



Presents:

THE VALUE OF CONTINUOUS GLUCOSE MONITORING during the **COVID-19** Pandemic and New Era of Digital Healthcare



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This activity is supported by an independent educational grant from Dexcom, Inc.

Live Webcast
Friday, June 19, 2020
1:00 PM – 2:30 PM ET



Welcome

Jeffrey Dunn, PharmD, MBA

(Former) Vice President, Clinical Strategy and Programs and Industry
Relations
Magellan Rx Management

Agenda



1:00 PM	Opening Comments/Overview Jeffrey Dunn, PharmD, MBA
1:05 PM	Clinical and Economic Consequences of Imprecise Glycemic Control in a New Era of Telehealth Management Daniel DeSalvo, MD
1:35 PM	Implementing CGM: Real World Insights Jeffrey Dunn, PharmD, MBA
1:55 PM	Optimal Clinical and Economic Outcomes in Diabetes: The Employer Perspective Troy Ross, MSM
2:15 PM	Audience Q&A Session Key Takeaways and Closing Comments
2:30 PM	Adjournment

Learning Objectives



- Describe the benefits of remote monitoring in the management of hospitalized patients with COVID-19 and dysglycemia
- Assess the value of rtCGM in improving quality of care and reducing societal health-costs in a new era of digital health
- Review the available consensus recommendations regarding evidence-based care in the management of diabetes
- Characterize the role of rtCGM as part of an employer-driven diabetes management strategy
- Identify appropriate benefit design strategies to reduce healthcare system burden and improve quality, clinical, and economic outcomes

Which of the following best describes your area of greatest educational need with regard to real-time remote monitoring for patients with diabetes?



- 1) What is the value of real-time remote monitoring for patients with diabetes on clinical, economic, and humanistic outcomes?
- 2) How can medical and pharmacy benefit policy be aligned with appropriate coverage criteria for accelerated access of continuous glucose monitoring devices under the pharmacy benefit?
- 3) How is remote patient monitoring used in the hospital setting to support COVID-19 health care-related efforts?
- 4) How can the role of remote patient monitoring as part of an employer-driven diabetes management strategy help to accelerate the uptake of telemedicine?



Clinical and Economic Consequences of Imprecise Glycemic Control in a New Era of Telehealth Management

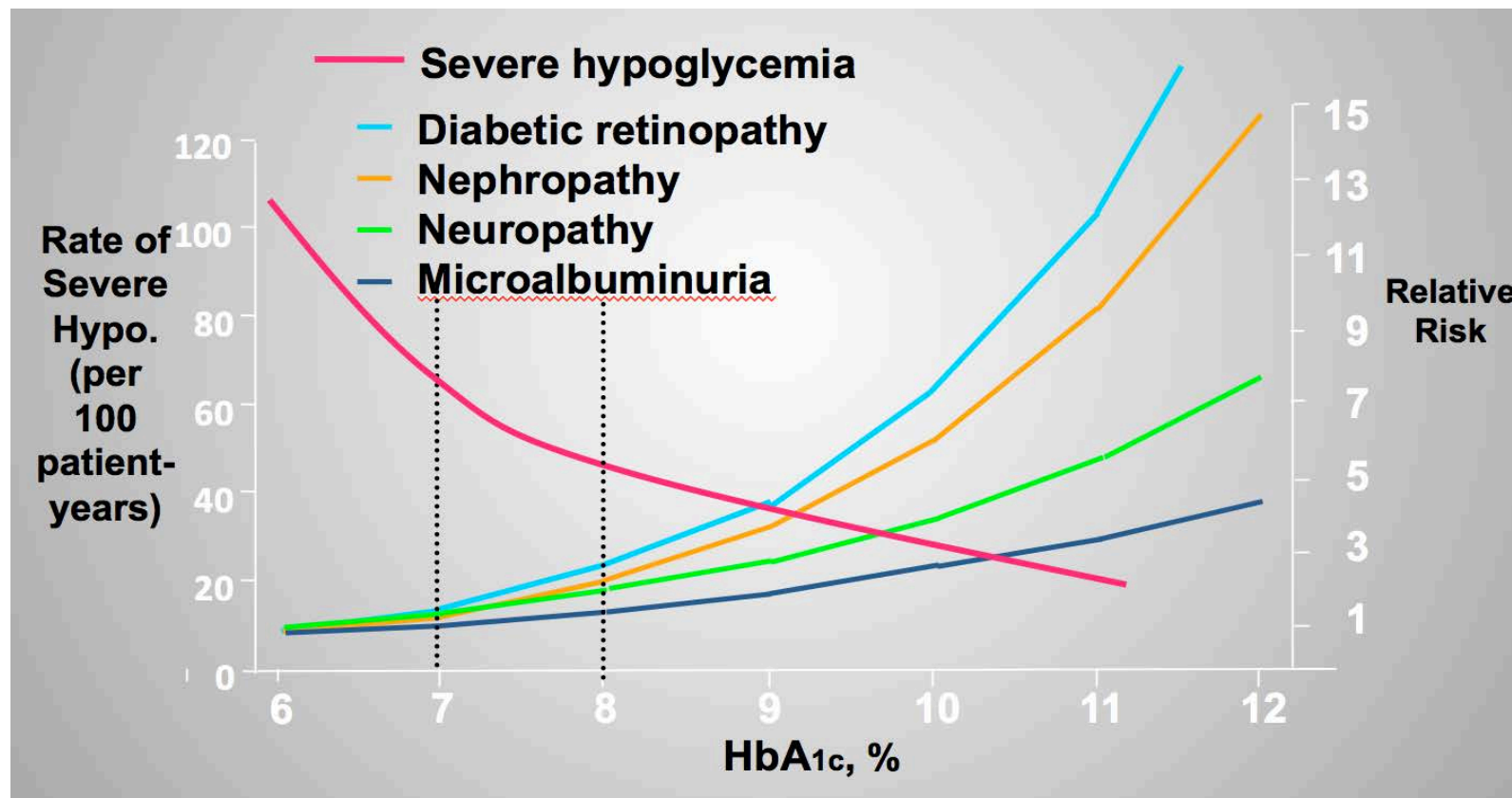
Daniel DeSalvo, MD

Pediatric Endocrinologist
Baylor College of Medicine
Texas Children's Hospital

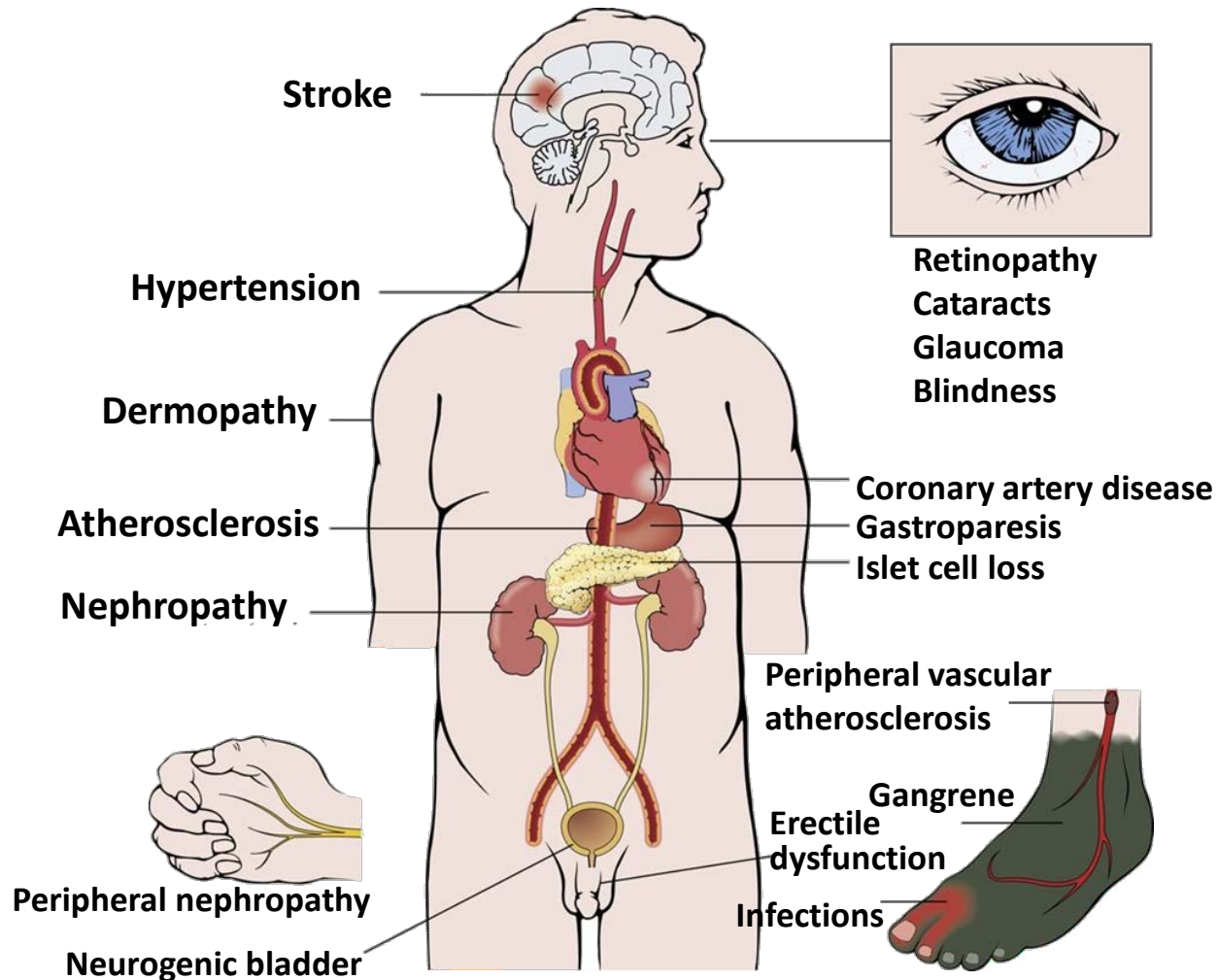
DCCT – Benefits of Tight Glycemic Control



- Lower A1c = lower risk of microvascular complications



Complications of Diabetes and the Benefits of Tight Glycemic Control

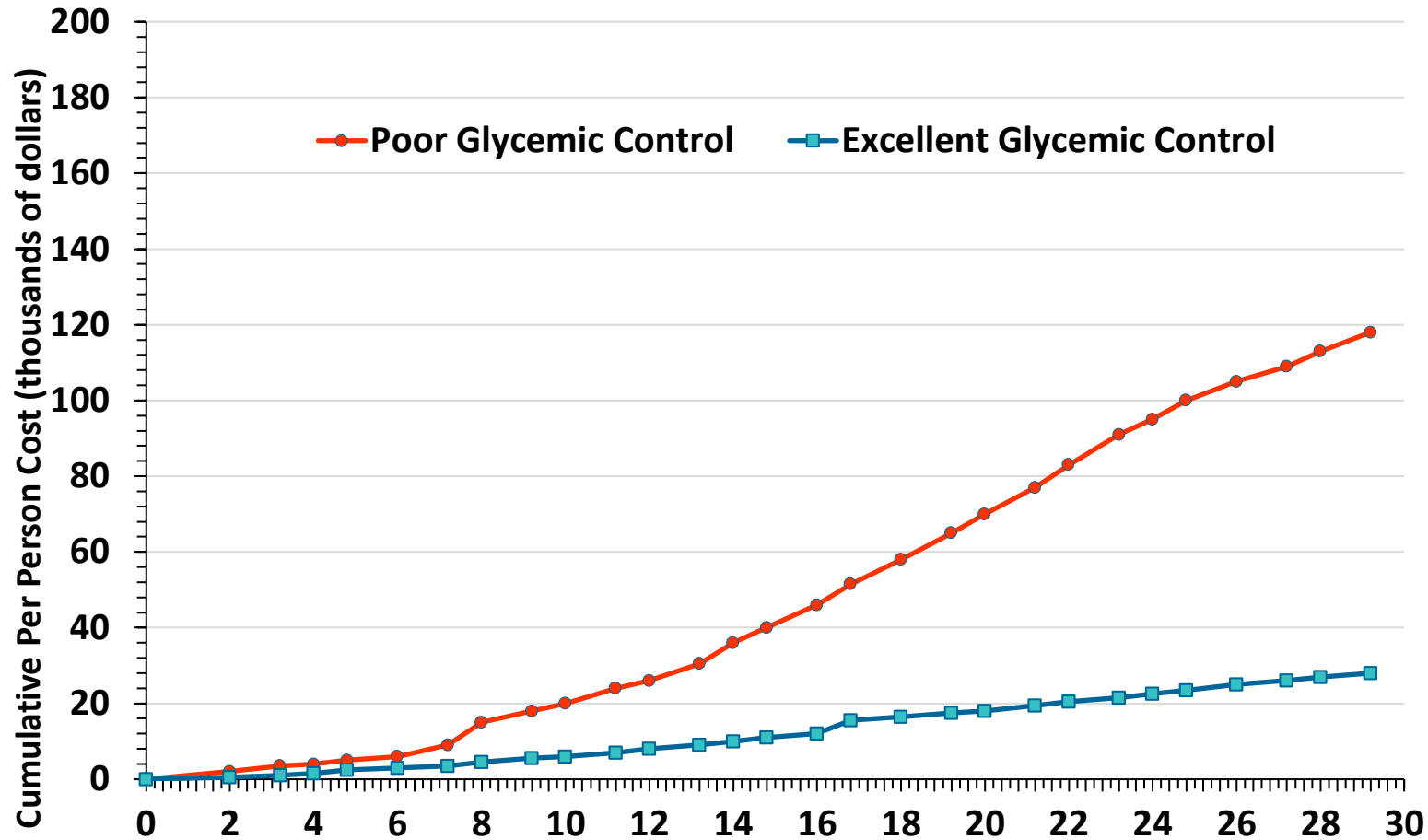


DCCT/EDIC Cohort:

30 years of excellent vs. poor glycemic control substantially reduced the incidence of the following:

- Retinopathy requiring laser therapy (5% vs. 45%)
- End-stage renal disease (0% vs. 5%)
- Clinical neuropathy (15% vs. 50%)
- Myocardial infarction (3% vs. 5%)
- Stroke (0.4% vs. 2%)
- Death (6% vs. 20%)

The Complications & Comorbidities of Poor Glycemic Control are Costly



Excellent glycemic control resulted averted **~\$90,000** in costs over 30 years

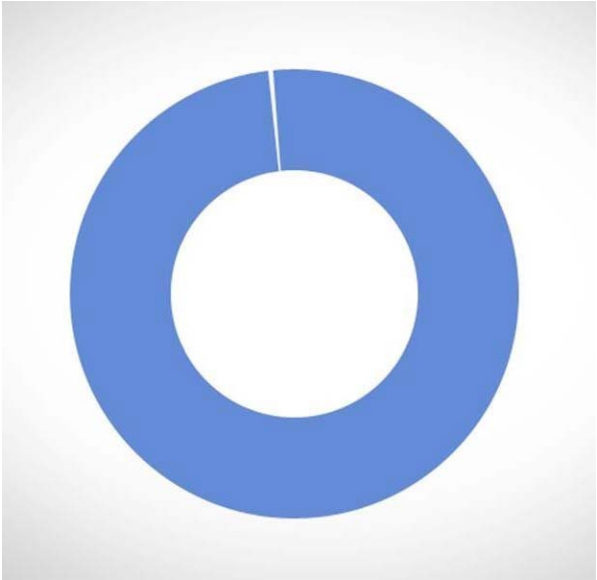
Self managing diabetes is challenging!



42

Factors That Affect BG

Food	Biological
<ul style="list-style-type: none"> ↑↑ 1. Carbohydrate quantity →↑ 2. Carbohydrate type →↑ 3. Fat →↑ 4. Protein →↑ 5. Caffeine ↓↑ 6. Alcohol ↓↑ 7. Meal timing ↑ 8. Dehydration ? 9. Personal microbiome 	<ul style="list-style-type: none"> ↑ 20. Insufficient sleep ↑ 21. Stress and illness ↓ 22. Recent hypoglycemia →↑ 23. During-sleep blood sugars ↑ 24. Dawn phenomenon ↑ 25. Infusion set issues ↑ 26. Scar tissue and lipodystrophy ↓↓ 27. Intramuscular insulin delivery ↑ 28. Allergies ↑ 29. A higher glucose level ↓↑ 30. Periods (menstruation) ↑↑ 31. Puberty ↓ 32. Celiac disease ↑ 33. Smoking
Medication	Environmental
<ul style="list-style-type: none"> →↓ 10. Medication dose ↓↑ 11. Medication timing ↓↑ 12. Medication interactions ↑↑ 13. Steroid administration ↑ 14. Niacin (Vitamin B3) 	<ul style="list-style-type: none"> ↑ 34. Expired insulin ↑ 35. Inaccurate BG reading ↓↑ 36. Outside temperature ↑ 37. Sunburn ? 38. Altitude
Activity	Behavioral & Decision Making
<ul style="list-style-type: none"> →↓ 15. Light exercise ↓↑ 16. High-intensity and moderate exercise →↓ 17. Level of fitness/training ↓↑ 18. Time of day ↓↑ 19. Food and insulin timing 	<ul style="list-style-type: none"> ↓ 39. Frequency of glucose checks ↓↑ 40. Default options and choices ↓↑ 41. Decision-making biases ↓↑ 42. Family relationships and social pressures



Hilliard et al. *Curr Diabetes Rep.* 2015

Credit: Adam Brown. *diatribe*, Feb 2018

Hypoglycemia: “The Greatest Limiting Factor in Diabetes Management”



- Almost 30 million people with diabetes in USA
 - 6-8 million persons with diabetes use insulin
- 300,000 emergency room visits yearly for hypoglycemia (T1D & T2D)
- Average cost for ER visit for hypoglycemia is **~\$800**
- Average cost for hospital admission for hypoglycemia is **~\$13,000**
- 4%-10% of deaths in patients with type 1 diabetes can potentially be attributed to hypoglycemia
- Prevalent clinical concern in patients with T2D as well as T1D

Non-Severe Hypoglycemic Events (NSHEs) Affect Work Productivity and Have an Adverse Economic Impact



4 country
online
survey of
adults
with
diabetes

(N=1,404)

Lost productivity was estimated to range from **\$15.26 to \$93.47 per NSHE**, representing 8.3 to 15.9 hours of lost work time per month

Among those reporting an NSHE at work, **18.3% missed work** (avg of ~10 hours)

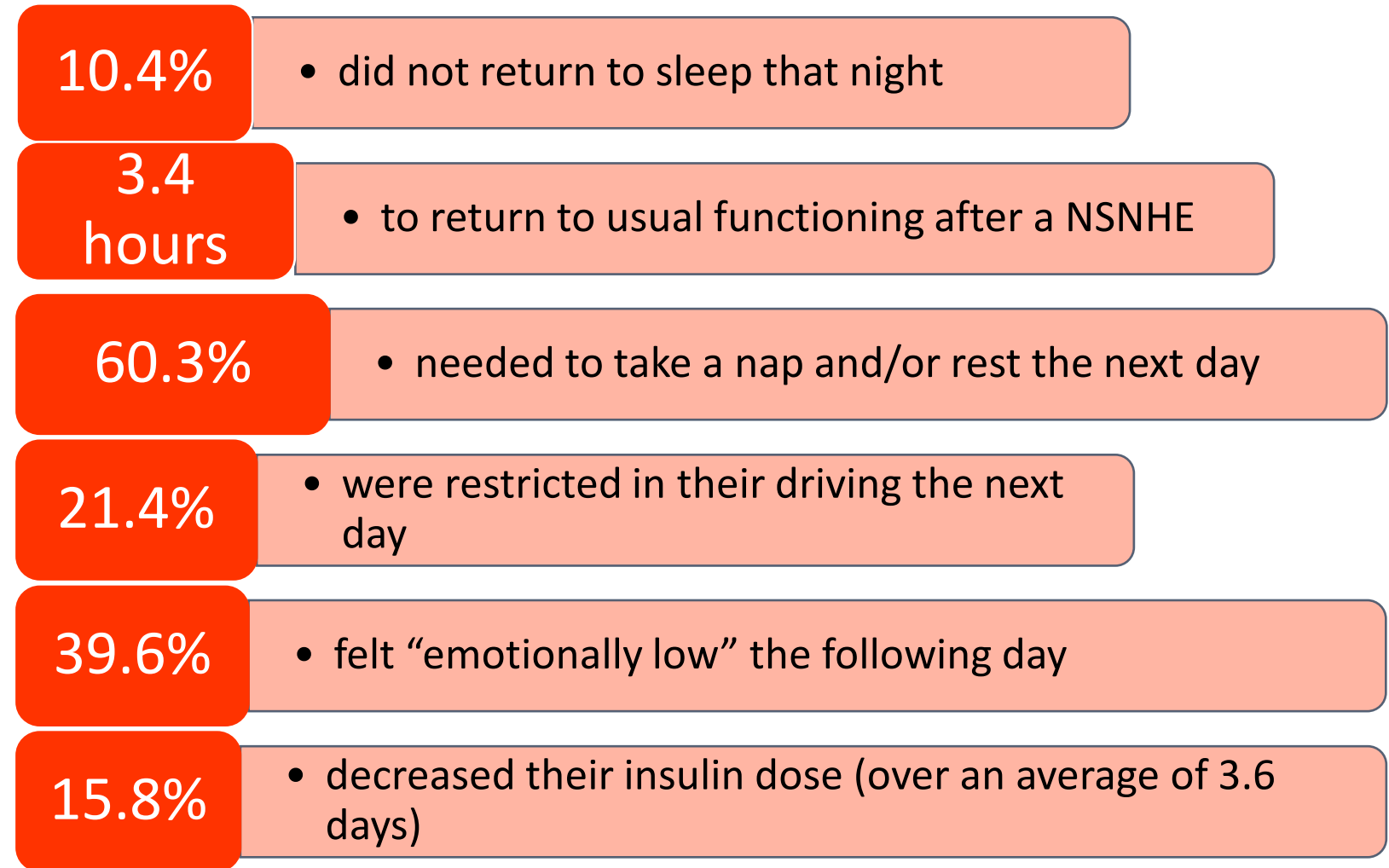
Among respondents experiencing an NSHE outside working hours, **22.7% arrived late for work or missed a full day**

Productivity loss was highest for NSHEs occurring during sleep (avg **14.7 working hours lost**)

Non-severe **Nocturnal** Hypoglycemic Events (NSNHEs) Have Severe Impact on Next-day Functioning and Well-Being

