

Measure Worksheet

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections. **To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return**

Brief Measure Information

NQF #: 3636

Corresponding Measures:

Measure Title: Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel **Measure Steward:** Surveillance Branch, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention

sp.02. Brief Description of Measure: This quarterly measure identifies the average percentage of healthcare personnel (HCP) who have ever received a primary COVID-19 vaccination course among the total number of HCP who regularly work in the facility.

The measure is reported for a quarter (3-month period). The quarterly COVID-19 vaccination coverage is determined by selecting one week per month and calculating the percentage of HCP who have ever received a primary COVID-19 vaccination course, then averaging 3 weekly percentages (one week from each of the 3 months in the quarter).

1b.01. Developer Rationale:

High COVID-19 vaccine uptake is needed to protect the healthcare workforce, but also protect patients and the community. For these reasons, the Advisory Committee on Immunization Practices (ACIP) recommended prioritizing healthcare personnel (along with long-term care facility residents) with the first phase of vaccine supplies.

- The healthcare setting can be high-risk for SARS-CoV-2 exposure and transmission and protecting healthcare personnel from infection is critical to preserving the capacity to care for patients with COVID-19 or other illnesses. For example, as of the week ending October 10, 2021, there have been 659,751 nursing home staff COVID-19 cases and 2,133 nursing home COVID-19 staff deaths (in addition to 710,264 nursing home resident COVID-19 cases and 138,205 nursing home resident COVID-19 deaths) (https://data.cms.gov/covid-19/covid-19-nursing-home-data, accessed October 25, 2021).
- 2. Tracking vaccination coverage among HCP can help improve uptake of highly efficacious COVID-19 vaccines which reduce the burden of illness and death,
- 3. Regular monitoring of vaccination coverage rates can help facilities maintain current efforts to vaccinate new staff and continue to engage and build confidence among staff who may be hesitant.

sp.12. Numerator Statement:

The numerator for this measure consists of the cumulative number of HCP in the denominator population, who:

- 1. have received a complete vaccination course against COVID-19 administered at the healthcare facility; or
- 2. reported in writing (paper or electronic) or provided documentation that a complete vaccination course against COVID-19 was received elsewhere

sp.14. Denominator Statement:

The target population is the number of healthcare personnel (HCP) eligible to work in the healthcare facility for at least one day during the one-week data collection reporting period, excluding persons with contraindications/exclusions to COVID-19 vaccination. The quarterly reported measure includes at least one week of data collection a month for each of the 3 months in a quarter.

The denominators are reported by aggregating categories below:

- 1. Employees: all persons who receive a direct paycheck from the reporting facility (i.e., on the facility's payroll).
- 2. Licensed independent practitioners: include physicians (MD, DO), advanced practice nurses, and physician assistants only who are affiliated with the reporting facility who do not receive a direct paycheck from the reporting facility.
- 3. Adult students/trainees and volunteers include all students/trainees and volunteers aged 18 or over who do not receive a direct paycheck from the reporting facility.
- 4. Other contract personnel: Facilities may also report on individuals who are contract personnel. However, reporting for this category is optional. Contract personnel are defined as persons providing care, treatment, or services at the facility through contract who do not fall into any of the above-mentioned denominator categories.

sp.16. Denominator Exclusions: Exclusions include individuals with contraindications to COVID-19 vaccination and individuals for whom the COVID-19 vaccine is not authorized or recommended.

Measure Type: Process

sp.28. Data Source: Other (specify) The source is not specified as it may vary by facility. Data may be collected from electronic sources or paper-based sources. It may be obtained from existing records or a system specifically designed for COVID-19 vaccination tracking.

sp.07. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: N/A Most Recent Endorsement Date: N/A

IF this measure is included in a composite, NQF Composite#/title: N/A

IF this measure is paired/grouped, NQF#/title: N/A

sp.03. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?:

Preliminary Analysis: New Measure

Criteria 1: Importance to Measure and Report

1a. Evidence

1a. Evidence. The evidence requirements for a *structure, process or intermediate outcome* measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

• Systematic Review of the evidence specific to this measure?

🛛 No

□ Yes

- Quality, Quantity and Consistency of evidence provided?
- Evidence graded?

Yes	\boxtimes	No
Yes	\boxtimes	No

Evidence Summary

- This is a new process measure utilizing National Health Survey Network (NHSN) data at the facility level to report on the average percentage of healthcare personnel (HCP), among those who work in long-term care facilities, who have ever received a primary COVID-19 vaccination course.
- The <u>logic model</u> presented by the developer links actions that can be taken by the accountable entity— such as conducting outreach and education among HCP about COVID-19 vaccination, providing vaccination opportunities to HCP, and identifying HCP who have received a complete COVID-19 vaccination course (even if elsewhere) – with calculating and reporting the number of HCP at a facility who have received a complete COVID-19 vaccination course, with the overall aim of increasing protection against COVID-19 infection (especially severe infection) for both HCP and patients and decreasing disease transmission and workforce disruption.
- The developer states that evidence for this measure derives from the Advisory Committee on Immunization Practices (ACIP) recommendations for allocation of COVID-19 vaccines as presented to the Director of the Centers of Disease Control and Prevention (CDC). The ACIP COVID-19 Vaccines Work Group considered evidence related to SARS-CoV-2 epidemiology, vaccination program implementation, and **ethical principles in** developing the interim recommendation on allocation of the initial supply of COVID-19 vaccine (Phase 1a).
 - The developer mentions seven public ACIP meetings during which evidence-based information addressing COVID-19 vaccine topics and early allocation has been explicitly and transparently reviewed.
 - The developer also states that a COVID-19 Vaccines Work Group, comprising experts in vaccines and ethics, held more than 25 meetings to review data regarding vaccine candidates, COVID-19 surveillance, and modeling, as well as the vaccine allocation literature from published and external expert committee reports in order to inform policy options for ACIP.
- The developer summarizes the critical evidence from ACIP's work, including:
 - Healthcare settings are high risk locations for SAR-CoV-2 exposure, and HCP are at risk of transmitting the virus to medically vulnerable patients as seen with long-term care facility (LTCF) outbreaks.
 - LTCF modeling predicted more cases and deaths averted at the facility by vaccinating staff compared with vaccinating residents. Early protection of HCP is critical to preserve healthcare capacity to care for COVID-19 patients and ensure hospitals maintain a workforce to care for non-COVID-19 patients.

Exception to evidence

• There is limited evidence on COVID-19. The developer relies on recommendations from ACIP to support vaccine distribution to HCP.

Questions for the Committee:

• Is the evidence directly applicable to the process of care being measured?

Guidance from the Evidence Algorithm

Process measure does not assess a health outcome (Box 1) \rightarrow Empirical evidence not systematically reviewed (Box 3) \rightarrow Empirical evidence not reviewed or graded (Box 7) \rightarrow There could be performance measures of a related health outcome (Box 10) \rightarrow There is evidence of a systematic assessment of expert opinion that the benefits outweigh potential harms (Box 11) \rightarrow Appears beneficial to hold the measured entity accountable in the absence of empirical evidence of benefits to patients (Box 12) \rightarrow Rate as INSUFFICIENT WITH EXCEPTION

Preliminary rating for evidence: High Moderate Low Insufficient

RATIONALE: The evidence provided (ACIP recommendations) recommend that HCP and long-term care facility residents be offered COVID-19 vaccination first. While the information in the recommendation supports that HCP should be vaccinated, the recommendation is not directly related to COVID-19 vaccination status among HCP.

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- In June 2021, CMS began to require CMS-certified long-term care facilities (LTCF) to collect and report weekly COVID-19 vaccination coverage through the National Healthcare Safety Network (NHSN).
- Performance gap data for the first three quarters of 2021 were as follows. Mean COVID-19 vaccination coverage, confidence intervals (CI), and standard deviation (SD) for each quarter:
 - Q1: N=4197; Mean: 35.0%; SD:23.8; 95% CI: 34.3% 35.7%)
 - Q2: N=15,156; Mean: 56.2% (SD: 20.9; 95% CI: 55.8% 56.5%)
 - Q3: N=15,267; Mean: 64.1% (SD: 18.8; 95% CI: 63.8% 64.4%)
- The developer reported quarterly COVID-19 vaccination coverage stratified by size of facility (according to number of HCP):
 - In Q1 2021, the gap in vaccination coverage between the 10th percentile of nursing homes and the 90th percentile was 67.2%.
 - By Q3 2021, the lowest 10th percentile of nursing homes improved vaccination coverage rates to 38.8% and the 90th percentile improved to 89.0%, leading to a gap of 50.2%.

Disparities

- The developer states that data for this measure is aggregated and data collection does not include race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.
- During March 1–April 4, 2021 a total of 1,898 LTCFs voluntarily reported HCP COVID-19 vaccination data through the NHSN, including 300 (16%) facilities from 47 states that reported numbers for HCP and vaccination status for every job category.
 - Vaccination rates by HCP type were as follows:
 - Physicians and other advanced practice providers: 75.1%
 - Therapists: 69.2%
 - Ancillary services employees: 58.5%
 - Nurses: 56.7%
 - Aides: 45.6%
 - Coverage was 68.5% among other HCP not reported in these categories (e.g., students, contractors).
 - The proportion of persons who declined COVID-19 vaccination ranged from 11.1% among physicians to 33.2% among aides.
 - The percentage of aides who were completely vaccinated was lower among those working in facilities located in ZIP-code areas with higher proportions of ethnic and racial minorities (43.5% versus 50.5%), lower household median income (40.5% versus 48.1%), higher poverty (42.4% versus 49.2%), and lower high school completion (42.2% vs 49.3%).
 - An analysis in COVID-19 vaccination coverage among HCP identified lower COVID-19 vaccination coverage rates among certain HCP categories (nurses and aides) and among facilities located in zip codes with indicators of social vulnerability.

 Other research has identified lower vaccination coverage among nurses and support staff, among Black and Hispanic healthcare personnel, and higher vaccination acceptance among doctoral-degree personnel. Various studies have found decreased likelihood of vaccine acceptance among healthcare personnel identified as Black, Latinx, female, or having lower educational attainment.

Questions for the Committee:

• Is there a gap in vaccination among HCP that warrants a national performance measure?

Preliminary rating for opportunity for improvement:	🛛 High	Moderate	🗆 Low 🛛 Insufficient
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Committee Pre-evaluation Comments:

Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

- The evidence of the benefit of vaccinating LTC staff against sarscov2 is well-established
- strong evidence presented
- Given the changing nature of the virus (and potentially vaccines), will a complete vaccination in 2021 mean the same thing in 2022, and where do boosters find their place? The evidence may change over time
- Process measure not a lot of evidence (new measure) insufficient
- No
- Insufficient evidence to support this Process measure. There is tangential support of the measures relationship to the outcome, as there is evidence of vaccine effectiveness against hospitalization, DOI: 10.15585/mmwr.mm7038e1external.
- No evidence offered. There are studies exploring attitudes and intentions of healthcare workers on the acceptance of the vaccine. Inclusion of such may contribute and inform the framework of the study.
- This is a new process measure. The developer did not provide direct evidence to support this measure. Instead, they reply on recommendations by ACIP and present a logical model to link COVID-19 vaccinations to increased protection against COVID-19 infection (especially severe infection) for both healthcare providers and patients and decreasing disease transmission and workforce disruption. The evidence is rated as insufficient because of the absence of empirical evidence of benefits to patients. But, the CDC data show vaccinations provide a strong protection against serious COVID infection in comparison to non-vaccinated, and real-world data also suggest that COVID-19 vaccines help reduce breakthrough cases. So I think more HCP take on vaccines, it will protect safety of patients and their co-workers. While I am concerned over the highly politicalized COVID vaccine issues and misinformation running rampage in the country, I think we need such data to enable the country make informed decisions to fight the pandemic.
- Evidence is limited at best. I do not see strong evidence that higher vaccination rates elicit less COVID spread. Breakthrough is common in vaccinated individuals, and some may have immunity from having the disease.
- Direct measure of average percentage of HCP who have received a primary COVID-19 vaccination
- No evidence offered, simply used consensus support
- I would not support this measure based on Insufficient evidence. There is no evidence that reporting vaccination rates among personnel does anything to improve patient outcomes. This measure is also premature for a number of reasons: 1) many places are already mandating vaccinations that may render this measure moot; 2) given the growing evidence that booster is needed to maintain immunity, this measure does not incorporate these nuances or the growing/changing evidence on this topic; 3) not sure how this information will lead to change per se, developer mentions "outreach, education, vaccination opportunities", it is hard to believe these are not already done; 4) how would one deal with people who have had COVID infection and may feel they have immunity without the vaccine?
- Rated as insufficient by NQF staff. The committee would benefit from further discussion of the rationale for this recommendation.
- Yes the mean and SD show considerable variation
- clear performance gap, and variation
- Large gap, especially between aides and physicians which may represent a disparity.
- High opportunity for improvement
- Yes. Concerning gaps in vaccine compliance with Nurses, aides and ancillary personnel.

- High. Disparities noted among type of healthcare personnel (physicians, nurse, therapist, etc), and among ethnicity, education, and zip code.
- Measured by subgroups, but may ignore the variances from state to state based on political views. Those despite high levels of educational attainment are declining the vaccine. This may be précised in the evaluation of threats.
- The developer provided current performance data collected by the CMS-certified long-term care facilities (LTCF). These facilities report weekly COVID-19 vaccination coverage through the National Healthcare Safety Network (NHSN). At Q1 2021, the gap in vaccination coverage between the 10th percentile of nursing homes and the 90th percentile was 67.2%. By Q3 2021, the lowest 10th percentile of nursing homes improved vaccination coverage rates to 38.8% and the 90th percentile improved to 89.0%, leading to a gap of 50.2%. The performance gap is significant.
- yes, and it demonstrates a gap in vaccination rates
- n/a
- Much clear opportunity across location and subgroups, and given workforce turnover, any achievements could be transient
- Yes there was performance gap, but this is shifting weekly to monthly and I think the data time lag here is very important.
- High performance gap.
- n/a
- denominator does not account for rigorousness of exemptions; employee definition does not include contractors who interact directly with patients (travel nurses, labcorps, etc)
- NA
- No concerns
- n/a
- NA
- Not apply.
- na
- n/A
- All makes sense despite evidence gap

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

Reliability

2a1. Specifications_requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented.

2a2. Reliability testing_demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Complex measure evaluated by Scientific Methods Panel? \Box Yes \boxtimes No

Evaluators: NQF Staff

Evaluation Summary

Reliability

- Reliability testing at the Patient/Encounter level (Developer states that reliability testing is at the accountable entity level but based on the testing information provided NQF defines this as patient/encounter level testing):
 - The overall Pearson Correlation Coefficient for the number of HCP who received COVID-19 vaccinations as reported to the NHSN (measure numerator) compared to the number of COVID-19 vaccinations administered by the PPP (independent comparator): 0.846, p<0.0001 (869 Facilities). The developer states that this correlation is linear and high, showing that the numerator is strongly associated with the data from the independent comparator.
 - Since the number of vaccinations is a nearly continuous value rather than categorical values, Kendall's Tau-b Correlation Coefficient (a non-parametric measure of association) was also calculated and was high (r=0.751).
 - After stratifying by hospital size/number of HCP, vaccination coverage, and reporting week, the strength of association remained high for both the Pearson Correlation Coefficient, and for Kendall's Tau-b Correlation Coefficient.
 - Pearson Correlation Coefficient
 - Tertiles stratified by vaccination coverage: 0.754, 0.886, 0.810
 - Tertiles stratified by reporting week (1-3): 0.746, 0.902, 0.901
 - Kendall's Tau-b Correlation Coefficient:
 - Tertiles stratified by facility size: 0.707, 0.644, 0.704
 - Tertiles stratified by vaccination coverage: 0.681, 0.738, 0.704
 - Tertiles stratified by reporting week (1-3): 0.676, 0.804, 0.774
 - The developer also plotted a line of unity (slope=1) on a scatterplot of the number of vaccinations reported by NHSN and by PPP reporting to show there is a linear 1:1 relationship between the number of HCP receiving COVID-19 vaccination reported by the proposed measure using NHSN and the number of vaccinations reported to be administered by the PPP.
 - The developer states this overall mean difference was minimal (mean difference of -0.699 vaccinations) for a narrow confidence interval (95% CI, -1.96 0.56 vaccinations) and not significant (p=0.278) between the number reported to NHSN and PPP reporting.
 - When stratifying by facility size/number of HCP and reporting week, the mean difference remained low (mean difference -1.76 to 0.56 vaccinations). In addition, all 95% CIs included the null value, indicating no statistically significant difference.
 - When stratified by vaccination coverage rate, the range of mean differences were larger by tertile (-4.81 vaccinations in the lower tertile of vaccination coverage to 3.57 vaccinations in the higher vaccination tertile).
 - The developer states that these small but statistically significant differences in the number of vaccinations delivered identified when stratified by vaccination coverage are likely because NHSN reports vaccinations HCP may have received elsewhere, while PPP only reports vaccinations delivered at the facility. In the high vaccination tertile, it may be more likely that HCP received vaccinations elsewhere and these vaccinations were reported to NHSN.
 - Second, when there were additional vaccine doses, PPP delivered vaccinations to others who may not have met the definition of HCP used by NHSN so as not

to have vaccine doses go unused. In the low vaccination coverage tertile this situation may be more likely to occur.

