NATIONAL QUALITY FORUM
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Measure Applications Partnership (MAP) Post-Acute Care /Long-Term Care: 2022-2023 Measures Under Consideration (MUC) Cycle Measure Specifications

MANUAL

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Skilled Nursing Facility Value-Based Purchasing Program

MUC2022-035 Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay)

Program

Skilled Nursing Facility Value-Based Purchasing Program

Section 1: Measure Information

Measure Specifications and Endorsement Status

Measure Description

This one-year measure reports the percentage of long-stay residents in a nursing home who have experienced one or more falls resulting in major injury (defined as bone fractures, joint dislocations, closed head injuries with altered consciousness, or subdural hematoma) reported in the look-back period no more than 275 days prior to the target assessment. The long stay nursing home population is defined as residents who have received 101 or more cumulative days of nursing home care by the end of the target assessment period. This measure uses data obtained through the Minimum Data Set (MDS) 3.0 OBRA, PPS, and/or discharge assessments during the selected quarter(s).

Numerator

The measure numerator includes long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury, including bone fractures, joint dislocations, closed-head injuries with altered consciousness, or subdural hematoma (J1900C = [1,2]).

Numerator Exclusions

N/A

Denominator

The measure denominator includes all long-stay nursing home residents with one or more look-back scan assessments except those with exclusions.

Denominator Exclusions

Residents are excluded if the following is true for all look-back scan assessments:

1. The number of falls with major injury was not coded (J1900C = [-]).

Denominator Exceptions

N/A

State of development

Fully Developed

State of Development Details

N/A

What is the target population of the measure?

Long-stay nursing home residents who have resided in the nursing home for 101 or more days.

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Nursing Homes participating in the SNF VBP Program

Measure Type

Outcome

Is the measure a composite or component of a composite?

Not a composite or component of a composite measure

If Other, Please Specify

N/A

What data sources are used for the measure?

Standardized Patient Assessments

If applicable, specify the data source

Minimum Data Set (MDS) 3.0

Description of parts related to these sources

The data source being used is the Minimum Data Set (MDS) 3.0. The collection instrument is the Resident Assessment Instrument (RAI). The measure uses elements from Section J and Section A of the MDS 3.0 Resident Assessment and Care Screening Nursing Home

At what level of analysis was the measure tested?

Facility

In which setting was this measure tested?

Nursing home

Multiple Scores

No

What one healthcare domain applies to this measure?

Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities

N/A

Is this measure in the CMS Measures Inventory Tool (CMIT)?

Yes

CMIT ID

04053-X-NHQI

Alternate Measure ID

N/A

What is the endorsement status of the measure?

Endorsed

CBE ID (CMS consensus-based entity, or endorsement ID)

0674

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

Yes

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

2021

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

2024

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

No

If eCQM, enter Measure Authoring Tool (MAT) number

N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?

N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?

No

Previous Measure Information

N/A

What is the history or background for including this measure on the new measures under consideration list?

Measure currently used in a CMS program being submitted as-is for a new or different program

Range of years this measure has been used by CMS Programs

Nursing Home Quality Initiative: (2010-present)

What other federal programs are currently using this measure?

Nursing Home Quality Initiative

Is this measure similar to and/or competing with a measure(s) already in a program?

Yes

Which measure(s) already in a program is your measure similar to and/or competing with?

[1] Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) - Inpatient Rehabilitation Facility Quality Reporting - CMIT ID: 02586-C-IRFQR

[2] Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) - Skilled Nursing Facility Quality Reporting - CMIT ID: 01299-C-SNFQRP

[3] Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) - Long-Term Care Hospital Quality Reporting - CMIT ID: 01299-C-LTCHQR

[4] Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) - Home Health Quality Reporting - CMIT ID: 03493-C-HHQR

How will this measure be distinguished from other similar and/or competing measures?

The Percent of Residents Experiencing One or More Falls with Major Injury measure differs from the Application of Percent of Residents Experiencing One or More Falls with Major Injury measures for the SNF, IRF, LTCH, and HH QRPs as the latter are not NQF endorsed and do not assess falls with major injury among the long-stay resident population. Although there is an Application of Percent of Residents Experiencing One or More Falls with Major Injury measure in the SNF QRP, this measure is topped out with a mean rate of 0.9% and does not include long-stay residents in its denominator.

How will this measure add value to the CMS program?

Approximately 94 percent of long-term care residents are dually certified as both SNF or nursing facilities (86 FR 42508). The majority of long-term care facility residents are also Medicare beneficiaries, regardless of whether they captured under a Medicare Part A SNF stay, because they are enrolled in Medicare Part B and receive Medicare coverage of certain services provided by the facility even if they are a long-term care resident (86 FR 42508). Therefore, it is important to capture quality of care received by the long-stay population within the SNF VBP Program. Currently there are no existing NQF-endorsed measures of falls in the SNF quality reporting or value-based purchasing programs that assess the long-stay population, justifying consideration of the Percent of Residents Experiencing One or More Falls with Major Injury measure for SNF VBP Program adoption.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

The 2021 Consolidation Appropriations Act

Section 2: Measure Evidence

How is the measure expected to be reported to the program?

Other: Minimum Data Set (MDS)

Stratification

No

Feasibility of Data Elements

ALL data elements are in defined fields in electronic sources

Feasibility Assessment

The Percent of Residents Experiencing One or More Falls with Major Injury measure utilizes the Minimum Data Set (MDS) 3.0 as a data source, in which the collection instrument is the Resident Assessment Instrument (RAI). The MDS is part of the federally mandated process for clinical assessment of all residents in Medicare- and Medicaid-certified nursing homes. Therefore, there is no additional burden associated with data collection of the Percent of Residents Experiencing One or More Falls with Major Injury measure.

Method of Measure Calculation

Other digital method

Hybrid measure: Methods of measure calculation

N/A

Evidence of Performance Gap

This measure intends to identify SNF providers that have a significantly higher or lower rate of falls with major injury in comparison to the average SNF with the same resident population. An analysis of 2018Q3 to 2019Q2 data indicates that there is a performance gap in falls with major injury across SNFs. Among 14,586 facilities included in the study population, measure scores ranged from 0.0% (min) to 20.6% (max) with a mean score of 3.4% and a standard deviation of 2.4%. The 25th percentile, median, and 75th percentile were 1.6%, 3.0% and 4.7%, respectively. Of the facilities with adequate sample size to report, 6.2% had perfect scores of 0.

Existing literature indicates that certain nursing home characteristics may influence the risk for falls with major injury, which may account for a performance gap between nursing homes. For instance, adequate staffing levels, staff education, and adequate levels of facility equipment have all been associated with higher risk of injurious falls (Vlaeyen et al., 2017). Nursing home characteristics/structures and resource allocation may affect key processes known to influence the rate of falls with major injury within a facility. These key processes include adherence to clinical guidelines and best practices in falls prevention. Therefore, nursing homes with better staffing, staff education, leadership, communication, and more available equipment may perform better with regards to fall prevention (Vlaeyen et al., 2017).

Reference:

Vlaeyen, E., Stas, J., Leysens, G., Van der Elst, E., Janssens, E., Dejaeger, E., Dobbels, F., & Milisen, K. (2017). Implementation of fall prevention in residential care facilities: A systematic review of barriers

and facilitators. International Journal of Nursing Studies, 70, 110-121. https://doi.org/10.1016/j.ijnurstu.2017.02.002

Unintended Consequences

Accounting for falls with major injury may influence providers to increase the use of unwanted or unnecessary physical and/or chemical restraints. One study examining the perceptions of nurse managers, registered nurses, and healthcare assistants of physical restraint use among older long-term care patients found that, while nurse managers and registered nurses did not favor physical restraint use, healthcare assistants were more positively in favor of using physical restraints to prevent falls (Leahy-Warren et al., 2018). Other studies and reviews have shown that a history of falls is associated with the decision to use physical restraints on patients (Heckman et al., 2017; Lan et al., 2017). It may also be possible that providers would increase the use of chemical restraints in residents to make them more bedbound, and thereby decrease their risk of falling. However, chemical restraints have been shown to increase the risk of falling (Bronskill et al., 2018). Overall, the overprescribing of physical and/or chemical restraints is one possible unintended consequence of the measure.

References:

Bronskill, S. E., Campitelli, M. A., Iaboni, A., Herrmann, N., Guan, J., Maclagan, L. C., Watt, J., Rochon, P. A., Morris, A. M., Jeffs, L., Bell, C. M., & Maxwell, C. J. (2018). Low-dose trazodone, benzodiazepines, and fall-related injuries in nursing homes: a matched-cohort study. J Am Geriatr Soc, 66(10), 1963-1971. https://doi.org/10.1111/jgs.15519

Heckman, G. A., Crizzle, A. M., Chen, J., Pringsheim, T., Jette, N., Kergoat, M. J., Eckel, L., & Hirdes, J. P. (2017). Clinical complexity and use of antipsychotics and restraints in long-term care residents with Parkinson's Disease. Journal of Parkinson's Disease, 7(1), 103-115. https://doi.org/10.3233/JPD-160931

Lan, S. H., Lu, L. C., Lan, S. J., Chen, J. C., Wu, W. J., Chang, S. P., & Lin, L. Y. (2017). Educational intervention on physical restraint use in long-term care facilities - systematic review and meta-analysis. The Kaohsiung Journal of Medical Sciences, 33(8), 411-421. https://doi.org/10.1016/j.kjms.2017.05.012

Leahy-Warren, P., Varghese, V., Day, M. R., & Curtin, M. (2018). Physical restraint: perceptions of nurse managers, registered nurses and healthcare assistants. International Nursing Review, 65(3), 327-335. https://doi.org/10.1111/inr.12434

Number of clinical guidelines, including USPSTF guidelines, that address this measure topic

1

Outline the clinical guidelines supporting this measure

Preventing Falls and Reducing Injury from Falls, Fourth Edition from the Registered Nurses Association of Ontario, 2017:

The Registered Nurses Association of Ontario (RNAO) developed these clinical practice guidelines to present evidence-based strategies to reduce falls and fall-related injuries in adults. The scope of these guidelines is the prevention of falls and injuries from falls in all adults 18 years of age or older at risk for falls who receive care from nurses and other providers across all health care settings, including residential patients. Despite this broader scope, long-term care settings (including nursing homes) are highlighted as one of the core domains for these recommendations. These guidelines strongly relate to

the Percent of Residents Experiencing One or More Falls with Major Injury measure as they address best practices for health care providers to reduce injurious falls among their patients. Further, with long-term care being one of the core domains for the RNAO's recommendations, this clinical practice guideline is pertinent to the Percent of Residents Experiencing One or More Falls with Major Injury measure.

Studies appraised and evaluated in systematic reviews and other high-quality guidelines are used as evidence for RNAO's recommendations. Five guidelines of moderate to high quality, graded using Appraisal of Guidelines for Research & Evaluation II (AGREE II), were included in the research for this guideline. 125 unique studies were included from systematic reviews appraised using A Measurement Tool to Assess Systematic Reviews (AMSTAR). Systematic reviews of low, moderate, and high quality were all included if they met the inclusion criteria. This guideline is therefore both consensus- and evidence-based, drawing from previous guidelines and from studies.

This guideline outlines best practices for nursing home and SNF processes that can reduce the number of falls leading to injuries, and highlighted several benefits of the best practices indicated in the studies it references. One moderate-rated review demonstrated that cognitive motor interference was shown to be effective for preventing falls among older adults in the short term. One strong-rated guideline recommended specific medications for people in long-term care who are at risk of fracture that should and should not be taken. Some medications as well as polypharmacy have been shown to increase the risk of falls, and therefore care decisions should be made to reflect this and mitigate the risk of injury from falls. A low-rated review found that a prompted voiding schedule in long-term care, together with increased physical activity, reduced rates of falls. In addition to these potential benefits, the guidelines also found that medication management, rounding, and vitamin D supplementation posed potential benefits based on the reviewed studies and guidelines. This evidence therefore informs best practices and prevention processes that providers can implement to reduce injurious fall rates.

This guideline recommends processes (e.g., best practices, adherence to guidelines, and other aspects of care), structures (e.g., staffing, staff education and leadership, accountability, resources, and physical environment), and interventions that can impact the outcome of injurious falls. The guideline recommends several processes that facilities can implement to reduce fall rates, including (1) screening residents for risk of falls, (2) conducting assessments of risk factors, (3) assigning high-risk residents to appropriate clinicians for their needs, (4) engaging with residents by educating them on fall risk, (5) communicating and establishing interventions, (6) working with prescribers and other providers and considering injury-reduction tools for residents, and (7) conducting post-fall assessments into outcomes and causes. The guidelines also identify several structures which influence fall rates, including (1) whether or not facilities properly train healthcare personnel on injurious fall prevention, (2) ensuring that the facility's physical space is secure, and (3) ensuring that leadership supports fall- and injury-reduction initiatives. Some of these recommendations are linked to reducing falls and injurious falls overall, while others seek to directly reduce the risk of injury from falling. In both cases, these recommendations strive to reduce injurious falls among nursing home residents.

The guidelines identified potential harms for only one of the recommendations, which is to consider the use of hip protectors on some residents. These potential harms include a slight increase in the risk of pelvic fractures and skin irritation.

Registered Nurses Association of Ontario (RNAO). (2017). Preventing falls and reducing injury from falls. Retrieved from: https://rnao.ca/bpg/guidelines/prevention-falls-and-fall-injuries

Name the guideline developer/entity

Registered Nurses Association of Ontario (RNAO)

Publication year

2017

Full citation +/- URL

Registered Nurses Association of Ontario (RNAO). (2017). Preventing falls and reducing injury from falls. Retrieved from: https://rnao.ca/bpg/guidelines/prevention-falls-and-fall-injuries

Is this an evidence-based clinical guideline?

Yes

Is the guideline graded?

Yes

List the guideline statement that most closely aligns with the measure concept.

The most relevant recommendation is Recommendation 2.4: Implement a combination of interventions tailored to the person and the health-care setting to prevent falls or fall injuries.

What evidence grading system did the guideline use to describe strength of recommendation?

Other (enter here): The AMSTAR and AGREE II tools were used to assess the quality of evidence used to develop recommendations.

List all categories and corresponding definitions for the evidence grading system used to describe strength of recommendation in the guideline?

Levels of evidence, adapted from the Scottish Intercollegiate Guidelines Network, were assigned to study designs to rank how well each study design was able to eliminate alternate explanations of the phenomena under study. The higher the level of evidence, the more likely it is that there were fewer potential sources of bias influencing the research findings. However, levels of evidence do not reflect the quality of individual studies or reviews.

In some cases, recommendations in this clinical practice guideline are assigned more than one level of evidence. This reflects the varied study designs that support the recommendation. For transparency, the level of evidence for each component of the recommendation statement is identified below.

Levels and Sources of Evidence:

- Level Ia - Evidence obtained from meta-analysis or systematic reviews of randomized controlled trials, and/or synthesis of multiple studies primarily of quantitative research.
- Level Ib - Evidence obtained from at least one randomized controlled trial.
- Level IIa - Evidence obtained from at least one well-designed controlled study without randomization.

- Level IIb - Evidence obtained from at least one other type of well-designed quasi-experimental study, without randomization.
- Level III - Synthesis of multiple studies primarily of qualitative research.
- Level IV - Evidence obtained from well-designed non-experimental observational studies, such as analytical studies or descriptive studies, and/or qualitative studies.
- Level V - Evidence obtained from expert opinion or committee reports, and/or clinical experiences of respected authorities.

For the guideline statement that most closely aligns with the measure concept, what is the associated strength of recommendation?

Level Ia, adapted from the Scottish Intercollegiate Guidelines Network

What evidence grading system did the guideline use to describe level of evidence or level of certainty in the evidence?

Other (enter here): The AMSTAR and AGREE II tools were used to assess the quality of evidence used to develop recommendations.

List all categories and corresponding definitions for the evidence grading system used to describe level of evidence or level of certainty in the evidence?

The quality of each of the reviews cited in the discussion of evidence was appraised and categorized as strong, moderate, or low based on the AMSTAR instrument for reviews. The quality rating is calculated by converting the score on the AMSTAR tool into a percentage. When other guidelines informed the recommendation and discussion of evidence, the AGREE II instrument was used to determine the quality rating.

Quality ratings for reviews using the AMSTAR tool are listed below:

1. A quality score on the AMSTAR greater than, or equal to, a converted score of 82.4% indicates a strong overall quality rating.
2. A quality score on the AMSTAR equal to a converted score of 62.5% to 82.4% indicates a moderate overall quality rating.
3. A quality score on the AMSTAR less than, or equal to, a converted score of 62.4% indicates a low overall quality rating.

Quality ratings for guidelines using the AGREE II Tool are listed below:

1. A score of 6 or 7 on the overall guideline quality indicates a strong quality rating.
2. A score of 5 on the overall guideline quality indicates a moderate quality rating.
3. A score of less than 4 on the overall guideline quality indicates a low quality rating (which is not used to support recommendations).

For the guideline statement that most closely aligns with the measure concept, what is the associated level of evidence or level of certainty in the evidence?

Other (enter here): The quality of reviews used to develop this recommendation were strong, moderate, and low. The quality of guidelines used to develop this recommendation were strong.

List the guideline statement that most closely aligns with the measure concept.

The most relevant recommendation is Recommendation 2.4: Implement a combination of interventions tailored to the person and the health-care setting to prevent falls or fall injuries.

Number of systematic reviews that inform this measure concept

6

Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept

Multiple systematic reviews address the link between falls with major injury and facility structural characteristics and interventions. Several studies observed that multifactorial interventions such as exercise, medication review, risk assessment, vision assessment, and environmental assessment significantly reduce fall rates (Gulka et al., 2020; Tricco et al., 2017; Vlaeyen et al., 2015). Exercise-based interventions have also shown promise in reducing the frequency of injurious falls (Crandall et al., 2016; Grossman et al., 2018; Gulka et al., 2020; Tricco et al., 2017). These interventions seek to improve or increase physical activity in residents to maintain functional capacity and reduce the risk of injurious falls. One study found that a single intervention of exercise reduced the number of fallers in the nursing home setting by 36% and the number of recurrent fallers by 41% (Gulka et al., 2020). Additionally, multifactorial interventions with resident assessments have shown promise in reducing injurious falls (Chang et al., 2004; Grossman et al., 2018; Gulka et al., 2020; Tricco et al., 2017; Vlaeyen et al., 2015; Vlaeyen et al., 2017). One review, found that multifactorial interventions, which typically include falls risk assessment, medication review, environmental assessment, exercise, and staff education, resulted in a significant decrease in number of falls (RR = 0.65, 95% CI = 0.45-0.94; I2 = 88.16%) (Gulka et al., 2020). In alignment with the RNAO clinical practice guideline referenced above, another systematic review recommends tailoring risk-reduction strategies to high-risk resident's specific needs (Crandall et al., 2016).

Additionally, various systematic reviews link facility structural characteristics to falls with major injury. For example, incorporation of adequate equipment, such as hip protectors or equipment used for staff education tasks, throughout the facility may reduce fall rates or fall-related injuries (Crandall et al., 2016; Vlaeyen et al., 2017). One meta-analysis examined multiple studies in the nursing home population to identify facilitators and barriers to fall prevention implementation and found the greatest number of determinants at the social and organizational levels of healthcare (Vlaeyen et al., 2017). Poor communication between staff (e.g., inadequate information transfer between staff working different shifts, tension between licensed and unlicensed staff), inadequate staffing levels, and limited facility equipment were among the greatest barriers to implementing a falls prevention program in a facility (Vlaeyen et al., 2017). Additionally, high staff turnover rates and a lack of adequate staffing levels may prevent caretakers from having sufficient time dedicated to a falls prevention program, as they must prioritize other tasks and responsibilities (Vlaeyen et al., 2017). Nursing home staff have cited feeling helpless, frustrated, overwhelmed, and highly concerned about their ability to control fall management (Vlaeyen et al., 2017). Other studies have shown that proper staff education can significantly reduce fall rates (Gulka et al., 2020; Tricco et al., 2017; Vlaeyen et al., 2015). Lastly, lacking qualities among facility leadership, such as failure to take accountability and inadequate quality improvement skills, may also influence rates of falls (Vlaeyen et al., 2017).

References:

Chang, J. T., Morton, S. C., Rubenstein, L. Z., Mojica, W. A., Maglione, M., Suttorp, M. J., Roth, E. A., & Shekelle, P. G. (2004). Interventions for the prevention of falls in older adults: systematic review and meta-analysis of randomized clinical trials. BMJ. 328(7441), 680. https://doi.org/10.1136/bmj.328.7441.680

Crandall, M., Duncan, T., Mallat, A., Greene, W., Violano, P., & Christmas, B. (2016). Prevention of fall-related injuries in the elderly: An eastern association for the surgery of trauma practice management guideline. Journal of Trauma and Acute Care Surgery, 81(1), 196-206. https://doi.org/10.1097/TA.0000000000001025

Gulka, H. J., Patel, V., Arora, T., McArthur, C., & Iaboni, A. (2020). Efficacy and generalizability of falls prevention interventions in nursing homes: A systematic review and meta-analysis. Journal of the American Medical Directors Association, 21(8), P1024-1035.E4. https://doi.org/10.1016/j.jamda.2019.11.012

Tricco, A. C., Thomas, S. M., Veroniki, A. A., Hamid, J. S., Cogo, E., Strifler, L., Khan, P. A., Robson, R., Sibley, K. M., MacDonald, H., Riva, J. J., Thavorn, K., Wilson, C., Holroyd-Leduc, J., Kerr, G. D., Feldman, F., Majumdar, S. R., Jaglal, S. B., Hui, W., & Straus, S. E. (2017). Comparisons of interventions for preventing falls in older adults: A systematic review and meta-analysis. Journal of the American Medical Association, 318(17), 1687-1699. https://doi.org/10.1001/jama.2017.15006

Vlaeyen, E., Coussement, J., Leysens, G., Van der Elst, E., Delbaere, K., Cambier, D., Denhaerynck, K., Goemaere, S., Wertelaers, A., Dobbels, F., Dejaeger, E., & Milisen, K. (2015). Characteristics and effectiveness of fall prevention programs in nursing homes: A systematic review and meta-analysis of randomized control trials. Journal of the American Geriatrics Society, 6(3), 211-21. https://doi.org/10.1111/jgs.13254

Vlaeyen, E., Stas, J., Leysens, G., Van der Elst, E., Janssens, E., Dejaeger, E., Dobbels, F., & Milisen, K. (2017). Implementation of fall prevention in residential care facilities: A systematic review of barriers and facilitators. International Journal of Nursing Studies, 70, 110-121. https://doi.org/10.1016/j.ijnurstu.2017.02.002

Source of empirical data

Published, peer-reviewed original research;Published and publicly available reports (e.g., from agencies)

Summarize the empirical data

Empirical evidence demonstrates risk factors that may be associated with greater fall risk, including fewer comorbidities, more agitation and depression, more time spent engaging in physical activity, and use of psychotropic medications (Galik et al., 2018). Obesity may be associated with reduced risk for falls among newly admitted nursing home residents, and mobility device use is not associated with greater incidence of falls among older adults (Gell et al., 2015; Zhang et al., 2018).

Various studies have supported the importance of preventive interventions and processes for reducing injurious falls in nursing homes. For instance, empirical evidence has observed the reduction in falls following receipt of function-focused care processes. Function-focused care recognizes an individual's existing functional capacity and helps the person to preserve/improve functioning through increased

physical activity. Rather than focusing on completing nursing-related tasks, such as dressing, bathing or feeding, function-focused care aims to enhance a resident's overall physical activity (Galik et al., 2014). Additionally, it is associated with improved/maintained functionality, it allows patients to maintain a sense of autonomy, it encourages residents to engage in continued activity, and it does not increase the risk of falling (Resnick et al., 2012; Resnick et al., 2009). Among residents living with cognitive impairment in a cluster-randomized controlled trial, there was a significant decrease in the number of residents who fell during the function-focused treatment period with those in the treatment group having fewer falls (25% as compared to 50% in the control group) (Galik et al., 2014). In addition to function-focused care, evidence supports the use of multifactorial falls assessment and intervention in reducing fall burden among cognitively intact older persons (Davison et al., 2005). Additional evidence shows reduction in fall rates may be higher among facilities with high levels of practitioner communication and collaboration (Arling et al., 2014).

References:

Arling, P. A., Abrahamson K., Miech E. J., Inui T. S., & Arling G. (2014). Communication and effectiveness in a US nursing home quality-improvement collaborative. Nurs Health Sci, 16(3), 291-297. https://doi.org/10.1111/nhs.12098

Davison, J., Bond, J., Dawson, P., Steen, I. N., & Kenny, R. A. (2005). Patients with recurrent falls attending Accident & Emergency benefit from multifactorial intervention--a randomised controlled trial. Age Ageing, 34(2), 162-168. https://doi.org/10.1093/ageing/afi053

Galik, E., Holmes, S., & Resnick, B. (2018). Differences Between Moderate to Severely Cognitively Impaired Fallers Versus Nonfallers in Nursing Homes. American journal of Alzheimer's disease and other dementias, 33(4), 247-252. https://doi.org/10.1177/1533317518761856

Galik, E., Resnick, B., Hammersla, M., & Brightwater, J. (2014). Optimizing function and physical activity among nursing home residents with dementia: testing the impact of function-focused care. Gerontologist 54(6), 930-943. https://doi.org/10.1093/geront/gnt108

Gell, N. M., Wallace, R. B., LaCroix, A. Z., Mroz, T. M., & Patel, K. V. (2015). Mobility device use in older adults and incidence of falls and worry about falling: findings from the 2011-2012 national health and aging trends study. J Am Geriatr Soc., 63(5), 853-859. https://doi.org/10.1111/jgs.13393

Resnick, B., Galik, E., Gruber-Baldini, A. L., & Zimmerman, S. (2012). Falls and fall-related injuries associated with function-focused care. Clinical Nursing Research, 21(1), 43-63. https://doi.org/10.1177/1054773811420060

Zhang, N., Lu, S. F., Zhou, Y., Zhang, B., Copeland, L., & Gurwitz, J. H. (2018). Body Mass Index, Falls, and Hip Fractures Among Nursing Home Residents. The journals of gerontology. Series A, Biological sciences and medical sciences, 73(10), 1403-1409. https://doi.org/10.1093/gerona/gly039

Name evidence type

Position Statements

Summarize the evidence

A 2016 position statement from the American Academy of Physical Medicine and Rehabilitation (AAPM&R) supports the measure domains, assessment categories, and data elements set forth by the IMPACT Act, including the incidence of major falls. The statement emphasizes the importance of standardized, assessment-based outcome measures to track spending and performance in post-acute care settings. One such domain for a quality measure is the incidence of major falls. The process of recording falls with major injury outcomes through this quality measure relates closely to the need to track such events and their costs. Further, a 2019 position statement from the American Physical Therapy Association (APTA) emphasizes the importance of falls prevention through procedural interventions. This position statement highlights health priorities for populations and individuals in the areas of prevention, wellness, fitness, health promotion, and management of disease and disability. APTA includes falls prevention as an injury prevention opportunity.

References:

American Academy of Physical Medicine and Rehabilitation. (2016). AAPM&R recommendations on post-acute care data standardization and quality measurement. https://www.aapmr.org/docs/default-source/advocacy/data-standardization-and-quality-measures-final.pdf?sfvrsn=7375547c_2

American Physical Therapy Association. (2019). Health priorities for populations and individuals. https://www.apta.org/apta-and-you/leadership-and-governance/policies/health-priorities-populations-individuals

Does the evidence discuss a link between at least one process, structure, or intervention with the outcome?

Yes

Estimated Impact of the Measure: Estimate of Annual Denominator Size

1,012,706

Type of Evidence to Support the Measure

Clinical Guidelines or USPSTF (U.S. Preventive Services Task Force) Guidelines; Peer-Reviewed Systematic Review; Empirical data; Other (enter here): Position Statements

Is the measure risk adjusted?

No

Risk adjustment variables

N/A

Patient-level demographics: please select all that apply:

N/A

Patient-level health status & clinical conditions: please select all that apply:

N/A

Patient functional status: please select all that apply:

N/A

Patient-level social risk factors: please select all that apply:

N/A

Proxy social risk factors: please select all that apply

N/A

Patient community characteristic: please select all that apply:

N/A

Risk model performance

N/A

Rationale for not using risk adjustment

Not conceptually or empirically indicated (enter here): Analysis of risk factors indicates the odds of falls with major injury are almost 1.6 times higher for residents over the age of 85, compared to those under the age of 85. This result seems reasonab

Cost estimate completed

No

Cost estimate methods and results

N/A

Section 3: Patient and Provider Perspective

Meaningful to Patients. Was input on the final performance measure collected from patient and/or caregiver?

No

Total number of patients and/or caregivers who responded to the question asking them whether the final performance measure helps inform care and decision making

N/A

Total number of patients/caregivers who agreed that the final performance measure helps inform care and decision making

N/A

Meaningful to Patients: Numbers consulted

N/A

Meaningful to Patients: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians: Numbers consulted

N/A

Meaningful to Clinicians: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians. Were clinicians and/or providers consulted on the final performance measure?

No

Total number of clinicians/providers who responded when asked if the final performance measure was actionable to improve quality of care.

N/A

Total number of clinicians/providers who agreed that the final performance measure was actionable to improve quality of care

N/A

Survey level testing

N/A

Type of Testing Analysis

N/A

Testing methodology and results

N/A

Burden for Provider: Was a provider workflow analysis conducted?

No

If yes, how many sites were evaluated in the provider workflow analysis?

N/A

Did the provider workflow have to be modified to accommodate the new measure?

N/A

Section 4: Measure Testing Details

Reliability

Yes

Reliability: Type of Reliability Testing

Signal-to-Noise;Random Split-Half Correlation

Signal-to-Noise: Name of statistic

The signal-to-noise ratio was estimated using a beta-binomial model. Data used to conduct the analysis were from 2018Q3 to 2019Q2.

Signal-to-Noise: Sample size

14,587

Signal-to-Noise: Statistical result

0.80

Signal-to-Noise: Interpretation of results

This analysis assessed whether one could confidently distinguish performance among nursing homes by calculating a signal-to-noise ratio. The signal-to-noise ratio conveys the proportion of variability in measured performance that can be explained by real differences in provider performance rather than variability within provider (i.e., measurement or sampling error). Because Falls with Major Injury is a binary outcome, reliability was estimated using a beta-binomial model. The beta-binomial model assumes that the provider score for the Percent of Residents Experiencing One or More Falls with Major Injury measure is a binomial random variable conditional on the provider's true value that comes from a beta distribution. Scores closer to 1 imply that most of the variability is attributable to real differences in performance and scores closer to 0 imply that all the variability in the measure is attributable to measurement error. Data from 2018Q3 to 2019Q2 were used to conduct this analysis. The average reliability score across all providers was 0.77 and the median score was 0.80, which suggests that the measure is very reliable in separating provider characteristics from variability within provider.

Random Split-Half Correlation: Name of statistic

Data from 2017Q3 to 2019Q2 were used to conduct the split-half reliability analysis. Spearman Rank Correlation and Pearson Correlation were used to measure internal reliability.

Random Split-Half Correlation: Sample size

12,376

Random Split-Half Correlation: Statistical result

0.66

Random Split-Half Correlation: Interpretation of results

The split-half correlation for this measure was positive (Pearson Correlation = 0.63; Spearman Rank Correlation = 0.66, $p < .01$), providing considerable evidence of internal reliability.

Other: Name of statistic

N/A

Other: Sample size

N/A

Other: Statistical result

N/A

Other: Interpretation of results

N/A

Empiric Validity

Yes

Empiric Validity: Statistic name

Multiple analyses were conducted to assess empiric validity of the Percent of Residents Experiencing One or More Falls with Major Injury measure, including convergent validity and confidence interval analyses. Convergent validity results, specifically the correlation between the Percent of Residents Experiencing One or More Falls with Major Injury measure and the Percentage of Long-Stay Residents Whose Need for Help with Daily Activities has Increased measure, most strongly supported the validity of the measure.

Empiric Validity: Sample size

14,586

Empiric Validity: Statistical result

0.086

Empiric Validity: Methods and findings

Two analyses were conducted to assess empiric validity of the Percent of Residents Experiencing One or More Falls with Major Injury measure:

1. Convergent Validity: To assess convergent validity, the relationships between the Percent of Residents Experiencing One or More Falls with Major Injury measure and other publicly reported quality measures were assessed. Groups of quality measures that reflect similar care processes or outcomes were examined with the hypothesis that a facility's percentile ranking (compared to all facilities reporting the measure) may be somewhat consistent among related quality measures. The direction of any correlation between the Percent of Residents Experiencing One or More Falls with Major Injury measure and the Percent of Long-Stay Residents Who Were Physically Restrained measure and Overall Facility Five-Star Ratings were expected to be negative. The direction of any correlations between the Percent of Residents Experiencing One or More Falls with Major Injury measure and the following MDS Quality Measures were expected to be positive: Percent of Long-Stay Residents Who Received Antipsychotic, Antianxiety, or Hypnotic Medication; Percent of Long-Stay Residents Who Have Depressive Symptoms; and Percent of Long-Stay Residents Whose Need for Help with Daily Activities has Increased. Since the related quality measures do not reflect closely tied care processes to the Percent of Residents Experiencing One or More Falls with Major Injury measure and instead capture other dimensions of quality, correlations were expected to be small, if present.

   Among facilities that could report both measures, the convergent validity analysis found a modest, statistically significant positive correlation between Percent of Residents Experiencing One or More Falls with Major Injury and Percent of Long-Stay Residents Whose Need for Help with Daily Activities has Increased (0.086), Percent of Long-Stay Residents Who Received an Antianxiety or Hypnotic Medication (0.077), Percent of Long-Stay Residents Who Received Antipsychotic Medication (0.061), Percent of Long-Stay Residents Who Have Depressive Symptoms (0.072), and Number of Outpatient Emergency Department Visits per 1,000 Long-Stay Resident Days (0.109). A modest, statistically significant negative correlation was observed between the Percent of Residents Experiencing One or More Falls with Major Injury measure and the Percent of Long-Stay Residents Who Were Physically Restrained (-0.033), as well as a modest but statistically significant negative correlation between the Percent of Residents

Experiencing One or More Falls with Major Injury measure and Overall Facility Five-Star Ratings (-0.032). All Spearman's rank correlations had a p-value of <0.001.

There may be several reasons for these relatively low correlations. First, the measures tested address different dimensions of care. Further, this measure captures only those falls that result in a significant injury; it is possible that these related quality measures have a stronger correlation with falls, but not major injury. Additionally, some of these quality measures are also low frequency measures, which could contribute to the low correlations with the Percent of Residents Experiencing One or More Falls with Major Injury measure. While the majority of these correlation coefficients are modest in magnitude, they are all statistically significant and in the expected direction.

2. Confidence interval analysis: Proportions of facilities with scores for the Percent of Residents Experiencing One or More Falls with Major Injury measure that are significantly different from the national facility-level mean were examined and stratified by facility denominator size. For this analysis, statistical significance was determined using 95% confidence intervals. A facility's quality measure score was significantly different from the national mean if the national mean was not included in the facility's 95% confidence interval. Because the Percent of Residents Experiencing One or More Falls with Major Injury measure focuses on an undesirable outcome, high-performing facilities should have scores that are significantly below average, and scores of low-performing facilities should be significantly above average. The analysis was stratified by facility denominator size to examine whether this feature of the measure varies by size.

   Results reveal that 22.7% of facilities had a score that was statistically significantly different from the national mean with 95% confidence. Approximately 3.1% of facilities had scores that were statistically significantly higher than the national mean, and 19.5% of facilities had scores that were statistically significantly lower than the national mean. Overall, the confidence interval analysis for the Percent of Residents Experiencing One or More Falls with Major Injury measure indicates that there are meaningful differences in facility-level scores for this measure.

Empiric Validity: Interpretation of results

Yes

Face Validity

No

Face Validity: Number of voting experts and patients/caregivers

N/A

Face Validity: Result

N/A

Patient/Encounter Level Testing

Yes

Type of Analysis

Agreement between other gold standard and manual reviewer

Sample Size

4,586

Statistic Name

Kappa

Statistical Results

0.945

Interpretation of results

As depicted in the 2008 Saliba & Buchanan study, the RAND corporation examined reliability and validity of the MDS 3.0.

1. Reliability analysis: The national test of MDS 3.0 items examined the agreement between assessors (reliability). Investigators employed Quality Improvement Organizations to identify gold-standard (research) nurses and recruit community nursing facilities to participate in the national evaluation. The gold-standard nurses were trained in the MDS 3.0 instrument, and they, in turn, trained a facility nurse from each participating nursing facility in their home states. Residents participating in the test were selected to capture a representative sample of short- and long-stay residents. In this national test of the Falls with Major Injury item, the gold-standard nurse to gold-standard nurse comparison (measures instrument performance with highly trained nurses using research protocols) and gold-standard to facility-nurse comparison (measures performance in a more operational environment in which one assessor has ongoing facility responsibilities) were examined. Saliba and Buchanan (2008) present Falls with Major Injury rates using the MDS 3.0 items at the resident-level, as well as Cohen's kappa, which was calculated to assess item reliability. Kappa is a statistical measure of inter-rater agreement for qualitative data, ranging from 0.0 to 1.0, where a rating of greater than 0.60 is considered substantial agreement (Landis & Koch, 1977).

   Results reveal the kappa for gold-standard to gold-standard on the MDS 3.0 item was 0.967, and the kappa for gold-standard to facility-nurse agreement on the MDS 3.0 item was 0.945. Ratings of 0.967 and 0.945 are considered "substantial agreements." These results are indicative of data element reliability. Overall, the RAND Development and Validation of MDS 3.0 national pilot test study demonstrated excellent reliability for MDS 3.0 items used to calculate this measure. Although the RAND testing was conducted 13 years ago, the MDS 3.0 forms used in the RAND study are similar to the latest MDS 3.0 forms used in the testing of this measure. The MDS 3.0 item set has remained stable since RAND created the recommended MDS 3.0 form in 2008, with the exception of select changes in item specifications and the addition of some new items. In particular, the Falls with Major Injury item has the same look-back period and the same item wording in the latest MDS 3.0 form and the 2008 recommended form.

2. Validity analysis: The RAND validation of MDS 3.0 study tested the criterion validity of the items by comparing how different nurses assessed the same residents using MDS 3.0. Investigators compared gold-standard research nurses to gold-standard nurses, and compared gold-standard nurses to staff nurses trained by the gold-standard nurses to calculate a kappa statistic. Additionally, nurses who participated in RAND's national study on the development and

validation of MDS 3.0 also completed a feedback survey at the end of the study to provide feedback on the MDS 3.0 falls items.

Results reveal excellent item level validity as the kappa for gold-standard nurse assessment to facility nurse assessment of the Falls with Major Injury measure was 0.959. The results of the survey conducted among nurses who participated in the RAND study on the development and validation of MDS 3.0 indicated that 88% believed the fall-related injury definitions were clear and 94% agreed that facility falls documentation should include the information needed to complete the section.

The authors of the RAND study also conducted an additional evaluation of the MDS 3.0 form in 2012 to determine whether their revisions improved reliability, validity, resident input, and clinical utility, all while decreasing collection burden. The results demonstrated that the reliability for research nurse-to-research nurse comparisons and for research nurse-to-facility staff comparisons was good or excellent for most MDS items, including falls with major injury, and there was increased validity compared with MDS 2.0.1.

References:

Landis, J. R., & Koch, G. G. (1977). The measurement of observer agreement for categorical data. Biometrics, 33(1), 159-174. PMID: 843571.

Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/downloads/MDS30FinalReport.pdf.

Saliba, D., & Buchanan, J. (2012). Making the investment count: revision of the minimum data set for nursing homes, MDS 3.0. Journal of American Medical Directors Association, 13(7), 602-10. https://doi.org/10.1016/j.jamda.2012.06.002

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Lower score is better

Mean performance score

3.4

Median performance score

3.0

Minimum performance score

0.0

Maximum performance score

20.6

Standard deviation of performance scores

2.4

Does the performance measure use survey or patient-reported data?

No

Surveys or patient-reported outcome tools

N/A

Section 5: Measure Contact Information

Measure Steward

Centers for Medicare & Medicaid Services

Measure Steward Contact Information

Rebekah Natanov

Centers for Medicare & Medicaid Services

7500 Security Boulevard

Baltimore, MD 21244

rebekah.natanov@cms.hhs.gov

(202) 205-2920

Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

Primary Submitter Contact Information

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Submitter Comments

N/A

MUC2022-099 Skilled Nursing Facility (SNF) Within-Stay (WS) Potentially Preventable Readmissions (PPR) Measure

Program

Skilled Nursing Facility Value-Based Purchasing Program

Section 1: Measure Information

Measure Specifications and Endorsement Status

Measure Description

This measure estimates the risk-standardized rate of unplanned, potentially preventable readmissions that occur during SNF stays among Medicare fee-for-service [FFS] beneficiaries. This measure applies two substantive refinements to the original measure (described in detail with the numerator and denominator), which was submitted and published to the MUC list in 2015 and finalized in the fiscal year (FY) 2017 SNF PPS final rule for use in the SNF VBP program in 2016. The measure is calculated in an identical manner using the following formula: (risk-adjusted numerator/risk-adjusted denominator)*national observed rate. The measure is calculated using two years of Medicare FFS claims data.

Numerator

The numerator is the number of SNF residents in the target population who have a potentially preventable readmission (PPR) to a short-stay acute care or Long Term Care Hospital (LTCH) during the SNF stay. The within-SNF stay observation window is a refinement from the original measure published in 2015, which implemented a 30-day observation window immediately following the prior acute care hospital discharge associated with the SNF stay. This refinement addresses previous Technical Expert Panel (TEP) feedback and Measures Application Partnership (MAP) recommendations to align specifications, such as the readmission observation window, across measures to avoid duplication of the readmission metrics (which is the current case between the original SNF VBP PPR measure and the SNF Quality Reporting Program (QRP) PPR measure). The refined measure is associated with improved reliability (as indicated by the random split-half correlation results), strong face and empirical validity results (as noted in the face and empirical validity sections), and complements the SNF QRP PPR measure which captures PPRs post-SNF discharge (as described in the similar in-use measures section).

This measure does not have a simple form for the numerator. Instead, the numerator is the risk-adjusted "predicted" estimate of the number of residents with a potentially preventable, unplanned readmission that occurred during a SNF stay. This estimate starts with the observed (or unadjusted) number of residents with a readmission and is then risk-adjusted for resident characteristics and a statistical estimate of the SNF's facility effect.

Numerator Exclusions

N/A

Denominator

The target population for the measure is Medicare FFS beneficiaries who are admitted to a SNF during the two-year measurement period and are not excluded based on the measure exclusion criteria (listed in the denominator exclusions). The index SNF admission must have occurred within 30 days of discharge from a prior proximal hospital stay (including an inpatient prospective payment system [IPPS] hospital, a critical access hospital [CAH], or a psychiatric hospital). The prior proximal hospitalization lookback window was refined from 1-day (in the original measure) to 30-days in the current SNF WS PPR measure to align with the lookback windows implemented in the PPR cross-setting measures included in the post-acute care quality reporting programs (QRP), and to align with the qualifying inpatient stay requirement for the Medicare SNF benefit. As noted above in the numerator field, this refinement addresses previous TEP feedback and MAP recommendations to align measure specifications across measures where possible. The refined measure is associated with improved reliability (as indicated by the random split-half correlation results), strong face and empirical validity results (as noted in the face and empirical validity sections), and complements the SNF QRP PPR measure which captures PPRs post-SNF discharge (as described in the similar in-use measures section).

The measure denominator is the risk-adjusted "expected" number of residents with a potentially preventable, unplanned readmission that occurred during a SNF stay. The "expected" number of residents with PPRs is the predicted number of residents with a PPR if the same residents were treated at the average facility. The denominator is computed in the same way as the numerator, but the facility effect is set at the average value of 0.

Denominator Exclusions

Stays are excluded from the measure if:

1. the resident is under 18 years old,
2. the resident does not have an acute care discharge within 30 days prior to SNF admission,
3. the resident does have an acute care discharge within 30 days prior to SNF admission but the principal diagnosis was cancer or pregnancy,
4. the resident did not have at least 12 months of continuous FFS Medicare enrollment prior to the SNF admission and through SNF discharge,
5. the resident was discharged against medical advice,
6. the resident received care from a provider located outside of the US or any US territory,
7. the stay occurred in a critical access hospital swing bed,
8. claims data from the SNF stay or prior proximal acute care stay is problematic (erroneous or contradictory), or
9. the resident was transferred to a federal hospital.

Denominator Exceptions

N/A

State of development

Fully Developed

State of Development Details

N/A

What is the target population of the measure?

Medicare Fee for Service SNF residents

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Nursing Homes

Measure Type

Outcome

Is the measure a composite or component of a composite?

Not a composite or component of a composite measure

If Other, Please Specify

N/A

What data sources are used for the measure?

Claims Data;Other: Common Medicare Environment (CME) Database and Enrollment Database (EDB) File

If applicable, specify the data source

N/A

Description of parts related to these sources

The stay construction, exclusions, and risk-adjustment model utilize data from Medicare claims, and exclusions and the risk-adjustment model utilize CME and EDB data.

At what level of analysis was the measure tested?

Facility

In which setting was this measure tested?

Skilled nursing facility

Multiple Scores

No

What one healthcare domain applies to this measure?

Seamless Care Coordination

MIPS Quality: Identify any links with related Cost measures and Improvement Activities

N/A

Is this measure in the CMS Measures Inventory Tool (CMIT)?

Yes

CMIT ID

02801-C-SNFVBP

Alternate Measure ID

N/A

What is the endorsement status of the measure?

Never Submitted

CBE ID (CMS consensus-based entity, or endorsement ID)

9999

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

N/A

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

No

If eCQM, enter Measure Authoring Tool (MAT) number

N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?

N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?

Yes

Previous Measure Information

MUC15-1048

In what prior years was this measure published?

2015

What was the MUC ID for the measure in this year?

MUC15-1048

List the CMS CBE MAP workgroup(s) in this year:

Post-Acute Care/Long Term Care, 2015

What were the programs that MAP reviewed the measure for in this year?

2015, SNF VBP

What was the MAP recommendation in this year?

2015, SNF VBP, Encourage continued development

Why was the measure not recommended by the MAP workgroups in this year?

N/A

MAP report page number being referenced for this year:

MAP 2016: Post-Acute Care/Long-Term Care Report, Page 9

What is the history or background for including this measure on the new measures under consideration list?

Measure currently used in a CMS program, but the measure is undergoing substantial change

Range of years this measure has been used by CMS Programs

N/A. See "Submitter Comments" section for details.

What other federal programs are currently using this measure?

None

Is this measure similar to and/or competing with a measure(s) already in a program?

Yes

Which measure(s) already in a program is your measure similar to and/or competing with?

This measure is similar to, but not competing with, the SNF PPR-post discharge (PD) measure.

How will this measure be distinguished from other similar and/or competing measures?

The two PPR measures complement each other: the SNF WS PPR measure strictly captures PPRs that occur during SNF stays while the SNF PPR-PD measure captures PPRs after discharge from SNF stays.

How will this measure add value to the CMS program?

This SNF WS PPR measure assesses the rates of potentially preventable readmission occurring while residents are in the care of a SNF. In contrast, the SNF PPR-PD measure assesses the rates of potentially preventable readmissions after residents are discharged from a SNF. Therefore, the two measures complement each other.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

The original version of the SNF WS PPR measure (titled "Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge" (SNFPPR)) was produced to meet the Protecting Access to Medicare Act (PAMA) of 2014. Section 215a of PAMA required that a resource use measure reflecting an all-condition risk-adjusted potentially preventable hospital readmission rate for skilled nursing facilities, which was to be developed and implemented by October 1, 2016, be used in the SNF VBP program [2]. CMS accordingly developed and submitted to the MUC list the SNFPPR measure referenced above, which was published in the MUC list in 2015 and finalized for adoption into the SNF VBP program in 2016 (FY2017 SNF final rule). The statute states that the SNF all-cause readmission measure (RM) currently implemented in the SNF VBP program could be replaced by a PPR measure as soon as practicable.

[2] United States Congress, H.R. 4302. Protecting Access to Medicare Act of 2014. 2014.

Section 2: Measure Evidence

How is the measure expected to be reported to the program?

Claims

Stratification

No

Feasibility of Data Elements

ALL data elements are in defined fields in electronic sources

Feasibility Assessment

All data elements used to calculate the measure appear in administrative data, which CMS uses for provider payments in the SNF PPS and SNF VBP, as well as in a wide variety of SNF QRP measures.

Method of Measure Calculation

Claims

Hybrid measure: Methods of measure calculation

N/A

Evidence of Performance Gap

In FY 2019-2020, the interquartile range of risk-standardized PPR rates (i.e., the measure scores) among 14,254 SNFs was 9.25% to 13.20%, with a standard deviation of 3.00%.

Unintended Consequences

It is possible that a SNF could try to avoid a within-stay PPR in this measure by discharging a resident on the verge of hospitalization to the community. Such a resident would not count in the WS PPR numerator in this case. However, the Discharge to Community (DTC) and Post-Discharge PPR measures mitigate this unintended consequence because if the discharged resident is admitted to the hospital shortly afterward, the facility that tried to avoid the PPR measure in the above manner would perform worse on both of these measures, which assess whether a resident remains in the community for 30 days after SNF discharge, and whether the readmission is a PPR, respectively.

Number of clinical guidelines, including USPSTF guidelines, that address this measure topic

N/A

Outline the clinical guidelines supporting this measure

N/A

Name the guideline developer/entity

N/A

Publication year

N/A

Full citation +/- URL

N/A

Is this an evidence-based clinical guideline?

N/A

Is the guideline graded?

N/A

List the guideline statement that most closely aligns with the measure concept.

N/A

What evidence grading system did the guideline use to describe strength of recommendation?

N/A

List all categories and corresponding definitions for the evidence grading system used to describe strength of recommendation in the guideline?

N/A

For the guideline statement that most closely aligns with the measure concept, what is the associated strength of recommendation?

N/A

What evidence grading system did the guideline use to describe level of evidence or level of certainty in the evidence?

N/A

List all categories and corresponding definitions for the evidence grading system used to describe level of evidence or level of certainty in the evidence?

N/A

For the guideline statement that most closely aligns with the measure concept, what is the associated level of evidence or level of certainty in the evidence?

N/A

List the guideline statement that most closely aligns with the measure concept.

N/A

Number of systematic reviews that inform this measure concept

N/A

Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept

N/A

Source of empirical data

Published, peer-reviewed original research

Summarize the empirical data

Non-negligible rates of potentially preventable readmissions (PPRs) to a hospital following a hospital discharge to a SNF among Medicare patients have been well documented. In 2007-2008, 33% and 18% of hospital discharges to a SNF were associated with a readmission within 7 and 30 days, respectively.[1] In a systematic review of 34 studies assessing the proportion of avoidable hospital readmission, the median proportion of avoidable readmissions was 27.1%, with a range of 5% to 79%.[2] Moreover, another study determined that 23.5% of Medicare beneficiaries discharged from a hospital to a SNF were directly readmitted to a hospital (i.e., a within-stay PPR) within 30 days of initial hospital discharge in 2006, and this rate was about 5% higher than the rate observed in 2000.[3] These findings are significant not only because they point to the need and potential to improve quality of care and care coordination to reduce PPRs, but also because rehospitalizations are costly - rehospitalizations from a SNF cost an estimated total of $4.34 billion in 2006.[3] As such, evidence suggests the need for a SNF WS PPR measure, to both monitor these rates and encourage process improvements, such as through care coordination, to enhance health outcomes.

Success at lowering PPR rates often depends on the tailoring of care and interventions to facility- and resident-level characteristics. Studies have shown rehospitalizations to be heterogeneous based on these characteristics. For example, rehospitalizations can vary notably by facility characteristics, with SNF rehospitalizations among residents previously residing in the community most often occurring in hospital-based SNFs or SNFs specializing in Medicare-financed SNF care, and rehospitalizations among prior nursing home patients often occurring from SNFs with high Medicaid-financed care.[3]

At a resident-level, rehospitalizations vary by race/ethnicity, age, gender, income, housing situation, diagnosis at the initial hospitalization, diagnosis/cause at rehospitalization, length between SNF admission and rehospitalization, the number of previous hospitalizations, a high comorbidity index, and a long length of the prior hospital stay.[4, 5, 6, 7] Studies of rehospitalizations by race/ethnicity have shown that among Medicare beneficiaries readmitted for diabetes-related conditions, Blacks and Hispanics were at a higher risk of readmission for acute complications and microvascular disease, while Whites were at an increased risk of readmission for macrovascular conditions.[4]

Evidence suggests that PPR rates and variations in rates can be reasonably mitigated, and the literature documents existing tools such as person-centered care plans, care coordination pathways, and predictive models, which have been or can be implemented by providers. A literature review investigating the applicability and effectiveness of quality improvement initiatives aimed at decreasing the rate of avoidable 30-day, SNF-to-hospital readmissions determined that incorporation of specialized staff (non-standard facility employees, such as pharmacists, nurse practitioners, telehealth neurologic consultants, nurse navigators, and post-discharge advocate nurses), tailored intervention in high-risk patients, and collaborative case management between SNFs and hospitals facilitated the lowering of within-stay readmission rates.[8] Other researchers proposed steps to evaluate four features: (i) patient, procedural, and structural characteristics; (ii) post-operative care; (iii) planning and executing patient discharge; and (iv) analyzing the readmission itself.[6] Collective implementation of all four steps could allow SNFs to tailor care to the residents' needs, actively engage in care coordination, and evaluate the provided care.

Overall, findings suggest that variation in PPR outcomes of SNF residents may be influenced by factoring in resident-specific needs, characteristics, and conditions when developing individualized care plans. In addition, literature indicates that SNF processes, such as care coordination between SNFs and hospitals, may influence PPR occurrence for residents during the SNF stay. Implementing the SNF WS PPR measure will encourage providers to access evidence-based strategies to reduce PPR rates and their associated disparities.

Limitations of the studies included above are described in an evidence attachment (MUC_SNF_WS_PPR_evidence_attachment_05202022.docx).

References:

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5. Brooke, B., De Martino, R., Girotti, M., Dimick, J. B., Goodney, P. P. (2012). Developing Strategies for Predicting and Preventing Readmissions in Vascular Surgery. Journal of Vascular Surgery, (2012), 56(2), 556-562. DOI: 10.1016/j.jvs.2012.03.260.

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9. Kansagara, D., Englander, H., Salanitro, A., Kagen, D., Cecelia, T., Freeman, M., Kripalani, S. (2011). Risk Prediction Models for Hospital Readmission: A Systematic Review. JAMA (2011), 306(15), 1688-1698. DOI: 10.1001/jama.2011.1515.

Name evidence type

N/A

Summarize the evidence

N/A

Does the evidence discuss a link between at least one process, structure, or intervention with the outcome?

Yes

Estimated Impact of the Measure: Estimate of Annual Denominator Size

1,590,027

Type of Evidence to Support the Measure

Empirical data

Is the measure risk adjusted?

Yes

Risk adjustment variables

Patient-level demographics ;Patient-level health status & clinical conditions

Patient-level demographics: please select all that apply:

Age;Sex

Patient-level health status & clinical conditions: please select all that apply:

Case-Mix Adjustment;Severity of Illness;Comorbidities

Patient functional status: please select all that apply:

N/A

Patient-level social risk factors: please select all that apply:

N/A

Proxy social risk factors: please select all that apply

N/A

Patient community characteristic: please select all that apply:

N/A

Risk model performance

We analyzed the model fit statistics to determine if the risk model can accurately predict PPRs while controlling for differences in resident case-mix. The c-statistic of the model was 0.704, which suggests good model discrimination.

Rationale for not using risk adjustment

N/A

Cost estimate completed

No

Cost estimate methods and results

N/A

Section 3: Patient and Provider Perspective

Meaningful to Patients. Was input on the final performance measure collected from patient and/or caregiver?

No

Total number of patients and/or caregivers who responded to the question asking them whether the final performance measure helps inform care and decision making

N/A

Total number of patients/caregivers who agreed that the final performance measure helps inform care and decision making

N/A

Meaningful to Patients: Numbers consulted

N/A

Meaningful to Patients: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians: Numbers consulted

N/A

Meaningful to Clinicians: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians. Were clinicians and/or providers consulted on the final performance measure?

