

con il patrocinio di



Percorsi in diabetologia: dai target ai benefici per la persona con diabete

Percorsi terapeutici della U.O.C. Medicina Interna
ad indirizzo Diabetologico DACP - AUSL Modena



24 Settembre 2022
Modena

RMH DES ARTS Hotel
Via Luigi Settembrini, 10

Dichiarazione dei conflitti d'interesse

- **Brunetti Massimo**

Direttore Comunicazione, Relazioni Esterne e Promozione della Salute Azienda
USL di Modena

Nessun conflitto di interesse

- **Daniela Piani**

FF Direttore UOC Medicina Interna ad indirizzo Diabetologico – DACP - Azienda
USL di Modena

ASTRA ZENECA

MSD

ELI LILLY

Persone con T1DM & Devices High Tech. Costo e qualità della vita a confronto

*Percorsi in diabetologia:
dai target ai benefici
per la persona con diabete*

Percorsi terapeutici della U.O.C. Medicina Interna
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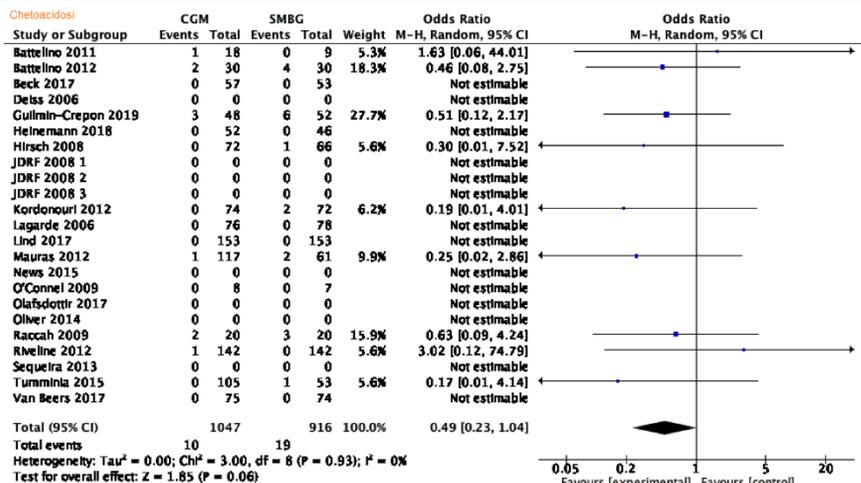
Daniela Piani

Con la collaborazione di Massimo Brunetti

CONTENUTI

- 1. Quali sono le evidenze che la tecnologia CGM migliori gli outcomes nella gestione del T1DM?**
- 2. Quali sono i costi della gestione del T1DM?**
- 3. Qual è il rapporto costo-efficacia della tecnologia CGM standalone?**

Quali sono le evidenze che la tecnologia CGM migliori gli outcomes nella gestione del T1DM?



Effects of real-time continuous glucose monitoring in type 1 diabetes: a meta-analysis of randomized controlled trials

I. Dicembrini^{1,2} · C. Cosentino¹ · M. Monami¹ · E. Mannucci^{1,2} · L. Pala¹

Acta Diabetologica 2021; 58:401-410

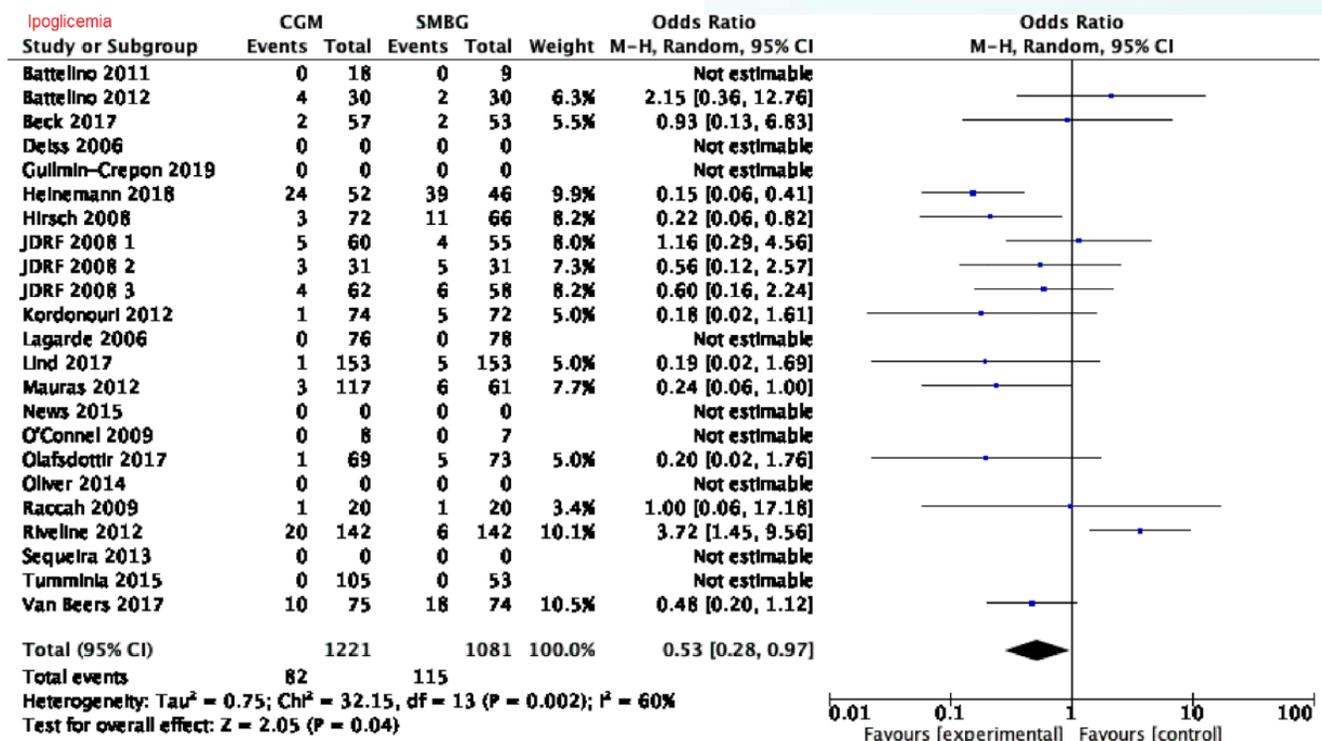
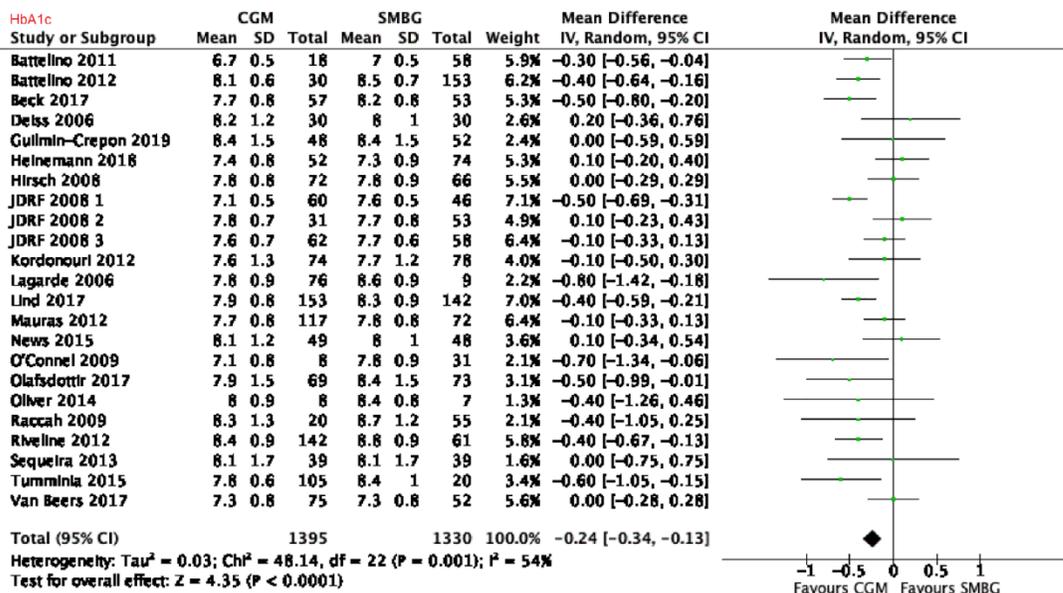


Table 1

Results for type 1 diabetes mellitus reduction in hemoglobin A1c and hypoglycemia

Study	Baseline			Outcome		
	n	Length	Hemoglobin A1c	Δ Hemoglobin A1c	Hemoglobin A1c <7.0%	Severe Hypoglycemia
JDRF-CGM	52	6 mo	7.6	-0.5	30%	21.8
JDRF-CGM 6 mo	51	1 y	7.6	-0.5	29%	7.1
Deiss	81	3 mo	8.1	-0.6	27%	NA
O'Connell	15	3 mo	7.3	-0.4	56%	NA

Studi:
JDRF-CGM
DIAMOND
IN-Controll

Nelle persone con T1DM e HbA1c elevata l'introduzione del CGM produce una **significativa e sostanziale riduzione della HbA1c**

