QUESTION 3. HOW SHOULD THE DATA AND REPORTING BE INTERPRETED?

Question 3a. Are there standard metrics that could inform therapy adjustment, such as should A1C be reported with a risk index based on CGM glucose profile or TIR report?

- Metrics should be standardized
  - Time in range, SD (% time above/below range), glycemic trending, point accuracy, composite hypoglycemia score, lability index
- Since A1C does not always reflect mean BG, CGM assessment of A1C would be helpful in treatment decision-making
- Risk index or predictive algorithm possibly based on history, especially of hypoglycemia, would be helpful if accurate
- Data should be verified for accurate reflection of user's true patterns—check for calibration frequency, time/date accuracy, etc
- MARD should be <12%
- The most meaningful therapy adjustments are based on analysis of inter-meal patterns and patient adherence
- Risk indices for hyper- and hypoglycemia
- Pattern recognition taught to the patient to enhance therapeutic decisions

See Notes view for citations

Question 3a. Are there standard metrics that could inform therapy adjustment, such as should A1C be reported with a risk index based on CGM glucose profile or TIR report?

- Avoid “risk” index
- TIR (TAR and TBR are better metrics and goals but need to be individualized for each patient)
- Get away from A1C-centric culture (understanding of glycation gap)
- Metrics should emphasize time in range and how to expand that rather than BG extremes that place *blame* on the patient
- Simple and understandable metrics
- A “reset” button as reality is based on a 20-minute interval

Question 3a. Are there standard metrics that could inform therapy adjustment, such as should A1C be reported with a risk index based on CGM glucose profile or TIR report?

- Composite outcomes might provide better assessment of glycemic control and inform therapeutic adjustments
  - Change in A1C + change in CGM use
  - Time in range + percent of readings in hypoglycemic range (eg, <70, <60, <50)

Question 3a. Are there standard metrics that could inform therapy adjustment, such as should A1C be reported with a risk index based on CGM glucose profile or TIR report?

- One standardized core format is needed
  - Each vendor should be free to develop additional displays/features
- Time in Range – expressed as mean minutes/day
  - <70
  - 70-180
  - >180
  - <55
  - <45
- Indices of hypoglycemic risk
- Indices of variability

Question 3b. Should additional patient descriptors based on standardized CGM reporting be included such as “hypo unaware,” “hyper unaware,” “high variability”? What are the most important factors clinicians need to focus on when interpreting CGM data?

Yes

- Descriptors could be helpful as a way of summarizing mitigating factors, especially for hypoglycemia
- Identification of “hypo-unaware” may justify use of CGM for patients not already using it
- Most important factors are captured in the AGP Dashboard
  - Glycemic exposure
  - Variability
  - Stability
  - TIR over a period of time

No

- Software cannot assess patients’ awareness of hypo- and hyperglycemia
- HCPs need to review data in context of patient’s behavior/lifestyle factors, as a discussion with patient

See Notes view for citations

Question 3b. Should additional patient descriptors based on standardized CGM reporting be included such as “hypo unaware,” “hyper unaware,” “high variability”? What are the most important factors clinicians need to focus on when interpreting CGM data?

Yes

- Notations such as “hypo unaware” and “highly variable” can help dictate the actions needed to improve DM management
- If data could be used to determine a “hypo unawareness” score, it could be useful in designing treatment regimens to restore awareness
- Descriptors such as these might help physicians personalize care

No

- Reporting should include target range settings, time in range, hypo- and hyperglycemia duration and frequency, glucose averages at different times of day
- **Such patient descriptors sound like clinical labels that may belittle patients and be counterproductive to DM management**
- Physicians should focus on teaching patients how to use CGM data rather than labels
- Difficult to define hypo “unawareness” so tracking time in hypoglycemic range and hypoglycemia risk is more important

Question 3b. Should additional patient descriptors based on standardized CGM reporting be included such as “hypo unaware,” “hyper unaware,” “high variability”? What are the most important factors clinicians need to focus on when interpreting CGM data?

- Descriptors might permit more effective personalized management
- Need to strike a balance between automatically generated information and manual inputs (eg, meals, stress, illness, medication, problems with insulin administration) to help with data interpretation

Question 3b. Should additional patient descriptors based on standardized CGM reporting be included such as “hypo unaware,” “hyper unaware,” “high variability”? What are the most important factors clinicians need to focus on when interpreting CGM data?

- Hypoglycemia unawareness
- High variability
- Hyperglycemia unawareness

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Question 3c. Who should interpret data to utilize it in an effective way? Who should be authorized to interpret standardized CGM report that will allow it to be part of permanent medical records and billable service? Is special training or certification necessary? Should the provider interpretation of data be standardized as well?

