Sepsis Workgroup Post-Field Test Refinement (PFTR) Meeting Summary

MACRA Episode-Based Cost Measures: Measure-Specific Workgroups
Post-Field Test Refinement (PFTR) Webinar, October 7, 2020
October 2020

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Project Overview

The Centers for Medicare & Medicaid Services (CMS) has contracted with Acumen, LLC to develop episode-based cost measures for potential use in the Merit-based Incentive Payment System (MIPS) to meet the requirements of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Acumen's measure development approach involves convening clinician expert panels to provide input in cycles of development ("waves").[1] The 4 Clinical Subcommittees (CS) that convened in May-June 2019 for Wave 3 were focused on the following clinical areas: Chronic Condition and Disease Management, Dermatologic Disease Management, General and Colorectal Surgery, and Hospital Medicine.[2] These CS provided input on selecting episode groups for development in Wave 3 and the composition of smaller, targeted workgroups to build out the measure. Acumen convened the following workgroups[3] (each composed of approximately 15 members) in mid-August 2019 for in-person meetings: Diabetes, Asthma/Chronic Obstructive Pulmonary Disease (COPD), Melanoma Resection, Sepsis, and Colon and Rectal Resection. Following the workgroup in-person meetings, Acumen convened the workgroups again in January 2020 for a Service Assignment and Refinement (SAR) webinar to revisit the specifications recommended during the in-person meeting and refine the measures prior to national field testing. In October 2020, Acumen reconvened the workgroups for Post-Field Test Refinement (PFTR) webinars to discuss potential measure refinements based on field testing feedback.

[1] For information on measure development in Waves 3, refer to the 2020 Episode-Based Cost Measures Field Testing Wave 3 Measure Development Process document (https://www.cms.gov/files/document/macra-cmft-ebcm-process-2020.pdf).
[2] Members for these Clinical Subcommittees were recruited through a public nomination period from March 11 to April 12, 2019.
[3] Members for these workgroups were recruited from within the CS as well as a standing pool of nominees between June and July, 2019.

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This meeting summary document outlines the purpose, discussion, and recommendations from the Sepsis Workgroup PFTR webinar. Section 1 provides an overview of the webinar goals and process. Section 2 summarizes the discussion and recommendations from the workgroup. Section 3 is an appendix that describes the materials and information provided to workgroup members prior to and at the beginning of the webinar as preparation for discussion on detailed measure specifications.

1. Overview

The goals of the Sepsis workgroup webinar on October 7, 2020, were the following:

(i) Discuss field testing feedback for the measure
(ii) Discuss and provide input on priority refinement topic areas and recommendations on measure specifications (based on field testing feedback and other topics)
(iii) Consider and discuss on the impact of COVID-19 on measure specifications

The meeting was held online via webinar and attended by 10 of the 20 workgroup members. The webinar was facilitated by an Acumen moderator, Nirmal Choradia. The Sepsis workgroup chair was Jennifer Bracey, who also facilitated meeting discussions, and the Hospital Medicine CS co-chairs were Rob Zipper and Carolyn Fruci. The MACRA Episode-Based Cost Measure Workgroup Composition List contains the full list of members, including names, professional roles, employers, and clinical specialties.[4]

Stakeholders beyond the workgroup members had access to a public dial-in number to observe the meeting as part of Acumen's continued effort to increase the transparency of the measure development process.

Prior to the webinar, workgroup members were provided with information and materials to inform their meeting discussions (see Section 3). After the webinar, workgroup members were sent a recording of the webinar and were polled on their preferences to ensure the measures are developed based on well-documented stakeholder input. Based on National Quality Forum practices, the threshold for support was >60% consensus among poll responses. This document summarizes the workgroup members' input from both the discussion as well as the polls.

This meeting was convened by Acumen as part of the measure development process to gather expert clinical input; as such, these are preliminary discussions and materials, which don't represent any final decisions about the measure specifications or MIPS.