No

Total number of clinicians/providers who responded when asked if the final performance measure was actionable to improve quality of care.

N/A

Total number of clinicians/providers who agreed that the final performance measure was actionable to improve quality of care

N/A

Survey level testing

N/A

Type of Testing Analysis

N/A

Testing methodology and results

N/A

Burden for Provider: Was a provider workflow analysis conducted?d

No

If yes, how many sites were evaluated in the provider workflow analysis?

N/A

Did the provider workflow have to be modified to accommodate the new measure?

N/A

Section 4: Measure Testing Details

Reliability

Yes

Reliability: Type of Reliability Testing

Random Split-Half Correlation

Signal-to-Noise: Name of statistic

N/A

Signal-to-Noise: Sample size

N/A

Signal-to-Noise: Statistical result

N/A

Signal-to-Noise: Interpretation of results

N/A

Random Split-Half Correlation: Name of statistic

Split-sample Reliability Testing: This testing examined agreement between two performance measure scores for a facility based on randomly-split, independent subsets of resident stays in the same measurement period. We randomly divided each facility's FY 2019-2020 resident stays into halves. We calculated performance measure scores for each split-half sample using the same measure specification. We calculated Shrout-Fleiss intraclass correlation coefficients ((ICC (2, 1) and ICC (3, 1)) between the split-half scores to measure reliability [1], with the Spearman-Brown correction applied. [1] McGraw, K. O., & Wong, S. P. (1996). Forming inferences about some intraclass correlation coefficients. Psychological methods, 1(1), 30.

Random Split-Half Correlation: Sample size

14,579

Random Split-Half Correlation: Statistical result

0.71

Random Split-Half Correlation: Interpretation of results

The ICC (for both ICC (2, 1) and ICC (3, 1), with the Spearman-Brown correction applied) for the overall SNF sample was 0.71, indicating good reliability.

This ICC is notably better than that of the SNF VBP all-cause readmission measure (0.56), the measure currently implemented in the SNF VBP program and statutorily slated to be replaced by a PPR measure in the future.

The sample for reliability testing included 14,579 SNFs that had 24 or more resident stays in the FY 2019-2020 measurement period.

Note: The public reporting threshold applied to this measure is 25 stays. For the purpose of the split-sample testing, we use an even number of stays for the testing threshold (i.e., minimum of 24 stays in the FY 2019-2020 measurement period) and then apply the Spearman-Brown correction.

Other: Name of statistic

N/A

Other: Sample size

N/A

Other: Statistical result

N/A

Other: Interpretation of results

N/A

Empiric Validity

Yes

Empiric Validity: Statistic name

Empirical validity testing for the performance measure score included tests of convergent validity (correlation analyses of measure scores). SNF WS PPR measure scores were compared to those of nine other measures (i.e., SNF Potentially Preventable Readmission Post Discharge (PPR-PD), Medicare Spending Per Beneficiary (MSPB), Percentage of short-stay residents who got antipsychotic medication for the first time, SNF Discharge to Community (DTC), Percentage of short-stay residents who needed and got a flu shot for the current flu season, Percentage of short-stay residents who needed and got a vaccine to prevent pneumonia, Percentage of short-stay residents who improved in their ability to move around on their own, Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients, and Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients), most of which are currently included in the SNF QRP. The subset of SNFs from the FY 2019-2020 data included in each of these analyses was restricted to those with publicly available data for each pair of measures.

Empiric Validity: Sample size

12,607-15,065

Empiric Validity: Statistical result

0.01-0.51

Empiric Validity: Methods and findings

The subsets of SNFs from FY2019-2020 included in the testing ranged from 12,607 to 15,065 SNFs.

SNF WS PPR measure scores were positively associated with scores of the SNF PPR-PD measure (0.13), MSPB measure (0.51), and short-stay quality measure of Percentage of short-stay residents who got antipsychotic medication for the first time (0.13), all of which assess negative outcomes.

SNF WS PPR measure scores were negatively associated with scores of short-stay measures assessing positive outcomes (i.e., DTC (-0.39), Percentage of short-stay residents who needed and got a flu shot for the current flu season (-0.13), Percentage of short-stay residents who needed and got a vaccine to prevent pneumonia (-0.11), and Percentage of short-stay residents who improved in their ability to move around on their own (-0.01), and functional outcome measures (i.e., Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (-0.06) and Application

of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (-0.05))).

Most correlation coefficients were small (absolute values ranged from 0.01 to 0.51), indicating that the SNF WS PPR measure is not duplicative and provides unique information about quality of care not captured by the other nine measures. Additionally, the directions of the correlation coefficients aligned with the expected directions between the SNF WS PPR measure and the other measures. Of the nine correlations assessed, all but one (Percentage of short-stay residents who improved in their ability to move around on their own) were statistically significant at the 0.05 level.

In addition to the empirical validity evidence described above, the specification for the existing SNF WS PPR measure (SNFPPR) was also reviewed with a TEP who were in support of the conceptual basis and structure of the measure. This measure has been routinely maintained to ensure the specifications remain consistent with current billing and documentation guidance. Clinicians routinely review the set of potentially preventable conditions such that the set remains consistent with current clinical practice.

Additionally, we analyzed the model fit statistics to determine if the risk model can accurately predict PPRs while controlling for differences in resident case-mix. The c-statistic of the risk adjustment model was 0.704, which suggests good model discrimination.

Although a formal vote of face validity was not taken at the TEP meeting, TEP members agreed with the conceptual and operational definition of the measure. See attached 2016 TEP Summary Report (Potentially Preventable Readmissions TEP Summary Report.pdf).

Empiric Validity: Interpretation of results

Yes

Face Validity

No

Face Validity: Number of voting experts and patients/caregivers

N/A

Face Validity: Result

N/A

Patient/Encounter Level Testing

Yes

Type of Analysis

Other (enter here): This measure is calculated using Medicare FFS administrative claims and uses data from Medicare eligibility and inpatient claims files which are routinely audited by CMS to ensure their accuracy.

The eligibility files provide information such as date of birth, date of death, sex, reasons for Medicare eligibility, periods of Part A coverage, and periods in the Medicare FFS program. The data elements from

the Medicare FFS claims are those basic to the operation of the Medicare payment systems and include data such as date of admission, date of discharge, diagnoses, procedures, and indicators for use of dialysis services. The inpatient claims data files contain stay-level post-acute care (PAC) and other hospital records. No data beyond the claims submitted in the normal course of business are required from SNFs for the calculation of this measure.

Sample Size

99999

Statistic Name

Other (enter here): Other (enter here):

Statistical Results

99999

Interpretation of results

Medicare FFS claims data are routinely used for research and quality measure calculation purposes and are considered highly reliable. Since this measure primarily uses risk adjustment variables from inpatient claims in the year preceding the SNF stay, and because the measure outcome is determined by the information on the inpatient claim subsequent to the SNF stay, the ability of SNF providers to influence the data and improve their measure performance is minimized.

The claims data elements used in this measure have been used in several NQF-endorsed measures, further supporting their reliability and appropriateness for use. These measures include, but are not limited to, the following: (i) Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) (NQF #1789), (ii) Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510); (iii) Discharge to Community-Post Acute Care Measure for Skilled Nursing Facilities (NQF #3481); (iv) Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171).

Where possible, variable selection for the development of this measure is based on the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510), which is harmonized with the construction of the HWR (NQF #1789). Same as for NQF #2510, selected data elements focus on variables that are likely to be coded more consistently across hospitals and SNFs because they are used for payment or are audited.

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Lower score is better

Mean performance score

11.39

Median performance score

11.07

Minimum performance score

2.18

Maximum performance score

37.75

Standard deviation of performance scores

3.00

Does the performance measure use survey or patient-reported data?

No

Surveys or patient-reported outcome tools

N/A

Section 5: Measure Contact Information

Measure Steward

Centers for Medicare & Medicaid Services

Measure Steward Contact Information

Alex Laberge

7500 Security Boulevard

Baltimore, Maryland 21244

alexandre.laberge@cms.hhs.gov

443-821-4178

Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

Primary Submitter Contact Information

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Secondary Submitter Contact Information

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(650) 558-8882 x1354

Submitter Comments

The original version of this measure was previously submitted and included on the MUC List in 2015 and was finalized for adoption into the SNF VBP program in 2016 (FY2017 SNF final rule), but has not yet been implemented into the program. When reviewed by the MAP in 2015, the MAP "encourage[d] continued development" of this measure.

MUC2022-113 Number of hospitalizations per 1,000 long-stay resident days

Program

Skilled Nursing Facility Value-Based Purchasing Program

Section 1: Measure Information

Measure Specifications and Endorsement Status

Measure Description

The number of unplanned hospitalizations (including observation stays) for long-stay residents per 1,000 long-stay resident days. For this measure, long-stay resident days are all days after the resident's 100th cumulative day in the nursing home

Numerator

The numerator for the measure is the number of admissions to an acute care or critical access hospital, for an inpatient or outpatient observation stay, occurring while the individual is a long-term nursing home resident.

Observation stays are included in the measure regardless of diagnosis. The numerator also excludes unplanned inpatient admissions and observation stays that occur while a resident is enrolled in hospice.

Numerator Exclusions

Planned inpatient admissions are not counted in the numerator since they are unrelated to the quality of care at the nursing home. Hospitalizations are classified as planned or unplanned using the same version of CMS Planned Readmissions Algorithm that is used to calculate the short-stay re-hospitalizations measure in the Nursing Home Compare Five-Star Rating system. The algorithm identifies planned admission using the principal discharge diagnosis category and all procedure codes listed on inpatient claims, coded using the AHRQ Clinical Classification System (CCS) software.

Denominator

The denominator is the sum of all long-stay days in the target period, divided by 1,000. A long-stay day is any day after a resident's one-hundredth cumulative day in the nursing home or the beginning of the 12-month target period (whichever is later) and until the day of discharge, the day of death, or the end of the 12-month target period (whichever is earlier). The denominator does not include the days between nursing home stays, including days that a resident is admitted to an inpatient facility or other institution, or days the resident was enrolled in hospice.

Denominator Exclusions

Long-stay residents who were not Medicare beneficiaries (enrolled in both Medicare Part A and Part B) or who were enrolled in Medicare managed care during any portion of the stay, i.e. between admission and discharge or the end of the target period (whichever is earlier) are excluded.

Long-stay days meeting any of the following criteria are excluded:

a) the resident was enrolled in hospice care;

b) the resident was not in the nursing home for any reason during the episode, including days admitted to an inpatient facility or other institution, or days temporarily residing in the community.

Denominator Exceptions

N/A

State of development

Specification

State of Development Details

N/A

What is the target population of the measure?

All Medicare and/or Medicaid certified nursing homes in the United States

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Nursing Homes

Measure Type

Outcome

Is the measure a composite or component of a composite?

Not a composite or component of a composite measure

If Other, Please Specify

N/A

What data sources are used for the measure?

Claims Data

If applicable, specify the data source

N/A

Description of parts related to these sources

Full measure specifications are available here: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/Nursing-Home-Compare-Claims-based-Measures-Technical-Specifications-April-2019.pdf

At what level of analysis was the measure tested?

Facility

In which setting was this measure tested?

Nursing home

Multiple Scores

No

What one healthcare domain applies to this measure?

Affordability and Efficiency

MIPS Quality: Identify any links with related Cost measures and Improvement Activities

N/A

Is this measure in the CMS Measures Inventory Tool (CMIT)?

Yes

CMIT ID

CMIT ID 0608

Alternate Measure ID

N/A

What is the endorsement status of the measure?

Never Submitted

CBE ID (CMS consensus-based entity, or endorsement ID)

N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

N/A

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

No

If eCQM, enter Measure Authoring Tool (MAT) number

N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?

N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?

No

Previous Measure Information

N/A

What is the history or background for including this measure on the new measures under consideration list?

Measure currently used in a CMS program being submitted as-is for a new or different program

Range of years this measure has been used by CMS Programs

This measure was first reported on Nursing Home Compare in October 2018.

What other federal programs are currently using this measure?

Nursing Home Care Compare and Nursing Home 5-Star Quality Rating System.

Is this measure similar to and/or competing with a measure(s) already in a program?

No

Which measure(s) already in a program is your measure similar to and/or competing with?

N/A

How will this measure be distinguished from other similar and/or competing measures?

N/A

How will this measure add value to the CMS program?

N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

N/A

Section 2: Measure Evidence

How is the measure expected to be reported to the program?

Other: Data files prepared for Nursing Home Care Compare will be shared with the SNF VBP program.

Stratification

No

Feasibility of Data Elements

ALL data elements are in defined fields in electronic sources

Feasibility Assessment

The measure is already operational. It was first reported on Nursing Home Care Compare in October 2018.

For an example of how the measure is calculated, consider the following scenario. Nursing Home Z had a total of 75 long-stay residents, who had a total of 27,375 eligible days as long-stay residents during the target period. There were a total of 28 unplanned hospitalizations and 7 observation stays among these residents during the period. The denominator is equal to 27,375 long-stay resident days divided by 1000, or 27.375. The numerator is equal to 35 (28 unplanned hospitalizations and 7 observation stays). Nursing Home Zâ??s long-stay hospitalizations rate for 2018 is 1.28 hospitalizations per 1,000 long-stay resident days (= 35 / 27.375). For a facility with an average daily census of 75 long-stay residents, this equates to approximately 3 residents being sent to the hospital in a given month (= 75 residents * 1.28 hospitalizations * 30 days / 1000 days).

Method of Measure Calculation

Claims

Hybrid measure: Methods of measure calculation

N/A

Evidence of Performance Gap

There is considerable variation in performance across nursing homes. The inter-quartile range is 1.186-2.318. The 10th percentile is 0.841 and the 90th percentile is 2.656.

Unintended Consequences

We do not believe that the are potential unintended consequences as the data for the measure are already being collected and the measure is publicly reported on Nursing Home Care Compare.

Recognizing that hospitalizations are sometimes necessary, the scoring rules used for the measure on Nursing Home Care Compare give the same number of points to nursing homes in the top decile, thus eliminating the incentive to avoid all hospitalizations of long-stay nursing home residents.

Number of clinical guidelines, including USPSTF guidelines, that address this measure topic

N/A

Outline the clinical guidelines supporting this measure

N/A

Name the guideline developer/entity

N/A

Publication year

N/A

Full citation +/- URL

N/A

Is this an evidence-based clinical guideline?

N/A

Is the guideline graded?

N/A

List the guideline statement that most closely aligns with the measure concept.

N/A

What evidence grading system did the guideline use to describe strength of recommendation?

N/A

List all categories and corresponding definitions for the evidence grading system used to describe strength of recommendation in the guideline?

N/A

For the guideline statement that most closely aligns with the measure concept, what is the associated strength of recommendation?

N/A

What evidence grading system did the guideline use to describe level of evidence or level of certainty in the evidence?

N/A

List all categories and corresponding definitions for the evidence grading system used to describe level of evidence or level of certainty in the evidence?

N/A

For the guideline statement that most closely aligns with the measure concept, what is the associated level of evidence or level of certainty in the evidence?

N/A

List the guideline statement that most closely aligns with the measure concept.

N/A

Number of systematic reviews that inform this measure concept

N/A

Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept

N/A

Source of empirical data

Internal data analysis

Summarize the empirical data

We examined the relationship between long-stay hospitalization rates and other measures of quality from CMS's Five-Star Quality Rating System, using data from the December 2019 Nursing Home Compare update.

Name evidence type

N/A

Summarize the evidence

N/A

Does the evidence discuss a link between at least one process, structure, or intervention with the outcome?

Yes

Estimated Impact of the Measure: Estimate of Annual Denominator Size

15,396

Type of Evidence to Support the Measure

Empirical data

Is the measure risk adjusted?

Yes

Risk adjustment variables

Patient-level demographics ;Patient-level health status & clinical conditions;Patient functional status

Patient-level demographics: please select all that apply:

Age;Sex;Race/ethnicity

Patient-level health status & clinical conditions: please select all that apply:

Severity of Illness;Comorbidities

Patient functional status: please select all that apply:

Ability to perform activities of daily living;Other (enter here): Level of cognitive impairment

Patient-level social risk factors: please select all that apply:

N/A

Proxy social risk factors: please select all that apply

N/A

Patient community characteristic: please select all that apply:

N/A

Risk model performance

The statistical performance of the model was strong.

Rationale for not using risk adjustment

N/A

Cost estimate completed

No

Cost estimate methods and results

N/A

Section 3: Patient and Provider Perspective

Meaningful to Patients. Was input on the final performance measure collected from patient and/or caregiver?

No

Total number of patients and/or caregivers who responded to the question asking them whether the final performance measure helps inform care and decision making

N/A

Total number of patients/caregivers who agreed that the final performance measure helps inform care and decision making

N/A

Meaningful to Patients: Numbers consulted

N/A

Meaningful to Patients: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians: Numbers consulted

N/A

Meaningful to Clinicians: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians. Were clinicians and/or providers consulted on the final performance measure?

No

Total number of clinicians/providers who responded when asked if the final performance measure was actionable to improve quality of care.

N/A

Total number of clinicians/providers who agreed that the final performance measure was actionable to improve quality of care

N/A

Survey level testing

N/A

Type of Testing Analysis

N/A

Testing methodology and results

N/A

Burden for Provider: Was a provider workflow analysis conducted?

No

If yes, how many sites were evaluated in the provider workflow analysis?

N/A

Did the provider workflow have to be modified to accommodate the new measure?

N/A

Section 4: Measure Testing Details

Reliability

Yes

Reliability: Type of Reliability Testing

Random Split-Half Correlation

Signal-to-Noise: Name of statistic

N/A

Signal-to-Noise: Sample size

N/A

Signal-to-Noise: Statistical result

N/A

Signal-to-Noise: Interpretation of results

N/A

Random Split-Half Correlation: Name of statistic

Measure Score Reliability

Random Split-Half Correlation: Sample size

15,396

Random Split-Half Correlation: Statistical result

0

Random Split-Half Correlation: Interpretation of results

Results will be updated prior to the MAP meeting.

Other: Name of statistic

N/A

Other: Sample size

N/A

Other: Statistical result

N/A

Other: Interpretation of results

N/A

Empiric Validity

Yes

Empiric Validity: Statistic name

Measure Score Validity

Empiric Validity: Sample size

15,396

Empiric Validity: Statistical result

-0.44

Empiric Validity: Methods and findings

We examined the relationship between long-stay hospitalization rates and other measures of quality from CMS's Five-Star Quality Rating System using data from the December 2019 Nursing Home Compare update. Analyses show a consistent relationship between lower hospitalization rates and better performance on other dimensions of quality such as health inspection survey results, staffing level, other quality measures, and overall ratings.. The correlation between overall rating and the long-stay hospitalization rate was -0.44 (Note that lower rates indicate better performance on the hospitalization measure.) Examining data from the December 2019 Nursing Home Compare update, we found the following relationship between the long-stay hospitalization rate and other quality measures. Note that lower values for the hospitalization measure indicate better performance. Overall Rating: One-star quality measure rating: 1.989 Two-star quality measure rating: 1.791 Three-star quality measure rating: 1.748 Four-star quality measure rating: 1.658 Five-star quality measure rating: 1.360 Health inspection rating: One-star health inspection rating: 1.841 Two-star health inspection rating: 1.752 Three-star health inspection rating: 1.684 Four-star health inspection rating: 1.615 Five-star health inspection rating: 1.535 One-star quality measure rating: 1.861 Two-star quality measure rating: 1.817 Three-star quality measure rating: 1.696 Four-star quality measure rating: 1.589 Five-star quality measure rating: 1.414 These findings indicate that better performance on the long-stay hospitalization measure is associated with better performance on other dimensions of quality, including higher staffing, better performance on health inspection surveys, a higher overall rating, and better performance on other QMs.

Empiric Validity: Interpretation of results

Yes

Face Validity

No

Face Validity: Number of voting experts and patients/caregivers

N/A

Face Validity: Result

N/A

Patient/Encounter Level Testing

No

Type of Analysis

N/A

Sample Size

N/A

Statistic Name

N/A

Statistical Results

N/A

Interpretation of results

N/A

Measure performance – Type of Score

Continuous Variable – Mean

Measure Performance Score Interpretation

Lower score is better

Mean performance score

1.706

Median performance score

1.634

Minimum performance score

0

Maximum performance score

1.909

Standard deviation of performance scores

0.739

Does the performance measure use survey or patient-reported data?

No

Surveys or patient-reported outcome tools

N/A

Section 5: Measure Contact Information

Measure Steward

Centers for Medicare & Medicaid Services

Measure Steward Contact Information

Evan Shulman
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7500 Security Blvd
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Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

Primary Submitter Contact Information

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Submitter Comments

N/A

MUC2022-126 Total nursing staff turnover

Program

Skilled Nursing Facility Value-Based Purchasing Program

Section 1: Measure Information

Measure Specifications and Endorsement Status

Measure Description

The percent of nursing staff that stop working in a facility within a given year.

Numerator

Total Individuals who no longer work at the nursing home are defined as eligible individuals who have a period of at least 60 consecutive days in which they do not work at all. The 60-day gap must start during the period covered by the turnover measure. This lengthy period without any reported work hours suggests that the individual is no longer working at the nursing home. The turnover date is defined as the last workday prior to the start of the 60-day gap.

Numerator Exclusions

Nursing homes with 100 percent daily total nurse staffing turnover for any day in the study period on which there were at least five eligible nurse staff are excluded. 100 percent daily turnover is typically the result of changes in the employee IDs used by nursing homes. Since gaps in days worked are identified based on the employee and nursing home IDs reported in the PBJ data, a change in employee IDs can result in a 100 percent turnover rate on a particular day (i.e., the day that the nursing home started using the new identifier), which reflects the change in the employee IDs and not actual staff turnover

Denominator

The total nursing staff turnover measure includes registered nurses (RNs), licensed practical nurses (LPNs), and nurse aides. The turnover measures for RNs and total nurse staff use the same job categories of the staffing measures that are reported on Care Compare. The RN category includes RNs, RN director of nursing and RNs with administrative duties. The LPN category includes LPNs and LPNs with administrator duties. The nurse aide category includes certified nursing assistants, nurse aides in training and medication aides/technicians. The measure includes only individuals who work at least 120 hours in a 90-day period across the baseline quarter (the quarter prior to the first quarter used in the turnover calculation) and the first two quarters used in the turnover calculation. For example, the turnover calculation for calendar year 2020 includes in the denominator, individuals who worked 120 or more hours in any 90-day period with the first workday of the 90-day period occurring in 2019Q4-2020Q2 (October 1, 2019 through June 30, 2020). This specification excludes individuals who work infrequently (e.g., occasionally covering shifts at a nursing home). Note that both regular employees and agency staff are included in the turnover measure if they work sufficient hours to be eligible for the denominator.

Denominator Exclusions

Nursing homes that are not included in the PBJ public use file (PUF) for one or more of the quarters of data used to calculate the turnover measures are excluded, using the current exclusion rules for the

staffing domain The PUFs only include data that were received by the reporting deadline (which is 45 days after the last day in the quarter) and exclude data from nursing homes that had aggregate nurse staffing levels for the quarter that were considered aberrant. Additionally, if a nursing home has no resident census information (derived from MDS assessments and needed for the calculation of staffing levels), the nursing home is excluded. Nursing homes are excluded if they have fewer than five eligible nurses (RNs, LPNs and nurse aides) in the denominator. The purpose of this exclusion is to increase the stability of the turnover measures.

Denominator Exceptions

N/A

State of development

Specification

State of Development Details

N/A

What is the target population of the measure?

All Medicare and/or Medicaid certified nursing homes in the United States

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Nursing Homes

Measure Type

Structure

Is the measure a composite or component of a composite?

Not a composite or component of a composite measure

If Other, Please Specify

N/A

What data sources are used for the measure?

Administrative Data (non-claims)

If applicable, specify the data source

N/A

Description of parts related to these sources

Data from CMS's Payroll Based Journal (PBJ) system

At what level of analysis was the measure tested?

Facility

In which setting was this measure tested?

Nursing home;Skilled nursing facility

Multiple Scores

No

What one healthcare domain applies to this measure?

Person-Centered Care

MIPS Quality: Identify any links with related Cost measures and Improvement Activities

N/A

Is this measure in the CMS Measures Inventory Tool (CMIT)?

No

CMIT ID

N/A

Alternate Measure ID

N/A

What is the endorsement status of the measure?

Never Submitted

CBE ID (CMS consensus-based entity, or endorsement ID)

N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

N/A

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

No

If eCQM, enter Measure Authoring Tool (MAT) number

N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?

N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?

No

Previous Measure Information

N/A

What is the history or background for including this measure on the new measures under consideration list?

Measure currently used in a CMS program being submitted as-is for a new or different program

Range of years this measure has been used by CMS Programs

Measure was first reported on Nursing Home Care Compare in January 2022

What other federal programs are currently using this measure?

Nursing Home Care Compare and CMS 5-Star Quality Rating System

Is this measure similar to and/or competing with a measure(s) already in a program?

No

Which measure(s) already in a program is your measure similar to and/or competing with?

N/A

How will this measure be distinguished from other similar and/or competing measures?

N/A

How will this measure add value to the CMS program?

N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

N/A

Section 2: Measure Evidence

How is the measure expected to be reported to the program?

Other: Data sets created as part of Care Compare updates

Stratification

No

Feasibility of Data Elements

ALL data elements are in defined fields in electronic sources

Feasibility Assessment

The measure is already operational. CMS started reporting measures of nursing home staff turnover on the Medicare.gov Care Compare website in January 2022. The turnover measure is calculated using nursing home staffing data that are collected through the CMS Payroll-Based Journal (PBJ) System that was introduced in 2016. The availability of PBJ provides a national data source for calculating turnover rates. CMS developed the PBJ system in response to the Affordable Care Act, which requires CMS to collect electronic staffing data from nursing homes. PBJ data have been collected since 2016. Data are submitted quarterly and report the number of hours each staff (both employees and contracted staff) is paid to work each day of that quarter. The data are auditable back to payroll and other verifiable sources.

Method of Measure Calculation

Other (enter here): Turnover is calculated using staffing data submitted by nursing homes through CMS's Payroll-Based Journal (PBJ) system.

Hybrid measure: Methods of measure calculation

N/A

Evidence of Performance Gap

There is considerable variability in turnover rates across nursing homes. The mean rate is 46.1, and the inter-quartile range is 36.6%-54.9%. The 10th percentile is 28.8%, and the 90th percentile is 64.1%.

Unintended Consequences

We do not anticipate any unintended consequences, although it is possible that some nursing homes may terminate employees more quickly, before they meet the minimum hours worked required to be included in the turnover measure.

Number of clinical guidelines, including USPSTF guidelines, that address this measure topic

N/A

Outline the clinical guidelines supporting this measure

N/A

Name the guideline developer/entity

N/A

Publication year

N/A

Full citation +/- URL

N/A

Is this an evidence-based clinical guideline?

N/A

Is the guideline graded?

N/A

List the guideline statement that most closely aligns with the measure concept.

N/A

What evidence grading system did the guideline use to describe strength of recommendation?

N/A

List all categories and corresponding definitions for the evidence grading system used to describe strength of recommendation in the guideline?

N/A

For the guideline statement that most closely aligns with the measure concept, what is the associated strength of recommendation?

N/A

What evidence grading system did the guideline use to describe level of evidence or level of certainty in the evidence?

N/A

List all categories and corresponding definitions for the evidence grading system used to describe level of evidence or level of certainty in the evidence?

N/A

For the guideline statement that most closely aligns with the measure concept, what is the associated level of evidence or level of certainty in the evidence?

N/A

List the guideline statement that most closely aligns with the measure concept.

N/A

Number of systematic reviews that inform this measure concept

N/A

Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept

N/A

Source of empirical data

Internal data analysis

Summarize the empirical data

Testing of the turnover measure focused on the relationship between turnover and a comprehensive set of measures of nursing home quality. In addition to nursing home ratings from Care Compare's Five-Star Quality Rating System, we examined how nursing home staff turnover is associated with claims-based measures of hospitalizations and outpatient Emergency Department (ED) visits for both short- and long-

stay nursing home residents. For the validity testing provided, indicate the statistical result(s) of the testing analysis. If data element validity was conducted, provide the scores for the critical data elements tested. If face validity was conducted, list the total number of voting members in addition to the percentage that voted in favor of the measure's face validity. Analyses of PBJ-based staffing measures show a consistent relationship between lower nursing staffing levels and higher ratings for other dimensions of quality such as health inspection survey results, staffing level, and quality measures.

Name evidence type

N/A

Summarize the evidence

N/A

Does the evidence discuss a link between at least one process, structure, or intervention with the outcome?

N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size

12,500

Type of Evidence to Support the Measure

Empirical data

Is the measure risk adjusted?

No

Risk adjustment variables

N/A

Patient-level demographics: please select all that apply:

N/A

Patient-level health status & clinical conditions: please select all that apply:

N/A

Patient functional status: please select all that apply:

N/A

Patient-level social risk factors: please select all that apply:

N/A

Proxy social risk factors: please select all that apply

N/A

Patient community characteristic: please select all that apply:

N/A

Risk model performance

N/A

Rationale for not using risk adjustment

Other (enter here): Measure is a structural measure that is not appropriate for risk-adjustment

Cost estimate completed

No

Cost estimate methods and results

N/A

Section 3: Patient and Provider Perspective

Meaningful to Patients. Was input on the final performance measure collected from patient and/or caregiver?

No

Total number of patients and/or caregivers who responded to the question asking them whether the final performance measure helps inform care and decision making

N/A

Total number of patients/caregivers who agreed that the final performance measure helps inform care and decision making

N/A

Meaningful to Patients: Numbers consulted

N/A

Meaningful to Patients: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians: Numbers consulted

N/A

Meaningful to Clinicians: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians. Were clinicians and/or providers consulted on the final performance measure?

No

Total number of clinicians/providers who responded when asked if the final performance measure was actionable to improve quality of care.

N/A

Total number of clinicians/providers who agreed that the final performance measure was actionable to improve quality of care

N/A

Survey level testing

N/A

Type of Testing Analysis

N/A

Testing methodology and results

N/A

Burden for Provider: Was a provider workflow analysis conducted?

No

If yes, how many sites were evaluated in the provider workflow analysis?

N/A

Did the provider workflow have to be modified to accommodate the new measure?

N/A

Section 4: Measure Testing Details

Reliability

Yes

Reliability: Type of Reliability Testing

Random Split-Half Correlation

Signal-to-Noise: Name of statistic

N/A

Signal-to-Noise: Sample size

N/A

Signal-to-Noise: Statistical result

N/A

Signal-to-Noise: Interpretation of results

N/A

Random Split-Half Correlation: Name of statistic

Measure Score Reliability

Random Split-Half Correlation: Sample size

12,549

Random Split-Half Correlation: Statistical result

0

Random Split-Half Correlation: Interpretation of results

Results will be updated prior to the MAP meeting.

Other: Name of statistic

N/A

Other: Sample size

N/A

Other: Statistical result

N/A

Other: Interpretation of results

N/A

Empiric Validity

Yes

Empiric Validity: Statistic name

Relationship of turnover to measures of nursing home quality

Empiric Validity: Sample size

12.549

Empiric Validity: Statistical result

1

Empiric Validity: Methods and findings

Analyses of PBJ-based staffing measures show a consistent relationship between lower nursing staffing levels and higher ratings for other dimensions of quality such as health inspection survey results, staffing level, and quality measures. Examining turnover between 10/1/2018 - 9/30/2019, we found the following relationship between nursing staff turnover and five-star ratings (using ratings from December 2019). Overall Rating: One-star quality measure rating: 53.42 Two-star quality measure rating: 48.87 Three-star quality measure rating: 46.45 Four-star quality measure rating: 44.02 Five-star quality measure rating: 40.74 Health inspection rating: One-star health inspection rating: 51.58 Two-star health inspection rating: 47.53 Three-star health inspection rating: 45.47 Four-star health inspection rating: 43.22 Five-star health inspection rating: 40.96 QM Rating: One-star quality measure rating: 51.01 Two-star quality measure rating: 50.15 Three-star quality measure rating: 46.76 Four-star quality measure rating: 43.86 Five-star quality measure rating: 39.83 Staffing Rating: One-star quality measure rating: 51.13 Two-star quality measure rating: 48.22 Three-star quality measure rating: 46.40 Four-star quality measure rating: 43.65 Five-star quality measure rating: 40.63 We estimated a series of ordinary least squares regression models to examine the relationship between claims-based quality measures (hospitalizations and outpatient ED visits for both short- and long-stay residents). After controlling for staffing ratings, selected facility characteristics and county-level unemployment rate, we found a

consistent and statistically significant relationship between higher turnover rates and poorer performance on these quality measures. Using annual total nurse staff turnover rates and the long-stay ED visits measure as an example, compared to facilities with low turnover rates, nursing homes with medium and high turnover rates had 0.1 and 0.2 more ED visits per 1,000 long-stay resident days respectively, all else equal. Similarly, relative to nursing homes with low turnover rates, facility with high turnover rates had about 0.1 more hospitalizations per 1,000 long-stay resident days, 1.1 percentage points higher in readmissions and 1.5 percentage points higher in outpatient ED visits for short-stay residents. Using ordered logit models to examine the relationship between turnover measures and CMS star ratings for the overall domain, we also found a consistent relationship between higher turnover and a lower probability of having a higher star rating across all rating domains. Compared to facilities with low total nurse staff turnover rates, nursing homes with high total nurse staff turnover rates were 16 percentage points more likely to have one-star rating, 10.5 percentage points more likely to have two stars, but 20.3 percentage points less likely to have five stars, after adjusting for other factors that may affect their star ratings.

Empiric Validity: Interpretation of results

Yes

Face Validity

No

Face Validity: Number of voting experts and patients/caregivers

N/A

Face Validity: Result

N/A

Patient/Encounter Level Testing

No

Type of Analysis

N/A

Sample Size

N/A

Statistic Name

N/A

Statistical Results

N/A

Interpretation of results

N/A

Measure performance – Type of Score

Continuous Variable – Mean

Measure Performance Score Interpretation

A lower score is better

Mean performance score

46.1

Median performance score

45.6

Minimum performance score

0

Maximum performance score

100

The standard deviation of performance scores

13.7

Does the performance measure use survey or patient-reported data?

No

Surveys or patient-reported outcome tools

N/A

Section 5: Measure Contact Information

Measure Steward

Centers for Medicare & Medicaid Services

Measure Steward Contact Information

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Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

Primary Submitter Contact Information

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Secondary Submitter Contact Information

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Submitter Comments

N/A

Cross-Program Measures

These measures were submitted to multiple federal programs.

MUC2022-084 COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (2022 revision)

Program

Ambulatory Surgical Center Quality Reporting Program; Hospital Inpatient Quality Reporting Program; Hospital Outpatient Quality Reporting Program; Hospital Value-Based Purchasing Program; Hospital-Acquired Condition Reduction Program; Inpatient Psychiatric Facility Quality Reporting Program; Inpatient Rehabilitation Facility Quality Reporting Program; Long-Term Care (LTC) Hospital Quality Reporting Program; Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program; Skilled Nursing Facility Quality Reporting Program; End-Stage Renal Disease (ESRD) Quality Incentive Program

Section 1: Measure Information

Measure Specifications and Endorsement Status

Measure Description

Percentage of healthcare personnel who are considered up to date with recommended COVID-19 vaccines.

Numerator

The numerator for this measure consists of the cumulative number of HCP in the denominator population who are considered up to date with recommended COVID-19 vaccines.

Facilities should refer to the definition of up to date as of the first day of the quarter.

https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-May2022-508.pdf

As of April 1, 2022, up to date includes:

1. Individuals who received their second dose in a two-shot primary vaccination series, (Pfizer-BioNTech or Moderna vaccines) less than 5 months ago
2. Individuals who received a J&J/Janssen as their primary vaccination less than 2 months ago
3. Individuals who have received a primary series and one booster dose when recommended.

Numerator Exclusions

None

Denominator

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 to COVID-19 vaccination.

This 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 the categories below:

There are four categories of HCP:

1. Employees: includes all persons who receive a direct paycheck from the reporting facility (i.e., on the facility's payroll).
2. Licensed independent practitioners (LIPs): This includes 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: This includes 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.

Denominator Exclusions

Denominator-eligible individuals with contraindications to COVID-19 vaccination. Medical contraindications are listed in a vaccine's FDA authorization or labeling and include severe allergic reaction. The current list of contraindications as well as exclusions may be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html and includes:

1. Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
2. Known diagnosed allergy to a component of the COVID-19 vaccine

Denominator Exceptions

None

State of development

Field (Beta) Testing

State of Development Details

Beta testing was conducted by assessing if the collection of information on additional/booster vaccine doses received by healthcare personnel (HCP) was feasible, as information on receipt of booster vaccine doses is required for determining if HCP are up to date with the current COVID-19 vaccination recommendations.

Feasibility was assessed by calculating proportion of facilities which reported additional/booster doses of COVID-19 vaccine.

This assessment was conducted in the following facility types based on vaccine coverage data for the first quarter of 2022 (January - March) reported through the National Healthcare Safety Network (NHSN):

Ambulatory Surgery Centers (ASCs)

Dialysis Centers

Hospitals

Inpatient Psychiatric Facilities (IPFs)

Inpatient Rehabilitation Facilities (IRFs)

Long Term Acute Care (LTACs)

Skilled Nursing Facilities (SNFs)

Reliability and validity testing of the measure as specified is planned based on vaccine coverage data for the third quarter of 2022 (July- September) reported through the National Healthcare Safety Network (NHSN) in the same facility types listed above.

What is the target population of the measure?

Healthcare Personnel

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Other: All Healthcare Personnel

Measure Type

Process

Is the measure a composite or component of a composite?

Not a composite or component of a composite measure

If Other, Please Specify

N/A

What data sources are used for the measure?

Administrative Data (non-claims);Electronic Clinical Data (non-EHR);Electronic Health Record;Paper Medical Records;Registries;Other: The source 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.

If applicable, specify the data source

N/A

Description of parts related to these sources

N/A

At what level of analysis was the measure tested?

Facility

In which setting was this measure tested?

Not yet tested

Multiple Scores

No

What one healthcare domain applies to this measure?

Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities

N/A

Is this measure in the CMS Measures Inventory Tool (CMIT)?

Yes

CMIT ID

08062-C-ASCQR, 08062-C-HOQR, 08062-C-IRFQR, 08062-C-ESRDQIP, 08062-C-PCHQR, 08062-C-SNFQRP, 08062-C-HIQR, 08062-C-LTCHQR, 08062-X-LTCHC

Alternate Measure ID

N/A

What is the endorsement status of the measure?

Submitted

CBE ID (CMS consensus-based entity, or endorsement ID)

3636

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

No

If not exactly as endorsed, specify the locations of the differences

Numerator

If not exactly as endorsed, describe the nature of the differences

The CDC recommendations for COVID-19 vaccination have changed since the initial formulation of the measure COVID-19 Vaccination Coverage among Healthcare Personnel (CMT 08062) which was originally titled: SARS-CoV-2 Vaccination Coverage Among Healthcare Personnel (MUC20-0044). CDC now recommends that individuals stay up to date with COVID-19 vaccination (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html). Therefore, this major revision updated the numerator to include up to date vaccination rather than only completion of primary vaccination.

If endorsed: Year of most recent CDP endorsement

2020

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

2022

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

No

If eCQM, enter Measure Authoring Tool (MAT) number

N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?

N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?

Yes

Previous Measure Information

2020: MUC20-0044: SARS-CoV-2 Vaccination Coverage Among Healthcare Personnel

In what prior year was this measure published?

2020

What was the MUC ID for the measure in this year?
2020: MUC20-0044: SARS-CoV-2 Vaccination Coverage Among Healthcare Personnel

List the CMS CBE MAP workgroup(s) in this year:

2020 - Coordinating Committee - Hospital - Post-Acute Care/Long-Term Care - Rural Health

What were the programs that MAP reviewed the measure for in this year?

2020-2021 - Hospital Outpatient Quality Reporting Program (Hospital OQR) - Hospital Inpatient Quality Reporting Program (Hospital IQR) - Ambulatory Surgical Center Quality Reporting Program (ASCQR) - Inpatient Psychiatric Facility Quality Reporting Program (IPFQR) - PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR) - End-Stage Renal Disease Quality Improvement Program (ESRD QIP) - Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) SARS-CoV-2 Measure - Long-Term Care Hospital Quality Reporting Program (LTCH QRP) SARS-CoV-2 Measure - Skilled Nursing Facility Quality Reporting Program (SNF QRP) SARS-CoV-2 Measure

What was the MAP recommendation in this year?

Conditional Support

Why was the measure not recommended by the MAP workgroups in this year?

N/A

MAP report page number being referenced for this year:

MAP Report for 2020, pages 24-25

What is the history or background for including this measure on the new measures under consideration list?

Measure currently used in a CMS program, but the measure is undergoing substantial change

Range of years this measure has been used by CMS Programs

Quality Reporting Programs indicated in question below, 2022 to present (except Skilled Nursing Facility Quality Reporting Program [last quarter of 2021-present])

What other federal programs are currently using this measure?

Ambulatory Surgical Center Quality Reporting Program;Hospital Inpatient Quality Reporting Program;Inpatient Psychiatric Facility Quality Reporting Program;Inpatient Rehabilitation Facility Quality Reporting Program;Long-Term Care (LTC) Hospital Quality Reporting Program;Skilled Nursing Facility Quality Reporting Program

Is this measure similar to and/or competing with a measure(s) already in a program?

No

Which measure(s) already in a program is your measure similar to and/or competing with?

N/A

How will this measure be distinguished from other similar and/or competing measures?

N/A

How will this measure add value to the CMS program?

N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

N/A

Section 2: Measure Evidence

How is the measure expected to be reported to the program?

Other: National Healthcare Safety Network (NHSN)

Stratification

No

Feasibility of Data Elements

Some data elements are in defined fields in electronic sources

Feasibility Assessment

CMS quality reporting programs have already required facilities to report data on COVID-19 vaccination coverage among healthcare personnel (HCP) for primary vaccination. Feasibility of reporting additional/booster doses of vaccine is evident by the proportion of facilities nationwide that have already reported vaccination additional/booster coverage data to CDC's National Healthcare Safety Network (NHSN).

Even though the deadline to report vaccination coverage data for the first quarter of 2022 is not until August 2022 (except for dialysis and nursing homes which have additional reporting requirements), the proportions of facilities already reporting vaccine coverage data including additional/booster coverage as of May 2022 are:

- Ambulatory Surgery Centers (ASCs): 64.4%
- Dialysis Centers: 97.0%
- Hospitals: 74.6%
- Inpatient Psychiatric Facilities (IPFs): 74.3%
- Inpatient Rehabilitation Facilities (IRFs): 63.9%
- Long Term Acute Care (LTACs): 90.3 %
- Skilled Nursing Facilities (SNFs): 99.2%
- These high reporting rates indicate reporting the measure is feasible.

Method of Measure Calculation

Other (enter here):

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 (see "Measure Information" #012)
3. Among eligible HCP, identify those who are considered up to date with recommended COVID-19 vaccines.
4. Among eligible HCP who are not considered up to date with recommended COVID-19 vaccines, identify those who have a contraindication to COVID-19 vaccination.
5. Among eligible HCP who are not considered up to date with recommended COVID-19 vaccines, and who do not have a contraindication to COVID-19 vaccination, identify those who have refused or declined vaccination.
6. Among eligible HCP are not considered up to date with recommended COVID-19 vaccines, identify those whose COVID-19 vaccination status cannot be determined.

Measure Calculation:

The weekly coverage rate is the numerator divided by the denominator (minus exclusions) for a particular week:

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 to COVID-19 vaccination.

2. Calculate the weekly COVID-19 up to date vaccination coverage percentage by dividing the number of HCP in the denominator who are considered up to date with recommended COVID-19 vaccines by the number of HCP in the denominator and multiplying by 100.

The measure is reported for a quarter (3-month period). Quarterly up to date COVID-19 vaccination coverage is determined by selecting one weekly coverage rate per month, then averaging 3 weekly coverage rates (one week from each of the 3 months in the quarter).

For facilities that report more than one week per month, the latest week of data for the reporting month will be used.

Hybrid measure: Methods of measure calculation

N/A

Evidence of Performance Gap

There are clinically significant differences in booster/additional dose vaccination coverage rates among facilities, indicating that facilities have room for improvement and implementing the revised measured would be meaningful.

The following performance scores are the reported booster/additional dose coverage rates for the first quarter of 2022 (January 1 - March 31, 2022) by facility type:

ASCs: median 34.0%; interquartile range 16.4% - 55.6%

Dialysis Centers: median 14.7%; interquartile range 5.4% - 31.3%%

Acute Care Hospitals: median 22.5%; interquartile range 9.1% - 38.7%

IPFs: median 19.1%; interquartile range 8.7% - 37.9%

IRFs: median 20.3%; interquartile range 8.9% - 37.7%

LTACs: median 22.6%; interquartile range 10.8% - 36.9%

SNFs: median 31.8%; interquartile range 18.9% - 49.7%

Unintended Consequences

None

Number of clinical guidelines, including USPSTF guidelines, that address this measure topic

N/A

Outline the clinical guidelines supporting this measure

N/A

Name the guideline developer/entity

N/A

Publication year

N/A

Full citation +/- URL

N/A

Is this an evidence-based clinical guideline?

N/A

Is the guideline graded?

N/A

List the guideline statement that most closely aligns with the measure concept.

N/A

What evidence grading system did the guideline use to describe strength of recommendation?

N/A

List all categories and corresponding definitions for the evidence grading system used to describe strength of recommendation in the guideline?

N/A

For the guideline statement that most closely aligns with the measure concept, what is the associated strength of recommendation?

N/A

What evidence grading system did the guideline use to describe level of evidence or level of certainty in the evidence?

N/A

List all categories and corresponding definitions for the evidence grading system used to describe level of evidence or level of certainty in the evidence?

N/A

For the guideline statement that most closely aligns with the measure concept, what is the associated level of evidence or level of certainty in the evidence?

N/A

List the guideline statement that most closely aligns with the measure concept.

N/A

Number of systematic reviews that inform this measure concept

N/A

Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept

N/A

Source of empirical data

N/A

Summarize the empirical data

N/A

Name evidence type

Observational studies of real-world effectiveness of COVID-19 vaccination

Summarize the evidence

The CDC recommendations for COVID-19 vaccination have changed since the initial formulation of the measure COVID-19 Vaccination Coverage among Healthcare Personnel (CMT 08062) which was originally titled: SARS-CoV-2 Vaccination Coverage Among Healthcare Personnel (MUC20-0044). It is now recommended that individuals stay up to date with COVID-19 vaccination (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html).

This revision of measure to include reporting of up to date vaccination is informed by a search of the published literature. There are no published data on the impact of reporting up to date COVID-19 coverage reporting among healthcare workers; however, the following real-world observational data support the positive impact of COVID-19 vaccination, healthcare personnel vaccination, and additional/booster COVID-19 vaccine.

1. COVID-19 vaccine uptake in the U.S. is associated with reduced COVID-19 incidence and mortality:

   Suthar AB, Wang J, Seffren V, et al. Public health impact of covid-19 vaccines in the US: observational study. BMJ 2022 Apr 27;377:e069317. doi: 10.1136/bmj-2021-069317.

   December 2020-December 2021 cross-sectional analysis of US county level surveillance and vaccine administration data from 48 states.

   It was observed that 10% improvement in vaccination coverage was associated with an 8% reduction in mortality rates and a 7% reduction in incidence.

2. Among U.S. healthcare workers, COVID-19 vaccine effectiveness has been found to be high:
3. Pilishvili T, Gierke R, Fleming-Dutra KE, et al. Effectiveness of mRNA Covid-19 Vaccine among U.S. Health Care Personnel. N Engl J Med 2021 Dec 16;385(25):e90. doi: 10.1056/NEJMoa2106599.

   This was a test-negative case-control study of US healthcare personnel from 25 states conducted from December 2020-May 2021.

   Vaccine effectiveness against infection was 88.8% (95% CI, 84.6 to 91.8) for BNT162b2 vaccine and 96.3% (95% CI, 91.3 to 98.4) for the mRNA-1273 vaccine.

   U.S. Healthcare worker COVID-19 vaccination was associated with reduced patient COVID-19 infections and deaths:

   McGarry BE, Barnett ML, Grabowski DC, et al. Nursing Home Staff Vaccination and Covid-19 Outcomes. N Engl J Med 2022 Jan 27;386(4):397-398. doi: 10.1056/NEJMc2115674.

   This study was a cross-sectional analysis of US nursing home staff vaccination and resident infection data reported to the US Centers for Medicare and Medicaid Services from June 2021-August 2021.

In the presence of high community prevalence of Covid-19, nursing homes with low staff vaccination coverage had COVID-19 infection and death rates 132% and 195% higher, respectively, than those with high staff vaccination coverage.

4. With the COVID-19 Omicron variant, despite continued protection against invasive mechanical ventilation and death, a decrement in COVID-19 vaccine effectiveness has been observed for Emergency Department visits and hospitalizations:

   Tenforde MW, Self WH, Gaglani M, et al. Effectiveness of mRNA Vaccination in Preventing COVID-19-Associated Invasive Mechanical Ventilation and Death - United States, March 2021-January 2022. MMWR Morb Mortal Wkly Rep 2022 Mar 25;71(12):459-465. doi: 10.15585/mmwr.mm7112e1.

   This study was a case-control study of mRNA vaccine effectiveness (VE) against COVID-19 associated invasive mechanical ventilation (IMV) and in-hospital death among adults hospitalized at 21 US hospitals from March 2021-January 2022.

   VE against IMV or in-hospital death was 90% overall; 88% for 2 doses and 94% for 3 doses, and 94% for 3 doses during the Omicron-predominant period.

   Ferdinands JM, Rao S, Dixon BE, et al. Waning 2-Dose and 3-Dose Effectiveness of mRNA Vaccines Against COVID-19Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance VISION Network, 10 States, August 2021-January 2022. MMWR Morb Mortal Wkly Rep 2022 Feb 18;71(7):255-263. doi: 10.15585/mmwr.mm7107e2.

   This study was a test-negative case-control study evaluating VE against COVID-19 emergency department/urgent care (ED/UC) visits and hospitalizations among adults at sites across 10 states from August 2021-January 2022.

   During the Omicron period, VE against ED/UC visits was 87% in the first two months after a 3rd dose and decreased to 66% among those vaccinated 4-5 months prior; VE against hospitalizations was 91% during the first two months following a 3rd dose and decreased to 78% >= months after a 3rd dose.

5. Additional or booster dosing has been associated with reduced infections in both patients and healthcare workers:

   Prasad N, Derado G, Nanduri SA, et al. Effectiveness of a COVID-19 Additional Primary or Booster Vaccine Dose in Preventing SARS-CoV-2 Infection Among Nursing Home Residents During Widespread Circulation of the Omicron Variant -United States, February 14- March 27, 2022. MMWR Morb Mortal Wkly Rep 2022 May 6;71(18):633-637. doi: 10.15585/mmwr.mm7118a4.

   This report is a cross-sectional analysis of data reported to CMS from 15,000 nursing homes from January-March 2022.

   Compared with primary series vaccination only, an additional or booster dose provided greater protection (relative VE = 46.9%) against SARS-CoV-2 infection during Omicron variant predominance.

Oster Y, Benenson S, Nir-Paz R, et al. The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. Clin Microbiol Infect 2022 May;28(5):735.e1-735.e3. doi: 10.1016/j.cmi.2022.01.019. Epub 2022 Feb 7.

This two-hospital cohort study evaluating COVID-19 infection rate among healthcare workers (HCWs) receiving a 3rd vaccine dose (booster) compared with those who had received only a two-dose regimen in August 2021.

HCWs who received only the two-dose regimen had an infection rate of 21.4% (85 of 398), compared with 0.7% (35/4973; relative risk 30) among the boosted group.

Does the evidence discuss a link between at least one process, structure, or intervention with the outcome?

N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size

9999

Type of Evidence to Support the Measure

Other (enter here): Individual peer-reviewed observational studies of waning effectiveness indicate "up to date" metric is needed.

Is the measure risk adjusted?

No

Risk adjustment variables

N/A

Patient-level demographics: please select all that apply:

N/A

Patient-level health status & clinical conditions: please select all that apply:

N/A

Patient functional status: please select all that apply:

N/A

Patient-level social risk factors: please select all that apply:

N/A

Proxy social risk factors: please select all that apply

N/A

Patient community characteristic: please select all that apply:

N/A

Risk model performance

N/A

Rationale for not using risk adjustment

Other (enter here): Not conceptually or empirically indicated

Cost estimate completed

No

Cost estimate methods and results

N/A

Section 3: Patient and Provider Perspective

Meaningful to Patients. Was input on the final performance measure collected from patient and/or caregiver?

No

Total number of patients and/or caregivers who responded to the question asking them whether the final performance measure helps inform care and decision making

N/A

Total number of patients/caregivers who agreed that the final performance measure helps inform care and decision making

N/A

Meaningful to Patients: Numbers consulted

N/A

Meaningful to Patients: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians: Numbers consulted

N/A

Meaningful to Clinicians: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians. Were clinicians and/or providers consulted on the final performance measure?

No

Total number of clinicians/providers who responded when asked if the final performance measure was actionable to improve quality of care.

N/A

Total number of clinicians/providers who agreed that the final performance measure was actionable to improve quality of care

N/A

Survey level testing

N/A

Type of Testing Analysis

N/A

Testing methodology and results

N/A

Burden for Provider: Was a provider workflow analysis conducted?

No

If yes, how many sites were evaluated in the provider workflow analysis?

N/A

Did the provider workflow have to be modified to accommodate the new measure?

N/A

Section 4: Measure Testing Details

Reliability

No

Reliability: Type of Reliability Testing

N/A

Signal-to-Noise: Name of statistic

N/A

Signal-to-Noise: Sample size

N/A

Signal-to-Noise: Statistical result

N/A

Signal-to-Noise: Interpretation of results

N/A

Random Split-Half Correlation: Name of statistic

N/A

Random Split-Half Correlation: Sample size

N/A

Random Split-Half Correlation: Statistical result

N/A

Random Split-Half Correlation: Interpretation of results

N/A

Other: Name of statistic

N/A

Other: Sample size

N/A

Other: Statistical result

N/A

Other: Interpretation of results

N/A

Empiric Validity

No

Empiric Validity: Statistic name

N/A

Empiric Validity: Sample size

N/A

Empiric Validity: Statistical result

N/A

Empiric Validity: Methods and findings

N/A

Empiric Validity: Interpretation of results

N/A

Face Validity

No

Face Validity: Number of voting experts and patients/caregivers

N/A

Face Validity: Result

N/A

Patient/Encounter Level Testing

No

Type of Analysis

N/A

Sample Size

N/A

Statistic Name

N/A

Statistical Results

N/A

Interpretation of results

N/A

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Higher score is better

Mean performance score

9999

Median performance score

9999

Minimum performance score

9999

Maximum performance score

9999

Standard deviation of performance scores

9999

Does the performance measure use survey or patient-reported data?

No

Surveys or patient-reported outcome tools

N/A

Section 5: Measure Contact Information

Measure Steward

Centers for Disease Control and Prevention

Measure Steward Contact Information

Natasha Poudyal

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qpp1@cdc.gov

707-975-9356

Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

Primary Submitter Contact Information

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Submitter Comments

Performance Scores by Facility Type are provided here. These have been indicated in the following sections by "9999" since only numerical values were allowed in the entry.

Row 064: Mean performance score

The scores in this subsection (Measure Performance) evaluate reporting of additional information that previously was not required to be collected under the measure SARS-CoV-2 Vaccination Coverage Among Healthcare Personnel (MUC20-0044). Since the implementation of MUC-0044, CDC has recommended that individuals stay up to date with COVID-19 vaccination, which requires vaccine booster data (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html).

