Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID-19 Vaccination-Related Items and Measures

November 19, 2021/December 15, 2021

Summary Report

November 2022

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EXECUTIVE SUMMARY

Under contract with the Centers for Medicare & Medicaid Services (CMS), Acumen, LLC and Abt Associates convened a Technical Expert Panel (TEP) for the purposes of soliciting feedback on the development of Post-Acute Care (PAC) patient-level COVID-19 vaccination measures for the PAC settings, along with the accompanying PAC patient-level COVID-19 vaccination assessment items. Feedback was solicited over the course of six topic-driven sessions: four on November 19, 2021 (first TEP meeting), and two on December 15, 2021 (second TEP meeting). The patient and family/caregiver advocate (PFA) perspective was also gathered on November 10, 2021 through a focus group in order to inform TEP discussion.

Throughout the course of these sessions, TEP panelists voiced their support for PAC patient-level COVID-19 vaccination measures and provided insightful and actionable feedback. Panelists agreed that given the severity and duration of the Public Health Emergency (PHE), more comprehensive information on patient vaccination status and administration would be useful to providers, patients and caregivers, as well as CMS. Furthermore, analyses presented during the TEP showed considerable variation in COVID-19 vaccination rates among nursing homes by state and within state, as well as nationwide variation by social risk factors such as race, sex, and age. Panelists indicated that the presence of large disparities in vaccination rates further justifies the development of measures on patient-level COVID-19 vaccination based on more comprehensive assessment items.

The PAC QRP Support team conducted and presented the panel with analyses detailing how Minimum Data Set (MDS) assessments in nursing homes capture more vaccination incidences in the nursing home setting than claims data, for both influenza and pneumococcal vaccines. Panelists agreed with using PAC assessment tools to collect data for a patient-level COVID-19 vaccination measure, rather than claims data. Panelists were not surprised to see results showing variations in vaccination reporting between claims and assessments in nursing homes and noted that these variations would likely exist across settings, due to confusion around billing policies and low vaccination reimbursement rates, based on their knowledge of each care setting.

Panelists recognized that among the measures assessing vaccination currently in use within the PAC Quality Reporting Programs (QRPs), there appear to be two distinct goals: (i) measures to convey the raw rate of vaccination among a certain population without exclusions based on contraindications, and (ii) measures that assess provider action towards boosting vaccination rates among their patient populations. PFA members of the TEP indicated that the first type of measure (raw rate of vaccination) would more directly inform their decisions on where to receive care for themselves or family members. Meanwhile, the other panelists felt that while raw vaccination rates are useful for patients deciding among facilities, these rates were not necessarily indicative of provider quality. The TEP expressed a concern that facilities/agencies

can only do so much to increase COVID-19 vaccination rates, especially if patients had already been offered the vaccine at an earlier stage of care and declined it. Panelists representing the PAC provider perspective instead noted that the second goal, to capture whether or not providers are taking appropriate actions to assess and administer vaccines, is more representative of provider quality as it directly measures provider effort and practices.

Ultimately, panelists agreed that the best course would be to have two measures that address both goals. To reiterate, the first measure would aim to provide information on the rate of COVID-19 vaccination among patients in PAC settings without exclusions due to contraindications. The second measure would provide data on whether providers are appropriately assessing and administering COVID-19 vaccinations. This approach ensures that the measures help inform patients on the COVID-19 vaccination rates for each care setting, while ensuring that provider quality and action is adequately reflected. In order to limit the increase in provider burden, assessment items would be developed in such a way that they can be used to calculate both measures.

The TEP highlighted four considerations that should be kept in mind when developing new assessment items. First, they emphasized that provider burden should be considered when developing new items. Second, the TEP suggested that assessment items should use language such as "up to date" or "current" (referring to a patient/resident having received the most current dose they are eligible for) in terms of vaccination status, as opposed to "fully vaccinated," (defined as a state that occurs two weeks after receipt of completed course or applicable boosters) in order to distinguish between the statuses of vaccination receipt. Third, the TEP stressed the importance of referring to public guidelines, so that the assessment items can remain relevant as guidance from the Centers for Disease Control and Prevention (CDC) continues to evolve. Fourth, panelists agreed on the importance of capturing provider education to unvaccinated persons about the effectiveness of the COVID-19 vaccines, although there were concerns about what exactly would qualify as education. The remaining sections of this report provide further detail on each of the discussion topics.

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1 INTRODUCTION

The Patient Protection and Affordable Care Act (ACA) of 2010 and Improving Medicare Post-Acute Care Transformation Act (IMPACT) of 2014 require public reporting of quality and cost measures through Post-Acute Care (PAC) Quality Reporting Programs (QRPs). The Centers for Medicare & Medicaid Services (CMS) has contracted with Acumen, LLC, and Abt Associates (hereafter referred to as the PAC QRP Support team) to develop and maintain measures for each PAC QRP, which includes Long-Term Care Hospitals (LTCHs), Skilled Nursing Facilities (SNFs), Home Health (HH) Agencies (HHAs) and Inpatient Rehabilitation Facilities (IRFs). Acumen, LLC operates under the *Quality Measure & Assessment Instrument Development & Maintenance & QRP Support for the Long-Term Care Hospital, Inpatient Rehabilitation Facility, Skilled Nursing Facility, Quality Reporting Programs, & Nursing Home Compare* contract (75FCMC18D0015/Task Order 75FCMC19F0003). Abt Associates operates under the *Home Health and Hospice Quality Reporting Program Quality Measures and Assessment Instruments Development, Modification and Maintenance, & Quality Reporting Program Oversight Support* contract (75FCMC18D0014/Task Order 75FCMC19F0001).

This report provides a summary of the feedback shared by panelists during the November 19 and December 15, 2021 Technical Expert Panel (TEP) meetings, which focused on the development of PAC QRP cross-setting patient-level COVID-19 vaccination measures, along with the potential refinement of existing vaccination measures and items. The remainder of this section briefly introduces the PAC QRP project. Specifically, Section 1.1 introduces the context of the project in relation to goals of convening the panel, and Section 1.2 lists the panelists that served on the TEP. Section 2 outlines the structure, materials, and composition of the TEP. Section 3 summarizes the meetings that occurred prior to the TEP, including the orientation meeting on November 3, 2021, and the patient and family caregiver focus group held on November 10, 2021. Section 4 presents a summary of the presentation, panelist discussion, and key findings for each session from the November 19, 2021 TEP meeting. Section 5 similarly summarizes the sessions from the December 15, 2021 TEP meeting along with the discussions and key findings. Section 6 outlines the next steps for this project that take into account the feedback obtained from the TEP.

1.1 Project Context

The PAC QRP Support team supports CMS in the development of quality and cost measures for use in the IRF, LTCH, SNF, and HH QRPs and the Nursing Home Quality Initiative (NHQI). These measures are designed to improve care quality and to enable Medicare beneficiaries to make informed choices when selecting a healthcare provider. The suite of PAC QRP measures covers several domains relevant to care quality, including vaccination – a dimension of care that is especially relevant in the context of the COVID-19 public health emergency (PHE). As mentioned earlier, the PAC QRP Support team convened a TEP to ensure

that any newly developed vaccination measures meet CMS program requirements and goals while maintaining high standards of scientific acceptability. The PAC QRP Support team sought guidance from the TEP on the prioritization of measure goals for cross-setting patient-level COVID-19 vaccination measures, the development of data elements to support such measures, and the potential refinement of existing vaccination measures and items under the PAC QRPs.

1.2 TEP Panelists

The PAC QRP Vaccination TEP included 11 stakeholders from all PAC settings. The TEP panelists represent a broad range of perspectives across healthcare, from physicians, administrators, policy experts, to patients and families/caregivers. Table 1 below provides the name, organizational affiliation, setting(s) of expertise, and conflict of interest disclosures for each panelist. Additionally, while their names are not provided in this report, an additional four patient and family/caregiver advocates were also present to provide their perspective.

Table 1. TEP Composition

Name, Credentials, Professional Role	Organizational Affiliation, City, State	Setting(s) of Expertise	Conflict of Interest Disclosure
Amy Aronsky, D.O, MBA, FCCP, Physician, Medical Director	UnitedHealthcare Group, Iselin, NJ	IRF, LTCH, SNF/NH, HH, ACH	No
Susan M. Battaglia, GERO-BC, RAC-CT, Director of Case Mix Management & Clinical Services	Tara Cares, Orchard Park, NY	SNF/NH	No
Amy J. Stewart, MSN, RAC-MT, RAC-MTA, DNS-MT, QCP-MT, Vice President of Post-Acute Care Nursing	American Association of Post-Acute Care Nursing, Denver, CO	SNF/NH	No
Stephen L. Davidow, MBA-HCM, LSSBB, CPHQ, APR, Healthcare Quality and Process Improvement Advisor	Davidow Quality, LaGrange Park, IL	IRF, SNF/NH, HH, ACH	No
Ghinwa Dumyati, MD, Division Director and Vice President of Clinical Strategy and Innovation	AMDA-The Society for Post-Acute and Long-Term Care Medicine, Rochester, NY	SNF/NH	No
Mary Ellen DeBardeleben, MBA, MPH, CJCP, National Director, Quality	Encompass Health, Birmingham, AL	HH	Yes, employee of Encompass Health
Caitlin Gillooley, MS, Senior Associate Director, Policy	American Hospital Association, Washington D.C.	IRF, LTCH, SNF/NH, HH, ACH	No

Name, Credentials, Professional Role	Organizational Affiliation, City, State	Setting(s) of Expertise	Conflict of Interest Disclosure
Mary S. Henschel, B.A, Director Regulatory Affairs, Home Health	PointClickCare, Minneapolis, MN	SNF/NH, HH	No
Suzanne Kauserud, PT, MBA, FACHE, Vice President of Continuing Care Services	Trium Health, Charlotte, NC	IRF, SNF/NH, HH, ACH, Hospice Care	No
Bruce Pomeranz, MD, MMM, CPE, FCCP, Chief Medical Officer, National Chief Quality Officer for Rehabilitation	Kessler Institute for Rehabilitation, West Orange, NJ	IRF, LTCH	Yes, employee of Kessler Institute
Sarah Ragone, MSPT, RAC-CT, QCP, Vice President of Reimbursement & Education	Core Tactics Healthcare Consulting, Rexford, NY	SNF/NH, HH	No

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2 MEETING OVERVIEW

This section provides an overview of the structure and schedule of the TEP orientation, a focus group that occurred prior to the TEP, and the TEP meetings. Section 2.1 provides an overview of the overall TEP structure and the sessions that were held. Section 2.2 lists the meeting materials provided to the panelists.

2.1 Structure

As shown in Table 2 below, four separate meetings were held between November and December 2021. First, an hour-long TEP orientation held on November 3, 2021 offered a brief introduction to the current state of vaccination measurement in the PAC QRP and established an understanding of the project goals. Prior to the TEP, Acumen also convened a focus group led by Patient and Family Centered Care (PFCC) Partners on November 10, 2021 (see Section 3.2). PFCC Partners is an organization which utilizes a network of healthcare providers, administrators, patients and caregivers in order to convene focus groups to design policies and programs that improve patient health and the patient experience.[1] Then, two TEP meetings were held where the PAC QRP Support team sought specific feedback on the existing vaccination-related assessment items across the PAC settings, the existing PAC QRP vaccination measures, developing a patient-level COVID-19 vaccination coverage measure or measures, and developing the requisite assessment item(s) that would be used for measure collection. The first 4-hour TEP meeting on November 19, 2021 included four topic-driven sessions, and the second 3-hour TEP meeting on December 15, 2021 included two sessions. Table 2 below provides the agenda for each session.

Table 2. TEP Orientation and Meeting Agenda

Session	Topic	Section
Orientation (November 3, 2021)		
1-A	Welcome and Introductions	-
1-B	Overview of Vaccination Measurement in Post-Acute Care	3.1
1-C	Next Steps and Closing Remarks	-
PFCC Partners Focus Group (November 10, 2021)		
2-A	Focus Group with Patient and Family Centered Care Partners	3.2
TEP Meeting 1 (November 19, 2021)		
3-A	Justification for a PAC Patient-level COVID-19 Vaccination Measure	4.1
3-B	Overview of Existing Vaccination Measures and Considerations for a PAC Patient-level COVID-19 Vaccination Measure	4.2
3-C	Overview of Existing Vaccination Assessment Items	4.3
3-D	Potential PAC Patient-level COVID-19 Vaccination Measure Specifications	4.4

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[1] More information on PFCC Partners and their work can be found at https://pfccpartners.com.

Session	Topic	Section
TEP Meeting 2 (December 15, 2021)		
4-A	Follow-up Analysis on COVID-19 Vaccination Rates	5.1
4-B	Draft Patient-level COVID-19 Vaccination Measure Assessment Items and Specifications	5.2

The PAC QRP Support team presented targeted questions to facilitate the discussion and solicit feedback to inform next steps in the development of patient-level COVID-19 vaccination measures for the PAC QRPs. Bulleted highlights of those discussions are presented in the Key Discussion Takeaways subsection of each section in this report.

2.2 Meeting Materials

Prior to the TEP, the *Technical Expert Panel: Charter,* outlining the purpose of the TEP and level of commitment expected, was distributed to the panelists for review. The PAC QRP Support team also provided panelists with a meeting agenda, background materials on assessment items and existing vaccination measures. The background materials included quality measure informational pages and specifications (see Appendix C).

