NATIONAL QUALITY FORUM

Memo

TO: NQF Members

FR: NQF Staff

RE: Voting Draft Report: *NQF-Endorsed Measures for Health and Well-Being*

DA: December 21, 2016

Background

Social, environmental, and behavioral factors can have significant negative impact on health outcomes and economic stability. These factors and other upstream determinants contribute to 60 percent of deaths in the United States; yet only three percent of national health expenditure is spent on prevention, while 97 percent is spent on healthcare services. Developing strategies to strengthen the measurement and analysis of health and well-being, given its multi-dimensional focus, can be best accomplished using a collaborative approach that includes public health, healthcare delivery systems, and other key sectors whose policies, practices, and procedures influence health. Using the right measures can determine how successful initiatives are in reducing mortality and excess morbidity and help focus future work to improve population health in appropriate areas.

On September 12-13, 2016, the Health and Well-Being Standing Committee evaluated 12 newly-submitted measures and 11 measures undergoing maintenance review against NQF's standard evaluation criteria. Fourteen measures were recommended for endorsement, three measures were recommended for Trial Use, one measure was recommended for inactive endorsement with reserve status. Additionally, the Committee did not recommend five measures.

Comments Received

NQF solicits comments on measures undergoing review in various ways and at various times throughout the evaluation process. First, NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). Second, NQF solicits member and public comments prior to the evaluation of the measures via an online tool located on the project webpage. Third, NQF opens a 30-day comment period to both members and the public after measures have been evaluated by the full committee and once a report of the proceedings has been drafted.

Pre-evaluation comments

The pre-evaluation comment period was open from August 10 through August 23, 2016 for all measures except *NQF #0279: Bacterial Pneumonia Admission Rate (PQI 11)*, which was assigned to the project after that period. Additionally, *NQF #3062: Hypertension Screening for Children Who Are Overweight or Obese* was available for pre-evaluation comment but was withdrawn prior to final Committee evaluation. No pre-evaluation comments were received during this pre-evaluation commenting period.

Post-evaluation comments

The Draft Report was made available for public and NQF member commenting period on October 24 through November 22, 2016. During this commenting period, NQF received 170[1] comments from 11 member organizations and 13 organizations/individuals that are not NQF members:

Consumers – 0	Professional – 0
Purchasers – 1	Health Plans – 4
Providers – 0	QMRI – 3
Supplier and Industry – 3	Public & Community Health - 10

A complete table of comments submitted post-evaluation, along with the responses to each comment and the actions taken by the Standing Committee, is posted to the project page on the NQF website, along with the measure submission forms.

Revisions to the draft report and the accompanying measure specifications are identified as red-lined changes.

Comments and their Disposition

Five major categories were identified in the post-evaluation comments, as follows:

1. Support for endorsement of Consensus Not reached (CNR) measure(s)
2. Disagreement with Committee recommendation
3. Support for Committee recommendation
4. General recommendation to Committee or support for report
5. Recommendation to developer (e.g., re: specifications)

Additionally, as discussed at the in-person meeting, NQF staff worked with the developer on the additional testing information for *NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay).* This measure is discussed as the first item under "Theme 1" because it is a measure for which consensus was not reached. The additional testing information is provided below.

Theme 1 - Support for endorsement of Consensus Not Reached measure

The 90 comments categorized under this area were submitted to provide additional information about or general support for measures where consensus was not reached; of note, several were multi-part comments (owing to NQF's character limitation), so the actual number of commenting organizations/individuals was 27. In addition to the information related to #0680, we categorized the comments for CNR measures in three groups: HIV viral load suppression

[1] Many of these comments were multi-part, owing to character limit constraints in the online system.

(#3086)[2] – see attachment; childhood immunization status (#0038); and three nutrition-related measures (#3087, #3088, #3089).

#0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Centers for Medicaid and Medicare Services) (Submission | Specifications)

During the in-person meeting, the Committee did not reach consensus on Reliability (H-1; M-6; L-5; I-2) and Validity (H-1; M-6; L-4; I-3). The developer had provided inter-rater reliability results using the nursing home database (MDS), but testing was not conducted on the reliability of the influenza measure items from the LTCH Care Data Set or the IRF-PAI. The developer had stated that it was reasonable to apply the reliability testing from the MDS to the LTCH CARE Data Set and the IRF-PAI, but also noted the populations are not identical and some differences in reliability may exist. The developer agreed to work with NQF staff following the in-person meeting to clarify the concerns about testing.

The developer provided the additional information. NQF staff reviewed and noted the following:

- For the nursing home (NH), inpatient rehabilitation facility (IRF), and long-term care hospital (LTCH) settings, the developer submitted a detailed explanation of testing methods, score-level reliability testing results, including analyses of variance and confidence interval.
    - For Reliability, the developer conducted measure score reliability testing for NH, IRF and LTCH settings. Using signal to noise analysis, the developer assessed the ratio of variance between facilities and the variance within facilities (patient or resident measure scores compared to the facility-level mean of those scores) to discern statistically significant differences in performance on the measure due to facility quality ("signal") rather than resident- or patient-level factors ("noise"). In this case, the η2 statistics measured the ratio of the variance attributable to facility-level differences to all variance associated with patient or resident level vaccination rates. The observed η2 statistics were 0.17 for IRFs, 0.37 for LTCHs, and 0.18 in the NH setting.
    - For Validity in the IRF and LTCH settings, the developer conducted construct validation at the measure score level and clearly described its hypotheses, expected results and analysis. Overall results were in the expected direction, although not statistically significant. However, when "receive vaccine" vs. "decline vaccine" were separated, the results were in the expected directions and there was statistical significance for the IRF setting for both (only for "receive vaccine" in the LTCH setting). Results for the contraindication were not statistically significant, and were in the wrong direction for IRFs.

[2] Because the commenter/developer (CDC) experienced difficulty with the on-line portal that could not be resolved by the deadline, the developer forwarded comments as Word and PDF files. This is part of the attachment below and is not in the Excel comment table

Action Taken: After reviewing additional material submitted by the developer, the Committee re-voted on the Reliability and Validity criteria and overall suitability for endorsement. Ultimately, the measure was recommended for endorsement.

#3086: Population Level HIV Viral Load Suppression (Centers for Disease Control and Prevention) (Submission | Specifications)

During the in-person meeting, the Committee did not reach consensus on Reliability (H-0; M-7; L-5; I-3) and Validity (H-0; M-9; L-3; I-3). For reliability testing, the developer cited state law and quality control for its data and did not provide any empirical testing at the score- or data element-levels, as is required by NQF. It was noted that, during the technical assistance phase of the project, NQF had recommended that the developer assess state audit data and related inputs, where available, to determine reliability and validity; literature or information directly from states was suggested. Committee members also recommended that the developer identify the "gold standard" – data audit of viral load captured in the CDC surveillance system against state records.

- In commenting on the measure, CDC further described the internal and state-based quality assurance systems related to completion and other data quality control and provided data related to these activities. CDC also provided specific literature, as originally suggested by NQF, which may be used to assess reliability and validity testing. CDC also posited that CDC and states continue to invest in strengthening state HIV surveillance and so the published data should be viewed as conservative estimates of reliability and validity.
- **For reliability**, CDC specifically presents data from an article that addresses the validity at the data element level (may be used for reliability under the NQF algorithm) of the state's data (electronic lab data then transmitted to CDC) as compared to the gold standard of the patient's medical record.[3]
    - The study of electronic lab reporting in Indiana and Wisconsin reported 98% or greater completeness rates (2010 data) in both states for the following data elements: patient identifier, patient name, patient date of birth, patient sex, test name, and test results. CDC notes that these elements speak to the utility of the lab report for generating new, or updating existing, HIV case records and state-level viral load suppression results. CDC did not report whether the paper provided additional statistical analyses (kappa, PPV, NPV, sensitivity, specificity).
- **For validity**, CDC presents data from three published articles and unpublished data to address potential validity issues of data from multiple sources (recall that, depending on the system, some states have e-lab reporting or manual entry or a mix); duplicate counting; and construct validity examining surveillance data as compared to measures derived from the medical record or a medical record abstraction project CDC supports in Georgia. The threats to validity are encompassed in the first two articles, and find:

[3] Dixon BE, Siegel JA, Oemig T, Grannis SJ (2013). Electronic Health Information Quality Challenges and Interventions to Improve Public Health Surveillance Data and Practice. Public Health Reports 128: 546-553

- CDC reports that a 2014 paper by Dombrowski et al. found no meaningful difference among King County (Washington) viral load suppression rates in samples from chart review, CDC-funded Medical Monitoring Project (MMP; chart review and interview), and the surveillance system: 59% from both chart review and adjusted MMP, and 57% from surveillance.[4]
- One source of bias in the viral load suppression state results could arise from the denominator, wherein people living with HIV may move from the state in which they are diagnosed to a new one. CDC reports that >95% of duplicates are resolved within 18 months; however, the measure timeframe is 12 months. CDC notes, however, that a recent paper by Ocampo et al. (2016) suggests that annual migration is low and that a new approach described by the paper (taking minutes) will further improve denominator bias.[5]
- CDC states that the Sabharwal paper provides evidence that the "retention in care" measure results (from New York City surveillance data) align with scores calculated on the basis of data available from medical records[6]. Specifically, CDC reports the paper finds that the sustained and continuous care measures exhibit agreement of >85%. NQF staff note that the paper speaks to the underlying data elements of the surveillance vs. medical record and, while somewhat indirect, relates to construct validity of measure scores (i.e., similar measure scores result from both, as hypothesized). (A direct relationship/empirical testing would have been #3086 as it correlates to the two "retention in care" measures.)

Committee Response: The Committee agreed the new information provided in the comment on testing addressed its concerns. These concerns specifically focused on the benefit of a state-level quality measure, especially given that the CDC can collect standardized data across states which will aid in surveillance and patient access to care. Additionally, the Committee expressed concern over possible misuse of the measure—while the measure is being endorsed at the population level, there are several examples of these types of NQF-endorsed measures now being used at facility and clinician levels.

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[4] Dombrowski JC, Buskin SE, Bennett A, Thiede H, Golden MR (2014). Use of Multiple Data Sources and Individual Case Investigation to Refine Surveillance-Based Estimates of the HIV Care Continuum. J Acquir Immune Defic Syndr. 2014 November 1; 67(3): 323–330.

[5] Ocampo JM, Smart JC, Allston A et al. (2016). Improving HIV Surveillance Data for Public Health Action in Washington, DC: A Novel Multiorganizational Data-Sharing Method. JMIR Public Health Surveill. 2 (1): e3

[6] Sabharwal CJ, Braunstein SL, Robbins RS, Shephard CW (2014). Optimizing the Use of Surveillance Data for Monitoring the Care Status of Persons Recently Diagnosed With HIV in NYC. JAIDS 65(5): 571-578

NQF Response: NQF notes that endorsement is intended to be specific to the level stated by the developer at the time of submission, but recognize that "off label" use is of concern and does not dispute the high stakes. Staff will continue to emphasize the endorsed level of analysis for this measure.

Action Taken: After review of the comments, the Committee re-voted on the Reliability and Validity criterion and overall suitability for endorsement. Ultimately, the measure was recommended for endorsement.

#0038: Childhood Immunization Status (CIS) (National Committee for Quality Assurance) (Submission | Specifications)
During the in-person meeting, the Committee did not reach consensus on the Composite Quality Construct and Rationale (H-3; M-4; L-4; I-1). The Committee stressed the importance of assessing individual components, but some Committee members expressed reservations about the all-10 composite. After the in-person meeting, the developer asked that the all-10 composite be withdrawn from consideration as part of #0038.

The developer submitted a comment requesting that language related to disparities data for this measure (and its other measures) be revised to indicate that NCQA will "consider" pursuing working with health plans or reviewing national data in order to provide disparities information in the next update. NQF staff confirmed, via notes and the meeting transcript, the accuracy of the language in the report that the developer *agreed* to pursue this information. Lastly, the developer proposed edits related to clarifying the source of statements related to its cervical cancer screening measure (#0032).

Committee Response: The measure will retain the disparities language to reflect an agreement by the developer to pursue during a future update. Based on the discussion, clarifying edits related to #0032, which address the Committee's concerns, will be incorporated into the technical report.

Action Taken: The Committee voted on the measure during the post-comment call and ultimately recommended for endorsement.

#3087: Completion of a Malnutrition Screening within 24 hours of Admission (Academy of Nutrition & Dietetics/Avalere) (Submission | Specifications)
#3088: Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening (Academy of Nutrition & Dietetics/Avalere) (Submission | Specifications)
#3089: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment (Academy of Nutrition & Dietetics/Avalere) (Submission | Specifications)
The Committee did not reach consensus on Evidence for #3087 (H-0; M-8; L-2; I-6) and #3088 (H-0; M-8; L-5; I-3) and for Validity on #3089 (M-9; L-7; I-0). Forty comments (some multi-part) were received from 23 organizations/individuals and the developer for #3087, 39 comments from 23 organizations/individuals and the developer for #3088, and 30 comments from 18 organizations/individuals and the developer for #3089. The comments were largely repetitive and supplied the same, or nearly so, list of references. Many of the references were part of the original submission and addressed findings that malnourished patients have increased lengths of

stays, increased mortality, and other adverse health outcomes but were not specific to the measure foci (screening, completion of assessment, care plan). In the sections that follow, the Committee's original decision is first presented, followed by a summary of what appeared to be the most salient information by the commenters and developers. Committee members are referred to the Comment Table for all comments.

For #3087, Committee members raised concern about the burden of screening each hospitalization (patients 18 and older) within 24 hours, regardless of patient risk or condition, as well as whether the screening to treatment link was substantiated by evidence. (Specific concerns with the 2011 American Society for Parenteral and Enteral Nutrition guidelines (Grade C) and the lack of requirement for a standardized tool, which the developer indicated was difficult at this time, as well as institutional variability (who does screening, with what tool, etc.)). The Committee did not reach consensus on Evidence for #3087. For #3088, Committee members debated whether the number of studies in the observation and randomized trials mentioned in the 2011 American Society for Parenteral and Enteral Nutrition guidelines (Grade E) were sufficient and able to discern the risk of bias; the Committee failed to reach consensus on the Evidence criterion for #3088. For #3089, the Committee did not achieve consensus on Validity, expressing concerns about the omission of exclusions, as well as variability of treatment protocols.

- In commenting on the measure, the developer notes it submitted a series of four measures that, in part, build on each other. Specifically, with respect to screening, the developer posits that #3087 triggers all subsequent care, noting the numerator for this measure becomes the denominator for #3088. The developer expresses concern that the lack of the initial universal screening (#3087) measure may lead to uneven implementation (i.e., ad hoc identification of the denominator) of the other measures.
- No additional information was provided through the comments linking screening to treatment/outcomes.
- A few commenters noted that malnutrition screening within 24 hours of admission had been a Joint Commission (TJC) standard for many years. One commenter noted that the TJC recently removed the standard, citing that it "addresses routine part[s] of operations or clinical care processes." The commenter noted, however, there are no quality measures in place to reliably evaluate such performance. A comment by TJC "welcomes" performance measures to assess the degree that screening occurs.
- As noted, most of the references overlapped with those in the submission or did not directly address the measure focus/specifications to improvement. NQF staff did examine further two 2016 articles commenters cited. Based on the publication date, these appeared to be available during the submission timeframe, but we did not identify them in a "search" of the original submission:
    - An April 2016 article from Kruizenga et al. notes that Dutch hospitals are required to screen for undernutrition on the first day of admission. One of two standardized instruments were used; study size was 564,063 patients from 2007-2014. Patients who had an undernourished screening score had a higher LOS than did patients who did not (median 6.8 compared with 4.0 d; $P < 0.001$). One out of 7 patients was scored as undernourished. For geriatrics, oncology,

gastroenterology, and internal medicine, this ratio was even greater (1 out of 3–4). Hospital stay was 1.4 d longer among undernourished patients than among those who were well nourished. The study confirms other literature that reports that patients who are malnourished have longer LOS, but in this case specifically identified the patients through the use of a standardized screening tool.[7]

- The other 2016 article (Allard) merely points to other similar articles that malnutrition at admission "is prevalent and associated with prolonged LOS." Patients first underwent "the main nutrition evaluation was subjective global assessment (SGA). Body mass index (BMI) and handgrip strength (HGS) were also performed to assess other aspects of nutrition." 1,500 pts enrolled in study, 45% found to be malnourished and LOS was found to be increased in that population. Screening of all patients per se is not addressed.[8]

- Regarding the Committee's concern about the burden of screening each hospitalization, a recommendation to endorse #3087 is argued by commenters that the burden is "low." A standardized 2-item questionnaire is cited as evidence of low burden; as noted during the in-person, the measure does not require a standard instrument.
- Several commenters cited an AHRQ statistical brief released after the Committee meeting (September 20, 2016), which characterizes hospital stays involving malnutrition, but which does not address whether the specific aspects of the measure specifications per se link to improved quality (i.e., screening, nutritional assessment, follow-up plan of care and documentation). Weiss AJ, et al. Characteristics of Hospital Stays Involving Malnutrition, 2013. HCUP Statistical Brief #r 210. September 2016. Agency for Healthcare Research and Quality, Rockville, MD. A copy of this new brief is provided.[9]
- For #3088 (completion of a nutrition assessment once identified as at-risk), commenters again largely cite literature previously included or that do not directly link the completion to outcome. The Allard (2016) article also is cited as "new" evidence. Again, the focus of the Allard article appears to be confirmatory evidence that malnutrition at admission is associated with increased LOS, not that completing a nutrition assessment reduced LOS.[8]
- Finally, for #3089 (documentation of a care plan for patients found to be malnourished based on a complete nutrition assessment), for which the Committee did not achieve consensus on validity, the commenters and developer again recommend the Committee advance the measure. No comments appear to address the Committee's concerns about the omission of exclusions. Regarding concerns about variability, one of the organizations (measure steward) (Hoggle, Academy of Nutrition & Dietetics on behalf of

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[7] Kruizenga H, Van keeken S, Weijs P, et al. Undernutrition screening survey in 564,063 patients: patients with a positive undernutrition screening score stay in hospital 1.4 d longer. Am J Clin Nutr. 2016;103(4):1026-32.

[8] Allard JP, Keller H, Jeejeebhoy KN, et al. Malnutrition at Hospital Admission-Contributors and Effect on Length of Stay: A Prospective Cohort Study From the Canadian Malnutrition Task Force. JPEN J Parenter Enteral Nutr. 2016;40(4):487-97.

[9] Weiss AJ, et al. Characteristics of Hospital Stays Involving Malnutrition, 2013. HCUP Statistical Brief #r 210. September 2016. Agency for Healthcare Research and Quality, Rockville, MD.

Informatics & Interoperability Committees) notes that its committees are working to ensure that terms from the Academy's Nutrition Care Processes (NCP) are mapped to clinical terminologies such as SNOMED-CT® and LOINC®. The comment notes, "upon malnutrition screening and appropriate assessment of at-risk patients, the nutrition intervention is developed using the NCP. Use of appropriate malnutrition language and terminologies (via the mapping of eNCPT to clinical and/or reimbursement terminologies), the intervention can be included in the electronic Care Plan. Selection of appropriate terminology possible for a problem-etiology-signs/symptoms documentation allows for structured coded data which is consistent with other areas of an EHR."

Committee Response #3087: Though we appreciate the support the nutrition measures received during the public and member commenting period, we see no salient information in the new addition provided. We remain concerned about the lack of evidence linking screening every patient to improved outcomes and also are concerned with the burden it would cause to screen every hospitalized patient, regardless of patient risk or condition, within 24 hours. We also are concerned about the lack of exclusions—including, for example, hospice patients or patients discharged against medical advice.

We understand and agree that malnourished patients have increased lengths of stays, increased mortality, and other adverse health outcomes, but the references the developer provided and those identified in the comment period are not specific to the measures' focus.

For the measure to be evaluated differently, evidence is needed that documents the impact on longer-term health because of screening, as well as the impact on utilization cost.

Developer response #3087: Exclusion criteria includes patients who have a length of stay of shorter than 24 hours. The measure focuses on malnutrition screening, which is the first step in the process of addressing malnutrition.

Committee Response #3088: The guidelines cited by the developer are based on three individual trials, and among those three trials were inconsistencies in the very limited evidence. Though the developer noted it provided several studies looking at the impact of quality improvement programs focused on nutrition and malnutrition, we note that the quantity, quality, and consistency of the evidence to address the measure construct is important. There was clear support from many commenters, but the comments were largely repetitive, and the additional information did not provide new evidence directly addressing the measure's focus to directly link the completion of a malnutrition assessment to improved outcomes.

Committee Response #3089: Though there was support for the measure from commenters, as with the other nutrition measures, we are concerned that the denominator excludes patients admitted to hospice care, who refused referrals, were discharged against medical advice, or had complications—although a few of us did feel the exclusions might be less of an issue with this measure. Some of us also feel the September 2016 AHRQ brief documenting the problem of malnutrition in hospitalized patients also address some concerns for this measure. On the other hand, we noted that a 2008 paper used by the developer to document a performance gap found that

patients who received intervention (getting feedings or vitamins) did not have improved clinical outcomes. We are also concerned about the capacity of EHRs to extract the many plan of care data components and skepticism, though we understand the developer is working to get more information in standardized formats. We emphasize that we recognize that nutritional status is an important area to be addressed by quality measurement.

Action Taken: After review of the comments for #3087 and #3088, the Committee voted and ultimately decided not to recommend these measures for endorsement. For #3089, the Committee voted and ultimately decided to recommend for endorsement.