The following performance scores are the reported booster/additional dose coverage rates for the first quarter of 2022 (January 1- March 31, 2022) by facility type:

ASCs: 38.3%

Dialysis Centers: 21.9%

Acute Care Hospitals: 26.3%

IPFs: 25.1%

IRFs: 25.4%

LTACs: 25.3%

SNFs: 36.2%

Row 065: Median performance score

ASCs: 34.0%

Dialysis Centers: 14.7%

Acute Care Hospitals: 22.5%

IPFs:19.1%

IRFs: 20.2%

LTACs: 22.6%

SNFs: 31.8%

Row 066: minimum performance score

Dialysis centers: 0%

Acute Care Hospitals: 0%

IPFs: 0%

IRFs: 0%

LTACs: 0%

SNFs: 0%

Row 067: maximum performance score

ASCs: 100%

Dialysis Centers:100%

Acute Care Hospitals: 93.1%

IPFs: 95.1%

IRFs: 96.8%

LTACs: 96.2%

SNFs: 100%

Row 068: standard deviation of performance scores

ASCs: 27.0%

Dialysis Centers: 22.2%

Acute Care Hospitals: 21.2%

IPFs: 21.3%

IRFs: 21.2%

LTACs: 18.5%

SNFs: 22.7%

Row 075: estimated impact of the measure: estimate of annual denominator size

ASCs: 1,096 facilities; 92,820 HCP

Dialysis Centers: 7,369 facilities; 217,348 HCP

Acute Care Hospitals: 2,589 facilities; 5,078,202 HCP

IPFs: 760 facilities; 258,190 HCP

IRFs: 769 facilities; 247,321 HCP

LTACs: 329 facilities; 91,470 HCP

SNFs: 14,250 facilities; 1,971,405 HCP

MUC2022-083 Cross-Setting Discharge Function Score

Program

Inpatient Rehabilitation Facility Quality Reporting Program

Section 1: Measure Information

Measure Specifications and Endorsement Status

Measure Description

This measure estimates the percentage of Inpatient Rehabilitation Facility (IRF) patients who meet or exceed an expected discharge function score.

Numerator

The numerator is the number of patients in an IRF with a discharge function score that is equal to or higher than the calculated expected discharge function score.

The function items used to determine the observed function score are: Eating (GG0130A3), Oral Hygiene (GGO130B3), Toileting Hygiene (GG0130C3), Roll left and right (GG0170A3), Lying to sitting on side of bed (GG0170C3), Sit to stand (GG0170D3), Chair/bed-to-chair transfer (GG0170E3), Toilet transfer (GG0170F3), and Walk 10 feet (GG0170I3) and Walk 50 feet with two turns (GG0170J3) if not wheelchair-bound, or Wheel 50 feet with two turns (GG0170R3) if wheelchair-bound. The definition of wheelchair bound is specified in the Technical Report attachment.

The expected discharge function score is a risk-adjusted estimate that accounts for patient characteristics.

Numerator Exclusions

N/A

Denominator

The total number of patient stay-level IRF-PAI records with a discharge date in the measure target period, which do not meet the exclusion criteria.

Denominator Exclusions

A patient's stay-level record is excluded if:

(i) Patient had an incomplete stay:

Length of stay is less than 3 days

Discharged against medical advice;

Died while in IRF;

Discharge destination indicates the patient had a medical emergency

(ii) Patient has the following medical conditions: Coma, persistent vegetative state, complete tetraplegia, locked-in syndrome, severe anoxic brain damage, cerebral edema or compression of brain.

(iii) Patient is younger than age 18

(iv) Patient is discharged to hospice

Denominator Exceptions

n/a

State of development

Fully Developed

State of Development Details

N/A

What is the target population of the measure?

IRF patients included in the IRF-PAI assessment instrument

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Physical medicine and rehabilitation

Measure Type

Outcome

Is the measure a composite or component of a composite?

Not a composite or component of a composite measure

If Other, Please Specify

N/A

What data sources are used for the measure?

Standardized Patient Assessments

If applicable, specify the data source

N/A

Description of parts related to these sources

All data elements are sourced from Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI)

At what level of analysis was the measure tested?

Facility

In which setting was this measure tested?

Inpatient rehabilitation facility

Multiple Scores

No

What one healthcare domain applies to this measure?

Person-Centered Care

MIPS Quality: Identify any links with related Cost measures and Improvement Activities

N/A

Is this measure in the CMS Measures Inventory Tool (CMIT)?

No

CMIT ID

N/A

Alternate Measure ID

N/A

What is the endorsement status of the measure?

Never Submitted

CBE ID (CMS consensus-based entity, or endorsement ID)

9999

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

N/A

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

2023

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

No

If eCQM, enter Measure Authoring Tool (MAT) number

N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?

N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?

No

Previous Measure Information

N/A

What is the history or background for including this measure on the new measures under consideration list?

New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs

N/A

What other federal programs are currently using this measure?

N/A

Is this measure similar to and/or competing with a measure(s) already in a program?

Yes

Which measure(s) already in a program is your measure similar to and/or competing with?

The following measures are used in the IRF QRP:

IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633) (CMS ID: I009.03)

IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635) (CMS ID: I011.03)

IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634) (CMS ID: I010.03)

IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636) (CMS ID: I012.03)

How will this measure be distinguished from other similar and/or competing measures?

This measure differs from existing functional outcome measures in the following ways:

1. It only incorporates GG items that are currently available across IRF, LTCH, SNF, and HH.

2. It uses self-care and mobility activities in the same measure.
3. Risk adjustment models have been modified to align across settings, where appropriate, and include terms that are relevant for both self-care and mobility.
4. Item scores are imputed for items with Not Attempted (NA) codes

How will this measure add value to the CMS program?

To determine how to construct a cross-setting function measure that adds value to the PAC QRPs, we consulted two Technical Expert Panel (TEP) meetings (July 2021 and January 2022) throughout the course of measure development. During these meetings, panelists expressed that:

1. The IRF QRP would benefit from having a cross-setting functional outcome measure to add to the in-use function process measure (Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) (CMS ID: S001.03)). IRFs tend to perform well on the process measure. The mean score for FY2019 was 99%. The Cross-Setting Discharge Function measure has higher variation in provider performance (see Field 98) and offers more informative comparisons between IRFs for patients, caregivers, and stakeholders.
2. Both self-care and mobility GG items should be used for the measure because this provides a more comprehensive readout of providers' capacity to improve functional status that considers both dimensions of function together.[1] This is a valuable addition to the IRF QRP self-care and mobility functional outcome measures that consider each dimension separately.
3. The Cross-Setting Discharge Function Score measure benefits from being specified to align across PAC settings (IRF, LTCH, SNF, HHA). Due to limited GG item availability in LTCH, only a subset of items can be used to produce measure scores that could be computed identically in each PAC setting. We calculated measure scores with all GG items available in IRF v. the subset available in LTCH. Panelists reviewed comparisons between provider scores and model fit and found that the narrower set of GG items provides similar capture of functional status. [1]
4. Not Attempted (NA) codes are used frequently on assessments for certain GG items and statistical imputation should be used as the method to estimate resulting missing item scores. In other IRF QRP measures, all missing item scores are recoded to the code signifying the patient is completely dependent for an activity (i.e., 1). Panelists reviewed evidence showing that discharge item scores for patients scored as NA at admission tended to be higher than those scored as 1 at admission. Combining this evidence with their experience seeing how clinicians code NAs in real-world practice, they agreed that NA codes do not always signify that a patient was dependent on a functional activity and that the recode approach could be improved upon. [1] As an alternative to the recode approach, statistical imputation predicts item scores based on patient clinical characteristics and function scores on other GG items. Panelists also reviewed empiric validity results on our statistical imputation approach (see Field 42) and agreed the method produced more accurate item score estimates than the recode approach.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

Improving Medicare Post-Acute Care Transformation Act of 2014 (H.R.4994)

Section 2: Measure Evidence

How is the measure expected to be reported to the program?

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

Stratification

No

Feasibility of Data Elements

ALL data elements are in defined fields in electronic sources

Feasibility Assessment

A feasibility assessment was not necessary. The IRF PAI data elements used for measure construction are part of the standard data collection processes for IRF providers and are already used in existing IRF QRP measures.

Method of Measure Calculation

Other digital method

Hybrid measure: Methods of measure calculation

N/A

Evidence of Performance Gap

An analysis of FY 2019 data indicates that there is a performance gap in Cross-Setting Discharge Function Scores across providers. Among 1,107 IRFs included, risk-adjusted measure scores ranged from 8.0% (min) to 95.2% (max) with a mean score of 56.4% and a standard deviation of 15.5%. The 25th percentile, median, and 75th percentile were 46.1%, 57.2%, and 67.8%, respectively.

Unintended Consequences

CMS monitors trends in the data elements that are used for the Cross-Setting Discharge Function measure and in measure scores and patient populations for IRF QRP functional outcome measures (Change in Self-Care, Discharge Self-Care, Change in Mobility, and Discharge Mobility). So far, CMS has not detected any evidence of unintended consequences with these data elements and will continue to monitor them.

One concern about unintended consequences with the Cross-Setting Discharge Function Score is that the measure may lead IRFs to selectively enroll residents, either by encouraging or avoiding admission of certain types of residents and residents with certain characteristics. To address this, providers' performance is evaluated among their peers after adjusting for difference in resident case-mix across IRFs. The risk adjustment methodology applied to this measure will help mitigate providers' incentive to selectively enroll residents. The variables included in the risk adjustment model are designed to capture resident characteristics that are associated with discharge functional status. Therefore, providers' performance on this measure will be adjusted for the characteristics of their resident population and level the playing field across providers. The detailed risk-adjustment strategy will be publicly available, allowing providers to understand that those who provide care for more 'high risk' residents are not at a disadvantage given their resident case mix. See the attached Technical Report for more details on the risk adjustment methodology.

Another potential concern about the Cross-Setting Discharge Function Score measure could be that it focuses on a subset of the available GG items in IRF. If the items are not included in this publicly reported measure, it could reduce the incentive to complete those items and could result in higher levels of NAs. However, the GG items excluded from the Cross-Setting Discharge Function Score measure are used in the IRF prospective payment system to calculate payment for IRFs and are included in the statistical imputation models for the Cross-Setting Discharge Function Score measure. Together, these circumstances should provide an incentive for continued reporting of these GG items.

Another possibility related to increased NA rates is that providers could strategically code NAs in an attempt to game the statistical imputation models. For instance, IRFs could record NA codes for patients who did not improve by discharge if the discharge imputation models would predict a higher scores based on that patient's characteristics. However, this type of gaming, where providers are determining in real-time which patients would perform better with statistical imputation than a true discharge score, would require sophisticated understanding and application of the imputation methodology.

The Cross-Setting Discharge Function Score measure will be monitored to identify unintended consequences, including patient selection patterns or changes in NA coding, which could lead to future re-specification of the measure as needed.

Number of clinical guidelines, including USPSTF guidelines, that address this measure topic

1

Outline the clinical guidelines supporting this measure

The Academy of Orthopaedic Physical Therapy of the American Physical Therapy Association created clinical practice guidelines to identify evidence-based physical therapy outcomes and interventions to address functional impairment, among other goals, for individuals above the age of 65 with hip fracture. These guidelines directly relate to the Cross-Setting Discharge Function Measure by identifying evidence-based interventions that can be used to improve functional mobility for patients throughout the continuum of care, including post-acute and home-based care. While these findings target rehabilitation after hip fractures specifically, the authors highlight that hip fractures cause over 316,000 hospital admissions annually and are a common cause of poor functional mobility, disability, long-term complications, and mortality. As such, these guidelines are relevant to a large proportion of post-acute care patients and are especially pertinent to the proposed Cross-Setting Discharge Function Measure.

The guidelines include two type of recommendations: outcome measures for patient examination and evidence-based intervention strategies for physical therapy practice. The master list of 40 outcome measures, including sit-to-standing, gait speed, and endurance, was previously compiled in 2013 through a comprehensive search. A literature review on the properties of each measure was updated in May 2019. Measures were graded based on metrics of reliability and validity. This literature was further graded based on the level of evidence. To identify intervention recommendations, the authors conducted a systematic review of literature on published literature from 2004 through 2020. A total of 51 studies were identified, including randomized control trials, systematic reviews and meta-analyses. Clinical practice guidelines were assessed for inclusion using the Appraisal of Guidelines for Research & Evaluation II (AGREE II) instrument. Individual clinical research articles were graded using an adapted version of the criteria from the Centre for Evidence-Based Medicine (Oxford, UK). Finally, the final

guidelines were posted for public comment and reviewed by a group of consumer and clinician stakeholders to solicit and incorporate feedback.

The guidelines include evidence-based best practices to improve physical function among patients after a hip fracture to meet their individual goals for recovery. The included literature cites a range of supported interventions that can be used to improve function, including specific physical activities, motivational interviewing, home-based exercise, structured exercise routines, multidisciplinary care teams, and patient-tailored intensity and frequency levels.

Name the guideline developer/entity

The Academy of Orthopaedic Physical Therapy and the Academy of Geriatric Physical Therapy of the American Physical Therapy Association (APTA).

Publication year

2021

Full citation +/- URL

McDonough CM, Harris-Hayes M, Kristensen MT, et al. Physical Therapy Management of Older Adults With Hip Fracture. J Orthop Sports Phys Ther. 2021;51(2):CPG1-CPG81. doi:10.2519/jospt.2021.0301

Is this an evidence-based clinical guideline?

Yes

Is the guideline graded?

Yes

List the guideline statement that most closely aligns with the measure concept.

In reference to the Early Post-Operative Period in Inpatient Settings, the guideline states:

Patients should be offered high-frequency (daily) in-hospital physical therapy following surgery for a hip fracture, with duration as tolerated, including instruction in a home program.

What evidence grading system did the guideline use to describe strength of recommendation?

Other (enter here): AGREE II

List all categories and corresponding definitions for the evidence grading system used to describe strength of recommendation in the guideline?

The grading categories and corresponding definitions are as follows:

A: Strong evidence

A preponderance of level I and/or level II studies support the recommendation. This must include at least 1 level I study.

B: Moderate Evidence

A single high-quality randomized controlled trial or a preponderance of level II studies support the recommendation.

C: Weak evidence

A single level II study or a preponderance of level III and IV studies, including statements of consensus by content experts, support the recommendation

D: Conflicting evidence

Higher-quality studies conducted on this topic disagree with respect to their conclusions. The recommendation is based on these conflicting studies

E: Theoretical/foundational evidence

A preponderance of evidence from animal or cadaver studies, from conceptual models/ principles, or from basic sciences/bench esearch support this conclusion

F: Expert opinion

Best practice based on the clinical experience of the guideline development group

For the guideline statement that most closely aligns with the measure concept, what is the associated strength of recommendation?

USPSTF Grade A, Strong recommendation or similar

What evidence grading system did the guideline use to describe level of evidence or level of certainty in the evidence?

Other (enter here): Centre for Evidence-Based Medicine Levels of Evidence (Oxford, UK)

List all categories and corresponding definitions for the evidence grading system used to describe level of evidence or level of certainty in the evidence?

The categories for grading evidence range from I to V and are defined as follows:

I: Evidence obtained from high-quality diagnostic studies, prospective studies, randomized controlled trials, or systematic reviews.

II: Evidence obtained from lesser-quality diagnostic studies, prospective studies, systematic reviews, or randomized controlled trials (eg, weaker diagnostic criteria and reference standards, improper randomization, no blinding, less than 80% follow-up)

III: Case-control studies or retrospective studies

IV: Case series

V: Expert opinionFor the guideline statement that most closely aligns with the measure concept, what is the associated level of evidence or level of certainty in the evidence?

High or similar

List the guideline statement that most closely aligns with the measure concept.

In reference to the Early Post-Operative Period in Inpatient Settings, the guideline states:

Patients should be offered high-frequency (daily) in-hospital physical therapy following surgery for a hip fracture, with duration as tolerated, including instruction in a home program.

Number of systematic reviews that inform this measure concept

2

Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept

1. AlHuthaifi et al (2017) sought to identify, classify, and rank predictors of functional improvement, as measured by the Functional Independence Measure (FIM) score, for patients with a spinal cord injury (SCI) after inpatient rehabilitation at discharge and one-year afterwards. Predictors were identified and categorized using the domains of the International Classification of disability and Functioning (ICF) model. The ICF model is a classification of health and health-related conditions developed by the World Health Organization that describes function, disability and health, and its interaction with environmental and personal factors. The researchers identified seven eligible articles through a systematic search of five databases for literature published from 2000 to 2015. Each article was evaluated for quality and risk of bias using the Risk of Bias Assessment Instrument for Prognostic Factor Studies (QUIPS) approach. Moderate to high bias was identified due to confounding variables and the limited information on participant attrition. The authors identified 27 predictors of the mFIM score across the studies. Six of the seven studies had ten or more predictors, while one study identified three. In the former, all had variables that overlapped with ICF's domains including body function and structure, activity and participation, and contextual domain. The authors found that the 27 variables were able to predicted mFIM scores at discharge and one-year post-discharge, and ten of these were consistently significant at both discharge and follow-up. Body structure and Function variables were the most consistent predictors of function at discharge. These findings suggest that some domains of the ICF have greater impact on functional outcomes depending on the stage of the rehabilitation process.
2. Alcusky et al., (2018) sought to synthesize literature characterizing the relationship between site of rehabilitation (SNF versus IRF) and health outcomes, including functional status, among stroke patients. Authors tracked the eligibility of articles using guidelines from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), which accounts for quality and biases of articles. Additionally, the accuracy of abstracted data was authenticated by a reviewer. The review yielded a total of 14 full-text articles meeting eligibility criteria, in which eight studies compared health outcomes between patients rehabilitated in SNFs and IRFs, and six studies evaluated relationships between facility characteristics and health outcomes. Out of the 14 total studies, four studies assessed physical functioning comparing IRF and SNF stroke patients. In one study, SNF residents made larger gains in mobility compared to IRF patients. In another study, clinically relevant functional gains among IRF patients were more common than those in SNFs. Similarly, another study found that patients in IRF settings regained more activities of daily living at six weeks compared to SNF residents. The final study revealed higher Activity Measure for Post-Acute Care (AM-PAC) scores at six months among IRF patients than those in SNFs, with higher scores representing greater functional independence. Overall, most studies showed greater functional status among IRF patients than those in SNFs among stroke patients. The difference between functional outcomes in IRFs versus SNFs may be related to

stringent IRF admission criteria which requires that patients are able to complete three hours of rehabilitation therapy daily.

References:

[1] AlHuthaifi F, Krzak J, Hanke T, Vogel LC. Predictors of functional outcomes in adults with traumatic spinal cord injury following inpatient rehabilitation: A systematic review. J Spinal Cord Med. 2017;40(3):282-294. doi:10.1080/10790268.2016.1238184

[2] Alcusky, M., Ulbricht, C. M., & Lapane, K. L. (2018). Postacute Care Setting, Facility Characteristics, and Poststroke Outcomes: A Systematic Review. Archives of physical medicine and rehabilitation, 99(6), 1124-1140.e9. https://doi.org/10.1016/j.apmr.2017.09.005

Source of empirical data

Published, peer-reviewed original research

Summarize the empirical data

A core service of IRF care is the provision of rehabilitation therapy to those experiencing functional deficits following discharge from a hospital stay. Research examining functional outcomes has focused on motor function, which encompasses self-care and mobility. Physical function is a modifiable predictor of several outcomes including successful discharge to the community [1], functional recovery [2, 3], and re-hospitalization rates [4, 5]. Evidence suggests that IRF care can improve functional outcomes and that outcomes vary in individual IRF facilities, which provides an opportunity to monitor provider-level variation through the Cross-Setting Discharge Function Score measure. IRF patients with different functional status at admission, cognitive function, and comorbidities will have different levels of expected functional gains, which is taken into account in this measure.

IRF care has been shown to improve patient functional status. Several studies have reported that IRF care improved patients' motor function at discharge for patients with various diagnoses, including traumatic brain injury [6, 7], stroke [3, 8], and lower extremity joint surgery [8, 9]. An additional retrospective analysis identified significant functional mobility improvement among IRF patients that survived severe COVID-19 [10].

Functional mobility improvement at discharge can vary based on the facility, indicating an opportunity to measure facility-level differences in patient outcomes. For example, two retrospective cohort studies including over 1,000 IRFs found that variation in functional improvement among patients after hip fractures [11] and strokes [12] was more strongly related to differences on facility-level than by region. Functional outcomes can depend on whether providers develop person-centered care plans that are unique to each patient's clinical needs. For example, a retrospective cohort study by Cogan et al. (2020) found that the rate of recovery and length of stay were significantly associated with functional improvement and emphasized the need to evaluate each patient's rate of functional gain and cater therapy intensity and time accordingly [15].

Patient characteristics are important predictors of functional status. Evidence suggests that patient case-mix is associated with functional improvement [13, 14]. Evans et al (2021) observed that patients with better motor and cognition scores at admission and lower comorbidity burden were more likely to improve mobility at discharge [6]. An observational study with nearly 500,000 IRF patients found that

IRF patients made significant functional improvement in mobility and self-care between admission and discharge, but the degree of improvement was negatively associated with the number of comorbidities [2].

Overall, literature indicates that IRFs can influence functional outcomes at discharge. As such, variations in functional status of IRF patients at discharge could be measured and monitored through the Cross-Setting Discharge Function Score Measure. Since function outcomes vary based on patient characteristics, the Cross-Setting Discharge Function Score measure adjusts for relevant risk factors. Study limitations are summarized in an evidence attachment due to character constraints.

References:

1. Minor M, Jaywant A, Toglia J, Campo M, O'Dell MW. Discharge Rehabilitation Measures Predict Activity Limitations in Patients with Stroke Six Months after Inpatient Rehabilitation. Am J Phys Med Rehabil. 2021 Oct 20. doi: 10.1097/PHM.0000000000001908. Epub ahead of print. PMID: 34686630.

2. Deutsch A, Palmer L, Vaughan M, Schwartz C, McMullen T. Inpatient Rehabilitation Facility Patients' Functional Abilities and Validity Evaluation of the Standardized Self-Care and Mobility Data Elements. Arch Phys Med Rehabil. 2022 Feb 11:S0003-9993(22)00205-2. doi: 10.1016/j.apmr.2022.01.147. Epub ahead of print. PMID: 35157893.

3. Hong I, Goodwin JS, Reistetter TA, Kuo YF, Mallinson T, Karmarkar A, Lin YL, Ottenbacher KJ. Comparison of Functional Status Improvements Among Patients With Stroke Receiving Postacute Care in Inpatient Rehabilitation vs Skilled Nursing Facilities. JAMA Netw Open. 2019 Dec 2;2(12):e1916646. doi: 10.1001/jamanetworkopen.2019.16646. PMID: 31800069; PMCID: PMC6902754.

4. Li CY, Haas A, Pritchard KT, Karmarkar A, Kuo YF, Hreha K, Ottenbacher KJ. Functional Status Across Post-Acute Settings is Associated With 30-Day and 90-Day Hospital Readmissions. J Am Med Dir Assoc. 2021 Dec;22(12):2447-2453.e5. doi: 10.1016/j.jamda.2021.07.039. Epub 2021 Aug 30. PMID: 34473961; PMCID: PMC8627458.

5. Middleton A, Graham JE, Lin YL, Goodwin JS, Bettger JP, Deutsch A, Ottenbacher KJ. Motor and Cognitive Functional Status Are Associated with 30-day Unplanned Rehospitalization Following Post-Acute Care in Medicare Fee-for-Service Beneficiaries. J Gen Intern Med. 2016 Dec;31(12):1427-1434. doi: 10.1007/s11606-016-3704-4. Epub 2016 Jul 20. PMID: 27439979; PMCID: PMC5130938.

6. Evans E, Krebill C, Gutman R, Resnik L, Zonfrillo MR, Lueckel SN, Zhang W, Kumar RG, Dams-O'Connor K, Thomas KS. Functional motor improvement during inpatient rehabilitation among older adults with traumatic brain injury. PM R. 2021 May 21:10.1002/pmrj.12644. doi: 10.1002/pmrj.12644. Epub ahead of print. PMID: 34018693; PMCID: PMC8606011.

7. Kowalski RG, Hammond FM, Weintraub AH, et al. Recovery of Consciousness and Functional Outcome in Moderate and Severe Traumatic Brain Injury. JAMA Neurol. 2021;78(5):548-557. doi:10.1001/jamaneurol.2021.0084

8. Li CY, Karmarkar A, Kuo YF, Haas A, Ottenbacher KJ. Impact of Self-Care and Mobility on One or More Post-Acute Care Transitions. J Aging Health. 2020;32(10):1325-1334. doi:10.1177/0898264320925259

9. Cogan AM, Weaver JA, McHarg M, Leland NE, Davidson L, Mallinson T. Association of Length of Stay, Recovery Rate, and Therapy Time per Day With Functional Outcomes After Hip Fracture Surgery. JAMA Netw Open. 2020 Jan 3;3(1):e1919672. doi: 10.1001/jamanetworkopen.2019.19672. PMID: 31977059; PMCID: PMC6991278.

10. Olezene CS, Hansen E, Steere HK, et al. Functional outcomes in the inpatient rehabilitation setting following severe COVID-19 infection. PLoS One. 2021;16(3):e0248824. Published 2021 Mar 31. doi:10.1371/journal.pone.0248824

11. Teppala, S., Ottenbacher, K. J., Eschbach, K., Kumar, A., Al Snih, S., Chan, W. J., & Reistetter, T. A. (2017). Variation in Functional Status After Hip Fracture: Facility and Regional Influence on Mobility and Self-Care. The journals of gerontology. Series A, Biological sciences and medical sciences, 72(10), 1376-1382. https://doi.org/10.1093/gerona/glw249

12. Reistetter TA, Kuo YF, Karmarkar AM, et al. Geographic and facility variation in inpatient stroke rehabilitation: multilevel analysis of functional status. Arch Phys Med Rehabil. 2015;96(7):1248-1254. doi:10.1016/j.apmr.2015.02.020

13. Cary MP Jr, Pan W, Sloane R, Bettger JP, Hoenig H, Merwin EI, Anderson RA. Self-Care and Mobility Following Postacute Rehabilitation for Older Adults With Hip Fracture: A Multilevel Analysis. Arch Phys Med Rehabil. 2016 May;97(5):760-71. doi: 10.1016/j.apmr.2016.01.012. Epub 2016 Feb 1. PMID: 26836951; PMCID: PMC5823692.

14. Oyesanya TO, Moran TP, Espinoza TR, Wright DW. Regional Variations in Rehabilitation Outcomes of Adult Patients With Traumatic Brain Injury: A Uniform Data System for Medical Rehabilitation Investigation. Arch Phys Med Rehabil. 2021 Jan;102(1):68-75. doi: 10.1016/j.apmr.2020.07.011. Epub 2020 Aug 27. PMID: 32861669.

15. Cogan AM, Weaver JA, McHarg M, Leland NE, Davidson L, Mallinson T. Association of Length of Stay, Recovery Rate, and Therapy Time per Day With Functional Outcomes After Hip Fracture Surgery. JAMA Netw Open. 2020 Jan 3;3(1):e1919672. doi: 10.1001/jamanetworkopen.2019.19672. PMID: 31977059; PMCID: PMC6991278.

Name evidence type

N/A

Summarize the evidence

N/A

Does the evidence discuss a link between at least one process, structure, or intervention with the outcome?

Yes

Estimated Impact of the Measure: Estimate of Annual Denominator Size

450,347

Type of Evidence to Support the Measure

Clinical Guidelines or USPSTF (U.S. Preventive Services Task Force) Guidelines; Peer-Reviewed Systematic Review; Empirical data

Is the measure risk adjusted?

Yes

Risk adjustment variables

Patient-level demographics; Patient-level health status & clinical conditions; Patient functional status

Patient-level demographics: please select all that apply:

Age

Patient-level health status & clinical conditions: please select all that apply:

Case-Mix Adjustment

Patient functional status: please select all that apply:

Body Function; Ability to perform activities of daily living

Patient-level social risk factors: please select all that apply:

N/A

Proxy social risk factors: please select all that apply

N/A

Patient community characteristic: please select all that apply:

N/A

Risk model performance

The risk adjustment model was an ordinary least squares (OLS) linear regression. A well-calibrated model demonstrates good predictive ability to distinguish high-risk from low-risk patients. To assess risk adjustment model calibration, we calculated the ratio of observed-to-predicted discharge function score across eligible stays by decile of predicted discharge function score (risk). The average ratio of observed-to-predicted scores for each risk decile ranged from 0.99 to 1.01, which suggested good calibration across the range of patients without evidence of concerning under- or over-estimation. We analyzed model fit using adjusted R-squared to determine if the risk adjustment model can accurately predict discharge function while controlling for patient case-mix. The adjusted R-squared value was 0.52, which suggests good model discrimination.

Rationale for not using risk adjustment

N/A

Cost estimate completed

No

Cost estimate methods and results

N/A

Section 3: Patient and Provider Perspective

Meaningful to Patients. Was input on the final performance measure collected from patient and/or caregiver?

No

Total number of patients and/or caregivers who responded to the question asking them whether the final performance measure helps inform care and decision making

N/A

Total number of patients/caregivers who agreed that the final performance measure helps inform care and decision making

N/A

Meaningful to Patients: Numbers consulted

N/A

Meaningful to Patients: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians: Numbers consulted

N/A

Meaningful to Clinicians: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians. Were clinicians and/or providers consulted on the final performance measure?

No

Total number of clinicians/providers who responded when asked if the final performance measure was actionable to improve quality of care.

N/A

Total number of clinicians/providers who agreed that the final performance measure was actionable to improve quality of care

N/A

Survey level testing

N/A

Type of Testing Analysis

N/A

Testing methodology and results

N/A

Burden for Provider: Was a provider workflow analysis conducted?

No

If yes, how many sites were evaluated in the provider workflow analysis?

N/A

Did the provider workflow have to be modified to accommodate the new measure?

N/A

Section 4: Measure Testing Details

Reliability

Yes

Reliability: Type of Reliability Testing

Random Split-Half Correlation

Signal-to-Noise: Name of statistic

N/A

Signal-to-Noise: Sample size

N/A

Signal-to-Noise: Statistical result

N/A

Signal-to-Noise: Interpretation of results

N/A

Random Split-Half Correlation: Name of statistic

Split-sample Reliability Testing: This testing examined agreement between two performance measure scores for a facility based on randomly-split, independent subsets of resident stays in the same measurement period. We randomly divided FY 2019 resident stays of each facility with at least 20 stays into halves. We calculated performance measure scores for each split-half sample using the same measure specification. We calculated Shrout-Fleiss intraclass correlation coefficients (ICC (2, 1)) between the split-half scores to measure reliability [ ], with the Spearman-Brown correction applied. [1] McGraw, K. O., & Wong, S. P. (1996). Forming inferences about some intraclass correlation coefficients. Psychological methods, 1(1), 30.

Random Split-Half Correlation: Sample size

1,107

Random Split-Half Correlation: Statistical result

0.95

Random Split-Half Correlation: Interpretation of results

Excellent reliability

Threshold referenced:

Poor <0.50

Moderate 0.50-0.75

Good 0.75-0.90

Excellent >0.90

Koo T.K. & Li M.Y. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. Journal of Chiropractic Medicine, 2016, 15(2), 155-163.

Thresholds for sufficient measure reliability vary across sources [1], with the threshold for moderate reliability ranging to 0.4[2], and the category above moderate ranging to 0.61[3], for example.

[1] Portney, L. G., & Watkins, M. P. (2009). Foundations of clinical research: applications to practice (Vol. 892). Upper Saddle River, NJ: Pearson/Prentice Hall.

[2] U.S. Department of Education (2018), What Works Clearinghouse (WWC) Standards Handbook version 4.0.

[3] Landis J, Koch G. The measurement of observer agreement for categorical data. Biometrics. 1977; 33:159-174.

Other: Name of statistic

N/A

Other: Sample size

N/A

Other: Statistical result

N/A

Other: Interpretation of results

N/A

Empiric Validity

Yes

Empiric Validity: Statistic name

Empirical validity testing included tests of convergent validity. To evaluate convergent validity of measure scores, we measured Spearman's rank correlation between the Cross-Setting Discharge Function Score measure and other IRF QRP measures. The analysis used FY2019 data and only included data from IRFs with at least 20 stays. Higher functional status corresponds with higher likelihood of community discharge [1]. As expected, this measure demonstrated positive correlation with the Discharge to Community measure (0.26) ($p<0.01$).

[1] Minor M, Jaywant A, Toglia J, Campo M, O'Dell MW. Discharge Rehabilitation Measures Predict Activity Limitations in Patients with Stroke Six Months after Inpatient Rehabilitation. Am J Phys Med Rehabil. 2021 Oct 20. doi: 10.1097/PHM.0000000000001908. Epub ahead of print. PMID: 34686630.

Empiric Validity: Sample size

1,070

Empiric Validity: Statistical result

0.26

Empiric Validity: Methods and findings

To assess face validity of the Cross-Setting Discharge Function Score measure, we convened two Technical Expert Panel (TEP) meetings (July 2021 and January 2022), [1] as well as a Patient and Family Engagement Listening Session. TEP members showed strong support for the face validity of this measure. Though a vote was not taken at the meeting, the TEP agreed with the conceptual and operational definition of the measure. Panelists reviewed the validity analyses described herein and agreed they demonstrated measure validity. Additionally, panelists agreed that the Cross-Setting Discharge Function Score measure adds value over the measures currently in-use in the IRF QRP (see Field 146). Additionally, the Patient and Family Engagement Listening Session demonstrated that the measure concept resonates with patients and caregivers. Participants' views of self-care and mobility were aligned with the functional domains captured by the measure, and they found them to be critical aspects of care. Participants emphasized the importance of measuring functional outcomes and were specifically interested in metrics that show how many patients discharged from particular facilities made improvements in self-care and mobility.

To evaluate convergent validity of measure scores, we measured Spearman's rank correlation between the Cross-Setting Discharge Function Score measure and other IRF QRP measures using FY 2019 data (see Field 39 for Discharge to Community). As expected, since the IRF QRP self-care and mobility functional outcome measures use overlapping but not identical GG items and a different method for handling missing data, scores for these measures correlated well but not perfectly with the Cross-Setting Discharge Function Score measure: Change in Self-Care (0.83), Discharge Self-Care (0.85), Change in Mobility (0.87), Discharge Mobility (0.88). All correlation coefficients were significant ($p<0.01$.

The risk adjustment model is an ordinary least squares (OLS) linear regression. We assessed risk adjustment model calibration and fit using FY 2019 data. A well-calibrated model demonstrates good predictive ability to distinguish high-risk from low-risk patients. To assess risk adjustment model calibration, we calculated the ratio of observed-to-predicted discharge function score across eligible stays by decile of predicted discharge function score (risk). The average ratios of observed-to-predicted scores for each risk decile ranged from 0.99 to 1.01, which suggested good calibration across the range of patients without evidence of concerning under- or over-estimation. We analyzed model fit using adjusted R-squared to determine if the risk adjustment model can accurately predict discharge function while controlling for patient case-mix. The adjusted R-squared value was 0.52, which suggests good model discrimination.

We evaluated internal consistency, which demonstrates how well items interrelate. We measured Cronbach's alpha coefficient for the GG items used in the numerator calculation, which reflects the average correlation of all possible item-pairs and ranges from 0 to 1 (where 0 indicates no consistency of measurement among the items and 1 indicates perfect consistency). General consensus is that Cronbach's alpha should be at least 0.70 for an adequate scale for group-level decisions. [2] Cronbach's alpha was 0.85 at admission and 0.92 at discharge for non-wheelchair-bound patients and was 0.87 at

admission and 0.93 for wheelchair-bound patients, indicating good consistency in GG item scores used in the measure score. Note that although only discharge item scores are used to calculate observed discharge function score, admission function scores are used in the risk adjustment model.

For in-use IRF QRP functional outcome measures, all missing item scores (i.e., Not Attempted, or NA, codes) are recoded to the code signifying the patient is completely dependent for an activity. However, TEP panelists agreed that NA codes may not always signify that a patient was dependent on a functional activity.[1] As a refinement for the Cross-Setting Discharge Function measure, statistical imputation was implemented to predict item scores for patients where a GG item was NA using models that adjust for patient clinical characteristics. We evaluated the empiric validity of our imputation methodology using the following analyses (see the Technical Report for full details).

1. We used ordered probit models to estimate admission and discharge scores for each GG item used in measure construction. To evaluate model fit of imputation models, we calculated C-statistics for each of the 22 imputation models. C-statistics ranged from 0.76-0.99, and the mean C-statistic was 0.92.
2. A bootstrapping method was used to measure bias and mean squared error (MSE) in the imputation method compared to the recode approach used in the self-care and mobility functional outcome measures. Bias measures the average amount by which the imputed value differs from the true value. Bias is signed, with a positive amount meaning that the imputed values were higher, on average, than were the true values. MSE measures how far away the method is, on average from the truth. It is unsigned and can be positive even if bias is zero. The absolute size of bias is an inverse measure of accuracy, while the size of MSE is an inverse measure of the combination of precision and accuracy. The goal of the bootstrapping method was to determine how similar imputed values were to the true item score. For each bootstrap, stays with complete item data were sampled using stratified random sampling. Two copies were made of this sample. The first copy was the original with known item scores. Missing item scores were imposed on the second copy, and now-missing item scores were estimated using both statistical imputation and the recode approach. Item scores estimated through each approach were compared to the known item scores from the first copy. The MSE and bias statistics were calculated as averages across bootstraps. For statistical imputation, average MSE was 1.44 at admission and 0.43 at discharge, and average bias was -0.28 at admission and -0.06 at discharge. For the recode approach, average MSE was 6.57 at admission and 3.83 at discharge, and average bias was -1.41 at admission and -0.61 at discharge. This result indicates that statistical imputation produced less biased, more precise estimates for missing item scores.
3. We calculated the difference in discharge function between stays that have bona fide item scores at admission and stays with NA codes at admission where we impute to estimate the item score. This difference provides a metric of how accurately imputed item scores reflect true patient function. For 9 out of 11 items, the difference was lower than if these NAs were recoded to the most dependent level of functional status. This result indicates that statistical imputation produced more accurate results.

[1] https://www.cms.gov/sites/default/files/2022-04/PAC-Function-TEP-Summary-Report-Jul2021.pdf

[2] Aron A, Aron EN Statistics for Psychology. 2nd ed. Upper Saddle River, NJ: Prentice Hall, 1999.

Empiric Validity: Interpretation of results

Yes

Face Validity

No

Face Validity: Number of voting experts and patients/caregivers

N/A

Face Validity: Result

N/A

Patient/Encounter Level Testing

Yes

Type of Analysis

Agreement between two manual reviewers

Sample Size

448

Statistic Name

Kappa

Statistical Results

0.558

Interpretation of results

A final report on the development of the Continuity Assessment Record and Evaluation (CARE) Tool included reliability and validity testing for self-care and mobility data elements, as well as data elements used as risk adjustors for the Cross-Setting Discharge Function Score measure. [1]

The inter-rater reliability of the GG items was tested in a subset of 34 providers (acute hospitals, HHAs, IRFs, LTCHs, and SNFs) distributed across 11 geographic areas. Each provider completed a duplicate admission or discharge assessment on 10-20 patients. The overall sample size was 449 for mobility items (448 for transfers). Kappa statistics were calculated to assess the level of agreement between raters since the GG item responses are ordinal (1, 2, 3, 4, 5, 6). Kappas ranged from 0.667 for walk 10 feet to 0.762 for sit to stand, which indicated substantial agreement of data element codes among raters.

[1] Gage BJ, Smith LM, Ross J, Coots LA, Shamsuddin KM, Deutsch A, Mallinson T, Reilly KE, Abbate JH, Gage-Croll Z. (August, 2012). The development and testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on Reliability Testing, Volume 2 of 3. Prepared for Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/files/document/development-and-testing-continuity-assessment-record-and-evaluation-care-item-set-final-report.pdf

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Higher score is better

Mean performance score

56.4

Median performance score

57.2

Minimum performance score

8.0

Maximum performance score

95.2

Standard deviation of performance scores

15.5

Does the performance measure use survey or patient-reported data?

No

Surveys or patient-reported outcome tools

N/A

Section 5: Measure Contact Information

Measure Steward

Centers for Medicare & Medicaid Services

Measure Steward Contact Information

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Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

Primary Submitter Contact Information

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Submitter Comments

N/A

MUC2022-085 Cross-Setting Discharge Function Score

Program

Home Health Quality Reporting Program

Section 1: Measure Information

Measure Specifications and Endorsement Status

Measure Description

This measure estimates the percentage of Home Health (HH) Medicare patients who meet or exceed an expected discharge function score.

Numerator

The numerator is the number of patients in a HH with a discharge function score that is equal to or higher than the calculated expected discharge function score.

The function items used to determine the observed function score are: Eating (GG0130A3), Oral Hygiene (GGO130B3), Toileting Hygiene (GG0130C3), Roll left and right (GG0170A3), Lying to sitting on side of bed (GG0170C3), Sit to stand (GG0170D3), Chair/bed-to-chair transfer (GG0170E3), Toilet transfer (GG0170F3), Walk 10 feet (GG0170I3), and Walk 50 feet with two turns (GG0170J3) if not wheelchair-bound or Wheel 50 feet with two turns (GG0170R3) if wheelchair-bound. The definition of wheelchair bound is specified in the Technical Report attachment.

The expected discharge function score is a risk-adjusted estimate that accounts for patient characteristics.

Numerator Exclusions

N/A

Denominator

The total number of Medicare patient stay-level OASIS records with a discharge date in the measure target period, which do not meet the exclusion criteria.

Denominator Exclusions

A patient's episode-level record is excluded if: (i) Patient had an incomplete stay: * Length of stay is less than 3 days * Died while in HH (Item M0100 equal to ''08''); * Discharge destination indicates the patient had a medical emergency (Item M0100 equal to ''06'' or ''07'') (ii) Patient has the following medical conditions: Coma, persistent vegetative state, complete tetraplegia, locked-in syndrome, severe anoxic brain damage, cerebral edema or compression of brain (must have a valid diagnosis in Items M1021 and M1023 and Item M1700 equal to ''04''). (iii) Patient is younger than age 18 (iv) Patient is discharged to hospice

Denominator Exceptions

N/A

State of development

Fully Developed

State of Development Details

N/A

What is the target population of the measure?

HH patients included in the OASIS assessment instrument

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Other: Physical Therapy/Occupational Therapy

Measure Type

Outcome

Is the measure a composite or component of a composite?

Not a composite or component of a composite measure

If Other, Please Specify

N/A

What data sources are used for the measure?

Standardized Patient Assessments

If applicable, specify the data source

N/A

Description of parts related to these sources

All data elements are sourced from OASIS

At what level of analysis was the measure tested?

Facility

In which setting was this measure tested?

Home health

Multiple Scores

No

What one healthcare domain applies to this measure?

Person-Centered Care

MIPS Quality: Identify any links with related Cost measures and Improvement Activities

N/A

Is this measure in the CMS Measures Inventory Tool (CMIT)?

No

CMIT ID

N/A

Alternate Measure ID

N/A

What is the endorsement status of the measure?

Never Submitted

CBE ID (CMS consensus-based entity, or endorsement ID)

N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

N/A

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

2023

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

No

If eCQM, enter Measure Authoring Tool (MAT) number

N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?

N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?

No

Previous Measure Information

N/A

What is the history or background for including this measure on the new measures under consideration list?

New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs

N/A

What other federal programs are currently using this measure?

N/A

Is this measure similar to and/or competing with a measure(s) already in a program?

No

Which measure(s) already in a program is your measure similar to and/or competing with?

N/A

How will this measure be distinguished from other similar and/or competing measures?

N/A

How will this measure add value to the CMS program?

N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act)

Section 2: Measure Evidence

How is the measure expected to be reported to the program?

Other: Outcome and Assessment Information Set (OASIS)

Stratification

No

Feasibility of Data Elements

ALL data elements are in defined fields in electronic sources

Feasibility Assessment

A feasibility assessment was not necessary. The OASIS data elements used for measure construction are part of the standard data collection processes for HH providers.

Method of Measure Calculation

Other digital method

Hybrid measure: Methods of measure calculation

N/A

Evidence of Performance Gap

An analysis of CY 2019 data indicates that there is a performance gap in Cross-Setting Discharge Function Scores across providers. Among 8,171 HHAs included, risk-adjusted measure scores ranged from 0.0% (min) to 100.0% (max) with a mean score of 58.5% and a standard deviation of 17.7%. The 25th percentile, median, and 75th percentile were 50.7%, 61.9%, and 69.8%, respectively.

Unintended Consequences

One concern about unintended consequences with the Cross-Setting Discharge Function Score is that the measure may lead HHAs to selectively enroll patients, either by encouraging or avoiding admission of certain types of patients and patients with certain characteristics. To address this, providers' performance is evaluated among their peers after adjusting for difference in patient case-mix across HHAs. The risk adjustment methodology applied to this measure will help mitigate providers' incentive to selectively enroll patients. The variables included in the risk adjustment model are designed to capture patient characteristics that are associated with discharge functional status. Therefore, providers' performance on this measure will be adjusted for the characteristics of their patient population and ''level the playing field'' across providers. The detailed risk-adjustment strategy will be publicly available, allowing providers to understand that those who provide care for more ''high risk'' patients are not at a disadvantage given their patient case-mix. See the attached Technical Report for more details on the risk adjustment methodology. Another potential concern about the Cross-Setting Discharge Function Score measure could be that it focuses on a subset of the available GG items in HH. If the items are not included in this publicly reported measure, it could reduce the incentive to complete those items and could result in higher levels of ANAs. However, the GG items excluded from the Cross-Setting Discharge Function Score measure may be used in the future for the HH prospective payment system to calculate payment for HHAs, and are included in the statistical imputation models for the Cross-Setting Discharge Function Score measure. Together, these circumstances should provide an incentive for continued reporting of these GG items. Another possibility related to increased NA rates is that providers could strategically code NAs in an attempt to game the statistical imputation models. For instance, HHAs could record NA codes for patients who did not improve by discharge if the discharge imputation models would predict higher scores based on that patient`s characteristics. However, this type of gaming, where providers are determining in real-time which patients would perform better with statistical imputation than a true discharge score, would require sophisticated understanding and application of the imputation methodology. The Cross-Setting Discharge Function Score measure will be monitored to identify unintended consequences, including patient selection patterns or changes in NA coding, which could lead to future re-specification of the measure as needed.

Number of clinical guidelines, including USPSTF guidelines, that address this measure topic

1

Outline the clinical guidelines supporting this measure

The Academy of Orthopaedic Physical Therapy of the American Physical Therapy Association created these clinical practice guidelines to identify evidence-based physical therapy outcomes and interventions to address functional impairment, among other goals, for individuals above the age of 65 with hip fracture. These guidelines directly relate to the Cross-Setting Discharge Function Measure by

identifying evidence-based interventions that can be used to improve functional mobility for patients throughout the continuum of care, including post-acute and home-based care. While these findings target rehabilitation after hip fractures specifically, the authors highlight that hip fractures cause over 316,000 hospital admissions annually and are a common cause of poor functional mobility, disability, long-term complications, and mortality. As such, these guidelines are relevant to a large proportion of post-acute care patients and are especially pertinent to the proposed Cross-Setting Discharge Function Measure.

The guidelines include two types of recommendations: outcome measures for patient examination and evidence-based intervention strategies for physical therapy practice. The master list of 40 outcome measures, including sit-to-standing, gait speed, and endurance, was previously compiled in 2013 through a comprehensive search. A literature review on the properties of each measure was updated in May 2019. This literature was further graded based on the level of evidence. To identify intervention recommendations, the authors conducted a systematic review of literature on published literature from 2004 through 2020. A total of 51 studies were identified, including randomized control trials, systematic reviews and meta-analyses. Clinical practice guidelines were assessed for inclusion using the Appraisal of Guidelines for Research & Evaluation II (AGREE II) instrument. Individual clinical research articles were graded using an adapted version of the criteria from the Centre for Evidence-Based Medicine (Oxford, UK). Finally, the final guidelines were posted for public comment and reviewed by a group of consumer and clinician stakeholders to solicit and incorporate feedback.

The guidelines include evidence-based best practices to improve physical function among patients after a hip fracture to meet their individual goals for recovery. The included literature cites a range of supported interventions that can be used to improve function, including specific physical activities, motivational interviewing, home-based exercise, structured exercise routines, multidisciplinary care teams, and patient-tailored intensity and frequency levels.

Name the guideline developer/entity

The Academy of Orthopaedic Physical Therapy and the Academy of Geriatric Physical Therapy of the American Physical Therapy Association (APTA).

Publication year

2021

Full citation +/- URL

McDonough CM, Harris-Hayes M, Kristensen MT, et al. Physical Therapy Management of Older Adults With Hip Fracture. J Orthop Sports Phys Ther. 2021;51(2):CPG1-CPG81. doi:10.2519/jospt.2021.0301

Is this an evidence-based clinical guideline?

Yes

Is the guideline graded?

Yes

List the guideline statement that most closely aligns with the measure concept.

In reference to the Post-Acute Period, the guideline states:

Physical therapists should test and document hip extensor and abductor muscle strength in post-acute clinical settings.

What evidence grading system did the guideline use to describe strength of recommendation?

Other (enter here): AGREE II

List all categories and corresponding definitions for the evidence grading system used to describe strength of recommendation in the guideline?

The grading categories and corresponding definitions are as follows:

A: Strong evidence

A preponderance of level I and/or level II studies support the recommendation. This must include at least 1 level I study.

B: Moderate evidence

A single high-quality randomized controlled trial or a preponderance of level II studies support the recommendation.

C: Weak evidence

A single level II study or a preponderance of level III and IV studies, including statements of consensus by content experts, support the recommendation

D: Conflicting evidence

Higher-quality studies conducted on this topic disagree with respect to their conclusions. The recommendation is based on these conflicting studies

E: Theoretical/foundational evidence

A preponderance of evidence from animal or cadaver studies, from conceptual models/ principles, or from basic sciences/bench research support this conclusion

F: Expert opinion

Best practice based on the clinical experience of the guideline development group

For the guideline statement that most closely aligns with the measure concept, what is the associated strength of recommendation?

USPSTF Grade A, Strong recommendation or similar

What evidence grading system did the guideline use to describe level of evidence or level of certainty in the evidence?

Other (enter here): AGREE II

List all categories and corresponding definitions for the evidence grading system used to describe level of evidence or level of certainty in the evidence?

The grading categories and corresponding definitions are as follows:

A: Strong evidence

A preponderance of level I and/or level II studies support the recommendation. This must include at least 1 level I study.

B: Moderate evidence

A single high-quality randomized controlled trial or a preponderance of level II studies support the recommendation.

C: Weak evidence

A single level II study or a preponderance of level III and IV studies, including statements of consensus by content experts, support the recommendation

D: Conflicting evidence

Higher-quality studies conducted on this topic disagree with respect to their conclusions. The recommendation is based on these conflicting studies

E: Theoretical/foundational evidence

A preponderance of evidence from animal or cadaver studies, from conceptual models/principles, or from basic sciences/bench research support this conclusion

F: Expert opinion

Best practice based on the clinical experience of the guideline development group

For the guideline statement that most closely aligns with the measure concept, what is the associated level of evidence or level of certainty in the evidence?

USPSTF Grade A, Strong recommendation or similar

List the guideline statement that most closely aligns with the measure concept.

In reference to the Post-Acute Period, the guideline states:

Physical therapists should test and document hip extensor and abductor muscle strength in post-acute clinical settings.

Number of systematic reviews that inform this measure concept

2

Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept

1. Wysocki et al (2012) outlined goals to compare long-term care (LTC) for older adults delivered through Home and Community-Based Services (HCBS) with care provided in nursing homes

(NHs) by evaluating (1) the characteristics of older adults served through HCBS and in NHs; (2) the impact of HCBS and NH care on outcome trajectories of older adults; and (3) the per person costs of HCBS and NH care, costs for other services such as acute care, and family burden. They sought to determine the impact of care settings on outcomes, including function, cognition, mental health, use of acute services and mortality. They identified 42 relevant studies (37 peer reviewed, 5 grey literature). They identified no RCTs. Of the 37 peer-reviewed articles, 22 evaluated recipient characteristics at a specific time, and 15 analyzed outcome trajectories over time (of which 14 were used in the longitudinal analytic set). The 14 studies that compared the outcome trajectories of HCBS recipients or AL residents with NH residents over time had a high risk of bias, resulting in low or insufficient evidence for all outcomes examined. In comparing AL with NH, low-strength evidence suggested no differences in outcomes for physical function, cognition, mental health, and mortality.

2. Hillier and Inglis-Jassiem (2010) completed a systematic review that sought to pool data from all retrieved studies that compared the functional benefits of home-based vs. facility-based care for people with stroke. A comprehensive search strategy was implemented in all major databases (Cochrane library, Medline, AMED, Embase, Ageline, Cinahl, PEDro) for randomized controlled trials investigating this question in relation to functional benefits as a primary outcome. Eleven trials were found and results pooled for the Barthel Index, the measure of functional independence used consistently across the majority of retrieved studies. There was a significant effect in favour of home-based rehabilitation at 6 weeks (P=0.03) and 3-6 months (P=0.01). The effects were less clear at 6 months, although this was using the less sensitive version of the Barthel Index (P=0.27 or adjusted P=0.04). The provision of rehabilitation for people living in the community should trend towards home-based.

Source of empirical data

Published, peer-reviewed original research

Summarize the empirical data

Patients' functional status is associated with important patient outcomes, so measuring and monitoring adults' extent of engaging in self-care and mobility is valuable. Older adults' difficulties with comprehension and communication strongly correlate with lack of medication management and increased risk for hospital readmission [1]. Difficulties with ADLs and Instrumental Activities of Daily Living (IADLs) among the elderly [2]; chronic illness comorbidities, such as chronic pain among the older adult population [3]; and financial instability in patients with a history of heart failure [4] are associated with decreases in self-sufficiency and patient activation (defined as the patient`s knowledge and confidence in self-managing their health). Impaired mobility, frailty, and low physical activity are associated with institutionalization [5], higher risk of falls and falls-related hip fracture and death, [6][7] greater risk of undernutrition [8], higher emergency department admissions [9], higher risk of readmissions following home care [10], and higher prevalence of hypertension and diabetes [11]. Predictors of poorer recovery in ADLs include greater age, complications after hospital discharge, and residence in a nursing home [12]. Understanding correlates of poorer ADL/IADL recovery facilitates the ability to estimate expected functional outcome recovery for patients, based on their personal characteristics. Home health care can positively impact functional outcomes. In stroke patients, home-based rehabilitation programs administered by home health clinicians significantly improved ADL function and gait performance [13]. Home health services, delivered by a registered nurse positivity

impacted patient Quality of Life (QOL) and clinical outcomes, including significant improvement in dressing lower body and bathing ADLs, meal preparation, shopping, and housekeeping IADLs [14]. In addition, a retrospective study, using data abstracted from the Minimum Data Set (MDS) and OASIS, reported that nursing home admissions were delayed in the study population receiving home health services by an average of eight months [15] and for a similar population, community dwelling adults receiving community-based services supporting aging in place, enhanced health and functional outcomes, improved cognition and lower rates of depression, ADL assistance, and incontinence were noted [16]. Overall, literature indicates that HHAs can influence functional outcomes at discharge. As such, variations in functional status of HHA patients at discharge could be measured and monitored through the Cross-Setting Discharge Function Score Measure. Since function outcomes vary based on patient characteristics, the Cross-Setting Discharge Function Score measure adjusts for relevant risk factors.

References:

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3. Roberts AR, Betts Adams K, Beckette & Warner C. (2016). Effects of chronic illness on daily life and barriers to self-care for older women: a mixed-methods exploration. J Women Aging, Jul 25:1-11.

4. Wu, J.-R., Lennie, T. A., & Moser, D. K. (2016). A prospective, observational study to explore health disparities in patients with heart failure-ethnicity and financial status. European Journal of Cardiovascular Nursing: Journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology. https://doi.org/10.1177/1474515116641296

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8. van der Pols-Vijlbrief, R., Wijnhoven, H. A. H., Bosmans, J. E., Twisk, J. W. R., & Visser, M. (2016). Targeting the underlying causes of undernutrition. Cost-effectiveness of a multifactorial personalized

intervention in community-dwelling older adults: A randomized controlled trial. Clinical Nutrition (Edinburgh, Scotland). https://doi.org/10.1016/j.clnu.2016.09.030

9. Hominick, K., McLeod, V., & Rockwood, K. (2016). Characteristics of older adults admitted to hospital versus those discharged home, in emergency department patients referred to internal medicine. Canadian Geriatrics Journal : CGJ, 19(1), 9-14. https://doi.org/10.5770/cgj.19.195

10. Middleton, A. Downer, B., Haas, A., Knox, S., & Ottenbacher, K.J. (2019) Functional status ss associated with 30-day potentially preventable readmissions following home health Care. Medical Care, 57(2):145-151.

