

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

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Specifications for the
COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date
Quality Measure

Abt Associates, Inc.

CMS Contract No. HHSM-500-2013-13001I; Task Order HHSM-500T0002 and
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CONTENTS

- 1 BACKGROUND.....3**
- 2 OVERVIEW4**
 - 2.1 Measure Name.....4**
 - 2.2 Measure Type4**
 - 2.3 Care Setting.....4**
 - 2.4 Data Source4**
 - 2.5 Brief Description of Measure4**
- 3 MEASURE SPECIFICATIONS5**
 - 3.1 Measure Description.....5**
 - 3.2 Purpose/Rationale.....5**
 - 3.3 Data Source6**
 - 3.4 Draft Item7**
 - 3.5 Denominator.....7**
 - 3.6 Numerator.....7**
 - 3.7 Measure Calculation.....7**

FIGURE

- Figure 1.1: Draft COVID-19 Vaccination OASIS Item..... 8

1 BACKGROUND

CMS has contracted with Abt Associates to develop the Patient/Resident COVID-19 Vaccine measure. This measure development work was completed under the contracts named Outcome and Assessment Information Set (OASIS) Quality Measure Development and Maintenance Project (HHSM -500-2013-13001I, Task Order HHSM- 500T0002) and Home Health and Hospice Quality Reporting Program Quality Measures and Assessment Instruments Development, Modification and Maintenance, & Quality Reporting Program Continued Contract (#75FCMC18D0014, Task Order # 75FCMC19F0001).

The reporting of quality data by home health agencies (HHAs) is mandated by Section 1895(b)(3)(B)(v)(II) of the Social Security Act (“the Act”). For more information on the statutory history of the HH Quality Reporting Program (QRP), please refer to <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html>.

This document describes the specifications for the home health Patient/Resident COVID-19 Vaccine measure.

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 Setting

Home Health

2.4 Data Source

Outcome and Assessment Information Set (OASIS)

2.5 Brief Description of Measure

This measure reports the percentage of home health quality episodes in which patients were up to date with their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) guidelines on current vaccination.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 02/21/2023).

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 source used to calculate the measure. Section 3.4 contains a draft version of the OASIS item. 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 home health quality episodes in which patients were up to date with their COVID-19 vaccinations, as defined by Centers for Disease Control and Prevention (CDC) guidelines on current vaccination. The definition of “up to date” may change based on the CDC’s latest guidance.³

The measure would require the collection of COVID-19 vaccination data at the end of each quality episode. This would include OASIS collection when a patient is transferred to an inpatient facility, with or without discharge (M0100 RFA 6 or 7), when a patient experiences a death at home (M0100 RFA 8), and when a patient is discharged from agency – not to an inpatient facility (M0100 RFA 9). Data would be collected using a standardized item harmonized across the post-acute care settings as collected on the OASIS for home health patients, the IRF-PAI for IRF patients, the LCDS for LTCH patients, and the MDS for SNF residents. The measure would be reported using one quarter of data, and updated quarterly based on data obtained through the OASIS assessment instrument.

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 and home health agencies. 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.

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 02/21/2023).

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 Secretary declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS-COV-2 on January 31, 2020, there have been more than 103 million cases and 1.12 million deaths in the United States as of March 15, 2023.^{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 13.4% 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

⁵ U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

⁶ Centers for Disease Control and Prevention. COVID Data Tracker. Accessed March 15, 2023. Available at <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.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 Demirci Üçşular, 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. 2023, March 15. Last accessed March 23, 2023. <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](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 expected²⁸ 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

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 Luring, 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/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.

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 provider. 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 Source

This measure would use information from the OASIS to obtain raw rates of the number of home health quality episodes in which patients were up to date with their COVID-19 vaccination. Home Health agencies 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 OASIS instrument, the item would be added to the OASIS and collected at the transfer, discharge and death at home to capture this information across all Medicare-certified home health agencies.

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>.

3.4 Draft Item

Figure 1.1 shows a mockup of the draft patient/resident COVID-19 vaccination OASIS item.

Figure 1.1: Draft COVID-19 Vaccination

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

Item

3.5 Denominator

The number of home health quality episodes ending with a discharge, transfer to an inpatient facility, or death at home during the reporting period.³⁴

3.6 Numerator

The number of home health quality episodes in which the patient was determined to be up to date with the COVID-19 vaccination (Q1=[1]) during the reporting period.

3.7 Measure Calculation

The following steps would be used to calculate the measure:

Step 1: Calculate the denominator count

Calculate the total number of home health quality episodes with a M0906 – Discharge/Transfer/Death Date within the reporting period. If a patient has multiple eligible home health quality episodes with a M0906 date within the reporting period, then include each eligible quality episode in the measure.

Step 2: Calculate the numerator count

Calculate the total number of home health quality episodes in the denominator in which the patient was determined to be up to date with the COVID-19 vaccination at the end of the quality episode (Q1=[1]).

Step 3: Calculate the agency observed score

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

³⁴ The reporting period is defined as one quarter in Section 3.1