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3 SUMMARY OF PRE-TEP MEETINGS

This section summarizes the two meetings held before the first TEP meeting. The information below is organized into two sections. First, Section 3.1 summarizes session 1-B, an orientation meeting held on November 3, 2021, in which the PAC QRP Support team introduced the panel to the purpose and goals of the TEP meetings, the TEP logistics, and TEP charter. Second, Section 3.2 reviews the focus group convened with Patient and Family Centered Care Partners on November 10, 2021, which was used to inform subsequent TEP discussions on patient and family perspectives.

3.1 Session 1-B: Overview of Vaccination Measurement in Post-Acute Care

The orientation meeting on November 3, 2021 opened with the TEP formally approving the TEP charter (see Appendix B). The PAC QRP Support team then presented information on current vaccination measures and assessment items used in the PAC settings or in the PAC QRPs. First, the PAC QRP Support team presented Table 3 and Table 4 below, listing the key publicly-reported vaccination measures currently utilized across PAC programs, as well as other vaccination measures.

Table 3. Current Publicly-Reported Vaccination Measures

#	Measure Name and Description	Data Source	Program Inclusion					
			LTCH QRP	IRF QRP	SNF QRP	HH QRP	NHQI	HHQI
1	COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)	NHSN	Yes	Yes	Yes	No	No	No
2	Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)	NHSN	Yes	Yes	No	No	No	No
3	Percent of Residents or Patients Assessed and Appropriately Given the Pneumococcal Vaccine (SS and LS measures) (NQF #0682 (SS) and #0683 (LS))	MDS Assessments	No	No	No	No	Yes	No
4	Percent of Residents or Patients Assessed and Appropriately Given the Seasonal Influenza Vaccine (SS and LS measures) (NQF #0680 (SS) and #0681 (LS))	MDS Assessments	No	No	No	No	Yes	No
5	Influenza Immunization Received for Current Flu Seasons (NQF #0522)	OASIS Assessments	No	No	No	Yes	No	No

Table 4. Other Vaccination Measures

#	Measure Name and Description	Data Source	Program Inclusion					
			LTCH QRP	IRF QRP	SNF QRP	HH QRP	NHQI	HHQI
6	Pneumococcal Polysaccharide Vaccine Ever Received	OASIS Assessments	No	No	No	No	No	Yes
7	Nursing Home Resident COVID-19 Vaccination Rates	NHSN	No	No	No	No	No	No

Next, panelists were presented with the current vaccination-related assessment items used to calculate the assessment-based measures listed above. These items include items O0250 – Influenza Vaccine (sub-items A-C) and O0300 – Pneumococcal Vaccine (sub-items A-B) from the Minimum Data Set (MDS) assessments, along with the following Home Health Outcome and Assessment Information Set-Version D (OASIS-D) Items (transfer or discharge): M1041 – Influenza Vaccine Data Collection period, M1046 – Influenza Vaccine Received, M1051 – Pneumococcal Vaccine, and M1056 – Reason Pneumococcal Vaccine Not Received.

3.2 Session 2-A: Focus Group with Patient and Family Centered Care Partners

During this hour-long session on November 10, 2021, the PAC QRP Support team met with a focus group of patient and family/caregiver advocates (PFAs) assembled by Patient and Family Centered Care (PFCC) Partners.[2] This session was held in order to inform the TEP discussion with 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 focus group included PFAs from different regions of the country who have had experience as PAC patients, family of patients, caregivers, and healthcare volunteers.

Section 3.2.1 lists the key findings of the discussion, and Section 3.2.2 provides more detail about the discussion.

3.2.1 Key Discussion Takeaways from Focus Group Members

- Overall, members indicated that they would appreciate having as much information as possible about current vaccination rates and provider efforts to improve them. Among the various possible data points, they concluded that the raw rate of vaccination coverage among patients, regardless of any reasons for a

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[2] PFCC staff who organized and led the focus group include Libby Hoy (founder/CEO) and Laura Jackson (community director).

patient not being vaccinated, would be the most pertinent to their decision-making and would therefore be the most valuable.

- Members felt that it would be useful to know if a provider engaged in vaccine education, and that they would view the quality of care at a facility/agency more favorably when such engagement occurs, regardless of the result.

- Members expressed that a measure indicating vaccination rates should not exclude patients that were offered and refused the vaccine, or patients for whom a vaccine could not be offered, since these patients would still be unvaccinated. However, an additional measure indicating whether a provider appropriately offered vaccines may be valuable.

3.2.2 Focus Group Discussion Details

The PAC QRP Support team asked a series of questions to the focus group, with a short discussion after each. The first question was structured as a poll:

Poll: If you or a loved one were going to receive post-acute care, would you want to know how many patients/residents:

- a) *Are fully vaccinated against COVID-19?*
- b) *Are partially vaccinated?*
- c) *Have received boosters?*
- d) *Were offered a vaccination but refused?*
- e) *All of the above*
- f) *None of the above.*

Members of the focus group widely indicated that they would prefer to know all of the above information. Specifically, they felt that the raw percentage of those fully vaccinated against COVID-19 would be the most immediately relevant to their decision of which facility/agency to choose for themselves or their families, as that most directly impacts the risk they incur when being admitted to that facility/agency. However, one panelist noted that this information may not be reliable if the data used to calculate a measure is not current, since the facility/agency patient population and their vaccine coverage at the time of a patient's admission may have changed since the end of the measure period. Members indicated that options b) (partial vaccination) and c) (booster receipt) would be helpful on top of option a) (full vaccination), since both options reflect efforts to ensure that patients' vaccination coverage is up to date and as current as possible. Additionally, they felt that option d) (offered but refused), while not indicating higher vaccination coverage, could show that a provider was making an active effort to increase vaccination rates among patients under their care.

The second question was the following:

Question: Would it matter to you whether the facility/agency provided education about the benefits of the COVID-19 vaccine to patients/residents who are not vaccinated? And if so, does this information influence how you view the quality of care provided by the facility/agency?

Members felt that facility/agency efforts to educate patients/residents on the benefits of vaccination against COVID-19 were indicative of that facility/agency prioritizing the patient experience and ensuring that patients and caregivers can make informed decisions, in lieu of simply prioritizing compliance with vaccination guidance without their patients understanding why. All members agreed that they would view a facility/agency more favorably if they were aware of facility/agency efforts to educate their patients, even if these efforts are ultimately unsuccessful. Some members noted that the method through which education is provided can have a significant impact on a patient's decision, and that a measure assessing vaccine education provided should reward providers who dedicate more time to this task. Similarly, a few members voiced concerns about what would qualify as an 'attempt' at educating a patient, citing concerns that not all facility/agency efforts may be fully understood and appreciated by the patient.

The third question was the following, and was presented along with the following example:

Question: Considering what you know about COVID-19 and the vaccines available, if you were to look at a facility/agency grading website, what information would you look for and/or make you feel confident in deciding which facility/agency to use?

Example: In Facility A, 80% of patients/residents are fully vaccinated and 20% are not fully vaccinated. The facility offered the vaccine to all the patients/residents who were not vaccinated, but all patients/residents declined the vaccination. In Facility B, 95% of patients/residents are fully vaccinated, and the facility did not offer vaccines to any of the patients/residents who were unvaccinated. If the measure only assessed the rate of vaccination, Facility A would have a score of 80% and Facility B would have a score of 95%. If the measure also provided "credit" to facilities who offered vaccinations, but the patient/resident refused, then Facility A would have a score of 100% and Facility B would have a score of 95%.

Members felt that the best approach to this dilemma would be to have two separate measures: one reflecting the first scenario in the example, and another reflecting the second scenario. Focus group members felt that the first scenario (in which the measure only assessed the rate of vaccination) would most closely reflect the potential risk of COVID-19 infection associated with being admitted to that facility. They agreed that for this scenario, a measure indicating the raw rate of vaccination among a facility's patients, with no denominator

exclusions based on reasons for vaccine refusal, would be helpful. However, they also indicated that provider efforts to provide vaccines and vaccine education to patients who have not yet received a complete primary course should be rewarded. Members approved of a hypothetical second measure concept to satisfy this objective, which would capture the rate at which patients were appropriately assessed to be vaccinated or were appropriately offered a vaccine, so long as the first measure concept would still be used as well. However, members felt that if asked to choose between the two measures, they would prefer the first, as they would be less concerned about the efforts made by facilities to encourage vaccination and more concerned about the rate of vaccination. Additionally, they felt that while providers may not offer vaccines due to an inability to store them, providers not having this ability may be indicative of broader structural concerns with the facility, particularly at this stage of the PHE.[3]

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[3] In addition to the feedback above, members expressed approval of the adoption of the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure in the SNF, LTCH and IRF settings, as they felt that higher performance on such a measure is indicative of higher overall provider quality. One member also proposed that such a measure should also account for whether third party contractors working within the facility/agency have been vaccinated as well, since their presence can also increase the risk of infection by COVID-19.

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4   SUMMARY OF TEP MEETING 1 PRESENTATION AND DISCUSSION

This section summarizes the first TEP meeting, which was held on November 19, 2021. The information presented is organized into four sections in this report, aligning with the session structure of the meeting itself. Each subsection summarizes the material presented to the TEP, the key findings extracted from TEP discussions, and details on the discussion among TEP panelists.[4] First, Section 4.1 summarizes the justification and need for a patient-level COVID-19 vaccination measure. Second, Section 4.2 reviews existing vaccination coverage measures for the PAC settings, and resulting considerations for developing patient-level COVID-19 vaccination measures for the PAC QRPs. Third, Section 4.3 reviews existing items for the PAC settings, and resulting considerations for developing a patient-level COVID-19 vaccination assessment item. Lastly, Section 4.4 presents proposed specifications for patient-level COVID-19 vaccination measures and the accompanying assessment items.

4.1   Session 3-A: Justification for a PAC Patient-level COVID-19 Vaccination Measure

This section summarizes session 3-A, which presented justification for the creation of patient-level COVID-19 vaccination measures and its inclusion in the PAC QRPs. Section 4.1.1 summarizes the content presented to the panel during this session in order to facilitate the discussion. Section 4.1.2 lists the key takeaways from the panelist discussion. Section 4.1.3 covers the discussion itself in greater detail, including the questions presented to the panelists and all responses received.

4.1.1 Summary of Presentation

At the beginning of the session, the PAC QRP Support team indicated that in general, vaccination measures are intended to meet at least one of two goals. The first is to provide consumers with information about the rate of patients who are vaccinated in each care setting, and the second is to incentivize providers to inquire about patients' vaccination status, so that providers can either provide vaccinations or educate patients about vaccine effectiveness.

Studies have shown the efficacy of Food and Drug Administration (FDA)-approved COVID-19 vaccines in reducing the risk of severe outcomes caused by COVID-19. COVID-19 vaccination measures can play a key role in promoting appropriate vaccine education and administration, as well as conveying information on vaccination rates. Studies show that prior to the emergence of the delta variant of the virus, vaccine effectiveness against COVID-19-associated hospitalizations among adults 65 years of age and older was 91% for those receiving a full mRNA vaccination (Pfizer-BioNTech or Moderna), and 84% for those having received a

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[4] As PFAs were also in attendance, the word "panelists" will be used to refer to those members indicated in both Table 1 and Table 5.

viral vector vaccination (Janssen).[5] Further, after the emergence of the delta variant, vaccine effectiveness against COVID-19-associated hospitalizations for adults who received full dosage of the Pfizer, Moderna, or Janssen vaccine was 76% among adults 75 years and older, and 89% among adults between the ages of 18 and 24.[6] Acumen's analysis of CDC's National Healthcare Safety Network (NHSN) COVID-19 data reported by nursing homes through September 12, 2021 also shows lower positive COVID-19 Antigen and PCR test rates among vaccinated residents compared to non-vaccinated residents. Figure 1 and Figure 2 show positive test rates for Antigen and Polymerase Chain Reaction (PCR) tests, respectively, by vaccination type. While there is some variation in positive test rates between populations that received different vaccines, both figures show that positive test rates are higher for those who did not receive any vaccines. Together, these figures demonstrate the dramatic effect COVID-19 vaccinations had on infections in nursing homes.