- Qualitative assessment of comparability using a Bland-Altman plot demonstrated no pattern of variability based on number of vaccines delivered with minimal bias (variability was random; mean difference very close to zero).
- The developer states that repeated measures over time in the same facility were not assessed as the number of HCP vaccinated will change over time due to vaccination uptake efforts and staffing changes (e.g., newly hired HCP, retirement of HCP).
- The developer states that denominator testing was not conducted for this measure since it uses the same denominator of HCP definitions and categories as the currently endorsed measure, NQF #0431 Influenza Vaccination Coverage Among Healthcare Personnel. The developer reiterated that in the reliability testing of this denominator agreement was high for all denominator categories (greater than 90%).
 - The developer cites a paper by Libby et al, "Reliability and validity of a standardized measure of influenza vaccination coverage among healthcare personnel," that thoroughly tested and examined the denominator reliability of the influenza measure.
 - The developer also noted that while some facilities excluded nonemployee contractors (denominator reporting item #4 in the current measure) for whom the numerator and denominator were difficult to determine in the influenza-related study conducted in 2010 2011, nonemployee contractors have become more commonplace and have been reported to NHSN throughout the pandemic response.

Validity

- Validity testing at the Accountable Entity level:.
 - The overall Pearson Correlation Coefficient between the quarterly COVID-19 coverage measure for Q3 2021 and annual Influenza Vaccination coverage (NQF #0431) was 0.4169, p<0.0001 (1,654 Facilities).
 - Correlation coefficient of 0.4169 indicates "medium" correlation using the generally accepted range for medium correlation, 0.30 0.49.
 - When the results were stratified into quartiles by facility size, the correlation coefficients for the largest facilities (quartile 3: 94-131 HCP and quartile 4: >132 HCP) were even larger than the overall correlation coefficient (0.457 and 0.450, respectively), though correlation coefficients for all four quartiles were statistically significant (p < 0.0001).
 - These data represent a medium correlation when stratified by facility size (number of HCP).
 - The developer details a number of factors outside of facilities' control which likely impact HCP COVID-19 vaccination coverage and are independent of influenza vaccination.
 - HCP may have reasons for which they decline COVID-19 vaccine which they do not apply similarly to the influenza vaccine.
 - Community rates of COVID-19 may vary from community rates of influenza and impact HCP vaccination decisions.
 - High numbers of facilities reported 99% or higher influenza vaccination coverage. With
 additional time for the new COVID-19 vaccines to gain acceptance and for
 implementation of vaccination programs to address COVID-19 vaccination hesitancy,
 coverage rates of COVID-19 and influenza vaccination are likely to correlate more
 strongly.
 - The developer states that this measure can identify statistically significant differences in performance across measured entities since the mean quarterly COVID-19 vaccination

coverage metric had 95% confidence intervals that were narrower than the interquartile range.

- In determining if there are statistically significant differences in performance measure scores among measured entities, the developer calculated the mean quarterly COVID-19 vaccination coverage rate and interquartile ranges for the first 3 quarters of 2021:
 - Q1: mean coverage 35.0% (34.3% 35.7%); interquartile range 17.3% 51.2%
 - Q2: mean coverage 56.2% (55.8% 56.5%); interquartile range 41.9% 71.2%
 - Q3: mean coverage is 64.1% (63.8% 64.4%); interquartile range is 50.8% 78.6%.
- The mean quarterly COVID-19 vaccination coverage metric was higher each of the first 3 quarters of 2021, based on non-overlapping 95% confidence intervals, showing the measure can identify differences in performance across quarters.

Questions for the Committee regarding reliability:

• Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?

Questions for the Committee regarding validity:

• Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?

Preliminary rating for reliability:	🗆 High	🛛 Moderate	🗆 Low	Insufficient
Preliminary rating for validity:	🛛 High	Moderate	🗆 Low	Insufficient

Committee Pre-evaluation Comments:

Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

- The reliability correlation co-efficient was higher than I expected (happily so)
- denominator does not account for rigorousness of exemptions- this creates concerns regarding consistency
- Will boosters be part of complete vaccination, 2nd booster, changed vaccine. Lots of nuance.
- Review panel rated moderate
- No concerns
- no concerns
- No concerns
- No concerns.
- What constitutes fully vaccinated is a moving target, and how to integrate thos who have had the disease and recovered is unclear.
- The source is not specified and may vary by facility.
- No concerns given simplicity
- no concerns
- No concerns with reliability
- no
- no
- Yes given the changes in vaccines that will be coming
- no
- No concerns
- no concerns. Pearson correlation 0.846 (#vaccine reported/#vaccine administered)
- No
- Both Pearson Correlation Coefficient and Kendall's Tau-b Correlation Coefficient were calculated and remained high after stratifying by hospital size/number of HCP, coverage, and reporting week, the strength of association.
- Workers could falsify vaccination data.
- yes
- No
- no concerns
- No concerns
- I don't believe so, but would be better convinced if the developers went to a few facilities and validated the reporting of vaccination status
- no
- No
- Review panel rate high
- Not at this time
- no
- No
- The developer states that this measure can identify statistically significant differences in performance across measured entities since the mean quarterly COVID-19 vaccination coverage metric had 95% confidence intervals that were narrower than the interquartile range. The preliminary rating for validity is high.
- Is this process measure a true reflection of COVID transmissability within a given facility?
- yes

- No concerns as things sit today, though boosting opportunities and rec'd may alter the testing strategy over time
- no concerns
- No concerns
- The only exclusion should be severe allergic reaction and there is no reason to think that this would vary among institutions non randomly
- Appropriate
- none noted
- Yes. NA
- No inappropriate exclusions.
- Measure is not risk adjusted.
- Not specified.
- Difficult to comply with due to various ways of counting appropriate numbers for numerator and denominator. Systems not in place for this at this time.
- No concerns
- I think there should be accounting for people who have had COVID infections.
- No concerns
- ok

Criterion 3. Feasibility

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- The developer states this measure is abstracted from by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry).
- The developer notes earlier in the submission that the data source is not specified as it may vary by facility. Data may be collected from electronic sources or paper-based sources, or it may be obtained from existing records or a system specifically designed for COVID-19 vaccination tracking.
- Some data elements are contained in defined fields.
- There are no fees, licensing, or other requirements associated with this measure.
- The developer states that some staff indicated a burden of reporting due to difficulty of tracking vaccine status contraindications and declinations and reporting vaccinations 1 week per month, rather than one time per quarter.

Questions for the Committee:

• Will LTCF be able to operationalize this measure?

	Preliminary rating for feasibility:	🗌 High	🛛 Moderate	🗆 Low	Insufficient
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Committee Pre-evaluation Comments:

Criteria 3: Feasibility

- Seems to be feasible however would want to assess burden of reporting
- these data are often not in the EHR, but as the developers state, it is necessary for healthcare systems to use systems to track COVID vaccinations, just as they likely do for other vaccinations such as HepB, TB tests, etc
- Will be more difficult to obtain this information from physicians who are not employees of the facility
- Moderate
- No concerns
- Frequency of data collection may pose a burden given that any week a month may be used of submission. There should be clarification about when the month closes to prevent double counting.
- Facilities can not be held accountable for healthcare workers who file exemptions. There is difficulty in collecting evidence of vaccination from non-employee workers (providers and vendors).
- The developer indicates that the data source may vary by facility and be collected from electronic sources, paper-based sources, or from a system specifically designed for COVID-19 vaccination tracking. The feasibility is rated as moderate. The developer reported some staff indicated a burden of reporting due to difficulty of tracking vaccine status contraindications and declinations and reporting vaccinations 1 week per month, rather than one time per quarter.
- Could be streamlined.
- I have significant concerns on the feasibility of obtaining accurate data for this measure.
- Again, given mult sources of vaccination, this will be a challenge
- no concerns
- Chart abstraction required. Moderate feasibility.

Criterion 4: Usability and Use

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported?	🛛 Yes 🛛	Νο
Current use in an accountability program?	🛛 Yes 🛛	No 🛛 UNCLEAR

Accountability program details

- The developer indicates that this measure is currently in use in public reporting, public health/disease surveillance, and regulatory and accreditation programs:
 - This measure is used by the National Healthcare Safety Network (NHSN) to support the nation's COVID-19 response by providing a Long-term Care Facilities (LTCFs) COVID-19 Module, which enables an assessment of the impact of COVID-19 through facility reported information. This is assessed at the state level for CMS-certified nursing homes and outpatient dialysis centers.

- This measure is also under the Interim Final Rule COVID-19 Vaccine Immunization Requirements for Residents and Staff (QSO-21-19-NH). LTCF must report COVID-19 vaccine and therapeutics treatment information to the CDC's NHSN. CMS will post the new information reported to the NHSN for viewing by facilities, stakeholders, or the general public on CMS's COVID-19 Nursing Home Data website.
- Massachusetts Department of Public Health, Bureau of Health Care Safety and Quality, uses the weekly COVID-19 vaccination modules at skilled nursing facilities to provide consistent reporting and comparable data across facilities. NHSN data can be used to monitor COVID-19 vaccination trends over time, identify facilities with lower resident and/or staff vaccination rates, and inform planning and implementation decisions regarding vaccine supply and distribution.

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- The developer states that prior to July 2021, facilities reporting results with vaccination coverage rates <10% were identified and contacted through email and telephone outreach to confirm the validity of reported results.
- Facilities with high week-to-week variation (>30% change in coverage week to week) were also identified and contacted by email and telephone outreach.
- Since July 2021, facilities with required reporting by CMS have been receiving automatic alerts which identify outlying data entries. https://www.cdc.gov/nhsn/pdfs/hps/covidvax/dq-alerts-508.pdf
- All facilities have full access to the data they have reported.
- The developer states that feedback on measured performance was obtained through a public comment period on proposed rulemaking by CMS to include this measure in quality reporting programs.
- The developer listed feedback received from users and others, which included expressions of support for the measure and concerns about the implementation of the measure.

Questions for the Committee:

- How have (or can) the performance results be used to further the goal of patient safety?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use: 🛛 Pass 🗌 No Pass

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

• The developer states that COVID-19 vaccination rates among HCPs working in CMS-certified skilled nursing facilities increased in each quarter of 2021. The number of facilities reporting vaccination

coverage has also increased significantly with CMS requirements to report vaccination coverage in May 2021.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving highquality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- The developer notes that although this is a quarterly measure, it is based on data collected for a reporting week. Examining data from a reporting week finds that COVID-19 vaccination coverage among HCP working in CMS-certified skilled nursing facilities varies considerably by state, which may impact the incidence of COVID-19 infection in nursing homes. For example, as COVID-19 case counts began to increase in the summer of 2021, COVID-19 vaccination coverage for CMS-certified nursing homes for the week ending July 18 varied by state, ranging from 46.6% [Louisiana, n=262 facilities] to 89.1% [Hawaii, n=43]).
- The developer also states that some public health entities (e.g., Massachusetts) identified the benefits of using NHSN to report this measure and required reporting for some facilities (e.g., nursing homes) within their jurisdiction prior to national requirements.

Potential harms

• No potential harms were identified.

Additional Feedback:

- This measure was submitted to the Measure Applications Partnership for 2020-2021 consideration for implementing measures in federal programs. MAP offered conditional support for rulemaking for this measure and encouraged the developer to fully specify the measure as soon as possible.
- Additional MAP feedback:
 - This measure would add value to the program measure set by providing visibility into an important intervention to limit COVID-19 infections in healthcare personnel and the patients for whom they provide care.
 - Collecting information on SARS-CoV-2 vaccination coverage among healthcare personnel and providing feedback to facilities will allow facilities to benchmark coverage rates and improve coverage in their facility. Reducing rates of COVID-19 in healthcare personnel will reduce transmission among patients and reduce instances of staff shortages due to illness.
 - Some MAP members questioned whether this measure will be critical in 2023, due to the availability of vaccines. Other MAP members pointed out that the duration of immunity conferred by COVID-19 vaccination is as yet unknown.
 - Some MAP members recommended CMS consider narrowing the denominator to frontline HCP, while other members affirmed that including the full range of HCP is appropriate and potentially less burdensome to facilities. MAP suggested that non-employee, non-contracted hospice workers should also be considered for inclusion in the measure denominator.

Questions for the Committee:

- How can the performance results be used to further the goal of patient safety?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability:	🛛 High	Moderate	🗆 Low	Insufficient
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Committee Pre-evaluation Comments:

Criteria 4: Usability and Use

- New measure and it is intended to be used as part of an accountability measure
- adequate
- OK
- Being used for public reporting and accountability
- No concerns
- Yes
- No concerns
- The developer indicates that this measure is currently in use in public reporting, public health/disease surveillance, and regulatory and accreditation programs. This measure is used by the NHSN to support the nation's assessment on the impact of COVID-19 at the state level for CMS-certified nursing homes and outpatient dialysis centers. The measure is also under the Interim Final Rule COVID-19 Vaccine Immunization Requirements for Residents and Staff (QSO-21-19-NH). LTCF must report COVID-19 vaccine and therapeutics treatment information to the CDC's NHSN. CMS will post the new information reported to the NHSN for viewing by facilities, stakeholders, or the general public on CMS's COVID-19 Nursing Home Data website. Various feedbacks were sought from users and others through a public comment period on proposed rulemaking by CMS to include this measure in quality reporting programs. Also, since July 2021, facilities with required reporting by CMS have been receiving automatic alerts and all facilities have full access to the data they have reported. The measure passes the preliminary rating for use.
- May be one of several ways to measure COVID transmisability.
- n/a
- Much interest and other forms of reporting on this exist at varying levels means it is usable but perhaps not unique
- no concerns
- High usability
- I can't think of unintended harms other than potential staffing challenges
- none
- None
- Passes, used in NHSN
- No concerns
- no unintended consequences noted
- No concerns
- The COVID-19 vaccination rates among HCPs working in CMS-certified skilled nursing facilities
 increased in each quarter of 2021. The number of facilities reporting vaccination coverage has also
 increased significantly with CMS requirements to report vaccination coverage in May 2021. Beside
 CMS-certified skill nursing facilities, I wonder if the number other types of facilities reporting
 vaccination coverage have also increased. And what kind barriers would be. No harms were identified.
 When this measure was presented to MAP, it offered conditional support for rulemaking for this
 measure and encouraged the developer to fully specify the measure as soon as possible. Usability is
 rated high.
- I have concerns that hospitals may simply fire all who refuse vaccination. Is that an acceptable result and a benefit to patient safety?
- If obtained the data can be useful in tracking the spread of COVID-19 in facilities vs. the percentage of staff vaccinated, however with the uncertainty about future variants, etc. it is not clear that a "primary" vaccine will be a sufficient measure.

- No concerns
- I think there could be many unintended consequences, given burnout and staffing shortage I worry this measure would contribute to that.
- benefits > harms

Criterion 5: Related and Competing Measures

Related or competing measures

• 0431: Influenza Vaccination Coverage Among Healthcare Personnel

Harmonization

- The developer states that the proposed measure is harmonized to use the same denominator categories as NQF #0431.
 - The target population of both NQF 0431 and the proposed measure is healthcare personnel (HCP) who may be encountered by other HCP and patients during the reporting period.
 - Because of the different time periods for data collection and reporting, NQF 0431 includes healthcare personnel (HCP) who worked for at least one day during the 6-month data collection, while the proposed measure includes HCP who are scheduled to work regularly (at least once a week). Many HCPs who regularly work in a facility may be temporarily absent from a facility for periods of up to two weeks due to illness, injury, or vacation/leave. Because the measurement period covered by the influenza vaccination measure is quite long (the entire 6-month influenza season), such absences will not impact the influenza measure denominator. However, the COVID-19 vaccination measure measurement period is only a week for each month of the quarter, so a number of regularly working HCP may be absent during this shortened period. Therefore, HCP who regularly work in the facility, but may be temporarily absent from the facility for up to 2 weeks, are still to be included.
 - The goal of each is measure is different: #0431 is focused on achieving influenza vaccination coverage while #3636 is focused on achieving COVID-19 vaccination coverage.

Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

- not for sars cov
- none
- 0431 Influenza vaccination of Healthcare personnel
- There are none.
- no.
- Yes
- A potential competing measure is 0431: Influenza Vaccination Coverage Among Healthcare Personnel. However, the developer points out that the goal of each is measure is different: #0431 is focused on achieving influenza vaccination coverage, whereas #3636 is focused on achieving COVID-19 vaccination coverage.
- none indicated
- no
- None

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: January 19, 2022

• No NQF members have submitted a support/non-support choice.

Scientific Acceptability: Preliminary Analysis Form

Measure Number: #3636

Measure Title: Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel

Measure is:

New Previously endorsed (NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented? X Yes I No

Submission document: "MIF_xxxx" document, items S.1-S.22

NOTE: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.

- 2. Briefly summarize any concerns about the measure specifications.
 - No concerns with measure specifications.