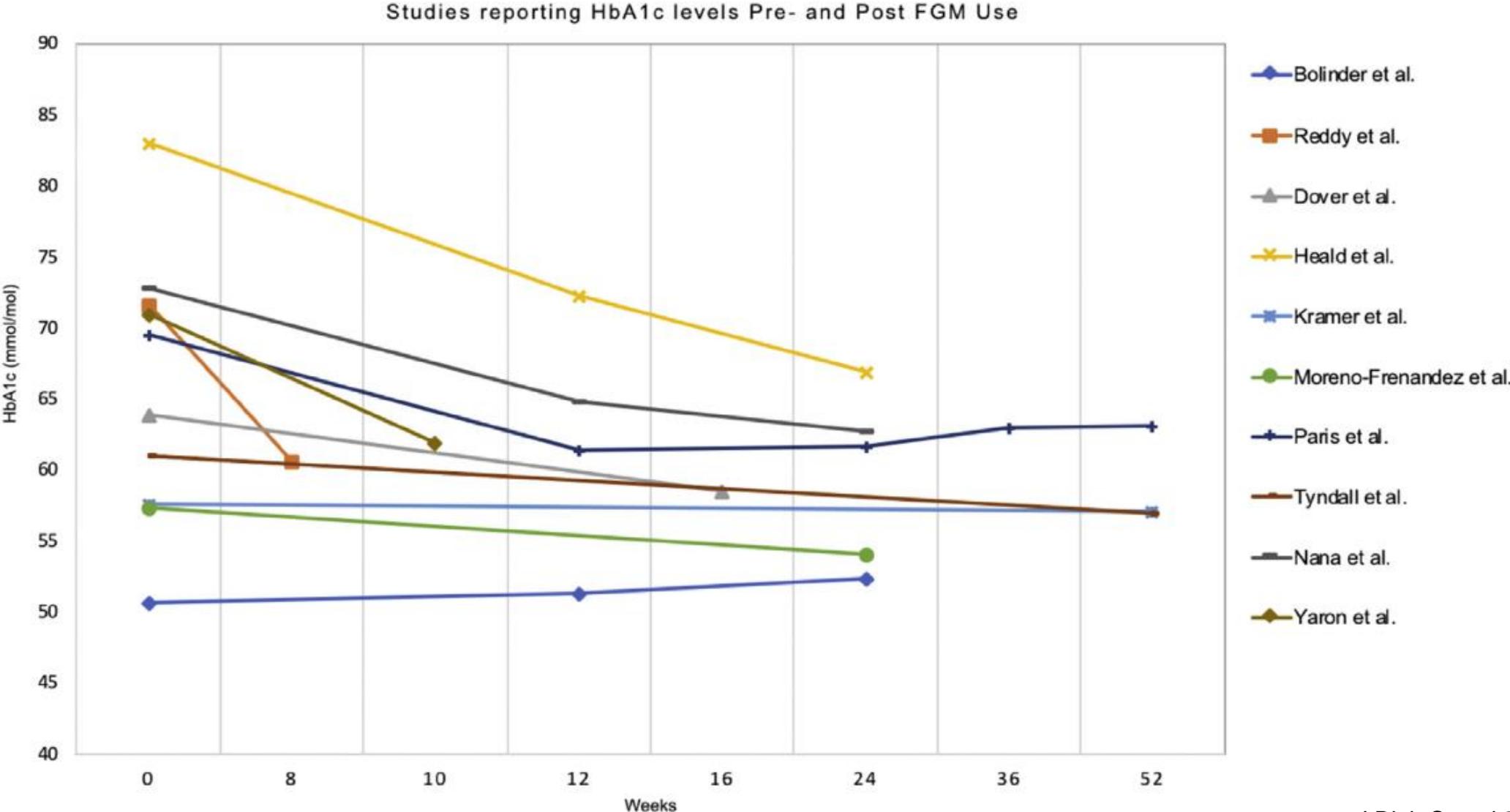
La riduzione della HbA1c è proporzionale al suo livello al baseline e al **tempo di uso del CGM**

Il miglioramento della HbA1c è stato dimostrato per tutte le fasce di età, ma in particolare per 8-14 anni e **>25 anni**

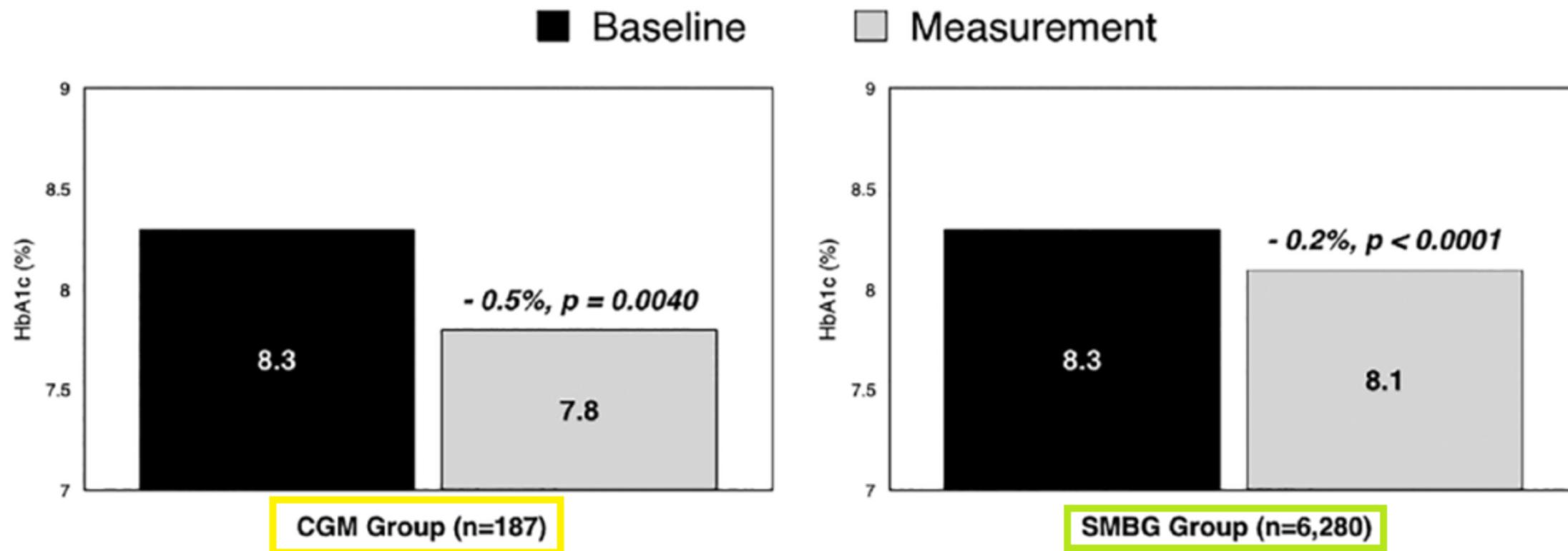
Nelle persone ad alto rischio di ipoglicemia, l'utilizzo del CGM consente di ridurre gli eventi ipoglicemici del **30-50%**



Flash glucose monitoring (FGM): A clinical review on glycaemic outcomes and impact on quality of life



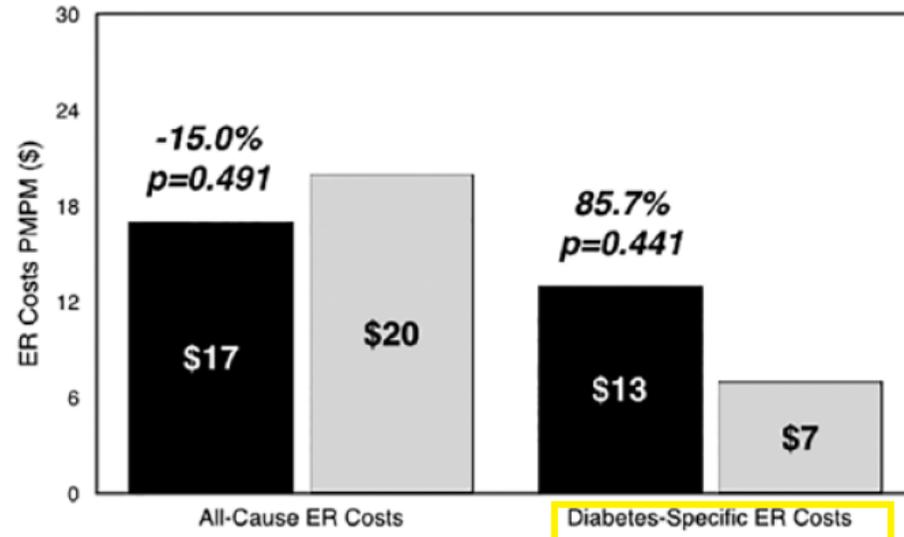
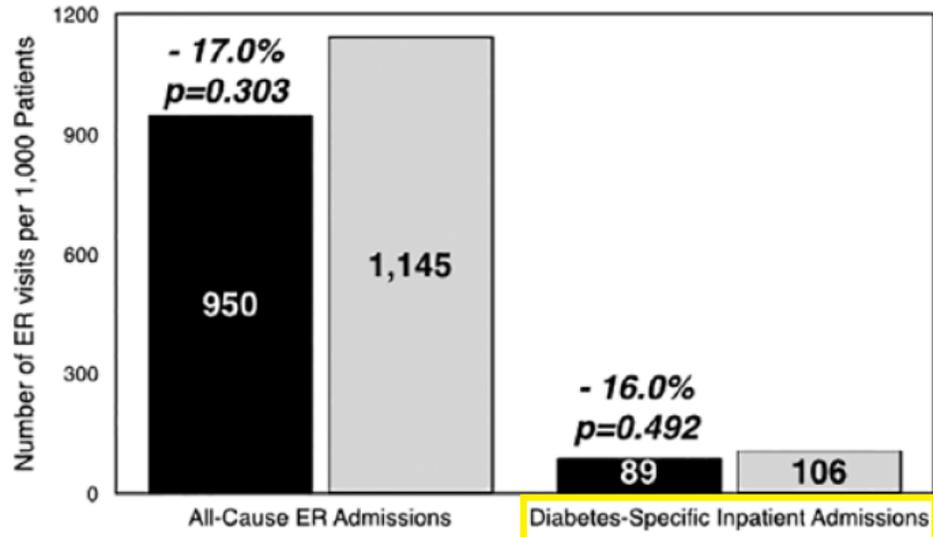
Continuous Glucose Monitoring Use in Type 1 Diabetes: Longitudinal Analysis Demonstrates Meaningful Improvements in HbA1c and Reductions in Health Care Utilization



Data for the study were obtained from the Optum Research Database (Optum, Eden Prairie, MN, USA), which contains eligibility, pharmacy claims, medical claims and laboratory data for more than 14 million enrollees in fully insured and self-funded health care plans.