Figure 1. NH Positive COVID-19 Antigen Test Rates, by Vaccination Type

Residents not vaccinated w/ a positive COVID-19 antigen test

— — Residents who received Pfizer vaccine (Dose 1 & 2) before positive COVID-19 antigen test

·········· Residents who received Moderna vaccine (Dose 1 & 2) before positive COVID-19 antigen test

- - - - - Residents who received complete unspecified COVID-19 vaccine before positive COVID-19 antigen test

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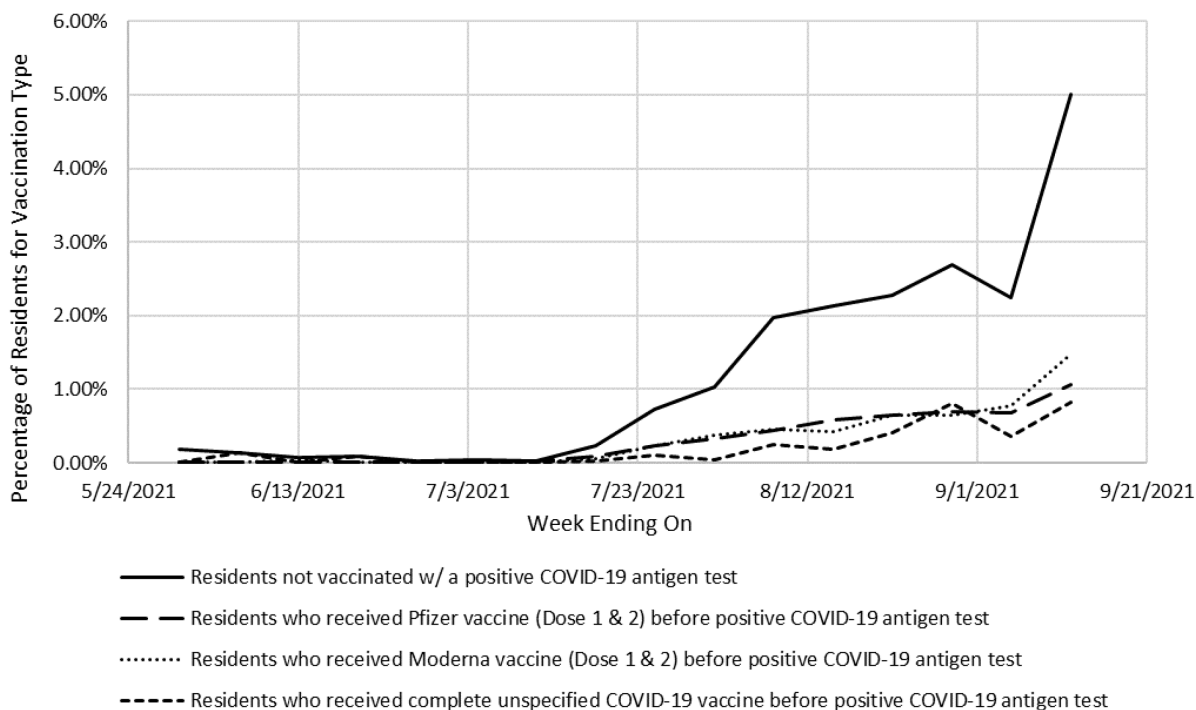
[5] Vaccine efficacy rates for mRNA and viral vector vaccination are based on data for 7,280 patients from the COVID-19–Associated Hospitalization Surveillance Network (COVID-NET) between February 1 and April 20, 2021 (Moline et al. 2021, 1090).

[6] Vaccine effectiveness after the emergence of the delta variant is based on data from the CDC's VISION Network, which examined medical encounters (32,867) from 187 hospitals and 221 emergency departments (EDs) and urgent care (UC) clinics across nine states during June–August 2021, beginning on the date the Delta variant accounted for over 50% of sequenced isolates in each medical facility's state (Grannis et al. 2021, 1291).

Figure 2. NH Positive COVID-19 PCR Test Rates, by Vaccination Type

Legend:
—— Residents not vaccinated w/ a positive COVID-19 PCR test
– – Residents who received Pfizer vaccine (Dose 1 & 2) before positive COVID-19 PCR test
······ Residents who received Moderna vaccine (Dose 1 & 2) before positive COVID-19 PCR test
- - - - Residents who received complete unspecified COVID-19 vaccine before positive COVID-19 PCR test
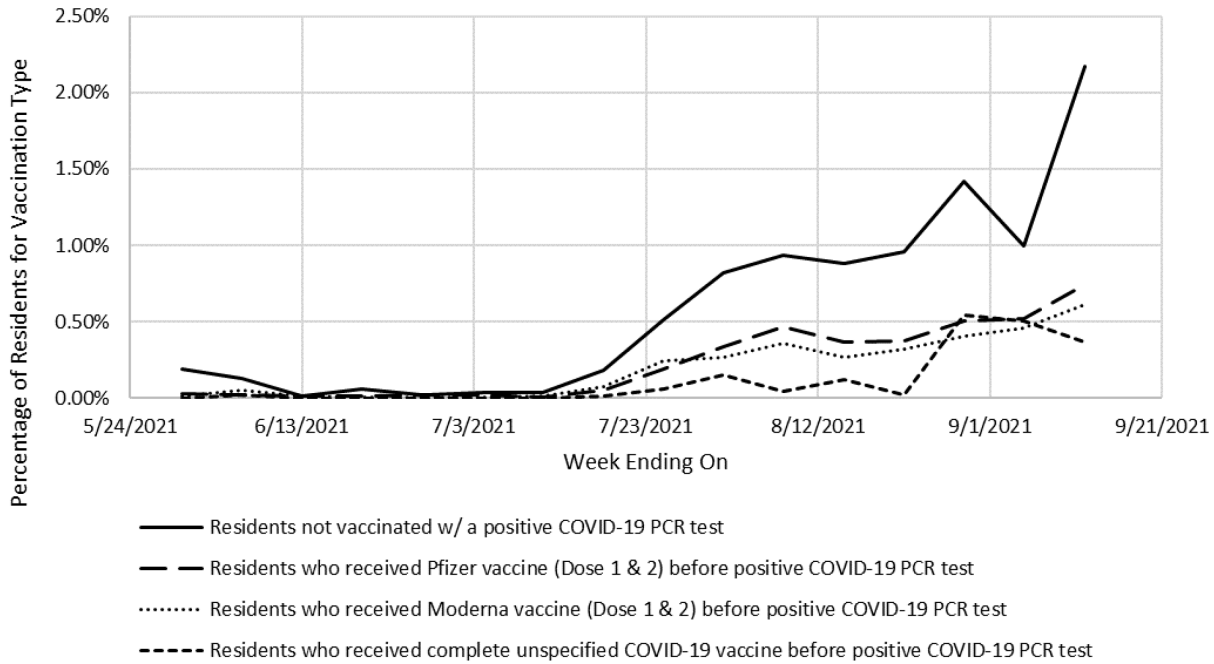
Additionally, in order to demonstrate that facilities vary in patients/residents' vaccination rates, Acumen conducted an analysis using NHSN COVID-19 Nursing Home Data as of September 2021, and identified a performance gap in COVID-19 vaccination rates between nursing homes. As shown in Table 5 below, the rate of complete vaccination among residents against COVID-19 ranged from 0% to 100% between nursing homes, showing a stark variation. These differences suggest that the push to vaccinate all nursing home residents may not be uniform across all providers, and that patients may see significant differences in vaccination rates among nursing homes that they may be considering for their care.

Table 5. Nursing Home Vaccination Rate Distribution, by Vaccination Status

Metric	Facility Level Vaccination Rates						
	Mean	Min	25th	50th	75th	90th	Max
Residents who received a complete COVID-19 vaccination	82.3%	0.0%	75.8%	84.5%	92.0%	96.5%	100.0%
Residents who received partial COVID-19 vaccination	2.5%	0.0%	0.3%	1.6%	3.4%	5.8%	77.0%
Residents with a medical contraindication to COVID-19 vaccination	0.5%	0.0%	0.0%	0.0%	0.1%	1.4%	83.8%
Residents who were offered but declined COVID-19 vaccination	8.6%	0.0%	2.7%	6.6%	12.2%	19.1%	100.0%

Further analyses on the same NHSN data as of September 2021 show that COVID-19 vaccination efforts vary by region, with states such as California (96.2%), Alaska (96.6%), and West Virginia (95.9%) experiencing higher rates of vaccination among their nursing home

residents, and the lowest rates being observed in Nevada (85.9%), Arizona (84.8%), and Florida (86.6%) (Figure 3). The TEP requested an additional analysis to determine the variation in vaccination rates within these states, which was presented during the second TEP meeting (see Section 5).

Figure 3. Nursing Home COVID-19 Vaccination Effort Variation by Region[7]
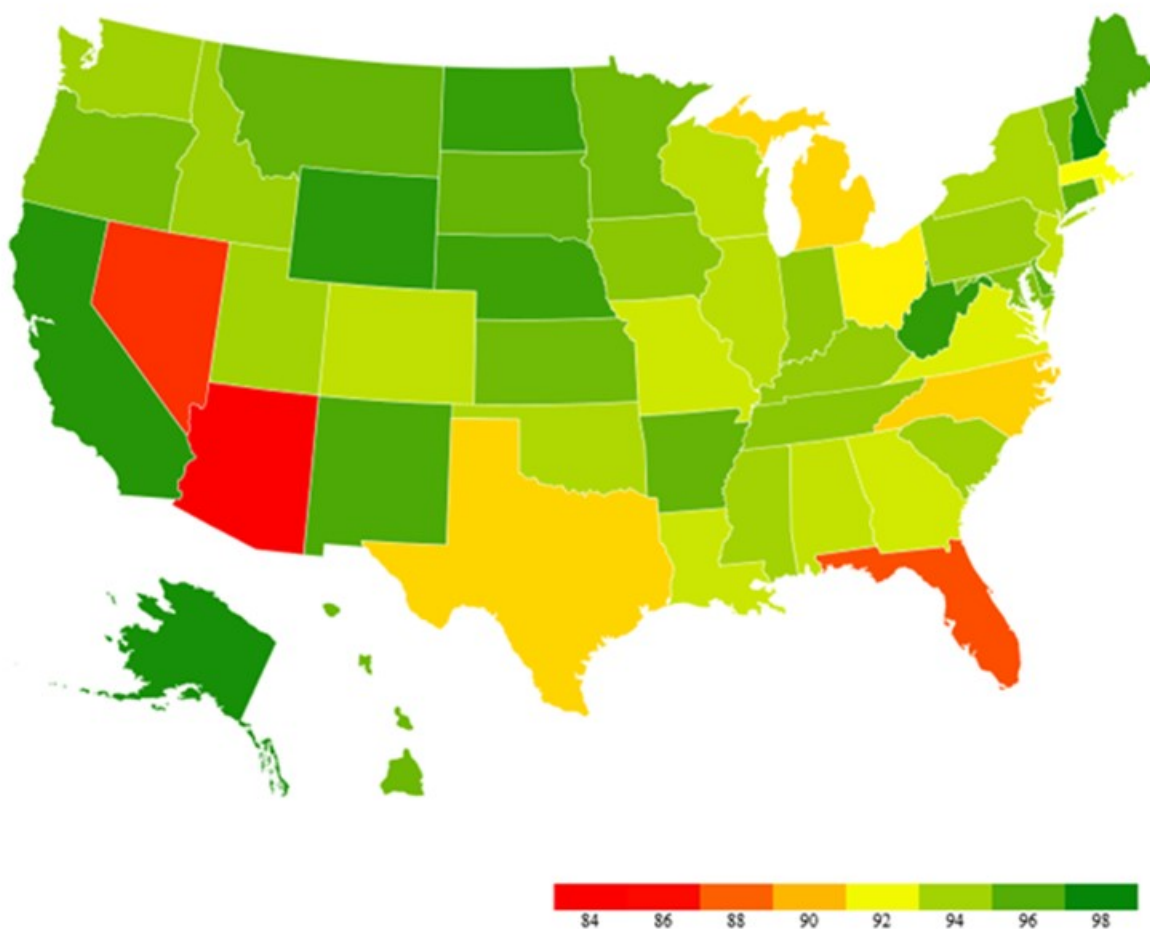
According to analyses on the same NHSN data, COVID-19 vaccination rates also vary by facility type and star rating, as shown in Figure 4 and Figure 5 below. Non-profit and government owned facilities on average have higher vaccination rates than for-profit facilities. Additionally, nursing home residents living in facilities with higher Medicare Five-Star ratings

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[7] This figure was generated using Acumen's analysis of NHSN data through 9/12/2021. Note that nursing home regional trends can be different from overall population regional trends. Based on the New York Times vaccination tracker (https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html), which uses the CDC COVID data tracker and reports from state health departments, as of 10/22/2021, COVID-19 vaccination rates are highest in the Northeast and West, and are lowest in the South and Midwest. Here, the state with the highest rate of fully vaccinated residents is Vermont (70.7%), and the state with the lowest is West Virginia (40.9%).

are more likely to receive full dosage of the COVID-19 vaccine than residents living in facilities with lower star ratings.

Figure 4. Complete COVID-19 Vaccination Rate, by Facility Type
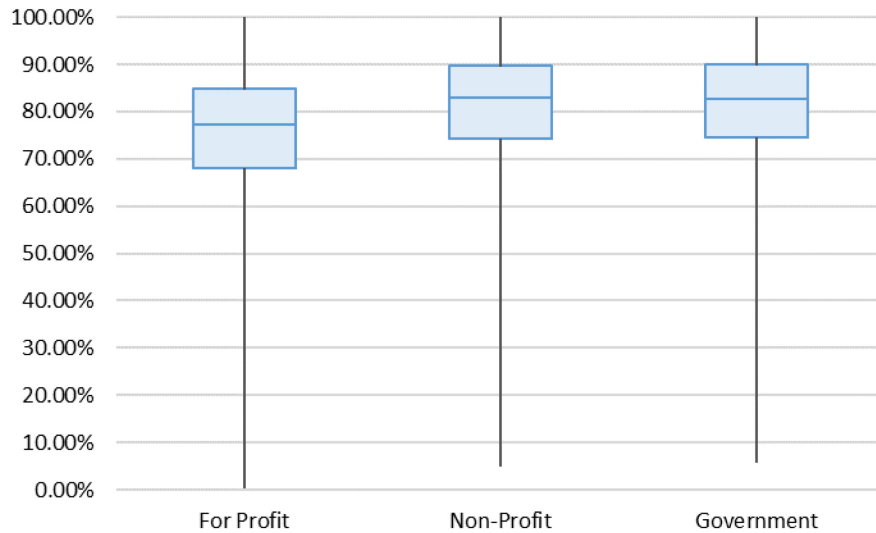
Figure 5. Complete COVID-19 Vaccination Rate, by Star Rating
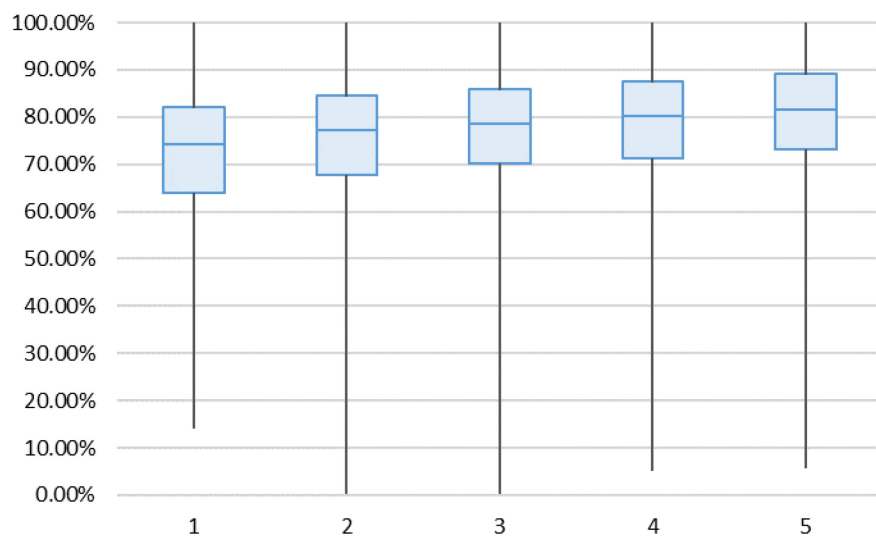
Lastly, according to literature gathered by the PAC QRP Support team prior to the TEP, the percent of adults who received at least one COVID-19 vaccine dose vary notably by patient characteristics, including race (Asian: 69%, White: 54%, Latino: 51%, and Black: 46%) and age (18-29 years of age: 38.3%, and 65 years of age and older: 80.0%). Figures on race are based on the Kaiser Family Foundation's (KFF) assessment of state-level data of vaccination trends among adults aged 18 years or older as of October 10, 2021. According to KFF, recent trends suggest that these disparities have been decreasing. The gap in vaccination rates between Black

