Meeting of the NGSP Clinical Advisory Committee Minutes

2023 ADA 83rd Scientific Sessions
San Diego, CA
Monday June 26, 2023 2:30 – 4:30 PM

Mandeep Bajaj	Baylor Coll of Med	Eric Ogg	Abbott Labs
Craig Cartwright	Bio-Rad Labs	Curt Rohlfing	NGSP
Marta Clendenin	Abbott Labs	David Sacks	NIH, NGSP
Guido Freckmann	Inst for Diab Tech	Elizabeth Selvin	Johns Hopkins
Christopher Holliday	CDC		
Kuanysh Kabytaev	Univ of Missouri	*Remote Audio via Zoom*	
David Leslie	UK	Beena Akolkar	NIDDK
Randie Little	NGSP	Paul Conlin	VA
Clair Meek	Univ of Cambridge	Salvador Secchi	NIDDK

Welcome and introduction: C. Holliday opened the meeting at 2:30 pm and welcomed everyone. Participants introduced themselves. The 2022 NGSP Clinical Advisory Committee meeting minutes were approved.

NGSP Update: R. Little

- Structure of the NGSP
    1. The NGSP network consists of an administrative core, the Central Primary Reference Laboratory (CPRL), backup PRLs , and 10 Secondary Reference Laboratories (SRLs).
    2. The NGSP network labs are located in the U.S., the Netherlands, Japan and China.
    3. The NGSP network is linked to the IFCC HbA1c network via an established master equation; twice-yearly sample exchanges between the networks ensure the stability of the relationship.
- NGSP Process
    1. Calibration: Informal process by which the NGSP works with manufacturers/laboratories to assist them in checking their calibration.
    2. Certification: Formal process by which manufacturers/labs perform a comparison against a SRL using fresh frozen whole blood; they must pass specific criteria to obtain certification.
    3. Proficiency Testing: Key to monitoring the progress and success of the NGSP in harmonizing HbA1c results. The CAP GH5 survey uses fresh whole blood with values assigned by the NGSP network.
- NGSP Certification: Year 1 to 26
    1. The number of certified methods continues to increase, the number of certified labs has leveled off, due at least in part to consolidation of some of the larger laboratories.
    2. Certified laboratories are distributed throughout the world.
- Current Limits for NGSP and CAP criteria

1. NGSP Manufacturer and Level II Lab Certification Criteria: 36/40 results must be within ±5%
2. The CAP Survey Grading for HbA1c is still ±6%

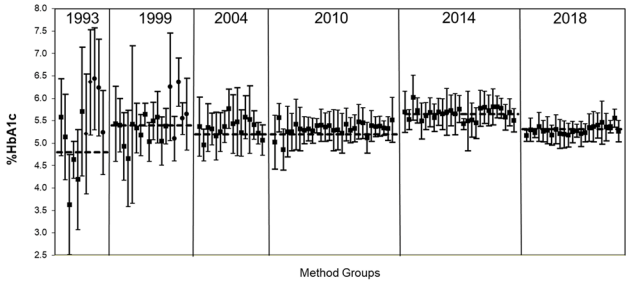
- 2023 CAP GH5A survey data (5 samples)
    1. There has been considerable improvement in the comparability of results since 1993 when the DCCT ended.
    2. CAP and NGSP criteria have been tightened over the years.
    3. The CAP HbA1c originally used peer-group grading, this was changed to accuracy-based grading in 2007.
    4. Overall pass rates were 96.9% to 98.2% for the 5 2023 survey samples. Individual method pass rates were 85.1% - 100%.
    5. All-method CVs on the survey have decreased between 2000 and 2023. Our goal for all-method CVs is ≤3.0%. CVs for the current survey were 2.4% - 3.0%.
    6. Method-specific, between-laboratory CVs ranged from 0.7% to 3.9%.
    7. Overall, 86% of laboratories are using methods with CVs < 3% at all five HbA1c levels.

CMS Guideline Update: D.Sacks

- Proficiency Testing
    1. PT is evaluation of lab performance against pre-established criteria by interlaboratory comparisons
    2. Also termed EQA (external quality assessment)
    3. In the US all labs that measure patient samples are required by law (CLIA) to perform PT
    4. Regulated by CMS (Centers for Medicare & Medicaid Services) through CLIA
    5. CAP is largest provider of PT material
- CAP Grading
    1. Initially, CAP used peer group grading for PT for HbA1c
    2. Subsequently, introduced whole blood PT, but maintained peer group grading
    3. In 2007 changed to accuracy-based grading
    4. Target values assigned by NGSP network
    5. ±15% acceptable
    6. 99% pass rate
- PT Criteria Tightened
    1. In 2008 acceptability reduced to 12%
    2. 2009 - 10%
    3. 2010 - 8%
    4. 2011 - 7%
    5. 2013 - 6%
- CAP 2010, 2012 & 2013 GH2A Pass Rates at ±6% HbA1c Cutoff