Theme 2 – Disagreement with Committee recommendation

Six comments (some multi-part) were received from two organizations/individuals on the following four measures:

- Influenza vaccination measures #0039 (NCQA), #0041 (PCPI Foundation), and #3070 (PCPI Foundation eMeasure version of 0041) were recommended by the Committee, but the American Academy of Family Physicians opposes these measures because they have not been included in the Core Measures Set for ACO/PCMH/Primary Care; concern also is expressed about the numerator specifications. The American Academy of Pediatrics does not explicitly oppose #0041 and #3070, but expressed concern that the specifications do not align with its recommendations for influenza vaccinations for patients 6 months to 8 years.
- As with the other nutrition-related measures, several commenters disagreed with the Committee's decision not to recommend #3090 (documentation of malnutrition diagnosis). The Committee failed the measure on Evidence. No new evidence is offered that links documentation of the diagnosis to improved outcomes, but the developer asks the Committee to consider granting an Exception to the Evidence.

Committee Response: NQF appreciates your comment. The developer requested the Committee to reconsider this measure for endorsement during the post comment call on December 6th. After discussion and deliberation, the Committee recommended not to consider this measure for endorsement.

Theme 3 - Support for Committee recommendation

Ten comments from six organizations were submitted in support of the Committee's recommendations to endorse the following five measures: *#0226: Influenza Immunization in the ESRD Population; #0032: Cervical Cancer Screening (CCS); #3059: One-Time Screening for Hepatitis C Virus; #3060: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users (Trial Use)*; *#3061: Appropriate Screening Follow-Up for Patients Identified with Hepatitis C Virus (HCV) Infection*; *#0431: Influenza Vaccination Coverage Among Healthcare Personnel; #0681: Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay); #2828: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan.* Some measures received support from more than one organization/individual.

Committee Response: NQF appreciates your comment.

Theme 4 – General comments on the report/project

Four comments from four organizations were submitted in general support of the report and project.

Committee Response: Thank you for your comment.

Theme 5 – Comments directed to the developer

Nine comments from three organizations/individuals disagreed with the developer's specifications or recommended that the developer consider revisions in future iterations. The seven measures for which developer response was specifically sought are*: #0039: Flu Vaccinations for Adults Ages 18 and Older (National Committee for Quality Assurance); #0041: Preventative Care and Screening Influenza Immunization (PCPI); #0279: Bacterial Pneumonia Admission Rate (Agency for Healthcare Research and Quality); #0431: Influenza Vaccination Coverage Among Healthcare (Centers for Disease Control and Prevention); #2828: Preventative Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Quality Insights Pennsylvania); #3059: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk (PCPI); #3070: Preventative Care Screening: Influenza Immunization (PCPI).*

Developer Response for #0039: This measure is specified and tested at the health plan and integrated system level of accountability. Flu shots are provided in a variety of acceptable settings (physician office, pharmacy, retail pop-up clinics, public health, and work-sites) which necessitates a survey-based approach to measurement. The intent of this measure is to assess whether members are getting vaccinated seasonally regardless of the site of vaccination. We expect health plans to ensure all adults 18 years and older receive a flu vaccine. We recognize some patients should not receive the flu vaccine due to medical reasons; however, we anticipate this to be evenly distributed across plans. We also do not expect vaccine shortages to have a significant impact on health plan rates for flu vaccination.

Developer Response for #0041: This measure is based on the CDC's Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2016–17 Influenza Season. Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications.

The expert work group constructed this measure based primarily on the CDC's recommendation in addition to data on peak month flu activity. While seasonal influenza may be active year-round, the CDC states that peak flu activity is between October and March[10]. Additionally, the flu season covered is aligned with other NQF endorsed flu vaccine measure and in alignment with NQF's National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations. Furthermore, the PCPI aims to develop broad measures in response to current national interest in the parsimonious use of measures to

[10] http://www.cdc.gov/flu/about/season/flu-season.htm

reduce the resource burden on health care providers without compromising the quality of patient care.

Finally, regarding the AAP's concern about the availability of the influenza vaccine, the expert work group raised this issue and opted to include a measure exception when the vaccine is not available so as not to inappropriately penalize a clinician for an issue not within his/her control.

- This measure is based on the CDC's Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2016–17 Influenza Season. Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications.
- Influenza may lead to serious complications and vaccination is the most effective protection against influenza virus infection. However, data indicate that less than half of all eligible individuals receive an influenza vaccination.
- This measure promotes annual influenza vaccination for all persons aged ≥ 6 months. The measure assesses whether a patient received the flu vaccine or reports previous receipt of the flu vaccine at any other location or via another provider. The measure does not account for patient counseling to receive the vaccine elsewhere because this does not ensure that the patient receives the vaccination thereby reducing the risk of adverse flu-related outcomes as is the intent of this measure.

Developer Response for #0279: AHRQ would like to clarify that this measure is intended to measure area-level access to care and community wellness, rather than the quality of physicians, hospitals or other provider groups. As such, higher rates in communities may reflect poorer health in the community, higher chronic disease burden and lower access to care. We observe disparities in populations with lower socioeconomic status, which simply highlights the need in such communities to improve the health of the population and the resources available to promote health in a community. When used as intended and tested, PQI 11 highlights communities in need rather than penalizing the physicians and hospitals in those areas. Possible mechanisms of community influence on hospitalization rates for pneumonia were discussed in the Health and Well Being Committee meeting and do span beyond the actions of any one physician. These mechanisms influence not only the vulnerability of patients in a population to develop pneumonia (e.g. Low access to vaccination) but also the resulting clinical severity of that pneumonia.

AHRQ would like to clarify two additional aspects of PQI 11. The commenter does discuss presentation to the ED, but PQI 11 will capture these encounters only if the patient is then hospitalized. Second, the AHRQ PQI software includes two risk models. The default uses only age and gender of the population, while an optional model adds poverty to the model. As was noted in the NQF Committee on socioeconomic adjustment of quality measures, there are valid reasons to both adjust and not adjust for socioeconomic status. As such, AHRQ provides two models to meet various user needs.

Developer Response for #0431: NQF 0431 is based on the National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations published by the National Quality Forum in 2008. In this report, NQF notes that the issue of denominator exclusions for delays in influenza vaccine availability was discussed by its Steering Committee of experts. Ultimately, the Steering Committee did not include an exclusion for delays in influenza vaccine supply in the standard measure specifications because (a) there was no systematic and consistent way to implement this exclusion and (b) influenza vaccine supply issues have become less frequent. The Committee further noted that in the event of a declared shortage of influenza vaccine, all healthcare providers purchasing the vaccine in question would be affected and a measure with no exclusions could be useful in assessing any differential impact of the delay or shortage on different providers.

The window for influenza vaccination (numerator) as measured by NQF 0431 begins as soon as vaccine for the current influenza season becomes available at the reporting facility and extends through March 31 of the following year. In the event of small or brief delays in vaccine availability, the length of this time window should permit reporting facilities adequate time to vaccinate and report data on vaccination even if the process begins later than usual. In the event of a more substantial or lengthier supply interruption, it is likely that many or most reporting facilities would be affected and that influenza vaccine supply concerns would be taken into account by measurement programs and organizations when scoring the measure for that season.

Developer Response for #2828: Regarding data capture, measure testing revealed that structured fields documenting follow-up are available in some, but not all, EHRs. Quality Insights is currently reviewing options to improve data capture, but testing suggests that the measure is feasible, at least in some provider practices.

The measure is intended to encourage clinicians to offer interventions to patients who are underweight, overweight, or obese, and clinicians from various specialties are eligible to report the measure. Furthermore, there are many follow-up approaches clinicians can use for these patient populations, each of which has varying levels of evidence. The measure therefore allows for a wide range of eligible follow-up plans. In future updates, we will consider codes for intensive obesity counseling to help address this issue. As more evidence becomes available to support specific follow-up plans that improve patient outcomes, we will update the measure accordingly.

Finally, we are reviewing waist circumference measurement with an expert work group. We designed the measure to align with current clinical guidelines which recommend screening for obesity using BMI. The measure does not currently include waist circumference measurement as an alternative because it may not apply to all patients, such as underweight patients. We will continue to monitor clinical guidelines and update the measure accordingly.

Developer Response for #3059: Measure 3059 is designed to promote the identification of hepatitis C to ensure early intervention and proper management of the virus through one-time screening for the birth cohort and other at risk populations. The measure, as drafted, is designed to be consistent with the recent recommendations from the CDC and USPSTF which outline various target populations for screening. As noted in the CDC recommendations, the recommendation for screening persons born during 1945-1965 does not replace previous guidelines for HCV testing that are based on known risk factors and clinical indications, but rather it defines an additional target population for one-time testing with the goal of achieving greater success in disease identification and engagement into treatment than risk-based strategies alone. HCV testing is the first step toward improving health outcomes for persons infected with HCV given that most persons with HCV do not know they are infected, do not receive needed care (e.g., education, counseling, and medical monitoring), and are not evaluated for treatment. Additionally, the measure has undergone initial feasibility testing at two different sites which supported the current measure construction and failed to identify any significant challenges in identifying or collecting the various data elements included in the measure. Additional testing will be conducted to meet additional NQF requirements and to advance the measure from approval for trial use to full endorsement.

Developer Response for #3070: This measure is based on the CDC's Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2016–17 Influenza Season. Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications.

The expert work group constructed this measure based primarily on the CDC's recommendation in addition to data on peak month flu activity. While seasonal influenza may be active year-round, the CDC states that peak flu activity is between October and March.11 Additionally, the flu season covered is aligned with other NQF endorsed flu vaccine measure and in alignment with NQF's National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations. Furthermore, the PCPI aims to develop broad measures in response to current national interest in the parsimonious use of measures to reduce the resource burden on health care providers without compromising the quality of patient care.

Finally, regarding the AAP's concern about the availability of the influenza vaccine, the expert work group raised this issue and opted to include a measure exception when the vaccine is not available so as not to inappropriately penalize a clinician for an issue not within his/her control.

This measure is based on the CDC's Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2016–17 Influenza Season. Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications.

Influenza may lead to serious complications and vaccination is the most effective protection against influenza virus infection. However, data indicate that less than half of all eligible individuals receive an influenza vaccination.

This measure promotes annual influenza vaccination for all persons aged ≥ 6 months. The measure assesses whether a patient received the flu vaccine or reports previous receipt of the flu vaccine at any other location or via another provider. The measure does not account for patient counseling to receive the vaccine elsewhere because this does not ensure that the patient receives the vaccination thereby reducing the risk of adverse flu-related outcomes as is the intent of this measure.

NQF Member Voting

Information for electronic voting has been sent to NQF Member organization primary contacts. Accompanying comments must be submitted via the online voting tool.

Please note that voting concludes on January 05, 2017 at 6:00 pm ET – no exceptions.

[11] http://www.cdc.gov/flu/about/season/flu-season.htm

RTI INTERNATIONAL | Memorandum

To: The National Quality Forum (NQF)

From: The Centers for Medicare & Medicaid Services (CMS) and RTI International

Date: November 15, 2016

Subject: **Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680): Response to NQF Steering Committee Concerns**

Background and Context

On September 12th, 2016 the NQF Steering Committee met, discussed, and voted on the quality measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680). This measure reports the percentage of short-stay nursing home (NH) residents, long-term care hospital (LTCH) or inpatient rehabilitation facility (IRF) patients who are assessed and appropriately given the seasonal influenza vaccine during the most recently-completed influenza season. This measure is based on the NQF´s National Voluntary Standards for Influenza and Pneumococcal Immunizations.

The committee did not reach a consensus on whether to recommend the measure for NQF endorsement. We note that a similarly conceived and structured measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Long- Stay) (NQF #0681), was discussed and recommended for endorsement by this steering committee.

We have drafted this memo to address the specific concerns identified by standing committee and NQF staff as reflected in the Health and Well-Being 2015-2017 Draft for Public Comment document.

RTI and CMS have summarized NQF's three areas of concern regarding the measure, as well as our response to each concern below:

(1) **Potential Issue: Data element reliability and validity.** NQF Staff and Committee Members questioned whether data element reliability and validity were sufficiently demonstrated for the IRF and LTCH settings given that item level testing was not provided specifically for IRF and LTCH settings.

Summary response: The Measure Worksheet prepared by NQF staff and circulated to the committee prior to the September 12th meeting suggested that the reliability testing results for NH was insufficient, despite the inclusion by RTI of data element reliability and validity results for the two Minimum Data Set (MDS) 3.0 items used for the quality measure calculation. These analyses included two different sets of near-perfect kappa statistics based on two different sets of paired interrater reliability data collection analyses, one comparing responses for gold-standard nurses to responses by staff nurses

of participating facilities, and the other comparing responses among pairs of gold-standard nurses. RTI and CMS argue that these testing results are appropriate to apply to the evaluation of the LTCH and IRF items because the items are identical across assessments, and there is substantial overlap in the populations cared for by these providers.

(2) **Potential Issue: Measure score reliability testing.** NQF Staff expressed concern that the measure score reliability testing was not sufficient for NH, IRF, or LTCH settings as it was difficult for NQF staff and committee members to interpret the submitted testing data.

Summary response: RTI and CMS submitted results of measure score reliability testing which examined the distribution of provider scores and their associated 95% confidence intervals relative to the national mean, as well as estimates of signal-to-noise as tested by an ANOVA analysis. These methods are appropriate for evaluating the reliability of measure scores as they compare differences in provider scores to the amount of uncertainty around provider scores. In this memo, RTI has included further explanation and justification of the measure score reliability testing methodology.

(3) **Potential Issue: Measure score validity.** NQF Staff expressed concern that the evidence put forth for the validity of the measure, including face validity, for the IRF and LTCH settings did not provide sufficient information to support the measure's use in distinguishing good from poor quality.

Summary response: RTI has included more evidence regarding the validity of the performance measure including (1) additional details in support of the face validity of the measure from a study which demonstrates that increase in vaccination of the population corresponds to decrease in mortality and pneumonia and influenza related hospitalization; and (2) a new analysis, the results of which indicate convergent validity between the influenza vaccination measure and health outcomes in the IRF and LTCH settings. This analysis examines the correlation of the influenza vaccination measures in the IRF and LTCH settings with measures of hospital readmission – All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from an IRF (NQF #2502) and All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from an LTCH (NQF #2512) – both of which have been endorsed by NQF and are accepted measures of quality.

CMS' Response to NQF Steering Committee Concerns

(1) *Data Element Reliability and Validity for IRF and LTCH Settings*

During the September 12th, 2016 NQF Steering Committee meeting, members were unable to come to a consensus on the reliability and validity criteria for this measure. NQF staff and committee members

questioned whether data element reliability and validity were sufficiently demonstrated for the IRF and LTCH settings given that item level testing was not provided specifically for IRF and LTCH settings. In this section we put forth an argument that the rigorous testing on the reliability and validity of the NH items in the MDS 3.0 provides evidence for the items used in the IRF and LTCH settings. Additionally, we provide two corrections to the information concerning the NH items put forth in the NQF# 0680 Measure Worksheet that was distributed to the Standing Committee.

A) *Correction to the information put forth in the NQF# 0680 Measure Worksheet*

We are concerned that the summary put forth in the NQF# 0680 Measure Worksheet reflected the testing submitted for the MDS 2.0 data elements during the initial submission of NQF# 0680 to NQF in 2012, rather than the recent results of the MDS 3.0 testing, which RTI submitted in the current Measure Testing Form for the current Health and Well-Being 2015-2017 project (see pages 8, 20-21, 29-30 and 32-37 of the NQF# 0680 Measure Worksheet).

We note that the MDS 3.0 testing results that RTI reported in support of the reliability and validity of this measure were based on the RAND Development and Validation of MDS 3.0 project, which consisted of a representative sample of for-profit and not-for- profit facilities, and hospital-based and freestanding facilities recruited for the study, which included 71 community nursing facilities in 8 states and 19 Veterans Affairs (VA) nursing homes. The sample included 3,822 residents from community nursing homes and 764 residents from VA nursing homes. The RAND pilot test of the MDS 3.0 items showed good reliability and are applicable to the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) and the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set. The kappa statistic for the item indicating whether the influenza vaccine was given gold-standard nurse to gold-standard nurse agreement was

.989, and the kappa for gold-standard nurse to facility nurse agreement was .941. The kappa statistic for the item requesting the reason the vaccine was not given for gold- standard nurse to gold-standard nurse agreement was .976, and the kappa for gold- standard nurse to facility nurse agreement was .820.[1] According to the benchmarks suggested by Landis and Koch,[2] these kappa statistics can all be considered "almost perfect." RTI argues that the kappa statistics comparing gold-standard nurse to facility nurse responses should be sufficient for evaluation of the validity of these items as well.

In addition, regarding the NH setting, the measure worksheet noted that "Patient-level data element testing results include percent agreement for two data elements only",

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[1] Saliba, D., & Buchanan, J. (2008, April). *Development and validation of a revised nursing home assessment tool: MDS 3.0*. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[2] Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. Biometrics 33(1), 159-174.

implying incorrectly that testing was missing for items. We would like to note that these are the only two assessment items used for the calculation of this measure so the testing results do cover all items that are used in the construction of this measure. The patient/resident's birthdate is used to calculate the patient/resident's age (used for the measure exclusion criteria) and is validated against administrative records during the data submission process so we have not included separate reliability statistics for birthdate.

B) *Reliability and Validity of Data Elements in the IRF and LTCH Settings*

To address the concern regarding the reliability and validity of the data elements used in the IRF and LTCH settings, we point to the original submission of evidence to support the continued endorsement of this measure for all three settings (IRF, LTCH and NH short stay population). Here, RTI cited results of inter-rater reliability testing done during the development of the MDS 3.0 to attest to the reliability and validity of the MDS items used in this measure. We further asserted that it would be appropriate to use the results of these tests to evaluate the reliability of the IRF and LTCH items used in this measure. This argument is appropriate given that a) the LTCH CARE Data Set and the IRF-PAI use identical items to the MDS to measure influenza vaccination, and b) there is significant similarity between the populations across these three settings.

In February 2012, NQF convened an Ad Hoc Review Steering Committee to review expanding the NQF #0680 measure to include LTCH and IRF settings. In the published proceedings, it was noted that although the validity of the influenza measure for the LTCH CARE dataset and the IRF-PAI dataset was untested, the populations in which these measures were applied and risk factors in these settings were similar. Furthermore, the publication noted that decisions about referring a patient to a given setting are often made based on geography and provider relationships. The Ad Hoc Review Steering Committee concluded that it is reasonable to apply the validity testing from the MDS to the LTCH CARE dataset and the IRF-PAI. Although the populations are not identical and some differences in validity may exist, the nursing home measure can be meaningfully utilized in LTCHs and IRFs.

Further, the short-stay influenza measure has been harmonized across all three settings and with the NQF´s National Voluntary Standards for Influenza and Pneumococcal Immunizations: it conforms to the measure specifications as identified by the NQF measure number 0432.[3] For nursing home residents, the definition of a short-stay is a resident whose length of stay is less than or equal to 100 days. The average length of stay for patients in LTCHs in 2014 was 26.3 days.[4] In IRFs, the average length of stay in 2014 was 12.8 days.[5] Because the average length of stay in each of these facilities is well under the 100-day maximum for short-stay nursing home residents, and because the averagelength of a short-stay nursing home episode is approximately 30 days[6], it is reasonable to utilize a short-stay measure to evaluate their performance.

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[3] National Quality Forum (2008, December). National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations. http://www.qualityforum.org/Projects/i-m/Influenza_and_Pneumococcal_Immunizations/Influenza_and_Pneumococcal_Immunizations.aspx.

(2) *Measure Score Reliability for NH, IRF and LTCH Settings*

Informed by pre-meeting Public and Member comments which suggested a rating of *insufficient* for measure score reliability in all three settings, committee members were unable to come to a consensus on the measure score reliability for this measure. NQF Staff expressed concern that the measure score reliability testing was not sufficient for NH, IRF or LTCH settings as it was difficult for NQF staff and committee members to interpret the submitted testing data.

In addition to the *data element reliability testing* discussed above (Section 1), RTI performed and presented multiple tests of *performance measure score reliability* for each setting including analysis of variance and confidence interval analysis which indicated that measure scores were reliable. We provide an overview here for additional clarity on what testing was completed and how it should be interpreted, but please also refer to the NQF testing form for this measure for details of these analyses.

A) As suggested by the CMS Guidelines for Measure Blueprints[7], RTI performed analysis of variance (ANOVA)[8] analyses on NQF# 0680 scores in all settings. In each setting, an *F*-test indicated that there was a significant effect of facility identification. In this case, the *F* statistic is the ratio of the variance between facilities (facility-level measure scores as compared the mean of these scores) and the variance within facilities (patient or resident measure scores compared to the facility-level mean of these scores). Because we are

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[4] MedPAC Report to the Congress: Medicare Payment Policy (2016, March) http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0

[5] MedPAC Report to the Congress: Medicare Payment Policy (2016, March) http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0

[6] Smith L., Zheng T.Z., Reilly, K., et al. (2012) Nursing Home 3.0 Quality Measures: Final Analytic Report. Report prepared for CMS. Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-instruments/NursingHomeQualityInits/NHQIQualityMeasures.html

[7] Health Services Advisory Group. "A Blueprint for the CMS Measures Management System, Volume I." Centers for Medicare and Medicaid Services: Baltimore, MD. January 2012; 9.1:308. Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-instruments/MMS/Downloads/BlueprintVolume1-combined-v90.pdf

[8] Because providers have different numbers of patients and therefore there is unequal sample size, the ANOVA was performed with a general linear model (GLM) and generated a standard ANOVA table. Unequal sample size has the effect of removing degrees of freedom for error, making the *F* test more conservative and making it more difficult to find a significant effect (See, for example, Fisher, L.D., van Belle, G. (1993). Biostatistics: A Methodology for the Health Sciences. New York: John Wiley & Sons). Since we found significant effects of provider identity, we do not believe that unequal sample size is an issue here.

interested in whether there are statistically significant differences performance on the measure due to facility quality rather than resident- or patient-level factors, the variance between facilities is considered the 'signal', while all other variance between patients or residents is considered 'noise'. The F statistic indicates that the differences in facility- level measure scores are large with respect to the sum of the variance within facilities and that these observed differences are likely to remain in future data collection periods.