11. Halaweh, H., Willen, C., Grimby-Ekman, A., & Svantesson, U. (2015). Physical activity and health-related quality of life among community dwelling elderly. J Clin Med Res, 7(11), 845-52.

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13. Asiri, F. Y., Marchetti, G. F., Ellis, J. L., Otis, L., Sparto, P. J., Watzlaf, V., & Whitney, S. L. (2014). Predictors of functional and gait outcomes for persons poststroke undergoing home-based rehabilitation. Journal of Stroke and Cerebrovascular Diseases: The Official Journal of National Stroke Association, 23(7), 1856-1864. https://doi.org/10.1016/j.jstrokecerebrovasdis.2014.02.025

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16. Marek, K.D., Popejoy, I., Petroski, G. et al. (2005). Clinical outcomes of aging in place. Nurs Res; 54:202-211.

Name evidence type

N/A

Summarize the evidence

N/A

Does the evidence discuss a link between at least one process, structure, or intervention with the outcome?

No

Estimated Impact of the Measure: Estimate of Annual Denominator Size

4,661,161

Type of Evidence to Support the Measure

Clinical Guidelines or USPSTF (U.S. Preventive Services Task Force) Guidelines; Peer-Reviewed Systematic Review; Empirical data

Is the measure risk adjusted?

Yes

Risk adjustment variables

Patient-level demographics ;Patient-level health status & clinical conditions;Patient functional status

Patient-level demographics: please select all that apply:

Age

Patient-level health status & clinical conditions: please select all that apply:

Case-Mix Adjustment

Patient functional status: please select all that apply:

Body Function; Ability to perform activities of daily living

Patient-level social risk factors: please select all that apply:

N/A

Proxy social risk factors: please select all that apply

N/A

Patient community characteristic: please select all that apply:

N/A

Risk model performance

The risk adjustment model was an ordinary least squares (OLS) linear regression. A well-calibrated model demonstrates good predictive ability to distinguish high-risk from low-risk patients. To assess risk adjustment model calibration, we calculated the ratio of observed-to-predicted discharge function score across eligible stays by decile of predicted discharge function score (risk). The average ratio of observed-to-predicted scores for each risk decile ranged from 0.98 to 1.02, which suggested good calibration across the range of patients without evidence of concerning under- or over-estimation. We analyzed model fit using adjusted R-squared to determine if the risk adjustment model can accurately predict discharge function while controlling for patient case-mix. The adjusted R-squared value was 0.51, which suggests good model discrimination.

Rationale for not using risk adjustment

N/A

Cost estimate completed

No

Cost estimate methods and results

N/A

Section 3: Patient and Provider Perspective

Meaningful to Patients. Was input on the final performance measure collected from patient and/or caregiver?

No

Total number of patients and/or caregivers who responded to the question asking them whether the final performance measure helps inform care and decision making

N/A

Total number of patients/caregivers who agreed that the final performance measure helps inform care and decision making

N/A

Meaningful to Patients: Numbers consulted

N/A

Meaningful to Patients: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians: Numbers consulted

N/A

Meaningful to Clinicians: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians. Were clinicians and/or providers consulted on the final performance measure?

No

Total number of clinicians/providers who responded when asked if the final performance measure was actionable to improve quality of care.

N/A

Total number of clinicians/providers who agreed that the final performance measure was actionable to improve quality of care

N/A

Survey level testing

N/A

Type of Testing Analysis

N/A

Testing methodology and results

N/A

Burden for Provider: Was a provider workflow analysis conducted?

No

If yes, how many sites were evaluated in the provider workflow analysis?

N/A

Did the provider workflow have to be modified to accommodate the new measure?

N/A

Section 4: Measure Testing Details

Reliability

Yes

Reliability: Type of Reliability Testing

Random Split-Half Correlation

Signal-to-Noise: Name of statistic

N/A

Signal-to-Noise: Sample size

N/A

Signal-to-Noise: Statistical result

N/A

Signal-to-Noise: Interpretation of results

N/A

Random Split-Half Correlation: Name of statistic

Split-sample Reliability Testing: This testing examined agreement between two performance measure scores for a facility based on randomly-split, independent subsets of HH episodes in the same measurement period. We randomly divided each HHA's CY 2019 HH episodes into halves. We calculated performance measure scores for each split-half sample using the same measure specification. We calculated Shrout-Fleiss intraclass correlation coefficients (ICC (2, 1)) between the split-half scores to measure reliability [ ]. [1] McGraw, K. O., & Wong, S. P. (1996). Forming inferences about some intraclass correlation coefficients. Psychological methods, 1(1), 30.

Random Split-Half Correlation: Sample size

8,171

Random Split-Half Correlation: Statistical result

0.94

Random Split-Half Correlation: Interpretation of results

Excellent reliability

Poor <0.50

Moderate 0.50-0.75

Good 0.75-0.90

Excellent >0.90

Koo T.K. & Li M.Y. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. Journal of Chiropractic Medicine, 2016, 15(2), 155-163.

Other: Name of statistic

N/A

Other: Sample size

N/A

Other: Statistical result

N/A

Other: Interpretation of results

N/A

Empiric Validity

Yes

Empiric Validity: Statistic name

Empirical validity testing included tests of convergent validity. To evaluate convergent validity of measure scores, we measured Spearman`s rank correlation between the Cross-Setting Discharge Function Score measure and other HH QRP measures. The analysis used CY 2019 data and only included data from HHAs with at least 20 stays. Higher functional status corresponds with higher likelihood of community discharge [1]. As expected, this measure demonstrated positive correlation with the Discharge to Community measure (0.23), which was significant ($p<0.05$). Correlation was also positive with Improvement in Ambulation (0.22), Improvement in Bed Transfer (0.33), Improvement in Bathing (0.20), Improvement in Dyspnea (0.25), and Improvement in Oral Medication Management (0.19). 1. Minor M, Jaywant A, Toglia J, Campo M, O'Dell MW. Discharge Rehabilitation Measures Predict Activity Limitations in Patients with Stroke Six Months after Inpatient Rehabilitation. Am J Phys Med Rehabil. 2021 Oct 20. doi: 10.1097/PHM.0000000000001908. Epub ahead of print. PMID: 34686630.

Empiric Validity: Sample size

7,599

Empiric Validity: Statistical result

0.23

Empiric Validity: Methods and findings

To assess face validity of the Cross-Setting Discharge Function Score measure, we convened two Technical Expert Panel (TEP) meetings (July 2021 and January 2022), [1] as well as a Patient and Family Engagement Listening Session. TEP members showed strong support for the face validity of this measure. Though a vote was not taken at the meeting, the TEP agreed with the conceptual and operational definition of the measure. Panelists reviewed the validity analyses described herein and agreed they demonstrated measure validity. Additionally, panelists agreed that the Cross-Setting Discharge Function Score measure adds value over the measures currently in-use in the SNF QRP (see

Similar Measures of the SNF MUC submission form). Additionally, the Patient and Family Engagement Listening Session demonstrated that the measure concept resonates with patients and caregivers. Participants understood and found important what self-care and mobility mean for patient outcomes. Participants emphasized the importance of measuring functional outcomes and were specifically interested in metrics that show how many patients discharged from particular HHAs made improvements in self-care and mobility.

To evaluate convergent validity of measure scores, we measured Spearman`s rank correlation between the Cross-Setting Discharge Function Score measure and other HH QRP measures (see Empiric validity: Statistic name).

The risk adjustment model is an ordinary least squares (OLS) linear regression. We assessed risk adjustment model calibration and fit using CY 2019 data. A well-calibrated model demonstrates good predictive ability to distinguish high-risk from low-risk patients. To assess risk adjustment model calibration, we calculated the ratio of observed-to-predicted discharge function score across eligible stays by decile of predicted discharge function score (risk). The average ratios of observed-to-predicted scores for each risk decile ranged from 0.98 to 1.02, which suggested good calibration across the range of patients without evidence of concerning under- or over-estimation. We analyzed model fit using adjusted R-squared to determine if the risk adjustment model can accurately predict discharge function while controlling for patient case-mix. The adjusted R-squared value was 0.51, which suggests good model discrimination.

We evaluated internal consistency, which demonstrates how well items interrelate. We measured Cronbach`s alpha coefficient for the GG items used in the numerator calculation, which reflects the average correlation of all possible item-pairs and ranges from 0 to 1 (where 0 indicates no consistency of measurement among the items and 1 indicates perfect consistency). General consensus is that Cronbach`s alpha should be at least 0.70 for an adequate scale for group-level decisions. [2] Cronbach`s alpha was 0.95 at admission and 0.97 at discharge for non-wheelchair-bound patients and was 0.95 at admission and 0.96 for wheelchair-bound patients, indicating good consistency in GG item scores used in the measure score. Note that although only discharge item scores are used to calculate observed discharge function score, admission function scores are used in the risk adjustment model.

In in-use SNF QRP functional outcome measures--of which the Cross-Setting Discharge Function Score for HH is modeled--all missing item scores (i.e., Not Attempted, or NA, codes) are recoded to the code signifying the patient is completely dependent for an activity. However, TEP panelists agreed that NA codes may not always signify that a patient was dependent on a functional activity.[1] As a refinement, statistical imputation was implemented to predict item scores for patients where a GG item was NA using models that adjust for patient clinical characteristics. We evaluated the empiric validity of our imputation methodology using the following analyses (see the Technical Report for full details).

1. We used ordered probit models to estimate admission and discharge scores for each GG item used in measure construction. To evaluate model fit of imputation models, we calculated C-statistics for each of the 22 imputation models. C-statistics ranged from 0.86-0.99, and the mean C-statistic was 0.96.
2. A bootstrapping method was used to measure bias and mean squared error (MSE) in the imputation method compared to the recode approach used in the self-care and mobility

functional outcome measures. Bias measures the average amount by which the imputed value differs from the true value. Bias is signed, with a positive amount meaning that the imputed values were higher, on average, than were the true values. MSE measures how far away the method is, on average from the truth. It is unsigned and can be positive even if bias is zero. The absolute size of bias is an inverse measure of accuracy, while the size of MSE is an inverse measure of the combination of precision and accuracy. The goal of the bootstrapping method was to determine how similar imputed values were to the true item score. For each bootstrap, episodes with complete item data were sampled using stratified random sampling. Two copies were made of this sample. The first copy was the original with known item scores. Missing item scores were imposed on the second copy, and now-missing item scores were estimated using both statistical imputation and the recode approach. Item scores estimated through each approach were compared to the known item scores from the first copy. The MSE and bias statistics were calculated as averages across bootstraps. For statistical imputation, average MSE was 1.44 at admission and 1.23 at discharge, and average bias was -0.22 at admission and -0.15 at discharge. For the recode approach, average MSE was 4.60 at admission and 13.30 at discharge, and average bias was -0.54 at admission and -0.70 at discharge. This result indicates that statistical imputation produced less biased, more precise estimates for missing item scores.

3. We calculated the difference in discharge function between episodes that have bona fide item scores at admission and stays with NA codes at admission where we impute to estimate the item score. This difference provides a metric of how accurately imputed item scores reflect true patient function. For all 11 items, the difference was lower than if these ANAs were recoded to the most dependent level of functional status. This result indicates that statistical imputation produced more accurate results.

[1] https://www.cms.gov/sites/default/files/2022-04/PAC-Function-TEP-Summary-Report-Jul2021.pdf

[2] Aron A, Aron EN Statistics for Psychology. 2nd ed. Upper Saddle River, NJ: Prentice Hall, 1999.

Empiric Validity: Interpretation of results

Yes

Face Validity

No

Face Validity: Number of voting experts and patients/caregivers

N/A

Face Validity: Result

N/A

Patient/Encounter Level Testing

Yes

Type of Analysis

Agreement between two manual reviewers

Sample Size

448

Statistic Name

Kappa

Statistical Results

0.558

Interpretation of results

A final report on the development of the Continuity Assessment Record and Evaluation (CARE) Tool included reliability and validity testing for self-care and mobility data elements, as well as data elements used as risk adjustors for the Cross-Setting Discharge Function Score measure. [1]

The inter-rater reliability of the GG items was tested in a subset of 34 providers (acute hospitals, HHAs, IRFs, LTCHs, and SNFs) distributed across 11 geographic areas. Each provider completed a duplicate admission or discharge assessment on 10-20 patients. The overall sample size was 449 for mobility items (448 for transfers). Kappa statistics were calculated to assess the level of agreement between raters since the GG item responses are ordinal (1, 2, 3, 4, 5, 6). Kappas ranged from 0.667 for walk 10 feet to 0.762 for sit to stand, which indicated substantial agreement of data element codes among raters.

[1] Gage BJ, Smith LM, Ross J, Coots LA, Shamsuddin KM, Deutsch A, Mallinson T, Reilly KE, Abbate JH, Gage-Croll Z. (August, 2012). The development and testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on Reliability Testing, Volume 2 of 3. Prepared for Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/files/document/development-and-testing-continuity-assessment-record-and-evaluation-care-item-set-final-report.pdf

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Higher score is better

Mean performance score

58.5

Median performance score

61.9

Minimum performance score

0.0

Maximum performance score

100.0

Standard deviation of performance scores

17.7

Does the performance measure use survey or patient-reported data?

No

Surveys or patient-reported outcome tools

N/A

Section 5: Measure Contact Information

Measure Steward

Centers for Medicare & Medicaid Services

Measure Steward Contact Information

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Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

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Submitter Comments

N/A

MUC2022-086 Cross-Setting Discharge Function Score

Program

Skilled Nursing Facility Quality Reporting Program; Skilled Nursing Facility Value-Based Purchasing Program

Section 1: Measure Information

Measure Specifications and Endorsement Status

Measure Description

This measure estimates the percentage of Medicare Part A SNF stays that meet or exceed an expected discharge function score.

Numerator

The number of Medicare Part A SNF stays in the denominator with a discharge function score that is equal to or higher than the calculated expected discharge function score.

The function items used to determine the observed function score are: Eating (GG0130A3), Oral Hygiene (GGO130B3), Toileting Hygiene (GG0130C3), Roll left and right (GG0170A3), Lying to sitting on side of the bed (GG0170C3), Sit to stand (GG0170D3), Chair/bed-to-chair transfer (GG0170E3), Toilet transfer (GG0170F3), and Walk 10 feet (GG0170I3) and Walk 50 feet with two turns (GG0170J3) if not wheelchair-bound, or Wheel 50 feet with two turns (GG0170R3) if wheelchair-bound. The definitionwheelchair-boundound is specified in the Technical Report attachment.

The expected discharge function score is a risk-adjusted estimate that accounts for resident characteristics.

Numerator Exclusions

N/A

Denominator

The total number of Medicare Part A SNF stays, except those that meet the exclusion criteria.

Denominator Exclusions

Medicare Part A SNF Stays are excluded if:

(i) The Medicare Part A SNF Stay is an incomplete stay: Residents with incomplete stays are identified based on the following criteria:

Unplanned discharge, which would include discharge against medical advice

Discharge to acute hospital, psychiatric hospital, long-term care hospital

SNF PPS Part A stay less than 3 days

The resident died during the SNF stay

(ii) The resident has the following medical conditions at the time of admission (i.e., on the 5-Day PPS assessment):

> Coma, persistent vegetative state, complete tetraplegia, locked-in syndrome, or severe anoxic brain damage, cerebral edema or compression of brain.

(iii) The resident is younger than age 18

(iv) The resident is discharged to hospice or received hospice while a resident

(v) The resident did not receive physical or occupational therapy services at the time of admission

Denominator Exceptions

N/A

State of development

Fully Developed

State of Development Details

N/A

What is the target population of the measure?

SNF patients included in the MDS assessment instrument

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Physical medicine and rehabilitation

Measure Type

Outcome

Is the measure a composite or component of a composite?

Not a composite or component of a composite measure

If Other, Please Specify

N/A

What data sources are used for the measure?

Standardized Patient Assessments

If applicable, specify the data source

N/A

Description of parts related to these sources

All data elements used to specify the measure are sourced from the Minimum Data Set (MDS).

At what level of analysis was the measure tested?

Facility

In which setting was this measure tested?

Skilled nursing facility

Multiple Scores

No

What one healthcare domain applies to this measure?

Person-Centered Care

MIPS Quality: Identify any links with related Cost measures and Improvement Activities

N/A

Is this measure in the CMS Measures Inventory Tool (CMIT)?

No

CMIT ID

N/A

Alternate Measure ID

N/A

What is the endorsement status of the measure?

Never Submitted

CBE ID (CMS consensus-based entity, or endorsement ID)

9999

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

N/A

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

2023

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

No

If eCQM, enter Measure Authoring Tool (MAT) number

N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?

N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?

No

Previous Measure Information

N/A

What is the history or background for including this measure on the new measures under consideration list?

New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs

N/A

What other federal programs are currently using this measure?

N/A

Is this measure similar to and/or competing with a measure(s) already in a program?

Yes

Which measure(s) already in a program is your measure similar to and/or competing with?

The following measures are used in the SNF QRP (but not the SNF VBP):

1) SNF Functional Outcome Measure: Discharge Self-Care Score for Skilled Nursing Facility Residents (NQF #2635) (CMS ID: S024.02)
2) SNF Functional Outcome Measure: Change in Self-Care Score for Skilled Nursing Facility Residents (NQF #2633) (CMS ID: S022.02)
3) SNF Functional Outcome Measure: Change in Mobility Score for Skilled Nursing Facility Residents (NQF #2634) (CMS ID: S023.02)
4) SNF Functional Outcome Measure: Discharge Mobility Score for Skilled Nursing Facility Residents (NQF #2636) (CMS ID: S025.02)

How will this measure be distinguished from other similar and/or competing measures?

This measure differs from in-use functional outcome measures in the following ways:

1) It only incorporates GG items that are currently available across IRF, LTCH, SNF, and HH.
2) It uses self-care and mobility activities in the same measure.

3) Risk adjustment models have been modified to align across settings, where appropriate, and include terms that are relevant for both self-care and mobility.
4) Item scores are estimated with statistical imputation for items with Not Attempted (NA) codes.

How will this measure add value to the CMS program?

To determine how to construct a cross-setting function measure that adds value to the PAC QRPs, we convened two Technical Expert Panel (TEP) meetings (July 2021 and January 2022) throughout the course of measure development. During these meetings, panelists expressed that:

1. The SNF QRP would benefit from having a cross-setting functional outcome measure to add to the in-use function process measure (Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) (CMS ID: S001.03)). SNFs tend to perform well on the process measure. The mean score for FY2019 was 99%. The Cross-Setting Discharge Function measure has higher variation in provider performance (see Field 98) and offers more informative comparisons between SNFs for patients, caregivers, and stakeholders.
2. Both self-care and mobility GG items should be used for the measure because this provides a more comprehensive readout of providers' capacity to improve functional status that considers both dimensions of function together.[1] This is a valuable addition to the SNF QRP self-care and mobility functional outcome measures that consider each dimension separately.
3. The Cross-Setting Discharge Function Score measure benefits from being specified to align across PAC settings (IRF, LTCH, SNF, HHA). Due to limited GG item availability in LTCH, only a subset of items can be used to produce measure scores that could be computed identically in each PAC setting. We calculated measure scores with all GG items available in SNF v. the subset available in LTCH. Panelists reviewed comparisons between provider scores and model fit and found that the narrower set of GG items provides similar capture of functional status. [1]
4. Not Attempted (NA) codes are used frequently on assessments for certain GG items, and statistical imputation should be used as the method to estimate resulting missing item scores. In other SNF QRP measures, all missing item scores are recoded to the code signifying the patient is completely dependent for an activity (i.e., 1). Panelists reviewed evidence showing that discharge item scores for patients scored as NA at admission tended to be higher than those scored as 1 at admission. Combining this evidence with their experience seeing how clinicians code NAs in real-world practice, they agreed that NA codes do not always signify that a patient was dependent on a functional activity and that the recode approach could be improved upon. [1] As an alternative to the recode approach, statistical imputation predicts item scores based on patient clinical characteristics and function scores on other GG items. Panelists also reviewed empiric validity results on our statistical imputation approach (see Field 42) and agreed the method produced more accurate item score estimates than the recode approach.

Notably, in addition to the SNF QRP, the Cross-Setting Discharge Function Score measure is intended for the SNF VBP, which does not use the self-care and mobility functional outcome measures. This would contribute a measure to the SNF VBP belonging to the person-centered care domain of CMS's Meaningful Measure Framework.

[1] https://www.cms.gov/sites/default/files/2022-04/PAC-Function-TEP-Summary-Report-Jul2021.pdf

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

Improving Medicare Post-Acute Care Transformation Act of 2014 (H.R.4994)

Section 2: Measure Evidence

How is the measure expected to be reported to the program?

Other: Minimum Data Set (MDS)

Stratification

No

Feasibility of Data Elements

ALL data elements are in defined fields in electronic sources

Feasibility Assessment

A feasibility assessment was not necessary. The MDS data elements used for measure construction are part of the standard data collection processes for SNF providers and are already used in existing SNF QRP measures.

Method of Measure Calculation

Other digital method

Hybrid measure: Methods of measure calculation

N/A

Evidence of Performance Gap

An analysis of FY 2019 data indicates that there is a performance gap in Cross-Setting Discharge Function Scores across providers. Among 12,703 SNFs included, risk-adjusted measure scores ranged from 0.0% (min) to 100.0% (max) with a mean score of 54.7% and a standard deviation of 15.1%. The 25th percentile, median, and 75th percentile were 45.0%, 55.8%, and 65.4%, respectively.

Unintended Consequences

CMS monitors trends in the data elements that are used for the Cross-Setting Discharge Function measure and in measure scores and patient populations for SNF QRP functional outcome measures (Change in Self-Care, Discharge Self-Care, Change in Mobility, and Discharge Mobility). So far, CMS has not detected any evidence of unintended consequences with these data elements and will continue to monitor them.

One concern about unintended consequences with the Cross-Setting Discharge Function Score is that the measure may lead SNFs to selectively enroll residents, either by encouraging or avoiding admission of certain types of residents and residents with certain characteristics. To address this, providers' performance is evaluated among their peers after adjusting for difference in resident case-mix across SNFs. The risk adjustment methodology applied to this measure will help mitigate providers' incentive to selectively enroll residents. The variables included in the risk adjustment model are designed to capture resident characteristics that are associated with discharge functional status. Therefore, providers'

performance on this measure will be adjusted for the characteristics of their resident population and 'level the playing field' across providers. The detailed risk-adjustment strategy will be publicly available, allowing providers to understand that those who provide care for more 'high risk' residents are not at a disadvantage given their resident case mix. See the attached Technical Report for more details on the risk adjustment methodology.

Another potential concern about the Cross-Setting Discharge Function Score measure could be that it focuses on a subset of the available GG items in SNF. If the items are not included in this publicly reported measure, it could reduce the incentive to complete those items and could result in higher levels of Not Attempted (NA) codes. However, the GG items excluded from the Cross-Setting Discharge Function Score numerator are used in the SNF prospective payment system to calculate payment for SNFs and are included in the statistical imputation models for the Cross-Setting Discharge Function Score measure. Together, these circumstances should provide an incentive for continued reporting of these GG items.

Another possibility related to increased NA rates is that providers could strategically code NAs in an attempt to game the statistical imputation models. For instance, SNFs could record NA codes for patients who did not improve by discharge if the discharge imputation models would predict a higher score based on that patient's characteristics. However, this type of gaming, where providers are determining in real-time which patients would perform better with statistical imputation than a true discharge score, would require sophisticated understanding and application of the imputation methodology.

The Cross-Setting Discharge Function Score measure will be monitored to identify unintended consequences, including patient selection patterns or changes in NA coding, which could lead to future re-specification of the measure as needed.

Number of clinical guidelines, including USPSTF guidelines, that address this measure topic

1

Outline the clinical guidelines supporting this measure

The Academy of Orthopaedic Physical Therapy of the American Physical Therapy Association created clinical practice guidelines to identify evidence-based physical therapy outcomes and interventions to address functional impairment, among other goals, for individuals above the age of 65 with hip fracture. These guidelines directly relate to the Cross-Setting Discharge Function Measure by identifying evidence-based interventions that can be used to improve functional mobility for patients throughout the continuum of care, including post-acute and home-based care. While these findings target rehabilitation after hip fractures specifically, the authors highlight that hip fractures cause over 316,000 hospital admissions annually and are a common cause of poor functional mobility, disability, long-term complications, and mortality. As such, these guidelines are relevant to a large proportion of post-acute care patients and are especially pertinent to the proposed Cross-Setting Discharge Function Measure.

The guidelines include two types of recommendations: outcome measures for patient examination and evidence-based intervention strategies for physical therapy practice. The master list of 40 outcome measures, including sit-to-standing, gait speed, and endurance, was previously compiled in 2013 through a comprehensive search. A literature review on the properties of each measure was updated in

May 2019. Measures were graded based on metrics of reliability and validity. This literature was further graded based on the level of evidence. To identify intervention recommendations, the authors conducted a systematic review of literature on published literature from 2004 through 2020. A total of 51 studies were identified, including randomized control trials, systematic reviews and meta-analyses. Clinical practice guidelines were assessed for inclusion using the Appraisal of Guidelines for Research & Evaluation II (AGREE II) instrument. Individual clinical research articles were graded using an adapted version of the criteria from the Centre for Evidence-Based Medicine (Oxford, UK). Finally, the final guidelines were posted for public comment and reviewed by a group of consumer and clinician stakeholders to solicit and incorporate feedback.

The guidelines include evidence-based best practices to improve physical function among patients after a hip fracture to meet their individual goals for recovery. The included literature cites a range of supported interventions that can be used to improve function, including specific physical activities, motivational interviewing, home-based exercise, structured exercise routines, multidisciplinary care teams, and patient-tailored intensity and frequency levels.

Name the guideline developer/entity

The Academy of Orthopaedic Physical Therapy and the Academy of Geriatric Physical Therapy of the American Physical Therapy Association (APTA).

Publication year

2021

Full citation +/- URL

McDonough CM, Harris-Hayes M, Kristensen MT, et al. Physical Therapy Management of Older Adults With Hip Fracture. J Orthop Sports Phys Ther. 2021;51(2):CPG1-CPG81. doi:10.2519/jospt.2021.0301

Is this an evidence-based clinical guideline?

Yes

Is the guideline graded?

Yes

List the guideline statement that most closely aligns with the measure concept.

In reference to the Post-Acute Period for Post-Acute Skilled-Nursing Settings, the guideline states:

Physical therapists should test and document hip extensor and abductor muscle strength in post-acute clinical settings.

What evidence grading system did the guideline use to describe strength of recommendation?

Other (enter here): AGREE II

List all categories and corresponding definitions for the evidence grading system used to describe strength of recommendation in the guideline?

The grading categories and corresponding definitions are as follows:

A: Strong evidence

A preponderance of level I and/or level II studies support the recommendation. This must include at least 1 level I study.

B: Moderate evidence

A single high-quality randomized controlled trial or a preponderance of level II studies support the recommendation.

C: Weak evidence

A single level II study or a preponderance of level III and IV studies, including statements of consensus by content experts, support the recommendation

D: Conflicting evidence

Higher-quality studies conducted on this topic disagree with respect to their conclusions. The recommendation is based on these conflicting studies

E: Theoretical/foundational evidence

A preponderance of evidence from animal or cadaver studies, from conceptual models/principles, or from basic sciences/bench research support this conclusion

F: Expert opinion

Best practice based on the clinical experience of the guideline development group

For the guideline statement that most closely aligns with the measure concept, what is the associated strength of recommendation?

USPSTF Grade A, Strong recommendation or similar

What evidence grading system did the guideline use to describe level of evidence or level of certainty in the evidence?

Other (enter here): Oxford Centre for Evidence-Based Medicine Levels of Evidence

List all categories and corresponding definitions for the evidence grading system used to describe level of evidence or level of certainty in the evidence?

The categories for grading evidence range from I to V and are defined as follows:

I: Evidence obtained from high-quality diagnostic studies, prospective studies, randomized controlled trials, or systematic reviews.

II: Evidence obtained from lesser-quality diagnostic studies, prospective studies, systematic reviews, or randomized controlled trials (eg, weaker diagnostic criteria and reference standards, improper randomization, no blinding, less than 80% follow-up)

III: Case-control studies or retrospective studies

IV: Case series

V: Expert opinion

For the guideline statement that most closely aligns with the measure concept, what is the associated level of evidence or level of certainty in the evidence?

High or similar

List the guideline statement that most closely aligns with the measure concept.

In reference to the Post-Acute Period for Post-Acute Skilled-Nursing Settings, the guideline states:

Physical therapists should test and document hip extensor and abductor muscle strength in post-acute clinical settings.

Number of systematic reviews that inform this measure concept

3

Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept

[1] Due to the October 2019 SNF Prospective Payment System's (PPS) shift from the Resource Utilization Group-IV (RUG-IV) to the Patient Driven Payment Model (PDPM) in which therapy minutes were removed as the basis for therapy payment, Prusynski et al. (2021) sought to synthesize current evidence on the relationship between therapy intensity (a SNF process) and patient outcomes, such as functional improvement, among short-stay SNF residents. Authors independently screened articles and assessed risk of bias of eligible full text articles using the Academy of Neurology (AAN) evidence classification scheme for causation questions. Based on AAN guidelines, the level of confidence in the evidence for causal relationships between therapy intensity and each outcome was determined. After identifying and screening 776 articles, eight articles were eligible for inclusion in the systematic review. Three studies in the systematic review assessed functional improvement and had moderately high risk of bias for functional improvement outcomes. One prospective study found no difference in improvement on Short Physical Performance Battery (SPPB) or in gait speed with additional therapy time for the general SNF population. Another study found a 0.43- and 0.69- point-per-day increase in total Functional Independence Measure (FIM) score for patients receiving 1-1.5 hours per day and more than 1.5 hours per day of therapy compared with those receiving less than 1 hour per day of therapy. The last study found a 0.29-point increase in total FIM score per additional hour of therapy provided during SNF admission. While studies of functional improvement included in the Prusynski et al. (2021) review found positive associations between processes of higher intensity therapy and patient functional improvement, the risk of bias in individual studies was moderately high. Overall, SNF processes such as the amount and intensity of therapy provisions may impact resident functional outcomes.

[2] Alcusky et al., (2018) sought to synthesize literature characterizing the relationship between site of rehabilitation (SNF versus IRF) and health outcomes, including functional status, among stroke patients. Authors tracked the eligibility of articles using guidelines from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), which accounts for quality and biases of articles. Additionally, the accuracy of abstracted data was authenticated by a reviewer. The review yielded a total of 14 full-text articles meeting eligibility criteria, in which eight studies compared health outcomes between patients rehabilitated in SNFs and IRFs, and six studies evaluated relationships between facility characteristics and health outcomes. Out of the 14 total studies, four studies assessed physical

functioning comparing IRF and SNF stroke patients. In one study, SNF residents made larger gains in mobility compared to IRF patients. In another study, clinically relevant functional gains among IRF patients were more common than those in SNFs. Similarly, another study found that patients in IRF settings regained more activities of daily living at six weeks compared to SNF residents. The final study revealed higher Activity Measure for Post-Acute Care (AM-PAC) scores at six months among IRF patients than those in SNFs, with higher scores representing greater functional independence. Overall, most studies showed greater functional status among IRF patients than those in SNFs among stroke patients. The difference between functional outcomes in IRFs versus SNFs may be related to stringent IRF admission criteria which requires that patients are able to complete three hours of rehabilitation therapy daily.* In alignment with the functional outcome results from the Prusynski et al. (2021) review [1], higher intensity therapy processes may result in better functional outcomes.

[3] Jewell et al., (2019) conducted a scoping review to examine the effectiveness of occupational therapy (OT) interventions provided within the SNF as there is a gap between the provision of best versus actual OT practices. This scoping review differed from a traditional systematic review in that it did not assess the quality of studies included in the review. However, the review process was guided by and documented with the Research Instruction Guide Review. A total of 21 articles were included in the review that identified at least one OT intervention. Overall, although there is evidence for best practices of occupation-centered curricula, a gap remains in clinical practice. Investigators found that 14 of the 21 studies included in the review did not use occupation as the primary therapy intervention. Additionally, the review did not find conclusive evidence supporting the use of occupation centered and non-occupation centered strategies for improvement in SNF functional outcomes. Authors emphasized that traditional approaches of exercise, rote practice, and passive interventions remain embedded within OT culture. Overall, SNF resident functional status may vary depending on the provision of occupation centered or non-occupation centered OT intervention.

References:

[1] Prusynski, R. A., Gustavson, A. M., Shrivastav, S. R., & Mroz, T. M. (2021). Rehabilitation Intensity and Patient Outcomes in Skilled Nursing Facilities in the United States: A Systematic Review. Physical therapy, 101(3), pzaa230. https://doi.org/10.1093/ptj/pzaa230

[2] Alcusky, M., Ulbricht, C. M., & Lapane, K. L. (2018). Postacute Care Setting, Facility Characteristics, and Poststroke Outcomes: A Systematic Review. Archives of physical medicine and rehabilitation, 99(6), 1124-1140.e9. https://doi.org/10.1016/j.apmr.2017.09.005

[3] Jewell, V., Pickens N.D., Burns, S. (2019). Occupational Therapy Interventions in Skilled Nursing Facilities: A Scoping Review. Annals of International Occupational Therapy, 2(2). https://doi.org/10.3928/24761222-20190218-03

[*] Hong, I., Goodwin, J.S., Reistetter, T.A., Kuo, Y.F., Mallinson, T., Karmarkar, A., Lin Y.L., Ottenbacher, K.J. (2019). Comparison of Functional Status Improvements Among Patients With Stroke Receiving Postacute Care in Inpatient Rehabilitation vs Skilled Nursing Facilities. JAMA Netw Open, 2(12), e1916646. https://doi.org/10.1001/jamanetworkopen.2019.16646

Source of empirical data

Published, peer-reviewed original research

Summarize the empirical data

SNF care is comprised of several core services, including the provision of rehabilitation therapy to those experiencing functional deficits following discharge from a hospital stay.[1] Physical function is a modifiable predictor of several outcomes including successful discharge to the community, functional recovery, and re-hospitalization rates.[2] However, patients' functional outcomes vary based on rehabilitation treatments provided by the SNF. For example, one retrospective observational study examining 10 SNFs found that residents had significantly different functional recovery rates even after controlling for resident demographics and characteristics.[3] Another study among residents 65 years or older receiving rehabilitation for hip fracture found that length of stay explained variance in mobility and self-care scores at SNF discharge.[4] Variations in the functional outcomes of SNF residents may be monitored by the Cross-Setting Discharge Function Score Measure. Evidence suggests that variation in SNF functional outcomes is associated with several interventions and processes of care, such as the intensity, type, and amount of therapy provided, as well as the use of enhanced medical rehabilitation (EMR). SNF residents with different cognitive function and comorbid conditions will have different levels of expected functional gains, which is taken into account in the Cross-Setting Discharge Function Score measure.

Intensity, type, and amount of therapy received in the facility may also influence SNF functional outcomes. One randomized controlled trial emphasized the safety and feasibility of the implementation of a high-intensity resistance training framework in SNFs.[2] Participants in the high-intensity rehabilitation program showed greater patient satisfaction, reduced length of stay, and faster gait speed change in comparison to the control group receiving usual care.[2] A retrospective cohort study among older adults with sepsis found that more hours of physical and occupational therapy during the first seven days of the SNF stay were associated with a significantly higher probability of improvement in ADL functional outcomes.[7]

SNF utilization of therapy intervention processes may also impact functional outcomes of SNF residents. Literature surrounding the SNF practice of Enhanced Medical Rehabilitation (EMR) demonstrates mixed results. EMR differs from standard rehabilitation efforts in that it uses a patient-directed approach that links therapy activities to personal goals of the patient resulting in a more motivational approach. Older adults assigned to the EMR group in one randomized controlled trial demonstrated 25% greater recovery of function compared to those assigned to the group receiving the standard of care.[8] However, another randomized controlled trial found that EMR may only benefit individuals with relatively intact executive functioning.[9]

Functional outcomes vary based on residents' cognitive function and medical complexity. Existing literature demonstrates that residents with higher cognitive function at SNF admission achieved larger gains in functional status compared to residents with cognitive impairment.[5] Another retrospective analysis found that short-stay nursing home residents with conditions such as cognitive impairment, delirium, dementia, and stroke showed less improvement in activities of daily living (ADL) performance in comparison to residents without these conditions.[6] A retrospective cohort study among older adults with sepsis found that the probability of improvement in ADL function decreased with more hospitalizations in the prior year, older age, and more severe cognitive impairment at SNF admission.[7]

Overall, literature indicates that SNF processes and interventions may influence the functional outcomes of residents at discharge. Therefore, variations in the functional status of SNF residents should be

monitored by an interoperable measure such as the Cross-Setting Discharge Function Score measure. Since function outcomes vary based on resident characteristics, the Cross-Setting Discharge Function Score measure adjusts for relevant risk factors. Limitations of each article are included in an evidence attachment

References:

1. Gustavson, A. M., Falvey, J. R., Forster, J. E., & Stevens-Lapsley, J. E. (2019). Predictors of Functional Change in a Skilled Nursing Facility Population. Journal of geriatric physical therapy (2001), 42(3), 189-195. https://doi.org/10.1519/JPT.0000000000000137

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3. Johnson J.K., Hohman J., Stilphen M., Bethoux F., Rothberg M.B. (2021). Functional Recovery Rate: A Feasible Method for Evaluating and Comparing Rehabilitation Outcomes Between Skilled Nursing Facilities. JAMDA, 22(8), P1633-1639.E3. https://doi.org/10.1016/j.jamda.2020.09.037

4. Cogan A.M., Weaver J.A., McHarg M., Leland N.E., Davidson L., Mallinson T. (2020). Association of Length of Stay, Recovery Rate, and Therapy Time per Day With Functional Outcomes After Hip Fracture Surgery. JAMA Netw Open, 3(1), e1919672. https://doi.org/10.1001/jamanetworkopen.2019.19672

5. Loomer, L., Downer, B., & Thomas, K. S. (2019). Relationship between Functional Improvement and Cognition in Short-Stay Nursing Home Residents. Journal of the American Geriatrics Society, 67(3), 553-557. https://doi.org/10.1111/jgs.15708

6. Wysocki, A., Thomas, K. S., & Mor, V. (2015). Functional Improvement Among Short-Stay Nursing Home Residents in the MDS 3.0. Journal of the American Medical Directors Association, 16(6), 470-474. https://doi.org/10.1016/j.jamda.2014.11.018

7. Downer, B., Pritchard, K., Thomas, K. S., & Ottenbacher, K. (2021). Improvement in Activities of Daily Living during a Nursing Home Stay and One-Year Mortality among Older Adults with Sepsis. Journal of the American Geriatrics Society, 69(4), 938-945. https://doi.org/10.1111/jgs.16915

8. Lenze E.J., Lenard E., Bland M., Barco, P., Miller, J.P., Yingling, M., Lang, C.E., Morrow-Howell, N., Baum C.M., Binder, E.F., Rodebaugh, T.L. (2019). Effect of Enhanced Medical Rehabilitation on Functional Recovery in Older Adults Receiving Skilled Nursing Care After Acute Rehabilitation: A Randomized Clinical Trial. JAMA Netw Open, 2(7):e198199. https://doi.org/10.1001/jamanetworkopen.2019.8199

9. Ercal, B., Rodebaugh, T. L., Bland, M. D., Barco, P., Lenard, E., Lang, C. E., Miller, J. P., Yingling, M., & Lenze, E. J. (2021). Executive Function Moderates Functional Outcomes of Engagement Strategies During Rehabilitation in Older Adults. American journal of physical medicine & rehabilitation, 100(7), 635-642. https://doi.org/10.1097/PHM.0000000000001739

Name evidence type

N/A

Summarize the evidence

N/A

Does the evidence discuss a link between at least one process, structure, or intervention with the outcome?

Yes

Estimated Impact of the Measure: Estimate of Annual Denominator Size

1259333

Type of Evidence to Support the Measure

Clinical Guidelines or USPSTF (U.S. Preventive Services Task Force) Guidelines; Peer-Reviewed Systematic Review; Empirical data

Is the measure risk adjusted?

Yes

Risk adjustment variables

Patient-level demographics; Patient-level health status & clinical conditions; Patient functional status

Patient-level demographics: please select all that apply:

Age

Patient-level health status & clinical conditions: please select all that apply:

Case-Mix Adjustment

Patient functional status: please select all that apply:

Body Function; Ability to perform activities of daily living

Patient-level social risk factors: please select all that apply:

N/A

Proxy social risk factors: please select all that apply

N/A

Patient community characteristic: please select all that apply:

N/A

Risk model performance

The risk adjustment model was an ordinary least squares (OLS) linear regression. A well-calibrated model demonstrates good predictive ability to distinguish high-risk from low-risk patients. To assess risk adjustment model calibration, we calculated the ratio of observed-to-predicted discharge function score across eligible stays by decile of predicted discharge function score (risk). The average ratio of observed-to-predicted scores for each risk decile ranged from 0.99 to 1.01, which suggested good calibration across the range of patients without evidence of concerning under- or over-estimation. We analyzed model fit using adjusted R-squared to determine if the risk adjustment model can accurately predict discharge function while controlling for patient case-mix. The adjusted R-squared value was 0.57, which suggests good model discrimination.

Rationale for not using risk adjustment

N/A

Cost estimate completed

No

Cost estimate methods and results

N/A

Section 3: Patient and Provider Perspective

Meaningful to Patients. Was input on the final performance measure collected from patient and/or caregiver?

No

Total number of patients and/or caregivers who responded to the question asking them whether the final performance measure helps inform care and decision making

N/A

Total number of patients/caregivers who agreed that the final performance measure helps inform care and decision making

N/A

Meaningful to Patients: Numbers consulted

N/A

Meaningful to Patients: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians: Numbers consulted

N/A

Meaningful to Clinicians: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians. Were clinicians and/or providers consulted on the final performance measure?

No

Total number of clinicians/providers who responded when asked if the final performance measure was actionable to improve quality of care.

N/A

Total number of clinicians/providers who agreed that the final performance measure was actionable to improve quality of care

N/A

Survey level testing

N/A

Type of Testing Analysis

N/A

Testing methodology and results

N/A

Burden for Provider: Was a provider workflow analysis conducted?

No

If yes, how many sites were evaluated in the provider workflow analysis?

N/A

Did the provider workflow have to be modified to accommodate the new measure?

N/A

Section 4: Measure Testing Details

Reliability

Yes

Reliability: Type of Reliability Testing

Random Split-Half Correlation

Signal-to-Noise: Name of statistic

N/A

Signal-to-Noise: Sample size

N/A

Signal-to-Noise: Statistical result

N/A

Signal-to-Noise: Interpretation of results

N/A

Random Split-Half Correlation: Name of statistic

Split-sample Reliability Testing: This testing examined agreement between two performance measure scores for a facility based on randomly-split, independent subsets of resident stays in the same measurement period. We randomly divided FY 2019 resident stays of each facility with at least 20 stays into halves. We calculated performance measure scores for each split-half sample using the same measure specification. We calculated Shrout-Fleiss intraclass correlation coefficients (ICC (2, 1)) between the split-half scores to measure reliability [1], with the Spearman-Brown correction applied. [1]

McGraw, K. O., & Wong, S. P. (1996). Forming inferences about some intraclass correlation coefficients. Psychological methods, 1(1), 30.

Random Split-Half Correlation: Sample size

12,703

Random Split-Half Correlation: Statistical result

0.81

Random Split-Half Correlation: Interpretation of results

Good reliability

Threshold referenced:

Poor <0.50

Moderate 0.50-0.75

Good 0.75-0.90

Excellent >0.90

Koo T.K. & Li M.Y. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. Journal of Chiropractic Medicine, 2016, 15(2), 155-163.

Thresholds for sufficient measure reliability vary across sources [1], with the threshold for moderate reliability ranging to 0.4[2], and the category above moderate ranging to 0.61[3], for example.

[1] Portney, L. G., & Watkins, M. P. (2009). Foundations of clinical research: applications to practice (Vol. 892). Upper Saddle River, NJ: Pearson/Prentice Hall.

[2] U.S. Department of Education (2018), What Works Clearinghouse (WWC) Standards Handbook version 4.0.

[3] Landis J, Koch G. The measurement of observer agreement for categorical data. Biometrics. 1977; 33:159-174.

Other: Name of statistic

N/A

Other: Sample size

N/A

Other: Statistical result

N/A

Other: Interpretation of results

N/A

Empiric Validity

Yes

Empiric Validity: Statistic name

Empirical validity testing included tests of convergent validity. To evaluate convergent validity of measure scores, we measured Spearman's rank correlation between the Cross-Setting Discharge Function Score measure and other SNF QRP measures. The analysis used FY2019 data and only included data from SNFs with at least 20 stays. Higher functional status corresponds with higher likelihood of community discharge and lower rates of re-hospitalizations [1]. As expected, this measure demonstrated positive correlation with the Discharge to Community measure (0.15) ($p<0.01$). [1] Gustavson, A. M., Malone, D. J., Boxer, R. S., Forster, J. E., & Stevens-Lapsley, J. E. (2020). Application of High-Intensity Functional Resistance Training in a Skilled Nursing Facility: An Implementation Study. Physical therapy, 100(10), 1746-1758. https://doi.org/10.1093/ptj/pzaa126

Empiric Validity: Sample size

12,703

Empiric Validity: Statistical result

0.15

Empiric Validity: Methods and findings

To assess face validity of the Cross-Setting Discharge Function Score measure, we convened two Technical Expert Panel (TEP) meetings (July 2021 and January 2022), [1] as well as a Patient and Family Engagement Listening Session. TEP members showed strong support for the face validity of this measure. Though a vote was not taken at the meeting, the TEP agreed with the conceptual and operational definition of the measure. Panelists reviewed the validity analyses described herein and agreed they demonstrated measure validity. Panelists also agreed that the Cross-Setting Discharge Function Score measure adds value over the measures currently in-use in the SNF QRP (see Field 146). Additionally, the Patient and Family Engagement Listening Session demonstrated that the measure concept resonates with patients and caregivers. Participants' views of self-care and mobility were aligned with the functional domains captured by the measure, and they found them to be critical aspects of care. Participants emphasized the importance of measuring functional outcomes and were specifically interested in metrics that show how many patients discharged from particular facilities made improvements in self-care and mobility.

To evaluate convergent validity of measure scores, we measured Spearman's rank correlation between the Cross-Setting Discharge Function Score measure and other SNF QRP measures (see Field 39 for Discharge to Community). Higher functional status corresponds with lower rates of re-hospitalizations [1]. As expected, this measure demonstrated negative correlation with the Potentially Preventable Readmissions within 30-Days Post-Discharge measure (-0.10). Because higher functioning patients are likely to have lower levels of medical complexity, it follows that their stays would cost less. As expected, this measure had a negative correlation with Medicare Spending Per Beneficiary (-0.09). Additionally, as expected, since the SNF QRP self-care and mobility functional outcome measures use overlapping but not identical GG items and a different method for handling missing data, scores for these measures correlated well but not perfectly with the Cross-Setting Discharge Function Score measure: Change in Self-Care (0.74), Discharge Self-Care (0.78), Change in Mobility (0.78), Discharge Mobility (0.80). All correlation coefficients were significant ($p<0.01$).

The risk adjustment model is an ordinary least squares (OLS) linear regression. We assessed risk adjustment model calibration and fit using FY 2019 data. A well-calibrated model demonstrates good predictive ability to distinguish high-risk from low-risk patients. To assess risk adjustment model calibration, we calculated the ratio of observed-to-predicted discharge function score across eligible stays by decile of predicted discharge function score (risk). The average ratios of observed-to-predicted scores for each risk decile ranged from 0.99 to 1.01, which suggested good calibration across the range of patients without evidence of concerning under- or over-estimation. We analyzed model fit using adjusted R-squared to determine if the risk adjustment model can accurately predict discharge function while controlling for patient case-mix. The adjusted R-squared value was 0.57, which suggests good model discrimination.

We evaluated internal consistency, which demonstrates how well items interrelate. We measured Cronbach's alpha coefficient for the GG items used in the numerator calculation, which reflects the average correlation of all possible item-pairs and ranges from 0 to 1 (where 0 indicates no consistency of measurement among the items and 1 indicates perfect consistency). General consensus is that Cronbach's alpha should be at least 0.70 for an adequate scale for group-level decisions. [2] Cronbach's alpha was 0.91 at admission and 0.95 at discharge for non-wheelchair-bound patients and was 0.89 at admission and 0.94 at discharge for wheelchair-bound patients, indicating good consistency in GG item scores used in the measure score. Note that although only discharge item scores are used to calculate observed discharge function score, admission function scores are used in the risk adjustment model.

For in-use SNF QRP functional outcome measures, all missing item scores (i.e., Not Attempted, or NA, codes) are recoded to the code signifying the patient is completely dependent for an activity. However, TEP panelists agreed that NA codes may not always signify that a patient was dependent on a functional activity. [1] As a refinement for the Cross-Setting Discharge Function measure, statistical imputation was implemented to predict item scores for patients where a GG item was NA using models that adjust for patient clinical characteristics. We evaluated the empiric validity of our imputation methodology using the following analyses (see the Technical Report for full details).

1. We used ordered probit models to estimate admission and discharge scores for each GG item used in measure construction. To evaluate model fit of imputation models, we calculated C-statistics for each of the 22 imputation models. C-statistics ranged from 0.83-0.99, and the mean C-statistic was 0.95.
2. A bootstrapping method was used to measure bias and mean squared error (MSE) in the statistical imputation method compared to the recode approach used in the self-care and mobility functional outcome measures. Bias measures the average amount by which the imputed value differs from the true value. Bias is signed, with a positive amount meaning that the imputed values were higher, on average, than were the true values. MSE measures how far away the method is, on average, from the truth. It is unsigned and can be positive even if bias is zero. The absolute size of bias is an inverse measure of accuracy, while the size of MSE is an inverse measure of the combination of precision and accuracy. The goal of the bootstrapping method was to determine how similar imputed values were to the true item score. For each bootstrap, stays with complete item data were sampled using stratified random sampling. Two copies were made of this sample. The first copy was the original with known item scores. Missing item scores were imposed on the second copy, and now-missing item scores were estimated using both statistical imputation and the recode approach. Item scores estimated

through each approach were compared to the known item scores from the first copy. The MSE and bias statistics were calculated as averages across bootstraps. For statistical imputation, average MSE was 1.10 at admission and 1.88 at discharge, and average bias was -0.22 at admission and -0.20 at discharge. For the recode approach, average MSE was 5.05 at admission and 5.49 at discharge, and average bias was -1.14 at admission and -0.69 at discharge. This result indicates that statistical imputation produced less biased, more precise estimates for missing item scores.

3. We calculated the difference in discharge function between stays that have bona fide item scores at admission and stays with NA codes at admission where we impute to estimate the item score. This difference provides a metric of how accurately imputed item scores reflect true patient function. For 10 out of 11 items, the difference was lower than if these ANAs were recoded to the most dependent level of functional status. This result indicates that statistical imputation produced more accurate results.

[1] https://www.cms.gov/sites/default/files/2022-04/PAC-Function-TEP-Summary-Report-Jul2021.pdf

[2] Aron A, Aron EN Statistics for Psychology. 2nd ed. Upper Saddle River, NJ: Prentice Hall, 1999.

Empiric Validity: Interpretation of results

Yes

Face Validity

No

Face Validity: Number of voting experts and patients/caregivers

N/A

Face Validity: Result

N/A

Patient/Encounter Level Testing

Yes

Type of Analysis

Agreement between two manual reviewers

Sample Size

448

Statistic Name

Kappa

Statistical Results

0.558

Interpretation of results

A final report on the development of the Continuity Assessment Record and Evaluation (CARE) Tool included reliability and validity testing for self-care and mobility data elements, as well as data elements used as risk adjustors for the Cross-Setting Discharge Function Score measure. [1]

The inter-rater reliability of the GG items was tested in a subset of 34 providers (acute hospitals, HHAs, IRFs, LTCHs, and SNFs) distributed across 11 geographic areas. Each provider completed a duplicate admission or discharge assessment on 10 to 20 patients. The overall sample size was 449 for mobility items (448 for transfers). Kappa statistics were calculated to assess the level of agreement between raters since the GG item responses are ordinal (1, 2, 3, 4, 5, 6). Kappas ranged from 0.667 for walk 10 feet to 0.762 for sit to stand, which indicated substantial agreement of data element codes among raters.

[1] Gage BJ, Smith LM, Ross J, Coots LA, Shamsuddin KM, Deutsch A, Mallinson T, Reilly KE, Abbate JH, Gage-Croll Z. (August, 2012). The development and testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on Reliability Testing, Volume 2 of 3. Prepared for Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/files/document/development-and-testing-continuity-assessment-record-and-evaluation-care-item-set-final-report.pdf

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Higher score is better

Mean performance score

54.7

Median performance score

55.8

Minimum performance score

0.0

Maximum performance score

100.0

Standard deviation of performance scores

15.1

Does the performance measure use survey or patient-reported data?

No

Surveys or patient-reported outcome tools

N/A

Section 5: Measure Contact Information

Measure Steward

Centers for Medicare & Medicaid Services

Measure Steward Contact Information

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Centers for Medicare & Medicaid Services
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Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

Primary Submitter Contact Information

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Submitter Comments

N/A

MUC2022-087 Cross-Setting Discharge Function Score

Program

Long-Term Care (LTC) Hospital Quality Reporting Program

Section 1: Measure Information

Measure Specifications and Endorsement Status

Measure Description

This measure estimates the percentage of Long-Term Care Hospital (LTCH) patients who meet or exceed an expected discharge function score.

Numerator

The numerator is the number of patients in a LTCH with a discharge function score that is equal to or higher than the calculated expected discharge function score.

The function items used to determine the observed function score are: Eating (GG0130A3), Oral Hygiene (GGO130B3), Toileting Hygiene (GG0130C3), Roll left and right (GG0170A3), Lying to sitting on side of bed (GG0170C3), Sit to stand (GG0170D3), Chair/bed-to-chair transfer (GG0170E3), Toilet transfer (GG0170F3), and Walk 10 feet (GG0170I3) and Walk 50 feet with two turns (GG0170J3) if not wheelchair-bound, or Wheel 50 feet with two turns (GG0170R3) if wheelchair-bound. The definition of wheelchair bound is specified in the Technical Report attachment.

The expected discharge function score is a risk-adjusted estimate that accounts for resident characteristics.

Numerator Exclusions

N/A

Denominator

The total number of LTCH stays with a discharge date in the measure target period, which do not meet the exclusion criteria.

Denominator Exclusions

A LTCH stay is excluded if:

(i) Patient had an incomplete stay

Unplanned discharge or discharged against medical advice

Patient died during LTCH stay

Discharge to hospital emergency department, short-stay acute hospital, psychiatric hospital/unit, or long-term care hospital

Length of stay is less than 3 days

(ii) Patients younger than age 18

(iii) Patient is discharged to hospice

(v) Patient is in a coma, persistent vegetative state, complete tetraplegia, or locked-in syndrome

Denominator Exceptions

N/A

State of development

Fully Developed

State of Development Details

N/A

What is the target population of the measure?

LTCH patients included in the LCDS assessment instrument

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Physical medicine and rehabilitation

Measure Type

Outcome

Is the measure a composite or component of a composite?

Not a composite or component of a composite measure

If Other, Please Specify

N/A

What data sources are used for the measure?

Standardized Patient Assessments

If applicable, specify the data source

N/A

Description of parts related to these sources

All data elements are sourced from the Long-Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS)

At what level of analysis was the measure tested?

Facility

In which setting was this measure tested?

Long-term care hospital

Multiple Scores

No

What one healthcare domain applies to this measure?