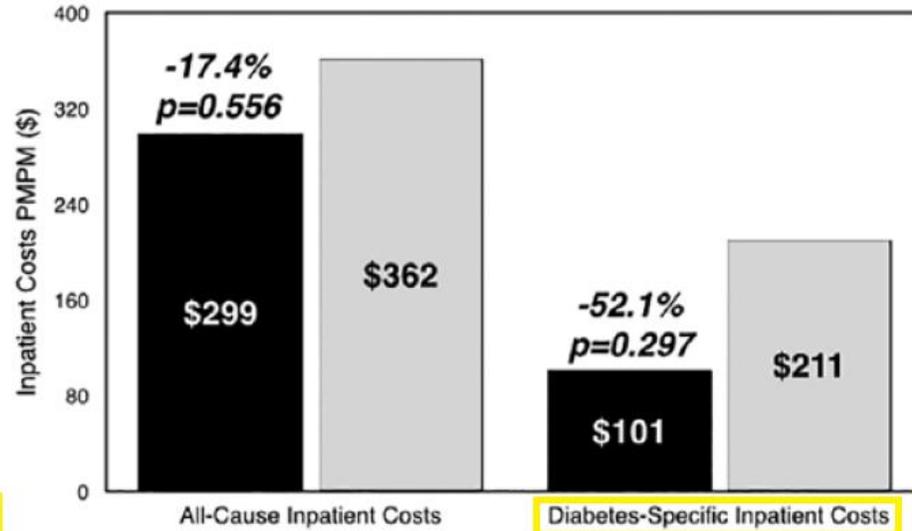
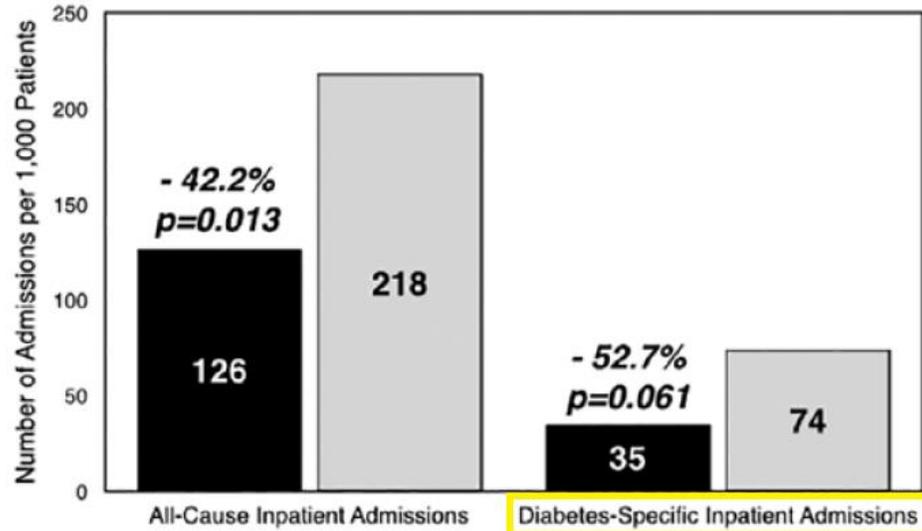
ACCESSO IN PRONTO SOCCORSO

■ CGM (n=565) ■ SMBG (n=565)



RICOVERI

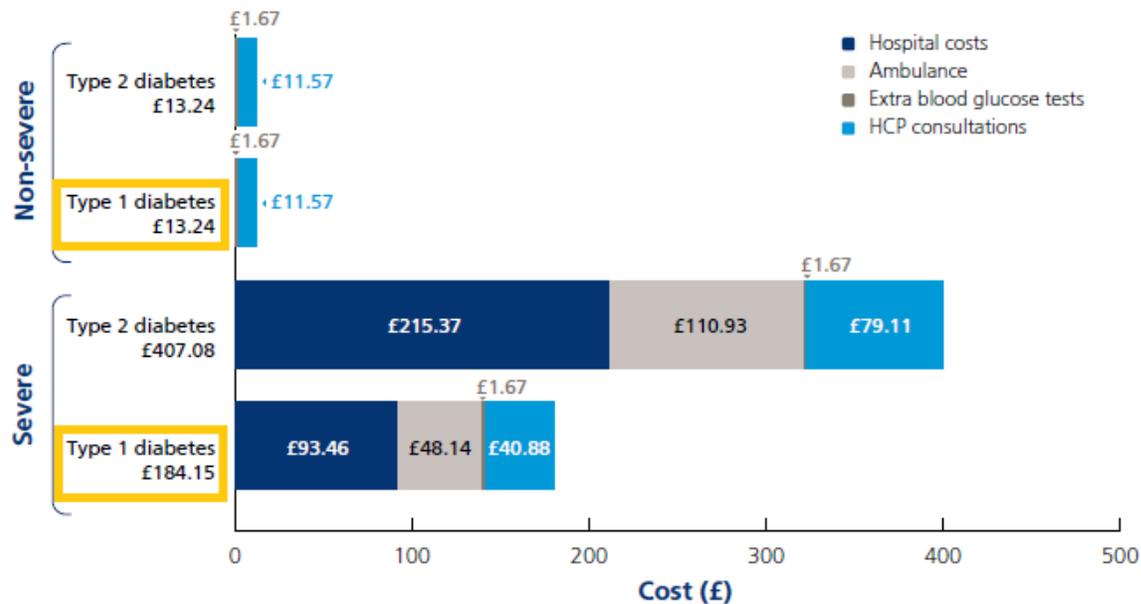
■ CGM (n=565) ■ SMBG (n=565)



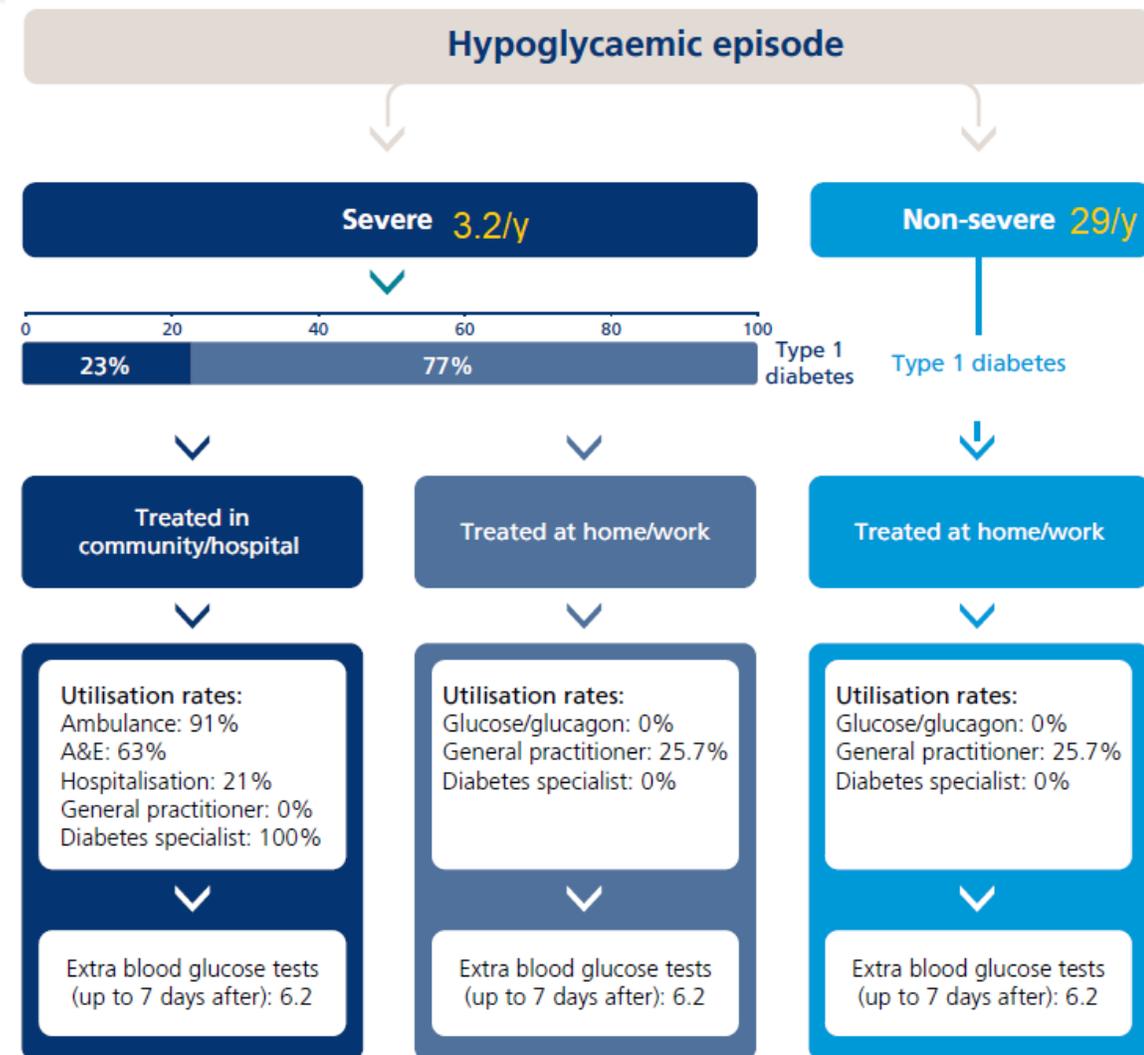
COSTI DIRETTI

COSTI «FISSI» E «SUNK COSTS»	COSTI VARIABILI
DIAGNOSI & SCREENING	MONITORAGGIO GLICEMICO
TERAPIA IPOGLICEMIZZANTE	COMPLICANZE ACUTE: IPOGLICEMIA SEVERA E CHETOACIDOSI
MEDICINA SPECIALISTICA	Ambulanze, accesso in PS, ospedalizzazione, SMBG, consulto medico
PROGRAMMI DI EDUCAZIONE TERAPEUTICA	COMPLICANZE CRONICHE
PROGRAMMI DI VACCINAZIONE	Terapie, cure, ricoveri per complicanze d'organo etc

Quali sono i costi della gestione del T1DM?



Population	Severe	Non-severe	Total
Sample general population (100 000)	Type 1 diabetes (474 people)		
	£279,317	£181,983	£461,300



COSTI DIRETTI USA

Vigersky RA J Diab Sci Thec 2015; 9(2):320-330

Estimate Cost of Hypoglycemia Admissions in Patients With Type I

	Lowest rate of hypoglycemia/year for type I diabetes	Highest rate of hypoglycemia/year for type I diabetes
Patients	1.0 million	1.0 million
Insulin-requiring patients	1.0 million	1.0 million
Hypoglycemia unaware patients ^b	200 000	200 000
Severe hypoglycemia events	480 000 ^c	1 600 000 ^d
Hospitalizations ^e	100 800	336 000
Cost of hospitalization (\$) ^f	1.8 billion	5.9 billion

^b20% hypoglycemia unawareness in type I diabetes

^cLow annual rate of severe hypoglycemia events: 2.4/pz/y

^dHigh annual rate of severe hypoglycemia events: 8.1/pz/y

^e21% hospitalization rate for severe hypoglycemia

^fCost of hospitalization for severe hypoglycemia = \$17 564.

Quali sono i costi della gestione del T1DM?