9 country
online survey
by adults with
diabetes

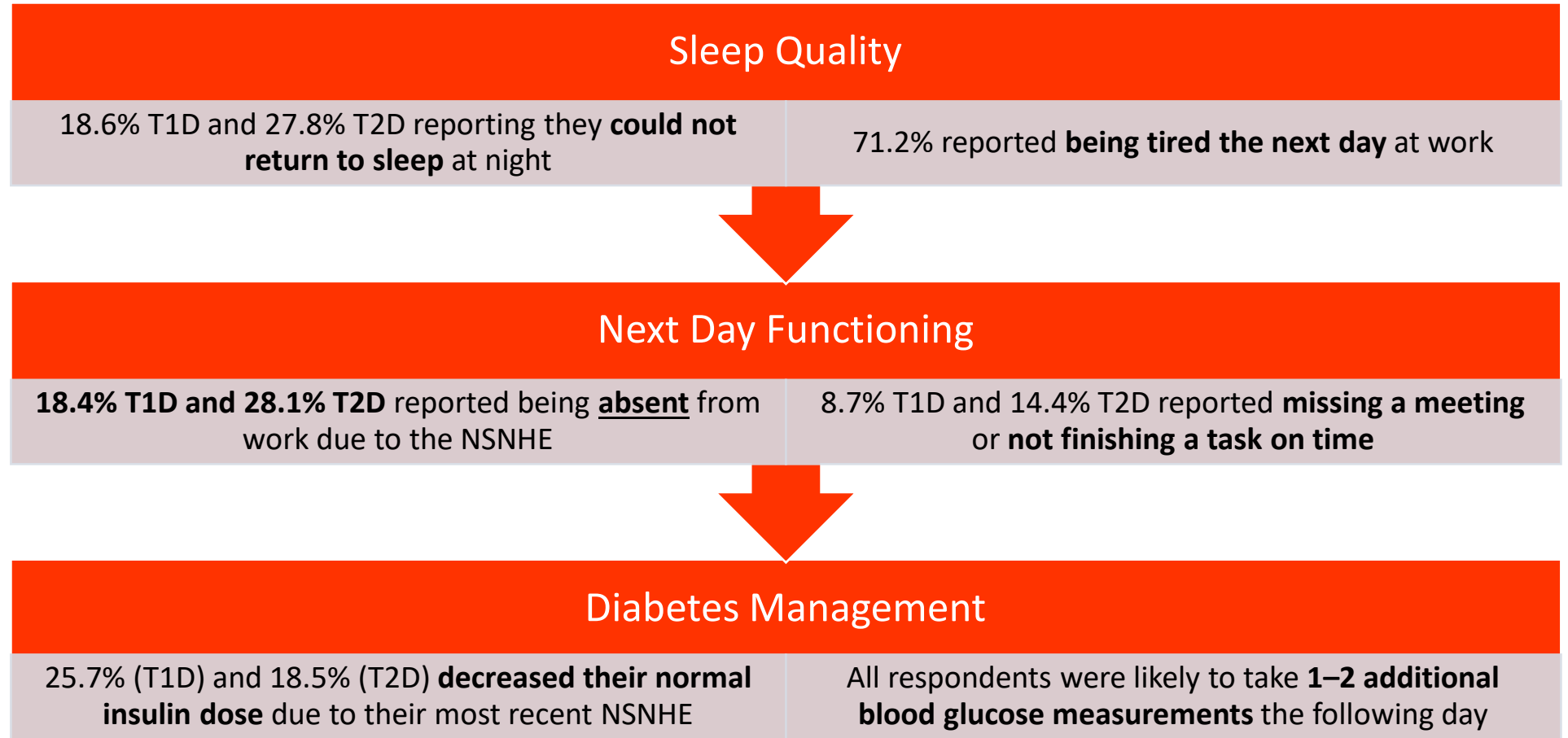
N=2,108



NSNHEs Have a Substantial Impact on Sleep Quality and Next Day Functioning




9 country
online survey
by adults with
diabetes
N=1,086



N=1,086

Far-Reaching Mental, Emotional and Physical Impact of Hypoglycemia



Among 4,540 adults with diabetes (T1D & T2D) who completed the *Hypoglycemic Attitudes and Behavior Scale*...

	Percentage of adults with diabetes	Estimate of total people affected in the USA
Do not feel confident they can stay safe while driving	33%	9.6 million
Terrified about passing out in public due to hypoglycemia	13%	3.0 million
Keep blood glucose higher than recommended to avoid hypoglycemia	17%	3.9 million
Will eat uncontrollably if they "feel a low"	25%	5.8 million

The resulting hyperglycemia from these approaches can lead to dangerous, debilitating, and costly complications in the long-term

Continuous Glucose Monitoring (CGM) Reduces Hypoglycemia Worry and Avoidance Behavior



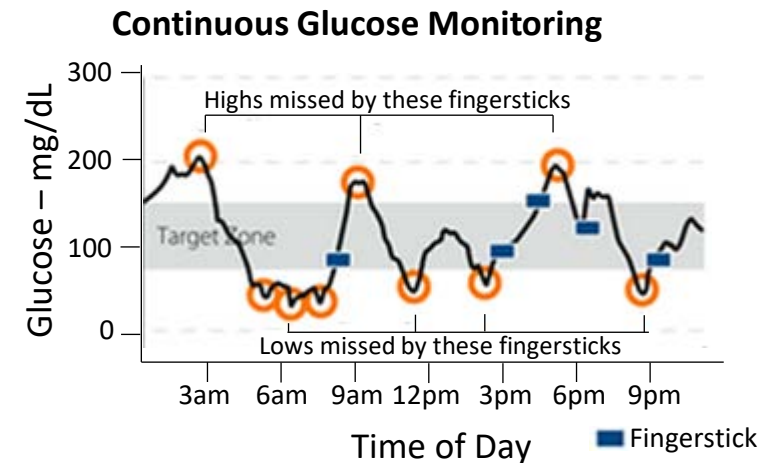
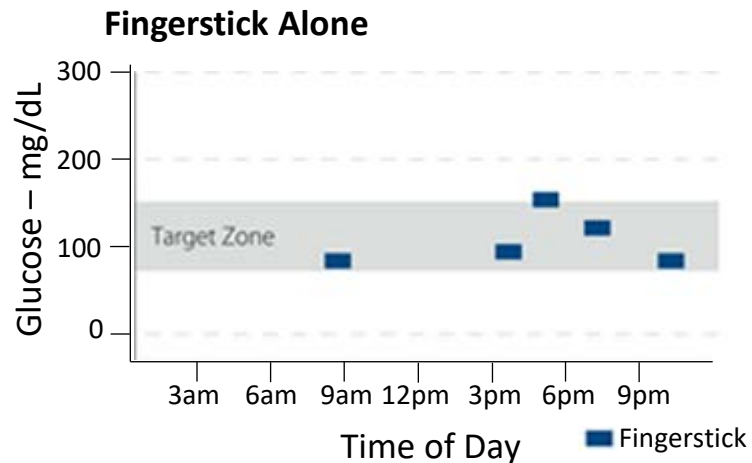
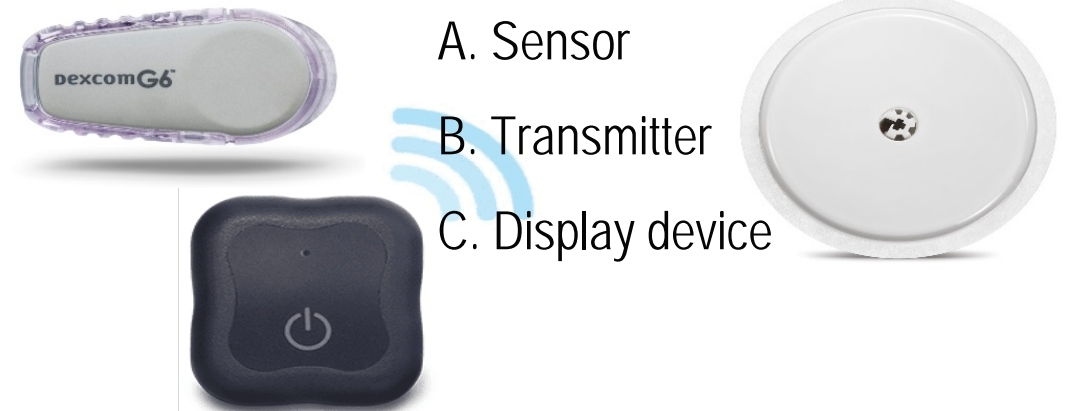
Hypoglycemic Attitudes and Behavior Scale	Percentage of adults with type 1 diabetes	
	CGM user (n=1,200)	CGM non-user (n=335)
High Anxiety Score	11%	17%
Low Confidence Score	16%	23%
High Avoidance Score	21%	31%

Review of Glucose Monitoring Methods

- Traditional “fingerstick” glucose testing



- Continuous glucose monitoring (CGM)



Currently Available CGM Systems



Real-time CGM (rtCGM)

CGM systems that measure glucose levels continuously and provide the user automated alarms and alerts at specific glucose levels and/or for changing glucose levels



Dexcom



Medtronic



Senseonics

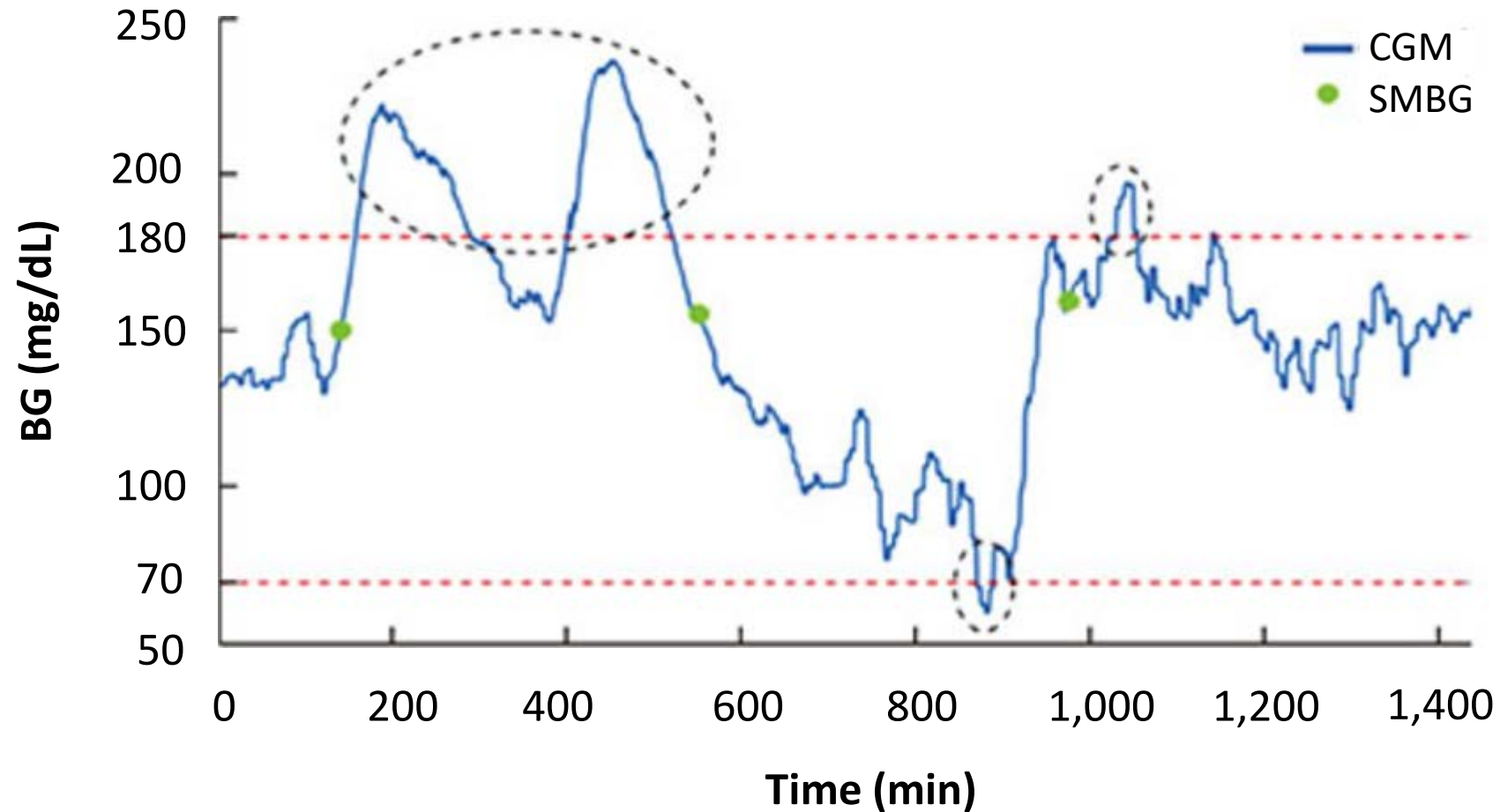
Intermittently scanned CGM (isCGM)

CGM systems that measure glucose levels continuously but only display glucose values when swiped by a reader or a smart phone that reveals the glucose levels.



FreeStyle Libre

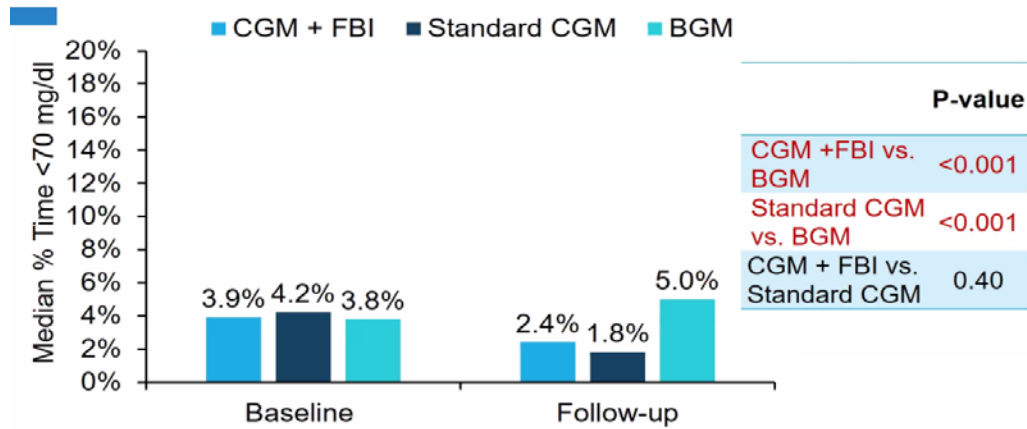
SMBG Does Not Offer Adequate Assessment of Blood Glucose to Optimize Glycemic Management



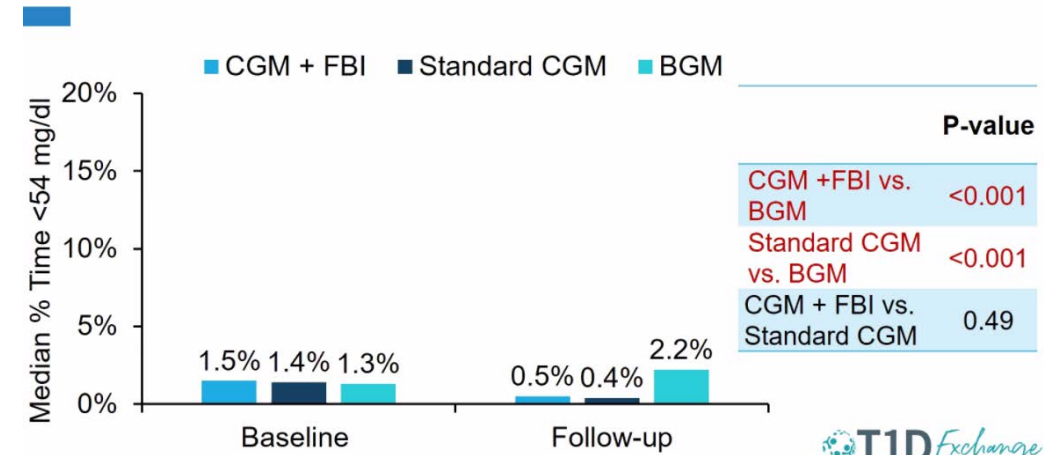
CGM reduces hypoglycemia and the associated worry



Time spent < 70 mg/dl

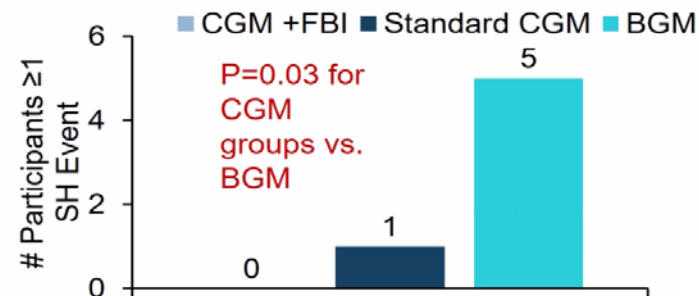


Time spent < 54 mg/dl

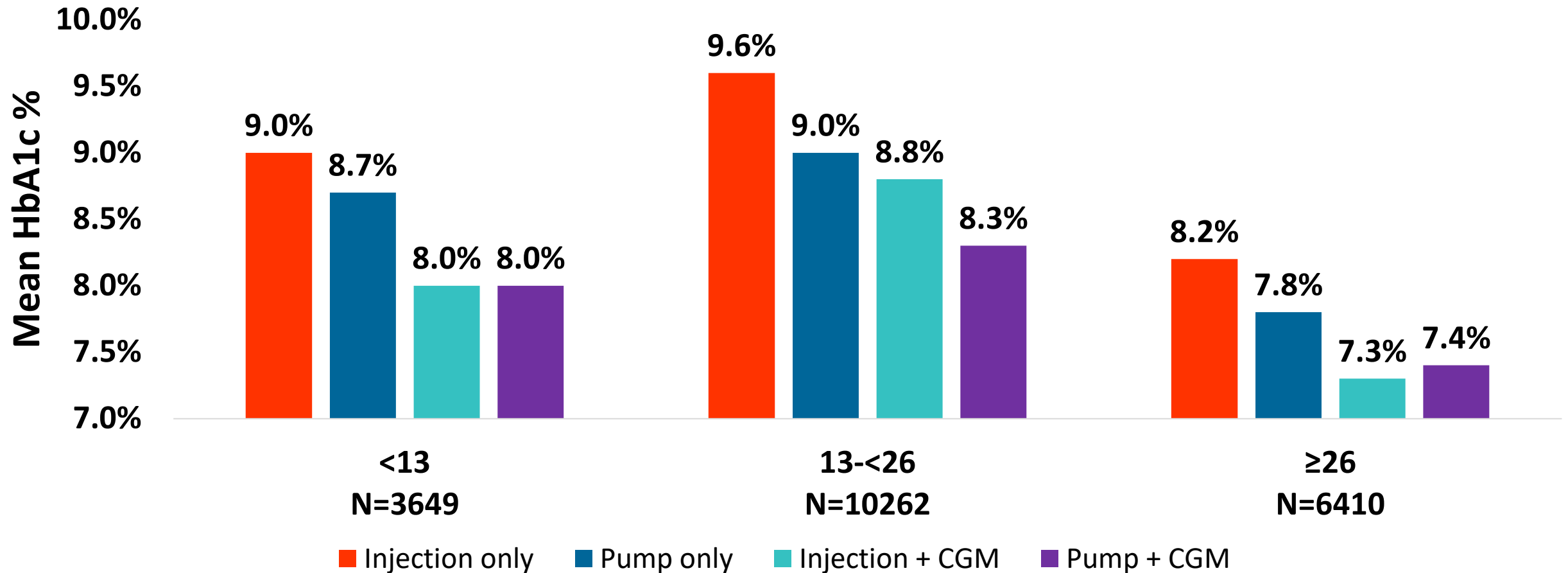


Severe Hypoglycemia Events

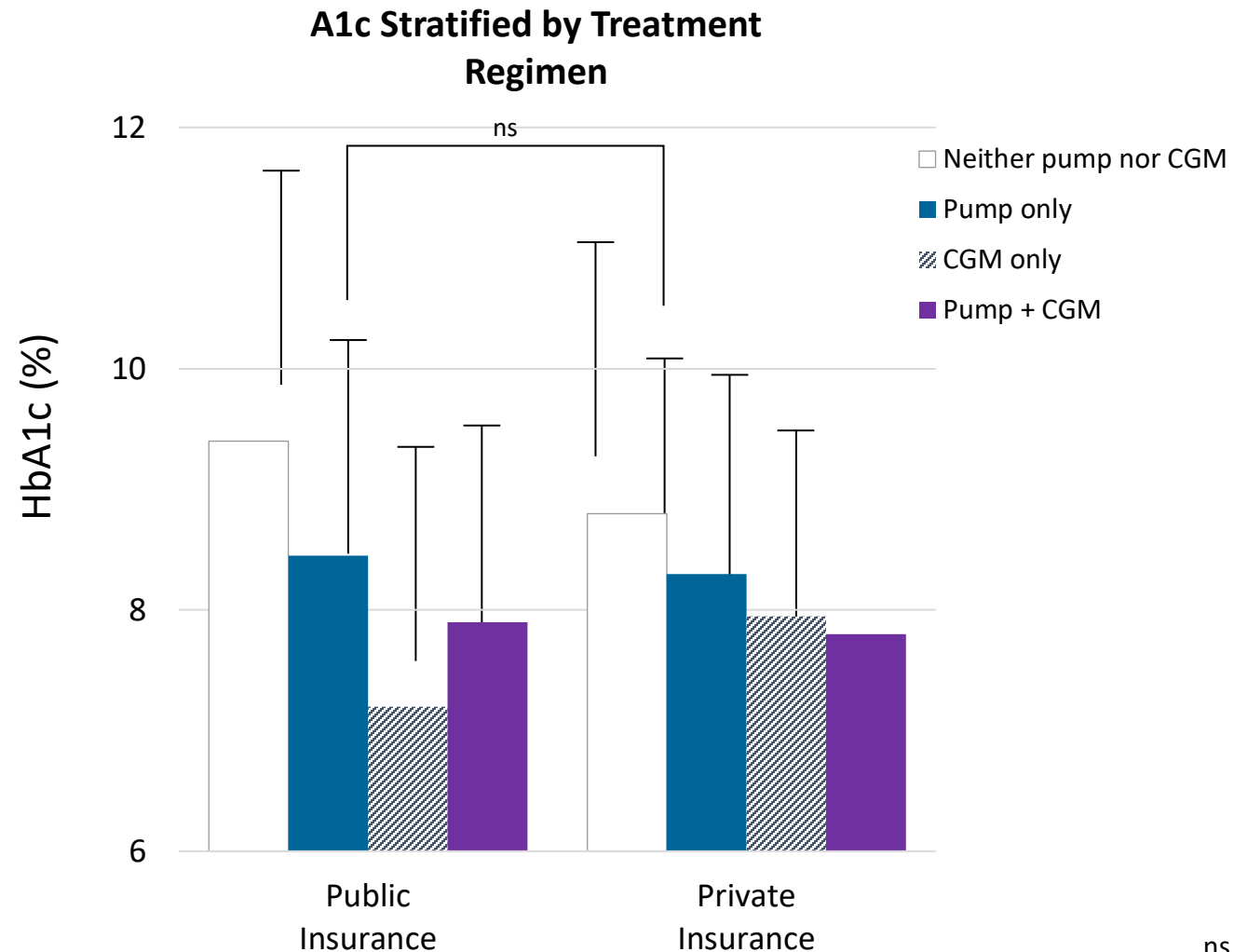
- Required another person to actively administer carbohydrate, glucagon, or other resuscitative actions