	2010	2012	2013
Low (5.1/5.6%/6.07)	91.0	95.8	93.4
Medium (6.0/7.2%/7.1)	91.6	92.9	95.3
High (8.4/9.4%/9.3)	88.6	92.5	94.3

- From Chaos to Order



- Proposed CAP PT Criterion 2020: ±5%
- CLIA
    1. In 2019 CMS proposed a rule to update CLIA PT requirements
    2. One of the recommendations was to establish a criterion for HbA1c of ±10%
- Implications of New CLIA Proposal
    1. HbA1c would become, for the first time, a regulated analyte
    2. CAP is not permitted to fail a lab if it meets CLIA criteria
    3. If CLIA accepts ±10%, CAP will have to loosen acceptability from ±6% to ±10%
- Response
    1. Multiple organizations (clinical and lab) and individuals sent comments to CMS
    2. Almost all the >100 comments received by CMS protested loosening HbA1c criteria
    3. Delegation from ADA went to speak to CMS
    4. An editorial was published in 2019 in a clinical diabetes journal criticizing the proposal (Klonoff et. al, J Diabetes Sci Technol 2019 May;13(3):424-427).
- CAP 2010, 2012, 2013 & 2022 GH2A Pass Rates at ±6% HbA1c Cutoff

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Medium (6.0/7.2%/7.1)	91.6	92.9	95.3	98.3, 98.6
High (8.4/9.4%/9.3)	88.6	92.5	94.3	97.5, 96.9

- Pass Rates for CAP 2020 GH5-C: ±6% vs. ±5%

Sample ID	Target (%)	±6%	±5%
GH-11	5.5	97.9	95.2
GH-12	8.3	97.7	95.4
GH-13	5.1	97.6	97.6
GH-14	10.1	96.9	95.1
GH-15	6.0	97.6	96.6

- CMS Response
    1. Not persuaded by comments
    2. Acknowledge improvement in accuracy
    3. Concerned that tighter criteria will limit access to testing
- Final CLIA Rule
    1. Acceptance limits for HbA1c are 8%
    2. Effective July 11, 2024

- Implications of New CLIA Regulation
    1. CMS indicated accreditation organizations can require labs to meet more stringent criteria
    2. Option of using 8% and adding more stringent limit "…for educational purposes"
    3. CAP has been considering options
- Updated guidelines to be published in Diabetes Care and Clinical Chemistry in July 2023
    1. Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus
    2. Accompanying executive summary will be published in the same issue
    3. Evidence-based recommendations for various analytes used in the diagnosis and treatment of diabetes

Discussion:

CAP Survey, new laboratory analysis guidelines

D. Sacks noted that CAP pass rates of 95% is considered excellent, there is basically never a 100% pass rate. Most failures are actually due to transcription rather than analytical error. He thanked the ADA for providing a great deal of support in the process of writing the updated treatment guidelines. The authors of the manuscript represent expertise in the different areas and analytes as well in laboratory and evidence-based medicine, it was a joint effort by the ADA and AACC. D. Leslie asked if there are any analytes of particular concern, D. Sacks responded that there are analytes discussed for which there is not currently strong evidence to support their use. The advantages, disadvantages and limitations of the analytes are all discussed. D. Leslie thought proinsulin, insulin and in terms of clinical practice C-peptide might be of some concern, D. Sacks agreed and said these are discussed. For example, under genetics there is a section discussing the settings in which testing could potentially be utilized and settings where it should not be used. C. Meek asked if clinical pre-diabetes is addressed, D. Sacks responded that the focus is on the laboratory aspects and not the clinical aspects of diabetes testing. People are referred to the ADA guidelines for the treatment recommendations. C. Meek said that the guidelines focus on clinical care, but issues such as the accuracy around diagnostic thresholds would seem to be analytical.