Person-Centered Care

MIPS Quality: Identify any links with related Cost measures and Improvement Activities

N/A

Is this measure in the CMS Measures Inventory Tool (CMIT)?

No

CMIT ID

N/A

Alternate Measure ID

N/A

What is the endorsement status of the measure?

Never Submitted

CBE ID (CMS consensus-based entity, or endorsement ID)

9999

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

N/A

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

2023

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

No

If eCQM, enter Measure Authoring Tool (MAT) number

N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?

N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?

No

Previous Measure Information

N/A

What is the history or background for including this measure on the new measures under consideration list?

New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs

N/A

What other federal programs are currently using this measure?

N/A

Is this measure similar to and/or competing with a measure(s) already in a program?

Yes

Which measure(s) already in a program is your measure similar to and/or competing with?

The following measure is used in the LTCH QRP:

Long-Term Care Hospital (LTCH) Functional Outcome Measure: Change in Mobility among Patients Requiring Ventilator Support (NQF #2632) (CMS ID: L011.03)

How will this measure be distinguished from other similar and/or competing measures?

This measure differs from existing functional outcome measure in the following ways:

1) The outcome is measured as function at discharge, rather than the change between admission and discharge.
2) It does not require that a patient was on ventilation at admission.
3) It uses self-care and mobility activities in the same measure.
4) Risk adjustment models have been modified to align across settings, where appropriate, and include terms that are relevant for both self-care and mobility.
5) Item scores are imputed for items with Not Attempted (NA) codes.

How will this measure add value to the CMS program?

To determine how to construct a cross-setting function measure that adds value to the PAC QRPs, we convened two Technical Expert Panel (TEP) meetings (July 2021 and January 2022) throughout the course of measure development. During these meetings, panelists expressed that:

1. The LTCH QRP would benefit from having a cross-setting functional outcome measure to add to the in-use function process measure (Application of Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) (CMS ID: S001.03)). LTCHs tend to perform well on the process measure. The mean score for FY2019 was 99%. The Cross-Setting Discharge Function measure has higher variation in provider performance (see Field 98) and offers more informative comparisons between LTCHs for patients, caregivers, and stakeholders.
2. Both self-care and mobility GG items should be used for the measure because this provides a more comprehensive readout of providers' capacity to improve functional status that considers both dimensions of function together.[1] This is a valuable addition to the LTCH QRP mobility functional outcome measure, which considers only mobility.
3. The Cross-Setting Discharge Function Score measure includes a larger set of LTCH stays than the in-use functional outcome measure, which requires that patients be admitted on ventilation. Panelists reviewed provider scores, model fit, and comparisons to the Change in Mobility for Ventilated LTCH Patients and agreed the Cross-Setting Function Discharge Score should use all LTCH stays, regardless of ventilation status. [1]
4. Not Attempted (NA) codes are used frequently on assessments for certain GG items and statistical imputation should be used as the method to estimate resulting missing item scores. For the in-use LTCH QRP functional outcome measure, all missing item scores are recoded to the code signifying the patient is completely dependent for an activity (i.e., 1). Panelists reviewed evidence showing that discharge item scores for patients scored as NA at admission tended to be higher than those scored as 1 at admission. Combining this evidence with their experience seeing how clinicians code NAs in real-world practice, they agreed that NA codes do not always signify that a patient was dependent on a functional activity and that the recode approach could be improved upon. [1] As an alternative to the recode approach, statistical imputation predicts item scores based on patient clinical characteristics and function scores on other GG items. Panelists also reviewed empiric validity results on our statistical imputation approach (see Field 42) and agreed the method produced more accurate item score estimates than the recode approach.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

Improving Medicare Post-Acute Care Transformation Act of 2014 (H.R.4994)

Section 2: Measure Evidence

How is the measure expected to be reported to the program?

Other: Long-Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS)

Stratification

No

Feasibility of Data Elements

ALL data elements are in defined fields in electronic sources

Feasibility Assessment

A feasibility assessment was not necessary. The LCDS data elements used for measure construction are part of the standard data collection processes for LTCH providers and are already used in existing LTCH QRP measures.

Method of Measure Calculation

Other digital method

Hybrid measure: Methods of measure calculation

N/A

Evidence of Performance Gap

An analysis of FY 2019 data indicates that there is a performance gap in Cross-Setting Discharge Function Scores across providers. Among 357 LTCHs included, risk-adjusted measure scores ranged from 12.3% (min) to 92.4% (max) with a mean score of 50.1% and a standard deviation of 14.4%. The 25th percentile, median, and 75th percentile were 40.0%, 49.7%, and 60.6%, respectively.

Unintended Consequences

CMS monitors trends in the data elements that are used for the Cross-Setting Discharge Function measure and in measure scores and patient populations for the LTCH QRP functional outcome measure (Change in Mobility for Ventilated Patients). So far, CMS has not detected any evidence of unintended consequences with these data elements and will continue to monitor them.

One concern about unintended consequences with the Cross-Setting Discharge Function Score is that the measure may lead LTCHs to selectively enroll residents, either by encouraging or avoiding admission of certain types of residents and residents with certain characteristics. To address this, providers' performance is evaluated among their peers after adjusting for difference in resident case-mix across LTCHs. The risk adjustment methodology applied to this measure will help mitigate providers' incentive to selectively enroll residents. The variables included in the risk adjustment model are designed to capture resident characteristics that are associated with discharge functional status. Therefore, providers' performance on this measure will be adjusted for the characteristics of their resident population and level the playing field across providers. The detailed risk-adjustment strategy will be publicly available, allowing providers to understand that those who provide care for more 'high risk' residents are not at a disadvantage given their resident case mix. See the attached Technical Report for more details on the risk adjustment methodology.

Another possibility related to increased NA rates is that providers could strategically code NAs in an attempt to game the statistical imputation models. For instance, LTCHs could record NA codes for patients who did not improve by discharge if the discharge imputation models would predict a higher score based on that patient's characteristics. However, this type of gaming, where providers are determining in real-time which patients would perform better with statistical imputation than a true discharge score, would require sophisticated understanding and application of the imputation methodology.

The Cross-Setting Discharge Function Score measure will be monitored to identify unintended consequences, including patient selection patterns or changes in NA coding, which could lead to future re-specification of the measure as needed.

Number of clinical guidelines, including USPSTF guidelines, that address this measure topic

1

Outline the clinical guidelines supporting this measure

The Academy of Orthopaedic Physical Therapy of the American Physical Therapy Association created clinical practice guidelines to identify evidence-based physical therapy outcomes and interventions to address functional impairment, among other goals, for individuals above the age of 65 with hip fracture. These guidelines directly relate to the Cross-Setting Discharge Function Measure by identifying evidence-based interventions that can be used to improve functional mobility for patients throughout the continuum of care, including post-acute and home-based care. While these findings target rehabilitation after hip fractures specifically, the authors highlight that hip fractures cause over 316,000 hospital admissions annually and are a common cause of poor functional mobility, disability, long-term complications, and mortality. As such, these guidelines are relevant to a large proportion of post-acute care patients and are especially pertinent to the proposed Cross-Setting Discharge Function Measure.

The guidelines include two type of recommendations: outcome measures for patient examination and evidence-based intervention strategies for physical therapy practice. The master list of 40 outcome measures, including sit-to-standing, gait speed, and endurance, was previously compiled in 2013 through a comprehensive search. A literature review on the properties of each measure was updated in May 2019. Measures were graded based on metrics of reliability and validity. This literature was further graded based on the level of evidence. To identify intervention recommendations, the authors conducted a systematic review of literature on published literature from 2004 through 2020. A total of 51 studies were identified, including randomized control trials, systematic reviews and meta-analyses. Clinical practice guidelines were assessed for inclusion using the Appraisal of Guidelines for Research & Evaluation II (AGREE II) instrument. Individual clinical research articles were graded using an adapted version of the criteria from the Centre for Evidence-Based Medicine (Oxford, UK). Finally, the final guidelines were posted for public comment and reviewed by a group of consumer and clinician stakeholders to solicit and incorporate feedback.

The guidelines include evidence-based best practices to improve physical function among patients after a hip fracture to meet their individual goals for recovery. The included literature cites a range of supported interventions that can be used to improve function, including specific physical activities, motivational interviewing, home-based exercise, structured exercise routines, multidisciplinary care teams, and patient-tailored intensity and frequency levels.

Name the guideline developer/entity

The Academy of Orthopaedic Physical Therapy and the Academy of Geriatric Physical Therapy of the American Physical Therapy Association (APTA).

Publication year

2021

Full citation +/- URL

McDonough CM, Harris-Hayes M, Kristensen MT, et al. Physical Therapy Management of Older Adults With Hip Fracture. J Orthop Sports Phys Ther. 2021;51(2):CPG1-CPG81. doi:10.2519/jospt.2021.0301

Is this an evidence-based clinical guideline?

Yes

Is the guideline graded?

Yes

List the guideline statement that most closely aligns with the measure concept.

In reference to the Early Post-Operative Period in Inpatient Settings, the guideline states:

Patients should be offered high-frequency (daily) in-hospital physical therapy following surgery for a hip fracture, with duration as tolerated, including instruction in a home program.

What evidence grading system did the guideline use to describe strength of recommendation?

Other (enter here): AGREE II

List all categories and corresponding definitions for the evidence grading system used to describe strength of recommendation in the guideline?

The grading categories and corresponding definitions are as follows:

A: Strong evidence

A preponderance of level I and/or level II studies support the recommendation. This must include at least 1 level I study.

B: Moderate evidence

A single high-quality randomized controlled trial or a preponderance of level II studies support the recommendation.

C: Weak evidence

A single level II study or a preponderance of level III and IV studies, including statements of consensus by content experts, support the recommendation

D: Conflicting evidence

Higher-quality studies conducted on this topic disagree with respect to their conclusions. The recommendation is based on these conflicting studies

E: Theoretical/foundational evidence

A preponderance of evidence from animal or cadaver studies, from conceptual models/principles, or from basic sciences/bench research support this conclusion

F: Expert opinion

Best practice based on the clinical experience of the guideline development group

For the guideline statement that most closely aligns with the measure concept, what is the associated strength of recommendation?

USPSTF Grade A, Strong recommendation or similar

What evidence grading system did the guideline use to describe level of evidence or level of certainty in the evidence?

Other (enter here): Centre for Evidence-Based Medicine (Oxford, UK)

List all categories and corresponding definitions for the evidence grading system used to describe level of evidence or level of certainty in the evidence?

The categories for grading evidence range from I to V and are defined as follows:

I: Evidence obtained from high-quality diagnostic studies, prospective studies, randomized controlled trials, or systematic reviews.

II: Evidence obtained from lesser-quality diagnostic studies, prospective studies, systematic reviews, or randomized controlled trials (eg, weaker diagnostic criteria and reference standards, improper randomization, no blinding, less than 80% follow-up)

III: Case-control studies or retrospective studies

IV: Case series

V: Expert opinion

For the guideline statement that most closely aligns with the measure concept, what is the associated level of evidence or level of certainty in the evidence?

High or similar

List the guideline statement that most closely aligns with the measure concept.

In reference to the Early Post-Operative Period in Inpatient Settings, the guideline states:

Patients should be offered high-frequency (daily) in-hospital physical therapy following surgery for a hip fracture, with duration as tolerated, including instruction in a home program.

Number of systematic reviews that inform this measure concept

N/A

Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept

N/A

Source of empirical data

Published, peer-reviewed original research

Summarize the empirical data

A service included in LTCH care is the provision of rehabilitation therapy to those experiencing functional deficits following discharge from an acute care hospital stay. Research examining functional outcomes

has focused on motor function, which encompasses self-care and mobility. Physical function is a modifiable predictor of several outcomes, including successful discharge to community or an acute rehabilitation facility [1] and functional decline [2, 3] among long-term care hospital (LTCH) patients. Evidence suggests that LTCH care can improve functional outcomes and that outcomes can vary in individual LTCH facilities, which provides an opportunity to monitor provider-level variation through the Cross-Setting Discharge Function Score measure. LTCH patients with different functional status at admission, cognitive function, and comorbidities will have different levels of expected functional gains, which is taken into account in this measure.

Physical therapy can improve LTCH patient function. Across post-acute care settings, evidence indicates that rehabilitation for functional impairment is associated with functional recovery and re-hospitalization rates [4, 5]. Since patients are often discharged from ICU to LTCHs [1], studies assessing function among ICU patients are informative. A ten-year retrospective analysis of 315 ICU patients that required Extracorporeal Membrane Oxygenation (ECMO) for a minimum of 72 hours found that a positive rate of improvement in a functional mobility and ability to reach mobility milestones in response to rehabilitation was associated with improved survival, reduced 30-day readmissions, and discharge to community [6]. While the patients in these studies did not receive treatment in the LTCH settings, recovery from mechanical ventilation and ECMO are commonly observed among LTCH patients.

Functional mobility improvement at discharge can vary based on the type of care provided by each facility, indicating an opportunity to measure facility-level differences in patient outcomes.

A prospective cohort study by Dublin et al (2021) examined patient goals and functional outcomes among intensive care unit (ICU) survivors admitted to a LTCH with a tracheostomy [1]. The authors emphasized the importance of establishing individual care plans informed by functional assessments to achieve patient goals. A retrospective cohort study by Cogan et al. (2020) found that the rate of recovery and length of stay for post-acute care patients were significantly associated with functional improvement and emphasized the need to evaluate each patient's rate of functional gain and cater therapy intensity and time accordingly [7].

Patient characteristics are important predictors of functional status. Research suggests that functional mobility outcomes at discharge can vary due to comorbidities. A multi-site prospective cohort study among recently admitted LTCH patients with dementia found a significant decline in functional mobility within 60 days of admission. Significant factors associated with functional decline included greater duration of stay and age, and depression. The authors highlight potential interventions targeting physical exercise and social to reduce functional decline [3]. Similarly, a longitudinal cohort study of over 12,000 patients across 633 LTCHs in Canada found that greater balance impairment and cognitive impairment among patients at admission were predictive of patient's rate of disablement over the subsequent two years [2]. The researchers recommend implementing interventions to address balance and cognitive impairment.

Overall, literature indicates that LTCHs can influence functional outcomes at discharge. As such, variations in functional status of LTCH patients at discharge could be measured and monitored through the Cross-Setting Discharge Function Score Measure. Since function outcomes vary based on patient characteristics, the Cross-Setting Discharge Function Score measure adjusts for relevant risk factors. Study limitations are summarized in an evidence attachment due to character constraints.

References:

1. Dubin R, Veith JM, Grippi MA, McPeake J, Harhay MO, Mikkelsen ME. Functional Outcomes, Goals, and Goal Attainment among Chronically Critically Ill Long-Term Acute Care Hospital Patients. Ann Am Thorac Soc. 2021;18(12):2041-2048. doi:10.1513/AnnalsATS.202011-1412OC

2. Chu CH, Quan AML, McGilton KS. Depression and Functional Mobility Decline in Long Term Care Home Residents with Dementia: a Prospective Cohort Study. Can Geriatr J. 2021;24(4):325-331. Published 2021 Dec 1. doi:10.5770/cgj.24.511

3. Lane NE, Stukel TA, Boyd CM, Wodchis WP. Long-Term Care Residents' Geriatric Syndromes at Admission and Disablement Over Time: An Observational Cohort Study. J Gerontol A Biol Sci Med Sci. 2019;74(6):917-923. doi:10.1093/gerona/gly151

4. Deutsch A, Palmer L, Vaughan M, Schwartz C, McMullen T. Inpatient Rehabilitation Facility Patients' Functional Abilities and Validity Evaluation of the Standardized Self-Care and Mobility Data Elements. Arch Phys Med Rehabil. 2022 Feb 11:S0003-9993(22)00205-2. doi: 10.1016/j.apmr.2022.01.147. Epub ahead of print. PMID: 35157893.

5. Li CY, Haas A, Pritchard KT, Karmarkar A, Kuo YF, Hreha K, Ottenbacher KJ. Functional Status Across Post-Acute Settings is Associated With 30-Day and 90-Day Hospital Readmissions. J Am Med Dir Assoc. 2021 Dec;22(12):2447-2453.e5. doi: 10.1016/j.jamda.2021.07.039. Epub 2021 Aug 30. PMID: 34473961; PMCID: PMC8627458. doi:10.1097/CCM.0000000000005089

6. Mayer KP, Pastva AM, Du G, et al. Mobility Levels With Physical Rehabilitation Delivered During and After Extracorporeal Membrane Oxygenation: A Marker of Illness Severity or an Indication of Recovery?. Phys Ther. 2022;102(3):pzab301. doi:10.1093/ptj/pzab301

7. Cogan AM, Weaver JA, McHarg M, Leland NE, Davidson L, Mallinson T. Association of Length of Stay, Recovery Rate, and Therapy Time per Day With Functional Outcomes After Hip Fracture Surgery. JAMA Netw Open. 2020 Jan 3;3(1):e1919672. doi: 10.1001/jamanetworkopen.2019.19672. PMID: 31977059; PMCID: PMC6991278.

Name evidence type

N/A

Summarize the evidence

N/A

Does the evidence discuss a link between at least one process, structure, or intervention with the outcome?

Yes

Estimated Impact of the Measure: Estimate of Annual Denominator Size

101738

Type of Evidence to Support the Measure

Clinical Guidelines or USPSTF (U.S. Preventive Services Task Force) Guidelines; Empirical data

Is the measure risk adjusted?

Yes

Risk adjustment variables

Patient-level demographics; Patient-level health status & clinical conditions; Patient functional status

Patient-level demographics: please select all that apply:

Age

Patient-level health status & clinical conditions: please select all that apply:

Case-Mix Adjustment

Patient functional status: please select all that apply:

Body Function; Ability to perform activities of daily living

Patient-level social risk factors: please select all that apply:

N/A

Proxy social risk factors: please select all that apply

N/A

Patient community characteristic: please select all that apply:

N/A

Risk model performance

The risk adjustment model was an ordinary least squares (OLS) linear regression. A well-calibrated model demonstrates good predictive ability to distinguish high-risk from low-risk patients. To assess risk adjustment model calibration, we calculated the ratio of observed-to-predicted discharge function score across eligible stays by decile of predicted discharge function score (risk). The average ratio of observed-to-predicted scores for each risk decile ranged from 0.96 to 1.06, which suggested good calibration across the range of patients without evidence of concerning under- or over-estimation. We analyzed model fit using adjusted R-squared to determine if the risk adjustment model can accurately predict discharge function while controlling for patient case-mix. The adjusted R-squared value was 0.66, which suggests good model discrimination.

Rationale for not using risk adjustment

N/A

Cost estimate completed

No

Cost estimate methods and results

N/A

Section 3: Patient and Provider Perspective

Meaningful to Patients. Was input on the final performance measure collected from patient and/or caregiver?

No

Total number of patients and/or caregivers who responded to the question asking them whether the final performance measure helps inform care and decision making

N/A

Total number of patients/caregivers who agreed that the final performance measure helps inform care and decision making

N/A

Meaningful to Patients: Numbers consulted

N/A

Meaningful to Patients: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians: Numbers consulted

N/A

Meaningful to Clinicians: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians. Were clinicians and/or providers consulted on the final performance measure?

No

Total number of clinicians/providers who responded when asked if the final performance measure was actionable to improve quality of care.

N/A

Total number of clinicians/providers who agreed that the final performance measure was actionable to improve quality of care

N/A

Survey level testing

N/A

Type of Testing Analysis

N/A

Testing methodology and results

N/A

Burden for Provider: Was a provider workflow analysis conducted?

No

If yes, how many sites were evaluated in the provider workflow analysis?

N/A

Did the provider workflow have to be modified to accommodate the new measure?

N/A

Section 4: Measure Testing Details

Reliability

Yes

Reliability: Type of Reliability Testing

Random Split-Half Correlation

Signal-to-Noise: Name of statistic

N/A

Signal-to-Noise: Sample size

N/A

Signal-to-Noise: Statistical result

N/A

Signal-to-Noise: Interpretation of results

N/A

Random Split-Half Correlation: Name of statistic

Split-sample Reliability Testing: This testing examined agreement between two performance measure scores for a facility based on randomly-split, independent subsets of resident stays in the same measurement period. We randomly divided FY 2019 resident stays of each facility with at least 20 stays into halves. We calculated performance measure scores for each split-half sample using the same measure specification. We calculated Shrout-Fleiss intraclass correlation coefficients (ICC (2, 1)) between the split-half scores to measure reliability [1], with the Spearman-Brown correction applied. [1] McGraw, K. O., & Wong, S. P. (1996). Forming inferences about some intraclass correlation coefficients. Psychological methods, 1(1), 30

Random Split-Half Correlation: Sample size

357

Random Split-Half Correlation: Statistical result

0.94

Random Split-Half Correlation: Interpretation of results

Excellent reliability

Threshold referenced:

Poor <0.50

Moderate 0.50-0.75

Good 0.75-0.90

Excellent >0.90

Koo T.K. & Li M.Y. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. Journal of Chiropractic Medicine, 2016, 15(2), 155-163.

Thresholds for sufficient measure reliability vary across sources [1], with the threshold for moderate reliability ranging to 0.4[2], and the category above moderate ranging to 0.61[3], for example.

[1] Portney, L. G., & Watkins, M. P. (2009). Foundations of clinical research: applications to practice (Vol. 892). Upper Saddle River, NJ: Pearson/Prentice Hall.

[2] U.S. Department of Education (2018), What Works Clearinghouse (WWC) Standards Handbook version 4.0.

[3] Landis J, Koch G. The measurement of observer agreement for categorical data. Biometrics. 1977; 33:159-174.

Other: Name of statistic

N/A

Other: Sample size

N/A

Other: Statistical result

N/A

Other: Interpretation of results

N/A

Empiric Validity

Yes

Empiric Validity: Statistic name

Empirical validity testing included tests of convergent validity. To evaluate convergent validity of measure scores, we measured Spearman's rank correlation between the Cross-Setting Discharge Function Score measure and other LTCH QRP measures. The analysis used FY2019 data and only included data from LTCHs with at least 20 stays. Higher functional status corresponds with higher likelihood of community discharge and lower rates of re-hospitalizations [1]. As expected, this measure demonstrated positive correlation with the Discharge to Community measure (0.37) ($p<0.05$).

1. Dubin R, Veith JM, Grippi MA, McPeake J, Harhay MO, Mikkelsen ME. Functional Outcomes, Goals, and Goal Attainment among Chronically Critically Ill Long-Term Acute Care Hospital Patients. Ann Am Thorac Soc. 2021;18(12):2041-2048. doi:10.1513/AnnalsATS.202011-1412OC

Empiric Validity: Sample size

340

Empiric Validity: Statistical result

0.37

Empiric Validity: Methods and findings

To assess face validity of the Cross-Setting Discharge Function Score measure, we convened two Technical Expert Panel (TEP) meetings (July 2021 and January 2022), [1] as well as a Patient and Family Engagement Listening Session. TEP members showed strong support for the face validity of this measure. Though a vote was not taken at the meeting, the TEP agreed with the conceptual and operational definition of the measure. Panelists reviewed the validity analyses described herein and agreed they demonstrated measure validity. Additionally, panelists agreed that the Cross-Setting Discharge Function Score measure adds value over the measures currently in-use in the LTCH QRP (see Field 146). Additionally, the Patient and Family Engagement Listening Session demonstrated that the measure concept resonates with patients and caregivers. Participants' views of self-care and mobility were aligned with the functional domains captured by the measure, and they found them to be critical aspects of care. Participants emphasized the importance of measuring functional outcomes and were specifically interested in metrics that show how many patients discharged from particular facilities made improvements in self-care and mobility.

To evaluate convergent validity of measure scores, we measured Spearman's rank correlation between the Cross-Setting Discharge Function Score measure and other LTCH QRP measures (see Field 39 for Discharge to Community). Higher functional status corresponds with lower rates of re-hospitalizations. As expected, this measure demonstrated negative correlation with the Potentially Preventable Readmissions within 30-Days Post-Discharge measure (-0.17). Because higher functioning patients are likely to have lower levels of medical complexity, it follows that their stays would cost less. As expected, this measure had a negative correlation with Medicare Spending Per Beneficiary (-0.13). Additionally, as expected, since the LTCH QRP mobility functional outcome measure uses overlapping but not identical GG items, a different method for handling missing data, and is subset to the ventilated population, scores for this measure correlated well but not perfectly with the Cross-Setting Discharge Function Score measure: Change in Mobility for Ventilated LTCH Patients (0.73). All correlation coefficients were significant ($p<0.05$).

The risk adjustment model is an ordinary least squares (OLS) linear regression. We assessed risk adjustment model calibration and fit using FY 2019 data. A well-calibrated model demonstrates good predictive ability to distinguish high-risk from low-risk patients. To assess risk adjustment model calibration, we calculated the ratio of observed-to-predicted discharge function score across eligible stays by decile of predicted discharge function score (risk). The average ratios of observed-to-predicted scores for each risk decile ranged from 0.96 to 1.06 which suggested good calibration across the range of patients without evidence of concerning under- or over-estimation. We analyzed model fit using adjusted R-squared to determine if the risk adjustment model can accurately predict discharge function while controlling for patient case-mix. The adjusted R-squared value was 0.66, which suggests good model discrimination.

We evaluated internal consistency, which demonstrates how well items interrelate. We measured Cronbach's alpha coefficient for the GG items used in the numerator calculation, which reflects the average correlation of all possible item-pairs and ranges from 0 to 1 (where 0 indicates no consistency of measurement among the items and 1 indicates perfect consistency). General consensus is that Cronbach's alpha should be at least 0.70 for an adequate scale for group-level decisions. [2] Cronbach's alpha was 0.96 at admission and 0.97 at discharge for non-wheelchair-bound patients and was 0.92 at admission and 0.95 for wheelchair-bound patients, indicating good consistency in GG item scores used in the measure score. Note that although only discharge item scores are used to calculate observed discharge function score, admission function scores are used in the risk adjustment model.

For in-use LTCH QRP functional outcome measure, all missing item scores (i.e., Not Attempted, or NA, codes) are recoded to the code signifying the patient is completely dependent for an activity. However, TEP panelists agreed that NA codes may not always signify that a patient was dependent on a functional activity. [1] As a refinement for the Cross-Setting Discharge Function measure, statistical imputation was implemented to predict item scores for patients where a GG item was NA using models that adjust for patient clinical characteristics. We evaluated the empiric validity of our imputation methodology using the following analyses (see the Technical Report for full details).

1. We used ordered probit models to estimate admission and discharge scores for each GG item used in measure construction. To evaluate model fit of imputation models, we calculated C-statistics for each of the 22 imputation models. C-statistics ranged from 0.85-0.98, and the mean C-statistic was 0.95.
2. A bootstrapping method was used to measure bias and mean squared error (MSE) in the statistical imputation method compared to the recode approach used in the self-care and mobility functional outcome measures. Bias measures the average amount by which the imputed value differs from the true value. Bias is signed, with a positive amount meaning that the imputed values were higher, on average, than were the true values. MSE measures how far away the method is, on average from the truth. It is unsigned and can be positive even if bias is zero. The absolute size of bias is an inverse measure of accuracy, while the size of MSE is an inverse measure of the combination of precision and accuracy. The goal of the bootstrapping method was to determine how similar imputed values were to the true item score. For each bootstrap, stays with complete item data were sampled using stratified random sampling. Two copies were made of this sample. The first copy was the original with known item scores. Missing item scores were imposed on the second copy, and now-missing item scores were estimated using both statistical imputation and the recode approach. Item scores estimated through each approach were compared to the known item scores from the first copy. The MSE and bias statistics were calculated as averages across bootstraps. For statistical imputation, average MSE was 3.46 at admission and 2.38 at discharge, and bias was -0.12 at admission and -0.24 at discharge. For the recode approach, average MSE was 21.06 at admission and 9.49 at discharge, and bias was -2.84 at admission and -1.47 at discharge. This result indicates that statistical imputation produced less biased, more precise estimates for missing item scores.
3. We calculated the difference in discharge function between stays that have bona fide item scores at admission and stays with NA codes at admission where we impute to estimate the item score. This difference provides a metric of how accurately imputed item scores reflect true patient function. For 10 out of 11 items, the difference was lower than if these NAs were

recoded to the most dependent level of functional status. This result indicates that statistical imputation produced more accurate results.

[1] https://www.cms.gov/sites/default/files/2022-04/PAC-Function-TEP-Summary-Report-Jul2021.pdf

[2] Aron A, Aron EN Statistics for Psychology. 2nd ed. Upper Saddle River, NJ: Prentice Hall, 1999.

Empiric Validity: Interpretation of results

Yes

Face Validity

No

Face Validity: Number of voting experts and patients/caregivers

N/A

Face Validity: Result

N/A

Patient/Encounter Level Testing

Yes

Type of Analysis

Agreement between two manual reviewers

Sample Size

448

Statistic Name

Kappa

Statistical Results

0.558

Interpretation of results

A final report on the development of the Continuity Assessment Record and Evaluation (CARE) Tool included reliability and validity testing for self-care and mobility data elements, as well as data elements used as risk adjustors for the Cross-Setting Discharge Function Score measure. [1]

The inter-rater reliability of the GG items was tested in a subset of 34 providers (acute hospitals, HHAs, IRFs, LTCHs, and SNFs) distributed across 11 geographic areas. Each provider completed a duplicate admission or discharge assessment on 10-20 patients. The overall sample size was 449 for mobility items (448 for transfers). Kappa statistics were calculated to assess the level of agreement between raters since the GG item responses are ordinal (1, 2, 3, 4, 5, 6). Kappas ranged from 0.667 for walk 10 feet to 0.762 for sit to stand, which indicated substantial agreement of data element codes among raters.

[1] Gage BJ, Smith LM, Ross J, Coots LA, Shamsuddin KM, Deutsch A, Mallinson T, Reilly KE, Abbate JH, Gage-Croll Z. (August, 2012). The development and testing of the Continuity Assessment Record and

Evaluation (CARE) Item Set: Final Report on Reliability Testing, Volume 2 of 3. Prepared for Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/files/document/development-and-testing-continuity-assessment-record-and-evaluation-care-item-set-final-report.pdf

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Higher score is better

Mean performance score

50.1

Median performance score

49.7

Minimum performance score

12.3

Maximum performance score

92.4

Standard deviation of performance scores

14.4

Does the performance measure use survey or patient-reported data?

No

Surveys or patient-reported outcome tools

N/A

Section 5: Measure Contact Information

Measure Steward

Centers for Medicare & Medicaid Services

Measure Steward Contact Information

Rebekah Natanov
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7500 Security Boulevard
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Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

Primary Submitter Contact Information

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Submitter Comments

N/A

MUC2022-089 COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date

Program

Inpatient Rehabilitation Facility Quality Reporting Program

Section 1: Measure Information

Measure Specifications and Endorsement Status

Measure Description

This one quarter measure reports the percentage of patients in an inpatient rehabilitation facility (IRF) who are up-to-date on their COVID-19 vaccinations per the Centers for Disease Control and Prevention's (CDC) latest guidance.

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 Your COVID-19 Vaccines", at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html (last accessed 5/18/2022).

This measure is based on data obtained through the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) discharge assessments during the selected quarter.

Numerator

The total number of patients who are up-to-date on the COVID-19 vaccine.

Numerator Exclusions

N/A

Denominator

The total number of IRF stays discharged during the reporting period.

Denominator Exclusions

N/A

Denominator Exceptions

N/A

State of development

Field (Beta) Testing

State of Development Details

Cognitive interviews and data collection for patient scenarios were conducted from June through July 2022. Nine IRFs participated in the cognitive interviews and each facility completed five patient scenarios, accounting for a total of 45 cases. The patient scenarios were developed in collaboration with a team of clinical experts and designed to represent the most common scenarios IRF providers would encounter. The correct responses to each scenario were agreed upon by a panel of clinical experts so that percent agreement could be calculated using a gold standard. Cognitive interviews with each participant were conducted after the completion of patient scenarios. The goal of the cognitive

interviews was to gauge providers' comprehension of the item's concept and intent, as well as understand their decision process for completing the assessment item. Upon completion of interviews and patient scenarios, the completed scenarios were evaluated against the gold standard responses. Percent agreement was calculated by dividing the total number of patient scenario responses that matched the gold standard by the total number of patient scenario responses.

What is the target population of the measure?

All IRF patient stays

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Public and/or population health

Measure Type

Process

Is the measure a composite or component of a composite?

Not a composite or component of a composite measure

If Other, Please Specify

N/A

What data sources are used for the measure?

Standardized Patient Assessments

If applicable, specify the data source

IRF-PAI

Description of parts related to these sources

All data elements are sourced from the IRF-PAI.

At what level of analysis was the measure tested?

Facility

In which setting was this measure tested?

Inpatient rehabilitation facility

Multiple Scores

No

What one healthcare domain applies to this measure?

Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities

N/A

Is this measure in the CMS Measures Inventory Tool (CMIT)?

No

CMIT ID

N/A

Alternate Measure ID

N/A

What is the endorsement status of the measure?

Never Submitted

CBE ID (CMS consensus-based entity, or endorsement ID)

9999

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

N/A

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

No

If eCQM, enter Measure Authoring Tool (MAT) number

N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?

N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?

No

Previous Measure Information

N/A

What is the history or background for including this measure on the new measures under consideration list?

New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs

N/A

What other federal programs are currently using this measure?

N/A

Is this measure similar to and/or competing with a measure(s) already in a program?

Yes

Which measure(s) already in a program is your measure similar to and/or competing with?

[1] COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (MUC20-0044) for the IRF QRP, LTCH QRP, and SNF QRP;

[2] SARS-CoV-2 Vaccination by Clinicians (MUC20-0045); and

[3] CDC/NHSN 'resident vaccination', 'resident boosters', 'staff vaccination', and 'staff boosters' COVID-19 vaccination and booster rates reported on Care Compare for long term Nursing Home residents

How will this measure be distinguished from other similar and/or competing measures?

Comparison of the Patient/Resident COVID-19 Vaccine and the SARS-CoV-2 Vaccination by Clinicians Measure:

The COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure assesses COVID-19 vaccinations for the IRF patient population, whereas the SARS-CoV-2 Vaccination by Clinician measure focuses on COVID-19 vaccination among ambulatory care patients and the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) focuses on healthcare personnel.

Comparison of the Patient/Resident COVID-19 Vaccine measure and the CDC/NHSN 'resident vaccination' and 'resident boosters' rates:

The COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure assesses COVID-19 vaccinations for the IRF patient population, whereas CDC/NHSN 'resident vaccination' and 'resident boosters' rates captures the Nursing Home (NH) resident population.

How will this measure add value to the CMS program?

The COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure complements the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure that is collected for the IRF QRP, LTCH QRP, and SNF QRP. An advantage to reporting a simple vaccination rate at the patient-level is that it provides useful information to the public and to providers. We received feedback from patient and family advocates that a measure capturing raw vaccination rates, irrespective of provider action,

would be highly valuable when making healthcare decisions to select a facility for themselves or a loved one.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

Section 1899B(d)(1) of the Social Security Act

Section 2: Measure Evidence

How is the measure expected to be reported to the program?

Other: IRF-PAI assessment data through the Internet Quality Improvement and Evaluation System (iQIES)

Stratification

No

Feasibility of Data Elements

ALL data elements are in defined fields in electronic sources

Feasibility Assessment

The IRF-PAI COVID-19 vaccination item will be completed to obtain raw rates of COVID-19 vaccination. Providers will be able to use all sources of information available to obtain the vaccination data, such as patient interview, medical records, proxy response, and vaccination cards provided by the patient/caregivers.

While this COVID-19 vaccination item does not yet exist on the IRF-PAI assessment instrument, the item will be added to the IRF-PAI assessment instrument to electronically capture this information.

We solicited feedback from the technical expert panel (TEP) on the proposed assessment item. No concerns were raised by the TEP regarding the obtainment of information required to complete the new COVID-19 vaccination item.

Method of Measure Calculation

Other digital method

Hybrid measure: Methods of measure calculation

N/A

Evidence of Performance Gap

To demonstrate that the Patient/Resident COVID-19 Vaccine measure has room for improvement, this appendix covers evidence on the variation of vaccination rates across facilities, geographic locations, and patient characteristics.

An internal analysis of September 2021 NHSN COVID-19 Nursing Home data identified a performance gap in COVID-19 vaccination rates among Nursing Home residents. Nursing Home vaccination rate distributions of Nursing Home residents who received a complete COVID-19 vaccination ranged from

0.0% (min) to 100% (max) with a mean score of 82.3%. The 25th percentile, median, and 75th percentile were 75.8%, 84.5%, and 92.0%, respectively. Nursing Home vaccination rate distributions of Nursing Home residents who received a partial COVID-19 vaccination ranged from 0.0% (min) to 77.0% (max) with a mean score of 2.5%. The 25th percentile, median, and 75th percentile were 0.3%, 1.6%, and 3.4%, respectively. This analysis was presented to the TEP and panelists indicated that the presence of disparities in vaccination rates makes the patient-level vaccination measure meaningful to develop. Additionally, panelists broadly agreed that the vaccination gaps identified for nursing homes were also likely present within other post-acute care settings.

Although literature is limited, there is some evidence of COVID-19 vaccination rates varying by facility type. A cross-sectional study used National Healthcare Safety Network (NHSN) facility-level data to examine the rate of full vaccination rates among nursing home residents and staff by facility type through July 18, 2021 (McGarry et al., 2021). The results of the analysis demonstrated that for-profit ownership status was associated with a 3.3 percentage point decrease in resident vaccination coverage compared to nonprofit ownership status. Medicare star ratings were also evaluated in this study, as each additional Medicare star rating a facility had was associated with a 1.2 percentage point increase in its residents' vaccination coverage. These findings suggest that residents living in nonprofit facilities with higher Medicare Five-Star ratings are more likely to receive full dosage of the COVID-19 vaccine than residents living in for-profit facilities with lower star ratings.

Evidence suggests that a sizable proportion of the US population is not fully vaccinated and the extent to which people are not fully vaccinated varies geographically. According to CDC data used by the New York Times, as of October 22, 2021, 57% of the total US population has been fully vaccinated (approximately 189.9 million people) against COVID-19, and 66% has received at least one dose of vaccine (roughly 219.6 million people). Additionally, since August 13, 2021, when the FDA approved third doses for some populations, 11.3 million of the 189.9 million fully vaccinated people have received a vaccine booster. Although only 57% of the total US population is fully vaccinated, COVID-19 vaccination rates vary by region. States in the Northeast have the highest vaccination rates, while states in the Midwest and South have lower vaccination rates. Vaccination rates in the West are also high, as 64.5% of New Mexico residents, 62.8% of Washington residents, and 62.3% of Oregon residents are fully vaccinated. With the exception of Virginia, Maryland, Washington DC, and Florida, the remaining Southern states all have lower fully vaccinated rates than the national average. In fact, the Southern state of West Virginia has the lowest vaccination rates in the country, as only 40.9% of its population is fully vaccinated. The Northeastern state of Vermont has the highest vaccination rates in the country, as 70.7% of its population is fully vaccinated.

In addition to variation by region, COVID-19 vaccination rates also vary by patient characteristics. To assess whether or not disparities exist among different racial and ethnic groups in the US, the CDC evaluated data from the CDC Vaccine Safety Datalink (CVS) that included vaccination coverage among persons aged 16 years and older between December 2020 and May 2021 (Pingali et al., 2021). For those who received at least one dose of the Pfizer, Moderna, or Johnson & Johnson vaccine, vaccination rates were highest among Asian persons (57.4%) and lowest among non-Hispanic Black (40.7%) and Hispanic (41.14%) persons. Non-Hispanic Black and Hispanic persons also had lower vaccination rates than Whites (54.6%). The Kaiser Family Foundation (KFF) assessed more recent state-reported data on COVID-19 vaccination rates and observed similar findings. As of October 4, 2021, 54% of White people has received at least one COVID-19 vaccine dose, which is 1.2 times higher than the rate for Black

people (46%) and 1.1 times higher than the rate for Hispanic people (51%) (Ndugga et al., 2021). Additionally, 69% of Asian people have received at least one COVID-19 vaccine dose, which aligns with Pingali et al.'s (2021) findings that Asian people have the highest vaccination rates. Although disparities in vaccination coverage are evident, the data suggests that these disparities have been decreasing over time. KFF reports that vaccination rates for Black and Hispanic people increased slightly more than vaccination rates for Asian and White people between September 20, 2021, and October 4, 2021, thereby decreasing the gaps in vaccination coverage. This gap in vaccination rates between Black and White people decreased from 14 percentage points to 8 percentage points between April and October 2021. The gap in vaccination rates between White and Hispanic people also decreased during this period of time from 13 percentage points to 3 percentage points. Despite the decreases in these gaps, disparities in vaccination coverage persist.

Other patient characteristics, such as age, sex, and high-risk conditions, also contribute to variations in vaccination rates in the US. A recent study by Diesel et al. (2021) examined CDC data on vaccination coverage for adults aged 18 and older between December 2020 and May 2021 and found that vaccination rates (greater than or equal to 1 COVID-19 vaccine dose) were lowest among persons aged 18-29 years (38.3%) and highest among persons aged 65 and older (80.0%). Pingali et al. (2021) investigated vaccination rates among persons with high-risk conditions and previous COVID-19 infections. Researchers observed a vaccination rate of 63.8% for persons with medical conditions deemed high-risk for severe COVID-19 infection and a vaccination rate of 41.5% for persons without such conditions. Regarding previous COVID-19 infection, the vaccination rate was 48.8% for those who had not had COVID-19 and 42.4% for those who had COVID-19 previously. Overall, these studies suggest that COVID-19 vaccination rates are highest among adults aged 65 and older who have medical conditions deemed high-risk but did not have a COVID-19 infection previously.

References:

Diesel, Jill et al. 2021. "COVID-19 Vaccination Coverage among Adults — United States, December 14, 2020–May 22, 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7025e1.

McGarry, Brian E., Karen Shen, Michael L. Barnett, David C. Grabowski, and Ashvin D. Gandhi. 2021. "Association of Nursing Home Characteristics with Staff and Resident COVID-19 Vaccination Coverage." JAMA Internal Medicine, September. https://doi.org/10.1001/jamainternmed.2021.5890.

Ndugga, Nambi et al. 2021. "Latest Data on COVID-19 Vaccinations by Race/Ethnicity." KFF. October 6, 2021. https://www.kff.org/coronavirus-covid-19/issue-brief/latest-data-on-covid-19-vaccinations-by-race-ethnicity/.

Pingali, Cassandra et al. 2021. "COVID-19 Vaccination Coverage among Insured Persons Aged ≥16 Years, by Race/Ethnicity and Other Selected Characteristics — Eight Integrated Health Care Organizations, United States, December 14, 2020–May 15, 2021." MMWR. Morbidity and Mortality Weekly Report 70 (28): 985–90. https://doi.org/10.15585/mmwr.mm7028a1.

The New York Times. 2021. "See How Vaccinations Are Going in Your County and State." The New York Times, October 22, 2021, sec. U.S. https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html.

Appendix A of the Evidence form (attached) provides information on COVID-19 vaccination rate variation across facility, geography, and patient characteristics.

Unintended Consequences

The measure may impact access to care in facilities. If facilities think they have to maintain high COVID-19 vaccination rates, they may reject patients that are not up to date on their COVID-19 vaccinations. We anticipate this risk to be low, given the current state of the pandemic and the knowledge and tools providers have to mitigate the spread of COVID-19 infection.

As part of CMS' measures quarterly monitoring activities, number and percent of patient stays stratified by vaccination status at discharge.

Number of clinical guidelines, including USPSTF guidelines, that address this measure topic

4

Outline the clinical guidelines supporting this measure

Appendix B of the evidence attachment summarizes four of the Advisory Committee on Immunization Practices' (ACIP) Recommendations that support the measure concept for the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure.

1. The Advisory Committee on Immunization Practices' Interim Recommendations for Use of Pfizer-BioNTech COVID-19 Vaccine – United States, December 2020
    a. The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Use of Pfizer Vaccine conducted an explicit, evidence-based review of available data for the use of the Pfizer COVID-19 vaccine in persons aged ≥ 16 years for the prevention of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for patients throughout the continuum of care, including post-acute and home-based care who may not be vaccinated for COVID-19. The body of evidence for the Pfizer-BioNTech COVID-19 vaccine was primarily informed by one large, randomized, double-blind, placebo-controlled Phase II/III clinical trial that enrolled >43,000 participants (median age = 52 years, range = 16–91 years). Interim findings from this clinical trial, using data from participants with a median of two months of follow-up, indicate that the Pfizer-BioNTech COVID-19 vaccine was 95.0% effective (95% confidence interval = 90.3%–97.6%) in preventing symptomatic laboratory-confirmed COVID-19 in persons without evidence of previous SARS-CoV-2 infection. Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Efficacy was similarly high in a secondary analysis including participants both with or without evidence of previous SARS-CoV-2 infection. Although numbers of observed hospitalizations and deaths were low, the available data were consistent with reduced risk for these severe outcomes among vaccinated persons

compared with that among placebo recipients. Using the GRADE evidence assessment, the authors concluded the level of certainty for the benefits of the Pfizer-BioNTech COVID-19 vaccine was type 1 (high certainty) for the prevention of symptomatic COVID-19. Evidence was type 3 (low certainty) for the estimate of prevention of COVID-19 associated hospitalization and type 4 (very low certainty) for the estimate of prevention of death. At the time of these recommendations, data on hospitalizations and deaths were limited, but a vaccine that effectively prevents symptomatic infection is expected to also prevent hospitalizations and deaths.

2. The Advisory Committee on Immunization Practices' Interim Recommendations for Use of Moderna COVID-19 Vaccine – United States, December 2020
    a. The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Use of Moderna Vaccine conducted a transparent, evidence-based review of available data for the use of the Moderna COVID-19 vaccine in persons aged ≥ 18 years for the prevention of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for patients throughout the continuum of care, including post-acute and home-based care who may not be vaccinated for COVID-19. The body of evidence for the Moderna COVID-19 vaccine was primarily informed by one large, randomized, double-blind, placebo-controlled Phase III clinical trial that enrolled approximately 30,000 participants aged 18–95 years (median = 52 years). Interim findings from this clinical trial, using data from participants with a median of two months of follow-up, indicate that the Moderna COVID-19 vaccine efficacy after two doses was 94.1% (95% confidence interval = 89.3%–96.8%) in preventing symptomatic, laboratory-confirmed COVID-19 among persons without evidence of previous SARS-CoV-2 infection, which was the primary study endpoint. High efficacy (≥86%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Using the GRADE evidence assessment, the authors concluded the level of certainty for the benefits of the Moderna COVID-19 vaccine was type 1 (high certainty) for the prevention of symptomatic COVID-19. Evidence was type 2 (moderate certainty) for the estimate of prevention of COVID-19–associated hospitalization and type 4 (very low certainty) for the estimates of prevention of asymptomatic SARS-CoV-2 infection and all-cause death. At the time of these recommendations, data on COVID-19–associated hospitalizations and deaths were limited; however, a vaccine that effectively prevents symptomatic infection is expected to also prevent associated hospitalizations and deaths.
3. The Advisory Committee on Immunization Practices' Interim Recommendations for Use of Janssen COVID-19 Vaccine – United States, February 2021
    a. The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Use of Janssen COVID-19 Vaccine conducted an evidence-based review of all available data on the use of the Janssen COVID-19 vaccine in persons aged ≥ 18 years for the prevention of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for patients throughout the continuum of care, including post-acute and home-based care who may not be vaccinated for COVID-19. The body of evidence for the

Janssen COVID-19 vaccine was primarily informed by one international Phase III clinical trial initiated in September 2020 that enrolled approximately 40,000 participants aged 18–100 years (median age = 52 years), using two coprimary endpoints: prevention of symptomatic, laboratory-confirmed¶ COVID-19 among persons without evidence of previous SARS-CoV-2 infection occurring 1) ≥14 days and 2) ≥28 days after vaccination. Interim findings from this clinical trial indicate that the Janssen COVID-19 vaccine efficacy against symptomatic, laboratory-confirmed COVID-19 was 66.3% (95% confidence interval [CI] = 59.9%–71.8%) ≥14 days after vaccination and 65.5% (95% CI = 57.2%–72.4%) ≥28 days after vaccination. At ≥14 days after vaccination, the efficacy of ≥63.0% was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Efficacy varied geographically and was highest in the United States (74.4%; 95% CI = 65.0%–81.6%). Vaccine recipients frequently experienced reactogenicity symptoms, defined as solicited local injection site or systemic adverse reactions during the 7 days after vaccination; however, the symptoms were mostly mild to moderate and resolved 1–2 days after vaccination. Symptoms were more frequent among persons aged 18–59 years than among those aged ≥60 years. From the GRADE evidence assessment, the level of certainty for the benefits of the Janssen COVID-19 vaccine was type 2 (moderate certainty) for the prevention of symptomatic COVID-19. Evidence was also type 2 (moderate certainty) for the estimate of prevention of COVID-19–associated hospitalization and death. Evidence was type 3 (low certainty) for the estimates of prevention of SARS-CoV-2 seroconversion. Regarding certainty of the evidence for possible harms after vaccination, evidence was type 1 (high certainty) for reactogenicity and type 2 (moderate certainty) for serious adverse events. Data reviewed within the EtR framework supported the use of the Janssen COVID-19 vaccine.

4. The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines – United States, 2021.
    a. The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines issued recommendations for an additional dose of the primary mRNA COVID-19 vaccine for immunocompromised persons and a COVID-19 vaccine booster dose in eligible groups, as well as persons who are at increased risk for exposure to or serious complications of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for remaining up to date with the COVID-19 vaccine for patients throughout the continuum of care, including post-acute and home-based care. Since June 2020, ACIP has convened 20 public meetings to review data relevant to the potential use of COVID-19 vaccines. To assess the certainty of the evidence for benefits and harms of a booster dose, ACIP used the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. To further guide its deliberations around the use of an additional or booster dose, ACIP used the Evidence to Recommendations (EtR) Framework to evaluate other factors, including the importance of COVID-19 as a public health problem as well as matters of resource use, benefits and harms, patients' values and preferences, acceptability, feasibility, and equity for use of the vaccines. ACIP concluded that the

evidence reviewed, including data and considerations from the EtR Frameworks, supported the use of an additional primary dose of an mRNA COVID-19 vaccine for certain immunocompromised recipients of an initial mRNA series, a COVID-19 vaccine booster dose for certain recipients of an mRNA primary series who are at increased risk for exposure to or serious complications of COVID-19, and a COVID-19 vaccine booster dose for all recipients of a Janssen COVID-19 vaccine dose.

Name the guideline developer/entity

The Advisory Committee on Immunization Practices (ACIP)

Publication year

[1] 2020

[2] 2020

[3] 2020

[4] 2021

Full citation +/- URL

[1] 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): 1922-1924. https://doi.org/10.15585/mmwr.mm6950e2.

[2] 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.

[3] 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): 329-332. https://doi.org/10.15585/mmwr.mm7009e4.

[4] 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): 1545-1552. https://doi.org/10.15585/mmwr.mm7044e2.

Is this an evidence-based clinical guideline?

Yes

Is the guideline graded?

Yes

List the guideline statement that most closely aligns with the measure concept.

[1] ACIP concluded the Pfizer COVID-19 vaccine has high efficacy for the prevention of symptomatic COVID-19.

[2] ACIP concluded the Moderna COVID-19 vaccine has high efficacy for the prevention of symptomatic COVID-19.

[3] ACIP concluded the Janssen COVID-19 vaccine has high efficacy against COVID-19-associated hospitalization and death.

[4] ACIP concluded that the evidence reviewed supported the use of an additional primary dose of an mRNA COVID-19 vaccine for certain immunocompromised recipients of an initial mRNA series, a COVID-19 vaccine booster dose for certain recipients of an mRNA primary series who are at increased risk for exposure to or serious complications of COVID-19, and a COVID-19 vaccine booster dose for all recipients of a Janssen COVID-19 vaccine dose.

What evidence grading system did the guideline use to describe strength of recommendation?

GRADE method

List all categories and corresponding definitions for the evidence grading system used to describe strength of recommendation in the guideline?

The GRADE certainty ratings and corresponding definitions are as follows:

1: High

The authors have a lot of confidence that the true effect is similar to the estimated effect.

2: Moderate

The authors believe that the true effect is probably close to the estimated effect.

3: Low

The true effect might be markedly different from the estimated effect.

4: Very low

The true effect is probably markedly different from the estimated effect.

For the guideline statement that most closely aligns with the measure concept, what is the associated strength of recommendation?

USPSTF Grade A, Strong recommendation or similar

What evidence grading system did the guideline use to describe level of evidence or level of certainty in the evidence?

GRADE method

List all categories and corresponding definitions for the evidence grading system used to describe level of evidence or level of certainty in the evidence?

The GRADE certainty ratings and corresponding definitions are as follows:

1: High

The authors have a lot of confidence that the true effect is similar to the estimated effect.

2: Moderate

The authors believe that the true effect is probably close to the estimated effect.

3: Low

The true effect might be markedly different from the estimated effect.

4: Very low

The true effect is probably markedly different from the estimated effect.

For the guideline statement that most closely aligns with the measure concept, what is the associated level of evidence or level of certainty in the evidence?

USPSTF Grade A, Strong recommendation or similar

List the guideline statement that most closely aligns with the measure concept.

Health care professionals play a critical role in COVID-19 vaccination efforts, including primary, additional primary, and booster vaccination, particularly to protect patients who are at increased risk for severe illness and death

Number of systematic reviews that inform this measure concept

4

Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept

Appendix C of the evidence attachment summarizes four peer-reviewed systematic review(s) that inform the measure concept for the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure and provides full citations and URLs for each review.

1. Korang et al.
    a. Korang et al. (2022) sought to assess the effectiveness and safety of COVID-19 vaccines through analyses of all currently available randomized clinical trials. The authors searched the databases CENTRAL, MEDLINE, Embase, and other sources from inception to June 17, 2021 for randomized clinical trials assessing vaccines for COVID-19. At least two independent reviewers screened studies, extracted data, and assessed risks of bias prior to conducting meta-analyses, network meta-analyses, and Trial Sequential Analyses (TSA). Authors assessed the certainty of evidence with GRADE, and found 35 trials to include in the analyses. The meta-analyses showed that mRNA vaccines (efficacy, 95% [95% confidence interval (CI 92% to 97%]; 71,514 participants; 3 trials; moderate certainty); inactivated vaccines (efficacy, 61% [95% CI, 52% to 68%]; 48,029 participants; 3 trials; moderate certainty); protein subunit vaccines (efficacy, 77% [95% CI, −5% to 95%]; 17,737 participants; 2 trials; low certainty); and viral vector vaccines (efficacy 68% [95% CI, 61% to 74%]; 71,401 participants; 5 trials; low certainty) prevented COVID-19. Viral vector vaccines decreased mortality (risk ratio, 0.25 [95% CI 0.09 to 0.67]; 67,563 participants; 3 trials, low certainty), but comparable data on

inactivated, mRNA, and protein subunit vaccines were imprecise. None of the vaccines showed evidence of a difference on serious adverse events, but observational evidence suggested rare serious adverse events. All the vaccines increased the risk of non-serious adverse events. The authors concluded the evidence suggests that all the included vaccines are effective in preventing COVID-19. The mRNA vaccines seem most effective in preventing COVID-19, but viral vector vaccines seem most effective in reducing mortality. Further trials and longer follow-ups are necessary to provide better insight into the safety profile of these vaccines.

b. 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." Edited by Stefanos Bonovas. PLOS ONE 17 (1): e0260733. https://doi.org/10.1371/journal.pone.0260733.