COSTI INDIRETTI della IPOGLICEMIA

PERDITA ORE DI LAVORO

PERDITA PRODUTTIVITA'

COSTI SOCIALI

COMPORAMENTI REATTIVI ->

SCELTE TERAPEUTICHE CHE INCIDONO SUGLI OUTCOMES INTERMEDI E DI ESITO

COSTI INTANGIBILI

PAURA DELLA IPOGLICEMIA

VITALITA'

RUOLO SOCIALE

PERCEZIONE SOGGETTIVA DEL BENESSERE FISICO

(SF-36 SelfFunctioning; Problem Areas in Diabetes, short form [PAID-SF Problem Areas in Diabetes short form] ;
Hypoglycemia Fear Survey [HFS]–Worry;
Diabetes Treatment Satisfaction Questionnaire [DTSQ]
EQ-5D 5-Level-Euro-QoI Dimension (mobility, self-care, usual activities, pain/discomfort, anxiety/depression)

The Impact of Non-Severe Hypoglycemic Events on Work Productivity and Diabetes Management

VALUE IN HEALTH 2011: 14:665-671

Meryl Brod, PhD^{1,*}, Torsten Christensen, MSc², Trine L. Thomsen, BSc, MSc², Donald M. Bushnell, MA³

¹The Brod Group, Mill Valley, CA, USA; ²Novo Nordisk A/S, Virum, Denmark; ³Health Research Associates, Mountlake Terrace, WA, USA

– Productivity impact of an NSHE.

	Total	USA	UK	Germany	France	P value
NSHE during working hours, N (with 5% trim)*	N = 963	N = 278	N = 232	N = 170	N = 283	
Missing work time, N (%)	176 (18.3%)	30 (10.8%)	54 (23.3%)	15 (8.8%)	77 (27.2%)	<0.001 [§]
If missing work time, what was the amount of work time lost, mean (SD)	9.9 (8.4)	10.2 (9.5)	11.4 (9.2)	8.3 (7.1)	8.9 (7.6)	0.467
Missing a meeting/appointment or not finishing a project in due time because of the NSHE, (N) %	231 (23.8%)	48 (17.2%)	68 (28.8%)	29 (17.0%)	86 (30.1%)	<0.001 [§]
NSHE outside working hours, N (with 5% trim)†	N = 1046	N = 307	N = 287	N = 173	N = 279	
Missing work time, N (%)	150 (14.3%)	26 (8.5%)	41 (14.3%)	14 (8.1%)	69 (24.7%)	<0.001 [§]
If missing work time, what was the amount of work time lost, mean (SD)	12.6 (11.0)	11.1 (10.5)	15.1 (13.6)	9.2 (7.4)	12.4 (9.9)	0.268
Missing a meeting/appointment or not finishing a project in due time because of the NSHE, N (%)	173 (16.4%)	39 (12.7%)	49 (17.0%)	17 (9.7%)	68 (24.2%)	<0.001 [§]
Nocturnal NSHE, N (with 5% trim)‡	N = 612	N = 205	N = 153	N = 88	N = 166	
Missing work time, N (%)	139 (22.7%)	29 (14.1%)	43 (28.1%)	14 (15.9%)	53 (31.9%)	<0.001 [§]
If missing work time, what was the amount of work time lost, mean (SD)	14.7 (11.6)	14.3 (11.8)	14.2 (10.2)	12.5 (12.7)	15.9 (12.5)	0.787
Missing a meeting/appointment or not finishing a project in due time because of the NSHE, N (%)	197 (31.8%)	48 (23.3%)	62 (40.3%)	20 (22.2%)	67 (39.4%)	<0.001 [§]

NSHE, non-severe hypoglycemic events.

COST INDIRETTI NSHE

– Productivity loss* of an NSHE. COSTOANNUO 1939-2986 USD

	USA	UK	Germany	France	P value
NSHE outside working hours \$, (SD), N	26.43 (121.26) N = 307	46.30 (157.60) N = 287	15.50 (67.24) N = 173	61.12 (144.41) N = 279	<0.001
NSHE at work \$, (SD), N	31.12 (124.91) N = 278	57.21 (140.51) N = 232	15.26 (65.16) N = 170	48.33 (111.58) N = 283	<0.001
NSHE at sleep at night \$, (SD), N	55.16 (184.17) N = 205	83.59 (177.30) N = 153	35.58 (130.27) N = 88	93.47 (197.62) N = 166	0.002

NSHE, non-severe hypoglycemic event.
* Costs provided in US dollars (USD).

Population	Severe	Non-severe	Total
Sample general population (100 000)	Type 1 diabetes (474 people) £42,493	£385,092	£427,585

Mild or Moderate Hypoglycemic

Episodes

Severe Hypoglycemic Episodes

Lifestyle Changes, %[†]

	T1DM (n = 193)	T2DM (n = 97)	T1DM (n = 55)	T2DM (n = 19)
Modified insulin dose to avoid future hypoglycemia	74.1	43.3	78.2	57.9
Ate extra food	66.8	62.9	70.9	63.2
Had greater fear of future hypoglycemia	37.8	29.9	63.6	84.2
Had additional concerns about driving	29.2	9.4 [‡]	36.4	15.8
Asked someone to check on them	9.3	14.4	45.5	57.9
Went home from school, work, activities	6.7	10.3	25.5	32.0
Stayed home the next day	1.6	9.3 [§]	20.0	26.3

Abbreviations: T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus.

*Reported within 24 hours after the event.

[†]Percentage of patients who "sometimes" or "always" made lifestyle changes after hypoglycemic episodes.

[‡] $P < .001$.

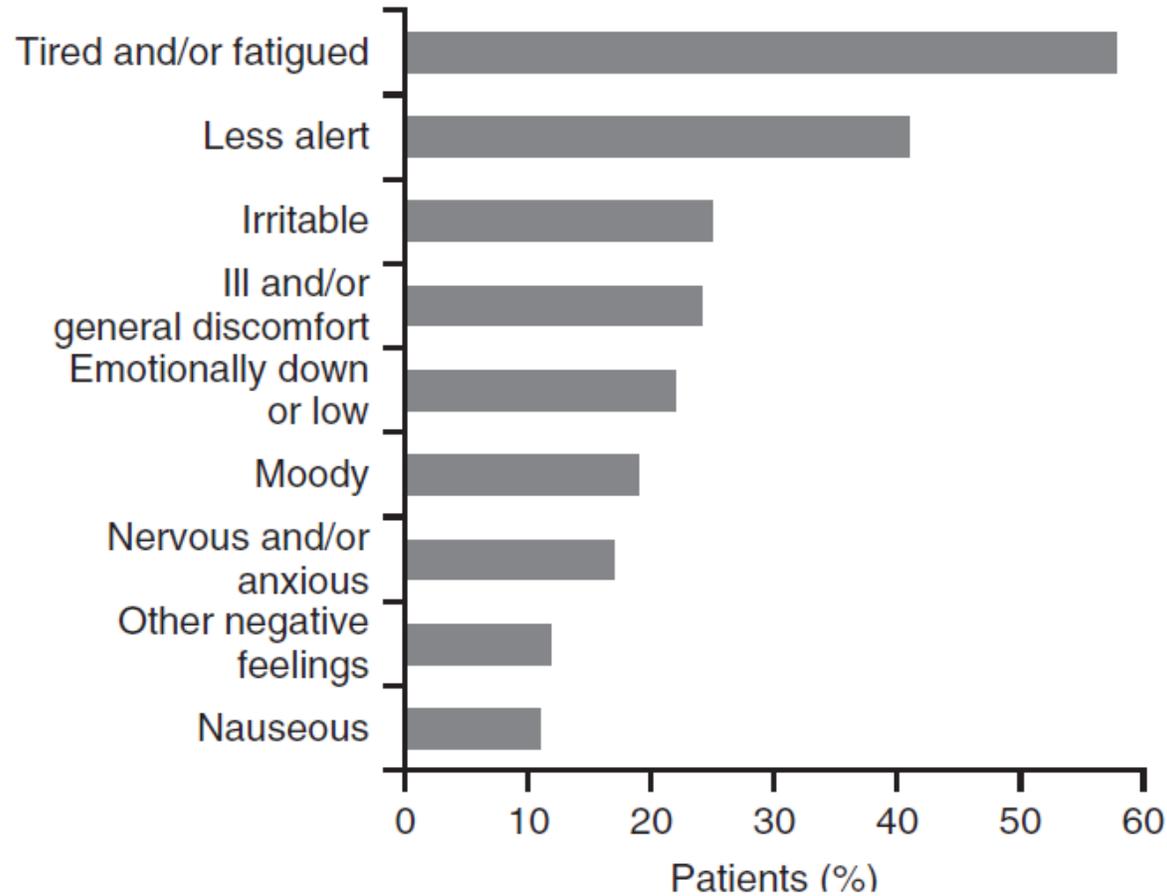
[§] $P < .01$. Reprinted with permission from Canadian Journal of Diabetes.

Respondents reported that their NSHEs lasted an average of 33.0 minutes (SD 60.6)

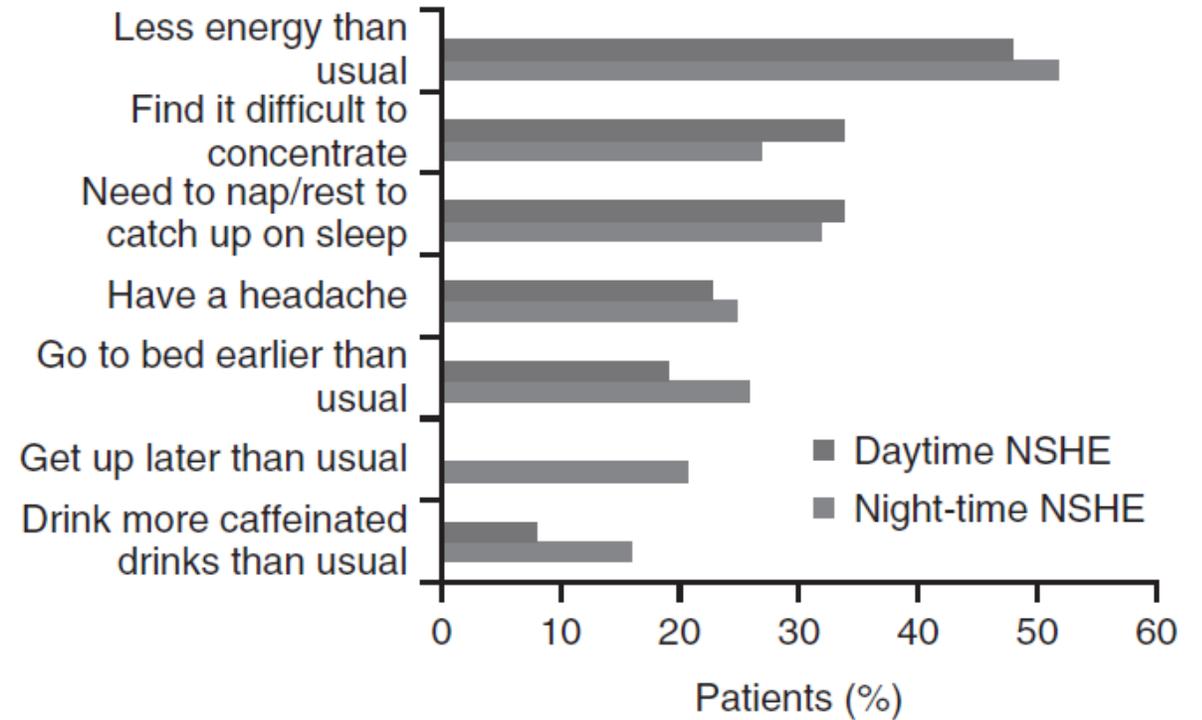
Diabetes management after last NSHE.