GMI: Use and Limitations: Elizabeth Selvin

- Continuous Glucose Monitoring (CGM): Small, minimally invasive devices that measure signal from interstitial glucose every minute or every few minutes for up to 2-weeks
- CGM Sensor Basics
    1. Sensor probe continuously measures interstitial glucose
    2. Enzymatic glucose-oxidase based electrochemical reaction
    3. Sensor response to electrical current is proportional to glucose
    4. Transmitter converts the signal to glucose in mg/dL using an algorithm
    5. Factory calibration - Assumes constant ratio between blood and tissue glucose
- CGM is transformative technology
    1. Has transformed the lives of people with diabetes (primarily type 1) and their families
    2. But CGM technology is not perfect
    3. By interrogating the strengths and limitations of CGM, we can improve the technology and optimize its use
- Concordance of CGM with venous glucose (FDA doc)

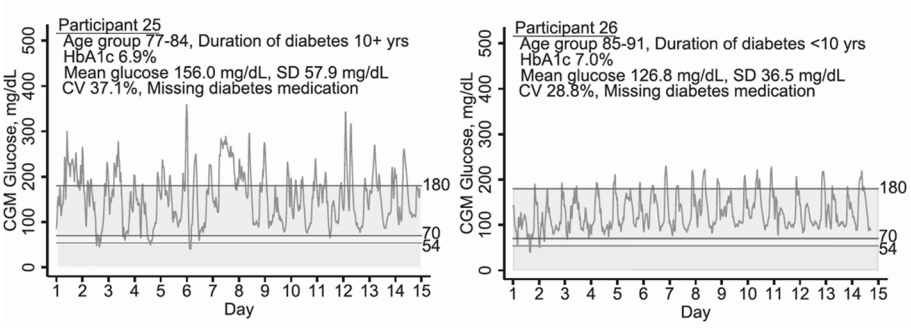
1. Dexcom G7 concordance with laboratory glucose

Concurrence of iCGM and Comparator by Comparator Glucose Range - ≥ 18 YO Arm (N=308)

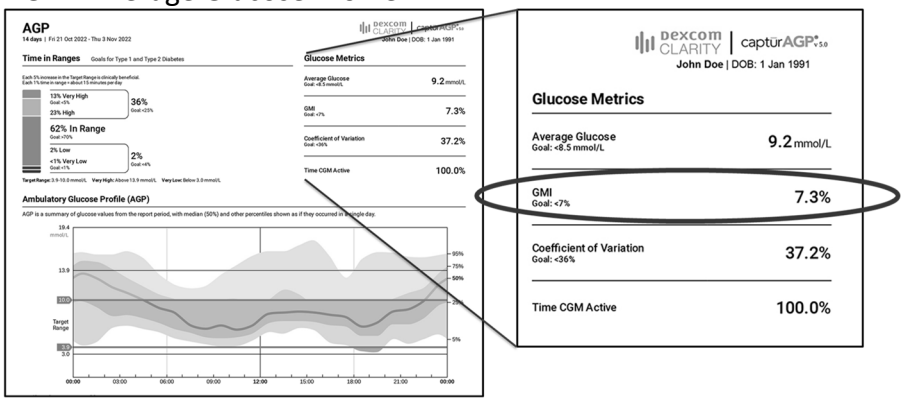
	Comparator Glucose Values (mg/dL)										
iCGM (mg/dL) (%)	**<40**	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400**
<40	16 61.5%	105 4.7%	97 1.5%	3 0.0%	3 0.1%						
40-60	9 34.6%	1,418 63.6%	944 14.8%	71 1.0%	2 0.0%						
61-80	1 3.8%	657 29.4%	4,134 65.0%	678 9.4%	11 0.2%	4 0.1%					
81-120		49 2.2%	1,175 18.5%	5,570 77.5%	671 12.6%	30 0.7%	7 0.2%				
121-160		2 0.1%	2 0.0%	855 11.9%	3,950 74.0%	636 15.2%	58 1.5%	5 0.1%			
161-200			6 0.1%	9 0.1%	691 12.9%	2,916 69.5%	668 16.8%	55 1.4%	4 0.1%		
201-250					9 0.2%	608 14.5%	2,687 67.8%	651 16.8%	51 1.1%	6 0.3%	3 1.7%
251-300						4 0.1%	538 13.6%	2,604 67.3%	1,187 25.9%	77 4.4%	
301-350							7 0.2%	547 14.1%	2,795 61.0%	598 33.9%	6 3.4%
351-400								9 0.2%	530 11.6%	940 53.3%	48 27.0%
>400									14 0.3%	143 8.1%	121 68.0%
Total	26	2,231	6,358	7,186	5,337	4,198	3,965	3,871	4,581	1,764	178

2. FDA standards of accuracy for CGM sensors are roughly based on reading being within ±15-20% of reference glucose values.