2. Fielkin et al.
   a. Fiekin et al. (2022) sought to systematically review the evidence for the duration of protection of COVID-19 vaccines against various clinical outcomes, and to assess changes in the rates of breakthrough infection caused by the delta variant with increasing time since vaccination. This study was designed as a systematic review and meta-regression. A systematic review of preprint and peer-reviewed published article databases from June 17, 2021, to Dec 2, 2021, was conducted, and randomized controlled trials of COVID-19 vaccine efficacy and observational studies of COVID-19 vaccine effectiveness were eligible. The following databases and preprint servers without language restrictions were included in the search: PubMed, Embase, medRxiv, BioRxiv, khub, Research Square, SSRN, Eurosurveillance.org, Europepmc.org, and the WHO COVID-19 database, which compiles searches of more than 100 databases, including Scopus, Web of Science, grey literature. The authors searched for studies with several variations of the primary key search terms "COVID-19", "SARS-CoV-2", and "vaccine" (including names of specific vaccines) and "randomized controlled trial" or "vaccine effectiveness" (including names of specific study designs). Studies with vaccine efficacy or effectiveness estimates at discrete time intervals of people who had received full vaccination and that met predefined screening criteria underwent full-text review. Random-effects meta-regression was used to estimate the average change in vaccine efficacy or effectiveness 1–6 months after full vaccination. After applying exclusion criteria, 18 studies of vaccine efficacy or effectiveness at discrete time intervals after full vaccination and seven studies in which risk of breakthrough infection could be assessed by time of vaccination were included. In addition, the same search strategy was used to find studies presenting analyses of breakthrough infections, in which the rate, risk, or odds of COVID-19 outcomes among different vaccine cohorts (i.e., vaccinated at different times) were included. The authors found that during the six months after full vaccination, vaccine efficacy or effectiveness against SARS-CoV-2 infection and symptomatic COVID-19 disease decreased by approximately 20–30 percentage points, on average, for the four vaccines that we evaluated. By contrast, most studies showed that vaccine efficacy or effectiveness against the severe disease was maintained above 70% after full vaccination, with a minimal decrease to six months (approximately 9–10 percentage points). The decrease in vaccine efficacy or effectiveness is likely caused by, at least in part, waning immunity, although an effect of bias cannot be ruled out.

Evaluating vaccine efficacy or effectiveness beyond six months will be crucial for updating the COVID-19 vaccine policy.

b. 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.

3. Lee et al.
    a. The focus of this systematic review and meta-analysis was to compare the efficacy of COVID-19 vaccines between immunocompromised and immunocompetent people. Vaccine trials have excluded immunocompromised groups, but these patients are of particular interest because of possible suppression or over-activation of the immune system attributable to the primary disease or concurrent treatment. Data are needed on immunocompromised patients, as infection and viral shedding have been reported to be more severe and persistent in this group. Immunocompromised patients show lower seroconversion rates than immunocompetent people after vaccination, such as with the influenza vaccine. Less is known about the response to COVID-19 vaccines, particularly mRNA-based vaccines. Lee et al. (2022) sought to compare the efficacy of covid-19 vaccines between immunocompromised and immunocompetent people. Several databases were searched (Medline via PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), CORD-19, WHO COVID-19 Research Database, ClinicalTrials.gov, and WHO international clinical trials registry platform) for articles published from December 1, 2020, to November 5, 2021. No restrictions on the language of publication were applied. To improve the validity of data, non-peer-reviewed articles in preprint databases were excluded. The authors assessed the certainty of evidence using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE). Overall, 82 studies were included for meta-analysis. Of these studies, 77 (94%) used mRNA vaccines, 16 (20%) viral vector vaccines, and 4 (5%) inactivated whole virus vaccines. The authors found that seroconversion rates after COVID-19 vaccination were significantly lower in immunocompromised patients, especially organ transplant recipients. A second dose was associated with consistently improved seroconversion across all patient groups, albeit at a lower magnitude for organ transplant recipients. The authors concluded that targeted interventions for immunocompromised patients, including a third (booster) dose, should be performed.
    b. Lee, Ainsley Ryan Yan Bin et al. 2022. "Efficacy of Covid-19 Vaccines in Immunocompromised Patients: Systematic Review and Meta-Analysis." BMJ 376 (March): e068632. https://doi.org/10.1136/bmj-2021-068632.
4. Norhayati et al.
    a. This review aimed to estimate the pooled proportion of COVID-19 vaccine acceptance worldwide. Determining the pooled estimated proportion of COVID-19 vaccination acceptance provides guidance to health authorities to prepare for an effective vaccination program. A systematic review and meta-analysis of studies were conducted to assess the proportion of COVID-19 vaccination acceptance. A systematic search was performed in the MEDLINE (PubMed) database for articles between January 1, 2021, and July 19, 2021. The search was done using the generic free-text search terms "COVID-19" AND "vaccine" AND "acceptance." All types of COVID-19 vaccines were included in this review. The search was restricted to full-text only and English language articles. Studies with cross-sectional, case-control, and cohort designs were included.

Case series/reports, conference papers, proceedings, articles available only in abstract form, editorial reviews, letters of communications, commentaries, systematic reviews, and qualitative studies were excluded. Assessment of critical appraisal for data quality was assessed using the Joann Briggs Institute (J.B.I.). Two authors performed bias assessments independently, and a total of 172 studies were included in the review and meta-analysis. The pooled proportion of COVID-19 vaccine acceptance involving 50 countries was 61% (95% CI: 59, 64%). This finding was lower compared to a previous estimate of 73.31% (95% CI: 70.52%, 76.01%) which involved 38 studies across 36 countries with limited data from low-income countries. Concern about the vaccine's safety, efficacy, and side effects, trust in the government or related authorities, and religious beliefs were primary factors that influenced vaccine acceptance. The pooled proportion of COVID-19 vaccine acceptance among regions ranged from 52 to 74%, while among population groups varied from 52 to 63%, with healthcare workers showing the highest proportion of vaccine acceptance. Since healthcare workers were among the first to receive COVID-19 vaccines, their attitude or perception toward COVID-19 vaccines would affect the other population's decisions to recommend the vaccination to friends, families, and their patients. The time during which the survey was conducted showed that the acceptance of the COVID-19 vaccine changed over time. The United States showed an increased pattern of vaccine acceptance in the second and third surveys. The authors concluded that the rate of COVID-19 vaccine acceptance varied by region, population type, gender, vaccine effectiveness, and survey time, with an overall pooled proportion of 61%. A high level of acceptance of vaccination is required to achieve herd immunity for the disease. A successful and effective vaccination program can provide sufficient vaccination coverage in a population to achieve herd immunity and subsequently control the COVID-19 pandemic.

b. Norhayati, Mohd Noor, Ruhana Che Yusof, and Yacob Mohd Azman. 2022. "Systematic Review and Meta-Analysis of COVID-19 Vaccination Acceptance." Frontiers in Medicine 8 (January). https://doi.org/10.3389/fmed.2021.783982.

Source of empirical data

Published, peer-reviewed original research;Published and publicly available reports (e.g., from agencies)

Summarize the empirical data

Appendix D of the Evidence form (attached) provides information the effectiveness of COVID-19 vaccinations in preventing COVID-19 related health outcomes.

Evidence of the effectiveness of COVID-19 vaccinations in preventing COVID-19 infections and related health outcomes is essential for guiding policymaking decisions regarding the ongoing public health emergency (PHE). As more data have become available, researchers have been able to assess the effectiveness of all COVID-19 vaccinations accessible in the United States across various populations and settings. These data demonstrate that the three COVID-19 vaccines approved for emergency use by the Food and Drug Administration (FDA), Pfizer-BioNTech (BNT162b2 mRNA), Moderna (mRNA-1273), and Johnson & Johnson/Janssen (JNJ-78436735), are highly effective for preventing COVID-19-related serious illness, hospitalization, and death (Rosenberg et al., 2021). In fact, for full messenger RNA (mRNA) vaccines (Pfizer and Moderna), vaccine effectiveness (VE) against COVID-19-associated hospitalizations was found to be 86% two to twelve weeks after receipt of the second dose and 84% 13 to 24 weeks after the second dose (Tenforde et. al, 2021). Note: These VE calculation estimates

presented in these studies pre-date the delta and omicron surges. A study conducted by the New York State Department of Health, assessed statewide laboratory testing, hospitalization, and immunization databases to determine rates of new COVID-19 cases and hospitalizations among adults age 18 or older and to evaluate VE between May and July 2021 (Rosenberg et al., 2021). Researchers observed a decline in VE against new infection from 91.7% to 79.8% between May and July 2021, which can be attributed to the increase in delta variant prevalence during the study window. Despite this decline in VE against new infection, the VE against hospitalization for fully vaccinated adults remained high at 90% (Rosenberg et al., 2021). These results indicate that all three COVID-19 vaccinations available in the US are still useful for preventing some infections and highly effective at preventing hospitalization in adults.

Several studies focusing on VE among older adults have also been published recently. A study by Thompson et al. assessed the VE for all three FDA-approved vaccines against laboratory-confirmed infection, infection-associated hospitalizations, ICU admissions, and visits to emergency departments or urgent cares among adults 50 years of age or older between January and June 2021. Researchers found that VE against infection leading to hospitalization was 89% after the second dose of a mRNA vaccine (Pfizer and Moderna). Effectiveness against infection leading to ICU admission and effectiveness against infection leading to an emergency department or urgent care visit for full mRNA vaccines were 90% and 91% respectively. The effectiveness of the Johnson & Johnson vaccine was lower than the full mRNA vaccines among the study population, as VE was 68% against infection leading to hospitalization and 73% against infection leading to an emergency department or urgent care clinic visit. The results of this study indicate that all three FDA-approved COVID-19 vaccines are highly effective against infection leading to hospitalization, ICU admission, or emergency department visit among adults 50 years of age or older, with full doses of the Pfizer and Moderna vaccines being somewhat more effective than Johnson & Johnson. Similar findings were observed in a recently published study focusing on VE among adults 65 years of age or older. In this study population, VE against COVID-19-associated hospitalizations was 91% and 84% for full vaccination with mRNA vaccines and vaccination with the Johnson & Johnson vaccine respectively (Moline et al., 2021). Overall, these studies provide evidence of the effectiveness of COVID-19 vaccinations in preventing hospitalization among older adults.

In addition to older adults, differences in VE among the three authorized COVID-19 vaccines have been observed in the broader adult population aged 18 and older. Among these adults who do not have any immunocompromising conditions, researchers observed that the VE against hospitalization was higher for the Moderna vaccine (93%) than the Pfizer vaccine (88%) (Self et al., 2021). The VE against hospitalization for the Johnson & Johnson vaccine was the lowest of the three authorized vaccines at 71%. Despite these differences in VE, all three authorized COVID-19 vaccines are still useful for preventing some infections and highly effective at preventing hospitalization.

The effectiveness of these vaccines has also been tested among healthcare and frontline workers, as these populations are at increased risk for COVID-19 infection. A recently published observational study

examined new COVID-19 infections among healthcare workers who received at least one dose of vaccine between January and May 2021. Researchers found that VE 14 days after the first dose was 49.2% and 38.2% for the Pfizer and Moderna vaccines, respectively (Paris et al., 2021). Effectiveness improved substantially 14 days after the second dose, as Pfizer VE increased to 100% and Moderna VE increased to 94.6%. Similar results were observed in a study that focused on a broader population of frontline workers, defined as healthcare personnel, first responders, and other essential workers (Fowlkes et al., 2021). Researchers evaluated VE against infection among frontline workers in six states between December 2020 and April 2021 and observed an adjusted VE of 91%. However, when researchers assessed data from May 2021 to August 2021 to account for surges in cases of the delta variant, the adjusted VE was 66%. These findings suggest that VE is higher against COVID-19 alpha infections than delta infections among frontline workers.

The VE against alpha and delta infections was also studied by Lopez Bernal et al., who estimated the VE against symptomatic disease caused by the delta variant among people 16 years of age and older between February and May 2021. After one dose of the Pfizer vaccine, the VE against the alpha variant was considerably higher (48.7%) than the VE against the delta variant (30.7%). This difference in VE decreased after participants received the second dose of the Pfizer vaccine, as the VE against the alpha variant increased to 93.7% while the VE against the delta variant increased to 88.0%. These findings deviate slightly from Fowlkes et al.'s study, where researchers observed a greater difference in VE against the alpha and delta variants. This is likely due to the different study windows used, as Fowlkes et al. examined data from May 2021 to August 2021 during the surge in delta infections, hospitalizations, and deaths.

Given the demonstrated higher VE against the alpha variant compared to the delta variant, researchers have focused on evaluating VE during periods of time when delta infections, hospitalizations, and deaths were surging. Grannis et al. examined medical encounters across nine states where adults 18 years of age or older received a COVID-19 discharge diagnosis from a hospital, emergency department, or urgent care between June and August 2021 when the delta variant accounted for more than 50% of cases in the respective states. Researchers found that VE for all three authorized COVID-19 vaccines was 86% against hospitalization and 82% against emergency department and urgent care visits. However, when stratified by age, VE against hospitalization was significantly lower for adults 75 years of age or older (76%) compared to adults between 18 and 74 (89%). Despite the lower VE for adults aged 75 years and older, vaccination still proves highly effective at preventing COVID-19-related hospitalization among this population during periods of high delta variant incidence.

Lauring et al. (2022) studied the effectiveness of the mRNA vaccines to prevent COVID-19 hospitalizations related to the alpha, delta, and omicron SARS-CoV-2 variants from March 11, 2021, to January 14, 2022. The effectiveness of two vaccine doses against hospitalization was 85% during the periods of the study when alpha and delta dominated but 65% during the omicron period—late December 2021 through mid-January 2022. The effectiveness of three vaccine doses during the Omicron

phase was 86%. mRNA vaccines were found to be highly effective in preventing COVID-19 associated hospital admissions related to the alpha, delta, and omicron variants, but three vaccine doses were required to achieve protection against omicron similar to the protection that two doses provided against the delta and alpha variants. Among adults admitted to hospital with COVID-19, the omicron variant was associated with less severe disease than the delta variant but still resulted in substantial morbidity and mortality. Vaccinated patients with COVID-19 hospitalizations had significantly lower disease severity than unvaccinated patients for all the variants.

Appendix D References:

Fowlkes, Ashley, et al. 2021. "Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection among Frontline Workers before and during B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7034e4.

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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, (March): e069761. https://doi.org/10.1136/bmj-2021-069761.

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 (7). https://doi.org/10.1056/nejmoa2108891.

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Paris, Christophe, et al. 2021. "Effectiveness of MRNA-BNT162b2, MRNA-1273, and ChAdOx1 NCoV-19 Vaccines against COVID-19 in Healthcare Workers: An Observational Study Using Surveillance Data." Clinical Microbiology and Infection, July. https://doi.org/10.1016/j.cmi.2021.06.043.

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Self, Wesley H., et al. 2021. "Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations among Adults without

Immunocompromising Conditions — United States, March–August 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7038e1.

Tenforde, Mark W., et al. 2021. "Effectiveness of Pfizer-BioNTech and Moderna Vaccines against COVID-19 among Hospitalized Adults Aged ≥65 Years — United States, January–March 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7018e1.

Thompson, Mark G., et al. 2021. "Effectiveness of Covid-19 Vaccines in Ambulatory and Inpatient Care Settings." New England Journal of Medicine, September. https://doi.org/10.1056/nejmoa2110362.

Appendix D Limitations:

1. Fowlkes, Ashley, et al. 2021
    a. The study was limited to a 35 week period of observations (December 14, 2020 – April 10, 2021) before and during the delta variant. Unmeasured and residual confounding might be present.
2. Grannis, Shaun J., et al. 2021
    a. Duration of VE was not examined and VE for partial vaccination was not assessed. Although the facilities in this study serve heterogenous populations in nine states, the findings might not be generalizable to the U.S. population.
3. Lauring, Adam S et al. 2022
    a. The use of in-patient controls might lead to biased estimates if control patients had different characteristics from people in the general community, however, the control population within this study tracked closely with the adult population in the US. The study was limited to VE for patients admitted to the hospital. The study only evaluated mRNA vaccines, not other types of covid-19 vaccines. Sequencing did not identify a variant for some cases—typically those with low viral loads in tested respiratory samples. Variant classification for cases without a sequencing confirmed variant was based on the predominant circulating variant at the time; variant misclassification was possible for these cases, but sensitivity analyses limited to sequencing confirmed cases produced results similar to those in the primary analysis.
4. Lopez Bernal, Jamie, et al. 2021
    a. The findings are observational and unmeasured and residual confounding might be present. Low sensitivity or specificity of PCR testing could result in cases and controls being misclassified, which would attenuate the estimates of vaccine effectiveness. Low sensitivity or specificity of PCR testing could also affect one variant more than another, although this might be expected to affect the alpha variant more than the delta variant, given that, with an emerging variant, more cases may be detected earlier in infection, which may result in higher viral loads and increased sensitivity and specificity. There may also be differences among the populations that received each vaccine. The analysis also relied on the assumptions that any residual confounding in the test-negative case–control design would affect the two estimates of vaccine effectiveness equally or at least would not bias the adjusted odds ratio for the comparison of vaccine effectiveness for a given vaccine against the two variants; that is, the accuracy of the sequencing would not depend on the variant

and the propensity among symptomatic persons to get tested would not differ according to variant.

5. Moline, Heidi L., et al. 2021
    a. VE estimates were adjusted for relevant potential confounders, residual confounding is possible (e.g., chronic conditions. the heterogeneity of disease risk, vaccination coverage within each site, and differences in the populations who received different vaccine products). The study period for this analysis occurred before the predominance of the delta variant; changes in circulating SARS-CoV-2 variants might affect vaccine effectiveness when assessed over time. Persons choosing to receive vaccine later in the rollout might have different risk characteristics than do those vaccinated earlier and might have experienced differences in access to vaccine products by time and location. This analysis was limited to adults at/above 65 years, and the results are not generalizable to younger age groups.
6. Paris, Christophe, et al. 2021
    a. Findings may not be generalizable to other settings, given the variability of the epidemiology of SARS-CoV-2 variants. The study was not powered to evaluate vaccine effectiveness more than 3 months after the first dose. The study was based on passive surveillance, so asymptomatic SARS-CoV-2 infection may have been underestimated.
7. Rosenberg, Eli S., et al. 2021
    a. Residual differences between fully vaccinated and unvaccinated groups have the potential to reduce estimated VE. The analysis excluded partially vaccinated persons, to robustly assess VE for fully vaccinated compared with that of unvaccinated persons. Exact algorithms were used to link databases; some persons were possibly not linked because matching variables were entered differently in the respective systems. This study did not estimate VE by vaccine product, and persons were categorized fully vaccinated at 14 days after final dose, per CDC definitions. Information on reasons for testing and hospitalization, including symptoms, was limited. Data were too sparse to reliably estimate VE for COVID-19-related deaths.
8. Self, Wesley H., et al. 2021
    a. The analysis excluded children, immunocompromised adults, or VE against COVID-19 that did not result in hospitalization. The confidence intervals for the Janssen VE estimates were wide because of the relatively small number of patients who received this vaccine. Follow-up time was limited to approximately 29 weeks since receipt of full vaccination, and further surveillance of VE over time is warranted. Although VE estimates were adjusted for relevant potential confounders, residual confounding is possible. Product-specific VE by variant, including against delta variants (B.1.617.2 and AY sublineages), was not evaluated. Antibody levels were measured at only a single time point 2–6 weeks after vaccination and changes in antibody response over time as well as cell-mediated immune responses were not assessed.
9. Tenforde, Mark W., et al. 2021
    a. The confidence intervals for VE estimates were wide because of the small sample size, and the number of participants was too small to assess VE by vaccine product, age group, or underlying conditions. As an interim analysis that included self-reported data, vaccination status might have been misclassified, or participants might have had imperfect recollection of vaccination or illness onset dates. Selection bias and residual confounding cannot be excluded. Although the analysis included hospitalized adults from 14 states, the participants were not geographically representative of the U.S. population. The case-control design infers protection based on associations between disease outcome and previous vaccination

but cannot establish causation. Duration of VE and VE for non-hospitalized COVID-19 was not assessed.

10. Thompson, Mark G., et al. 2021
    a. VE estimates were adjusted for relevant potential confounders, unmeasured and residual confounding is possible (e.g., occupations of the patients, which is associated with exposure to virus and access to and use of vaccination and personal protective equipment). The percentage of patients who were clinically tested for SARS-CoV-2 by molecular assay differed across network partners and clinical settings, and vaccine-effectiveness estimates can be biased if clinicians make testing decisions based on vaccination status.

Name evidence type

N/A

Summarize the evidence

N/A

Does the evidence discuss a link between at least one process, structure, or intervention with the outcome?

N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size

520,260

Type of Evidence to Support the Measure

Clinical Guidelines or USPSTF (U.S. Preventive Services Task Force) Guidelines;Peer-Reviewed Systematic Review; Empirical data

Is the measure risk adjusted?

No

Risk adjustment variables

N/A

Patient-level demographics: please select all that apply:

N/A

Patient-level health status & clinical conditions: please select all that apply:

N/A

Patient functional status: please select all that apply:

N/A

Patient-level social risk factors: please select all that apply:

N/A

Proxy social risk factors: please select all that apply

N/A

Patient community characteristic: please select all that apply:

N/A

Risk model performance

N/A

Rationale for not using risk adjustment

Addressed through exclusions (e.g., process measures)

Cost estimate completed

No

Cost estimate methods and results

N/A

Section 3: Patient and Provider Perspective

Meaningful to Patients. Was input on the final performance measure collected from patient and/or caregiver?

Yes

Total number of patients and/or caregivers who responded to the question asking them whether the final performance measure helps inform care and decision making

5

Total number of patients/caregivers who agreed that the final performance measure helps inform care and decision making

5

Meaningful to Patients: Numbers consulted

N/A

Meaningful to Patients: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians: Numbers consulted

N/A

Meaningful to Clinicians: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians. Were clinicians and/or providers consulted on the final performance measure?

Yes

Acumen convened a Technical Expert Panel (TEP) for the purposes of soliciting feedback on the development of a Post-Acute Care (PAC) patient-level COVID-19 vaccination measure for the PAC

settings, along with the accompanying PAC patient-level COVID-19 vaccination assessment item. The PAC QRP Vaccination TEP comprised of 11 stakeholders with diverse perspectives and areas of expertise representing clinical, policy and program, measure development, and technical expertise. Additionally, the PAC QRP Support team met with a patient and family/caregiver advocates focus group assembled by Patient and Family Centered Care (PFCC) Partners. This session was held in order to inform the TEP discussion of the viewpoints of patients and family/caregivers who actively utilize the Care Compare website in order to make informed decisions about their or their loved one's healthcare.

The patient and family/caregiver advocates felt a measure capturing raw vaccination rate, irrespective of provider action, would be most helpful to them when deciding to choose a facility for either their own care or for a loved one. TEP Panelists agreed that reporting the rate of vaccination in a PAC/NH setting without denominator exclusions is important to meet when designing a measure.

Total number of clinicians/providers who responded when asked if the final performance measure was actionable to improve quality of care.

0

Total number of clinicians/providers who agreed that the final performance measure was actionable to improve quality of care

0

Survey level testing

N/A

Type of Testing Analysis

N/A

Testing methodology and results

N/A

Burden for Provider: Was a provider workflow analysis conducted?

No

If yes, how many sites were evaluated in the provider workflow analysis?

N/A

Did the provider workflow have to be modified to accommodate the new measure?

N/A

Section 4: Measure Testing Details

Reliability

No

Reliability: Type of Reliability Testing

N/A

Signal-to-Noise: Name of statistic

N/A

Signal-to-Noise: Sample size

N/A

Signal-to-Noise: Statistical result

N/A

Signal-to-Noise: Interpretation of results

N/A

Random Split-Half Correlation: Name of statistic

N/A

Random Split-Half Correlation: Sample size

N/A

Random Split-Half Correlation: Statistical result

N/A

Random Split-Half Correlation: Interpretation of results

N/A

Other: Name of statistic

N/A

Other: Sample size

N/A

Other: Statistical result

N/A

Other: Interpretation of results

N/A

Empiric Validity

No

Empiric Validity: Statistic name

N/A

Empiric Validity: Sample size

N/A

Empiric Validity: Statistical result

N/A

Empiric Validity: Methods and findings

N/A

Empiric Validity: Interpretation of results

N/A

Face Validity

No

Face Validity: Number of voting experts and patients/caregivers

N/A

Face Validity: Result

N/A

Patient/Encounter Level Testing

Yes

Type of Analysis

Other (enter here): Agreement with gold standard.

Sample Size

45

Statistic Name

Percent agreement

Statistical Results

84%

Interpretation of results

Our team used five patient scenarios for testing. Percent agreement was calculated by dividing the total number of patient scenario responses that matched the gold standard by the total number of patient scenario responses. Overall percent agreement for IRFs was 84%. Across all provider types, those who used the CDC website or the guidance manual and the CDC website had the highest percent agreement (100% and 88% respectively).

The results of the item testing support the use of a Patient-level COVID-19 Vaccination Coverage measure item. When providers use the available materials, percent agreement of the item increases to 85% or higher. The findings from the cognitive interviews provide information to improve the item itself, as well as the accompanying guidance. Based on the feedback received from providers during testing, we are able to add additional clarification to the coding guidance, such as providing the patient's age in the coding examples and including examples for coding certain unique patient scenarios. With these additional updates, we expect that the percent agreement would go up.

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Higher score is better

Mean performance score

99999

Median performance score

99999

Minimum performance score

99999

Maximum performance score

99999

Standard deviation of performance scores

99999

Does the performance measure use survey or patient-reported data?

No

Surveys or patient-reported outcome tools

N/A

Section 5: Measure Contact Information

Measure Steward

Centers for Medicare & Medicaid Services

Measure Steward Contact Information

Rebekah Natanov
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
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Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

Primary Submitter Contact Information

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Submitter Comments

N/A

MUC2022-090 COVID-19 Vaccine: Percent of Patients/Residents Who Are up to Date

Program

Home Health Quality Reporting Program

Section 1: Measure Information

Measure Specifications and Endorsement Status

Measure Description

The measure assesses the percent of home health patients that are up to date on their COVID-19 vaccinations as defined by CDC guidelines on current vaccination.

Up to date as defined by CDC is outlined at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html

Numerator

Total number of home health patients that are up to date on the Covid-19 vaccination.

Numerator Exclusions

None

Denominator

Total number of home health stays with a planned or unplanned discharge during the reporting period.

Denominator Exclusions

None

Denominator Exceptions

N/A

State of development

Field (Beta) Testing

State of Development Details

Item level testing was completed in July 2022. Testing was designed to test a clinician's ability to appropriately code likely clinical scenarios providers would encounter. A team of clinicians established correct responses to each scenario that would serve as the gold standard response and percent agreement to the gold standard response could be assessed. Five scenarios were completed by nine home health providers for a total of 45 cases. The testing team reviewed with participants an overview of a proposed COVID-19 patient measure and items used to calculate the measure in advance of participants completing clinical scenarios. After completing clinical scenarios, testing participants participated in a cognitive interview to determine the respondent's understanding of the item and rationale for coding the item. From the cognitive interviews, the team gained an understanding of the provider's decision-making process to complete the item for each scenario. A total percent agreement was calculated by dividing the total number of scenario responses that matched the gold standard by the total number of scenario responses completed (45).

What is the target population of the measure?

All home health stays receiving skilled care.

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Public and/or population health

Measure Type

Process

Is the measure a composite or component of a composite?

Not a composite or component of a composite measure

If Other, Please Specify

N/A

What data sources are used for the measure?

Standardized Patient Assessments;Other: OASIS assessment data

If applicable, specify the data source

N/A

Description of parts related to these sources

All data elements are part of the OASIS

At what level of analysis was the measure tested?

Facility

In which setting was this measure tested?

Home health

Multiple Scores

No

What one healthcare domain applies to this measure?

Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities

N/A

Is this measure in the CMS Measures Inventory Tool (CMIT)?

No

CMIT ID

N/A

Alternate Measure ID

N/A

What is the endorsement status of the measure?

Never Submitted

CBE ID (CMS consensus-based entity, or endorsement ID)

9999

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

N/A

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

No

If eCQM, enter Measure Authoring Tool (MAT) number

N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?

N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?

No

Previous Measure Information

N/A

What is the history or background for including this measure on the new measures under consideration list?

New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs

N/A

What other federal programs are currently using this measure?

N/A

Is this measure similar to and/or competing with a measure(s) already in a program?

No

Which measure(s) already in a program is your measure similar to and/or competing with?

N/A

How will this measure be distinguished from other similar and/or competing measures?

N/A

How will this measure add value to the CMS program?

N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

Section 1899B(d)(1) of the Social Security Act

Section 2: Measure Evidence

How is the measure expected to be reported to the program?

Other: OASIS data via IQIES

Stratification

No

Feasibility of Data Elements

ALL data elements are in defined fields in electronic sources

Feasibility Assessment

Two technical expert panel (TEP) meetings were organized to review of scope of issues related to the measure and data elements utilized to derive a measure score. The TEP represented experts from across post-acute care and with deep measure development experience. The TEP raised no feasibility concerns in collecting the COVID-19 vaccine item.

As an item on the OASIS, the item will be completed based on interview of patient/caregiver and/or review of medical records. Supplied guidance will outline best practices for item completion.

This item is not currently on the OASIS and when added would be collected electronically.

Method of Measure Calculation

Other digital method

Hybrid measure: Methods of measure calculation

N/A

Evidence of Performance Gap

Although literature is limited, there is some evidence of COVID-19 vaccination rates varying by facility type. A cross-sectional study used National Healthcare Safety Network (NHSN) facility-level data to examine the rate of full vaccination rates among nursing home residents and staff by facility type through July 18, 2021 (McGarry et al., 2021). The results of the analysis demonstrated that for-profit ownership status was associated with a 3.3 percentage point decrease in resident vaccination coverage compared to nonprofit ownership status. Medicare star ratings were also evaluated in this study, as each additional Medicare star rating a facility had was associated with a 1.2 percentage point increase in its residents vaccination coverage. These findings suggest that residents living in nonprofit facilities with higher Medicare Five-Star ratings are more likely to receive full dosage of the COVID-19 vaccine than residents living in for-profit facilities with lower star ratings.

Evidence suggests that a sizable proportion of the US population is not fully vaccinated and the extent to which people are not fully vaccinated varies geographically. According to CDC data used by the New York Times, as of October 22, 2021, 57% of the total US population have been fully vaccinated (approximately 189.9 million people) against COVID-19, and 66% have received at least one dose of vaccine (roughly 219.6 million people). Additionally, since August 13, 2021, when the FDA approved third doses for some populations, 11.3 million of the 189.9 million fully vaccinated people have received a vaccine booster. Although only 57% of the total US population is fully vaccinated, COVID-19 vaccination rates vary by region. States in the Northeast have the highest vaccination rates, while states in the Midwest and South have lower vaccination rates. Vaccination rates in the West are also high, as 64.5% of New Mexico residents, 62.8% of Washington residents, and 62.3% of Oregon residents are fully vaccinated. With the exception of Virginia, Maryland, Washington DC, and Florida, the remaining Southern states all have lower fully vaccinated rates than the national average. In fact, the Southern state of West Virginia has the lowest vaccination rates in the country, as only 40.9% of its population is fully vaccinated. The Northeastern state of Vermont has the highest vaccination rates in the country, as 70.7% of its population is fully vaccinated.

In addition to variation by region, COVID-19 vaccination rates also vary by patient characteristics. To assess whether or not disparities exist among different racial and ethnic groups in the US, the CDC evaluated data from the CDC Vaccine Safety Datalink (CVS) that included vaccination coverage among persons aged 16 years and older between December 2020 and May 2021 (Pingali et al., 2021). For those who received at least one dose of the Pfizer, Moderna, or Johnson & Johnson vaccine, vaccination rates were highest among Asian persons (57.4%) and lowest among non-Hispanic Black (40.7%) and Hispanic (41.14%) persons. Non-Hispanic Black and Hispanic persons also had lower vaccination rates than Whites (54.6%). The Kaiser Family Foundation (KFF) assessed more recent state-reported data on COVID-19 vaccination rates and observed similar findings. As of October 4, 2021, 54% of White people have received at least one COVID-19 vaccine dose, which is 1.2 times higher than the rate for Black people (46%) and 1.1 times higher than the rate for Hispanic people (51%) (Ndugga et al., 2021). Additionally, 69% of Asian people have received at least one COVID-19 vaccine dose, which aligns with Pingali et al. findings that Asian people have the highest vaccination rates. Although disparities in vaccination coverage are evident, the data suggests that these disparities have been decreasing over time. KFF reports that vaccination rates for Black and Hispanic people increased slightly more than

vaccination rates for Asian and White people between September 20, 2021 and October 4, 2021, thereby decreasing the gaps in vaccination coverage. This gap in vaccination rates between Black and White people decreased from 14 percentage points to 8 percentage points between April and October 2021. The gap in vaccination rates between White and Hispanic people also decreased during this period of time from 13 percentage points to 3 percentage points. Despite the decreases in these gaps, disparities in vaccination coverage persist.

Other patient characteristics, such as age, sex, and high-risk conditions, also contribute to variations in vaccination rates in the US. A recent study by Diesel et al. (2021) examined CDC data on vaccination coverage for adults aged 18 and older between December 2020 and May 2021 and found that vaccination rates (1 COVID-19 vaccine dose) were lowest among persons aged 18-29 years (38.3%) and highest among persons aged 65 and older (80.0%). Pingali et al. investigated vaccination rates among persons with high-risk conditions and previous COVID-19 infections. Researchers observed a vaccination rate of 63.8% for persons with medical conditions deemed high-risk for severe COVID-19 infection and a vaccination rate of 41.5% for persons without such conditions. Regarding previous COVID-19 infection, the vaccination rate was 48.8% for those who had not had COVID-19 and 42.4% for those who had COVID-19 previously. Overall, these studies suggest that COVID-19 vaccination rates are highest among adults aged 65 and older who have medical conditions deemed high-risk but did not have a COVID-19 infection previously.

References:

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Pingali, Cassandra et al. 2021. COVID-19 Vaccination Coverage among Insured Persons Aged 16 Years, by Race/Ethnicity and Other Selected Characteristics Eight Integrated Health Care Organizations, United States, December 14, 2020 May 15, 2021. MMWR. Morbidity and Mortality Weekly Report 70 (28): 98590. https://doi.org/10.15585/mmwr.mm7028a1.

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Diesel, Jill et al. 2021. COVID-19 Vaccination Coverage among Adults United States, December 14, 2020 May 22, 2021. MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7025e1.

Unintended Consequences

The measure may impact access to care due to the perception of a HHA from its COVID-19 rates. If HHAs think they have to maintain high COVID-19 vaccination rates, they may reject patients that are not up to date on their COVID-19 vaccinations. We anticipate this risk to be low, given the current state of the pandemic.

CMS regularly monitors trends in vaccination as well as enrollment in HHAs to assess changes in care provision that may require further review.

Number of clinical guidelines, including USPSTF guidelines, that address this measure topic

4

Outline the clinical guidelines supporting this measure

[1] The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Use of Pfizer Vaccine conducted an explicit, evidence-based review of available data for the use of the Pfizer COVID-19 vaccine in persons aged ≥ 16 years for the prevention of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for patients throughout the continuum of care, including post-acute and home-based care who may not be vaccinated for COVID-19.

The body of evidence for the Pfizer-BioNTech COVID-19 vaccine was primarily informed by one large, randomized, double-blind, placebo-controlled Phase II/III clinical trial that enrolled >43,000 participants (median age = 52 years, range = 16–91 years). Interim findings from this clinical trial, using data from participants with a median of two months of follow-up, indicate that the Pfizer-BioNTech COVID-19 vaccine was 95.0% effective (95% confidence interval = 90.3%–97.6%) in preventing symptomatic laboratory-confirmed COVID-19 in persons without evidence of previous SARS-CoV-2 infection. Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Efficacy was similarly high in a secondary analysis including participants both with or without evidence of previous SARS-CoV-2 infection. Although numbers of observed hospitalizations and deaths were low, the available data were consistent with reduced risk for these severe outcomes among vaccinated persons compared with that among placebo recipients.

Using the GRADE evidence assessment, the authors concluded the level of certainty for the benefits of the Pfizer-BioNTech COVID-19 vaccine was type 1 (high certainty) for the prevention of symptomatic COVID-19. Evidence was type 3 (low certainty) for the estimate of prevention of COVID-19–associated hospitalization and type 4 (very low certainty) for the estimate of prevention of death. At the time of these recommendations, data on hospitalizations and deaths were limited, but a vaccine that effectively prevents symptomatic infection is expected to also prevent hospitalizations and deaths.

[2] The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Use of Moderna Vaccine conducted a transparent, evidence-based review of available data for the use of the Moderna COVID-19 vaccine in persons aged ≥ 18 years for the prevention of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for patients throughout the continuum of care, including post-acute and home-based care who may not be vaccinated for COVID-19.

The body of evidence for the Moderna COVID-19 vaccine was primarily informed by one large, randomized, double-blind, placebo-controlled Phase III clinical trial that enrolled approximately 30,000 participants aged 18–95 years (median = 52 years). Interim findings from this clinical trial, using data from participants with a median of two months of follow-up, indicate that the Moderna COVID-19 vaccine efficacy after two doses was 94.1% (95% confidence interval = 89.3%–96.8%) in preventing symptomatic, laboratory-confirmed COVID-19 among persons without evidence of previous SARS-CoV-2 infection, which was the primary study endpoint. High efficacy (≥86%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions.

Using the GRADE evidence assessment, the authors concluded the level of certainty for the benefits of the Moderna COVID-19 vaccine was type 1 (high certainty) for the prevention of symptomatic COVID-19. Evidence was type 2 (moderate certainty) for the estimate of prevention of COVID-19–associated hospitalization and type 4 (very low certainty) for the estimates of prevention of asymptomatic SARS-CoV-2 infection and all-cause death. At the time of these recommendations, data on COVID-19–associated hospitalizations and deaths were limited; however, a vaccine that effectively prevents symptomatic infection is expected to also prevent associated hospitalizations and deaths.

[3] The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Use of Janssen COVID-19 Vaccine conducted an evidence-based review of all available data on the use of the Janssen COVID-19 vaccine in persons aged ≥ 18 years for the prevention of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for patients throughout the continuum of care, including post-acute and home-based care who may not be vaccinated for COVID-19.

The body of evidence for the Janssen COVID-19 vaccine was primarily informed by one international Phase III clinical trial initiated in September 2020 that enrolled approximately 40,000 participants aged 18–100 years (median age = 52 years), using two coprimary endpoints: prevention of symptomatic, laboratory-confirmed¶ COVID-19 among persons without evidence of previous SARS-CoV-2 infection occurring 1) ≥14 days and 2) ≥28 days after vaccination. Interim findings from this clinical trial indicate that the Janssen COVID-19 vaccine efficacy against symptomatic, laboratory-confirmed COVID-19 was 66.3% (95% confidence interval [CI] = 59.9%–71.8%) ≥14 days after vaccination and 65.5% (95% CI = 57.2%–72.4%) ≥28 days after vaccination. At ≥14 days after vaccination, efficacy of ≥63.0% was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Efficacy varied geographically and was highest in the United States (74.4%; 95% CI = 65.0%–81.6%). Vaccine recipients frequently experienced reactogenicity symptoms, defined as solicited local injection site or systemic adverse reactions during the 7 days after vaccination; however, the symptoms were mostly mild to moderate and resolved 1–2 days after vaccination. Symptoms were more frequent among persons aged 18–59 years than among those aged ≥60 years.

From the GRADE evidence assessment, the level of certainty for the benefits of the Janssen COVID-19 vaccine was type 2 (moderate certainty) for the prevention of symptomatic COVID-19. Evidence was also type 2 (moderate certainty) for the estimate of prevention of COVID-19–associated hospitalization and death. Evidence was type 3 (low certainty) for the estimates of prevention of SARS-CoV-2 seroconversion. Regarding certainty of evidence for possible harms after vaccination, evidence was type 1 (high certainty) for reactogenicity and type 2 (moderate certainty) for serious adverse events. Data reviewed within the EtR framework supported the use of the Janssen COVID-19 vaccine.

[4] The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines issued recommendations for an additional dose of the primary mRNA COVID-19 vaccine for immunocompromised persons and a COVID-19 vaccine booster dose in eligible groups, as well as persons who are at increased risk for exposure to or serious complications of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for remaining up to date with the COVID-19 vaccine for patients throughout the continuum of care, including post-acute and home-based care.

Since June 2020, ACIP has convened 20 public meetings to review data relevant to the potential use of COVID-19 vaccines. To assess the certainty of evidence for benefits and harms of a booster dose, ACIP used the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. To further guide its deliberations around the use of an additional or booster dose, ACIP used the Evidence to Recommendations (EtR) Framework to evaluate other factors, including the importance of COVID-19 as a public health problem as well as matters of resource use, benefits and harms, patients' values and preferences, acceptability, feasibility, and equity for use of the vaccines.

ACIP concluded that the evidence reviewed, including data and considerations from the EtR Frameworks, supported the use of an additional primary dose of an mRNA COVID-19 vaccine for certain immunocompromised recipients of an initial mRNA series, a COVID-19 vaccine booster dose for certain recipients of an mRNA primary series who are at increased risk for exposure to or serious complications of COVID-19, and a COVID-19 vaccine booster dose for all recipients of a Janssen COVID-19 vaccine dose.

Name the guideline developer/entity

The Advisory Committee on Immunization Practices (ACIP)

Publication year

2020

Full citation +/- URL

[1] Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' Interim Recommendations for Use of Pfizer-BioNTech COVID-19 Vaccine – United States, December 2020. MMWR Morb Mortal Wkly Rep 2020;69:1922-1924. DOI: http://dx.doi.org/10.15585/mmwr.mm6950e2.

[2] Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' Interim Recommendations for Use of Moderna COVID-19 Vaccine – United States, December 2020. MMWR Morb Mortal Wkly Rep 2021;69;1653-1656. DOI: http://dx.doi.org/10.15585/mmwr.mm695152e1

[3] Oliver SE, Gargano JW, Scobie H, et al. The Advisory Committee on Immunization Practices' Interim Recommendations for Use of Janssen COVID-19 Vaccine – United States, February 2021. MMWR Mob Mortal Wkly Rep 2021;70:329-332. DOI: http://dx.doi.org/10.15585/mmwr.mm7009e4.

[4] Mbaeyi S, Oliver SE, Collins JP, et al. The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines – United States, 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70:1545-1552. DOI: http://Doi:10.15585/mmwr.mm7044e2.

Is this an evidence-based clinical guideline?

Yes

Is the guideline graded?

Yes

List the guideline statement that most closely aligns with the measure concept.

[1] ACIP concluded the Pfizer COVID-19 vaccine has high efficacy for the prevention of symptomatic COVID-19.

[2] ACIP concluded the Moderna COVID-19 vaccine has high efficacy for the prevention of symptomatic COVID-19.

[3] ACIP concluded the Janssen COVID-19 vaccine has high efficacy against COVID-19 associated hospitalization and death.

[4] ACIP concluded that the evidence reviewed supported the use of an additional primary dose of an mRNA COVID-19 vaccine for certain immunocompromised recipients of an initial mRNA series, a COVID-19 vaccine booster dose for certain recipients of an mRNA primary series who are at increased risk for exposure to or serious complications of COVID-19, and a COVID-19 vaccine booster dose for all recipients of a Janssen COVID-19 vaccine dose.

What evidence grading system did the guideline use to describe strength of recommendation?

GRADE method

List all categories and corresponding definitions for the evidence grading system used to describe strength of recommendation in the guideline?

The GRADE certainty ratings and corresponding definitions are as follows:

1: High

The authors have a lot of confidence that the true effect is similar to the estimated effect.

2: Moderate

The authors believe that the true effect is probably close to the estimated effect.

3: Low

The true effect might be markedly different from the estimated effect.

4: Very low

The true effect is probably markedly different from the estimated effect.

For the guideline statement that most closely aligns with the measure concept, what is the associated strength of recommendation?

USPSTF Grade A, Strong recommendation or similar

What evidence grading system did the guideline use to describe level of evidence or level of certainty in the evidence?

GRADE method

List all categories and corresponding definitions for the evidence grading system used to describe level of evidence or level of certainty in the evidence?

The GRADE certainty ratings and corresponding definitions are as follows:

1: High

The authors have a lot of confidence that the true effect is similar to the estimated effect.

2: Moderate

The authors believe that the true effect is probably close to the estimated effect.

3: Low

The true effect might be markedly different from the estimated effect.

4: Very low

The true effect is probably markedly different from the estimated effect.

For the guideline statement that most closely aligns with the measure concept, what is the associated level of evidence or level of certainty in the evidence?

USPSTF Grade A, Strong recommendation or similar

List the guideline statement that most closely aligns with the measure concept.

[1] ACIP concluded the Pfizer COVID-19 vaccine has high efficacy for the prevention of symptomatic COVID-19.

[2] ACIP concluded the Moderna COVID-19 vaccine has high efficacy for the prevention of symptomatic COVID-19.

[3] ACIP concluded the Janssen COVID-19 vaccine has high efficacy against COVID-19 associated hospitalization and death.

[4] ACIP concluded that the evidence reviewed supported the use of an additional primary dose of an mRNA COVID-19 vaccine for certain immunocompromised recipients of an initial mRNA series, a COVID-19 vaccine booster dose for certain recipients of an mRNA primary series who are at increased risk for exposure to or serious complications of COVID-19, and a COVID-19 vaccine booster dose for all recipients of a Janssen COVID-19 vaccine dose.

Number of systematic reviews that inform this measure concept

4

Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept

[1] Korang et al. sought to assess the effectiveness and safety of COVID-19 vaccines through analyses of all currently available randomized clinical trials. The authors searched the databases CENTRAL, MEDLINE, Embase, and other sources from inception to June 17, 2021 for randomized clinical trials assessing vaccines for COVID-19. At least two independent reviewers screened studies, extracted data,

and assessed risks of bias prior to conducting meta-analyses, network meta-analyses, and Trial Sequential Analyses (TSA). Authors assessed the certainty of evidence with GRADE, and found 35 trials to include in the analyses. The meta-analyses showed that mRNA vaccines (efficacy, 95% [95% confidence interval (CI 92% to 97%]; 71,514 participants; 3 trials; moderate certainty); inactivated vaccines (efficacy, 61% [95% CI, 52% to 68%]; 48,029 participants; 3 trials; moderate certainty); protein subunit vaccines (efficacy, 77% [95% CI, −5% to 95%]; 17,737 participants; 2 trials; low certainty); and viral vector vaccines (efficacy 68% [95% CI, 61% to 74%]; 71,401 participants; 5 trials; low certainty) prevented COVID-19. Viral vector vaccines decreased mortality (risk ratio, 0.25 [95% CI 0.09 to 0.67]; 67,563 participants; 3 trials, low certainty), but comparable data on inactivated, mRNA, and protein subunit vaccines were imprecise. None of the vaccines showed evidence of a difference on serious adverse events, but observational evidence suggested rare serious adverse events. All the vaccines increased the risk of non-serious adverse events.

The authors concluded the evidence suggests that all the included vaccines are effective in preventing COVID-19. The mRNA vaccines seem most effective in preventing COVID-19, but viral vector vaccines seem most effective in reducing mortality. Further trials and longer follow-up are necessary to provide better insight into the safety profile of these vaccines.

Korang SK, von Rohden E, Veroniki AA, Ong G, Ngalamika O, Siddiqui F, 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

[2] Fiekin, et. al. sought to systematically review the evidence for the duration of protection of COVID-19 vaccines against various clinical outcomes, and to assess changes in the rates of breakthrough infection caused by the delta variant with increasing time since vaccination. This study was designed as a systematic review and meta-regression. A systematic review of preprint and peer-reviewed published article databases from June 17, 2021, to Dec 2, 2021 was conducted, and randomized controlled trials of COVID-19 vaccine efficacy and observational studies of COVID-19 vaccine effectiveness were eligible. The following databases and preprint servers without language restrictions were included in the search: PubMed, Embase, medRxiv, BioRxiv, khub, Research Square, SSRN, Eurosurveillance.org, Europepmc.org, and the WHO COVID-19 database, which compiles searches of more than 100 databases, including Scopus, Web of Science, grey literature. The authors searched for studies with several variations of the primary key search terms “COVID-19”, “SARS-CoV-2”, and “vaccine” (including names of specific vaccines) and “randomized controlled trial” or “vaccine effectiveness” (including names of specific study designs). Studies with vaccine efficacy or effectiveness estimates at discrete time intervals of people who had received full vaccination and that met predefined screening criteria underwent full-text review. Random-effects meta-regression was used to estimate the average change in vaccine efficacy or effectiveness 1–6 months after full vaccination. After applying exclusion criteria, 18 studies of vaccine efficacy or effectiveness at discrete time intervals after full vaccination and seven studies in which risk of breakthrough infection could be assessed by time of vaccination were included. In addition, the same search strategy was used to find studies presenting analyses of breakthrough infections, in which the rate, risk, or odds of COVID-19 outcomes among different vaccine cohorts (i.e., vaccinated at different times) were included.

The authors found that during the six months after full vaccination, vaccine efficacy or effectiveness against SARS-CoV-2 infection and symptomatic COVID-19 disease decreased by approximately 20–30

percentage points, on average, for the four vaccines that we evaluated. By contrast, most studies showed that vaccine efficacy or effectiveness against severe disease was maintained above 70% after full vaccination, with minimal decrease to six months (approximately 9–10 percentage points). The decrease in vaccine efficacy or effectiveness is likely caused by, at least in part, waning immunity, although an effect of bias cannot be ruled out. Evaluating vaccine efficacy or effectiveness beyond six months will be crucial for updating COVID-19 vaccine policy.

Feikin DR, Higdon MM, Abu-Raddad LJ, et al. Duration of effectiveness of vaccines against SARS-CoV-2 infection and covid-19 disease: results of a systematic review and meta-regression. Lancet 2022; 399:924-44. https://doi.org/10.1016/S0140-6736(22)00152-0

[3] The focus of this systematic review and meta-analysis was to compare the efficacy of COVID-19 vaccines between immunocompromised and immunocompetent people. Vaccine trials have excluded immunocompromised groups, but these patients are of particular interest because of possible suppression or over-activation of the immune system attributable to the primary disease or concurrent treatment. Data are needed on immunocompromised patients, as infection and viral shedding have been reported to be more severe and persistent in this group.

Immunocompromised patients show lower seroconversion rates than immunocompetent people after vaccination, such as with the influenza vaccine. Less is known about the response to COVID-19 vaccines, particularly mRNA based vaccines. Lee, et al (2022) sought to compare the efficacy of covid-19 vaccines between immunocompromised and immunocompetent people. Several databases were searched (Medline via PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), CORD-19, WHO COVID-19 Research Database, ClinicalTrials.gov, and WHO international clinical trials registry platform) for articles published from December 1, 2020 to November 5, 2021. No restrictions on language of publication were applied. To improve validity of data, non-peer reviewed articles in preprint databases were excluded. The authors assessed the certainty of evidence using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE). Overall, 82 studies were included for meta-analysis. Of these studies, 77 (94%) used mRNA vaccines, 16 (20%) viral vector vaccines, and 4 (5%) inactivated whole virus vaccines. The authors found that seroconversion rates after COVID-19 vaccination were significantly lower in immunocompromised patients, especially organ transplant recipients. A second dose was associated with consistently improved seroconversion across all patient groups, albeit at a lower magnitude for organ transplant recipients. The authors concluded targeted interventions for immunocompromised patients, including a third (booster) dose, should be performed.

Bin Lee ARY, Wong, SY, Chai LYA, et. al. Efficacy of COVID-19 vaccines in immunocompromised patients: systematic review and meta-analysis. BMJ 2022;376:e068632. http://dx.doi.org/10.1136/bmj-2021-068632.

[4] This review aimed to estimate the pooled proportion of COVID-19 vaccine acceptance worldwide. Determining the pooled estimated proportion of COVID-19 vaccination acceptance provides guidance to health authorities to prepare for an effective vaccination program.

A systematic review and meta-analysis of studies were conducted to assess the proportion of COVID-19 vaccination acceptance. A systematic search was performed in the MEDLINE (PubMed) database for

articles between January 1, 202 and July 19, 2021. The search was done using the generic free-text search terms "COVID-19" AND "vaccine" AND "acceptance." All types of COVID-19 vaccines were included in this review. The search was restricted to full-text only and English language articles. Studies with cross-sectional, case-control, and cohort designs were included. Case series/reports, conference papers, proceedings, articles available only in abstract form, editorial reviews, letters of communications, commentaries, systematic reviews and qualitative studies were excluded.

Assessment of critical appraisal for data quality was assessed using the Joann Briggs Institute (J.B.I.). Two authors performed bias assessments independently, and a total of 172 studies were included for the review and meta-analysis. The pooled proportion of COVID-19 vaccine acceptance involving 50 countries was 61% (95% CI: 59, 64%). This finding was lower compared to a previous estimate of 73.31% (95% CI: 70.52%, 76.01%) which involved 38 studies across 36 countries with limited data from low-income countries. Concern about the vaccine's safety, efficacy, and side effects, trust in the government or related authorities, and religious beliefs were primary factors that influenced vaccine acceptance. The pooled proportion of COVID-19 vaccine acceptance among regions ranged from 52 to 74%, while among population groups varied from 52 to 63%, with healthcare workers showing the highest proportion of vaccine acceptance. Since healthcare workers were among the first to receive COVID-19 vaccines, their attitude or perception toward COVID-19 vaccines would affect the other population's decisions to recommend the vaccination to friends, families and their patients. The time during which the survey was conducted showed that the acceptance of the COVID-19 vaccine changed over time. The United States showed an increased pattern of vaccine acceptance in the second and third surveys. The authors concluded that the rate of COVID-19 vaccine acceptance varied by region, population type, gender, vaccine effectiveness, and survey time, with an overall pooled proportion of 61%. A high level of acceptance of vaccination is required to achieve herd immunity for the disease. A successful and effective vaccination program can provide sufficient vaccination coverage in a population to achieve herd immunity and subsequently control the COVID-19 pandemic.

Norhayati MN, Che Yusof R and Azman YM (2022). Systematic Review and Meta-Analysis of COVID-19 Vaccination Acceptance. Front. Med. 8:783982. Doi: 10.3389/fmed.2021.783982.

Source of empirical data

Published, peer-reviewed original research;Published and publicly available reports (e.g., from agencies)

Summarize the empirical data

Evidence of the effectiveness of COVID-19 vaccinations in preventing COVID-19 infections and related health outcomes is essential for guiding policymaking decisions regarding the ongoing public health emergency (PHE). As more data have become available, researchers have been able to assess the effectiveness of all COVID-19 vaccinations accessible in the United States across various populations and settings. These data demonstrate that the three COVID-19 vaccines approved for emergency use by the Food and Drug Administration (FDA), Pfizer-BioNTech (BNT162b2 mRNA), Moderna (mRNA-1273), and Johnson & Johnson/Janssen (JNJ-78436735), are highly effective for preventing COVID-19-related serious illness, hospitalization, and death (Rosenberg et al., 2021). In fact, for full messenger RNA (mRNA) vaccines (Pfizer and Moderna), vaccine effectiveness (VE) against COVID-19-associated hospitalizations was found to be 86% two to twelve weeks after receipt of the second dose and 84% 13

to 24 weeks after the second dose (Tenforde et. al, 2021). Note: These VE calculation estimates presented in these studies pre-date the delta and omicron surges. A study conducted by the New York State Department of Health, assessed statewide laboratory testing, hospitalization, and immunization databases to determine rates of new COVID-19 cases and hospitalizations among adults age 18 or older and to evaluate VE between May and July 2021 (Rosenberg et al., 2021). Researchers observed a decline in VE against new infection from 91.7% to 79.8% between May and July 2021, which can be attributed to the increase in delta variant prevalence during the study window. Despite this decline in VE against new infection, the VE against hospitalization for fully vaccinated adults remained high at 90% (Rosenberg et al., 2021). These results indicate that all three COVID-19 vaccinations available in the US are still useful for preventing some infections and highly effective at preventing hospitalization in adults.

Several studies focusing on VE among older adults have also been published recently. A study by Thompson et al. assessed the VE for all three FDA approved vaccines against laboratory-confirmed infection, infection-associated hospitalizations, ICU admissions, and visits to emergency departments or urgent cares among adults 50 years of age or older between January and June 2021. Researchers found that VE against infection leading to hospitalization was 89% after the second dose of a mRNA vaccine (Pfizer and Moderna). Effectiveness against infection leading to ICU admission and effectiveness against infection leading to an emergency department or urgent care visit for full mRNA vaccines were 90% and 91% respectively. Effectiveness of the Johnson & Johnson vaccine was lower than the full mRNA vaccines among the study population, as VE was 68% against infection leading to hospitalization and 73% against infection leading to an emergency department or urgent care clinic visit. The results of this study indicate that all three FDA-approved COVID-19 vaccines are highly effective against infection leading to hospitalization, ICU admission, or emergency department visit among adults 50 years of age or older, with full doses of the Pfizer and Moderna vaccines being somewhat more effective than Johnson & Johnson. Similar findings were observed in a recently published study focusing on VE among adults 65 years of age or older. In this study population, VE against COVID-19-associated hospitalizations was 91% and 84% for full vaccination with mRNA vaccines and vaccination with the Johnson & Johnson vaccine respectively (Moline et al.). Overall, these studies provide evidence of the effectiveness of COVID-19 vaccinations in preventing hospitalization among older adults.

