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CENTERS FOR MEDICARE AND MEDICAID SERVICES
Medicare Evidence Development & Coverage
Advisory Committee

Zoom Virtual Meeting

May 21, 2024

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland

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1 **Panelists**

2

3 **Chairperson**

4 **Joseph Ross, MD, MHS**

5

6 **Vice-Chair**

7 **Sanket Dhruva, MD, MHS, FACC**

8

9 **Voting Members**

10 **Brian Isetts, RPh PhD, BS-Pharm**

11 **Alexander Fanaroff, MD, MHS**

12 **Melissa M. Garrido, PhD, BS**

13 **Fred Kobylarz, MD, MPH**

14 **Joy H. Lewis, DO, PhD, FACP**

15 **Eric Wall, MD, MPH**

16 **Heather Young**

17

18 **HCFA Liaison**

19 **Tamara Syrek Jensen, JD**

20

21 **Patient Advocate**

22 **Naftali Z. Frankel**

23

24 **Industry Representative**

25 **Mark D. Carlson, MD, MA**

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1 **PANEL PROCEEDINGS**

2 **(The meeting was called to order at**

3 **10:00 a.m., Tuesday, May 21, 2024.)**

4 **MS. HALL: Good morning and welcome**

5 **committee chairperson, vice chairperson,**

6 **members and guests to our virtual MEDCAC**

7 **meeting.**

8 **I am Tara Hall, the Medicare Evidence**

9 **Development and Coverage Advisory Committee**

10 **MEDCAC coordinator.**

11 **The committee is here to discuss the**

12 **devices for self-management of Type 1 and**

13 **insulin-dependent Type 2 diabetes. This**

14 **meeting will examine the growing challenges**

15 **associated with the decreased level of evidence**

16 **of certain new and innovative technologies. By**

17 **voting on specific questions and by their**

18 **discussion, MEDCAC panel members will advise**

19 **CMS about the ideal health outcomes and**

20 **research studies of devices for diabetes**

21 **self-management, appropriate measurement**

22 **instruments, and adequate follow-up durations**

23 **to help them provide clarity and transparency**

24 **in future national coverage analysis.**

25 **The following announcement addresses**

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1 conflict of interest issues associated with
 2 this meeting and is made part of the record.
 3 The conflict of interest statute prohibits
 4 special government employees from participating
 5 in matters that could affect their or their
 6 employer's financial interests. Each member
 7 will be asked to disclose any financial
 8 conflicts of interest during the introduction.
 9 We ask in the interest of fairness
 10 that all persons making statements or
 11 presentations disclose if you or any member of
 12 your immediate family owns stock or has another
 13 formal financial interest in any company that
 14 is related to this topic, diabetes or insulin.
 15 This includes speaker fees, salaries, grants
 16 and other support.
 17 If you require a financial disclosure
 18 statement, please email Ruth McKesson so she
 19 can send you the form for completion. Her
 20 email is ruth.mckesson@cms.hhs.gov.
 21 We ask that all presenters please
 22 adhere to their time limit. We have numerous
 23 presenters and a tight agenda; therefore, we
 24 cannot allow for extra time. During each
 25 presentation presenters will receive reminders

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1 informing them how much time they have
 2 remaining to help them stay within their
 3 allotted time. Speakers will receive a prompt
 4 two minutes prior to their speaking time to
 5 insure they are ready to present.
 6 During the open public comments,
 7 attendees who wish to address the will have
 8 that opportunity on a first come basis.
 9 Please email Ruth McKesson if you want
 10 to address the panel by 8:30 a.m. eastern
 11 standard time -- excuse me, 10:30 a.m. eastern
 12 standard time.
 13 For the record, voting members present
 14 for today's meeting are Sanket Dhruva, Brian
 15 Isetts, Heather Young, Melissa Garrido, Eric
 16 Wall, Alexander Fanaroff, Naftali Frankel, Fred
 17 Kobylarz and Joy Lewis. Nonvoting panel
 18 members are Joseph Ross and Mark Carlson. A
 19 quorum is present and no one has been recused
 20 because of conflicts of interest.
 21 The panel, including nonvoting
 22 members, will participate in the voting
 23 dialogue but the nonvoting members will not
 24 participate in the online voting. The voting
 25 results will be available on our website

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1 following the meeting.
 2 We ask that all speakers state their
 3 name each time they speak, speak slow and
 4 concise so everyone can understand, speak
 5 directly into microphones, and do not use your
 6 speaker phones to help achieve best audio
 7 quality. Ensure your devices are on mute when
 8 not speaking. While speaking, please place
 9 ring on silent, remove pets from the area and
 10 anything else that will minimize distractions
 11 and limit background noises.
 12 This virtual meeting is being
 13 transcribed. By your attendance, you are
 14 giving consent to the use and distribution of
 15 your name, likeness and voice during the
 16 meeting. You are also giving consent to the
 17 use and distribution of any personally
 18 identifiable information that you or others may
 19 disclose about you during today's meeting.
 20 Please do not disclose personal health
 21 information.
 22 In the spirit of the Federal Advisory
 23 Committee Act and the Government in the
 24 Sunshine Act, we ask that the advisory
 25 committee members take heed that their

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1 conversations about the topic at hand take
 2 place in the open forum of the meeting.
 3 We are aware that meeting attendees,
 4 including the media, are anxious to speak with
 5 the panel about these proceedings. However,
 6 CMS and the committee will refrain from
 7 discussing the details of this meeting with the
 8 media until its conclusion. Also, the
 9 committee is reminded from discussing the
 10 meeting topics during the break.
 11 I just want to remind everybody, if
 12 you want to speak, please send an email to Ruth
 13 McKesson by 10:30 this morning.
 14 And now I would like to turn the
 15 meeting over to Steve Farmer.
 16 DR. FARMER: Thank you so much. CMS
 17 remains committed to modernizing its coverage
 18 pathways to direct, efficient, predictable and
 19 transparent coverage. We are equally committed
 20 to covering items and services based on
 21 scientifically sound clinical evidence and with
 22 appropriate safeguards.
 23 When developing premarket clinical
 24 studies, CMS believes manufacturers will be
 25 better positioned for multiple product

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1 development stages if they anticipate both FDA
 2 and CMS expectations.

3 For coverage decisions, CMS
 4 specifically requires evidence of benefit in
 5 the Medicare population, which is often older,
 6 has more complex medical records and is often
 7 inadequately represented in clinical studies
 8 used to obtain FDA market authorization.

9 As part of CMS' commitment to improve
 10 the transparency of the NCD process, CMS
 11 expects to finalize guidance soon about how we
 12 review bodies of evidence during national
 13 coverage analyses and our expectations for
 14 coverage with evidence studies.

15 We also expect to publish proposed
 16 guidance on fit-for-purpose study designs soon.

17 CMS is developing this clinical
 18 endpoints guidance series to improve to the
 19 predictability and transparency of our evidence
 20 reviews for treatments addressing these areas.
 21 These reviews will assist interested parties
 22 seeking Medicare coverage for an item or
 23 service such as a drug or device in
 24 understanding the typed of evidence CMS expects
 25 to review when making NCDs.

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1 Please not that clinical endpoint
 2 guidance documents do not review specific
 3 technologies and are not national coverage
 4 analyses or NCDs. Instead, they identify
 5 health outcomes of interest to CMS when
 6 reviewing technologies and considering
 7 reasonable and necessary NCDs.

8 For the current review, CMS engaged
 9 with a contractor to complete a clinical
 10 endpoints review of devices for self management
 11 of Type 1 and insulin dependent Type 2
 12 diabetes. This topic was selected because of
 13 the high burden of diabetes in the Medicare
 14 beneficiary population, and because
 15 technologies are being developed to treat this
 16 condition.

17 This review compiles a succinct list
 18 of outcomes and instruments that represent the
 19 most relevant meaningful outcomes that will be
 20 used to evaluate these devices for Medicare
 21 beneficiaries. It also identifies any
 22 published evidence that defines clinically
 23 meaningful differences for each endpoint.

24 The clinical endpoints review and the
 25 input from this MEDCAC will inform the

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1 development of guidance for this therapeutic
 2 area. This guidance is intended as a reference
 3 for clinical investigators developing studies
 4 and for CMS staff who may review studies in
 5 this therapeutic area. CMS would consider
 6 endpoints other than those identified in this
 7 review and this MEDCAC if there is good reason
 8 to include them. Even so, CMS will strongly
 9 prefer endpoints that have been validated and
 10 for which an MCID has been established.

11 We hope that the MEDCAC will consider
 12 several important factors in this discussion
 13 today.

14 The appropriateness of each endpoint
 15 for the Medicare population. CMS recommends
 16 that investigators carefully consider the
 17 intended recipients of an item or service when
 18 designing clinical studies, such that the
 19 findings may be credibly generalized to the
 20 relevant Medicare beneficiary population,
 21 including important subpopulations.

22 Second, the ability of established
 23 clinically meaningful differences. CMS does
 24 not recommend any specific clinical endpoint or
 25 instrument identified in this review but

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1 generally recommends that the body of evidence
 2 address a range of outcomes that reflect
 3 multiple attributes of an item or service. And
 4 when choosing among the clinical endpoint
 5 options, CMS recommends that clinical studies
 6 prioritize validated endpoints and instruments,
 7 and those with well established or published
 8 minimal clinically meaningful important
 9 differences, because those study findings using
 10 those endpoints are more readily interpreted.

11 And thirdly, the appropriate duration
 12 of followup. CMS may have difficulty reaching
 13 conclusions regarding potential risks and harms
 14 associated with an item or service if the
 15 studies lack sufficient followup to demonstrate
 16 the durability of improved health outcomes.

17 CMS thanks the MEDCAC afternoon and
 18 the public for your thoughtful deliberations on
 19 this topic. I look forward to this meeting,
 20 and now I would like to turn to my colleague,
 21 Terry Rogstad to summarize the findings of the
 22 clinical endpoints review. Terry?

23 MS. ROGSTAD: Good morning. I'm
 24 trying to get my screen shared. All right. Is
 25 my slide showing okay?

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1 DR. YOUNG: You're not in presentation
 2 mode.
 3 DR. ROSS: And Terry, we can't see you
 4 on video either.
 5 MS. ROGSTAD: All right, okay. So I'm
 6 going to stop sharing for a second. All right.
 7 Is it still on in presentation mode?
 8 DR. ROSS: No, it looks like you're
 9 working now, and we can see you on video.
 10 MS. ROGSTAD: Great -- I will be
 11 presenting --
 12 MS. HALL: Terry, can you stop sharing
 13 your screens? We're going to do all the
 14 slides.
 15 MS. ROGSTAD: Stop sharing my screen?
 16 MS. HALL: Yes, Leah will present the
 17 slide.
 18 MS. ROGSTAD: I'm sorry, okay. That
 19 makes it easier. I'm a little confused. Do
 20 people see the slide?
 21 DR. WALL: Not yet, we just see you.
 22 MS. ROGSTAD: All right. Leah, are
 23 you ready to put that in presentation mode?
 24 All right.
 25 I will do a very quick review of the

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1 clinical endpoints review which as Steve said,
 2 was a literature review that CMS commissioned
 3 to an outside contractor. There is an
 4 executive summary of the CER, it is a document
 5 that was posted online and if you haven't done
 6 so already, it would be helpful to open that
 7 document on your screen or have a hard copy on
 8 your desk to refer to during the meeting.
 9 There's more detail in that executive summary
 10 than what I'm going to present with the slides.
 11 Next slide please.
 12 So the CER started out with some
 13 background information. There are two key
 14 measures of high blood sugar in people with
 15 diabetes. A1c represents the percentage of red
 16 blood cells with sugarcoated hemoglobin and it
 17 is usually averaged over the past three months.
 18 And since it is an average value, it doesn't
 19 give any information about glycemic variation,
 20 so other measures are taken to determine
 21 whether the blood sugar is in an acceptable
 22 range or whether the patient is under a
 23 condition of hyperglycemia, too much sugar in
 24 the blood, or hypoglycemia, blood sugar is too
 25 low.

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1 There is a good general consensus on
 2 the optimal blood glucose range of 70 to 180
 3 milligrams of sugar per decaliter of blood.
 4 Hypoglycemia is particularly an issue
 5 for older adults and accounts for more hospital
 6 admissions than does hyperglycemia.
 7 Hypoglycemia can cause dizziness, weakness,
 8 trouble speaking and confusion. With older
 9 adults that may be on medications not related
 10 to their diabetes that can also contribute to
 11 these symptoms, and of course risk of falling
 12 in older adults can make these symptoms more
 13 serious.
 14 Hyperglycemia can cause ketoacidosis
 15 which happens when the body starts breaking
 16 down fat instead of sugar because of a lack of
 17 insulin, and this can lead to a dangerous
 18 buildup of ketones in the blood. Next slide
 19 please.
 20 Devices for self managing diabetes may
 21 be appropriate for patients with Type 1 or
 22 insulin-dependent Type 2 diabetes. The three
 23 devices that were included in the CER were
 24 continuous glucose monitors, insulin pumps, and
 25 closed loop systems which included a CGM. Next

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1 slide please.
 2 The CER involved a systematic search
 3 of the published literature between the years
 4 2018 and 2023 and collected research reports on
 5 the three device types. Those reports could be
 6 systematic reviews, formal consensus statements
 7 or prospective clinical trials, which were
 8 defined as RCTs, nonrandomized studies and
 9 single-arm trial. Several study designs were
 10 excluded.
 11 When the panel subcommittee met, they
 12 pointed out that the inclusion-exclusion
 13 criteria are a bit confusing. It is not
 14 readily apparent how a nonrandomized study or a
 15 single-arm trial is different from prospective
 16 observational studies which were excluded, and
 17 we never could figure that out, so we looked at
 18 the studies that actually made it into the CER.
 19 There were mostly RCTs. There were
 20 several single-arm studies. There was one
 21 study that was labeled a quasi experimental
 22 study and another one that appeared to be a
 23 cohort study. So the selection criteria matter
 24 if it means that important endpoints or
 25 outcomes were missed because certain study

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1 designs were excluded.

2 So with that in mind, the panel

3 subcommittee considered whether from their

4 perspective there were any important endpoints

5 missing from the one prioritized in the CER,

6 and those were added and appear in the voting

7 questions along with the important clinical

8 endpoints identified by the CER itself. Next

9 slide.

10 As I said before, there is a document

11 called an executive summary of the CER. The

12 Tables A1, A2 and B in that document include

13 the information I'm about to present in greater

14 detail. Next slide.

15 Six statements were identified that

16 have been issued by professional associations

17 with recommendations on the measures that

18 should be used to monitor patients with

19 diabetes. The most frequently recommended

20 measures were A1c, hypoglycemia of any level,

21 Level 2 hypoglycemia, time in range, and

22 Level 2 hyperglycemia. Time in range refers to

23 the percentage of time that a patient is in,

24 that they have blood and glucose levels in an

25 acceptable range.

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1 One of the six statements was

2 restricted to older adults and they recommended

3 three of the five measures recommended by other

4 statements. None of these statements defined

5 minimal clinically important differences, and

6 there's a typo on my slide, that should be

7 differences, not definitions. However, three

8 of the statement agreed on target values that

9 clinicians can use to monitor patients with

10 diabetes, so target values for the various

11 glycemic measures. Next slide please.

12 Then the CER looked at the clinical,

13 the primary clinical studies that met its

14 selection criteria and found that the most

15 frequently investigated outcomes in those

16 studies were time in range, Level 1

17 hypoglycemia, A1c, and Level 1 hyperglycemia.

18 27 of the 69 studies enrolled older adults.

19 They were not, those studies were not limited

20 to older adults but they had a good number of

21 patients over the age of 65 in the study

22 groups. And those studies, the same outcomes

23 were frequently investigated, plus Level 3

24 hypoglycemia, the most severe level of

25 hypoglycemia.

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1 In the executive summary you will find

2 a table that lists all of the surrogate markers

3 that were identified in the primary studies

4 including the ones less frequently cited, so

5 those don't appear on that slide but you can

6 get the full list in the executive summary. No

7 MCIDs were identified in the studies or in the

8 published systematic review of glycemic

9 outcomes. However, the National Institute for

10 Health and clinical Excellence in the UK,

11 otherwise known as NICE, and the American

12 Diabetes Association agreed that an absolute

13 change in A1c of .5 percentage points is

14 accepted as clinically significant. Next

15 slide.

16 The other set of outcomes that

17 appeared in the 69 studies were quality of life

18 measures. That was the only type of

19 patient-reported outcome that was frequently

20 investigated and this was an endpoint in most

21 of the studies, and in about half of the

22 studies that focused on older adults.

23 Four quality of life instruments were

24 identified and all have been validated. Three

25 of them have been, or MCIDs have been

Page 21

1 identified or defined for three of those

2 instruments. Two quality of life measures were

3 added by the panel subcommittee and a search

4 was made for MCIDs for those two additional

5 instruments, but none were found. Next slide.

6 Adverse events were also sometimes

7 investigated, either categorized as serious or

8 any adverse event. However, the CER did not

9 provide any detail on the specific events that

10 were recorded, and no MCIDs were identified.

11 Next slide.

12 The CER made some additional

13 observations about these clinical endpoints.

14 No studies evaluated more than three of the

15 five endpoints most commonly recommended by the

16 professional associations, and few studies

17 evaluated as many as, even as many as three of

18 those five endpoints.

19 The CER also observed that some of the

20 frequently cited endpoints varied in frequency,

21 varied in the frequency of citation according

22 to the type of diabetes that was, characterized

23 the patients in the study, or the type of

24 device that was being investigated.

25 And perhaps the most pertinent

Page 22

1 observation was that time in range was the only
 2 endpoint to differ in frequency between studies
 3 that enrolled older adults than in studies that
 4 did not. The studies that included older
 5 adults were more likely to study time in range,
 6 and the difference between those studies and
 7 studies without older adults was statistically
 8 significant. Next slide.
 9 Lastly, the CER identified four
 10 systematic reviews of studies of these devices
 11 and they focused on A1c, time in range, severe
 12 hypoglycemia and patient-reported outcomes.
 13 Next slide.
 14 So that's the end of my summary. As I
 15 said, more detail is available in the executive
 16 summary document. Thank you.
 17 DR. ROSS: Thank you, Terry. And
 18 Leah, you can stop sharing.
 19 So my name is Joe Ross. I'm the
 20 acting chair, or the chair of the MEDCAC for
 21 this meeting. I want to just take a moment to
 22 thank everybody for their time and their
 23 participation. I think the biggest challenge
 24 ahead of us is the very tight timeframe in
 25 which these conversations and public comments

Page 23

1 will be made, and so I appreciate the CMS
 2 presentation on the clinical endpoints review
 3 holding right on time, so we are on track.
 4 So just by short way of introduction,
 5 the MEDCAC is a group of experts that's been
 6 convened to provide advice and recommendations
 7 relating to Medicare coverage, specifically in
 8 this case the types of endpoints that should be
 9 addressed in a body of evidence regarding
 10 devices for self management of Type 1 or
 11 insulin-dependent Type 2 diabetes in older
 12 adults. And over the course of this meeting
 13 we're going to, towards the end specifically,
 14 our panelists are going to be using rating
 15 scales to indicate the importance they attach
 16 to each endpoint domain broken in to four
 17 groups that reflect the clinical evidence
 18 endpoint review that Terry just presented.
 19 Surrogate markers, which are indirect
 20 assessments, using biomarkers, physiological
 21 measures or imaging intended to predict or act
 22 as a proxy for target outcome of interest, for
 23 example the percentage of time in hypoglycemia.
 24 The second domain being health
 25 outcomes or direct assessments of a target

Page 24

1 outcome of interest, for example complications
 2 of diabetes.
 3 The third domain being quality of
 4 life, patient-reported assessment of symptoms,
 5 burden or function, for example the diabetes
 6 distress scale.
 7 And then device safety, for example
 8 hypoglycemia-related emergency department
 9 visits.
 10 We will discuss the appropriateness of
 11 these measures, the ideal duration of followup
 12 that we would want to see these endpoints
 13 ascertained over, and any conventional or
 14 validated threshold for the minimal clinically
 15 important difference or MCID. And we will
 16 encourage our panelists to provide
 17 justification and rationale for their point of
 18 view when it comes time to actually use the
 19 rating skills and cast a vote.
 20 At this point we're going to turn to
 21 the scheduled list of public comments unless
 22 any of our panelists have a specific question
 23 for CMS after the clinical endpoints review.
 24 Please just use the raise your hand function.
 25 Okay. There will be plenty of time for

Page 25

1 questions during deliberation.
 2 We are going to turn to the public
 3 comments. We have a list of 13 speakers, each
 4 of whom has five minutes, and I have to just
 5 inform everyone that we will be very adherent
 6 to time, there will be no going over, and there
 7 will be an opportunity for questions and
 8 clarifications immediately afterwards; is that
 9 right, Tara?
 10 MS. HALL: Yes, that's correct. And I
 11 Candace DeMatteis, I think I'm saying your name
 12 correctly, I apologize if I'm saying it wrong,
 13 you will be the first speaker.
 14 DR. ROSS: Great. So I'm just going
 15 to use the timer, and Candace, the floor is
 16 yours.
 17 MS. DEMATTEIS: Thank you. Good
 18 morning. I'm Candace DeMatteis, policy
 19 director for the Partnership to Fight Chronic
 20 Disease. We do not have any financial
 21 relationship with manufacturers of the products
 22 being discuss today or their competitors.
 23 Diabetes, and more particularly Type 2
 24 diabetes, is one of the most prevalent and most
 25 costly conditions for Medicare. More than 29

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1 percent of adults aged 65 or over in the U.S.
 2 have diabetes and diabetes is often one of a
 3 constellation of chronic conditions people
 4 covered by Medicare are managing on a
 5 day-to-day basis. Often the symptoms of Type 2
 6 diabetes aren't discernible by the person
 7 affected until there's a major problem, leading
 8 many people living with Type 2 diabetes to go
 9 undiagnosed and under treated.

10 Being diagnoses with a chronic
 11 condition is an emotional event, causing
 12 frustration and a feeling of loss of control.
 13 Managing diabetes effectively means significant
 14 lifestyle changes involving diet, exercise,
 15 medication use, often including insulin and
 16 frequent glucose monitoring to minimize the
 17 impact of the disease on health.

18 The devices under consideration today
 19 provide meaningful tools that help people
 20 regain not only a sense of control but actual
 21 control over their blood glucose levels,
 22 control that decades of research have
 23 demonstrated is essential to prevent the
 24 predictable complications that poor diabetes
 25 control manifests. Behavior changes are best

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1 achieved when reinforced by regular feedback.
 2 That's an important consideration of these
 3 devices but one which I did not see mentioned
 4 within your considerations.