In addition to statistical significance testing, we also examined the effect size associated with differences between facilities using η^2 statistics. The η^2 statistic measures the ratio of the variance associated with an effect as compared to the total variance. In this case, the η^2 statistics measured the ratio of the variance attributable to facility-level differences to all variance associated with patient or resident level vaccination rates. The observed η^2 statistics were .17 for IRFs, .37 for LTCHs, and .18 in the NH setting[9]. Put another way, the particular facility in which an individual stays explains a substantial proportion of the overall variance in vaccination rates in all three settings.

Thus, this measure is able to identify meaningful, statistically significant differences between providers in each setting, and the measure itself is a reliable indicator of the construct of determining the relative quality of providers with regard to assessing and appropriately administering the influenza vaccine.

B) We also examined the proportion of providers that were significantly different than the national mean for each setting (at the $\alpha < .05$ significance level) to test the ability of the measure to discern performance between providers. To do this we calculated a 95% confidence interval (CI) about the measure score for each provider. We then compared each provider's 95% CI to the national mean: if the national mean fell within a provider's 95% CI, then that facility's score was not considered significantly different from the mean. If the upper limit of the CI was below the national mean, that facility's score was considered significantly worse than the national mean. Similarly, if the lower limit of the CI was above the national mean that score was considered significantly better than the national mean. This analysis is equivalent to conducting a two-tailed, one-sample *t*-test against the national mean for each provider. In each setting, approximately two thirds or more of providers had measure scores that were either significantly better than or worse than the national mean. The Committee of Presidents of Statistical Societies has recommended the public reporting of confidence intervals around performance measure scores as a way of as a way of communicating the amount of information in a provider's score and the amount of uncertainty in the provider's score.[10] By showing the proportion

[9] For guidelines for assessing effect size with η^2, see Cohen, J. (1988). Statistical power analysis for the behavioral sciences (2nd ed.). Hillsdale, NJ: Lawrence Earlbaum Associates. The η^2 statistics in each setting represented large effect sizes according to Cohen's criteria.

[10] Ash A, Fienberg SE, Louis TA, Normand S-LT, Stukel TA, Utts J. Statistical Issues in Assessing Hospital Performance January 27, 2012.

of providers with scores that are significantly higher and lower than the national average, RTI is supplying an additional way of evaluating how much information is in the data relative to random error. Thus, we concluded that this measure is, in fact, able to distinguish high- and low- performing providers.

3) Measure Score Validity for IRF and LTCH Settings

During the September 12th, 2016 NQF Steering Committee meeting, members were unable to come to a consensus on the validity criterion for this measure. Specifically, there was lack of consensus among committee members that there was sufficient evidence to pass the measure on validity for the IRF and LTCH settings. Committee members found that the evidence available for the measure fell short of the criterion for face validity of the measures score. Some committee members felt that an illustration that performance scores resulting from the measure can be used to distinguish good from poor quality, was not adequately shown for the IRF and LTCH settings.

Given this concern, we provide literature and recent analyses that illustrate the measure's face validity and ability to distinguish between good and poor quality in these settings. We have also added results from a new analysis evaluating the convergent validity of the measure by examining the correlation between NQF #0680 and NQF endorsed measures of quality that focus on readmissions, specifically NQF #2502: All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from an IRF and NQF #2512: All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from an LTCH.

A) As noted by the Steering Committee at the September 12th, 2016 NQF meeting, reference 8 on page 36 of the NQF #0680 Measure Worksheet, which was also included in the evidence form, presents evidence for face validity of the measure. Specifically, that an increase in vaccination of the population corresponds to decrease in mortality and pneumonia and influenza (P&I) hospitalization.[11] Therefore, differences in the percent of patients and residents assessed and appropriately vaccinated correspond to quality differences.

While this study focuses specifically on the nursing home setting, as described in Section 1 above, and as cited by a NQF committee member at the September 12th, 2016 NQF meeting, decisions about which setting a patient is referred to are often made based on geography and provider relationships. The 2012 NQF Ad Hoc Review Steering Committee concluded that validity would not differ by setting, and thus nursing home measures can be meaningfully utilized in LTCHs and IRFs. Pop-Vicas et al note that their study results are broadly generalizable because of consistent results in P&I mortality

[11] Pop-Vicas, A., Rahman, M., Gozalo, P. L., Gravenstein, S., and Mor, V. (2015). Estimating the effect of influenza vaccination on nursing home residents' morbidity and mortality. Journal of the American Geriatrics Society 2015; 63(9): 1798–1804. doi:10.1111/jgs.13617

reduction reported among CDC sentinel cities. This study also demonstrates that the vaccine match rate did not affect hospitalization for illnesses not related to influenza, providing a control. Finally, their estimate of a 2% vaccine-associated annual mortality reduction among NH residents falls under the 10% threshold of overall seasonal influenza-attributable mortality, giving greater face validity to their regression model.[12]

B) To further assess the validity of the measure in the IRF and LTCH settings, we conducted an exploratory analysis to investigate a possible statistical relationship between this process measure and an existing measure of health outcomes – hospital readmissions. Hospital readmissions are events that indicate reduced patient safety and quality of care, and are the focus of NQF-endorsed quality measures in multiple care settings, including IRFs, LTCHs, and Skilled Nursing Facilities (SNFs). We looked at correlations between the vaccination measure and its submeasures with observed and risk-standardized readmissions rates in the IRF and LTCH settings. We hypothesized that facilities with higher scores for the vaccination measures should tend to have lower rates of readmission and vice versa.

For this analysis, we used the most recent available data for NQF #0680, which were collected during the 2014-2015 influenza vaccination season (IVS), and the most recent available data for NQF #2502: All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from an IRF and NQF #2512: All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from an LTCH, which were calculated from claims data for calendar years 2013 and 2014. Of the 1,103 IRFs with adequate sample size for reporting NQF #0680, 1,081 (98.0%) had readmissions data; of the 413 LTCHs that could report NQF #0680, 402 (97.3%) had readmissions data.

Correlations between NQF #0680 scores and observed and risk-standardized readmission rates for the IRF and for the LTCH settings are presented in ***Table 1*** and ***Table 2***, respectively. We found similar patterns across settings, but with more significant correlations in the IRF setting which is likely due to the larger sample size. In both settings, the direction of the correlation between the vaccination measure scores and both the observed and risk-standardized readmissions rates is negative as hypothesized, but none of these were statistically significant at the α = .05 level. However, in each setting there was a weak but significant inverse correlation between observed readmission rates and the observed vaccination rates as measured by submeasure NQF #0680A (i.e., received the influenza vaccine either in the facility/hospital or outside the facility/hospital). In LTCHs, the relationship between submeasure NQF #0680A was smaller, but also significant. This indicates that having a higher number of vaccinated patients is correlated with lower readmission rates. In addition, there was a significant

[12] Pop-Vicas, A., Rahman, M., Gozalo, P. L., Gravenstein, S., and Mor, V. (2015). Estimating the effect of influenza vaccination on nursing home residents' morbidity and mortality. Journal of the American Geriatrics Society 2015; 63(9): 1798–1804. doi:10.1111/jgs.13617

direct relationship in IRFs between observed readmissions and submeasure NQF #0680b, which is the proportion of residents who were offered and declined the vaccine (the correlation was positive but not significant in LTCHs). This indicates that, in the IRF setting, having a higher number of patients who declined the influenza vaccine is correlated with higher readmission rates.

RTI notes a few limitations to this analysis, but asserts that these results are still supportive of the convergent validity of the measure. First, the data come from two different time periods with two different data collection intervals, so that although the facilities are the same, the patients are likely not the same. Those patients in the vaccination process measure are not likely to be the same patients included in the readmission measure. Second, the strength of the associations between the vaccination process measure and the risk-adjusted readmission outcomes measure may be obscured by differences in distributions of measure scores: the application of shrinkage estimators in the risk-standardized readmission rates (RSRRs) narrows the range of RSRRs and thus provides less opportunity for correlation with the more broadly-distributed NQF #0680 scores. However, the significant inverse correlation between vaccination rates and raw observed readmission rates indicates that vaccination is associated with reducing at least one adverse health outcome and is consistent with the literature cited in the immediately prior section.

Table 1. Facility-level correlations between NQF #0680 and its Submeasures with Observed and Risk-Standardized All-Cause Readmission Rates: IRF (n = 1,081)

Measure or sub-measure	Observed readmission rate	Risk-Standardized readmission rate
0680: Full measure	-0.049	-0.021
0680A: Received vaccine	-0.129***	-0.079*
0680B: Offered and declined the vaccine	0.117**	0.085
0680C: Did not receive due to medical contraindication	-0.021	-0.024

*$p < .05$, **$p < .001$, ***$p < .0001$

SOURCE: RTI Analysis of 2013-2014 Medicare Claims Data and 2015 IRF-PAI Data (programming reference: DB49a Readmissions merge.xlsx)

Table 2. Facility-level correlations between NQF #0680 and its Submeasures with Observed and Risk-Standardized All-Cause Readmission Rates: LTCH (n = 402)

Measure or sub-measure	Observed readmission rate	Risk-Standardized readmission rate

Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680): Response to NQF Steering Committee Concerns

0680: Full measure	-0.086	-0.014
0680A: Received vaccine	-0.118*	-0.078
0680B: Offered and declined the vaccine	0.050	0.077
0680C: Did not receive due to medical contraindication	0.007	0.068

*$p < .05$, **$p < .001$, ***$p < .0001$

SOURCE: RTI Analysis of 2013-2014 Medicare Claims Data and 2015 IRF-PAI Data (programming reference: DB01_20160917.xml)

Based on support from the literature, as well as the NQF committee pre-evaluation comments for the September 2016 review, we conclude that the NQF #0680 influenza measure is valid in LTCH and IRF settings, as is the case in the NH setting for short-stay and long-stay populations.

This is further supported by the new analysis conducted by the developer, indicating that there is a statistically significant inverse relationship between influenza vaccination and hospital readmission, evidence that this process is linked to at least one adverse outcome that has been established as an indicator of provider quality.

Summary and Conclusion

RTI and CMS have addressed each of NQF's concerns as follows:

(1) Concern that the data element reliability and validity was not sufficiently demonstrated for the IRF and LTCH settings given that item level testing was not provided specifically for IRF and LTCH settings.

RTI notes that the Measure Worksheet prepared by NQF staff and circulated to the committee suggested that the reliability testing results for NH were insufficient, despite the inclusion by RTI of data element reliability and validity results for the two MDS 3.0 items used for the QM calculation. RTI has restated the results of the inter-rater agreement analyses for the MDS 3.0 items for which the kappa statistics indicated almost perfect agreement and restates the argument with additional support that these testing results are appropriate to apply to the evaluation of the LTCH and IRF items because the items are identical across assessments, and there is significant overlap in the populations cared for by these providers.

(2) Concern that the measure score reliability testing was not sufficient for NH, IRF or LTCH settings as it was difficult for NQF staff and committee members to interpret.

RTI and CMS has provided a summary of the performance measure score reliability for each setting including analysis of variance and confidence interval analysis which indicated that measure scores were reliable.

(3) Concern that the evidence for the face validity of the measure for the IRF and LTCH settings do not provide sufficient information to support the measure's use in distinguishing good from poor quality.

RTI and CMS addressed this concern, providing literature which suggests that influenza vaccination is associated with decrease in mortality and pneumonia and influenza (P&I) hospitalization is further supported by the new analysis conducted by the developer, indicating that there is a statistically significant inverse relationship between influenza vaccination and hospital readmission, evidence that this process is linked to at least one adverse outcome.

STATISTICAL BRIEF #210

CDC is submitting this response to concerns raised by the panel during its discussion of the evidence available to support the validity and reliability of NQF candidate population measure number 3086: Population Level HIV Viral Load Suppression. The assembled information demonstrates that this measure (and the systems from which it is generated) has been, and continues to be, evaluated according to rigorous federal and state performance criteria—and that, where those criteria are met, measure results are considered reliable and useful enough to both evaluate and drive (e.g., via CDC's Data to Care initiative[1]) public health responses. However, we also feel it is imperative to emphasize that both CDC and states continue to invest heavily in strengthening state HIV surveillance systems and activities; thus, the published data presented in this response should be considered conservative estimates of current system (and measure) accuracy, utility, reliability, and validity.

The National HIV Surveillance System (NHSS) is, structurally and operationally, a partnership: first, between states and healthcare service providers (which include laboratories) obliged by state and local laws/regulations to report HIV-related information (e.g., new diagnoses; viral load test results) to the state, and second, between the states and CDC. In brief, data flows and sources are as follows:

1. HIV test results (e.g., tests performed according to the HIV diagnostic algorithm published by CDC; viral load and CD4 tests) and other information required by the state and available to the submitting entity are transmitted to the health department. Key notes about this step:
   a. AIDS case reporting has been required in all 50 states since 1986. Beginning in 1985, many states implemented HIV case reporting as part of an integrated HIV and AIDS surveillance system. As of 2008, all states had implemented confidential, name-based HIV infection reporting.
   b. As of December 2015, all but 6[2] states require by law that all viral load and CD4 lab test results be reported to the state surveillance program.
   c. While states may statutorily require healthcare providers or other entities to report certain information (e.g., submit a case report in the event that one of their patients is newly diagnosed with HIV), most state HIV surveillance programs primarily rely upon laboratories to report required tests and test results. Reporting completeness rates from other sources (e.g., individual clinicians or clinics) are generally far lower than those of laboratories; nevertheless, they do offer an important secondary source of data (and may become more complete in the future, especially if case reporting can be automated through EHRs).
   d. CDC provides supports the implementation of electronic laboratory reporting (ELR) solutions and has assisted health departments with developing ELR infrastructure. All jurisdictions receive ELC funds, and most have implemented tools supported by ELC (i.e., Orion Rhapsody) for receiving ELR. The ELC program at the state-level typically resides in the communicable

[1] Data to Care is a new public health strategy that aims to use HIV surveillance data to identify HIV-diagnosed individuals not in care, link them to care, and support the HIV Care Continuum. For additional information, see https://effectiveinterventions.cdc.gov/en/HighImpactPrevention/PublicHealthStrategies/DatatoCare/ProgramIntroductionandGoals.aspx

[2] Two of these states (VT, NJ) actually statutorily require complete viral load test reporting (see Table 10 of http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-21-4.pdf). However, CDC requires states to have complete reporting for both test types in place in order to generate robust state estimates around outcomes such as % of individuals living with HIV who are in care or who are virally suppressed.

disease program. HIV programs are encouraged to use existing ELC-funded resources when implementing ELR for HIV. This digitization of the reporting system has significantly enhanced the completeness and "currency" of state HIV surveillance records.

2. The state uses the reported information to create a new, or update an existing, HIV surveillance case records
3. The state takes additional steps to ensure that all case records (and the fields therein) are complete and up-to-date, and that the states surveillance system includes records for all persons diagnosed with HIV and currently living in that state
   a. As a condition of funding, CDC requires that state surveillance programs engage in a variety of active and passive surveillance strategies, as well as quality assurance activities, aimed at ensuring the timeliness, completeness, reliability and validity of data captured in the state's HIV surveillance system. In addition to routine death ascertainment, intra- and inter-state deduplication activities (mentioned in more detail below), states surveillance staff may use extant public (e.g., Department of Motor Vehicles) and private (Lexus Nexus People Finder programs) databases to identify missing, or update existing, fields (e.g., current address) in a case record. State staff also frequently review medical charts to obtain missing, or update existing, case data, as well as to verify that the state surveillance system is capturing all persons living with HIV (newly diagnosed or established and in care for their infections) who reside in the state.
   b. Data quality control activities include:
      i. Visual editing (proofreading) of hard copy case report forms (all forms, all data items, and all comments) before data entry
      ii. Identifying records in eHARS that do not yet meet the surveillance case definition of HIV infection, but have at least one laboratory test result that is indicative of HIV infection (such records should be prioritized for epi follow-up).
      iii. Identifying cases newly diagnosed or reported that meet the surveillance case definition of HIV infection but have a eHARS Person View status of 'E – Error', 'R – Required field missing', or 'W - Warning'. Surveillance staff should determine the reasons for the error(s), missing data field(s), and the warning status and correct or obtain the missing information prior to data transmission to CDC.
      iv. Duplicate abstracting (optional activity).
      v. Addressing inconsistencies in the data discovered during data analyses.
4. States submit de-identified case data to CDC for further aggregation and analysis
   a. As explained in greater detail below, CDC also performs rigorous assessments of the quality of data submitted (and the systems that generated them) and provides ongoing technical assistance to states to help them improve the completeness, timeliness, validity and reliability of the data they collect.

Please see http://www.cdc.gov/hiv/statistics/surveillance/systems/index.html for additional background on the HIV case surveillance system.

Data from the NHSS are currently used in a wide variety of fashions, including national (cite NHAS) and state (cite our annual monitoring report) performance monitoring and accountability efforts; federal, state, and local resource allocation decisions (cite RW and note statutory basis, HOPWA, our own

FOAs); and public health action (including direct outreach to and reengagement of individuals who, per surveillance data, appear to have fallen out of HIV care –cite D2C). Accordingly, CDC and its partners—particularly states—are highly invested in ensuring that NHSS data, and the indicators (like viral load suppression) calculated from those data, are, among other things, complete, accurate, timely, high quality, sensitive, and acceptable. To this end, in 2004, CDC and the Council for State and Territorial Epidemiologists (CSTE) collaborated to build upon CDC's *Updated Guidelines for Evaluating Public Health Surveillance Systems* (CDC 2001)[3] by developing an evaluation framework and standards for NHSS that, when met, "indicate a fully functioning surveillance system with high- quality data" (Hall and Mokotoff 2007)[4]. These standards, and the processes used by CDC and states to evaluate performance against them, also ensure that the NHSS is a "learning"—and continuously improving—surveillance system. It is this combination of high standards and continuous investment in state's performance against them that forms the basis for CDC and other stakeholders' confidence in the reliability and validity of both the data captured in NHSS and the indicators (including numbers of persons living with HIV in the United States, and estimates of the proportion of those PLWH who are in care and virally suppressed) generated from it.

As the attached document demonstrates, CDC evaluates state HIV surveillance systems annually against numerous process and outcome standards, and state responses to each evaluation question must be accompanied by supporting data sets and the raw SAS codes used to calculate those data sets. In terms of assessing the validity and reliability of both the key data elements that make up CDC's viral load suppression measure, as well as state level viral load suppression estimates, the following evaluation metrics are particularly important:

1. Completion of all three standards under "Death Ascertainment"
2. Completion of all standards under "Routine Interstate Duplicate Review (RIDR)"
3. Completion of all standards under "Laboratory"
4. Achievement of the following outcome standards:
    a. Did your surveillance program ascertain at least (≥) 85% of the expected number of persons newly diagnosed with HIV infection in 2014 by the end of December 2015?
    b. Were there less than or equal to (≤) 1% duplicate case reports among all (cumulative) cases reported to your surveillance program through December 31, 2014 by the end of December 2015?
    c. In 2015, did 97% of case records pass all selected data edits? That is, did 97% of cases contain no errors?
    d. Did at least (≥) 60% of adults and adolescents newly diagnosed with HIV infection in 2014 have a viral load based on a specimen collected within three months following their initial diagnosis reported by the end of December 2015? (see below for additional context around this standard)

[3] German RR, Lee LM, Horan JM, Milstein RL, Pertowski CA, Waller MN; Guidelines Working Group Centers for Disease Control and Prevention (CDC) (2001). Updated guidelines for evaluating public health surveillance systems: recommendations from the Guidelines Working Group. *MMWR Recomm Rep.* 50 (RR-13): 1-35

[4] Hall HI and Mokotoff ED (2007). Setting Standards and an Evaluation Framework for Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome Surveillance. *J Public Health Management Practice*, 13 (5): 519–523

Thorough performance and completion of the first two processes, in combination with the first and third outcome standards, are essential for denominator validity and reliability, as they ensure the data elements needed to calculate the denominator statement below are complete, up to date, and accurate:

Number of persons aged ≥13 years who were diagnosed with HIV before the measurement year and were alive at end of measurement year.

Specifically, these standards, when met, ensure that the denominator is neither over-inflated (e.g., due to erroneous inclusion of deceased individuals or individuals who have moved away for the state) nor under-inflated (due to incomplete ascertainment of and accounting for HIV-infected and diagnosed persons migrating into the state, incomplete lab reporting of new diagnoses, or incomplete case records that preclude ascertainment of a diagnosed person's age). As the accompanying score card illustrates, the states currently deemed to have HIV surveillance systems that are sufficiently complete and reliable to generate valid measures of state viral load suppression rates (highlighted in attached scorecard) meet or exceed all the standards most critical for valid and reliable estimation of viral suppression rates. When present, performance exceptions are generally isolated (i.e., a state falls short on one measure, not 5); affect standards that are less critical to accurate, aggregate state level viral load suppression estimation (e.g., complete risk factor ascertainment); or not sizeable enough to warrant concern[5].

