COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date

Draft Measure Specifications

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1 INTRODUCTION

The Improving Post-Acute Care Transformation Act of 2014 (IMPACT Act) requires the Secretary to specify resource use measures and other measures, on which post-acute care (PAC) providers are required to submit necessary data specified by the Secretary. The Centers for Medicare & Medicaid Services (CMS) has contracted with Acumen, LLC to develop the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure for the Inpatient Rehabilitation Facility (IRF), Long-Term Care Hospital (LTCH), and Skilled Nursing Facility (SNF) settings. Acumen, LLC operates under the Quality Measure & Assessment Instrument Development & Maintenance & QRP contract (75FCMC18D0015, Task Order 75FCMC19F0003).

This document presents the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID-19 Vaccine) draft measure specifications. Section 2 provides an overview of the measure and a high-level summary of its key features. Section 3 describes the methodology used to calculate the draft Patient/Resident COVID-19 Vaccine measure including its data sources, study population, draft items, and steps for calculating the final measure score.

2 OVERVIEW

This section provides an overview of basic descriptive information on the Patient/Resident COVID-19 Vaccine measure, summarizing the key points contained in the rest of the document. A detailed explanation of the measure specifications is given in Section 3.

2.1 Measure Name

COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date

2.2 Measure Type

Process Measure

2.3 Care Settings

IRF, LTCH, and SNF

2.4 Data Sources

IRF: Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI)

LTCH: LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS)

SNF: Minimum Data Set (MDS)

2.5 Brief Description of Measure

This measure reports the percentage of stays in which patients in an IRF/LTCH and residents in a SNF are up to date with their COVID-19 vaccinations per the latest guidance of the Centers for Disease Control and Prevention (CDC).[1]

[1] The definition of "up to date" may change based on the CDC's latest guidance, and can be found on the CDC webpage "Stay Up to Date with COVID-19 Vaccines Including Boosters," https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html (last accessed 12/5/2022).

3 MEASURE SPECIFICATIONS

This section describes the methodology used to calculate the cross-setting Patient/Resident COVID-19 Vaccine measure. Section 3.1 presents a detailed description of the measure. Section 3.2 details the rationale for the measure. Section 3.3 presents the data sources used to calculate the measure by setting. Section 3.4 contains a draft version of the item by setting. Sections 3.5 and 3.6 define the denominator and numerator, respectively. Section 3.7 presents the steps involved in calculating the measure score.

3.1 Measure Description

This cross-setting process measure reports the percentage of stays[2] in which patients in an IRF/LTCH and residents in a SNF are up to date with their COVID-19 vaccinations per the CDC's latest guidance. The definition of "up to date" may change based on the CDC's latest guidance.[3]

Data collection and measure calculation would be conducted separately for each setting. The measure would require the collection of COVID-19 vaccination data from the discharge assessments on the IRF-PAI for IRF patients, LCDS for LTCH patients, and MDS for SNF residents. Data would be collected using a standardized item harmonized across the assessment instruments. The measure would be reported using one quarter of data, and updated quarterly based on data obtained through the assessment instruments.

3.2 Purpose/Rationale

The purpose of the Patient/Resident COVID-19 Vaccine measure is to report the rate of patient/resident-level vaccination in PAC facilities. The elderly population has been especially affected by the virus, and is more likely to experience serious health outcomes from COVID-19 infection.[4] Given the demonstrated positive impact of COVID-19 vaccination, PAC providers are in a unique position to leverage their care processes to address vaccination coverage in these settings. Additionally, this draft measure supports CMS's Meaningful Measure Initiative 2.0 goal of providing consumers with transparent and patient-directed information to support good healthcare decisions. The remainder of this section addresses these points in detail.

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[2] Stays for each setting are defined in Section 3.7.

[3] Information regarding the definition of "up to date" can be found on the CDC webpage "Stay Up to Date with COVID-19 Vaccines Including Boosters." https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html (last accessed 12/5/2022).

