Summary of Technical Expert Panel (TEP) Meetings Diabetes Excess Days in Acute Care (EDAC)

October 2024

Prepared by:

Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE)

This material was prepared by CORE under contracts to the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy.

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Background

The Centers for Medicare & Medicaid Services (CMS) contracted Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation (CORE) to develop a measure of 30-day risk-standardized Excess Days in Acute Care (EDAC) following hospitalization for diabetes. The contract name is Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospitals and Eligible Clinicians, Hospital Base Period. The contract number is HHSM-75FCMC18D0042, Task Order HHSM-75FCMC24F0042.

While the CORE Diabetes EDAC measure development team is comprised of experts in quality outcomes measure development, CORE is obtaining expert and stakeholder input on the proposed measure. As is standard in the measure development process, CORE convened a Technical Expert Panel (TEP) of clinicians, patients, patient advocates, and other stakeholders. Collectively, TEP members brought expertise in clinical content; performance measurement; coding and informatics; quality improvement; hospital administration; and patient and caregiver experience.

This report summarizes the feedback and recommendations received from the TEP during three TEP meeting. The first TEP meeting (December 7th, 2023) focused on the Diabetes EDAC measure's cohort definition. The second TEP meeting (February 15th, 2024) focused on discussion of current options for the Diabetes EDAC cohort definition. The third TEP meeting (August 6th, 2024) focused on risk variable selection and further measure specifications. In addition to the TEP meeting feedback, results from the TEP Surveys seeking feedback on draft diabetes cohort measure specifications conducted after the first TEP meeting are included in the report.

Measure Development Team

Doris Peter, PhD, leads the measure development team for the Diabetes EDAC measure, and Mariel Thottam, MS, BCBA and Roisin Healy, BA lead Stakeholder Engagement for the Diabetes EDAC measure. The remainder of the measure development team provides a range of expertise in outcome measure development, health services research, clinical medicine, statistics, and measurement methodology. See <u>Appendix A</u> for the full list of CORE Diabetes EDAC Measure Development Team members.

The TEP

In alignment with the CMS Measures Management System (MMS), and due to a compressed timeline in completing Diabetes EDAC measure development and testing, CORE, with CMS approval, opted to take a pragmatic approach and reconvene the Risk Model Respecification

(RMR) TEP that previously held a 30-day public call for nomination. CORE solicited prospective TEP members via emails to individuals and organizations previously part of the RMR TEP and utilized Rainmakers Strategic Solutions LLC to obtain patient and caregiver candidates through structured interviews. The Yale CORE team sent a comprehensive recruitment request to the Rainmakers team, outlining specific criteria such as the Person and Family Engagement (PFE) partner characteristics, timeline expectations, and diversity requirements. The Rainmakers team identified potential candidate bios from their internal network and shared them with the Yale CORE team. After careful review of the potential candidate bios, the team selected candidates for interviews, which were conducted in a structured manner. Through this process, candidates meeting the outlined criteria were successfully identified, recruited, and onboarded. Ultimately, the TEP consisted of 14 members, listed in Table 1.

The role of the TEP is to provide feedback and recommendations on key methodological and clinical decisions; their specific responsibilities are outlined below. The appointment term for the TEP is from September 2023 to January 2025.

Specific Responsibilities of the TEP Members

- Complete and submit TEP Nomination Form
- Review background materials provided by CORE prior to each TEP meeting
- Attend and actively participate in TEP conference calls
- Provide input on key clinical, methodological, and other decisions
- Provide feedback on key policy or other non-technical issues
- Review the TEP Summary Report prior to public release
- Be available to discuss recommendations and perspectives following TEP meetings and public release of the TEP Summary Report to CMS

Name and Credentials	Organization (if applicable) and Role	Location
Rosie Bartel, MA	PFANetwork, PFCCPartners; Person Family Engagement Partner	Chilton, WI
Ann Borzecki, MD, MPH	VA Bedford Healthcare; Physician- Investigator	Bedford, MA
Jean Boyer	Person Family Engagement Partner	Picayune, MS
Sophia Brasil, MPH	Stratis Health; Senior Data Analyst	Boise, ID

Table 1. TEP Member Name, Affiliation, and Location

Name and Credentials	Organization (if applicable) and Role	Location
Steven Coffee, MA, EM CQSL	Headquarters U.S. Cyber Command, Patients for Patient Safety, U.S., Head2HeartConnections, LLC; Colonel, USAF Director, Military Personnel, Patient Advocate/Caregiver	Dumfries, VA
Craig Davies	Person Family Engagement Partner New Orleans, LA	
Michael Duan, MS	Premier, Inc.; Principal Data Scientist	Charlotte, NC
Sachin Shah, MD, MPH	Massachusetts General Hospital, Harvard University; Physician; Clinical Researcher	Boston, MA
Donté Smith	Legacy Community Health; Person FamilyEngagement Partner, Caregiver/PatientHouston, TXNavigatorNavigator	
Brian Stein, MD, MS	Rush University Medical Center; Physician and Chief Quality Officer	Chicago, IL
Mary Vaughan- Sarrazin, PhD	University of Iowa Department of Internal Medicine, VA Medical Center; Associate Professor, Department of Internal Medicine	lowa City, IA
Bonnie Weiner, MD, MSEC, MBA, MSCAI, FACC, FAHA, DNBPAS	Saint Vincent Hospital, Worcester Medical Center, Accreditation for Cardiovascular Excellence; Physician and Director – Interventional Cardiology; Associate Program Director of Cardiovascular Medicine Fellowship; Chief Medical Officer at Accreditation for Cardiovascular Excellence Inc.	Harvard, MA
	Prior TEP Members	
Matt Cheung, PhD, RPh Dates of TEP service: 2023-2024	University of the Pacific, Thomas J Long School of Pharmacy (part-time); Adjunct Professor of Pharmacy Practice, Independent Consultant (Medical Reviewer, Patient/Stakeholder Research Partner)	Gatos, CA

Name and Credentials	Organization (if applicable) and Role	Location
	University of Chicago Medicine	
Ryan Merkow, MD, MS	Comprehensive Cancer Center and Cancer	
	Service Line, Department of Surgery;	
Dates of TEP service:	Director for Surgical Cancer Quality,	Chicago, IL
2023-2024	Associate Director of Health Services	
	Research, Director Hepatic Artery Infusion	
	Pump Program	

TEP Meetings

CORE's Diabetes EDAC team held its first TEP meeting on December 7, 2023. Topics of discussion specific to Diabetes EDAC included options for the diabetes cohort definition (see <u>Appendix B</u> for the TEP meeting schedule).

CORE's Diabetes EDAC team held its second TEP meeting on February 14, 2024. Topics specific to Diabetes EDAC included discussion of the revised cohort for the Diabetes EDAC measure.

CORE's Diabetes EDAC team held its third TEP meeting on August 6, 2024. This TEP meeting provided a brief refresher for EDAC methodology, and continued measure specification discussion, specific to Diabetes EDAC risk variable selection and results.

This summary report includes a summary of the first, second, and third TEP meetings.

TEP meetings follow a structured format consisting of the presentation of CORE's measure development activities, as well as CORE's proposed approach, followed by an open discussion by the TEP members.

First TEP Meeting Overview

Prior to the first TEP meeting, TEP members received detailed meeting materials outlining the measure background and proposed approach for the development of the Diabetes EDAC cohort.

During the first TEP meeting: CORE provided an update about the development activities CORE has conducted so far and solicited the TEP's feedback on options for the Diabetes EDAC cohort.

The following bullets represent a **high-level summary** of what was presented and discussed during the first TEP meeting specific to the Diabetes EDAC measure. For further details, please see <u>Appendix C</u>.

EDAC Measure Background

• CORE provided an overview of the EDAC measure methodology, including: background information on the development of the EDAC measures; how the EDAC outcome is calculated; and EDAC inclusion and exclusion criteria.

Diabetes EDAC Cohort Definition

• CORE reviewed the goals and considerations for the new Diabetes EDAC measure cohort development, noting the goal of the measure was to improve care for patients

hospitalized **for** (not **with**) diabetes; considerations include preventing overlap with other EDAC cohorts to avoid double counting, and trying to balance between measuring quality for people hospitalized **for** diabetes versus those that have sequelae of uncontrolled diabetes (complications of uncontrolled diabetes that are not always caused by diabetes).

- CORE's approach to cohort development included review of existing measures and literature for inclusion/exclusion criteria and specific codes used for inclusion; review of an existing "grouper" that gathers diabetes diagnoses together, such as the Agency for Health Research and Quality's (AHRQ's) Clinical Classification Software (CCS); and exploratory analyses using the Hospital-Wide Readmission (HWR) measure data (July 1, 2021 – June 30, 2022 Medicare FFS admissions), to explore diabetes coding practices, initial cohort definition, estimation of cohort size, observed outcomes for unplanned readmission, and estimation of overlap with existing EDAC cohorts (AMI, HF, and pneumonia).
 - Codes for diabetes with complications are grouped together (CCS50)
 - Codes for diabetes without complications are in a separate group (CCS49)
- CORE reviewed the results of exploratory analyses and two initial options for the TEP's consideration:
 - Option 1: A more narrowly defined cohort that includes admissions for 1) a principal diagnoses of diabetes with complications (CCS50), and 2) amputation procedures (CCS157) with a secondary diagnosis of diabetes with complications (CCS50) (noting that admissions with a principal diagnoses are captured in the first part of the cohort; pros include the measure provides a quality signal for patients hospitalized **for** diabetes, it does not overlap significantly with other EDAC cohorts, and it does not include sequelae, while the cons are that the measure would be missing admissions for people with sequelae (but would still capture amputations).
 - Option 2: A more broadly defined cohort that also includes the criteria #1 and #2 above and adds a third criterion: admissions for patients with only a secondary diagnosis of diabetes with complications (CCS50) that have a principal diagnosis of diabetes sequelae. The pros include that the measure would capture admissions for all people with diabetes, while the cons include that: the measure's cohort would overlap with the cohort of other existing EDAC measures (in particular HF), diabetes sequelae are not definitively caused by poor diabetes management, and there is no gold standard for what to include as diabetes sequelae. CORE noted that outcomes for these patients are already captured in the HWR measure.

- CORE shared an Excel file with additional details of the exploratory analyses (specific code definitions and their related frequency and readmission rates) along with the TEP materials distributed prior to the meeting.
- CORE shared that the projected cohort sizes for a measure combining both cohorts, for a 2-year and 3-year measure were 392,492 and 588,738, respectively (assuming addition of MA patients), and the observed readmission rate (based on Medicare FFS patients only) was 18.8%; approximately 10% of principal diagnosis codes considered diabetes complications overlap with the HF EDAC measure cohort.
- CORE considered if additional diabetes-specific exclusions should be considered, beyond those already in the standard EDAC definition, and none were identified.
- CORE proposed the following Diabetes EDAC cohort inclusion/exclusion criteria:
 - Inclusion criteria:
 - Medicare FFS and MA patients
 - Aged 65 and over
 - Admitted to an acute care hospital with:
 - (1) Principal diagnosis of CCS50 "Diabetes with Complications;" or
 - (2) Procedure with CCS157 "Amputation" and a secondary diagnosis of CCS50 "Diabetes with Complications"
 - Exclusion criteria:
 - Discharged against medical advice
 - Without at least 30 days post-discharge enrollment
 - Admission for the same condition or procedure (diabetes with complications or diabetes-related amputation) within 30 days of a prior diabetes index admission
 - With a principal diagnosis code of COVID-19 (ICD-10-CM code U07.1) or with a secondary diagnosis code of COVID-19 coded as present on admission (POA) on the index admission claim

Key Questions & TEP Discussion

• TEP members responded to the following questions, providing specific feedback about the proposed EDAC measures in development.

Question 1: Do you have any initial concerns with any of the diabetes inclusion/exclusion criteria?

• TEP participants noted the following concerns regarding the proposed diabetes inclusion/exclusion criteria:

- Several participants expressed concerns about the coding reliability and "muddy" coding scenarios (such as an admission for ketoacidosis that could result from urinary tract infection/sepsis, or stroke with blood glucose control challenges), and there might be less concordance because of variation in billing for complex cases with multiple problems (the population of people with diabetes tends to have multiple comorbidities).
 - Coding tends to be more reliable for procedures than conditions, and use of chart review to validate a sample of cases was recommended to ensure the claims adequately match what is in patients' charts.
 - A TEP participant recommended exploring whether AHRQ has already done chart review to validate CCS.
 - CORE noted they would review literature to identify studies that utilized chart validation of the CCS codes related to diabetes.
 - TEP participants noted hospital coding practices to maximize reimbursement, such as use of software to order diagnoses to maximize the diagnosis-related group (DRG), represent financial incentives that could create bias.
 - CORE noted hospital coding practices to keep a patient out of a measurement cohort was another potential source of bias.
- The TEP asked about the use of CCS rather than Clinical Classification Software Refined (CCSR).
 - CORE explained CCS was better for identifying chronic conditions like diabetes, as diabetes falls within a broader category "endocrine diseases" in the CCSR.
- The TEP seemed to reach some consensus (confirmed by a post-TEP survey in <u>Appendix D</u>) that a narrower approach to defining the measure cohort (emphasizing principal diagnoses in CCS50) would be the most practical approach, as it would prevent overlap with other EDAC cohorts and result in cleaner cohort definition.
 - The TEP expressed concern about the complexity of risk modeling for the heterogeneous measure (including both admissions for diabetes and for amputation); and about including only amputations and no other procedures common to patients with diabetes, such as revascularization.

Second TEP Meeting Overview

Prior to the second TEP meeting, TEP members received:

- TEP presentation materials;
- Supplemental materials including EDAC measure score calculation and interpretation analogies, simplified examples of analytic terms used in CORE presentations, and administrative materials; and
- Additional attachments:
 - **Diabetes Cohort Definition**: counts and observed outcomes for admissions used for diabetes cohort definition.
 - **Diabetes Cohort Responses from EDAC Post-First TEP Survey**: de-identified survey results from post-first TEP Survey.

During the second TEP meeting: CORE provided an update about development and testing activities since the first TEP meeting; solicited the TEP's feedback on a revised approach to the Diabetes EDAC cohort.

The following bullets represent a **high-level summary** of what was presented and discussed during the second TEP meeting. For further details, please see <u>Appendix E</u>.

EDAC Measure Background

• CORE provided an overview of the EDAC measure methodology, including: background information on the development of the EDAC measures; how the EDAC outcome is calculated; and EDAC inclusion and exclusion criteria.