- The clinician managing the patient should be responsible for interpretation and management decisions.
- Given the time and multi-disciplinary expertise required, skills of the CDEs should be incorporated into the care of the patient.
  - Patients do most data interpretation in real time, so they must be trained on proper setting and use of alerts, rate of change information, and sensor glucose values
  - Patient and HCP should interpret data together based on details such as diet, activity, emotions, medications, hormone changes, etc
- HCPs with sufficient training, either during their medical or post-graduate training
- Standardization of the reports would ensure patients get quality feedback and assessment
- Patients should receive training before they start using CGM

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Question 3c. Who should interpret data to utilize it in an effective way? Who should be authorized to interpret standardized CGM report that will allow it to be part of permanent medical records and billable service? Is special training or certification necessary? Should the provider interpretation of data be standardized as well?

Most generally favored certified training, especially for PCPs and other HCPs who are not diabetes specialists

Comments

- Patients, CDEs, endocrinologists, and PCPs with certified training should interpret data
  - Some PCPs use professional CGM for billing purposes and do not adequately train patients in SMBG or utilize the data themselves
  - Training is needed for PCPs; certification would be helpful but would need to constantly updated
- Patients—they must understand and use the data or CGM is meaningless
- All HCPs should have specific training
- Ideally, there should be an algorithm, such as addressing hypoglycemia first, then periods of hyperglycemia, basal insulin rates, etc
- Interpretation of CGM cannot be standardized because each report is unique to each patient
  - CGM interpretation is time-intensive and must be individualized
- Tools such as Tidepool, Glooko, and Diasend can help make data interpretation easy for all

Question 3c. Who should interpret data to utilize it in an effective way? Who should be authorized to interpret standardized CGM report that will allow it to be part of permanent medical records and billable service? Is special training or certification necessary? Should the provider interpretation of data be standardized as well?

- Trained HCPs should interpret data
- Standardized remote monitoring and analysis may be useful for HCPs and patients/caregivers

Question 3c. **Who should interpret data to utilize it in an effective way? Who should be authorized to interpret standardized CGM report that will allow it to be part of permanent medical records and billable service?** Is special training or certification necessary? Should the provider interpretation of data be standardized as well?

- Reports should be intended for and interpreted by clinicians trained in diabetes management but should be simple enough to be understood by patients
- Standard metrics and displays (such as AGP) would streamline training and interpretation.

Question 3c. Who should interpret data to utilize it in an effective way? Who should be authorized to interpret standardized CGM report that will allow it to be part of permanent medical records and billable service? Is special training or certification necessary? **Should the provider interpretation of data be standardized as well?** Cont.

Vote Count Yes to certification	No to certification
3	3

- **For**
  - Special training or certification would be appropriate for non-endocrinologists
  - A well-defined minimum level of training should be necessary for therapeutic decision-making as well as billing/reimbursement; certification may help in obtaining HCP reimbursement
- **Against**
  - Certification creates barriers to adoption and adds another layer of complexity for clinicians
  - Requiring certification will limit use of CGM

Question 3d. What is the impact of blood glucose monitoring? What would be the impact of CGM on patients frequency of self-monitoring of blood glucose (SMBG)?

- Currently, SMBG at least twice a day is necessary for proper CGM calibration to ensure data are valid
- As more accurate, substitution-class CGM becomes available, SMBG use might decrease by 50% to >75%
  - However, T1D Exchange data indicate that SMBG by CGM users increases after starting CGM
- CGM has potential to overtake SMBG has patient- and HCP-preferred method of glucose monitoring
- Payers should consider benefits of coverage that come with a more complete dataset

See Notes view for citations

Question 3d. What is the impact of blood glucose monitoring? What would be the impact of CGM on patients frequency of self-monitoring of blood glucose (SMBG)? (Cost Analysis Study)

CGM Can Replace SMBG

- Patients using CGM do not use SMBG to confirm readings; they instead rely on CGM for dosing and identification of mild hypoglycemia
  - Manufacturers are working on algorithms and clinical trials to show reduced frequency of SMBG is not harmful
  - We are moving toward an era where CGM will replace fingersticks as standard glucose measurement
- The term 'monitoring' should not be device-specific, and more information about glucose levels helps patients minimize swings outside targets
- Once CGM systems' reliability and accuracy are better established, SMBG will be needed minimally if at all

CGM Cannot Replace SMBG

- Wide variation between SMBG and CGM readings, interdevice variability, the need for fingerstick calibration mean that it's too soon to abandon SMBG
- SMBG frequency may decrease but SMBG should always be available and used for calibration and confirmation

Question 3d. What is the impact of blood glucose monitoring? What would be the impact of CGM on patients frequency of self-monitoring of blood glucose (SMBG)?