CGM Use Lowers A1C Regardless of Insulin Delivery Method



CGM Use Results in Significantly Lower A1C: Cross-sectional Study Among Youth With T1D at Texas Children's Hospital



CGM – The standard of care in diabetes management



CGM is useful tool for improving glycemic control in:

- Adults with **T1D, T2D**
- Pregnant women
- Children & adolescents

American Diabetes Association (ADA)¹



*CGM usage improves glycemic control, reduces hypoglycemia, and may reduce overall diabetes management costs

*CGM should be used **in all patients** who have severe hypoglycemia or hypoglycemia unawareness

American Association of Clinical Endocrinologists (AACE)²



- Recommends CGM for adults with **T1D**
- Recommends short-term, intermittent CGM for adults with **T2D** and A1c $\geq 7\%$
- Recommend CGM for children & adolescents with T1D

Endocrine Society^{3,4}



CGM should be used **in conjunction with A1C** for glycemic status assessment and therapy adjustment in ALL patients with **T1D -AND- T2D** treated with insulin who are not achieving glucose targets

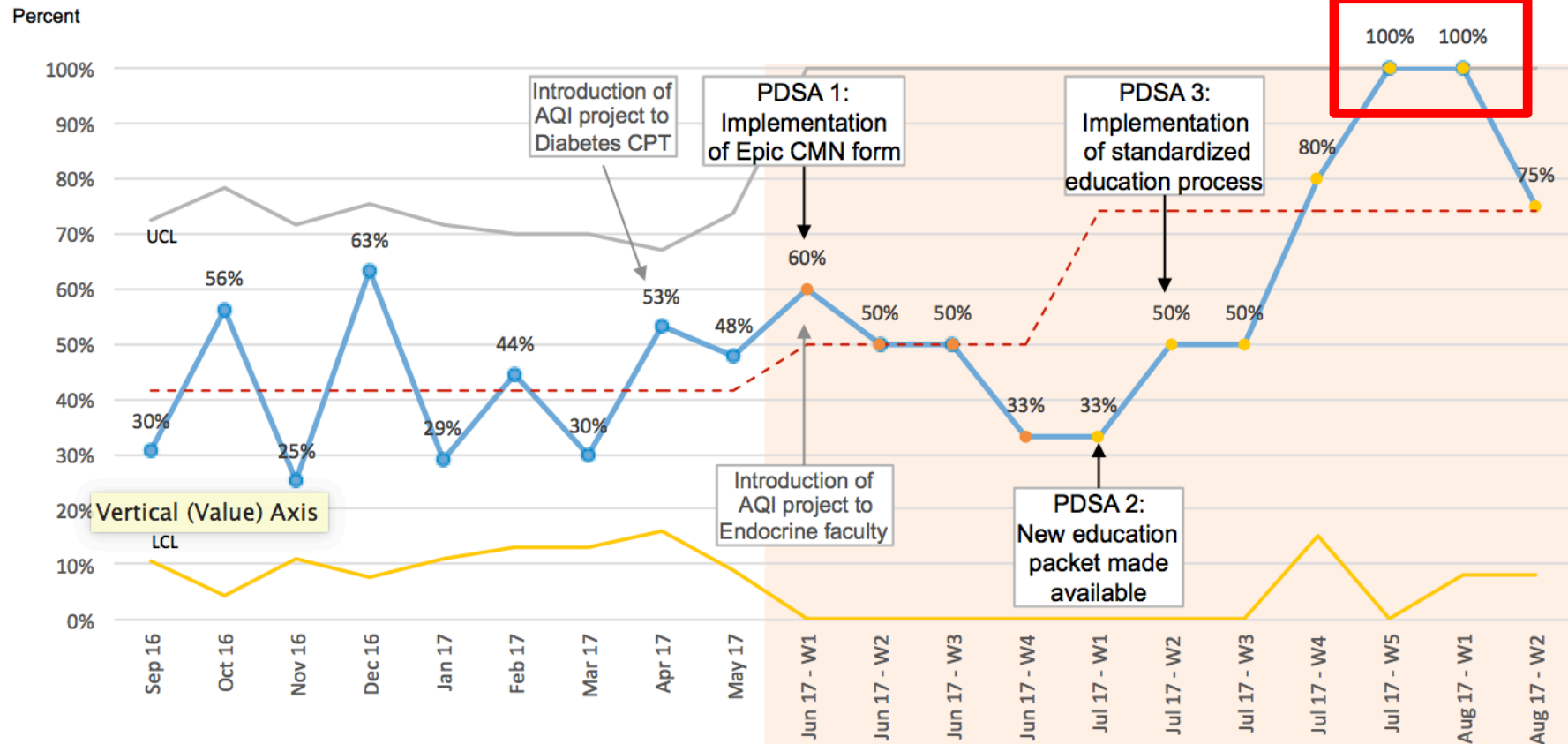
Advanced Technologies & Treatments for Diabetes (ATTD)⁵



Quality Improvement Project to Improve CGM use at Texas Children's Hospital



Rate of CGM Initiation in Newly Diagnosed Patients (all TCH locations)



The COVID-19 Pandemic Has Further Complicated the Management of Diabetes



- Diabetes is one of the most important comorbidities linked to the severity of all three known human pathogenic coronavirus infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
- Patients with diabetes have an increased risk of severe complications including Adult Respiratory Distress Syndrome, multi-organ failure and death
- Depending on the global region, 20%–50% of hospitalized patients in COVID-19 pandemic had diabetes

COVID-19 in Hospitalized Patients with Diabetes Presents Additional Challenges



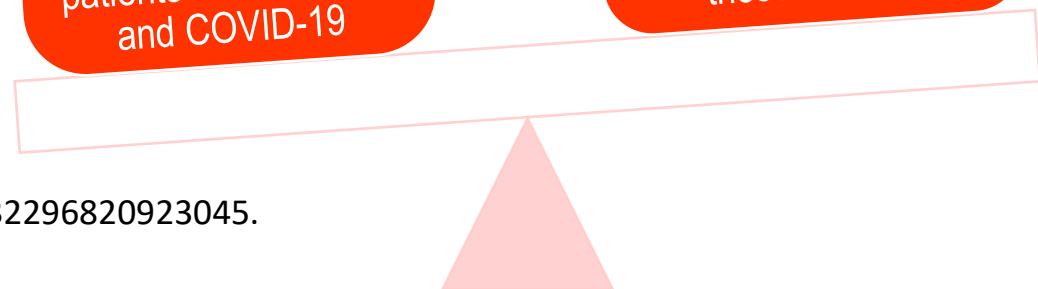
Diabetes is associated with poor clinical outcomes in hospitalized patients with COVID-19

Many centers are improvising care strategies, including the implementation of technology to prevent healthcare workers' exposures and reduce the waste of invaluable personal protective equipment (PPE)

Many hospitals have already become overwhelmed around the world and are rapidly entering crisis mode

Not optimizing glycemic control due to clinical inertia driven by fear or lack of supplies may lead to poor outcomes in patients with diabetes and COVID-19

Individualized care strategies, novel therapeutic regimens, and the use of diabetes technology may reduce these barriers

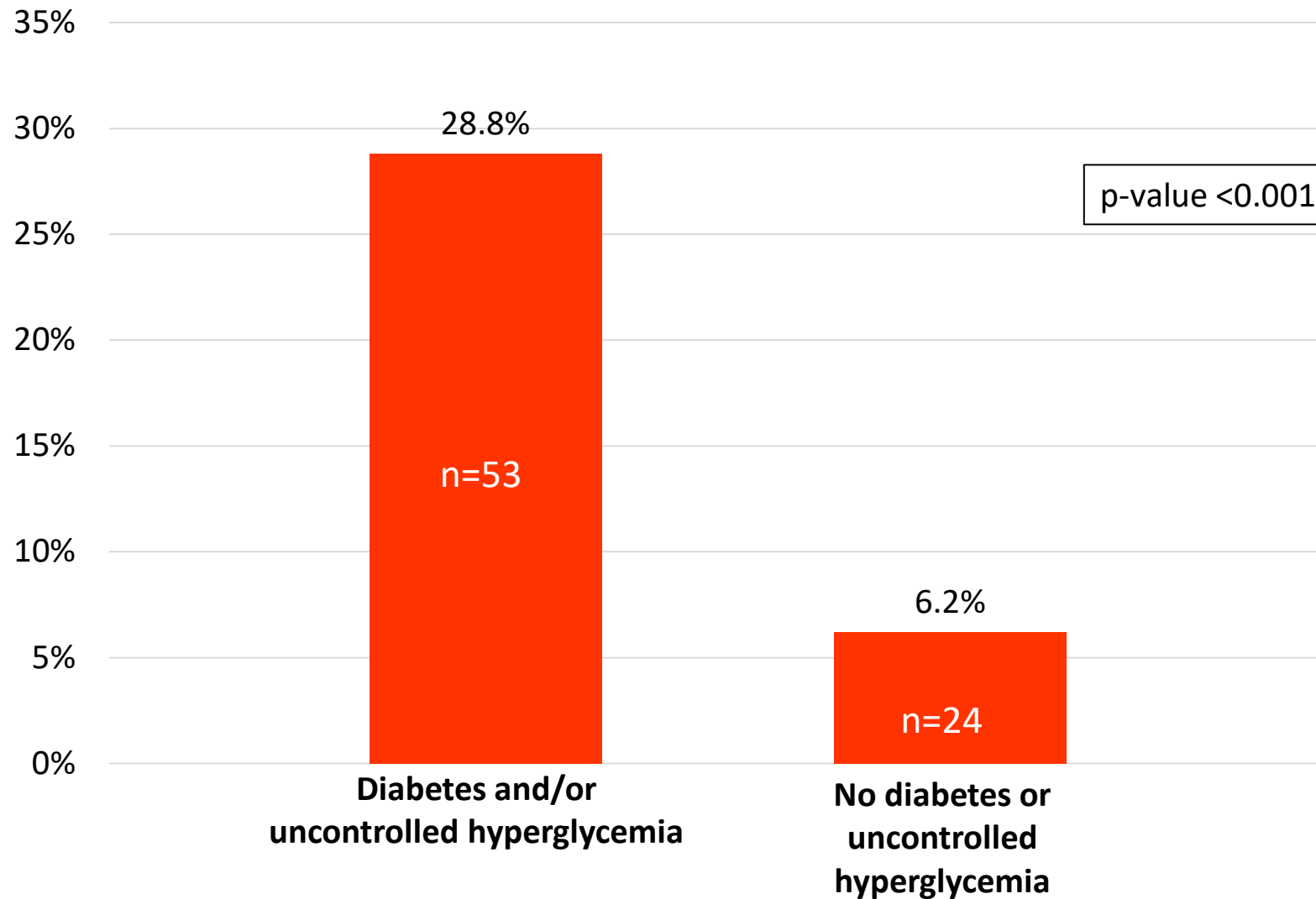


What is the risk for significantly increased mortality due to COVID-19 for patients with diabetes and/or uncontrolled hyperglycemia?

- 1) 8%
- 2) 11%
- 3) 19%
- 4) 29%
- 5) 35%

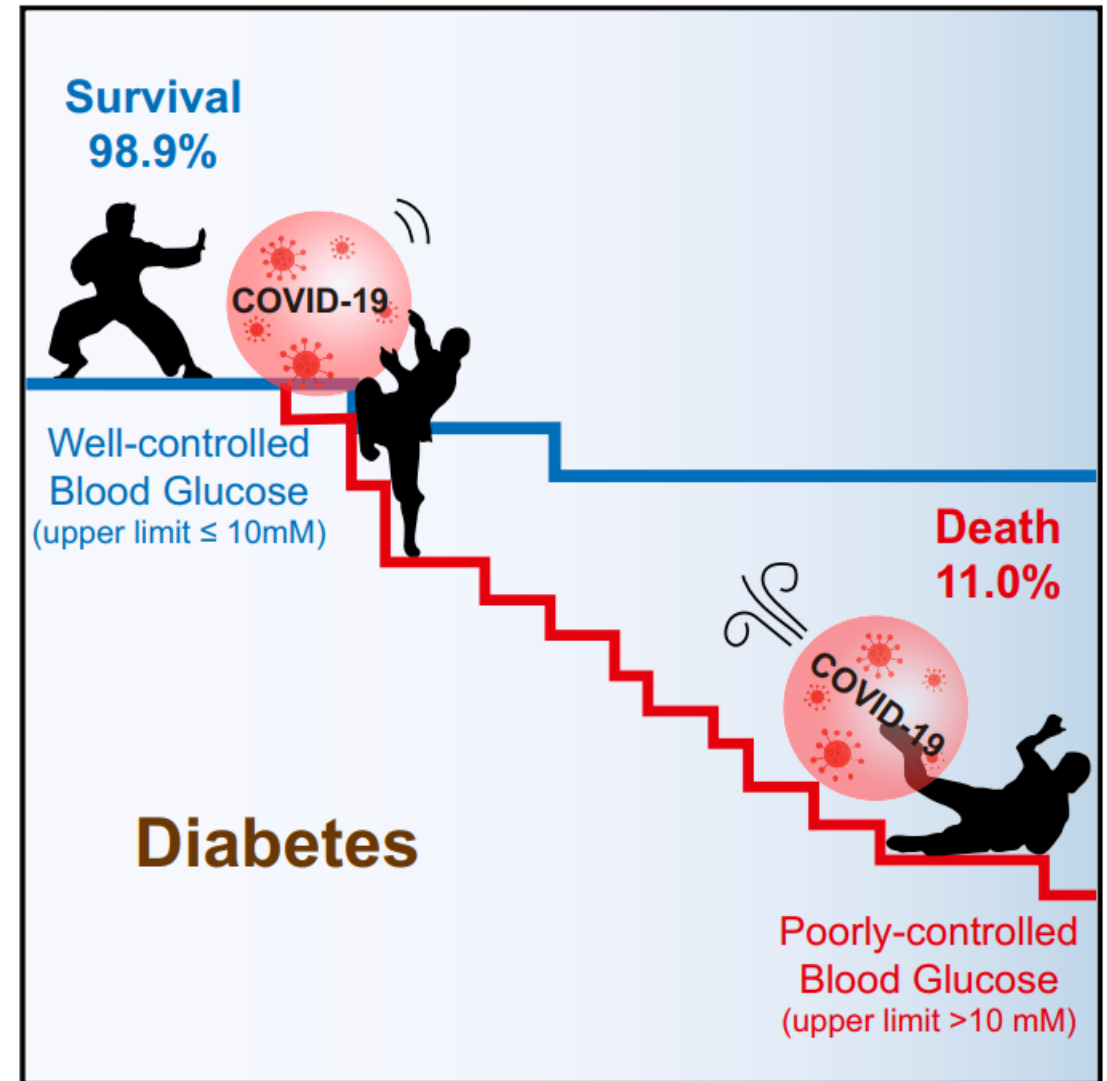


Diabetes and/or Uncontrolled Hyperglycemia Are Risk Factors for Significantly Increased Mortality Due to COVID-19

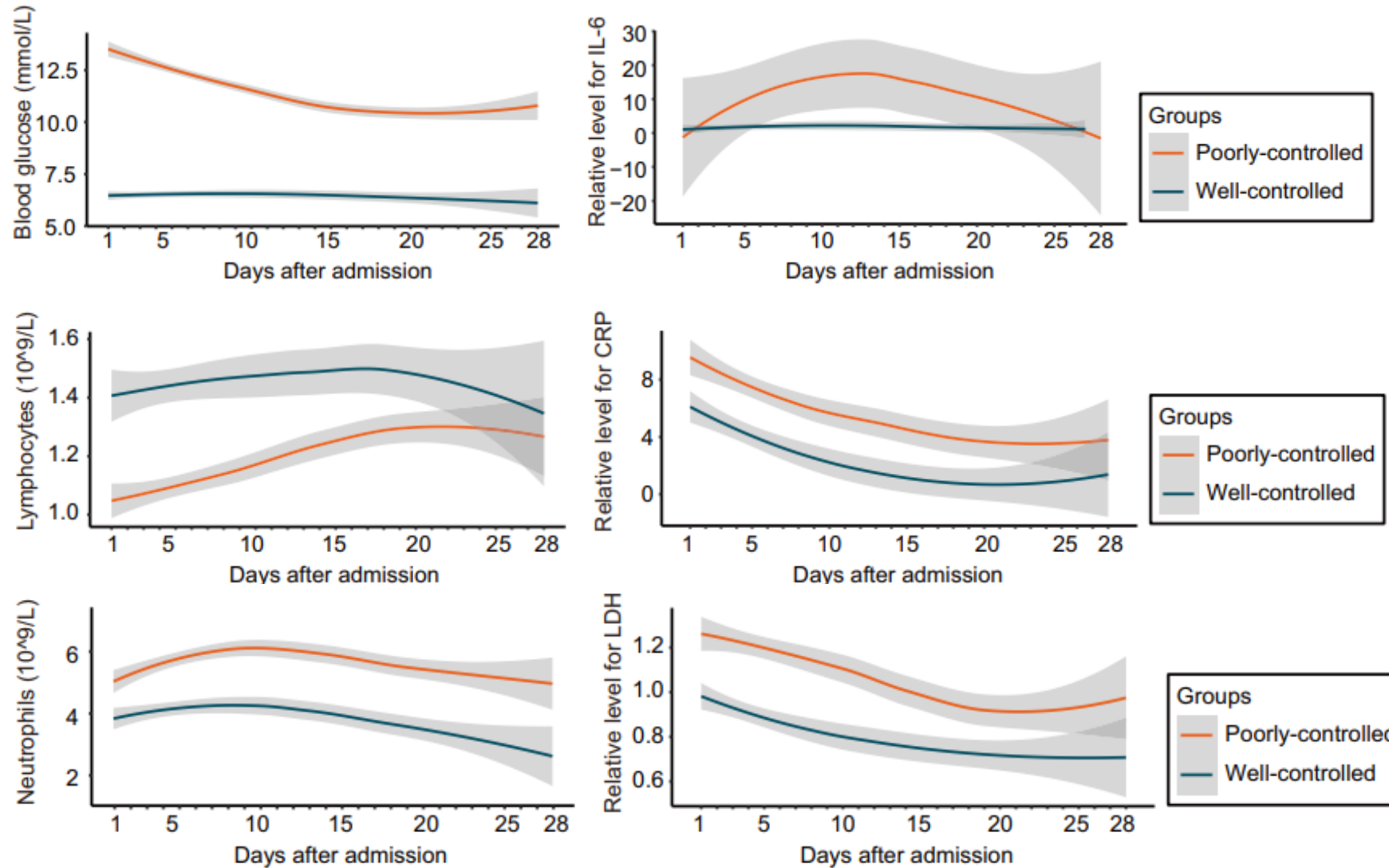


T2D Patients with COVID-19 Have Demonstrated Increased Mortality, Particularly Among Those with Poorly Controlled Blood Glucose

- T2D correlates with worsening outcomes in COVID-19
- Among ~7,300 cases of COVID-19, T2D was associated with a higher death rate
- Patients with better controlled blood glucose have lower mortality rate than those with poorly controlled glucose



The Dynamics of Specific Clinical Markers Among COVID-19 Patients with T2D Demonstrate the Value of Glycemic Management in the Hospital Setting



As A Result of Worsening Outcomes in Patients with Diabetes and COVID-19, Specialized Management Implementing Health Technology Must Be Considered



Consensus Recommendations for COVID-19 and Metabolic Disease

In-patient or intensive care unit

Monitor for new onset diabetes in infected patients (in-patient care)

- Plasma glucose monitoring, electrolytes, pH, blood ketones, or β -hydroxybutyrate
- Liberal indication for early intravenous insulin therapy in severe courses (ARDS, hyperinflammation) for exact titration, avoiding variable subcutaneous resorption, and management of commonly seen very high insulin consumption

Management of infected patients with diabetes (intensive care unit)

Therapeutic aims

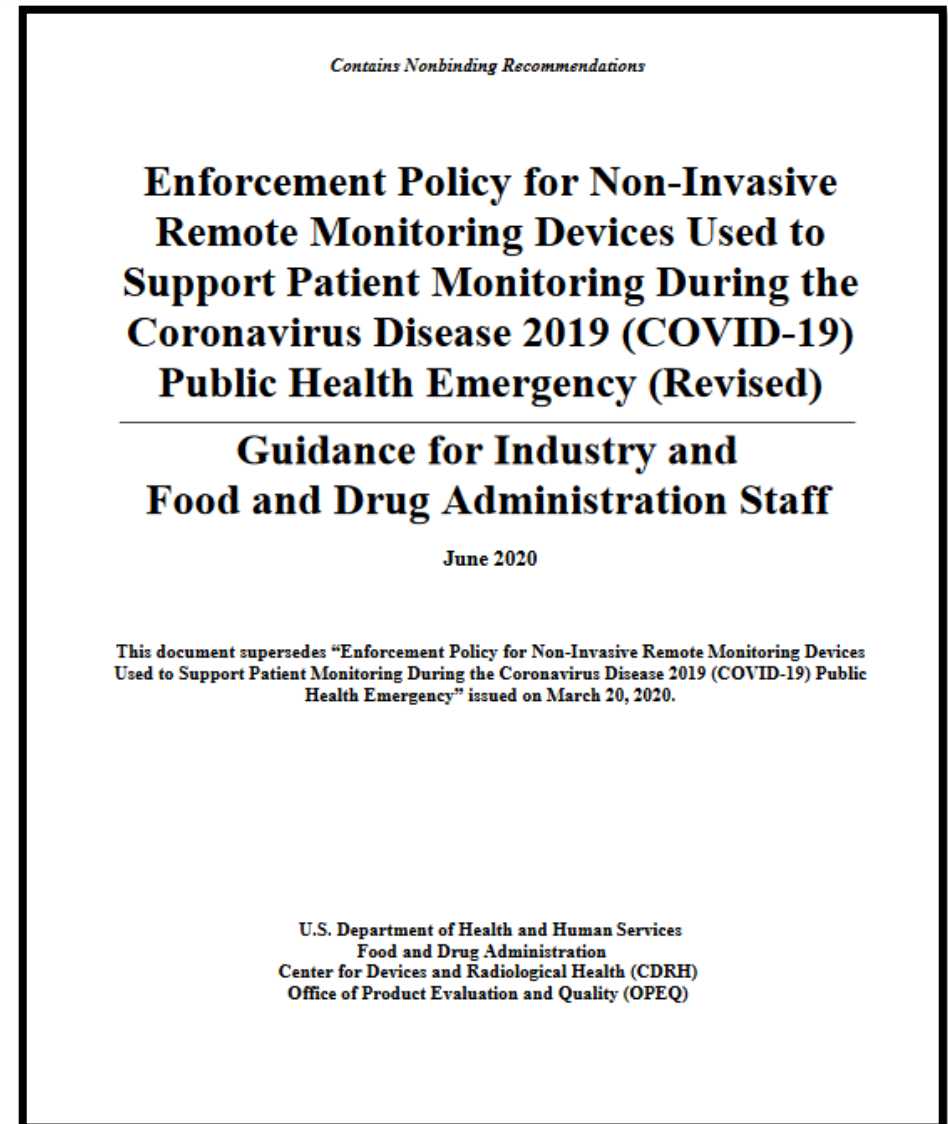
- Plasma glucose concentration: 4–8 mmol/L (72–144 mg/dL)*
- HbA_{1c}: † less than 53 mmol/mol (7%)
- CGM/FGM targets
 - TIR (3.9–10 mmol/L): more than 70% (>50% in frail and older people)
 - Hypoglycaemia (<3.9 mmol/L): less than 4% (<1% in frail and older people)