Diabetes EDAC Revised Cohort & Discussion

- CORE provided a recap of the discussion from the first TEP meeting, shared results of the post-first TEP survey and communications, reviewed additional cohort validation analyses, and shared TEP-provided recommendations to further refine the Diabetes EDAC cohort definition.
- CORE reviewed the narrow cohort definition presented during the first TEP meeting, which included admissions having a principal discharge diagnosis in CCS50 (diabetes with complications), or amputations (CCS157) and a secondary diagnosis in CCS50.
- CORE described a new refined version of the narrow approach, recommended by a TEP member, which removes admissions with amputations (CCS157) with a secondary diagnosis within CCS50 (diabetes with complications). Therefore, the new cohort definition is limited to admissions with a principal diagnosis of diabetes.

- CORE presented analyses that identified the admissions that would no longer be included and a clinical comparison of the subgroups.
- CORE then polled the TEP members on: Which of the two cohort options ("narrow" or "refined narrow") is the most appropriate for the Diabetes EDAC measure?
 - The majority of TEP members voted for the **refined narrow** Diabetes cohort definition (9 of 11) versus the narrow Diabetes cohort definition (2 of 11). The rationale for the refined narrow Diabetes cohort definition was that:
 - not all amputations are due to diabetes (even when a secondary diagnosis in CCS50 is present);
 - the patient population admitted primarily for amputation represents a different patient population;
 - it results in a cleaner, more homogeneous cohort with better measure specificity;
 - it maintains a focus on patients admitted for diabetes; and
 - it allows for targeted, condition-specific intervention to improve quality of care.
 - Those who favored the **narrow** Diabetes cohort definition cited concerns about potentially excluding very sick patients having amputations due to poorly controlled diabetes from the cohort.
 - The TEP asked questions about:
 - coding practices related to principal discharge diagnoses and consistency of coding;
 - other clinical scenarios, besides diabetes and infection, leading to amputations being performed;
 - potential for public reporting of the new Diabetes EDAC measure for small hospitals; and
 - amputation procedures occurring without vascular assessment, potentially resulting in surgery where non-surgical intervention might have been possible.
 - A TEP member offered a suggestion for future analyses, specifically to evaluate the distribution of claims with amputation procedures remaining in the Diabetes EDAC cohort.
- The TEP expressed additional thoughts about quality measurement for diabetes:
 - A TEP member commented about the importance of having diabetes measures for other outpatient settings in addition to the hospital measure, as outpatient clinicians are primarily responsible for the management of diabetes.

- A TEP member noted challenges to accessing post-discharge services (e.g., home health, skilled nursing facility [SNF]) in rural areas likely increases readmission and excess days.
- A TEP member noted that including both Readmission and EDAC measures in the same program would result in double counting.

Third TEP Meeting Overview

Prior to the third TEP meeting, TEP members received:

- TEP presentation materials;
- Supplemental materials describing the risk variable selection process and various terms used within the third TEP presentation; and
- Additional attachments:
 - Diabetes EDAC Risk Variable Results.xlsx.

During the third TEP meeting: CORE provided a brief overview of EDAC measure methodology; decisions made on the Diabetes EDAC cohort during the first and second TEP meetings; and reviewed risk variable selection results and solicited the TEP's feedback on those results.

The following bullets represent a **high-level summary** of what was presented and discussed during the third TEP meeting. For further details, please see <u>Appendix F</u>.

EDAC Measure Background

- CORE provided an overview of the EDAC measure methodology, including: background information on the development of the EDAC measures; how the EDAC outcome is calculated; and general EDAC inclusion and exclusion criteria.
- CORE noted that the measure outcome includes all eligible events within a 30-day period, including readmissions, emergency department visits, and observation stays, with emergency visits counted as one day each and observation stays rounded to the nearest integer. The measures, which are risk-adjusted for demographic factors and comorbidities, cover both Medicare fee-for-service and Medicare Advantage beneficiaries.
- The current work on the Diabetes EDAC measure is focused on identifying risk variables and assessing model performance.

Diabetes EDAC: Background & Decisions Made During First and Second TEP Meetings

- CORE described the rationale for including only admissions with a principal diagnosis of diabetes with complications (AHRQ CCS50) in the Diabetes EDAC cohort.
 - Pros: This approach is pragmatic for identifying the cohort, focuses on care for patients hospitalized for diabetes, creates a homogenous cohort, and does not overlap with other EDAC measures.
 - Cons: It might be desirable to capture care for all hospitalized diabetes patients, it leaves subsets of admissions unmeasured (e.g., those with a principal diagnosis of infection or secondary diabetes complications), and the cohort size is relatively small.
- CORE compared the Diabetes EDAC cohort size (2-year projection = 344,286, 3-year projection = 516,429) with those of COPD, CABG, and THA/TKA EDAC measures. The Diabetes EDAC cohort size is similar to the THA/TKA cohort, larger than the CABG cohort, and smaller than the COPD cohort.
- CORE presented the unadjusted measure score distribution for the Diabetes EDAC, and noted that the outcome is primarily driven by readmission days.

Diabetes EDAC Risk Variable Selection

- CORE provided an overview of the Diabetes EDAC risk variable selection process and emphasized the importance of risk adjustment for fair hospital comparisons by accounting for differences in patient risk/case mix; for example, for hospitals that perform more amputations (which is associated with higher risk of the EDAC outcome).
- Risk adjustment for the Diabetes EDAC measure uses claims data variables associated with outcomes with available data coming from billing records, including diagnosis codes, comorbidities, age, sex, and frailty.
- The CORE team used an empiric method for identifying risk variables by focusing on individual codes for precision using data from the index hospitalization in addition to the previous 12 months.
- More than a thousand codes were initially identified, which were then narrowed by applying frequency thresholds, and combining codes. Finally, using a statistical method (bootstrapping) CORE identified variables significantly associated with the outcome.

Diabetes EDAC Measure Risk Variable Selection Results

- CORE explained the risk variable selection results.
 - The selection process involved frequency thresholds, combining codes, and bootstrapping methods, starting with 1,200-1,300 codes, reducing to 661, and finally identifying 46 significant variables.

- This list does not yet include consideration of additional variables like frailty, COVID adjustments, and social risk factors, which we will test after examining clinical risk factors.
- CORE addressed questions and feedback from TEP members regarding the selection and combination of variables, including issues related to specific codes such as "encounter for palliative care" and "do not resuscitate" (DNR), as well as concerns about capturing different patient populations like those with chronic kidney disease or long-term HIV survivors.
- The discussion highlighted the importance of statistical methods in variable selection, the potential need for separate measures for different patient groups, and the consideration of additional claims data or adjustments for variables like DNR status.
- Participants provided feedback on the candidate variables, with overall approval of the selection process and the final list of variables. They noted adequacy and practicality for understanding and treating diabetes-specific issues.
- Concerns were raised about the absence of certain variables like myocardial infarction codes and the variability in coding practices for DNR status, with some suggestions for further analysis and refinement of the model to ensure it accurately reflects patient care and outcomes.
- CORE addressed the issue of inclusion of patients with amputations by analyzing model calibration. The team showed that the risk model works similarly for patients with and without amputations, and shared graphs comparing outcomes for all admissions, admissions with amputations, and admissions without amputations.
 - Participants inquired about the inclusion of interventional procedures like revascularizations in the current CCS used for the model, noting their prevalence over amputations. One TEP member suggested that using amputations might not be appropriate as it represents a worst-case scenario and proposed peripheral atherosclerosis-related conditions as a better grouping variable.
 - The discussion highlighted whether all revascularization procedures are included in the CCS Grouper and emphasized that amputation is a last resort, with many patients undergoing limb salvage procedures.
 - TEP members suggested adding a CCS code to capture revascularization procedures and to conduct a calibration plot on these patients, since there are differences between populations and their impact on models.
 - CORE mentioned that they will examine the inclusion of revascularization procedures further and consider separate cohorts for surgical patients in other measures.

Key Questions & TEP Discussion

• TEP members responded to the following questions, providing specific feedback about the proposed risk variables for the Diabetes EDAC measure.

Question 1: Please provide your feedback on the risk variable selection process: Are there any parts of the process that need to be clarified? Do you have any feedback on the process?

- TEP participants noted the following regarding the risk variable selection process:
 - Consideration of separating out patients with type 1, type 2, and other types of diabetes for separate analysis; and
 - Consideration of adding prior admissions as a risk variable.

Question 2: Please provide your feedback on the list of candidate variables. Do you feel that the variables selected up to this point make sense (you would expect them to be associated with greater or lesser risk of EDAC for patients hospitalized for diabetes)?

- TEP members noted the following concerns regarding the proposed risk variables and the impact on the risk model:
 - Risk variables selected show two distinct populations, one with ischemic gangrene and vascular disease, and the other with hyperglycemia;
 - That patients hospitalized from a nursing home may impact the risk model;
 - Differences between type 1, type 2, and other types of diabetes; and
 - DNR status and variability in coding.

Question 3: Are there additional risk variables that you think should be considered?

- TEP members noted the following additional risk variables to consider:
 - Acute myocardial infarction or other cardiac-related codes;
 - ICD-10 code, Z794, long term use of insulin;
 - Other conditions (i.e., cancer, HIV, chronic kidney disease) that may impact the risk model; and
 - Other procedural CCSs (outside of amputation).

Appendix A. CORE Measure Development Team

Name	Role
Doris Peter, PhD	Team Lead
Jon Niederhauser, MPH, MSW	Project Coordinator
Kashika Sahay, PhD, MPH	Project Division Lead
Katie Balestracci, PhD, MSW	Associate Director
Lana Aldos, MSPH	Research Support
Kerry McDowell, M.Phil.Ed., M.S.Ed.	Project Manager
Lisa Suter, MD	Contract Director of Quality Measurement Programs
Mariel Thottam, MS, BCBA	Stakeholder Engagement Co-Lead
Roisin Healy, BA	Stakeholder Engagement Co-Lead
Jacqueline Grady, MS	Analytic Director, Subject Matter Expert (SME)
Zhenqiu Lin, PhD	Senior Director of Healthcare Analytics, Subject Matter Expert (SME)
Huihui Yu, PhD	Analyst, Subject Matter Expert (SME)
Jin Cho, PhD	Analyst
Yahui Tian, PhD	Analyst

Center for Outcomes Research and Evaluation (CORE) Team Members

Appendix B. TEP Call Schedule

First TEP Meeting

Thursday, December 7, 2023, 4:00 – 6:00PM EST (Zoom Teleconference)

Second TEP Meeting

Thursday, February 15, 2024, 3:00 – 5:00 PM EST (Zoom Teleconference)

Third TEP Meeting

Tuesday, August 6, 2024, 4:00 – 6:00 PM EST (Zoom Teleconference)

Appendix C. Detailed Summary of First TEP Meeting

New Excess Days in Acute Care (EDAC) Technical Expert Panel (TEP) Meeting #1 Minutes

Thursday, November 7, 2023, 4:00 – 6:00 PM ET

Participants

- Yale New Haven Health Services Corporation Center for Outcomes Research and Evaluation (YNHHSC/CORE): Katie Balestracci, Melinda Bateman, Jin Cho, Darinka Djordjevic, Jackie Grady, Roisin Healy, Stephanie Lambert (X4 Health), Zhenqiu (ZQ) Lin, Kerry McDowell, Jon Niederhauser, Doris Peter, Ruihan Qin, Kashika Sahay, Lisa Suter, Mariel Thottam, Ariel Williams, Si Zhou
- Technical Expert Panel (TEP) Participants: Rosie Bartel, Ann Borzecki, Sophia Brasil, Matt Cheung, Craig Davies, Michael Duan, Sachin Shah, Donté Smith, Brian Stein, Mary Vaughan-Sarrazin, Bonnie Weiner

Executive Summary

- The purpose of the first Excess Days in Acute Care (EDAC) Technical Expert Panel (TEP) meeting was for the Yale New Haven Health Services Corporation Center for Outcomes Research (CORE) team to share with the TEP the EDAC measure background & history; and review potential cohort inclusion/exclusion criteria for the proposed Diabetes EDAC measure.
- The TEP members shared reservations regarding the EDAC outcome, such as including 30-day length of follow up, dichotomous outcome vs. length of stay for the readmission, need to weigh types of stays, access-to-care barriers, and the "all-cause" readmission criteria.
- The TEP members reviewed the diabetes cohort pros and cons, with majority of TEP members favoring the narrow cohort, and a recommendation for further validation of coding practices and characterization of the cohort. Additional questions were posed on if the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (CCS) is the best grouper for diabetes or if CORE should use Hierarchical Condition Categories (HCC) or some other grouper to validate the most clinically and reimbursable accurate cohort that truly represents diabetic patients.
 - The TEP members completed a post-TEP survey following the first TEP meeting, and stated the following for the narrow vs. broad cohort definition:
 - 8 respondents were in favor of narrow definition

- 2 respondents were in favor of broad definition
- 1 respondent was in favor of "other", commenting agreement with narrow definition, but to "just use principal for diabetes with complication and not use secondary codes to identify the cohort."
- The TEP participants commented about the noisiness in the COPD cohort and stated concern about whether coding can accurately capture the cohort of patients for the measure.

TEP Action Items

- TEP members were asked to complete the <u>doodle poll</u> for the second EDAC TEP meeting by December 22, 2023.
- TEP members were encouraged to complete the evaluation survey, to be provided by CORE the week of December 11, 2023, to be completed by December 22, 2023.
- TEP members were invited to email <u>jon.niederhauser@yale.edu</u> with any additional comments and suggestions.

CORE Action Items

- CORE will identify studies that have analyzed billing codes and patient's charts to validate feasibility of using CCS codes for Diabetes EDAC cohort definition.
- CORE will send the agenda and meeting materials for the second TEP meeting in late January or early February 2024.
- CORE will convene the second EDAC TEP Meeting in early- to mid-February 2024.
- CORE will distribute meeting summaries for the first TEP meeting and the second TEP meeting, for the TEP's review, following the second TEP meeting.