In addition to older adults, differences in VE among the three authorized COVID-19 vaccines have been observed in the broader adult population aged 18 and older. Among these adults who do not have any immunocompromising conditions, researchers observed that the VE against hospitalization was higher for the Moderna vaccine (93%) than the Pfizer vaccine (88%) (Self, et al., 2021). The VE against hospitalization for the Johnson & Johnson vaccine was the lowest of the three authorized vaccines at 71%. Despite these differences in VE, all three authorized COVID-19 vaccines are still useful for preventing some infections and highly effective at preventing hospitalization.

The effectiveness of these vaccines has also been tested among healthcare and frontline workers, as these populations are at increased risk for COVID-19 infection. A recently published observational study examined new COVID-19 infections among healthcare workers who received at least one dose of vaccine between January and May 2021. Researchers found that VE 14 days after first dose was 49.2% and 38.2% for the Pfizer and Moderna vaccines, respectively (Paris et al., 2021). Effectiveness improved substantially 14 days after the second dose, as Pfizer VE increased to 100% and Moderna VE increased to 94.6%. Similar results were observed in a study that focused on a broader population of frontline workers, defined as healthcare personnel, first responders, and other essential workers (Fowlkes et al.,

2021). Researchers evaluated VE against infection among frontline workers in six states between December 2020 and April 2021 and observed an adjusted VE of 91%. However, when researchers assessed data from May 2021 to August 2021 to account for surges in cases of the delta variant, the adjusted VE was 66%.These findings suggest that VE is higher against COVID-19 alpha infections than delta infections among frontline workers.

The VE against alpha and delta infections was also studied by Lopez Bernal et al., who estimated the VE against symptomatic disease caused by the delta variant among people 16 years of age and older between February and May 2021. After one dose of the Pfizer vaccine, the VE against the alpha variant was considerably higher (48.7%) than the VE against the delta variant (30.7%). This difference in VE decreased after participants received the second dose of the Pfizer vaccine, as the VE against the alpha variant increased to 93.7% while the VE against the delta variant increased to 88.0%.These findings deviate slightly from Fowlkes et al.'s study, where researchers observed a greater difference in VE against the alpha and delta variants. This is likely due to the different study windows used, as Fowlkes et al. examined data from May 2021 to August 2021 during the surge in delta infections, hospitalizations, and deaths.

Given the demonstrated higher VE against the alpha variant compared to the delta variant, researchers have focused on evaluating VE during periods of time when delta infections, hospitalizations, and deaths were surging. Grannis et al. examined medical encounters across nine states where adults 18 years of age or older received a COVID-19 discharge diagnosis from a hospital, emergency department, or urgent care between June and August 2021 when the delta variant accounted for more than 50% of cases in the respective states. Researchers found that VE for all three authorized COVID-19 vaccines was 86% against hospitalization and 82% against emergency department and urgent care visits. However, when stratified by age, VE against hospitalization was significantly lower for adults 75 years of age or older (76%) compared to adults between 18 and 74 (89%). Despite the lower VE for adults aged 75 years and older, vaccination still proves highly effective at preventing COVID-19-related hospitalization among this population during periods of high delta variant incidence.

Some studies have also looked at the VE of the currently available vaccinations against the two main omicron variants. Lauring et. al found that effectiveness of the mRNA vaccines' 2 vaccine doses against hospitalization was 85% during the periods of their study when alpha and delta dominated but 65% during the omicron period—late December 2021 through mid-January 2022. The effectiveness of 3 vaccine doses (2 does plus booster) during the Omicron phase was 86%. Another study by Stowe et. al found that the mRNA vaccines' 2 vaccine doses protection against hospitalization and death remained strong and was even more robust after a booster.

References:

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Name evidence type

N/A

Summarize the evidence

N/A

Does the evidence discuss a link between at least one process, structure, or intervention with the outcome?

N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size

5,323,281

Type of Evidence to Support the Measure

Clinical Guidelines or USPSTF (U.S. Preventive Services Task Force) Guidelines; Peer-Reviewed Systematic Review; Empirical data

Is the measure risk adjusted?

No

Risk adjustment variables

N/A

Patient-level demographics: please select all that apply:

N/A

Patient-level health status & clinical conditions: please select all that apply:

N/A

Patient functional status: please select all that apply:

N/A

Patient-level social risk factors: please select all that apply:

N/A

Proxy social risk factors: please select all that apply

N/A

Patient community characteristic: please select all that apply:

N/A

Risk model performance

N/A

Rationale for not using risk adjustment

Addressed through exclusions (e.g., process measures)

Cost estimate completed

No

Cost estimate methods and results

N/A

Section 3: Patient and Provider Perspective

Meaningful to Patients. Was input on the final performance measure collected from patient and/or caregiver?

Yes

Total number of patients and/or caregivers who responded to the question asking them whether the final performance measure helps inform care and decision making

5

Total number of patients/caregivers who agreed that the final performance measure helps inform care and decision making

5

Meaningful to Patients: Numbers consulted

N/A

Meaningful to Patients: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians: Numbers consulted

N/A

Meaningful to Clinicians: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians. Were clinicians and/or providers consulted on the final performance measure?

Yes

Total number of clinicians/providers who responded when asked if the final performance measure was actionable to improve quality of care.

0

Total number of clinicians/providers who agreed that the final performance measure was actionable to improve quality of care

0

Survey level testing

N/A

Type of Testing Analysis

N/A

Testing methodology and results

N/A

Burden for Provider: Was a provider workflow analysis conducted?

No

If yes, how many sites were evaluated in the provider workflow analysis?

N/A

Did the provider workflow have to be modified to accommodate the new measure?

N/A

Section 4: Measure Testing Details

Reliability

No

Reliability: Type of Reliability Testing

N/A

Signal-to-Noise: Name of statistic

N/A

Signal-to-Noise: Sample size

N/A

Signal-to-Noise: Statistical result

N/A

Signal-to-Noise: Interpretation of results

N/A

Random Split-Half Correlation: Name of statistic

N/A

Random Split-Half Correlation: Sample size

N/A

Random Split-Half Correlation: Statistical result

N/A

Random Split-Half Correlation: Interpretation of results

N/A

Other: Name of statistic

N/A

Other: Sample size

N/A

Other: Statistical result

N/A

Other: Interpretation of results

N/A

Empiric Validity

No

Empiric Validity: Statistic name

N/A

Empiric Validity: Sample size

N/A

Empiric Validity: Statistical result

N/A

Empiric Validity: Methods and findings

N/A

Empiric Validity: Interpretation of results

N/A

Face Validity

No

Face Validity: Number of voting experts and patients/caregivers

N/A

Face Validity: Result

N/A

Patient/Encounter Level Testing

Yes

Type of Analysis

Other (enter here): Agreement to gold standard

Sample Size

45

Statistic Name

Percent agreement

Statistical Results

66.8%

Interpretation of results

We assessed percent agreement in 45 patient scenarios. Total percent agreement was 66.8%. Relative to other PAC settings, HH testing results were lower. The source of discrepancy between participant response and the gold standard in most cases was a result of misunderstanding of CDC guidance on how up-to-date vaccine status is defined or a misapplication of the dash vs 'no' response in item coding. Based on input from participants during cognitive interviews, the team has determined areas in which the item and guidance language can be improved. These updates would likely increase percent agreement scores.

The results of the item testing, with improvements to guidance integrated into materials available to clinicians, support the use of a Patient-level COVID-19 Vaccination Coverage measure item. We anticipate as public health guidelines for COVID-19 primary and boosters vaccinations become more

established, coding to a consistent standard would further lead to improvement in percent agreement scores.

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Higher score is better

Mean performance score

9999

Median performance score

9999

Minimum performance score

9999

Maximum performance score

9999

Standard deviation of performance scores

9999

Does the performance measure use survey or patient-reported data?

No

Surveys or patient-reported outcome tools

N/A

Section 5: Measure Contact Information

Measure Steward

CMS

Measure Steward Contact Information

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Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

Primary Submitter Contact Information

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Submitter Comments

N/A

MUC2022-091 COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date

Program

Long-Term Care (LTC) Hospital Quality Reporting Program

Section 1: Measure Information

Measure Specifications and Endorsement Status

Measure Description

This one quarter measure reports the percentage of patients in a long-term care hospital (LTCH) who are up-to-date on their COVID-19 vaccinations per the Centers for Disease Control and Prevention's (CDC) latest guidance.

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 Your COVID-19 Vaccines", at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html (last accessed 5/18/2022).

This measure is based on data obtained through the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) discharge assessments during the selected quarter.

Numerator

The total number of patients who are up-to-date on the COVID-19 vaccine.

Numerator Exclusions

N/A

Denominator

The total number of LTCH stays discharged during the reporting period.

Denominator Exclusions

N/A

Denominator Exceptions

N/A

State of development

Field (Beta) Testing

State of Development Details

Cognitive interviews and data collection for patient scenarios were conducted from June through July 2022. Nine LTCHs participated in the cognitive interviews and each facility completed five patient scenarios, accounting for a total of 45 cases. The patient scenarios were developed in collaboration with a team of clinical experts and designed to represent the most common scenarios LTCH providers would encounter. The correct responses to each scenario were agreed upon by a panel of clinical experts so that percent agreement could be calculated using a gold standard. Cognitive interviews with each participant were conducted after the completion of patient scenarios. The goal of the cognitive

interviews was to gauge providers' comprehension of the item's concept and intent, as well as understand their decision process for completing the assessment item. Upon completion of interviews and patient scenarios, the completed scenarios were evaluated against the gold standard responses. Percent agreement was calculated by dividing the total number of patient scenario responses that matched the gold standard by the total number of patient scenario responses.

What is the target population of the measure?

All LTCH patient stays

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Public and/or population health

Measure Type

Process

Is the measure a composite or component of a composite?

Not a composite or component of a composite measure

If Other, Please Specify

N/A

What data sources are used for the measure?

Standardized Patient Assessments

If applicable, specify the data source

LCDS

Description of parts related to these sources

All data elements are sourced from LCDS.

At what level of analysis was the measure tested?

Facility

In which setting was this measure tested?

Long-term care hospital

Multiple Scores

No

What one healthcare domain applies to this measure?

Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities

N/A

Is this measure in the CMS Measures Inventory Tool (CMIT)?

No

CMIT ID

N/A

Alternate Measure ID

N/A

What is the endorsement status of the measure?

Never Submitted

CBE ID (CMS consensus-based entity, or endorsement ID)

9999

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

N/A

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

No

If eCQM, enter Measure Authoring Tool (MAT) number

N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?

N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?

No

Previous Measure Information

N/A

What is the history or background for including this measure on the new measures under consideration list?

New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs

N/A

What other federal programs are currently using this measure?

N/A

Is this measure similar to and/or competing with a measure(s) already in a program?

Yes

Which measure(s) already in a program is your measure similar to and/or competing with?

[1] COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (MUC20-0044) for the IRF QRP, LTCH QRP, and SNF QRP

[2] SARS-CoV-2 Vaccination by Clinicians (MUC20-0045)

[3] CDC/NHSN 'resident vaccination', 'resident boosters', 'staff vaccination, and 'staff boosters' COVID-19 vaccination and booster rates reported on Care Compare for long term Nursing Home residents

How will this measure be distinguished from other similar and/or competing measures?

Comparison of the Patient/Resident COVID-19 Vaccine and the SARS-CoV-2 Vaccination by Clinicians Measure:

The COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure assesses COVID-19 vaccinations for the LTCH patient population, whereas the SARS-CoV-2 Vaccination by Clinician measure focuses on COVID-19 vaccination among ambulatory care patients and the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) focuses on healthcare personnel.

Comparison of the Patient/Resident COVID-19 Vaccine measure and the CDC/NHSN 'resident vaccination' and 'resident boosters' rates:

The COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure assesses COVID-19 vaccinations for the LTCH patient population, whereas CDC/NHSN 'resident vaccination' and 'resident boosters' rates captures the Nursing Home (NH) resident population.

How will this measure add value to the CMS program?

The COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure complements the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure that is collected for the IRF QRP, LTCH QRP, and SNF QRP. An advantage to reporting a simple vaccination rate at the patient-level is that it provides useful information to the public and to providers. We received feedback from patient and family advocates that a measure capturing raw vaccination rates, irrespective of provider action,

would be highly valuable when making healthcare decisions to select a facility for themselves or a loved one.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

Section 1899B(d)(1) of the Social Security Act

Section 2: Measure Evidence

How is the measure expected to be reported to the program?

Other: LCDS assessment data through the Internet Quality Improvement and Evaluation System (iQIES)

Stratification

No

Feasibility of Data Elements

ALL data elements are in defined fields in electronic sources

Feasibility Assessment

The LCDS COVID-19 vaccination item will be completed to obtain raw rates of COVID-19 vaccination. Providers will be able to use all sources of information available to obtain the vaccination data, such as patient interview, 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 will be added to the LCDS assessment instrument to electronically capture this information.

We solicited feedback from the technical expert panel (TEP) on the proposed assessment item. No concerns were raised by the TEP regarding the obtainment of information required to complete the new COVID-19 vaccination item.

Method of Measure Calculation

Other digital method

Hybrid measure: Methods of measure calculation

N/A

Evidence of Performance Gap

To demonstrate that the Patient/Resident COVID-19 Vaccine measure has room for improvement, this appendix covers evidence on the variation of vaccination rates across facilities, geographic locations, and patient characteristics.

An internal analysis of September 2021 NHSN COVID-19 Nursing Home data identified a performance gap in COVID-19 vaccination rates among Nursing Home residents. Nursing Home vaccination rate distributions of Nursing Home residents who received a complete COVID-19 vaccination ranged from 0.0% (min) to 100% (max) with a mean score of 82.3%. The 25th percentile, median, and 75th percentile

were 75.8%, 84.5%, and 92.0%, respectively. Nursing Home vaccination rate distributions of Nursing Home residents who received a partial COVID-19 vaccination ranged from 0.0% (min) to 77.0% (max) with a mean score of 2.5%. The 25th percentile, median, and 75th percentile were 0.3%, 1.6%, and 3.4%, respectively. This analysis was presented to the TEP and panelists indicated that the presence of disparities in vaccination rates makes the patient-level vaccination measure meaningful to develop. Additionally, panelists broadly agreed that the vaccination gaps identified for nursing homes were also likely present within other post-acute care settings.

Although literature is limited, there is some evidence of COVID-19 vaccination rates varying by facility type. A cross-sectional study used National Healthcare Safety Network (NHSN) facility-level data to examine the rate of full vaccination rates among nursing home residents and staff by facility type through July 18, 2021 (McGarry et al., 2021). The results of the analysis demonstrated that for-profit ownership status was associated with a 3.3 percentage point decrease in resident vaccination coverage compared to nonprofit ownership status. Medicare star ratings were also evaluated in this study, as each additional Medicare star rating a facility had was associated with a 1.2 percentage point increase in its residents' vaccination coverage. These findings suggest that residents living in nonprofit facilities with higher Medicare Five-Star ratings are more likely to receive full dosage of the COVID-19 vaccine than residents living in for-profit facilities with lower star ratings.

Evidence suggests that a sizable proportion of the US population is not fully vaccinated and the extent to which people are not fully vaccinated varies geographically. According to CDC data used by the New York Times, as of October 22, 2021, 57% of the total US population has been fully vaccinated (approximately 189.9 million people) against COVID-19, and 66% has received at least one dose of vaccine (roughly 219.6 million people). Additionally, since August 13, 2021, when the FDA approved third doses for some populations, 11.3 million of the 189.9 million fully vaccinated people have received a vaccine booster. Although only 57% of the total US population is fully vaccinated, COVID-19 vaccination rates vary by region. States in the Northeast have the highest vaccination rates, while states in the Midwest and South have lower vaccination rates. Vaccination rates in the West are also high, as 64.5% of New Mexico residents, 62.8% of Washington residents, and 62.3% of Oregon residents are fully vaccinated. With the exception of Virginia, Maryland, Washington DC, and Florida, the remaining Southern states all have lower fully vaccinated rates than the national average. In fact, the Southern state of West Virginia has the lowest vaccination rates in the country, as only 40.9% of its population is fully vaccinated. The Northeastern state of Vermont has the highest vaccination rates in the country, as 70.7% of its population is fully vaccinated.

In addition to variation by region, COVID-19 vaccination rates also vary by patient characteristics. To assess whether or not disparities exist among different racial and ethnic groups in the US, the CDC evaluated data from the CDC Vaccine Safety Datalink (CVS) that included vaccination coverage among persons aged 16 years and older between December 2020 and May 2021 (Pingali et al., 2021). For those who received at least one dose of the Pfizer, Moderna, or Johnson & Johnson vaccine, vaccination rates were highest among Asian persons (57.4%) and lowest among non-Hispanic Black (40.7%) and Hispanic (41.14%) persons. Non-Hispanic Black and Hispanic persons also had lower vaccination rates than Whites (54.6%). The Kaiser Family Foundation (KFF) assessed more recent state-reported data on COVID-19 vaccination rates and observed similar findings. As of October 4, 2021, 54% of White people has received at least one COVID-19 vaccine dose, which is 1.2 times higher than the rate for Black people (46%) and 1.1 times higher than the rate for Hispanic people (51%) (Ndugga et al., 2021).

Additionally, 69% of Asian people have received at least one COVID-19 vaccine dose, which aligns with Pingali et al.'s (2021) findings that Asian people have the highest vaccination rates. Although disparities in vaccination coverage are evident, the data suggests that these disparities have been decreasing over time. KFF reports that vaccination rates for Black and Hispanic people increased slightly more than vaccination rates for Asian and White people between September 20, 2021, and October 4, 2021, thereby decreasing the gaps in vaccination coverage. This gap in vaccination rates between Black and White people decreased from 14 percentage points to 8 percentage points between April and October 2021. The gap in vaccination rates between White and Hispanic people also decreased during this period of time from 13 percentage points to 3 percentage points. Despite the decreases in these gaps, disparities in vaccination coverage persist.

Other patient characteristics, such as age, sex, and high-risk conditions, also contribute to variations in vaccination rates in the US. A recent study by Diesel et al. (2021) examined CDC data on vaccination coverage for adults aged 18 and older between December 2020 and May 2021 and found that vaccination rates (>= 1 COVID-19 vaccine dose) were lowest among persons aged 18-29 years (38.3%) and highest among persons aged 65 and older (80.0%). Pingali et al. (2021) investigated vaccination rates among persons with high-risk conditions and previous COVID-19 infections. Researchers observed a vaccination rate of 63.8% for persons with medical conditions deemed high-risk for severe COVID-19 infection and a vaccination rate of 41.5% for persons without such conditions. Regarding previous COVID-19 infection, the vaccination rate was 48.8% for those who had not had COVID-19 and 42.4% for those who had COVID-19 previously. Overall, these studies suggest that COVID-19 vaccination rates are highest among adults aged 65 and older who have medical conditions deemed high-risk but did not have a COVID-19 infection previously.

References:

Diesel, Jill et al. 2021. "COVID-19 Vaccination Coverage among Adults — United States, December 14, 2020–May 22, 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7025e1.

McGarry, Brian E., Karen Shen, Michael L. Barnett, David C. Grabowski, and Ashvin D. Gandhi. 2021. "Association of Nursing Home Characteristics with Staff and Resident COVID-19 Vaccination Coverage." JAMA Internal Medicine, September. https://doi.org/10.1001/jamainternmed.2021.5890.

Ndugga, Nambi et al. 2021. "Latest Data on COVID-19 Vaccinations by Race/Ethnicity." KFF. October 6, 2021. https://www.kff.org/coronavirus-covid-19/issue-brief/latest-data-on-covid-19-vaccinations-by-race-ethnicity/.

Pingali, Cassandra et al. 2021. "COVID-19 Vaccination Coverage among Insured Persons Aged ≥16 Years, by Race/Ethnicity and Other Selected Characteristics — Eight Integrated Health Care Organizations, United States, December 14, 2020–May 15, 2021." MMWR. Morbidity and Mortality Weekly Report 70 (28): 985–90. https://doi.org/10.15585/mmwr.mm7028a1.

The New York Times. 2021. "See How Vaccinations Are Going in Your County and State." The New York Times, October 22, 2021, sec. U.S. https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html.

Appendix A of the Evidence form (attached) provides information on COVID-19 vaccination rate variation across facility, geography, and patient characteristics.

Unintended Consequences

The measure may impact access to care in facilities. If facilities think they have to maintain high COVID-19 vaccination rates, they may reject patients that are not up to date on their COVID-19 vaccinations. We anticipate this risk to be low, given the current state of the pandemic and the knowledge and tools providers have to mitigate the spread of COVID-19 infection.

As part of CMS' measures quarterly monitoring activities, number and percent of patient stays stratified by vaccination status at discharge.

Number of clinical guidelines, including USPSTF guidelines, that address this measure topic

4

Outline the clinical guidelines supporting this measure

Appendix B of the evidence attachment summarizes four of The Advisory Committee on Immunization Practices' (ACIP) Recommendations that support the measure concept for the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure.

1. The Advisory Committee on Immunization Practices' Interim Recommendations for Use of Pfizer-BioNTech COVID-19 Vaccine – United States, December 2020
    a. The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Use of Pfizer Vaccine conducted an explicit, evidence-based review of available data for the use of the Pfizer COVID-19 vaccine in persons aged ≥ 16 years for the prevention of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for patients throughout the continuum of care, including post-acute and home-based care who may not be vaccinated for COVID-19. The body of evidence for the Pfizer-BioNTech COVID-19 vaccine was primarily informed by one large, randomized, double-blind, placebo-controlled Phase II/III clinical trial that enrolled >43,000 participants (median age = 52 years, range = 16–91 years). Interim findings from this clinical trial, using data from participants with a median of two months of follow-up, indicate that the Pfizer-BioNTech COVID-19 vaccine was 95.0% effective (95% confidence interval = 90.3%–97.6%) in preventing symptomatic laboratory-confirmed COVID-19 in persons without evidence of previous SARS-CoV-2 infection. Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Efficacy was similarly high in a secondary analysis including participants both with or without evidence of previous SARS-CoV-2 infection. Although numbers of observed hospitalizations and deaths were low, the available data were consistent with reduced risk for these severe outcomes among vaccinated persons compared with that among placebo recipients. Using the GRADE evidence assessment, the authors concluded the level of certainty for the benefits of the Pfizer-BioNTech

COVID-19 vaccine was type 1 (high certainty) for the prevention of symptomatic COVID-19. Evidence was type 3 (low certainty) for the estimate of prevention of COVID-19 associated hospitalization and type 4 (very low certainty) for the estimate of prevention of death. At the time of these recommendations, data on hospitalizations and deaths were limited, but a vaccine that effectively prevents symptomatic infection is expected to also prevent hospitalizations and deaths.

2. The Advisory Committee on Immunization Practices' Interim Recommendations for Use of Moderna COVID-19 Vaccine – United States, December 2020
    a. The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Use of Moderna Vaccine conducted a transparent, evidence-based review of available data for the use of the Moderna COVID-19 vaccine in persons aged ≥ 18 years for the prevention of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for patients throughout the continuum of care, including post-acute and home-based care who may not be vaccinated for COVID-19. The body of evidence for the Moderna COVID-19 vaccine was primarily informed by one large, randomized, double-blind, placebo-controlled Phase III clinical trial that enrolled approximately 30,000 participants aged 18–95 years (median = 52 years). Interim findings from this clinical trial, using data from participants with a median of two months of follow-up, indicate that the Moderna COVID-19 vaccine efficacy after two doses was 94.1% (95% confidence interval = 89.3%–96.8%) in preventing symptomatic, laboratory-confirmed COVID-19 among persons without evidence of previous SARS-CoV-2 infection, which was the primary study endpoint. High efficacy (≥86%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Using the GRADE evidence assessment, the authors concluded the level of certainty for the benefits of the Moderna COVID-19 vaccine was type 1 (high certainty) for the prevention of symptomatic COVID-19. Evidence was type 2 (moderate certainty) for the estimate of prevention of COVID-19–associated hospitalization and type 4 (very low certainty) for the estimates of prevention of asymptomatic SARS-CoV-2 infection and all-cause death. At the time of these recommendations, data on COVID-19–associated hospitalizations and deaths were limited; however, a vaccine that effectively prevents symptomatic infection is expected to also prevent associated hospitalizations and deaths.
3. The Advisory Committee on Immunization Practices' Interim Recommendations for Use of Janssen COVID-19 Vaccine – United States, February 2021
    a. The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Use of Janssen COVID-19 Vaccine conducted an evidence-based review of all available data on the use of the Janssen COVID-19 vaccine in persons aged ≥ 18 years for the prevention of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for patients throughout the continuum of care, including post-acute and home-based care who may not be vaccinated for COVID-19. The body of evidence for the Janssen COVID-19 vaccine was primarily informed by one international Phase III clinical trial initiated in September 2020 that enrolled approximately 40,000 participants aged

18–100 years (median age = 52 years), using two coprimary endpoints: prevention of symptomatic, laboratory-confirmed¶ COVID-19 among persons without evidence of previous SARS-CoV-2 infection occurring 1) ≥14 days and 2) ≥28 days after vaccination. Interim findings from this clinical trial indicate that the Janssen COVID-19 vaccine efficacy against symptomatic, laboratory-confirmed COVID-19 was 66.3% (95% confidence interval [CI] = 59.9%–71.8%) ≥14 days after vaccination and 65.5% (95% CI = 57.2%–72.4%) ≥28 days after vaccination. At ≥14 days after vaccination, the efficacy of ≥63.0% was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Efficacy varied geographically and was highest in the United States (74.4%; 95% CI = 65.0%–81.6%). Vaccine recipients frequently experienced reactogenicity symptoms, defined as solicited local injection site or systemic adverse reactions during the 7 days after vaccination; however, the symptoms were mostly mild to moderate and resolved 1–2 days after vaccination. Symptoms were more frequent among persons aged 18–59 years than among those aged ≥60 years. From the GRADE evidence assessment, the level of certainty for the benefits of the Janssen COVID-19 vaccine was type 2 (moderate certainty) for the prevention of symptomatic COVID-19. Evidence was also type 2 (moderate certainty) for the estimate of prevention of COVID-19–associated hospitalization and death. Evidence was type 3 (low certainty) for the estimates of prevention of SARS-CoV-2 seroconversion. Regarding certainty of the evidence for possible harms after vaccination, evidence was type 1 (high certainty) for reactogenicity and type 2 (moderate certainty) for serious adverse events. Data reviewed within the EtR framework supported the use of the Janssen COVID-19 vaccine.

4. The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines – United States, 2021.
    a. The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines issued recommendations for an additional dose of the primary mRNA COVID-19 vaccine for immunocompromised persons and a COVID-19 vaccine booster dose in eligible groups, as well as persons who are at increased risk for exposure to or serious complications of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for remaining up to date with the COVID-19 vaccine for patients throughout the continuum of care, including post-acute and home-based care. Since June 2020, ACIP has convened 20 public meetings to review data relevant to the potential use of COVID-19 vaccines. To assess the certainty of the evidence for benefits and harms of a booster dose, ACIP used the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. To further guide its deliberations around the use of an additional or booster dose, ACIP used the Evidence to Recommendations (EtR) Framework to evaluate other factors, including the importance of COVID-19 as a public health problem as well as matters of resource use, benefits and harms, patients' values and preferences, acceptability, feasibility, and equity for use of the vaccines. ACIP concluded that the evidence reviewed, including data and considerations from the EtR Frameworks, supported the use of an additional primary dose of an mRNA COVID-19 vaccine for

certain immunocompromised recipients of an initial mRNA series, a COVID-19 vaccine booster dose for certain recipients of an mRNA primary series who are at increased risk for exposure to or serious complications of COVID-19, and a COVID-19 vaccine booster dose for all recipients of a Janssen COVID-19 vaccine dose.

Name the guideline developer/entity

The Advisory Committee on Immunization Practices (ACIP)

Publication year

[1] 2020

[2] 2020

[3] 2020

[4] 2021

Full citation +/- URL

[1] 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): 1922-1924. https://doi.org/10.15585/mmwr.mm6950e2.

[2] 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.

[3] 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): 329-332. https://doi.org/10.15585/mmwr.mm7009e4.

[4] 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): 1545-1552. https://doi.org/10.15585/mmwr.mm7044e2.

Is this an evidence-based clinical guideline?

Yes

Is the guideline graded?

Yes

List the guideline statement that most closely aligns with the measure concept.

[1] ACIP concluded the Pfizer COVID-19 vaccine has high efficacy for the prevention of symptomatic COVID-19.

[2] ACIP concluded the Moderna COVID-19 vaccine has high efficacy for the prevention of symptomatic COVID-19.

[3] ACIP concluded the Janssen COVID-19 vaccine has high efficacy against COVID-19-associated hospitalization and death.

[4] ACIP concluded that the evidence reviewed supported the use of an additional primary dose of an mRNA COVID-19 vaccine for certain immunocompromised recipients of an initial mRNA series, a COVID-19 vaccine booster dose for certain recipients of an mRNA primary series who are at increased risk for exposure to or serious complications of COVID-19, and a COVID-19 vaccine booster dose for all recipients of a Janssen COVID-19 vaccine dose.

What evidence grading system did the guideline use to describe strength of recommendation?

GRADE method

List all categories and corresponding definitions for the evidence grading system used to describe strength of recommendation in the guideline?

The GRADE certainty ratings and corresponding definitions are as follows:

1: High

The authors have a lot of confidence that the true effect is similar to the estimated effect.

2: Moderate

The authors believe that the true effect is probably close to the estimated effect.

3: Low

The true effect might be markedly different from the estimated effect.

4: Very low

The true effect is probably markedly different from the estimated effect.

For the guideline statement that most closely aligns with the measure concept, what is the associated strength of recommendation?

USPSTF Grade A, Strong recommendation or similar

What evidence grading system did the guideline use to describe level of evidence or level of certainty in the evidence?

GRADE method

List all categories and corresponding definitions for the evidence grading system used to describe level of evidence or level of certainty in the evidence?

The GRADE certainty ratings and corresponding definitions are as follows:

1: High

The authors have a lot of confidence that the true effect is similar to the estimated effect.

2: Moderate

The authors believe that the true effect is probably close to the estimated effect.

3: Low

The true effect might be markedly different from the estimated effect.

4: Very low

The true effect is probably markedly different from the estimated effect.

For the guideline statement that most closely aligns with the measure concept, what is the associated level of evidence or level of certainty in the evidence?

USPSTF Grade A, Strong recommendation or similar

List the guideline statement that most closely aligns with the measure concept.

Health care professionals play a critical role in COVID-19 vaccination efforts, including primary, additional primary, and booster vaccination, particularly to protect patients who are at increased risk for severe illness and death.

Number of systematic reviews that inform this measure concept

4

Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept

Appendix C of the evidence attachment summarizes four peer-reviewed systematic review(s) that inform the measure concept for the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure and provides full citations and URLs for each review.

1. Korang et al.
    a. Korang et al. (2022) sought to assess the effectiveness and safety of COVID-19 vaccines through analyses of all currently available randomized clinical trials. The authors searched the databases CENTRAL, MEDLINE, Embase, and other sources from inception to June 17, 2021 for randomized clinical trials assessing vaccines for COVID-19. At least two independent reviewers screened studies, extracted data, and assessed risks of bias prior to conducting meta-analyses, network meta-analyses, and Trial Sequential Analyses (TSA). Authors assessed the certainty of evidence with GRADE, and found 35 trials to include in the analyses. The meta-analyses showed that mRNA vaccines (efficacy, 95% [95% confidence interval (CI 92% to 97%]; 71,514 participants; 3 trials; moderate certainty); inactivated vaccines (efficacy, 61% [95% CI, 52% to 68%]; 48,029 participants; 3 trials; moderate certainty); protein subunit vaccines (efficacy, 77% [95% CI, −5% to 95%]; 17,737 participants; 2 trials; low certainty); and viral vector vaccines (efficacy 68% [95% CI, 61% to 74%]; 71,401 participants; 5 trials; low certainty) prevented COVID-19. Viral vector vaccines decreased mortality (risk ratio, 0.25 [95% CI 0.09 to 0.67]; 67,563 participants; 3 trials, low certainty), but comparable data on

inactivated, mRNA, and protein subunit vaccines were imprecise. None of the vaccines showed evidence of a difference on serious adverse events, but observational evidence suggested rare serious adverse events. All the vaccines increased the risk of non-serious adverse events. The authors concluded the evidence suggests that all the included vaccines are effective in preventing COVID-19. The mRNA vaccines seem most effective in preventing COVID-19, but viral vector vaccines seem most effective in reducing mortality. Further trials and longer follow-ups are necessary to provide better insight into the safety profile of these vaccines.

b. 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." Edited by Stefanos Bonovas. PLOS ONE 17 (1): e0260733. https://doi.org/10.1371/journal.pone.0260733.

2. Fielkin et al.
   a. Fiekin et al. (2022) sought to systematically review the evidence for the duration of protection of COVID-19 vaccines against various clinical outcomes, and to assess changes in the rates of breakthrough infection caused by the delta variant with increasing time since vaccination. This study was designed as a systematic review and meta-regression. A systematic review of preprint and peer-reviewed published article databases from June 17, 2021, to Dec 2, 2021, was conducted, and randomized controlled trials of COVID-19 vaccine efficacy and observational studies of COVID-19 vaccine effectiveness were eligible. The following databases and preprint servers without language restrictions were included in the search: PubMed, Embase, medRxiv, BioRxiv, khub, Research Square, SSRN, Eurosurveillance.org, Europepmc.org, and the WHO COVID-19 database, which compiles searches of more than 100 databases, including Scopus, Web of Science, grey literature. The authors searched for studies with several variations of the primary key search terms "COVID-19", "SARS-CoV-2", and "vaccine" (including names of specific vaccines) and "randomized controlled trial" or "vaccine effectiveness" (including names of specific study designs). Studies with vaccine efficacy or effectiveness estimates at discrete time intervals of people who had received full vaccination and that met predefined screening criteria underwent full-text review. Random-effects meta-regression was used to estimate the average change in vaccine efficacy or effectiveness 1–6 months after full vaccination. After applying exclusion criteria, 18 studies of vaccine efficacy or effectiveness at discrete time intervals after full vaccination and seven studies in which risk of breakthrough infection could be assessed by time of vaccination were included. In addition, the same search strategy was used to find studies presenting analyses of breakthrough infections, in which the rate, risk, or odds of COVID-19 outcomes among different vaccine cohorts (i.e., vaccinated at different times) were included. The authors found that during the six months after full vaccination, vaccine efficacy or effectiveness against SARS-CoV-2 infection and symptomatic COVID-19 disease decreased by approximately 20–30 percentage points, on average, for the four vaccines that we evaluated. By contrast, most studies showed that vaccine efficacy or effectiveness against the severe disease was maintained above 70% after full vaccination, with a minimal decrease to six months (approximately 9–10 percentage points). The decrease in vaccine efficacy or effectiveness is likely caused by, at least in part, waning immunity, although an effect of bias cannot be ruled out.

Evaluating vaccine efficacy or effectiveness beyond six months will be crucial for updating the COVID-19 vaccine policy.

b. 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.

3. Lee et al.
   a. The focus of this systematic review and meta-analysis was to compare the efficacy of COVID-19 vaccines between immunocompromised and immunocompetent people. Vaccine trials have excluded immunocompromised groups, but these patients are of particular interest because of possible suppression or over-activation of the immune system attributable to the primary disease or concurrent treatment. Data are needed on immunocompromised patients, as infection and viral shedding have been reported to be more severe and persistent in this group. Immunocompromised patients show lower seroconversion rates than immunocompetent people after vaccination, such as with the influenza vaccine. Less is known about the response to COVID-19 vaccines, particularly mRNA-based vaccines. Lee et al. (2022) sought to compare the efficacy of covid-19 vaccines between immunocompromised and immunocompetent people. Several databases were searched (Medline via PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), CORD-19, WHO COVID-19 Research Database, ClinicalTrials.gov, and WHO international clinical trials registry platform) for articles published from December 1, 2020, to November 5, 2021. No restrictions on the language of publication were applied. To improve the validity of data, non-peer-reviewed articles in preprint databases were excluded. The authors assessed the certainty of evidence using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE). Overall, 82 studies were included for meta-analysis. Of these studies, 77 (94%) used mRNA vaccines, 16 (20%) viral vector vaccines, and 4 (5%) inactivated whole virus vaccines. The authors found that seroconversion rates after COVID-19 vaccination were significantly lower in immunocompromised patients, especially organ transplant recipients. A second dose was associated with consistently improved seroconversion across all patient groups, albeit at a lower magnitude for organ transplant recipients. The authors concluded that targeted interventions for immunocompromised patients, including a third (booster) dose, should be performed.
   b. Lee, Ainsley Ryan Yan Bin et al. 2022. "Efficacy of Covid-19 Vaccines in Immunocompromised Patients: Systematic Review and Meta-Analysis." BMJ 376 (March): e068632. https://doi.org/10.1136/bmj-2021-068632.
4. Norhayati et al.
   a. This review aimed to estimate the pooled proportion of COVID-19 vaccine acceptance worldwide. Determining the pooled estimated proportion of COVID-19 vaccination acceptance provides guidance to health authorities to prepare for an effective vaccination program. A systematic review and meta-analysis of studies were conducted to assess the proportion of COVID-19 vaccination acceptance. A systematic search was performed in the MEDLINE (PubMed) database for articles between January 1, 2021, and July 19, 2021. The search was done using the generic free-text search terms "COVID-19" AND "vaccine" AND "acceptance." All types of COVID-19 vaccines were included in this review. The search was restricted to full-text only and English language articles. Studies with cross-sectional, case-control, and cohort designs were included.

Case series/reports, conference papers, proceedings, articles available only in abstract form, editorial reviews, letters of communications, commentaries, systematic reviews, and qualitative studies were excluded. Assessment of critical appraisal for data quality was assessed using the Joann Briggs Institute (J.B.I.). Two authors performed bias assessments independently, and a total of 172 studies were included in the review and meta-analysis. The pooled proportion of COVID-19 vaccine acceptance involving 50 countries was 61% (95% CI: 59, 64%). This finding was lower compared to a previous estimate of 73.31% (95% CI: 70.52%, 76.01%) which involved 38 studies across 36 countries with limited data from low-income countries. Concern about the vaccine's safety, efficacy, and side effects, trust in the government or related authorities, and religious beliefs were primary factors that influenced vaccine acceptance. The pooled proportion of COVID-19 vaccine acceptance among regions ranged from 52 to 74%, while among population groups varied from 52 to 63%, with healthcare workers showing the highest proportion of vaccine acceptance. Since healthcare workers were among the first to receive COVID-19 vaccines, their attitude or perception toward COVID-19 vaccines would affect the other population's decisions to recommend the vaccination to friends, families, and their patients. The time during which the survey was conducted showed that the acceptance of the COVID-19 vaccine changed over time. The United States showed an increased pattern of vaccine acceptance in the second and third surveys. The authors concluded that the rate of COVID-19 vaccine acceptance varied by region, population type, gender, vaccine effectiveness, and survey time, with an overall pooled proportion of 61%. A high level of acceptance of vaccination is required to achieve herd immunity for the disease. A successful and effective vaccination program can provide sufficient vaccination coverage in a population to achieve herd immunity and subsequently control the COVID-19 pandemic.

b. Norhayati, Mohd Noor, Ruhana Che Yusof, and Yacob Mohd Azman. 2022. "Systematic Review and Meta-Analysis of COVID-19 Vaccination Acceptance." Frontiers in Medicine 8 (January). https://doi.org/10.3389/fmed.2021.783982.

Source of empirical data

Published, peer-reviewed original research;Published and publicly available reports (e.g., from agencies)

Summarize the empirical data

Appendix D of the Evidence form (attached) provides information the effectiveness of COVID-19 vaccinations in preventing COVID-19 related health outcomes.

The following appendix summarizes empirical data and how it informs the measure concept for the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure. This appendix will also provide the limitations of the data and provide a full citation for each source of empirical data.

Evidence of the effectiveness of COVID-19 vaccinations in preventing COVID-19 infections and related health outcomes is essential for guiding policymaking decisions regarding the ongoing public health emergency (PHE). As more data have become available, researchers have been able to assess the effectiveness of all COVID-19 vaccinations accessible in the United States across various populations and settings. These data demonstrate that the three COVID-19 vaccines approved for emergency use by the Food and Drug Administration (FDA), Pfizer-BioNTech (BNT162b2 mRNA), Moderna (mRNA-1273), and Johnson & Johnson/Janssen (JNJ-78436735), are highly effective for preventing COVID-19-related

serious illness, hospitalization, and death (Rosenberg et al., 2021). In fact, for full messenger RNA (mRNA) vaccines (Pfizer and Moderna), vaccine effectiveness (VE) against COVID-19-associated hospitalizations was found to be 86% two to twelve weeks after receipt of the second dose and 84% 13 to 24 weeks after the second dose (Tenforde et. al, 2021). Note: These VE calculation estimates presented in these studies pre-date the delta and omicron surges. A study conducted by the New York State Department of Health, assessed statewide laboratory testing, hospitalization, and immunization databases to determine rates of new COVID-19 cases and hospitalizations among adults age 18 or older and to evaluate VE between May and July 2021 (Rosenberg et al., 2021). Researchers observed a decline in VE against new infection from 91.7% to 79.8% between May and July 2021, which can be attributed to the increase in delta variant prevalence during the study window. Despite this decline in VE against new infection, the VE against hospitalization for fully vaccinated adults remained high at 90% (Rosenberg et al., 2021). These results indicate that all three COVID-19 vaccinations available in the US are still useful for preventing some infections and highly effective at preventing hospitalization in adults.

Several studies focusing on VE among older adults have also been published recently. A study by Thompson et al. assessed the VE for all three FDA-approved vaccines against laboratory-confirmed infection, infection-associated hospitalizations, ICU admissions, and visits to emergency departments or urgent cares among adults 50 years of age or older between January and June 2021. Researchers found that VE against infection leading to hospitalization was 89% after the second dose of a mRNA vaccine (Pfizer and Moderna). Effectiveness against infection leading to ICU admission and effectiveness against infection leading to an emergency department or urgent care visit for full mRNA vaccines were 90% and 91% respectively. The effectiveness of the Johnson & Johnson vaccine was lower than the full mRNA vaccines among the study population, as VE was 68% against infection leading to hospitalization and 73% against infection leading to an emergency department or urgent care clinic visit. The results of this study indicate that all three FDA-approved COVID-19 vaccines are highly effective against infection leading to hospitalization, ICU admission, or emergency department visit among adults 50 years of age or older, with full doses of the Pfizer and Moderna vaccines being somewhat more effective than Johnson & Johnson. Similar findings were observed in a recently published study focusing on VE among adults 65 years of age or older. In this study population, VE against COVID-19-associated hospitalizations was 91% and 84% for full vaccination with mRNA vaccines and vaccination with the Johnson & Johnson vaccine respectively (Moline et al., 2021). Overall, these studies provide evidence of the effectiveness of COVID-19 vaccinations in preventing hospitalization among older adults.

In addition to older adults, differences in VE among the three authorized COVID-19 vaccines have been observed in the broader adult population aged 18 and older. Among these adults who do not have any immunocompromising conditions, researchers observed that the VE against hospitalization was higher for the Moderna vaccine (93%) than the Pfizer vaccine (88%) (Self et al., 2021). The VE against hospitalization for the Johnson & Johnson vaccine was the lowest of the three authorized vaccines at 71%. Despite these differences in VE, all three authorized COVID-19 vaccines are still useful for preventing some infections and highly effective at preventing hospitalization.

The effectiveness of these vaccines has also been tested among healthcare and frontline workers, as these populations are at increased risk for COVID-19 infection. A recently published observational study examined new COVID-19 infections among healthcare workers who received at least one dose of vaccine between January and May 2021. Researchers found that VE 14 days after the first dose was 49.2% and 38.2% for the Pfizer and Moderna vaccines, respectively (Paris et al., 2021). Effectiveness

improved substantially 14 days after the second dose, as Pfizer VE increased to 100% and Moderna VE increased to 94.6%. Similar results were observed in a study that focused on a broader population of frontline workers, defined as healthcare personnel, first responders, and other essential workers (Fowlkes et al., 2021). Researchers evaluated VE against infection among frontline workers in six states between December 2020 and April 2021 and observed an adjusted VE of 91%. However, when researchers assessed data from May 2021 to August 2021 to account for surges in cases of the delta variant, the adjusted VE was 66%. These findings suggest that VE is higher against COVID-19 alpha infections than delta infections among frontline workers.

The VE against alpha and delta infections was also studied by Lopez Bernal et al., who estimated the VE against symptomatic disease caused by the delta variant among people 16 years of age and older between February and May 2021. After one dose of the Pfizer vaccine, the VE against the alpha variant was considerably higher (48.7%) than the VE against the delta variant (30.7%). This difference in VE decreased after participants received the second dose of the Pfizer vaccine, as the VE against the alpha variant increased to 93.7% while the VE against the delta variant increased to 88.0%. These findings deviate slightly from Fowlkes et al.'s study, where researchers observed a greater difference in VE against the alpha and delta variants. This is likely due to the different study windows used, as Fowlkes et al. examined data from May 2021 to August 2021 during the surge in delta infections, hospitalizations, and deaths.

Given the demonstrated higher VE against the alpha variant compared to the delta variant, researchers have focused on evaluating VE during periods of time when delta infections, hospitalizations, and deaths were surging. Grannis et al. examined medical encounters across nine states where adults 18 years of age or older received a COVID-19 discharge diagnosis from a hospital, emergency department, or urgent care between June and August 2021 when the delta variant accounted for more than 50% of cases in the respective states. Researchers found that VE for all three authorized COVID-19 vaccines was 86% against hospitalization and 82% against emergency department and urgent care visits. However, when stratified by age, VE against hospitalization was significantly lower for adults 75 years of age or older (76%) compared to adults between 18 and 74 (89%). Despite the lower VE for adults aged 75 years and older, vaccination still proves highly effective at preventing COVID-19-related hospitalization among this population during periods of high delta variant incidence.

Lauring et al. (2022) studied the effectiveness of the mRNA vaccines to prevent COVID-19 hospitalizations related to the alpha, delta, and omicron SARS-CoV-2 variants from March 11, 2021, to January 14, 2022. The effectiveness of two vaccine doses against hospitalization was 85% during the periods of the study when alpha and delta dominated but 65% during the omicron period—late December 2021 through mid-January 2022. The effectiveness of three vaccine doses during the Omicron phase was 86%. mRNA vaccines were found to be highly effective in preventing COVID-19 associated hospital admissions related to the alpha, delta, and omicron variants, but three vaccine doses were required to achieve protection against omicron similar to the protection that two doses provided against the delta and alpha variants. Among adults admitted to hospital with COVID-19, the omicron variant was associated with less severe disease than the delta variant but still resulted in substantial morbidity and mortality. Vaccinated patients with COVID-19 hospitalizations had significantly lower disease severity than unvaccinated patients for all the variants.

Appendix D References:

Fowlkes, Ashley, et al. 2021. "Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection among Frontline Workers before and during B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7034e4.

Grannis, Shaun J., et al. 2021. "Interim Estimates of COVID-19 Vaccine Effectiveness against COVID-19–Associated Emergency Department or Urgent Care Clinic Encounters and Hospitalizations among Adults during SARS-CoV-2 B.1.617.2 (Delta) Variant Predominance — Nine States, June–August 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7037e2.

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, (March): e069761. https://doi.org/10.1136/bmj-2021-069761.

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 (7). https://doi.org/10.1056/nejmoa2108891.

Moline, Heidi L., et al. 2021. "Effectiveness of COVID-19 Vaccines in Preventing Hospitalization among Adults Aged ≥65 Years — COVID-NET, 13 States, February–April 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mThemwr.mm7032e3.

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Self, Wesley H., et al. 2021. "Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations among Adults without Immunocompromising Conditions — United States, March–August 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7038e1.

Tenforde, Mark W., et al. 2021. "Effectiveness of Pfizer-BioNTech and Moderna Vaccines against COVID-19 among Hospitalized Adults Aged ≥65 Years — United States, January–March 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7018e1.

Thompson, Mark G., et al. 2021. "Effectiveness of Covid-19 Vaccines in Ambulatory and Inpatient Care Settings." New England Journal of Medicine, September. https://doi.org/10.1056/nejmoa2110362.

Appendix D Limitations:

11. Fowlkes, Ashley, et al. 2021
    a. The study was limited to a 35 week period of observations (December 14, 2020 – April 10, 2021) before and during the delta variant. Unmeasured and residual confounding might be present.
12. Grannis, Shaun J., et al. 2021
    a. Duration of VE was not examined and VE for partial vaccination was not assessed. Although the facilities in this study serve heterogenous populations in nine states, the findings might not be generalizable to the U.S. population.
13. Lauring, Adam S et al. 2022
    a. The use of in-patient controls might lead to biased estimates if control patients had different characteristics from people in the general community, however, the control population within this study tracked closely with the adult population in the US. The study was limited to VE for patients admitted to the hospital. The study only evaluated mRNA vaccines, not other types of covid-19 vaccines. Sequencing did not identify a variant for some cases—typically those with low viral loads in tested respiratory samples. Variant classification for cases without a sequencing confirmed variant was based on the predominant circulating variant at the time; variant misclassification was possible for these cases, but sensitivity analyses limited to sequencing confirmed cases produced results similar to those in the primary analysis.
14. Lopez Bernal, Jamie, et al. 2021
    a. The findings are observational and unmeasured and residual confounding might be present. Low sensitivity or specificity of PCR testing could result in cases and controls being misclassified, which would attenuate the estimates of vaccine effectiveness. Low sensitivity or specificity of PCR testing could also affect one variant more than another, although this might be expected to affect the alpha variant more than the delta variant, given that, with an emerging variant, more cases may be detected earlier in infection, which may result in higher viral loads and increased sensitivity and specificity. There may also be differences among the populations that received each vaccine. The analysis also relied on the assumptions that any residual confounding in the test-negative case–control design would affect the two estimates of vaccine effectiveness equally or at least would not bias the adjusted odds ratio for the comparison of vaccine effectiveness for a given vaccine against the two variants; that is, the accuracy of the sequencing would not depend on the variant and the propensity among symptomatic persons to get tested would not differ according to variant.
15. Moline, Heidi L., et al. 2021
    a. VE estimates were adjusted for relevant potential confounders, residual confounding is possible (e.g., chronic conditions. the heterogeneity of disease risk, vaccination coverage within each site, and differences in the populations who received different vaccine products). The study period for this analysis occurred before the predominance of the delta variant; changes in circulating SARS-CoV-2 variants might affect vaccine effectiveness when assessed over time. Persons choosing to receive vaccine later in the rollout might have different risk characteristics than do those vaccinated earlier and might have experienced differences in access to vaccine products by time and location. This analysis was limited to adults at/above 65 years, and the results are not generalizable to younger age groups.
16. Paris, Christophe, et al. 2021

a. Findings may not be generalizable to other settings, given the variability of the epidemiology of SARS-CoV-2 variants. The study was not powered to evaluate vaccine effectiveness more than 3 months after the first dose. The study was based on passive surveillance, so asymptomatic SARS-CoV-2 infection may have been underestimated.

17. Rosenberg, Eli S., et al. 2021
    a. Residual differences between fully vaccinated and unvaccinated groups have the potential to reduce estimated VE. The analysis excluded partially vaccinated persons, to robustly assess VE for fully vaccinated compared with that of unvaccinated persons. Exact algorithms were used to link databases; some persons were possibly not linked because matching variables were entered differently in the respective systems. This study did not estimate VE by vaccine product, and persons were categorized fully vaccinated at 14 days after final dose, per CDC definitions. Information on reasons for testing and hospitalization, including symptoms, was limited. Data were too sparse to reliably estimate VE for COVID-19-related deaths.
18. Self, Wesley H., et al. 2021
    a. The analysis excluded children, immunocompromised adults, or VE against COVID-19 that did not result in hospitalization. The confidence intervals for the Janssen VE estimates were wide because of the relatively small number of patients who received this vaccine. Follow-up time was limited to approximately 29 weeks since receipt of full vaccination, and further surveillance of VE over time is warranted. Although VE estimates were adjusted for relevant potential confounders, residual confounding is possible. Product-specific VE by variant, including against delta variants (B.1.617.2 and AY sublineages), was not evaluated. Antibody levels were measured at only a single time point 2–6 weeks after vaccination and changes in antibody response over time as well as cell-mediated immune responses were not assessed.
19. Tenforde, Mark W., et al. 2021
    a. The confidence intervals for VE estimates were wide because of the small sample size, and the number of participants was too small to assess VE by vaccine product, age group, or underlying conditions. As an interim analysis that included self-reported data, vaccination status might have been misclassified, or participants might have had imperfect recollection of vaccination or illness onset dates. Selection bias and residual confounding cannot be excluded. Although the analysis included hospitalized adults from 14 states, the participants were not geographically representative of the U.S. population. The case-control design infers protection based on associations between disease outcome and previous vaccination but cannot establish causation. Duration of VE and VE for non-hospitalized COVID-19 was not assessed.
20. Thompson, Mark G., et al. 2021
    a. VE estimates were adjusted for relevant potential confounders, unmeasured and residual confounding is possible (e.g., occupations of the patients, which is associated with exposure to virus and access to and use of vaccination and personal protective equipment). The percentage of patients who were clinically tested for SARS-CoV-2 by molecular assay differed across network partners and clinical settings, and vaccine-effectiveness estimates can be biased if clinicians make testing decisions based on vaccination status.

Name evidence type

N/A

Summarize the evidence

N/A

Does the evidence discuss a link between at least one process, structure, or intervention with the outcome?

N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size

154,611

Type of Evidence to Support the Measure

Clinical Guidelines or USPSTF (U.S. Preventive Services Task Force) Guidelines;Peer-Reviewed Systematic Review; Empirical data

Is the measure risk adjusted?

No

Risk adjustment variables

N/A

Patient-level demographics: please select all that apply:

N/A

Patient-level health status & clinical conditions: please select all that apply:

N/A

Patient functional status: please select all that apply:

N/A

Patient-level social risk factors: please select all that apply:

N/A

Proxy social risk factors: please select all that apply

N/A

Patient community characteristic: please select all that apply:

N/A

Risk model performance

N/A

Rationale for not using risk adjustment

Addressed through exclusions (e.g., process measures)

Cost estimate completed

No

Cost estimate methods and results

N/A

Section 3: Patient and Provider Perspective

Meaningful to Patients. Was input on the final performance measure collected from patient and/or caregiver?

Yes

Total number of patients and/or caregivers who responded to the question asking them whether the final performance measure helps inform care and decision making

5

Total number of patients/caregivers who agreed that the final performance measure helps inform care and decision making

5

Meaningful to Patients: Numbers consulted

N/A

Meaningful to Patients: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians: Numbers consulted

N/A

Meaningful to Clinicians: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians. Were clinicians and/or providers consulted on the final performance measure?

Yes

Acumen convened a Technical Expert Panel (TEP) for the purposes of soliciting feedback on the development of a Post-Acute Care (PAC) patient-level COVID-19 vaccination measure for the PAC settings, along with the accompanying PAC patient-level COVID-19 vaccination assessment item. The PAC QRP Vaccination TEP comprised of 11 stakeholders with diverse perspectives and areas of expertise representing clinical, policy and program, measure development, and technical expertise. Additionally, the PAC QRP Support team met with a patient and family/caregiver advocates focus group assembled by Patient and Family Centered Care (PFCC) Partners. This session was held in order to inform the TEP discussion of the viewpoints of patients and family/caregivers who actively utilize the Care Compare website in order to make informed decisions about their or their loved one's healthcare.