	Total	USA	UK	Germany	France	P value
Contacted a health-care professional [†] after last NSHE						
Yes, N (%)	349 (24.9%)	56 (13.7%)	99 (25.7%)	56 (23.7%)	138 (36.9%)	<0.001*
Did your LAST NSHE cause you to decrease your normal insulin dose?						
Yes, N (%)	351 (25.0%)	109 (26.7%)	101 (26.2%)	33 (14.0%)	108 (28.9%)	<0.001*
Total units decreased, mean (SD)	6.5 (13.1)	6.3 (8.0)	6.2 (9.9)	6.5 (9.3)	6.8 (19.4)	0.988 [‡]
Days decreased, mean (SD)	3.6 (5.1)	4.7 (6.5)	3.1 (4.2)	3.1 (4.8)	3.2 (4.0)	0.062 [‡]

Effects of patient-reported non-severe hypoglycemia on healthcare resource use, work-time loss, and wellbeing in insulin-treated patients with diabetes in seven European



Patient feelings following a non-severe hypoglycemic event.



Patients' experience on the day following a daytime or nocturnal NSHE. NSHE, non-severe hypoglycemic event.

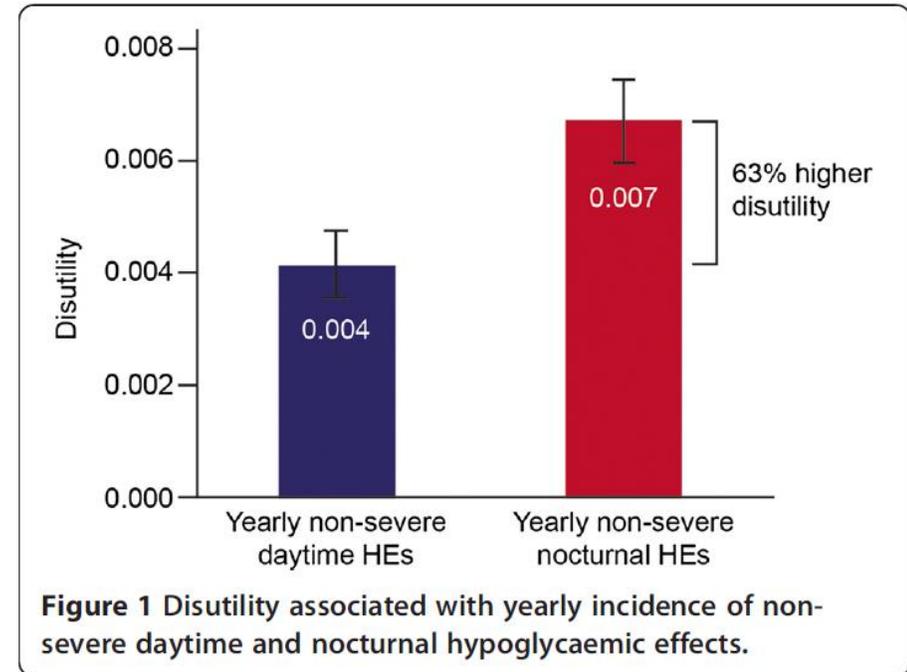
Health Related Quality of Life (HRQoL)

Health-related quality of life associated with daytime and nocturnal hypoglycaemic events: a time trade-off survey in five countries

8286 people interviewed; 551 with T1DM, 1603 with T2DM across Canada, Germany, Sweden, UK, USA

Average time trade-off utility values for health states [95% CIs, bootstrapped]

Health state	Frequency of hypoglycaemic events				
	One a year	One a quarter	One a month	One a week	Three a week
Baseline diabetes	0.844 [0.839 to 0.848]	-	-	-	-
Non-severe daytime hypoglycaemia	-	0.812 [0.802 to 0.822]	0.812 [0.802 to 0.822]	0.808 [0.799 to 0.817]	0.773 [0.762 to 0.784]
Non-severe nocturnal hypoglycaemia	-	0.809 [0.800 to 0.819]	0.804 [0.794 to 0.813]	0.775 [0.764 to 0.786]	0.729 [0.717 to 0.740]
Severe daytime hypoglycaemia	-	0.762 [0.751 to 0.773]	0.739 [0.739 to 0.750]	-	-
Severe nocturnal hypoglycaemia	-	0.759 [0.749 to 0.770]	0.738 [0.726 to 0.748]	-	-



The Potential Cost Implications of Averting Severe Hypoglycemic Events Requiring Hospitalization in High-Risk Adults With Type 1 Diabetes Using Real-Time Continuous Glucose Monitoring

J Diab Sci Thec 2016; 10(4): 905-913

Estimates for Cost Calculation.

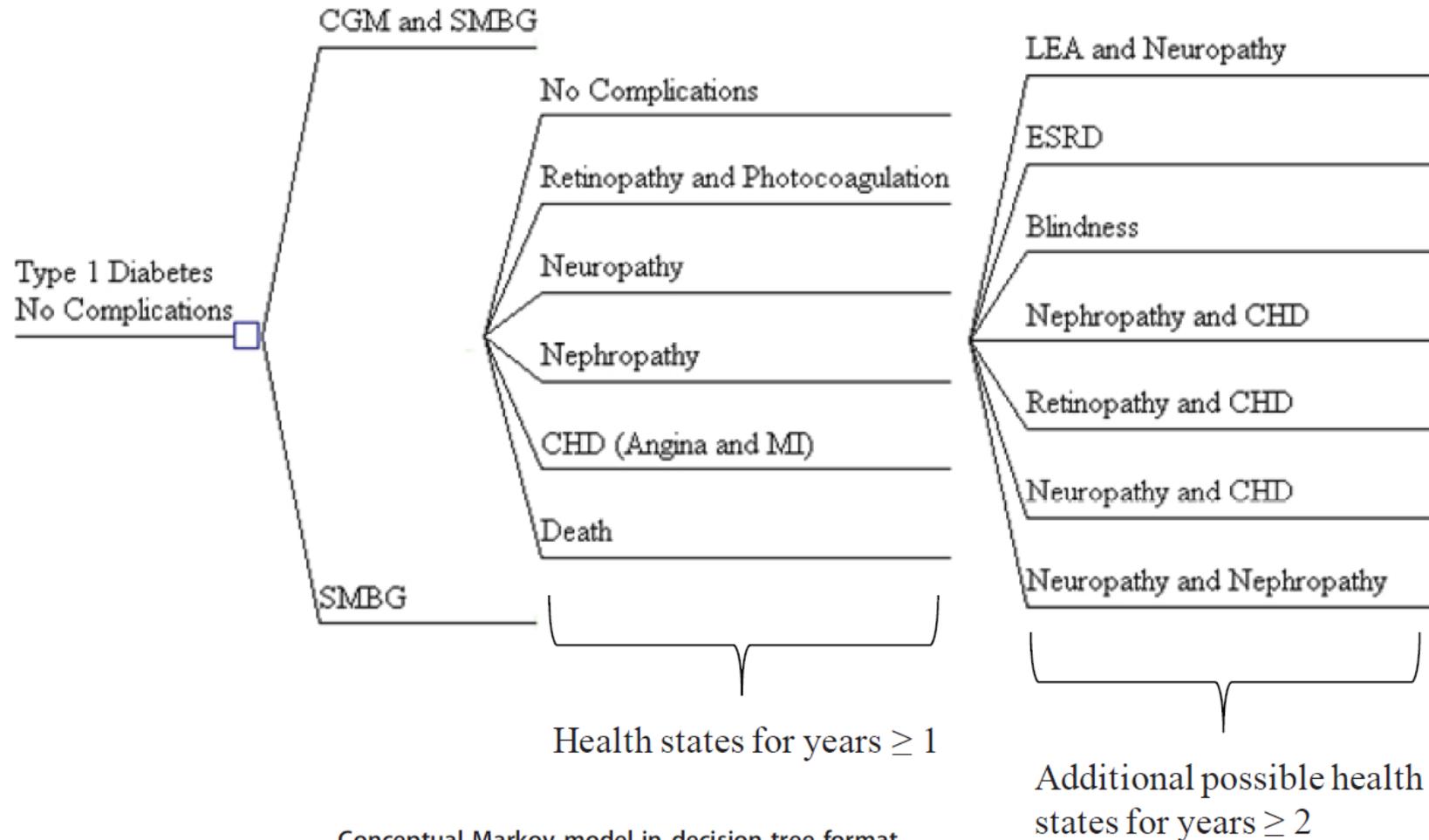
Parameter	Estimate
% of T1DM adults with hypoglycemia unawareness	20% ²²
Annual rate of severe hypoglycemia in adults with T1DM	1.0 ^{8-10,12}
Increased risk of severe hypoglycemia in T1DM adults with hypoglycemia unawareness	6 times ^{22,23}
% of severe hypoglycemic episodes requiring hospitalization	14.5% ²⁷
% reduction in severe hypoglycemic episodes conferred by RT-CGM in adults with T1DM	32% ³⁹
Average cost of a hypoglycemia-related hospitalization	\$21 000 ^{a26}
Cost of RT-CGM	\$4500 to \$4900

Cost Calculation Inputs and Results for a Commercial Health Plan.