2. Summary of Sessions and Discussion

This section is organized based on meeting sessions and describes workgroup member discussions and recommendations on addressing sub-populations of interest and service

[4] For a list of Sepsis workgroup members in Wave 3, please download the MACRA Episode-Based Cost Measures Measure-Specific Workgroup Composition (Membership) List available on the MACRA Feedback Page (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-workgroup-comp-list.pdf)

assignment. Additionally, there is a sub-section for the session on the potential impact of COVID-19 on the Sepsis measure.

2.1 Addressing Patient Sub-Populations of Interest

Members held detailed discussions revisiting their earlier recommendations from the August 2019 workgroup in-person meeting and SAR webinar regarding how to account for various sub-populations within the Sepsis episode group. Sub-populations are patient cohorts as defined by particular characteristics. To ensure meaningful clinical comparisons, specific sub-populations/patient cohorts can be handled in the following ways: (i) stratifying the episode group into mutually exclusive and exhaustive sub-groups to define more homogeneous patient cohorts, (ii) including as a variable in the risk adjustment model, (iii) excluding the sub-population from the measure, and (iv) monitoring and testing the sub-population for future consideration.

As a follow-up topic from the SAR webinar, the workgroup discussed how to address episodes in which the sepsis was acquired during the hospitalization. The Acumen team clarified that the claims-based approach for identifying the hospital-acquired sepsis cases is identifying episodes where the sepsis diagnosis doesn't have a "present on admission" modifier code on the triggering inpatient claim. The workgroup reviewed the benefits and drawbacks of various approaches:

(i) Leaving these cases as is retains the cohort and can hold providers accountable for those cases, though some clinicians may not have reasonable influence over the hospital-acquired infection.
(ii) Excluding these episodes removes a relatively small patient cohort of which many clinicians may not have reasonable influence; however, these cases will go unaccounted for.
(iii) Risk adjusting retains the cohort and reduces cost variation; however, this approach is meant for clinical risk factors outside of the reasonable influence of the attributed provider, and it may be the case that the clinician group does have reasonable influence over this.

One member mentioned that there may be cases where the patient acquired sepsis during the hospitalization and others where the patient came in for an infection (e.g., pneumonia) and the sepsis wasn't recognized until later, leading to possible heterogeneity within cases labeled as hospital-acquired. Another comment supported this assessment, stating that patients that develop sepsis after being admitted for another condition would be expected to have delayed recovery and may require additional post-discharge services (e.g., long-term care hospitalization). Upon review of data on sepsis episodes without the present on admission modifier, some workgroup members mentioned that hospital-acquired cases make up a small, heterogeneous sub-population and favored exclusion. A workgroup member expressed that the hospital should be held accountable for these hospital-acquired sepsis cases; however, based on the attribution of episodes to individual clinicians, it may be more reasonable to exclude these cases. Members generally weren't in favor of risk adjusting for hospital-acquired sepsis cases, and a member expressed concern with potentially excluding these cases from cost measurement. However, other members noted the small size of this sub-population and recommended exclusion.

The workgroup also discussed cases where the patient received interventional radiology (IR) abscess drainage in the 30 days before or during the sepsis hospitalization, which is another carryover topic from the SAR webinar. A member mentioned that the attributed clinician (e.g.,

hospitalist) has a lack of influence regarding whether the patient received the drainage before the hospitalization, though they may have influence when the drainage is during the hospitalization. Another member expressed support for retaining abscess drainage during the hospitalization in the measure, since it is a part of the treatment, like antibiotics. However, a separate member noted that IR abscess drainage could potentially spread around the bacteria. Workgroup members generally expressed interest in excluding cases where the drainage occurred in the 30 days prior and potentially risk adjusting for cases where the drainage occurs during the hospitalization.