Detailed Discussion Summary

Welcome & Introductions

- Ms. Roisin Healy welcomed the TEP members, introduced herself as a CORE Stakeholder Engagement Lead, provided instructions about the meeting controls for closed captioning, provided participation guidelines and ground rules for the discussion, shared details about the specific CMS funding source supporting this work, and reminded members about the confidentiality of meeting materials and discussion (until they are made public by CMS).
- Mr. Jon Niederhauser shared (in chat) definitions for the acronyms likely to be referenced in the discussion:
 - The Centers for Medicare & Medicaid Services (CMS)

- Excess days in acute care (EDAC)
- Ms. Healy provided an overview of the EDAC project, including development of a cohort definition for Diabetes.
- Mr. Niederhauser introduced himself as the CORE EDAC Project Coordinator, discussed meeting goals and objectives, shared details of the New EDAC measure development timeline, and outlined content overview for the first TEP meeting and the second TEP meeting.
 - He noted the goal of these TEP meetings is to obtain perspectives through professional input and lived experience to provide feedback to inform development of the cohort for the Diabetes EDAC measure.
 - He noted the objectives were to ensure TEP understanding of EDAC measures, review initial results, and request TEP member feedback.
- Ms. Healy reviewed the meeting agenda, including:
 - welcome &introductions;
 - review and approval of the TEP Charter;
 - EDAC measure background & history;
 - Diabetes EDAC cohort inclusion/exclusion criteria & discussion;
 - additional discussion as needed; and
 - o next steps
- Ms. Healy outlined the speakers for the TEP meeting including herself, Dr. Doris Peter (EDAC Project Lead), and Mr. Niederhauser (EDAC Project Coordinator).
- Ms. Healy acknowledged the additional CORE team members working on the EDAC project; those on the CORE Stakeholder Engagement (SE) team participating in the call to assist with responding to the TEP members' questions that arise within the discussion; potential CMS staff that may attend the meeting, and an expert clinical consultant who have supported the CORE team in development of the proposed measure including Dr. Rozalina McCoy, an Endocrinologist.
- Ms. Healy asked the TEP members to introduce themselves by providing their name, role, what interests them in the TEP, and any changes in conflicts of interest (COI). She reminded the TEP members they represent themselves and not their nominating organizations.
 - Ms. Rosie Bartel noted she works primarily as a Patient Partner, a Caregiver, and an Educator; she is here because she has received four THA/TKA procedures with three of those going well and one having complications. She noted no changes in her COI.
 - Dr. Ann Borzecki noted she is a Physician-Investigator working for the Department of Veterans Affairs (VA) Bedford Healthcare System, conducting

research focused on validation of performance and quality measures, including AHRQ measures. She noted she has no COI.

- Ms. Sophia Brasil noted she is a Senior Research Analyst affiliated with Stratis Health and has experience working in Quality Improvement Organizations.
- Dr. Matt Cheung noted he serves in multiple roles including as a pharmacist who has worked in teaching hospitals on quality improvement. His work has focused on patient outcomes and the use of drugs in the inpatient setting. He noted he represents patient engagement efforts with regards to working on two research projects funded by the Patient-Centered Outcomes Research Institute (PCORI). He noted no COI.
- Mr. Craig Davies noted he is a Person Family Engagement Partner and a Caregiver for his dad, who has been hospitalized with COPD and has a history of readmission in Louisiana.
- Mr. Michael Duan noted he is a Principal Data Scientist for Premiere, Inc. who has 20 years of healthcare experience, and is interested in measure development and risk adjustment model development. He notes that though Premiere, Inc. provides healthcare data solutions, he only represents himself on the TEP.
- Dr. Sachin Shah noted he is a Physician and Clinical Researcher who cares for people in the hospital admitted with these [COPD, CABG, THA/TKA, Diabetes] conditions and he hoped to provide a physician perspective from the hospital setting.
- Mx. Dontè Smith noted they are a Patient Navigator and Caregiver for their uncle who is living with type 2 diabetes.
- Dr. Brian Stein noted he is the Chief Quality Officer for Rush System for Health in Chicago. He is also a Pulmonary and Critical Care Physician. He noted his interest in joining comes from his current work with quality metrics at Rush System for Health. He noted no COI.
- Dr. Mary Vaughan-Sarrazin noted she is an Associate Professor at the University of Iowa Department of Internal Medicine with a background in health management and policy. She has used claims data including Medicare data in her research career spanning nearly 25 years and is interested in risk adjustment and how we measure quality performance, compare hospital outcomes, and consider disparities by region and patient subgroup.
- Dr. Bonnie Weiner noted she is a Professor of Medicine at the University of Massachusetts and an Interventional Cardiologist at St. Vincent Hospital. She is also the Chief Medical Officer for Accreditation for Cardiovascular Excellence and has no COI.

Review and Approval of TEP Charter

- Ms. Healy reviewed the TEP Charter, including the responsibilities of TEP members.
 - TEP members voiced no concerns and the TEP Charter was unanimously approved.

EDAC Measure Background & History

- Dr. Peter introduced herself as the Project Lead and noted the return of several TEP members that previously participated in the Risk Model Respecification (RMR) TEP, and encouraged an interactive discussion where participants speak up throughout the meeting as questions might arise.
- Dr. Peter reviewed the measure background and history, by first providing a definition
 of the EDAC measure, which CORE developed, and CMS implemented, to supplement
 several 30-day all-cause readmission measures for certain conditions (e.g. heart failure
 [HF], pneumonia, and acute myocardial infarction [AMI], CABG, COPD, and THA/TKA).
 Dr. Peter noted that further measure background slides were available in Appendix 1,
 and the supplemental materials.
 - The EDAC measures (specifically AMI, HF, and pneumonia) were developed to address concerns that readmission measures did not capture a full picture of acute care as they were missing emergency department (ED) and observation stays.
 - The EDAC measures used the same cohort and risk adjustment as readmission measures and capture broader utilization following an index hospitalization, including:
 - unplanned inpatient readmissions;
 - ED visits; and
 - observation stays.
 - The EDAC measures are calculated for short-term acute care hospitals, including critical access hospitals (CAHs). Current EDAC measure development includes both the Medicare Fee-for-Service (FFS) and Medicare Advantage (MA) aged 65 and older populations, and have cohort-specific inclusion and exclusion criteria:
 - Inclusion criteria are general enrollment + condition/procedure specific diagnosis codes.
 - Exclusion criteria are general enrollment population sizes, patients readmitted due to COVID and consider deduplication (or those already counted within other inclusion criteria EDAC measures).

- Dr. Peter noted slide 55 in Appendix 1 outlines conditions and procedurespecific inclusion and exclusion criteria for the EDAC measures of focus during this TEP meeting.
- The EDAC measures' risk adjustment includes demographic factors and comorbidities from the corresponding readmission measures.
- The EDAC measure score is a ratio of predicted over expected utilization and represents the number of days the patient spends in acute care within 30 days after the date of discharge from the index admission for any cause. She compared the readmission measure and EDAC measures, stating that the readmission measure captures a binary (yes/no) of whether a readmission occurred, and the EDAC measure goes further because it captures days of acute care. For example, ED visits are counted as one day each and observation stays are recorded in terms of hours and rounded up to the nearest integer of days. All outcomes occurring within 30 days are counted and if there were three ED visits, they would all be included. Planned readmissions, such as for planned follow up or chemotherapy, are not counted. In summary,
 - All eligible outcomes occurring in the 30-day period are counted, even if they are repeat occurrences;
 - ED visits are counted as 1 day each;
 - Observation stays are recorded in hours and rounded up to the nearest integer of days; and
 - Planned readmissions are not counted.
- Dr. Peter noted interpretation of the EDAC measures scores, with a ratio greater than one being interpreted as worse performance, and a ratio less than one interpreted as better performance.
- Dr. Peter noted for Diabetes EDAC, as there is not a corresponding readmission measure, the CORE team is focused on the cohort definition for the New Diabetes EDAC measure.

Diabetes EDAC Cohort Inclusion/Exclusion Criteria

- Dr. Peter reviewed the goals and considerations for the New Diabetes EDAC measure.
 - The goal of the measure is to improve care for patients hospitalized for (not with) diabetes.
 - The CORE team's project goal is to specify the measure cohort.
 - Considerations include preventing overlap with other EDAC cohorts to avoid double counting, and trying to balance between measuring quality for people who are hospitalized for diabetes versus those hospitalized that have sequelae

of uncontrolled diabetes (complications of uncontrolled diabetes that are not always caused by diabetes).

- Dr. Peter noted the CORE team's approach to cohort development included:
 - Review of existing measures and literature for inclusion/exclusion criteria and the specific codes used for inclusion;
 - Review of existing "grouper" that gathers diabetes diagnoses codes together (i.e., AHRQ CCS).
 - Diabetes with complications codes are grouped together (CCS50)
 - Diabetes without complications codes are in a separate group (CCS49)
 - Exploratory analyses using the Hospital-Wide Readmission (HWR) measure data and Medicare FFS claims data from July 1, 2021 – June 30, 2022, to explore coding practices; initial cohort definition; estimation of cohort size; observed outcomes for unplanned readmissions; and estimation of overlap across the diabetes, HF, pneumonia, and AMI EDAC cohorts.
- Dr. Peter reviewed the results of the diabetes exploratory analyses. She noted Dr. McCoy (CORE's contracted diabetes clinical consultant) recommended including claims for Amputations (CCS157) having a principal or secondary diagnosis in CCS50 in the cohort.
 - The projected cohort size for admissions (Medicare FFS and MA combined) for a 2-year measure and 3-year measure for Diabetes with Complications (CCS50) were 278,144 and 417,216, respectively, and the unobserved readmission rate (Medicare FFS only) was 18.4%.
 - The projected cohort size for admissions (Medicare FFS and MA combined) for a 2-year measure and 3-year measure having an Amputation procedure (CCS157) and a principal or secondary diagnosis in CCS50 were 114,348 and 171,522, respectively, and the unobserved readmission rate (Medicare FFS only) was 19.8%.
 - The projected cohort sizes for a measure combining both cohorts, for a 2year and 3-year measure were 392,492 and 588,738, respectively, and the observed readmission rate (Medicare FFS only) was 18.8%.
 - Dr. Peter noted a concern for the TEP to consider: since anyone with a principal diagnosis of diabetes (that had any procedure) would be included in this cohort already, should the cohort include secondary diagnosis of CCS50 for those that had an amputation procedure (CCS157)?

- Dr. Peter noted it may be possible to run similar analyses for other procedures (e.g., revascularization) using the same methodology as was used for the amputation procedures.
- Dr. Peter noted the CORE team also considered including all secondary diagnoses in CCS50 that were POA (Dr. Peter noted this analysis was shared with the TEP members as an excel attachment, specifically Tab 4 in document titled HOP4 Diabetes Cohort Definition_EDAC12042023.xlsx); however, some principal diagnosis codes overlapped with the cohorts of other EDAC measures.
 - For example, the principal diagnosis of "Hypertensive Heart Disease with Heart Failure" (International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM] diagnosis code I11.0).
 - Overall, the CORE team estimated approximately 10% of principal diagnosis codes considered diabetes complications overlap with the HF EDAC measure cohort.
- Dr. Peter noted the CORE team considered the pros and cons of both a narrowly defined diabetes cohort and an expanded (or broad) diabetes cohort.
 - For a narrowly defined cohort that includes 1) principal diagnoses of diabetes with complication (CCS50), and 2) amputation procedures (CCS157) with a secondary diagnosis of diabetes with complications (CCS50):
 - The pros are the measure is a quality signal that represented patient hospitalized **for** diabetes; the measure does not overlap significantly with other EDAC cohorts; and it does not include sequelae (complications of uncontrolled diabetes that are not always caused by diabetes) such as Peripheral Arterial Disease, and/or are not modifiable in acute care.
 - The cons are that the measure would be missing admissions for people with sequelae (complications of uncontrolled diabetes that are not always caused by diabetes).
 - For a more broadly defined cohort that also includes a principal diagnosis of diabetes sequelae associated with a secondary diagnosis of diabetes with complications (CCS50):
 - The pros include that the measure would capture all people **with** diabetes.
 - The cons are that the measure would overlap with existing EDAC measure cohorts, which may not be acceptable to stakeholders; many sequelae are not definitively caused by poor diabetes management; there is no gold standard for what to include as sequelae; and these outcomes are already captured in the HWR measure.

- Were the more broadly defined definition used, the definition of sequelae would need to be determined by clinical experts or through the use of established code sets (e.g., <u>Diabetes</u> <u>Complication Severity Index</u>).
- Dr. Peter noted that beyond the standard EDAC exclusions, the CORE team and Dr. McCoy (the diabetes clinical consultant) considered if any diabetes-specific exclusions should be considered, and no diabetes-specific exclusions were identified.
- Dr. Peter noted the CORE team proposed the following inclusion/exclusion criteria for the Diabetes EDAC measure cohort.
 - Inclusion criteria:
 - Medicare FFS and MA patients
 - Aged 65 and over
 - Admitted to an acute care hospital with:
 - (1) Principal diagnosis of CCS50 "Diabetes with Complications;" or
 - (2) Procedure with CCS157 "Amputation" and a secondary diagnosis of CCS50 "Diabetes with Complications"
 - Exclusion criteria:
 - Discharged against medical advice
 - Without at least 30 days post-discharge enrollment
 - Admission for the same condition or procedure (diabetes with complications or diabetes-related amputation) within 30 days of a prior diabetes index admission
 - With a principal diagnosis code of COVID-19 (ICD-10-CM code U07.1) or with a secondary diagnosis code of COVID-19 coded as POA on the index admission claim
- Dr. Peter noted a list of the individual ICD-10 codes included in each of the CCS groups was provided with the materials provided in the TEP meeting invitation (HOP4 Diabetes Cohort Definition_EDAC12042023.xlsx).

Key Questions & Discussion

• TEP members were asked the following series of three questions (in bold) corresponding with specific EDAC measures.

Question 1: Do you have questions or concerns about the EDAC measures' specifications?

• A TEP member asked if inpatient stays are counted as a binary variable (yes/no) or if it is counted as days.

- Dr. Zhenqiu (ZQ) Lin clarified that unplanned readmissions are included in the EDAC measures as a count of days for each unplanned readmission that occurred in the 30-day period following the index admission. He noted, for example, that if a readmission occurred with a three-day length of stay, that would be counted as three days for the EDAC measure.
- The same TEP member asked if CORE had given any thought to counting readmission differently (example being weighting inpatient stay more than an ED stay, or an observation stay), as there are many factors that can impact length of stay and some of these are beyond a hospital's control. They also inquired whether the EDAC measure is intended to be a hospital-level metric or if it might be an attributable metric for accountable care organizations (ACOs), the network, or the attributed provider.
 - Dr. Peter noted the measure was designed as a hospital-level measure, and that affects how we consider events like transfers. She suggested you would need to adjust the measure and attribution of transfers differently for systems such as ACOs, and she was unaware of consideration of other types of attribution.
 - The same TEP member noted for the ACO-level there is a push for attribution of the provider's management of patients once they leave the hospital. They thought this was something important to consider.
 - Dr. Lin noted the EDAC measure expands beyond readmission to include ED and observation stays as the CORE team and CMS observed shifts in care from the inpatient setting to the ED and observation stays. The EDAC measure provides a more complete capture of acute care utilization.
 - The same TEP member acknowledged that the EDAC measure captures additional acute care utilization by including the ED and observation stay data in the measure.
 - A different TEP member noted that they live in a rural area where if patients need long-term care, assisted living services, or rehab because of what is happening to them and there is no place for them, they are held in the hospital. They wondered if that was counted against the procedure they had done or if it was counted a different way.
 - The previous TEP member stated this was the point he was trying to make before.
 - Another TEP member noted it is also true beyond rural areas, which is clearly an issue related to access to care. They also noted social determinants of health (SDOH) are factors that are not captured, as we do not have a good way of capturing that and how it influences some of these metrics.