5 The substantial health disparities
 6 associated with diabetes should also be a
 7 paramount consideration. Black, American
 8 Indian, Alaskan native, Hispanic, native
 9 Hawaiian, southeast Asian and many other
 10 communities of color are significantly and
 11 disproportionately affected by Type 2 diabetes,
 12 both in terms of higher prevalence and in
 13 poorer outcomes. Those diabetes complications
 14 include blindness, amputations and premature
 15 death. Though your discussions include a focus
 16 on hypoglycemia that reality, the reality that
 17 hospitalizations for diabetes-related
 18 amputations are more than three times higher
 19 than hospitalizations for hypoglycemia should
 20 be noted. People with lower socioeconomic
 21 status and lower education levels are also
 22 affected disproportionately.

23 So where is the clinical, clinically
 24 relevant discussion about what imposing
 25 additional criteria on Medicare coverage will

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1 do for access for these people? These
 2 decisions don't happen in a vacuum without
 3 consequences, and have been used by CMS in the
 4 past to justify imposing coverage with evidence
 5 development requirements that by definition
 6 condition Medicare coverage and limit access.
 7 These are real-world consequences that impact
 8 Medicare and more importantly, the people
 9 Medicare covers. That should be considered.

10 In 2022 the American Diabetes
 11 Association released a study examining claims
 12 data on continuous glucose monitors, including
 13 Medicare claims. That study found that people
 14 with lower incomes and people living in states
 15 with the highest rates of diabetes, prevalence
 16 and mortality are the least likely to get
 17 access to a CGM. So the people experiencing
 18 the highest burden of disease had the least
 19 access to tools that your recommendations could
 20 make even more difficult to access.

21 So it's important to consider those
 22 life and death factors when you're discussing
 23 these questions. Those realities should factor
 24 heavily in your discussion and decisions today,
 25 and we urge you to consider the exercise you

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1 undertake not just as an intellectually or
 2 clinically interesting one, but one with real
 3 life potentially devastating consequences for
 4 some of the most vulnerable Medicare
 5 beneficiaries.

6 Thank you for the opportunity to share
 7 these concerns.

8 DR. ROSS: Thank you. Any questions
 9 from the panel? Okay. Our next speaker is
 10 Janet McGill, Dr. Janet McGill.

11 MS. HALL: No, the next will be Aaron.

12 DR. ROSS: Oh, okay. Tara, I will let
 13 you introduce the speakers because I may have
 14 an outdated list.

15 MS. HALL: Okay, thank you.

16 DR. ROSS: Aaron, whenever you're
 17 ready.

18 MR. TURNER-PHIFER: I think Susan was
 19 going to go next, but I don't want to jump her
 20 in line.

21 MS. PESCHIN: I saw that. Tara, am I
 22 going next, or is Aaron?

23 MS. HALL: I'm sorry, Susan, you can
 24 go. I apologize.

25 MS. PESCHIN: Okay, that's okay, thank

Page 30

1 you. Thanks, Aaron, for being willing to jump.
 2 Hi everybody. I'm Sue Peschin, I
 3 serve as president and CEO of the Alliance for
 4 Aging Research. The alliance is the leading
 5 nonprofit organization dedicated to changing
 6 the narrative to achieve healthy aging and
 7 equitable access to care and we do receive
 8 unrestricted support from industry and others
 9 for our mission.
 10 We're locking arms today with 25 other
 11 non diabetes organizations to oppose any
 12 efforts by CMS to restrict beneficiary access
 13 to FDA approved devices for self management of
 14 Type 1 and insulin-dependent Type 2 diabetes.
 15 We sent a letter signed by 26 organizations to
 16 Administrator Brooks-Lasure and to this MEDCAC,
 17 along with key congressional staff, and the
 18 letter is publicly available on the alliance's
 19 website at agingresearch.org and it was mailed
 20 to all of you, and I'll read just a few of the
 21 groups here so you can see the diversity of the
 22 organizations. American Kidney Fund, Melanoma
 23 Research Alliance, National Grange, National
 24 Hispanic Council on Aging, National Medical
 25 Association, Prevent Blindness and Voice of

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1 Alzheimer's.
 2 And in part, the letter states we're
 3 increasingly disturbed by the CMS coverage and
 4 analysis group's creation and leveraging of
 5 research debates to justify utilization
 6 management of Part B items and services. This
 7 process of positioning this advisory committee
 8 to reevaluate clinical outcomes for an entire
 9 class of medical products that the FDA already
 10 legitimately determined to be safe and
 11 efficacious takes valuable time and resources
 12 away from researchers, clinicians and patient
 13 advocates serving people living with diabetes.
 14 No external organizations requested this
 15 evidence review or the endpoints for trials of
 16 diabetes devices, nor was the Agency for
 17 Healthcare Research and Quality consulted, and
 18 that's the HHS agency that's charged with
 19 conducting evidence reviews.
 20 CMS instead convened a MEDCAC subgroup
 21 on its own in February of 2024 that was not
 22 publicly announced until about a month after it
 23 occurred. This subgroup reviewed a report
 24 written by an outside contractor on devices for
 25 diabetes self management and enlisted one guest

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1 endocrinologist to provide responses to CMS'
 2 questions. To us it raises questions about the
 3 Agency's judgment when it pursues this topic
 4 without reasonable justification in light of
 5 its struggles to manage resources.
 6 To be clear, no one in the diabetes
 7 community asked for this. Here's where CMS'
 8 interests lie. Diabetes is the most expensive
 9 chronic disease in the U.S. That makes medical
 10 devices for diabetes self management a rich
 11 target for Medicare Part B coverage
 12 restrictions. This should not be done.
 13 The standards of care established by
 14 the American Diabetes Association and American
 15 Association of Clinical Endocrinology
 16 unequivocally endorse the use of continuous
 17 glucose monitors and insulin pumps by people
 18 who are insulin dependent. These endorsements
 19 rest on the foundation of voluminous clinical
 20 data with scores of studies affirming th
 21 medical necessity of these technologies. The
 22 use of these devices is established science,
 23 and there is no basis whatsoever for calling
 24 them into question.
 25 This exercise is similar to the one

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1 CMS staged in 2021 when mundane academic debate
 2 on targeting amyloid was leveraged to squash
 3 coverage for the entire class of FDA approved
 4 disease modifying therapies for the treatment
 5 of early Alzheimer's in April of 2022. The
 6 effectiveness of CMS' cost cutting strategy in
 7 Alzheimer's lies in the small number of
 8 Medicare related claims that have been paid for
 9 Leqembi, the second FDA approved therapy in the
 10 class. Since last July of 2023 based on claims
 11 data, only a scant four to 5,000 patients have
 12 been started on Leqembi with approximately
 13 2,000 to 2,500 patients currently on treatment.
 14 This is a fraction of potentially eligible
 15 patients.
 16 The federal statute authorizing
 17 Medicare starts with a noninterference clause
 18 that prohibits CMS from, quote, supervision or
 19 control over the practice of medicine or the
 20 manner in which medical services are provided,
 21 end quote. Clinicians should be able to help
 22 Medicare patients decide which interventions
 23 are best for them without complicating coverage
 24 barriers dictating care.
 25 DR. ROSS: One minute.

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1 MS. PESCHIN: CMS is a payer. It's
 2 not a biomedical expert agency like the FDA or
 3 anybody's family doctor. The actions being
 4 taken by CMS on diabetes self care devices are
 5 an overreach of agency authority and
 6 undermining the public trust in the FDA, and
 7 more broadly in biomedical science itself.
 8 Ultimately the Agency and this advisory
 9 committee should not be staging research
 10 debates to vindicate itself on what's really
 11 happening here, a setup to the rationing of
 12 patient care. Thank you.

13 DR. ROSS: Thank you for your
 14 comments. Are there any questions for the
 15 speaker?

16 MS. HALL: Okay, Aaron, now you can
 17 go. Thank you.

18 MR. TURNER-PHIFER: Good morning
 19 everyone. Name's Aaron Turner, director of
 20 health policy at JDRF. I'm just background.
 21 JDRF is the leading global Type 1 diabetes
 22 research and advocacy organization. Our
 23 mission is to accelerate life changing
 24 breakthroughs to cure, prevent and to treat
 25 diabetes and its complications. I appreciate

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1 the opportunity to provide our perspective at
 2 today's meeting.

3 We don't have a financial conflict.
 4 However, we do work with the different
 5 manufacturers that are impacted, particularly
 6 around things like our charity walks and rides,
 7 so happy to complete documentation there, and
 8 we'll follow up afterwards.

9 So jumping into comments here, just as
 10 background, T1D is an insidious autoimmune
 11 disease that strikes children and adults, and
 12 is fatal without lifelong insulin therapy.
 13 Recent advances in technology have given people
 14 with T1D access to life changing devices that
 15 are allowing them to better manage their
 16 diabetes. These devices, pumps and the CGMs
 17 used with those monitors are the standard of
 18 care for everyone living with T1D and it's
 19 clear given the compelling evidence that their
 20 impact is having a positive one on folks'
 21 lives.

22 Closed loop systems comprised of a
 23 pump and CGM working together to deliver
 24 insulin directly to the wearer with limited
 25 input by the person represent the latest

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1 advancement in care. Evidence indicates that
 2 these systems are having an even greater
 3 impact, positive impact on wearers of all ages.

4 And now for JDRF's perspective. 20
 5 years removed from our first grant funding a
 6 closed loop system prototype, there are
 7 multiple closed loop systems available in the
 8 market, with a growing rate of adoption by
 9 those in the T1D community. Both CGMs and
 10 closed loop are directly impactful and in a
 11 significant way in the wellbeing and livelihood
 12 of those living with T1D.

13 Given our decades of experience
 14 advancing care and technology, JDRF has funded
 15 and/or supported many of the studies and
 16 consensus statements cited in the endpoints
 17 review report. We're pleased to see such a
 18 thorough review be completed, happy to see all
 19 the positive data years of work and investment
 20 from the community has had. We do believe the
 21 endpoints set up by CMS to review are all
 22 relevant and important to everyone living with
 23 T1D.

24 We want to call attention to two
 25 endpoints in particular, time in range and

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1 level one hypoglycemia, level one defined as 70
 2 milligrams per decaliter. Those are important
 3 to the delivery of care, particularly for folks
 4 with Type 1. The growing body of evidence
 5 continues to link time in range to clinical
 6 outcomes, including the development of
 7 retinopathy and further complications of T1D.

8 A JDRF funded 2020 study on T1D
 9 glycemic outcomes showed adults with T1D review
 10 or -- excuse me, sorry -- showed adults with
 11 T1D were avoiding one to five, on a level of
 12 one to five, only one hypoglycemic event per
 13 week to be five times as important than being
 14 .5 percent above their target A1c.

15 I mangled that. Basically what our
 16 study showed was that avoiding hypoglycemic
 17 events was more important to people with Type 1
 18 diabetes than an improvement in their A1c.

19 As such, any consideration of
 20 endpoints should include both the time in range
 21 metrics and level one hypoglycemic metrics in
 22 addition to the other endpoints utilized by the
 23 FDA such as A1c levels and level two
 24 hypoglycemia, which is defined as 54 milligrams
 25 per decaliter.

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1 As highlighted in the endpoints
 2 review, MCIDs are an important metric that
 3 warrant consideration. While the prepared
 4 report notes that there is a lack of clear
 5 definition at present for MCIDs, at least a
 6 universally accepted clear definition, this
 7 currently allows care to focus on the unique
 8 patient needs at any given moment.
 9 We caution against CMS action to
 10 establish its own MCID definition that would in
 11 any way restrict the ability of physicians to
 12 tailor care to the unique needs of the
 13 individuals living with diabetes.
 14 We further caution against any
 15 suggestion as implied in the prepared documents
 16 for this meeting, that there is a lack of clear
 17 evidence regarding the impact of diabetes on
 18 older adults living with T1D. We do not
 19 believe that there is a fundamental difference
 20 in the physiology of older adults that warrant
 21 separate data relative to those who are
 22 younger, such as is the case that may be
 23 required for pediatric populations versus adult
 24 populations.
 25 As shown in the data provided by

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1 CMS --
 2 DR. ROSS: 30 seconds.
 3 MR. TURNER-PHIFER: -- benefits of
 4 devices remain constant across adult age
 5 groups. For example, JDRF has supported
 6 several studies demonstrating the use of CGM in
 7 older adults, and showing statistically
 8 significant reductions in hypoglycemia relative
 9 to the standard relative to standard glucose
 10 monitoring.
 11 A final note of caution. Here after
 12 years of research and direct advocacy by JDRF
 13 in the broader T1D community, we applauded CMS'
 14 final expansion of coverage for all approved
 15 CGMs in 2022, but we appreciate that
 16 Medicare --
 17 DR. ROSS: Wrap up.
 18 MR. TURNER-PHIFER: -- now covers CGMs
 19 for all people with T1D. Yet we remember with
 20 concern that it took CMS nearly a decade to
 21 provide initial access to CGMs.
 22 DR. ROSS: Aaron, I've got to stop
 23 you. You're over time.
 24 MR. TURNER-PHIFER: Okay. Thank you
 25 very much. I appreciate it.

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1 DR. ROSS: Any questions for the
 2 speaker? And I do apologize for not giving a
 3 one-minute advance, but only 30 seconds.
 4 MR. FRANKEL: Yeah, one clarification
 5 question.
 6 DR. ROSS: Yes, good. Go ahead.
 7 MR. FRANKEL: To your points that you
 8 just made regarding not differentiating between
 9 the younger and elderly population, do you view
 10 that across the board in terms of when you were
 11 viewing the materials in terms of clinical
 12 outcomes and concerns for example about
 13 hypoglycemia? Is that your position as an
 14 organization, that that should not be
 15 specifically focused on for the elderly
 16 population, which may have more concerns
 17 regarding those specific clinical outcomes?
 18 MR. TURNER-PHIFER: I think -- I'll
 19 respond two ways. The first is that
 20 organizationally our position is that you know,
 21 we've seen both in study data, but also real
 22 world evidence that the impact of these devices
 23 is a positive one across population
 24 demographics. And we also know, and I think
 25 the ADA standard of care reflects it, that

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1 older adults have different concerns than
 2 younger adults with respect to outcomes,
 3 particularly around avoiding hypoglycemic
 4 events.
 5 And so there may be, as you're
 6 considering what's more important, I think we
 7 would expect those considerations to be
 8 weighted more heavily, what a person values and
 9 what their physician may value. But with
 10 respect to the underlying data about the impact
 11 of the devices, I think that we would consider
 12 it to be positive across the board.
 13 DR. ROSS: Thank you. Tara, who's
 14 next?
 15 MS. HALL: Laura is next.
 16 MS. FRIEDMAN: Hi everyone. My name
 17 is Laura Friedman. I'm the vice president of
 18 regulatory affairs at the American Diabetes
 19 Association, I appreciate the opportunity to
 20 share our remarks with you today.
 21 We do not have any specific financial
 22 disclosures to share, but we do receive funding
 23 from industry for various aspects of our
 24 operation, and we're happy to follow up if
 25 needed as well.

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1 A little background. ADA is the
 2 nation's leading voluntary health organization
 3 fighting to bend the curve on the diabetes
 4 epidemic. Founded in 1940, the ADA has been
 5 driving discover and research to treat, manage
 6 or prevent diabetes while working relentlessly
 7 for a cure. We review and author the most
 8 authoritative and widely followed clinical
 9 practice guide recommendations, guidelines and
 10 standards for the treatment of diabetes, and
 11 publish the most influential professional
 12 journals concerning diabetes treatment and
 13 research.

14 In our chapter on diabetes technology,
 15 ADA standards of care states that when coupled
 16 with diabetes self management, education and
 17 support, diabetes technology can improve the
 18 lives and health of people with diabetes, and
 19 has transformed the management landscape by
 20 improving outcomes and making the condition
 21 easier to live with. People with diabetes who
 22 have been using CGM insulin pumps and/or
 23 automated insulin delivery systems for diabetes
 24 management should have continued access across
 25 third party payers, regardless of age or A1c

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1 levels.

2 We acknowledge the troubling trend of
 3 the time delay between when a device is
 4 approved by the FDA and the period of time it
 5 takes to receive Medicare coverage, and note
 6 that the ADA broadly supports measures that
 7 will expand access to technology for
 8 beneficiaries with diabetes, whether this
 9 refers to technologies on the market today or
 10 in the future.

11 We urge that CMS take extra care to
 12 avoid making choices that would limit access
 13 for people with diabetes, especially once the
 14 device has already been thoroughly tested and
 15 proven safe and effective, like CGM, insulin
 16 pumps and automated insulin delivery systems
 17 where CGM informed algorithms modulate insulin
 18 delivery, as well as diabetes self management
 19 support software serving as medical devices.

20 We are grateful to the DME MAC medical
 21 directors for expanding access to technology
 22 for Medicare beneficiaries by making important
 23 coverage criteria changes to the LCD for
 24 glucose monitors. We appreciate specifically
 25 the elimination of the four or more times a day

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1 blood glucose monitoring testing requirement in
 2 2021 as well as the 2023 expansion allowing all
 3 insulin dependent people with diabetes and
 4 others who have a history of problematic
 5 hypoglycemia to have access to this important
 6 technology.

7 Each of these changes has removed
 8 significant barriers for beneficiaries with
 9 diabetes, and we respectfully caution the
 10 Agency against directing additional barriers to
 11 devices and technology that have been
 12 rigorously tested in people with all types of
 13 diabetes and at all ages.

14 The ADA recommends that CGM devices
 15 should be offered for diabetes management in
 16 adults with diabetes on multiple daily
 17 injections, insulin pumps, AID systems or basal
 18 insulin who are capable of using the devices
 19 safely, as well as for youth with Type 1
 20 diabetes or Type 2 diabetes on multiple daily
 21 injections.

22 Based on the Agency's comments in the
 23 MEDCAC issue brief about diabetes technologies
 24 in older people, we draw your attention to a
 25 recommendation that older individuals with

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1 Type 1 diabetes benefit from ongoing insulin
 2 pump therapy and access to insulin pump therapy
 3 including AID systems, and should be allowed or
 4 continued in older adults as it is in younger
 5 people. Multiple randomized control trials
 6 have been performed using real-time CGM devices
 7 and the results have largely been positive in
 8 terms of reducing A1c levels and/or episodes of
 9 hypoglycemia as long as participants regularly
 10 wore the devices.

11 The initial studies were done
 12 primarily in adults and youth with Type 1
 13 diabetes on insulin pump therapy and/or on
 14 multiple daily injections. The primary outcome
 15 was met and showed benefit in adults of all
 16 ages, including seniors. Real-time --
 17 randomized control trial data and real-time CGM
 18 use in different --

19 DR. ROSS: One minute.

20 MS. FRIEDMAN: -- types of diabetes on
 21 MDI, mixed therapies and basal insulin have
 22 consistently shown reductions in A1c levels and
 23 increases in time in range. The benefits of
 24 intermittently scanned CGM for adults with
 25 Type 2 diabetes not using insulin were recently

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1 reported in a randomized control trial showing
 2 that the use of intermittently scanned CGM plus
 3 diabetes education versus diabetes education
 4 alone showed decreased A1c levels and increased
 5 time in range as well as an increase in --
 6 DR. ROSS: Sorry, we've reached the
 7 five minutes. Does anyone have any questions
 8 for this speaker? Okay. Thank you for
 9 presenting. Sorry I had to cut you off.
 10 Tara, who is the next speaker?
 11 MS. HALL: Next we have Jessica
 12 Castle.
 13 DR. CASTLE: And will you be pulling
 14 up my slides or should I start sharing my
 15 screen? Perfect.
 16 Good morning, everybody. I'm Jessica
 17 Castle, VP of medical affairs from Dexcom. We
 18 can go to the next slide in presentation mode
 19 if we can. So I am an employee and shareholder
 20 of Dexcom. Next slide please.
 21 I'm going to speak to three different
 22 items, one on trial duration, one on A1c, and
 23 finally on time in range.
 24 So the DCCT definitively showed that
 25 improving A1c results in reduction of

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1 microvascular complications in people living
 2 with Type 1 diabetes. The UKPDS similarly
 3 showed improvements in A1c reduced
 4 microvascular complications in people living
 5 with Type 2 diabetes. The EDIC study and the
 6 UKPDS follow-up study demonstrated a reduced
 7 risk of cardiovascular disease in people living
 8 with Type 1 and Type 2 diabetes respectively.
 9 And therefor, A1c has been shown to be an
 10 appropriate surrogate outcome for
 11 diabetes-related complications, and A1c can be
 12 measured after 12 weeks. Requiring trials
 13 longer than 12 weeks increases participant
 14 burden, as well as an increased risk of
 15 participant dropout. Also, requiring trials of
 16 longer duration delays the length of time that
 17 therapies reach patients and would be
 18 prohibitively expensive in the development of
 19 technology, and therefore recommend a minimum
 20 trial duration of no longer than 12 weeks.
 21 Next slide please.
 22 A1c, so the magnitude of A1c
 23 improvement is correlated with baseline A1c
 24 levels, and therefore with patients as they
 25 approach the typical target of seven percent,

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1 that these lower baseline levels typically
 2 result in a lower magnitude of improvement,
 3 which is important to keep in mind. An A1c
 4 change of .3 percent is clinically meaningful
 5 and has been associated with reduced risk of
 6 retinopathy. Guidance from both the FDA and
 7 the European Medicines Agency uses this .3
 8 percent threshold when evaluating drugs to
 9 improve glycemic control, and therefore, we
 10 recommend establishing a minimally clinical
 11 difference in A1c of no higher than .3 percent.
 12 Next slide.
 13 Time in range is the time in which the
 14 blood glucose is between 70 and 180 milligrams
 15 per decaliter. CGM allows for the measurement
 16 of time in range, which has significant
 17 advantages over A1c. The time in range derived
 18 from the seven-point finger stick testing in
 19 the DCCT was strongly associated with the
 20 reduced risk of microvascular complications. A
 21 10 percent increase in time in range correlates
 22 with a .6 to .8 percent reduction in A1c, and
 23 so logic would indicate that a five percent
 24 increase in time in range would correlate with
 25 .3 to .4 reduction in A1c, which is clinically

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1 meaningful. A five percent increase in time in
 2 range correlated in a case control study
 3 recently published in the Diabetes Technology
 4 and Therapeutics Journal, with a significant
 5 reduction in risk of retinopathy, a clinically
 6 meaningful vascular complication.
 7 Two international consensus
 8 statements, one in 2019 and one in 2023,
 9 indicated that a time in range improvement of
 10 five percent is clinically significant, and
 11 therefor we recommend establishing a minimum
 12 clinically important difference for time in
 13 range of no higher than seven percent, or no
 14 higher than five percent.
 15 And that is my last slide. Happy to
 16 take any questions.
 17 DR. ROSS: Thank you, Jessica. Any
 18 questions from the panel?
 19 MS. HALL: Okay, Gregory, you're up
 20 next.
 21 DR. FORLENZA: Yes, so thank you.
 22 Good morning, and thank you for inviting me to
 23 present today. My name is Greg Forlenza, I'm a
 24 pediatric endocrinologist and technology
 25 researcher at Barbara Davis Center in Denver,

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1 Colorado. Next slide.
 2 And our team here at University of
 3 Colorado and Barbara Davis Center conducts
 4 research on all the devices currently on the
 5 market in the United States to help people with
 6 Type 1 and Type 2 diabetes improve blood sugar
 7 control, improve their quality of life and
 8 improve their care. Next slide.
 9 So our group conducted an analysis of
 10 Medicare and Medicaid beneficiaries who had
 11 started a novel closed loop system or automated
 12 insulin delivery system, and that's what I'm
 13 going to be sharing with you in a moment. You
 14 guys obviously know what Medicare and Medicaid
 15 are all about, but the reason that we conducted
 16 this analysis was everything in the field that
 17 you look at shows that both older adults and
 18 low income individuals, particularly low income
 19 children, have much lower rates of technology
 20 use than the general population, and that there
 21 is some provider bias and coverage barriers
 22 that contribute to that. And so what we aimed
 23 to show in this analysis is how beneficial
 24 these technologies can be in these groups that
 25 are currently under utilizing them.