and White people fell from 14 percentage points to 8 percentage points between April and October 2021, while the gap in vaccination rates between White and Hispanic people decreased from 13 percentage points to 3 percentage points. Figures on age are based on an analysis of NHSN data that assessed patterns of COVID-19 vaccination coverage among U.S. adults aged 18 years or older between December 2020 and May 2021 (Diesel et al. 2021). Additionally, there are significant disparities by sex (women under age 75 are more likely to receive at least one COVID-19 vaccine dose than men in the same age group) and medical complexity (with high-risk conditions for severe COVID-19 infection – 63.8%, and without these high-risk conditions – 41.5%). Figures on sex and high-risk conditions are based on an analysis of the CDC's Vaccine Safety Datalink that assessed disparities in vaccination coverage among persons aged 16 years or older by race and ethnicity from December 2020 to May 2021 (Pingali et al. 2021). These results were calculated from populations that were not exclusively Medicare beneficiaries, and so the TEP requested that the PAC QRP Support team conduct additional analyses to determine these figures based on NHSN and MDS data. These findings were presented in the second TEP meeting (see Section 5).

4.1.2 Key Discussion Takeaways

- The TEP voiced that more information on patient vaccination status and date would be useful to providers and should be collected, rather than less information.

- Panelists indicated that the presence of large disparities in vaccination rates makes it meaningful to develop measures on patient-level COVID-19 vaccination.

- The TEP expressed a concern that providers can only do so much to convince hesitant patients to receive COVID-19 vaccinations.

4.1.3 Panelist Discussion Details

The PAC QRP Support team posed the following questions to the panel:

1. *Does the variation in nursing homes' COVID-19 vaccination rate indicate meaningful performance gaps in vaccination?*

2. *Are there vaccination performance gaps observed in other PAC settings? Are the gaps likely to be larger or smaller among patients/residents in different PAC settings?*

3. *Is the variation in vaccination rates across nursing home types and patient characteristics consistent with your expectations? Why or why not?*

4. *Do vaccination rates vary by facility/agency and patient/resident characteristics in your settings?*

5. *How could staff use information on vaccination rates to improve quality of care?*

6. *Is it useful to have information for sub-group stratifications that are not currently widely available? What are examples of such sub-group information?*

Overall, TEP members agreed that it would be beneficial for providers to capture any information available about a patient's specific vaccination status, vaccination date, or reason for refusal, and that it may be worth the additional burden required to collect this information. Panelists did not specifically discuss variation rates for the other PAC settings, but broadly agreed that the vaccination gaps described in Section 4.1.1 within nursing homes were also likely present within other PAC settings. Panelists felt that variation in vaccination rates within states would be helpful to understand, particularly in states that tend to have the worst vaccination rates. Panelists agreed about the importance of capturing disparities in vaccination rates across demographic groups as well.

Some panelists expressed concerns that providers can only do so much to convince hesitant patients to receive a vaccine. Panelists linked differences in vaccination rates to a variety of factors, including organizational commitment, local vaccine hesitancy and family influence, and local vaccine supply. Panelists also noted that in many cases, patients arriving in post-acute care settings have already been offered a vaccine dose in an earlier care setting and may not be inclined to change their mind if they have already refused an earlier offer.

4.2 Session 3-B: Overview of Existing Vaccination Measures and Considerations for a PAC Patient-level COVID-19 Vaccination Measure

This section summarizes session 3-B, which provided a summary of existing vaccination measures and presented to the panel considerations for potential PAC patient-level vaccination measures for COVID-19. Section 4.2.1 summarizes the content presented to the panel during this session in order to facilitate the discussion, Section 4.2.2 lists the key takeaways from this discussion, and Section 4.2.3 covers the discussion itself in greater detail.

4.2.1 Summary of Presentation

The PAC QRP Support team began this session by presenting to the panelists a list of currently existing vaccination measures used in the PAC settings. This information is summarized by Table 6 below.

Table 6. Current PAC QRP Vaccination Measures

Measure #	Measure Name	Program(s)	Target Condition	Target Population	Data Source
1	COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)	LTCH QRP, IRF QRP, SNF QRP	COVID-19	HCP	NHSN
2	Nursing Home Resident COVID-19 Vaccination Rates	N/A	COVID-19	Nursing Home Residents	NHSN
3	Influenza Vaccination among Healthcare Personnel (NQF ID: 0431)	LTCH QRP, IRF QRP*	Influenza	HCP	NHSN
4	Percent of Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (SS and LS measures) (NQF ID: 0680 (SS), 0681 (LS))	NHQI	Influenza	Nursing Home Residents	MDS Assessments
5	Influenza Immunization Received for Current Flu Seasons (NQF ID: 0522)	HH QRP	Influenza	Home Health Patients	OASIS Assessments
6	Percent of Residents or Patients Assessed and Appropriately Given the Pneumococcal Vaccine (SS and LS measures) (NQF ID: 0682 (SS), 0683 (LS))	NHQI	Pneumococcal disease	Nursing Home Residents	MDS Assessments
7	Pneumococcal Polysaccharide Vaccine Ever Received (NQF ID: 0525)	HHQI**	Pneumococcal disease	Home Health Patients	OASIS Assessments

*Subsequent to the TEP meetings, the Influenza Vaccination among Healthcare Personnel measure was added to the FY 2024 SNF QRP (87 FR 42489).

**This measure has been removed from the HHQI effective January 2021. Collection of the items used to calculate this measure will end on 1/1/2023.

After reviewing the above table, the PAC QRP Support team proposed to the panel that in general, the existing vaccination measures are established in order to satisfy one of the three following goals (followed by the measures which are intended to meet that goal and their respective measure number reflected in Table 6):

- *Goal A. Report the rate of vaccination among a specific population without denominator exclusions.*

    - Influenza Vaccination among Healthcare Personnel (LTCH QRP, IRF QRP) (#3)

- *Goal B. Report the rate of vaccination among a specific population, excluding persons with medical contraindications.*

    - COVID-19 Vaccination Coverage among Healthcare Personnel (LTCH QRP, IRF QRP, SNF QRP) (#1)

    - Influenza Immunization Received for Current Flu Seasons (HH QRP) (#5)

    - Pneumococcal Polysaccharide Vaccine Ever Received (HHQI) (#7)

- *Goal C. Assess actions providers take to improve vaccination rates.*

    - Percent of Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NHQI) (#4)

    - Percent of Residents or Patients Assessed and Appropriately Given the Pneumococcal Vaccine (NHQI) (#6)

The PAC QRP team then discussed how each measure's denominator and numerator specifications align with the measure's goal, as presented above. First, the PAC QRP Support team found that measures vary in whether or not persons with medical contraindications are excluded from the measure denominator. Specifically, measures 3, 4, and 6 from Table 6 include individuals with medical contraindications in the measure denominator, while measures 1, 5, and 7 do not. Second, measures also vary in whether the numerator includes persons who declined the vaccine or had medical contraindications. In particular, measures 4 and 6 include these individuals, while the others (measures 1, 3, 5, and 7) do not. These specifications align with whether the measure aims to convey a true rate of vaccination (measure 3), the rate of vaccination among those who are eligible (measures 1, 5, 7), or the act of appropriately assessing and administering vaccines (measures 4, 6).

Further, the PAC QRP Support team found that the definition of "complete vaccination course" is not uniform across the measures, and varies depending on the nature of the vaccine. The influenza vaccine measures define this concept as one shot per year during each year's

influenza vaccination season (October 1 through March 31 of the following year). The pneumococcal vaccine measures refer to a complicated dosing schedule dependent upon a person's age, immune system status, medical conditions, and receipt of a previous pneumonia vaccine. Meanwhile, the existing COVID-19 vaccination measures use different definitions depending on the type of vaccine received (which require different numbers of doses). Measures also differ in methods of accounting for vaccine availability, with the NHSN-collected Nursing Home Resident COVID-19 Vaccination Rates (#2) taking into account whether there were issues with vaccine availability or supply.

Lastly, PFCC partners walked through their findings from the focus group held on November 10, 2021 (see Section 3.2). The focus group participants, a collection of PFAs with extensive consumer experience with both various post-acute care settings and Medicare, expressed a desire for detailed information about vaccination rates and status because it would provide valuable information in their decision-making process for care selection. While they had felt that more data would be helpful in their decision-making processes, participants had expressed a preference for a measure that captures the rate of COVID-19 vaccination. PFCC conveyed that participants had also expressed that they would like information describing the efforts providers took to educate to unvaccinated patients on vaccine efficacy, noting that this would be an indicator of care quality.

4.2.2 Key Discussion Takeaways

- Panelists agreed with the presence of clear distinctions among measure goals.

- Panelists felt that Goal A is not a clear representation of provider quality, as there are a number of reasons that it may be inappropriate or infeasible for a provider to vaccinate some of their patients.

- Panelists felt that Goal C is the best representation of provider quality, as it directly highlights provider effort in leveraging resources they have control over.

- Panelists proposed that Goal A and C could be met in tandem to highlight quality and meet PFA panel member requests.

- The definition of a "completed course" should be flexible in order to allow for the COVID-19 vaccination items and measures to remain valid as CDC guidance evolves.

4.2.3 Panelist Discussion Details

The PAC QRP team presented the following questions to the TEP panelists:

1. *What types of challenges have providers experienced with the existing vaccination measures?*

2. *Do providers see a clear distinction between Goals A, B, and C for vaccination measures?*

3. *What are challenges, if any, with how the influenza and pneumococcal vaccination measures define a "complete vaccination course"?*

4. *Has vaccine availability/supply been a concern for any vaccinations other than COVID-19?*

Panelists indicated that there are a variety of reasons why a provider may not be able to vaccinate a patient, or may choose not to. The first is that patients who arrive at a PAC facility/agency have likely already been offered the vaccine at earlier stages of their care and declined, meaning that provider efforts to convince these patients to get vaccinated would already be futile. Another is that some providers may not have access to vaccines during the patient's stay or may not have the ability to store vaccines, making it unreasonable to expect them to provide the vaccine. Finally, panelists pointed out that in some cases, providers may be reluctant to administer a vaccine since it might adversely affect the care that the patient is there to receive. For example, an IRF patient experiencing strong symptoms post-COVID-19 vaccination might be unable to participate in the critical rehabilitation program for which they were admitted. Panelists concluded that a measure meeting Goal A would not be able to account for these factors outside of the provider's control, nor would it be indicative of facility/agency efforts to vaccinate their patients. However, a measure meeting Goal C would successfully account for these factors.

PFAs in attendance shared that they felt a measure capturing raw vaccination rate, irrespective of provider action, would be most helpful to them when deciding a facility/agency for either their own care or for a loved one. Panelists agreed that Goal A is important to meet when designing a measure, even if it is not a reflection of quality. Panelists ultimately agreed that it would be ideal to have two measures – one measure reflecting raw vaccination rates and one reflecting actions taken by the provider.

Panelists also indicated the definition of a "completed course" needed to be updated for the Pneumococcal vaccine measures due to updated guidance. Panelists suggested that in order to avoid similar situations arising with the COVID-19 vaccine measures, a "completed course" should be defined with as much flexibility as possible, and in a way that can be applicable and satisfactory even as CDC guidance continues to evolve, particularly regarding the administration of boosters.

4.3   Session 3-C: Overview of Existing Vaccination Assessment Items

This section summarizes session 3-C, which provided a summary of existing vaccination assessment items which support the measures discussed in session 3-B and discussed their key

differences. Section 4.3.1 summarizes the content presented to the panel during this session in order to facilitate the discussion, Section 4.3.2 lists the key takeaways from this discussion, and Section 4.3.3 covers the discussion itself in greater detail.