- Plasma glucose concentration: 4–10 mmol/L (72–180 mg/dL)*

Recognizing the Value of Remote Patient Monitoring During the COVID-19 Pandemic, FDA Has Expanded the Use of CGM to the Hospital Setting



- FDA issued guidance in March 2020 to expand the availability and capability of non-invasive remote monitoring devices during the COVID-19 pandemic
- The change was made in an effort to improve the ability of health care providers to monitor their patients while reducing their exposure to the novel coronavirus
- The new policy will apply to non-invasive patient monitoring technology, including CGM, and expands their indication so that they can be used in inpatient hospital settings



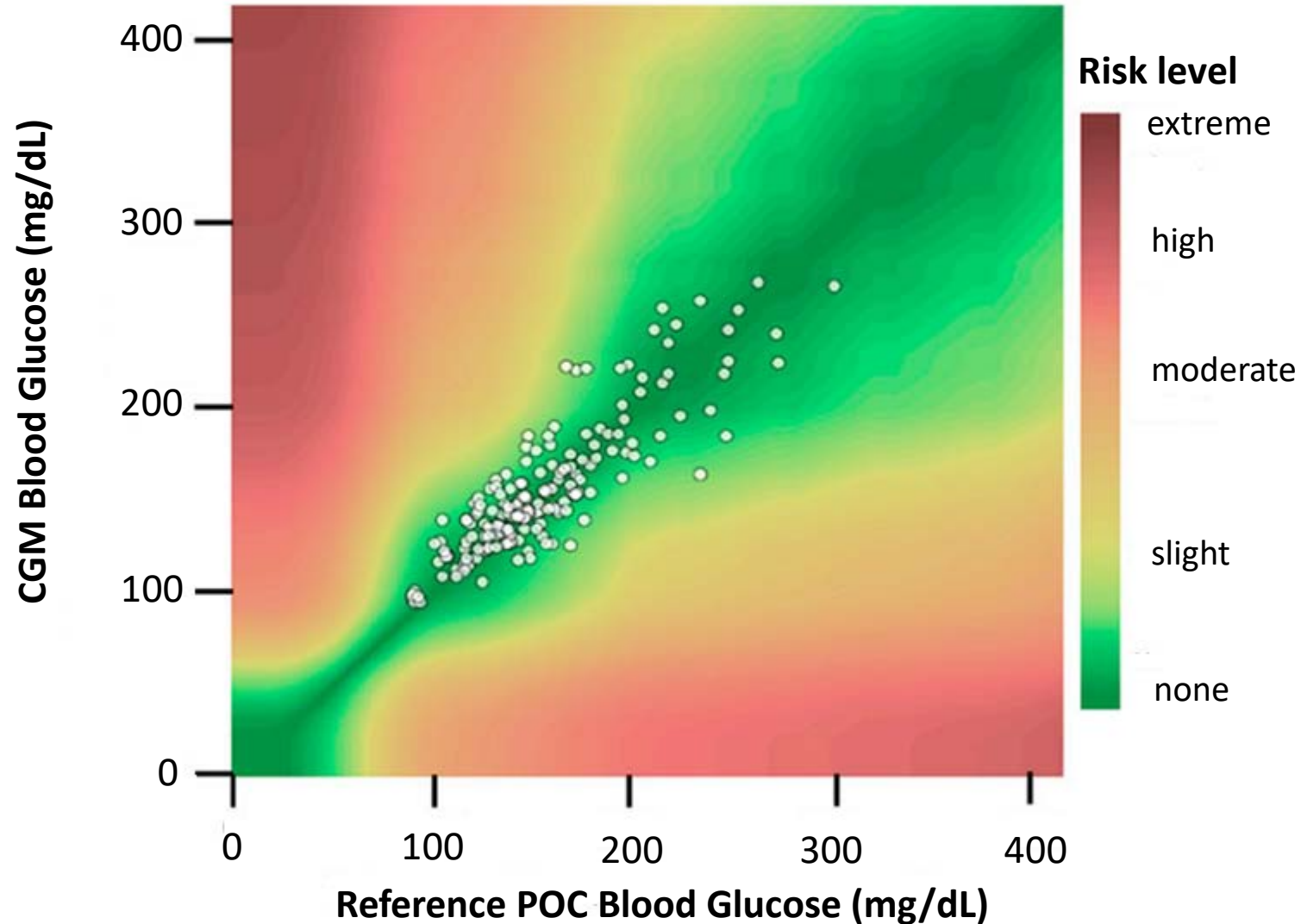
The Use of Diabetes Technology in the Inpatient Has Demonstrated Significant Promise



- Ambulatory use of diabetes technology, (CGM, insulin pumps, and closed-loop systems) has rapidly expanded with more recent studies evaluating its translation to the hospital setting
- Preliminary data show improvement in detection of both hyperglycemia and hypoglycemia with use of CGM in the hospital



CGM Specifically Demonstrates Feasibility and Accuracy in the Inpatient Setting



Diabetes Technology is Poised to Play a Crucial Role During the COVID-19 Pandemic



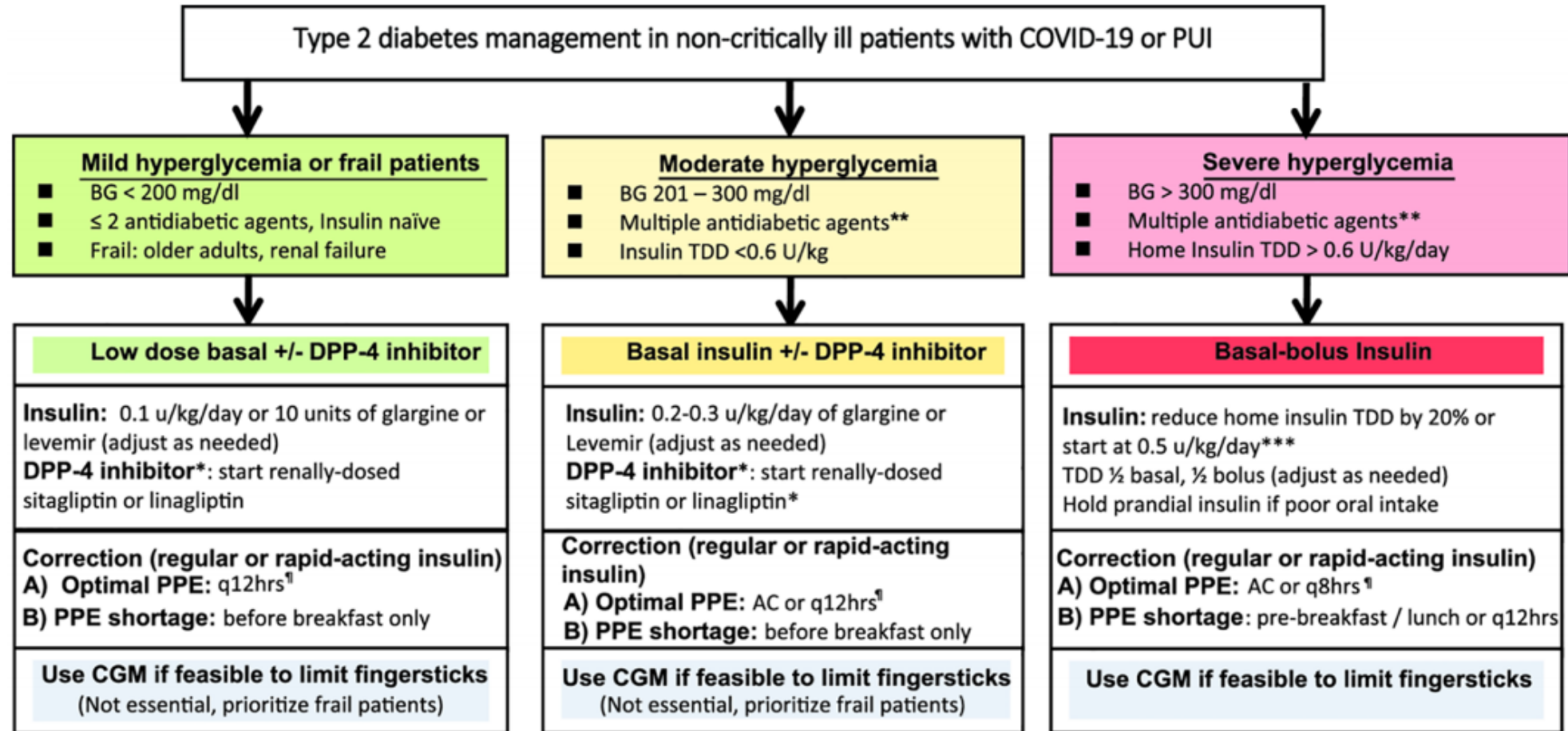
Patients with T1D and acute infections are likely to develop diabetic ketoacidosis (DKA)

- Although less frequent, DKA may occur in T2D during acute illness or among those with long-standing disease and precipitating factors
- T2D patients may be prone to hyperglycemic hyperosmolar state (HHS)

Patients hospitalized with DKA or HHS require continuous insulin infusion to manage their condition

The current approach of hourly point-of-care (POC) glucose testing may be impractical and demonstrates an urgent need for systematic changes incorporating novel diabetes technology (i.e., CGM and closed-loop systems)

CGM Can Be Used to Limit Fingersticks and Manage Non-Critically Ill patients with COVID-19



Intensify therapy if glycemic target (BG 100-180 mg/dl) not achieved

As A Result of Worsening Outcomes in Patients with Diabetes and COVID-19, Specialized Management Implementing Health Technology Must Be Considered



Consensus Recommendations for COVID-19 and Metabolic Disease

Out-patient care

Prevention of infection in diabetes

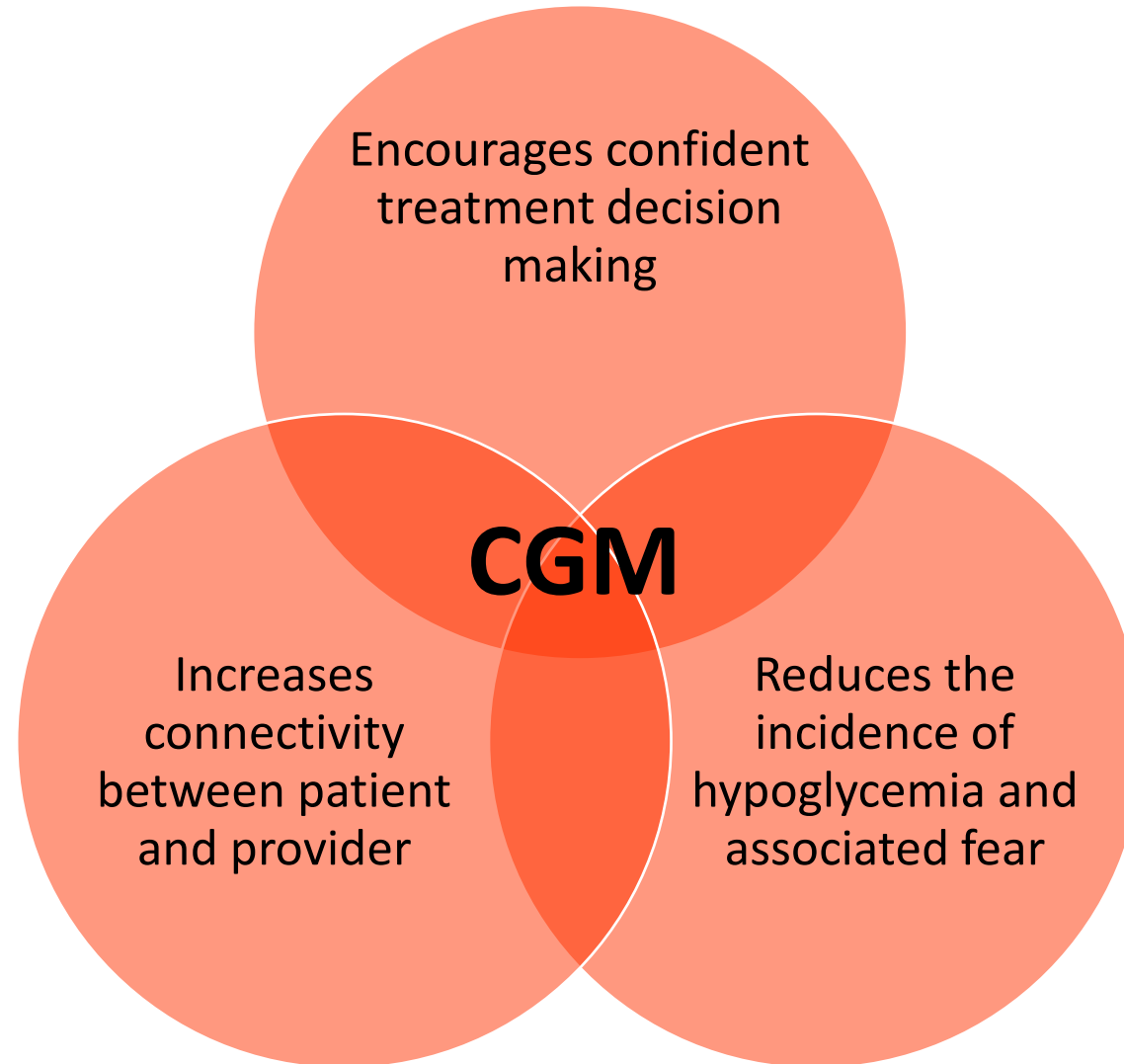
- Sensitisation of patients with diabetes for the importance of optimal metabolic control
- Optimisation of current therapy if appropriate
- Caution with premature discontinuation of established therapy
- Utilisation of Telemedicine and Connected Health models if possible to maintain maximal self containment

Therapeutic aims

- Plasma glucose concentration: 4–8 mmol/L (72–144 mg/dL)*
- HbA_{1c}: † less than 53 mmol/mol (7%)
- CGM/FGM targets
 - TIR (3.9–10 mmol/L): more than 70% (>50% in frail and older people)
 - Hypoglycaemia (<3.9 mmol/L): less than 4% (<1% in frail and older people)

- Plasma glucose concentration: 4–10 mmol/L (72–180 mg/dL)*

Real-time, Remote Glucose Monitoring Enhances Telehealth Efforts and Addresses Specific Components of Patient QoL



The COVID-19 Pandemic Has Demonstrated the Utility of CGM in Telehealth Interventions



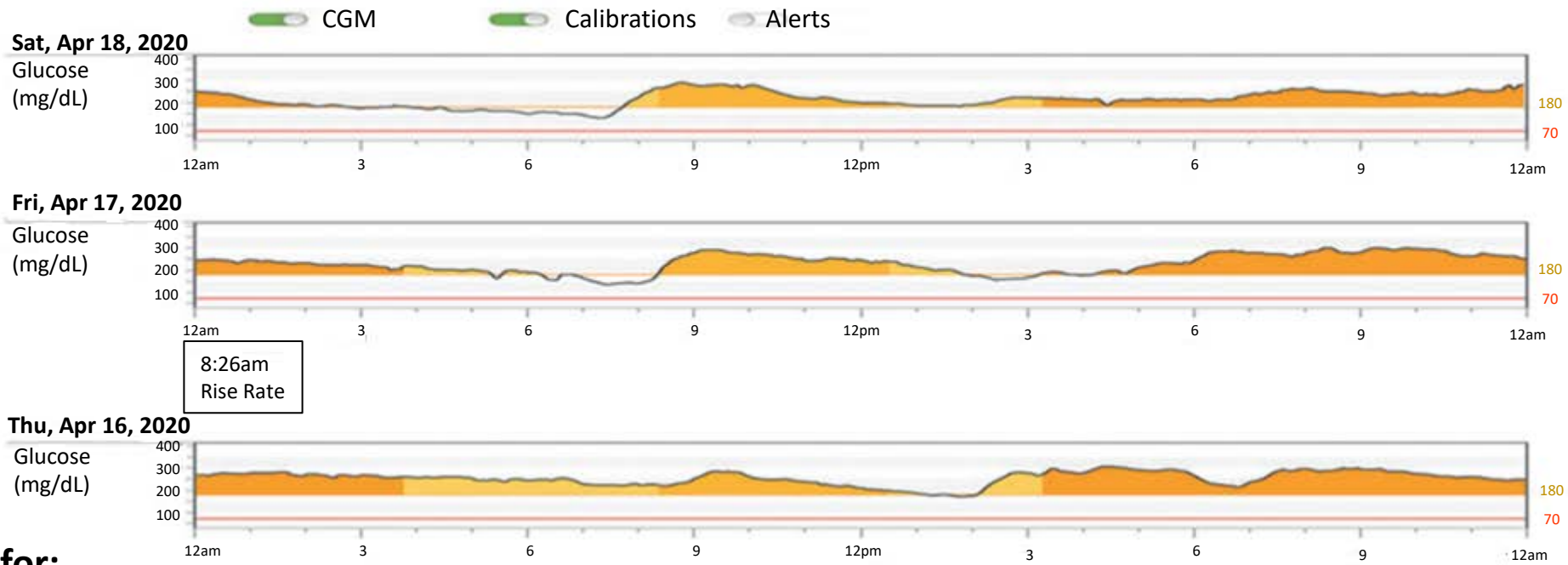
- The COVID-19 pandemic has forced endocrinologists/diabetologists to adapt to providing diabetes care remotely through telehealth
- Shared glucose data through CGM facilitates frequent insulin dose adjustments and sick-day management to prevent hospital admissions

CASE REPORT: 26-year-old with new onset diabetes (BG 500 mg/dL)

- Presented to clinic to begin insulin regimen and receive diabetes education
- Instead of admitting her to hospital, she started on CGM to allow remote monitoring from home

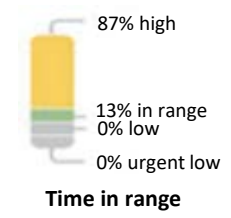


In the First 3 Days, Most Glucose Readings Were >200–300 mg/dL and Only 13% of the Glucose Readings Were in the Target Range



Overview for: Thu, Apr 16, 2020 – Sat, Apr 18, 2020 Statistics for this date range

N/A	233	42	N/A
Glucose Management Indicator	mg/dL Average glucose (CGM)	mg/dL Standard deviation (CGM)	Hypoglycemia risk

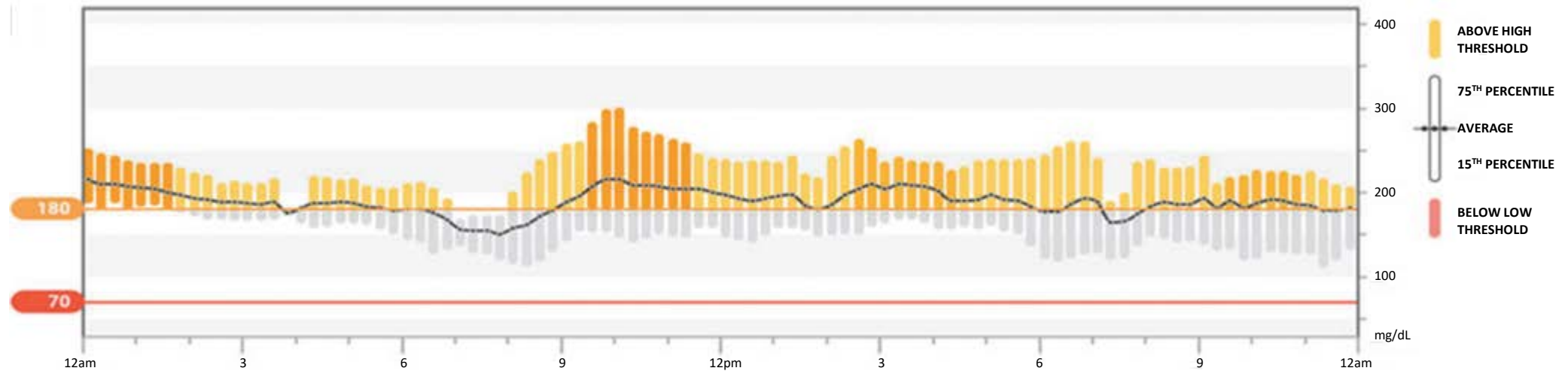


Days with CGM data	100% 3/3
Avg. calibrations per day	0.0

Sensor usage

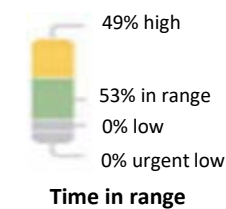
Peters AL, Garg SK. *Diabetes Technol Ther.* 2020;22(6):449-453. [ePub ahead of print, May 5, 2020.]

During the Next 5 Days, 51% of the Readings Were in the Target Range with a Mean Glucose of 189 mg/dL



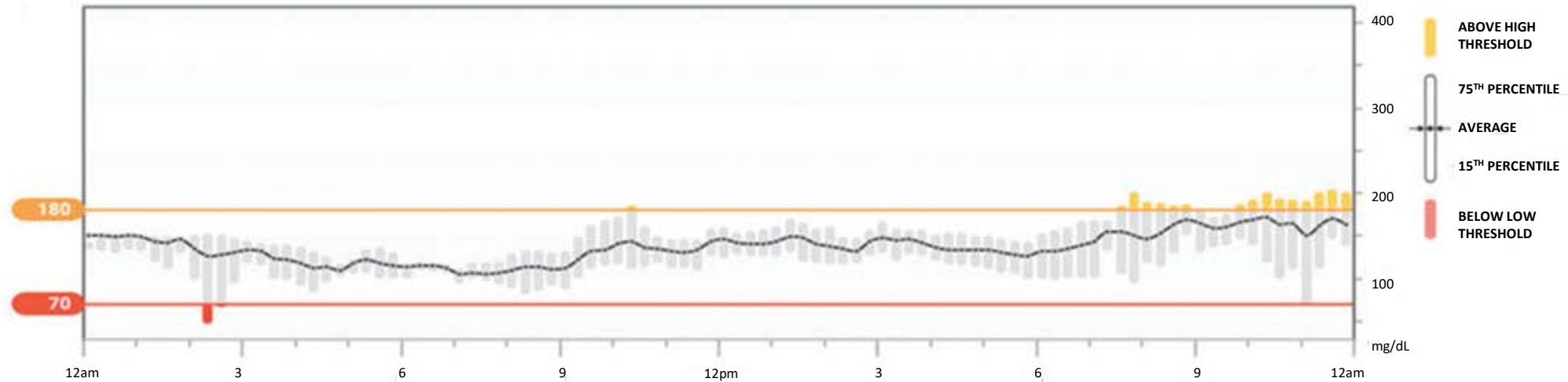
Overview for: Sun, Apr 19, 2020 – Wed, Apr 22, 2020 Statistics for this date range

N/A	189	43	N/A
Glucose Management Indicator	mg/dL Average glucose (CGM)	mg/dL Standard deviation (CGM)	Hypoglycemia risk



Days with CGM data 100%
4/4
Avg. calibrations per day 0.0
Sensor usage

The Most Recent 5-day Period Showed >90% of Glucose Readings in the Target Range and a Mean Glucose of 137 mg/dL



Overview for:

Thu, Apr 23, 2020 – Mon, Apr 27, 2020

Statistics for this date range

N/A

137

28

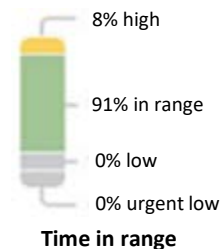
N/A

Glucose Management Indicator

mg/dL
Average glucose (CGM)

mg/dL
Standard deviation (CGM)

Hypoglycemia risk



Days with CGM data 80%
4/5

Avg. calibrations per day 0.0

Sensor usage

Peters AL, Garg SK. *Diabetes Technol Ther.* 2020;22(6):449-453. [ePub ahead of print, May 5, 2020.]