In response to a cross-cutting field testing feedback item regarding Part D drugs, the workgroup discussed whether to risk adjust for episodes in which the patient had recent Part D antibiotic use prior to the hospitalization. The rationale in support of risk adjusting is that patients already on antibiotics may have had a progression of the infection and require more potent and potentially costlier antibiotics due to antibiotic-resistant organisms, which may lead to more serious complications. A member noted that there is a lack of available data in the literature to understand this topic, and another member advocated for risk adjusting over excluding this sub-population and narrowing the lookback period to a much shorter timeframe than the standard 120 days. Workgroup members recommended either around 7 or 30 days for the lookback period for this sub-population. Although the majority of Medicare beneficiaries have Part D coverage, some workgroup members did express some concern with this potential risk adjustor not being applied uniformly across Medicare beneficiaries with and without Part D enrollment if the risk adjustor was limited to Part D antibiotic use. (Due to this concern, the Acumen team can specify this potential risk adjustor for recent antibiotic use with Part D services as well as available antibiotic Current Procedural Terminology/Healthcare Common Procedure Coding System [CPT/HCPCS] codes to also capture beneficiaries not enrolled in Part D.) The Acumen team clarified that there is a risk adjustor for Part D enrollment itself.

The workgroup discussed whether episodes in which the patient had implanted hardware (e.g., knee replacement, metal heart valve) should be addressed separately. One workgroup member noted that this is a risk factor that could yield different treatment (e.g., longer antibiotic use). Upon questions from the workgroup, the Acumen team clarified that a potential sub-population for implanted hardware would look in the 120 days prior to the hospitalization for certain procedure or diagnosis codes that are indicative of the patient having implanted hardware. A member mentioned that this may be a very small sub-population of patients. Another member noted that this sub-population may include patients with shunts, spinal hardware, ports for chemotherapy, or tunneled dialysis catheter lines, and that these patients may be different relative to patients with bloodstream infections and no hardware. Based on the meeting discussion, the Acumen team added a question in the poll regarding whether to risk adjust for cases where the patient had implanted hardware.

<u>Key Takeaways from Discussion and/or Polls for Addressing Sub-Populations of Interest</u>:

- Members recommended to keep episodes with hospital-acquired sepsis (i.e., leave as is without risk adjustment), as there wasn't consensus reached on the alternative (i.e., excluding these episodes).
- Members recommended to exclude episodes in which the patient received IR abscess drainage in the 30 days prior to the sepsis hospitalization.
- Members recommended to risk adjust for episodes in which the patient received IR abscess drainage during the sepsis hospitalization.
- Members recommended to risk adjust for episodes in which the patient had recent antibiotic use (i.e., in the 30 days prior to the sepsis hospitalization).

- Members recommended that we don't risk adjust for cases in which the patient had implanted hardware (e.g., knee replacement, metal heart valve, spinal fusion) prior to the sepsis hospitalization.

2.2 Assigning Services to the Episode Group

The workgroup discussed some services that aren't currently part of the service assignment rules for the Sepsis measure. The service assignment topics that the workgroup discussed at this meeting include the following: (i) surgical removal of catheters due to infection, (ii) patient education and prevention training, and (iii) Part D drugs beyond antibiotics.

In response to feedback received during field testing, the workgroup discussed whether to assign the cost of services for the surgical removal of catheters due to infection. A member mentioned that if there is a patient being hospitalized for the surgical removal of an implanted catheter, then they're likely going to be receiving antibiotics and other services that would be captured by a readmission hospitalization (or observation stay); the workgroup discussion also noted that outpatient removals of catheters are also not likely to be surgical per se, and they likely don't occur very often.

In response to feedback received during field testing, the workgroup discussed whether to assign the cost of services for patient education and prevention training. A member mentioned that it would be worthwhile to assign the education/training for a variety of topics (e.g., peripherally inserted central catheter [PICC] lines, intravenous antibiotics, wound dressings). One member mentioned that patients hospitalized for sepsis usually get a treatment plan from the infectious disease clinician, which sometimes includes visiting nursing services for PICC line dressing. Based on the person and family perspective, the workgroup also discussed the challenges in communication for patients and their families regarding follow-up care, noting that communication with the infectious disease clinician often doesn't continue, whereas it may with the hospitalist. The workgroup also noted that there may not be applicable patient education and prevention training codes for the topics discussed (e.g., PICC lines).