4.3.1 Summary of Presentation

The PAC QRP Support team began by presenting a list of advantages and disadvantages of using assessment data for the construction of patient-level COVID-19 vaccination measures. First, one advantage is that assessments, which are captured at the patient-level, allow for flexibility in monitoring social risk factors and stratified reporting. Second, assessment items have high data element reliability. For example, reliability for the influenza MDS item is high, where the Kappa for the gold-standard nurse to facility nurse is 0.94. Third, assessment items can be collected consistently across PAC settings. However, a disadvantage is that vaccination data is self-reported, so some performance or payment incentives can lead to provider over-reporting or underreporting.

In order to better understand this potential limitation around self-reporting of vaccination status, Acumen conducted an investigation comparing influenza vaccination data from the MDS with claims data. The analysis was conducted using MDS assessment data and professional and outpatient claims from the 2018-2019 flu season. The study population was restricted to beneficiaries continuously enrolled in Medicare Parts A and B, and not C, from July 2018 through June 2019. Vaccination incidences reported on the MDS were defined as item O0250A in [1, 2] on the latest OBRA, PPS or Discharge assessments in the flu season. Vaccination incidences on claims was defined as a professional or outpatient claim reporting flu vaccination administration any day from July 1st, 2018 to the target date of the target assessment. Figure 6 is a visual depiction of how different vaccination incidences where captured on the MDS compared to claims, and how a noticeable segment of vaccination is reported on MDS but is not found on claims. These findings are also reflected in Table 7, where MDS assessments are shown to capture a higher portion of vaccination events occurring within nursing homes.

Figure 6. Existing MDS Influenza Vaccination Data
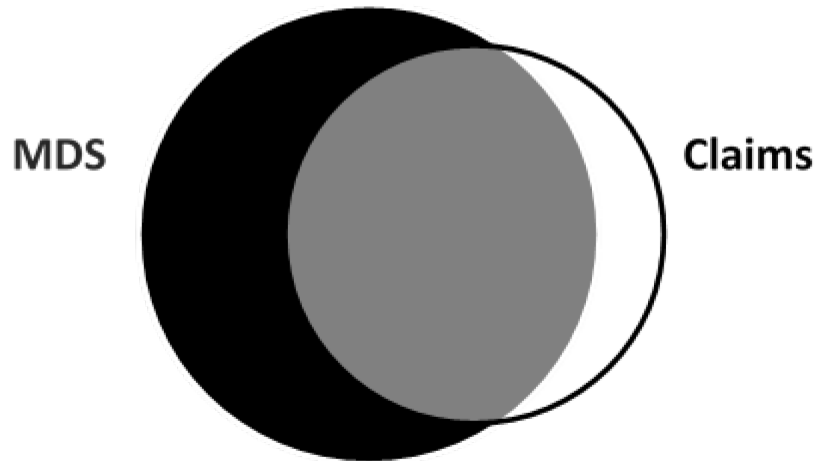
Table 7. Existing MDS Influenza Vaccination Data Capture Distribution

Influenza Vaccination Data Source	% NH Residents	Facility Level Vaccination Rates						
		Mean	Standard Deviation	Min	P25	P50	P75	Max
MDS or Claims	79.1%	79.5%	12.2%	0.0%	73.3%	81.3%	87.8%	100.0%
Claims	50.1%	48.5%	24.2%	0.0%	27.3%	53.3%	67.8%	100.0%
MDS	71.5%	72.6%	17.0%	0.0%	64.2%	75.9%	84.6%	100.0%

The investigation also looked at when the vaccination occurred, and the PAC QRP Support team found that the distribution of influenza vaccination is very similar on both claims and the MDS.[8] For in-facility influenza vaccinations reported on MDS and claims, 76% of influenza vaccinations occurred in October and over 95% of vaccinations occurred between September and November. Figure 7 shows the proportions of vaccinations occurring in each month for each data type.

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[8] Analysis was conducted by Acumen using data from MDS and CWF Professional and Outpatient claims for the 2018-2019 flu season. The study population was restricted to beneficiaries continuously enrolled in Medicare Parts A and B and not C from July 2018 – June 2019. The distribution was only calculated for residents that had an influenza vaccination date reported for the current flu season on MDS.

Figure 7. Influenza Vaccination Recorded Month Frequency for MDS and Claims
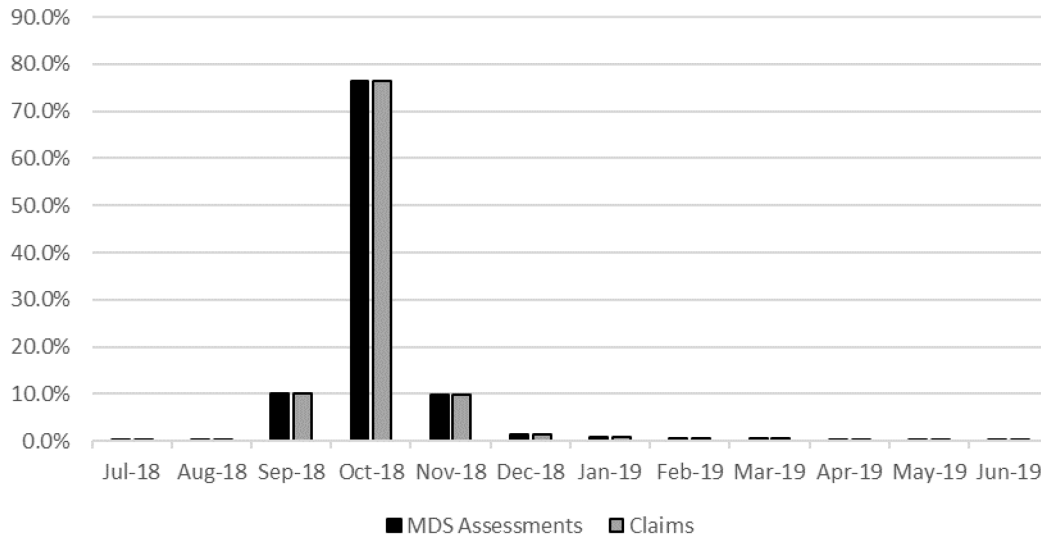
Further analyses were conducted to compare the date of vaccination recorded in claims versus MDS assessments. For in-facility influenza vaccinations reported on both MDS and claims, 80% of the specific vaccination date recorded on the MDS matched exactly with the date reported on the claims. Table 8 shows the distribution of the difference in the number of days ("gap days") between the vaccination dates recorded on the MDS versus claims, for each month of vaccination according to records from the claims. For example, during the month of October 2018, there was little variation in the number of gap days between MDS and claims. During this month, each percentile point between the 10th percentile and 90th percentile marked a zero day difference (i.e. exact match) in vaccination date recorded on the MDS versus claims. However, there are other months during which discrepancies in vaccination dates between the MDS and claims are more frequent.

Table 8. Distribution of Gap Days between MDS and Claims Vaccination Dates

Month	% Residents	Min	P10	P25	P50	P75	P90	Max
Jul-18	0.0%	0	52	63	84	92	96	204
Aug-18	0.2%	-34	0	0	40	70	140	266
Sep-18	10.9%	-72	0	0	0	0	16	255
Oct-18	75.7%	-115	0	0	0	0	0	264
Nov-18	10.2%	-116	-15	0	0	0	0	232
Dec-18	1.4%	-126	-64	-34	0	0	1	151

Month	% Residents	Min	P10	P25	P50	P75	P90	Max
Jan-19	0.7%	-175	-97	-43	0	0	0	98
Feb-19	0.4%	-208	-122	-88	0	0	0	58
Mar-19	0.4%	-225	-160	-140	0	0	0	49
Apr-19	0.1%	-220	-206	-181	-137	0	0	45
May-19	0.0%	-225	-224	-212	-205	-182	-39	0
Jun-19	0.0%	-267	-267	-239	-231	-225	-92	-92

4.3.2 Key Discussion Takeaways

- The TEP indicated that the discrepancy described above (that is, vaccination events being more likely to appear on assessments versus claims) is not surprising.

- Panelists shared that communication between physicians or assessment coders and those completing the claim forms is not always conducive to the vaccination being recorded on claims, as information on ancillary procedures can get lost.

- Billing issues, such as confusion around consolidated billing and low vaccination reimbursement rates, also reduce the provider's financial incentive to spend the time to file a claim for vaccination.

4.3.3 Panelist Discussion Details

The PAC QRP Support team posed the following questions to the TEP:

1. *What explains the degree of under-counting of MDS-reported vaccinations in claims data? How can it help inform the design of COVID-19 Vaccination items on assessments?*

2. *What explains the discrepancy between influenza vaccination dates in MDS and claims for 20% of the population? Why is the difference more prominent in certain months?*

Panelists discussed the presented results, which showed that for both pneumococcal and influenza vaccination, there is a discrepancy between what shows up in claims versus assessment data, as a sizeable proportion of vaccination instances get left off of Medicare claims. Panelists overall were not entirely surprised by this, noting that there is often little to no financial incentive

to spend the time recording each vaccination on a claim, given the reimbursement amount. Additionally, there is not always clear communication between those who complete the assessment forms and those who fill out the claims. These issues lead to more minor or ancillary procedures, such as vaccination, not being recorded on the claim, even though they were recorded on the assessments. Some panelists stressed that assessment items should be aligned across settings as much as feasible. They voiced a concern that these items could eventually be so complex that a lack of standardization could lead to coding errors or confusion, reducing item reliability.

4.4 Session 3-D: Potential PAC Patient-level COVID-19 Vaccination Measure Specifications

This section summarizes session 3-D, in which panelists reviewed draft measure specifications for a potential PAC patient-level COVID-19 vaccination measure. Section 4.4.1 summarizes the content presented to the panel during this session in order to facilitate the discussion, Section 4.4.2 lists the key takeaways from this discussion, and Section 4.4.3 covers the discussion itself in greater detail.

4.4.1 Summary of Presentation

To begin this session, the PAC QRP Support team indicated that they require expert input on four areas of development for a PAC patient-level COVID vaccination measure. These areas were the following:

1. Measure goals and their relevance to each PAC/NH setting.

2. Key concepts and their relevance to defining COVID-19-related assessment items and measures.

3. Assessment items and possible item responses to support construction of the measures.

4. Development of measure specifications using the proposed COVID-19 vaccination item responses.

This session was broken up into smaller sections, beginning with a short period of content followed by a more targeted set of questions and discussion.

Measure goals and their relevance to each PAC/NH setting

The PAC QRP Support team began this section by providing Table 9 in order to solicit feedback on the pros and cons of addressing each measure goal with the potential PAC patient-level vaccination measure.

Table 9. Pros and Cons for Each Measure Goal in a Patient-Level COVID-19 Vaccination Measure

Measure Goals	Pros	Cons
Goal (A): Report the rate of vaccination in a PAC/NH setting without denominator exclusions.	Provides an actual (i.e. 'pure') rate of vaccination rate within facility/agency	Does not account for factors outside provider control (e.g., medical contraindications to vaccine) May disproportionately affect providers whose patients/residents have multiple comorbidities Does not provide consumers with information on actions taken to improve vaccination rate May not be as meaningful to HH patients since it is not a congregate living setting
Goal (B): Report the rate of vaccination in a PAC/NH setting, excluding persons with medical contraindications.	Provides a rate of vaccination among eligible persons, i.e., those persons providers can influence	Does not reflect a true rate of vaccination among all patients Does not provide consumers with information on actions taken to improve vaccination rates May not be as meaningful to HH patients since it is not a congregate living setting
Goal (C): Assess actions providers take to improve vaccination rates.	Incentivizes providers to implement actions to improve vaccination rates	Does not reflect an actual rate of vaccination rate within facility/agency

Key concepts and their relevance to defining COVID-19-related assessment items and measures

The team noted that panelists should consider the CDC definition of "fully vaccinated" and how this definition may evolve. For COVID-19, full vaccination occurs two weeks after receipt of the second dose of the two-dose series, and two weeks after receipt of the single dose

of the one-dose vaccine.[9] For influenza and pneumococcal, this is defined as approximately two weeks after vaccination receipt.[10] [11]

The team then demonstrated that the definition of a "complete vaccination course" also varies depending on the vaccine. For COVID-19, this is defined as an initial completed series which includes dose 1 and dose 2 of a COVID-19 vaccine requiring two doses for completion, or one dose of a COVID-19 vaccine requiring only one dose for completion. For influenza, this is defined as one vaccine received annually. However, for pneumococcal, CDC recommends pneumococcal vaccination for all adults 65 years or older. For adults without compromising conditions, this involves PPSV23 only or one dose of PCV13 first and one dose of PPSV23 at least one year later. For adults with compromising conditions, this involves one dose of PCV13 first and one dose of PPSV23 at least eight weeks later.

The PAC QRP Support team noted that CDC considers a history of the following to be a contraindication to vaccination with COVID-19 vaccines: severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or a known diagnosed allergy to a component of the COVID-19 vaccine.

Next, the team presented the measure windows currently in use by the existing vaccination measures, as shown in Table 10:

Table 10. Breakdown of Measure Windows for Three Existing Vaccination Measures

	COVID-19 HCP Measure	**Influenza HCP and Patient Measures**	**Pneumococcal Patient Measures**
Data Calculated	Using one quarter of data and the most recent quarter is reported	Using data collected October 1 through March 31 and reported annually	Using data from selected target assessments during the 12-month reporting period

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[9] Information from the CDC on COVID-19 vaccination timelines is available here:
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html
[10] Information from the CDC on influenza vaccination is available here:
https://www.cdc.gov/flu/prevent/vaccinations.htm
[11] Information from the CDC on pneumococcal vaccination is available here:
https://www.cdc.gov/vaccines/vpd/pneumo/index.html

	COVID-19 HCP Measure	Influenza HCP and Patient Measures	Pneumococcal Patient Measures
PRO	Data is regularly updated and reflects the most recent reporting period	N/A	Data reflects an average over a longer period of time with fewer fluctuations
CON	Data can fluctuate and may be less reliable compared to options based on longer time windows	N/A	Data may not reflect most recent provider actions

Assessment items and possible item responses to support construction of the measures

The team began this section by proposing two possible options for a PAC patient-level COVID-19 vaccination assessment item:

a) **O/MXXXX. COVID Vaccination Received:** Has the patient/resident received the COVID-19 vaccine?

b) **O/MXXXX. COVID Vaccination:** Is the patient/resident's COVID-19 vaccination up-to-date?