- Dr. Lisa Suter noted these are important points that the CORE team will share with CMS, which have broader implications for quality measurement. The EDAC measures under consideration in this discussion are intended to match the measures already in use for other conditions (e.g., HF, pneumonia, and AMI) and those measures have already been through this process under a different TEP and have achieved Consensus-Based Endorsement (CBE). She agreed these points are valuable and noted the readmission outcome is less affected by comorbidities than the mortality measures. CMS is thinking about equity and SDOH, and there are SDOH measures currently moving through their program adoption processes now. She noted CMS and its contractors can take these important points into account as they review all EDAC measures in the future.
- A TEP member asked about line three of slide 23 and noted concern about including acute care readmissions "for any cause."
 - Dr. Suter noted social factors can influence length of stay and she agreed that has implications for all the EDAC measures, including those under discussion today. She noted planned readmissions (e.g., chemotherapy, CABG surgery following an AMI) are not included in this measure and are identified using the Planned Readmission Algorithm, a process created and vetted by statistical, methodological, and clinical experts to exclude readmissions for expected reasons.
- The same TEP member asked if care due to accidents was counted, noting concerns about including admissions that are completely unrelated to the index admission.
 - Dr. Suter noted accidents are counted and she provided an example of a person with HF whose blood pressure medication was adjusted during their index admission and then they fell because the medication doses were too low. In previous TEP discussions, the consensus was not to adjust the measure methodology for every little thing, like vehicle accidents or other admissions that have nothing to do with medical care, discharge planning, or discharge communication with the primary care doctor. There are a lot of things hospitals cannot influence.
- The same TEP member asked about inclusion of extreme situations, such as the person being shot by another person and being admitted to the ED because they were shot.
 - Dr. Suter noted such an ED visit within 30 days of a qualifying index admission would be counted. She acknowledged the risk of gun violence is geographically asymmetrical, with dissimilar risk across the nation. As patients are aggregated across the hospital, hospitals that have fewer patients have fewer adjustments, and the risk models were developed to be conservative when there are fewer

patients to make inferences about. For hospitals with many discharges, one event is less likely to have an extreme effect on their rates. As a result, extreme cases are unlikely to change the rate in either situation.

- Another TEP member (in chat) suggested for a patient that had a THA/TKA, a fall could be directly attributed to a problem with the procedure.
- Another TEP member (in chat) noted 3M tried to come up with a potentially
 preventable readmission algorithm in development of their Physician Coding and
 Reimbursement System, and a chart review study they conducted for CMS Readmission
 measures suggested the CMS algorithm was as reliable as 3M's system for attributing
 preventable readmission.
 - Dr. Kashika Sahay (in chat) thanked the TEP member and asked if the study they referenced was published in a peer reviewed journal, or whether it was the result of an unpublished internal analysis. The same TEP member (in chat) clarified 3M software was used for the study and provided the following citations:
 - Borzecki AM, et al. BMJ Qual Saf 2015; 24(12):753-63;
 - Borzecki AM, et al. Circ Cardiovasc Qual Outcomes 2016; Sep;9(5):532-541
- A TEP member asked in the measure calculation, if a patient had no readmission, ED visit, or observation stay, would the end result for utilization be zero and therefore, would it be true most of the patients in this scenario have a score of zero.
 - Dr. Lin confirmed that patients with no readmission, ED visit, or observation stay would have an actual utilization value of zero.

Question 2: Do you have any initial concerns with any of the diabetes inclusion/exclusion criteria?

- A TEP member asked if only principal diagnosis codes, or also secondary diagnosis codes for diabetes, were included for cohort creation.
 - Dr. Peter clarified this was a decision the CORE team wanted to discuss with the TEP; if we were to broaden the definition to include both principal and (irrespective of principal diagnoses) also capture secondary diagnoses of diabetes, this would capture all patients with diabetes, rather than those patients admitted for diabetes. In the case of including secondary diagnoses for diabetes, the cohort would become much larger, and it would be more difficult to determine which of the individual ICD-10 codes should and should not be included in the cohort.

- A TEP member asked about inclusion of the amputations in the diabetes cohort, and whether it really reflected patients hospitalized **for** diabetes; they wondered why other procedures (such as revascularization) were not included.
 - Dr. Peter noted this concern and stated that this is one question we have to address in the cohort definition — should we include admissions for amputation procedures when there is only a secondary diagnosis of codes within CCS50 (all procedures with a principal diagnosis of CCS50 will be included if we define the cohort using the requirement for a principal diagnosis of CCS50, regardless of a procedure).
- A TEP member asked whether the CCS definitions were validated using chart review or in some other way. They noted the underlying coding is probably reliable for procedures like THA/TKA, but they were less confident it would be reliable for diabetes.
 - Dr. Sahay noted that the CORE team used the AHRQ CCS as a clinical grouper for convenience as a starting point for the cohort definition, and some additional codes outside CCS50 were assessed in collaboration with Dr. McCoy (the diabetes clinical consultant) in addition to amputations.
- A TEP member noted concerns about coding consistency and proposed an example of a
 patient admitted for ketoacidosis with preexisting diabetes, noting this condition would
 likely occur due to an inciting event like an infection or gangrene. In a case like this, the
 principal diagnosis might be sepsis. They suggested it is an example of a "muddy" coding
 scenario that could be coded differently by hospitals.
 - Dr. Peter noted the CORE team considered scenarios with a secondary diagnosis of diabetes in the exploratory analyses and evaluated the frequencies of secondary diagnoses co-occurring with a principal diagnosis in CCS50. She noted the example of hypertensive heart disease with HF (which falls in HF EDAC cohort) and stated that overlap meant hospitals would be measured on that admission twice.
- A TEP member noted the complexity when you get to risk modeling and adjustment for this heterogeneous group of admissions (with both amputations and diabetes). They thought this would be challenging, as a patient having an amputation has different postdischarge risks than a patient undergoing something else. They liked the broader definition that would capture patients with uncontrolled diabetes that were admitted for something like an amputation because it is clearly a diabetes-related issue. On the other hand, they were concerned, from a quality measurement perspective, of lumping amputations due to a diabetes-related issue, in with patients with diabetes that are readmitted to get their blood sugar under control.

- Dr. Peter clarified that the narrow definition proposed would include amputation procedures, whereas the broader definition is more about the sequelae (complications of uncontrolled diabetes that are not always caused by diabetes). Including these would result in a much broader cohort of all people hospitalized with diabetes instead of for diabetes.
- A TEP member noted for the Medicare population, these patients are unlikely to be hospitalized purely for their diabetes; there is usually something else going on that is causing the diabetes to be out of control. It is difficult to say someone was admitted for diabetes when they also had a stroke. If they had a stroke and did not eat for three days, impacting their blood sugar and causing diabetes to be uncontrolled, it would be hard to determine attribution for the elevated blood sugar. Validity of coding in these situations would be a concern.
 - A different TEP member agreed that the principal diagnosis could vary in situations like these. They thought in most cases, the scenario described above would be coded with a principal diagnosis of Stroke. Otherwise, you might end up having to scrap the measure all together. They thought limiting the cohort definition to those with a principal diagnosis in CCS50 was a safer bet. They noted concern about using the secondary diagnoses and diluting the population, and they were still not sure about including the amputation procedures.
 - Dr. Peter requested clarification whether they proposed only including amputations when they are coded in secondary diagnoses. She stated that a principal diagnosis of diabetes with complication (CCS50) would include amputation procedures. However, the question of concern is whether or not to include amputations that have a secondary diagnosis of CCS50.
 - The same TEP member clarified their suggestion was to limit the cohort to patients hospitalized for diabetes based on a principal diagnosis of CCS50, and then measure the excess acute in acute care for that group; they felt more comfortable just looking at diabetes and not including amputations. If we are going to include amputations, they thought more common procedures such as revascularization should be considered as well.
 - A TEP member noted their concern was about who determined the principal diagnosis, which is the coders at hospitals and not necessarily the clinicians. They asked how we would know those are being accurately identified as the primary diagnosis, which could open debate about if it is appropriate to use billing administrative data for the measure.

- A different TEP member noted you could ask this about any of the claims-based measures.
- A different TEP member noted this is a question that could be answered if you had the charts for a sample of x number of people and reviewed them to see how often claims correspond with the definition in the Chronic Conditions Data Warehouse (CCW). Medicare has looked at this in the past, and they thought it was fair to argue about validity of using claims codes for this measure, given we know that claims codes are much more reliable for procedures (where the billing incentives and the clinical care match more clearly). However, for diabetes diagnoses, there is not as much concordance due to financial incentives to bill vs. the way the case may present. For a new quality measure to judge quality of care for a condition like diabetes, it may be worthwhile to take the approach of validating coding using chart review through a proper sensitivity/specificity test to identify if the codes billed match the patient's charts.
 - A different TEP member suggested AHRQ may have already done chart review to validate the CCS, and asked if that would satisfy these concerns. They also wondered if these concerns extended to a principal diagnosis of diabetes or were related to the proposed use of secondary diagnoses.
- TEP member thought what he heard was concern about attribution. For example, if a patient has ketoacidosis, whether that is the primary driver or if it might have been due to a urinary tract infection (UTI) instead, and how that interpretation may result in variation of the principal diagnosis coding.
 - A different TEP member thought it may be possible to look for studies that have already been done. For this example, they thought coding practice would depend on the severity of the UTI, which could be urosepsis, where sepsis would almost certainly be coded as a primary diagnosis.
 - Action Item: CORE to identify studies that have analyzed billing codes and patient's charts to validate feasibility of using CCS codes for Diabetes EDAC cohort definition.

- Dr. Peter shared a spreadsheet with frequencies of admissions that had a secondary diagnosis of diabetes with complications (CCS50) coded POA, sorted by principal diagnosis code based on frequency (HOP4 Diabetes Cohort Definition_EDAC12042023.xlsx, Tab 4-Princ._SecondaryCCS50). She noted sepsis was the most frequent principal diagnosis, and that this table was helpful to the CORE team in determining what conditions are frequently coded with diabetes. It is difficult to adjudicate each of these codes to see what is related to diabetes (or not). She noted the CORE team started to work through this and decided it was very difficult to parse.
- A TEP member suggested that from a practical perspective, a narrowly defined approach is better. When you look at the data, a patient with diabetes having COPD or HF is very common. If we expanded the cohort beyond the narrow definition, to include a secondary diagnosis code of CCS50, it is very likely some of the patients would fall into multiple cohorts. They noted that people with diabetes having comorbidity is very common and most patients would fall in multiple cohorts. It is not ideal to measure the same patient multiple times.
- Another TEP member agreed using a narrower definition for quality measurement purposes would be better. He stated from past experience looking at COPD and ICD-9 codes for cohort definitions, narrowing the focus results in cleaner definitions and quality measurement.
- Another TEP member agreed with a narrow definition, as long as we in some way validate that diabetes is really the principal diagnosis for the admission.
- A TEP member who does not have diabetes and has experienced three amputations due to Methicillin-resistant *Staphylococcus aureus* (MRSA) infection noted in their experience as a patient, they have had to be very clear and repetitive with the medical staff that they do not have diabetes.
- Dr. Peter noted, regarding the TEP members' recommendation to only include principal diagnoses in CCS50, that Dr. McCoy (the diabetes clinical consultant) recommended being more inclusive and including the secondary diagnosis of CCS50 along with a procedure code for amputation (CCS157).
- A TEP member voted for the cleaner (narrower) Diabetes EDAC cohort definition.
- A TEP member noted questions about how reimbursement might create bias. In the example of someone undergoing an amputation, the complication drives the assigned Diagnosis-Related Group (DRG) used for assigning reimbursement. They wondered if when a patient has an infection, whether there is truly a financial incentive to code it with a principal diagnosis of infection, and whether different hospitals would code it differently. They noted a past project where they erroneously selected the CABG

surgery based on the DRG, they learned if the patient ended up experiencing complications leading to another procedure (e.g., tracheostomy) that a different DRG was assigned. They wondered if by excluding the secondary diagnoses in CCS50 we might lose patients we want to include. They also added that complications and comorbidities may increase reimbursement, regardless of if they are assigned as a secondary diagnosis or assigned to the tenth diagnosis in a patient record. She noted her overall concern is more related to missing patients in some hospitals vs. others due to how they code diagnoses, with respect to maxing reimbursement.

- Dr. Peter agreed this is an important consideration and she did not know the specific financial incentives that might apply; she suggested coding to keep a patient out of the cohort could be considered an incentive.
- Another TEP member noted that nearly all hospitals use coding software that prioritizes the codes in assignment of the DRG to maximize reimbursement. The software works by reordering the diagnoses to enable the selection of the highest DRG that is clinically appropriate.
- A TEP member noted if we are looking at what happens in the 30 days following discharge using the narrow cohort definition that they almost always have something going on. They wondered whether the measure would only capture revisits for diabetes control or if it would also capture revisits for a complication or secondary diagnosis.
 - Dr. Peter clarified it is an all-cause measure.
 - The same TEP member stated that under these circumstances the measure would not be reliably attributing the follow up acute care events to their diabetes.
- A TEP member asked about the use of CCS instead of Clinical Classification Software Refined (CCSR).
 - Dr. Sahay noted the CCS was a beta version based upon ICD-10 codes, and the CCSR is based on the CCS. The CORE team elected to use CCS as it is easier to identify chronic conditions like diabetes, as compared with CCSR. Diabetes falls within a broader category of "endocrine diseases" in the CCSR which would make it more difficult to apply a narrower definition. She noted AHRQ had their reasons for switching to CCSR from a health services perspective and clarified that all of CORE's quality measures utilize the CCS. As such, the CORE team maintains a CCS map.

Wrap Up & Next Steps

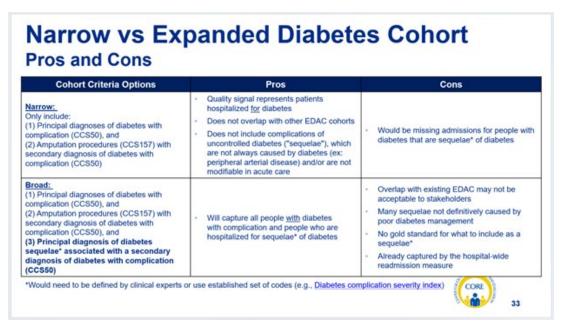
• On behalf of CORE, Mr. Niederhauser thanked the TEP participants for their time and valuable feedback. He noted their continued feedback was welcome and encouraged

TEP members to send emails with additional input at any time to jon.niederhauser@yale.edu.