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1 In my sharing it with you today, I
 2 wanted to share with you how experts in the
 3 field who are actively doing clinical care and
 4 actively conducting clinical research are
 5 evaluating the use of these technologies and
 6 how these evaluations could contribute to us
 7 determining whether or not these should be
 8 used, and thereby showing you that they should
 9 be covered. Next slide.
 10 So in this analysis we looked at users
 11 who were six years old and older, which was on
 12 label use of the device at the time of
 13 analysis, and had at least 12 consecutive
 14 months of data available in our industry
 15 partner for this analysis, Tandem, makers of
 16 the control IQ pump, in their online database,
 17 and participants had to have at least 30 days
 18 with greater than 75 percent available CGM data
 19 after initiation of the technology. And for
 20 our analysis, this group, some of whom we're
 21 going to be presenting in some of the other
 22 talks today, we're looking first at time in
 23 range, time in target range which we've heard
 24 about today, percent of time the blood sugar is
 25 between 70 and 180. We all were in universal

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1 agreement that was the most important metric.
 2 The second metric is one I actually
 3 haven't heard folks talk about today, is
 4 glucose management indicator or GMI. GMI is a
 5 mathematical abstraction of average sensor
 6 glucose to determine what your hemoglobin A1c
 7 would be based on that blood sugar. During the
 8 pandemic when we couldn't draw blood on
 9 participants, that was a very valuable tool to
 10 sort of approximate hemoglobin A1c and for data
 11 driven analysis where you can't get biological
 12 samples, that's also a very useful indicator.
 13 And then we looked at the standard blood sugar
 14 rate, which is for Level 1 and Level 2
 15 hypoglycemia and Level 1 and Level 2
 16 hyperglycemia. Next slide.
 17 So this is the baseline data for whom
 18 we were looking at, and what we're seeing here
 19 is about 4,000 Medicare beneficiaries, about
 20 1,300 Medicaid beneficiaries, and within that
 21 about 500 people who are currently using the
 22 device off label with Type 2 diabetes, and here
 23 we see the baseline statistics for each of
 24 those groups, including looking at GMI, sensor
 25 glucose and time in range statistics and those

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1 are folded in to the next data set. And just
 2 as an FYI, most of the people that we're
 3 analyzing here, we're currently using a system
 4 that minimized hypoglycemia, and so we're
 5 seeing a transition from a hypo minimizing
 6 system to a system which minimizes both hyper
 7 and hypoglycemia. Next slide.
 8 And so this is the payoff slide, this
 9 is the data that we were looking at that we
 10 were so excited as clinical researchers to be
 11 seeing. We were seeing among the Medicare
 12 population, we saw a GMI, which is again that
 13 mathematical abstraction for a hemoglobin A1c,
 14 a reduction from 7.3 to 7.0 percent, and
 15 supporting what Dr. Castle said on the last
 16 slide, we all felt this was clinically
 17 meaningful. It's obviously statistically
 18 significant. For the Medicaid population we
 19 saw a .4 percent reduction in GMI.
 20 For time in range we saw a 10 percent
 21 improvement among the Medicare population
 22 and --
 23 DR. ROSS: One minute.
 24 DR. FORLENZA: -- a 14 percent
 25 improvement among the Medicaid population.

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1 And in Type 2 we saw similar data, and
 2 you can see that for hypoglycemia, that was
 3 maintained, severe hypo was reduced, and time
 4 above ranges were all reduced. Next slide.
 5 And so in summarizing this data, what
 6 we can conclude, I just want to go to the last
 7 slide here, is that existing data on over 5,500
 8 Medicare and Medicaid beneficiaries,
 9 demonstrates individual and group level
 10 improvement with AID systems. An understanding
 11 of this baseline comparison is important
 12 because hypo was already reduced, and at a
 13 group level, the percentage meeting ADA goals,
 14 which is the slide I'm not showing but I can go
 15 over it if there's a question. It's also of
 16 high interest, because as a clinician that's
 17 what you see and that's what makes a difference
 18 for payers.
 19 And so we recommend both individual
 20 and group level analysis of people meeting ADA
 21 goals and of the standard CGM metrics being
 22 presented today.
 23 And just to wrap up, as a clinician
 24 conducting this research --
 25 DR. ROSS: Thank you, Dr. Forlenza.

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1 DR. FORLENZA: Thank you guys for
 2 listening, and thank you for your advocacy.
 3 DR. ROSS: Thank you. If I could just
 4 ask one question, I'm sorry about the slide.
 5 The post CIQ data, was that 12 months,
 6 if I understood?
 7 DR. FORLENZA: Yes, 12-month data,
 8 correct.
 9 DR. ROSS: Great. Any other questions
 10 for this speaker from the panel? Okay, thank
 11 you.
 12 DR. FORLENZA: Thank you guys very
 13 much.
 14 MS. HALL: Next we'll have Davida.
 15 MS. KRUGER: Thank you. Next slide
 16 please.
 17 These are my financial disclosures. I
 18 work at Henry Ford Health division of
 19 endocrinology. I have been in this position
 20 for more than 42 years as a clinician and a
 21 researcher. Next slide.
 22 So this is just general comments about
 23 diabetes technology in terms of the ADA
 24 guidelines. They clearly state that real-time
 25 CGM and insulin pump therapy should be

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1 available for all individuals with Type 1
 2 diabetes or insulin-requiring Type 2 diabetes.
 3 The clinical benefits of these technologies,
 4 they're not in dispute, we've been using them
 5 for years, they're FDA approved, we know how to
 6 use these devices. Glucose control as
 7 evidenced by current standards of care improves
 8 outcomes. Glucose control is best achieved
 9 currently through CGMs and insulin
 10 administration devices, notably we believe
 11 insulin pumps. I manage more than, in our
 12 clinic, 2,000 individuals on insulin pumps,
 13 both Type 1 and Type 2, from all walks of life.
 14 We use all devices that are on the markets and
 15 do clinical research on them as well.
 16 The benefits of diabetes technology is
 17 consistent across people with diabetes,
 18 regardless of the type of diabetes and the age.
 19 And I wanted to make a comment about the age.
 20 Since I've been in this position for more than
 21 42 years and started using pumps in 1982 when I
 22 was the national chairperson of the Diabetes
 23 Control and Complications Trial, all of our
 24 clinical patients of course were also offered
 25 insulin pumps. So I've got all of these

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1 individuals who have aged into the Medicare
 2 population, both Type 1 and insulin-requiring
 3 Type 2. I've got several people in their 90s,
 4 many people in their 80s and in the 70s, and
 5 they use them effectively. When they turn 65,
 6 there's no way I can say you're no longer going
 7 to be able to use this, and we offer those
 8 patients as they pass Medicare who will benefit
 9 by it if they've not been seen in our practice
 10 before that. So it's across all people with
 11 diabetes regardless of the type of diabetes and
 12 age and education, although I hope we do better
 13 than the data my friend Greg just showed you,
 14 in making sure all people in all walks of life
 15 get to use this technology. Next slide please.
 16 And the general, the Diabetes Control
 17 and Complications Trial conclusively
 18 demonstrated that good glucose control directly
 19 reduces the rates of several significant
 20 complications. This is a landmark study that I
 21 believe you're all familiar with. At 6.5 years
 22 we showed an A1c of less than seven percent
 23 reduced the risks of complications to our
 24 patients. The primary consideration should be
 25 whether a device demonstrates the capacity to

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1 move patients to their target glucose range.
 2 And of course, in our clinical practice we
 3 absolutely believe that. Next slide please.
 4 And then clinical trials. I've been
 5 doing clinical trials in Type 2 diabetes. They
 6 are very much beholden to the FDA, and so I
 7 heard one of the speakers also say that, how do
 8 we live to the needs of the FDA and the needs
 9 of CMS. But clinical trials for diabetes
 10 technology are needed to demonstrate the
 11 accuracy and utility of the these devices,
 12 which I believe are being done, and I believe
 13 shortly you will be able to see the outcomes of
 14 two trials we recently completed in Type 2
 15 diabetes, and the current device trial compares
 16 new technology to recently available
 17 technology.
 18 Clinical benchmark and study outcomes
 19 must be tailored to real world considerations.
 20 Our control groups may be using diabetes
 21 technology, CGM or current pumps. Accuracy and
 22 utility can be demonstrated in clinical trials
 23 of three months, that's what we did in these
 24 recent clinical studies. The FDA believed that
 25 to be enough, and we certainly saw differences

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1 in our patients. And while you talk --
 2 DR. ROSS: One minute.
 3 MS. KRUGER: -- about MCI, it's an
 4 important metric, should be in the specific
 5 clinical trial design and population study.
 6 And I'll conclude, and then I know
 7 Janet will be behind me and she will go on.
 8 I want to say a quote my friend Henry
 9 Anhafe (phonetic) said. Living with diabetes
 10 doesn't mean sacrificing a vibrant and
 11 fulfilling like as we age. In fact it's quite
 12 the opposite. With the right tools, mindset
 13 and support, individuals can navigate to their
 14 golden years with grace and vitality, and I
 15 hope you grow to remember that so that we can
 16 get what we need to continue to manage people
 17 in clinical practice. Thank you.
 18 DR. ROSS: Thank you for your
 19 comments. Any questions for the speaker?
 20 Thank you very much.
 21 MS. HALL: Next will be Laurel.
 22 DR. DHURVA: Joe, I think we have a
 23 question from Melissa. Sorry.
 24 DR. ROSS: Oh. Please jump in. Thank
 25 you, Sanket.

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1 DR. GARRIDO: Thank you. Did you say
 2 anything about the MCID and how that might, the
 3 optimal MCID might differ with age? You
 4 mentioned it might differ with a population
 5 study. Would it be different for someone in
 6 their 90s, say versus in their 70s?
 7 MS. KRUGER: Well, you know, I think
 8 that we have to keep that all consideration,
 9 but I don't think it should dictate anything,
 10 that it should be the only dictation. I think
 11 we have to look at the individual sitting in
 12 front of us. We are concerned about their
 13 education, making sure they get all of the
 14 clinical support. I think certainly the person
 15 who's starting the pump before 65 versus the
 16 pump patient that we give it to them in their
 17 80s, their educational needs, their
 18 hypoglycemia, they may need different family
 19 support. All those things I think are very
 20 very important.
 21 One of the things we noticed in
 22 clinical practice is the individual who got a
 23 pump, say in their 40s, 50s and 60s, when
 24 they're in their 80s they're so used to owning
 25 their own diabetes and managing their own

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1 diabetes that we need to be able to help
 2 support them as they age. So I'm not negating
 3 that. I just don't think that's the only
 4 thing, and I don't think that as a person ages
 5 we should say they can't have these
 6 technologies, because I see every day, both in
 7 clinical practice and research, how well they
 8 do. And we prevent hypoglycemia, we keep them
 9 in time in range, and I can't do that on
 10 injections alone.
 11 DR. ROSS: Great, thank you very much.
 12 Next speaker. Tara, who is next?
 13 MS. HALL: Laurel Messer.
 14 DR. MESSER: Hi. Is Janet on before
 15 me?
 16 MS. HALL: We're having an issue, so
 17 we need you to go first.
 18 DR. MESSER: Oh, okay. Thank you,
 19 everyone, for your time. I thank the panel for
 20 convening and listening. My name is Dr. Laurel
 21 Messer. I'm senior director of medical affairs
 22 at Tandem Diabetes Care. I am a nurse, nurse
 23 scientist, and have been in practice working
 24 with insulin dependent people with diabetes
 25 using diabetes technologies for over 20 years.

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1 Next slide please.
 2 I am currently an employee and
 3 shareholder of Tandem Diabetes Care. Next
 4 slide.
 5 So, I appreciate all the comments so
 6 far in calling out the unique vulnerabilities
 7 of older people living with diabetes. First of
 8 all, this is a highly heterogeneous population
 9 with wide varieties in life expectancy,
 10 baseline health, comorbidities and cognitive
 11 function. Cognitive function is particularly
 12 called out by the American Diabetes Association
 13 as an important characteristic in this
 14 population, and because of this heterogeneity
 15 there's high individualization that occurs in
 16 clinical care as well as glycemic targets. So
 17 for example in a population like this, there's
 18 no agreed upon hard stop of what a glycemic
 19 target should be because of high risk for
 20 hypoglycemia and other heterogeneous factors,
 21 and so it's really important to consider
 22 individual needs in older people living with
 23 diabetes. Also of note, they are at higher
 24 risk for hypoglycemia for a variety of reasons,
 25 including erratic meal intake, progressive

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1 renal insufficiency, and treatment with other
 2 hypoglycemic agents and polypharmacy. Next
 3 slide please.
 4 So looking at the domains that the
 5 panel is evaluating, our opinion is to
 6 prioritize surrogate markers and device-related
 7 safety, which I will talk about in the next two
 8 slides. While health outcomes are important,
 9 they are expensive, they are complicated by
 10 comorbidities, and the long duration of study
 11 required may prevent getting the devices into
 12 the hands of individuals who need it. And
 13 quality of life, while also very important, has
 14 a wide variation in how it is measured and no
 15 agreed standard. Next slide please.
 16 To keep this simple, our
 17 recommendation is to prioritize time in range
 18 and hypoglycemia measures using CGM derived
 19 measures. We agree with Dr. Castle and others
 20 that a three-month study is sufficient to
 21 determine safety and efficacy for these
 22 measures.
 23 One thing that's important to call
 24 out, especially for time in range, two things:
 25 Number one, the within person change of five

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1 percent has been endorsed by a clinical
 2 international consensus to be clinically
 3 meaningful, so a five percent within person
 4 change would be a recommended MCID for time in
 5 range. This is important for the fact that
 6 there's individualization needed within this
 7 group, so it would not be appropriate to look
 8 at a fixed glycemic target of, say 70 percent
 9 time in range and look at the percentage of
 10 individuals who achieve this. It's more
 11 important to look at within person change.
 12 And then the other reason to look at
 13 this is that every randomized clinical trial
 14 has a different control group. So if you're
 15 looking to evaluate a change compared to a
 16 randomized clinical trial, it's important to
 17 consider that that control group may include in
 18 class devices. Typically RCTs are designed to
 19 look at one particular device compared to other
 20 treatments, but this may not get at the class
 21 effect and importance of one device over
 22 others, which is why we endorse a clinically
 23 meaningful time at five percent time in range
 24 with an individual.
 25 And hypoglycemia, of course, is

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1 important for older adults with diabetes and
 2 needs to be taken within context of CGM derived
 3 metrics, and any percentage of hypoglycemia
 4 reduced, we believe, is an MCID. Next slide
 5 please.
 6 DR. ROSS: One minute.
 7 DR. MESSER: All of the other ones are
 8 best captured in the 70 to 180 in time and
 9 hypo. A1c is also important. However, as
 10 Dr. Castle brought out, lower baseline means
 11 lower magnitude of improvement, and this may
 12 not be the best metric. Next slide.
 13 Finally, for safety and efficacy,
 14 device discontinuation rates and adherence to
 15 device use indicate that older adults can use
 16 these devices safely and effectively, and are
 17 easily measured with clinical trials. Next
 18 slide please. Next slide.
 19 So in summary, our recommendation is
 20 let's keep it simple. Let's look at
 21 improvement in time in range as well as
 22 hypoglycemia as the most important metric for
 23 approval of diabetes devices. Device
 24 continuation and adherence rates directly
 25 indicate whether older adults can safely

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1 tolerate these therapies. We ask that CMS does
 2 not require long costly trials or stringent
 3 MCIDs, which would inappropriately deny
 4 coverage for a variety of older individuals
 5 affected with diabetes. Thank you very much
 6 for your time.
 7 DR. ROSS: Thank you, Dr. Messer. Any
 8 questions for the speaker? Okay. Tara, who's
 9 next?
 10 MS. HALL: Next we have Janet.
 11 DR. ROSS: Dr. McGill, are you ready?
 12 DR. MCGILL: Thank you very much, and
 13 I want to thank MEDCAC for holding this
 14 meeting, for inviting us to participate. I'm
 15 professor of medicine, I'll go to the next
 16 slide, at Washington University School of
 17 Medicine.
 18 I've been in this role for 37 years,
 19 similar to Davida. Consequently, my patients
 20 are getting older, they're very older. I see
 21 many patients with Type 1 and Type 2 diabetes
 22 who are insulin requiring as a result of both
 23 insulin deficiency, duration of disease. I use
 24 these devices, I use every single device on the
 25 market, and have done studies in these devices.

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1 Okay, next slide.
 2 So, general commentary. ADA clearly
 3 states that real-time CGM and insulin pump
 4 therapies should be available for individuals
 5 with Type 1 or insulin-requiring Type 2
 6 diabetes. And I might add that those are
 7 patients who require physiologic replacement of
 8 insulin, not just insulin therapy or basal
 9 insulin therapy or other newer therapies that
 10 have limited this group, now to people who
 11 really need physiologic replacement. The
 12 benefit of these technologies is not in
 13 dispute, as was mentioned, as has been
 14 mentioned by other speakers. Glucose control
 15 improves, time in range improves. The benefit
 16 is consistent across people with diabetes,
 17 regardless of type of diabetes and age. Next
 18 slide.
 19 We've talked about the Diabetes
 20 Control and Complications Trial, that and the
 21 UKPDS, and other trials have now, now it's
 22 settled science that improved glucose control
 23 improves outcomes. This does not to be
 24 revisited. We need, simply need to know the
 25 best ways for achieving excellent glucose

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1 control. Next slide.
 2 So clinical trials for diabetes
 3 technologies are needed to demonstrate accuracy
 4 and utility of the device, whether CGM or
 5 insulin administration, whether pumps or smart
 6 bands, they should compare new technology to
 7 available technology. When that is done, then
 8 we need to modify our expectations, for this
 9 minimally clinically important difference
 10 depends on the control group. If your control,
 11 the control group is using older therapies,
 12 such as injection therapies, we expect to see
 13 an improvement in A1c, reduction in
 14 hypoglycemia, improvement in time in range.
 15 So the accuracy and utility is
 16 commonly demonstrated in a clinical trial of
 17 three months duration, such as the recent
 18 clinical trial for the Islet Beta Bionics
 19 insulin pump system. Using CGM, it was a
 20 three-month trial, and significantly limits
 21 user input functions, is available for people
 22 who have difficulty with clinical decision
 23 making achieve, achieve outcomes that are
 24 really quite remarkable.
 25 MCID is an important metric, but needs

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1 to consider the trial design and population
 2 studied. Next slide.
 3 Across all domains, a three-month
 4 followup for devices is adequate and
 5 appropriate. It reflects changes in A1c should
 6 there be any, average blood glucose levels,
 7 time in range, and rates of hypoglycemia,
 8 and --
 9 DR. ROSS: One minute.
 10 DR. MCGILL: -- may determine device
 11 safety. And there is no data that suggests
 12 that longer follow-up periods are necessary for
 13 quality of life or health outcomes, there is a
 14 complete lack of data. What we need is safety.
 15 Next slide.
 16 That's the end of my slides.
 17 So endpoints should be specific to the
 18 types of technology studied, the study
 19 population, Type 2 diabetes, we see reduction
 20 in hyperglycemia. Type 1 diabetes it's
 21 hyperglycemia and hypoglycemia. Non
 22 inferiority should be considered when a current
 23 device is compared to recent technology with
 24 respect to glycemc controls including
 25 hypoglycemia. The MCID for surrogate markers

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1 is detailed in the written response, and we
 2 advise no worsening quality of life with
 3 respect to the current assessment tool scores,
 4 which --
 5 DR. ROSS: Dr. McGill, I'm sorry,
 6 that's time.
 7 DR. MCGILL: Yes, thank you.
 8 DR. ROSS: Thank you very much. Any
 9 questions for this speaker?
 10 MS. HALL: If no questions, Medha,
 11 you're next.
 12 DR. MUNSHI: Hello. I am Medha
 13 Munshi, a professor of medicine at Harvard
 14 Medical School. I lost my slides.
 15 DR. ROSS: Don't worry, Dr. Munshi,
 16 I'm not taking this against your time.
 17 DR. MUNSHI: Thank you. This is what
 18 happens to geriatric patients. Sometimes it
 19 just takes a little time.
 20 DR. ROSS: Just a reminder for all
 21 members of the panel to try to keep your camera
 22 on, and for speakers, when you finish speaking,
 23 then turn your camera off. Thank you very
 24 much. Okay.
 25 DR. MUNSHI: Thank you again. Hi, I'm

