

CONTINUOUS GLUCOSE MONITORING DEVICES FOR PATIENTS WITH DIABETES
MELLITUS ON INSULIN
A Technology Assessment

INTRODUCTION

The California Technology Assessment Forum is requested to update its review of the published scientific literature on the use of continuous blood glucose monitoring (CGM) devices in patients with diabetes mellitus. There has been considerable more literature published on this topic since the most recent CTAF assessment in 2003 which concluded that there was not yet sufficient evidence that CGM devices improved net health outcomes.¹ There are additional new devices which have U.S. Food and Drug Administration (FDA) since that time as well.

BACKGROUND

Diabetes Mellitus

Diabetes is a disease condition of altered glucose metabolism, resulting in elevated blood glucose levels. Type I diabetes, which accounts for 5-10% of diagnosed cases, results from a deficiency in insulin production in the beta cells of the pancreas, and usually has its onset in children and young adults. Individuals with Type I diabetes must take exogenous insulin either via multiple daily injections or via an insulin pump. Type II diabetes, the most common form of diabetes in adults, results from disordered insulin action and insulin resistance. While much of Type II diabetes is treated with oral medication, it can ultimately result in the inability of the pancreatic beta cells to produce insulin, thus requiring treatment with exogenous insulin. Between 2004-2006, 13% of adults with diabetes were treated with both insulin and oral medication, while 14% were treated with insulin only.²

The U.S. Centers for Disease Control and Prevention estimates that in 2007, 7.8% (23.6 million people) of the population had diabetes. This prevalence differs by age group, with increasing prevalence for older age groups: 0.2% of the population under 20 has diabetes, while 10.7% of all adults over 20 and 32.1% of adults over 60 have diabetes.² Diabetes carries with it a significant risk of microvascular (retinopathy, nephropathy, neuropathy) and macrovascular complications (cardiovascular and cerebrovascular disease). Diabetes is the leading cause of new cases of

blindness among adults, and is the leading cause of kidney disease.² Among adults, those with diabetes have a 2-4 fold increased risk of cardiovascular disease.³

Intensive Glucose Control

Randomized controlled trials (RCT) have shown that intensive glucose control, generally to a Hemoglobin A1C (HbA1C) <7%, in both Type I and Type II diabetes decreases risk for microvascular complications and possibly for macrovascular complications as well.^{4,5} More recent RCTs with macrovascular endpoints were unable to demonstrate that very intensive control – with goal HbA1C in the normal range - reduced risk in Type II diabetes, and in fact results are concerning for increased mortality risk, possibly related to hypoglycemia.^{6,7} Additionally, poorly controlled diabetes in pregnant women with Type I diabetes is associated with major birth defects, increased rates of spontaneous abortions, and high birth-weight babies.²

Self-monitoring Blood Glucose

The standard of care for home glucose measurement is self-monitoring of blood glucose (SMBG) with a blood glucose meter and a lancet to collect a drop of blood for measurement. This type of glucose measurement provides a snapshot in time with considerable accuracy. Patients on multiple insulin injections per day as well as on insulin pumps are frequently provided with algorithms to adjust their insulin dose according to their blood glucose measurement. What SMBG cannot provide is insight into the blood glucose trajectory – e.g. if it is on its way up or down.

Continuous Glucose Monitoring

Continuous glucose monitoring devices are intended to provide fairly continuous data (every one to ten minutes) over the time that the device is worn by an individual. Devices for CGM measure interstitial glucose concentration via sensors which are inserted subcutaneously. The newer generation of devices appear to have glucose measurements which are more highly correlated with plasma glucose than those from the older devices.^{8,9} Yet, there is clearly still some variability among devices, particularly in the hypoglycemia range^{10,11}, and there is evidence that interstitial glucose values may lag behind blood glucose whether glycemia is rising or falling.¹² The CGM sensors require regular calibration with SMBG, and it is still recommended that acute treatment decisions for hyper- or hypoglycemia be based on confirmatory SMBG.¹³

Theoretical advantages of CGM use include use of alarms for recognition of hypoglycemia, including nocturnal hypoglycemia which often goes unrecognized, particularly in children¹⁴, as well as use of intensive data for fine-tuned adjustment of insulin regimen by either injection or pump, leading to improved glycemic control.