Parameter	Calculation	Result
Number of adult members with T1DM	10 million × 9.3% × 5%	46 500
Number of adult members with T1DM and hypoglycemia unawareness	46 500 × 20%	9300
Number of annual severe hypoglycemic events without RT-CGM	9300 × 6 episodes	55 800
Number of annual severe hypoglycemic events requiring hospitalization without RT-CGM	55 800 × 14.5%	8091
Number of annual severe hypoglycemic events with RT-CGM	55 800 – (55 800 × 32%)	37 944
Number of annual severe hypoglycemic events requiring hospitalization with RT-CGM	37 944 × 14.5%	5502
Annual cost of severe hypoglycemic events requiring hospitalization		
Without RT-CGM	8091 × \$21 000	\$169 911 000
With RT-CGM	5502 × \$21 000	\$115 542 000
Difference in cost		\$54 369 000
Cost of RT-CGM (low estimate)	9300 × \$4500	\$41 850 000
Cost of RT-CGM (high estimate)	9300 × \$4900	\$45 570 000
Net cost savings conferred by RT-CGM (based on lower device cost)	\$54 369 000 – \$41 850 000	\$12 519 000
Net cost savings conferred by RT-CGM (based on higher device cost)	\$54 369 000 – \$45 570 000	\$8 799 000
Per patient cost savings conferred by RT-CGM (based on lower device cost)	\$12 519 000/9300	\$1346
Per patient cost savings conferred by RT-CGM (based on higher device cost)	\$8 799 000/9300	\$946

Cost-effectiveness of continuous glucose monitoring and intensive insulin therapy for type 1 diabetes

R Brett McQueen^{1*}, Samuel L Ellis^{2†}, Jonathan D Campbell^{1†}, Kavita V Nair^{1†} and Patrick W Sullivan^{3†}



McQueen Parametri

Table 1 Parameters for Type 1 Diabetes Markov Model

Transition Probabilities [Annual cycle length] ^a	Mean	2.5% ^b	97.50%	Reference
Retinopathy to blindness	0.101	0.057	0.156	Hoerger et al. [16,17]
Diabetes with no complications to CHD	0.031	0.018	0.048	Hoerger et al. [16,17]
Subsequent LEA	0.110	0.062	0.169	Hoerger et al. [16,17]
Diabetes with no complications to nephropathy	0.072	0.041	0.112	Klein et al. [18]
Nephropathy to CHD	0.022	0.013	0.034	Klein et al. [18]
Nephropathy to ESRD	0.072	0.041	0.109	Hoerger et al. [16,17]
Diabetes with no complications to neuropathy	0.035	0.020	0.055	Klein et al. [18]
Neuropathy to CHD	0.029	0.016	0.044	Hoerger et al. [16,17]
Neuropathy to LEA	0.131	0.074	0.200	Hoerger et al. [16,17]
Neuropathy to nephropathy	0.097	0.055	0.149	Wu et al. [19]
Diabetes with no complications to retinopathy	0.011	0.006	0.017	Hoerger et al. [16,17]
Retinopathy to CHD	0.028	0.016	0.043	Klein et al. [18]

Cost Parameters [Annual or initial costs represented in 2007 US\$]^c

Blindness and retinopathy	9,912	7,251	12,945	ADA [1]
CGM technology	4,189	3,062	5,492	CGM website [24]
Initial cost of CGM technology	4,809	3,499	6,321	CGM website [24]
CHD	35,271	25,820	46,433	ADA [1]
Diabetes with no complications	6,705	4,879	8,788	ADA [1]
ESRD	36,370	26,377	47,708	ADA [1]
LEA	50,150	36,541	65,798	ADA [1]
Nephropathy	20,161	14,614	26,643	ADA [1]
Neuropathy	25,075	18,226	33,004	ADA [1]
Retinopathy	4,956	3,578	6,489	ADA [1]

Utility Parameters [Annual cycle length]^a

Blindness	0.569	0.531	0.607	Sullivan et al. [22] ICD-9 250
CHD	0.552	0.513	0.591	Sullivan et al. [22] ICD-9 250, 593
ESRD	0.521	0.485	0.558	Sullivan et al. [22] ICD-9 250, 355
LEA	0.572	0.538	0.604	Sullivan et al. [22] ICD-9 250, 362
Nephropathy	0.575	0.545	0.606	Sullivan et al. [22] ICD-9 250, 355, 593
Nephropathy and CHD	0.516	0.465	0.567	Sullivan et al. [22] ICD-9 250, 593, 410, 413
Neuropathy	0.603	0.573	0.632	Sullivan et al. [22] ICD-9 250, 355, 410, 413
Neuropathy and CHD	0.544	0.495	0.593	Sullivan et al. [22] ICD-9 250, 362, 410, 413
Neuropathy and nephropathy	0.557	0.520	0.595	Sullivan et al. [22] ICD-9 250, 410, 413
Diabetes with no complications	0.757	0.747	0.767	Sullivan et al. [22] ICD-9 250, 593, 586
Retinopathy	0.612	0.581	0.643	Sullivan et al. [22] ICD-9 250, 355, 354
Retinopathy and CHD	0.553	0.503	0.605	Sullivan et al. [22] ICD-9 250, 362, 369
Disutility of age	-0.0003			Sullivan et al. [22]

Other Parameters^d

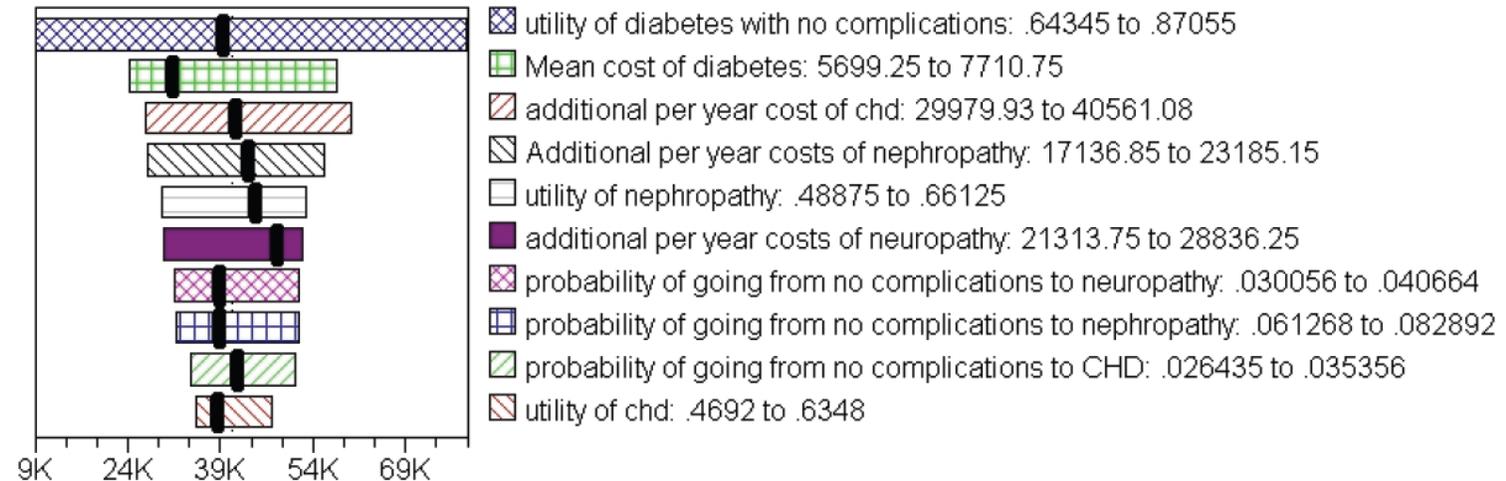
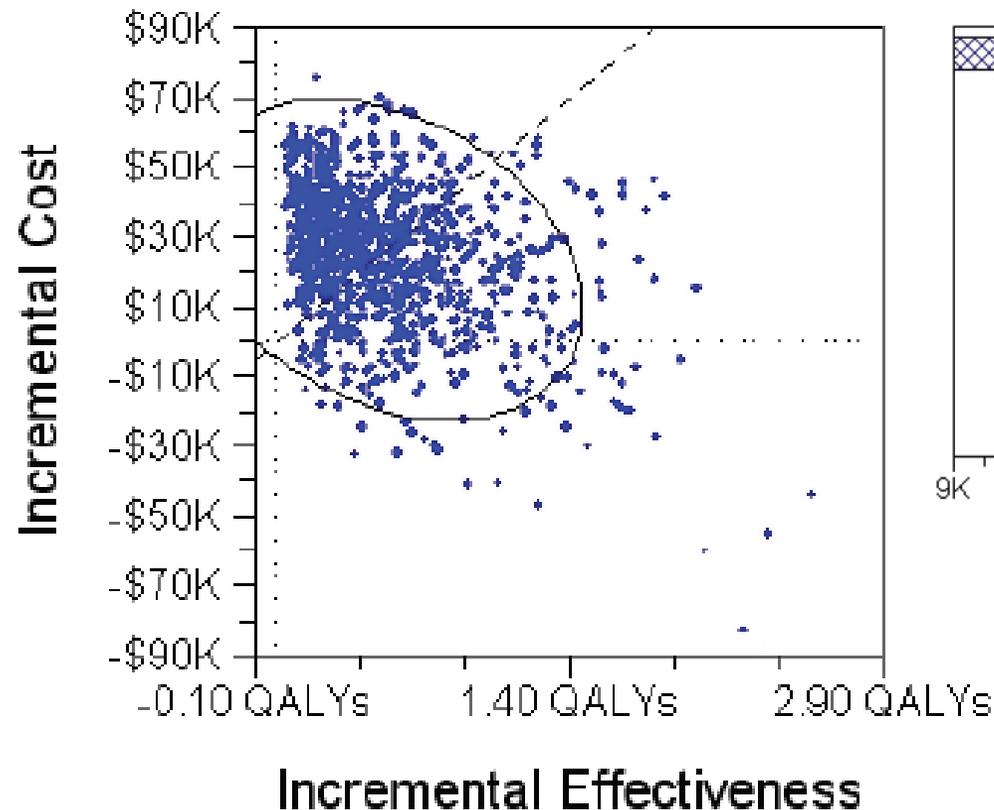
CGM risk reduction for CHD	0.050	0.013	0.107	DCCT [20]
CGM risk reduction for nephropathy	0.270	0.006	0.768	DCCT [20]
CGM risk reduction for neuropathy	0.188	0.004	0.593	DCCT [20]
CGM risk reduction for retinopathy	0.306	0.075	0.618	Selvin et al. [21]
Start age	40			Assumption
Years since diagnosis	20			Assumption
Discount rate	0.03			Assumption

Table Expected Cost and Effectiveness of Continuous Glucose Monitoring (CGM) and Self-Monitoring of Blood Glucose (SMBG)

Strategy	Expected Cost in 2007 \$US (range)*	Expected Effectiveness QALYs (range)*	Incremental cost-effectiveness ratio (ICER)
SMBG	470,583 (397,782 - 550,598)	10.289 (9.615 - 10.957)	
CGM and SMBG	494,135 (420,381 - 571,631)	10.812 (9.894 - 11.887)	US \$45,033/QALY