- Continuous Glucose Monitoring (CGM): Examples of glucose readings (Abbott Libre Pro) from two study participants with similar A1C



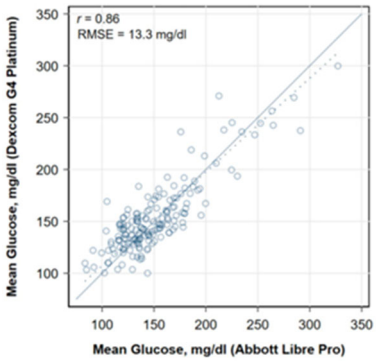
- AGP – Average Glucose Profile



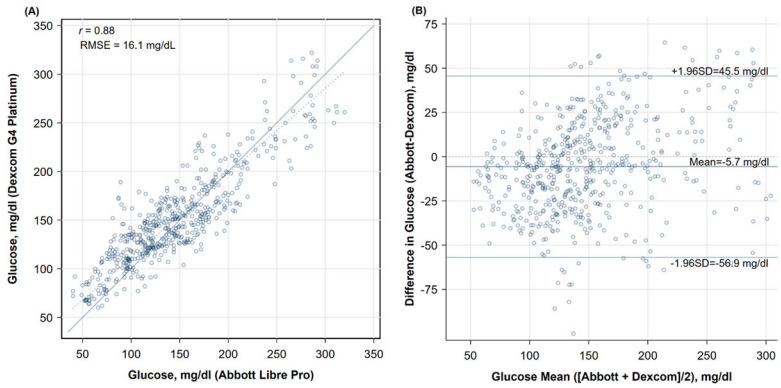
- ADAG Study-Estimated A1C (eA1C)
    1. Nathan et al. Translating the A1C Assay Into Estimated Average Glucose Values. Diabetes Care 2008 Aug;31(8):1473-8.
    2. N=507 (type 1, type 2 diabetes, and no diabetes)
    3. AG calculated from 2 days (x 4 times) of CGM and 7-pt SMBG (>3 days/wk)
    4. Resulting linear regression equation: (AG(mg/dl) = 28.7 x A1C - 46.7, R(2) = 0.84, P < 0.0001).
- What is the Glucose Management Indicator (GMI)?
    1. Term for estimation of HbA1c from CGM data.

2. Perspectives paper published (Bergenstal et al. Glucose Management Indicator (GMI): A New Term for Estimating A1C From Continuous Glucose Monitoring. Diabetes Care 2018;41(11):2275–2280).
3. Study population, N=528 adults with type 1 or type 2 diabetes receiving insulin
4. 4 trials examining effectiveness of CGM (3 funded by Dexcom)
5. Dexcom G4: Mean CGM glucose prior to A1C measurement (48 days, range 13-89)
6. A1C (Tosoh G8)
7. Ordinary least squares regression of CGM mean glucose on A1C
    - GMI (%) = 3.31+ 0.02392 x [CGM mean glucose in mg/dL]
    - GMI (mmol/L) = 12.71 + 4.70587 x [mean glucose in mmol/L]

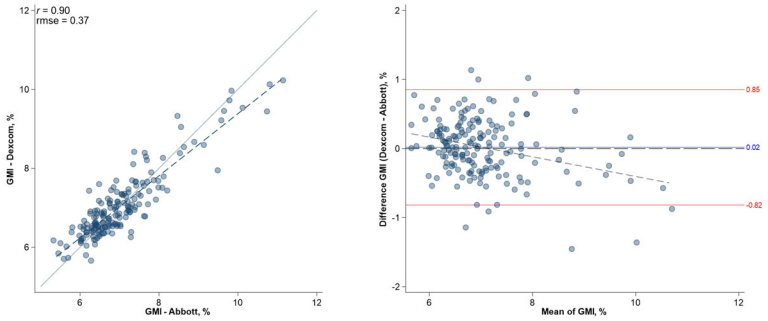
- Questions re GMI
    1. Unknown details regarding performance of GMI equation: SE, RMSE, measures of model fit
        - Performance of GMI equation across population subgroups
        - Trial control vs intervention arms
        - Age
        - Sex
        - Anemia, kidney function, etc
        - Duration of CGM wear
    2. External generalizability?
        - Children and adolescents, pregnancy, persons not on insulin, persons without diabetes
        - Other CGM sensors
- Between-Sensor Variability in CGM Metrics: Selvin et. al Clin Chem 2022
    1. The Hyperglycemic Profiles in Obstructive Sleep Apnea (HYPNOS) randomized clinical trial
        - 186 participants with type 2 diabetes who were not receiving insulin therapy and who had sleep apnea
        - 2 weeks of CGM data at baseline and after 3-months using 2 different CGM devices - worn simultaneously
            - Dexcom G4
            - Abbott Libre Pro
        - Participants masked to all CGM measurements
    2. HYPNOS: Mean CGM Glucose – Dexcom G4 vs Abbott Libre Pro
        - CGM devices worn simultaneously (up to 2 weeks), n=172
        - Mean wear time 12.4 days
        - Mean glucose from Dexcom calculated from approximately 3572 readings (every 5 min)
        - Mean glucose from Abbott sensor calculated from approximately 1190 readings (every 15 min)