- Well-trained users of newer CGM systems tend to perform SMBG less frequently
- Greater satisfaction with accuracy is linked to improved QOL, less reliance on SMBG, and potentially less alarm fatigue
- Calibration-free CGM would have potential to replace SMBG
  - Cost of sensor would be offset by decreased usage of test strips
  - FDA approval of direct insulin dosing from CGM rather than test strip data would most dramatically change CGM cost-benefit equation

Question 3d. What is the impact of blood glucose monitoring? What would be the impact of CGM on patients frequency of self-monitoring of blood glucose (SMBG)?

- Impact is highly variable
- Data suggests that high frequency SMBG testers reduce SMBG when perceive accurate CGM
- Replacement (non-adjunctive) claim is currently approved, but in real-life is used by patients.

Question 3e. What outcome measures (behavioral, clinical, laboratory, etc.) can be used by providers and payers to assess Meaningful Use of CGM in their patients and justify decisions on continued need and coverage?

- Glycemic outcomes:
  - Achieving glycemic targets without hypoglycemia
  - CGM data conversion to expected A1C value
- Clinical outcomes:
  - Reduction in the number of absolute and relative hypoglycemic events
  - ER and hospital admissions
  - Frequency of EMS calls

See Notes view for citations

Question 3e. What outcome measures (behavioral, clinical, laboratory, etc.) can be used by providers and payers to assess Meaningful Use of CGM in their patients and justify decisions on continued need and coverage? Cont.

- Behavioral outcomes:
  - Reduction of anxiety associated with GV
  - Improvement in treatment satisfaction
  - Improvement in quality of life measures
  - Improvement in patient's perception of diabetes management and autonomy in diabetes care
  - Improvement in adherence (amount of time CGM is worn)
- Comparative report showing progress over time with change in risk status
- Caution: QOL measures are not reliable because they often relate to an individual's traits rather than current state and also are insensitive to change with new technology

See Notes view for citations

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Question 3e. What outcome measures (behavioral, clinical, laboratory, etc.) can be used by providers and payers to assess Meaningful Use of CGM in their patients and justify decisions on continued need and coverage?

- Potential for improvement in QOL and diabetes complications
- Consistent CGM use and/or as prescribed by HCP
- Glycemic variability
  - Variability and rate of change scores reflect the impact on day to day living of diabetes and provide more insight into QOL scores
- Change in A1C, reduced hypoglycemia (either time in hypo range or absolute events)
- Reduced ER visits and hospitalizations
- Increased time in optimal range
- Lower prescription expenditures (glucometer strips, glucagon)
- Lower rates of DM complications—especially important with DM epidemic
- Data showing that CGM can alleviate workplace concerns/improve outcomes
  - Hypoglycemia endangering patient and coworkers
  - DM-related absenteeism and presenteeism (ie, poor productivity due to hypoglycemia and other effects of DM)

Question 3e. What outcome measures (behavioral, clinical, laboratory, etc.) can be used by providers and payers to assess Meaningful Use of CGM in their patients and justify decisions on continued need and coverage?

- Blood glucose metrics
- QOL
- Burden of care
- Fear of hypoglycemia
- CGM adherence
- Device calibration
- Cost-benefit analyses

Question 3e. What outcome measures (behavioral, clinical, laboratory, etc.) can be used by providers and payers to assess Meaningful Use of CGM in their patients and justify decisions on continued need and coverage?

- HbA1c
- Healthcare expenditures
- TIR (Time in Range)
- Hypoglycemia and hypoglycemia risk scores

Question 3e. What outcome measures (behavioral, clinical, laboratory, etc.) can be used by providers and payers to assess Meaningful Use of CGM in their patients and justify decisions on continued need and coverage? Cont.

- Clinical measures: improvement in A1C, FPG, and PPG; decrease in hypoglycemia episodes and severe hypoglycemia; decrease in ER visits
- Behavioral measurements: frequency of SMBG, quality of sleep for patients and caregivers, number of days the CGM device was used, work performance/absenteeism, school performance and burden on school resources
- **Comment:** CGM increases patients' engagement, which might help with behavioral modification for improved lifestyle management and treatment adherence. This is a criterion of the CMS Meaningful Use program