The patient and family/caregiver advocates felt a measure capturing raw vaccination rate, irrespective of provider action, would be most helpful to them when deciding to choose a facility for either their own care or for a loved one. TEP Panelists agreed that reporting the rate of vaccination in a PAC/NH setting without denominator exclusions is important to meet when designing a measure.

Total number of clinicians/providers who responded when asked if the final performance measure was actionable to improve quality of care.

0

Total number of clinicians/providers who agreed that the final performance measure was actionable to improve quality of care

0

Survey level testing

N/A

Type of Testing Analysis

N/A

Testing methodology and results

N/A

Burden for Provider: Was a provider workflow analysis conducted?

No

If yes, how many sites were evaluated in the provider workflow analysis?

N/A

Did the provider workflow have to be modified to accommodate the new measure?

N/A

Section 4: Measure Testing Details

Reliability

No

Reliability: Type of Reliability Testing

N/A

Signal-to-Noise: Name of statistic

N/A

Signal-to-Noise: Sample size

N/A

Signal-to-Noise: Statistical result

N/A

Signal-to-Noise: Interpretation of results

N/A

Random Split-Half Correlation: Name of statistic

N/A

Random Split-Half Correlation: Sample size

N/A

Random Split-Half Correlation: Statistical result

N/A

Random Split-Half Correlation: Interpretation of results

N/A

Other: Name of statistic

N/A

Other: Sample size

N/A

Other: Statistical result

N/A

Other: Interpretation of results

N/A

Empiric Validity

No

Empiric Validity: Statistic name

N/A

Empiric Validity: Sample size

N/A

Empiric Validity: Statistical result

N/A

Empiric Validity: Methods and findings

N/A

Empiric Validity: Interpretation of results

N/A

Face Validity

No

Face Validity: Number of voting experts and patients/caregivers

N/A

Face Validity: Result

N/A

Patient/Encounter Level Testing

Yes

Type of Analysis

Other (enter here): Agreement with gold standard

Sample Size

45

Statistic Name

Percent agreement

Statistical Results

80%

Interpretation of results

Our team used five patient scenarios for testing. Percent agreement was calculated by dividing the total number of patient scenario responses that matched the gold standard by the total number of patient scenario responses. Overall percent agreement for LTCHs was 80%. LTCH providers have lower percent agreement (80%) in comparison to the other PAC settings; however, during the cognitive interviews, four out of nine LTCH providers reported that they did not read the guidance materials or refer to the CDC's website prior to or during the coding activities. Two additional LTCH providers only used the guidance materials, and did not go to the CDC website for the definition of what it means to be "up to date" on the COVID-19 vaccination as the guidance materials instruct. Across all provider types, those who used the CDC website or the guidance manual and the CDC website had the highest percent agreement (100% and 88% respectively).

The results of the item testing support the use of a Patient-level COVID-19 Vaccination Coverage measure item. When providers use the available materials, percent agreement of the item increases to 85% or higher. The findings from the cognitive interviews provide information to improve the item itself, as well as the accompanying guidance. Based on the feedback received from providers during testing, we are able to add additional clarification to the coding guidance, such as providing the patient's age in the coding examples and including examples for coding certain unique patient scenarios. With these additional updates, we expect that the percent agreement would go up.

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Higher score is better

Mean performance score

99999

Median performance score

99999

Minimum performance score

99999

Maximum performance score

99999

Standard deviation of performance scores

99999

Does the performance measure use survey or patient-reported data?

No

Surveys or patient-reported outcome tools

N/A

Section 5: Measure Contact Information

Measure Steward

Centers for Medicare & Medicaid Services

Measure Steward Contact Information

Rebekah Natanov
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
rebekah.natanov@cms.hhs.gov
(202) 205-2913

Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

Primary Submitter Contact Information

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Submitter Comments

N/A

MUC2022-092 COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date

Program

Skilled Nursing Facility Quality Reporting Program

Section 1: Measure Information

Measure Specifications and Endorsement Status

Measure Description

This one quarter measure reports the percentage of patients in a Skilled Nursing Facility (SNF) who are up-to-date on their COVID-19 vaccinations per the Centers for Disease Control and Prevention's (CDC) latest guidance.

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 Your COVID-19 Vaccines", at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html (last accessed 5/18/2022).

This measure is based on data obtained through the Minimum Data Set (MDS) discharge assessments during the selected quarter.

Numerator

The total number of patients who are up-to-date on the COVID-19 vaccine.

Numerator Exclusions

N/A

Denominator

The total number of Medicare Part A covered SNF Stays discharged during the reporting period.

Denominator Exclusions

N/A

Denominator Exceptions

N/A

State of development

Field (Beta) Testing

State of Development Details

Cognitive interviews and data collection for patient scenarios were conducted from June through July 2022. Nine SNFs participated in the cognitive interviews and each facility completed five patient scenarios, accounting for a total of 45 cases. The patient scenarios were developed in collaboration with a team of clinical experts and designed to represent the most common scenarios SNF providers would encounter. The correct responses to each scenario were agreed upon by a panel of clinical experts so that percent agreement could be calculated using a gold standard. Cognitive interviews with each participant were conducted after the completion of patient scenarios. The goal of the cognitive

interviews was to gauge providers' comprehension of the item's concept and intent, as well as understand their decision process for completing the assessment item. Upon completion of interviews and patient scenarios, the completed scenarios were evaluated against the gold standard responses. Percent agreement was calculated by dividing the total number of patient scenario responses that matched the gold standard by the total number of patient scenario responses.

What is the target population of the measure?

Medicare Part A Fee For Service beneficiaries

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Public and/or population health

Measure Type

Process

Is the measure a composite or component of a composite?

Not a composite or component of a composite measure

If Other, Please Specify

N/A

What data sources are used for the measure?

Standardized Patient Assessments

If applicable, specify the data source

MDS

Description of parts related to these sources

All data elements are sourced from MDS.

At what level of analysis was the measure tested?

Facility

In which setting was this measure tested?

Skilled nursing facility

Multiple Scores

No

What one healthcare domain applies to this measure?

Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities

N/A

Is this measure in the CMS Measures Inventory Tool (CMIT)?

No

CMIT ID

N/A

Alternate Measure ID

N/A

What is the endorsement status of the measure?

Never Submitted

CBE ID (CMS consensus-based entity, or endorsement ID)

9999

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

N/A

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

No

If eCQM, enter Measure Authoring Tool (MAT) number

N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?

N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?

No

Previous Measure Information

N/A

What is the history or background for including this measure on the new measures under consideration list?

New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs

N/A

What other federal programs are currently using this measure?

N/A

Is this measure similar to and/or competing with a measure(s) already in a program?

Yes

Which measure(s) already in a program is your measure similar to and/or competing with?

[1] COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (MUC20-0044) for the IRF QRP, LTCH QRP, and SNF QRP

[2] SARS-CoV-2 Vaccination by Clinicians (MUC20-0045)

[3] CDC/NHSN 'resident vaccination', 'resident boosters', 'staff vaccination', and 'staff boosters' COVID-19 vaccination and booster rates reported on Care Compare for long term Nursing Home residents

How will this measure be distinguished from other similar and/or competing measures?

Comparison of the Patient/Resident COVID-19 Vaccine and the SARS-CoV-2 Vaccination by Clinicians Measure:

The COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure assesses COVID-19 vaccinations for the SNF patient population, whereas the SARS-CoV-2 Vaccination by Clinician measure focuses on COVID-19 vaccination among ambulatory care patients and the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) focuses on healthcare personnel.

Comparison of the Patient/Resident COVID-19 Vaccine measure and the CDC/NHSN 'resident vaccination' and 'resident boosters' rates:

These measures assess two distinct patient populations. The Patient/Resident COVID-19 Vaccine measure captures the SNF patient population whereas the CDC/NHSN 'resident vaccination' and 'resident boosters' rates capture the Nursing Home (NH) resident population.

The patient population receiving skilled nursing facility (SNF) care under the Medicare fee-for-service program differs from the patient population receiving long-term care services in the nursing home in several ways. SNF patients typically enter the facility after an inpatient stay for specialized post-acute care in the SNF. Additionally, SNF care is temporary. For example, a SNF patient may be in need of rehabilitation services after surgery, and aims to return home as soon as medically possible. The average length of SNF stay is 26.5 days (MedPAC Report to Congress, March 2022). The SNF QRP also includes

data submitted by non-critical access hospital swing bed units whose lengths of stay are frequently less than 25 days. The patients receiving care in a non-critical access hospital are not included in the data reported with the nursing home NHSN COVID reporting but will be represented in this measure.

Long-term care is for seniors or others with chronic or progressive medical conditions when the level of care exceeds what can be provided at home. For example, a long-term care resident with Parkinson's disease may be in the nursing home for permanent custodial assistance. Long-care residents often stay in the facility for years.

How will this measure add value to the CMS program?

The COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure complements the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure that is collected for the IRF QRP, LTCH QRP, and SNF QRP. An advantage to reporting a simple vaccination rate at the patient-level is that it provides useful information to the public and to providers. We received feedback from patient and family advocates that a measure capturing raw vaccination rates, irrespective of provider action, would be highly valuable when making healthcare decisions to select a facility for themselves or a loved one.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

Section 1899B(d)(1) of the Social Security Act

Section 2: Measure Evidence

How is the measure expected to be reported to the program?

Other: MDS assessment data through the Internet Quality Improvement and Evaluation System (iQIES)

Stratification

No

Feasibility of Data Elements

ALL data elements are in defined fields in electronic sources

Feasibility Assessment

The MDS COVID-19 vaccination item will be completed to obtain raw rates of COVID-19 vaccination. Providers will be able to use all sources of information available to obtain the vaccination data, such as patient interview, medical records, proxy response, and vaccination cards provided by the patient/caregivers.

While this COVID-19 vaccination item does not yet exist on the MDS assessment instrument, the item will be added to the MDS assessment instrument to electronically capture this information.

We solicited feedback from the technical expert panel (TEP) on the proposed assessment item. No concerns were raised by the TEP regarding the obtainment of information required to complete the new COVID-19 vaccination item.

Method of Measure Calculation

Other digital method

Hybrid measure: Methods of measure calculation

N/A

Evidence of Performance Gap

To demonstrate that the Patient/Resident COVID-19 Vaccine measure has room for improvement, this appendix covers evidence on the variation of vaccination rates across facilities, geographic locations, and patient characteristics.

An internal analysis of September 2021 NHSN COVID-19 Nursing Home data identified a performance gap in COVID-19 vaccination rates among Nursing Home residents. Nursing Home vaccination rate distributions of Nursing Home residents who received a complete COVID-19 vaccination ranged from 0.0% (min) to 100% (max) with a mean score of 82.3%. The 25th percentile, median, and 75th percentile were 75.8%, 84.5%, and 92.0%, respectively. Nursing Home vaccination rate distributions of Nursing Home residents who received a partial COVID-19 vaccination ranged from 0.0% (min) to 77.0% (max) with a mean score of 2.5%. The 25th percentile, median, and 75th percentile were 0.3%, 1.6%, and 3.4%, respectively. This analysis was presented to the TEP and panelists indicated that the presence of disparities in vaccination rates makes the patient-level vaccination measure meaningful to develop. Additionally, panelists broadly agreed that the vaccination gaps identified for nursing homes were also likely present within other post-acute care settings.

Although literature is limited, there is some evidence of COVID-19 vaccination rates varying by facility type. A cross-sectional study used National Healthcare Safety Network (NHSN) facility-level data to examine the rate of full vaccination rates among nursing home residents and staff by facility type through July 18, 2021 (McGarry et al., 2021). The results of the analysis demonstrated that for-profit ownership status was associated with a 3.3 percentage point decrease in resident vaccination coverage compared to nonprofit ownership status. Medicare star ratings were also evaluated in this study, as each additional Medicare star rating a facility had was associated with a 1.2 percentage point increase in its residents' vaccination coverage. These findings suggest that residents living in nonprofit facilities with higher Medicare Five-Star ratings are more likely to receive full dosage of the COVID-19 vaccine than residents living in for-profit facilities with lower star ratings.

Evidence suggests that a sizable proportion of the US population is not fully vaccinated and the extent to which people are not fully vaccinated varies geographically. According to CDC data used by the New York Times, as of October 22, 2021, 57% of the total US population has been fully vaccinated (approximately 189.9 million people) against COVID-19, and 66% has received at least one dose of vaccine (roughly 219.6 million people). Additionally, since August 13, 2021, when the FDA approved third doses for some populations, 11.3 million of the 189.9 million fully vaccinated people have received a vaccine booster. Although only 57% of the total US population is fully vaccinated, COVID-19 vaccination rates vary by region. States in the Northeast have the highest vaccination rates, while states in the Midwest and South have lower vaccination rates. Vaccination rates in the West are also high, as 64.5% of New Mexico residents, 62.8% of Washington residents, and 62.3% of Oregon residents are fully vaccinated. With the exception of Virginia, Maryland, Washington DC, and Florida, the remaining Southern states all have lower fully vaccinated rates than the national average. In fact, the Southern

state of West Virginia has the lowest vaccination rates in the country, as only 40.9% of its population is fully vaccinated. The Northeastern state of Vermont has the highest vaccination rates in the country, as 70.7% of its population is fully vaccinated.

In addition to variation by region, COVID-19 vaccination rates also vary by patient characteristics. To assess whether or not disparities exist among different racial and ethnic groups in the US, the CDC evaluated data from the CDC Vaccine Safety Datalink (CVS) that included vaccination coverage among persons aged 16 years and older between December 2020 and May 2021 (Pingali et al., 2021). For those who received at least one dose of the Pfizer, Moderna, or Johnson & Johnson vaccine, vaccination rates were highest among Asian persons (57.4%) and lowest among non-Hispanic Black (40.7%) and Hispanic (41.14%) persons. Non-Hispanic Black and Hispanic persons also had lower vaccination rates than Whites (54.6%). The Kaiser Family Foundation (KFF) assessed more recent state-reported data on COVID-19 vaccination rates and observed similar findings. As of October 4, 2021, 54% of White people has received at least one COVID-19 vaccine dose, which is 1.2 times higher than the rate for Black people (46%) and 1.1 times higher than the rate for Hispanic people (51%) (Ndugga et al., 2021). Additionally, 69% of Asian people have received at least one COVID-19 vaccine dose, which aligns with Pingali et al.'s (2021) findings that Asian people have the highest vaccination rates. Although disparities in vaccination coverage are evident, the data suggests that these disparities have been decreasing over time. KFF reports that vaccination rates for Black and Hispanic people increased slightly more than vaccination rates for Asian and White people between September 20, 2021, and October 4, 2021, thereby decreasing the gaps in vaccination coverage. This gap in vaccination rates between Black and White people decreased from 14 percentage points to 8 percentage points between April and October 2021. The gap in vaccination rates between White and Hispanic people also decreased during this period of time from 13 percentage points to 3 percentage points. Despite the decreases in these gaps, disparities in vaccination coverage persist.

Other patient characteristics, such as age, sex, and high-risk conditions, also contribute to variations in vaccination rates in the US. A recent study by Diesel et al. (2021) examined CDC data on vaccination coverage for adults aged 18 and older between December 2020 and May 2021 and found that vaccination rates (>=1 COVID-19 vaccine dose) were lowest among persons aged 18-29 years (38.3%) and highest among persons aged 65 and older (80.0%). Pingali et al. (2021) investigated vaccination rates among persons with high-risk conditions and previous COVID-19 infections. Researchers observed a vaccination rate of 63.8% for persons with medical conditions deemed high-risk for severe COVID-19 infection and a vaccination rate of 41.5% for persons without such conditions. Regarding previous COVID-19 infection, the vaccination rate was 48.8% for those who had not had COVID-19 and 42.4% for those who had COVID-19 previously. Overall, these studies suggest that COVID-19 vaccination rates are highest among adults aged 65 and older who have medical conditions deemed high-risk but did not have a COVID-19 infection previously.

References:

Diesel, Jill et al. 2021. “COVID-19 Vaccination Coverage among Adults — United States, December 14, 2020–May 22, 2021.” MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7025e1.

McGarry, Brian E., Karen Shen, Michael L. Barnett, David C. Grabowski, and Ashvin D. Gandhi. 2021. "Association of Nursing Home Characteristics with Staff and Resident COVID-19 Vaccination Coverage." JAMA Internal Medicine, September. https://doi.org/10.1001/jamainternmed.2021.5890.

Ndugga, Nambi et al. 2021. "Latest Data on COVID-19 Vaccinations by Race/Ethnicity." KFF. October 6, 2021. https://www.kff.org/coronavirus-covid-19/issue-brief/latest-data-on-covid-19-vaccinations-by-race-ethnicity/.

Pingali, Cassandra et al. 2021. "COVID-19 Vaccination Coverage among Insured Persons Aged ≥16 Years, by Race/Ethnicity and Other Selected Characteristics — Eight Integrated Health Care Organizations, United States, December 14, 2020–May 15, 2021." MMWR. Morbidity and Mortality Weekly Report 70 (28): 985–90. https://doi.org/10.15585/mmwr.mm7028a1.

The New York Times. 2021. "See How Vaccinations Are Going in Your County and State." The New York Times, October 22, 2021, sec. U.S. https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html.

Appendix A of the Evidence form (attached) provides information on COVID-19 vaccination rate variation across facility, geography, and patient characteristics.

Unintended Consequences

The measure may impact access to care in facilities. If facilities think they have to maintain high COVID-19 vaccination rates, they may reject patients that are not up to date on their COVID-19 vaccinations. We anticipate this risk to be low, given the current state of the pandemic and the knowledge and tools providers have to mitigate the spread of COVID-19 infection.

As part of CMS' measures quarterly monitoring activities, number and percent of patient stays stratified by vaccination status at discharge.

Number of clinical guidelines, including USPSTF guidelines, that address this measure topic

4

Outline the clinical guidelines supporting this measure

Appendix B of the evidence attachment summarizes four of The Advisory Committee on Immunization Practices' (ACIP) Recommendations that support the measure concept for the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure.

1. The Advisory Committee on Immunization Practices' Interim Recommendations for Use of Pfizer-BioNTech COVID-19 Vaccine – United States, December 2020
    a. The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Use of Pfizer Vaccine conducted an explicit, evidence-based review of available data for the use of the Pfizer COVID-19 vaccine in persons aged ≥ 16 years for the prevention of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for patients throughout the continuum of care, including post-acute and home-based care who may not be vaccinated for COVID-19. The body of evidence for the Pfizer-BioNTech COVID-19 vaccine was primarily informed by one large, randomized, double-blind, placebo-

controlled Phase II/III clinical trial that enrolled >43,000 participants (median age = 52 years, range = 16–91 years). Interim findings from this clinical trial, using data from participants with a median of two months of follow-up, indicate that the Pfizer-BioNTech COVID-19 vaccine was 95.0% effective (95% confidence interval = 90.3%–97.6%) in preventing symptomatic laboratory-confirmed COVID-19 in persons without evidence of previous SARS-CoV-2 infection. Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Efficacy was similarly high in a secondary analysis including participants both with or without evidence of previous SARS-CoV-2 infection. Although numbers of observed hospitalizations and deaths were low, the available data were consistent with reduced risk for these severe outcomes among vaccinated persons compared with that among placebo recipients. Using the GRADE evidence assessment, the authors concluded the level of certainty for the benefits of the Pfizer-BioNTech COVID-19 vaccine was type 1 (high certainty) for the prevention of symptomatic COVID-19. Evidence was type 3 (low certainty) for the estimate of prevention of COVID-19 associated hospitalization and type 4 (very low certainty) for the estimate of prevention of death. At the time of these recommendations, data on hospitalizations and deaths were limited, but a vaccine that effectively prevents symptomatic infection is expected to also prevent hospitalizations and deaths.

2. The Advisory Committee on Immunization Practices' Interim Recommendations for Use of Moderna COVID-19 Vaccine – United States, December 2020
    a. The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Use of Moderna Vaccine conducted a transparent, evidence-based review of available data for the use of the Moderna COVID-19 vaccine in persons aged ≥ 18 years for the prevention of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for patients throughout the continuum of care, including post-acute and home-based care who may not be vaccinated for COVID-19. The body of evidence for the Moderna COVID-19 vaccine was primarily informed by one large, randomized, double-blind, placebo-controlled Phase III clinical trial that enrolled approximately 30,000 participants aged 18–95 years (median = 52 years). Interim findings from this clinical trial, using data from participants with a median of two months of follow-up, indicate that the Moderna COVID-19 vaccine efficacy after two doses was 94.1% (95% confidence interval = 89.3%–96.8%) in preventing symptomatic, laboratory-confirmed COVID-19 among persons without evidence of previous SARS-CoV-2 infection, which was the primary study endpoint. High efficacy (≥86%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Using the GRADE evidence assessment, the authors concluded the level of certainty for the benefits of the Moderna COVID-19 vaccine was type 1 (high certainty) for the prevention of symptomatic COVID-19. Evidence was type 2 (moderate certainty) for the estimate of prevention of COVID-19–associated hospitalization and type 4 (very low certainty) for the estimates of prevention of asymptomatic SARS-CoV-2 infection and all-cause death. At the time of these recommendations, data on COVID-19–associated hospitalizations and deaths were limited; however, a vaccine that effectively prevents

symptomatic infection is expected to also prevent associated hospitalizations and deaths.

3. The Advisory Committee on Immunization Practices' Interim Recommendations for Use of Janssen COVID-19 Vaccine – United States, February 2021
    a. The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Use of Janssen COVID-19 Vaccine conducted an evidence-based review of all available data on the use of the Janssen COVID-19 vaccine in persons aged ≥ 18 years for the prevention of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure by identifying criteria for patients throughout the continuum of care, including post-acute and home-based care who may not be vaccinated for COVID-19. The body of evidence for the Janssen COVID-19 vaccine was primarily informed by one international Phase III clinical trial initiated in September 2020 that enrolled approximately 40,000 participants aged 18–100 years (median age = 52 years), using two coprimary endpoints: prevention of symptomatic, laboratory-confirmed¶ COVID-19 among persons without evidence of previous SARS-CoV-2 infection occurring 1) ≥14 days and 2) ≥28 days after vaccination. Interim findings from this clinical trial indicate that the Janssen COVID-19 vaccine efficacy against symptomatic, laboratory-confirmed COVID-19 was 66.3% (95% confidence interval [CI] = 59.9%–71.8%) ≥14 days after vaccination and 65.5% (95% CI = 57.2%–72.4%) ≥28 days after vaccination. At ≥14 days after vaccination, the efficacy of ≥63.0% was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Efficacy varied geographically and was highest in the United States (74.4%; 95% CI = 65.0%–81.6%). Vaccine recipients frequently experienced reactogenicity symptoms, defined as solicited local injection site or systemic adverse reactions during the 7 days after vaccination; however, the symptoms were mostly mild to moderate and resolved 1–2 days after vaccination. Symptoms were more frequent among persons aged 18–59 years than among those aged ≥60 years. From the GRADE evidence assessment, the level of certainty for the benefits of the Janssen COVID-19 vaccine was type 2 (moderate certainty) for the prevention of symptomatic COVID-19. Evidence was also type 2 (moderate certainty) for the estimate of prevention of COVID-19–associated hospitalization and death. Evidence was type 3 (low certainty) for the estimates of prevention of SARS-CoV-2 seroconversion. Regarding certainty of the evidence for possible harms after vaccination, evidence was type 1 (high certainty) for reactogenicity and type 2 (moderate certainty) for serious adverse events. Data reviewed within the EtR framework supported the use of the Janssen COVID-19 vaccine.
4. The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines – United States, 2021.
    a. The Advisory Committee on Immunization Practices' (ACIP) Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines issued recommendations for an additional dose of the primary mRNA COVID-19 vaccine for immunocompromised persons and a COVID-19 vaccine booster dose in eligible groups, as well as persons who are at increased risk for exposure to or serious complications of COVID-19. These recommendations directly relate to the "COVID-19 Vaccine: Percent of

Patients/Residents Who Are Up to Date" measure by identifying criteria for remaining up to date with the COVID-19 vaccine for patients throughout the continuum of care, including post-acute and home-based care. Since June 2020, ACIP has convened 20 public meetings to review data relevant to the potential use of COVID-19 vaccines. To assess the certainty of the evidence for benefits and harms of a booster dose, ACIP used the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. To further guide its deliberations around the use of an additional or booster dose, ACIP used the Evidence to Recommendations (EtR) Framework to evaluate other factors, including the importance of COVID-19 as a public health problem as well as matters of resource use, benefits and harms, patients' values and preferences, acceptability, feasibility, and equity for use of the vaccines. ACIP concluded that the evidence reviewed, including data and considerations from the EtR Frameworks, supported the use of an additional primary dose of an mRNA COVID-19 vaccine for certain immunocompromised recipients of an initial mRNA series, a COVID-19 vaccine booster dose for certain recipients of an mRNA primary series who are at increased risk for exposure to or serious complications of COVID-19, and a COVID-19 vaccine booster dose for all recipients of a Janssen COVID-19 vaccine dose.

Name the guideline developer/entity

[1] The Advisory Committee on Immunization Practices (ACIP) [2] The Advisory Committee on Immunization Practices (ACIP) [3] The Advisory Committee on Immunization Practices (ACIP) [4] The Advisory Committee on Immunization Practices (ACIP)

Publication year

[1] 2020

[2] 2020

[3] 2020

[4] 2021

Full citation +/- URL

[1] 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): 1922-1924. https://doi.org/10.15585/mmwr.mm6950e2.

[2] 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.

[3] 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): 329-332. https://doi.org/10.15585/mmwr.mm7009e4.

[4] 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): 1545-1552. https://doi.org/10.15585/mmwr.mm7044e2.

Is this an evidence-based clinical guideline?

Yes

Is the guideline graded?

Yes

List the guideline statement that most closely aligns with the measure concept.

[1] ACIP concluded the Pfizer COVID-19 vaccine has high efficacy for the prevention of symptomatic COVID-19.

[2] ACIP concluded the Moderna COVID-19 vaccine has high efficacy for the prevention of symptomatic COVID-19.

[3] ACIP concluded the Janssen COVID-19 vaccine has high efficacy against COVID-19 - associated hospitalization and death.

[4] ACIP concluded that the evidence reviewed supported the use of an additional primary dose of an mRNA COVID-19 vaccine for certain immunocompromised recipients of an initial mRNA series, a COVID-19 vaccine booster dose for certain recipients of an mRNA primary series who are at increased risk for exposure to or serious complications of COVID-19, and a COVID-19 vaccine booster dose for all recipients of a Janssen COVID-19 vaccine dose.

What evidence grading system did the guideline use to describe strength of recommendation?

GRADE method

List all categories and corresponding definitions for the evidence grading system used to describe strength of recommendation in the guideline?

The GRADE certainty ratings and corresponding definitions are as follows:

1: High

The authors have a lot of confidence that the true effect is similar to the estimated effect.

2: Moderate

The authors believe that the true effect is probably close to the estimated effect.

3: Low

The true effect might be markedly different from the estimated effect.

4: Very low

The true effect is probably markedly different from the estimated effect.

For the guideline statement that most closely aligns with the measure concept, what is the associated strength of recommendation?

USPSTF Grade A, Strong recommendation or similar

What evidence grading system did the guideline use to describe level of evidence or level of certainty in the evidence?

GRADE method

List all categories and corresponding definitions for the evidence grading system used to describe level of evidence or level of certainty in the evidence?

The GRADE certainty ratings and corresponding definitions are as follows:

1: High

The authors have a lot of confidence that the true effect is similar to the estimated effect.

2: Moderate

The authors believe that the true effect is probably close to the estimated effect.

3: Low

The true effect might be markedly different from the estimated effect.

4: Very low

The true effect is probably markedly different from the estimated effect.

For the guideline statement that most closely aligns with the measure concept, what is the associated level of evidence or level of certainty in the evidence?

USPSTF Grade A, Strong recommendation or similar

List the guideline statement that most closely aligns with the measure concept.

Health care professionals play a critical role in COVID-19 vaccination efforts, including primary, additional primary, and booster vaccination, particularly to protect patients who are at increased risk for severe illness and death.

Number of systematic reviews that inform this measure concept

4

Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept

Appendix C of the evidence attachment summarizes four peer-reviewed systematic review(s) that inform the measure concept for the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure and provides full citations and URLs for each review.

1. Korang et al.

a. Korang et al. (2022) sought to assess the effectiveness and safety of COVID-19 vaccines through analyses of all currently available randomized clinical trials. The authors searched the databases CENTRAL, MEDLINE, Embase, and other sources from inception to June 17, 2021 for randomized clinical trials assessing vaccines for COVID-19. At least two independent reviewers screened studies, extracted data, and assessed risks of bias prior to conducting meta-analyses, network meta-analyses, and Trial Sequential Analyses (TSA). Authors assessed the certainty of evidence with GRADE, and found 35 trials to include in the analyses. The meta-analyses showed that mRNA vaccines (efficacy, 95% [95% confidence interval (CI 92% to 97%]; 71,514 participants; 3 trials; moderate certainty); inactivated vaccines (efficacy, 61% [95% CI, 52% to 68%]; 48,029 participants; 3 trials; moderate certainty); protein subunit vaccines (efficacy, 77% [95% CI, −5% to 95%]; 17,737 participants; 2 trials; low certainty); and viral vector vaccines (efficacy 68% [95% CI, 61% to 74%]; 71,401 participants; 5 trials; low certainty) prevented COVID-19. Viral vector vaccines decreased mortality (risk ratio, 0.25 [95% CI 0.09 to 0.67]; 67,563 participants; 3 trials, low certainty), but comparable data on inactivated, mRNA, and protein subunit vaccines were imprecise. None of the vaccines showed evidence of a difference on serious adverse events, but observational evidence suggested rare serious adverse events. All the vaccines increased the risk of non-serious adverse events. The authors concluded the evidence suggests that all the included vaccines are effective in preventing COVID-19. The mRNA vaccines seem most effective in preventing COVID-19, but viral vector vaccines seem most effective in reducing mortality. Further trials and longer follow-ups are necessary to provide better insight into the safety profile of these vaccines.
b. 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." Edited by Stefanos Bonovas. PLOS ONE 17 (1): e0260733. https://doi.org/10.1371/journal.pone.0260733.

2. Fielkin et al.
   a. Fiekin et al. (2022) sought to systematically review the evidence for the duration of protection of COVID-19 vaccines against various clinical outcomes, and to assess changes in the rates of breakthrough infection caused by the delta variant with increasing time since vaccination. This study was designed as a systematic review and meta-regression. A systematic review of preprint and peer-reviewed published article databases from June 17, 2021, to Dec 2, 2021, was conducted, and randomized controlled trials of COVID-19 vaccine efficacy and observational studies of COVID-19 vaccine effectiveness were eligible. The following databases and preprint servers without language restrictions were included in the search: PubMed, Embase, medRxiv, BioRxiv, khub, Research Square, SSRN, Eurosurveillance.org, Europepmc.org, and the WHO COVID-19 database, which compiles searches of more than 100 databases, including Scopus, Web of Science, grey literature. The authors searched for studies with several variations of the primary key search terms "COVID-19", "SARS-CoV-2", and "vaccine" (including names of specific vaccines) and "randomized controlled trial" or "vaccine effectiveness" (including names of specific study designs). Studies with vaccine efficacy or effectiveness estimates at discrete time intervals of people who had received full vaccination and that met predefined screening criteria underwent full-text review.

Random-effects meta-regression was used to estimate the average change in vaccine efficacy or effectiveness 1–6 months after full vaccination. After applying exclusion criteria, 18 studies of vaccine efficacy or effectiveness at discrete time intervals after full vaccination and seven studies in which risk of breakthrough infection could be assessed by time of vaccination were included. In addition, the same search strategy was used to find studies presenting analyses of breakthrough infections, in which the rate, risk, or odds of COVID-19 outcomes among different vaccine cohorts (i.e., vaccinated at different times) were included. The authors found that during the six months after full vaccination, vaccine efficacy or effectiveness against SARS-CoV-2 infection and symptomatic COVID-19 disease decreased by approximately 20–30 percentage points, on average, for the four vaccines that we evaluated. By contrast, most studies showed that vaccine efficacy or effectiveness against the severe disease was maintained above 70% after full vaccination, with a minimal decrease to six months (approximately 9–10 percentage points). The decrease in vaccine efficacy or effectiveness is likely caused by, at least in part, waning immunity, although an effect of bias cannot be ruled out. Evaluating vaccine efficacy or effectiveness beyond six months will be crucial for updating the COVID-19 vaccine policy.

b. 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.

3. Lee et al.

a. The focus of this systematic review and meta-analysis was to compare the efficacy of COVID-19 vaccines between immunocompromised and immunocompetent people. Vaccine trials have excluded immunocompromised groups, but these patients are of particular interest because of possible suppression or over-activation of the immune system attributable to the primary disease or concurrent treatment. Data are needed on immunocompromised patients, as infection and viral shedding have been reported to be more severe and persistent in this group. Immunocompromised patients show lower seroconversion rates than immunocompetent people after vaccination, such as with the influenza vaccine. Less is known about the response to COVID-19 vaccines, particularly mRNA-based vaccines. Lee et al. (2022) sought to compare the efficacy of covid-19 vaccines between immunocompromised and immunocompetent people. Several databases were searched (Medline via PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), CORD-19, WHO COVID-19 Research Database, ClinicalTrials.gov, and WHO international clinical trials registry platform) for articles published from December 1, 2020, to November 5, 2021. No restrictions on the language of publication were applied. To improve the validity of data, non-peer-reviewed articles in preprint databases were excluded. The authors assessed the certainty of evidence using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE). Overall, 82 studies were included for meta-analysis. Of these studies, 77 (94%) used mRNA vaccines, 16 (20%) viral vector vaccines, and 4 (5%) inactivated whole virus vaccines. The authors found that seroconversion rates after COVID-19 vaccination were significantly lower in immunocompromised patients, especially organ transplant recipients. A second dose was associated with consistently improved seroconversion across all patient groups, albeit at a lower magnitude for organ transplant recipients. The authors concluded that targeted

interventions for immunocompromised patients, including a third (booster) dose, should be performed.

b. Lee, Ainsley Ryan Yan Bin et al. 2022. "Efficacy of Covid-19 Vaccines in Immunocompromised Patients: Systematic Review and Meta-Analysis." BMJ 376 (March): e068632. https://doi.org/10.1136/bmj-2021-068632.

4. Norhayati et al.
   a. This review aimed to estimate the pooled proportion of COVID-19 vaccine acceptance worldwide. Determining the pooled estimated proportion of COVID-19 vaccination acceptance provides guidance to health authorities to prepare for an effective vaccination program. A systematic review and meta-analysis of studies were conducted to assess the proportion of COVID-19 vaccination acceptance. A systematic search was performed in the MEDLINE (PubMed) database for articles between January 1, 2021, and July 19, 2021. The search was done using the generic free-text search terms "COVID-19" AND "vaccine" AND "acceptance." All types of COVID-19 vaccines were included in this review. The search was restricted to full-text only and English language articles. Studies with cross-sectional, case-control, and cohort designs were included. Case series/reports, conference papers, proceedings, articles available only in abstract form, editorial reviews, letters of communications, commentaries, systematic reviews, and qualitative studies were excluded. Assessment of critical appraisal for data quality was assessed using the Joann Briggs Institute (J.B.I.). Two authors performed bias assessments independently, and a total of 172 studies were included in the review and meta-analysis. The pooled proportion of COVID-19 vaccine acceptance involving 50 countries was 61% (95% CI: 59, 64%). This finding was lower compared to a previous estimate of 73.31% (95% CI: 70.52%, 76.01%) which involved 38 studies across 36 countries with limited data from low-income countries. Concern about the vaccine's safety, efficacy, and side effects, trust in the government or related authorities, and religious beliefs were primary factors that influenced vaccine acceptance. The pooled proportion of COVID-19 vaccine acceptance among regions ranged from 52 to 74%, while among population groups varied from 52 to 63%, with healthcare workers showing the highest proportion of vaccine acceptance. Since healthcare workers were among the first to receive COVID-19 vaccines, their attitude or perception toward COVID-19 vaccines would affect the other population's decisions to recommend the vaccination to friends, families, and their patients. The time during which the survey was conducted showed that the acceptance of the COVID-19 vaccine changed over time. The United States showed an increased pattern of vaccine acceptance in the second and third surveys. The authors concluded that the rate of COVID-19 vaccine acceptance varied by region, population type, gender, vaccine effectiveness, and survey time, with an overall pooled proportion of 61%. A high level of acceptance of vaccination is required to achieve herd immunity for the disease. A successful and effective vaccination program can provide sufficient vaccination coverage in a population to achieve herd immunity and subsequently control the COVID-19 pandemic.
   b. Norhayati, Mohd Noor, Ruhana Che Yusof, and Yacob Mohd Azman. 2022. "Systematic Review and Meta-Analysis of COVID-19 Vaccination Acceptance." Frontiers in Medicine 8 (January). https://doi.org/10.3389/fmed.2021.783982.

Source of empirical data

Published, peer-reviewed original research;Published and publicly available reports (e.g., from agencies)

Summarize the empirical data

Appendix D of the Evidence form (attached) provides information the effectiveness of COVID-19 vaccinations in preventing COVID-19 related health outcomes.

Evidence of the effectiveness of COVID-19 vaccinations in preventing COVID-19 infections and related health outcomes is essential for guiding policymaking decisions regarding the ongoing public health emergency (PHE). As more data have become available, researchers have been able to assess the effectiveness of all COVID-19 vaccinations accessible in the United States across various populations and settings. These data demonstrate that the three COVID-19 vaccines approved for emergency use by the Food and Drug Administration (FDA), Pfizer-BioNTech (BNT162b2 mRNA), Moderna (mRNA-1273), and Johnson & Johnson/Janssen (JNJ-78436735), are highly effective for preventing COVID-19-related serious illness, hospitalization, and death (Rosenberg et al., 2021). In fact, for full messenger RNA (mRNA) vaccines (Pfizer and Moderna), vaccine effectiveness (VE) against COVID-19-associated hospitalizations was found to be 86% two to twelve weeks after receipt of the second dose and 84% 13 to 24 weeks after the second dose (Tenforde et. al, 2021). Note: These VE calculation estimates presented in these studies pre-date the delta and omicron surges. A study conducted by the New York State Department of Health, assessed statewide laboratory testing, hospitalization, and immunization databases to determine rates of new COVID-19 cases and hospitalizations among adults age 18 or older and to evaluate VE between May and July 2021 (Rosenberg et al., 2021). Researchers observed a decline in VE against new infection from 91.7% to 79.8% between May and July 2021, which can be attributed to the increase in delta variant prevalence during the study window. Despite this decline in VE against new infection, the VE against hospitalization for fully vaccinated adults remained high at 90% (Rosenberg et al., 2021). These results indicate that all three COVID-19 vaccinations available in the US are still useful for preventing some infections and highly effective at preventing hospitalization in adults.

Several studies focusing on VE among older adults have also been published recently. A study by Thompson et al. assessed the VE for all three FDA-approved vaccines against laboratory-confirmed infection, infection-associated hospitalizations, ICU admissions, and visits to emergency departments or urgent cares among adults 50 years of age or older between January and June 2021. Researchers found that VE against infection leading to hospitalization was 89% after the second dose of a mRNA vaccine (Pfizer and Moderna). Effectiveness against infection leading to ICU admission and effectiveness against infection leading to an emergency department or urgent care visit for full mRNA vaccines were 90% and 91% respectively. The effectiveness of the Johnson & Johnson vaccine was lower than the full mRNA vaccines among the study population, as VE was 68% against infection leading to hospitalization and 73% against infection leading to an emergency department or urgent care clinic visit. The results of this study indicate that all three FDA-approved COVID-19 vaccines are highly effective against infection leading to hospitalization, ICU admission, or emergency department visit among adults 50 years of age or older, with full doses of the Pfizer and Moderna vaccines being somewhat more effective than Johnson & Johnson. Similar findings were observed in a recently published study focusing on VE among adults 65 years of age or older. In this study population, VE against COVID-19-associated hospitalizations was 91% and 84% for full vaccination with mRNA vaccines and vaccination with the Johnson & Johnson vaccine respectively (Moline et al., 2021). Overall, these studies provide evidence of the effectiveness of COVID-19 vaccinations in preventing hospitalization among older adults.

In addition to older adults, differences in VE among the three authorized COVID-19 vaccines have been observed in the broader adult population aged 18 and older. Among these adults who do not have any immunocompromising conditions, researchers observed that the VE against hospitalization was higher for the Moderna vaccine (93%) than the Pfizer vaccine (88%) (Self et al., 2021). The VE against hospitalization for the Johnson & Johnson vaccine was the lowest of the three authorized vaccines at 71%. Despite these differences in VE, all three authorized COVID-19 vaccines are still useful for preventing some infections and highly effective at preventing hospitalization.

The effectiveness of these vaccines has also been tested among healthcare and frontline workers, as these populations are at increased risk for COVID-19 infection. A recently published observational study examined new COVID-19 infections among healthcare workers who received at least one dose of vaccine between January and May 2021. Researchers found that VE 14 days after the first dose was 49.2% and 38.2% for the Pfizer and Moderna vaccines, respectively (Paris et al., 2021). Effectiveness improved substantially 14 days after the second dose, as Pfizer VE increased to 100% and Moderna VE increased to 94.6%. Similar results were observed in a study that focused on a broader population of frontline workers, defined as healthcare personnel, first responders, and other essential workers (Fowlkes et al., 2021). Researchers evaluated VE against infection among frontline workers in six states between December 2020 and April 2021 and observed an adjusted VE of 91%. However, when researchers assessed data from May 2021 to August 2021 to account for surges in cases of the delta variant, the adjusted VE was 66%. These findings suggest that VE is higher against COVID-19 alpha infections than delta infections among frontline workers.

The VE against alpha and delta infections was also studied by Lopez Bernal et al., who estimated the VE against symptomatic disease caused by the delta variant among people 16 years of age and older between February and May 2021. After one dose of the Pfizer vaccine, the VE against the alpha variant was considerably higher (48.7%) than the VE against the delta variant (30.7%). This difference in VE decreased after participants received the second dose of the Pfizer vaccine, as the VE against the alpha variant increased to 93.7% while the VE against the delta variant increased to 88.0%. These findings deviate slightly from Fowlkes et al.'s study, where researchers observed a greater difference in VE against the alpha and delta variants. This is likely due to the different study windows used, as Fowlkes et al. examined data from May 2021 to August 2021 during the surge in delta infections, hospitalizations, and deaths.

Given the demonstrated higher VE against the alpha variant compared to the delta variant, researchers have focused on evaluating VE during periods of time when delta infections, hospitalizations, and deaths were surging. Grannis et al. examined medical encounters across nine states where adults 18 years of age or older received a COVID-19 discharge diagnosis from a hospital, emergency department, or urgent care between June and August 2021 when the delta variant accounted for more than 50% of cases in the respective states. Researchers found that VE for all three authorized COVID-19 vaccines was 86% against hospitalization and 82% against emergency department and urgent care visits. However, when stratified by age, VE against hospitalization was significantly lower for adults 75 years of age or older (76%) compared to adults between 18 and 74 (89%). Despite the lower VE for adults aged 75 years and older, vaccination still proves highly effective at preventing COVID-19-related hospitalization among this population during periods of high delta variant incidence.

Lauring et al. (2022) studied the effectiveness of the mRNA vaccines to prevent COVID-19 hospitalizations related to the alpha, delta, and omicron SARS-CoV-2 variants from March 11, 2021, to January 14, 2022. The effectiveness of two vaccine doses against hospitalization was 85% during the periods of the study when alpha and delta dominated but 65% during the omicron period—late December 2021 through mid-January 2022. The effectiveness of three vaccine doses during the Omicron phase was 86%. mRNA vaccines were found to be highly effective in preventing COVID-19 associated hospital admissions related to the alpha, delta, and omicron variants, but three vaccine doses were required to achieve protection against omicron similar to the protection that two doses provided against the delta and alpha variants. Among adults admitted to hospital with COVID-19, the omicron variant was associated with less severe disease than the delta variant but still resulted in substantial morbidity and mortality. Vaccinated patients with COVID-19 hospitalizations had significantly lower disease severity than unvaccinated patients for all the variants.

Appendix D References:

Fowlkes, Ashley, et al. 2021. "Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection among Frontline Workers before and during B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7034e4.

Grannis, Shaun J., et al. 2021. "Interim Estimates of COVID-19 Vaccine Effectiveness against COVID-19–Associated Emergency Department or Urgent Care Clinic Encounters and Hospitalizations among Adults during SARS-CoV-2 B.1.617.2 (Delta) Variant Predominance — Nine States, June–August 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7037e2.

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, (March): e069761. https://doi.org/10.1136/bmj-2021-069761.

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 (7). https://doi.org/10.1056/nejmoa2108891.

Moline, Heidi L., et al. 2021. "Effectiveness of COVID-19 Vaccines in Preventing Hospitalization among Adults Aged ≥65 Years — COVID-NET, 13 States, February–April 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mThemwr.mm7032e3.

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Self, Wesley H., et al. 2021. "Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations among Adults without Immunocompromising Conditions — United States, March–August 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7038e1.

Tenforde, Mark W., et al. 2021. "Effectiveness of Pfizer-BioNTech and Moderna Vaccines against COVID-19 among Hospitalized Adults Aged ≥65 Years — United States, January–March 2021." MMWR. Morbidity and Mortality Weekly Report 70. https://doi.org/10.15585/mmwr.mm7018e1.

Thompson, Mark G., et al. 2021. "Effectiveness of Covid-19 Vaccines in Ambulatory and Inpatient Care Settings." New England Journal of Medicine, September. https://doi.org/10.1056/nejmoa2110362.

Appendix D Limitations:

21. Fowlkes, Ashley, et al. 2021
    a. The study was limited to a 35 week period of observations (December 14, 2020 – April 10, 2021) before and during the delta variant. Unmeasured and residual confounding might be present.
22. Grannis, Shaun J., et al. 2021
    a. Duration of VE was not examined and VE for partial vaccination was not assessed. Although the facilities in this study serve heterogenous populations in nine states, the findings might not be generalizable to the U.S. population.
23. Lauring, Adam S et al. 2022
    a. The use of in-patient controls might lead to biased estimates if control patients had different characteristics from people in the general community, however, the control population within this study tracked closely with the adult population in the US. The study was limited to VE for patients admitted to the hospital. The study only evaluated mRNA vaccines, not other types of covid-19 vaccines. Sequencing did not identify a variant for some cases—typically those with low viral loads in tested respiratory samples. Variant classification for cases without a sequencing confirmed variant was based on the predominant circulating variant at the time; variant misclassification was possible for these cases, but sensitivity analyses limited to sequencing confirmed cases produced results similar to those in the primary analysis.
24. Lopez Bernal, Jamie, et al. 2021
    a. The findings are observational and unmeasured and residual confounding might be present. Low sensitivity or specificity of PCR testing could result in cases and controls being misclassified, which would attenuate the estimates of vaccine effectiveness. Low sensitivity or specificity of PCR testing could also affect one variant more than another, although this might be expected to affect the alpha variant more than the delta variant, given that, with an emerging variant, more cases may be detected earlier in infection, which may result in higher viral loads and increased sensitivity and specificity. There may also be differences among the populations that received each vaccine. The analysis also relied on the assumptions that any residual confounding in the test-negative case–control design would affect the two estimates of vaccine effectiveness equally or at least would not bias the adjusted odds ratio for the comparison of vaccine effectiveness for a given vaccine against

the two variants; that is, the accuracy of the sequencing would not depend on the variant and the propensity among symptomatic persons to get tested would not differ according to variant.

25. Moline, Heidi L., et al. 2021
    a. VE estimates were adjusted for relevant potential confounders, residual confounding is possible (e.g., chronic conditions. the heterogeneity of disease risk, vaccination coverage within each site, and differences in the populations who received different vaccine products). The study period for this analysis occurred before the predominance of the delta variant; changes in circulating SARS-CoV-2 variants might affect vaccine effectiveness when assessed over time. Persons choosing to receive vaccine later in the rollout might have different risk characteristics than do those vaccinated earlier and might have experienced differences in access to vaccine products by time and location. This analysis was limited to adults at/above 65 years, and the results are not generalizable to younger age groups.
26. Paris, Christophe, et al. 2021
    a. Findings may not be generalizable to other settings, given the variability of the epidemiology of SARS-CoV-2 variants. The study was not powered to evaluate vaccine effectiveness more than 3 months after the first dose. The study was based on passive surveillance, so asymptomatic SARS-CoV-2 infection may have been underestimated.
27. Rosenberg, Eli S., et al. 2021
    a. Residual differences between fully vaccinated and unvaccinated groups have the potential to reduce estimated VE. The analysis excluded partially vaccinated persons, to robustly assess VE for fully vaccinated compared with that of unvaccinated persons. Exact algorithms were used to link databases; some persons were possibly not linked because matching variables were entered differently in the respective systems. This study did not estimate VE by vaccine product, and persons were categorized fully vaccinated at 14 days after final dose, per CDC definitions. Information on reasons for testing and hospitalization, including symptoms, was limited. Data were too sparse to reliably estimate VE for COVID-19-related deaths.
28. Self, Wesley H., et al. 2021
    a. The analysis excluded children, immunocompromised adults, or VE against COVID-19 that did not result in hospitalization. The confidence intervals for the Janssen VE estimates were wide because of the relatively small number of patients who received this vaccine. Follow-up time was limited to approximately 29 weeks since receipt of full vaccination, and further surveillance of VE over time is warranted. Although VE estimates were adjusted for relevant potential confounders, residual confounding is possible. Product-specific VE by variant, including against delta variants (B.1.617.2 and AY sublineages), was not evaluated. Antibody levels were measured at only a single time point 2–6 weeks after vaccination and changes in antibody response over time as well as cell-mediated immune responses were not assessed.
29. Tenforde, Mark W., et al. 2021
    a. The confidence intervals for VE estimates were wide because of the small sample size, and the number of participants was too small to assess VE by vaccine product, age group, or underlying conditions. As an interim analysis that included self-reported data, vaccination status might have been misclassified, or participants might have had imperfect recollection of vaccination or illness onset dates. Selection bias and residual confounding cannot be excluded. Although the analysis included hospitalized adults from 14 states, the participants were not geographically representative of the U.S. population. The case-control design infers protection based on associations between disease outcome and previous vaccination

but cannot establish causation. Duration of VE and VE for non-hospitalized COVID-19 was not assessed.

30. Thompson, Mark G., et al. 2021
    a. VE estimates were adjusted for relevant potential confounders, unmeasured and residual confounding is possible (e.g., occupations of the patients, which is associated with exposure to virus and access to and use of vaccination and personal protective equipment). The percentage of patients who were clinically tested for SARS-CoV-2 by molecular assay differed across network partners and clinical settings, and vaccine-effectiveness estimates can be biased if clinicians make testing decisions based on vaccination status.

Name evidence type

N/A

Summarize the evidence

N/A

Does the evidence discuss a link between at least one process, structure, or intervention with the outcome?

N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size

1,824,946

Type of Evidence to Support the Measure

Clinical Guidelines or USPSTF (U.S. Preventive Services Task Force) Guidelines;Peer-Reviewed Systematic Review; Empirical data

Is the measure risk adjusted?

No

Risk adjustment variables

N/A

Patient-level demographics: please select all that apply:

N/A

Patient-level health status & clinical conditions: please select all that apply:

N/A

Patient functional status: please select all that apply:

N/A

Patient-level social risk factors: please select all that apply:

N/A

Proxy social risk factors: please select all that apply

N/A

Patient community characteristic: please select all that apply:

N/A

Risk model performance

N/A

Rationale for not using risk adjustment

Addressed through exclusions (e.g., process measures)

Cost estimate completed

No

Cost estimate methods and results

N/A

Section 3: Patient and Provider Perspective

Meaningful to Patients. Was input on the final performance measure collected from patient and/or caregiver?

Yes

Total number of patients and/or caregivers who responded to the question asking them whether the final performance measure helps inform care and decision making

5

Total number of patients/caregivers who agreed that the final performance measure helps inform care and decision making

5

Meaningful to Patients: Numbers consulted

N/A

Meaningful to Patients: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians: Numbers consulted

N/A

Meaningful to Clinicians: Number indicating survey/tool is meaningful

N/A

Meaningful to Clinicians. Were clinicians and/or providers consulted on the final performance measure?

Yes

Acumen convened a Technical Expert Panel (TEP) for the purposes of soliciting feedback on the development of a Post-Acute Care (PAC) patient-level COVID-19 vaccination measure for the PAC

settings, along with the accompanying PAC patient-level COVID-19 vaccination assessment item. The PAC QRP Vaccination TEP comprised of 11 stakeholders with diverse perspectives and areas of expertise representing clinical, policy and program, measure development, and technical expertise. Additionally, the PAC QRP Support team met with a patient and family/caregiver advocates focus group assembled by Patient and Family Centered Care (PFCC) Partners. This session was held in order to inform the TEP discussion of the viewpoints of patients and family/caregivers who actively utilize the Care Compare website in order to make informed decisions about their or their loved one's healthcare.

The patient and family/caregiver advocates felt a measure capturing raw vaccination rate, irrespective of provider action, would be most helpful to them when deciding to choose a facility for either their own care or for a loved one. TEP Panelists agreed that reporting the rate of vaccination in a PAC/NH setting without denominator exclusions is important to meet when designing a measure.

Total number of clinicians/providers who responded when asked if the final performance measure was actionable to improve quality of care.

0

Total number of clinicians/providers who agreed that the final performance measure was actionable to improve quality of care

0

Survey level testing

N/A

Type of Testing Analysis

N/A

Testing methodology and results

N/A

Burden for Provider: Was a provider workflow analysis conducted?

No

If yes, how many sites were evaluated in the provider workflow analysis?

N/A

Did the provider workflow have to be modified to accommodate the new measure?

N/A

Section 4: Measure Testing Details

Reliability

No

Reliability: Type of Reliability Testing

N/A

Signal-to-Noise: Name of statistic

N/A

Signal-to-Noise: Sample size

N/A

Signal-to-Noise: Statistical result

N/A

Signal-to-Noise: Interpretation of results

N/A

Random Split-Half Correlation: Name of statistic

N/A

Random Split-Half Correlation: Sample size

N/A

Random Split-Half Correlation: Statistical result

N/A

Random Split-Half Correlation: Interpretation of results

N/A

Other: Name of statistic

N/A

Other: Sample size

N/A

Other: Statistical result

N/A

Other: Interpretation of results

N/A

Empiric Validity

No

Empiric Validity: Statistic name

N/A

Empiric Validity: Sample size

N/A

Empiric Validity: Statistical result

N/A

Empiric Validity: Methods and findings

N/A

Empiric Validity: Interpretation of results

N/A

Face Validity

No

Face Validity: Number of voting experts and patients/caregivers

N/A

Face Validity: Result

N/A

Patient/Encounter Level Testing

Yes

Type of Analysis

Other (enter here): Agreement with gold standard

Sample Size

45

Statistic Name

Percent agreement

Statistical Results

84%

Interpretation of results

Our team used five patient scenarios for testing. Percent agreement was calculated by dividing the total number of patient scenario responses that matched the gold standard by the total number of patient scenario responses. Overall percent agreement for SNFs was 84%. Across all provider types, those who used the CDC website or the guidance manual and the CDC website had the highest percent agreement (100% and 88% respectively).

The results of the item testing support the use of a Patient-level COVID-19 Vaccination Coverage measure item. When providers use the available materials, percent agreement of the item increases to 85% or higher. The findings from the cognitive interviews provide information to improve the item itself, as well as the accompanying guidance. Based on the feedback received from providers during testing, we are able to add additional clarification to the coding guidance, such as providing the patient's age in the coding examples and including examples for coding certain unique patient scenarios. With these additional updates, we expect that the percent agreement would go up.

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Higher score is better

Mean performance score

99999

Median performance score

99999

Minimum performance score

99999

Maximum performance score

99999

Standard deviation of performance scores

99999

Does the performance measure use survey or patient-reported data?

No

Surveys or patient-reported outcome tools

N/A

Section 5: Measure Contact Information

Measure Steward

Centers for Medicare & Medicaid Services

Measure Steward Contact Information

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Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

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Submitter Comments

N/A