Following this discussion, the PAC QRP Support team provided the TEP with possible 'yes' and 'no' item responses that contain either 'more' or 'less' information. These options are detailed in Table 11 and Table 12.

Table 11. Possible 'Yes' Options for PAC Patient-Level COVID Vaccination Responses

More Information	Less Information
Yes; received a complete vaccine course from your [agency/facility] during this [episode of care/stay]	Yes; received a complete vaccine course
Yes; received a complete vaccine course from your [agency/facility] during a prior [episode of care/stay]	
Yes; received a complete vaccine course from another health care provider	

Table 12. Possible 'No' Options for PAC Patient-Level COVID Vaccination Responses

More Information	Less Information
No; received a partial vaccine course from your [agency/facility] during this [episode of care/stay]	No; patient has received a partial vaccine course
No; received a partial vaccine course from your [agency/facility] during a prior [episode of care/stay]	
No; received a partial vaccine course from another health care provider	
No; patient has not received a booster	No; patient has not received a booster
No; patient offered and declined	No; patient offered and declined
No; patient offered and declined due to religious beliefs	
No; patient assessed and determined to have medical contraindication(s)	No; patient assessed but did not meet guidelines
No; not indicated-patient does not meet age/condition guidelines	
No; inability to obtain vaccine due to declared shortage	No; inability to obtain vaccine due to declared shortage
No; not offered	No; did not receive for other reasons
No; patient did not receive the vaccine due to reasons other than those listed	

Development of measure specifications using the proposed COVID-19 vaccination item responses

The PAC QRP Support team first presented potential measure specifications to calculate the rate of complete COVID vaccination, as shown in Table 13:

Table 13. Measure Specifications to Calculate Rate of Complete COVID Vaccination

Measure Component	Proposed Specifications
Numerator	Persons who meet the definition of fully vaccinated per clinical guidelines (e.g. initial course + booster(s))
Denominator	Total stays during reporting period
Exclusions	Length of stay < 3 days

Second, the PAC QRP Support team presented potential measure specifications to calculate the assessment and appropriate administration of COVID vaccines, as shown in Table 14:

Table 14. Measure Specifications to Calculate Assessment and Appropriate Administration of COVID-19 Vaccine

Measure Component	Proposed Selections
Numerator	Persons who meet the definition of fully vaccinated per clinical guidelines [e.g. initial course + booster(s)] *and* Persons assessed and who have a documented reason for why the COVID-19 vaccine is not current per clinical guidelines, i.e. ▪ No; patient has received a partial vaccine course ▪ No; patient has not received a booster ▪ No; patient offered and declined ▪ No; patient assessed but did not meet guidelines ▪ No; inability to obtain vaccine due to declared shortage
Denominator	Total stays during reporting period
Exclusions	Length of stay < 3 days

4.4.2 Key Discussion Takeaways

- Some panelists were concerned with the burden associated with collecting information for two measures (one for Goal A and another for Goal C). However, this concern was assuaged when the PAC QRP Support team noted that any item that can inform one measure could also inform the other without additional burden.

- Panelists were concerned with how quickly the definition of fully vaccinated can evolve, which could influence the effectiveness of the measure.

- Others were skeptical of the actual frequency of contraindications, and suggested that this should be left out of the clinician's interpretation and left to an outside reference source if possible.

- Assessment items should use language such as "up to date" or "current" in terms of vaccination status, as opposed to "fully vaccinated." This is because the term "fully vaccinated" has a specific definition that includes the two-week post-dose inoculation period.

- Most panelists agreed that it would be preferable for a potential assessment item to be comprehensive, even if that comes with additional burden for the provider.

- The TEP ultimately concluded that developing two measures would be the best way to meet measure goals and patient/family advocate preferences, while also being able to accurately reflect provider quality.

4.4.3 Panelist Discussion Details

This section summarizes the discussion held by the TEP during this session. The organization of this section corresponds to the order of topics presented in Section 4.4.1.

Measure goals and their relevance to each PAC/NH setting

The PAC QRP Support team posed the following question to the TEP:

Given these pros/cons, which measure goal(s) should be addressed in each setting?

Panelists indicated that Goal A would likely be associated with the lowest provider burden for data collection, as the information required is comparatively minimal. However, panelists agreed with the potential downsides of this goal presented in Table 9. Pros and Cons for Each Measure Goal in a Patient-Level COVID-19 Vaccination Measure, noting that a number of important factors that might be relevant to patient decisions would be missed. Here, the PAC QRP Support team noted any data used to meet Goals B or C would also be able to meet Goal A, since information on a patient's current vaccination status would be inherently necessary for all of the goals. Therefore, the burden associated with reporting a measure for Goals C and A would

not be any higher than that associated with reporting a measure for Goal C alone. The TEP agreed with this conclusion. Panelists expressed a concern with Goal B, specifically noting that the actual rate of true medical contraindications is low compared to how often providers tend to report it. This may be due to providers misinterpreting side effects as actual contraindications due to misinformation or lack of clear communication about contraindications. Panelists also noted that any deficiencies in vaccine availability would make it challenging for providers to perform well on a measure meeting either Goal A or B, as these assess vaccination rates regardless of a provider's ability to offer them.

Key concepts and their relevance to defining COVID-19-related assessment items and measures

The following questions were posed to the TEP:

1. *Given these time frames [duration between receiving a vaccine and being considered 'fully vaccinated'], is it important to consider the period between vaccine administration and being 'fully vaccinated' [in measure development]?*

2. *Should receipt of a booster based on most current recommendations factor into the definition of a "completed course"?*

3. *When considering contraindications, should there be methods to allow/identify for reasons beyond those defined by the CDC?*

4. *When considering the pros and cons of each measure calculation period, should the measures align with the COVID-19 for HCP measure or the pneumonia measure?*

Panelists agreed the two-week time period post-vaccination is necessary for a patient to be considered 'fully vaccinated' according to the CDC's definition,[12] and that considering this timeline may not give credit to providers who administer vaccines to patients who then leave before the end of the two-week inoculation period. Some panelists also pointed out that there are patients who have recently had COVID-19, meaning that they have boosted immunity, and that this factor would also need to be accounted for if true protection against the virus were to be the intended metric.

Panelists indicated that the list of contraindications defined by the CDC[13] has been subject to constant change. The TEP noted that even referring to the CDC's list as an objective reference source might be insufficient due to how frequently this list has been updated, since

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[12] The CDC definition of fully vaccinated against COVID-19 is available here: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fvaccines%2Ffully-vaccinated.html.
[13] The CDC's list of what they consider to be contraindications is available here: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

those filling out the assessments may not be aware of the most recent guidance. Panelists suggested that in addition to referring to the CDC for up to date guidance, guidance manuals should include as specific instructions as possible to avoid confusion.

Panelists pointed out that similar to guidance on contraindications, CDC guidance regarding vaccine boosters will continue to change rapidly and for the foreseeable future. The TEP was concerned with potential reference to CDC guidance in the assessments more generally, noting that the guidance manuals for the assessments are only updated annually, and those responsible for filling out the assessments may not be able to keep up to date with the most recent guidance. While acknowledging that referring to outside guidance from the CDC would be unavoidable in order to allow the items to remain relevant over time, they advocated that any assessment language should leave as little up to interpretation as possible and that the guidance will need to be carefully crafted to ensure the assessments items are used as intended.

One panelist indicated that the COVID-19 Vaccination Coverage for HCP measure, while reported quarterly, only uses one week of data from NHSN, and contended that this actually causes more burden than intended. Panelists also noted that it may be unreasonable to align with the influenza measure since a "COVID-19 season" has not been established, and these potential patient-level COVID-19 vaccination measures should instead reward providers for administering COVID-19 vaccines regardless of the time of year. Another panelist suggested that the measures could build into a rolling twelve-month window, being reported monthly, in order to account for any potential fluctuation.

Assessment items and possible item responses to support construction of the measures

The PAC QRP Support team presented the following questions to the TEP:

1. *Would one [proposed Assessment item] influence provider action more than the other?*

2. *Are there other Assessment items to consider?*

The TEP as a whole agreed that option b) ("**O/MXXXX. COVID Vaccination:** Is the patient/resident's COVID-19 vaccination up-to-date?") would be the more preferable assessment item, as this choice allows for providers to indicate that a patient is vaccinated, even if they were already up to date with their vaccines before admission. However, panelists also noted that the definition of "up-to-date" may need to be altered over time to account for evolving CDC guidance, and that the potential response options to such an item may need to change in response to this as well. One panelist suggested that there be an exclusion for a short length of stay, since providers may not have the opportunity to even offer a vaccine in these cases if the patient is not there for long enough. Another questioned whether providers should also ask when the patient

last received a COVID-19 vaccine dose if the ultimate intent of the measures is to capture their current vaccination status. Finally, one panelist noted that a follow-up item should ask whether or not the facility/agency offered a dose if the patient is found to not be up to date on their vaccines.

Some panelists indicated that while they generally prefer items with less information in order to reduce their burden, the particular intricacies of vaccine hesitancy and refusal merit response options that are more complex and convey more information. Additionally, they noted that the options with "more information" were better suited to reflect provider effort. One panelist noted that in addition to being able to indicate a declared shortage, providers should also be able to note if supply change issues inhibited them from offering a vaccine at that time. One panelist felt that the nuance provided by the "more information" options is likely available from other data sources, making the additional burden and potential confusion unnecessary.

Development of measure specifications using the proposed COVID-19 vaccination item responses

The PAC QRP Support team presented the following final questions to the TEP:

1. *Are there other considerations to the proposed measure specification, such as exclusions based on age?*

2. *Are there other considerations to the proposed measure specification?*

One panelist suggested that there be an exclusion for patients that were discharged against medical advice, since such an occurrence would hinder a provider's ability to offer a vaccine dose to the patient even if they had planned to do so. Another panelist noted that providers simply cannot administer a full vaccine course in under ten days, and so the length of stay exclusion may need to be extended.

Panelists agreed that these specifications should not be combined into one measure, but should instead be used to develop two separate measures. The panelists agreed that the first set of specifications meets Goal A, while the second set meets Goal C.

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5 SUMMARY OF TEP MEETING 2 PRESENTATION AND DISCUSSION

This section summarizes content that was presented during the second TEP meeting, as well as feedback shared by TEP panelists during this meeting. The information is organized into two sections. First, Section 5.1 summarizes new analyses that were performed and presented as a follow-up to TEP input received during the first TEP meeting. Second, Section 5.2 reviews the draft patient-level COVID-19 vaccination measure assessment items and measure specifications, and corresponding TEP feedback. Each subsection summarizes the material presented to the TEP, the key findings extracted from TEP discussions, and details on the discussion among TEP panelists.

## 5.1 Session 4-A: Follow-up Analysis on COVID-19 Vaccination Rates

During this session, the PAC QRP Support team presented findings from follow-up analyses on COVID-19 vaccination rates, which were performed in response to TEP input received during the first TEP meeting.

5.1.1 Summary of Presentation

During the first TEP meeting, panelists shared that it would be helpful to see more detailed information on variations in COVID-19 vaccination rates by state, within state, and by patient composition. In response, the PAC QRP Support team presented findings from the two follow-up analyses described below.

First, the PAC QRP Support team presented findings pertaining to variation in COVID-19 vaccination rates by state and within state. This analysis leveraged data from the NHSN COVID-19 Nursing Home dataset as of September 12th, 2021. As shown in Figure 8 below, the states with the highest rates of complete COVID-19 vaccination such as North Dakota, New Hampshire, Vermont, Nebraska and Massachusetts have an average complete vaccination rate of about 87% and a median vaccination rate of 88%. In this figure, the interquartile range for each state (the height of each box) is relatively small, indicating limited within-state variation. In contrast, Figure 9 shows that the states with the lowest rates of complete COVID-19 vaccination such as Nevada, Florida, Arizona, Texas and Tennessee have an average complete vaccination rate of 69% and a median vaccination rate of 71%. Additionally, the interquartile range for each state is larger in Figure 9 than in Figure 8. For example in Nevada, a quarter of nursing homes had a complete vaccination rate of 55% or lower. In the same state, a quarter of nursing homes had a complete vaccination rate of 82% or higher, pointing to the considerable level of within-state variation.