- Ms. Healy thanked all the TEP members for a great discussion and noted the Stakeholder Engagement Team planned to provide a debrief survey for the Patient and Family Caregiver participants the week of December 11, 2023.
- Mr. Niederhauser noted the meeting summaries would be provided following the second TEP meeting, anticipated for early- to mid-February, and the CORE team requested all TEP members to complete the doodle poll for the second EDAC TEP meeting by December 22, 2023.

Appendix D. Diabetes Cohort First TEP Meeting Survey Results

Question 1: In our discussion during the TEP on 12/7/23, CORE presented two possible options for a diabetes cohort: a "narrow" option and a "broad" option (shown below, slide 33 from the presentation). Please select the option you feel aligns with your opinion on the best approach for this cohort; please also provide the reason you prefer option A, B, or C.



8 respondents chose the narrow option (A)

- "Will be able to describe more specifically the population of interest and reduce affiliate noise."
- "This narrow cohort better defines diabetes as the primary reason of admission."
- o "I think it's better to prioritize a cleaner quality signal."
- "More information is better especially in this situation."

3 respondents chose the broad option (B)

 "I believe going forward with the expanded version. I'd like to think of everything, completely involved without missing a beat. Overlapping shows a 'mission with a purpose'. To me it's more of a directive of everything involved."

1 respondent chose "other/variant" (C)

 "I would just use principal for diabetes with complication and not use secondary codes to identify the cohort. I think you have to go back to the purpose of this measure. Is it do measure excess days after hospitalization for diabetes or excess days after hospitalization for complications from diabetes. Vascular disease leading to amputation

is just one of many complications from long-term diabetes. You'd want to pick up revascularization procedures, renal failure, cardiovascular disease and all the other secondary complications if going to use procedure codes to identify the cohort. otherwise, amputation itself makes no sense. Also, a very different clinical cohort than those hospitalized for diabetes in of itself. Narrower population will be more clinically acceptable. When I have seen secondary diagnoses for disease of interest used (e.g., resp failure + secondary COPD (exclude pneumonia), it is because the principal diagnosis doesn't capture all the patients hospitalized for that condition. amputation in my opinion is not an acute hospitalization for diabetes. So again, I'd recommend go with most narrow definition. If going for a with diabetes cohort, you'd want to expand the principal diagnoses beyond amputation, but run the risk of overlap with other EDAC measures."

Question 2: We will be conducting further analyses regarding the options above. In the box below, please provide any specific analyses or questions you would like to suggest. We would like to focus on validation studies and are interested in your suggestions. We note that our time and resources are limited, so we will have to prioritize among the list of analyses and may not be able to address all suggested analyses.

- "I presume you will be comparing c stats, decile plots, and r squares for the narrow and broad cohorts."
- "Depends on whether you leave in the amputation + secondary diabetes codes. if going to do that, then would be good to know that you're identifying the cohort of interest. Separate from the diabetes EDAC measure. For all EDAC measures I think hospital days should not be counted, but rather be assigned a value. The actual days spent in hospital are not necessarily a measure of quality but rather medical necessity, SDOH and home support, and availability of intended disposition (e.g., SNF, LTACH, IRF). The hospitals don't need any extra motivation to move patients through as quickly as possible."
- "The current analyses have already demonstrated that patients could have a wide range
 of principal diagnosis when diabetes is recorded as secondary diagnosis. It may be
 helpful to analyze the frequency of chronic conditions that are documented along with
 diabetes among secondary diagnosis codes. The 'broad' definition would likely result in
 substantial overlapping with other patient cohorts, i.e., COPD."
- "Explore hospital-level differences in coding of diabetes.... Whether diabetes as first or second diagnosis differs substantially across hospital types."
- "Want to make sure we are actually analyzing true "excess" days and interested in how we can be sure we are truly looking at excess, rather than just above the average stay of

similar patients at different hospitals. We do not want to encourage less than necessary and relevant care, especially for orgs such as CAHs with very small volume.

- "Admission and discharge HbA1c."
- "I am convinced that the narrow cohort is the better option of the 2. The data is messy, and they overlap with other measures, even though we may miss some admissions."
- "My uncle's hospitalization would only be considered in the second measure. The first measure would miss him since diabetes is considered a tertiary condition to his hyperglycemia (which he was hospitalized for) and chronic kidney disease (caused by diabetes)."
- "I would love to know if the broad would include people with pre diabetes conditions."
- "A Secondary Diagnosis is always a good thing. It provides further detail, concrete explorations (if procedure needs to be done) Especially in amputations, a person only has ONE chance of saving or removing a limb."

Appendix E. Detailed Summary of Second TEP Meeting

New Excess Days in Acute Care (EDAC) Technical Expert Panel (TEP) Meeting #2 Minutes

Thursday, February 15, 2024, 3:00 – 5:00 PM ET

Participants

- Yale New Haven Health Services Corporation Center for Outcomes Research and Evaluation (YNHHSC/CORE): Katie Balestracci, Jin Cho, Darinka Djordjevic, Roisin Healy, Stephanie Lambert (X4 Health), Zhenqiu (ZQ) Lin, Kerry McDowell, Jon Niederhauser, Patricia Faraone Nogelo, Doris Peter, Kashika Sahay, Lisa Suter, Mariel Thottam, Ruihan Qin, Si Zhou
- **Technical Expert Panel (TEP) Participants:** Rosie Bartel, Ann Borzecki, Jean Boyer, Sophia Brasil, Matt Cheung, Steven Coffee, Craig Davies, Michael Duan, Sachin Shah, Donté Smith, Brian Stein, Mary Vaughan-Sarrazin, Bonnie Weiner
- Centers for Medicare & Medicaid Services (CMS): Raquel Myers, Jennifer Tate

Executive Summary

- The purpose of the second Excess Days in Acute Care (EDAC) Technical Expert Panel (TEP) meeting was for the Yale New Haven Health Services Corporation — Center for Outcomes Research (CORE) team to discuss current options for the Diabetes EDAC cohort definition and request TEP member feedback.
- Diabetes EDAC cohort: The majority of TEP members voted for the Refined Narrow Diabetes cohort definition (9 of 11) versus the Narrow Diabetes cohort definition (2 of 11). The rationale for the Refined Narrow Diabetes cohort definition was that not all amputations are due to diabetes (even when a secondary diagnosis in CCS50 is present); the patient population with principal diagnosis of amputation represents a different patient population; it results in a cleaner, more homogeneous cohort with better measure specificity; it maintains a focus on patients admitted for diabetes; and it allows for targeted, condition-specific intervention to improve quality of care.
 - Those who favored the Narrow Diabetes cohort definition cited concerns about potentially excluding very sick patients having amputations due to poorly controlled diabetes from the cohort.
 - The TEP asked questions about:
 - coding practices related to principal discharge diagnoses and consistency of coding;

- other clinical scenarios, besides diabetes and infection, leading to amputations being performed; and
- potential for public reporting of the new Diabetes EDAC measure for small hospitals.
- The TEP offered suggestions for future analyses, including:
 - A suggestion to evaluate the coding profile of claims with amputations procedures remaining in the Diabetes EDAC cohort; and
 - A comment that suggested excluding HWR from the comparator measures for future validity testing.
- The TEP expressed potential concerns related to the EDAC measures:
 - A TEP member commented about amputation procedures occurring without vascular assessment, potentially resulting in surgery where nonsurgical intervention might have been possible.
 - A TEP member commented about the importance of having diabetes measures for other outpatient settings in addition to the hospital measure, as outpatient clinicians are primarily responsible for the management of diabetes.
 - A TEP member noted challenges to accessing post-discharge services (e.g., home health, skilled nursing facility [SNF]) in rural areas likely increases Readmission and EDAC.
 - A TEP member noted that including both Readmission and EDAC in the same program would result in double counting.

TEP Action Items

- TEP members were encouraged to watch for and respond to a follow-up survey about their perception of the meeting.
 - The first follow up survey was sent on Tuesday, February 20th, which asked TEP members to provide measure-specific feedback on measure validity.
- TEP members were invited to email <u>jon.niederhauser@yale.edu</u> with any additional comments and suggestions.

CORE Action Items

- CORE will distribute the meeting summary for the second TEP Meeting.
- CORE will send TEP members follow up survey. (completed)

Detailed Discussion Summary

Welcome & Introductions

- Ms. Roisin Healy welcomed the TEP members; introduced herself as a CORE Stakeholder Engagement Lead; provided instructions about meeting decorum and the meeting controls for closed captioning; shared details about the CMS funding source for the project; and reminded members about the confidentiality of meeting materials and discussion.
- Mr. Jon Niederhauser introduced himself as the Project Coordinator, shared the goals and objectives of the second TEP meeting, and reviewed the EDAC project timeline.
 - He noted the meeting goal is to obtain the TEP's perspective through professional input and lived experience to continue to inform development of the cohort for the Diabetes EDAC measure.
 - He noted the meeting objectives were to discuss current options for the Diabetes EDAC cohort and to obtain TEP feedback via a survey following the meeting to capture TEP members' meeting experience.
- Ms. Healy reviewed the meeting agenda, including:
 - welcome & introductions;
 - Diabetes EDAC revised cohort & discussion;
 - Recap first TEP meeting, post-meeting communication, and discuss new cohort direction;
 - narrow versus "refined" narrow cohort definition;
 - o additional discussion as needed; and
 - o next steps
- Ms. Healy acknowledged the additional CORE team members participating in the call who would assist with responding to the TEP members' questions, along with the expert clinical consultant who have supported the CORE team in development of the proposed measures including Dr. Rozalina McCoy, an Endocrinologist.
- Ms. Healy asked the TEP members who were not present during the first meeting in December to introduce themselves by providing their name, role, what interests them in the TEP, and any changes in conflicts of interest (COI).
 - Ms. Jean Boyer noted she is a caregiver for a family member who had a CABG procedure.
 - Col. Steven Coffee noted he is a caregiver for a family member.

EDAC Measure Background

• Dr. Doris Peter introduced herself as the Project Lead and noted changes in the meeting format to address TEP member concerns following the first TEP meeting in December. These updates include the use of a round robin format to ensure all TEP members have

an opportunity to be heard, and the addition of lay explanations of research-specific terms in the supplemental materials.

• Dr. Peter provided an overview of the EDAC measure methodology, including background information on the development of the EDAC measures; how the EDAC outcome is calculated; and general EDAC inclusion and exclusion criteria.

Diabetes EDAC Revised Cohort & Discussion

- Dr. Peter noted that the structure of the Diabetes EDAC portion of the second TEP meeting will be a recap of the first TEP meeting, results from post-first TEP communications, and the review of additional cohort validation analyses that led to the recommendation to further refine the Diabetes EDAC cohort definition.
- Dr. Peter noted that during the first TEP meeting, CORE shared the following:
 - The Diabetes EDAC goal is to improve care for patients hospitalized **for** diabetes (not **with** diabetes).
 - The current project's goal is to specify the cohort for the measure.
 - Additional considerations include avoiding overlap with other EDAC cohorts and balancing between hospitalizations for diabetes versus sequelae of uncontrolled diabetes.
- Dr. Peter noted that during the first TEP meeting, she provided the pros and cons of a "narrow" (using principal discharge diagnoses) versus "broad" (using both principal and secondary diagnoses) cohort definition. She reminded TEP members that they were asked to provide feedback on these two options. She continued that TEP members were then asked to vote on their choice of cohort definition through the post-first TEP survey.
- A TEP member asked for additional clarification about differentiating between <u>for</u> versus <u>with</u> diabetes. They noted it is difficult to discern whether somebody had diabetes or heart disease first, and that CORE stated earlier that the concern of counting patients already measured by other EDAC measures, such as for heart disease. The TEP member provided an example, that if they were a patient diagnosed with diabetes as a teenager and later developed heart disease, would the EDAC measure only capture this patient under the Heart Disease EDAC and not the Diabetes EDAC?
 - Dr. Peter noted that the accountable entity for the EDAC measure is the hospital providing the care. The EDAC measure is specific to readmission for any hospital visits after an index admission.
 - Dr. Lisa Suter noted when we look at these EDAC measures, we are using principal discharge diagnosis, or the diagnosis that reflects the reason the patient came to the hospital. By looking at principal discharge diagnosis, readmission measures can tell if the patient was admitted for heart failure or

diabetes. For a patient admitted with uncontrolled diabetes or a direct complication of diabetes, the principal discharge diagnosis will reflect that. There are also secondary diagnoses that could indicate other conditions like heart failure.

- The same TEP member asked if there can be multiple principal discharge diagnoses and who decides on those codes.
- Dr. Suter responded there is only one principal discharge diagnosis, and the hospital usually has professional coders that review the patient's hospitalization and use an algorithm for determining the principal discharge diagnosis.
- A different TEP member noted in the chat that to be clear, clinically it is not always clear even to the treating physicians whether diabetes or another diagnosis is the actual reason for admission. For example, sepsis and diabetic ketoacidosis (DKA) are not meaningfully discernible.
- Dr. Peter noted there is a slide in the Appendix of the presentation (slide 67) with the inclusion criteria for the other EDAC measures. She noted the examples of the COPD and Pneumonia EDAC, where the cohort is mostly based on the principal discharge diagnosis but may include some instances where a particular coding combination really captures the same population and where the measure focus (e.g., COPD, pneumonia) is in the secondary diagnoses with a principal discharge diagnosis of something else.
 - This is analogous to the discussion about the Diabetes EDAC inclusion criteria, and whether or not to include amputation procedures with a secondary diagnosis of diabetes.
 - Dr. Peter noted that excel attachment titled, "HOP4 Diabetes Cohort Definition_EDAC.xlsx" includes a tab with the principal discharge diagnoses coded with a secondary diagnosis of diabetes with complications. The number one code is always sepsis for almost any condition, followed by codes related to heart disease, hypertension, and kidney disease, suggesting it is already a heterogeneous population, which aligns with TEP feedback during the first TEP meeting about structuring the Diabetes EDAC measure to be more homogeneous.
 - The coding is not always clean and straightforward which is why it is important to have this discussion with the TEP and obtain a vote, as readmissions measures must rely on accurate coding to be able to pull in the patients intended for the measure.
- A different TEP member agreed this is an important concept to understand [inclusion criteria and hospital coding practices] and noted they have done research on COPD exacerbation, evaluating the principal and secondary diagnosis and different ways to

structure cohorts. They stated the importance of knowing what patients are hospitalized for vs. with, and for diabetes whether for hyperglycemia, DKA, dehydration, versus with sequelae of long-term diabetes as a secondary diagnosis. When looking at amputation, the patient may not have been hospitalized with diabetes per se, but a complication of longstanding diabetes. Following this logic, one could start going down the list of other long-term complications of diabetes (e.g., end-stage renal disease, coronary disease, limb ischemia); no one develops limb ischemia overnight and it is a multi-year complication known to be associated with long-standing diabetes. This goes to the point of a more refined Diabetes EDAC cohort. The TEP member stated it is different for diabetes than the COPD metrics where COPD may initially present as respiratory failure.