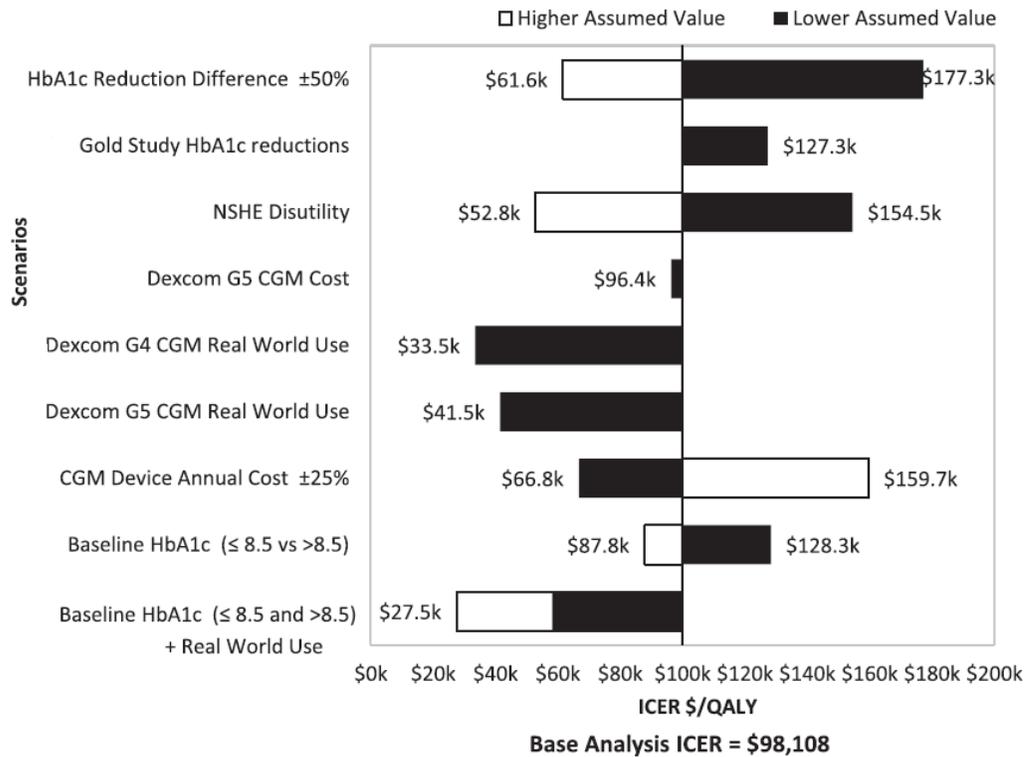
*95% credible ranges based on the results from the 10,000 Monte Carlo simulations

ICE Scatterplot CGM and SMBG vs. SMBG only



33 Ys; life expectancy 73 Ys
CORE Diabetes Model

Cost-effectiveness of Continuous Glucose Monitoring for Adults With Type 1 Diabetes Compared With Self-Monitoring of Blood Glucose: The DIAMOND Randomized Trial



—Results of base-case lifetime CEA

	Control	CGM
Lifetime probability of		
Diabetic retinopathy, %		
Background	33.5	27.3
Proliferative	28.9	24.6
Macular edema, %	8.4	6.4
Blindness, %	1.9	1.8
Macroalbuminuria, %	19.7	17.2
End-stage renal disease, %	11.7	10.1
Neuropathy, %	33.2	27.3
Amputation, %	8.1	7.1
Myocardial infarction, %	37.8	37.0
Stroke, %	7.2	7.0
Angina, %	20.6	20.6
Heart failure, %	11.1	10.7
Expected life-years	24.29	25.01
Difference in expected life-years		0.72
Discounted QALYs, means	12.78	13.32
Difference in QALYs, mean		0.54
Discounted total costs, mean	305,278	360,486
Difference in costs, mean		55,208
ICER, mean (95% CI*) lifetime		98,108 (90,298–105,144)

Sheffield T1DM Policy Model; 158 pz 2:1 CGM:SMBG; 6 mesi

-Within-trial cost-effectiveness results	Control (n = 53)		CGM (n = 103)		P value ^b
	Mean (SD)	Median (range or IQR)	Mean (SD)	Median (range or IQR)	
Utility and QALYs					
Utility change from baseline	0.0 (0.08)	0 (-0.27, 0.26)	-0.01 (0.09)	0 (-0.33, 0.32)	0.78
QALYs	0.46 (0.06)	0.47 (0.13, 0.50)	0.46 (0.05)	0.47 (0.24, 0.50)	0.61
Costs, \$					P value^b
Total direct costs	3,118 (3,120)	2,565 (1,928, 3,277)	5,336 (3,070)	5,092 (4,485, 5,726)	<0.01
Direct trial personnel	96 (205)	47 (0, 94)	60 (77)	47 (0, 94)	0.41
Medical care	3,022 (3,088)	2,478 (1,880, 3,122)	2,921 (3,065)	2,509 (1,909, 3,095)	0.86
CGM	0 (0)	0	2,554 (0)	2,554	<0.01
Total indirect costs	36 (121)	0 (0, 0)	54 (314)	0 (0, 0)	0.85
Missed work	26 (101)	0 (0, 0)	36 (307)	0 (0, 0)	0.65
Poor performance	10 (40)	0 (0, 0)	18 (70)	0 (0, 0)	0.63
Self-management	4,012 (5,529)	2,829 (0, 5,610)	5,473 (10,300)	2,829 (2,259, 5,658)	0.86
Total costs	7,236 (6,097)	5,287 (4,586, 8,223)	11,200 (11,300)	8,178 (6,864, 10,300)	<0.01
Total costs ^a	3,154 (3,122)	2,565 (1,999, 3,513)	5,593 (3,083)	5,105 (4,496, 5,780)	<0.01
Clinical outcomes: reduction from baseline					P value^b
HbA _{1c}	-0.39 (0.70)	-0.30 (-3.20, 0.90)	-0.99 (0.77)	-1.00 (-3.00, 0.70)	<0.01
Daily strip tests	0.1 (1.5)	0 (-4, 3)	-0.5 (1.5)	0 (-5, 3)	0.04
Insulin dose	1.0 (11)	1 (-23, 25)	-2.3 (22)	0 (-145, 52)	0.31
Daily rate of NSHEs	-0.06 (0.27)	0 (-0.93, 0.47)	-0.12 (0.29)	-0.08 (-1.07, 0.63)	0.02^c
BMI	0.27 (1.07)	0.15 (-2.22, 2.80)	0.59 (1.38)	0.56 (-3.42, 5.28)	0.16
Patients having severe hyperglycemic events, n (%)	1 (2)		0 (0)		0.34
Patients having severe hypoglycemic events, n (%)	2 (4)		2 (2)		0.6

Cost-effectiveness of G5 Mobile continuous glucose monitoring device compared to self-monitoring of blood glucose alone for people with type 1 diabetes from the Canadian societal perspective

Sensitivity analyses (base-case—G5 Mobile CGM vs SMBG alone).

Parameter	ICER (CAD) (CI)
Discount rate = 0%	\$34,411 (33,166–33,785)
Discount rate = 3%	\$33,729 (33,550–34,078)
Cohort baseline HbA1c = 7.6%	\$34,781 (34,579–35,067)
Cohort baseline HbA1c = 9.5%	\$32,816 (32,530–33,129)
Hypoglycemia disutilities decrease by 50%	\$65,363 (65,394–66,617)
Hypoglycemia disutilities increase by 50%	\$22,783 (22,618–22,977)
Non-severe hypoglycemic events reduction = 50%	\$19,715 (19,569–19,868)
Severe hypoglycemic event reduction = 25%	\$39,662 (39,417–39,987)
Severe hypoglycemic event reduction = 75%	\$29,140 (28,922–29,387)
Starting utility of cohort = 0.71	\$34,382 (34,137–34,655)
Starting utility of cohort = 0.95	\$33,656 (33,429–33,951)
G5 Mobile CGM vs SMBG with 6 fingersticks per day	\$29,871 (29,642–30,138)
G5 Mobile CGM vs SMBG with 8.2 fingersticks per day	\$25,731 (25,496–25,990)
% HbA1c reduction for CGM vs SMBG = 0.3	\$34,738 (34,453–35,023)
% HbA1c reduction for CGM vs SMBG = 0.9	\$32,723 (32,463–32,984)
G 5 Mobile CGM (with receiver) vs SMBG	\$ 33,789/Quality

Orizzonte temporale: 50 anni

Outcomes	CGM + SMBG, Mean	SMBG, Mean	Difference, Mean
Life expectancy (years)	23.233 (CI: 23.216–23.25)	23.197 (CI: 23.18–23.213)	0.037 (CI: 0.013–0.061)
Quality-adjusted life years (QALYs)	8.382 (CI: 8.375–8.388)	5.027 (CI: 5.023–5.032)	3.354 (CI: 3.346–3.326)
Total lifetime direct costs (CAD)	339,196 (CI: 338,567–339,825)	225,862 (CI: 225,278–226,447)	113,334 (CI: 112,468–114,199)
Incremental costs/QALY gained (CAD)			33,789 (CI: 33,558–34,079)