RELIABILITY: TESTING

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

- 3. Reliability testing level 🛛 Measure score 🛛 Data element 🗖 Neither
- 4. Reliability testing was conducted with the data source and level of analysis indicated for this measure ☑ Yes □ No
- 5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of patient-level data conducted?

🗆 Yes 🛛 No

6. Assess the method(s) used for reliability testing

Submission document: Testing attachment, section 2a2.2

- Reliability testing at patient/encounter level. (Developer states that reliability testing is at the accountable entity level, but based on the testing information provided NQF defines this as data element testing at the patient/encounter level.)
- **Numerator Testing:** Reliability of the numerator was tested at the accountable entity level using a signal-to-noise analysis.
- The developer tested reliability using the 869 CMS-certified nursing homes that participated in both National Healthcare Safety Network (NHSN) COVID-19 vaccination coverage reporting as well as the Pharmacy Partnership for Long-Term Care Program. The time period was the 3 weeks between December 18, 2020 and January 17, 2021.
- Reliability testing of the numerator was conducted by comparing the number of HCP who had received COVID-19 vaccinations as reported to the National Healthcare Safety Network (NHSN) to

the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program, and independent comparator, at each facility during the same week.

- The developer assessed the strength of the association between the NHSN reporting and PPP reporting of the number of HCP receiving COVID-19 vaccinations using a linear association with Pearson Correlation Coefficient and a nonparametric association (based on number of concordances and discordances in paired observations) with Kendall's Tau-b Correlation Coefficient.
- The developer assess comparability (bias) in measurement of the number of HCP receiving COVID-19 vaccinations by NHSN reporting and PPP reporting using a qualitative visualization of NHSN and PPP reporting
- Mean difference was assessed using a paired t-test of NHSN and PPP reporting and a Bland-Altman plot of difference between NHSN and PPP reporting against the mean of the two measurements.
- **Denominator Testing:** Data element reliability testing was not conducted for the data element of the number of HCP eligible to receive COVID-19 vaccination for each measured entity. The proposed measure uses the same denominator HCP definitions and categories as the previously NQF-endorsed measure, NQF 0431 Influenza Vaccination Coverage Among Healthcare Personnel.

7. Assess the results of reliability testing

Submission document: Testing attachment, section 2a2.3

- The overall Pearson Correlation Coefficient for the number of HCP who received COVID-19 vaccinations as reported to the NHSN (measure numerator) compared to the number of COVID-19 vaccinations administered by the PPP (independent comparator): 0.846, p<0.0001 (869 Facilities). The developer states that this correlation is linear and high, showing that the numerator is strongly associated with the data from the independent comparator.
 - Since the number of vaccinations is a nearly continuous value rather than categorical values, Kendall's Tau-b Correlation Coefficient (a non-parametric measure of association) was also calculated and was high (r=0.751).
 - After stratifying by hospital size/number of HCP, vaccination coverage, and reporting week, the strength of association remained high for both the Pearson Correlation Coefficient, and for Kendall's Tau-b Correlation Coefficient.
 - Pearson Correlation Coefficient
 - Tertiles stratified by vaccination coverage: 0.754, 0.886, 0.810
 - Tertiles stratified by reporting week (1-3): 0.746, 0.902, 0.901
 - Kendall's Tau-b Correlation Coefficient:
 - Tertiles stratified by facility size: 0.707, 0.644, 0.704
 - Tertiles stratified by vaccination coverage: 0.681, 0.738, 0.704
 - Tertiles stratified by reporting week (1-3): 0.676, 0.804, 0.774
 - The developer also plotted a line of unity (slope=1) on a scatterplot of the number of vaccinations reported by NHSN and by PPP reporting to show there is a linear 1:1 relationship between the number of HCP receiving COVID-19 vaccination reported by the proposed measure using NHSN and the number of vaccinations reported to be administered by the PPP.
- The developer states this overall mean difference was minimal (mean difference of -0.699 vaccinations) for a narrow confidence interval (95% CI, -1.96 0.56 vaccinations) and not significant (p=0.278) between the number reported to NHSN and PPP reporting.
 - When stratifying by facility size/number of HCP and reporting week, the mean difference remained low (mean difference -1.76 to 0.56 vaccinations). In addition, all 95% CIs included the null value, indicating no statistically significant difference.

- When stratified by vaccination coverage rate, the range of mean differences were larger by tertile (-4.81 vaccinations in the lower tertile of vaccination coverage to 3.57 vaccinations in the higher vaccination tertile).
 - The developer states that these small but statistically significant differences in the number of vaccinations delivered identified when stratified by vaccination coverage are likely because NHSN reports vaccinations HCP may have received elsewhere, while PPP only reports vaccinations delivered at the facility. In the high vaccination tertile, it may be more likely that HCP received vaccinations elsewhere and these vaccinations were reported to NHSN.
 - Second, when there were additional vaccine doses, PPP delivered vaccinations to others who may not have met the definition of HCP used by NHSN so as not to have vaccine doses go unused. In the low vaccination coverage tertile this situation may be more likely to occur.
- Qualitative assessment of comparability using a Bland-Altman plot demonstrated no pattern of variability based on number of vaccines delivered with minimal bias (variability was random; mean difference very close to zero).
- The developer states that repeated measures over time in the same facility were not assessed as the number of HCP vaccinated will change over time due to vaccination uptake efforts and staffing changes (e.g., newly hired HCP, retirement of HCP).
- The developer states that denominator testing was not conducted for this measure since it uses the same denominator of HCP definitions and categories as the currently endorsed measure, NQF #0431 Influenza Vaccination Coverage Among Healthcare Personnel. The developer reiterated that in the reliability testing of this denominator agreement was high for all denominator categories (greater than 90%).
 - The developer cites a paper by Libby et al, "Reliability and validity of a standardized measure of influenza vaccination coverage among healthcare personnel," that thoroughly tested and examined the denominator reliability of the influenza measure.
 - The developer also noted that while some facilities excluded nonemployee contractors (denominator reporting item #4 in the current measure) for whom the numerator and denominator were difficult to determine in the influenza-related study conducted in 2010 – 2011, nonemployee contractors have become more commonplace and have been reported to NHSN throughout the pandemic response.
- 8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

Submission document: Testing attachment, section 2a2.2

imes Yes

 \Box No

- □ Not applicable (score-level testing was not performed)
- Was the method described and appropriate for assessing the reliability of ALL critical data elements?
 Submission document: Testing attachment, section 2a2.2

🛛 Yes

🗆 No

□ Not applicable (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and <u>all</u> testing results):

□ High (NOTE: Can be HIGH only if score-level testing has been conducted)

⊠ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has <u>not</u> been conducted)

□ **Low** (NOTE: Should rate LOW if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

□ **Insufficient** (NOTE: Should rate INSUFFICIENT if you believe you do not have the information you need to make a rating decision)

11. Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.

Specifications are precise and unambiguous (Box 1) \rightarrow Empirical reliability testing conducted using the measure as specified (Box 2) \rightarrow Reliability testing was not conducted using computed measure score (Box 4) \rightarrow Reliability testing conducted with the data elements used to construct the measure (Box 8) \rightarrow Method described by developer was appropriate for all critical data elements (Box 9) \rightarrow There is moderate certainty this data is reliable (Box 10a.)

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. Please describe any concerns you have with measure exclusions.

Submission document: Testing attachment, section 2b2.

- Measure exclusions include those with contraindications/restrictions. No concerns with the measure's exclusions.
 - The developer also notes that HCP personal preference or vaccine hesitancy is not considered a contraindication or exclusion.
- For 15,267 facilities reporting COVID-19 vaccination coverage for HCP during Q3 2021, the mean number of HCP per facility was 117.0, with a standard deviation of 77.0. Among these 15,267 facilities, the mean percentage of HCP with contraindications was 0.6%, with a standard deviation of 2.0%. The proportion of HCP with contraindications/exclusions was similar when facilities were stratified by number of HCP and region.
- The developer asserts that identification of HCP with contraindications/exclusions is important to
 collect since a facility should not be penalized for employing a HCP with a contraindication which
 precludes COVID-19 vaccination, and HCP with certain identified contraindications or other
 exclusions should not be vaccinated according to FDA authorization and ACIP/HHS
 recommendations.
 - The developer also states that the number of HCP with contraindications/exclusions would be expected to decline because receipt of monoclonal antibody treatment or convalescent plasma within 90 days and isolation for/recovering from COVID-19 are exclusions that should decline in frequency as more HCP are vaccinated.

13. Please describe any concerns you have regarding the ability to identify meaningful differences in performance.

Submission document: Testing attachment, section 2b4.

• No concerns. The developer states that a meaningful difference in performance would lead to fewer symptomatic cases at the facility. They used mathematical modeling to show that an increase in vaccination rates at a facility would produce this result.

14. Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.

Submission document: Testing attachment, section 2b5.

- The data source at the facility level is not specified but all facility level data is reported to the NHSN using a standardized form. The measure relies on this NHSN output, which has comparability across facilities.
- Denominator category #4, nonemployee contractors, is considered 'optional' for facilities to report in calculating their measure score. The developer notes that nonemployee contractors have become more commonplace and have been reported to NHSN throughout the pandemic response.
- No concerns regarding comparability of results.

15. Please describe any concerns you have regarding missing data.

Submission document: Testing attachment, section 2b6.

- The developer compared the measure's coverage rates for facilities that met the measure's reporting requirements as well as for facilities that were missing one or two months of data. The developer reiterates that all three months must be reported to adequately meet the measure's requirements. In other cases, the measure score is likely to be affected by the missing data.
- Greater than 98% of facilities (15,106 facilities) reported all three months. Less than half of one percent, .41%, reported just one month and .65% reported just two months. Twenty-nine facilities did not report at all in the time period.

16. Risk Adjustment

6a. Risk-adjustment method	🛛 None	Statistical model	Stratification

16b. If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?

 \Box Yes \Box No \boxtimes Not applicable

16c. Social risk adjustment:

16c.1 Are social risk factors included in risk model? \Box Yes \Box No \boxtimes Not applicable

16c.2 Conceptual rationale for social risk factors included?
Ves No

16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus?
Yes No

16d.Risk adjustment summary:

- 16d.1 All of the risk-adjustment variables present at the start of care? \Box Yes \Box No
- 16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion?
- 16d.3 Is the risk adjustment approach appropriately developed and assessed? \Box Yes \Box No
- 16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration)
 - 🗆 Yes 🛛 🗆 No

16d.5.Appropriate risk-adjustment strategy included in the measure?
Ves No

16e. Assess the risk-adjustment approach

• The developer states that demographic factors are not collected as part of this measure's reporting system.

For cost/resource use measures ONLY:

17. Are the specifications in alignment with the stated measure intent?

□ Yes □ Somewhat □ No (If "Somewhat" or "No", please explain)

18. Describe any concerns of threats to validity related to attribution, the costing approach, carve outs, or truncation (approach to outliers):

• Public comments showed a concern with attribution since a facility does not entirely have control over whether its HCP population chooses to receive a COVID-19 vaccine; however, most HCP personnel on many national and local levels have been required to receive a COVID-19 vaccine.

VALIDITY: TESTING

- 19. Validity testing level: 🛛 Measure score 🛛 Data element 🖓 Both
- 20. Method of establishing validity of the measure score:
 - □ Face validity
 - ☑ Empirical validity testing of the measure score
 - □ N/A (score-level testing not conducted)
- 21. Assess the method(s) for establishing validity

Submission document: Testing attachment, section 2b2.2

- The developer tested the measure's validity by correlating the measure scores with another similar NQF-endorsed measure, #0431 Influenza Vaccination Coverage Among Healthcare Personnel, hypothesizing that facilities committed to ensuring high rates of influenza vaccination in their HCP are likely to be committed to ensuring high rates of COVID-19 vaccination in their HCP.
- The developer assessed the Pearson Correlation Coefficients between the Quarterly COVID-19 coverage measure for Q3 2021 and NQF #0431.
- The data used for testing were the 1,807 CMS-certified nursing homes which participated in both NHSN COVID-19 vaccination coverage reporting for Quarter 3 (July, August, September) 2021 and NHSN annual influenza vaccination coverage reporting for the 2020-2021 influenza season.
- To determine if there are statistically significant differences in performance measure scores among measured entities, the developer compared the mean scores and 95% confidence intervals for each quarter first to each other and then to the performance measure scores for the 25th- and 75th-percentile facilities.

22. Assess the results(s) for establishing validity

Submission document: Testing attachment, section 2b2.3

- The overall Pearson Correlation Coefficient between the quarterly COVID-19 coverage measure for Q3 2021 and annual Influenza Vaccination coverage (NQF #0431) was 0.4169, p<0.0001 (1,654 Facilities).
 - Correlation coefficient of 0.4169 indicates "medium" correlation using the generally accepted range for medium correlation, 0.30 0.49.
- When the results were stratified into quartiles by facility size, the correlation coefficients for the largest facilities (quartile 3: 94-131 HCP and quartile 4: >132 HCP) were even larger than the overall correlation coefficient (0.457 and 0.450, respectively), though correlation coefficients for all four quartiles were statistically significant (p < 0.0001).
 - These data represent a medium correlation when stratified by facility size (number of HCP).
- The developer details a number of factors outside of facilities' control which likely impact HCP COVID-19 vaccination coverage and are independent of influenza vaccination.
 - HCP may have reasons for which they decline COVID-19 vaccine which they do not apply similarly to the influenza vaccine.
 - Community rates of COVID-19 may vary from community rates of influenza and impact HCP vaccination decisions.

- High numbers of facilities reported 99% or higher influenza vaccination coverage. With additional time for the new COVID-19 vaccines to gain acceptance and for implementation of vaccination programs to address COVID-19 vaccination hesitancy, coverage rates of COVID-19 and influenza vaccination are likely to correlate more strongly.
- The developer states that this measure can identify statistically significant differences in performance across measured entities since the mean quarterly COVID-19 vaccination coverage metric had 95% confidence intervals that were narrower than the interquartile range.
 - In determining if there are statistically significant differences in performance measure scores among measured entities, the developer calculated the mean quarterly COVID-19 vaccination coverage rate and interquartile ranges for the first 3 quarters of 2021:
 - Q1: mean coverage 35.0% (34.3% 35.7%); interquartile range 17.3% 51.2%
 - Q2: mean coverage 56.2% (55.8% 56.5%); interquartile range 41.9% 71.2%
 - Q3: mean coverage is 64.1% (63.8% 64.4%); interquartile range is 50.8% 78.6%.
 - The mean quarterly COVID-19 vaccination coverage metric was higher each of the first 3 quarters of 2021, based on non-overlapping 95% confidence intervals, showing the measure can identify differences in performance across quarters.

23. Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?

Submission document: Testing attachment, section 2b1.

- oxtimes Yes
- 🗆 No
- □ **Not applicable** (score-level testing was not performed)
- 24. Was the method described and appropriate for assessing the accuracy of ALL critical data elements? *NOTE that data element validation from the literature is acceptable.*

Submission document: Testing attachment, section 2b1.

🗌 Yes

🗆 No

Not applicable (data element testing was not performed)

- 25. OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.
 - High (NOTE: Can be HIGH only if score-level testing has been conducted)
 - □ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)
 - □ **Low** (NOTE: Should rate LOW if you believe that there are threats to validity and/or relevant threats to validity were not assessed OR if testing methods/results are not adequate)
 - □ Insufficient (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level is required; if not conducted, should rate as INSUFFICIENT.)
- 26. Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.

Threats to validity were assessed (Box 1) \rightarrow Empirical validity testing conducted using measure as specified (Box 2) \rightarrow Validity testing conducted using computed measure scores (Box 5) \rightarrow Method was appropriate for

assessing hypothesized relationships (Box 6) \rightarrow There is high certainty that these scores are an indicator of quality (Box 7a.)

FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

27. What is the level of certainty or confidence that the empirical analysis demonstrates that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct?

🗆 High

□ Moderate

□ Insufficient

28. Briefly explain rationale for rating of EMPIRICAL ANALYSES TO SUPPORT COMPOSITE CONSTRUCTION

ADDITIONAL RECOMMENDATIONS

29. If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.

1. Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Measure and Report: Evidence section. For example:

2021 Submission: Updated evidence information here.

2018 Submission: Evidence from the previous submission here.

Evidence

1a.01. Provide a logic model.

Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

[Response Begins]



Based on Table 4 of Weber, D., Al-Tawfiq, J., Babcock, H., Bryant, K., Drees, M., Elshaboury, R., . . . Young, H. (2021). Multisociety statement on coronavirus disease 2019 (COVID-19) vaccination as a condition of employment for healthcare personnel. Infection Control & Hospital Epidemiology, 1-9. doi:10.1017/ice.2021.322

[Response Ends]

1a.02. Select the type of source for the systematic review of the body of evidence that supports the performance measure.

A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data.

[Response Begins]

Other (specify)

Dooling K, Marin M, Wallace M, et al. The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020. MMWR Morb Mortal Wkly Rep 2021;69:1657-1660. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm695152e2</u> [Response Ends]

If the evidence is not based on a systematic review, skip to the end of the section and do not complete the repeatable question group below. If you wish to include more than one systematic review, add additional tables by clicking "Add" after the final question in the group.