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1 Mehda Munshi, professor of medicine at Harvard
 2 Medical School, director of the Joslin
 3 Geriatric Diabetes program, I'm a primary care
 4 geriatrician at Beth Israel Deaconess Medical
 5 Center and the founding president of the
 6 International Geriatric Diabetes Society. My
 7 area of research and primary clinical interests
 8 are the technology and care of older adults
 9 with diabetes. Here are my disclosures, and I
 10 have no financial interest in the outcome of
 11 this meeting. Next slide.
 12 So I would like to comment the
 13 clinical endpoints that are important for
 14 consideration of older adults with diabetes.
 15 Next. The time spent?
 16 So time spent in hypoglycemia, both
 17 Level 1 and Level 2, is a primary concern in
 18 this population. Next.
 19 Older adults have hypoglycemia
 20 unawareness that results in lack of adrenergic
 21 warning symptoms and lack of recognition and
 22 reporting of hypoglycemia, as well as failure
 23 of prompt treatment, as seen in our study
 24 published in 2011. Next.
 25 The consequences of hypoglycemia are

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1 catastrophic -- next -- in this population,
 2 resulting in higher risk of falls, fractures,
 3 cognitive decline, cardiac events, emergency
 4 room visits and hospitalization, as well as
 5 long-term care facility admissions. Next
 6 please.
 7 Thus, the recognition of asymptomatic
 8 hypoglycemia by CGM has significant clinical
 9 implications and benefits in this frail
 10 population. Next. Next slide please. Next
 11 slide please.
 12 Hypoglycemia thus, should be
 13 considered as health outcome of interest in
 14 older population with diabetes. The goal for
 15 hypoglycemia duration should be really aimed at
 16 near zero percent, as a risk of any amount of
 17 hypoglycemia will outweigh the benefits of
 18 controlling hyperglycemia in this population
 19 and the MCID will depend on the sample size and
 20 study characteristics of the study cohort.
 21 Next slide please.
 22 The time in range, next please, is
 23 usually between 70 to 180 milligrams per
 24 decaliter, but that may need to be adjusted
 25 based on overall health status in this

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1 population, next please, the same way as A1c
 2 goals in the older population are currently
 3 recommended. Next please.
 4 CGM targets of clinical significance
 5 including time below range, time in range and
 6 time above range should be considered based on
 7 healthy, intermediate and poor health overall
 8 status of the older individual. Time in
 9 hyperglycemia, both Level 1 and 2, thus should
 10 be adjusted based on health of an older adult
 11 as well as quality of life concerns with
 12 increasing complexity of the treatment that
 13 might be needed. Next please.
 14 The high coefficient or variation or
 15 CV percentage reflecting glycemic variability
 16 correlates with the risk of hypoglycemia in
 17 older adults and is an important outcome, as
 18 shown in our study published in 2020. Next
 19 please.
 20 Hemoglobin A1c is typically considered
 21 a clinical endpoint important for individuals
 22 with diabetes. However, clinical conditions
 23 that impact RBC lifespan and impact A1c
 24 measurement occur frequently, especially in
 25 frail older adults, making interpretation of

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1 A1c unreliable in many instances. Next please.
 2 In addition, hemoglobin A1c does not
 3 correlate with hypoglycemia as seen in our
 4 study. Next please.
 5 As shown here, next please, A1c values
 6 less than seven percent, eight percent, eight
 7 to nine percent, or more than nine percent did
 8 not correlate with risk of hypoglycemia as
 9 measured by CGM.
 10 DR. ROSS: One minute.
 11 DR. MUNSHI: Next please.
 12 A1c doses not identify glycemc
 13 excursions and the same hemoglobin A1c can have
 14 a variable pattern as seen on CGM. A1c thus
 15 should be deemphasized as outcome of older
 16 adults in diabetes. Next please.
 17 Distress about hypoglycemia, next
 18 please, and its feared consequences lead to
 19 fear of hypoglycemia and important quality of
 20 life issue, as well as limiting factor for
 21 improved glycemc control in the older
 22 population. These qualify of life parameters
 23 improve with CGM use in our studies. Next
 24 please.
 25 So in summary, the priority for

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1 clinical outcomes in older adults should
 2 include the risk of hypoglycemia as the first
 3 priority followed by decreasing glycemc
 4 variability, individualizing optimal time in
 5 range, and finally control of hyperglycemia.
 6 Thank you for this time.
 7 DR. ROSS: Thank you. Any questions
 8 for the speaker.
 9 DR. WALL: Joe, I do. Dr. Munshi, I
 10 appreciated your slides and your talk. You
 11 know, a number of presenters have addressed the
 12 MCID as depending on the population and also on
 13 the, basically the clinical trial design.
 14 Could you elaborate a little bit more as to
 15 what that actually means, how that translates
 16 in practice or in doing studies?
 17 DR. MUNSHI: Yeah. Thank you for the
 18 question. I feel like it's important with the
 19 outcome of interest, and that was my point
 20 about the hypoglycemia. Many times we consider
 21 less than one percent as the goal for
 22 hypoglycemia. However, you know, one
 23 hypoglycemc episode, one fall, one hip
 24 fracture and nursing home admission makes it
 25 really irrelevant whether the MCID is, you

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1 know, in those studies. So I feel like
 2 basically depending on the population that is
 3 being studied, if it is high risk in older
 4 adults in intermediate or poor health versus
 5 healthy population, that might actually end the
 6 outcome, primary outcome, that may actually
 7 affect the MCID in those instances. I don't
 8 know if that answers you.
 9 DR. WALL: No, that's great, thank
 10 you.
 11 DR. ROSS: Dr. Munshi, if I may, could
 12 you talk about how you measured variability,
 13 which you emphasized in your comments?
 14 DR. MUNSHI: Yes. So with continuous
 15 glucose monitoring, we are able to actually
 16 identify the CV percent, the coefficient of
 17 variation percentage, and again, that is known
 18 to be, have 36 percent as the optimal level.
 19 But when you get to the appropriate
 20 population, it's the variability that causes
 21 the highs and lows, and an important variable
 22 which is not really measured unless continuous
 23 glucose monitoring is done. So it's one of the
 24 biggest, big fallibility of the other measures,
 25 of the A1c.

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1 DR. ROSS: I may ask one last
 2 question. You're the only speaker thus far
 3 that's talked about the distress scale. Could
 4 you just remark upon its utility and how you've
 5 used it?
 6 DR. MUNSHI: Yes. So many times, and
 7 diabetes-related distress, again, is different
 8 for different populations. We have sometimes a
 9 hard time taking the validated surveys because
 10 they are meant for the younger population, you
 11 know, what kind of distress that causes. What
 12 we have found is that the biggest distress in
 13 older adults are about the hypoglycemia and
 14 fear of hypoglycemia, and having a technology
 15 that warns them and prevents the hypoglycemia
 16 is of tremendous comfort to them. So even
 17 beyond the control of glycemc, which is
 18 important, I'm not putting that down, but the
 19 ability for the patient to feel reassured that
 20 they are not going to be hypoglycemc and
 21 passed out and no one will find them, is of
 22 tremendous comfort to them. That's what we
 23 have seen repeatedly.
 24 DR. ROSS: Thank you for those
 25 comments. Okay. We should move to the next

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1 speaker. Tara, who would that be?
 2 MS. HALL: Robert is next.
 3 DR. VIGERSKY: Good morning. My name
 4 is Bob Vigersky. I'm an adult endocrinologist
 5 and currently the chief medical office for
 6 Medtronic Diabetes. I'm also a Red Cross
 7 volunteer at Walter Reed, where I spent 27
 8 years in the Army Medical Corps, and I still
 9 see patients, and speaking of seeing patients
 10 for long periods of time, some of my patients
 11 have been seeing me for 20, 25 years, and have
 12 aged into Medicare or in the case of the
 13 military, into TRICARE. I also am the past
 14 president of the Endocrine Society. Next
 15 slide.
 16 I'm, as I mentioned, I am an employee
 17 of Medtronic. These are my disclosures. Next
 18 slide.
 19 I'm not going to read this, but I
 20 think it's clear from certainly the last four
 21 speakers and I support this, that we don't want
 22 Medicare to impose further restrictions on
 23 these technologies which have really been
 24 supported by enormous amounts of evidence, and
 25 have been adopted by the medical community. We

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1 do recognize that there are important endpoints
 2 that we have to identify, and I think I would
 3 agree with the other sneakers that A1c plus
 4 time in range are the really important
 5 endpoints, but time in range as a composite of
 6 time in range and time below range. We all
 7 know that we can give more and more insulin and
 8 get better time in range, but without the
 9 devices that we're discussing, CGM, insulin
 10 pumps and automated insulin delivery systems.
 11 They are giving you low time below range in
 12 addition to time, increased time in range. And
 13 this is really a composite endpoint in a sense,
 14 so the key would be as high a time in range as
 15 possible without exceeding the goals for time
 16 below range. Next slide.
 17 Now you have heard allusions to this
 18 paper by Tony Bedalino. This has been adopted
 19 by the American Diabetes Association and other
 20 professional organizations around the world.
 21 And you've heard about what the goals are of
 22 time in range greater than 70 percent for
 23 Type 1 and Type 2 diabetes but what you haven't
 24 heard, at least not directly, except from
 25 Dr. Munshi, is the goals are different for our

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1 older adults in high risk and the guideline
 2 development committee recognized that time in
 3 range between 70 and 180 may not be 70 percent
 4 but perhaps somewhat lower, like greater than
 5 50, and importantly, the time below range of
 6 less than 70 shouldn't be less than four
 7 percent, but rather less than one percent, and
 8 as Dr. Munshi said, maybe it should be zero
 9 percent.
 10 On the right is the relationship of
 11 time in range to A1c. This was also alluded to
 12 and directly, this is a study, one of two
 13 studies, this one is mine, that shows the
 14 relationship of time in range to A1c, basically
 15 saying that for every 10 percent change in time
 16 in range, there's a .8 percent change in A1c on
 17 average.
 18 And so that gets back to the
 19 clinically meaningful change in time in range,
 20 which would be five percent, which is
 21 equivalent to .4 percent A1c. Next slide.
 22 Now I thought it would be instructive
 23 to show a case, because this really tells you
 24 what's going on in the clinic with our
 25 patients. This is a 69-year-old gentleman.

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1 He's had diabetes for 58 years and his A1c is
 2 6.3. And before we had these technologies we
 3 would say this gentleman is doing great. But
 4 he had 16 percent time below range when he was
 5 on an insulin pump that didn't have automation.
 6 And then when he transitioned to the 780G,
 7 which is a Medtronic device and automated
 8 insulin delivery system --
 9 DR. ROSS: One minute.
 10 DR. VIGERSKY: -- he actually got 93
 11 percent time in range but three percent time
 12 below range, which is too high for his age per
 13 those guidelines I just showed you. Next
 14 slide.
 15 And this is my next to last slide, and
 16 the daily reports I think are instructive. So
 17 you can see there are days here where this
 18 gentleman actually became hypoglycemic to
 19 Level 1 and some Level 2. So this really aids
 20 in analyzing the patient's case and making
 21 changes in the settings of this device to keep
 22 the person safe. Next slide.
 23 And we've for this meeting, we've --
 24 next slide please. We have mined data from --
 25 next slide please.

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1 We have mined data from our database
 2 and looked at in those of us aged 65 and
 3 greater, over 5,000 individuals, and we found
 4 that in this population 84 percent had a time
 5 in range greater than 70, and 95.8 percent
 6 maintained a time below range less than four
 7 percent, and 97 percent kept the time below
 8 range of 54 less than one percent. So these
 9 automated insulin devices are very effective in
 10 reducing time below range and increasing time
 11 in range. Thank you.

12 DR. ROSS: Thank you, Dr. Vigersky,
 13 right on time. Any questions for this speaker?

14 MR. FRANKEL: One question. What are
 15 your thoughts about what Dr. Munshi mentioned
 16 about the deprioritization of A1c? What's your
 17 vantage point on that one specific point,
 18 because you also mentioned A1c on your slides.

19 DR. VIGERSKY: Yes, so I think A1c
 20 still has value, because it is the one metric
 21 that is generally related to complications.
 22 But there are, and I didn't show this, there
 23 are a number of papers now that show the
 24 relationship of time in range to complications.
 25 So I think we're in a transition point where we

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1 really need both A1c and time in range.

2 DR. ROSS: Okay, thank you. I think
 3 we're going to our last presentation; is that
 4 right, Tara?

5 MS. HALL: Yes. We've got Sethu next.

6 DR. REDDY: Good afternoon. Thank you
 7 for this opportunity to present to this group
 8 doing very important work, and the topic is
 9 very close to our hearts. If I could have the
 10 first slide up?

11 I'm Dr. Sethu Reddy, past chief of
 12 endocrinology diabetes at the Cleveland Clinic,
 13 past chief of adult diabetes at the Joslin
 14 Diabetes Center, currently finished my term as
 15 the past president of AACE, if we can have that
 16 in the show mode, and being an endocrinologist
 17 for 40 years plus, and hopefully I'll express
 18 some of those sentiments in the next couple of
 19 minutes that we have.

20 I'm not seeing the slides up, but can
 21 you hear me?

22 DR. SCHULMAN-ROSENBAUM: Yeah, we can
 23 hear you, but the slide's not up.

24 DR. REDDY: And my pleasure to also
 25 introduce my partner for today, Dr. Rifka

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1 Schulman-Rosenbaum, who is one of our leaders
 2 of our diabetes state network at AACE, and also
 3 has had much experience dealing with pump
 4 patients and CGM as well.

5 And certainly we realize that CGM is
 6 the real safety blanket no matter what we
 7 decide on managing peoples diabetes. CGM
 8 offers a great safety blanket, security blanket
 9 for our patients and their relatives.

10 They're not showing up in the show
 11 mode. I have no control over them.

12 MS. HALL: Give us one second please.

13 DR. REDDY: But we have no conflicts
 14 to report, neither myself nor
 15 Dr. Schulman-Rosenbaum.

16 I do want to highlight two references
 17 for you that AACE has published, our diabetes
 18 guidelines. One of the highlights, I think, is
 19 that we recommend that anyone on insulin
 20 therapy is deserving of potentially using CGM,
 21 and we've just seen so many behavioral changes
 22 from using CGM on patients lifestyle and
 23 nutrition and control. We also published in
 24 2021 on the use of advanced technology in the
 25 management of people with diabetes.

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1 We want to get to the heart of the
 2 matter and I'm going to hand it over to Rifka
 3 to go over the surrogate markers that the
 4 committee has proposed, and she will express
 5 our opinions about those.

6 DR. SCHULMAN-ROSENBAUM: Thank you,
 7 Dr. Reddy. And you know, just as a little bit
 8 of background, we're giving our input from the
 9 standpoint of clinical endocrinologists. We
 10 acknowledge that there is a paucity of studies
 11 focused solely on older adults, even fewer
 12 studies focused on Type 2 diabetes older
 13 adults, which is a large portion of Medicare.
 14 And so we have to do the best we can to come up
 15 with what makes the most sense clinically,
 16 especially when there is a paucity of data, and
 17 we wanted to really highlight the importance of
 18 avoiding hypoglycemia in the elderly, as has
 19 been mentioned by many other speakers, which
 20 can contribute to altered mental status,
 21 cognitive impairment, falls, motor vehicle
 22 accidents, hospitalizations and immediate
 23 quality of life issues which we think are
 24 really important, and some other factors that
 25 are more longer term may be less appropriate to

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1 focus on in the older population.
 2 So starting with the surrogate
 3 markers, we felt that number of hypoglycemic
 4 episodes was extremely important, appropriate,
 5 and that's five. Now we did put six months
 6 here for duration, but to acknowledge that
 7 three months could be also acceptable. It
 8 really depends on the incidence of events, but
 9 let's say three to six months. And we were
 10 suggesting for the MCID a reduction by 25
 11 percent from baseline, so an incidence of four
 12 percent hypoglycemia going to three percent
 13 would be clinically meaningful.
 14 A few words about hemoglobin A1c. You
 15 know, we acknowledge that the MCID standard is
 16 the 0.5 percent which is reasonable in most
 17 cases. Of course it does matter what the
 18 baseline hemoglobin A1c is, which can affect
 19 what percent drop would be meaningful. But you
 20 know, a hemoglobin A1c has accuracy
 21 limitations. For many older patients they have
 22 comorbidities, they may have anemia or chronic
 23 kidney disease which can affect the accuracy of
 24 hemoglobin A1c. And as mentioned earlier, you
 25 know, it's an average, and so it doesn't

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1 account for hypoglycemia or glyceic
 2 variability, which is very important, avoiding
 3 hypoglycemia in the elderly. So we gave that a
 4 four.
 5 In terms of time in range, we also
 6 agree with many of the other speakers of the
 7 importance of valuing the time in range with
 8 the relatively shorter studies of three months
 9 and as mentioned earlier, the five or 10
 10 percent difference as a suggested MCID. You
 11 can go to the next slide please.
 12 In terms of health outcomes, you know,
 13 for restoration of hypoglycemia awareness, we
 14 thought this may be a little difficult to
 15 quantify so we didn't put as strong of a grade
 16 on that one. We do think cognitive function
 17 change is a very important variable. We would
 18 rely on our colleagues in geriatrics to
 19 identify what the standard would be, but we do
 20 think that that would be an extremely important
 21 measure for cognitive function, especially
 22 since cognitive function can be cyclically
 23 involved with hypoglycemia, leading to further
 24 cognitive function or further hypoglycemia.
 25 DR. ROSS: One minute.

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1 DR. SCHULMAN-ROSENBAUM: We believe
 2 that hospitalizations, both ED and admission,
 3 are extremely important, so we put those at
 4 level five, looking for a 50 percent reduction.
 5 And we didn't not want to put the priority on
 6 the longer term outcomes. While very important
 7 for an elderly population, this should not be
 8 the focus. Next slide.
 9 We did put some comments on the
 10 quality of life indicators. We agree with
 11 Dr. Munshi that focusing on the fear of
 12 hypoglycemia is really the most important one,
 13 and left some comments on suggestions for MCIDs
 14 for these. Next slide.
 15 And in terms of device-related safety,
 16 I know we put four here but it could be also a
 17 five, four to five for hypoglycemia-related
 18 emergency department visits. We're not aware
 19 of any tissues damage typically from these
 20 devices so that was rated low, and you know --
 21 DR. ROSS: We're out of time,
 22 Dr. Schulman-Rosenbaum.
 23 DR. SCHULMAN-ROSENBAUM: Thank you.
 24 THE COURT: I'm sorry to interrupt,
 25 Dr. Schulman-Rosenbaum. Are there any

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1 questions for the presenters?
 2 DR. SCHULMAN-ROSENBAUM: I see a
 3 question.
 4 DR. FANAROFF: Yeah, so this is
 5 Alexander from the panel. You know, you and a
 6 lot of the speakers have indicated a
 7 three-month duration for hemoglobin A1c or time
 8 in range would be appropriate, which makes
 9 sense because that's how long it takes to see a
 10 change in the parameter.
 11 The question is, you know, it seems
 12 like you would have to have changes in A1c or
 13 time in range that were sustained to reduce the
 14 risk of microvascular complications. In your
 15 experience clinically, I guess, once patients
 16 start on these devices and they lower their
 17 hemoglobin A1c or they change their time in
 18 range, is it maintained over a long time, and
 19 do patients continue using the devices over a
 20 long period of time.
 21 DR. SCHULMAN-ROSENBAUM: So obviously
 22 there's variation between patients, but I would
 23 say that in most of the patients they really
 24 enjoy the devices and do very well using them
 25 compared to the time before they used the

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1 device.
 2 And obviously, again, there are
 3 exceptions for different circumstances,
 4 individual reasons, but most patients, I think,
 5 would continue, and so the three month would be
 6 a surrogate for a longer term control.
 7 DR. REDDY: It's hard to put in words
 8 the safety psychologically that they feel.
 9 It's really like riding a bicycle with training
 10 wheels. They know that they can go about their
 11 life without worrying about severe
 12 hypoglycemia, so they're more likely to stay
 13 on, I think.
 14 DR. ROSS: Thank you. Any last
 15 questions? Great, thank you. I want to thank
 16 all of the public speakers who submitted
 17 comments to consider to this committee.
 18 It's 11:45 or so, so we're a little
 19 bit behind schedule, but there has been no one
 20 who volunteered to present during the open
 21 public comment period. Rather than taking a
 22 ten-minute break, I'm going to give us 20
 23 minutes, so those of us on the east coast can
 24 try to eat lunch quickly. And we will
 25 reconvene and then go forward with discussion

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1 beginning at ten minutes after 12 on the east
 2 coast. So that's now 17 or so minutes,
 3 whatever it is, it's about 20 minutes, okay?
 4 So we'll start at ten minute after 12 p.m.
 5 eastern time. And you can leave yourself
 6 logged in, so just go off video and make sure
 7 you're muted. Thank you.
 8 (Recess.)
 9 DR. ROSS: Thanks everybody for coming
 10 back so we can get started pretty close to on
 11 time.
 12 Tara, I have one quick question for
 13 you. In past virtual meetings as we've entered
 14 into the open panel discussion, you've asked us
 15 to state our name because someone who is doing
 16 the transcript is working off the audio
 17 recording, not with the video. Do you want us
 18 to continue to do that, so for instance, say
 19 this is Joe Ross?
 20 MS. HALL: Yes, please say your name
 21 each time you talk.
 22 DR. ROSS: Okay. And I'm sorry I
 23 didn't clarify that beforehand, during the
 24 first part of the meeting. So keep that in
 25 mind everybody.

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1 So now we have, thankfully actually, a
 2 good couple of hours to talk about this
 3 clinical evidence endpoints review and the
 4 presentations that we heard over the course of
 5 the morning.
 6 We have -- I thought it might be
 7 helpful just to start by talking through the
 8 domains and just thinking a little bit more in
 9 general about what we've heard, what we've
 10 read, and we reviewed the clinical endpoints
 11 review that was prepared, potential things that
 12 arose in your mind that were or were not
 13 discussed or should be points of emphasis.
 14 And I just want to remind folks that
 15 in terms of device-related safety, we are going
 16 to work under the assumption that accuracy of
 17 the device has been confirmed by the FDA as
 18 part of the authorization process, and so
 19 inaccuracy on its own is not a safety-related
 20 domain, unless we're talking about accuracy as
 21 it may apply to an older adult. For instance,
 22 if there isn't information around the device's
 23 accuracy for an older adult as compared to the
 24 general population in terms of false positives,
 25 false negatives, but we're going to work under

Page 93

1 the assumption that accuracy has been confirmed
 2 as part of the FDA authorization process.
 3 So I'm just going to open it up for
 4 now, and I'll try to keep us on time. I think
 5 we'll try to move towards the discussion of the
 6 actual voting questions to see if there's any
 7 points of clarification at around half past the
 8 hour, but for the next 15 minutes, do people
 9 want to reflect on the domains, the endpoint
 10 domains and the material you heard and what has
 11 or has not come up. Please just raise your
 12 hand, and state your name. Dr. Isetts, that's
 13 how you come up.
 14 DR. ISETTS: Yes, thank you, Dr. Ross.
 15 Isetts, University of Minnesota, a professor
 16 and a pharmacist. Dr. Ross, are we able to
 17 comment on some of the presentations at this
 18 point or from earlier in the morning?
 19 DR. ROSS: Oh, we can, and we can talk
 20 about them. And if you have questions that
 21 have come up over the break, sometimes the
 22 presenters stay on and we can ask them
 23 questions, but there's no guarantee that
 24 they're still there.
 25 DR. ISETTS: Thank you, because I'd

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1 like to address the letter from the 26
 2 non-diabetes organizations. They characterize,
 3 with all due respect, characterized our work as
 4 similar to rationing of medicine, and I'd like
 5 to turn that from an adversarial discussion
 6 more to a collaborative discussion.