Figure 8. States with the Highest Complete COVID-19 Vaccination Rates in Nursing Homes (Data as of September 12ᵗʰ, 2021)
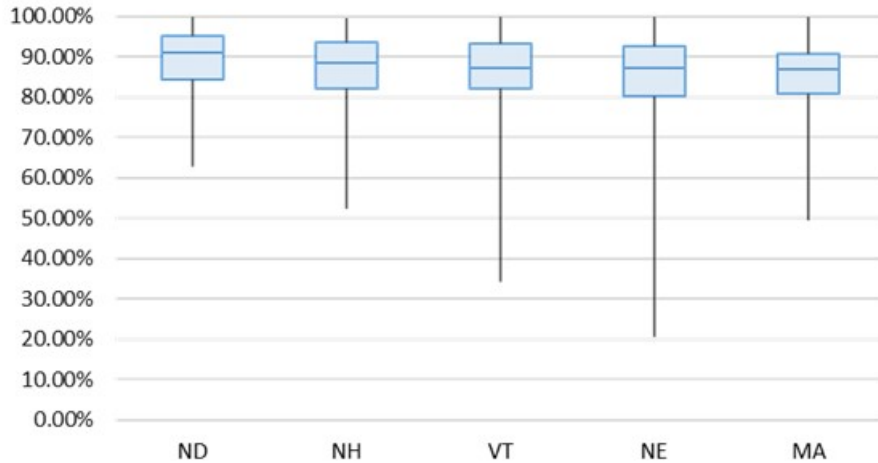
Figure 9. States with the Lowest Complete COVID-19 Vaccination Rates in Nursing Homes (Data as of September 12ᵗʰ, 2021)
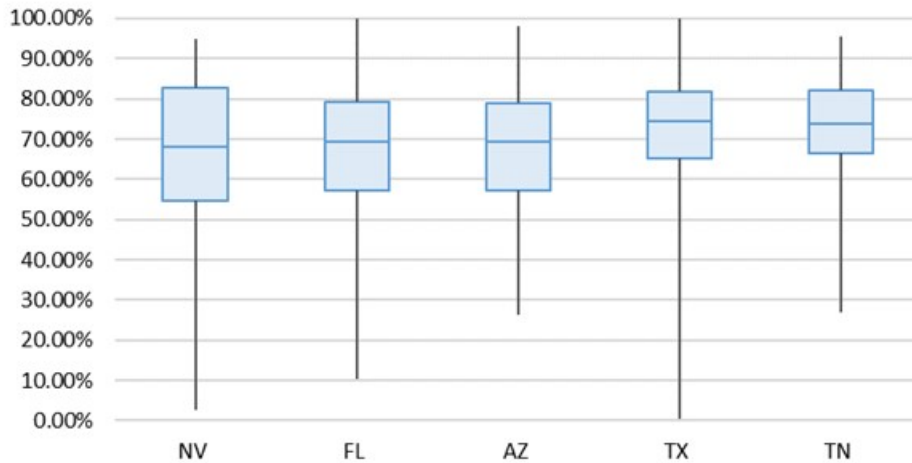
Second, the PAC QRP Support team presented findings on an analysis of differences in COVID-19 vaccination rates in nursing homes by patient composition. This analysis used the NHSN COVID-19 Nursing Home dataset as of September 12ᵗʰ, 2021, combined with data from the Minimum Data Set (MDS) as of October 31ˢᵗ, 2021. Results identified the following patient composition factors at the provider level to be associated with higher COVID-19 vaccination rates in nursing homes: providers with a higher proportion of Asian, White, Medicare-Medicaid dually enrolled, or older residents (age 85 and older), or residents with certain medical conditions such as cancer, brain injury, ESRD, heart failure, neurological conditions such as dementia, cerebral palsy etc., mental health conditions such as depression, schizophrenia etc. In contrast, the following patient composition factors were associated with lower COVID-19 vaccination

rates in nursing homes: providers with a higher proportion of Black or African American, Hispanic or Latino, neither Medicare nor Medicaid enrolled, or younger residents (under age 65), or residents with certain medical conditions such as asthma, psychosis, pneumonia, and septicemia. Due to the lack of details of patient-level vaccination information when conducting this analysis, complications of COVID-19 contraction may show up as conditions associated with lower vaccination rates.

5.1.2 Key Discussion Takeaways

- Analyses show considerable variation in COVID-19 vaccination rates among nursing homes by state and within state. States with the highest complete vaccination rates have an average complete vaccination rate of about 87%, while states with the lowest complete vaccination rates have an average complete vaccination rate of about 69%. Further, states with the lowest complete vaccination rates also show wider within-state variations in vaccination rates among nursing homes.

- Analyses identify different patient composition factors to be associated with high versus low COVID-19 vaccination rates in nursing homes. Factors such as a high proportion of Asian, White, and older residents (age 85 and older), certain high-risk medical conditions are associated with higher rates of COVID-19 vaccination in nursing homes. In contrast, factors such as a high proportion of Black or African American, Hispanic or Latino, and younger residents (under age 65) are associated with lower rates of COVID-19 vaccination in nursing homes.

5.1.3 Panelist Discussion Details

There was no TEP panelist discussion on this topic. TEP panelists thanked the PAC QRP support team for producing these follow-up analyses.

5.2 Session 4-B: Draft Patient-level COVID-19 Vaccination Measure Assessment Items and Specifications

During this session, the PAC QRP Support team presented draft patient-level COVID-19 vaccination measure assessment items and specifications and solicited TEP feedback. The draft assessment items and measure specifications were built based on TEP input received during the first TEP meeting.

5.2.1 Summary of Presentation

The presentation for this session was organized into three subsections: a summary of key measure terms and definitions as used in the draft patient-level COVID-19 vaccination measures, a presentation of draft assessment items and responses, and a walk through of draft measure specifications. Key points from each presentation are summarized by subsection below. Key

findings and details on the TEP discussion surrounding these topics are available in Section 5.2.2 and Section 5.2.3.

Measure Terms

The PAC QRP team presented the following terms and definitions in order to obtain feedback for measure development:

Table 15. Terms and Definitions for Measure Consideration

Term	Definition
Primary Vaccine Series	• An initial completed series includes dose 1 and dose 2 of COVID-19 vaccines requiring 2 doses for completion *or* • One dose of COVID-19 vaccine requiring only one dose for completion
Contraindications	Per the CDC: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine • Known diagnosed allergy to a component of the COVID-19 vaccine
Partial Vaccination	• Person has received only one dose of the 2-dose primary series or Person has completed the primary series, and has not received a recommended booster
Booster Dose	• An extra administration of vaccine following an earlier (primary) dose.
CDC Guidelines for Patient-level Vaccination Measure Exemptions	• Patients with reasonable accommodation for a disability, sincerely held religious belief, observance, or practice and for medical reasons
Declared Shortage	• Vaccine availability is limited as announced by CDC, FDA
Provider Restrictions	• Provider unable to obtain vaccine, e.g. due to limited distribution
Education	• Provider delivered information to patient in verbal, written, or other media

Assessment items and Responses

To begin the presentation for this subsection, the PAC QRP Support team presented the following table, outlining the time points at which the PAC patient-level COVID-19 vaccination assessment item would be collected:

Table 16. Assessment Item Collection Time Point

Collection Time Point	LTCH	IRF	SNF	NH	HH
Admission/SOC	NA	NA	NA	NA	NA
ROC	NA	NA	NA	NA	✓
Recertification	NA	NA	NA	NA	NA*
Quarterly / Annual	NA	NA	NA	✓	NA
Transfer	✓	NA	NA	NA	✓
Discharge	✓	✓	✓	✓	✓
Death	✓	NA	NA	NA	✓

*This represents a correction to what was presented to the TEP.

Next, the PAC QRP Support team proposed an assessment item with three questions as presented in the following three tables. The first question gathers data on current vaccination status by asking about whether the patient has received a primary COVID-19 vaccine series in the past, and is up to date on recommended boosters. Answers offer multiple options to explain why a patient may not qualify as a "Yes," such as not having received any COVID-19 vaccine, or having received a partial COVID-19 vaccination series, but not yet eligible to receive a second dose. The second question, in contrast, asks specifically about whether the patient received a COVID-19 vaccine *during their stay* in the PAC setting. Here, answers provide insight on the reason why a patient qualified as a "Yes" (such as the patient having received a second dose of a vaccine series during the stay), or a "No" (such as the patient was offered but refused the vaccine, or was up to date on the vaccine). Lastly, the third question reflects feedback from TEP panelists representing patients and families, and asks about whether the patient received education on the benefits of receiving a COVID-19 vaccine.

Table 17. Draft Assessment Items: Question 1

O/MXXXX COVID Vaccination:

1. Has the patient received a primary COVID-19 vaccine series and is up to date on recommended boosters?

□ a. Yes. *

□ b. No, patient has received a partial COVID-19 vaccine series, and is not yet eligible for second dose.

□ c. No, patient has received a partial COVID-19 vaccine series, and is eligible for the second dose, but has not received it.

□ d. No, patient has received a primary COVID-19 vaccine series, and a booster is recommended, but has not received it yet.

□ e. No, patient has not received a COVID-19 vaccine.

□ f. Not assessed.

* Patient has received the full series and is up-to-date on boosters; **OR** Patient has received the full series and is not yet eligible for a booster.

Table 18. Draft Assessment Items: Question 2

O/MXXXX COVID Vaccination:

2. Did the patient receive a COVID-19 vaccine {IRF/LTCH: since Admission} {{SNF: since Admission/Entry or Reentry or Prior Assessment} {HH:} since SOC/ROC whichever is more recent}?

☐ a. Yes   Continue to O/MXXXX.2.a.X (MM/DD/YYYY of vaccination)

   ○   The patient received the first dose of a vaccine series.

   ○   The patient received the second dose of a vaccine series.

   ○   The patient received a booster dose.

   ○   Date COVID-19 vaccine received:

☐ b. No   Continue to O/MXXXX.2.b.X

   ○   Patient is up-to-date on COVID-19 vaccine.

   ○   Patient did not meet CDC guidelines for vaccination.

   ○   Inability to obtain vaccine due to declared shortage.

   ○   Inability to obtain vaccine due to other restrictions.

   ○   Offered, but patient refused.

   ○   Not offered.

Table 19. Draft Assessment Items: Question 3

O/MXXXX COVID Vaccination:

3. Did the patient receive education on the benefits of receiving a COVID-19 vaccine?

☐ a. Yes

☐ b. No

Measure Specifications

To conclude this session, the PAC QRP Support team presented draft specifications for two measures pertaining to patient-level COVID-19 vaccination. Draft specifications are summarized in the following two tables. Measure #1 aims to provide data on the percentage of patients/residents who have received the COVID-19 vaccination. This measure captures persons who qualified as "Yes" in their response to assessment item question #1 (Has the patient

received a primary COVID-19 vaccine series and is up to date on recommended boosters?) in the numerator. In contrast, measure #2 aims to provide insight on the appropriate assessment and administration of COVID-19 vaccines to patients. To align with this measure objective, this measure numerator includes persons who received a COVID-19 vaccine during their stay in the PAC setting, as well as persons who were assessed for vaccination status, who have a documented reason for why the COVID-19 vaccine is not current per clinical guidelines, *and* who received education on the benefits of the COVID-19 vaccination. For example, in measure #2, patients who were offered but declined the vaccine would count towards the numerator, so long as the answer to assessment item question 3 (Did the patient receive education on the benefits of receiving a COVID-19 vaccine?) was "Yes."

Table 20. Proposed Specifications for Measure #1:
Percentage of Patient/Residents Who Have Received the COVID-19 Vaccination

Measure Component	Proposed Specifications
Numerator	Persons who meet the definition of being up to date on vaccines. *Response to* O/MXXXX COVID Vaccination: 1. Has the patient received a primary COVID-19 vaccine series and is up to date on recommended boosters? *is* a. Yes
Denominator	Total stays during reporting period
Exclusions	Length of stay < 3 days

Table 21. Proposed Specifications for Measure #2:
Percentage of Patient/Residents Who Were Assessed and Appropriately Administered the
COVID-19 Vaccination

Measure Component	Proposed Specifications
Numerator	Persons who received a COVID-19 vaccine {*IRF/LTCH:* since Admission} {*SNF/NH:* since Admission/Entry or Reentry or Prior Assessment, whichever is more recent} {*HH:* since SOC/ROC, whichever is more recent} **AND** Persons assessed for vaccination status, who have a documented reason for why the COVID-19 vaccine is not current per clinical guidelines, *and* who received education on the benefits of the COVID-19 vaccination
Denominator	Total stays during reporting period
Exclusions	Length of stay < 3 days

5.2.2 Key Discussion Takeaways

The following key takeaways emerged from TEP panelist discussions on each topic.

Measure Terms

- When defining concepts such as a complete vaccination series or partial vaccination, it would be helpful to refer to CDC guidelines. This will help the measures be flexible and responsive to the fluid and evolving vaccination requirements.

Assessment Items and Responses

- The proposed time points at which the new assessment item would be collected are reasonable.

- The number of new assessment items should be minimized while still supporting the goal of calculating the two measures.

- Since the definition of what it means to be "up to date" in vaccination status is an evolving concept, it is important to design assessment items and measures with some flexibility.

- Assessment item question #2 and its responses could be clarified to ensure consistent information is collected (i.e. more guidance on the vaccination date field).

- Consideration should be given to adding a response to assessment item question #2 to collect information about when a vaccination is not administered due to medical and/or clinical reasons that are not already included in CDC's list of contraindications.

- Education is important for all vaccination measures, including the influenza and pneumococcal vaccines, but there is uncertainty about the utility of collecting it for the influenza and pneumococcal vaccine measures given current survey and certification requirements.

Measure Specifications

- It is helpful to have two measures that tailor to different needs. The first measure would aim to provide insight into the rate of COVID-19 vaccination among patients in PAC settings. The second measure would provide data on whether providers are appropriately assessing and administering COVID-19 vaccinations.

- The measure specifications should defer to the CDC for how a primary vaccine series is defined.

- The measure specifications should defer to the CDC, ACIP and other appropriate sources for how contraindications are defined.

- It is important to capture which providers educated unvaccinated persons about the benefits of the COVID-19 vaccines.