- Dr. Peter agreed it is different for diabetes than COPD, and clinically it may be a poor analogy; for both COPD and Pneumonia EDAC we are using the combinations of principal and secondary diagnosis codes to capture patients that are clinically similar.
- A TEP member shared an example of a family member who was diabetic being hospitalized for a coronary episode, which may have been aggravated by diabetes, but was not admitted primarily for diabetes.
 - Dr. Peter noted this was a good example and thanked them for sharing it.
- Dr. Peter noted during the first TEP meeting, CORE presented "narrow" and "broad" options for defining the Diabetes EDAC cohort, and TEP members provided input during and following the meeting on these approaches.
 - The narrow approach was intended to focus on patients hospitalized for diabetes and the broad approach was intended to encompass sequalae of diabetes, or patients hospitalized with diabetes. Most TEP members agreed during the first TEP meeting that the narrow cohort was more pragmatic.
 - After the first TEP meeting, CORE sent out a post-TEP survey, asking which cohort option TEP members preferred.
 - The post-first TEP survey reflected 9 of 12 respondents were in favor of the narrow cohort definition, with comments stating it would provide a cleaner quality signal.
 - The remaining three were in favor of the broad approach, with one TEP member specifying the concern of overlap as a positive, in that it means less likelihood of missing patients that would otherwise not be captured in the Diabetes EDAC.
 - The TEP also provided suggestions for cohort validation studies via the survey.

- Dr. Peter reviewed the additional cohort validation questions that were developed with feedback from the TEP (from the post-first TEP survey) to identify clinical differences between patients that would be in the "narrow" and "broad" cohorts. These analyses attempted to answer:
 - Are patients coded with a principal diagnosis of diabetes with complications (CCS50) different clinically from patients coded with only a secondary diagnosis of diabetes with complications? Analyses to address this question included:
 - Comparing the diagnosis codes associated with the readmission (reason for readmission), and
 - Comparing principal diagnosis of the prior hospitalization.
 - 2. Do hospitals code diabetes patients differently? Analyses to address this question included:
 - Examining variation in hospital-level diabetes coding ratios (ratio of the count admissions with a principal diagnosis of diabetes [codes in AHRQ CCS50] divided by the count of all principal and secondary diagnoses within CCS50.
- Dr. Peter shared results for cohort validation question 1a (included in the supplemental spreadsheet HOP4 Diabetes Cohort Definition_EDAC.xlsx tabs 6-7), based on the Hospital-wide Readmission (HWR) cohort (2021 data) that includes only Medicare Feefor-service (FFS) and not Medicare Advantage (MA).
 - For index admissions with a principal diagnosis of CCS50 (diabetes with complications), 6 of the top 10 principal diagnosis codes associated with a readmission are in the same CCS (CCS50); for admissions with a secondary diagnosis of CCS50 only, none of the top 10 are within the same CCS.
- Dr. Peter shared results for the cohort validation question 1b (included in the supplemental spreadsheet HOP4 Diabetes Cohort Definition_EDAC.xlsx tabs 8-9), based on the HWR cohort that includes only Medicare FFS and not MA.
 - For index admissions with a principal diagnosis of CCS50 (diabetes with complications), 5 of the top 10 principal diagnosis codes associated the prior hospitalization are in the same CCS; for admissions with a secondary diagnosis of CCS50 only, none of the top 10 are within the same CCS.
- Dr. Peter stated these results support the notion that patients with a principal diagnosis of diabetes with complication are clinically different from patients with only a secondary diagnosis of diabetes with complication, and that therefore the narrow definition (principal diagnosis of CCS50) provides a clinically more homogeneous group of patients.

- Dr. Peter shared results for the cohort validation question 2, assessing coding variation across hospitals, based on the same HWR cohort that includes only Medicare FFS beneficiaries.
 - Results suggest there is variation in coding across hospitals with some clustering and some outliers, variation may represent differences in patient mix.
 - These results will serve as a baseline for after the measure is implemented, as the coding may shift.
- Dr. Peter reiterated that during the first TEP meeting, CORE discussed the "broad" versus "narrow" cohort definitions. From this position forward in the second TEP meeting, she will shift the discussion to a "narrow" versus "refined narrow" cohort definition.
 - The "refined narrow" approach was introduced in response to the recommendation of one TEP member to further narrow the cohort and remove the inclusion criterion for patients that had an amputation procedure but who only had a secondary diagnosis of CCS50 (diabetes with complications).
- Dr. Peter noted the CORE team conducted additional analyses based on the "refined narrow" approach, with results shared with the TEP in January 2024, requesting TEP members to share additional feedback via email prior to the second TEP meeting.
 - She added that the "refined narrow" cohort definition simply removes patients with a procedure code in CCS157, which is specific to amputations, who have a secondary diagnosis in CCS50 (diabetes with complications). She continued that this does remove all patients with an amputation, just those without a principal diagnosis in CCS50.
- Dr. Peter reviewed the admission counts related to amputations (HWR cohort, Medicare FFS only), noting 49% of amputation procedures in CCS157 (those with a principal diagnosis in CCS50 [diabetes with complications]) would remain in the "refined narrow" cohort. Those patients with an amputation procedure in CCS157 and only a secondary diagnosis of CCS50 (no principal diagnosis in CCS50) would not be included in the "refined narrow" cohort and account for 27%, with the remaining 24% having amputation coded as a procedure and neither a principal nor secondary diagnosis of CCS50.
- Dr. Peter reviewed the impact of removing amputation procedures in CCS157 that only have a secondary diagnosis code within CCS50 (diabetes with complications) (HWR cohort, Medicare FFS only), noting refining the cohort based on TEP input would remove about 10% of the overall admissions from the cohort.

- Dr. Peter noted that CORE requested feedback from the TEP in January 2024, based on this same data that was sent to them, and that CORE had received 6 responses prior to January 29th with a mixture of perspectives.
 - Most comments suggested agreement with the "refined narrow" cohort approach, with one commenter noting concern about hospitals coding infections as a principal diagnosis instead of diabetes.
 - One commenter noted disagreement with the "refined narrow" cohort due to excluding amputations, stating amputations are an avoidable complication of diabetes.
 - Dr. Peter provided additional analyses based on email responses, using the new Diabetes EDAC dataset that includes both Medicare FFS and MA claims.
 - The first analysis (included in the supplemental spreadsheet HOP4 Diabetes Cohort Definition_EDAC.xlsx tab 5) looked at principal diagnoses for admissions with only a secondary diagnosis of diabetes with complications (CCS50) and an amputation procedure (CCS157) and found that the majority of the top principal diagnosis were infection of the foot.
 - The second analysis compared outcome rates patients with a principal diagnosis of diabetes with complications and an amputation versus patients that have only a secondary diagnosis of diabetes with complications and an amputation.
 - These analyses are based on 2022 data that include Medicare Advantage (MA) and FFS beneficiaries.
 - Results who that amputation-related admissions with a secondary diagnosis within CCS50 (diabetes with complications) have higher patient-level unadjusted EDAC outcomes compared with admissions having only a principal diagnosis in CCS50. This suggests that these are two different patient populations, and the results may have implications for risk adjustment.
- A TEP member (in chat) asked if there was a broad (across the board) mandatory way things are coded throughout all hospitals.
 - Dr. Peter noted there is coding guidance for International Classification of Diseases, Ninth Revision (ICD-9) and later International Classification of Diseases, Tenth Revision (ICD-10) that she reviewed at the beginning of this project. When that transition from ICD-9 to ICD-10 happened, there was a lot of confusion over how to code patients with diabetes and then additional guidance was released. The American Diabetes Association and various organizations tried to make the coding practice clearer, and based on the data CORE reviewed, it appears the

coding guidance is being consistently followed, although there is some variation in coding which could be due to patient mix. Dr. Peter noted there are some ways that coding can be used to maximize payment which drives coding in practice.

- A TEP member asked if CORE looked at differences in coding by medical specialties.
 - Dr. Peter noted they had not, as the EDAC measure is a hospital-level measure. She suggested it may be possible to look at the specialty type of the attending physician on the claim. She asked if the clinicians present or someone with more coding expertise had additional comments.
 - The same TEP member noted the reason they asked the question was that half
 of the patients who get amputations do not receive a vascular assessment prior
 to the amputation. If a patient has a principal diagnosis of diabetes, they are
 more likely to be admitted to a medical service and depending on the hospital
 might be more likely to receive a vascular assessment and potentially be offered
 a non-surgical option for treatment. If amputations are included in the cohort,
 there is a possibility the measure will be biased toward the surgical cohort as
 opposed to the larger diabetes cohort.
 - A different TEP member noted the discharge attending physicians may split between surgeons for amputations and medical doctors for diabetes. They suggested it depends on how the patient enters the hospital. In the case of a patient coming to the emergency department (ED) for an elective amputation, they could leave with the same principal diagnosis, and that may determine whether it is an infection or diabetes. This reinforces that the patients with a primary CCS50 diagnosis and amputation vs. those with a secondary CCS50 diagnosis and amputation are different populations.

TEP Feedback

Question 1: Dr. Peter introduced the first question for the TEP, prior to opening a poll to get a vote of the TEP members: Which of the two cohort options ("narrow" or "refined narrow") is the most appropriate for the Diabetes EDAC measure?

- Dr. Peter clarified the "refined narrow" cohort would still include amputations reflected by procedure coding on the claim so long as the principal discharge diagnosis was in CCS50 (diabetes with complications).
 - A TEP member asked if patients might undergo an amputation procedure without having an infection or it being caused by diabetes.

- A different TEP member noted there are a lot of patients that have vascular insufficiency, and diabetes is the most common cause but not the only cause. They noted atherosclerosis and neuropathy as examples.
- Another TEP member suggested that trauma may be the most common alternative cause of amputation, followed by vascular disease that is unrelated to diabetes.
- Ms. Healy shared the results of the poll with 10 responses; 80% of the TEP voted for the "refined narrow" approach and 20% voted for the "narrow" approach. She opened a round robin discussion asking the TEP to share the reason for their selection.
 - A TEP member noted they selected the narrow option because it included amputations.
 - A TEP member noted they selected refined narrow because a patient could have been admitted because of an infection that is unrelated to diabetes that results in an amputation. They noted surgical infections could lead to amputation, and even if there is a secondary diagnosis in CCS50 (diabetes with complications) the amputation can still be due to something else. They did not believe all amputations happen because of diabetes, even if the patient has diabetes.
 - A TEP member noted they selected refined narrow because from the data that was shared with the TEP, it would reflect a cleaner, more homogeneous cohort.
 - A TEP member noted they voted for narrow in the poll, but based on the discussion so far, they would change their vote to refined narrow because not everyone has amputations.
 - A TEP member noted they voted for refined narrow because it provides more clarity and keeps it closer to the population of interest.
 - A TEP member noted they voted for refined narrow due to the clarification around what the principal discharge diagnosis means, and having a better understanding of why the narrower approach is appropriate. We are not trying to ding a hospital for anything that happened to a patient coming in. As a patient advocate, they like to see the hospital taking more responsibility for the patient that has diabetes.
 - A TEP member noted they voted for the narrow approach because they were not comfortable with excluding 10 percent of the cohort.
 - A TEP member noted they voted for the refined narrow approach because the data analysis showed that it is a more homogeneous group of patients, and they thought it was better.
 - A TEP member noted they voted for the refined narrow approach as the narrower the population the better specificity you have for the measure. They

noted understanding of the risk of reducing the population too much and suggested in terms of identifying a population of interest, it was helpful to work backwards from what the point of a readmission or EDAC measure is, to be able to have condition-specific interventions around these populations. Otherwise, it would make more sense to have an all-cause EDAC measure and not bother with condition-specific measures. Also, you get a lot of noise when you put in a principal diagnosis of something else unless you are using a group of codes that function as a surrogate for the same thing, as discussed earlier for COPD. The complication of diabetes patient population is much different than acute diabetes patient population.

- A TEP member noted they voted for the refined narrow approach, but stated they had mixed feelings about it as you could potentially be missing some important, severely sick patients by tossing out those with primary diagnosis of sepsis or infection. If you are capturing a cohort that is distributed across hospitals, so the metric is fair, there is no reason to think the refined narrow model is going to penalize one hospital over another.
- A TEP member noted they voted for the refined narrow approach for the many reasons previously stated. They also thought in the same way that "a man with a hammer thinks everything is a nail," that a patient admitted primarily for amputation would not be coded the same way as a patient admitted primarily for diabetes, and including those cases could lead to a distorted and somewhat biased cohort and so it is better to exclude them.
- Upon further round robin discussion of the "refined narrow" vs. "narrow" TEP vote, 9 (82%) confirmed their vote for "refined narrow" and 2 for "narrow" (18%). Three TEP members were not present during this vote.
- Dr. Peter thanked the TEP members for their input and presented results of additional analyses comparing the "refined narrow" Diabetes EDAC cohort with the other EDAC measures currently in development (COPD, CABG, and THA/TKA).
 - These analyses were conducted using the new Diabetes EDAC dataset that includes calendar year (CY) 2022 claims for both Medicare FFS and MA beneficiaries, and focused on the EDAC outcome, including readmission days, ED visits, and observation days.
 - The analyses included evaluation of cohort size, distribution of hospital volume, and distribution of the hospital-level unadjusted EDAC outcomes.
 - The results of these analyses suggested:
 - The cohort size for Diabetes EDAC was smaller than the COPD cohort, similar to the THA/TKA cohort, and was larger than the CABG cohort;

- The distribution of the Diabetes EDAC cohort volume is similar to the COPD and THA/TKA cohorts;
- Like the other EDAC measures, the Diabetes EDAC outcome is driven by readmission days; and
- The distribution of unadjusted days in acute care for Diabetes EDAC is similar to COPD and has more variation than CABG or THA/TKA.
 - A TEP member asked if CORE evaluated the hospital-level coding profiles for amputations in the Refined Narrow cohort.
 - Dr. Peter noted this was a good question and she did not expect there to be huge differences because only 10-percent of the cohort included amputations at this point; she stated this was something the CORE team might consider looking at because if the amputations are unequally distributed it could suggest differences among the hospitals.