7 And the fact that, you know, sure CMS
 8 is the evil payer and they want to stop payment
 9 on things, and that is a common concern that
 10 many of us have had over the years, tongue in
 11 cheek sometimes, and the reasoning they were
 12 using is that if the FDA approves, in this case
 13 a device, or a drug, CMS should cover it, no
 14 questions asked, although they used the
 15 discussion of the amyloid agents in which there
 16 was this push and pull FDA, particularly the
 17 FDA advisory panel, in terms of they did not
 18 support coverage of the agent, all right? So
 19 there was this, almost a rare discrepancy
 20 between CMS and FDA in terms of FDA doing their
 21 work, as many of the panelists resigned from
 22 the advisory panel, and so it was almost
 23 counterproductive to that discussion.

24 So I want to turn this into a positive
 25 in terms of, let's look at this as a

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1 collaboration of stewards of the Medicare trust
 2 fund, all right? So you conduct clinical
 3 trials, there was a set of patients that may
 4 not be the patients we care for, and so a lot
 5 of the discussion we heard today was very
 6 helpful in terms of tailoring our work to real
 7 world considerations. How can we work together
 8 to make sure that the devices are out there,
 9 can be used with both safety and effectiveness
 10 in the populations that may not have been
 11 tested in FDA work. And so I really found many
 12 of the discussions and the other, particularly
 13 the clinical endocrinologists to be very
 14 helpful in helping us figure out how can we
 15 enable this to used in a more effective and
 16 safer way.

17 DR. ROSS: I appreciate that. If I
 18 could just briefly comment, I just want to
 19 remind us that we are not here to discuss the
 20 authorization or payment for any specific
 21 technology regardless, and public commenters
 22 can say anything they want in there allotted
 23 time. We are really here to help advise and
 24 recommend to CMS what they should be looking
 25 for in the body of evidence regarding devices

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1 for self management of Type 1 or insulin
 2 dependent Type 2 diabetes in older adults.

3 And so I did, also found that the
 4 comments that addressed that question were of
 5 far greater utility to me in advancing my
 6 understanding. Dr. Wall?

7 DR. WALL: Yeah, this is Eric Wall in
 8 Seattle. Joe, I'm just trying to -- there was
 9 one of the speakers and I should have written
 10 this down, that suggested we missed a domain,
 11 because I think we were initially supposed to
 12 address the domain issue right now which is,
 13 are we missing anything in the domains. But I
 14 didn't make a note of it. Did anyone remember
 15 what was suggested that we were missing?

16 DR. ROSS: This is Joe. I'm curious
 17 what others heard. A handful of the earlier
 18 speakers I thought, you know, really
 19 emphasized, actually I thought kind of
 20 equitable access, particularly inequities, and
 21 I didn't know if they were suggesting that as a
 22 domain of endpoints that should be looked for.
 23 They kept talking about equity and inequity,
 24 but I didn't get, I didn't think that that's
 25 what they were suggesting, that we should be

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1 looking for evidence of equitable use or
 2 equitable outcomes.

3 There was an endpoint that was raised,
 4 that was the GMI endpoint, which I believe
 5 would be considered a surrogate measure in our,
 6 you know, in this framework that CMS has
 7 developed, as it was a proxy for hemoglobin
 8 A1c. Is that what you mean?

9 DR. WALL: Yeah, okay. Great.

10 DR. ROSS: That came from
 11 Dr. Forlenza.

12 DR. WALL: This is Eric Wall. One
 13 more time I'm just going to use my question on
 14 here. I've not seen data, maybe I missed it.
 15 There's been a recurring theme of hypoglycemia
 16 in the elderly, which I think we all might
 17 agree to, but the prevalence of hyperglycemia,
 18 in other words really ketoacidotic
 19 hyperglycemia in the elderly, I'm just not sure
 20 of the prevalence of that in this population.
 21 Does anyone know that, or can anyone comment on
 22 that?

23 DR. ROSS: This is Joe Ross. I don't
 24 have those numbers at my fingertips, but I did
 25 also find it interesting that none of the

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1 speakers really emphasized hyperglycemia so
 2 much as they focused on hypoglycemia.
 3 Fred, you're on mute.
 4 DR. KOBYLARZ: I think Melissa had her
 5 hand up before me.
 6 DR. ROSS: Oh, I'm sorry. I thought
 7 it came up earlier. Dr. Garrido?
 8 DR. GARRIDO: This is Melissa Garrido.
 9 Just back to the point about the equity
 10 concerns in the beginning, I think the concern
 11 wasn't that it was a missing endpoint or a
 12 domain, I think the concern was that additional
 13 endpoints that CMS may or may not require could
 14 lead to inequities.
 15 DR. ROSS: Thank you. Fred, you want
 16 to go now, or no?
 17 DR. KOBYLARZ: Yes. Fred Kobylarz,
 18 Rutgers, Robert Johnson Medical School, you
 19 know, geriatrician. Let me just start with
 20 the, you know, the domains regarding, I think
 21 there was one comment in the -- I'm just sorry
 22 here -- the surrogate markers, you know,
 23 regarding minimally, you know, clinically
 24 important differences. And just given this,
 25 you know, older adult population, you know,

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1 there are healthy adults, you know, that have
 2 few coexisting, you know, chronic, you know,
 3 medical conditions, they're cognitively intact.
 4 And then you have more complex individuals that
 5 have more chronic illnesses, and there may be
 6 some, you know, cognitive impairment.
 7 So I think what struck me here was in
 8 terms of just trying to establish like
 9 minimally clinical important differences in
 10 this population may be challenging.
 11 DR. ROSS: Dr. Fanaroff, I think your
 12 hand came up first.
 13 DR. FANAROFF: Alex Fanaroff from
 14 University of Pennsylvania. I think the other
 15 thing about MCID is that, you know, when
 16 thinking about an MCID from like a clinical
 17 trial statistics perspective, I think that
 18 there's the difference between groups, the
 19 average difference in the groups, and then
 20 there's also the change within any one patient,
 21 and those numbers may not be the same, you
 22 know, and I think that, so when we think about
 23 what the MCID is, you know, to me it makes more
 24 sense to think about it as the change that any
 25 one patient might need to have, and that might

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1 not reflect between group changes in a clinical
 2 trial. I think it's important to keep that in
 3 mind.
 4 DR. ROSS: Dr. Lewis? You're on mute.
 5 DR. LEWIS: Sorry about that, thank
 6 you. Joy Lewis, and I agree with Fred and Alex
 7 regarding the MCID and the fact that we need to
 8 look at the individual changes and the
 9 individual studies and what they're uniquely
 10 looking at.
 11 And I wanted to speak to what Eric
 12 brought up before about a potential different
 13 domain. I too remember hearing that, but I
 14 never wrote down those words but I did, looking
 15 at my notes I see that Candace from the chronic
 16 disease group talked about the sense of control
 17 versus actual control that people might feel
 18 when they are using these devices, and that the
 19 regular feedback can lead to behavioral
 20 changes. That led me to think about the
 21 quality of life indices and that some of them
 22 might not capture what we're really intending,
 23 so this sense of freedom and ability to enjoy
 24 life might not always be measured, depending on
 25 what metric is used. And then that ties in to

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1 what some of the endocrinologists brought up in
 2 terms of the psychological safety and the
 3 decrease in fear of hypoglycemia. So it just
 4 leads me as I start thinking about these
 5 measures that we can call it health-related
 6 quality of life, but that encompasses in my
 7 mind all of these factors and not necessarily
 8 limitations of current measures that we listed
 9 on the -- of the current validated
 10 health-related quality of life metrics that we
 11 have right now. Thanks.
 12 DR. ROSS: Thank you. Naftali
 13 Frankel?
 14 MR. FRANKEL: Yeah, I think that
 15 Candace DeMatteis also had mentioned, I guess
 16 this goes along with health outcomes under that
 17 rubric of, that she noted that there was no
 18 reference to amputations, so I know that was
 19 also noted in that presentation. So you know,
 20 I know that we listed some different examples,
 21 I don't think it was an all inclusive one, but
 22 that was one she did note that wasn't
 23 specifically mentioned in the packet.
 24 DR. ROSS: Dr. Young?
 25 DR. YOUNG: Yes, thank you. Heather

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1 Young. I was really struck by the comments
 2 that related to the heterogeneity of older
 3 adults and the heterogeneity within the 65-plus
 4 population that we all know is actually three
 5 generations of people. And so given the
 6 comorbidities, given the different histories of
 7 diabetes experience, time of diagnosis and all
 8 those kinds of issues, that the potential for a
 9 great deal of variability in outcomes could be
 10 there. And I think the more we can focus in on
 11 the most proximal outcomes to the technology
 12 that's under study, the better we will be as
 13 the further we go out to more distal indicators
 14 and health indicators, the more difficult it is
 15 to sort out what's confounding those outcomes.
 16 And so the presenters really reinforced,
 17 particularly those with a geriatric
 18 perspective, really reinforce the importance of
 19 staying very proximal to both the population of
 20 interest as well as the devices under
 21 consideration, what's actually being studied.
 22 Thank you.
 23 DR. ROSS: No, thank you. If I can
 24 just riff on that a little bit, I also thought
 25 that there was kind of an offhand comment made

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1 that related to familiarity with the technology
 2 and how starting it when they were younger was
 3 obviously easier, because then to continue it
 4 when they were older when some of the cognitive
 5 function may be more challenging, or the need
 6 for a caregiver to assist, I just thought that
 7 was an interesting comment.
 8 Fred? I'm sorry, I always say Fred
 9 instead of Dr. Kobylarz. I'm always concerned
 10 I'm going to misstate your last name.
 11 DR. KOBYLARZ: So, Fred Kobylarz.
 12 Again, I just want to piggyback on what you're
 13 saying, and this came out in one of the
 14 presentations regarding cognitive function.
 15 And this also ties in to other geriatric
 16 syndromes, polypharmacy, depression, falls, and
 17 this can all significantly affect diabetes
 18 management. So you know, I do think that, you
 19 know, there should be some screening, you know,
 20 for cognitive impairment for older adults, and
 21 then the issue is, you know, if there is
 22 cognitive impairment, you know, if you're, you
 23 know, let's say in the older group, if you're
 24 older it might be more challenging to reach
 25 glycemic, you know, control and just make it

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1 more difficult to monitor and adjust for
 2 example, your insulin or you know, or your
 3 medications that you're taking. So you know, I
 4 think cognitive function here is, you know, and
 5 other geriatric symptoms are very important to
 6 consider.
 7 DR. ROSS: Dr. Dhruva, and Mark, I did
 8 see your hand go up. I'll call you next.
 9 DR. DHRUVA: Thanks. Sanket Dhruva,
 10 San Francisco. I wanted to -- this has been a
 11 great discussion, I really agree with those
 12 points. I wanted to, a lot of the comments
 13 talked about in terms of the time duration,
 14 that about three months was sufficient, and we
 15 know obviously that that's the timeframe for an
 16 A1c change that can be captured.
 17 I did wonder and I think Joe, one of
 18 your questions to one of the endocrinology
 19 presentations, you know, the changes that we
 20 see, though, overall sometimes often take
 21 longer. For example, the University of
 22 Colorado presentation, the results were changed
 23 at one year. So I did wonder, I understand
 24 three months is a minimum to see a change in
 25 A1c, but I also did wonder around issues with

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1 the comfort of the device, the continuing use
 2 of the device, if a longer time period -- three
 3 months just felt a little bit too short in my
 4 view.
 5 DR. ROSS: Dr. Carlson?
 6 DR. CARLSON: So a question for
 7 Heather. I just wanted to make sure I
 8 understood correctly what you mean by proximal
 9 and more distal outcomes. I think I know but I
 10 want to make sure. Could you be more precise?
 11 DR. YOUNG: Thank you, yes, I can. I
 12 think some of the health outcomes that are
 13 sequelae of problems with glycemic control are
 14 more distal, whereas the time in range is more
 15 proximal, and even hemoglobin A1c is an average
 16 running over three months, and so if you start
 17 a therapy on day one, you may start to get
 18 benefits day 15, 20, into that time and the
 19 average wouldn't be as accurate as when you're
 20 looking at time in range over time. And so
 21 just thinking about what really it's measuring
 22 is what you're indicating, what you're looking
 23 for, rather than lagging and potentially
 24 confounded.
 25 DR. CARLSON: We're on the same page,

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1 and I agree with you, violently agree with you.
 2 DR. ROSS: Mr. Frankel?
 3 DR. FRANK: Naftali Frankel. I just
 4 want to quickly reference a point that was made
 5 earlier just on a very high level that, my
 6 understanding of course, and I think that this
 7 was understood in advance of this meeting and
 8 during this meeting, is that all our
 9 conversation is not in any way, when we're
 10 talking about equity issues, which of course
 11 was raised repeatedly amongst the speakers,
 12 that there is no guidance at all that we're
 13 providing to create any sort of obstruction or
 14 impediments towards physicians and patients
 15 access to these devices.
 16 And you know, obviously as the patient
 17 representative on this panel, that's of course
 18 important to note, that that should be a
 19 presumption. And when we're talking about
 20 rationing, you know, I'm not going to get into
 21 that really in depth, because I think it's also
 22 a given, that we're not looking at all in terms
 23 of trying to identify determinations of whether
 24 to provide access or not, but collection of
 25 data. And if there's any mistake in that

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1 assumption, then that would be great to have
 2 that clarification on record.
 3 DR. ROSS: And just to clarify, you
 4 are right, we are not making any advice or
 5 recommendations about, you know, the technology
 6 itself or themselves. It's all about what body
 7 of evidence we would advise CMS to ask for when
 8 making a coverage decision.
 9 MR. FRANKEL: Okay. So I just thought
 10 it would help just to put that on the record.
 11 In terms of A1c, that's something that
 12 I referenced before, after Dr. Munshi's
 13 presentation, and I think it might be helpful
 14 if it's possible to go back to that and ask for
 15 further input from her given her expertise in
 16 the area, because there was obviously a
 17 divergence on that specific point from a lot of
 18 the other presenters and other data that we
 19 reviewed. It would be helpful, I think, to
 20 have a little bit more clarity in terms of
 21 Dr. Munshi's perspective on deprioritizing
 22 that.
 23 It sounded like in a very substantial
 24 way that that was, there was some emphasis over
 25 there on the lack of reliability, particularly

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1 because of the heterogeneity in the population
 2 we're talking about. So when we're talking
 3 about an elderly population where there's
 4 multiple comorbidities that can have a very
 5 broad spectrum and range, it seems that
 6 particularly in that population, she felt that
 7 this was something that should be
 8 deprioritized. And I just thought it would be
 9 helpful if maybe we can get a little bit more
 10 clarity on that specific point, given the fact
 11 that we're specifically mentioning that as one
 12 of the metrics.
 13 DR. ROSS: Tara, are we able to invite
 14 Dr. Munshi back into the presenter so that we
 15 could ask for clarification? And maybe while
 16 that's happening, I can ask Dr. Isetts to --
 17 DR. ISETTS: Dr. Fanaroff was first.
 18 DR. ROSS: Oh, thank you. That's my
 19 Dutch panel. Sorry.
 20 DR. FANAROFF: Thanks. Just in
 21 response to one of the things that Dr. Dhruva
 22 said, I was going to ask the question about,
 23 you know, whether a three-month change in A1c
 24 would be sustained and if, you know,
 25 continuous, continuation of using these

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1 devices. And actually Dr. Forlenza had sent me
 2 a message in the chat that I'm going to just
 3 like read it into the record so you guys can
 4 hear it too because it was sent to me.
 5 So he said that when they looked at
 6 continuation of CGM and AID systems at their
 7 center, with 4,000 cases and 500 adults with
 8 Type 1 diabetes, they have a 99 percent
 9 continuation rate when they exclude coverage
 10 loss.
 11 So it does sound like, at least in
 12 that one center's experience, that people tend
 13 to remain, you know, continue to use these
 14 devices.
 15 DR. ROSS: That's helpful.
 16 DR. ISETTS: Okay, Brian Isetts,
 17 University of Minnesota. I want to just
 18 address one of the comments that were submitted
 19 that was not covered in any of the
 20 presentations or discussions today. We had a
 21 colleague from the University of Washington
 22 introduce the measure that he characterized as
 23 being dormant over the last 20 years of the
 24 high glycation index, and that there's a
 25 greater risk for hypoglycemia in patients where

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1 there's a high glycation index and a greater
 2 risk for cardiovascular disease. Now I
 3 recognize that this, you know, high glycation
 4 index may not be ready for prime time in terms
 5 of our evidence review, although I want to make
 6 sure that we get it in the record for possible
 7 future considerations, that we acknowledge that
 8 it's out there, that the research is building,
 9 and we include that in our report.

10 DR. ROSS: Thanks. Actually, the
 11 other endpoint that was measured, although it
 12 wasn't described explicitly as a surrogate
 13 endpoint in addition to the GMI, which I
 14 thought Dr. Munshi spoke about, was this issue
 15 of variability and whether that's measured at
 16 the individual level during the course of
 17 treatment and its implications for
 18 hypoglycemia. So again, I didn't see in our
 19 evidence review, maybe others -- oh, I guess it
 20 is. The coefficient of variation was also
 21 mentioned, so I'm mistakenly speaking.

22 Was Dr. Munshi able to be rejoined
 23 into the meeting, Tara?

24 MS. HALL: I just sent her a message,
 25 I'm waiting for a response.

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1 DR. ROSS: Oh, okay. I believe
 2 Dr. Wall was next. Please correct me if I'm
 3 wrong.

4 DR. WALL: Yeah, this is Eric Wall.
 5 Just a quick clarification, Joe. When we get
 6 to the voting, we're voting on ranking or
 7 whatever it is we're doing, it's actually
 8 domains. We're not really ranking within a
 9 domain, we are not ranking measures, you know,
 10 the suggested measures. Let's say the
 11 surrogate markers, we're not prioritizing those
 12 measures one over the other. Am I correct?

13 DR. ROSS: This is Joe. That is
 14 correct, although for instance, like the
 15 presentation that came from Dr. Reddy and
 16 Dr. Schulman-Rosenbaum, I thought that was
 17 actually useful. They talked about individual
 18 measures within each domain, and I would
 19 encourage you that if you do have an opinion
 20 about one measure versus another within a
 21 domain that when you do vote, you can talk
 22 about that.

23 Because again, just for a point of
 24 emphasis and for the public record, it is our
 25 spoken comments that are then used as part of

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1 the transcript that CMS then relies on more so
 2 than the votes themselves. So that for
 3 instance, if you were to vote on, I don't know,
 4 the quality of life or patient-reported outcome
 5 domain, you might think that's very important
 6 and rate that a five, but you would say if it's
 7 really this measure that you value highly, and
 8 these other measures that were listed there's
 9 much less evidence for, or something to that
 10 effect, so just to speak openly as to how and
 11 why you're making that vote. Does that help?

12 DR. WALL: Yeah, thank you.

13 DR. ROSS: Dr. Kobylarz?

14 DR. KOBYLARZ: Again, just to
 15 piggyback on what you, Dr. Ross, were just
 16 talking about, I think looking at the surrogate
 17 markers, emphasizing, you know, primary
 18 secondary type of endpoints, and at least what
 19 I was hearing, time in range, hypoglycemia were
 20 much more towards the top of the list, and just
 21 given the variability in things like A1c, maybe
 22 that could be a little bit lower or some kind
 23 of secondary endpoint.

24 DR. ROSS: Dr. Lewis?

25 DR. LEWIS: Thank you. Joy Lewis, and

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1 I think regarding -- forget it. And I
 2 appreciate Joe's comments that we can
 3 prioritize, agreeing with Fred that we can
 4 prioritize within each of the domains to which
 5 surrogate markers are mentioned.

6 I raised my hand because I just wanted
 7 to address the question that was raised
 8 regarding the duration of the studies, and the
 9 way I'm looking at this is that we're looking
 10 at devices that have been approved by the FDA,
 11 so they've been studied for a duration long
 12 enough to get FDA approval to measure the
 13 safety and effectiveness of the devices. But
 14 then we're tasked with looking at what studies
 15 need to be done or what needs to be considered,
 16 not necessarily a new study, but what needs to
 17 be considered to look at these for this
 18 Medicare population. And so for me, not
 19 wanting to add additional burden, I would say
 20 the three months, there was good evidence and
 21 there were compelling arguments made for the
 22 three-month minimum time period rather than a
 23 longer time period, given that these are
 24 already approved devices.

25 I recognize that the FDA approval

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1 might require some longer timeframes to show
 2 some of the safety and effectiveness, but
 3 that's not at the realm that we're operating
 4 in. In my mind, we're operating on what is the
 5 minimum for us, for an approved device that's
 6 already been FDA approved.

7 DR. ROSS: Other comments or questions
 8 about the domains or information that we've
 9 heard? Dr. Kobylarz?

10 DR. KOBYLARZ: Just another comment
 11 regarding device-related safety. At least what
 12 I heard here from one of the presenters, what
 13 would be key here would, at least what I heard
 14 was device continuation and adherence, you
 15 know, to the actual, you know, technology might
 16 be something here to think about.

17 DR. ROSS: Yeah, I think that's an
 18 excellent point. I also heard someone talk
 19 about specifically the capability of using the
 20 device safely but there, that wasn't defined in
 21 any way. You know, it's just an interesting
 22 challenge with medical devices in terms of both
 23 the individual user and the caregiver, how to
 24 assure, you know, that that's what's happening.
 25 I'm not sure that came up very much in the

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1 evidence, the endpoint review of the evidence
 2 in terms of sort of adverse events or safety
 3 seem to be much more related to device
 4 malfunction as opposed to device use or misuse,
 5 so that might be something that we might want
 6 to think about more.

