

American Diabetes Association (ADA): Standards of Medical Care in Diabetes 2020

- ▶ Overall statement: “Use of technology should be individualized based on a patient’s needs, desires, skill level and availability of devices”
- ▶ Barriers
 - ▶ Insurance coverage lagging behind device availability
 - ▶ Patient interest in device technology
 - ▶ Patient willingness to change
 - ▶ Providers keeping up with newly released technology

Diabetes Care 2020 Jan; 43 (Supplement 1): s77-s88)

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ADA Standard of Care guidelines recommendations on the use of CGM

- Real-time Continuous Glucose Monitor Use in Youth:
 - ▶ “Real-time CGM should be considered in children and adolescents with type 1 diabetes, whether using multiple daily injections or continuous subcutaneous insulin infusion, as an additional tool to help improve glucose control and reduce the risk of hypoglycemia. Benefits of continuous glucose monitoring correlate with adherence to ongoing use of the device”
- ▶ Real-time Continuous Glucose Monitor Use in Adults:
 - ▶ “When used properly, real-time CGM in conjunction with intensive insulin regimens is a useful tool to lower A1C in adults with type 1 diabetes who are not meeting glycemic targets”
 - ▶ “Real-time CGM may be a useful tool in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes.”
 - ▶ “Real-time CGM should be used as close to daily as possible for maximal benefit”
 - ▶ “Real-time CGM may be used effectively to improve A1C levels and neonatal outcomes in pregnant women with type 1 diabetes”
 - ▶ “Sensor-augmented pump therapy with automatic low-glucose suspend may be considered for adults with type 1 diabetes at high risk of hypoglycemia to prevent episodes of hypoglycemia and reduce their severity”
- ▶ Intermittently Scanned Continuous glucose Monitor Use:
 - ▶ “Intermittently scanned CGM use may be considered as a substitute for self-monitoring of blood glucose in adults with diabetes requiring frequent glucose testing”

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Continuous Glucose Monitoring (CGM)

- ▶ Subcutaneous sensor measures interstitial fluid glucose and translates to equivalent blood glucose, reporting in real time.
- ▶ Benefits
 - ▶ More numbers - not just single "points in time" - glucose readings update every 5 minutes
 - ▶ Can see trends - both retrospective and predictive
 - ▶ With most systems, can set alarms for lows and highs (individualized)
 - ▶ Some systems allow remote "following" by designated caregivers/others
- ▶ Draw-backs
 - ▶ Cost
 - ▶ Some require calibration - still must check blood glucoses
 - ▶ "Another thing to wear" - can cause skin integrity problems

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Dexcom G6



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Dexcom

- ▶ FDA-approved for age 2+
- ▶ G6 is approved for 10 days of wear with no calibration
- ▶ Approved for making insulin dose decisions
- ▶ Potential to communicate with multiple devices
 - ▶ Dexcom receiver
 - ▶ Mobile device (most Apple and some Android) - smart watches can display data from the mobile phone apps
 - ▶ Tandem X2 pump - coming soon, OmniPod 5 pump system
- ▶ Share app through a mobile device - can have up to 5 remote "followers"

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DEXCOM G7 in collaboration with Verily



- ▶ Sensor and transmitter will be fully integrated
- ▶ Fully disposable (sensor and transmitter)
- ▶ Thinner
- ▶ Extended wear of 14-15 days
- ▶ No SMBG calibration required
- ▶ Planning commercial launch in 2021 (delayed due to Covid19 restrictions on studies)

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Libre 2 (Flash CGM)



- ▶ Sensor and transmitter is fully integrated
- ▶ Fully disposable (sensor and transmitter)
- ▶ FDA approved down to age 4
- ▶ 14 day wear
- ▶ No glucose calibration required
- ▶ Optional, real-time glucose alarms that notify too low or high
- ▶ Reader required, but expect phone app to be available in the near future
- ▶ Waiting on FDA to approve this device as an iCGM designation - probably next generation

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Freestyle Libre

- ▶ FDA-approved for age 4+
- ▶ 6 hour trend graphs, current glucose reading and current trend arrows with every scan of sensor
- ▶ 14 days of wear
- ▶ 1 hour warm-up
- ▶ No calibration
- ▶ Approved for insulin dosing
- ▶ Lower cost than other CGM systems

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Medtronic Guardian 3 Sensor

- ▶ Works with the Medtronic 630G and 670G pumps, or as stand-alone CGM system: Guardian Connect
- ▶ FDA approved 3+ as CGM, 7+ w/670G pump
- ▶ 7 days sensor wear
- ▶ Minimum calibration q12 hours, best 3-4/day



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Eversense Implantable CGM



- ▶ 90 day implantable sensor
- ▶ No calibration required
- ▶ It's mobile app however requires two calibrations / day to ensure accuracy
- ▶ Waiting on FDA approval for a longer wear time of 180 day sensor (Eversense XL)