TECHNOLOGY ASSESSMENT (TA)

TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.

There are now at least three CGM devices available on the market.

The DexCom™ STS™ Continuous Glucose Monitoring System (DexCom, Inc., San Diego, CA) received FDA Premarket Approval (PMA) on March 23, 2005.

The Guardian-RT (Real-Time) CGMS (Medtronic MiniMed, Northridge, CA) received FDA PMA in July 2005 - previous versions also received FDA clearance,

The Abbott FreeStyle Navigator Continuous Glucose Monitoring System (Abbott Diabetes Care, Alameda, CA) received FDA PMA on March 12, 2008.

The GlucoWatch® Biographer family of CGM devices is no longer available. This device was included in the previous CTAF assessment but is not included in this assessment.

TA Criterion 1 is met.

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The PubMed, Embase, and Cochrane clinical trials database, Cochrane reviews database and the Database of Abstracts of Reviews of Effects (DARE) were searched for relevant references published since the previous CTAF review on this subject in 2003 through January 2009. (See appendix for search terms) The bibliographies of systematic reviews and key articles were manually searched for additional references. Abstracts of citations were reviewed and all relevant articles reviewed in full. Of 60 potentially relevant citations, we found 22 studies to include in this assessment. (See Figure below for study selection details) Of these 22 studies, 11 were randomized control trials, ¹⁵⁻²⁵ and 11 were observational studies.^{9, 14, 26-36}

Thirty-seven additional references were reviewed, but did not meet criteria for inclusion in this assessment. (References 38 –75).

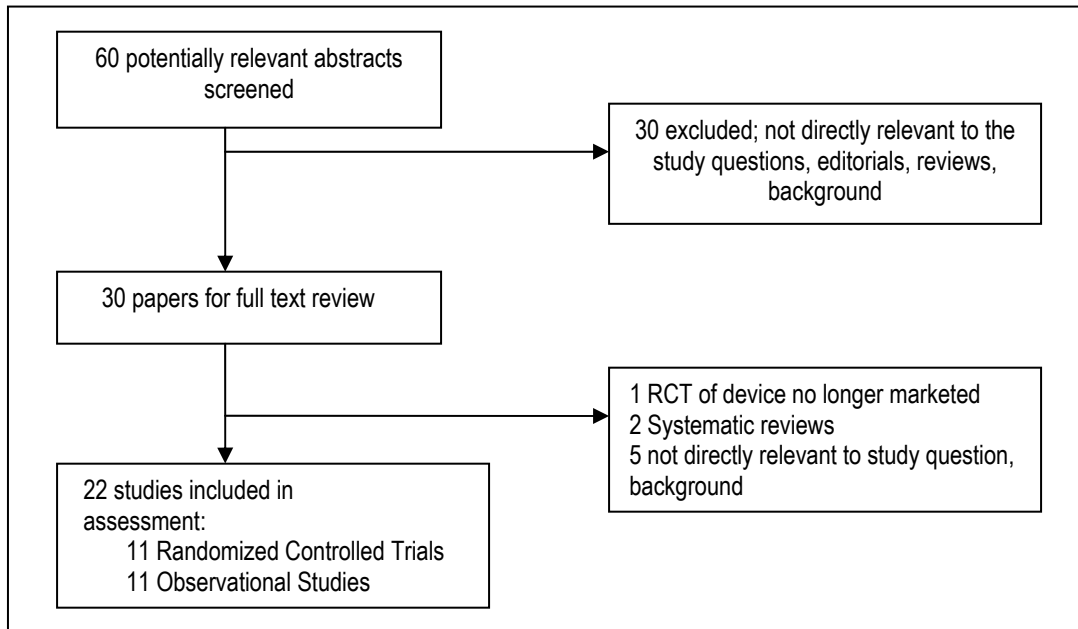


Figure: Study Selection Process

Level of Evidence: 1, 2, 5
 TA Criterion 2 is met.

TA Criterion 3: The technology must improve net health outcomes.