7 But Dr. Young, I saw your hand coming
 8 up first I believe, but if I'm getting these
 9 wrong, because I'm juggling multiple things,
 10 just please correct me. Who was up first?

11 DR. YOUNG: I think Joy Lewis was up
 12 before me.

13 DR. ROSS: Joy?

14 DR. LEWIS: It's really okay, but
 15 thanks. Speaking directly to what you just
 16 talked about, I too wrote down that device
 17 discontinuation and patient preferences
 18 regarding use, which we hadn't initially
 19 discussed as part of safety, but that came up
 20 in the comments and in the presentations.

21 And I'm also just curious where the
 22 panel members would place cognitive function,
 23 into what domain. It's not necessarily
 24 measured in quality of life, it might be but
 25 not in all of these markers. It is a health

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1 outcome but it's, but we have talked a lot
 2 about these long-term health outcomes and
 3 deemphasizing those as measures of assessment
 4 for shorter term, and the unnecessarily complex
 5 nature and length of trials for really hard and
 6 fast health outcomes. So I'm just curious what
 7 others think about where they would put the
 8 cognitive function.

9 DR. ROSS: Yeah. I'll just note that
 10 there was a discrepancy in term in the table
 11 versus the question, where the table used the
 12 term patient-reported outcomes of the life
 13 impact domain, whereas the questions say
 14 quality of life, but then define that as
 15 patient-reported assessments of symptom burden
 16 or function. So I think I probably would have
 17 put cognitive function as an endpoint there, as
 18 opposed to an outcome per se.

19 DR. LEWIS: Yeah, that's how I put it
 20 in my notes as well.

21 DR. ROSS: Yeah. Dr. Young?

22 DR. YOUNG: Yes, thank you, Heather
 23 Young. I'd like to address the issue of the
 24 cognitive function. I think that cognitive
 25 function includes both dementia and delirium,

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1 and is looking at an outcome of treatment that
 2 the delirium aspect is probably more relevant
 3 than the dementia status. I would say that the
 4 cognitive ability, executive function and
 5 ability to engage with the device is a
 6 precursor to whether it's going to be
 7 successful or not, but I'd like to call
 8 attention to the fact that family caregivers
 9 provide about 80 percent of all long-term care
 10 or chronic care for older adults, and they in
 11 their capacity are acting on their behalf. And
 12 so assessing the individual who might be using
 13 the device may not necessarily link to the
 14 outcomes that are possible for that individual
 15 with the assistance of others. So I wouldn't
 16 want to see discrimination against people who
 17 have cognitive impairment based simply on their
 18 status because they're often aided by other
 19 people.

20 And related to the safety aspect, I
 21 was a little puzzled to actually see
 22 preferences and discontinuation as a safety
 23 issue, because there are many different reasons
 24 people discontinue that may or may not be
 25 safety related. And so as we think about that,

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1 it's in a domain of perhaps patient preference
 2 and also efficacy for that person and using a
 3 particular device. I'm not sure I would
 4 categorize it as safety per se, unless there
 5 was a discontinuation that was related to some
 6 kind of a skin reaction or some element that
 7 was very specific to the use of that device.
 8 So it gets to this issue, again, of
 9 distal, proximal. Something that is
 10 discontinuation has multiple explanations. And
 11 so I would urge us to be more precise if that's
 12 a safety factor.
 13 DR. ROSS: Those are all excellent
 14 points. Dr. Dhruva?
 15 DR. DHRUVA: Thanks. I was going to
 16 make a similar point around the device
 17 discontinuation. I think that it matters as to
 18 why the device is discontinued. We know with a
 19 lot of medical devices, they might be
 20 discontinued, explanted for a safety
 21 indication, but it might also be related to a
 22 parent preference and the patient not wanting
 23 to continue.
 24 I also wanted to, just to Dr. Lewis'
 25 good point around cognitive function changes, I

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1 think that, I think that I'm, I do I think
 2 place greater value on health outcomes like
 3 cognitive function changes, hypoglycemia that
 4 requires intervention from a caregiver or
 5 someone else than the surrogate markers. I
 6 know that it's easier to measure obviously
 7 Level 2 hypoglycemia, Level 1 hypoglycemia but
 8 to me what's important is the consequence to
 9 patients, less so the number, and sort of what
 10 happened to the patient, did they need a
 11 caregiver to intervene, did they have a fall,
 12 did they have any other adverse sequelae?
 13 DR. ROSS: Mr. Frankel?
 14 DR. FRANK: Yeah. You know, I think
 15 in some ways I'm echoing what Dr. Lewis as well
 16 as Dr. Young had mentioned before with
 17 cognitive function. You know, one of the
 18 things that I am a little bit concerned about,
 19 though, when listening to the conversation in
 20 terms of really what the substance is, in
 21 theory it all makes a lot of sense. You know,
 22 it was mentioned before in terms of potential
 23 screening mechanisms to be able to identify,
 24 but the problem is that of course when we're
 25 dealing with a national population and you're

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1 going to have different access to care and
 2 different clinicians involved, and different
 3 screening mechanisms potentially and different
 4 expertise amongst the physicians that are
 5 performing those screening mechanisms, there is
 6 a concern of a slippery slope which leads to
 7 the side of less access to patients in
 8 inappropriate ways.
 9 You know, it was mentioned before by
 10 Dr. Young specifically with caregivers for
 11 example. There's a lot of different points of
 12 the equation which can extremely be in variance
 13 from one patient to another, depending on where
 14 the patient is receiving their care. And
 15 because of that, my thought process at least is
 16 to take a step back and say this is a device
 17 that was shown to be safe and effective by FDA
 18 and when we get to a certain point of granular
 19 data we have to in some way be trusting that
 20 physician and patient relationship is really
 21 crucial over here. And when we're starting to
 22 put metrics in that may be a little bit
 23 arbitrary and perhaps misused if it's not used
 24 completely effectively across the board, then
 25 it can potentially cause a creep of more

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1 problems than solution.
 2 DR. ROSS: Dr. Fanaroff?
 3 DR. FANAROFF: Yes. So thinking about
 4 cognitive function as an outcome of a study or
 5 something you'd want to see, I didn't see any
 6 data presented that would suggest that, you
 7 know, that the proximate outcome of better
 8 glucose control would lead to measurably
 9 different cognitive performance. And so you
 10 know, just thinking about that as an outcome,
 11 I'm not sure that it makes sense, unless
 12 there's somebody that knows something about,
 13 you know, whether better glucose control or
 14 avoiding hypoglycemia should affect cognitive
 15 function as would be measured on some kind of
 16 cognitive function test.
 17 DR. ROSS: I would just say, if I
 18 could just jump on that point, which I also --
 19 no one presented data on that, although several
 20 of the endocrinologists instead talked a lot
 21 about the distress scale. This is not about
 22 cognitive function per se, but about, almost
 23 like cognitive stress about hypoglycemia, and I
 24 thought that was actually quite interesting.
 25 DR. WALL: Joe, this is Eric Wall.

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1 Just, I'm sorry, but I thought I was hearing
 2 that repeated episodes of hypo, repeated
 3 hypoglycemic episodes does have a long-term
 4 effect on cognition. I didn't see any support
 5 for that, but I thought I heard that in at
 6 least one or two of the speakers.
 7 DR. ROSS: That is what I heard too,
 8 but there wasn't subsequent data presented by
 9 any of the speakers. Dr. Garrido?
 10 DR. GARRIDO: I'm just going back to
 11 Dr. Dhruva's point about prioritizing health
 12 outcomes that require intervention. I
 13 completely agree that those are important, but
 14 I think what was important to note about the
 15 materials presented today is there's a really
 16 strong association between those surrogate
 17 markers and the health outcomes. I was
 18 concerned that measuring meaningful outcomes,
 19 meaningful differences in health outcomes might
 20 require large lengthy trials. It's not clear
 21 to me that the benefit of that information
 22 outweighs the cost, time or patient burden that
 23 would be involved in a big randomized trial. I
 24 mean, we could use real world evidence and use
 25 observational data, but then it's. I don't

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1 have a good sense of how accurately we can
 2 attribute a hospitalization or an ED visit to
 3 diabetes, and not to any one of the many
 4 confounding factors that Dr. Young was
 5 mentioning earlier.
 6 DR. ROSS: Dr. Lewis?
 7 DR. LEWIS: Thank you. Just getting
 8 back to the -- and I think those are great
 9 points, Dr. Garrido, thank you for that.
 10 And getting back to the discussion
 11 around the cognitive function, I agree with
 12 Dr. Ross regarding what was highlighted most
 13 was the psychological safety, any changes in
 14 fear of hypoglycemia, feeling of reassurance
 15 and ability to do more in your life and
 16 feelings of freedom from having to do the
 17 continuous monitoring and less fear, and that
 18 can be related to cognitive function. We also
 19 know if you fall from a hypoglycemic episode
 20 and break a hip and are in the hospital, then a
 21 lot of older adults ends up having, you know,
 22 as Dr. Young mentioned, some delirium, it could
 23 be more of an acute onset from other things
 24 that are happening or from the fall, from being
 25 hospitalized, et cetera.

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1 And so I'm saying all this to just
 2 make sure that, just to share that the way I'm
 3 looking at this is if we include these measures
 4 it's not, I don't believe in making a
 5 recommendation that you need to see an
 6 improvement in cognitive function. And I agree
 7 with Mr. Frankel that we don't want to set
 8 limits on what cognitive function one possesses
 9 prior to obtaining these devices, but instead
 10 showing that if you can show an improvement or
 11 perceived cognitive function, a person feels
 12 better about their abilities in their life,
 13 then that's a bonus.
 14 And to me, that's as much of a bonus
 15 as some of the other measures that we've
 16 already discussed. So I'm not trying, I don't
 17 believe in setting this as a requirement, but
 18 just to invite inclusion of these other domains
 19 so that the people studying these devices have
 20 the best ability to show the real world
 21 benefits in people using them.
 22 DR. ROSS: Very helpful, and good
 23 level setting. Before we go into talking about
 24 the specific questions that we're going to vote
 25 on, does anyone have any -- I want to leave us

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1 an hour to go through them, because I think
 2 people are going to have things they want to
 3 say as part of the vote, which is what I really
 4 want to encourage. But does anyone else have
 5 any -- this is Joe Ross speaking. Does anyone
 6 have any last questions or point of
 7 clarification that they want to make for the
 8 panel members, or issues to surface?
 9 Mr. Frankel?
 10 MR. FRANKEL: Yeah. The only thing
 11 I'd mention is that before it was asked about
 12 the hyperglycemia, because there was little
 13 focus on it. I just noticed, and again, I
 14 didn't have a chance to actually look up the
 15 paper, but one of the materials that were
 16 provided to us by the diatribe foundation, it
 17 references a specific piece of literature
 18 regarding hyperglycemia and how it has been
 19 shown to improve mood. Again, I can't speak to
 20 the validity of that paper, I didn't even look
 21 it up, but I'm not sure if anyone else here has
 22 anything to add on that specific point
 23 regarding that intersection between
 24 hyperglycemia and an improvement of mood for
 25 that patient population.

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1 DR. ROSS: Dr. Fanaroff?

2 DR. FANAROFF: I don't have anything

3 to say to that particular question. I think

4 one thing that just in general worth saying is

5 that Dr. McGill talked about how the MCID for a

6 given measure changed based on site design and

7 comparators. I think that that is, you know, I

8 wanted to raise that flag, I think it's

9 important, I think in some of the studies the

10 technology advancements almost certainly will

11 compare, you know, new technology to already

12 very good technology, potentially with not

13 inferior devices, you know, where they're the

14 same for measures of A1c and time in range, but

15 better from a patient satisfaction standpoint.

16 And I think that, you know, in that

17 case maybe the MCID becomes the non authority

18 margin, I don't know exactly how that will be

19 designed, but I think it's an important

20 consideration to raise, because study designs

21 do matter when determining an MCID.

22 DR. ROSS: No, I think that's actually

23 quite a good point, right, the idea that if

24 there is a known minimally clinically important

25 difference, you would want any comparative

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1 research between technologies to use that MCID

2 as the non authority margin, saying that it's

3 no worse than this. And I will just say, I

4 think the biggest challenge for all of us and

5 for CMS largely, is the comments that were made

6 at the very end that just the general paucity

7 of studies in older adults and in older adults

8 specifically with Type 2 diabetes requiring

9 insulin, and how to sort of make heads or tails

10 of that. Dr. Dhruva?

11 DR. DHRUVA: Thanks, Dr. Dhruva,

12 San Francisco. That was actually, Joe, that's

13 the point that I was going to make, just as we

14 sort of get to the voting. As I was reflecting

15 on the clinical endpoints review that I read

16 again last night, that we have a single

17 clinical practice guideline for the treatment

18 of diabetes in older adults, and despite that

19 comprehensive lit search, few studies include

20 older adults, include subgroup analyses by

21 older adults, and so it just helped me to

22 recenter in thinking about the fact that we may

23 be looking at these outcomes in an older adult

24 population that often has multimorbidity and

25 other conditions.

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1 DR. ROSS: So with that, I would like

2 us to move towards the voting portion of the

3 meeting, and I'm going to remind us exactly

4 what we will be voting on, because we will need

5 essentially 15 minutes or so for each of the

6 domains in order to allow everyone to have

7 ample time to make their comments as part of

8 the voting process.

9 But just, you know, the clinical

10 endpoints review was a literature review to

11 identify endpoints that have been tested or

12 were found to have been used in research

13 studies for technologies that are delivered in

14 a part of care for Type 1 diabetes and Type 2

15 diabetes requiring insulin. Our role is to

16 provide advice and recommendations on the body,

17 you know, the body of evidence regarding these

18 devices for self management in older adults,

19 what type of endpoints would you want to see

20 and how you would prioritize them, or should

21 CMS want to see them and how you would

22 prioritize.

23 And we're going to go through kind of

24 one by one surrogate markers of domain, health

25 outcomes as a domain, quality of life as a

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1 domain, and device-related safety as a domain.

2 I'm going to ask each of you when you vote on

3 that domain on a scale of one to five, from not

4 at all important to extremely important. And

5 then at our hands in the appendix, there are

6 specific endpoint measures that have been

7 identified, some of which have been studied

8 very well, some of which not. Others were

9 named or you know, or raised in the public

10 comment period. So there's a series of

11 surrogate markers, health outcomes, quality of

12 life measures and device-related safety

13 measures that have been named. You can talk

14 about those which you think to be more suitable

15 versus less suitable when you cast your vote,

16 or you can say your vote is based on this

17 specific measure but you don't have a strong

18 opinion on these other measures.

19 And then I'm going to ask each of you

20 to talk about the ideal duration of followup

21 that should be required when using those

22 measures, and whether you're aware or would

23 want to see a specific minimally clinically

24 important difference in the evidence, or that

25 you would say is a valid threshold. Any

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1 questions about that?

2 Can everybody go to the voting site?

3 I just want to remind everyone that I am a

4 nonvoting member, although I'm sure I will be

5 making comments as part of this process.

6 Dr. Carlson is also a nonvoting member,

7 although my understanding is I ask you how you

8 would have voted, right? Is that right? Yes,

9 okay.

10 Tara, is everyone set up on the voting

11 as far as you can tell? You're on mute.

12 MS. HALL: Is everyone able to log on?

13 DR. YOUNG: Working on it.

14 MS. HALL: Hold on, I can't hear you.

15 DR. ROSS: As this is getting figured

16 out, I'm going to -- after everybody votes, I'm

17 going to ask you how you voted and your

18 explanations and rationale, and I'm going to go

19 in the order on the roster, so I'll start with

20 the committee vice chair, go member by member,

21 then the industry representative and then the

22 patient advocate.

23 MS. HALL: I'm sorry, I had a glitch

24 with my sound. What did you say, Heather?

25 DR. YOUNG: I'm working on it, Tara.

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1 DR. ROSS: So as this is being worked

2 on, our first vote is about the endpoint domain

3 ratings of surrogate markers. Just to remind

4 everyone, these are indirect assessments using

5 biomarkers, physiologic measures or imaging

6 intended to predict or act as a proxy for a

7 target outcome of interest. Examples include

8 percentage of time in hypoglycemia, hemoglobin

9 A1C. We heard other things around time in

10 range or time below range, and coefficients of

11 variability.

12 And so how, I'm asking you to vote,

13 how important are endpoints in this domain as

14 part of the body of evidence, with a one being

15 not at all important and a five being extremely

16 important? Everyone can cast their votes.

17 (The panel voted and votes were

18 recorded by staff.)

19 MS. HALL: Everyone has voted.

20 DR. ROSS: Great. Dr. Dhruva, I'm

21 going to ask for you to start, to explain your

22 vote and to address the points in the

23 discussion around which endpoint measures you

24 were thinking of the duration of followup in

25 the MCID.

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1 DR. DHRUVA: Thanks. I voted a three,

2 that these surrogate markers I think are

3 somewhat important. I think I was in between a

4 little bit. I think these are important

5 because they can be easily measured, these are

6 data that are more easily available and so

7 therefore can be assessed. But at the same

8 time, I think they are less important than

9 clinical outcomes to patients.

10 I would prioritize Level 2 and Level 3

11 hypoglycemia. I think a lot of what we heard,

12 particularly for older adults, we know from the

13 2019 guideline on diabetes in older adults that

14 A1c, despite it being the easiest measure it is

15 not prioritized, but that the metrics around

16 hypoglycemia, I think are particularly

17 important.

18 Given that these are relatively rare,

19 the hypoglycemic episodes hopefully, I think

20 that probably three months is too short, and

21 probably something like six months is more

22 helpful.

23 DR. ROSS: Dr. Fanaroff?

24 DR. FANAROFF: So I said five for this

25 one. And I think that, you know, the rationale

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1 for that is that this is really, to borrow

2 Dr. Young's terminology, this is the most

3 proximal outcomes to what the device purports

4 to do. So you know, I think this is important

5 because essentially what you're asking is does

6 the device do what it says it's trying to do.

7 If not, it's not doing that, what else is it

8 doing?

9 I think the important markers here are

10 A1c, time in range and time below range. I

11 think that those are important, I think that

12 probably the minimal clinically important

13 difference for hemoglobin A1c, I would favor

14 0.3 percent, based on the fact that that's how,

15 you know, the criterion that the FDA and the

16 AMA used to approve diabetes drugs.

17 To make sure there's nothing else that

18 I wanted to say here, yeah. And I think the

19 other important thing to think about is that I

20 think the other rationale for this is that

21 there's a strong association between these,

22 between many of these surrogate markers and

23 outcomes that are important to patients,

24 including cardiovascular and other

25 microvascular events.

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1 DR. ROSS: Dr. Garrido?
 2 DR. GARRIDO: I voted a five. My
 3 rationale is similar to Dr. Fanaroff's. These
 4 are the most proximal measures. We know that
 5 they are strongly associated with other
 6 meaningful outcomes in the other domains
 7 without being subjected to confirming factors
 8 because the group of older adults with diabetes
 9 is so heterogeneous.
 10 I heard a lot of support for time in
 11 range. There was one speaker this morning that
 12 mentioned an adjustment related to making sure
 13 you're not going below the acceptable range
 14 might be warranted. I think that might be
 15 something that should be considered.
 16 I don't think I have enough
 17 information to make a recommendation to the
 18 meaningful follow-up time.
 19 I would think for clinically
 20 meaningful differences, examining individual
 21 variability rather than trying to have a fixed
 22 endpoint I think would be important to
 23 consider.
 24 DR. ROSS: Dr. Isetts?
 25 DR. ISETTS: Brian Isetts, University

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1 of Minnesota College of Pharmacy. When I look
 2 at the scales here I need to look at the
 3 practical anchoring, and I really enjoyed the
 4 application of the Dr. Joy Lewis anchoring
 5 measuring scale. So the five is we can't live
 6 without it, okay? Four is it's expected and
 7 highly desirable. Three would be well, you can
 8 live with it or without it.
 9 And so in the first domain, I want to
 10 just use the relationship of surrogate measures
 11 to in vivo measures. Because it would sure be
 12 nice, you know, if we could get measures inside
 13 the pancreas and inside the endovascular system
 14 and what have you in the kidneys, but we really
 15 can't. So my vote is that we can't live
 16 without it, it's extremely important, a five.
 17 And specifically the measures, this is
 18 really the patients that I serve as a geriatric
 19 practitioner, are the hypoglycemic measures. I
 20 also want to go on record as I said previously,
 21 to make sure that for future research we look
 22 at this, begin to look at the high glycation
 23 index because that does relate to hypoglycemia.
 24 And I do believe that three to six
 25 months is appropriate followup.