[4] Centers for Disease Control and Prevention. "COVID-19 Risks and Vaccine Information for Older Adults." August 4, 2021. https://www.cdc.gov/aging/covid19/covid19-older-adults.html#:~:text=Older%20adults%20are%20more%20likely,or%20they%20might%20even%20die.

Since the outbreak of COVID-19 in March of 2020, there have been over 97 million cases resulting in over 5.5 million hospitalizations and 1.07 million deaths in the US.[5,6] The elderly population has been especially impacted; research attributes the prevalence of more-severe symptoms and adverse outcomes to the type and number of comorbidities present.[7,8,9] Adults age 65 and older comprise over 75% of total COVID-19 deaths despite representing 12.7% of reported cases.[10] Data also show that adults age 60 and older who experience COVID-19 infections are at a higher risk of hospitalization.[11] Though the COVID-19 pandemic has varied in severity, COVID-19 remains a pressing health concern. Evidence has shown the efficacy of Food and Drug Administration (FDA)-approved COVID-19 vaccines in preventing symptomatic COVID-19[12,13] and COVID-19-associated hospitalization and death.[14,15,16,17] Similar, though often more modest, benefits appear to have persisted as time has passed since

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[5] Centers for Disease Control and Prevention. "Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory." COVID Data Tracker. November 30, 2022. https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00.

[6] Centers for Disease Control and Prevention. "New Admissions of Patients with Confirmed COVID-19, United States." COVID Data Tracker. December 3, 2022. https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions.

[7] Centers for Disease Control and Prevention. "COVID-19 Risks and Vaccine Information for Older Adults." August 4, 2021. https://www.cdc.gov/aging/covid19/covid19-older-adults.html#:~:text=Older%20adults%20are%20more%20likely,or%20they%20might%20even%20die.

[8] Demicri Üçsular, Fatma et al. 2022. "Clinical Differences between Elderly and Non-Elderly Patients with COVID-19." *Turkish Thoracic Journal* 23 (3): 238-45. https://doi.org/10.5152/TurkThoracJ.2022.21288.

[9] Gadò, Klara, et al. 2022. "COVID-19 and the Elderly." *Physiology International* 109 (2): 177–85. https://doi.org/10.1556/2060.2022.00203.

[10] Centers for Disease Control and Prevention. "Demographic Trends of COVID-19 Cases and Deaths in the US Reported to CDC." COVID Data Tracker. December 1, 2022. https://covid.cdc.gov/covid-data-tracker/#demographics.

[11] Centers for Disease Control and Prevention. "New Admissions of Patients with Confirmed COVID-19, United States." COVID Data Tracker. December 3, 2022. https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions.

[12] Korang, Steven Kwasi, et al. 2022. "Vaccines to Prevent COVID-19: A Living Systematic Review with Trial Sequential Analysis and Network Meta-Analysis of Randomized. Clinical Trials." *PLoS One* 17 (1): e0260733. https://doi.org/10.1371/journal.pone.0260733.

[13] Feikin, Daniel R., et al. 2022. "Duration of Effectiveness of Vaccines against SARS-CoV-2 Infection and COVID-19 Disease: Results of a Systematic Review and Meta-Regression." *The Lancet* 399 (10328): 924–44. https://doi.org/10.1016/s0140-6736(22)00152-0.

[14] Oliver, Sara E., et al. 2020. "The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020." *MMWR Morbidity and Mortality Weekly Report* 69 (50): 1922–24. https://doi.org/10.15585/mmwr.mm6950e2.

[15] Oliver, Sara E., et al. 2021. "The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020." *MMWR Morbidity and Mortality Weekly Report* 69 (5152): 1653–56. https://doi.org/10.15585/mmwr.mm695152e1.

[16] Oliver, Sara E., et al. 2021. "The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021." *MMWR Morbidity and Mortality Weekly Report* 70 (9): 329–32. https://doi.org/10.15585/mmwr.mm7009e4.