Evidence - Systematic Reviews Table (Repeatable)

Group 1 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

[Response Begins] N/A [Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

[Response Begins] N/A [Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

[Response Begins] N/A [Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

[Response Begins] N/A NATIONAL QUALITY FORUM 1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

[Response Begins] N/A [Response Ends]

1a.08. Provide all other grades and definitions from the recommendation grading system.

[Response Begins] N/A [Response Ends]

1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

[Response Begins] N/A [Response Ends]

1a.10. Provide the estimates of benefit, and consistency across studies.

[Response Begins] N/A [Response Ends]

1a.11. Indicate what, if any, harms were identified in the study.

[Response Begins] N/A [Response Ends]

1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

[Response Begins] N/A [Response Ends]

1a.13. If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, describe the evidence on which you are basing the performance measure.

[Response Begins]

The **Advisory Committee on Immunization Practices (ACIP)** provides advice and guidance to the Director of the CDC regarding use of vaccines and related agents for control of vaccine-preventable diseases in the civilian population of the United States. Recommendations made by the ACIP are reviewed by the CDC Director and, if adopted, are published as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report (MMWR).

[Response Ends]

1a.14. Briefly synthesize the evidence that supports the measure.

[Response Begins]

Healthcare settings are high risk locations for SAR-CoV-2 exposure.¹

As of December 1, 2020, approximately 245,000 COVID-19 cases and 860 COVID-19-associated deaths have been reported among HCP.²

HCP are at risk of transmitting the virus to medically vulnerable patients as seen with long-term care facility (LTCF) outbreaks. $\frac{3.4}{2}$

From a subset of jurisdictions reporting occupation type and job setting for HCP with COVID-19, health care support workers accounted for the largest overall group of occupation types (32%) and residential care facilities were the most common job setting (67%).¹

Analysis of COVID-19 hospitalization data from 13 sites through May 31 indicated that 6% of adults hospitalized with COVID-19 were HCP. Of those hospitalized with HCP, 52% were non-Hispanic blacks. Approximately 28% of hospitalized HCP were admitted to an intensive care unit, 16% required invasive mechanical ventilation, and 4% died.⁵

LTCF modeling predicted more cases and deaths averted at the facility by vaccinating staff compared with vaccinating residents. $\frac{6}{2}$

Early protection of HCP is critical to preserve healthcare capacity to care for COVID-19 patients and ensure hospitals maintain a workforce to care for non-COVID-19 patients.

- Hughes MM, Groenewold MR, Lessem SE, et al. Update: Characteristics of health care personnel with COVID-19

 United States, February 12–July 16, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1364–1368.
 DOI: https://dx.doi.org/10.15585/mmwr.mm6938a3external.con.
- 2. <u>CDC COVID Data Tracker</u>. Accessed November 29, 2020.
- McMichael TM, Clark S, Pogosjans S, et al. COVID-19 in a Long-Term Care Facility King County, Washington, February 27–March 9, 2020. MMWR Morb Mortal Wkly Rep 2020;69:339-342.
 DOI: <u>http://dx.doi.org/10.15585/mmwr.mm6912e1external%20icon</u>
- Dora AV, Winnett A, Jatt LP, et al. Universal and serial laboratory testing for SARS-CoV-2 at a long-term care skilled nursing facility for veterans—Los Angeles, California, 2020. MMWR Morb Mortal Wkly Rep 2020;69:651– 5. DOI: <u>https://dx.doi.org/10.15585/mmwr.mm6921e1external%20icon</u>
- Kambhampati AK, O'Halloran AC, Whitaker M, et al. COVID-19–Associated hospitalizations among health care personnel — COVID-NET, 13 States, March 1–May 31, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1576–1583. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm6943e3external%20icon</u>
- 6. Slayton R. Modeling allocation strategies for the initial SARS-CoV-2 vaccine supply. **Presentation to ACIP**. August 21, 2020.

[Response Ends]

1a.15. Detail the process used to identify the evidence.

[Response Begins]

The ACIP COVID-19 Vaccines Work Group considered evidence related to SARS-CoV-2 epidemiology, vaccination program implementation, and **ethical principles in** developing the interim recommendation on allocation of the initial supply of COVID-19 vaccine (Phase 1a).

Evidence-based information addressing COVID-19 vaccine topics including early allocation has been explicitly and transparently reviewed during seven public ACIP meetings (Advisory Committee on Immunization Practices. ACIP meeting information. Atlanta, GA: US Department of Health and Human Services, CDC; 2020. <u>https://www.cdc.gov/vaccines/acip/meetings/index.html</u>).

To inform policy options for ACIP, the COVID-19 Vaccines Work Group, comprising experts in vaccines and ethics, held more than 25 meetings to review data regarding vaccine candidates, COVID-19 surveillance, and modeling, as well as the vaccine allocation literature from published and external expert committee reports. **[Response Ends]**

1a.16. Provide the citation(s) for the evidence.

[Response Begins]

Dooling K, McClung N, Chamberland M, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1857-1859. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm6949e1external icon</u>

ACIP Evidence Table for COVID-19 Vaccines Allocation in Phase 1a of the Vaccination Program is available at:

https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/evidence-table.html [Response Ends]

Performance Gap

1b.01. Briefly explain the rationale for this measure.

Explain how the measure will improve the quality of care, and list the benefits or improvements in quality envisioned by use of this measure.

[Response Begins]

High COVID-19 vaccine uptake is needed to protect the healthcare workforce, but also protect patients and the community. For these reasons, the Advisory Committee on Immunization Practices (ACIP) recommended prioritizing healthcare personnel (along with long-term care facility residents) with the first phase of vaccine supplies.

- The healthcare setting can be high-risk for SARS-CoV-2 exposure and transmission and protecting healthcare personnel from infection is critical to preserving the capacity to care for patients with COVID-19 or other illnesses. For example, as of the week ending October 10, 2021, there have been 659,751 nursing home staff COVID-19 cases and 2,133 nursing home COVID-19 staff deaths (in addition to 710,264 nursing home resident COVID-19 cases and 138,205 nursing home resident COVID-19 deaths) (https://data.cms.gov/covid-19/covid-19-nursing-home-data, accessed October 25, 2021).
- 2. Tracking vaccination coverage among HCP can help improve uptake of highly efficacious COVID-19 vaccines which reduce the burden of illness and death,
- 3. Regular monitoring of vaccination coverage rates can help facilities maintain current efforts to vaccinate new staff and continue to engage and build confidence among staff who may be hesitant.

[Response Ends]

1b.02. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Include mean, std dev, min, max, interquartile range, and scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]

In December 2020, the National Healthcare Safety Network (NHSN) released the COVID-19 vaccination coverage reporting module for voluntary reporting of COVID-19 vaccination coverage among healthcare personnel (HCP) in long-term care (post-acute care) and inpatient.

In June 2021, CMS began to require CMS-certified long-term care facilities to collect and report weekly COVID-19 vaccination coverage through the National Healthcare Safety Network (NHSN). (Interim Final Rule - COVID-19 Vaccine Immunization Requirements for Residents and Staff: QSO-21-19-NH. May 11, 2021. Center for Clinical Standards and Quality/Quality, Safety & Oversight Group, CMS. <u>https://www.cms.gov/files/document/gso-21-19-nh.pdf</u>)

Quarterly COVID-19 vaccination coverage among healthcare personnel (HCP) among CMS-certified nursing homes, National Healthcare Safety Network (NHSN), 2021

Facility Characteristic	Quarter 1 (Jan, Feb, Mar)	Quarter 2 (Apr, May, Jun)	Quarter 3 (Jul, Aug, Sep)
No. Facilities	4,197	15,156	15,267
Mean No. HCP (SD)	112.3 (72.4)	117.0 (77.5)	117.0 (77.0)
COVID-19 vaccination coverage percentage (SD)	35.0 (23.8)	56.2 (20.9)	64.1 (18.8)
95% Confidence Interval	34.3, 35.7	55.8, 56.5	63.8, 64.4
COVID-19 vaccination coverage percentage by quantile	Quarter 1 (Jan, Feb, Mar)	Quarter 2 (Apr, May, Jun)	Quarter 3 (Jul, Aug, Sep)
0%	0.0	0.0	0
1%	0.0	1.4	19.8
5%	0.0	21.6	31.9
10%	0.0	29.0	38.8
25% (Q1)	17.3	41.9	50.8
50% (median)	33.4	56.2	64.9
75% (Q3)	51.2	71.2	78.6
90%	67.2	84.1	89.0
95%	77.2	90.7	93.3
99%	95.6	99.2	98.7
100%	100.0	100.0	100.0
Region, No. of facilities (%)	Quarter 1 (Jan, Feb, Mar)	Quarter 2 (Apr, May, Jun)	Quarter 3 (Jul, Aug, Sep)
Northeast	902 (21.5)	2,503 (16.5)	2,514 (16.4)
South	1,463 (34.9)	5,364 (35.4)	5,405 (35.3)
Midwest	1,276 (30.4)	4,936 (32.6)	4,972 (32.5)
West	552 (13.2)	2,346 (15.5)	2,369 (15.5)
Puerto Rico or territory	4 (0.1)	7 (0.1)	36 (0.2)

[Response Ends]

1b.03. If no or limited performance data on the measure as specified is reported above, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement. Include citations.

[Response Begins] N/A [Response Ends]

1b.04. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]

Data for the measure are aggregated (not collected at an individual level) and not collected by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. [Response Ends]

1b.05. If no or limited data on disparities from the measure as specified is reported above, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in above.

[Response Begins]

An analysis of disparities in COVID-19 vaccination coverage among healthcare personnel (HCP) types has identified lower COVID-19 vaccination coverage rates among certain HCP categories (nurses and aides) and among facilities located in zip codes with indicators of social vulnerability (*MMWR* 2021;70:1036–1039. DOI: http://dx.doi.org/10.15585/mmwr.mm7030a2).

During March 1–April 4, a total of 1,898 LTCFs voluntarily reported HCP COVID-19 vaccination data through the National Healthcare Safety Network (NHSN), including 300 (16%) facilities from 47 states that reported numbers for HCP and vaccination status for every job category.

In this convenience sample, the HCP type with the highest vaccination percentage was physicians and other advanced practice providers (75.1%), followed by therapists (69.2%), ancillary services employees (58.5%), nurses (56.7%), and aides (45.6%). Coverage was 68.5% among other HCP not reported in these categories (e.g., students, contractors). The proportion of persons who declined COVID-19 vaccination ranged from 11.1% among physicians to 33.2% among aides.

The percentage of aides who were completely vaccinated was lower among those working in facilities located in ZIP-code areas with higher proportions of ethnic and racial minorities (43.5% versus 50.5%), lower household median income (40.5% versus 48.1%), higher poverty (42.4% versus 49.2%), and lower high school completion (42.2% vs 49.3%).

Other research has identified lower vaccination coverage among nurses and support staff, among Black and Hispanic healthcare personnel, and higher vaccination acceptance among doctoral-degree personnel.¹ Various studies have found decreased likelihood of vaccine acceptance among healthcare personnel identified as Black^{2,3,4,5,6,7,8}, Latinx², female ^{2,3,5,7,8}, or having lower educational attainment^{3,6,7,8}.

- 1. A Cross-Sectional Study of SARS-CoV-2 Vaccination Among Employees of an Urban Safety-Net Health Care System. Ann Intern Med 2021 Sep;174(9):1340-1343.
- 2. COVID-19 vaccine acceptance among health care workers in the United States. *Vaccines* 2021;9(2):119.
- 3. Perspectives on the receipt of a COVID-19 vaccine: A survey of employees in two large hospitals in Philadelphia. *Vaccine* 2021 Mar 19;39(12):1693-1700.

- 4. Assessment of US health care personnel (HCP) attitudes towards COVID-19 vaccination in a large university health care system. *Clin Infect Dis* 2021 Jan 25;ciab054.
- 5. COVID-19 vaccination hesitancy among healthcare personnel in the emergency department deserves continued attention. *Am J Emerg Med* 2021 Feb 2;S0735-6757(21)00100-5.
- 6. Vaccination rates and acceptance of SARS-CoV-2 vaccination among US emergency department health care personnel. *Acad Emerg Med* 2021 Apr;28(4):455-458.
- 7. Acceptance of COVID-19 Vaccination Among Health System Personnel. *J Am Board Fam Med* May-Jun 2021;34(3):498-508.
- Coronavirus disease 2019 (COVID-19) vaccine hesitancy among physicians, physician assistants, nurse practitioners, and nurses in two academic hospitals in Philadelphia. *Infect Control Hosp Epidemiol* 2021 Sep 20;1-9.

[Response Ends]

2. Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.

sp.01. Provide the measure title.

Measure titles should be concise yet convey who and what is being measured (see <u>What Good Looks Like</u>).

[Response Begins] Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel [Response Ends]

sp.02. Provide a brief description of the measure.

Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).

[Response Begins]

This quarterly measure identifies the average percentage of healthcare personnel (HCP) who have <u>ever</u> received a primary COVID-19 vaccination course among the total number of HCP who regularly work in the facility.

The measure is reported for a quarter (3-month period). The quarterly COVID-19 vaccination coverage is determined by selecting one week per month and calculating the percentage of HCP who have ever received a primary COVID-19 vaccination course, then averaging 3 weekly percentages (one week from each of the 3 months in the quarter). **[Response Ends]**

sp.04. Check all the clinical condition/topic areas that apply to your measure, below.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

• Surgery: General

[Response Begins] Infectious Diseases (ID): Pneumonia and respiratory infections [Response Ends]

sp.05. Check all the non-condition specific measure domain areas that apply to your measure, below.

[Response Begins] Immunization Safety: Healthcare Associated Infections [Response Ends]

sp.06. Select one or more target population categories.

Select only those target populations which can be stratified in the reporting of the measure's result.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options

and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

• Populations at Risk: Populations at Risk

[Response Begins] Adults (Age >= 18) [Response Ends]

sp.07. Select the levels of analysis that apply to your measure.

Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- Clinician: Clinician
- Population: Population

[Response Begins] Facility [Response Ends]

sp.08. Indicate the care settings that apply to your measure.

Check ONLY the settings for which the measure is SPECIFIED and TESTED. [Response Begins] Post-Acute Care [Response Ends]

sp.09. Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials.

Do not enter a URL linking to a home page or to general information. If no URL is available, indicate "none available".

[Response Begins]

The data collection forms and instructions for long-term care (post-acute care) facilities (LTCFs) are available here:

- Healthcare Personnel COVID-19 Vaccination Cumulative Summary (CDC 57.219, Rev 5) https://www.cdc.gov/nhsn/forms/57.219-p.pdf
- Instructions for Completion of the Weekly Healthcare Personnel COVID-19 Vaccination Cumulative Summary (57.219, REV 5) <u>https://www.cdc.gov/nhsn/forms/57.219-p.pdf</u>

Additional training and supporting materials for long-term care (post-acute care) facilities are available at: <u>https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html</u>

[Response Ends]

sp.11. Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.

Attach an excel or csv file; if this poses an issue, <u>contact staff</u>. Provide descriptors for any codes. Use one file with multiple worksheets, if needed. [Response Begins]

No data dictionary/code table – all information provided in the submission form **[Response Ends]**

Attachment: 3636_57.219-p CDC NHSN Form.pdf Attachment: 3636_57.219-p CDC NHSN Form.pdf

sp.12. State the numerator.

Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome).

DO NOT include the rationale for the measure.

[Response Begins]

The numerator for this measure consists of the cumulative number of HCP in the denominator population, who:

- 1. have received a complete vaccination course against COVID-19 administered at the healthcare facility; or
- 2. reported in writing (paper or electronic) or provided documentation that a complete vaccination course against COVID-19 was received elsewhere

[Response Ends]

sp.13. Provide details needed to calculate the numerator.

All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

The time period for data collection is one week. A week always begins at 12:01 AM on a Monday and ends on the following Sunday at midnight.

Collect the **cumulative number** of healthcare personnel (HCP) who have received a primary vaccination course against COVID-19 vaccines at this facility or elsewhere since December 2020. Data sources may include HCP health records and paper and/or electronic documentation of vaccinations given at the healthcare facility or elsewhere. vaccinations elsewhere should provide documentation of the vaccination, which includes the vaccine type.

A completed primary COVID-19 vaccine series is defined by the FDA authorization for use COVID-19 Vaccines | FDA and recommendations made by the Advisory Committee on Immunization Practices ACIP COVID-19 Vaccine Recommendations | CDC which are reviewed and, if adopted by CDC and the Department of Health and Human Services, published in the Morbidity and Mortality Weekly Report (MMWR).

These recommendations are further described Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. As of November 1, 2021, completion of a primary vaccination series is receipt of two doses of mRNA vaccines (manufactured by Pfizer-BioNTech or Moderna) or one dose of viral vector vaccine (manufactured by Janssen).

[Response Ends]

sp.14. State the denominator.

Brief, narrative description of the target population being measured.