Question 2: Do you have any additional questions or concerns about the cohort size, distribution of volume, or unadjusted outcome rates for the refined diabetes cohort?

- Ms. Healy instructed the TEP members to use the "raise hand" function in the virtual meeting if they had comments to share.
 - A TEP member voiced that for the narrower cohort, there is a greater responsibility for hospitals to address the needs of this important population. By defining the cohort more narrowly, there is less burden on hospitals to do more for these patients.
 - A TEP member noted they appreciate the concern the previous speaker stated, and they wished it was possible to do a broader diabetes measure at the same time. They also noted that these are not the patients that hospitals are ultimately responsible for; because diabetes is largely managed in the outpatient setting and there are other measures in pay-for-performance programs and Medicare Star Ratings to address diabetes control. Reducing the cohort does not let everyone off the hook because there are other diabetes measures.
 - A TEP member thought the claims volumes looked good, and asked about whether there would still be some smaller hospitals represented, and if there is any minimum volume requirement to report their performance.
 - Dr. Peter noted that later in the measure development process, once the risk variables are available, the CORE team would look at the measure reliability for Diabetes EDAC to identify the cutoff for public reporting. She noted the public reporting cutoff points vary for different measures (e.g., ≥25, ≥50, ≥100), and all hospitals with any data will receive results

of the measure, even if they are below the public reporting threshold that will be established.

 She clarified that the analyses presented for Diabetes EDAC were all unadjusted as there are not yet risk variables.

Additional Discussion

- A TEP member asked if the intent is to replace readmission measures with EDAC measures, as they double measure if you include them both in a program.
 - Dr. Suter noted the EDAC measures (for acute myocardial infarction, heart failure, and pneumonia) are currently used in a pay-for reporting through the Hospital Inpatient Quality Reporting (IQR) program. CORE did not have any information about how CMS anticipates using the new EDAC measures in the context of readmission measures in the future. The original EDAC measures were created to supplement and balance the readmission measures, and at least thus far CMS has not used EDAC measures to replace readmission measures.
- A TEP member asked how to access Care Compare.
 - Ms. Mariel Thottam shared the link to Care Compare in the meeting chat: <u>https://www.medicare.gov/care-compare/</u>

Wrap Up & Next Steps

- On behalf of CORE, Mr. Niederhauser thanked the TEP participants for their time and valuable feedback. He noted their continued feedback was welcome and encouraged TEP members to send emails with additional input at any time to jon.niederhauser@yale.edu.
- Mr. Niederhauser noted TEP members could expect to receive a follow-up survey about their perception of the meeting.
- Mr. Niederhauser noted the final version of the first TEP summary report would be posted to CMS website soon.

Appendix F. Detailed Summary of Third TEP Meeting

Diabetes Excess Days in Acute Care (EDAC) Technical Expert Panel (TEP) Meeting #3 Minutes

Tuesday, August 6, 2024, 4:00 – 6:00 PM ET

Participants

- Yale New Haven Health Services Corporation Center for Outcomes Research and Evaluation (YNHHSC/CORE): Katie Balestracci, Jin Cho, Darinka Djordjevic, Roisin Healy, Kerry McDowell, Jon Niederhauser, Doris Peter, Kashika Sahay, Lisa Suter, Jacqueline Grady, Lana Aldos
- Technical Expert Panel (TEP) Participants: Rosie Bartel, Jean Boyer, Sophia Brasil, Craig Davies, Michael Duan, Sachin Shah, Donté Smith, Brian Stein, Mary Vaughan-Sarrazin, Bonnie Weiner
- Centers for Medicare & Medicaid Services (CMS): Melissa Hager

Executive Summary

- The purpose of the third Excess Days in Acute Care (EDAC) Technical Expert Panel (TEP) meeting was for the Yale New Haven Health Services Corporation Center for Outcomes Research (CORE) team to review prior work (cohort development) on the Diabetes EDAC measure, ensure TEP understanding of risk adjustment and the risk variable selection process, and receive TEP feedback on initial risk variables selected.
- The majority of TEP members agreed with the current list of 46 risk variables for the Diabetes EDAC measure. Additional considerations suggested by TEP members included:
 - Whether a differentiation between type 1 and type 2 diabetes will impact the model;
 - Whether other conditions (i.e., cancer, HIV, chronic kidney disease) could impact the risk model;
 - Whether the model adequately accounts for two different populations with complications due to diabetes, those with revascularization-specific complications (i.e., wounds and amputations) and those with metabolic-specific conditions (i.e., diabetic ketoacidosis);
- TEP members suggested consideration of the following factors or risk variables for further analysis:
 - Acute myocardial infarction and other cardiac-related codes;
 - o DNR status; and

- Other procedural CCSs (outside of amputation).
- CORE noted that during the fourth Diabetes EDAC TEP meeting, they will bring model testing results, as well as social risk factors to consider for addition to the risk model.

TEP Action Items

- TEP members were encouraged to watch for the follow-up survey and Doodle poll to ensure their feedback is incorporated and to help schedule the next TEP meeting.
- TEP members were invited to email jon.niederhauser@yale.edu with any additional comments and suggestions.

CORE Action Items

- If there are sufficient numbers of patients with other types of diabetes in the cohort (Type 1, chemically induced, etc.), CORE will examine model performance for these different types of diabetes.
- CORE to consider if prior admissions should be accounted for in the risk variable selection process.
- CORE to consider the impact on the risk model for patients from nursing homes.
- Dr. Peter to add the topic of variability in DNR capture (POA vs. not POA) to the list for discussion with the CORE EDAC team after the meeting.
- CORE will examine CCS groupings to determine if there are other procedural subgroups to examine in terms of calibration.
- CORE to consider if ICD-10 code Z794, long term use of insulin, is necessary to add into the risk model.
- CORE will distribute the meeting summary for the third TEP Meeting.
- CORE will send TEP members one follow-up survey.

Detailed Discussion Summary

Welcome & Introductions

- Ms. Roisin Healy welcomed the TEP members; introduced herself as a CORE Stakeholder Engagement Lead; provided instructions about meeting decorum and the meeting controls for closed captioning; shared details about the CMS funding source for the project; and reminded members about the confidentiality of meeting materials and discussion.
- Mr. Jon Niederhauser introduced himself as the Project Coordinator, shared the goals and objectives of the third TEP meeting, and reviewed the EDAC project timeline.

- He noted the meeting goal is to obtain the TEP's input on the cohort for the Diabetes EDAC measure, and review and provide input on candidate risk variables for risk adjustment.
- He provided an overview of content covered during the first and second TEP meetings, along with prospective content for the fourth TEP meeting in October 2024.
- Mr. Niederhauser reviewed the meeting agenda.
- Ms. Healy acknowledged the additional CORE team members participating in the call who would assist with responding to the TEP members' questions, along with the expert clinical consultants who have supported the CORE team in development of the proposed measures including Dr. Rozalina McCoy, an Endocrinologist; and Dr. Kasia Lipska, an Endocrinologist.

EDAC Measure Background

- Dr. Doris Peter provided an overview of the EDAC measure methodology, including background information on the development of the EDAC measures; how the EDAC outcome is calculated; and general EDAC inclusion and exclusion criteria.
- Dr. Peter noted that each measure assesses the number of days a patient spends in acute care within 30 days after being discharged from their original or index admission, focusing on all causes. The index admission varies depending on the measure; for this discussion, the focus is on diabetes.
- Dr. Peter mentioned that the outcome includes all eligible outcomes within the 30-day period, even if repeated. For instance, a readmission and an emergency department visit within 30 days both count towards the patient's outcome. Emergency department visits are counted as one day each. Observation stays are recorded by hours and rounded to the nearest integer of days. Unplanned readmissions are counted as days, excluding planned readmissions such as elective surgeries or chemotherapy treatments.
- She noted that the measures include Medicare fee-for-service and Medicare Advantage beneficiaries, reflecting cohort expansion since earlier versions of these measures. The measures are risk-adjusted, accounting for demographic factors and comorbidities (the same variables as in the related readmission measures).
- For the diabetes measure, Dr. Peter explained that since there was no pre-existing readmission measure, a risk model was created to assess the outcome of readmissions, which is currently in draft form for the TEP's review.
- The EDAC measure score is the ratio of predicted to expected outcomes.

Diabetes EDAC: Background & Decisions Made During First and Second TEP Meetings

- Dr. Peter stated that the goal of the Diabetes EDAC measure is to improve care for patients hospitalized **for** diabetes, rather than those hospitalized **with** diabetes, to avoid an overly broad cohort. Current efforts are focused on identifying risk variables, testing the risk model, and considering potential overlap with other EDAC measures.
- Dr. Peter described the rationale for including only admissions with a principal diagnosis of diabetes with complications (AHRQ CCS50) in the Diabetes EDAC cohort.
 - o Pros:
 - This approach is pragmatic for identifying the cohort.
 - It focuses on care for patients hospitalized for diabetes, not with diabetes.
 - The cohort is homogenous.
 - There is no overlap with other EDAC measures.
 - Cons:
 - It might be desirable to have a measure capturing care for all hospitalized patients with diabetes.
 - It leaves subsets of admissions unmeasured, such as those with a principal diagnosis of infection or secondary diabetes complications.
 - The cohort size is relatively small.
- Dr. Peter compared the Diabetes EDAC cohort size with those of COPD, CABG, and THA/TKA. The Diabetes EDAC cohort size is similar to the THA/TKA cohort and larger than the CABG cohort, but smaller than the COPD cohort.
 - The 2-year projected cohort sizes are:
 - Diabetes: 344,286
 - COPD: 428,010
 - CABG: 143,746
 - THA/TKA: 341,682
 - The 3-year projected cohort sizes are:
 - Diabetes: 516,429
 - COPD: 642,016
 - CABG: 215,619
 - THA/TKA: 512,523
- Dr. Peter illustrated the unadjusted measure score distribution for the Diabetes EDAC, noting that is it similar to other EDAC measures.
 - The outcome is primarily driven by readmission days.
 - Hospital-level unadjusted EDAC outcome per 100 discharges (n = 3,927) included:

- Days in acute care: Mean (Standard Deviation [SD]) = 146 (144), Median = 135
- Readmission days: Mean (SD) = 115 (135), Median = 105
- Observation days: Mean (SD) = 15 (32), Median = 7
- ED days: Mean (SD) = 24 (31), Median = 18

Diabetes EDAC Measure Risk Variable Selection

- Dr. Peter reviewed the risk variable selection process. To identify risk variables for the Diabetes EDAC measure, the CORE EDAC team used a method consistent with other EDAC and readmission measures, focusing on individual codes (rather than groupers) for more precision. This method includes combining highly correlated variables and considering changes due to situations like COVID.
- Dr. Peter mentioned that thousands of codes can initially be identified, reduced by frequency thresholds, and further combined if frequently co-coded. Statistical methods like bootstrapping are used to identify variables significantly associated with outcomes.
- Dr. Peter stated that the goal for the current work is to create a draft risk model for the TEP's review, focusing on variables significantly associated with the outcome (readmission in this case, to be consistent with the approach used by other EDAC measures). Additional variables considered for consistency with other measures include frailty variables, COVID-related adjustments, a Medicare Advantage indicator, and social risk factors.
- Dr. Peter noted the six-step risk variable selection process utilized:
 - 1. Identifying a measurement period.
 - a. Data from CY 2022.
 - 2. Identifying ICD-10 codes from patient medical claims.
 - a. Secondary diagnosis codes POA from index admission, principal and secondary diagnosis codes from medical history (12 months prior); both in- and outpatient; and the exclusion of non-clinical social risk factor codes for separate analysis.
 - 3. Applying a frequency threshold to identified ICD-10 codes from step 2.
 - a. Index diagnosis codes with greater than or equal to 0.5% threshold, and pre-index (or history) codes from claims in the prior 12 months with a greater than or equal to 2.5% threshold.
 - 4. Combining ICD-10 codes that are highly correlated.
 - a. Different codes that are frequently coded together (using a threshold of 0.8 or 80%), and,

- b. Identical ICD-10 codes that occur in both index and history data, with odds ratios (ODs) that are in the same direction and differ by less than 0.2.
- 5. Identifying variables that meet a frequency threshold for significance.
 - a. CORE identified variables that are consistently (frequency threshold = 80% of the time or higher) significantly associated with the outcome (readmission) within 1,000 bootstrapped samples. CORE then checked to see if additional variables should be added by lowering the frequency threshold (below 80%) with a resultant increase in the c-statistic.
- 6. Considering additional risk variables.
 - a. Additional risk variables CORE will consider, include: a multiple chronic condition (MCC) frailty; history of COVID; MA indicator; others as identified; and social risk factors (which are tested after other variable selections are completed).

TEP Feedback

Question 1: Please provide your feedback on the risk variable selection process: Are there any parts of the process that need to be clarified? Do you have any feedback on the process?

- A TEP member asked what happens to the other 20% of the outcome (step 5)?
 - Dr. Peter clarified that the 80% should be read as a threshold, where the variables selected are significantly associated with the Diabetes EDAC outcome 80% of the time or more with the 1,000 bootstrapped samples.
- A TEP member asked for clarification on secondary diagnosis codes that are on the Always POA Exempt List.
 - Dr. Jacqueline Grady noted that CORE has a process where clinical review is obtained for codes to be added to this list. She provided an example of congenital conditions as codes that would be added to this list.
 - In the chat, Mr. Niederhauser shared the <u>POA Exempt List</u> as a resource for TEP members.
- A TEP member stated that many Z-codes (e.g., homelessness) can be influential and should be considered for the Diabetes EDAC risk model.
 - Dr. Peter noted that Z-codes that are non-clinical, such as homelessness, will be prioritized during a later stage (stage 6) in the risk variable selection process.
- A TEP member asked if information or codes related to telehealth visits are also captured within patient claims data.
 - Dr. Peter confirmed that telehealth visits should be captured as it would be in claims data.