Each of these reported results is rooted in a combination of verification procedures and evaluation processes that include active and passive case finding and follow-up activities, as well as peer-reviewed and widely endorsed statistical estimation procedures. In the interest of brevity, we offer the following example: completeness of new case ascertainment. As described in greater detail in Karch et al. (2014)[6]--which presents a systematic evaluation of the NHSS for the 2011 diagnosis year—states use one of two methods to evaluate and quantify the degree to which their surveillance systems accurately capture new diagnoses. Those two methods are:

1. **3-Source Log-Linear Capture-Recapture Model. As** described in its application to 2011 new diagnoses, the model was used "to estimate the completeness of reporting of persons newly diagnosed with HIV infection in 2011 and reported to the PA surveillance system by the end of 2012. The 3 sources, health care provider, laboratory, and other (e.g., other public health databases such as sexually transmitted disease or hepatitis surveillance systems), represent the most common sources from which a diagnosis of HIV infection may be reported to the surveillance system. If "1" represents being reported by a source and "0" otherwise, each new diagnosis in 2011 was classified into 1 of the 7 cells 100, 010, 001, 110, 101, 011, and 111. On the basis of the observed frequency count in each of the 7 cells, the log-linear models estimated the number of new diagnoses in 2011 that were not reported by any of the 3 sources by the end of 2012, or f (000), the frequency of 000 outcomes. The estimated completeness of reporting of persons newly diagnosed in 2011 by the end

[5] The one possible exception is that of Georgia's data quality. As data presented later in this response will demonstrate (see Unpublished Data from Georgia, pages 9-10), it is likely that the state's relatively poor performance score in 2014 on this data element was due to quality failures in fields other that those most critical to calculating viral load suppression.
[6] Karch DL, Chen M, Tang T (2014). Evaluation of the National Human Immunodeficiency Virus Surveillance System for the 2011 Diagnosis Year. *J Public Health Manag Pract*. 20 (6): 598-607

of 2012 was the sum of the 7 frequency counts divided by the sum of the 7 frequency counts plus f(000)." Additional details about this methods are available from Hall et al. (2006)[7].

2. **Reporting Delay (RD) Method.** This alternative method is generally used by states with low HIV incidence/prevalence rates (which can impede accurate application of capture-recapture statistical methods) and/or states for which one of the three systems used in capture-recapture approaches contributes a relatively small (e.g., <20%) share of new diagnoses. As detailed by Karch et al., for the 2011 diagnosis year, this analytic method "examines the year of HIV diagnosis among persons newly reported to the PA from 2008 to 2012 and estimates the probability of being reported within 12 months after the diagnosis year using conditional probabilities that are estimated on the basis of historical data. The method assumes that all diagnoses were reported within 4 years after the diagnosis year. For these PAs, the estimated timeliness was derived as the product between the estimated conditional probability of being reported within 6 months following diagnosis, given that the diagnosis was reported within 1 year after the diagnosis year and the estimated probability of being reported within 1 year after the diagnosis year."

As demonstrated by the mapping below, the same standards also support the complete, accurate reporting (and, hence, validity and reliability) of the data elements used in the numerator:

Number of HIV-diagnosed persons, aged ≥13 years and alive at the end of the measurement year, whose most recent viral load test showed that HIV viral load was suppressed (where viral suppression is defined as a viral load result < 200 copies/mL).

Specifically,

1. Completion of all three standards under "Death Ascertainment" → **Needed to determine "alive at the end of the measurement year"**
2. Completion of all standards under "Routine Interstate Duplicate Review (RIDR)"→ **Needed to ensure only HIV-diagnosed persons who were residing in the state during the measurement year are included in the numerator and denominator**
3. Completion of all standards under "Laboratory"→ **Needed to ensure the HIV surveillance system contains all HIV diagnostic and monitoring test results. Complete reporting of the former ensure the reliability and validity of the data element "HIV diagnosed persons", while reporting complete reporting of the latter ensure the reliability and validity of the data element "whose most recent viral load test showed that HIV viral load was suppressed"**
4. Achievement of the following outcome standards:
   a. Did your surveillance program ascertain at least (≥) 85% of the expected number of persons newly diagnosed with HIV infection in 2014 by the end of December 2015? → **Addresses reliability and validity of "HIV diagnosed" data element**
   b. Were there less than or equal to (≤) 1% duplicate case reports among all (cumulative) cases reported to your surveillance program through December 31, 2014 by the end of December

[7] Hall HI, Song R, Gerstle JE III, Lee LM (2006). Assessing the Completeness of Reporting of Human Immunodeficiency Virus Diagnoses in 2002-2003: Capture-Recapture Methods. *Am J Epidemiol*. 164 (4): 391-7

2015? → **Addresses proper delineation of eligible population for denominator and numerator (i.e., HIV-diagnosed persons *residing in the state* during the measurement year)**

c. In 2015, did 97% of case records pass all selected data edits? That is, did 97% of cases contain no errors? → **Addresses reliability and validity of age, residence, successful matching of lab results to case records, successful matching of case records to vital records, etc.**

d. Did at least (≥) 60% of adults and adolescents newly diagnosed with HIV infection in 2014 have a viral load based on a specimen collected within three months following their initial diagnosis reported by the end of December 2015? (see below for additional context around this standard)

→ Proxy indicator for assessing likely completeness of VL test results reporting.

i. **NOTE:** this is NOT a direct measure of VL test result reporting completeness and cannot be read as such, as three separate processes can affect performance—laboratory reporting timeliness affect, laboratory reporting completeness, and failure of the newly diagnoses person to enter care. The first two processes (and particularly the second) do have the potential to affect the overall reliability and validity of the associated data element in the CDC Viral Load Suppression measure; by contrast, failures resulting from the third (i.e., incomplete linkage to care) will be interpreted as "failure to achieve viral suppression" under the measure and so correctly captured in the numerator. Thus, a state's linkage to care rate for newly diagnosed individuals, rather than 100%, offers a ***better***[8] "maximum" against which to assess the completeness of VL reporting, as indicated in this performance standard.

ii. The able below compares presents the following information for 2014: state linkage to care rates[9], state performance against the viral load reporting standard used by CDC[10], and the difference between the two. Clearly, the two are strongly related and in most states, the difference is small enough to suggest that the state does, in fact, enjoy robust, timely, and complete VL reporting.

State	% Linked to Care within 3 Mos.	% for Which VL Benchmark Achieved	Difference (Abs Value)
Alabama	78.2.	82.0	3.8
Alaska	92.3	92.5	0.2
California	81.8	80.0	1.8
District of Columbia	79.6	74.5	5.1

[8] It is important to note that "better" does not mean "exact" because states rely on two types of reported lab tests—those that quantify viral load and those that quantify CD4 counts—to assess linkage to care. Thus, linkage to care rates will generally be somewhat greater than state performance against this viral load reporting standard—even if the state receives the results of every single viral load test performed on state residents living with HIV. However, the different should generally not be too sizeable. Where it is extremely large, this can correctly be read as indicative of less complete—or at least, less timely (this standard includes BOTH timeliness and completeness elements)—laboratory reporting of VL test results to the state.

[9] Linkage to HIV medical care was measured by documentation of at least 1 CD4 or viral load test performed ≤1 month or ≤3 months after diagnosis. Linkage data taken from: Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2014. HIV Surveillance Supplemental Report 2016;21(No. 4). http://www.cdc.gov/hiv/library/reports/surveillance/.

[10] Data for this column come from the table that accompanied this comment: SER Results Summary 2014 Diagnosis Year HICSB_VLS states highlighted

Georgia	84.9	80.7	4.2
Hawaii	90.0	87.9	2.1
Illinois	81.7	78.0	3.7
Indiana	80.6	76.0	3.4
Iowa	93.7	87.5	6.2
Louisiana	82.4	79.8	2.6
Maine	96.4	93.0	3.4
Maryland	82.4	80.1	2.3
Massachusetts	94.0	93.2	0.8
Michigan	85.7	82.8	2.9
Minnesota	87.8	85.4	2.4
Mississippi	93.2	87.1	6.1
Missouri	83.7	82.0	1.7
Nebraska	90.9	65.8	25.1
New Hampshire	90.0	89.5	0.5
New Mexico	92.5	94.0	1.5
New York	87.0	85.3	1.7
North Dakota	81.8	78.3	3.5
Oregon	88.4	87.4	1.0
South Carolina	88.9	86.6	2.3
South Dakota	82.1	80.0	2.1
Tennessee	77.5	74.7	2.8
Texas	82.6	78.0	4.6
Utah	85.1	80.2	4.9
Virginia	80.6	74.0	6.6
Washington	91.5	91.1	0.4
West Virginia	95.5	89.0	6.5
Wisconsin	90.0	87.3	2.7
Wyoming	80.0	72.7	7.3

Relevant Published and Unpublished Analyses

Several published analyses provide additional support for CDC's position that the viral load suppression measure provides valid, reliable information about state performance—at least, when applied to those states whose systems meet CDC's criteria for reporting this measure (in the 2014 CDC report, this group included 32 states and the District of Columbia).

1. **Dixon BE, Siegel JA, Oemig T, Grannis SJ (2013). Electronic Health Information Quality Challenges and Interventions to Improve Public Health Surveillance Data and Practice. *Public Health* Reports 128: 546-553**
   a. With the advent and rapid, widespread adoption of electronic lab reporting, health department surveillance programs now directly receive the same test results as are entered into the patient's medical record. Accordingly, the accuracy of the data health departments receive is equivalent to the so-called "gold standard": the patient's medical record. A more important concern for surveillance systems (and any measures derived therefrom) is completeness: are all labs

performing tests for state residents reporting those results to the state (or local, depending on relevant state and local laws) health department, and are the reported elements sufficiently complete (or, at least, complete enough in the necessary fields to support state health department supplemental data collection efforts (active surveillance follow-up). **In this study of electronic lab reporting in two states (Indiana, Wisconsin), the authors report 98% or greater completeness rates in both states for the following data elements (all of which would directly affect the utility of the lab report for generating new, or updating existing, HIV case records and generating state-level viral load suppression results): patient identifier, patient name, patient date of birth, patient sex, test name, and test results.** In addition, over 90% of reports contained the name of the attending provider, clinic, hospital or other entity submitting the specimen. Given that the authors conducted their study using 2010—when states were still in the midst of creating robust capacity to accept electronic lab reports[11]--the completeness of key lab report fields is likely to have increased. However, even if it had not, the elements that are well-reported provide a starting point for further, active case investigation— and CDC's HIV surveillance standard (which is evaluated against submissions from the state's surveillance systems) ensures that states will perform the necessary supplemental surveillance activities needed to ensure at least 97% of all case records pass data quality checks (including around completeness).

2. **Ocampo JM, Smart JC, Allston A et al. (2016). Improving HIV Surveillance Data for Public Health Action in Washington, DC: A Novel Multiorganizational Data-Sharing Method. *JMIR Public Health Surveill.* 2 (1): e3**

a. A key source of potential bias in the viral load suppression state specific results comes from the denominator: specifically, people living with HIV (PLWH) may move from the state in which they are diagnosed to a new one. If these movements aren't adequately captured in the surveillance systems of the sending and receiving states, the denominator used in the viral load suppression measure will be biased[12]. Not surprisingly, then, as part of the Routine Interstate Duplicate Review (RIDR) process, state surveillance programs work in concert with CDC to identify PLWH who have relocated from or to their state. As the previously referenced state specific 2014 performance rates from CDC demonstrate, the vast majority[13] of states complete their required, semi-annual deduplication process in a timely manner and in accordance with CDC performance standards (i.e., >95% of RIDR pairs resolved within 18 months of the list's

[11] And before additional resources, and requirements, under the meaningful use program and other initiatives propelled additional, rapid uptake across the health system in electronic means of capturing, storing, using, and communicating patient-related data

[12] In particular, consider the case of the sender state: Since the person who moved from that state would no longer receive HIV care in that state, the state would not receive Viral Load monitoring test results associated with that individual's ongoing care. But if the state's surveillance system still (erroneously) recognized that individual as a state resident, he or she will remain in the VLS measure denominator—and lack of VL test data will be interpreted as the individual being out of care and not virally suppressed. The result would be an inaccurate downward bias in calculated state viral load suppression performance.

[13] In 2014, only one state extremely short of the performance threshold, and it is not currently one included in the viral load suppression measure's calculation)

generation). Nevertheless, the process is time and resource (especially labor) intensive, so if inter-state migration rates among PLWH were extremely high on a per annum basis, the potential for the RIDR process to quickly detect and correct for new migrations may be strained, and the risk for measurement bias increased. To date, there have been few published evaluations of interstate migration rates among PLWH—and most aren't recent. **However, the above referenced piece by Ocampo et al. (2016)[14] suggests that overall per annum migration rates are likely to be sufficiently low that, as states have attested in their performance reports to CDC, most of those residency changes are being captured in a reasonable time frame through the RIDR process (and so, not overly biasing the state-specific viral load suppression results calculated by CDC).**

3. **Dombrowski JC, Buskin SE, Bennett A, Thiede H, Golden MR (2014). Use of Multiple Data Sources and Individual Case Investigation to Refine Surveillance-Based Estimates of the HIV Care Continuum. *J Acquir Immune Defic Syndr*. 2014 November 1; 67(3): 323–330.**
    a. This paper, which comes from one of the states that does have complete viral load laboratory reporting, provides important evidence for the reliability and validity of population-level viral load suppression rates calculated from HIV surveillance data. Importantly, because this analysis focused on a single county (Seattle-King County), the findings may be considered conservative, as intrastate migration is more frequent than interstate migration (thus creating an additional challenge for maintenance of accurate, county-level figures of the number of persons living with HIV who are currently residing in that county).

b. In brief, the authors calculated and compared viral load suppression rates from three separate population samples, each of which was constructed from a separate data source: the King County HIV surveillance system[15], a population-based sample of medical charts[16], and persons enrolled in the Medical Monitoring Project[17]. Unadjusted analyses generated the following rates of viral

[14] The focus of the Ocampo et al. (2016) piece is on a new approach to quickly and efficiently performing the RIDR process. However, the results from this paper also provide important insight into inter-state migration of PLWH in a highly mobile portion of the country (DC, MD, and VA) and over an extended period of time.

[15] "Procedures for HIV surveillance in King County are described in detail elsewhere. Briefly, WA State implemented requirements that laboratories report all CD4 count and plasma HIV RNA [viral load (VL)] results to the health department in 2006. In addition to standard surveillance procedures, our public health program staff investigates all CD4 and VL results reports that cannot be linked to a previously reported HIV/AIDS case. This captures in-migration of persons diagnosed with HIV outside of King County. Since 2007, we have investigated all HIV cases with no CD4 or VL results reported to the health department for ≥12 months to ascertain which PLWHA continue to reside in King County and the HIV care engagement status of persons for whom laboratories have reported no results."

[16] "In order to generate additional local estimates of the proportion of PLWHA who are in care, prescribed ART, and virally suppressed, we conducted a chart review of cases randomly selected from all HIV cases recorded in the electronic HIV/AIDS Reporting System (eHARS); this population included persons diagnosed with HIV outside of King County. We attempted to review the medical record of each selected case to ascertain dates of HIV medical visits and CD4 count and VL results. The sampling frame for this effort was designed to be more inclusive than the MMP sample. Table 1 provides details of the populations sampled, sampling methods, and completion rates for each data source."

[17] A CDC-funded supplemental surveillance system. Briefly, states that receive funding for MMP use a 2-stage sampling design to select an appropriate sample of persons from which locally and nationally representative data can be derived. The first stage is selecting geographic areas (within the state) to participate. The second stage is selecting adults diagnosed with HIV within those participating project areas. Trained MMP interviewers and abstractors collect data through interviews and medical record abstraction.

load suppression for the three samples: 70% for population based chart review, 82% from the MMP-derived sample, and 67% for the HIV surveillance-derived sample. However, because the population that is captured by the MMP sample is, by definition, "in care" population[18], the authors also calculated adjusted rates for all three samples—rates that provide a more reasonable, apples to apples comparison. **For those rates, they found no meaningful difference between the viral load suppression rates in each sample: 59% from both chart review and adjusted MMP, and 57% from surveillance.**

4. **Sabharwal CJ, Braunstein SL, Robbins RS, Shephard CW (2014). Optimizing the Use of Surveillance Data for Monitoring the Care Status of Persons Recently Diagnosed With HIV in NYC. *JAIDS* 65(5): 571-578**
   - **a.** This paper provides evidence that "retention in care" measures results, as calculated from the New York City HIV surveillance system, align with those calculated on the basis of data available from medical records (MR). While this paper thus presents results for a different, population-based measure of the HIV care continuum, the results offer a reasonable proxy for the likely performance of the viral load suppression measure (if evaluated under similar circumstances) for the following reasons:
     - **i.** Surveillance based measures use lab results—particularly reported CD4 and viral load test results-- as proxy indicators for receipt of HIV care (i.e., an HIV-care oriented visit with an HIV care providers, as outlined in NQF endorsed measures from HRSA). This proxy approach, which is rooted in current HIV care guidelines[19] (specifically, recommend routine VL monitoring), has been shown to be broadly reliable and valid[20]. If a person living with HIV is fully engaged in and receiving care for his/her HIV infection, he/she should routinely receive HIV viral load test--and, if lab reporting in the state is relatively complete, HIV surveillance programs should receive the same results as provider (via electronic lab reporting).
     - **ii.** Thus, if lab result-based and visit based measures of retention broadly align, this finding indicates that 1) the HIV surveillance program is getting most if not all of same lab test results as provider, and 2) the surveillance system as a whole provides a reasonable and valid proxy measure of population level outcomes (one that would align with a similar measure if calculated from a random sample of the longitudinal medical records of PLWH).

[18] Thus, the alignment between the population chart sample and the HIV surveillance rates—and the statistically significant difference between these values and the one calculated for the MMP sample—can be explicable in terms of systematic biases in the construction of the denominator—at least, in the case of unadjusted values.

[19] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at: https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/0

[20] See for example: Firth CL, Shafer SD, Greene K (2014). Monitoring Retention in Care: Using Multiple Laboratory Tests as an Indicator for HIV Medical Care. *AIDS Care* Vol. 26, No. 12, 1546–1549.

Dean BB, Hart RLD, Buchacz K, Bozzette SA, Wood K, Brooks JT, HOPS Investigators (2015). HIV Laboratory Monitoring Reliably Identifies Persons Engaged in Care. *J Acquir Immune Defic Syndr.* 68 (2): 133–139.

b. Four measures of the establishment of outpatient HIV primary care in the first year were assessed: (1) sustained care (first visit within 3 months; second visit, 3–9 months later), (2) continuous care (2 visits at least 90 days apart), (3) trimester visits (visit in each 4-month period), and (4) visit constancy (visit in each 3-month period). The validity of surveillance data for measuring this outcome was assessed by comparing results for each of the 4 measures calculated using surveillance data to those calculated using MR data[21]. The authors found that, across these four measures of care retention[22], agreement between surveillance based and medical record based estimates ranged from 73% (for visit constancy measure) to 89% (for sustained care). It's worth noting that, **in the case of the two measures most closely aligned with current national HIV treatment recommendations—i.e., the sustained and continuous care measures— percentage agreement was over 85%.**

5. **Unpublished Data from Georgia Department of Health**
   a. Georgia currently receives funding from CDC for several surveillance activities, including HIV case surveillance (the "core" system from which viral load suppression and other HIV care continuum measures are derived) and the Medical Monitoring Project[23]. As previously noted, MMP data are all derived from medical record abstraction and, in the case of behavioral data and other non-medical information, from patient interviews. Because all persons sampled under MMP are "in care" at the time of their interview, it is reasonable to expect that, if a state has complete laboratory reporting (as captured by CDC performance data), then most, if not all, of that person's HIV-related test results will have been reported to, and captured in, the state HIV surveillance system. Thus, for the sample of persons living with HIV who are captured in both eHARS and MMP, viral load suppression rates calculated from the two separate systems should be similar.
   b. The data presented below represent the results of two, complementary analyses. The first, which presents comparative data from eHARS (the HIV surveillance system) and MMP for the 2014 MMP participant group, demonstrates relatively good alignment between viral load suppression results calculated from the two systems. This is to be expected since, in 2014, Georgia met all of CDC's criteria for inclusion in the group of states for which viral load suppression could be reliably and validly calculated.

	MMP	**EHARS**
Not Suppressed (%)	30 (16.8%)	26 (14.5%)

[21] In brief, the author's methods were as follows: "All patients diagnosed with HIV in 2009 at 24 New York City high-volume, HIV diagnostic and treatment facilities who linked to care within 12 months at the same site as defined by the presence of >=1 CD4/VL report received by surveillance were selected for MR review to confirm linkage to outpatient HIV primary care within the first year. All HIV care visit dates were abstracted and considered associated with a surveillance laboratory report, if within 14 days of a care visit."

[22] Measure stringency grows as you move along the continuum from retention measure 1 to retention measure 4. [23] A more detailed description of this supplemental surveillance system is available at: http://www.cdc.gov/hiv/statistics/systems/mmp/index.html

Suppressed (%)	140 (78.2%)	144 (80.4%)
Missing	7	2
Total (N)	179	179

c. The second analysis provides a similar comparison of viral load suppression rates among a cohort of 234 Georgians living with HIV who participated in MMP in 2013 and were captured in eHARS. These data cover a 24 month look back period and so allow us to compare viral load suppression results generated from the two systems for those years—both of which were years during which Georgia's HIV surveillance system did NOT meet the CDC requirements for valid and reliable estimates of viral load suppression. As you can see, performance improves over time, such that, by 2013 (the last year for which Georgia was excluded from CDC's published viral load suppression estimates), the difference is no longer statistically significant.

	eHARS (%)	**MMP (%)**	**p value**
Suppressed - 2013	62.8 [95%CI: 56.5 – 68.8]	67.1 [95%CI: 60.8 – 72.8]	0.0987
Suppressed - 2012	69.7% [95%CI: 63.5 – 75.2]	77.8 [95%CI: 72.0 – 82.7]	**0.0005**

Together, these two analyses from Georgia further support the validity and reliability of CDC's approach to, and calculations of, state viral load suppression rates. Specifically, these measures are likely to be reliable and valid measures of "true" viral load suppression rates when calculated from state HIV surveillance systems that meet CDC's rigorous performance requirements.