[17] Mbaeyi, Sarah, et al. 2021. "The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021." *MMWR Morbidity and Mortality Weekly Report* 70 (44): 1545–52. https://doi.org/10.15585/mmwr.mm7044e2.

inoculation, as the dominant variant has shifted from Alpha to Delta to Omicron.[18,19,20] One study found that vaccines were at least 89% effective in preventing hospitalization, intensive care unit (ICU) admissions, and emergency department visits for adults age 50 or older between January and June 2021.[21] Another study found similar results in effectiveness against the later Delta and Omicron variants.[22] Additionally, guidance has also been revised to reflect the introduction of a first booster shot, a second booster for designated individuals over 50 or immunocompromised,[23] and a third bivalent booster.[24,25] The most recent update came with the FDA's August 31, 2022 authorization of the bivalent booster dose to specifically combat the prevalent BA.4/BA.5 Omicron subvariants.[26] Early evidence has demonstrated this bivalent booster's effectiveness in the current climate, and underscores the role of up-to-date vaccination protocols to effectively counter the spread of COVID-19.[27] The CDC has also stated that further COVID variants are expected[28] and a December 6, 2022 statement by the National Institutes of Health (NIH) recommends against the use of Bebtelovmiab (monoclonal antibodies), which had been a previously effective tool against COVID-19, due to the increasing prevalence of resistant

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[18] Lopez Bernal, Jamie, et al. 2021. "Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant." *New England Journal of Medicine* 385: 585–94. https://doi.org/10.1056/NEJMoa2108891.
[19] Rosenberg, Eli, et al. 2021. "New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status – New York, May 3–July 25, 2021." *MMWR Morbidity and Mortality Weekly Report* 70 (37): 1306–11. https://doi.org/10.15585/mmwr.mm7037a7.
[20] Andrews, Nick, et al. 2022. "Covid-19 Vaccine Effectiveness against the Omicron (B.1.1.529) Variant." *New England Journal of Medicine* 386 (16): 1532–46. https://doi.org/10.1056/NEJMoa2119451.
[21] Thompson, Mark G., et al. 2021. "Effectiveness of COVID-19 Vaccines in Ambulatory and Inpatient Care Settings." *New England Journal of Medicine* 385 (15): 1355–71. https://doi.org/10.1056/NEJMoa2110362.
[22] Lauring, Adam S., et al. 2022. "Clinical Severity of, and Effectiveness of mRNA Vaccines against, Covid-19 from Omicron, Delta, and Alpha SARS-CoV-2 Variants in the United States: Prospective Observational Study." *BMJ* 376: e069761. https://doi.org/10.1136/bmj-2021-069761.
[23] Berg, Sara. "Second COVID-19 Vaccine Booster Dose: Answering Patients' Questions." ama-assn.org: Public Health. July 27, 2022. https://www.ama-assn.org/delivering-care/public-health/second-covid-19-vaccine-booster-dose-answering-patients-questions.
[24] Link-Gelles, Ruth, et al. 2022. "Effectiveness of 2, 3, and 4 COVID-19 mRNA Vaccine Doses Among Immunocompetent Adults During Periods when SARS-CoV-2 Omicron BA.1 and BA. 2/BA.2.12.1 Sublineages Predominated – VISION Network, 10 States, December 2021–June 2022." *MMWR Morbidity and Mortality Weekly Report* 71 (29): 931–39. https://doi.org/10.15585/mmwr.mm7129e1.
[25] Chenchula, Santenna, et al. 2022. "Current Evidence on Efficacy of COVID-19 Booster Dose Vaccination against the Omicron Variant: A Systemic Review." *Journal of Medical Virology* 94 (7): 2969–76. https://doi.org/10.1002/jmv.27697.
[26] Food and Drug Administration. "Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose." FDA Newsroom*.* August 31, 2022. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use.
[27] Chalkias, Spyros, et al. 2022. "A Bivalent Omicron-Containing Booster Vaccine against COVID-19." *New England Journal of Medicine* 387 (14): 1279–91. https://doi.org/10.1056/NEJMoa2208343.
[28] Centers for Disease Control and Prevention. "Variants of the Virus." COVID-19. August 11, 2021. https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html.