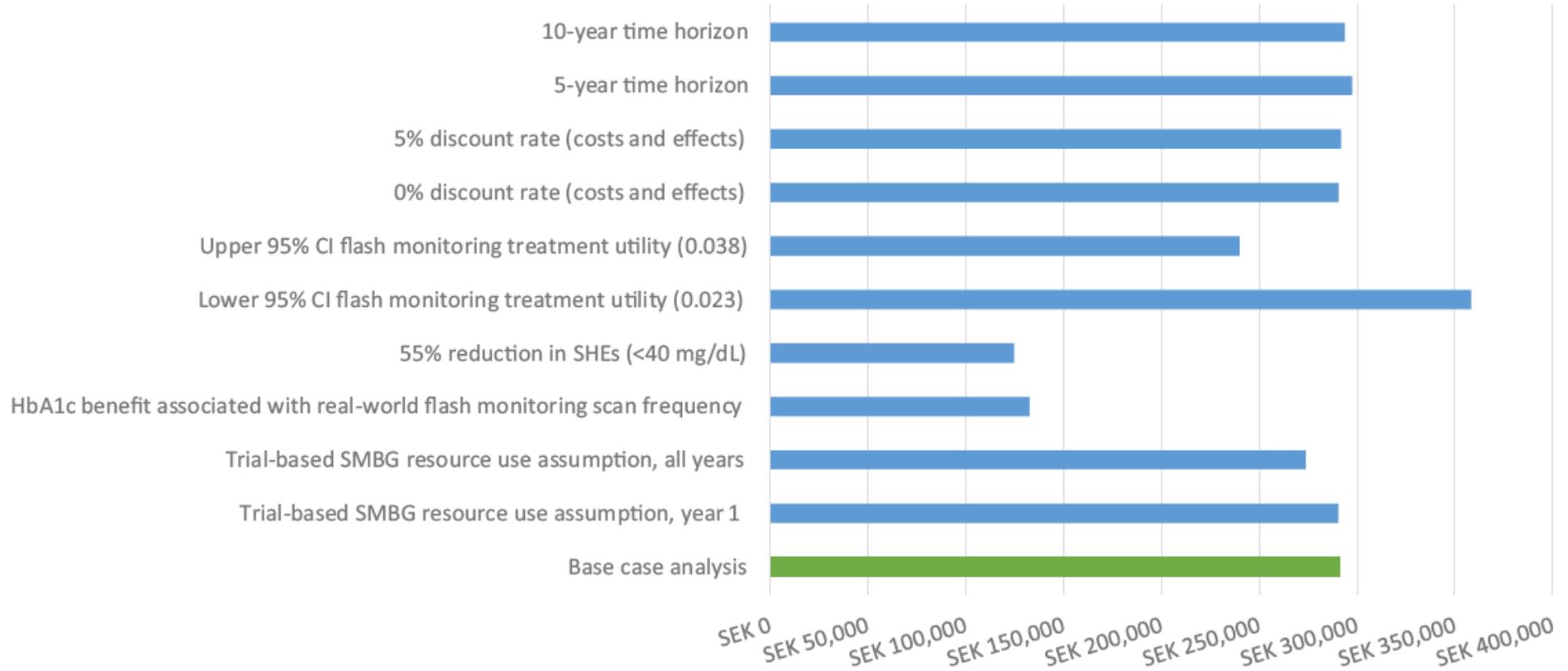
Base case parameter	Assumption	References
<i>Patient demographics</i>		
Mean cohort baseline HbA1c	8.6% (SD 0.7%)	Beck <i>et al.</i> ¹³
Mean age	46 years	Beck <i>et al.</i> ¹³
Mean duration of diabetes	19 years	Beck <i>et al.</i> ¹³
Proportion of male	53%	Beck <i>et al.</i> ¹³
<i>Treatment effects</i>		
Mean change in HbA1c		
SMBG only	-0.4% (SD 0.7%)	Beck <i>et al.</i> ¹³
CGM + SMBG	-1.0% (SD 0.7%)	Beck <i>et al.</i> ¹³
Hypoglycemia event rates		
SMBG only		
NSHE	2,900/100 patient years	UK Hypoglycemia Study Group ²¹
SHE 1	278/100 patient years	UK Hypoglycemia Study Group ²¹
SHE 2	42/100 patient years	UK Hypoglycemia Study Group ²¹
% requiring medical services	13%	Foos <i>et al.</i> ²²
CGM + SMBG		
NSHE	26% reduction	Battelino <i>et al.</i> ²³
SHE 1	50% reduction	JDRF Continuous Glucose Monitoring Study Group ^{24,25}
SHE 2	50% reduction	JDRF Continuous Glucose Monitoring Study Group ^{24,25}
<i>Key utility inputs</i>		
Starting utility for people with type 1 diabetes adult cohort	0.90	Solli <i>et al.</i> ²⁶
Disutilities for hypoglycemic events		
NSHE	-0.0142	Currie <i>et al.</i> ²⁷ ; Beaudet <i>et al.</i> ²⁸
SHE 1	-0.0142	Currie <i>et al.</i> ²⁷ ; Beaudet <i>et al.</i> ²⁸
SHE 2	-0.047	Currie <i>et al.</i> ²⁷ ; Beaudet <i>et al.</i> ²⁸
Approach to hypoglycemia disutility progression	Stable impact	CDM default assumption
<i>Key acute event costs</i>		
Direct costs hypoglycemic events		
NSHE	4.79	Harris <i>et al.</i> ²⁹
SHE 1	29.47	O'Brien <i>et al.</i> ³⁰
SHE 2	2,101.6	CADTH ³¹
Simulation time horizon	50 years	Convention
Discount rate	1.5%	CADTH ²⁰

Long-term cost-effectiveness of Dexcom G6 real-time continuous glucose monitoring system in people with type 1 diabetes in Australia

	rt-CGM	SMBG	Difference
Cost, AUD	246,146	224,549	21,597
Quality-adjusted life expectancy, QALY	9.362	8.163	1.199
ICER, AUD per QALY gained	18,020		
	rt-CGM	FGM	Difference
Cost, AUD	246,146	235,082	11,064
Quality-adjusted life expectancy, QALY	9.362	8.235	0.569
ICER, AUD per QALY gained	19,455		

Analysis	Cost, AUD			Quality-adjusted life expectancy, QALYs			ICER, AUD per QALY gained
	rt-CGM	SMBG	Difference	rt-CGM	SMBG	Difference	
Base case	246,146	244,549	+21,597	9.362	8.163	+1.199	18,020
rt-CGM utility benefit 0%	246,146	244,549	+21,597	8.556	8.163	+0.393	54,912
rt-CGM utility benefit -50%	246,146	244,549	+21,597	8.959	8.163	+0.796	27,135
rt-CGM utility benefit +50%	246,146	244,549	+21,597	9.764	8.163	+1.601	13,489
rt-CGM HbA _{1c} -30%	253,968	224,549	+29,419	9.278	8.163	+1.115	26,375
rt-CGM HbA _{1c} +30%	239,102	224,549	+14,553	9.431	8.163	+1.268	11,408
rt-CGM SHE rate -50%	244,792	224,549	+20,242	9.369	8.163	+1.206	16,780
rt-CGM SHE rate +50%	247,447	224,549	+22,898	9.344	8.163	+1.181	19,385
rt-CGM NSHE rate -50%	246,146	224,549	+21,597	9.533	8.163	+1.370	15,760
rt-CGM NSHE rate +50%	246,146	224,549	+21,597	9.309	8.163	+1.146	18,840
4 SMBG/day	246,146	224,075	+22,071	9.362	8.163	+1.199	18,416
5.2 SMBG/day	246,146	225,024	+21,122	9.362	8.163	+1.199	17,624
10 SMBG/day	246,146	228,819	+17,327	9.362	8.163	+1.199	14,458
QoL of T1D with no complications =0.672	246,146	244,549	+21,597	8.547	7.400	+1.148	18,821
Time horizon 2 years	21,802	17,092	+4,710	1.100	0.965	+0.135	34,810
Time horizon 5 years	49,907	39,247	+10,600	2.697	2.380	+0.317	33,640
Time horizon 10 years	93,032	75,597	+17,435	4.851	4.280	+0.571	30,562
Time horizon 25 years	188,716	166,258	+22,458	8.199	7.202	+0.998	22,510
Discount rate 3.5%	318,245	294,889	+23,356	11.384	9.896	+1.488	15,699
Discount rate 0%	675,215	648,377	+26,838	20.241	17.406	+2.836	9465

Cost-effectiveness Analysis of a Flash Glucose Monitoring System for Patients with Type 1 Diabetes Receiving Intensive Insulin Treatment in Sweden



Quality of Life and Glucose Control After 1 Year of Nationwide Reimbursement of Intermittently Scanned Continuous Glucose Monitoring in Adults Living With Type 1 Diabetes (FUTURE): A Prospective Observational Real-World Cohort Study

Diabetes-related acute complications and work absenteeism before and after initiation of isCGM

	Baseline	6 months	<i>P</i> value§	12 months	<i>P</i> value§
People with					
Hospitalizations due to hypoglycemia and/or ketoacidosis*†	63 (3.3)	—	—	37 (2.2)	0.031
Hospitalizations due to hypoglycemia†	36 (1.9)	—	—	21 (1.2)	0.104
Hospitalizations due to ketoacidosis*†	27 (1.4)	—	—	17 (1.0)	0.242
Help from third parties due to hypoglycemia‡	280 (14.6)	153 (8.4)	<0.0001	134 (7.8)	<0.0001
Hypoglycemic comas‡	52 (2.7)	16 (0.9)	<0.0001	18 (1.1)	0.001
Work absenteeism‡	111 (5.8)	59 (3.2)	<0.0001	49 (2.9)	<0.0001
Number per 100 patient-years of					
Help from third parties due to hypoglycemia‡	97.2	63.9	0.024	64.6	0.022
Hypoglycemic comas‡	11.2	2.6	<0.0001	4.3	0.017
Days per 100 patient-years of					
Hospitalizations due to hypoglycemia and/or ketoacidosis*†	9.3	—	—	6.6	0.021
Hospitalizations due to hypoglycemia†	2.5	—	—	1.8	0.129
Hospitalizations due to ketoacidosis*†	6.8	—	—	4.8	0.078
Work absenteeism‡	109.5	49.3	0.038	53.5	0.058

The Benefits, Limitations, and Cost-Effectiveness of Advanced Technologies in the Management of Patients With Diabetes Mellitus

Cost-effectiveness of health technologies in adults with type 1 diabetes: a systematic review and narrative synthesis

**Continuous Glucose Monitoring:
A Review of Recent Studies Demonstrating
Improved Glycemic Outcomes**

Evaluating optimal utilisation of technology in type 1 diabetes mellitus from a clinical and health economic perspective: protocol for a systematic review

Utilità della tecnologia CGM nella gestione del T1DM

- **OUTCOMES:**

Riduzione HbA1c nel tempo

Riduzione della variabilità glicemica

Riduzione della frequenza delle ipoglicemie, non severe e severe

- **COSTI**

Diretti, indiretti, intangibili

- **OTTIMIZZAZIONE**

- **Dei processi di cura : focalizzazione su dati di processo trasparenti, condivisi, informativi**
- **Dei tempi della cura: focalizzazione su integrazione tra abitudini di vita e ricadute terapeutiche**
- **Della educazione terapeutica: focalizzazione su scelte terapeutiche e procedure in funzione degli obiettivi terapeutici**
- **Della relazione sanitari-persone con T1DM: peer-to-peer e bottom-up al fine di favorire un apprendimento continuo, reciproco**
- **Rinforzo motivazionale reciproco**

...i vantaggi a lungo termine superano i costi a breve?

Schierarsi dal lato giusto della storia è stato un investimento a lungo termine.

Alec Ross

Circolare 13 del 09 OTT 2015

REGIONE EMILIA ROMAGNA

SANITA' E POLITICHE SOCIALI PER L'INTEGRAZIONE

LINEE DI INDIRIZZO REGIONALI PER UN USO APPROPRIATO DEI DISPOSITIVI MEDICI PER
L'AUTOCONTROLLO E L'AUTOGESTIONE DEL DIABETE MELLITO

GRAZIE!