Summary



- Inadequate glycemic management can result in significant clinical and economic implications resulting from both hyperglycemia and hypoglycemia
- Hypoglycemia is often overlooked as a consequence of diabetes treatment but can adversely affect clinical outcomes, health care resource utilization, management strategies, physical functioning, and productivity
- CGM offers a more precise and comprehensive approach to management, with increased treatment confidence and patient-provider connectivity, with potential for incorporation in telehealth initiatives
- The COVID-19 pandemic disproportionately affects individuals with diabetes, demonstrating worsening outcomes in this population as well as increased mortality
- Enhanced glycemic control contributes to improved outcomes in COVID-19 patients with diabetes, presenting an opportunity for technology interventions such as insulin pump and CGM in the hospital setting to reduce direct physical contact and conserve valuable PPE
 - These interventions offer potential cost savings for payers by facilitating rigorous patient management despite limited direct contact and reducing disease-related complications

Thank you!



Daniel DeSalvo, M.D. @MDwithT1D · Aug 29

I've never been so thankful to see blue skies at @TexasChildrens
#HoustonStrong



Be in touch:
DeSalvo@bcm.edu



Implementing Coverage for CGM: Real-World Insights





Jeffrey Dunn, PharmD, MBA

(Former) Vice President, Clinical Strategy and Programs and Industry Relations
Magellan Rx Management

Diabetes is a Significant Driver of Health Care Spending for Payers

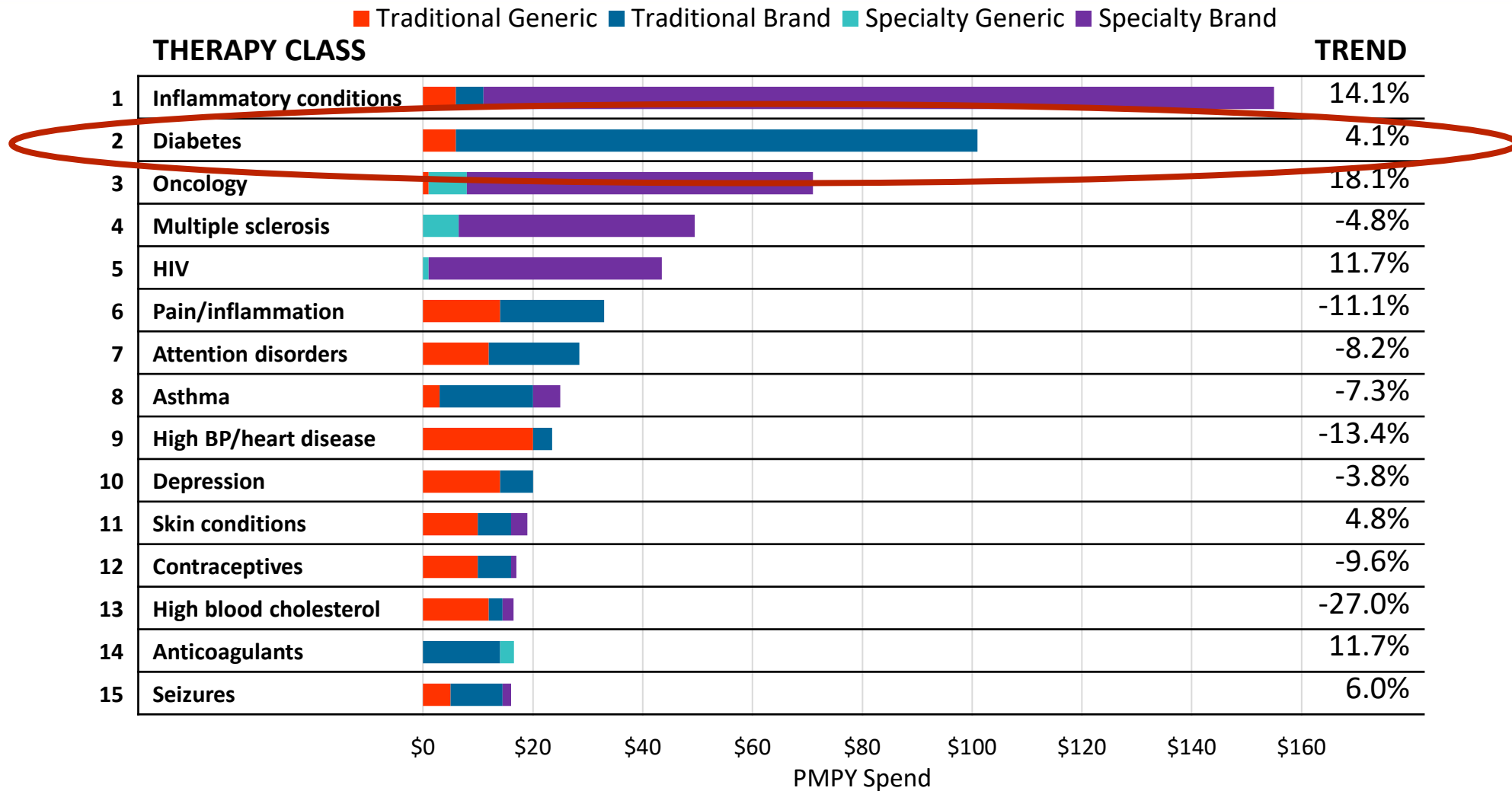


\$237 Billion in Direct Costs Annually

 <p>30% Hospital inpatient care</p>	 <p>15% Anti-diabetic agents and diabetes supplies</p>
 <p>30% Prescription medications to treat complications of diabetes</p>	 <p>13% Physician office visits</p>

Members with diagnosed diabetes incur average medical expenditures of **\$16,752 per year**, of which **about \$9,601 is attributed to diabetes**, compared with annual expenditures of **\$7,151** among members **without diabetes**

Diabetes is a Significant Driver of Health Drug Trend for Payers



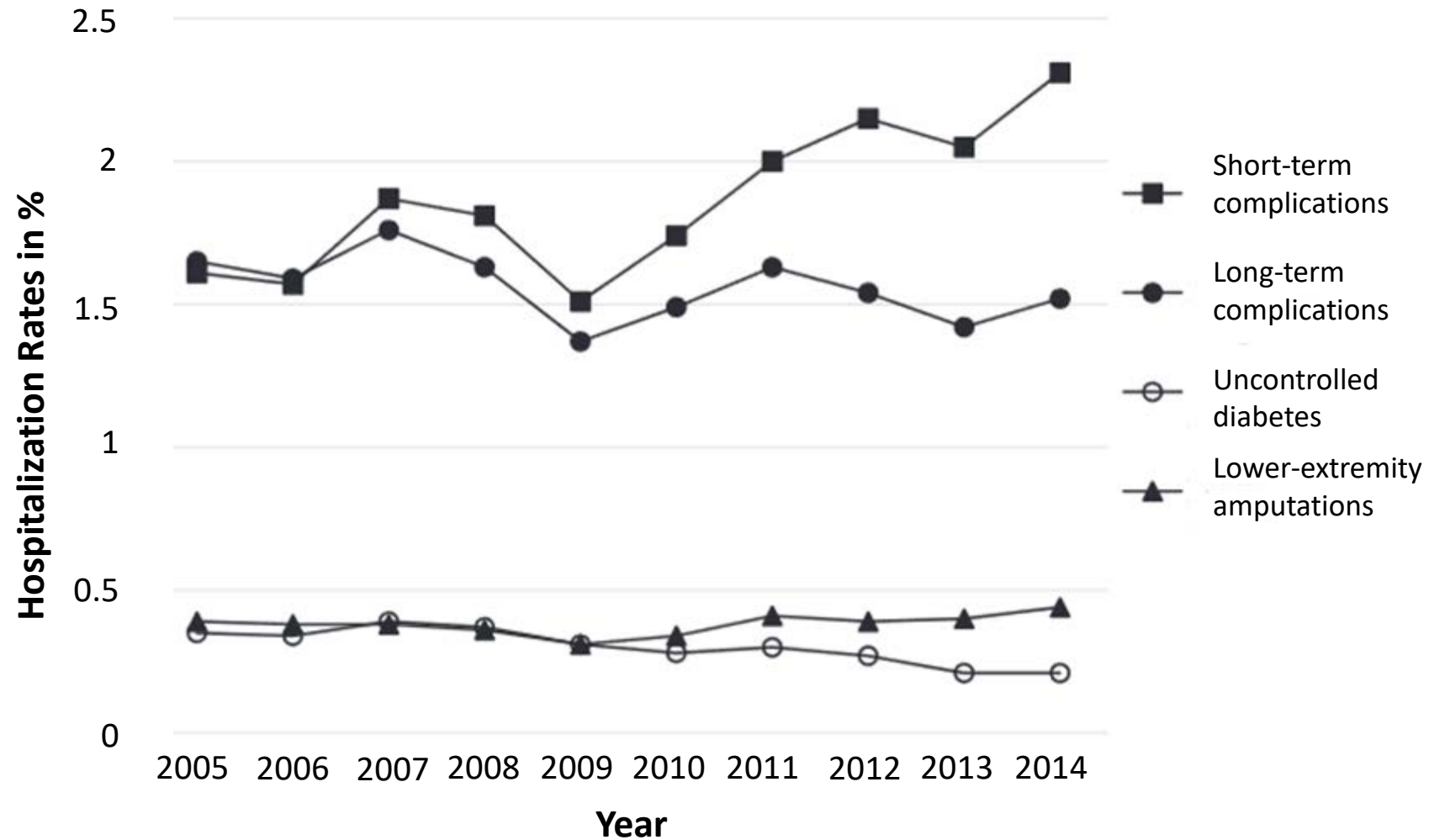
A1C Screening Has Long Been Robust, but Management by Minimal Standards Remains Inadequate



HBA1C SCREENING					
	Commercial		Medicaid	Medicare	
Year	HMO	PPO	HMO	HMO	PPO
2018	91.3	90.2	87.8	94.4	93.9
2017	91.2	89.8	87.6	93.7	93.5
2016	90.6	89.3	86.7	93.5	93.6
2015	90.1	88.8	86.0	93.2	92.7

HBA1C CONTROL (<8.0%)					
	Commercial		Medicaid	Medicare	
Year	HMO	PPO	HMO	HMO	PPO
2018	58.2	51.1	48.7	66.1	68.4
2017	57.6	47.9	49.4	64.4	67.2
2016	56.0	46.6	47.1	62.9	66.3
2015	55.3	46.6	45.5	62.7	63.8

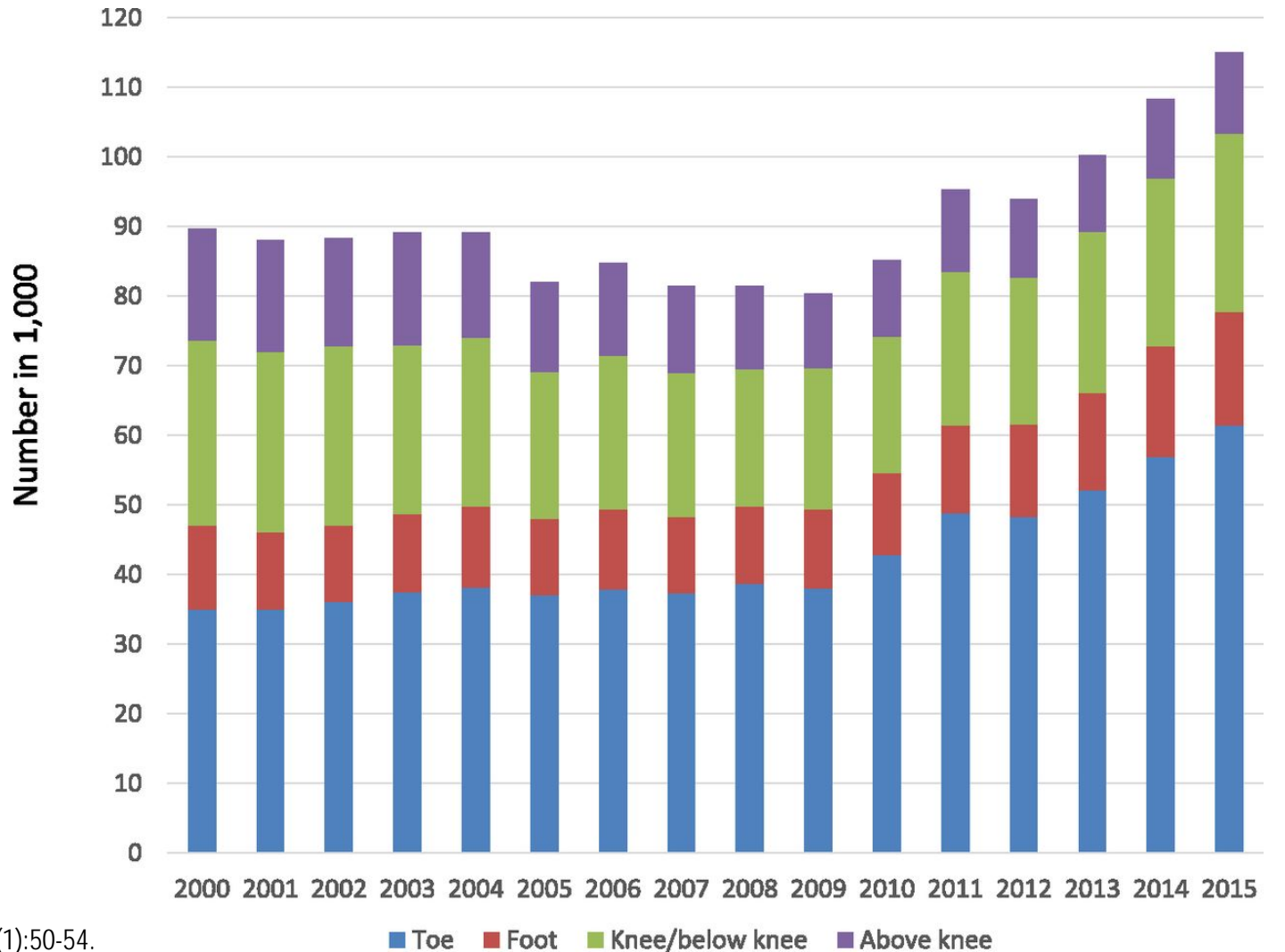
Hospitalizations for Short-Term Complications Such as Hypoglycemia Are a Key Component of Health Care Resource Utilization



Trends in Surgery Point to Further Suboptimal Care



After a two-decade decline in diabetes-related lower-extremity amputations, the US may now be experiencing a reversal in the progress, particularly in young and middle-aged adults



Opportunities Exist to Improve the Quality of Care Via Increased Monitoring, which Improves Time in Range (TIR) and Can Lead to Reduced Disease-Related Complications



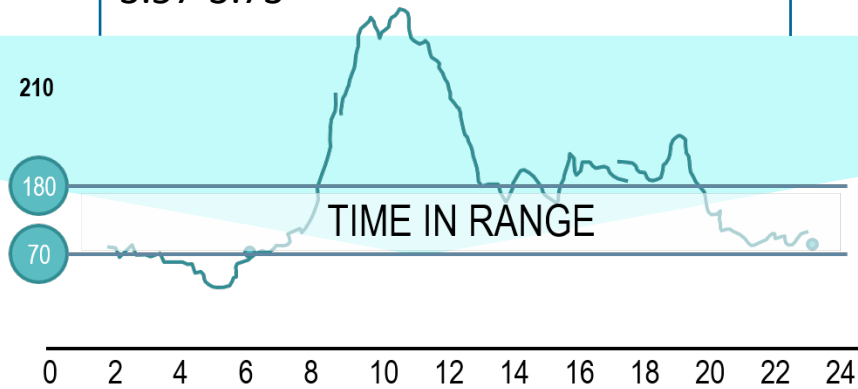
10-year Cumulative Incidence of Developing Diabetes-Related Complications After Improving TIR in PwD with T1 and T2D

TYPE 1 DIABETES

COMPLICATION	58% TIR	70% TIR	80% TIR
Myocardial infarction	3.29	2.65-2.97	2.25-2.70
End-stage renal disease	3.85	3.79-3.81	3.72-3.73
Severe vision loss	9.12	7.99-8.44	7.55-8.0
Amputation	3.96	3.73-3.82	3.57-3.73

TYPE 2 DIABETES

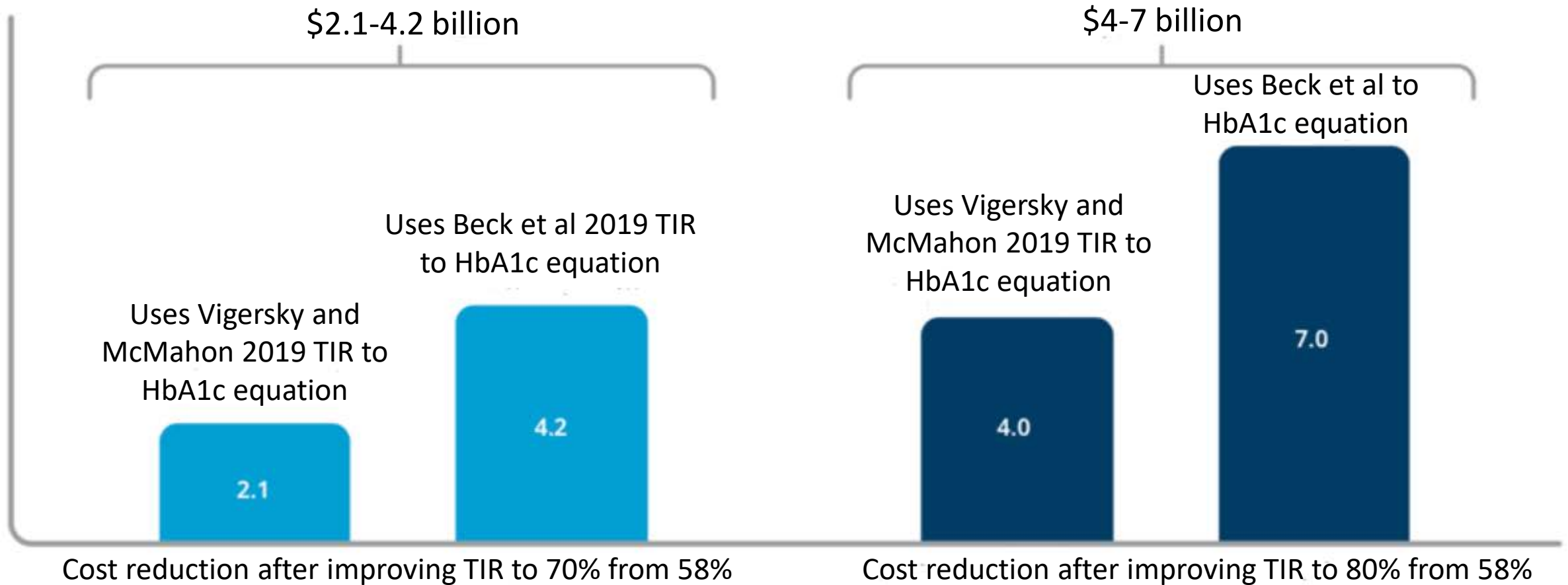
COMPLICATION	58% TIR	70% TIR	80% TIR
Myocardial infarction	12.76	11.99-12.39	11.37-11.97
End-stage renal disease	2.84	1.94-2.34	1.42-1.98
Severe vision loss	5.18	4.78-4.98	4.56-4.83
Amputation	1.00	0.97	0.95-0.96



The Potential Cost Savings with Increased Monitoring and Improvements in TIR are Significant Across T1 and T2 Diabetes



10-Year Cost Reduction by Improving TIR in People with T1 and T2 Diabetes to 70% and 80% TIR (US\$ Bn)



Telemedicine and Remote Monitoring Offer an Opportunity for Cost Management and Improved Quality According to Metrics Such as TIR in Chronic Disease



Where?

Top Services Provided to Patient Through Telehealth



N=475 health care organizations

Why?

Top 3 Reasons to Provide Telehealth Services



How?

