (3) lack of standards to validate results, (4) limited data on quantitation thresholds to define significance, (5) interpretation when there are multiple potential pathogens, (6) lack of antibiotic sensitivity data on pathogens, and (7) lack of realistic application for facilities that outsource laboratory services or have limited resources, night coverage, and so forth." [vii]

   In the future when we do have molecular tests to provide identification and susceptibility data directly from blood samples without any incubation period, then the argument of substituting a molecular test for a blood culture will have merit. But for now it makes a big difference for pathogen-directed therapy if susceptibility data is available to guide antimicrobial choice. Currently available urinary antigen tests are useful for guiding empiric antibiotic therapy but provide no information on pathogen susceptibility to guide pathogen-directed antibiotic treatment.

In summary, we long ago dropped performance measures that promoted blood cultures in all patients who presented to the hospital with community-acquired pneumonia. However despite few randomized trials of the efficacy of blood cultures, we still believe based on a number of observational trials and the need to promote pathogen-directed therapy, that blood cultures remain a part of the standard of care when a patient is sick enough, because of pneumonia, to require admission to the intensive care unit.

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[i] Bratzler DW. Blood cultures in pneumonia patients. [Letter] *Ann Emerg Med*. 2006; 47:580. PMID: 16713791

[ii] Metersky M, Ma A, Bratzler DW, Houck PM. Predicting bacteremia in patients with community-acquired pneumonia. *Am J Resp Crit Care Med*. 2004; 169:342-347. PMID: 14630621

[iii] Mandell LA, Marrie TJ, Grossman RF, et al. Canadian guidelines for the initial management of community-acquired pneumonia: an evidence-based update by the Canadian Infectious Diseases Society and the Canadian Thoracic Society: the Canadian Community-Acquired Pneumonia Working Group. *Clin Infect Dis*. 2000; 31:383–421.

[iv] van der Eerden MM, Vlaspolder F, de Graaff CS, et al. Comparison between pathogen-directed antibiotic treatment and empirical broad spectrum antibiotic treatment in patients with community acquired pneumonia: a prospective randomised study. *Thorax* 2005; 60:672–8.

[v] Waterer GW, Wunderink RG. The influence of the severity of community-acquired pneumonia on the usefulness of blood cultures. *Respir Med.* 2001; 95:78-82.

[vi] Mandell LA, Wunderink RG, Anzueto A, et al. Infectious Diseases Society of America/American Thoracic Society consensus guidelines on the management of community-acquired pneumonia in adults. *Clin Infect Dis*. 2007 ;44 Suppl 2:S27-72.

[vii] Bartlett JG. Diagnostic tests for agents of community-acquired pneumonia. *Clin Infect Dis*. 2011; 52 Suppl 4:S296-304.

[viii] Avdic E, Cushinotto LA, Hughes AH, et al. Impact of an antimicrobial stewardship intervention on shortening the duration of therapy for community-acquired pneumonia. *Clin Infect Dis*. 2012; 54:1581-7.

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September 7, 2012

Reva Winkler, MD, MPH
Senior Director, Performance Measures
National Quality Forum
1030 15th Street, NW, Suite 800
Washington, DC 20005

Dear Ms. Winkler,

On behalf of the Infectious Diseases Society of America, I would like to express our appreciation for the opportunity to share our perspective on the quality measure (#0356) PN3a – "Blood Cultures Performed Within 24 Hours Prior to or 24 Hours After Hospital Arrival for Patients Who Were Transferred or Admitted to the ICU Within 24 Hours of Hospital Arrival."

The National Quality Forum has asked two specific questions, related to this quality measure and we provide our respective responses below.

1. *What are IDSA's thoughts on the evidence for this measure?*

Response:

IDSA recognizes that this measure applies to a limited population of patients - those who have a diagnosis of pneumonia and are transferred to the ICU because of the pneumonia or complication of pneumonia (sepsis, respiratory failure, etc). We also recognize that this measure may be construed as promoting the use of blood cultures in patients who have already had their initial antibiotic dose, where the utility of a blood culture may be diminished or unwarranted. Furthermore, we understand that there may be an expectation that rapid molecular diagnostic tests may become the more preferred replacement to blood culture.

Performing blood cultures (preferably before antimicrobial therapy) for patients with severe CAP admitted to the ICU is the correct patient management. Our IDSA/ATS Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults, 2007, includes "Pretreatment blood samples for culture should be obtained from hospitalized patients with indication listed in table 5" (the number 1 indication is ICU admission) and is graded as "Moderate

recommendation, Level I" evidence.[1] We believe this level of evidence is sufficient enough to endorse this process of care and therefore this measure.

From the 2007 IDSA/ATS CAP guidelines, "The strongest indication for blood cultures is severe CAP. Patients with severe CAP are more likely to be infected with pathogens other than S. pneumoniae, including S. aureus, P. aeruginosa, and other gram-negative bacilli. Many of the factors predictive of positive blood culture results overlap with risk factors for severe CAP (table 4). Therefore, blood cultures are recommended for all patients with severe CAP because of the higher yield, the greater possibility of the presence of pathogens not covered by the usual empirical antibiotic therapy, and the increased potential to affect antibiotic management."