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1 DR. ROSS: Dr. Kobylarz?
 2 DR. KOBYLARZ: Yes, Joe. So I also
 3 voted five. I think this is extremely
 4 important. I think the focus should be on time
 5 in range, percent time that's, you know, in
 6 Level 1 and Level 2. I think the other
 7 surrogate markers like A1c, which lend
 8 themselves to variability, would be lower on
 9 the list but should be looked at.
 10 I feel just, you know, given the
 11 heterogeneity of this, you know, population,
 12 and differences between a let's say 65-year-old
 13 and a 90-year-old, you know, I think minimal
 14 clinically difference, you know, could be
 15 challenging here, so I'm not sure if I can give
 16 you a number or percent.
 17 You know, I do think that the duration
 18 of these studies, you know, minimum of three,
 19 perhaps six months would need to happen.
 20 DR. ROSS: Dr. Lewis?
 21 DR. LEWIS: Thank you. I also voted
 22 five. I oscillated between four and five as I
 23 was thinking about the utility of some of the
 24 measures, but given that we're able to explain
 25 what measures we think are most important, I

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1 went with the five. And I agree with the
 2 comments that have been made round time in
 3 range and time below range, as well as the
 4 ability to recognize Level 1, Level 2
 5 hypoglycemia. And then also quite important to
 6 me, the ability to recognize asymptomatic
 7 hypoglycemia, which can particularly put
 8 elderly patients at risk, so the ability to
 9 avoid hypoglycemic unawareness to me, may be
 10 surrogate markers of the utmost importance.
 11 I also appreciate the mention of the
 12 combination, the importance of the combination
 13 between time in range with control of time
 14 below range, so a composite endpoint that was
 15 mentioned by some of the endocrinologists, I
 16 think that's really important. The A1c we've
 17 used for quite some time, but I do agree that
 18 it's less important for this population than it
 19 might be for others, and so I weighted that
 20 down.
 21 If we did want to look at minimally
 22 clinically important differences, even though
 23 I'm weighing in my mind the A1c as less, I
 24 think the 0.3 percent difference, and I know
 25 the literature says 0.5 percent, but others

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1 have mentioned 0.3 percent. And what I found
 2 quite compelling was one of the comments, I
 3 don't believe it was said today but was in the
 4 materials that we were given, that said we
 5 don't want people to have to have worse control
 6 going into a trial just to see a difference in
 7 the trial. If they're already well controlled,
 8 you don't have as much room. So that's why to
 9 me, looking strictly for a difference is less
 10 important that looking at the individual
 11 changes that might occur.
 12 And then similarly for time in range,
 13 the numbers that have been presented are the
 14 five percent, or even a three percent. So if
 15 you're looking for a difference between groups,
 16 or someone that already has good control, I
 17 would encourage us to look at the three percent
 18 rather than the five percent difference. It
 19 was also mentioned, the non inferiority, and I
 20 think that's really important that we keep in
 21 mind, so that we don't stick with strict
 22 minimally clinically important differences in
 23 these measures, but instead think about non
 24 inferiority, and then the ability to use other
 25 measures to show the benefits to the patient of

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1 these devices, and those might be in different
 2 domains such as quality of life.
 3 And then for the duration, I think
 4 given what I mentioned before, I would stick
 5 with the minimum of the three-month timeframe.
 6 Thank you.
 7 DR. ROSS: Dr. Wall?
 8 DR. WALL: Yeah, the advantage of
 9 being at the end is that everything has been
 10 said. But I also voted a five, for much of the
 11 same reasons. I think I'll only comment on
 12 some issues that may or may not have been
 13 raised. You know, it's interesting to me that
 14 the time in range is a pretty high priority
 15 surrogate marker. I'm surprised that since
 16 hyperglycemia is so rare in this population,
 17 you could almost have another measure which is
 18 time out of range, and that would be, include
 19 below and above, and not have to deal with time
 20 below range, but it seems to be a standardized
 21 metric in some of the device reporting.
 22 Where I get hung up is not so much in
 23 the time measurement, which I can go for three
 24 months because that's what clinicians are used
 25 to, and I'm not terribly impressed with the A1c

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1 value, the clinical value in this population,
 2 but it clearly has some value.
 3 So far what I've heard with the MCID
 4 is I kept thinking about what's the evidence
 5 basis, not just someone's opinion about what is
 6 minimally clinically important, and the only
 7 metric that I saw any suggestion that there was
 8 evidence for was the A1c MCID, which was five
 9 percent or greater than five percent. The
 10 thing that I kept trying to keep in mind is
 11 that because this is such a heterogeneous
 12 population, many, or some individuals who
 13 entered seniorhood will already be on these
 14 devices. So to suggest that someone has to
 15 jump through a hoop when they've already
 16 achieved these differences at an earlier point
 17 in their lives makes this kind of problematic
 18 and it gets to the whole idea of, you know,
 19 looking at what the studies, what the study
 20 population, the study goals are in the clinical
 21 trial design, makes it very critical to
 22 interpret that again, outside of the A1c, which
 23 I will throw in there only because it seemed to
 24 be a standardized metric. I didn't find, I
 25 don't know what to make of an MCID outside of

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1 that, so those are my comments.
 2 DR. ROSS: Dr. Young?
 3 DR. YOUNG: Thank you. I gave this,
 4 rated this a five as well, because I like the
 5 proximal nature of these indicators and I in
 6 general am in favor of the time in acceptable
 7 range and the hypoglycemic indicators of
 8 Level 1 and Level 2 hypoglycemia, because I
 9 think that they're probably the most sensitive
 10 in this particular population, and also the
 11 most appropriate given the heterogeneity of the
 12 population. I'm less excited about A1c for a
 13 variety of reasons, the heterogeneity.
 14 Also because I think these monitors
 15 provide some data for patients, for people to
 16 start making decisions around their lifestyle,
 17 it's insulin management but it's more than
 18 that, it's their nutritional intake and their
 19 physical activity, and it take a while to use
 20 actionable data, there's a lag between getting
 21 that data and making some changes and doing the
 22 little experiments that will result in ultimate
 23 changes in glycemic control. And so I think
 24 that, coupled with the confounding by other
 25 conditions, makes me less excited about A1c as

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1 a surrogate marker for this purpose, so I
 2 definitely will go more with the percentage of
 3 time in range and the hypoglycemic indicators.
 4 As far as time goes, I think the
 5 duration of three months is adequate to
 6 demonstrate the issues that we need to see, and
 7 I also share the perspective of Dr. Wall around
 8 it depends on where you start with what's a
 9 meaningful difference, a clinical difference.
 10 And if someone has been in control for a long
 11 period of time, the goal might be to maintain
 12 that control, not necessarily to improve it.
 13 And so I think that the within patient
 14 comparisons are really important in that
 15 indication, and if people are already achieving
 16 high levels of control, it's a tool to enable
 17 them to keep that high level of control,
 18 whereas those who are less in control, a
 19 meaningful difference would be five percent,
 20 say. Thank you.
 21 DR. ROSS: I'm going to call on
 22 Mr. Frankel next so that we go through all the
 23 voting members first, and then Dr. Carlson,
 24 I'll come to you. So, Mr. Frankel?
 25 MR. FRANKEL: Naftali Frankel. I

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1 voted four because I think that there were
 2 certain caveats mentioned here today that would
 3 limit it from a five, but of course four as
 4 stated on our voting is very important. Of
 5 course there is the challenge that we talked
 6 about before, really differentiating that from
 7 extremely important, but you know, the fact
 8 that there were certain limitations led me in
 9 that direction rather than a five.
 10 In terms of the specifics, I'll just
 11 quickly echo what mostly has already been
 12 mentioned. Number of hypoglycemic events,
 13 percentage of time in range seems to be more
 14 important in terms of prioritization than A1c,
 15 let's important.
 16 I agree also that it seems that 0.5,
 17 the lean would be towards 0.3 based on
 18 consensus with the limitations that were
 19 discussed and identified in the materials as
 20 well as today, particularly in this population
 21 where the metrics may not be as accurate in the
 22 first place.
 23 In terms of followup, it seems that
 24 the broad consensus is three months, and I'm in
 25 agreement with that.

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1 DR. ROSS: Dr. Carlson? Are you
 2 speaking? Sorry, I don't hear you.
 3 DR. CARLSON: I had to get off mute,
 4 sorry.
 5 DR. ROSS: How would you have voted,
 6 and your rationale?
 7 DR. CARLSON: Okay. My rankings are
 8 focused on what evidence should be appropriate
 9 and adequate for CMS to consider in making
 10 decisions, in other words, what should be
 11 important to make a coverage decision. I agree
 12 with ranking these surrogate endpoints as five.
 13 They predict and correlate with health
 14 outcomes. In my view they are the most
 15 important of the domains listed to make
 16 coverage decisions. Time in range and some
 17 measure of hypoglycemia duration or episodes
 18 are important.
 19 I agree with the consensus that three
 20 months is an appropriate duration for studies
 21 using surrogate endpoints.
 22 DR. ROSS: Great. So that, we
 23 finished that domain and I think we took
 24 longer, which is not surprising since we have
 25 the most endpoints to review as part of the

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1 surrogate marker domain.
 2 As we move to the second domain of
 3 health outcomes, I do just want to remind that
 4 this is regarding devices for self management
 5 of Type 1 or incident dependent Type 2 diabetes
 6 in older adults, so we're not talking about all
 7 diabetes. You know, in therapies, broadly
 8 we're talking about these devices for self
 9 management. The health outcomes domain is
 10 around direct assessments, the target outcome
 11 of interest, for instance complications of
 12 diabetes or diabetes-related emergency
 13 department visits or hospitalizations, which
 14 could include both hypo and hyperglycemic
 15 reasons for admission.
 16 And I'll ask you to go to the voting
 17 system, and talk about whether this domain and
 18 endpoints, how they rate to you from a scale of
 19 one, not at all important, to five, extremely
 20 important, and everyone should cast their vote.
 21 Tara, I am still seeing domain number
 22 one on the screen.
 23 MS. HALL: Yes. Next screen please,
 24 John.
 25 DR. ROSS: There we go, thank you. So

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1 people should cast their vote.
 2 (The panel voted and votes were
 3 recorded by staff.)
 4 MS. HALL: Everyone has voted.
 5 DR. ROSS: Great. And the scores have
 6 a little more of a spread. So we will start
 7 with, talk about please, explain what you
 8 voted, which endpoint measures you were
 9 considering, the ideal duration of followup and
 10 the MCID. Dr. Dhruva?
 11 DR. DHRUVA: Sanket Dhruva,
 12 San Francisco. I voted a four, very important.
 13 I think that what matters to patients and what
 14 patients care about is the sequelae of diabetes
 15 that could be improved through the use of these
 16 devices that we're discussing today. I think
 17 these are more important in my view than
 18 surrogate markers, and I think those, although
 19 they certainly take more time to accumulate
 20 endpoints, I think it's the most important.
 21 And I think that all of the health outcomes,
 22 cognitive function changes, emergency
 23 department visits and hospitalizations from
 24 hypo and hyperglycemia, as well as all their
 25 complications, are relevant, again, fully

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1 acknowledging it adds length to the duration of
 2 studies that are needed, but for patients for
 3 whom I care, I think that this is what matters
 4 most to them.
 5 DR. ROSS: Dr. Fanaroff?
 6 DR. FANAROFF: So I put a three for
 7 this one, somewhat important. I agree with
 8 what Dr. Dhruva said, these are important
 9 outcomes to patients, they matter to patients.
 10 But thinking about each of the endpoints
 11 individually, I think some of them are more
 12 important than others, and I think that most of
 13 them are sort of infeasible in this population,
 14 in this device, or have other challenges. We
 15 have the recitation of hypoglycemic awareness
 16 in there. I'm not, I think there are some
 17 questions to how that's measured.
 18 We talked about cognitive function
 19 changes. I think there's a question there
 20 about whether we expect this intervention to
 21 improve cognitive function. I think the
 22 diabetes-related emergency department visits
 23 are important and if I had to, I would give
 24 that one a four. But the diabetes-related
 25 hospitalizations, I think there are questions

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1 about definitions and how you define a
 2 diabetes-related hospitalization. Is a
 3 hospitalization for an amputation considered a
 4 diabetes-related hospitalization? Should that
 5 be affected by this technology, I think that's
 6 the asking question.
 7 And then last is the question about
 8 complications of diabetes. I'm a cardiologist.
 9 As nice as it would be to actually know whether
 10 these devices and interventions improve
 11 cardiovascular outcomes, yeah, it's probably in
 12 practice but you'd need trials with, you know,
 13 7,000-plus patients like we have in our
 14 cardiovascular trials, and that's probably
 15 impractical with the pace of technological
 16 change. I will say, I think it's an important
 17 scientific question whether in an era with,
 18 especially for patients with Type 2 diabetes,
 19 whether that's GLP-2 inhibitors or GLP-1
 20 antagonists, that if the relationship that we
 21 found in the UKPDS study, you know, a long time
 22 ago still holds today, but that's sort of
 23 outside the realm of what maybe these device
 24 numbers should be ideal.
 25 DR. ROSS: Dr. Garrido?

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1 DR. GARRIDO: I also voted a three,
 2 somewhat important, and that relates to the use
 3 of these measures for making coverage
 4 decisions. I think these are highly important
 5 clinical outcomes, especially for patients and
 6 family members. I am concerned about the
 7 amount of time it would take to measure these,
 8 and I think the surrogate outcomes are kind of
 9 necessary conditions for these outcomes to be
 10 realized. So I'm not seeing the added benefit
 11 of requiring the health outcomes to be produced
 12 or provided to CMS for a coverage decision.
 13 If these were to be measured, I would
 14 think we would need probably a 12-month
 15 followup to get adequate power to be able to
 16 actually observe it. And again, I would be
 17 concerned that, about whether we could
 18 attribute changes in emergency department
 19 visits and hospitalizations to use of the
 20 device itself.
 21 DR. ROSS: Dr. Isetts?
 22 DR. ISETTS: Brian Isetts from
 23 Minnesota. I rated this as very important, and
 24 that's in comparison to extremely important,
 25 and really relates to what Dr. Fanaroff said.

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1 I have concerns about the reliability of the
 2 measures, all right, the fact that you have
 3 patients with diabetes who have multiple
 4 comorbidities and how is it, how can we say
 5 that fall may be from a high blood pressure
 6 medication, hypertension, it's splitting hairs.
 7 It's an important measure because it is
 8 important to patients, and so that's why I rate
 9 it as a four.
 10 And of course in the duration, the
 11 complications of diabetes such as major
 12 cardiovascular events and death, these are
 13 taking, we're talking years now, and so a
 14 one-year followup really may not be enough, it
 15 may have to be longer.
 16 DR. ROSS: Dr. Kobylarz?
 17 DR. KOBYLARZ: Thank you. I voted a
 18 four and I thought that, you know, this is a
 19 highly desirable measure, domain, but
 20 essentially we need data. I was during the
 21 discussion of the presenters earlier today and
 22 just our discussion, I was just thinking of how
 23 this could be framed, and what was kind of
 24 coming to mind was the four Ms, you know, what
 25 matters, mentation, mobility and you know,

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1 medication. You know, what matters to these
 2 patients is they don't want to end up in the
 3 hospital, they want to avoid hospitalization,
 4 they want to avoid amputation, they want to
 5 avoid blindness or visual impairment.
 6 Regarding mentation, I think what's
 7 important is to just have a baseline screen for
 8 detection of a cognitive impairment, I think
 9 just having some baseline screening. And then
 10 I also think screening for other geriatric
 11 syndromes, not only cognitive impairment but
 12 depression, falls, pain, you know, all those.
 13 I think you know, regarding mobility,
 14 other complications, there's neuropathy, you
 15 know, again falls, so I think we just need data
 16 on this, and you know, trials would take -- I
 17 mean, these would be long studies. I don't
 18 know if I can comment on a particular timeframe
 19 but again, it's highly desirable information
 20 and we just need data in this area.
 21 DR. ROSS: Dr. Lewis?
 22 DR. LEWIS: Thank you, this is Joy
 23 Lewis. I voted two for this, slightly
 24 important, and I actually oscillated between
 25 one and two on this, and I chose two because of

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1 the inclusion of admissions for hypoglycemia
 2 and hyperglycemia in this category.
 3 And I agree with the overall
 4 importance of health outcomes as being
 5 extremely important, complications of diabetes
 6 are extremely important to measure, but not for
 7 this task. And for this task we're saying what
 8 do we need to measure for CMS to make a
 9 coverage decision of already approved devices,
 10 and with that in mind I'm fearful that having
 11 strict measures that require looking at
 12 diabetes complications including kidney disease
 13 and major cardiovascular events, for CMS to
 14 cover these devices would be prohibitively
 15 expensive, long and expensive for the
 16 manufacturers, and would then make it so the
 17 devices would not be available for the Medicare
 18 population. So that was my framework for
 19 deemphasizing these outcomes despite how
 20 important they are.
 21 I also agree with Dr. Garrido that
 22 there is already great evidence that shows that
 23 the surrogate markers, shorter term measures,
 24 do provide good evidence of correlating with
 25 longer term outcomes, and with the use of these

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1 devices, we are now going to have better
 2 evidence going forward of these correlations
 3 between things like time in range, lack of time
 4 below range, the GMI and clinical endpoints,
 5 but I don't think that those studies are
 6 necessary for CMS coverage of these devices
 7 right now right now.
 8 In my mind, the restoration of
 9 hypoglycemic awareness fell under a surrogate
 10 marker. I know it's on our list as a health
 11 outcome but I was counting it under the
 12 surrogate markers, because the surrogate
 13 markers are meant to help with recognition of
 14 hypoglycemia. And then we also discussed the
 15 cognitive function changes that I was putting
 16 more in the quality of life, because I think
 17 they're harder to change, and we discussed that
 18 earlier. So leaving this more to the emergency
 19 zoom visits, that's why I felt it was
 20 important, but because these visits may be more
 21 rare, I don't think we need to prove a decrease
 22 in order to approve a device when you have
 23 strong evidence in other domains, and that's
 24 why I deemphasized this domain as well.
 25 Thanks.

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1 DR. ROSS: Dr. Wall?
 2 DR. WALL: Like Dr. Kobylarz and
 3 Dr. Fanaroff, I also rated this a four and I
 4 actually did this for a couple reasons. I
 5 looked at this in terms of wearing two hats,
 6 one was that hat of a researcher and this kind
 7 of prevented me from going to a five. I mean,
 8 I find to do some of the studies about, to
 9 study complications of diabetes, I just don't
 10 know how you would do that. It would take
 11 forever to do a study that shows that that kind
 12 of outcome would be directly attributable to an
 13 intervention over, I mean over a long period of
 14 time, and you'd have to do an immense amount of
 15 controlling.
 16 Cognitive function changes, some of
 17 these metrics are worth tracking, but I'm not
 18 sure I would require them as kind of a ticket
 19 of entry.
 20 But I think what got my attention as
 21 kind of a coverage decision person is, I mean,
 22 I do think there has to be something in here
 23 about healthcare utilization, and a reduction
 24 in healthcare utilization in some way that is a
 25 direct result of this technology. Otherwise,

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1 I'm not sure if we're paying for it, you know,
 2 we haven't really talked about cost
 3 effectiveness on this because it's kind of a
 4 dirty word, but I actually do think that
 5 somehow you've got to be able to show that as a
 6 metric, that at least it's not increased and
 7 potentially it's decreased.
 8 And I do think there are probably ways
 9 of teasing out diabetes-related
 10 hospitalizations, although I put a question
 11 mark after that, saying it's not easy to
 12 measure that, but I'm certain someone has. For
 13 these reasons I gave this a four.
 14 DR. ROSS: Dr. Young?
 15 DR. YOUNG: Yes, thank you, Heather
 16 Young. I rated this a two. I do think that
 17 these health outcomes are vitally important for
 18 patients and also have broader implications,
 19 but there is a well-established evidence base
 20 for connection between glycemic control and
 21 health outcomes. And for the purposes that
 22 we're charged to think about, which is about
 23 evaluating the CGM, insulin pumps and AID, I
 24 think these outcomes are too far out and
 25 problematic. It takes much more time to show

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1 the effects, there are other confounders that
 2 are involved, and it also involved the
 3 physician and the disease trajectory. So if
 4 someone has had undiagnosed or untreated
 5 diabetes for a long period of time, the
 6 complications may be there, but it may not be
 7 attributable to the device and using the
 8 device, and it could be a longstanding
 9 condition.
 10 I'm also a little concerned about the
 11 healthcare utilization indicators because
 12 hypoglycemia may be undetected, and it's
 13 something that someone has been unaware of, and
 14 once they get the CGM they find they are having
 15 hypoglycemic episodes, which leads to a visit
 16 for healthcare utilization. And so it's
 17 actually a benefit that they get treated for
 18 something that's occurring that they were
 19 previously unaware about. So I think there's
 20 just too many complications in using this as an
 21 indicator for the purpose of granting access to
 22 these technologies. Thank you.
 23 DR. ROSS: Mr. Frankel?
 24 MR. FRANKEL: Yes. Naftali Frankel.
 25 I voted four, but I would like to say that

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1 juxtaposed to that with a very strong caveat,
 2 which is that, you know, theory versus
 3 practicality. And in theory this sounds great,
 4 and I think that it was pointed out before,
 5 this is what patient want to know. As a
 6 practical matter, it was also mentioned by
 7 those that were more detractors towards the
 8 utility of this measure, of whether or not it's
 9 confounded. And I think it's essential, first
 10 of all, for there to be direct adjudication, if
 11 that's possible, towards the device when we're
 12 looking at this. And if it's not possible,
 13 then I would say that this is not useful at
 14 all, you know, I would say that was a one, not
 15 a four.
 16 So going with the assumption, with the
 17 premise that we're going to be able to apply
 18 specific health outcomes that are directly
 19 attributed towards the device and it can
 20 actually be measured in that way, and that it
 21 won't cause additional burden towards access
 22 towards the device, then that's my four. So I
 23 just want to, I think it's an important
 24 footnote for that four and again, if those
 25 premises are incorrect, then obviously that's

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1 what that four is grounded in.
 2 DR. ROSS: Dr. Carlson?
 3 DR. CARLSON: Sorry. I ranked this a
 4 two and I yield my time to Drs. Lewis and
 5 Young, who could have written my comments.
 6 DR. ROSS: Okay, great. So we're
 7 going to move to the third domain if that
 8 voting question can be opened up. Here we're
 9 going to rate the importance of quality of life
 10 as an endpoint domain. These are
 11 patient-reported assessments of burden or
 12 function, including measures we've heard, like
 13 the Audit of Diabetes Quality of Life
 14 questionnaire, the distress scale, impacting
 15 better scale. Some people have talked about
 16 patient preference and using these devices, I'm
 17 sure there's scales that get at that.
 18 I'm going to ask you to rate from one
 19 to five, with five being not at all important,
 20 to five being extremely important, how
 21 important is it that this domain of evidence be
 22 developed as part that CMS should be looking at
 23 for use in older adults.
 24 (The panel voted and votes were
 25 recorded by staff.)

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1 MS. HALL: So, waiting for one more
 2 vote. Everyone has voted. The voting is
 3 closed.
 4 DR. ROSS: Great. You guys voted
 5 faster than I could get that mouthful out, and
 6 again, we have a wide range of scores.
 7 Dr. Dhruva?
 8 DR. DHRUVA: Thanks. Sanket Dhruva,
 9 San Francisco. I voted a four, very important.
 10 I'll make a couple of points. I think that
 11 quality of life is incredibly important to
 12 patients, so I voted very important.
 13 I just wanted to make a couple of
 14 points. A very rich discussion over the past
 15 half hour or 35 minutes as we've been going
 16 through the voting. I think it would be nice
 17 to know if the -- I am not as convinced. It
 18 would be nice to know if the metrics that we're
 19 able to measure from these devices around time
 20 in range for example, was definitively
 21 correlated with, for example, patient-reported
 22 outcomes or other clinical outcomes. And if
 23 that's not the case, then in this case I have
 24 voted a four, and I think that these need to be
 25 evaluated.