Establishing Face Validity at the National Level: Viral Load Suppression as an NHAS Indicator

As part of the process used to develop the National HIV/AIDS Strategy (NHAS): Updated to 2020 (hereafter referred to as the "NHAS Update"), a work group comprised of representatives from agencies within the Department of Health and Human Services was charged with developing recommendations for indicators, measures, and targets to monitor progress toward achieving the NHAS Update goals. The work group established the following criteria for reviewing existing, and developing new, indicators; selecting data sources; and evaluating measures and targets:

Indicators: All indicators were required to have a direct relationship to one or more of the Strategy goals. In addition, each indicator needed to reflect current HIV science, policy, and practice; represent measurable outcomes or impacts rather than processes; and be derived from quantitative data from an appropriate source.

Data Sources: In evaluating data sources, the work group considered favorably those that were nationally representative; provided data on a timely, routine basis; expected that the data would be comparable across years; had data that were amenable to stratification by age, geographic region, race/ethnicity, sex, and transmission category to monitor disparities; and retained sufficient flexibility to adapt definitions, as needed, in response to changes in guidelines or clinical practice. A priority was placed on data sources that would allow States to monitor progress toward Strategy goals in their jurisdictions.

Measures: The measure for each indicator needed to demonstrate face validity, in that it appeared to assess what was intended. In addition, measures needed to be simple and easy to communicate to a range of audiences.

The work group reviewed surveillance data and pertinent published literature and held a technical expert consultation, during which it solicited input on proposed indicators and associated measures from stakeholders representing a broad array of key constituencies, including Federal agencies, academia, clinical care providers, public health agencies, and advocacy groups. Based on this input and information, the work group finalized a set of updated indicators (and associated measures) with ambitious, yet feasible, targets that would inspire action and maintain progress toward meeting the NHAS Update's HIV prevention, treatment, and care outcomes. **Although the proceedings from the technical expert consultation and indicator workgroup meetings are not publicly available, the highly deliberate, iterative, and collaborative process used to identify a final set of NHAS indicators and measures was as rigorous as any Delphi process and should be interpreted as strong support for their face validity.**

Importantly, among the indicators newly proposed and adopted as part of this process was the following: "Increase the percentage of persons with diagnosed HIV-infection who are virally suppressed to at least 80 percent." **To assess national and state progress towards this objective, CDC's Population-Level Viral Load Suppression (VLS) Measure (i.e., the measure currently before the NQF panel) was adopted.** While the workgroup recognized that not all states currently capture and report the data necessary to calculate this measure, they felt the temporary nature of this limitation rendered it acceptable, as the number of states submitting complete viral load and CD4 data to CDC is expected to continue to grow. As of December 2015, all but 6 states now have statutory requirements that all CD4 and viral load (VL) test results be reported to HIV surveillance programs; and among states where these

reporting requirements *are* in place, the vast majority (73%, or 32 states and the District of Columbia) are reporting complete data to CDC[24] (CDC 2016)[25].

[24] Reporting is considered complete if the following criteria are met: 1) laboratories that perform HIV-related testing have reported a minimum of 95% of HIV-related test results to the state or local health department, and 2) the state has reported to CDC at least 95% of all CD4 and viral load test results received during the applicable measurement period.

[25] Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2014. *HIV Surveillance Supplemental Report* 2016; 21(No. 4). http://www.cdc.gov/hiv/library/reports/surveillance/. Published July 2016. Accessed November 2016.

2015 Standards Evaluation Report (SER) and Lab Survey

PART 1. Process and Outcome Standards for Case Surveillance

Process Standards for Case Surveillance

A. Death Ascertainment

☐ We are a separately funded city AND all death ascertainment is done at the state level. (*Skip to section B: Routine Interstate Duplicate Review (RIDR)).*

☐ We are a state, territory, or separately funded city and perform our own death ascertainment. (*Respond to the questions below by completing the tables*).

1. Date of Death. In 2015, did your surveillance program perform record linkage of HIV case reports with the following data sources to identify all deaths occurring in 2014?

NOTE: You are required to link and load into eHARS vital statistics records **AND** the SSDMF				
Death File	**Linked Deaths Through what Date?*** (e.g., March 2013, July 2014, etc.)		**All Results Loaded in eHARS?**	**Results Loaded Manually or Imported?**
☐ Vital statistics	Choose an item.	Choose an item.	☐Yes ☐No	☐ Manually ☐ Imported
AND				
☐ SSDMF	Choose an item.	Choose an item.	☐Yes ☐No	☐ Manually ☐ Imported

*Enter the end date of the most recent file you linked. For example: In 2015, if you linked a vital statistics file that included death records from January 2013 to July 2014, you would respond July 2014.

2. Cause of Death. In 2015, did your surveillance program perform record linkage of HIV case reports with the following data sources?

NOTE: At a minimum, you are required to link and load into eHARS the NDI-Plus (if not prohibited) or, if NDI is prohibited, you are required to link and load a final vital statistics file.					
Death File	**Linked Deaths Through what Date?*** (e.g., July 2012 or if prohibited by law indicate "**Prohibited**")			**All Results Loaded in eHARS?**	**Results Loaded Manually or Imported?**
☐ NDI-Plus	Choose an item.	Choose an item.	☐ Prohibited	☐Yes ☐No	☐ Manually ☐ Imported
☐ Vital statistics - final	Choose an item.	Choose an item.		☐Yes ☐No	☐ Manually ☐ Imported

*Enter the end date of the most recent file you linked. For example: In 2014, if you linked a vital statistics file that included death records from January 2010 to July 2012, you would respond July 2012.

3. HIV cases not reported to eHARS. In 2015, did your surveillance program search all vital records for deaths mentioning HIV-infection and for which there was no previously reported case in eHARS? ☐ Yes ☐ No

☐ No death record linkage was performed in 2015. (*Respond to the items directly below*).

If you did not meet all three standards in 1, 2, and 3 above, please describe:
a. Why you did not meet the minimum standards for death record linkage in 2015. b. Your plan to ensure your program meets this standard in 2016.

B. Routine Interstate Duplicate Review (RIDR)

☐ We are a separately funded city and all RIDR resolution is done at the state level. (*Skip to section C: Laboratory*).

☐ We are a state, territory, or separately funded city, and perform our own RIDR resolution. *(Please complete the table below for the **July 2014** round).*

Please confirm that you have attached the RIDR SAS outcome table to your APR submission. ☐ Yes ☐ No (*Respond to items below*).

In 2015 (within a month of availability), did you import into eHARS the tab delimited text (txt filename extension) file provided with the **RIDR list released in July 2014**, thereby setting the value for duplicate status to "3-Pending"?	☐ Yes ☐ No	
Percent of RIDR pairs resolved by December 31, 2015 for RIDR each list received July 2014: *(Based on CDC-supplied RIDR completion report)*	%	If ≥ 95%, *skip to section C: Laboratory*.
		If <95%, respond to the questions directly below.
If <95% of the pairs on your RIDR list received in July 2014 were not resolved by December 31, 2015, please describe: a. Why you did not completely resolve the RIDR pairs on the July 2015 lists. b. Your plan to ensure your program meets this standard in 2016.		

C. Laboratory

1. **In 2015, did your surveillance program identify the number of laboratories (in state and out of state laboratories) that conducted HIV-related testing for providers and facilities in your jurisdiction?**

☐ Yes
- Number of laboratories? Click here to enter text.

o Please describe how your program obtained this number.
Click here to enter text.

☐ No
- What is the number of HIV-testing laboratories that reported at least one HIV test result to your program during 2015?

o Number of laboratories: Click here to enter text.

2. **Are you aware of any laboratories that conducted HIV-related testing for providers and facilities within your jurisdiction that did not report any results to your program?**

☐ Yes
- Approximately what percentage of your jurisdiction's patients are missing laboratory results because of this? Click here to enter text.

☐ No

3. **Of the laboratories that reported to your program during 2015, are you aware of any laboratories that did not submit all positive/reactive HIV detection test results, all CD4 results (<200 and ≥200), or all viral load results (detectable and undetectable)? For example, Laboratory XYZ usually sends 500 viral load results (both detectable and undetectable) each month. However, during August, undetectable viral load results were not received from Laboratory XYZ.**

☐Yes
- Approximately what percentage of all test results in a given year is typically reported by this laboratory or laboratories? Click here to enter text.
- Approximately what percentage of the test results expected from this laboratory or laboratories in 2015 was not received? Click here to enter text.
- Please describe the expected test results that were not received from this laboratory or laboratories: Click here to enter text.
- After the error was identified, did the laboratory or laboratories report the missing test results during 2015? ☐ Yes ☐ No
- If the laboratory reported the missing test results, were the test results entered into eHARS before the December 2015 data transfer? ☐ Yes ☐ No

☐ No
- In 2015, did your program monitor the quality of incoming reports of laboratory test results (including test result volumes) on a quarterly basis or more frequently? ☐ Yes ☐ No

4. **Did any other issues arise that prevented your program from receiving all CD4 and viral load results performed in 2015? For example, Laboratory XYZ was transmitting CD4 results via ELR but the laboratory reports parsed from the HL7 ELR reader/translator were not sent to the HIV Program.**

☐ Yes

- Estimate the percentage of test results that were missing among all CD4 and viral load results performed in 2015. Click here to enter text.
- Were the issues resolved? ☐ Yes ☐ No
- If the issues were resolved, were the results entered into eHARS before the December 2015 data transfer? ☐ Yes ☐ No

☐ No

5. By December 2015, did your surveillance program transfer to CDC via eHARS all CD4 (< 200 and ≥ 200) and viral load (detectable and undetectable) test results from laboratory reports received from 2013-2015*?

Year reports were received	CD4 results				Viral load results			
	Yes	No	If "no", what % of results received have been transferred to CDC?	Describe type of CD4 results received (e.g., All values, <500, <200)	Yes	No	If "no", what % of results received have been transferred to CDC?	Describe type of viral load results received (e.g., Any result, detectable)
2013	☐	☐	%	Click here to enter text.	☐	☐	%	Click here to enter text.
2014	☐	☐	%	Click here to enter text.	☐	☐	%	Click here to enter text.
2015*	☐	☐	%	Click here to enter text.	☐	☐	%	Click here to enter text.

*At minimum, reports received from January 2015 through September 2015

Outcome Standards for Case Surveillance

NOTE:** All areas **MUST** use the CDC-supplied SAS program against the December 2015 frozen SAS datasets to evaluate and report on your program's outcome standards. **In addition, all SAS table output MUST be attached to your APR submission.

6. Submission of Required SAS Outcome Standard Tables

Please confirm that you have attached the following five SAS outcome table sets to your APR submission. I have attached:

Case ascertainment tables:	☐	Yes	☐	No
Intrastate case duplication rate tables:	☐	Yes	☐	No
Risk factor ascertainment tables:	☐	Yes	☐	No
Completeness of CD4 and VL tables:	☐	Yes	☐	No
Data quality for case surveillance tables:	☐	Yes	☐	No

Measure	Standard	Result	
Completeness of Case Ascertainment	Did your surveillance program ascertain at least (≥) 85% of the expected number of persons newly diagnosed with HIV infection in 2014 by the end of December 2015?	%	
Intrastate Duplicate Review	Were there less than or equal to (≤) 1% duplicate case reports among all (cumulative) cases reported to your surveillance program through December 31, 2014 by the end of December 2015?	%	
Risk Factor Ascertainment	Did at least (≥) 70% of HIV cases newly reported to your surveillance program in 2014 have sufficient risk factor information to be classified into a known HIV transmission category by the end of December 2015?	%	
Completeness of Initial CD4	Did at least (≥) 60% of adults and adolescents newly diagnosed with HIV infection in 2014 have a CD4 count or percent based on a specimen collected within three months following their initial diagnosis, reported by the end of December 2015?	%	
Completeness of Initial Viral Load	Did at least (≥) 60% of adults and adolescents newly diagnosed with HIV infection in 2014 have a viral load based on a specimen collected within three months following their initial diagnosis reported by the end of December 2015?	%	
Data Quality	In 2015, did 97% of case records pass all selected data edits? That is, did 97% of cases contain no errors?	%	
		Yes	**No**
Data Reporting and Dissemination	In 2015, did you develop and disseminate a comprehensive revision of your integrated HIV Epidemiologic Profile?	☐	☐
	In 2015, did you develop and disseminate Updates to the HIV Epidemiologic Profile in the form of updates to core epidemiologic tables and figures, fact sheets, supplemental reports, slide sets, or other publications (but not a comprehensive revision)?	☐	☐
	In 2015, did you develop and disseminate An annual HIV surveillance report?	☐	☐
Security and Confidentiality	Has your program submitted a document (signed by the ORP) certifying that in 2015 your program was in full compliance with the *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action (2011)*?	☐	☐
	In 2015, did all persons with access to any HIV surveillance data (including all IT personnel with access to eHARS or other HIV surveillance databases) complete an annual security and confidentiality training and sign a confidentiality statement?	☐	☐
	Did your program conduct the required annual review of your written security and confidentiality policies and procedures to assess whether changes in legislation, technology, or priorities, personnel, or other situations require changes in policies and procedures?	☐	☐
	While under FOA PS13-1302 has your program completed (or participated in the completion of) an initial assessment across	☐	☐

	relevant programs to identify policy and environmental needs for implementing the *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action (2011)*?		

PART 2. Process and Outcome Standards for HIV Incidence Surveillance (HIS)
(Only for Areas Conducting HIS)

Please indicate if you used HIS funds only, case surveillance funds only, or both HIS and case surveillance funds to conduct HIS activities for 2015.

☐ HIS funds only ☐ Case funds only ☐ Both HIS and case funds

NOTE: *All areas* ***MUST*** *use the CDC-supplied SAS program against the December 2014 frozen SAS datasets to evaluate and report your program's testing treatment history (TTH) and serologic testing algorithm for recent HIV seroconversion (STARHS) result completeness.* ***Please confirm that you have attached****:*

Incidence Completeness Report: ☐ Yes ☐ No. (*Respond to items below*).
Incidence Data Quality Report: ☐ Yes ☐ No. (*Respond to items below*).

Measure	**Standard**	**Result**	
		Yes	**No**
Completeness of Testing and Treatment History (TTH)	For cases diagnosed in 2014, did at least (≥) 85% have testing and treatment history (TTH) data entered in eHARS by the end of December 2015 (see line 10 of the Incidence Completeness Report)?	%	
Completeness of STARHS Result	For cases diagnosed in 2014 (excluding AIDS cases diagnosed within 6 months), did at least (≥) 60% have a valid STARHS result from a specimen that was collected within 3 months of HIV diagnosis entered by the end of December 2015 (see line 14 of the Incidence Completeness Report)?	%	
Data Quality	In 2014, did 97% of case records pass all selected data edits related to HIS data (see line 3 of the Incidence Data Quality Report)?	%	
Measure	**Process**	**Yes**	**No**
Data Transfer	In 2015, did your program successfully transfer quarterly HIV incidence data to CDC by the 15th of January, April, July and October	☐	☐

OPTIONAL ACTIVITIES

PART 3. Molecular HIV Surveillance (MHS)

(Only for Areas Conducting MHS)

Please indicate if you used MHS funds only, case surveillance funds only, or both MHS and case surveillance funds to conduct MHS activities for 2015.

☐ MHS funds only ☐ Case funds only ☐ Both MHS and case funds

Process Measures for MHS Surveillance

Process	Result	
	Yes	No
In 2015, did your program identify all laboratories that conduct HIV genotypic testing?	☐	☐
In 2015, did your program establish or improve processes for receiving HIV nucleotide sequence data from laboratories?	☐	☐
In 2015, did your program validate HIV nucleotide sequence data received from laboratories?	☐	☐
In 2015, did your program routinely import HIV nucleotide sequence data into eHARS?	☐	☐
In 2015, did your program establish or improve processes to collect ARV use history data for all persons newly diagnosed with HIV infection?	☐	☐
In 2015, did your program successfully transfer molecular HIV surveillance data quarterly to CDC via SDN/SAMS?	☐	☐

Outcome Standards for MHS Surveillance

HIV nucleotide sequence data completeness and antiretroviral (ARV) use history data completeness should be assessed using molecular HIV surveillance data entered through December 31, 2015 and the SAS program provided by CDC.

Please confirm that you have attached the MHS SAS outcome table to your APR submission.

☐ Yes ☐ No

Measure	Standard	Result
Completeness of Initial NIV Nucleotide Sequence	For cases diagnosed in 2014, did at least (≥) 50% of newly diagnosed persons have an initial HIV nucleotide sequence (i.e., obtained from a specimen collected for HIV genotype [resistance] testing within 3 calendar months following HIV diagnosis) in eHARS by the end of December, 2015?	%
Completeness of ARV Use History	For cases diagnosed in 2013, did at least (≥) 85% of newly diagnosed persons with an initial HIV nucleotide sequence have ARV use data in eHARS by the end of December 2015?	%

PART 4. Perinatal HIV Exposure Surveillance

(Only for Areas that Conducted PHERS)

Please indicate if you used case surveillance funds to conduct Perinatal HIV Exposure Surveillance for 2015. ☐ Yes ☐ No

Process	Result	
	Yes	No
In 2015, did your program conduct active and passive surveillance on perinatal HIV exposure, including medical record review for opportunistic infections, adverse outcomes of ARV exposure, and linkage to birth registries?	☐	☐
In 2015, did your program conduct active and passive surveillance on HIV-infected women?	☐	☐

PART 5. Geocoding and Data Linkage (GDL)

(Only for Areas that Conducted GDL Activities)

Please indicate if you used case surveillance funds to conduct Geocoding and Data Linkage activities for 2015. ☐ Yes ☐ No

Process	Result	
	Yes	No
Did your program collect HIV surveillance information according to routine surveillance procedures, including local street address, city, and state of residence at diagnosis, for each newly diagnosed HIV case?	☐	☐
Did your program have a Memorandum of Agreement (MOA) for the 5-year funding period in place?	☐	☐
Did your program apply geocoding standards provided by CDC, including cleaning and standardizing the data and the collection of variables derived from the geocoding process?	☐	☐
Did your program geocode, to the census tract level, residence at HIV disease diagnosis information for cases diagnosed in 2015 per CDC guidance?	☐	☐
Did your program report data to CDC?	☐	☐

	Death Ascertainment*		Case Outcome Measures*											Incidence*			MHS*	
														TTH	STARHS	Data	Nucleotide Sequence	ARV
	Last Vital Statistics Year Matched	Vital Statistics Result Loaded in eHARS	Completeness Case Ascertainment	Completeness Measure (CR=capture/recapture, RD=reporting delay)	Timeliness	Data Quality	Risk Factor Ascertainment	Intrastate Duplicate Review	RIDR List January	RIDR List August	Initial CD4	Initial Viral Load	Disseminated Epi Profile or Annual Surveillance Report	Testing and Treatment History Entered for Incidence Cases	Cases with Valid STARHS Result from Specimen collected ≤3 months of HIV Dx	Data Quality	Cases with an HIV Nucleotide Sequence from Genotype Testing from Specimen collected ≤3 months of HIV Diagnosis	Cases with an initial sequence that had ARV use history data
Standard	**Dec 2014**	**Yes**	**≥85%**	**NA**	**≥85%**	**≥97%**	**≥70%**	**≤1%**	**≥95%**	**≥95%**	**≥60%**	**≥60%**	**Yes**	**≥85%**	**≥60%**	**≥97%**	**≥50%**	**≥85%**
	1		**2**		**3**	**4**	**5**	**6**	**7**		**8**	**9**	**10**	**1**	**2**	**3**	**1**	**2**
AK	Dec 14	Yes	100	RD	97.5	100	97.6	0.0	100	94.7	90.0	92.5	Yes					
AL	Dec 14	Yes	95.0	RD	86.8	99.7	71.9	0.0	100	100	81.7	82.0	Yes	94.8	50.7	99.1	29.5	99.1
AR	Dec 14	Yes	98.5	CR	94.0	100	81.8	0.0	100	100	62.7	56.1	Yes					
AZ	Dec 15	Yes	98.7	RD	97.2	99.7	88.7	0.0	80.3	99.7	78.5	80.9	Yes	96.6	49.8	98.9	10.4	69.2
CA-LAC	Dec 14	Yes	99.4	CR	86.2	100	77.8	0.0	100	100	74.2	76.6	Yes	95.0	19.1	94.3	58.7	96.9
CA-SF	Dec 15	Yes	99.0	CR	95.5	100	96.6	0.0	100	100	88.1	89.9	Yes	99.1	66.3	99.5	48.6	100
CA-XLAC/SF	Dec 14	Yes	96.5	CR	90.0	99.8	87.9	0.0	100	99.1	78.4	76.7	Yes	93.8	17.4	98.6	26.6	91.0
CO	Nov 15	Yes	97.3	RD	96.7	100	87.2	0.0	99.7	100	91.0	93.1	Yes	99.8	63.3	99.3	18.9	100
CT	Dec 14	Yes	95.2	RD	92.5	100	90.7	0.0	100	100	79.9	88.6	Yes	95.7	47.6	100	59.3	97.8
DC	Dec 14	Yes	88.2	RD	74.2	99.5	67.4	0.1	96.4	97.2	72.0	74.5	Yes	96.8	30.5	97.9	16.5	98.0
DE	Jun 15	Yes	96.5	CR	94.0	99.1	91.4	0.0	98.4	100	80.7	78.9	Yes					
FL	Dec 14	Yes	99.9	CR	97.0	100	93.7	0.0	100	100	72.4	77.5	Yes	99.3	28.2	92.1	26.3	99.2
GA	Jun 15	Yes	99.7	CR	95.2	86.1	60.2	0.0	97.0	96.2	78.3	80.7	Yes					
HI	Dec 15	No	98.7	CR	85.8	100	86.7	0.0	99.7	100	84.8	87.9	Yes					
IA	Dec 14	Yes	99.3	CR	99.3	100	88.9	0.0	100	100	82.3	87.5	Yes					
ID	Dec 14	Yes	96.8	RD	96.8	95.2	72.2	0.0	100	100	90.5	76.2	Yes				0	0
IL-Chicago	NA	NA	95.6	CR	87.0	99.4	87.4	0.0	NA	NA	75.5	79.3	Yes	92.2	38.4	97.8		
IL-Xchicago	Nov 15	Yes	98.3	CR	93.3	95.6	79.6	0.0	98.4	99.8	74.3	77.7	Yes				20.6	79.3
IN	Dec 14	Yes	99.8	CR	98.5	100	87.9	0.1	100	100	71.6	76.0	Yes	78.4	21.4	97.2		
KS	Oct 14	Yes	100	CR	98.5	100	81.7	0.0	100	99.3	78.8	87.9	Yes					
KY	Dec 15	Yes	97.8	CR	88.9	99.7	67.5	0.0	100	100	75.1	79.8	Yes					
LA	Aug 15	Yes	98.5	CR	95.2	99.9	75.3	0.0	100	100	79.8	79.8	Yes	93.1	42.3	98.5	44.1	99.8
MA	Dec 14	Yes	99.8	CR	73.6	100	78.7	0.0	99.9	100	89.9	93.2	Yes	94.2	31.3	97.3		