[Response Begins]
The target population is the number of healthcare personnel (HCP) eligible to work in the healthcare facility for at least one day during the one-week data collection reporting period, excluding persons with contraindications/exclusions to COVID-19 vaccination. The quarterly reported measure includes at least one week of data collection a month for each of the 3 months in a quarter.

The denominators are reported by aggregating categories below:

- 1. Employees: all persons who receive a direct paycheck from the reporting facility (i.e., on the facility's payroll).
- 2. Licensed independent practitioners: include physicians (MD, DO), advanced practice nurses, and physician assistants only who are affiliated with the reporting facility who do not receive a direct paycheck from the reporting facility.
- 3. Adult students/trainees and volunteers include all students/trainees and volunteers aged 18 or over who do not receive a direct paycheck from the reporting facility.
- 4. Other contract personnel: Facilities may also report on individuals who are contract personnel. However, reporting for this category is optional. Contract personnel are defined as persons providing care, treatment, or services at the facility through contract who do not fall into any of the above-mentioned denominator categories.

[Response Ends]

sp.15. Provide details needed to calculate the denominator.

All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

To identify all healthcare personnel (HCP) eligible to work during the reporting week.

- 1. Include all HCP who were eligible to have worked at this healthcare facility for at least 1 day during the reporting week, regardless of clinical responsibility or patient contact.
- 2. HCP who are eligible to have worked include those who are scheduled to work in the facility at least 1 day of the week. Working any part of 1 day is considered as working 1 day.
- 3. Include HCP even if they are on temporary leave during the reporting week. Temporary leave is defined as less than or equal to 2 weeks in duration. Examples of temporary leave may include sick leave or vacation. In instances where temporary leave extends past two weeks, the healthcare worker should not be included for the current week of data collection.
- 4. Include persons who worked full-time and part-time.
- 5. Each person should be counted only once in the denominator.
- 6. HCP categories should be mutually exclusive. Do not count a person in more than one category.
- 7. If HCP were eligible to have worked in two or more facilities, each facility should include such personnel in their denominator.
- 8. Count HCP as individuals rather than full-time equivalents.
- 9. Data sources for determining eligibility may include payroll, attendance, or other records.

[Response Ends]

sp.16. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

[Response Begins]

Exclusions include individuals with contraindications to COVID-19 vaccination and individuals for whom the COVID-19 vaccine is not authorized or recommended.

[Response Ends]

sp.17. Provide details needed to calculate the denominator exclusions.

All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

Medical contraindications are listed in a vaccine's FDA authorization or labeling and include severe allergic reaction. The most up-to-date list of contraindications as well as exclusions may be found <u>at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html</u> and includes:

 Contraindications include severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine or immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

Individuals for whom the COVID-19 vaccine is not authorized or recommended include the following:

- 1. COVID-19 vaccines are not currently authorized for individuals 11 years of age or younger.
- COVID-19 vaccination should be deferred for at least 90 days for individuals who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. <u>https://www.cdc.gov/vaccines/covid-19/clinicalconsiderations/covid-19-vaccines-us.html</u>

COVID-19 vaccines may be administered without regard to the timing of other vaccines. This includes simultaneous administration of the COVID-19 vaccine and other vaccines on the same day. It is not known if the reactogenicity of COVID-19 vaccines is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines. When deciding whether to administer an(other) vaccine(s) with a COVID-19 vaccine, vaccination providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines. <u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html</u>

[Response Ends]

sp.18. Provide all information required to stratify the measure results, if necessary.

Include the stratification variables, definitions, specific data collection items/responses, code/value sets, and the riskmodel covariates and coefficients for the clinically-adjusted version of the measure when appropriate. Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format in the Data Dictionary field.

[Response Begins] N/A [Response Ends]

sp.19. Select the risk adjustment type.

Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section. [Response Begins] No risk adjustment or risk stratification [Response Ends]

sp.20. Select the most relevant type of score.

Attachment: If available, please provide a sample report.

sp.21. Select the appropriate interpretation of the measure score.

Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score

[Response Begins]

Better quality = Higher score [Response Ends]

sp.22. Diagram or describe the calculation of the measure score as an ordered sequence of steps.

Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.

[Response Begins]

Data Collection:

- 1. Identify all healthcare personnel (HCP) eligible to work during the selected week. The week always begins on a Monday at 12:00 midnight and ends on Sunday at 11:59 pm.
- 2. Categorize all eligible HCP into one of four HCP categories (a d)
- 3. Among eligible HCP, identify those who have received a primary COVID-19 vaccination course administered at the healthcare facility or elsewhere.
- 4. Among eligible HCP who have not received a primary COVID-19 vaccination course, identify those who have a contraindication or exclusion to vaccination.
- 5. Among eligible HCP who have not received any COVID-19 vaccines and who do not have a contraindication or exclusion to vaccination, identify those who have refused or declined vaccination.
- 6. Among eligible HCP who have not received any COVID-19 vaccines, identify those whose COVID-19 vaccination status can not be determined.

Measure Calculation:

- 1. For each one week period, tabulate the denominator by summing the number of HCP in each of the categories of HCP minus the number of HCP with contraindications or exclusions to COVID-19 vaccination.
- 2. Calculate the weekly COVID-19 vaccination coverage percentage by dividing the number of HCP in the denominator who have received a complete COVID-19 vaccination course by the number of HCP in the denominator and multiplying by 100.

Report quarterly COVID-19 vaccination coverage by averaging 3 weekly coverage percentages (one week from each of the 3 months in the quarter).

If facilities calculate COVID-19 vaccination coverage more than one week per month, the last full week in the reporting month should be used.

[Response Ends]

sp.25. If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.

[Response Begins] N/A [Response Ends]

sp.28. Select only the data sources for which the measure is specified.

[Response Begins]

Other (specify)

The source is not specified as it may vary by facility. Data may be collected from electronic sources or paper-based sources. It may be obtained from existing records or a system specifically designed for COVID-19 vaccination tracking. **[Response Ends]**

sp.29. Identify the specific data source or data collection instrument.

For example, provide the name of the database, clinical registry, collection instrument, etc., and describe how data are collected.

[Response Begins]

Data are collected using the National Healthcare Safety Network of the U.S. Centers for Disease Control and Prevention - <u>https://www.cdc.gov/nhsn/index.html</u>

[Response Ends]

sp.30. Provide the data collection instrument.

[Response Begins] Available at measure-specific web page URL identified in sp.09 [Response Ends]

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate fields in the Scientific Acceptability sections of the Measure Submission Form.

• Measures must be tested for all the data sources and levels of analyses that are specified. If there is more than one set of data specifications or more than one level of analysis, contact NQF staff about how to present all the testing information in one form.

• All required sections must be completed.

• For composites with outcome and resource use measures, Questions 2b.23-2b.37 (Risk Adjustment) also must be completed.

• If specified for multiple data sources/sets of specifications (e.g., claims and EHRs), Questions 2b.11-2b.13 also must be completed.

• An appendix for supplemental materials may be submitted (see Question 1 in the Additional section), but there is no guarantee it will be reviewed.

• Contact NQF staff with any questions. Check for resources at the Submitting Standards webpage.

• For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for the 2021 Measure Evaluation Criteria and Guidance.

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF's evaluation criteria for testing. 2a. Reliability testing demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.

2b1. Validity testing demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument based measures (including PRO-PMs) and composite performance measures, validity should be demonstrated for the computed performance score.

2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure;

AND

If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

2b3. For outcome measures and other measures when indicated (e.g., resource use):

• an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; 14,15 and has demonstrated adequate discrimination and calibration

OR

• rationale/data support no risk adjustment/ stratification.

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful 16 differences in performance;

OR

there is evidence of overall less-than-optimal performance.

2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results. 2b6. Analyses identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias.

2c. For composite performance measures, empirical analyses support the composite construction approach and demonstrate that:

2c1. the component measures fit the quality construct and add value to the overall composite while achieving the related objective of parsimony to the extent possible; and

2c2. the aggregation and weighting rules are consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible.

(if not conducted or results not adequate, justification must be submitted and accepted)

Definitions

Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.

Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.

Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions. Risk factors that influence outcomes should not be specified as exclusions.

With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of \$25 in cost for an episode of care (e.g., \$5,000 v.\$5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers.

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Scientific Acceptability sections. For example:

2021 Submission:

Updated testing information here.

2018 Submission:

Testing from the previous submission here.

2a.01. Select only the data sources for which the measure is tested.

[Response Begins]

Other (specify)

The source is not specified as it may vary by facility. Data may be collected from electronic sources or paper-based sources. It may be obtained from existing records or a system specifically designed for COVID-19 vaccination tracking. This approach is consistent with the implementation of NQF 0431 - "Data sources for the required data elements include management/personnel data, medical or occupational health records, and vaccination records." (The National Healthcare Safety Network (NHSN) Manual, Healthcare Personnel Safety Component Protocol, Healthcare Personnel Vaccination Module: Influenza Vaccination Summary. <u>https://www.cdc.gov/nhsn/pdfs/hps-manual/vaccination/hps-flu-vaccine-protocol.pdf</u>)

[Response Ends]

2a.02. If an existing dataset was used, identify the specific dataset.

The dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).

[Response Begins] N/A [Response Ends]

2a.03. Provide the dates of the data used in testing.

Use the following format: "MM-DD-YYYY - MM-DD-YYYY"

[Response Begins]

Data used for reliability testing: 12-28-2020 – 01-17-2021

Data used for validity testing: 07-4-2021 – 09-26-2021

Data used for assessing missing data and exclusions: 07-4-2021 – 09-26-2021 [Response Ends]

2a.04. Select the levels of analysis for which the measure is tested.

Testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- Clinician: Clinician
- Population: Population

[Response Begins] Facility [Response Ends]

2a.05. List the measured entities included in the testing and analysis (by level of analysis and data source).

Identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample.

[Response Begins]

For reliability testing:

Individual-level data element testing for the numerator data element of healthcare personnel (HCP) COVID-19
vaccination was conducted in 869 CMS-certified nursing homes (NHs) based on data collected from December
2020 – January 2021.

Immediately following the authorization of the first COVID-19 vaccines in December 2020, NHSN released COVID-19 reporting modules for tracking vaccination coverage among residents and staff of long-term care facilities. These modules allow for voluntary weekly reporting by facilities and are designed to collect data on the number of current residents and staff eligible for vaccination and who have been vaccinated. Also beginning in December 2020, the Pharmacy Partnership for Long-Term Care Program was designed as a time-limited initiative to facilitate a limited number of vaccination clinics at each participating facility. The collection of HCP vaccination data by facilities which participated in both of these independent systems allowed for reliability testing of the key new data element of the COVID-19 vaccination coverage measure. The measured entities included in reliability testing were **869 CMS-certified NHs** which participated in both the Pharmacy Partnership for Long-Term Care Program and reported COVID-19 vaccination coverage to NHSN during one of the three weeks from December 28, 2020 through January 17, 2021.

These NHs represent 48 states, ranging from 1 participating facility in WY and MT to 91 participating facilities in TX.

 Individual-level data element testing for the denominator data element of number of HCP was assessed in prior reliability testing for NQF measure 0431, which included long term care settings (Libby TE, Lindley MC, Lorick SA, MacCannell T, Lee SJ, Smith C, Geevarughese A, Makvandi M, Nace DA, Ahmed F. Reliability and validity of a standardized measure of influenza vaccination coverage among healthcare personnel. Infect Control Hosp Epidemiol. 2013 Apr;34(4):335-45. doi: 10.1086/669859. Epub 2013 Feb 19. PMID: 23466904. Appendix

For validity testing:

- Computed performance measure scores for the proposed quarterly COVID-19 vaccination measure for Q3 of 2021 (July – September) were compared to the NQF endorsed measure scores for influenza vaccination of HCP for the 2020-2021 influenza season for 1,807 CMS-certified NHs. These NHs represent 50 states.
- 1. Weekly HCP & Resident COVID-19 Vaccination. National Healthcare Safety Network (NHSN) Long-term Care Facility Component. <u>https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html</u>
- Gharpure R, Guo A, Bishnoi CK, et al. Early COVID-19 First-Dose Vaccination Coverage Among Residents and Staff Members of Skilled Nursing Facilities Participating in the Pharmacy Partnership for Long-Term Care Program — United States, December 2020–January 2021. MMWR Morb Mortal Wkly Rep 2021;70:178–182. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm7005e2</u>

[Response Ends]

2a.06. Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis), separated by level of analysis and data source; if a sample was used, describe how patients were selected for inclusion in the sample.

If there is a minimum case count used for testing, that minimum must be reflected in the specifications.

[Response Begins]

Healthcare personnel (HCP) in all the participating facilities were included in the analysis.

The number of HCP at the facilities ranged from 15 to 591 HCP, with a median of 96 HCP and an inter-quartile range of 70-135 HCP.

Individual HCP characteristics (e.g., age, sex, race) were not collected in the COVID-19 vaccination measure and were not collected for testing. [Response Ends]

2a.07. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing.

[Response Begins] For reliability testing,

The 869 CMS-certified nursing homes which participated in both National Healthcare Safety Network (NHSN) COVID-19 vaccination coverage reporting and the Pharmacy Partnership for Long-Term Care Program for the 3 weeks between December 18, 2020 and January 17, 2021 were used.

For validity testing,

The 1,807 CMS-certified nursing homes which participated in both NHSN COVID-19 vaccination coverage reporting for Quarter 3 (July, August, September) 2021 and NHSN annual influenza vaccination coverage reporting for the 2020-2021 influenza season were used.

For additional assessment of missing data and exclusions (contraindications)

All 15,267 CMS-certified nursing homes which participated in NHSN COVID-19 vaccination coverage reporting and NHSN for at least one month of Quarter 3 (July, August, September) 2021 were used. [Response Ends]

2a.08. List the social risk factors that were available and analyzed.

For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

[Response Begins] N/A [Response Ends] Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.07 check patient or encounter-level data; in 2a.08 enter "see validity testing section of data elements"; and enter "N/A" for 2a.09 and 2a.10.

Reliability

2a.09. Select the level of reliability testing conducted.

Choose one or both levels. [Response Begins] Accountable Entity Level (e.g., signal-to-noise analysis) [Response Ends]

2a.10. For each level of reliability testing checked above, describe the method of reliability testing and what it tests.

Describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used.

[Response Begins] Reliability Testing

Numerator testing: Data element reliability testing was conducted for the critical data element of the number of HCP who have received COVID-19 vaccination for each measured entity using multiple statistical methods to assess the amount of variability compared to an independent comparator.

Reliability testing was conducted by comparing the number of HCP who had received COVID-19 vaccinations as reported to the National Healthcare Safety Network (NHSN) (measure numerator) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator) at each facility during the same week.

The steps and statistical analyses conducted to assess repeatability and bias were the following (1,2):

1. Assess the strength of the association between the NHSN (measure numerator) reporting and PPP (independent comparator) reporting of the number of HCP receiving COVID-19 vaccinations.

(a) linear association with Pearson Correlation Coefficient

(b) nonparametric association (based on number of concordances and discordances in paired observations) with Kendall's Tau-b Correlation Coefficient

2. Assess comparability (bias) in measurement of the number of HCP receiving COVID-19 vaccinations by NHSN (measure numerator) reporting and PPP (independent comparator) reporting

(a) Qualitative visualization - plot a line of unity (slope=1) on the scatterplot of NHSN and PPP reporting

(b) Assess mean difference:

i. Quantitative assessment - paired t-test of the mean difference between NHSN and PPP reporting

ii. Qualitative assessment - Bland-Altman plot of difference between NHSN and PPP reporting against the mean of the two measurements

- 3. Assess the strength of association and comparability stratified by:
- (a) Facility size (stratified by number of HCP [tertiles])
- (b) Weekly vaccination coverage rate (stratified by NHSN coverage rate [tertiles])
- (c) Reporting week (stratified by week ending January 3, January 10, or January 17, 2021)

Repeated measures over time in the same facility were not assessed, as the number of HCP vaccinated will change over time due to vaccination uptake efforts and staffing changes (e.g., new hired HCP, retirement of HCP).

Denominator Testing: Data element reliability testing was not conducted for the data element of the number of HCP eligible to receive COVID-19 vaccination for each measured entity. The proposed measure uses the same denominator HCP definitions and categories as the previously NQF-endorsed measure, NQF 0431 Influenza Vaccination Coverage Among Healthcare Personnel. (3)

- Johnson M and Waller J. Simple Methods for Repeatability and Comparability: Bland-Altman Plots, Bias, and Measurement Error, Paper 1815-2018. <u>https://www.sas.com/content/dam/SAS/support/en/sas-global-forum-proceedings/2018/1815-2018.pdf</u>
- Giavarina D. Understanding Bland Altman analysis. Biochem Med (Zagreb). 2015;25(2):141-51. doi: 10.11613/BM.2015.015. PMID: 26110027; PMCID: PMC4470095.
- Libby TE, Lindley MC, Lorick SA, MacCannell T, Lee SJ, Smith C, Geevarughese A, Makvandi M, Nace DA, Ahmed F. Reliability and validity of a standardized measure of influenza vaccination coverage among healthcare personnel. Infect Control Hosp Epidemiol. 2013 Apr;34(4):335-45. doi: 10.1086/669859. Epub 2013 Feb 19. PMID: 23466904. Appendix

[Response Ends]

2a.11. For each level of reliability testing checked above, what were the statistical results from reliability testing?