3. HYPNOS: Scatterplot of glucose readings from two CGM devices at baseline (matched at time of measurement), 2-weeks of data



4. HYPNOS: Performance of GMI
    - ~40% of participants had clinically significant discordance (>0.5 %-points) between HbA1c and GMI
    - Discordance was higher for Abbott Libre Pro vs Dexcom G4
    - GMI may be unreliable in patients with type 2 diabetes
5. HYPNOS: GMI Abbott vs GMI Dexcom (4 weeks of data)



6. Findings from HYPNOS
    - Mean CGM glucose and GMI from 2 different CGM sensors worn simultaneously, were correlated but showed substantial differences
    - High variability for glucose readings from the 2 sensors matched on time of occurrence: Only 71% of the Abbott (or Dexcom) CGM individual sensor readings were within 20% of the Dexcom (or Abbott)
    - Substantial discordance between GMI and A1C in this type 2 diabetes population

- Variability within and across CGM sensors is not well recognized: Underlying reasons for variability are poorly understood but reflect limitations of CGM technology
    1. Lack of standardization of interstitial glucose methods

2. Different approaches to calibration and proprietary algorithms which generate glucose readings
3. Nonglycemic factors that may influence interstitial glucose (e.g., sensor placement, blood flow, and other local conditions)

- Advantages of GMI
    1. Translation of mean glucose values to an estimated A1C which is familiar to patients and providers
        - Same units
        - A1C ranges are well-established
    2. Provides an 'estimated A1C' if you don't have a laboratory A1C
- Considerations in the use and interpretation of CGM: Selvin E. Kelly West Lecture. Diabetes Care 2021
    1. Interstitial glucose levels are determined by glucose diffusion from plasma and will be affected by uptake by subcutaneous tissue, blood flow, permeability, and metabolic factors
    2. CGM readings will lag behind other glucose measurements (plasma, serum, capillary)
    3. CGM values will not necessarily align with finger-stick (capillary) glucose levels, which can be confusing to patients
    4. CGM sensor characteristics (placement, pressure, bleeding, inflammation) can affect glucose levels
    5. CGM readings are influenced by the calibration of the device
    6. Different sensors will give different results—often very different results
    7. Accuracy (vs. venous glucose) is poor in the low glucose (hypoglycemic) range
    8. Trends in CGM values are typically thought to be more informative than absolute levels
    9. CGM sensors generate huge amounts of data; it is not always clear how to optimize the use of the data for patients and health care providers
    10. Expensive, and coverage by health plans is currently limited
    11. Acetaminophen, aspirin, and vitamin C interfere with some devices. Other drug interferences are possible
    12. Adoption in hospitalized patients has been slow due to concerns about accuracy related to concomitant medication use or theoretical alterations in correlation between interstitial and blood glucose caused by serious illness
    13. Relatively few studies linking CGM to long-term clinical (hard) outcomes
    14. Sparse data for diverse populations (underrepresented groups, older adults) and people with type 2 diabetes
- Why might A1C and CGM glucose (GMI) be discordant?
    1. GMI (CGM measurements) have inherent error, especially at the low range
    2. A1C is measured with error
    3. A1C and CGM glucose are distinct entities – would not expect them to align perfectly
    4. Duration of CGM wear
    5. Timing of A1C measurement relative to period of CGM wear
    6. Imperfect performance of equation that estimates GMI from CGM mean glucose
- Concerns
    1. Putting GMI on same scale (units) as A1C may create the impression that the two measures are equivalent and interchangeable
        - Patients might cancel A1C testing
        - Confusion about treatment target (lab A1C vs GMI)
        - Confusion about what to do when there is discordance

2. GMI equation assumes the association between CGM glucose and A1C is the same for all patients: Growing evidence of poor performance of GMI in many settings (10 studies all showing greater discordance than original GMI paper)

- Steps forward?
    1. Emphasize CGM mean glucose
        - A1C and CGM mean glucose are separate but complementary
        - Will generally track with A1C
    2. Different units might be an advantage? Highlights the distinction
    3. Avoids issues of equation model performance
    4. Patient and provider education on strength and limitations of CGM
    5. Need guidance on discordance and education about 'average glucose ranges' (targets)
    - Studies of GMI-A1C Discordance