Omicron strains.[29] COVID-19 vaccination will continue to be an important tool to minimize severe illness, hospitalization, and death.

Given the demonstrated positive impact of COVID-19 vaccination on mortality rates and poor clinical outcomes from COVID-19 infections, promoting and establishing high levels of up-to-date COVID-19 vaccination in patients of PAC facilities and agencies is critical to patient safety and prevention of negative outcomes. PAC settings are uniquely qualified to assess older adults, especially those who are more susceptible to viruses due to their weakened physical state, and to incorporate a vaccination needs assessment into every episode of care. PAC providers utilize a number of care processes that can be leveraged to address vaccination coverage. For example, PAC providers routinely work with standing admission order sets for various admitting conditions, which would allow for a routine vaccination needs assessment. PAC providers utilize patient-specific care plans as a mechanism to address patients' identified healthcare needs through evidence-based approaches, which could include vaccine administration.

Finally, this draft measure supports CMS's Meaningful Measure Initiative 2.0 goal to empower consumers to make good healthcare choices through patient-directed quality measures and public transparency objectives. The measure would empower patients and caregivers, including those who are at high risk for developing serious complications from COVID-19, through transparency of data and public reporting as they seek to choose a PAC facility. The measure also captures activities that PAC providers are already performing. Specifically, establishing and maintaining an infection prevention and control program is a condition of participation for hospitals (42 CFR §482.42),[30] SNFs (42 CFR §483.65),[31] and home health agencies (42 CFR §484.70).[32] Inadequate prevention of infections is likely to result in poor healthcare outcomes for PAC patients, as well as wasteful resource use. For example, healthcare-acquired infections are associated with longer lengths of stay, use of higher-intensity care, increased mortality, and high healthcare costs. Therefore, this quality measure has the potential to align with PAC providers' quality improvement activities.

3.3 Data Sources

IRF: This measure would use information from the IRF-PAI to obtain raw rates of the number of stays in which patients in an IRF are up to date with their COVID-19 vaccination. Providers would be able to use all sources of information available to obtain the vaccination data, such as patient interviews, medical records, proxy response, and vaccination cards provided by

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[29] National Institutes of Health. "The COVID-19 Treatment Guidelines Update on Bebtelovimab." Therapies. December 6, 2022. https://www.covid19treatmentguidelines.nih.gov/therapies/update-on-bebtelovimab/.
[30] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482/subpart-C/section-482.42.
[31] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-483/subpart-B/section-483.65.
[32] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-484/subpart-B/section-484.70.

the patient/caregivers. While this COVID-19 vaccination item does not yet exist on the IRF-PAI assessment instrument, the item would be added to the IRF-PAI and collected at the time of discharge to capture this information across all IRFs.

LTCH: This measure would use information from the LCDS to obtain raw rates of the number of stays in which patients in an LTCH are up to date with their COVID-19 vaccination. Providers would be able to use all sources of information available to obtain the vaccination data, such as patient interviews, medical records, proxy response, and vaccination cards provided by the patient/caregivers. While this COVID-19 vaccination item does not yet exist on the LCDS assessment instrument, the item would be added to the LCDS and collected at the time of discharge to capture this information across all LTCHs.

SNF: This measure would use information from the MDS to obtain raw rates of the number of Medicare Part A covered stays in which residents in a SNF are up to date with their COVID-19 vaccination. Providers would be able to use all sources of information available to obtain the vaccination data, such as resident interviews, medical records, proxy response, and vaccination cards provided by the resident/caregivers. While this COVID-19 vaccination item does not yet exist on the MDS assessment instrument, the item would be added to the MDS and collected at the time of discharge to capture this information across all SNFs.

3.4 Draft Items

Figures 1.1-1.3 show mockups of the draft patient/resident COVID-19 vaccination item for IRF, LTCH, and SNF settings, respectively.