Observational Studies

Of the 11 observational studies included in this assessment, four focused on the pediatric population.^{31, 32, 35, 36} All were small studies, ranging in size from ten to 60 participants. The largest, with 60 participants, found a statistically significant decrease from baseline in HbA1C after a three month study period (-.4%). This study did not find a difference in number of hypoglycemic episodes or daily insulin dose, but number and duration of hyperglycemic episodes were decreased.³¹ Two smaller studies also found a modest decrease in HbA1C,^{32, 35} and one of these also found a modest decrease from baseline in the time participants spent in a hypoglycemic and hyperglycemic glucose range.³² The fourth study was a feasibility study which found that children tolerated wearing a CGM sensor with wireless transmission for longer than three days.³⁶

Five of the 11 observational studies focused on **non-pregnant adults**.^{26, 27, 29, 30, 33} These studies ranged in size from five to 137 participants. Of the two largest studies, one found a significant reduction in HbA1C ($-0.4 \pm .05\%$) and note that the greatest reductions in HbA1C were observed in those participants who had very poor glycemic control at baseline (HbA1C $>9.0\%$), and for those who used the CGM more.²⁶ The other found a significant reduction in the time participants spent with clinically important hypoglycemia.²⁷ Two of the remaining smaller studies had similar findings of a modest reduction in HbA1C,²⁹ and reduced time spent in clinical significant hypoglycemia.³⁰ The final study was a small pilot measuring the ability of CGM to capture and alert for late onset hypoglycemia related to vigorous exercise.³³

The remaining two observational studies were of **pregnant women**.^{28, 34} These were feasibility studies of using CGM in pregnancy to adjust insulin regimens.

Randomized Controlled Trials (Table)

Three of the 11 RCT's included in this assessment focused exclusively on the **pediatric population**.^{19, 25, 37} These studies were all small, ranging from 27-36 participants, and none of them found any difference in glycemic control for the intervention group (CGM users) compared with the control group. A fourth study focused exclusively on **pregnant teens and adult women**.²⁰ This trial included 71 women with both Type I and Type II diabetes and also found no difference for the intervention group (CGM users) compared with the control group. It did find a moderately significant decrease in birth weight and borderline significant decrease in macrosomia for the intervention group.

Five RCT's focused exclusively on **non-pregnant adults**.^{15, 18, 21, 22, 24} The largest of these, with 128 participants, found no difference in HbA1C or number of hypoglycemic episodes for the intervention (CGM) group, but did find a decrease in the duration of hypoglycemic episodes for the intervention group compared with the control group.²⁴ Two other trials also found that the CGM group either spent less time in severe hypoglycemic glucose range¹⁸ or had decreased duration of hypoglycemic episodes.¹⁵ Of the two remaining small studies, one found a decrease in HbA1C for the intervention group,²² while the other – a pilot of an integrated pump-CGM system – found no

decrease in HbA1C, but increased satisfaction with the intervention system compared with multiple daily injections.²¹

Two RCT's included both children and non-pregnant adults.^{17, 23} The earlier and smaller of the two, randomized within age group to two intervention arms, one with three months of ongoing CGM, and one with CGM for three days every two weeks over three months, and to a control group with conventional SMBG.¹⁷ This study found a significant reduction in HbA1C only for the intervention group with ongoing CGM compared with the control group. This study adjusted for age group rather than presenting results for children and adults separately. The recently published and largest RCT (N=322), randomized stratified by three age groups (8-14yrs, 15-24, ≥25yrs), clinical site and baseline HbA1C to daily CGM or four times daily SMBG over 26 weeks.²³ The main outcome was glycemic control as measured by HbA1C at the end of 26 weeks. Only the ≥25 year old group had a significant decrease in HbA1C compared to the control group. There were very few severe hypoglycemic episodes in any age group, with no differences between intervention and control group. In secondary outcomes of relative decrease of HbA1C by ≥10%, absolute decrease by ≥.5%, and 26-week level of <7.0% with no severe hypoglycemic events, the intervention group (ages ≥25 and 8-14yrs) had significantly higher proportion achieve these goals than the control group. There were no differences in these outcomes for the 15-24 year old age group. Adherence to CGM sensor use varied by age group, with the ≥25 year old group having the highest rate of adherence and the 15-24 year old group the lowest rate of adherence.