Authors	Device	Population	Setting	Proportion with discordance >=0.5 %-points
Bergenstal et al	Dexcom G4	T1DM/T2DM	Trial	28
Salam et al 2023	Dexcom G4	T1DM	Trial	31
Salam et al 2023	Dexcom G4	T2DM	Trial	34
Fang et al 2023	Dexcom G4	T2DM	Trial	37
Fang et al 2023	Abbott Libre Pro	T2DM	Trial	42
Oriot et al 2022	Abbott Libre 1	T1DM/T2DM no CKD	EHR	42
Toschi et al 2020	Dexcom G4	T1DM	Trial	46
Perlman et al 2021	Dexcom, Abbott, Medtronic	T1DM and T2DM	EHR	50
Shah et al 2023	Dexcom G6	No DM	Cohort	57
Oriot et al 2022	Abbott Libre 1	T1DM/T2DM with CKD	EHR	68

Discussion:

CGM Use

E. Selvin noted that the manufacturers of CGM devices use proprietary algorithms in turning the signals from the sensor that measures ISF glucose into venous glucose values. CGM is a valuable and useful technology, her concern is that many in the clinical community are not aware of the limitations of the technology. In terms of the comparisons between CGM and venous glucose, the data are often presented in ways that are not very clear, without the standard scatterplots, Bland/Altman analyses, etc., and it is often not clear what acceptance limits are based on. D. Leslie noted that there are data showing that patients can have very similar HbA1c values but significantly different times in range. From a clinical standpoint no one really knows what it means, it is important that these issues get sorted out. E. Selvin said that there are many considerations with these studies, including duration of CGM monitoring and frequency of HbA1c measurements. Regarding the CGM measurements there are factors to consider other than just TIR, for example the time below range. D. Leslie agreed and added that the question is what is best in terms of patient outcomes: Is it better to have more TIR or not, and if there a treatment to address TIR is that better than a treatment that just maintains targeted HbA1c levels? E. Selvin said important broader considerations regarding HbA1c are that it is linked to outcomes, it is measured very precisely and it is inexpensive. Even so there are parts of the world where HbA1c is not available, let along CGM sensors which are relatively expensive. Outside of intensive insulin users, which are a very important but small fraction of patients, we need to be careful when considering the use of an expensive technology that has not yet been demonstrated to improve quality of life or overall outcomes. There is a real potential for widening the gaps in healthcare. In Europe CGM devices are now being sold over the counter and people without diabetes such as elite athletes are using them. Meanwhile, there are people that are not even being screened for diabetes. We need to think about the role of CGM in the broader context, in terms of the large number of people with Type 2 diabetes who are not on insulin and are not even able to see a healthcare provider

regularly. C. Holliday asked what potential harms could result from the use of CGM given the observed discordances. E. Selvin responded that we should not just take new, exciting technology and use it uncritically. The technology is amazing but it is not perfect. For example, the manufacturers design the devices mainly for people with Type 1 diabetes and do not want to miss low blood sugars, so they design the algorithms for high sensitivity on the low end. The tradeoff is that they overreport lows. This is important for patients and providers to understand, but it is not clear that the message is getting out there. As scientists we look retrospectively at the CGM data, which is different than actively using it in the field in real time. The devices have all of this technology including algorithms that look at trends, alarms, etc., all of these things that help "fix up" the inherent limitations of the technology. When we examine data retrospectively we can look at it more agnostically. There seems to be a certain amount of "blindness" to the limitations of the technology on the part of users. D. Leslie said it is "black box" technology, we do not and will never know the actual algorithms, they are trade secrets. It is appropriate that the devices are designed to detect lows, but false lows can also potentially result in providers trying to push glucose levels higher unnecessarily. E. Selvin said another issue she has struggled with is they use the older sensors in their studies since they are masked. The companies are marketing newer sensors with improved interfaces, phone app capabilities, etc. and they are presented as having improved accuracy. However, they are really just using newer algorithms, the underlying technology is the same. One of the criticisms of their study data is that older sensors were being used, but that is not the case, the sensors have not changed. R. Little asked why people without diabetes are using CGMs, E. Selvin replied that it is the same reason people use a lot of other technologies (Fitbits, etc.). They just think it is neat to see their glucose levels go up and down, there is no reason for people without diabetes to use this technology. C. Meek said the issues with gestational diabetes are even more challenging, they are trying to keep glucose levels within a tight range and the overreporting of lows can have negative consequences. P. Conlin said he understands the rationale for people wanting to have a surrogate for HbA1c, and asked if GMI should be included in CGM reports, or if so should it include caveats. Physicians tend to interpret numbers as if they are being reported with very high precision, but the data presented show that is not the case for CGM. The question is should GMI even be included in the reports or is it just a distraction from the wealth of other data in the reports such as Ambulatory Glucose Profile. E. Selvin agreed, saying there is a paradox where endocrinologists will say the best thing about the technology is they can look at trends over time, ups and downs, and nuances, but then GMI reduces it all down to a single number. It would be best if people would focus on the nuances instead, it would be better to talk about average glucose as opposed to GMI to distinguish it from A1C, it would avoid confusion. P. Conlin asked about the relationship between CGM average glucose and A1C, is there a relationship between glycemic variability around that mean and what the A1C is? E. Selvin said no. R. Little asked if there are still efforts to standardize CGM, C. Holliday asked about the timeline for regulation/standardization of CGM. G. Freckmann said standardization is needed, they also saw differences between CGM devices in their studies but people do not want to hear about it. It was difficult getting their results published. E. Selvin agreed saying that her group has also had trouble getting their findings published. It is important to note that CGMs are considered devices, not lab tests, and they are regulated as devices which is a different world. The device world needs to communicate with and learn from the laboratory world in order to help patients and providers to optimize the use of this important technology. D. Leslie added that neither the laboratory nor the technology people should be concerned about doing so, we will be using both in patient care. E. Selvin said one of her biggest concerns is there has been a trend emerging in the literature referring to replacing HbA1c with CGM and moving "beyond A1C". It gives the impression that the two are pitted against each other. We need to explain to people how to use them to complement each other, this group can play a role due to its expertise in clinical and laboratory aspects of diabetes. D. Sacks could not understand why people are pushing for using CGM