For example, provide the percent agreement and kappa for the critical data elements, or distribution of reliability statistics from a signal-to-noise analysis. For score-level reliability testing, when using a signal-to-noise analysis, more than just one overall statistic should be reported (i.e., to demonstrate variation in reliability across providers). If a particular method yields only one statistic, this should be explained. In addition, reporting of results stratified by sample size is preferred (pg. 18, <u>NQF Measure Evaluation Criteria</u>).

[Response Begins]

1a. Linear association assessed by Pearson Correlation Coefficients

Overall Pearson Correlation Coefficient for the number of HCP who received COVID-19 vaccinations as reported to the National Healthcare Safety Network (NHSN) (measure numerator) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator): 0.846, p<0.0001 (869 Facilities)

Pearson Correlation Coefficient Stratified by Facility Size (Number of healthcare personnel [HCP])

Statistic	Tertile 1 (<=76 HCP, n=290 facilities)	Tertile 2 (77-116 HCP, n=292 facilities)	Tertile 3 (>=117 HCP, n=287 facilities)
Pearson Correlation Coefficient	0.839	0.692	0.769
P-value	<0.0001	<0.0001	<0.0001

Pearson Correlation Coefficient Stratified by Vaccination Coverage

Statistic	Tertile 1 (<=30.7% vaccination, n=290 facilities)	Tertile 2 (30.7-48.9% vaccination, n=290 facilities)	Tertile 3 (>=49.0% HCP vaccination, n=289 facilities)
Pearson Correlation Coefficient	0.754	0.886	0.810
P-value	<0.0001	<0.0001	<0.0001

Pearson Correlation Coefficient Stratified by Reporting Week

Statistic	Week 1 (n=305 facilities)	Week 2 (n=361 facilities)	Week 3 (n=203 facilities)
Pearson Correlation Coefficient	0.746	0.902	0.901
P-value	<0.0001	<0.0001	<0.0001

1b. Nonparametric association assessed by Kendall's Tau-b Correlation Coefficient

Overall Kendall's Tau-b Correlation Coefficient: 0.751, p<0.0001 (869 Facilities)

Kendall's Tau-b Correlation Coefficient Stratified by Tertiles of Facilities by Facility Size, Vaccination %, and Reporting Week

Kendall's Tau-b Correlation Coefficient Stratified by Facility Size (Number of healthcare personnel [HCP])

Statistic	Tertile 1 (<=76 HCP, n=290 facilities)	Tertile 2 (77-116 HCP, n=292 facilities)	Tertile 3 (>=117 HCP, n=287 facilities)
Kendall's Tau-b Correlation Coefficient	0.707	0.644	0.704
P-value	<0.0001	<0.0001	<0.0001

Kendall's Tau-b Coefficient Stratified by Vaccination Coverage

Statistic	Tertile 1 (<=30.7% vaccination, n=290 facilities)	Tertile 2 (30.7-48.9% vaccination, n=290 facilities)	Tertile 3 (>=49.0% HCP vaccination, n=289 facilities)
Kendall's Tau-b Correlation Coefficient	0.681	0.738	0.704
P-value	<0.0001	<0.0001	<0.0001

Kendall's Tau-b Correlation Coefficient Stratified by Reporting Week

Statistic	Week 1 (n=305 facilities)	Week 2 (n=361 facilities)	Week 3 (n=203 facilities)
Kendall's Tau-b Correlation Coefficient	0.676	0.804	0.774
P-value	<0.0001	<0.0001	<0.0001

[Response Ends]

2a.12. Interpret the results, in terms of how they demonstrate reliability.

(In other words, what do the results mean and what are the norms for the test conducted?)

[Response Begins]

Qualitative visualization of the correlation between the number of HCP who received COVID-19 vaccinations as reported to the National Healthcare Safety Network (NHSN) (measure numerator) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator)

Overall (869 facilities) scatterplot of the number of HCP who had received COVID-19 vaccination as reported to the National Healthcare Safety Network (NHSN) (measure numerator, Y-axis) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator, X-axis)



Scatterplots by tertiles of facility size (number of HCP)

Facility Size Tertile 1 (<=76 HCP, n=290 facilities) scatterplot of the number of HCP who had received COVID-19 vaccination as reported to the National Healthcare Safety Network (NHSN) (measure numerator, Y-axis) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator, X-axis



Facility Size Tertile 2 (77-116 HCP, n=292 facilities) scatterplot of the number of HCP who had received COVID-19 vaccination as reported to the National Healthcare Safety Network (NHSN) (measure numerator, Y-axis) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator, X-axis)



Facility Size Tertile 3 (>=117 HCP, n=287 facilities) scatterplot of the number of HCP who had received COVID-19 vaccination as reported to the National Healthcare Safety Network (NHSN) (measure numerator, Y-axis) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator, X-axis)



Scatterplots by tertiles of vaccine coverage

Facility Size Tertile 1 (<=30.7% vaccination, n=290 facilities) scatterplot of the number of HCP who had received COVID-19 vaccination as reported to the National Healthcare Safety Network (NHSN) (measure numerator, Y-axis) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator, X-axis)



Facility Size Tertile 2 (30.7-48.9% vaccination, n=290 facilities) scatterplot of the number of HCP who had received COVID-19 vaccination as reported to the National Healthcare Safety Network (NHSN) (measure numerator, Y-axis) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator, X-axis)



Facility Size Tertile 3 (>=49.0% HCP vaccination, n=289 facilities) scatterplot of the number of HCP who had received COVID-19 vaccination as reported to the National Healthcare Safety Network (NHSN) (measure numerator, Y-axis) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator, X-axis)



Scatterplots by reporting week

Reporting Week 1 (n=305 facilities) scatterplot of the number of HCP who received COVID-19 vaccinations as reported to the National Healthcare Safety Network (NHSN) (measure numerator, Y-axis) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator, X-axis)



Reporting Week 2 (n=361 facilities) scatterplot of the number of HCP who received COVID-19 vaccinations as reported to the National Healthcare Safety Network (NHSN) (measure numerator, Y-axis) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator, X-axis)



Reporting Week 3 (n=203 facilities) scatterplot of the number of HCP who vaccinations received COVID-19 vaccination as reported to the National Healthcare Safety Network (NHSN) (measure numerator, Y-axis) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator, X-axis)



2b. Quantitative assessment of mean difference

i. The overall vaccinations of the mean difference in the number of HCP who received COVID-19 vaccinations as reported to the National Healthcare Safety Network (NHSN) (measure numerator) to the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator) was Not_Significantly Different: -0.70 vaccinations, p=0.278, 95% CI -1.96 - 0.56

Mean Difference Stratified by Facility Siz	e (Number of healthcare personnel [HCP])
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*	Tertile 1 (<=76 HCP, n=290 facilities)	Tertile 2 (77-116 HCP, n=292 facilities)	Tertile 3 (>=117 HCP, n=287 facilities)
Mean Difference in number of vaccinations	-0.731	-1.30	0.056
95% Confidence Interval	(-1.65-0.19)	(-3.10-0.51)	(-3.28-3.17)

*Cell left intentionally blank.

Mean Difference Stratified by Vaccination Coverage

*	Tertile 1 (<=30.7% vaccination, n=290 facilities)	Tertile 2 (30.7-48.9% vaccination, n=290 facilities)	Tertile 3 (>=49.0% HCP vaccination, n=289 facilities)
Mean Difference in number of vaccinations	-4.81	-0.848	3.57
95% Confidence Interval	(-6.912.70)	(-2.28-0.59)	(0.85-6.29)

*Cell left intentionally blank.

Mean Difference Stratified by Reporting Week

*	Week 1 (n=305 facilities)	Week 2 (n=361 facilities)	Week 3 (n=203 facilities)	
Mean Difference in number of vaccinations	0.564	-1.17	-1.76	
95% Confidence Interval	(-2.21-3.34)	(-2.69-0.36)	(-3.88-0.35)	

*Cell left intentionally blank.

2b. Qualitative visualization of mean difference

ii. Bland-Altman scatter plot of the difference in the number of HCP who had received COVID-19 vaccination as reported to the National Healthcare Safety Network (NHSN) (measure numerator, M1) and the number of COVID-19 vaccinations administered by Pharmacy Partnership for Long-Term Care Program (independent comparator, M2) (y-axis) vs the mean of vaccinations reported ([M1+M2]/2) (x-axis) for each facility



** a reference line for 0 difference is indicated on the x-axis and with a solid blue **

** a reference line for the mean of the difference is indicated by solid red **

** a reference line for +/- 2 SD of the mean of the difference is indicated by long red dashes **

** a reference line for +/- 3 SD of the mean of the difference is indicated by short green dashes **

Numerator Testing

1. The number of HCP receiving COVID-19 vaccinations reported by the methodology of the proposed measure using NHSN is **strongly associated with an independent comparator** - the number of vaccinations reported to be administered by independently reported data from the federal PPP.

- The **Pearson Correlation Coefficient** is the most reasonable assessment of the strength of association as the number of HCP vaccinated is close to a continuous variable and the expected relationship between the number of vaccinations measured using NHSN and PPP is a linear one. The overall **correlation coefficient (r=0.846) is high.**
- Although not the best measure of association, as the number of vaccinations is a nearly continuous value rather than a categorical value, a non-parametric measure of association, Kendall's Tau-b Correlation Coefficient, was also calculated and was also high (r=0.751).

• After stratifying by hospital size/number of HCP, stratifying by vaccination coverage, and stratifying by reporting week, strength of association remained high for both the Pearson Correlation Coefficient (r=0.692 to r=0.912) and for Kendall's Tau-b Correlation Coefficient (r=0.644 to r=0.804)

2. **Comparability to an independent comparator was a 1:1 relationship**. While high correlation alone does not necessarily indicate comparability of two assessment methods, plotting a line of unity (slope=1) on a scatterplot of number of vaccinations reported by NHSN and by federal PPP reporting provides an initial qualitative assessment, there is not only a linear relationship but a **1:1 relationship** between the number of HCP receiving COVID-19 vaccination reported by the methodology of the proposed measure using NHSN and the number of vaccinations reported to be administered by the PPP, an independent comparator.

Quantitative assessment of comparability with an independent comparator was high. Comparability was quantitatively assessed by calculating the mean difference between NHSN and PPP reporting of the number of HCP who have received COVID-19 vaccine shows the overall mean difference was minimal (mean difference of -0.699 vaccinations) for a narrow confidence interval (95% Cl, -1.96 - 0.56 vaccinations) between the number reported to NHSN and PPP reporting; p=0.28 indicating no statistically significant difference.

- When stratifying by facility size/number of HCP and reporting week, the mean difference remained low, indicating high comparability (mean difference -1.76 to 0.56 vaccinations) and all 95% CIs included the null value, rate, indicating no statistically significant difference.
- When stratified by vaccination coverage rate, the range of mean differences were larger by tertile, ranging from (-4.81 vaccinations in the lower tertile of vaccination coverage to 3.57 vaccinations in the higher vaccination tertile). These small but statistically significant differences in the number of vaccinations delivered identified when stratified by vaccination coverage are likely because NHSN reports vaccinations HCP may have received elsewhere, while PPP only reports vaccinations delivered at the facility. In the high vaccination tertile, it may be more likely that HCP received vaccinations elsewhere and these vaccinations were reported to NHSN. Second, when there were additional vaccine doses, PPP delivered vaccinations to others who may not have met the definition of HCP used by NHSN so as not to have vaccine doses go unused. In the low vaccination coverage tertile this situation may be more likely to occur.

Qualitative assessment of comparability to an independent comparator with a Bland-Altman plot demonstrated **random variability** (no pattern of variability based on number of vaccines delivered) **with minimal bias** (mean difference very close to zero). Of note, there are 869 COVID-19 vaccination measurements assessed in this plot.

Denominator Testing

The proposed measure uses the same denominator HCP definitions and categories as the previously endorsed NQFendorsed measure, NQF 0431 Influenza Vaccination Coverage Among Healthcare Personnel. The reliability testing of this denominator has been previously reported. Agreement was high (more than 90%) for all denominator categories. While some facilities excluded nonemployee contractors for whom the numerator and denominator were difficult to determine in this study conducted in 2010 – 2011, nonemployee contractors have become more commonplace and have been reported to NHSN throughout the pandemic response.

 Libby TE, Lindley MC, Lorick SA, MacCannell T, Lee SJ, Smith C, Geevarughese A, Makvandi M, Nace DA, Ahmed F. Reliability and validity of a standardized measure of influenza vaccination coverage among healthcare personnel. Infect Control Hosp Epidemiol. 2013 Apr;34(4):335-45. doi: 10.1086/669859. Epub 2013 Feb 19. PMID: 23466904. Appendix

[Response Ends]

Validity Testing

2b.01. Select the level of validity testing that was conducted.

[Response Begins]

2b.02. For each level of testing checked above, describe the method of validity testing and what it tests.

Describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used.

[Response Begins]

The method of validity testing was to compute the measure score for each measured entity (quarterly COVID-19 vaccination coverage of healthcare personnel [HCP] at each facility) and then correlate these measure scores with performance on another very similar quality measure, influenza vaccination coverage of HCP.

We hypothesize that facilities committed to ensuring high rates of influenza vaccination in their HCP are likely to be committed to ensuring high rates of COVID-19 vaccination in their HCP. Facilities with lower rates of influenza vaccination in their HCP are likely to have lower rates of COVID-19 vaccination in their HCP.

Based on an internet panel survey of 2,401 U.S. HCP, vaccination coverage was highest among HCP in ambulatory care and hospital settings with vaccination requirements (96.1% and 95.7%, respectively), and lowest in ambulatory and long-term care settings without vaccination requirements, promotion, or on-site offer (47.7% and 49.9%, respectively).

https://www.cdc.gov/flu/fluvaxview/hcp-coverage 1920estimates.htm

We expect that facilities with high rates of influenza vaccination and requirements and promotion will also institute COVID-19 vaccination requirements and promotion, which will lead to high coverage rates.

Pearson Correlation Coefficients between the Quarterly COVID-19 coverage measure for Q3 (July, August, September) 2021 and the annual Influenza Vaccination coverage measure NQF 0431. [Response Ends]

2b.03. Provide the statistical results from validity testing.

Examples may include correlations or t-test results.

[Response Begins]

The **Overall Pearson Correlation Coefficient between the quarterly** COVID-19 coverage measure for Q3 (July, August, September) 2021 and annual Influenza Vaccination coverage measure NQF 0431: **0.4169**, **p<0.0001 (1,654 Facilities)**

Scatterplot of quarterly COVID-19 coverage measure for Q3 (July, August, September) 2021 (y-axis) and annual Influenza Vaccination coverage measures by NQF 0431 (x-axis)

Relationship between influenza vaccination % coverage and COVID-19 vaccination avg. % coverage with 95% CI (N = 1,654)



Pearson Correlation Coefficient between quarterly COVID-19 coverage measure for Q3 (July, August, September) 2021 and annual influenza vaccination coverage measures by NQF 0431 **stratified by Quartiles of Facilities by Facility Size**

Pearson Correlation Coefficient Stratified by Facility Size (Number of healthcare personnel [HCP])

Statistic	1 (<=67 HCP)	Quartile 2 (64-93 HCP)	Quartile 3 (94-131 HCP)	Quartile 4 (>=132 HCP)
Pearson Correlation Coefficient	0.388	0.378	0.457	0.450
P-value	<0.0001	<0.0001	<0.0001	<0.0001

Distribution of quarterly COVID-19 coverage measure for matched National Healthcare Safety Network facilities, Q3 (July, August, September) 2021



Distribution of the annual influenza coverage measure for matched National Healthcare Safety Network facilities, 2020-2021 season



[Response Ends]

2b.04. Provide your interpretation of the results in terms of demonstrating validity. (i.e., what do the results mean and what are the norms for the test conducted?)

[Response Begins]

The overall Pearson Correlation Coefficient between the between Quarterly COVID-19 coverage measure for Q3 (July, August, September) 2021 and annual influenza vaccination coverage measure NQF 0431 for facilities that reported both measures indicate "medium" correlation (generally accepted range for medium correlation, 0.30 - 0.49) between the proposed and previously endorsed coverage measure. This medium correlation was consistent when stratified by facility size (number of healthcare personnel [HCP]).

There are factors outside of the facilities' control which impact HCP COVID-19 vaccination coverage which are independent of influenza vaccination. A key reason that the correlation may not have been stronger, is that HCP may have reasons for which they decline COVID-19 vaccine which they do not apply similarly to the influenza vaccine. In addition, community rates of COVID-19 may vary from community rates of influenza and impact HCP vaccination decisions. Finally, it is notable that high numbers of facilities reported 99% or higher influenza vaccination coverage. With additional time for the new COVID-19 vaccines to gain acceptance and for implementation of vaccination programs to address COVID-19 vaccination hesitancy, coverage rates of COVID-19 and influenza vaccination are likely to correlate more strongly.