5.2.3 Panelist Discussion Details

The PAC QRP Support team posed the following questions for the TEP:

1. *Do you agree with capturing the information at the time points presented? Are there other Assessment types or time points at which the information should be collected?*

2. *Do you agree with the definition of "Yes" in the first question in the Assessment Item?*

3. *Do you think having three separate questions clearly and comprehensively capture the information needed to calculate both measures?*

4. *Should responses be condensed further?*

5. *Do you agree with referring providers to the CDC guidelines, or should other guidelines also be referenced?*

6. *Are there other terms the TEP thinks CMS should define in more detail?*

7. *Is patient education an important topic to consider in future updates to the influenza and pneumococcal vaccine measures?*

8. *In what situations do providers choose 'None of the above" or "No, due to reasons other than those listed in responses 4-7" (e.g. in questions pertaining to patient influenza vaccination status)?*

TEP panelist discussion on the above questions are summarized by topic below.

Measure Terms

The TEP discussed specifics around what it means to be up to date on COVID-19 vaccines. Panelists expressed that the guidance around recommended boosters for patients is likely to evolve over time. Given the fluid situation, they noted that assessment items and measure design should offer flexibility in order to respond to future changes in guidelines. The PAC QRP Support team shared some ways in which the draft assessment items do offer flexibility, such as referring to CDC guidelines for vaccination, and not distinguishing between specific rounds of booster doses.

Panelists also discussed important differences between the terms "fully vaccinated" versus terms such as being "up to date" or "current" on vaccines. They emphasized that assessment items and measure specifications should use language such as "up to date" or "current" in terms of vaccination status, as opposed to "fully vaccinated." This is because the term "fully vaccinated" has a specific definition that includes the two-week post-vaccine period, which is more relevant from a clinical standpoint rather than for monitoring vaccination status.

Assessment Items and Responses

The TEP first reviewed the proposed time points at which assessment items would be collected, and agreed that the time points align with practice patterns for each PAC setting.

Panelists then discussed each proposed assessment item question and response, with a particular focus on question #2 of the proposed assessment item. The first discussion on question #2 pertained to the vaccination date field in the item response. Here, some panelists stated it is unclear which vaccination date should be populated on the form. They suggested that clear guidance on this detail be provided to avoid confusion (e.g. date when last COVID-19 vaccine was received). Further, the TEP discussed the potential benefit of collecting dates for all COVID-19 vaccination doses. While comprehensive data can be helpful, the panelists agreed that that would be more burdensome for providers, and that the date of the most recent dose is the most important to capture.

Continuing the discussion on question #2, the TEP shared that in practice, there are certain patients who have medical reasons not currently captured in the CDC's definition of contraindications that make them ineligible to receive a COVID-19 vaccination. In order to

sufficiently capture cases like this, the TEP suggested adding a response to assessment item question #2 to collect information about cases in which a vaccination is not administered due to medical and/or clinical reasons that are not included in CDC's list of contraindications.

Measure Specifications

Upon reviewing the draft specifications for measure #1 and #2, the TEP panelists and the PAC QRP Support team walked through some specific scenarios of how a given patient would be counted in measure #1 versus measure #2. For example, a scenario in which a patient received one COVID-19 vaccine dose during their stay and could not receive future doses due to a medical reaction to the first dose. In this scenario, this patient <u>would not </u>count towards the numerator for measure #1 since they did not complete a primary COVID-19 vaccine series, regardless of the reason. However, they <u>would</u> count towards the numerator for measure #2, as long as they received education on the benefits of the COVID-19 vaccine. This scenario showcases a key distinction between the objectives of measure #1 and #2, where measure #1 aims to convey information on the vaccination rate, while measure #2 aims to capture proper assessment and administration of vaccines where applicable/possible.

Some panelists then expressed concern that the measure results may be hard to compare over time, due to evolving guidelines (e.g. the list of CDC contraindications may change). The PAC QRP Support team clarified that valid comparisons of measure rates over time can still be done in this case, because persons with contraindications consistently do not count toward the measure numerator for measure #1, and count toward measure #2 as long as they were given education on the benefits of the COVID-19 vaccination.

Lastly, on the topic of education, panelists agreed that patient education is an important aspect of COVID-19 vaccine administration. While education is an important aspect for vaccinations against other conditions (influenza, pneumococcal disease) as well, TEP panelists expressed skepticism about capturing provider education on vaccines for those conditions, given the already prevalent education associated with consent forms and other existing administrative processes.

6 NEXT STEPS

The input provided by this TEP will provide guidance to the PAC QRP Support team throughout the COVID-19 vaccination-related assessment item and measure development and implementation effort. This section will discuss how we plan to address and incorporate the feedback received from these TEP meetings.

As next steps, the PAC QRP Support team envisions the following:

- Refine the draft assessment items and responses using TEP feedback.

- Conduct cognitive testing of the draft assessment items and responses

    o Refine the wording of draft assessment items based on cognitive testing results

- Draft Coding Tips/Guidance Manual updates for future assessment items

    o This would reflect areas where the TEP panelists expressed the need for extra clarification.

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Appendix A: PAC QRP VACCINATION ITEMS AND MEASURES DEVELOPMENT TEAM

The PAC QRP Support team is multidisciplinary and includes individuals with knowledge and expertise in the areas of measure development, clinician payment policy, health economics, clinical practice, public reporting, pay-for-performance, and value-based purchasing and quality improvement. The following individuals from the project team attended the TEP:

Acumen Team:

- Sri Nagavarapu, Co-Project Director

- Stephen McKean, Co-Project Director

- Cheng Lin, Co-Project Manager

- Ellen Strunk, Clinical Lead

- Vasudha Narayanan, Operations Manager

- Yuki Hayashi, Information Gathering Lead

- Tom Goldberg, Data and Policy Analyst

- Aathira Santhosh, Policy Associate

- Layla Taha, Data and Policy Analyst

- Francisco Ambrosini, Data and Policy Analyst

Abt Team:

Abt Associates

- Alrick Edwards, Project Manager

- Jennifer Riggs, Clinical Lead

- Nicole Keane, Clinical Lead

- Morris Hamilton, Data Analytics Lead

OASIS Answers

- Linda Krulish, Clinical Lead

- Marian Essey, Clinical Lead

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Appendix B: TEP CHARTER

All TEP panelists formally ratified the TEP charter, which outlines the TEP objectives, requirements, scope of responsibilities, guiding principles, and estimated meeting schedule. The full text of the TEP charter is below:

Project Title:

Cross-setting Technical Expert Panel (TEP) for the Maintenance and Development of Vaccination-Related Items and Measures for the Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Home (NH), and Home Health (HH) Settings

Dates:

November 2021 (specific date to be determined)

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Acumen, LLC and Abt Associates Inc. (hereafter referred to as Acumen and Abt) to develop quality and cost measures for use in the Post-Acute Care (PAC) Quality Reporting Program (QRP) and Nursing Home Compare as mandated by the Patient Protection and Affordable Care Act (PPACA) of 2010 and the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. Acumen's contract name is "Quality Measure & Assessment Instrument Development & Maintenance & QRP Support for the Long Term Care Hospital, Inpatient Rehabilitation Facility, Skilled Nursing Facility, Quality Reporting Programs, & Nursing Home Compare." The contract number is 75FCMC18D0015, Task Order 75FCMC19F0003. Abt's contract name is "Home Health and Hospice Quality Reporting Program Quality Measures and Assessment Instruments Development, Modification and Maintenance, & Quality Reporting Program Oversight Support." The contract number is 75FCMC18D0014, Task Order 75FCMC19F0001.

As part of its measure development process, Acumen and Abt convene groups of stakeholders and experts who contribute direction and input during measure development and maintenance.

Project Objectives:

Acumen and Abt support CMS in the development of quality and cost measures for use in the IRF, LTCH, SNF, and HHQRPs and the Nursing Home Quality

Initiative (NHQI). These measures fall into several domains including hospitalizations, patient safety, healthcare-associated infections, and function, to name a few, and are designed to improve care quality and to enable Medicare beneficiaries to make informed choices when selecting a healthcare provider. Over the last decade, CMS has introduced measures addressing vaccinations, a dimension of care that is especially relevant to each of the PAC settings. CMS is now investigating the potential for creating a new COVID-19 vaccination measure.

To ensure existing and newly developed measures meet CMS program requirements and goals while maintaining high levels of scientific acceptability, Acumen and Abt are convening a TEP. Acumen and Abt will assemble a panel of stakeholders from a broad base of expertise (e.g., clinical, policy and program, measure development, technical, etc.) and solicit their input regarding vaccination-related items and measures, with a special focus on developing a COVID vaccination standardized patient/resident assessment data element and COVID-19 vaccination measure. This input will be used to guide improvements and additions to the existing assessment instruments and to inform the refinement and development of vaccination measures.

Technical Expert Panel (TEP) Objectives:

The TEP will provide input and guidance on the maintenance and development of vaccination-related items and measures for the IRF, LTCH, SNF/NH, and HH settings. Specifically, we will seek guidance on the following:

- *Review and identification of potential improvements to the existing vaccination measures; and*

- *Development of an assessment-based COVID patient/resident-level vaccination measure for each setting, as appropriate.*

TEP Requirements:

A TEP of approximately 8-15 individuals will provide guidance on important concepts related to the maintenance and development of vaccination-related items and measures in the IRF, LTCH, SNF/NH, and HH settings. TEP attendees must collectively represent expertise in all settings.

Specifically, the TEP will aid in the review and identification of potential improvements to the existing vaccination measures and development of a COVID resident/patient-level measure for each setting, as appropriate. The TEP will

consist of individuals with differing areas of expertise and perspectives, including the following:

- *Clinical Experts with expertise in the IRF, LTCH, SNF/NH, and HH settings, including medical doctors and nurses;*

- *Other subject matter experts in the IRF, LTCH, SNF/NH, and HH settings;*

- *Clinicians with expertise using the assessment tools and/or assessing vaccination status. The following assessment tools are included:*

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

  - *IRF: IRF-Patient Assessment Instrument (PAI)*

  - *SNF/NH: Minimum Data Set (MDS)*

  - *HH: Outcome and Assessment Information Set (OASIS)*

- *Quality Improvement Specialists; and*

- *Measure development experts.*

Scope of Responsibilities:

The TEP's role is to provide input and advice to Acumen and Abt on the maintenance and development of vaccination-related items and measures. Holding a TEP allows Acumen and Abt to leverage the members' experience, which increases the clinical and face validity of the measures and helps to maximize the number of critical dimensions of care being addressed. As such, members are expected to attend all meetings and to notify Acumen and Abt should circumstances change where they no longer wish to participate. Acumen and Abt will work with members to schedule meetings at least one month in advance. In the case of last-minute scheduling conflicts, we ask members to provide any feedback or thoughts on the materials and discussion questions for Acumen and Abt to share with the panel. In some circumstances, a TEP member may designate a temporary replacement from their organization. Any substitute is subject to approval, as we strive to ensure a balanced and diverse composition.

If a TEP member is no longer able to meet membership commitments, Acumen and Abt will identify a replacement from the nominees from the most recent call for nominations or by working with the TEP member's affiliated professional society to nominate another member. Upon identification of an appropriate

alternate member any TEP obligations will transfer to the replacement TEP member.

Guiding Principles:

Participation as a TEP member is voluntary and the participant's input will be recorded in the meeting minutes, which will be summarized in a report that may be disclosed to the public. Acumen and Abt will ensure confidentiality in the report by summarizing discussion topics and removing the names of TEP members who make specific comments during the meeting. If a participant has chosen to disclose private, personal data, then related material and communications are not deemed to be covered by patient-provider confidentiality. Acumen and Abt will answer any questions about confidentiality.

All potential TEP members must disclose any significant financial interest or other relationships that may influence their perceptions or judgment. It is unethical to conceal (or fail to disclose) conflicts of interest. However, the disclosure requirement is not intended to prevent individuals with particular perspectives or strong points of view from serving on the TEP. The intent of full disclosure is to inform the measure developer, other TEP members, and CMS about the source of TEP members' perspectives and how that might affect discussions or recommendations.

Input, advice, and recommendations provided by TEP members will be considered by the measure developer. An appointed TEP chair will help facilitate discussion and build consensus.

Estimated Number and Frequency of Meetings:

The TEP is expected to meet through a webinar twice. The scheduled meetings are as follows:

- *A one hour Pre-TEP Meeting scheduled for early November 2021 (specific date to be determined).*

- *One half-day TEP Meeting scheduled for mid-November 2021(specific date to be determined).*

- *If necessary and feasible, follow-up webinars may be held to present decisions made based on TEP input and/or request additional input.*

Date Approved by TEP:

TBD

TEP Membership:

TBD

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Appendix C: BACKGROUND MATERIALS

The following table presents the background materials provided to the TEP panelists for review prior to the TEP meetings.

Table 22. Background Materials

Setting	URL
LTCH, IRF, SNF	COVID-19 Vaccination Coverage among HCP. https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf
LTCH, IRF	Influenza Vaccination Among HCP (NQF #0431). https://cmit.cms.gov/cmit/#/FamilyView?familyId=390
HH	Pneumococcal Polysaccharide Vaccine Ever Received. https://cmit.cms.gov/cmit/#/FamilyView?familyId=565
NH	Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (LS). https://cmit.cms.gov/cmit/#/FamilyView?familyId=528
NH	Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (SS). https://cmit.cms.gov/cmit/#/FamilyView?familyId=1figure189
LTCH	Weekly HCP & Resident COVID-19 Vaccination Webpage: https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html Weekly COVID-19 Vaccination Summary Form for Residents at LTCFs (57.218). https://www.cdc.gov/nhsn/forms/57.218-p.pdf Weekly COVID-19 Vaccination Summary Form for Healthcare Personnel at LTCFs (57.219). https://www.cdc.gov/nhsn/forms/57.219-p.pdf