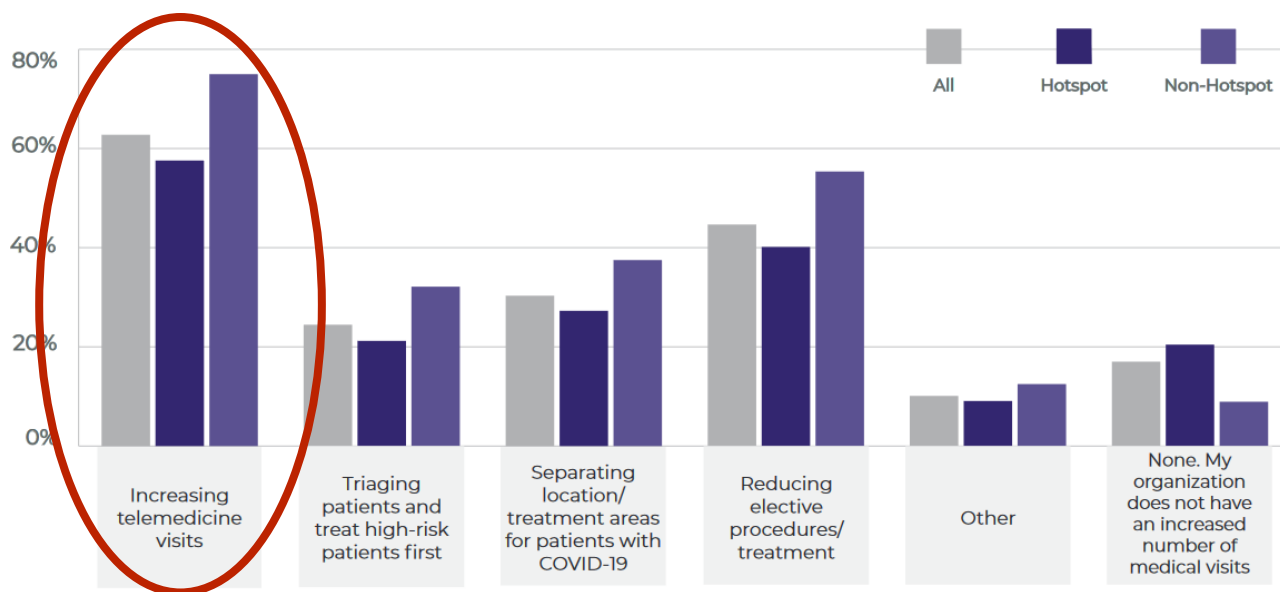
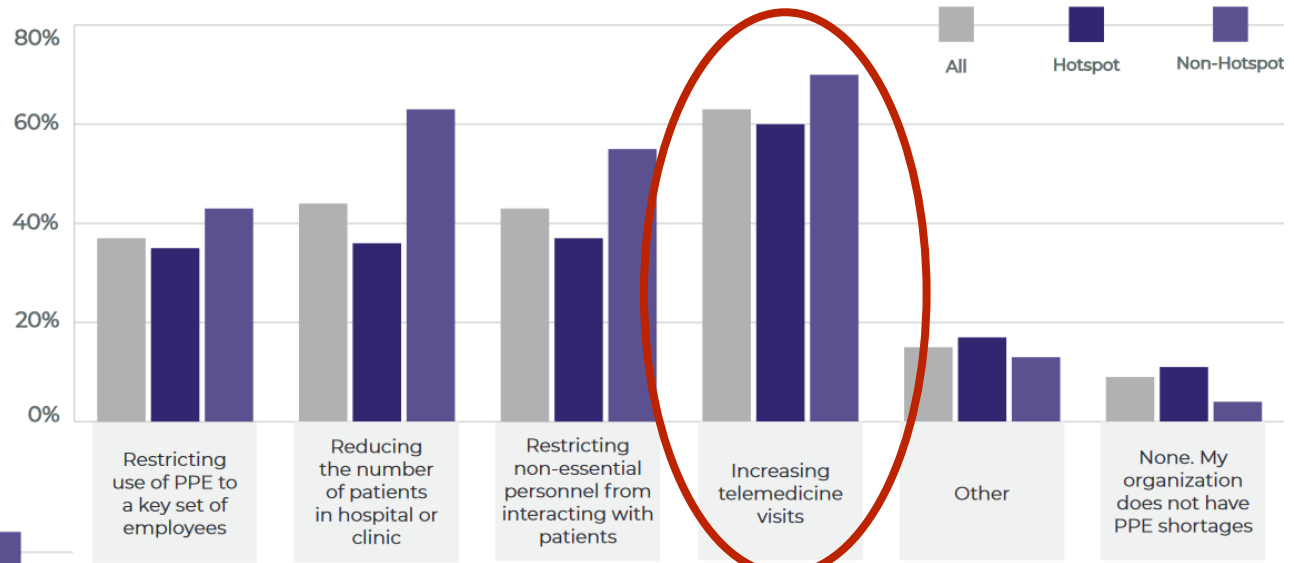
Telehealth Technology Used



Telemedicine and Remote Monitoring are Further Playing a Role for Payers During the COVID-19 Pandemic



Strategies for Personal Protective Equipment (PPE) Shortages



N=275 payers, ACOs, providers, and health systems

Strategies for Increased Visits

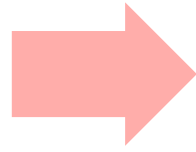


Considerations on Benefit Design Approach for rtCGM



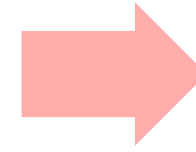
Rationale

- rtCGM offers personalized, precise glycemic management and is recommended by the *ADA Standards of Medical Care* in select patient populations
- Utilization of rtCGM can enhance the quality of care by improving A1C and time in range (TIR) while reducing hypoglycemic episodes and resultant resource utilization



Evaluation

- Coverage of rtCGM under the pharmacy benefit facilitates patient access and utilization and eases administrative burden for providers
- rtCGM coverage is typically at least cost neutral for payers across both benefits and potentially lower under the pharmacy benefit due to administrative efficiencies and rebates



Implementation

- After evaluating potential costs, coverage of rtCGM can be moved from the medical to the pharmacy benefit by consulting with medical, checking policy language, and implementing the appropriate utilization management interventions under pharmacy

Clinical Evidence Supports the Use of CGM, which is an Integral Component of Consensus Guidelines for Diabetes



Consensus statements from endocrine experts have now become more specific on the demonstrated benefits of CGM



- **American Diabetes Association 2020¹**

- RT-CGM used in conjunction with intensive insulin therapy is a useful tool to lower A1c in adults with type 1 and type 2 diabetes who are not meeting glycemic targets, have episodes of hypoglycemia, and/or hypoglycemia unawareness



- **American Association of Clinical Endocrinologists (AACE) 2016²**

- CGM usage improves glycemic control, reduces hypoglycemia, and may reduce overall diabetes management costs
- CGM should be used in all patients who have severe hypoglycemia or hypoglycemia unawareness



- **Endocrine Society 2016³**

- Recommends CGM for adults with type 1 diabetes and
- Recommends short-term, intermittent CGM for adults with type 2 diabetes and A1c $\geq 7\%$
- 2016 recommendations addressed use in adults only. The 2011 guidelines recommended CGM for children and adolescents with T1D and A1c $> 7\%$ ⁴



- **Advanced Technologies & Treatments for Diabetes (ATTD) 2017⁵**

- CGM should be considered in conjunction with A1c to assess glycemic status and adjust therapy in all patients with type 1 diabetes and in patients with type 2 diabetes treated with intensive insulin therapy who are not achieving glucose targets

1. American Diabetes Association. *Diabetes Care*. 2020;43(Suppl 1):S77-S88. 2. Fonseca VA, Grunberger G, Anhalt H, et al. *Endocr Pract*. 2016;22(8):1008-21. 3. Peters AL, Ahmann AJ, Battelino T, et al. *J Clin Endocrinol Metab*. 2016;101(11):3922-3937. 4. Klonoff DC, Buckingham B, Christiansen JS, et al. *J Clin Endocrinol Metab*. 2011;96(10):2968-79. 5. Danne T, Nimri R, Battelino T, et al. *Diabetes Care*. 2017;40(12):1631-1640.

What is the percent of patients using intensive insulin therapy (IIT) that check their glucose 6-10 times/day as recommended by ADA Standards of Care?

- 1) <5%
- 2) 6-10%
- 3) 11-15%
- 4) 16-20%

Advances in CGM Systems Facilitate Optimal Outcomes and Cost Efficacy



- CGM results in improved outcomes:¹
 - Reduced A1C
 - Reduced time in hypoglycemia and hypoglycemic events, presumably with reduced associated health care resource utilization
 - More clinically appropriate and cost-effective use of insulin therapy
- CGM reduces hypoglycemic fear and increases confidence in treatment decision making
- CGM minimizes adherence issues with traditional self blood glucose monitoring (SMBG) or traditional blood glucose monitoring
 - While test strips create an opportunity for patients to be nonadherent several times a day, sensors need only be changed every 7-14 days
 - <5% of patients using intensive insulin therapy (IIT) check their glucose 6-10 times/day as recommended by ADA Standards of Care^{2,3}
- CGM interventions have come down significantly in cost since their introduction, improving cost effectiveness

1. Charleer S, Mathieu C, Nobels F, et al. *J Clin Endocrinol Metab.* 2018;103(3):1224-1232.

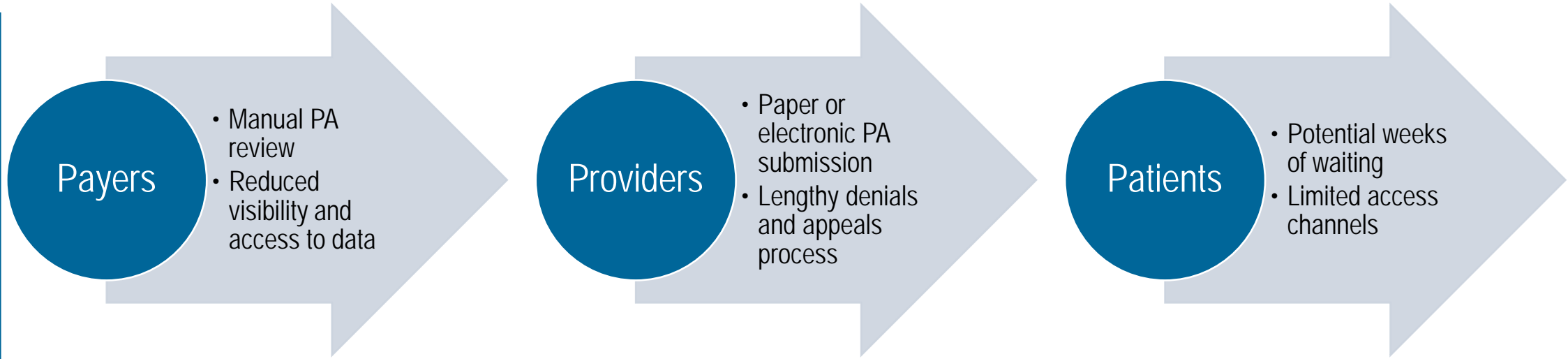
2. Miller KM, Foster NC, Beck RW, et al. *Diabetes Care.* 2015;38(6):971-8.

3. American Diabetes Association. Standards of Medical Care in Diabetes —2020. *Diabetes Care.* 2020;43(Suppl 1):S1-S206.

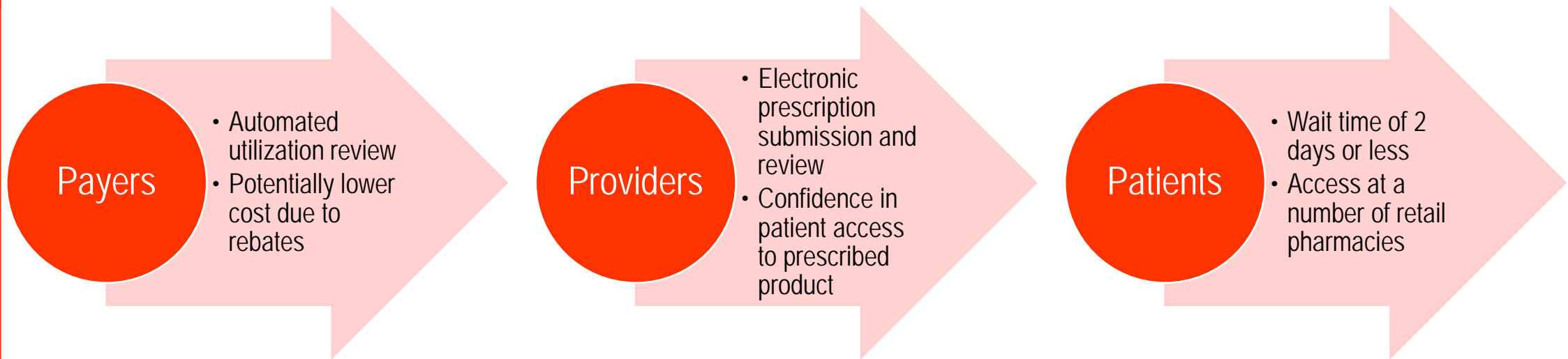
Coverage of CGM via the Pharmacy Benefit Offers a Number of Advantages Over the Medical Benefit for Payers, Providers, and Patients



Medical Benefit



Pharmacy Benefit



Payer Management Effort and Efficiency Varies According to Benefit



Medical

More effort required to monitor and manage utilization due to retroactive claims payment

Paper or electronic form filing for prior authorization

Inefficiencies and potential confusion resulting from standard A-code billing



Pharmacy

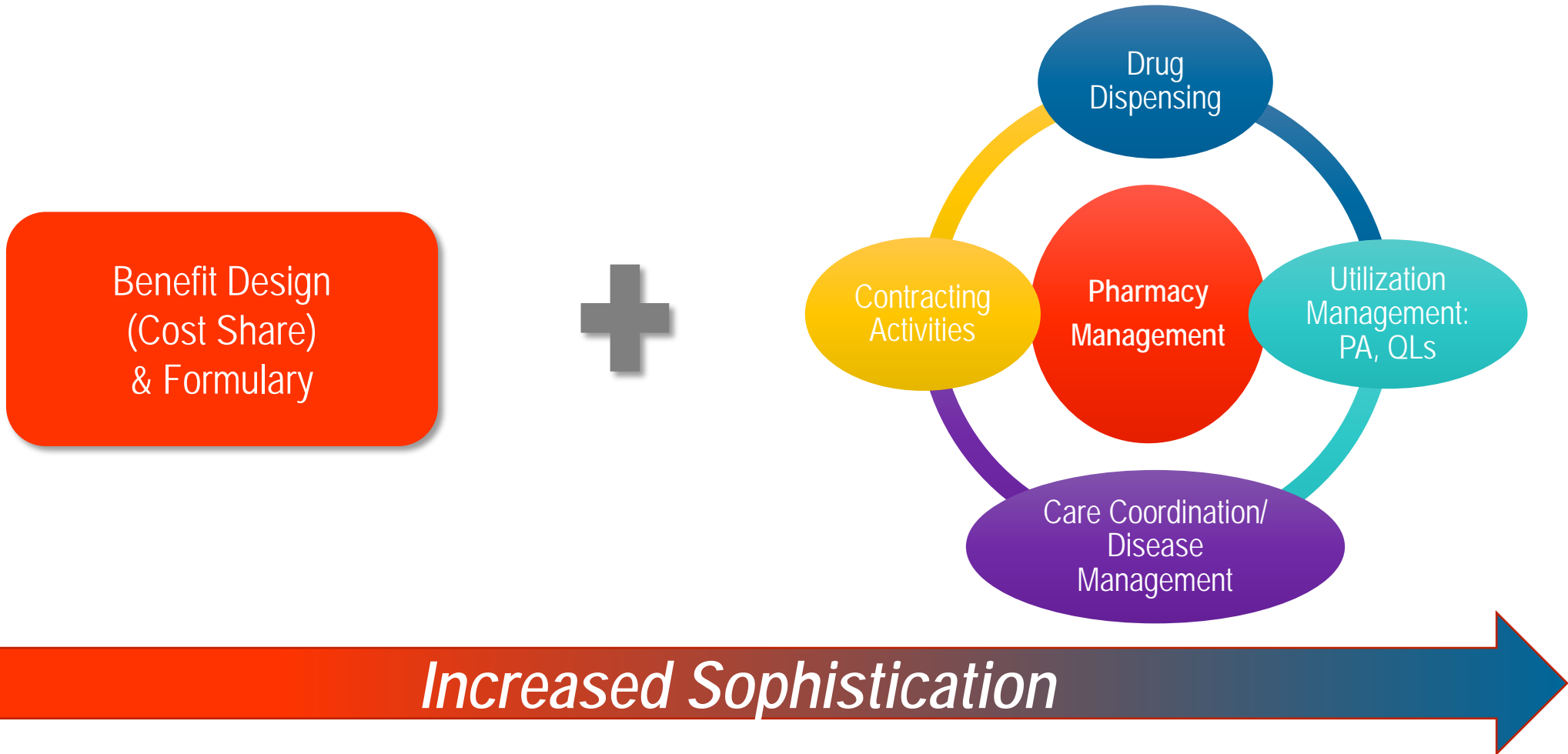
Automated monitoring and management as a function of real-time claims adjudication

Simplified electronic claims approval/denial via step edits

Potential cost savings for payers via management efficiencies



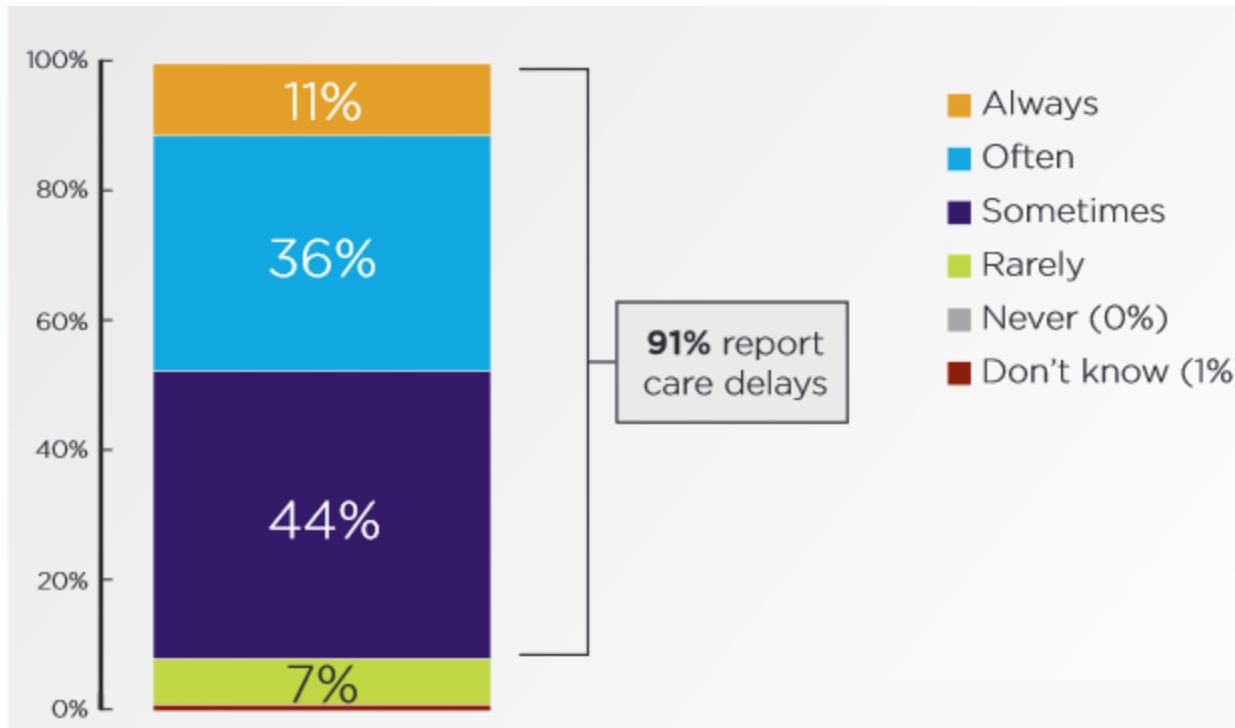
As Interventions Become More Sophisticated, So Must Payer Management Approaches



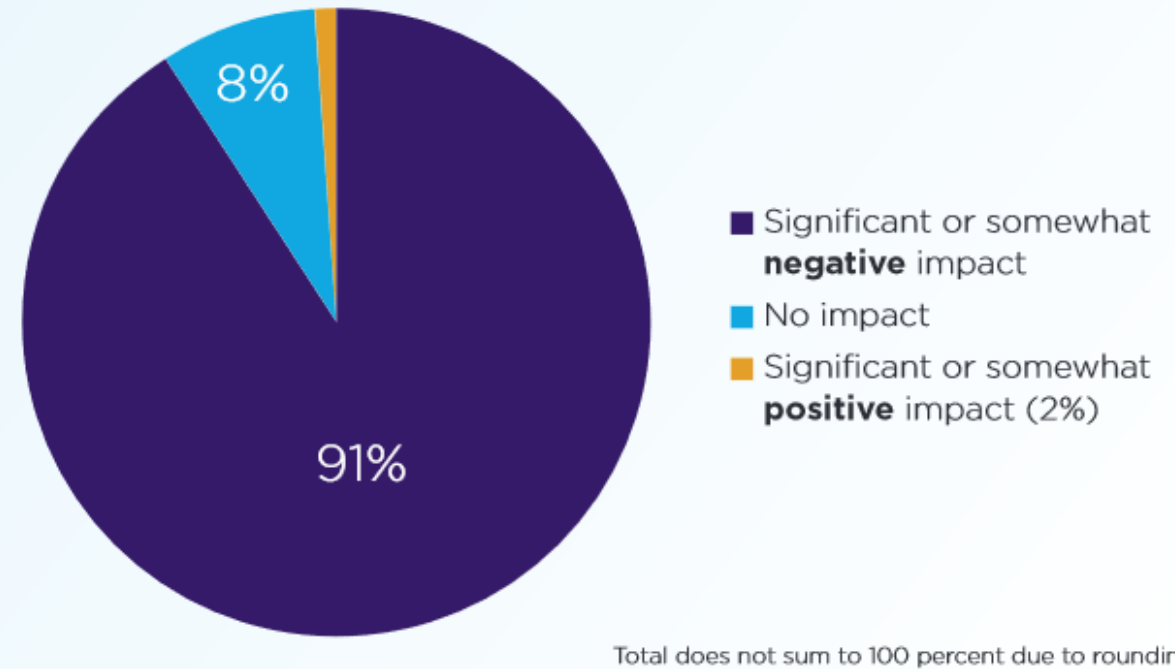
Providers Report Delays in Care and a Negative Impact on Clinical Outcomes as a Result of PA Under the Medical Benefit



Q: For those patients whose treatment requires PA, how often does this process delay access to necessary care?



Q: For those patients whose treatment requires PA, what is your perception of the overall impact of this process on patient clinical outcomes?



Transforming Utilization Management

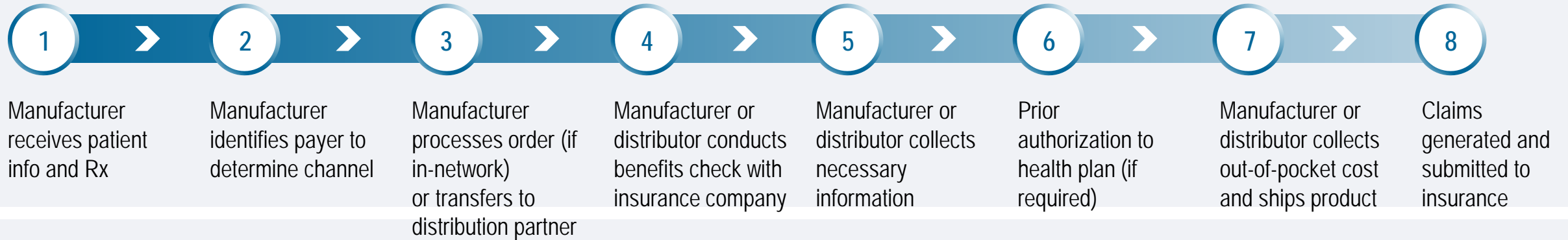


- Reduce cost and utilization management inefficiencies, increase value
- Patient lobbying and physician burden are leading to increased transparency in utilization management outcomes
- Each pre-authorization costs payers and providers \$50-\$100
- Methods to decrease unnecessary UM activities:
 - Automate authorizations in workflow
 - Limit prior authorization to drugs not in national guideline/pathway
 - Limit drug therapy choice in disease states where multiple options targeting same oncogene/tumor suppressor gene are available
 - Link EHRs to medical review to streamline authorizations
 - Track trends in authorization and utilization in aggregate and by provider
 - Refine and update
 - Reflect current guidelines for care
 - Monitor provider outliers

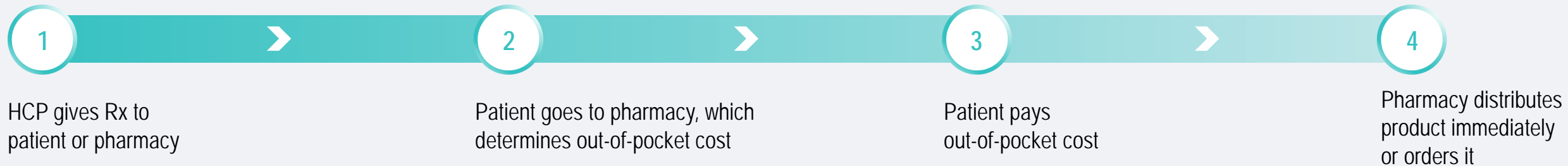
The Pharmacy Channel Improves Efficiencies and Enhances the Member Experience



DME Channel (3-4 Weeks)



Pharmacy Channel (1-2 Days)



Coverage under the pharmacy channel reduces the waiting time by up to 4 weeks

What Does it Look Like to Move rtCGM from the Medical to the Pharmacy Benefit?