MD	Dec 14	Yes	96.6	RD	93.4	97.1	81.7	0.0	99.8	100	72.4	80.1	Yes				25.6	53.4
ME	Dec 14	Yes	97.3	RD	95.6	98.3	85.2	0.0	94.1	90.9	89.5	93.0	Yes					
MS	Apr 15	Yes	99.6	RD	97.9	99.8	83.8	0.1	97.6	99.1	84.4	87.1	Yes	86.8	69.5	99.4		
MN	Dec 15	Yes	96.7	RD	93.3	98.1	76.3	0.0	100	100	81.6	85.4	Yes					
MO	Dec 14	Yes	97.8	RD	97.2	100	89.7	0.0	100	100	71.0	82.0	Yes					
MI	Dec 15	Yes	99.6	CR	98.5	99.4	84.1	0.0	100	100	78.8	82.8	Yes	93.1	81.9	99.7	59.9	91.1
MT	Dec 14	Yes	100	RD	100	100	88.2	0.0	98.1	100	100	100	Yes				0	0
NC	Dec 14	Yes	98.3	RD	97.3	100	75.3	0.0	96.8	100	72.0	77.2	Yes	93.5	56.1	100		
ND	Nov 15	Yes	100	100	73.9	100	68.0	0.0	100	100	73.9	78.3	Yes					
NE	Nov 15	Yes	100	RD	98.9	100	87.4	0.0	96.7	98.4	69.7	65.8	Yes					
NH	Dec 15	Yes	92.9	RD	75.8	100	85.7	0.0	100	100	76.3	89.5	Yes					
NJ	Dec 14	Yes	98.5	CR	94.9	94.0	65.5	0.0	97.2	97.4	71.5	82.1	Yes	83.2	20.6	97.4		
NM	Sep 15	Yes	99.5	CR	99.5	99.2	89.3	0.0	96.3	97.1	92.4	94.0	Yes					
NV	Dec 15	Yes	99.5	CR	98.2	99.7	86.8	0.0	100	100	92.1	93.4	Yes					
NY-NYC	Dec 15	Yes	100	CR	97.2	100	84.6	0.3	99.9	99.9	84.7	85.3	Yes	62.9	47.6	99.9	46.8	57.3
NY-XNYC	Dec 14	Yes	99.8	CR	92.8	97.7	80.0	0.0	99.9	99.9	84.1	85.3	Yes	85.5	56.4	99.9	57.4	89.3
OH	Dec 14	Yes	99.9	CR	97.5	98.8	78.5	0.0	100	100	52.6	64.0	Yes					
OK	Dec 15	Yes	99.6	CR	97.9	100	85.9	0.0	100	100	50.2	71.3	Yes					
OR	May 15	Yes	89.7	RD	88.5	100	86.0	0.0	100	99.4	85.3	87.4	Yes				27.7	100
PA-PHIL	Sep 15	Yes	99.5	CR	97.0	100	99.5	0.0	57.4	71.0	79.9	77.1	Yes	97.7	62.7	99.0	44.4	98.6
PA-XPHIL	Dec 14	Yes	91.8	RD	90.2	100	96.0	0.0	99.2	99.5	49.5	76.8	Yes					
RI	Dec 14	Yes	82.8	RD	81.9	98.0	85.7	0.0	98.2	95.1	71.0	96.0	Yes					
SC	Dec 14	Yes	97.7	RD	96.5	98.0	77.4	0.0	99.8	100	84.6	86.6	Yes	93.6	61.7	99.9	39.0	98.7
SD	Jun 15	Yes	100	RD	96.7	100	96.7	0.0	97.1	100	50.0	80.0	Yes					
TN	Dec 14	Yes	95.6	CR	92.8	100	88.3	0.0	100	100	55.3	74.7	Yes					
TX-H	NA	NA	97.2	RD	96.3	99.6	77.5	0.0	NA	NA	77.4	77.6	Yes	99.3	43.8	99.0	43.1	96.9
TX-XH	Dec 14	Yes	95.8	RD	94.8	99.8	80.0	0.0	99.6	99.2	81.7	79.4	Yes	93.7	58.2	99.1	41.7	91.0
UT	Dec 14	Yes	100	RD	100	97.4	77.9	0.0	99.4	98.0	71.6	80.2	Yes				11.2	100
VA	Dec 14	Yes	99.3	CR	97.9	100	79.6	0.0	99.6	98.3	70.0	74.0	Yes	99.8	57.1	100	32.9	99.1
VT	Jan 15	Yes	78.5	RD	78.5	100	69.2	0.0	98.5	100	64.7	88.2	Yes					
WA	Sep 15	Yes	98.5	CR	96.3	99.8	83.0	0.0	100	99.7	89.7	91.1	Yes	83.0	32.3	99.7	44.9	86.8
WI	Dec 14	Yes	99.0	CR	97.2	100	82.3	0.0	99.1	100	86.8	87.3	Yes				6.3	17.6
WV	Jun 15	Yes	99.5	CR	95.1	100	86.3	0.1	100	100	73.6	89.0	Yes					
WY	Oct 15	Yes	100	RD	100	100	81.3	0.0	96.4	100	72.7	72.7	Yes					
PR	Dec 14	Yes	88.8	CR	69.9	100	89.9	0.0	100	99.7	65.3	63.0	Yes				0	66.2
VI	Sep 14	Yes	100	RD	100	100	70.4	0.1	100	100	78.9	84.2	Yes					

* Red value indicates the jurisdiction did not meet the standard

HEALTHCARE COST AND UTILIZATION PROJECT

Agency for Healthcare Research and Quality

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Characteristics of Hospital Stays Involving Malnutrition, 2013

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Introduction

Undernutrition is a form of malnutrition characterized by a lack of adequate calories, protein, or other nutrients needed for tissue maintenance and repair.[1] Malnutrition (undernutrition) occurs among approximately 3 percent of adult hospital inpatient stays in the United States and is associated with increased morbidity, mortality, and health care costs.[2] Adult hospitalizations with a diagnosis of malnutrition have a longer length of stay, higher costs, more comorbidities, and 5 times the likelihood of death, compared with other adult hospital stays.[3]

Evidence suggests that early nutritional intervention may reduce complication rates, mortality, and resource use associated with malnutrition. However, many cases of malnutrition are unrecognized and untreated.[4] Clinical definitions of malnutrition and the set of diagnostic codes used to identify malnutrition in hospital administrative data have varied.[5] Standardizing definitions and treatment protocols for malnutrition is complicated by the fact that its etiology is heterogeneous. Malnutrition may result from chronic starvation and conditions such as anorexia, but it also may be a consequence of acute and chronic illness or injury.[6,7] Using a consistent set of diagnostic criteria and understanding the diseases that are associated with malnutrition are important for recognizing and treating malnutrition, as well as tracking its incidence, prevalence, and outcomes.[8]

[1] White JV, Guenter P, Jensen G, Malone A, Schofield M, Academy Malnutrition Work Group, et al. Consensus statement: Academy of Nutrition and Dietetics and American Society for Parenteral and Enteral Nutrition: characteristics recommended for the identification and documentation of adult malnutrition (undernutrition). Journal of Parenteral and Enteral Nutrition. 2012:36(3):275–83.
[2] Corkins MR, Guenter P, DiMaria-Ghalili RA, Jensen GL, Malone A, Miller S, et al. Malnutrition diagnoses in hospitalized patients: United States, 2010. Journal of Parenteral and Enteral Nutrition. 2014;38(2):186–95.
[3] Ibid.
[4] Tappenden KA, Quatrara B, Parkhurst ML, Malone AM, Fanjiang G, Ziegler TR. Critical role of nutrition in improving quality of care: an interdisciplinary call to action to address adult hospital malnutrition. Journal of the Academy of Nutrition and Dietetics. 2013;113(9):1219–37.

Highlights

- In 2013, there were nearly 2 million hospital inpatient stays involving malnutrition. The most common type was protein-calorie malnutrition (63.9 percent of all malnutrition stays), accounting for 4.5 percent of all inpatient stays and 9.1 percent of aggregate costs (nonmaternal and nonneonatal only).
- Other malnutrition-related stays were for weight loss or failure to thrive (21.6 percent of all malnutrition stays), cachexia (8.3 percent), underweight (4.4 percent), postsurgical nonabsorption (1.7 percent), and nutritional neglect (0.1 percent).
- Patients with malnutrition tended to be older (especially 85 years or older), black, and from low income and rural areas.
- Compared with other types of malnutrition, in-hospital mortality was higher for stays with cachexia (11.7 percent died in the hospital) and protein-calorie malnutrition (8.4 percent)—4 to 5 times the in-hospital death rate of all nonmaternal, nonneonatal stays (2.4 percent).
- Average hospital costs were higher for stays involving protein-calorie malnutrition ($25,200) and postsurgical nonabsorption ($23,000) than for other malnutrition stays.
- Principal diagnoses varied by type of malnutrition: medical, surgical, or device complications were common for postsurgical nonabsorption; injuries and conditions due to external causes were common for nutritional neglect. Septicemia was common among all types of malnutrition.

[5] White et al., 2012. Op. cit.
[6] Lean M, Wiseman M. Malnutrition in hospitals. BMJ. 2008;336(7639):290.
[7] White et al., 2012. Op. cit.
[8] Ibid.

This Healthcare Cost and Utilization Project (HCUP) Statistical Brief presents national estimates on the characteristics of malnutrition reported during nonmaternal and nonneonatal hospital inpatient stays in 2013. Although malnutrition can include high caloric intake associated with overweight and obesity when defined broadly as nutritional imbalance, this Statistical Brief examines undernutrition only.

Malnutrition was identified using a broad set of diagnostic codes that included the following six categories:

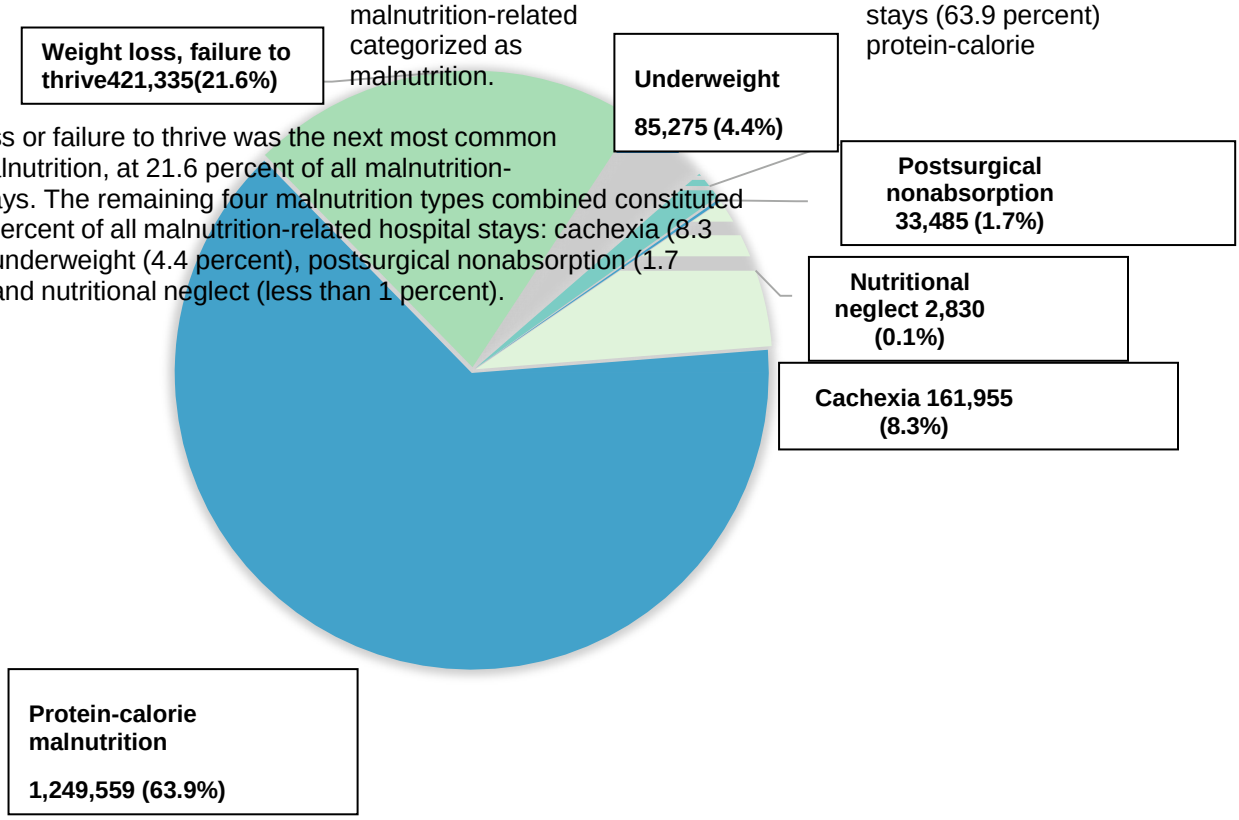
- Postsurgical nonabsorption
- Nutritional neglect
- Cachexia
- Protein-calorie malnutrition
- Weight loss or failure to thrive
- Underweight.

This Statistical Brief presents the frequency of occurrence of the six types of malnutrition. Patient-level characteristics, admission and discharge characteristics, and outcomes for malnutrition-related stays are provided by malnutrition type. Finally, the most common primary conditions and specific principal diagnoses are presented for the different types of malnutrition-related stays. Differences in estimates of 10 percent or greater are noted in the text.

Findings

Hospital stays involving malnutrition, 2013
Figure 1 provides the distribution of six types of malnutrition among hospital inpatient stays in 2013.

Figure 1. Types of malnutrition among hospital stays with malnutrition, 2013



Source: Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample (NIS), 2013

- **Protein-calorie malnutrition was the most common type of malnutrition among hospital inpatient stays.**

In 2013, there were 1.95 million hospital stays that involved malnutrition, representing 7.1 percent of the 27.6 million total nonmaternal and nonneonatal stays (data not shown). Approximately 1.25 million malnutrition-related stays (63.9 percent) were categorized as protein-calorie malnutrition.

Weight loss or failure to thrive was the next most common type of malnutrition, at 21.6 percent of all malnutrition-related stays. The remaining four malnutrition types combined constituted about 15 percent of all malnutrition-related hospital stays: cachexia (8.3 percent), underweight (4.4 percent), postsurgical nonabsorption (1.7 percent), and nutritional neglect (less than 1 percent).

Characteristics and outcomes of hospital stays involving malnutrition, 2013
Table 1 provides characteristics of malnutrition-related hospital stays by type of malnutrition in 2013.

Table 1. Characteristics of hospital stays with malnutrition by malnutrition type, 2013

Characteristic	Postsurgical nonabsorption	Nutritional neglect	Cachexia	Protein-calorie malnutrition	Weight loss, failure to thrive	Under-weight
Total number	**33,485**	**2,830**	**161,955**	**1,249,559**	**421,335**	**85,275**
Rate per 100,000 population	**10.6**	**0.9**	**51.2**	**395.3**	**133.3**	**27.0**
Age, mean years	47.1	47.5	68.3	66.9	59.7	65.0
Age, years, rate per 100,000 population						
<18	8.8	1.4	1.3	21.1	88.2	3.8
18–39	3.8	0.1	8.6	88.4	25.0	10.3
40–64	13.1	0.4	51.6	378.9	87.9	21.8
65–84	22.7	2.4	181.1	1,439.3	415.0	84.8
85+	17.8	6.6	524.0	3,612.8	1,412.7	308.1
Sex, rate per 100,000 population						
Male	7.8	0.8	53.4	383.2	131.3	19.7
Female	13.3	1.0	49.5	410.0	136.2	34.2
Race/ethnicity, rate per 100,000 population						
White	10.9	0.7	51.7	419.9	135.7	29.1
Black	11.3	1.7	73.7	450.8	157.0	31.5
Hispanic	5.5	0.5	21.8	174.7	69.5	9.2
Other	6.8	0.6	47.8	331.0	118.6	24.1
Community-level income, rate per 100,000 population						
Quartile 1 (lowest)	11.2	1.5	65.5	493.7	162.6	34.6
Quartile 2	11.5	1.0	50.8	423.4	138.0	28.0
Quartile 3	10.6	0.6	43.4	350.9	117.0	22.7
Quartile 4 (highest)	8.3	0.4	40.3	285.3	106.7	20.9
Location of residence, rate per 100,000 population						
Large central metropolitan	9.9	0.9	56.5	389.2	128.7	26.4
Large fringe metropolitan (suburbs)	10.5	0.7	48.0	348.7	133.0	25.7
Medium/small metropolitan	10.8	0.9	46.7	397.5	128.4	26.1
Micropolitan/noncore (rural)	11.8	1.0	52.4	469.9	149.6	31.3

Source: Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample (NIS), 2013

- **On average, patients with cachexia, protein-calorie malnutrition, and underweight were older, whereas patients with postsurgical nonabsorption and nutritional neglect tended to be younger.**

The mean patient age among malnutrition-related hospital stays was highest for stays involving cachexia (68.3 years), protein-calorie malnutrition (66.9 years), and underweight (65.0 years). Mean patient age was approximately 20 years younger for malnutrition-related stays involving postsurgical nonabsorption (47.1 years) and nutritional neglect (47.5 years).

The rate of hospitalization was highest for patients aged 65 years and older across all six types of malnutrition. Furthermore, the hospitalization rate for patients aged 85 years and older was 2.5–3.5

times higher than for patients aged 65–84 years for all types of malnutrition except postsurgical nonabsorption. For example, among patients aged 85+ years, there were 3,613 hospital stays per 100,000 population for protein-calorie malnutrition compared with 1,439 stays per 100,000 among those aged 65–84 years. A similar pattern was seen for weight loss, failure to thrive—1,413 stays per 100,000 for those aged 85 years and older compared with 415 per 100,000 among 65–84 year olds.

- **Blacks had the highest rate of hospitalization involving malnutrition-related stays, and Hispanics had the lowest rate.**

Across all six types of malnutrition-related hospital stays, Blacks had the highest hospitalization rate, Whites had the next highest rate, and Hispanics had the lowest rate. For example, for the most common type of malnutrition (protein-calorie malnutrition), there were 451 stays per 100,000 population among Blacks compared with 175 stays per 100,000 population among Hispanics.

- **The rate of malnutrition-related hospital stays was highest for the lowest-income communities.**

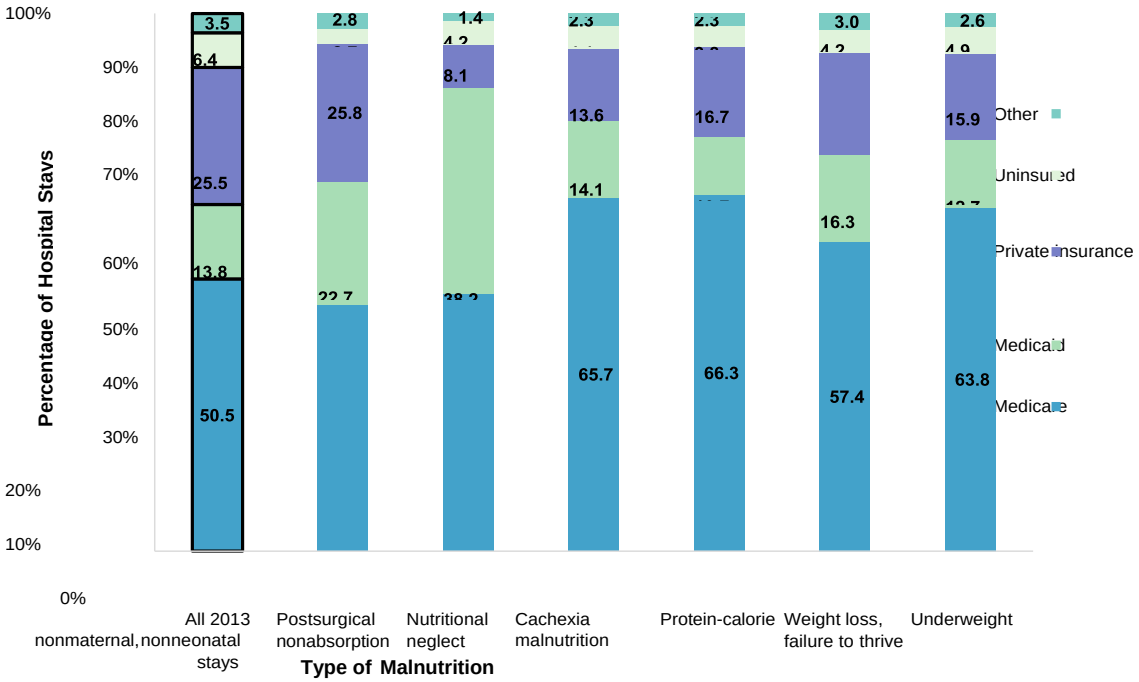
Across all six types of malnutrition-related hospital stays, the rate of hospitalization was generally highest in low-income communities and decreased progressively with increases in community income level. Again, focusing on the most common type of malnutrition (protein-calorie malnutrition), there were 494 hospital stays per 100,000 population in the lowest-income communities (quartile 1) compared with 285 stays per 100,000 in the highest-income communities (quartile 4).