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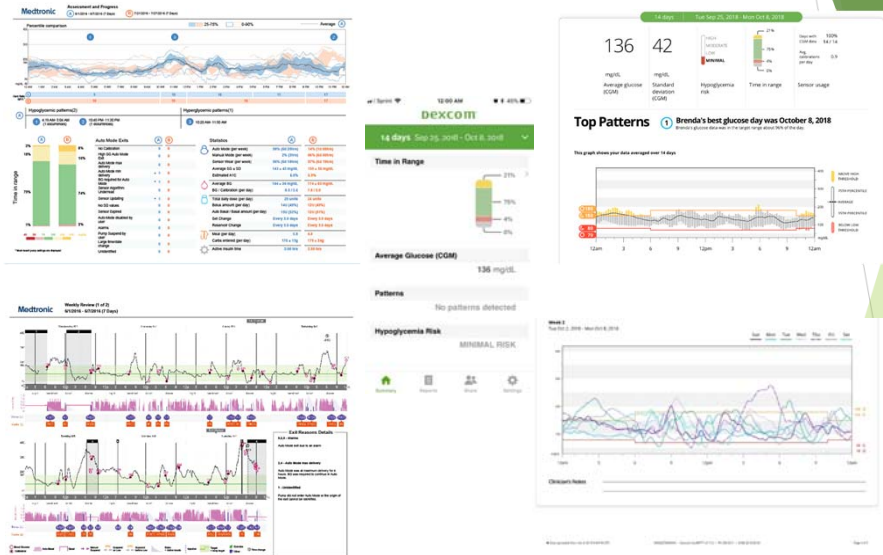
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DATA changes everything

- ▶ Focus is shifting away from Hemoglobin A1C as a measure of glycemic control
 - ▶ Better to consider **time in range**
- ▶ All diabetes tech can be uploaded to create reports for both patients and medical care teams.
 - ▶ Many of these reports will integrate multiple devices, and patients can add comments regarding specific events.
 - ▶ Some devices are connected to the cloud, so patients can choose to link their device to a clinic and reports can be generated without needing to upload the device specifically.

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Data



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Time in range, "The new A1c"

- ▶ For many years, A1c has been used as the standard for diabetes control and adherence:
 - ▶ Adults, A1c goal < 7.0% (ADA standard of care for Type 1 DM)
 - ▶ Pediatrics, A1c goal < 7.5% (ADA standard of care for Type 1 DM)
- ▶ Additional information now available through CGM analysis / reports:
 - ▶ Average glucose with standard deviations (SD) around the average or variability
 - ▶ Percentage of time in hypoglycemic range (<70 mg/dl) (GOAL: <3%, <1% under 55)
 - ▶ Percentage of time in glycemic target range (70-180 mg/dl) (GOAL: 70%+)
 - ▶ Percentage of time in hyperglycemic range (>180 mg/dl) (GOAL: <10% over 250)
 - ▶ Estimated A1C (eA1C) or glucose management indicator (GMI) is the expected A1c based on CGM.

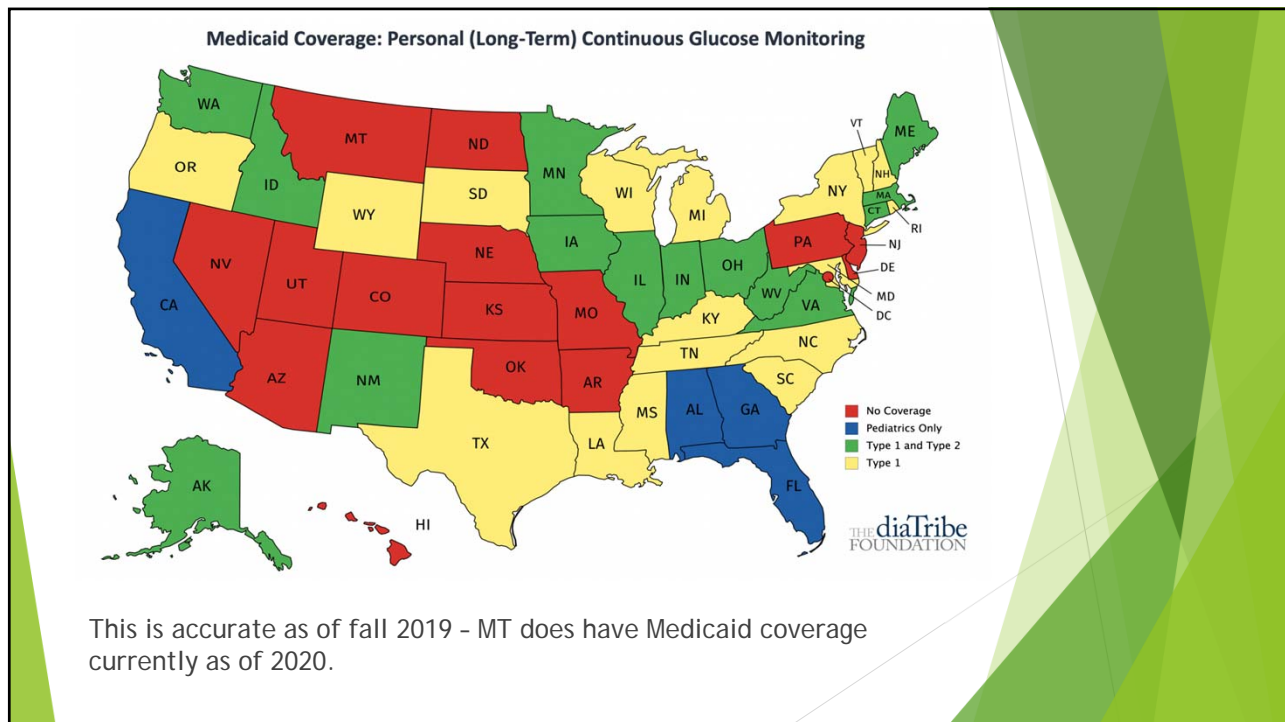
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Insurance coverage

- ▶ Currently essentially every major commercial payer provides coverage for CGM
 - ▶ BC/BS ND and SHP are pharmacy benefit - no DME/mail order needed
 - ▶ High deductible plans may have coverage, but out of pocket costs are still an issue (increasingly frequent issue)
- ▶ Medicare Part B covers (new as of 2019)
- ▶ ND Medicaid is in the minority of states with no CGM coverage

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