to replace HbA1c when there are no outcomes data for CGM. You cannot just throw away the DCCT and UKPDS results and call this the new gold standard without any long-term outcomes data. D. Leslie said the assumption is that CGM is a proxy for HbA1c, but as we just heard it is not. C. Holliday asked if industry is the reason for the difficulty in getting the data published, E. Selvin responded that it has more to do with the endocrinologists. The reviews stated that the technology used in the study was outdated, which is not true as discussed earlier, and also there were statements indicating "we know this already". It was only when the manuscript was finally reviewed by clinical chemists that we were able to get it published. R. Little asked about the current status of CGM standardization. G. Freckmann said ISO is slow, they have submitted a review encompassing accuracy studies performed over the last 20 years. They are preparing a proposal for a study to compare CGMs, it will be submitted for review in two weeks. C. Meek asked about moving forward, how will this be done given that you don't have a QA scheme or proficiency testing, etc. G. Freckmann said at this time they are focused on developing a procedure where they will be able to show the actual differences between the devices, this will demonstrate the need for standardization. Right now the companies pursue their own calibration schemes. D. Leslie suggested pregnancy would be a good thing to study, C. Meek agreed saying that with pregnancy you do not have the luxury of having a 3-month window. Children are also an issue, they represent a riskier population where measurement accuracy is crucial. D. Sacks mentioned the GOMOMS study where they are having pregnant women wear CGMs, they already have data for more than 1,000 patients. C. Meek said they have CGM data looking at gestational diabetes but they have generally been focused on clinical endpoints, we need to be more strategic and make sure the data are also being used to look at measurement accuracy. D. Leslie said the data were good in terms of outcome measures, C. Meek said yes, even though HbA1c is not generally regarded as accurate in pregnancy, it performed well. The CGM metrics also performed well. This does not mean that we cannot improve on that in terms of CGM accuracy.

From Guidance to Practice: How Adopting New Diabetes Screening Guidelines Could Increase Access to DSMES: Christopher Holliday

- Impact of changes in diabetes screening guidelines on testing eligibility and potential yield among adults without diagnosed diabetes in the United States. Ali et. al, Diabetes Res. Clin. Pract. 1997; 2023, 110572. https://doi.org/10.1016/j.diabres.2023.110572
    1. Over the past two decades, expert groups have updated guidelines regarding whom to test and at what frequency.
    2. We looked at USPSTF and ADA guidelines, both have expanded their criteria for testing.
        - USPSTF
            - Previously recommended glucose testing for 40-70 years of age with overweight or obesity
            - Recently expanded to 35-70 with overweight or obesity
        - ADA
            - Previously recommended ≥45 years of age regardless of weight or risk be screened for diabetes and pre-diabetes
            - In 2022, lowered the minimum age to 35
            - Also recommends that adults of any age with at least one risk factor for T2 diabetes receive glucose testing
    3. Both guidelines consider other risk factors (family history, physical inactivity)
    4. We studied over 6,000 non-pregnant U.S. adults to:
        - Estimate the percentage that reported having glucose testing.
        - Examine whether screening practices aligned with guidelines