IRF

Figure 1.1: Draft COVID-19 Vaccination Item for IRF-PAI

Q1. Patient's COVID-19 vaccination is up to date.
0. No, patient is not up to date **1.** Yes, patient is up to date

LTCH

Figure 1.2: Draft COVID-19 Vaccination Item for LCDS

Q1. Patient's COVID-19 vaccination is up to date.
0. No, patient is not up to date **1.** Yes, patient is up to date

SNF

Figure 1.3: Draft COVID-19 Vaccination Item for MDS

Q1. Resident's[33] COVID-19 vaccination is up to date.
0. No, resident is not up to date **1.** Yes, resident is up to date

3.5 Denominator

IRF: The total number of IRF stays discharged during the target period.[34]

LTCH: The total number of LTCH stays discharged during the target period.[34]

SNF: The total number of Medicare Part A covered SNF stays discharged during the target period.[34]

[33]The MDS use of the term "residents" refers to both SNF residents and Nursing Home (NH) residents.
[34] The target period is defined as one quarter in Section 3.1.

3.6 Numerator

IRF: The total number of IRF stays in the denominator in which patients are up to date with the COVID-19 vaccine (Q1=[1]) during the target period.

LTCH: The total number of LTCH stays in the denominator in which patients are up to date with the COVID-19 vaccine (Q1=[1]) during the target period.

SNF: The total number of Medicare Part A covered SNF stays in the denominator in which residents are up to date with the COVID-19 vaccine (Q1=[1]) during the target period.

3.7 Measure Calculation

The following steps would be used to calculate the measure:

<u>Step 1: Calculate the denominator count</u>

IRF: Calculate the total number of IRF stays with a target date (discharge date (Item 40)) within the target period. If a patient has multiple eligible IRF stays with a discharge date within the target period, then include each eligible stay in the measure.

LTCH: Calculate the total number of LTCH stays with a matched pair of Admission and Discharge assessments (or Admission assessment and Expired Record) during the target period. For quality measure calculation purposes, both the Admission and Discharge assessments included in the LTCH stay sample are assigned to the target period of the Discharge Date (Item A0270). If a patient has multiple LTCH stays with a discharge date within the data target period, then include each eligible LTCH stay in the measure.

SNF: Calculate the total number of Medicare Part A covered SNF stays that end on or after the beginning of the target period and on or before the end of the target period, based on the date (A2300) of the Medicare Part A Discharge Record (A0310H = [1]) or the target date (A2000) of the Death in Facility Tracking Record (A0310F = [12]). If there is a PPS Discharge Assessment (A0310H = [1]) that is combined with an OBRA Discharge Assessment and the End date of the most recent Medicare stay (A2400C) on this PPS Discharge Assessment (A0310H = [1]) is the last day of this search window, the Target Date of this assessment will be on or one day after the search window end date. If a patient has multiple SNF stays with a discharge date within the data target period, then include each eligible SNF stay in the measure.

Step 2: Calculate the numerator count

IRF: Calculate the total number of IRF stays in the denominator in which patients are up to date with the COVID-19 vaccine (Q1=[1]).

LTCH: Calculate the total number of LTCH stays in the denominator in which patients are up to date with the COVID-19 vaccine (Q1=[1]).

SNF: Calculate the total number of Medicare Part A covered SNF stays in the denominator in which residents are up to date with the COVID-19 vaccine (Q1=[1]).

Step 3: Calculate the facility/agency observed score

IRF: Divide the facility's numerator count (Step 2) by its denominator count (Step 1) to obtain the facility-level observed score; and then multiply by 100 to obtain a percent value.

LTCH: Divide the facility's numerator count (Step 2) by its denominator count (Step 1) to obtain the facility-level observed score; and then multiply by 100 to obtain a percent value.

SNF: Divide the facility's numerator count (Step 2) by its denominator count (Step 1) to obtain the facility-level observed score; and then multiply by 100 to obtain a percent value.