- A TEP member asked if the effect of COVID on emergency departments is still important to consider in the model if the measurement period is in CY 2022 when the impact of COVID had lessened.
 - Dr. Peter noted that the COVID variable was added to other EDAC measures per CMS rulemaking and has not yet been removed. To be consistent with other measures, Diabetes EDAC will include the variable, but CORE expects that at some point this measure modification may be removed.
- A TEP member asked about the quality of MA data, and differences between MA and FFS data related to patient populations versus coding.
 - Dr. Peter responded that other EDAC measures had an issue with coding differences across MA that may not be related to patient's acuity and the MA indicator was added as a risk variable because of this.
 - Dr. Grady added that MA indicator was added to account for differences in frequency of coding, and not specifically quality of data.
 - A TEP member iterated the importance of adding a MA indicator into the risk model because hospital incentives are high to code morbidities in MA plans.
- A TEP member asked if CORE has considered including the principal diagnosis code for the index hospitalization in the risk model because of different effects dependent upon the type of diabetes.
 - Dr. Grady noted that most claims-based measures have not done this, but the AMI measures do adjust based upon the type of AMI.
 - Dr. Peter noted that during development of the cohort, CORE looked at the reason for readmission and prior admissions to identify similarities between patients with a principal or secondary diagnosis related to diabetes complication. This is what resulted in the narrowing of the cohort, and the consideration of whether patients with amputations affect the risk model. She added that the Hospital Wide Mortality (HWM) measure has five groupings of patients that are different from one another, but due to the size of the Diabetes EDAC cohort, it might become too small if differentiated by type of diabetes. She suggested creating calibration plots over model performance for the different types of diabetes in patients to see if the model changes based upon the type of diabetes.
 - Action Item: CORE to create calibration plots over model performance by different types of diabetes.
- A TEP member asked if there is an adjustment step for prior admissions as the most predictive variable of a readmission a prior admission.

- Dr. Lisa Suter noted the complexity for this kind of risk variable, as it is related to a patient's comorbidities and a proclivity for a hospital to admit a patient. Other steps during risk adjustment (i.e., frailty, social risk factors) may accurately adjust for this concern, but she noted the importance of considering this in the risk model.
- Action Item: CORE to consider if prior admissions should be accounted for in the risk variable selection process.

Diabetes EDAC Measure Risk Variable Selection Results

- Dr. Peter provided results of the risk variable selection process.
 - The CORE EDAC team started with approximately 1200-1300 codes, reduced by frequency thresholds to about 1000, then further combined to 661 codes.
 Bootstrapping reduced these to 46 codes significantly associated with outcomes.
 These include commonalities with other EDAC measures, like frailty variables and DNR. The CORE EDAC team used the bootstrapping method to identify significant variables, avoiding adding variables beyond the 80% cutoff as it didn't improve model performance. The final draft risk model includes the most frequent and significant variables associated with outcomes.
 - Frequencies for Medicare Advantage and fee-for-service patients reveal some differences, usually with higher coding frequencies for Medicare Advantage.

TEP Feedback

Question 2: Please provide your feedback on the list of candidate variables. Do you feel that the variables selected up to this point make sense (you would expect them to be associated with greater or lesser risk of EDAC for patients hospitalized for diabetes)?

- TEP members first asked questions related to the risk variables.
 - A TEP member asked why both "encounter for palliative care" and "do not resuscitate" appear separately on the list, despite being closely related, and expressed surprise that both are ranked highly.
 - Dr. Peter explained that individual codes are selected if they each meet the threshold for association with the outcome. Even if related, like "encounter for palliative care" and "do not resuscitate," they get selected independently if not coded together frequently enough to meet the threshold for combining. She offered to check how often these two codes were co-coded but noted they didn't meet the criteria for automatic combination.

- A TEP member noticed two distinct populations within the data: one with ischemic gangrene and vascular disease, and the other with hyperglycemia. They observed that codes related to hyperglycemia are highly correlated with each other, as are those related to vascular conditions. They asked how these correlated codes are statistically parsed out in the model.
 - Dr. Peter noted that they considered removing all amputation cases from the population, based on a recommendation from a TEP member, to address the concern of having these two highly correlated groups.
 - A TEP member mentioned that the risk model reflects preliminary testing and that they considered recommending excluding the amputation group. However, they pointed out that many patients with atherosclerotic conditions are now treated non-surgically with revascularization procedures to prevent amputation. Excluding them might not be appropriate and could overlook the nature of these patients.
 - Dr. Peter agreed with the TEP member's point, emphasizing that excluding the amputation group might not accurately reflect the current treatment practices and patient characteristics. She acknowledged that excluding these patients could miss important aspects of their care and outcomes.
- A TEP member asked if the analysis considered differences in care for people from nursing homes compared to regular patients, particularly regarding their entry and discharge from the hospital.
 - Dr. Peter responded that the analysis did not differentiate between patients from nursing homes and those from other settings in any of the results. This consideration could be included in the future. The CORE EDAC team could explore it further if additional resources are available. There is a measure that looks at days at home instead of days in acute care, which includes a nursing home adjustment. Although this adjustment had minimal impact, it was included due to face validity. The CORE EDAC team hasn't seen hospital-level adjustments related to this kind of measure but is open to insights from others with relevant experience.
 - Action Item: CORE to consider the impact on the risk model for patients from nursing homes.

- A TEP member asked for clarification on the process of collapsing diagnoses and wanted to know if it was based on their frequency or performance and asked for a more detailed description of this process.
 - Dr. Peter responded that the process involved two collapsing steps: (1) Combining two different variables coded together at least 80% of the time (see slide 52 in the TEP slide deck for codes that were commonly coded together), (2) combining identical codes present both 12 months prior to admission and at the index admission if their association with the outcome was within 0.2 odds ratios of each other and in the same direction.
 - The TEP member inquired if adjacent codes or different categories (e.g., different types of gangrene) were collapsed based on local frequency.
 - Dr. Peter clarified that CORE previously used groupings of related codes (CCs) for risk adjustment but shifted to an individual code method because of better risk model performance. The CORE Diabetes EDAC team considered combining related codes but decided against that approach to avoid the complexity of endless collapsing and the implications for maintaining the collapsed codes.
 - The TEP member noted understanding and approval of the collapsing approach and referenced the significant improvement in C-statistics from the previous method. They acknowledged common questions about related codes and face validity issues.
 - Dr. Peter confirmed the method's effectiveness and mentioned that odds ratios for individual variables were available in the spreadsheet, although these are univariate and will be more meaningful once all variables are tested together.
- TEP members provided their input on the risk variables selected.
 - A TEP member stated that the list of variables is adequate, functional, and more usable, meeting the needs without involving unrelated factors. They expressed that it focuses on diabetes-specific issues, making it practical for understanding and treatment, particularly noting differences between type 1 and type 2 diabetes hospitalizations.
 - A TEP member stated that the list of the top 46 variables comprehensively addresses many aspects of diabetes care. They noted the chart and flow look good and mentioned no further questions beyond those previously asked. They also pointed out that the list does not differentiate between type 1, type 2, and pre-diabetics, which could be addressed in the next cohort.

- A TEP member stated that they had no additional feedback and thinks the list looks good.
- A TEP member expressed that they are impressed by the detailed list and appreciate the inclusion of additional conditions. They noted that the list does not significantly differentiate between people with type 1 diabetes, type 2 diabetes, or those with other medical conditions like cancer. Overall, they believe the list is very good.
- A TEP member questioned whether a plot had been created comparing the frequency of variables with their actual occurrence among patients. They suggested that variables lower on the list might not have met the 80% frequency requirement due to their lower occurrence in the data, not necessarily their insignificance in the model. They suspected that less frequent variables might be excluded from some bootstrap samples, but this doesn't mean they are insignificant. They asked if there was data to clarify this, noting that both significance and frequency might influence variable selection.
 - Dr. Peter highlighted 11 such variables and mentioned that she could map the frequency data for further analysis. She explained that variable selection involves considering frequency, odds ratios, and significance. She noted that while high-frequency variables might not be selected due to low odds ratios, the model's performance is key. The team tested additional variables to see if the C-statistic improved, but it didn't justify including more variables, which suggested that the team isn't missing significant predictors.
- A TEP member felt that the chosen variables made sense and effectively identified two main patient groups: vascular and hypoglycemic. They appreciated the attention given to LTC variables. However, they had concerns about chronic kidney disease potentially being underrepresented and wondered if long-term HIV survivors might be overlooked due to providers listing HIV as the primary diagnosis and diabetes as secondary, especially in hospitalizations related to diabetes complications.
 - Dr. Peter asked the TEP member to clarify their concern about chronic kidney disease (CKD) patients, specifically whether they are worried that CKD was not being adequately adjusted for.
 - The TEP member clarified that their concern was that the variable included for CKD doesn't capture enough patients. Additionally, they worried that using only a principal diagnosis of diabetes with

complications might miss patients, particularly those with infections like HIV.

- A TEP member acknowledged the concern about reducing the denominator population but emphasized that the measure might be looking at two distinct populations (metabolic disease and vascular complications) with different care needs and suggested creating separate measures for revascularization and wound care. They also noted discomfort with coefficients that contradict clinical expectations, such as MRSA infection reducing EDAC risk, which they see as proxies for unmeasured factors.
 - Dr. Peter shared that she also questions why some variables, like hypertension, show coefficients in the opposite direction of clinical expectations. She noted that hypertension often serves as a proxy for better care and frequent provider visits, acknowledging the TEP member's concern.
- A TEP member agreed that the list is generally good but expressed concerns about "opportunistic" diagnoses or codes, such as those for general health screenings. They noted that metabolic patients often receive follow-up care focused on overall health, while vascular patients typically receive specialized care for wound healing and preventing amputation. They highlighted the different treatment approaches and outcomes for these populations and expressed concern about how they are represented in the list.
- Dr. Peter asked if there were other variables that participants expected to see included. She reminded them that social determinants, frailty variables, and a MA indicator would be considered separately and asked for any additional suggestions.
 - A TEP member mentioned that myocardial infarction and other cardiac codes did not appear in the list, noting the distinct absence of these codes compared to peripheral vascular disease codes.
 - A TEP member flagged a concern in the chat about some variables, like myocardial infarction (AMI), not appearing in the top 80%, and asked for Dr. Peter's response. The TEP member mentioned that certain variables might be further down the list and not selected. They also shared a personal example of their daughter having hyperthyroidism and diabetes and questioned whether these were included or important.
 - A TEP member noted that certain AMI codes, particularly type 2 MI and NSTEMI, were missing from the list. They mentioned that type 2 MI codes might be underreported because of reimbursement issues. They found it interesting and surprising that traditional type 1 MI codes did not appear, while other cardiac

diagnoses like heart failure did. They noted that type 2 MI codes appeared significant in only 40% of the bootstrap samples. In the end the TEP and CORE recognized that AMI would be coded as a principal diagnosis and be captured by the AMI EDAC measure.

- Dr. Peter noted that the identified variables are consistent with the literature, except for long-term insulin therapy, which was missing. She speculated that patients admitted for MI with diabetes as a principal diagnosis might be coded differently and might be captured by the AMI measure instead.
- A TEP member asked if there was access to additional claims data, such as pharmacy claims, noting that medication refills and similar information could potentially be highly predictive of readmissions.
 - Dr. Peter acknowledged that they theoretically have access to pharmacy claims data (Part D) for fee-for-service patients, but may not for Medicare Advantage patients. She noted that Part D data hasn't been used in any CORE measure to date and that incorporating it would be a significant change. She mentioned the potential future use of electronic health records (EHR) data and highlighted the reliability concerns of medication variables in EHRs. Dr. Peter agreed that there are codes for non-compliance, which could serve as a proxy, and appreciated the suggestion.
 - The TEP member asked about the variability in coding Do Not Resuscitate (DNR) status and noted that standards change frequently and there's inconsistency in how and when DNR is captured nationally. They highlighted the differing practices among coders, some coding it within 24 hours and others before admission orders, and questioned its impact on the model.
 - Dr. Peter acknowledged the concern and recognized the variability in DNR capture. She noted that the issue is worth considering in the model.
 - Action item: Dr. Peter to add the topic of variability in DNR capture (POA vs. not POA) to the list for discussion with the CORE EDAC team after the meeting.

Diabetes EDAC Measure Risk-Decile Plots

• Dr. Peter addressed the concern TEP members raised about including patients with amputations in the risk model by showing a calibration plot comparing observed versus predicted outcomes within deciles of predicted risk for patients with and without amputations. She shared three risk-decile graphs showing all admissions, admissions

with amputations, and admissions without amputations, noting that the risk model appears to work similarly for both groups.

TEP Feedback

Question 3: Are there additional risk variables that you think should be considered?

- Dr. Peter noted the risk-decile plots and asked whether they influence the decision to keep both groups of patients in the model, and to consider the different interventions hospitals might undertake for each group.
 - A TEP member asked if interventional procedures, like revascularizations, which are now more common than amputations, are included in the cohort. They inquired specifically about the inclusion of these procedures within the current CCS used.
 - Another TEP member suggested that using amputations as a metric might not be appropriate since it represents a worst-case scenario. They proposed that peripheral atherosclerosis-related conditions, which aim to prevent amputations, might serve as a better grouping variable and questioned whether this would result in different outcomes.
 - The TEP member clarified that their question was about whether revascularization procedures are included in the CCS Grouper, which is being used for amputations. They expressed doubt that all revascularization procedures are included in the CCS.
 - Dr. Peter highlighted that amputation is a last resort and that many patients undergo limb salvage procedures like angioplasty and stenting.
 - The TEP member suggested adding another CCS code to capture these revascularization procedures to see if they influence the model's outcomes, considering that the same population at risk of amputations might already be represented in the model through other procedures.
 - Dr. Peter agreed that it is worth analyzing and suggested doing a calibration plot on patients undergoing revascularization procedures to explore this further.
 - Another TEP member clarified that they are note suggesting the removal of these populations but rather acknowledging they are different, and the models might differ.
 - Dr. Peter mentioned that other measures include separate cohorts for surgical patients, which might offer a broader perspective, and emphasized the need to consider the measure's use and its impact on risk

adjustment. She committed to examining the inclusion of revascularization procedures further.

- Action Item: CORE will examine procedures that occur for patients in the Diabetes EDAC cohort (such as revascularization procedures) to determine if further analyses are required.
- In the chat, a TEP member noted that ICD-10 code Z794, long term use of insulin, is a high frequency code that they would like to see added to the risk variable list. Another TEP member agreed with this statement.
 - Action Item: CORE to consider if Z794, long term use of insulin, is necessary to add into the risk model.

Next steps

- Ms. Healy wrapped up the session and provided meeting participants with next steps.
 - She encouraged participants to provide additional feedback via email.
 - The CORE EDAC team will refine and test the risk model for the EDAC diabetes measure.
 - Ms. Healy and her team will send out a follow-up survey within the next week to gather feedback on the third TEP meeting, and any suggestions for improvement.
 - A Doodle poll will be sent to schedule the fourth TEP meeting within the next few weeks, with tentative dates for a mid-to-late-October date.
 - A TEP summary report from this meeting will be sent out with a formal request for TEP member review in early September 2024.