In addition, the rationale to support blood cultures for severe CAP even if prior antimicrobials have been administered is (also from our guidelines): "The yield for positive blood culture results is halved by prior antibiotic therapy. Therefore, when performed, samples for blood culture should be obtained before antibiotic administration. However, when multiple risk factors for bacteremia are present, blood culture results after initiation of antibiotic therapy are still positive in up to 15% of cases and are, therefore, still warranted in these cases, despite the lower yield."

Furthermore, our 2007 IDSA/ATS guidelines state, "The only randomized controlled trial of diagnostic strategy in CAP has demonstrated no statistically significant differences in mortality rate or LOS between patients receiving pathogen-directed therapy and patients receiving empirical therapy. <u>However, pathogen-directed therapy was associated with lower mortality among the small number of patients admitted to the ICU</u>," [underline added].

Finally, the present tests for rapid diagnosis of bacteremia are based on an early assessment of blood cultures which have early growth, and are unavailable to provide susceptibility tests, (with the exception of tests for MRSA). Once molecular tests are available to provide identification and susceptibility directly from blood without any incubation period, then whether they are preferred over blood culture can be discussed. For now, the diagnostic utility of blood cultures makes them integral to providing care.

2. *Does IDSA believe that this measure provides a solid relationship to outcomes and therefore, meets NQF's criteria for evidence?*

<u>Response:</u>

Regarding the issue of 'strong relation to outcomes', IDSA recognizes this measure to be a "process of care" measure, with much of the underlying evidence being level II (e.g. observational studies). We cannot state that this measure has a "solid" relationship with outcomes, due to the lack of strong evidence. Furthermore, we suggest that this measure may be lacking in validity if the intent is to establish a strong link to positive outcomes (for patients in the ICU due to pneumonia) with this process measure.

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[1] Mandell LA, Wunderink RG, Anzueto, A, Bartlett, JG, Campbell GD, et al. Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults. CID 2007:44.

Again, we thank you for the opportunity to provide comments on this quality measure. Please feel free to contact Andres Rodriguez, Sr. Program Officer of Practice & Payment Policy at IDSA, via email (arodriguez@idsociety.org) or phone (703-299-5146). We look forward to collaborating with the NQF in the development of quality measures in the near future.

Respectfully,

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Dr. Winkler,

Please find below a summary of points related to the measure PN3a. SCCM could not provide this detail on the website as the comment section is too limited. As the steering committee is in a review process we wish to provide the following for consideration:

After review, the SCCM cannot endorse Measure PN3a based on the following:

- The NQF notes the low overall yield of blood cultures, a limitation compounded by studies showing a 5% contamination rate in blood cultures.
- The IDSA/ATS CAP Guidelines recommend investigation for specific, decision-altering pathogens only in hospitalized pneumonia patients meeting specific criteria. ICU admission only one of these criteria and it's utility as an isolated identifier is not supported by evidence.
- Metersky et al found that high risk in pneumonia patients could be predicted by the presence of liver disease, temp < 35 or > 40 ° C, HR > 125, systolic blood pressure < 90, BUN > 30 mg/dl, Na < 130, WBC < 5000 or >20,000 but NOT ICU admission or transfer. Even so, only 11% of these high-risk patients were bacteremic.
- Metersky also found that antibiotic administration prior to blood cultures reduced the value of cultures. The proposed measure does not allow for this.
- Van der Eerden et al, comparing pathogen directed (PDT) to broad spectrum therapy, chose PCT antibiotics based on clinical suspicion. They did *not* use blood cultures and found that the two approaches were indistinguishable. It is not clear how this study supports the recommended measure.
- The data in section 1c.1 was NOT derived from ICU patients, and reveals that the measure would not affect in-hospital or 30 day mortality. The re-admission rate was different but was not corrected for co-morbidities. It is unclear that these data are derived from ICU patients.
- None of the data presented address cost. Given the low yield of blood cultures, the measure could add to expense.

In summary, we do not believe that there is sufficient support for the proposed measure. This document has been submitted on behalf of the SCCM Council.

Lori A. Harmon, RRT, MBA
Manager, Quality Implementation Programs

American College of Emergency Physicians (ACEP)

August 22, 2012: ACEP's views are congruent with SCCM's, and we stand by our original comments.

Original comments:

ACEP QPC does not support the endorsement of the PN3a blood culture measure. ACEP notes the potential threat to the validity of this measure due to the lack of any high level evidence that this process measure is directly linked to improved patient outcomes for pneumonia patients. In addition, ACEP QPC objects to this measure in that it may create an unnecessary distraction from the delivery of more important care that needs to be delivered in the ED or ICU settings.

Association for Professionals in Infection Control and Epidemiology (APIC)

August 29, 2012: The expert panel that reviewed the measure indicated that the other measure notwithstanding, they did not support because they felt the single measure should indicate that the blood culture was taken prior to initiation of treatment.

Original comments from APIC: APIC does NOT support the use of this measure. Blood cultures should be obtained before the initiation of treatment and this measure does not state that.

Developer's response to original comments from APIC: There is another measure that assesses whether blood cultures were performed in the ED prior to the initial antibiotic. That measure is NQF #0148 (for the Hospital Inpatient Quality Reporting Program, the measure number is PN-3b). This review is only for NQF ID# 0356