[Response Ends]

2b.05. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified.

Describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided in Importance to Measure and Report: Gap in Care/Disparities.

[Response Begins]

To determine if statistically significant differences in performance measure scores among measured entities, the mean scores and 95% confidence intervals for each quarter were compared to each other and to the performance measure scores for the 25th- and 75th-percentile facilities.

To determine if practically meaningful differences in performance measure scores among measured entities, quarterly COVID-19 coverage for the top and bottom 10% of facilities were compared for clinically meaningful differences in coverage rates within a quarter and across quarters for the first 3 quarters of 2021. **[Response Ends]**

2b.06. Describe the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities.

Examples may include number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined.

[Response Begins]

Please see the table in question 1b.02) Quarterly COVID-19 vaccination coverage among healthcare personnel (HCP) among CMS-certified nursing homes, National Healthcare Safety Network (NHSN), 2021, for the primary data table.

Statistical differences.

The mean quarterly COVID-19 vaccination coverage rate (95% confidence intervals) and inter quartile ranges for the first 3 quarters of 2021 were:

Q1: mean coverage 35.0% (34.3% – 35.7%); interquartile range 17.3% – 51.2%

Q2: mean coverage 56.2% (55.8% – 56.5%); interquartile range 41.9% – 71.2%

Q3 mean coverage is 64.1% (63.8% - 64.4%); interquartile range is 50.8% – 78.6%.

Clinical differences.

The quarterly COVID-19 vaccination coverage metric identified that the lowest 10th-percentile of nursing homes reporting had 0% coverage in Q1 of 2021, while the 90th-percentile of nursing homes reported coverage of 67.2%.

By Q3 of 2021, the lowest 10th-percentile of nursing homes improved vaccination coverage rates to 38.8% and the 90th-percentile of nursing homes improved to 89.0%.

A clinically meaningful difference in COVID-19 healthcare personnel vaccination rates is a difference that would be expected to lead to fewer symptomatic infections. Based on mathematical modeling, assuming 90% baseline resident coverage and symptom-based testing only, increasing vaccination coverage among staff from 0% to 90% reduces total symptomatic cases in the nursing home by 33%-63% depending upon vaccine effectiveness against infection and vaccine effectiveness in prevention of infectiousness. (1)

 Kahn R, Holmdahl I, Reddy S, Jernigan J, Mina MJ, Slayton RB. Mathematical modeling to inform vaccination strategies and testing approaches for COVID-19 in nursing homes. medRxiv [Preprint]. 2021 Mar 1:2021.02.26.21252483. doi: 10.1101/2021.02.26.21252483. Update on: Clin Infect Dis. 2021 Jun 04; PMID: 33688668; PMCID: PMC7941643.)

[Response Ends]

2b.07. Provide your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities.

In other words, what do the results mean in terms of statistical and meaningful differences?

[Response Begins]

The quarterly measure can identify statistically significant differences in performance across measured entities. The mean quarterly COVID-19 vaccination coverage metric had 95% confidence intervals, that were narrower than the interquartile range.

The quarterly measure can identify statistically significant differences in performance across quarters of measurement. The mean quarterly COVID-19 vaccination coverage metric was significantly higher each of the first 3 quarters of 2021, based on non-overlapping 95% confidence intervals.

Most importantly, the measure can identify clinically significant differences in performance across measured entities. Applying the modeled estimated decrease in symptomatic cases, there would be 33%-63% more symptomatic cases in the lowest 10th-percentile of nursing homes in Q1 of 2021 than the 90th-percentile nursing homes in Q3 of 2021 (assuming similar community disease rates, resident vaccination rates, and testing and infection control practices). **[Response Ends]**

2b.08. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders). Include how the specified handling of missing data minimizes bias.

Describe the steps—do not just name a method; what statistical analysis was used.

[Response Begins]

The quarterly COVID-19 vaccination coverage is determined by selecting one week per month and calculating the percentage of HCP who have ever received a primary COVID-19 vaccination course, then averaging 3 weekly percentages

(one week from each of the 3 months in the quarter).

For the quarter 3 (July - September) 2021, the number of facilities which did not report (had missing data) for one or more of the three months in the quarter were identified.

For facilities with only 1 or 2 months of data, a modified coverage measure using only those months was calculated and standard deviations and 95% confidence intervals were calculated for the average measure for facilities missing 1 or 2 months of data. The average vaccination coverage rates for facilities with and without a month of data reported were compared.

[Response Ends]

2b.09. Provide the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data.

For example, provide results of sensitivity analysis of the effect of various rules for missing data/non-response. If no empirical sensitivity analysis was conducted, identify the approaches for handling missing data that were considered and benefits and drawbacks of each).

[Response Begins]

CMS-certified nursing home reporting of COVID-19 vaccination coverage for healthcare personnel (HCP) through the National Healthcare Safety Network (NHSN) at least once a month during Q3 (July – August), 2021*

No. months reporting vaccination coverage	No. of facilities	Percentage of facilities	COVID-19 vaccination coverage, mean percent (SD)	95% CI of COVI-19 vaccination coverage
1 month	62	0.41	65.17 (22.59)	59.43, 70.91
2 months	99	0.65	59.06 (23.69)	54.33, 63.78
3 months	15,106	98.95	64.17 (18.76)	63.88, 64.47
At least 1 month	15,267	100	64.15 (18.81)	63.84, 64.44

*29 facilities do not have any COVID-19 vaccination coverage data during Q3

[Response Ends]

2b.10. Provide your interpretation of the results, in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders), and how the specified handling of missing data minimizes bias.

In other words, what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis was conducted, justify the selected approach for missing data.

[Response Begins]

If a facility is missing vaccination coverage data for a month in the quarter, the facility is not considered to have completed the requirements of the measure. It is possible to calculate vaccination coverage using the months for which data is reported, but it must be noted that all 3 months were not reported as specified by the measure.

Missing a month of coverage data can affect the quarterly measure. For the quarter 3 (July - September) 2021, the number of facilities which did not report (had missing data) for one or more of the three months in the quarter was quite low; however, the 95% confidence intervals for the mean quarterly vaccination coverage for facilities which were missing 1 month of coverage data are just statistically significant difference from the mean quarterly vaccination coverage for those facilities which reported vaccination coverage for all 3 months. On the other hand, the mean quarterly vaccination coverage for all 3 months.

In addition, if a facility could still be considered reporting in accordance with the specifications, but only report coverage for 2 months or just a single month, to maximize the reported coverage, it would be logical for facilities to simply not report their lowest coverage months, which would not accurately reflect the level of vaccine protection for residents or other healthcare personnel.

Thus, even though the calculated vaccination coverage for a facility which is missing 1 or 2 months of vaccination coverage data using the months that are reported is better than no vaccination coverage data at all, to be in accordance with the vaccination coverage measure, vaccination coverage must be reported for at least one week of each month in the quarter.

[Response Ends]

Note: This item is directed to measures that are risk-adjusted (with or without social risk factors) OR to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eCQMs). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

2b.11. Indicate whether there is more than one set of specifications for this measure.

[Response Begins] No, there is only one set of specifications for this measure [Response Ends]

2b.12. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications.

Describe the steps—do not just name a method. Indicate what statistical analysis was used.

[Response Begins] [Response Ends]

2b.13. Provide the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications.

Examples may include correlation, and/or rank order.

[Response Begins] [Response Ends]

2b.14. Provide your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications.

In other words, what do the results mean and what are the norms for the test conducted.

[Response Begins] [Response Ends]

2b.15. Indicate whether the measure uses exclusions.

[Response Begins] NATIONAL QUALITY FORUM

2b.16. Describe the method of testing exclusions and what was tested.

Describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used?

[Response Begins]

The average proportion of healthcare personnel (HCP) reported to have contraindications/restrictions was calculated as well as the range, interquartile range, standard deviation for the 15,267 CMS-certified nursing homes (NHs) participating in COVID-19 vaccination coverage reporting in Q3 (July, August, September), 2021.

The average proportion of healthcare personnel (HCP) reported to have contraindications/restrictions was stratified by facility size (number of HCP) and region.

The impact on performance measure score was calculated for sample week **[Response Ends]**

2b.17. Provide the statistical results from testing exclusions.

Include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores.

[Response Begins]

Among 15,267 facilities reporting COVID-19 vaccination coverage among healthcare personnel (HCP) during Q3 (July, August, September), 2021, the mean number of HCP per facility was 117.0, with a standard deviation of 77.0.

Among these 15,267 facilities, the mean percentage of HCP with contraindications was 0.6%, with a standard deviation of 2.0%.

Frequency of contraindications to COVID-19 vaccination among healthcare personnel (HCP) during Q3 (July, August, September), 2021 (N=15,267 facilities)

Facility Quantile of HCP with contraindications	Percentage of HCP with contraindications
0%	0.0
1%	0.0
5%	0.0
10%	0.0
25% (Q1)	0.0
50% (median)	0.0
75% (Q3)	0.5
90%	1.7
95%	3.0
99%	8.4
100%	49.1

Frequency of contraindications to COVID-19 vaccination among healthcare personnel (HCP) reported during Q3 (July, August, September), 2021, stratified by facility size (No. of HCP), COVID-19 vaccination coverage, and region (N=15,267 facilities)

Quantile of HCP per facility (No. of facilities)	Percentage of HCP with contraindications (standard deviation)
Q1 (N = 3,759)	0.8 (2.3)
Q2 (N = 3,769)	0.7 (2.3)
Q3 (N = 3,898)	0.6 (2.0)
Q4 (N = 3,841)	0.5 (1.3)
Quantile of COVID-19 vaccination coverage	Percentage of HCP with contraindications (standard deviation)
Q1 (N = 3,816)	0.5 (1.5)
Q2 (N = 3,818)	0.6 (1.9)
Q3 (N = 3,817)	0.7 (2.0)
Q4 (N = 3,816)	0.8 (2.5)
Region	Percentage of HCP with contraindications (standard deviation)
Northeast (N = 2,514)	0.5 (1.4)
Midwest (N = 4,972)	0.7 (2.6)
South (N = 5,405)	0.5 (1.7)
West (N = 2,369)	0.8 (1.8)
PR and territories (N = 7)	0.7 (1.2)

[Response Ends]

2b.18. Provide your interpretation of the results, in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results.

In other words, the value outweighs the burden of increased data collection and analysis. Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion.

[Response Begins]

While contraindications/exclusions to COVID-19 vaccination are not frequent (reported for 1 in 167 healthcare personnel [HCP] on average), more than 10% of nursing homes reported at least 1 HCP with a contraindication to vaccination.

The proportion of HCP with contraindications/exclusions was similar when facilities were stratified by number of HCP and region.

The number of HCP with contraindications/exclusions would be expected to decline because receipt of monoclonal antibody treatment or convalescent plasma within 90 days and isolation for/recovering from COVID-19 are exclusions that should decline in frequency as more HCP are vaccinated.

However, identification of HCP with contraindications/exclusions to vaccination is important for acceptability/fairness to

facilities and HCP, as a facility should not be penalized for employing a HCP with a contraindication which precludes COVID-19 vaccination, and HCP with contraindications or other exclusions identified in in Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States should not be vaccinated according to FDA authorization and ACIP/HHS recommendations.

It is important to note that HCP personal preference or vaccine hesitancy is not considered a contraindication or exclusion.

[Response Ends]

2b.19. Check all methods used to address risk factors.

[Response Begins] No risk adjustment or stratification [Response Ends]

2b.20. If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.

[Response Begins] N/A [Response Ends]

2b.21. If an outcome or resource use measure is not risk-adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (i.e., case mix) is not needed to achieve fair comparisons across measured entities.

[Response Begins]

Risk adjustment is not appropriate for the proposed measure. By virtue of their work environment, all HCP are potentially at risk of contracting COVID-19 and transmitting the SARS-CoV-2 virus to patients. The ACIP and CDC/HHS recommend that all HCP without contraindications receive a COVID-19 vaccination.

Social risk factors are not directly available, as data is collected at the aggregate level rather than at the individual level.

[Response Ends]

2b.22. Select all applicable resources and methods used to develop the conceptual model of how social risk impacts this outcome.

[Response Begins] Published literature [Response Ends]

2b.23. Describe the conceptual and statistical methods and criteria used to test and select patient-level risk factors (e.g., clinical factors, social risk factors) used in the statistical risk model or for stratification by risk.

Please be sure to address the following: potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10 or other statistical tests; correlation of x or higher. Patient factors should be present at the start of care, if applicable. Also discuss any "ordering" of risk factor inclusion; note whether social risk factors are added after all clinical factors. Discuss any considerations regarding data sources (e.g., availability, specificity).

[Response Begins] N/A [Response Ends] **2b.24.** Detail the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model/stratification.

[Response Begins] N/A [Response Ends]

2b.25. Describe the analyses and interpretation resulting in the decision to select or not select social risk factors.

Examples may include prevalence of the factor across measured entities, availability of the data source, empirical association with the outcome, contribution of unique variation in the outcome, or assessment of between-unit effects and within-unit effects. Also describe the impact of adjusting for risk (or making no adjustment) on providers at high or low extremes of risk.

[Response Begins] N/A [Response Ends]

2b.26. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used). Provide the statistical results from testing the approach to control for differences in patient characteristics (i.e., case mix) below. If stratified ONLY, enter "N/A" for questions about the statistical risk model discrimination and calibration statistics.

Validation testing should be conducted in a data set that is separate from the one used to develop the model.

[Response Begins] N/A [Response Ends]

2b.27. Provide risk model discrimination statistics.

For example, provide c-statistics or R-squared values.

[Response Begins] N/A [Response Ends]

2b.28. Provide the statistical risk model calibration statistics (e.g., Hosmer-Lemeshow statistic).

[Response Begins] N/A [Response Ends]

2b.29. Provide the risk decile plots or calibration curves used in calibrating the statistical risk model.

The preferred file format is .png, but most image formats are acceptable.

[Response Begins] N/A [Response Ends]
2b.30. Provide the results of the risk stratification analysis.

[Response Begins] N/A [Response Ends]

2b.31. Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix).

In other words, what do the results mean and what are the norms for the test conducted?

[Response Begins] N/A [Response Ends]

2b.32. Describe any additional testing conducted to justify the risk adjustment approach used in specifying the measure.

Not required but would provide additional support of adequacy of the risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed.

[Response Begins] N/A [Response Ends]

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3.01. Check all methods below that are used to generate the data elements needed to compute the measure score.

[Response Begins]

Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

[Response Ends]

3.02. Detail to what extent the specified data elements are available electronically in defined fields.

In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields.

[Response Begins] Some data elements are in defined fields in electronic sources [Response Ends]

3.03. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using data elements not from electronic sources. [Response Begins] N/A

[Response Ends]

3.04. Describe any efforts to develop an eCQM. [Response Begins] N/A [Response Ends]

3.06. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

[Response Begins]

Difficulties reported by facilities are included in the response to section **4a.08** [Response Ends]

Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

3.07. Detail any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm),

Attach the fee schedule here, if applicable. [Response Begins] No fees, licensing, or other requirements. [Response Ends]

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making.

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement, in addition to demonstrating performance improvement.

4a.01.

Check all current uses. For each current use checked, please provide:

Name of program and sponsor

URL

Purpose

Geographic area and number and percentage of accountable entities and patients included

Level of measurement and setting

[Response Begins]

Public Reporting Public Health/Disease Surveillance

Regulatory and Accreditation Programs

Since initiation of voluntary reporting of COVID-19 vaccination coverage reporting through NHSN was initiated in December 2020, data have been used by public health authorities for response to the public health emergency. Since CMS-certified nursing homes and outpatient dialysis facilities have been required to report HCP COVID-19 vaccination coverage weekly using the NHSN weekly COVID-19 Vaccination Coverage Module state-based data have been publicly available.

- Name of program: National Healthcare Safety Network (NHSN)
- URL: <u>https://www.cdc.gov/nhsn/covid19/ltc-vaccination-dashboard.html</u>
- Purpose: CDC's National Healthcare Safety Network (NHSN) supports the nation's COVID-19 response by
 providing a Long-term Care Facilities (LTCFs) COVID-19 Module, which enables an assessment of the impact of
 COVID-19 through facility reported information.
- Geographic area: United States; 50 states
- Level of Measurement and Setting:
 - State level for CMS-certified Nursing Homes
 - State level for Outpatient Dialysis Centers

For emergency response during the pandemic phase of COVID-19, as of May 2021, CMS-certified nursing homes have been required to report HCP COVID-19 vaccination coverage weekly using the NHSN weekly COVID-19 Vaccination Coverage Module.

For emergency response during the pandemic phase of COVID-19, different HCP categories are being used to calculate vaccine coverage using NHSN and reporting frequency is every week.