Finally, the workgroup discussed whether there are any other Part D drugs beyond antibiotics that ought to be assigned in the post-trigger period. One member mentioned that it may be best to just focus on the infection treatment, and other members agreed. Some members noted that it may invite outlier cases to look beyond antibiotic treatment for infection, and other types of drugs are less likely to be ordered by an attributed clinician.

Key Takeaways from Discussion and/or Polls for Assigned Services:

- Workgroup members recommended we don't assign services for the surgical removal of catheters due to infection in the post-trigger period.
- Members recommended to assign services for patient education and prevention training for PICC lines/catheters and intravenous antibiotics at any time during the post-trigger period. (However, the Acumen team has found that there are currently no codes for this. Acumen will continue to monitor this area for future consideration.)
- Members recommended we don't assign services for any Part D drugs beyond antibiotics in the post-trigger period.

2.3 Potential Impacts of COVID-19 on Cost Measures

In this session, workgroup members had an open discussion regarding potential impacts of COVID-19 on the measure specifications and related considerations. A workgroup member noted that the cost and the amount of support that COVID-19 patients require can be very high

due to certain needs for intensive care (e.g., dialysis, ventilators for prolonged periods of time, tracheostomy, services for cardiomyopathy, etc.). This member also mentioned that we don't currently know the long-term complications of this virus (e.g., long-term care hospital utilization, respiratory failure readmissions), so it will be valuable to further consider the upfront costs as well as the downstream, post-acute care needs. A member mentioned it would be valuable to know what proportion of COVID-19 hospitalizations are being coded as sepsis. Members recommended potentially risk adjusting for these cases in the future based on the results and noted that excluding cases with COVID-19 may be a disservice. Another member observed that it's relatively recently that there has been consensus on guidelines for sepsis itself; learning from this, COVID-19 is very new, and we don't have much information on the virus or its long-term effects.

2.4 Next Steps

In the last session, Acumen provided an overview of the next steps. After the meeting, Acumen distributed the PFTR Webinar Poll to gather input from members on the discussions held during the webinar. The survey also consisted of open comment boxes to provide additional thoughts on quality measure alignment, future refinements based on potential impacts of COVID-19, and a space to share additional comments. Acumen will operationalize input for the measure specifications based on PFTR Webinar Poll results and will follow up with workgroup members with more information about the final steps in the measure development process.

3. Appendix: Overview of Workgroup Member Preparation and Shared Materials

3.1 Introduction

Section 3.2 provides an overview of materials shared with the workgroup members prior to the PFTR webinar, and Section 3.3 provides a recap of concepts of the measure development process presented by Acumen.

3.2 Overview of Meeting Materials

Prior to the meeting, workgroup members were provided with the following information to inform their discussions and votes:

- Agenda and Slide Deck, which was sent one week prior to the meeting and outlined the topics and process used for the webinar
- Sepsis Field Testing Feedback Summary, which provided the feedback received during field testing and the discussion topics and questions for the measure that were discussed at the webinar
- Investigation workbooks sent one week prior to the meeting, which presented detailed findings from empirical analyses:
    - An updated Sub-Population Summary Investigation Workbook, which provided updated data on the frequency and cost associated with an updated set of sub-populations, as recommended by the workgroup during the August 2019 in-person meeting and January 2020 SAR webinar
    - An updated Candidate Services Over Time Investigation Workbook, which contained updated information on frequency, cost, and timing for up to 200 of the most commonly performed services after a trigger event to inform discussions on service assignment and included the share of episodes where the service was assigned based on the service assignment rules

The materials shared were based on analyses run on triggering methodologies with the field testing version of the trigger codes and specifications, which were developed based on input from the August 2019 workgroup in-person meetings and January 2020 SAR webinars.

3.3 Overview of Cost Measure Development

At the beginning of the meeting, Acumen presented a very brief introductory session as a refresher on the following topics:

- The activities done to date since the previous convening of the workgroup, including the national field testing
- The goals of the meeting, including a session to gather workgroup members' thoughts on potential impacts of COVID-19 on measure specifications
- A recap on the different sources of information for the workgroup to consider in addition to their clinical expertise, including analyses and data, as well as the stakeholder input from field testing and the Person and Family Questionnaire