PA Criteria:

- Insulin dependent with > 3 insulin injections per day OR insulin pump therapy with frequent dosage adjustments for > 6 months
- Diabetes is uncontrolled with documented average frequency of glucose self-testing > 4 times per day during the previous two months
- A1c > 7.0% OR frequent hypoglycemic episodes

Medical

Pharmacy

- Automated edit that looks back 120 days for a rapid-acting insulin
- 50% savings in acquisition costs resulting from contracting/rebates



Summary



- Diabetes management is improving in managed care, but outcomes remain suboptimal and disease-related costs are significant
- Health technology interventions such as CGM are endorsed by consensus guidelines and have the potential to improve patient-provider connectivity while enhancing the member experience
- Administrative burden and restrictive benefit design can have a detrimental effect on provider prescribing and member access to appropriate clinical interventions
- Access to CGM technology under the pharmacy benefit facilitates prescribing and use of this proven intervention among patients and providers, respectively



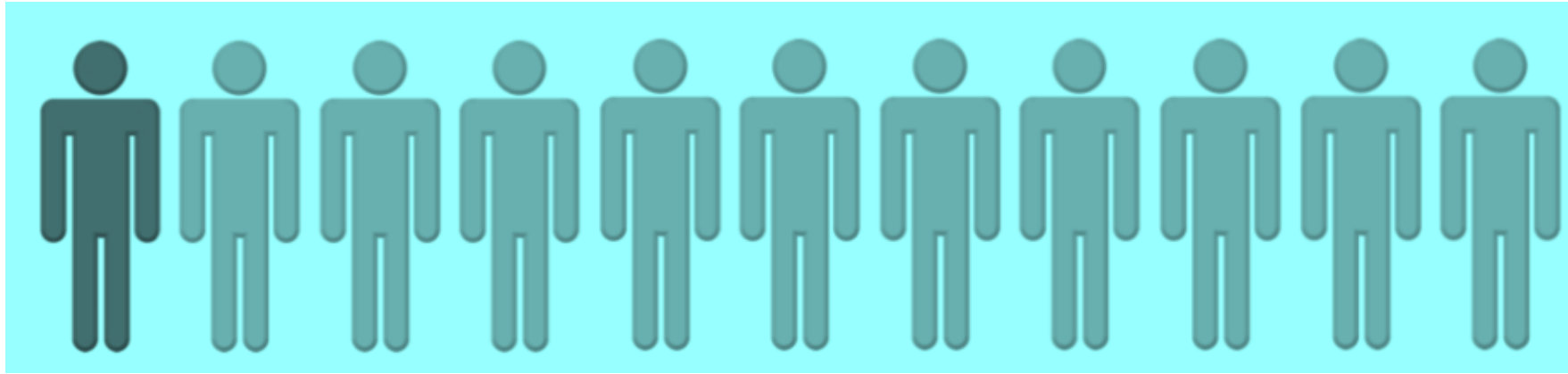
*Optimal Clinical and Economic
Outcomes in Diabetes:
The Employer Perspective*

Troy Ross, MSM

President & CEO

Mid-America Coalition on Health Care

Roughly 1 of Every 11 Adult Americans is Living with Diabetes, Representing a Priority in Employer-Purchased Health Care



This translates to approximately...

...9 employees in a workforce of 100

...45 employees in a workforce of 500

...90 employees in a workforce of 1,000

Plus any affected dependents



Diabetes is the Underlying Cause in 44% of Cases of ESRD, a Leading Stop-Loss Claims Condition

Total payments

31.3%
Top 3 conditions

51.2%
Top 10 conditions

Medical Condition	2015-2018		2014-2017		Stop-loss claim reimbursements 2015-2018	
	Rank	Rank	Total Reimbursements	% of total *		
Malignant neoplasm (cancer)	1	1	\$674.0M	19.3%		
Leukemia , lymphoma, and/or multiple myeloma (cancers)	2	2	\$262.3M	7.5%		
Chronic/end-stage renal disease (kidneys)	3	3	\$159.3M	4.6%		
Congenital anomalies (conditions present at birth)	4	4	\$141.9M	4.1%		
Transplant	5	5	\$117.1M	3.3%		
Septicemia (infection)	6	6	\$104.5M	3.0%		
Liveborn **	7	9	\$93.7M	2.7%		
Complications of surgical and medical care	8	7	\$89.9M	2.6%		
Hemophilia/bleeding disorder	9	10	\$76.7M	2.2%		
Cerebrovascular disease (brain blood vessels)	10	12	\$70.9M	2.0%		
Top 10 conditions			\$1.8B	51.2%		
Total stop-loss reimbursements			\$3.5B			

Source: Sun Life Financial book of business data, 2014–2018.
 2019 Sun Life Stop-Loss Research Report. Sun Life Financial.
https://www.sunlife.com/us/News+and+insights/Insights/ch.2019+Stop-Loss+Research+Report+Injectable+drug+trends.mobile?vgnLocale=en_CA Accessed June 2020.
 Burrows NR, et al. *MMWR*. 2017;66(43):1165–1170

*Percentage of total stop-loss claims reimbursements that Sun Life provided to its policyholders from 2014 to 2017.
 **When the Liveborn diagnosis becomes a high-cost claim, it is often accompanied by additional diagnosis.

The Indirect Cost Burden of Diabetes on Employers Totals \$90 Billion Annually



\$3.3 billion

- increased absenteeism

\$26.9 billion

- reduced productivity while at work for the employed population

\$2.3 billion

- reduced productivity for those not in the labor force

\$37.5 billion

- inability to work as a result of disease-related disability

\$19.9 billion

- lost productive capacity due to early mortality

Employer Approaches to the Management of Diabetes and Other Chronic Conditions are Ever-Evolving and Integrate Multiple Components

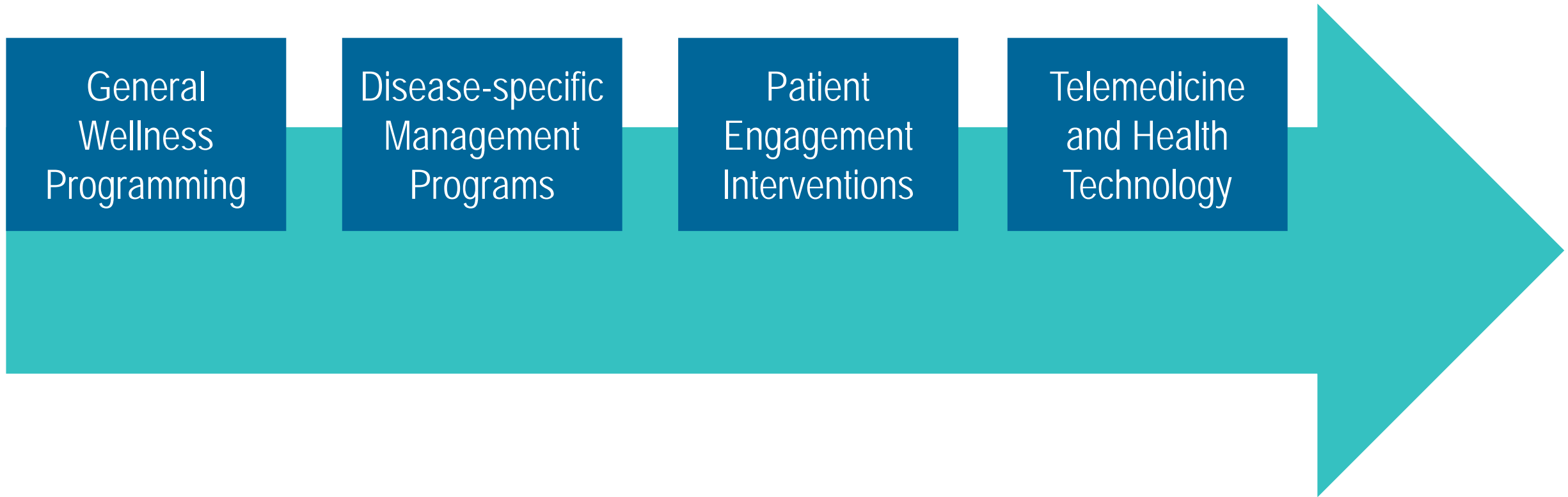


General
Wellness
Programming

Disease-specific
Management
Programs

Patient
Engagement
Interventions

Telemedicine
and Health
Technology



Telehealth and Remote Monitoring Are Further Seeing Increased Uptake Among Employers as a Result of the COVID-19 Pandemic



According to an April 2020 survey of 816 employers...

- 64% believe COVID-19 will have a moderate to large impact on employee wellbeing
- 70% have waived telehealth costs related to COVID-19
- 77% are offering or expanding access to virtual mental health services
- 60% are offering new easy-to-implement virtual solutions such as virtual workouts to support employees who work from home
 - 19% are planning or considering these solutions

Continuous Glucose Monitoring (CGM) is a Key Component of the Health Care Stakeholder Response to COVID-19



Cloud-based software programs (e.g., CLARITY) make it possible to safely reduce in-person, patient-physician encounters while improving outcomes in new-onset T1D

The “Glucose Management Indicator” (a validated, CGM-based “estimated A1C” metric) and Time in Range (TIR) provide critical insights into managing patients without the need to wait 3 months for an A1C

Remote monitoring allows for more frequent communications with the patient via texting, e-mail, and phone with oversight by diabetes specialists

Diabetes Management Programs Have Proven Effective and Center on Patient Engagement



- Studies have shown diabetes management programs have a significant impact on improving A1c and increasing patient-initiated preventative medical screenings for those enrolled
- Early findings of diabetes management programs show results are clearly in favor of such an approach, with enrollees experiencing a number of benefits:
 - More frequent primary care physician visits
 - Increased likelihood of receiving eye, lipid, and kidney screenings
 - Lower blood glucose levels
 - Reduced ED visits
 - 20% lower average monthly cost
- The most effective components of these programs were a high level of provider-to-patient interaction and the ability of coaches to be more proactive in diabetes management

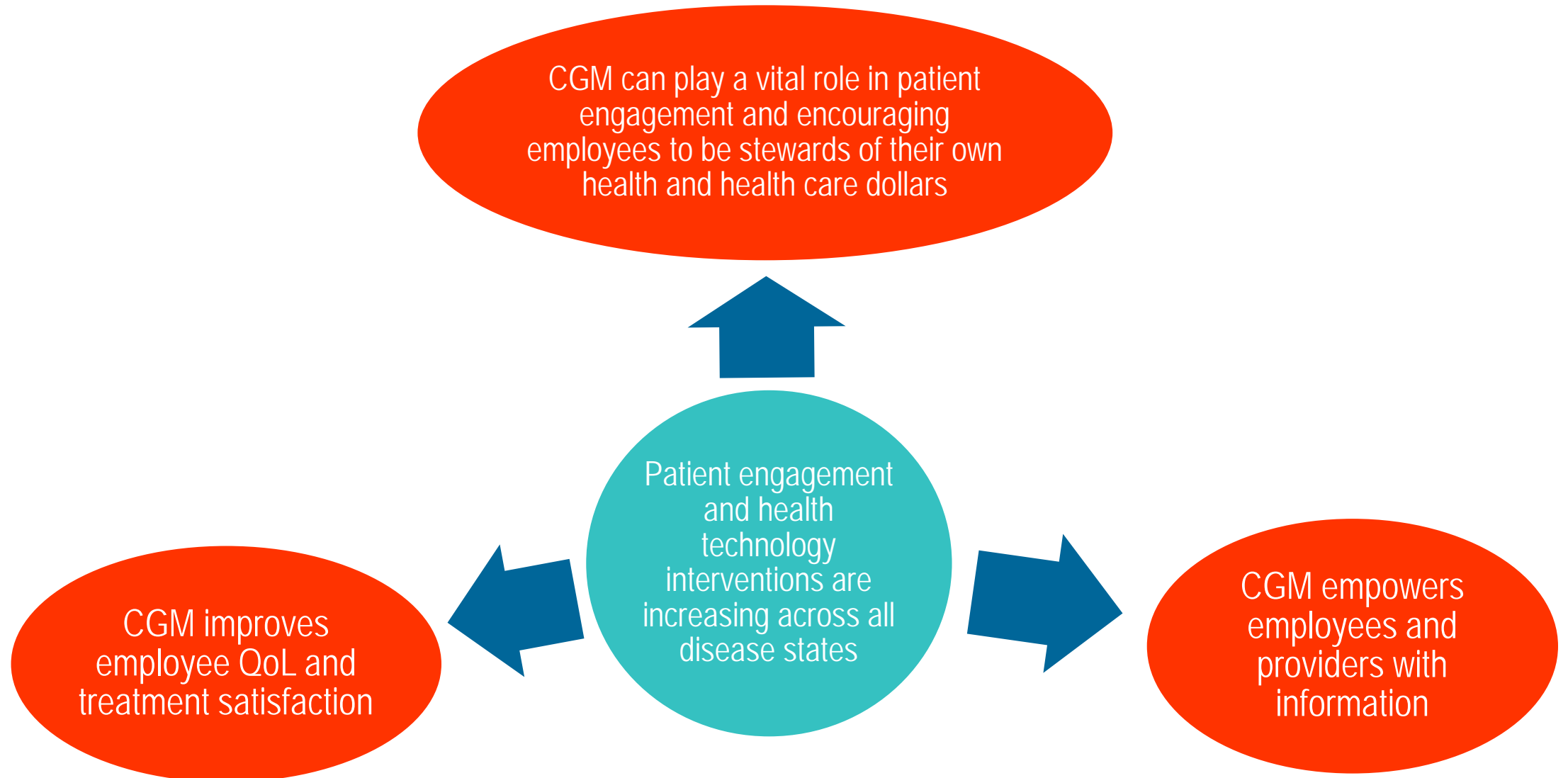
The Economic Implications of Health Technology in Diabetes are Significant



JRDF economic modeling revealed the following:

- Adjunct therapies that reduce HbA1c and improve TIR beyond the rates patients are achieving with insulin therapy would have meaningful economic benefits
 - Medications and interventions that reduce HbA1c by 1.0%-1.5% and improve TIR to 65%+, without significant safety risks, would achieve \$5B-\$10B of annual economic impact in the US
 - Future fully closed-loop CGM and pump systems, which achieve TIR of 95% and minimize user burden, would achieve \$18B in US annual economic impact

The Role of CGM Technology in Employer-driven Health Care



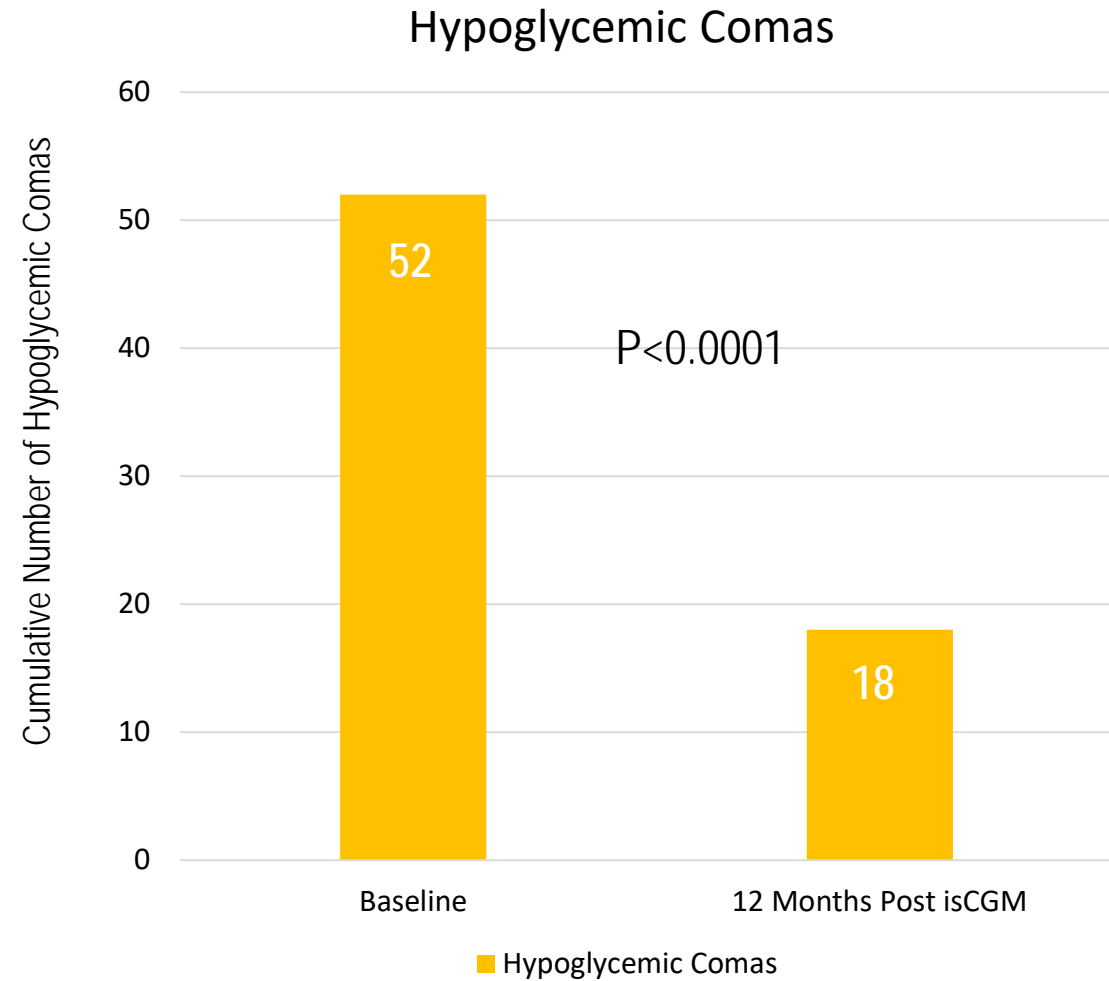
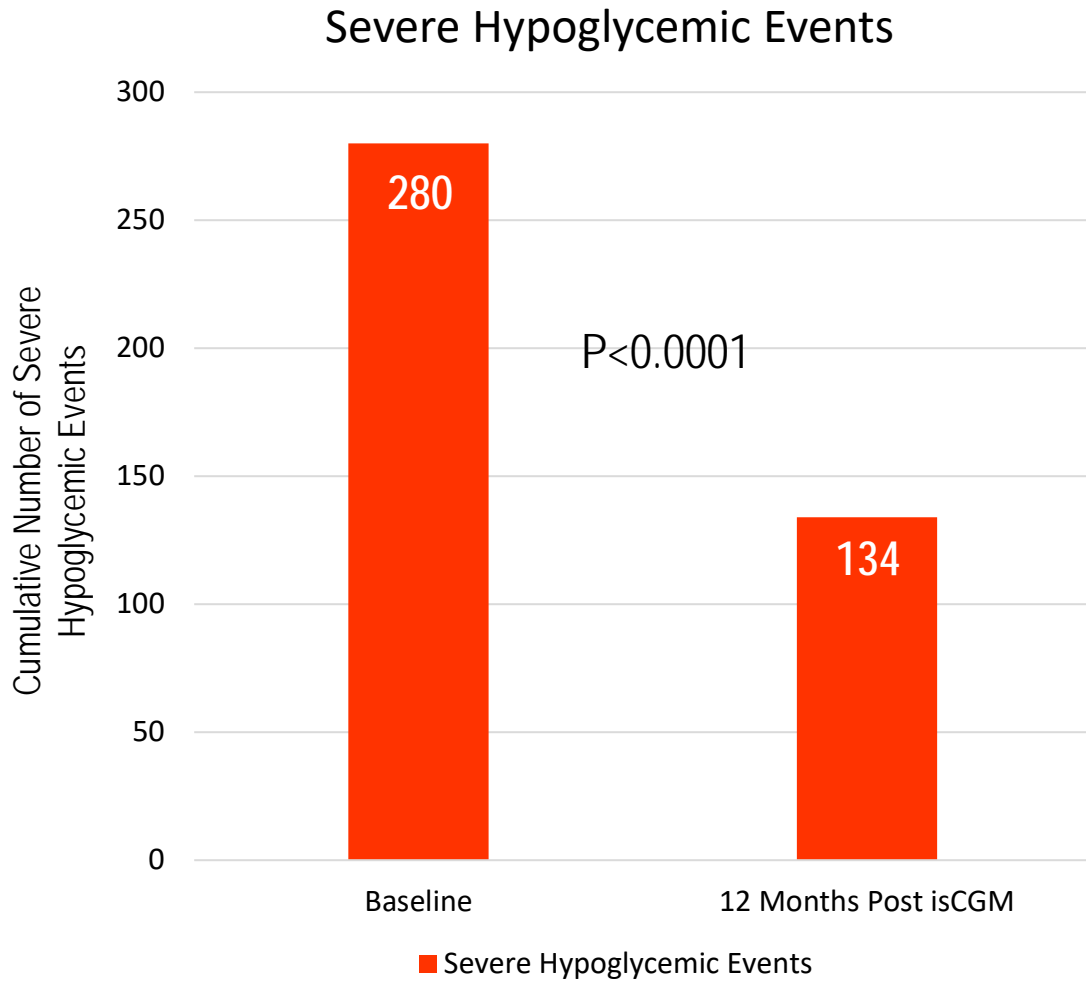
rtCGM Systems with Integrated Smartphone Apps, Push Notifications, and Data Sharing with HCPs Enhance Patient Engagement and Treatment Decision Support