Table. Randomized Controlled Trials of FDA Approved and Currently Marketed Continuous Glucose Monitoring Devices for Diabetes Mellitus

Author/Year	Comparison Groups (N) / Intervention	Outcomes	Results	Comments
Bode 2004 ¹⁵ Adults Type I DM Guardian	Intervention: alert Group (N=35) – CGM alerts off (period one) CGM alerts on (period two) Control group (N=36) – CGM alerts off (period one) CGM alerts off (period two)	<i>Accuracy:</i> Sensitivity & Specificity of sensor compared with home blood glucose meter readings <i>Clinical Effectiveness</i> Number & duration of hypoglycemic excursions Number & duration of hyperglycemic excursions	Low alert threshold of 80mg/dL: 83% sensitivity 86% specificity False alert rate of 51% Low alert threshold of 70mg/dL; 67% sensitivity 90% specificity False alert rate of 47% No significant difference in number of hypoglycemic excursions. Duration decreased 27.8 min/excursion for alert group compared with 4.5 min/excursion for control group (p=.03) No significant difference in number or duration of hyperglycemic excursions	Multicenter. Small N overall & presumably per center. Not an intention to treat analysis; 3 excluded from analysis in alert group; 2 excluded from analysis in control group
Deiss 2006a ¹⁷ Children & Adolescents Type I DM CGMS, Medtronic	N=30; stratified by pubertal stage before randomization. Randomized crossover trial Two arms: Intervention: display (CGM data/alerts);	Glycemic control HbA1C	At 3 months no significant difference between groups; display group HbA1C mean 7.8 ± 1.1 vs. blinded group HbA1C mean 8.3 ± 1.1 (p=.23); no significant change from baseline HbA1C. Average 24hour glucose, hyperglycemia, and hypoglycemia also without significant difference. Similar findings after crossover.	More frequent changes in insulin therapy made in open group. European study.

	Control: blinded (to CGM data/alerts); CGM administered at baseline, 3 and 6 months; crossover after 3 months.			
Deiss 2006b ¹⁶ Children & Adults Type I DM Guardian	N= 162 (81 children, 81 adults) Randomized within age-group Arm 1: 3 months ongoing CGM; Arm 2: CGM biweekly for 3-days every 2 weeks; Arm 3: control, conventional self-monitoring blood glucose	Glycemic control HbA1c at 1 month and at 3 months.	Significant reduction in HbA1c for Arm 1 (ongoing CGM) compared to control group at 1 month (-.6 ± .8 vs. -.2 ± .8; p=.008), and at 3 months (-1.0 ± 1.1 vs. -.4 ± 1.0; p=.003). No significant difference between Arm 2 and control group. At 3 months percent per group with ≥1% reduction HbA1c: Arm 1 (ongoing): 50% Arm 2 (intermittent): 37% Arm 3 (active control): 15%	Intention to treat, last value carried forward analysis. Age adjusted (children /adults). Multicenter trial (8 European centers). No significant change from baseline in total insulin dose per day in any of the arms. Did not present data for children and adults separately.
Garg 2006 ¹⁸ Adults Type I DM Type II DM DexCom STS	N=91 (75 Type I; 16 Type II) Intervention: display (CGM data/alerts); Control: blinded (to CGM data/alerts); 3 consecutive 3-day periods of CGM for both groups	Time spent in high, low and target (81-140) glucose ranges	Display group spent 26% more time in the target glucose range of 81-140mg/dL than the control group (6.98 hours/day vs. 5.62 hours/day; p<.0001); 23% less time in highest glucose range of 241-400mg/dL (4.99 hours/day vs. 6.46 hours/day; p<.0001); 21% less time in the lowest glucose range of <55mg/dL (.74 hours/day vs. .94 hours per day; p<.0001). Both groups spent similar amounts of time in medium low (55-80mg/dL) and medium high (141-240mg/dL) ranges.	Multicenter trial (4 U.S. sites) Combine results for Type I and Type II DM
Lagarde 2006 ¹⁹	N=27	Glycemic control	Intervention group with greater decrease in HbA1C at 6	Small trial