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1 And I think just another point, I
 2 think a lot of people made great points around
 3 the clinical trials, and just the need to
 4 continue these clinical trials. I'd just say
 5 that these trials are often being conducted to
 6 receive FDA authorization, and so it's, I don't
 7 think it necessarily has to be a new trial to
 8 look at the clinical outcomes, but I think the
 9 trial needs to include older adults, have
 10 sufficient followup and incorporate quality of
 11 life metrics as well.
 12 DR. ROSS: Dr. Fanaroff?
 13 DR. FANAROFF: So I said two, slightly
 14 important, mostly because I'm not sure that any
 15 of these scales necessarily measure the concept
 16 that, as a lot of these scales measure the
 17 patient-reported outcomes in a way that
 18 necessarily reflects the value that patients
 19 get from it. I think that the idea of quality
 20 of life is important, I just don't know how
 21 important it is to see that evidence prior to
 22 approval for payment.
 23 I also think that, again, this is one
 24 where it depends, it depends on what the goal
 25 of the study is and what it's being compared

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1 to. You know, if it's a device that is
 2 intended to achieve equivalent outcomes by
 3 seeing a control that gives patients some
 4 benefit in terms of usability, then it's more
 5 important than a device that's intended to --
 6 basically, I think it's just a big it depends
 7 for this one.
 8 DR. ROSS: Dr. Garrido?
 9 DR. GARRIDO: I gave this one a one,
 10 and not to say that quality of life isn't
 11 important, I think the quality of life measures
 12 are important, should continue to be studied,
 13 but I don't think they should factor in to a
 14 CMS coverage decision.
 15 I'm thinking of a scenario where maybe
 16 fear of hypoglycemia goes down with use of a
 17 device but we don't see any meaningful movement
 18 in the measures of glycemic control. I'm not
 19 sure, then, that that warrants coverage of a
 20 specific device. I'll stop there.
 21 DR. ROSS: Dr. Isetts?
 22 DR. ISETTS: Yeah, Brian Isetts from
 23 Minnesota. This is the one domain I wavered
 24 and struggled with from this time that we've
 25 been together. I started out at first that it

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1 was somewhat important, because I had concerns
 2 about the practical application to the scales
 3 in practice, but I really have now migrated to
 4 it's very important, and I'll tell you why.
 5 And Dr. Kobylarz hit the nail on the
 6 head in the last discussion when he addressed
 7 the four Ms, okay? So I might have mentioned
 8 to you folks that this is one of the things
 9 I've done in life is to, I spent an extended
 10 sabbatical at CMS for two-and-a-half years
 11 right after the Affordable Care Act was passed,
 12 and who was the administrator, we talk about
 13 the 4 Ms at The Institute for Healthcare
 14 Improvement, it was Don Brewick. And the first
 15 thing he did when he walked in was say wait,
 16 let's stop this. The patients are always in
 17 the room, they're always first, we hear their
 18 stories that start and stop, and all contacts
 19 include a person and family engagement
 20 component.
 21 And all of the measures listed here, I
 22 don't have a lot of confidence in the context
 23 of what we're doing here. We need to do more
 24 to hear from those patients. If we're talking
 25 about self management, self efficacy, maybe we

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1 have to use more qualitative studies in terms
 2 of focus group sessions to hear what's
 3 happening, and I think that will also play into
 4 the discussion we're going to have about device
 5 discontinuation here in a minute.
 6 So for those reasons, that's why I
 7 voted very important.
 8 DR. ROSS: Dr. Kobylarz?
 9 DR. KOBYLARZ: Thank you for that
 10 segue because I gave this, I voted this a five,
 11 and I think it's extremely important. I think
 12 these need to be included. They focus on, you
 13 know, symptom burden, you know, focus on
 14 function. They should not be exploratory. I
 15 feel that, you know, any validated instrument
 16 that could be used in, you know, diverse
 17 populations that you know, that pertain to
 18 diabetes can be utilized. It is a challenge
 19 because we need to think about, you know, these
 20 are self reported, you know, measures, so that
 21 does present a challenge.
 22 And you know, I think in terms of the
 23 time duration, I would say no less than three
 24 months, you know, and we could expect to maybe
 25 see a change. So I see this as very important.

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1 DR. ROSS: Dr. Lewis?
 2 DR. LEWIS: Thank you. Joy Lewis. I
 3 too deliberated over this number. I considered
 4 a five but then given the limitations of the
 5 existing measures, I didn't want it to stand in
 6 the way of a device that could benefit Medicare
 7 patients being approved. I ended up settling
 8 on a four because I do feel these are very
 9 important. And I actually feel that if a
 10 device can be measured as non inferior in terms
 11 of the ability with the surrogate markers, if
 12 it then can show benefit in the quality of life
 13 domain, then I think that's worth covering.
 14 And whether that's non, whether that's an
 15 improvement in psychological safety and
 16 hypoglycemic awareness, or even just someone
 17 more able to eat what they choose to eat and to
 18 exercise without fear, to sleep safely, maybe
 19 there's a device that has a better way of
 20 waking you up if you're hypoglycemic and it's
 21 less stressful, then that's a benefit from the
 22 alarm going off. Or for the integrated devices
 23 that you don't even get an alarm, you just get
 24 some glucose, so that there could be a benefit
 25 to the overall wellbeing. I think that's of

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1 utmost importance, and I'm hoping that we can
 2 get improvement in measures and really
 3 emphasize the importance of studying
 4 health-related quality of life in Medicare
 5 patients, so that even early in the FDA process
 6 these measures can be included as a norm and
 7 not an abstract. But maintaining my approach
 8 of what's needed for this population, I feel
 9 the four, it is a very important step.
 10 DR. ROSS: Dr. Wall?
 11 DR. WALL: I struggled between a three
 12 and a four on this and I settled on three but I
 13 could go, easily be talked into a four. Like
 14 the previous panel members, I feel this is an
 15 incredibly important measure. You know,
 16 empowerment, self control, self empowerment of
 17 patients and assessing that is enormously
 18 important. And we certainly do need more
 19 quality of life metrics when we work on
 20 approving any technology as part of the
 21 approval process.
 22 That being said, again, I kind of
 23 focused on -- I'm not all that familiar with
 24 most of these questionnaires or surveys, so I
 25 couldn't speak to which was preferable. It

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1 seems like the ADQOL was cited in a number of
 2 studies. But again from a coverage standpoint
 3 I kept thinking, you know, many, a substantial
 4 population of Medicare eligibles and Medicare
 5 age individuals are entering this kind of
 6 decision making with many years of, with the
 7 use of this device, and I don't know how you
 8 control for, you know, that in kind of a study.
 9 And I just felt like it relative to the other
 10 domains, this was not as high for me, and I
 11 feel a little guilty as a family doctor saying
 12 that, but it is really important that we
 13 address this, but from a coverage standpoint I
 14 had do drop it to a three.
 15 DR. ROSS: Dr. Young?
 16 DR. YOUNG: Thank you, Heather Young.
 17 I'm in the same camp as Dr. Wall around, I
 18 think that these measures are incredibly
 19 important and vital for understanding the
 20 effects of different treatment for people in
 21 their lives. I'm troubled by them being used
 22 as a coverage decision, and I voted a three for
 23 that reason. I think that these measures
 24 include broader considerations that can affect
 25 their score. When you look at the item level

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1 issues, they're not all really proximal to the
 2 device itself. And other considerations like
 3 being in pain or having a relationship that's
 4 not so positive with a provider, or financial
 5 pressures, can change someone's rating on these
 6 scales when it's really not related to the
 7 specific indication that we're thinking about.
 8 Also, older adults commonly have
 9 multiple comorbidities, and people don't
 10 separate their perspectives and say I feel this
 11 way about my diabetes, I feel this way about
 12 something else, and quality of life in many of
 13 these indicators are really a more global
 14 assessment of one's subjective wellbeing. And
 15 so I think it's difficult to get highly valid,
 16 we can have reliable measures but they may not
 17 be valid for a specific purpose and so they may
 18 not be salient, these measures may not be
 19 actually salient for what we're trying to
 20 address here in particular.
 21 I think it is really important for us
 22 to have indicators of quality of life. If I
 23 were to pick one, I would pick the Diabetes
 24 Dependent Quality of Life Index, because I feel
 25 looking at the item level that they're the most

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1 connected to what we're trying to assess, but
 2 in general I would urge that we look at these
 3 issues in broader studies because they're
 4 relevant and important, but not for the
 5 purposes of the coverage.
 6 DR. ROSS: Mr. Frankel?
 7 MR. FRANKEL: I also have some
 8 reservations about this metric. I voted three
 9 and my concerns have already been voiced by
 10 multiple different members of this panel, but
 11 predominantly that in theory this is of course
 12 a very important thing to understand and to
 13 receive input from patients in terms of quality
 14 of life. But when we're discussing coverage,
 15 there are questions in terms of the specifics
 16 of that individual patient. I'm always very
 17 hesitant when we're talking about policy for a
 18 patient population, quote-unquote, when we're
 19 talking about quality of life, because the
 20 measure of quality of life varies depending on
 21 the individual patient, and I feel that
 22 sometimes there's somewhat of a sense of
 23 paternalism even, where we're deciding for the
 24 patient in effect by determining that something
 25 should not be covered rather than for them to

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1 determine that as an individual with their
 2 specific physician. And you know, in terms of
 3 practicality, in terms of application of these
 4 measurements, the accuracy of them, the
 5 potential confounders, for example when we're
 6 talking about something under the category of
 7 patient-reported outcomes, PROs, there's
 8 sometimes the question of, you know, you're
 9 asking the patient what their quality of life,
 10 how they're measuring it based on the current
 11 treatment or the specific medical device, you
 12 don't really have a picture of how they'd
 13 answer that same question in a control group
 14 where they were not actually receiving that
 15 therapy or treatment.
 16 So you know, these are different
 17 scenarios where I've seen in the past where
 18 sometimes we're saying yes, of course, this is
 19 extremely important because we care about the
 20 patient, but sometimes they can actually get in
 21 the way between the patient and the treatment
 22 that they may actually benefit and actually
 23 appreciate having.
 24 DR. ROSS: Dr. Carlson?
 25 DR. CARLSON: I would have ranked this

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1 a three also, for the reasons that have been
 2 stated. I think that quality of life is most
 3 important to physicians and patients who are
 4 making decisions about an individual patient's
 5 therapy. I think it's less important, if
 6 important at all, for making coverage
 7 decisions, for the reasons that others have
 8 stated.

9 DR. ROSS: Okay. We have one last
 10 domain to discuss, we might end up going a
 11 little bit over, I apologize, let's try to move
 12 the last domain as quickly as possible to meet
 13 the two o'clock meeting end.

14 But this relates to device-related
 15 safety as a body of evidence, for example
 16 hypoglycemia related emergency department
 17 visits or other harms, perhaps illustrated by
 18 device discontinuation rates. Please vote on a
 19 scale of one to five, one being not at all
 20 important, five being extremely important.

21 (The panel voted and votes were
 22 recorded by staff.)

23 MS. HALL: Everyone has voted, voting
 24 is closed.

25 DR. ROSS: Great. Dr. Dhruva?

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1 DR. DHRUVA: Sanket Dhruva,
 2 San Francisco. I voted for very important,
 3 I'll be brief. I think that ensuring the
 4 safety of these devices when used in an older
 5 adult patient population that has
 6 multimorbidity oftentimes, usually has greater
 7 risk that a younger patient population without
 8 other co-occurring condition, I think is very
 9 important to assess.

10 DR. ROSS: Dr. Fanaroff?

11 DR. FANAROFF: I said five. I'll echo
 12 what Dr. Dhruva said, that safety is important
 13 to an older population, and I think device, I
 14 don't know if this really falls under safety,
 15 but I think that ensuring that an older adult
 16 population is capable of using this device and
 17 continuing to use the device over, I would say
 18 a six-month followup, is probably necessary to
 19 make sure they get the benefits related to
 20 glycemic control.

21 DR. DHRUVA: I think --

22 DR. ROSS: Sorry, my Zoom froze and I
 23 got kicked out. Did Dr. Fanaroff finish his
 24 explanation?

25 DR. FANAROFF: I did.

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1 DR. ROSS: Okay. Dr. Garrido, I
 2 apologize.

3 DR. GARRIDO: I gave it a three. I
 4 was waffling between a three and a four. I
 5 think demonstrating safety in the older adult
 6 population is extremely important. I'm
 7 concerned about some of the metrics that were
 8 listed in this domain, being able to
 9 disentangle discontinuation of a device from
 10 safety reasons versus patient reasons, so that
 11 was the reason I gave it a three rather than a
 12 four.

13 DR. ISETTS: Dr. Ross, you look frozen
 14 again. You're on mute.

15 DR. DHRUVA: Joe, I think you're on
 16 mute.

17 DR. ROSS: Ah, thank you. Dr. Isetts,
 18 my apologies.

19 DR. ISETTS: No problem, thank you.
 20 Brian Isetts from Minnesota. On the rating I
 21 have written down on my notes here is 4.5. In
 22 light of the fact that we have to use whole
 23 integers, I registered a vote of four, very
 24 important, and here's the context of why I was
 25 leaning towards that half integer.

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1 It is okay, we're going to include
 2 device accuracy, correct? Of course. If I'm a
 3 patient, I want to make sure it's accurate. We
 4 kind of talked about device discontinuation,
 5 and I also want to address equitable use
 6 because when the devices are being used,
 7 there's a lot of things, stuff happens to
 8 patients, okay, in the real world, so I'll
 9 address this equitable use.

10 So you're living in a section of town,
 11 in south Chicago for instance, and the only
 12 time that you can get help is after hours, and
 13 you don't have transportation. How do you get
 14 to the pharmacy or the clinic to get the
 15 support you need or the supplies that you may
 16 need?

17 Also device discontinuation, we need
 18 to study this further in terms of, I saw rates
 19 as high as 20 percent. Let's sit down with
 20 those that have discontinued the device and
 21 find out what those reasons are, because maybe
 22 it's that they don't have the cognitive
 23 ability, or maybe it was really related to
 24 safety. I think that's going to be critical as
 25 we move forward in terms of as we keep talking

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1 about these coverage decisions, why were these
 2 devices discontinued? I think that's important
 3 because it's such a qualitative measure.
 4 DR. ROSS: Dr. Kobylarz?
 5 DR. KOBYLARZ: I gave this a four and
 6 I thought this was very important, you know,
 7 highly desirable information, and so the data
 8 should be, you know, expected. I kind of
 9 focused on the discontinuation rates just to
 10 echo my colleague, and I think focus on
 11 capability, adherence, this is all very
 12 important, and I think this could be studied in
 13 a relatively short time, I don't think this
 14 would, you know, be a long trial, but I'll stop
 15 there.
 16 DR. ROSS: Dr. Lewis?
 17 DR. LEWIS: Thank you. I also gave
 18 this a four, many of the same reasons that have
 19 been mentioned, and in our initial review the
 20 endocrinologist who reviewed the clinical
 21 evidence review mentioned the accuracy of
 22 devices at lower levels of glucose reading in
 23 the older population and I just wanted to
 24 highlight that. I know that the accuracy would
 25 have been evaluated by the FDA, but looking for

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1 coverage for Medicare, I think we would also
 2 want to insure that there were older patients
 3 included and that the question she raised
 4 regarding accuracy at the lower levels of the
 5 glucose measurement is addressed by each of the
 6 devices that are included for safety reasons
 7 for the Medicare population.
 8 And I had similar questions regarding,
 9 and thoughts regarding the importance of the
 10 patient's perspectives and device
 11 discontinuation, and I want to echo the
 12 importance of studying the reasons why patients
 13 would, as Dr. Isetts brought up, would
 14 discontinue the devices. I think that's very
 15 important, so that we can continue to do better
 16 to meet the needs of all patients. Thanks.
 17 DR. ROSS: Dr. Wall?
 18 DR. WALL: I vacillated between a four
 19 and a five, and settled on a four for the
 20 following reasons. Device-related safety is
 21 pretty key and I would have given it a five
 22 just by its name. The measures that are listed
 23 here I was troubled with, only because when I
 24 looked at the hypoglycemia related ED visits,
 25 you know, we already kind of addressed that as

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1 a health outcome I think, so it's already
 2 subsumed in another domain and we already heard
 3 that tissue damage was pretty miniscule.
 4 So then I got to the device
 5 discontinuation rate and I think it's been
 6 already mentioned, I think there's multiple
 7 reasons why people might discontinue a device
 8 or the use of a CGM or a pump, and that's not
 9 necessarily inherent in the device itself.
 10 Clearly we need to know more about that. I
 11 thought one of the speakers spoke to an MCID of
 12 looking at less than a 20 percent
 13 discontinuation rate as an MCID. I don't know
 14 where that came from, sounds nice to me, but
 15 again, I don't think there's any evidence
 16 supporting any kind of MCID.
 17 And then patient preferences, you
 18 know, again, I think it's really patient
 19 adherence is to me, and again it's, relating
 20 that to the domain is a bit problematic for me.
 21 Patient adherence, is that really a
 22 device-related safety issue, is it a quality of
 23 life issue, is it a health outcome issue? But
 24 I don't -- so I was troubled with the measures
 25 that were listed here and I was trying to come

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1 up with something other than that which are
 2 kind of the obvious stuff which is we are
 3 assuming that these are a hundred percent
 4 accurate, so what other safety issues would be
 5 talking about? So again, it's kind of more,
 6 the semantics here troubled me a little bit,
 7 which had me drop from a five to a four.
 8 DR. ROSS: Dr. Young?
 9 DR. YOUNG: So I voted as a four on
 10 this because I believe safety is an important
 11 consideration. I was troubled, like Dr. Wall,
 12 with the actual elements in this category and
 13 these particular measures as not being
 14 necessarily indicative of safety, particularly
 15 the discontinuation and patient preferences
 16 elements. And there are many different reasons
 17 that people might discontinue use.
 18 I think the hypoglycemia related
 19 emergency department visits is a good safety
 20 indicator as long as it's positive and not, and
 21 the benefits of being monitored, that someone
 22 ends up at the ER and is checked out for a
 23 hypoglycemic episode. So that's why I voted
 24 for a four. Thank you.
 25 DR. ROSS: Mr. Frankel?

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1 MR. FRANKEL: I thought this was
 2 extremely important. So you may be wondering
 3 then, why I voted one, and the answer to that
 4 really is that first of all, what was just
 5 mentioned by Dr. Young and Dr. Wall, the
 6 subsets that we have under device-related
 7 safety, it's a little bit unclear to me how
 8 those are directly defined as device-related
 9 safety using a strict measure.

10 But the overarching thought process
 11 that I had was that this is literally FDA's
 12 job, to ensure safety. For those that know the
 13 history of FDA, before they were tasked with
 14 safety and effectiveness it was just safety.
 15 So it's foundational to FDA to get this right.
 16 And if we do trust the FDA, it is very
 17 questionable to me why we would be looking at
 18 this as a precondition for coverage, set aside
 19 from the FDA already deciding that it is indeed
 20 safety from looking at a device-related safety
 21 perspective, and that's why I voted one.

22 DR. ROSS: Dr. Carlson?

23 DR. CARLSON: I would have ranked this
 24 as a four for all the reasons that have been
 25 discussed, including the questionable relevance

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1 of some of the specific measurements to safety.

2 However, having heard Mr. Frankel, I
 3 think he make the overall arching important
 4 point that this has already been done and why
 5 should we have to reinvent the wheel. So I
 6 have the option of changing my vote from a four
 7 to one, and will do so.

8 DR. ROSS: Okay. I want to thank all
 9 of our panel members, both voting and nonvoting
 10 for just their thoughtfulness, the way they
 11 approached these issues, their consideration
 12 and their ability to sort of explain broadly,
 13 you know, what was driving their votes and what
 14 was most important to them.

15 I know we're over time, not by much,
 16 which is pretty impressive given the amount of
 17 ground we had to cover. I don't know,
 18 Dr. Farmer, from CMS, if you want to make any
 19 closing remarks? This is the first of the
 20 clinical endpoints reviews as part of this
 21 guidance program to CMS and hopefully this is
 22 what you were looking for, as I asked all
 23 along.

24 DR. FARMER: Yes. CMS thanks you for
 25 your participation in today's meeting. I

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1 wanted to take this opportunity just to
 2 reiterate the meeting's intent, which was to
 3 identify the endpoints that are most relevant
 4 to the Medicare beneficiary population, the
 5 changes in those outcomes that are clinically
 6 meaningful, and the duration of followup that
 7 we should be looking for.

8 CMS does not consider cost when
 9 reviewing technologies for coverage.

10 As a next step, CMS will carefully
 11 review the public comments, panel notes and
 12 dialogue from today's MEDCAC. This input will
 13 assist Medicare in developing a clinical
 14 endpoints, guidance document on this topic.
 15 Guidance documents do not review specific
 16 technologies and are not national coverage
 17 analyses or NCDs. Instead, they identify
 18 health outcomes of interest to CMS from
 19 reviewing technologies and considering
 20 reasonable and necessary NCDs.

21 CMS does recognize that some endpoints
 22 discussed in today's meeting may not be
 23 commonly used. Nonetheless, we hope that
 24 guidance from this meeting will be helpful to
 25 manufacturers as they conceive future studies

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1 such that they can offer greater clarity on the
 2 benefits and harms of these technologies for
 3 the Medicare beneficiary population. So again,
 4 thank you so much for your participation today.

5 DR. ISETTS: Brian Isetts, I have a
 6 quick questions procedurally. So will we
 7 receive a copy of the draft of this, or it just
 8 goes final and you'll send us a link that I can
 9 share with my dean and my department chair?

10 DR. FARMER: You mean the guidance
 11 document?

12 DR. ISETTS: Yeah. So whatever the
 13 product of this, or these meetings, will be
 14 published somewhere. Will we see a copy of
 15 that and how will that work? What are the
 16 procedures there?

17 DR. FARMER: A copy of today's
 18 transcript of the meeting will be made public,
 19 along with all the other related meeting
 20 materials and the voting scores from the panel
 21 vote.

22 As to the guidance document, a
 23 guidance document will be proposed, and also
 24 will be subject to public comment, so the
 25 public will have ample opportunity to

1 contribute to this review.

2 DR. ISETTS: Great, and you'll share
3 all that with us?

4 DR. FARMER: Yes.

5 DR. ISETTS: Thank you.

6 DR. DHRUVA: Joe, I think you're on
7 mute.

8 DR. ROSS: Thank you again everyone
9 for making the time today, I appreciate it, and
10 have a good rest of your day.

11 (Whereupon, the meeting adjourned at
12 11:10 a.m. EDT.)
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