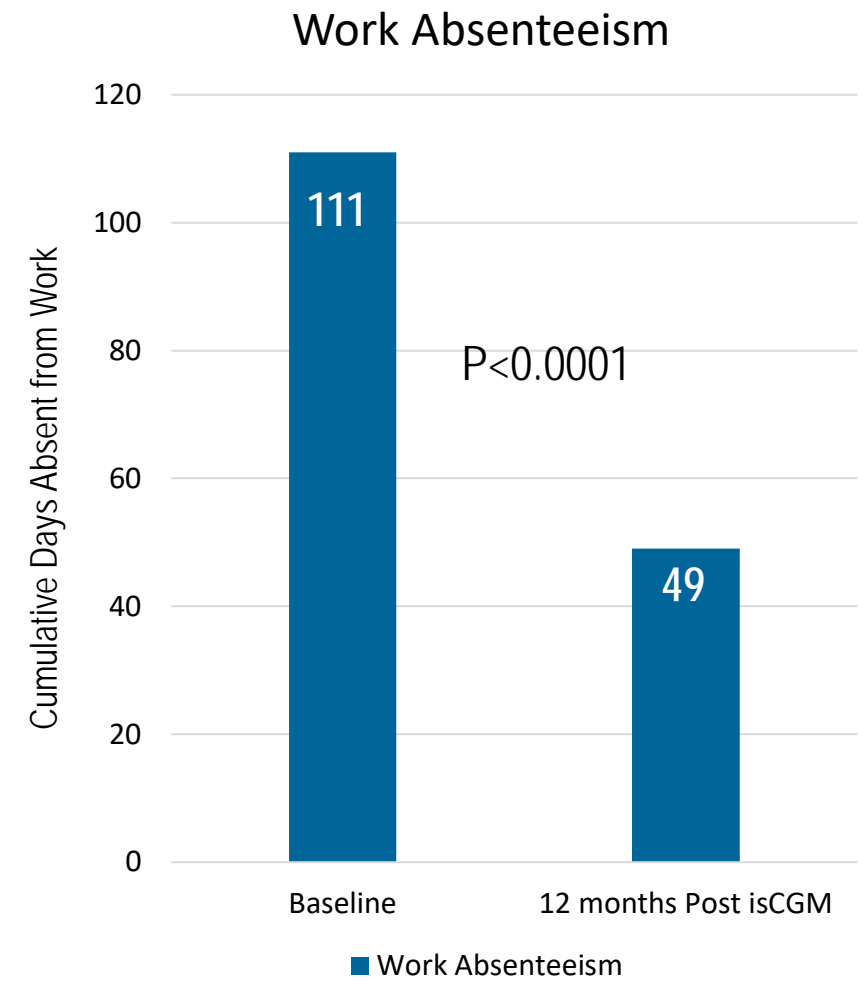
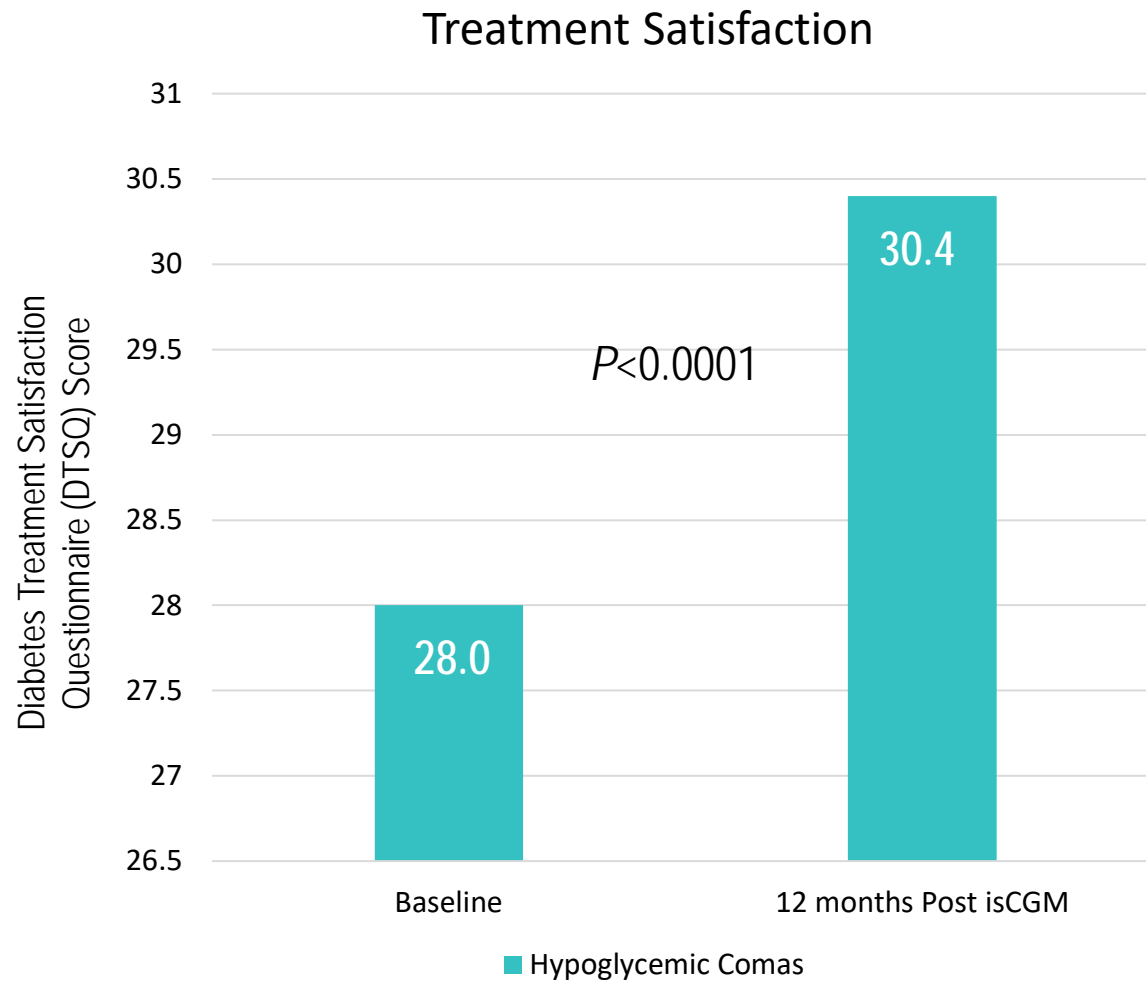
Notifies both patients and clinicians for retrospective review and pattern identification

From an analysis of 50,000 users; patients who logged in four or more times in a month had significantly more time in range (TIR), lower mean sensor glucose values, and less time in hyperglycemia than patients who did not log in during this interval

Reimbursement for isCGM has Demonstrated Improvements in Clinical Outcomes that Drive Health Care Resource Utilization



Reimbursement for isCGM has Demonstrated Improvements in Work Absenteeism and Treatment Satisfaction



Following reimbursement for real-time continuous glucose monitoring in one plan population of 515 adult patients, the reduction in hospitalizations for diabetic ketoacidosis and severe hypoglycemia was ____?

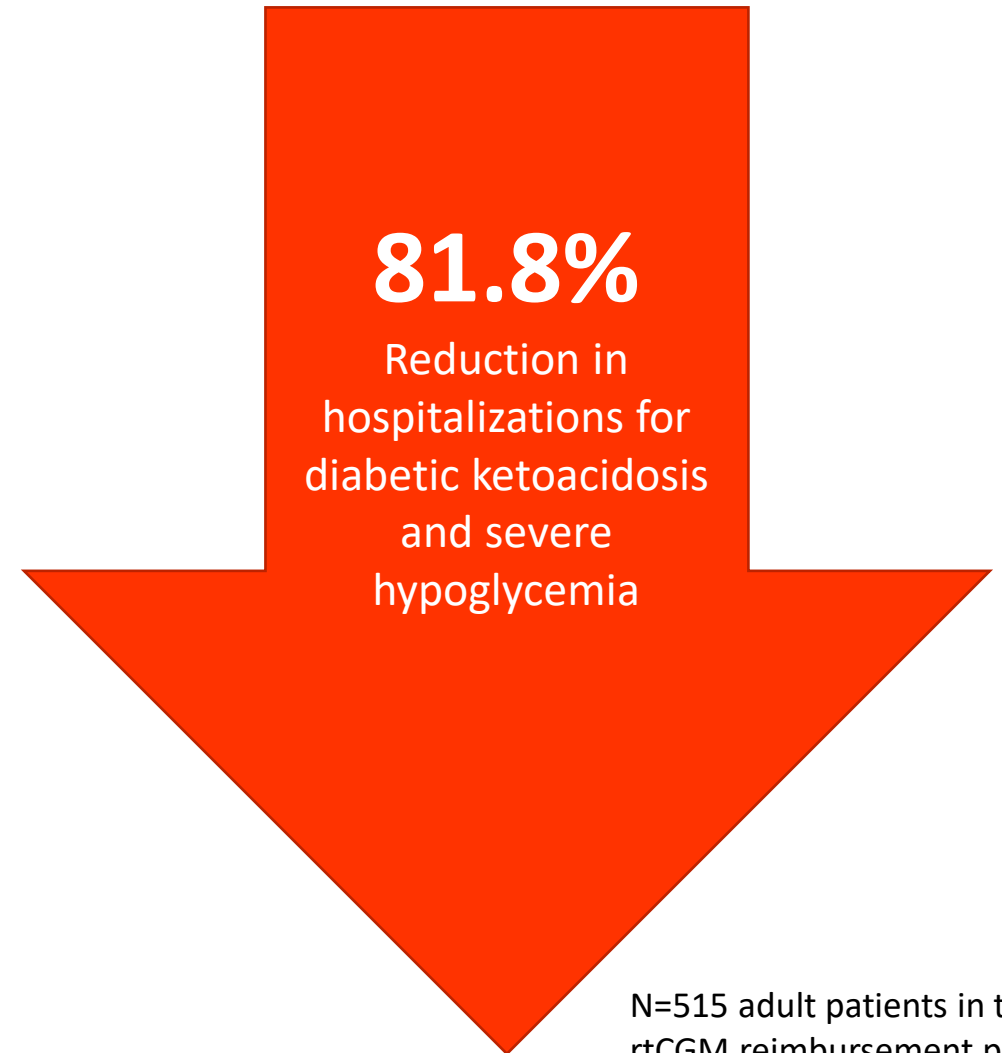
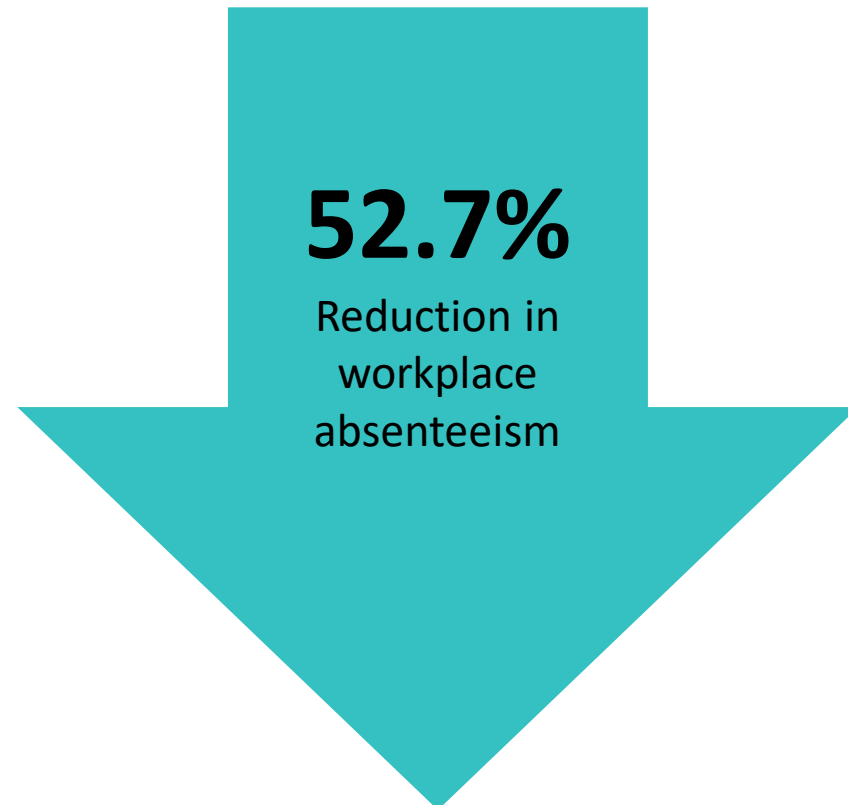
- 1) 28%
- 2) 47%
- 3) 61%
- 4) 82%



The Benefits Associated with Implementation of Reimbursement for rtCGM Have Been Demonstrated in Other Plan Populations



After implementation of reimbursement for rtCGM in one plan population...



N=515 adult patients in the
rtCGM reimbursement program

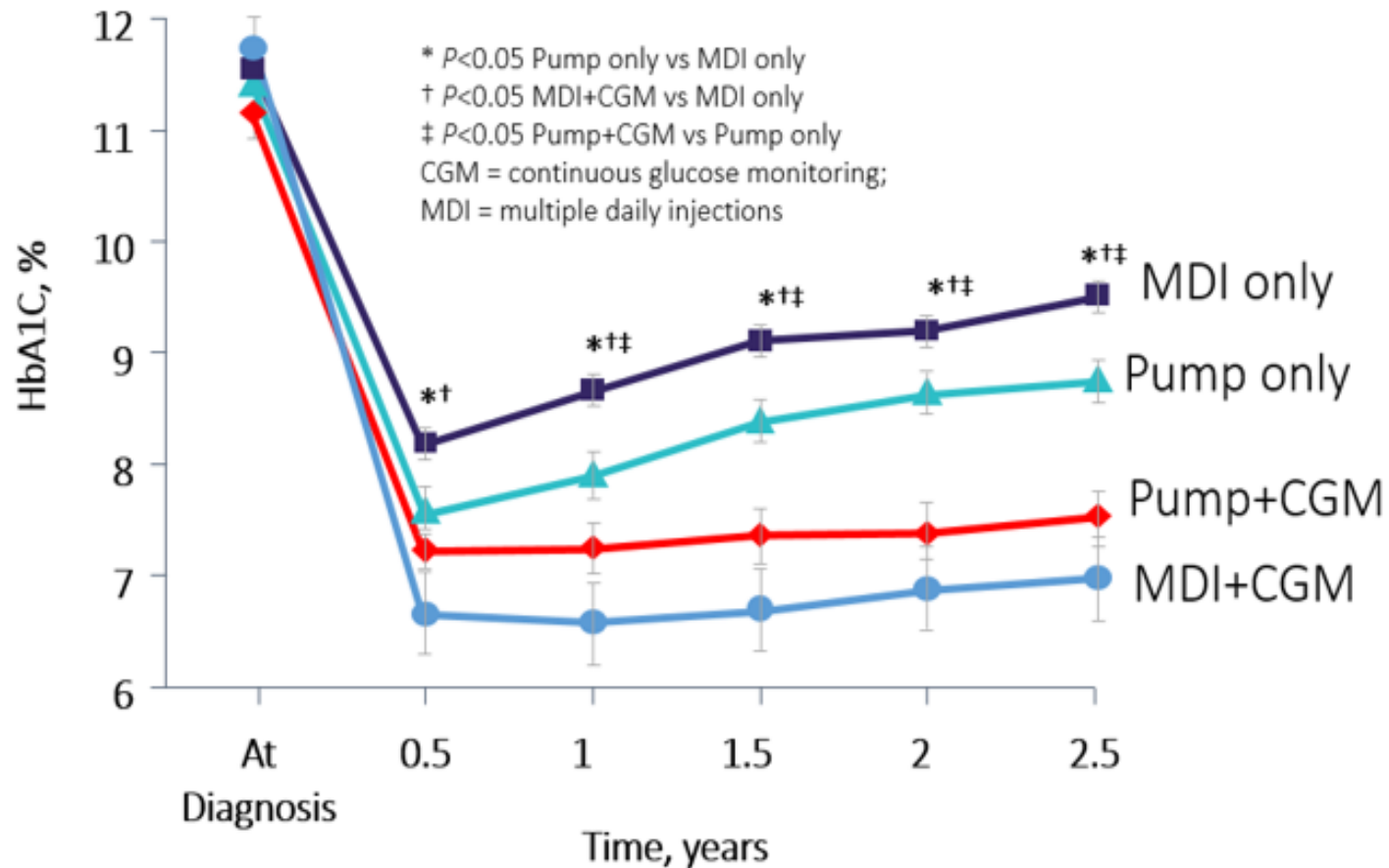
CGM with Remote Monitoring for Dependents Improves Quality of Life Measures Among Beneficiaries



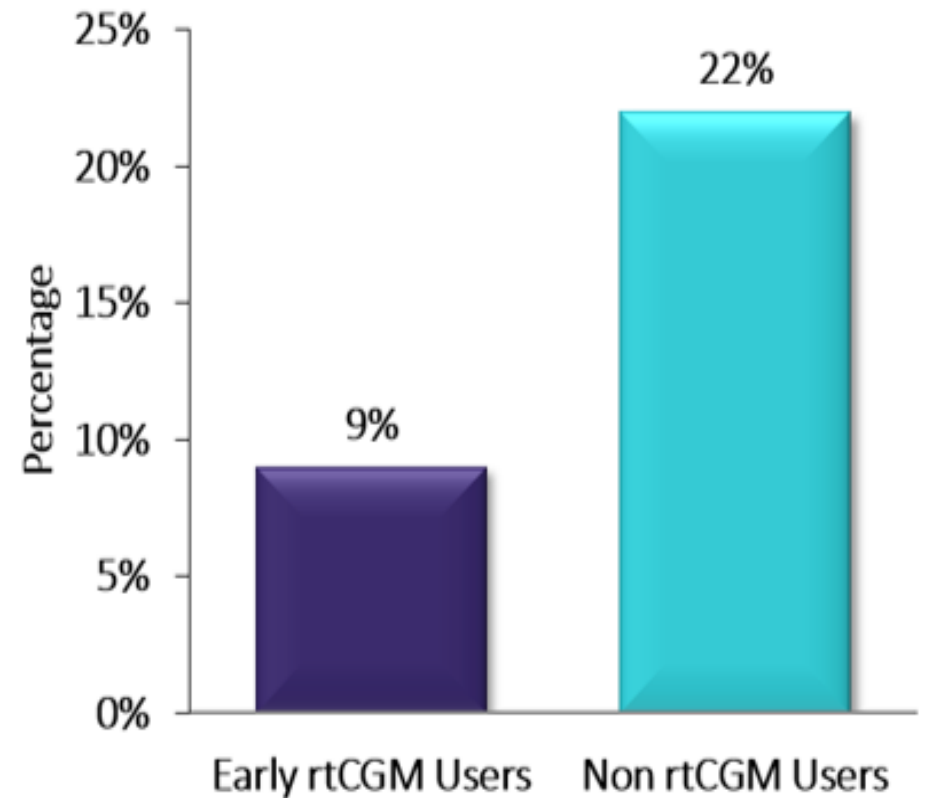
- A survey among 49 children and their parents revealed that Parental Hypoglycemia Fear Survey scores were lower while the child was using CGM with remote monitoring ($P < 0.001$)
- CGM with remote monitoring also improved the following:
 - Parental health-related quality of life and family functioning
 - Stress-related measures
 - Anxiety-related measures
 - Sleep-related measures

Early Initiation of CGM After Diagnosis Improves A1C and Reduces ED Utilization

A1C over 2.5 years after initiation of CGM plus MDI or CSII versus SMBG plus MDI or CSII within 1 year of diagnosis



ED visits over 2.5 after initiation of CGM versus non-CGM users



Plan Document Language can Provide Clear Approval for Pharmacy Coverage of rtCGM for Beneficiaries to Ensure Appropriate Access



Covered Under Both the Medical and Pharmacy Benefit

- The Plan Document is the central mechanism by which a plan sponsor can control the coverage of medical and pharmacy services and directs the claims administrator
- Claims administrators prefer clear and concise guidance in their employers' Plan Documents
- A Plan Document can be a living document addressing new needs on a frequent basis in an ever-changing landscape

Financing



- Education (Follow the money)
- Managing Cost / Risk
- Carve Out
- Reinsurance

Plan Document

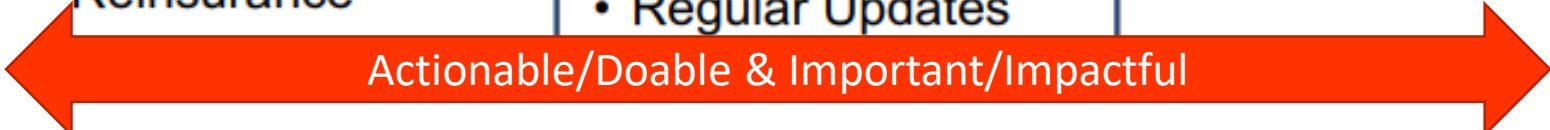


- Pre-Cert / Pre-Authorization
- Step Therapies
- Steerage
- Utilization
- Waiting Periods
- Regular Updates

Roles & Responsibilities



- TPA/PBM
- Broker
- Carrier
- Plan Sponsor
- Medical Management



Summary



- Collectively, employers represent the largest single purchaser of health care in the United States
- While the direct medical costs of diabetes are significant, the indirect cost of the disease on employers may pose an even greater economic burden
- Patient engagement and health technology represent key areas of employer focus in the management of diabetes and other chronic conditions
- CGM leverages these elements in the care of employees with diabetes
- Coverage and reimbursement of CGM has been associated with reduced health care resource utilization, reduced workplace absenteeism, and increased treatment satisfaction
- Plan Document language should clearly outline coverage of rtCGM under the pharmacy benefit to ensure appropriate access for beneficiaries

Faculty Idea Exchange and Q&A Session



Daniel DeSalvo, MD
Assistant Professor
Pediatric Endocrinologist
Baylor College of Medicine
Texas Children's Hospital



Jeffrey Dunn, PharmD, MBA
(Formerly) Vice President, Clinical
Strategy and Programs and Industry
Relations
Magellan Rx Management



Troy Ross, MSM
President & CEO
Mid-America Coalition on Health Care

How to Claim Credit



Option 1: Complete the online post-survey and evaluation form immediately following the live webcast. The link to the survey will appear on your screen at the conclusion of the webcast. If you are unable to fill out the evaluation immediately following the webcast, please note that a personalized evaluation link will be emailed to you following the webcast at the account you registered with. Once you fill out your evaluation, your certificate will be emailed to you.

For Pharmacists, in order to submit your credit to the CPE Monitor:

Please go to www.impactedu.net/cpe

Enter code: **0619**

You will then need to log in or create an account ensuring your NABP information is entered and correct. Be sure to enter today's date, **June 19, 2020**, as the date of participation. You will be immediately notified if your submission has been accepted or if there are any issues. Once accepted, the record of your participation will appear in the CPE Monitor within 48 hours. **Credit must be uploaded to CPE Monitor within 30 days.**

Option 2: Print the 'Fax Evaluation Form' in the *Handouts* section and turn in the completed version via fax or email to the number or email address located at the top of the form. A certificate will be emailed to you within 3-4 weeks.

For Pharmacists: upon receipt of the completed evaluation form, you will receive an email within 3 weeks with a link and directions to submit your credit to the NABP CPE Monitor Service. **Pharmacists have up to 30 days to complete the evaluation and claim credit for participation so that information can be submitted to CPE Monitor as required.**



THE VALUE OF CONTINUOUS GLUCOSE MONITORING during the **COVID-19** Pandemic and New Era of Digital Healthcare



Jointly provided by



This activity is supported by an independent educational grant from Dexcom, Inc.

Live Webcast

**Friday, June 19, 2020
1:00 PM – 2:30 PM ET**