    - Determine which population groups were less likely to receive testing
- Diabetes Research and Clinical Practice Article Findings
    1. 12–14 million more asymptomatic adults would become eligible for glucose testing.
    2. 52% of all US adults reported having a glucose test in the past 3 years.
        - However, nearly 25% were not eligible for the test yet based on the new USPSTF guideline
        - 5% were not eligible based on the new ADA guideline.
    3. People from several different groups (younger adults, men, Hispanic adults, etc.) were less likely to receive glucose testing.
    4. Updated guidelines do not directly address the social determinants of health, which present barriers to receiving glucose testing.
- Diabetes Self-Management and Support (DSMES) Services
    1. Improve hemoglobin A1C, blood pressure, and cholesterol.
    2. Save money on health care costs.
    3. Reduce the need for emergency care.
    4. Help people stay on track with their treatment plan and prescriptions.
    5. Learn practical tips like how to use diabetes devices, eat healthy, be active, and solve problems.
    6. Get the support people need from their family, friends, community, and health care team.
    7. Handle the emotional side of diabetes.
- Expanding DSMES
- DSMES is currently offered in 56% of counties across the U.S.
- About 62% of rural counties have limited access to these services.
- CDC is working to expand the reach of these services, one way is through technology including:
    1. Telehealth
    2. Text
    3. Telephone
    4. Web-based and mobile applications
- DSMES Toolkit
    1. Division of Diabetes Translation at CDC released toolkit in 2018
    2. Comprehensive set of diabetes management resources
    3. Currently being updated
    4. Trying to tailor DSMES to target groups that are underserved:
        - Racial and ethnic minorities
        - Lower incomes
        - Rural areas
- CDC'S NEW BEGINNINGS: A DISCUSSION GUIDE FOR LIVING WELL WITH DIABETES
    1. A resource to help African American individuals with diabetes and their family members take positive action to manage their condition.
    2. Topics address the emotional side of managing diabetes - family support, goal setting, stress management, and problem solving.
    3. Focuses on helping people with diabetes and their families build positive, supportive relationships.
    4. For use with faith-based, community-based, worksite, and other diabetes support groups, whether in person or online.
- Looking forward

1. DDT recently completed 5 year strategic plan.
2. Already known for Diabetes Prevention Program lifestyle change program..
3. Trying to bring DSMES to more parts of the country.
4. Looking at population-level prevention through mitigating structural barriers.
5. Re-doubling efforts aimed at health equity

Discussion

DSMES

R. Little asked how people with diabetes even know about these programs. C. Holliday said part of what CDC, and specifically DDT, do are large national campaigns. They promote awareness on the part of physicians and healthcare teams but also people that are at risk or have diabetes, they specifically target these people to make them aware of these programs. There is a simple online risk test people can take so they can know their risk, then they can talk to their physician and see if one of these programs is appropriate for them. They receive $200 million annually from Congress, 95% of these funds go directly out into the community. These funds go into state and local health communities as well as national organizations like the ADA that help promote awareness of these resources. These campaigns include TV and radio ads, bus stops, etc. They also partner with national media outlets. These messages are not only general but also tailored to the specific audiences they are trying to reach. E. Ogg asked if the CDC partners with hospitals and clinics in underserved areas. C. Holliday said yes, they have a huge effort to work with the National Association of Community Health Centers and free and charitable health clinics where people in these underserved communities go to receive care. They are working to ensure that the programs are covered by public and commercial insurance. Currently 28 states are covering them under Medicaid, there is also the Medicare DPP program which covers that program for Medicare patients. E. Ogg asked if they have thought about reaching out to the largest employers in underserved areas, C. Holliday said yes. They are making a huge effort to get more employers to cover DPP as part of their wellness benefits. They have just launched HEALM, an employer-based platform that talks about the savings, decrease in absenteeism and increase in productivity in terms of people with pre-diabetes who can move on the develop diabetes unless they have access to these programs. Employers are responding to these efforts. E. Ogg asked if they have diabetes educators included on the program staff. C. Holliday replied that the diabetes educators come from the Association of Diabetes Care and Education Specialists, they partner with them. They have behavioral specialists, scientist, epidemiologists and statisticians who do implementation science but they do not actually deploy the health educators.

C. Holliday thanked everyone for their attendance and the discussions. The meeting was adjourned at 4:30 PM.

Minutes prepared by Curt Rohlfing 07/18/2023. Modified by David Sacks 09/12/2023.