- **For most types of malnutrition, the highest rate of hospitalization was in rural areas.**

Patients from rural areas tended to be hospitalized with malnutrition at a higher rate than did those from more populated areas. For example, among patients with protein-calorie malnutrition, there were 470 hospital stays per 100,000 population for rural patients compared with 349 stays per 100,000 for patients from suburban areas.

Figure 2 provides the expected payer distribution of malnutrition-related hospital stays by type of malnutrition in 2013. For reference, the distribution of all 2013 nonmaternal, nonneonatal stays also is provided.

Figure 2. Distribution of expected payer across hospital stays with malnutrition by malnutrition type, 2013



Source: Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample (NIS), 2013

- **Medicaid was the expected payer for a disproportionate share of malnutrition stays involving postsurgical nonabsorption and nutritional neglect; Medicare was the expected payer for a disproportionate share of other types of malnutrition-related stays.**

Compared with all nonmaternal, nonneonatal hospital stays in 2013, a higher proportion of stays involving postsurgical nonabsorption or nutritional neglect had an expected primary payer of Medicaid (22.7 and 38.2 percent, respectively, vs. 13.8 percent for all stays). Among the other four types of malnutrition-related stays, between 57.4 and 66.3 percent of stays had an expected primary payer of Medicare compared with only half of all nonmaternal, nonneonatal stays (50.5 percent).

Table 2 provides admission and discharge characteristics and outcomes for malnutrition-related hospital stays by malnutrition type, in 2013.

Table 2. Admission and discharge characteristics and outcomes for hospital stays involving malnutrition by malnutrition type, 2013

Characteristic or outcome	Postsurgical nonabsorption	Nutritional neglect	Cachexia	Protein-calorie malnutrition	Weight loss, failure to thrive	Under-weight
Total number	**33,485**	**2,830**	**161,955**	**1,249,559**	**421,335**	**85,275**
Admission, %						
Malnutrition diagnosis present on admission	84.1	88.0	88.6	80.2	88.5	—[a]
Malnutrition listed as secondary diagnosis only	93.8	82.5	99.9	99.4	96.8	100.0
Elective admission	15.2	5.8	7.5	11.7	13.1	12.4
Received emergency department services	60.9	70.0	76.6	68.8	65.9	71.4
Discharge status, %						
Routine discharge	53.1	39.9	31.2	29.0	47.5	48.5
Transfer to another acute care hospital	2.8	3.7	2.6	3.1	2.6	1.9
Transfer to another facility[b]	13.8	41.0	31.2	38.5	27.8	26.2
Home health care	27.2	10.4	21.8	20.2	16.7	18.3
Against medical advice	0.7	0.9	1.3	0.7	0.7	1.3
Died during hospital stay	2.3	3.9	11.7	8.4	4.5	3.7
Outcome						
Length of stay, mean days	9.6	9.2	7.5	10.7	6.5	6.0
Hospital costs, mean $	23,000	14,700	16,200	25,200	14,100	12,100
Aggregate hospital costs, mean $ millions	770	42	2,627	31,465	5,945	1,034
Receipt of enteral/parenteral nutrition, %						
Received enteral nutrition	5.1	3.2	3.1	4.7	3.8	1.8
Received parenteral nutrition	28.7	1.6	2.4	6.6	2.0	1.2

[a] Because two frequent codes in the underweight malnutrition type (V85.0 and V85.51) are exempt from present-on-admission reporting, this information is not reported.

[b] Includes transfer to a skilled nursing facility, intermediate care facility, or another type of health care facility.

Source: Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample (NIS), 2013

- **Malnutrition was present on admission and was reported as a secondary diagnosis for the majority of malnutrition-related hospital stays.**

Malnutrition was identified as present on admission for more than 80 percent of hospital stays involving malnutrition across all types of malnutrition except underweight.[9] (For this condition, several diagnostic codes are exempt from present-on-admission reporting.) Malnutrition also was much more likely to be reported as a secondary than as a principal diagnosis, ranging from 82.5 percent of stays involving nutritional neglect to 100.0 percent of stays with underweight diagnoses.

[9] Only 28.3 percent of stays with underweight diagnoses were reported as present on admission. However, the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) V codes for body mass index that are part of the underweight malnutrition type (V85.0 and V85.51) are exempt from present-on-admission reporting.

- **Hospital stays involving malnutrition accounted for over 12 percent of aggregate hospital costs among nonmaternal and nonneonatal stays in 2013.**

In 2013, the aggregate cost of all nonmaternal and nonneonatal stays was $346.1 billion (data not shown). Hospital stays involving malnutrition accounted for nearly $42 billion, or 12.1 percent of aggregate nonmaternal, nonneonatal hospital costs. In contrast, as described earlier, hospital stays involving malnutrition constituted only 7.1 percent of all nonmaternal and nonneonatal hospital stays in 2013.

- **Hospitals stays involving malnutrition were discharged to home less often compared with all nonmaternal, nonneonatal stays.**

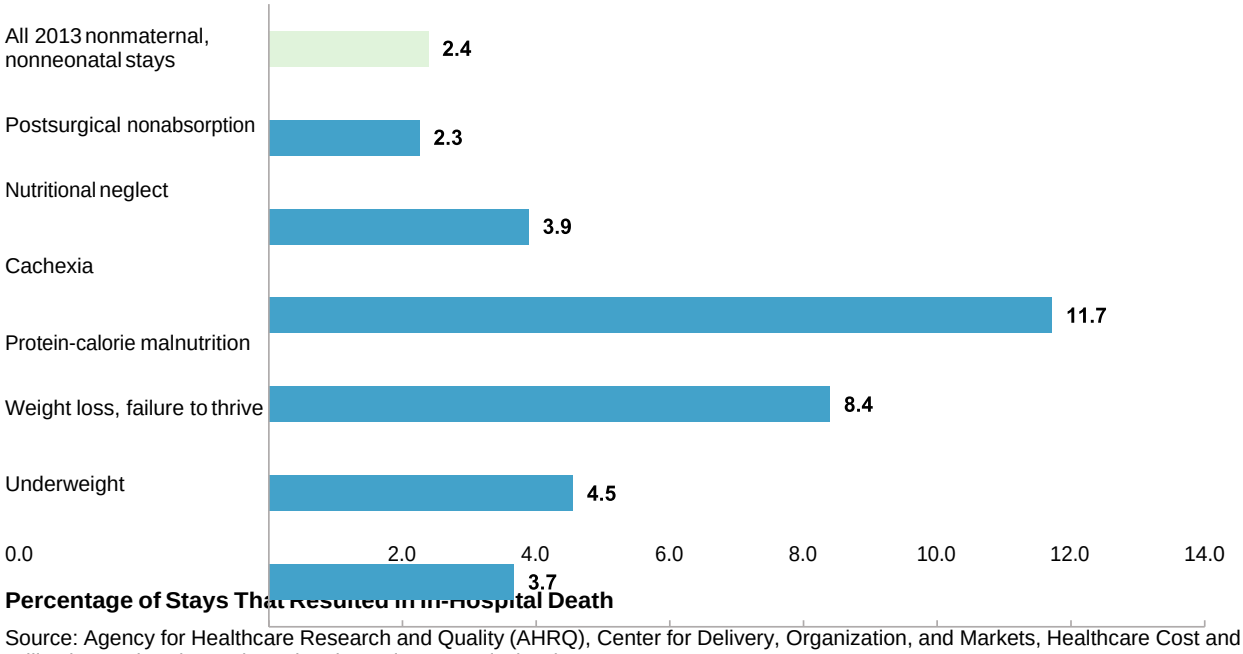
Compared with all nonmaternal, nonneonatal hospital stays in 2013, a lower proportion of stays across all six types of malnutrition had a routine discharge (ranging from a low of 31.2 percent for cachexia to a high of 53.1 percent for postsurgical nonabsorption, vs. 62.5 percent for all nonmaternal, nonneonatal stays, data not shown).

- **Very few malnutrition-related stays included enteral or parenteral nutrition services.**

With one exception, fewer than 7 percent of malnutrition-related stays, across malnutrition types, included coding of enteral or parenteral nutrition services. Parenteral nutrition was coded during 28.7 percent of stays involving postsurgical nonabsorption.

Figure 3 presents information on in-hospital deaths by type of malnutrition in 2013. For reference, the proportion of in-hospital deaths among all nonmaternal, nonneonatal hospital stays also is provided.

Figure 3. Percentage of stays that resulted in in-hospital death by malnutrition type, 2013



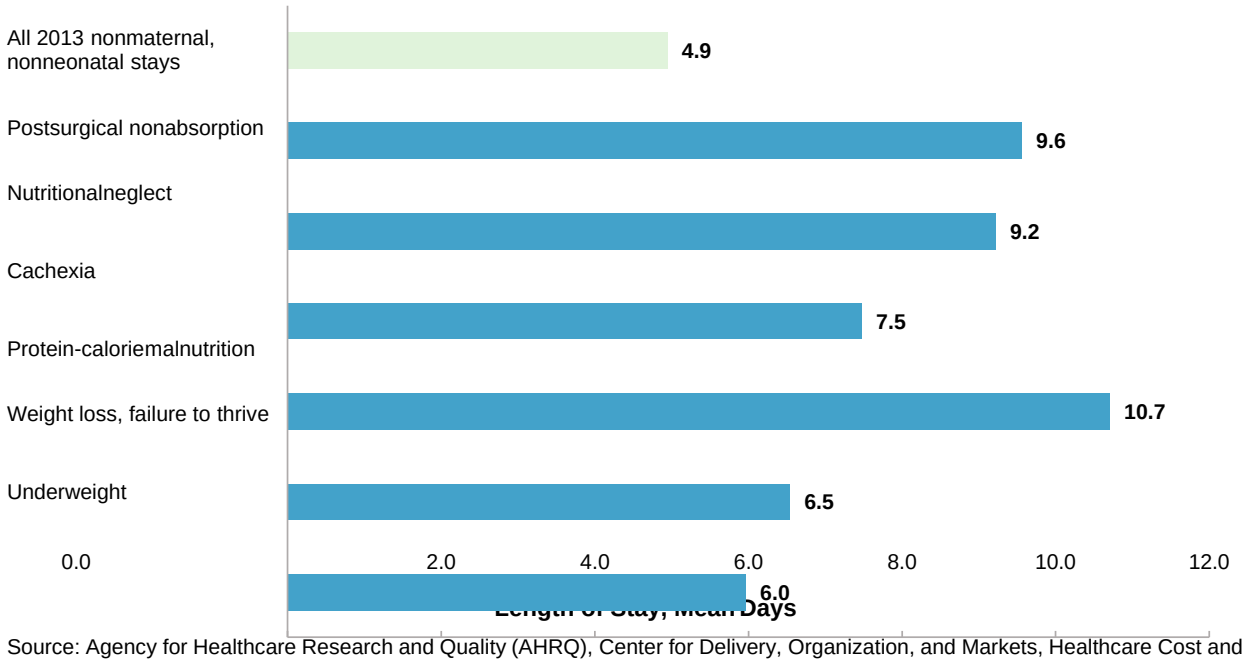
Source: Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample (NIS), 2013

- **Hospital stays involving cachexia and protein-calorie malnutrition had the highest mortality rate compared with other malnutrition-related hospital stays.**

Compared with the in-hospital death rate among all nonmaternal, nonneonatal hospital stays (2.4 percent), malnutrition-related stays for all types of malnutrition except postsurgical nonabsorption had a substantially higher proportion of in-hospital deaths, ranging from 1.5 times higher for underweight diagnoses to nearly 5 times higher for cachexia. Overall, more than 1 in 10 hospital stays involving cachexia (11.7 percent) and more than 1 in 12 stays involving protein-calorie malnutrition (8.4 percent) resulted in death in the hospital.

Figure 4 presents the average length of stay in the hospital by type of malnutrition in 2013. For reference, the average length of stay among all nonmaternal, nonneonatal hospital stays also is provided.

Figure 4. Average length of hospital stay by malnutrition type, 2013



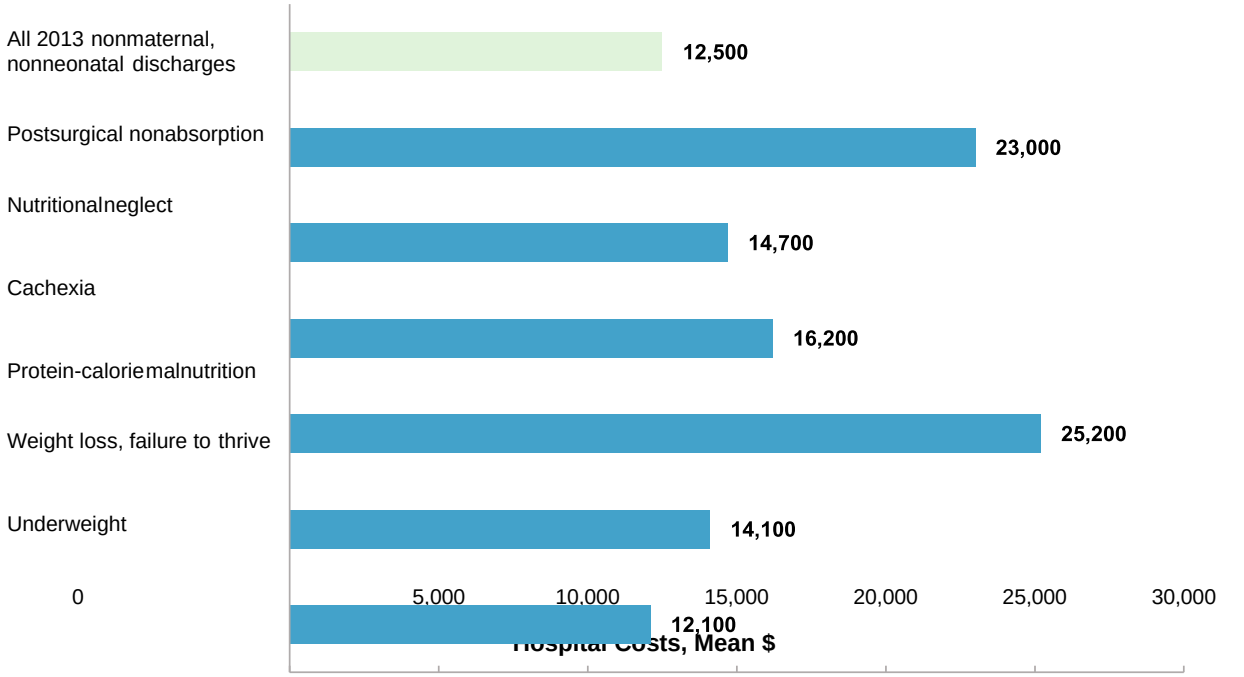
Source: Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample (NIS), 2013

- **Hospital stays involving protein-calorie malnutrition, postsurgical nonabsorption, and nutritional neglect were longer on average compared with other malnutrition-related hospital stays and about twice as long as the average length of stay overall.**

Compared with the average length of all nonmaternal, nonneonatal hospital stays (4.9 days), malnutrition-related stays for all six types of malnutrition were longer on average, ranging from 20 percent longer for underweight diagnoses to more than twice as long for protein-calorie malnutrition. On average, the longest malnutrition-related stays involved protein-calorie malnutrition (10.7 days), postsurgical nonabsorption (9.6 days), and nutritional neglect (9.2 days).

Figure 5 presents average hospital costs for stays by type of malnutrition in 2013. For reference, the average hospital cost among all nonmaternal, nonneonatal hospital stays also is provided.

Figure 5. Average hospital costs by malnutrition type, 2013



Source: Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample (NIS), 2013

- **Hospital stays involving protein-calorie malnutrition and postsurgical nonabsorption were the most costly compared with other malnutrition-related hospital stays.**

Compared with the average cost of all nonmaternal, nonneonatal hospital stays ($12,500), malnutrition-related stays for all types of malnutrition except underweight were more costly, ranging from 13 percent more costly for weight loss or failure to thrive diagnoses to twice as costly for protein- calorie malnutrition. On average, the highest-cost malnutrition-related stays involved protein-calorie malnutrition ($25,200) and postsurgical nonabsorption ($23,000).

Reasons for hospital stays with malnutrition, 2013

The most common reasons for hospital stays involving malnutrition by malnutrition type in 2013 are provided in Table 3 (general reasons) and Table 4 (specific reasons). Table 3 focuses on primary condition groupings, which are based on broad body systems or etiology. Table 4 focuses on principal diagnoses, which are more specific categories of conditions.

Table 3. Top five primary condition groupings among hospital stays involving malnutrition by malnutrition type, 2013

Primary condition grouping[a]	Postsurgical non-absorption		Nutritional neglect		Cachexia		Protein-calorie malnutrition		Weight loss, failure to thrive		Under-weight	
	Rank	%	Rank	%	Rank	%	Rank	%	Rank	%	Rank	%
Injury and poisoning[b]	1	27.5	1	27.4	–	–	5	9.9	–	–	4	9.3
Digestive system	2	20.5	–	–	5	10.0	2	14.6	1	14.0	3	13.6
Genitourinary system	3	8.8	5	8.3	–	–	–	–	–	–	–	–
Endocrine/nutritional/ metabolic	4	7.6	2	13.3	–	–	–	–	3	11.6	–	–
Infectious and parasitic	5	7.5	3	10.4	2	14.6	1	17.1	–	–	–	–
Mental illness	–	–	4	10.2	–	–	–	–	–	–	–	–
Respiratory system	–	–	–	–	1	20.5	3	12.7	2	13.5	1	17.3
Circulatory system	–	–	–	–	3	12.5	4	11.7	4	11.2	2	13.6
Neoplasms	–	–	–	–	4	12.0			5	9.8	5	7.5

Notes: A dash indicates that the condition did not rank among the top five primary condition groupings for that type of malnutrition. Denominators for all percentage calculations are the total number of hospital stays for each malnutrition type.

[a] Primary condition grouping was identified based on the diagnosis chapter of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM).

[b] Includes complications of surgical procedures or medical care, and complication of device, implant or graft.

Source: Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample (NIS), 2013

- **Injury and poisoning was the most common primary condition grouping for malnutrition-related stays involving postsurgical nonabsorption and nutritional neglect; respiratory and digestive system diseases were common among other types of malnutrition-related stays.**

More than one-fourth of malnutrition-related hospital stays involving postsurgical nonabsorption or nutritional neglect had an injury and poisoning primary condition grouping, a broad category of conditions that includes trauma, burns, hip fractures, and complications of care. Respiratory system disease was the most common primary condition grouping among stays involving cachexia (20.5 percent) and underweight diagnoses (17.3 percent). Respiratory system disease also was common for malnutrition-related stays involving weight loss or failure to thrive diagnoses (13.5 percent) and protein-calorie malnutrition (12.7 percent).

Other common primary condition groupings included digestive system disease (ranked in the top five conditions for all malnutrition types except nutritional neglect, and first for weight loss or failure to thrive), infectious and parasitic disease (ranked in the top five conditions for all malnutrition types except weight loss/failure to thrive and underweight, and first for protein-calorie malnutrition), and circulatory system disease (ranked in the top 5 conditions for all malnutrition types except postsurgical nonabsorption and nutritional neglect).

Mental illness was the fourth most common primary condition grouping and represented more than 10 percent of malnutrition-related stays involving nutritional neglect. Neoplasms were among the top five grouped conditions for stays involving cachexia, weight loss or failure to thrive, and underweight diagnoses.

Table 4 lists the five most common principal diagnoses for malnutrition-related hospital stays by malnutrition type in 2013. These are more specific categories of conditions than the body system/etiology groupings in Table 3.

Table 4. Top five principal diagnoses among hospital stays involving malnutrition by malnutrition type, 2013

Principal diagnosis CCS	Postsurgical non-absorption		Nutritional neglect		Cachexia		Protein-calorie malnutrition		Weight loss, failure to thrive		Under-weight	
	Rank	%	Rank	%	Rank	%	Rank	%	Rank	%	Rank	%
Complication of device; implant or graft	1	15.3	–	–	–	–	5	2.8	–	–	–	–
Complications of surgical procedures or medical care	2	10.6	–	–	–	–	–	–	–	–	–	–
Septicemia (except in labor)	3	6.4	2	9.5	1	11.5	1	15.7	1	5.4	2	5.6
Acute and unspecified renal failure	4	6.2	5	3.9	–	–	3	3.6	4	4.5	5	3.1
Intestinal obstruction without hernia	5	5.7	–	–	–	–	–	–	–	–	–	–
Other injuries and conditions due to external causes	–	–	1	19.1	–	–	–	–	–	–	–	–
Other nutritional; endocrine; and metabolic disorders	–	–	3	5.3	–	–	–	–	3	4.5	–	–
Urinary tract infections	–	–	4	4.4	–	–	–	–	–	–	–	–
Pneumonia	–	–	–	–	2	6.3	2	4.6	2	4.5	1	5.7
Chronic obstructive pulmonary disease and bronchiectasis	–	–	–	–	3	5.2	–	–	–	–	3	5.4
Respiratory failure; insufficiency; arrest (adult)	–	–	–	–	4	4.1	–	–	–	–	–	–
Congestive heart failure; nonhypertensive	–	–	–	–	5	3.6	4	2.8	–	–	–	–
Fluid and electrolyte disorders	–	–	–	–	–	–	–	–	5	4.2	4	3.2

Abbreviation: CCS, Clinical Classifications Software

Notes: A dash indicates that the condition did not rank among the top five principal Clinical Classifications Software (CCS) diagnoses for that type of malnutrition. Denominators for all percentage calculations are the total number of hospital stays for each malnutrition type.