- Name of program: Interim Final Rule COVID-19 Vaccine Immunization Requirements for Residents and Staff (QSO-21-19-NH) <u>https://www.cms.gov/medicareprovider-enrollment-and-</u> <u>certificationsurveycertificationgeninfopolicy-and-memos-states-and/interim-final-rule-covid-19-vaccine-</u> <u>immunization-requirements-residents-and-staff</u>
- URL: https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg
- Purpose: CMS is committed to continually taking critical steps to ensure America's healthcare facilities continue to respond effectively to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE). Furthermore, LTC facilities must report COVID-19 vaccine and therapeutics treatment information to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). CMS will post the new information reported to the NHSN for viewing by facilities, stakeholders, or the general public on CMS's COVID-19 Nursing Home Data website.
- Geographic area: United States; >15,000 facilities; >1,600,000 individuals
- Level of Measurement and Setting: Facility level and state level for CMS-certified Nursing Homes

Prior to CMS requirements to report COVID-19 vaccination coverage, state health departments encouraged, and some required, reporting of COVID-19 vaccination coverage.

- Name of program: Massachusetts Department of Public Health, Bureau of Health Care Safety and Quality
- URL: <u>https://www.mass.gov/doc/covid-19-vaccination-reporting-for-long-term-care-facilities/download</u>
- Purpose: The weekly COVID-19 vaccination modules provide consistent reporting and comparable data across facilities. NHSN data can be used to monitor COVID-19 vaccination trends over time, identify facilities with lower resident and/or staff vaccination rates, and inform planning and implementation decisions regarding vaccine supply and distribution.
- Geographic area: Massachusetts; 350+ facilities
- Level of Measurement and Setting:
 - Skilled Nursing Facilities

[Response Ends]

4a.02. Check all planned uses.

[Response Begins] Public reporting [Response Ends]

4a.03. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.

For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?

[Response Begins] N/A [Response Ends]

4a.04. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.

A credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.

[Response Begins]

N/A [Response Ends]

4a.05. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

Detail how many and which types of measured entities and/or others were included. If only a sample of measured entities were included, describe the full population and how the sample was selected.

[Response Begins]

Prior to July 2021, facilities reporting results with low vaccination coverage rates (<10% coverage) were identified and contacted through email and telephone outreach to confirm the validity of reported results. Facilities with high week-to-week variation (>30% change in coverage week to week) were also identified and contacted by email and telephone outreach.

Since July 2021, facilities with required reporting by CMS have been receiving automatic alerts which identify outlying data entries. <u>https://www.cdc.gov/nhsn/pdfs/hps/covidvax/dq-alerts-508.pdf</u> [Response Ends]

4a.06. Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

[Response Begins]

All facilities have full access to the data which they reported.

https://www.cdc.gov/nhsn/pdfs/ltc/covidvax/covidvax-ltc-linelist-508.pdf

https://www.cdc.gov/nhsn/pdfs/ltc/covidvax/linelist-checkdates-508.pdf

Facilities can also utilize preformatted charting and other analysis capabilities of NHSN to assist in the interpretation of reported data.

https://www.cdc.gov/nhsn/pdfs/ltc/covidvax/covidvax-ltc-barchart-508.pdf

Facilities were offered numerous training sessions and educational opportunities both when the NHSN modules were initially released and when CMS policies began to require reporting by dialysis facilities and nursing homes.

https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html

Finally, facilities may contact the NHSN Helpdesk by email at any time.

[Response Ends]

4a.07. Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.

[Response Begins]

Feedback on measured performance was obtained through a public comment period on proposed rulemaking by CMS to include this measure in quality reporting programs.

4a.08. Summarize the feedback obtained from those being measured.

[Response Begins]

- 1. There may be lack of access to vaccine and one dose vaccine products were not equally available across all states and so some facilities may be disadvantaged because of the 4-week waiting period between doses of the 2-dose vaccination products
- 2. There may be unintended consequences and legal risks to their organization if HCP experience an adverse event related to vaccination
- 3. A concern was expressed of staff intimidation if they elect not to receive the vaccine, and that facilities do not have control over the vaccination status of their employees.
- 4. Request to consider including all HCP in the denominator, at least for an initial reporting period and to allow for consistent cross-provider reporting and accurate measurement and comparisons
- 5. Noted that the measure was not aligned with the Influenza Vaccination Coverage among HCP (NQF #0431) measure and includes "eligible" workers.
- 6. There should be flexibility in defining contraindications and contraindications are in flux.
- 7. The measure for one quarter should not be combined with the next quarter because the most up-to-date data should be available
- 8. There is burden of reporting due to difficulty of tracking vaccine status contraindications and declinations and reporting vaccinations 1 week per month, rather than one time per quarter.

[Response Ends]

4a.09. Summarize the feedback obtained from other users.

[Response Begins]

A number of commenters wrote in support of the measure's concept and the need to encourage widespread vaccination for HCP.

- The measure would help assess the degree to which facilities are taking steps to limit the spread of COVID-19 and reduce the risk of transmission within their facilities.
- Public reporting of COVID-19 vaccinations among HCP would provide consumers with important information with which to make informed decisions about the safety of a facility.
- The measure would provide greater transparency for federal officials and other stakeholders seeking to effectively target vaccine hesitancy, as well as provide resources related to the COVID-19 vaccines.

Concerns expressed included:

- 9. The measure specifications and testing data should be submitted for NQF endorsement.
- 10. It is unknown whether a booster vaccination will be necessary. How will vaccine recommendations and potential recommendations for booster doses be accounted for in reporting requirements?
- 11. Concern that the vaccinations have not received full FDA approval.

[Response Ends]

4a.10. Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

[Response Begins]

 Efforts by facilities, states, federal agencies, and public-private partnerships have been engaged in ensuring adequate vaccination availability and vaccine availability rarely been identified as a limiting factor by nursing homes and other facilities, so the measure was not modified because the reporting period is 3 months and there will be time during each quarter for persons receiving the two-dose vaccine to reach complete vaccination status.

- 2. It is unclear what unintended consequences and legal risks the commenters are referring to in terms of adverse events. Reporting this vaccination coverage for measures does not require HCP to be vaccinated in order to successfully report the measure, so the measure was not modified.
- 3. The Equal Employment Opportunity Commission (EEOC) has stated the federal equal employment opportunity (EEO) laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID-19, so long as the employer complies with the reasonable accommodation provisions of the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 and other EEO considerations. (What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws. Available at https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.) In addition, over 50 healthcare professional organizations have endorsed a requirement for healthcare personnel to be vaccinated. Thus, the measure has not been modified.
- 4. Assessing HCP contraindications and excluding from the measure denominator strikes a balance between obtaining accurate estimates of vaccine rates among HCP in a facility and not holding a facility accountable for HCP with a COVID-19 vaccination contraindication.
- 5. Because the measurement period covered by the Influenza Vaccination Coverage for HCP (NQF #0431) is quite long (the entire 6-month influenza season), HCP absences for illness, vacation, or other short-term leave do not impact the measure denominator. However, in order to provide more timely measurement of COVID-19 vaccination coverage while also reducing the burden of data collection for facilities, the data collection period of the COVID-19 vaccination for HCP measures is only one week, and a number of regularly working HCP who would be counted within a 6-month period may be absent during this shortened period. Therefore, HCPs who regularly work in the nursing facility, but may be temporarily absent for up to 2 weeks, are still to be included in the COVID-19 vaccination coverage measure.
- 6. Contraindications to COVID-19 vaccination have not changed since the vaccines have been authorized. There are additional considerations around the timing of the vaccine that are more clearly understood now. A summary of interim clinical considerations can be found <u>https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf</u> which is referenced in the measure. Like any medical product, considerations for use may change with increased knowledge.
- 7. An earlier version of the measure considered combining 4 quarters of data into an annual coverage measure. Combination of quarters in this way is not the way the current measure is specified.
- 8. Healthcare facilities have experience of tracking information and collecting data to inform their care approaches and business practices. We are confident in facilities' abilities to track the COVID-19 vaccination information of their HCP. The specifications for collecting vaccine status, contraindications and declinations and reporting vaccinations 1 week per month are designed to balance timely information with the reporting burden.
- 9. The measure specifications and testing data are being submitted for NQF endorsement.
- 10. Currently, additional COVID-19 vaccines are not required as part of the primary vaccination series. If substantive revisions to the measure are needed in the future, revisions to the definition of the completed course of COVID-19 vaccination can be made.
- 11. Vaccines have been FDA approved.

[Response Ends]

4b.01. You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included). If no improvement was demonstrated, provide an explanation. If not in use for performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

[Response Begins]

COVID-19 vaccination rates among HCPs working in CMS-certified skilled nursing facilities increased in each quarter of 2021. Of note, the number of facilities reporting vaccination coverage has increased significantly with CMS requirements to report vaccination coverage, which were published in May 2021.

At the beginning of Q4, 2021, for the 2-week period, ending October 24, 2021, 14,417 CMS-certified skilled nursing facilities (87.3%) CMS-certified skilled nursing facilities) reported COVID-19 vaccination coverage data for HCP from across

the United States, with 1,317,841 (75.0%) of HCP reported to have completed COVID-19 vaccination.

The weekly data that are used for the quarterly measure are at: <u>https://www.cdc.gov/nhsn/covid19/ltc-vaccination-dashboard.html</u>

[Response Ends]

4b.02. Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.

[Response Begins]

While the measure is a quarterly measure, it is based on data collected for a reporting week. Examining data from a reporting week finds that COVID-19 vaccination coverage among HCP working in CMS-certified skilled nursing facilities varies considerably by state, which may impact the incidence of COVID-19 infection in nursing homes.

For example, as COVID-19 case counts began to increase in the summer of 2021, COVID-19 vaccination coverage for CMS-certified nursing homes for the week ending July 18 varied by state, ranging from 46.6% [Louisiana, n=262 facilities] to 89.1% [Hawaii, n=43])

COVID-19 Vaccination Coverage Among CMS-certified Skilled Nursing Facility Staff (excluding those with medical contraindications) reporting within the last 2 weeks through the Week Ending July 18, 2021



Data reported to the National Healthcare Safety Network (NHSN)

[Response Ends]

4b.03. Explain any unexpected benefits realized from implementation of this measure.

[Response Begins]

Some public health entities (e.g., Massachusetts) identified the benefits of using NHSN to report this measure and required reporting for some facilities (e.g., nursing homes) within their jurisdiction prior to national requirements. **[Response Ends]**

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

If you are updating a maintenance measure submission for the first time in MIMS, please note that the previous related and competing data appearing in question 5.03 may need to be entered in to 5.01 and 5.02, if the measures are NQF endorsed. Please review and update questions 5.01, 5.02, and 5.03 accordingly.

5.01. Search and select all NQF-endorsed related measures (conceptually, either same measure focus or target population).

(Can search and select measures.) [Response Begins] 0431: INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL [Response Ends]

5.02. Search and select all NQF-endorsed competing measures (conceptually, the measures have both the same measure focus or target population).

(Can search and select measures.) [Response Begins] [Response Ends]

5.03. If there are related or competing measures to this measure, but they are not NQF-endorsed, please indicate the measure title and steward.

[Response Begins] N/A [Response Ends]

5.04. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQFendorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.

[Response Begins] Yes [Response Ends]

5.05. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

[Response Begins]

The proposed measure is harmonized to use the same denominator categories as NQF 0431.

The target population of both NQF 0431 and the proposed measure is healthcare personnel (HCP) who may be encountered by other HCP and patients during the reporting period.

However, the data collection and reporting period is annually for the 6 months from October to March for NQF 0431; The data collection period for the proposed measure is one week a month and the reporting period is quarterly (every 3 months).

The rationale for the shorter data collection period for the proposed measure is to reduce the reporting burden; the rationale for the more frequent reporting period that is not seasonal is that COVID-19 vaccination coverage is a public health priority and COVID-19 has not yet demonstrated consistent seasonality like influenza.

Because of the different time periods for data collection and reporting, NQF 0431 includes healthcare personnel (HCP) who worked for at least one day during the 6-month data collection, while the proposed measure includes HCP who are scheduled to work regularly (at least once a week). Many HCPs who regularly work in a facility may be temporarily absent from a facility for periods of up to two weeks due to illness, injury, or vacation/leave. Because the measurement period covered by the influenza vaccination measure is quite long (the entire 6-month influenza season), such absences will not impact the influenza measure denominator. However, the COVID-19 vaccination measure measurement period is only a week for each month of the quarter, so a number of regularly working HCP may be absent during this shortened period. Therefore, HCP who regularly work in the facility, but may be temporarily absent from the facility for up to 2 weeks, are still to be included.

For many facilities, collecting data for workers who regularly work in the facility will reduce the data collection burden as a daily accounting of HCP work hours is not required. Reporting and calculating coverage rates for 3-month time periods rather than annually for a 6-month time period is a higher burden but one that is warranted for a disease which has and continues to be the cause of a world-wide pandemic. **[Response Ends]**

5.06. Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.

Provide analyses when possible.

[Response Begins] N/A [Response Ends]

Appendix

Supplemental materials may be provided in an appendix.: Available in attached file Attachment: 3636_Libby_ReliabilityAndValidityOfNQF0431InfluenzaVaccination.2013.pdf

Contact Information

Measure Steward (Intellectual Property Owner) : Surveillance Branch, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention Measure Steward Point of Contact: Shehab, Nadine, nshehab@cdc.gov Golshir, Beth, kqo9@cdc.gov Griffith, Ashley, rwz6@cdc.gov

Measure Developer if different from Measure Steward: Surveillance Branch, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention Measure Developer Point(s) of Contact: Budnitz, Daniel, dbudnitz@cdc.gov Shehab, Nadine, nshehab@cdc.gov Griffith, Ashley, rwz6@cdc.gov

Additional Information

1. Provide any supplemental materials, if needed, as an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be collated one file with a table of contents or bookmarks. If material pertains to a specific criterion, that should be indicated.

[Response Begins] Available in attached file [Response Ends]

Libby TE, Lindley MC, Lorick SA, MacCannell T, Lee SJ, Smith C, Geevarughese A, Makvandi M, Nace DA, Ahmed F. Reliability and validity of a standardized measure of influenza vaccination coverage among healthcare personnel. Infect Control Hosp Epidemiol. 2013 Apr;34(4):335-45. doi: 10.1086/669859. Epub 2013 Feb 19. PMID: 23466904.

Attachment: 3636_Libby_ReliabilityAndValidityOfNQF0431InfluenzaVaccination.2013.pdf

2. List the workgroup/panel members' names and organizations.

Describe the members' role in measure development.

[Response Begins]

Name	Organization	Role
Allison Binder	CDC	Epidemiologist, assisted with measure testing
Hannah Reses	CDC	Epidemiologist, assisted with measure testing
Ashley Griffith	Lantana Consulting Group, Inc. (Contractor for CDC)	Measure management
Suparna Bagchi	CDC	Post-acute care subject matter expert, assisted with measure development
Jeneita Bell	CDC	Post-acute care subject matter expert, assisted with measure development, lead for surveillance data collection
Andrea Benin	CDC	Subject matter expert, assisted with measure development
Daniel Budnitz	CDC	Healthcare safety and public health surveillance subject matter expert
Susan Cali	CACI, Inc., Contractor to CDC NHSN	Dialysis component subject matter expert
Heather Dubendris	Lantana Consulting Group, contractor for CDC	Subject matter expert, assisted with measure development and analytics

Name	Organization	Role
Jonathan Edwards	CDC	Statistical consultation on measuring development and assessment of reliability and validity
Andrew Geller	CDC	Post-acute care subject matter expert, assisted with measure development
Elizabeth Kalayil	Lantana Consulting Group, Inc. (Contractor for CDC)	Influenza and COVID-19 vaccination subject matter expert
Beth Pallo	CDC	Measure management
Lauren Wattenmaker	CDC	Health policy subject matter expert, coordinate measure input from federal stakeholders
Hsiu Wu	CDC	Healthcare safety and public health surveillance subject matter expert, assisted with measure development
Megan Lindley	CDC	Subject matter expert in immunization quality measurement
Suchita Patel	CDC	Influenza and COVID-19 vaccination subject matter expert; assisted with measure development.
Shannon Novasad	CDC	Dialysis subject matter expert
Nimale Stone	CDC	Longterm care subject matter expert
Alan Levitt	CMS	Post-acute care subject matter expert

[Response Ends]

3. Indicate the year the measure was first released.

[Response Begins]

Voluntary reporting of COVID-19 vaccination coverage to the National Healthcare Safety Network (NHSN) was first available in December 2020 as part of the public health response to the COVID-19 public health emergency. **[Response Ends]**

4. Indicate the month and year of the most recent revision.

[Response Begins]

Revisions to NHSN reporting described in this proposed measure are planned to be available in by September 2021.

[Response Ends]

5. Indicate the frequency of review, or an update schedule, for this measure.

[Response Begins] To be determined based on the course of the COVID-19 public health emergency. [Response Ends]

6. Indicate the next scheduled update or review of this measure.

[Response Begins] To be determined based on the course of the COVID-19 public health emergency. [Response Ends]

7. Provide a copyright statement, if applicable. Otherwise, indicate "N/A".

[Response Begins] N/A [Response Ends]

8. State any disclaimers, if applicable. Otherwise, indicate "N/A".

[Response Begins] N/A [Response Ends]

9. Provide any additional information or comments, if applicable. Otherwise, indicate "N/A".

[Response Begins] N/A [Response Ends]