Source: Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample (NIS), 2013

- **Septicemia was a common principal diagnosis among all types of malnutrition-related stays.**

Septicemia—a potentially overwhelming infection of the bloodstream—was the most common principal diagnosis among malnutrition-related stays categorized as protein-calorie malnutrition (15.7 percent of stays), cachexia (11.5 percent of stays), and weight loss or failure to thrive (5.4 percent of stays). Septicemia also was the second most common principal diagnosis for stays involving nutritional neglect (9.5 percent of stays) and stays with underweight diagnoses (5.6 percent of stays), and it ranked third for stays involving postsurgical nonabsorption (6.4 percent of stays).

- **Other common principal diagnoses among malnutrition-related stays included medical or device complications (for postsurgical nonabsorption), injuries and conditions due to external causes (for nutritional neglect), and pneumonia (for other types of malnutrition-related stays).**

More than one-fourth of stays involving postsurgical nonabsorption were for complications of medical devices (15.3 percent) or medical or surgical care (10.6 percent). Nearly one in five stays involving

nutritional neglect were for injuries and conditions due to external causes (19.1 percent). For the remaining four malnutrition types, pneumonia was a leading primary condition, ranking first among stays categorized as underweight and second among stays categorized as cachexia, protein-calorie malnutrition, and weight loss or failure to thrive.

Data Source

The estimates in this Statistical Brief are based upon data from the Healthcare Cost and Utilization Project (HCUP) 2013 National Inpatient Sample (NIS). Supplemental sources included population denominator data derived from demographic data provided by the Nielsen Company, a vendor that compiles and adds value to the U.S. Bureau of Census data. Nielsen uses intra-census methods to estimate household and demographic statistics by ZIP Code.[10]

Definitions

Diagnoses, procedures, ICD-9-CM, Clinical Classifications Software (CCS)
The *principal diagnosis* is that condition established after study to be chiefly responsible for the patient's admission to the hospital. *Secondary diagnoses* are concomitant conditions that coexist at the time of admission or develop during the stay. *All-listed diagnoses* include the principal diagnosis plus these additional secondary conditions.

All-listed procedures include all procedures performed during the hospital stay, whether for definitive treatment or for diagnostic or exploratory purposes. The *first-listed procedure* is the procedure that is listed first on the discharge record. Inpatient data define this as the *principal procedure*—the procedure that is performed for definitive treatment rather than for diagnostic or exploratory purposes (i.e., the procedure that was necessary to take care of a complication).

ICD-9-CM is the International Classification of Diseases, Ninth Revision, Clinical Modification, which assigns numeric codes to diagnoses and procedures. There are approximately 14,000 ICD-9-CM diagnosis codes and 4,000 ICD-9-CM procedure codes.

CCS categorizes ICD-9-CM diagnosis codes and procedure codes into a manageable number of clinically meaningful categories.[11] This clinical grouper makes it easier to quickly understand patterns of diagnoses and procedure use. CCS categories identified as Other typically are not reported; these categories include miscellaneous, otherwise unclassifiable diagnoses and procedures that may be difficult to interpret as a group.

Case definition
The six types of malnutrition were defined using the ICD-9-CM diagnosis codes listed in Table 5. Maternal and neonatal discharges, identified by Major Diagnostic Category (MDC) 14 (Pregnancy, Childbirth & the Puerperium) and MDC 15 (Newborns and Other Neonates With Conditions Originating in the Perinatal Period), were excluded from the analysis. Discharges identified only as a personal history or screening for malnutrition were not included (V12.1, Personal history of nutritional deficiency; V77.2, Special screening for malnutrition).

[10] The Nielsen Company. *Nielsen Demographic Data*. Available: http://www.tetrad.com/demographics/usa/nielsen/. Accessed August 31, 2016.
[11] Agency for Healthcare Research and Quality. HCUP Clinical Classifications Software (CCS). Healthcare Cost and Utilization Project (HCUP). Rockville, MD: Agency for Healthcare Research and Quality. Updated June 2015. http://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp. Accessed February 17, 2016.

Table 5. ICD-9-CM diagnosis codes for malnutrition

ICD-9-CM diagnosis code	Description
Postsurgical nonabsorption	
579.3	Other and unspecified postsurgical nonabsorption
Nutritional neglect	
995.52	Child neglect (nutritional)
995.84	Adult neglect (nutritional)
Cachexia	
799.4	Cachexia
Protein-calorie malnutrition	
260	Kwashiorkor
261	Nutritional marasmus
262	Other severe protein-calorie malnutrition
263.0	Malnutrition of moderate degree
263.1	Malnutrition of mild degree
263.2	Arrested development following protein-calorie malnutrition
263.8	Other protein-calorie malnutrition
263.9	Unspecified protein-calorie malnutrition
Weight loss, failure to thrive	
783.21	Loss of weight
783.3	Feeding difficulties and mismanagement
783.41	Failure to thrive (child)
783.7	Adult failure to thrive
Underweight	
783.22	Underweight
V85.0	Body Mass Index less than 19, adult
V85.51	Body Mass Index, pediatric, less than 5th percentile for age

Each hospital stay involving malnutrition was categorized into only one malnutrition type based on the following hierarchy:

1. Postsurgical nonabsorption or nutritional neglect
2. Cachexia or protein-calorie malnutrition
3. Weight loss/failure to thrive or underweight

If a single inpatient record included multiple diagnosis codes indicating different types of malnutrition (e.g., nutritional neglect and underweight), the record was classified into the higher-ranked type of malnutrition (in this example, nutritional neglect). If both types of malnutrition at the same hierarchy level appeared on a discharge record (e.g., both postsurgical nonabsorption and nutritional neglect), then the record was classified into the malnutrition type that appeared first on the record.

Table 6 reports the frequency of the six different types of malnutrition by individual diagnosis code among hospital inpatient stays in 2013. The following two additional statistics are provided: (1) the frequency with which each code is the only type of malnutrition code reported on the hospital discharge record and (2) the frequency with which each code occurs either alone or before any other malnutrition code reported on the record.

Table 6. Number and co-occurrence of different types of malnutrition, 2013

Malnutrition type	Diagnosis code	Code description	Total records with this malnutrition code	Records with only this malnutrition code		Records with only this malnutrition code or with this malnutrition code listed first	
			N	N	%	N	%
Postsurgical nonabsorption	579.3	Other and unspecified postsurgical nonabsorption	33,500	21,665	64.7	27,550	82.2
Nutritional neglect	995.52	Child neglect (nutritional)	1,035	510	49.3	825	79.7
	995.84	Adult neglect (nutritional)	1,800	820	45.6	1,195	66.4
Cachexia	799.4	Cachexia	211,210	78,995	37.4	154,180	73.0
Protein-calorie malnutrition	260	Kwashiorkor	1,990	1,380	69.3	1,885	94.7
	261	Nutritional marasmus	85,795	51,975	60.6	82,625	96.3
	262	Other severe protein-calorie malnutrition	270,475	179,265	66.3	261,765	96.8
	263.0	Malnutrition of moderate degree	195,225	150,205	76.9	183,620	94.1
	263.1	Malnutrition of mild degree	75,335	61,150	81.2	71,540	95.0
	263.2	Arrested development following protein-calorie malnutrition	85	55	64.7	70	82.4
	263.8	Other protein-calorie malnutrition	16,340	12,345	75.6	15,250	93.3
	263.9	Unspecified protein-calorie malnutrition	650,320	496,530	76.4	610,375	93.9
Weight loss, failure to thrive	783.21	Loss of weight	257,195	164,140	63.8	173,550	67.5
	783.3	Feeding difficulties and mismanagement	47,595	32,380	68.0	35,630	74.9
	783.41	Failure to thrive (child)	36,740	23,075	62.8	30,530	83.1
	783.7	Adult failure to thrive	305,215	177,275	58.1	195,815	64.2
Underweight	783.22	Underweight	29,470	5,975	20.3	8,710	29.6
	V85.0	Body Mass Index less than 19, adult	307,915	39,980	13.0	98,450	32.0
	V85.51	Body Mass Index, pediatric, less than 5th percentile for age	2,980	615	20.6	880	29.5

Source: Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample (NIS), 2013

Receipt of enteral and parenteral nutrition was based on CCS procedure category 223. CCS 223 includes ICD-9-CM procedure code 966 (Enteral infusion of concentrated nutritional substances) and ICD-9-CM procedure code 9915 (Parenteral infusion of concentrated nutritional substances).

Types of hospitals included in the HCUP National Inpatient Sample

The National Inpatient Sample (NIS) is based on data from community hospitals, which are defined as short-term, non-Federal, general, and other hospitals, excluding hospital units of other institutions (e.g., prisons). The NIS includes obstetrics and gynecology, otolaryngology, orthopedic, cancer, pediatric, public, and academic medical hospitals. Excluded are long-term care facilities such as rehabilitation, psychiatric, and alcoholism and chemical dependency hospitals. Beginning in 2012, long-term acute care hospitals are also excluded. However, if a patient received long-term care, rehabilitation, or treatment for a psychiatric or chemical dependency condition in a community hospital, the discharge record for that stay will be included in the NIS.

Unit of analysis
The unit of analysis is the hospital discharge (i.e., the hospital stay), not a person or patient. This means that a person who is admitted to the hospital multiple times in 1 year will be counted each time as a separate discharge from the hospital.

Costs and charges
Total hospital charges were converted to costs using HCUP Cost-to-Charge Ratios based on hospital accounting reports from the Centers for Medicare & Medicaid Services (CMS).[12] *Costs* reflect the actual expenses incurred in the production of hospital services, such as wages, supplies, and utility costs; *charges* represent the amount a hospital billed for the case. For each hospital, a hospital-wide cost-to-charge ratio is used. Hospital charges reflect the amount the hospital billed for the entire hospital stay and do not include professional (physician) fees. For the purposes of this Statistical Brief, mean costs are reported to the nearest hundred.

How HCUP estimates of costs differ from National Health Expenditure Accounts
There are a number of differences between the costs cited in this Statistical Brief and spending as measured in the National Health Expenditure Accounts (NHEA), which are produced annually by CMS.[13] The largest source of difference comes from the HCUP coverage of inpatient treatment only in contrast to the NHEA inclusion of outpatient costs associated with emergency departments and other hospital-based outpatient clinics and departments as well. The outpatient portion of hospitals' activities has been growing steadily and may exceed half of all hospital revenue in recent years. On the basis of the American Hospital Association Annual Survey, 2012 outpatient gross revenues (or charges) were about 44 percent of total hospital gross revenues.[14]

Smaller sources of differences come from the inclusion in the NHEA of hospitals that are excluded from HCUP. These include Federal hospitals (Department of Defense, Veterans Administration, Indian Health Services, and Department of Justice [prison] hospitals) as well as psychiatric, substance abuse, and long-term care hospitals. A third source of difference lies in the HCUP reliance on billed charges from hospitals to payers, adjusted to provide estimates of costs using hospital-wide cost-to-charge ratios, in contrast to the NHEA measurement of spending or revenue. HCUP costs estimate the amount of money required to produce hospital services, including expenses for wages, salaries, and benefits paid to staff as well as utilities, maintenance, and other similar expenses required to run a hospital. NHEA spending or revenue measures the amount of income received by the hospital for treatment and other services provided, including payments by insurers, patients, or government programs. The difference between revenues and costs include profit for for-profit hospitals or surpluses for nonprofit hospitals.

Location of patients' residence
Place of residence is based on the urban-rural classification scheme for U.S. counties developed by the National Center for Health Statistics (NCHS):

- Large Central Metropolitan: Central counties of metropolitan areas with 1 million or more residents
- Large Fringe Metropolitan: Fringe counties of counties of metropolitan areas with 1 million or more residents
- Medium Metropolitan: Counties in metropolitan areas of 250,000–999,999 residents
- Small Metropolitan: Counties in metropolitan areas of 50,000–249,999 residents
- Micropolitan: Nonmetropolitan counties areas of 10,000 or more residents
- Noncore: Nonmetropolitan and nonmicropolitan counties

[12] Agency for Healthcare Research and Quality. HCUP Cost-to-Charge Ratio (CCR) Files. Healthcare Cost and Utilization Project (HCUP). 2001–2013. Rockville, MD: Agency for Healthcare Research and Quality. Updated November 2015. http://www.hcup-us.ahrq.gov/db/state/costtocharge.jsp. Accessed February 17, 2016.
[13] For additional information about the NHEA, see Centers for Medicare & Medicaid Services (CMS). National Health Expenditure Data. CMS Web site May 2014. http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html?redirect=/NationalHealthExpendData/. Accessed February 17, 2016.
[14] American Hospital Association. TrendWatch Chartbook, 2014. Table 4.2. Distribution of Inpatient vs. Outpatient Revenues, 1992–2012. http://www.aha.org/research/reports/tw/chartbook/2014/table4-2.pdf. Accessed February 17, 2016.

Median community-level income
Median community-level income is the median household income of the patient's ZIP Code of residence. Income levels are separated into population-based quartiles with cut-offs determined using ZIP Code demographic data obtained from the Nielsen Company. The income quartile is missing for patients who are homeless or foreign.

Payer
Payer is the expected payer for the hospital stay. To make coding uniform across all HCUP data sources, payer combines detailed categories into general groups:

- Medicare: includes patients covered by fee-for-service and managed care Medicare
- Medicaid: includes patients covered by fee-for-service and managed care Medicaid
- Private Insurance: includes Blue Cross, commercial carriers, and private health maintenance organizations (HMOs) and preferred provider organizations (PPOs)
- Uninsured: includes an insurance status of *self-pay* and *no charge*
- Other: includes Workers' Compensation, TRICARE/CHAMPUS, CHAMPVA, Title V, and other government programs

Hospital stays billed to the State Children's Health Insurance Program (SCHIP) may be classified as Medicaid, Private Insurance, or Other, depending on the structure of the State program. Because most State data do not identify patients in SCHIP specifically, it is not possible to present this information separately.

For this Statistical Brief, when more than one payer is listed for a hospital discharge, the first-listed payer is used.

Admission source or point of origin
Admission source (now known as the patient's point of origin) indicates where the patient was located prior to admission to the hospital. Emergency admission indicates that the patient was admitted to the hospital through the emergency department. Admission from another hospital indicates that the patient was admitted to this hospital from another short-term, acute-care hospital. This usually signifies that the patient required the transfer in order to obtain more specialized services that the originating hospital could not provide. Admission from a long-term care facility indicates that the patient was admitted from a long- term facility such as a nursing home.

Discharge status
Discharge status reflects the disposition of the patient at discharge from the hospital and includes the following six categories: routine (to home); transfer to another short-term hospital; other transfers (including skilled nursing facility, intermediate care, and another type of facility such as a nursing home); home health care; against medical advice (AMA); or died in the hospital.

Reporting of race and ethnicity
Data on Hispanic ethnicity are collected differently among the States and also can differ from the Census methodology of collecting information on race (White, Black, Asian/Pacific Islander, American Indian/Alaska Native, Other (including mixed race)) separately from ethnicity (Hispanic, non-Hispanic). State data organizations often collect Hispanic ethnicity as one of several categories that include race. Therefore, for multistate analyses, HCUP creates the combined categorization of race and ethnicity for data from States that report ethnicity separately. When a State data organization collects Hispanic ethnicity separately from race, HCUP uses Hispanic ethnicity to override any other race category to create a Hispanic category for the uniformly coded race/ethnicity data element, while also retaining the original race and ethnicity data. This Statistical Brief reports race/ethnicity for the following categories: Hispanic, non-Hispanic White, non-Hispanic Black, and non-Hispanic Other.

Present on admission
In many cases the hospital discharge record includes an indication that the diagnosis was present on admission, the diagnosis occurred during the hospital stay, or onset could not be determined.[15]

About HCUP

The Healthcare Cost and Utilization Project (HCUP, pronounced "H-Cup") is a family of health care databases and related software tools and products developed through a Federal-State-Industry partnership and sponsored by the Agency for Healthcare Research and Quality (AHRQ). HCUP databases bring together the data collection efforts of State data organizations, hospital associations, and private data organizations (HCUP Partners) and the Federal government to create a national information resource of encounter-level health care data. HCUP includes the largest collection of longitudinal hospital care data in the United States, with all-payer, encounter-level information beginning in 1988. These databases enable research on a broad range of health policy issues, including cost and quality of health services, medical practice patterns, access to health care programs, and outcomes of treatments at the national, State, and local market levels.

HCUP would not be possible without the contributions of the following data collection Partners from across the United States:

Alaska State Hospital and Nursing Home Association
Arizona Department of Health Services
Arkansas Department of Health
California Office of Statewide Health Planning and Development
Colorado Hospital Association
Connecticut Hospital Association
District of Columbia Hospital Association **Florida**
Agency for Health Care Administration **Georgia**
Hospital Association
Hawaii Health Information Corporation
Illinois Department of Public Health **Indiana**
Hospital Association
Iowa Hospital Association
Kansas Hospital Association
Kentucky Cabinet for Health and Family Services
Louisiana Department of Health and Hospitals **Maine**
Health Data Organization
Maryland Health Services Cost Review Commission **Massachusetts**
Center for Health Information and Analysis **Michigan** Health &
Hospital Association
Minnesota Hospital Association
Mississippi Department of Health **Missouri**
Hospital Industry Data Institute
Montana MHA - An Association of Montana Health Care Providers
Nebraska Hospital Association
Nevada Department of Health and Human Services
New Hampshire Department of Health & Human Services
New Jersey Department of Health **New**
Mexico Department of Health **New**
York State Department of Health
North Carolina Department of Health and Human Services
North Dakota (data provided by the Minnesota Hospital Association)
Ohio Hospital Association
Oklahoma State Department of Health

[15] Centers for Medicare & Medicaid Services. Hospital-Acquired Conditions (Present on Admission Indicator). Reporting. Last modified February 12, 2014. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Reporting.html. Accessed June 29, 2016.

Oregon Association of Hospitals and Health Systems
Oregon Office of Health Analytics
Pennsylvania Health Care Cost Containment Council
Rhode Island Department of Health
South Carolina Revenue and Fiscal Affairs Office **South**
Dakota Association of Healthcare Organizations
Tennessee Hospital Association
Texas Department of State Health Services
Utah Department of Health
Vermont Association of Hospitals and Health Systems
Virginia Health Information
Washington State Department of Health **West**
Virginia Health Care Authority **Wisconsin**
Department of Health Services **Wyoming**
Hospital Association

About Statistical Briefs

HCUP Statistical Briefs are descriptive summary reports presenting statistics on hospital inpatient and emergency department use and costs, quality of care, access to care, medical conditions, procedures, patient populations, and other topics. The reports use HCUP administrative health care data.

About the NIS

The HCUP National (Nationwide) Inpatient Sample (NIS) is a nationwide database of hospital inpatient stays. The NIS is nationally representative of all community hospitals (i.e., short-term, non-Federal, nonrehabilitation hospitals). The NIS includes all payers. It is drawn from a sampling frame that contains hospitals comprising more than 95 percent of all discharges in the United States. The vast size of the NIS allows the study of topics at the national and regional levels for specific subgroups of patients. In addition, NIS data are standardized across years to facilitate ease of use. Over time, the sampling frame for the NIS has changed; thus, the number of States contributing to the NIS varies from year to year. The NIS is intended for national estimates only; no State-level estimates can be produced.

The 2012 NIS was redesigned to optimize national estimates. The redesign incorporates two critical changes:

- Revisions to the sample design—starting with 2012, the NIS is now a *sample of discharge records from all HCUP-participating hospitals*, rather than a sample of hospitals from which all discharges were retained (as is the case for NIS years before 2012).

- Revisions to how hospitals are defined—the NIS now uses the *definition of hospitals and discharges supplied by the statewide data organizations* that contribute to HCUP, rather than the definitions used by the American Hospital Association (AHA) Annual Survey of Hospitals.

The new sampling strategy is expected to result in more precise estimates than those that resulted from the previous NIS design by reducing sampling error: for many estimates, confidence intervals under the new design are about half the length of confidence intervals under the previous design. The change in sample design for 2012 necessitates recomputation of prior years' NIS data to enable analysis of trends that uses the same definitions of discharges and hospitals.

For More Information

For more information about HCUP, visit http://www.hcup-us.ahrq.gov/.

For additional HCUP statistics, visit HCUP Fast Stats at http://www.hcup-us.ahrq.gov/faststats/landing.jsp for easy access to the latest HCUP-based statistics for health information topics, or visit HCUPnet, HCUP's interactive query system, at http://hcupnet.ahrq.gov/.

For information on other hospitalizations in the United States, refer to the following HCUP Statistical Briefs located at http://www.hcup-us.ahrq.gov/reports/statbriefs/statbriefs.jsp:

- Statistical Brief #180, Overview of Hospital Stays in the United States, 2012
- Statistical Brief #181, Costs for Hospital Stays in the United States, 2012
- Statistical Brief #186, Most Frequent Operating Room Procedures Performed in U.S. Hospitals, 2003–2012
- Statistical Brief #162, Most Frequent Conditions in U.S. Hospitals, 2011

For a detailed description of HCUP and more information on the design of the National Inpatient Sample (NIS), please refer to the following database documentation:

Agency for Healthcare Research and Quality. Overview of the National (Nationwide) Inpatient Sample (NIS). Healthcare Cost and Utilization Project (HCUP). Rockville, MD: Agency for Healthcare Research and Quality. Updated November 2015. http://www.hcup-us.ahrq.gov/nisoverview.jsp. Accessed February 17, 2016.

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AHRQ welcomes questions and comments from readers of this publication who are interested in obtaining more information about access, cost, use, financing, and quality of health care in the United States. We also invite you to tell us how you are using this Statistical Brief and other HCUP data and tools, and to share suggestions on how HCUP products might be enhanced to further meet your needs. Please e-mail us at hcup@ahrq.gov or send a letter to the address below:

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