<p>Children Type I DM Medtronic MiniMed</p>	<p>Intervention: display (CGM data/alerts) (N=18) ; Control: blinded (to CGM data/alerts) (N=9) ; 3 interval 3-day periods of CGM for both groups over 4 months</p>	<p>HbA1C</p>	<p>months than control group (.61 ± .68% vs. .28 ± .78%; p=.13), but not statistically significant.</p>	<p>Single site Australian</p>
<p>Murphy 2008²⁰ 1st trimester pregnant teens & women Type I DM Type II DM Medtronic MiniMed</p>	<p>N=71(46 Type I; 25 Type II) Intervention group – (N=38) antenatal care plus CGM Control group – (N=33) standard antenatal care</p>	<p>Glycemic control 2nd & 3rd trimesters HbA1C Birth weight Risk of macrosomia</p>	<p>No statistical difference in mean HbA1C over course of pregnancy. Trend toward reduction in HbA1C in weeks 32-26 of pregnancy; Trend toward lower mean birth weight in CGM group (3340g vs. 3630g; p=.07); Mean birth weight centile lower in CGM group (69% vs. 93%; p.02); Fewer babies with macrosomia in CGM group (13% vs. 18%; p=.05).</p>	<p>All women seen in antenatal diabetes clinic. No separation of results by type of diabetes (I or II) & higher proportion of Type I diabetics in CGM group which could account for difference in birth weight and macrosomia.</p>
<p>Peyrot 2009²¹ Adults Type I DM Medtronic Paradigm 722 System</p>	<p>N=28. Intervention (N=14): integrated insulin pump with CGM Control (N=14): multiple daily injections with home blood glucose monitoring 16 week study</p>	<p>Glycemic control HbA1C Insulin Delivery System Ration Questionnaire (IDSRQ) Blood Glucose Monitoring System</p>	<p>No difference in HbA1C change between intervention and control group at 16 weeks (-1.7% intervention vs. -1.0% control; p=.07). Intervention participants reported significantly more convenience, blood glucose control, as well as less blood glucose burden, worry, social burden than the control group. Reports of interference and well-being were the same in both groups. Intervention participants reported significantly more blood</p>	<p>Small study Two-sites</p>

		<p>Rating Questionnaire (BGMSRQ)</p> <p>User Acceptance Questionnaires (UAQs)</p>	<p>glucose control than the control group, but reports of convenience, interference and blood glucose burden were not different between groups.</p> <p>Intervention participants had high acceptability ratings for the new system. No comparison was made with control group.</p>	
<p>Rigla 2008²²</p> <p>Adults Type I Medtronic MiniMed</p>	<p>N=10 All on insulin pumps. Crossover trial: 4 weeks each phase, 6 week washout period between.</p> <p>Intervention phase: CGM for 3 days/week.</p>	<p>Glycemic control HbA1C</p>	<p>Significant decrease in HbA1C after intervention phase (mean decrease .8g/dL) compared to no change in the control phase.</p>	<p>Small trial. All subjects also used telemedical assistance to follow glucose readings and changes in therapy throughout the trial.</p>
<p>Tamborlane 2008²³</p> <p>Adults & children Type I DexCom Medtronic MiniMed FreeStyle Navigator</p>	<p>All on insulin pumps or ≥3 injections per day N=322; (98 ≥25yrs; 110 15-24yrs; 114 8-14yrs) Randomization stratified by 3 age groups, clinical site, HbA1C level.</p> <p>Intervention: daily CGM (change device every 3-7 days);</p> <p>Control: 4xdaily home blood glucose monitoring.</p> <p>26-week study; visits at 1,4,8,13,19 & 26 weeks and phone visits between in-person visits.</p>	<p>Glycemic control</p> <p>Change in HbA1C from baseline to 26 weeks.</p> <p>Mean minutes per day in target glucose range, hyperglycemic and hypoglycemic ranges. Number of severe hypoglycemic episodes.</p> <p>2ndary outcomes: Relative decrease of HbA1C by ≥10%, absolute decrease by ≥.5%, 26-week level <7.0%</p>	<p>Significant decrease for ≥25 year old age group for intervention group compared to control group (-.50 ± .56 vs. .02 ± .45; p<.001). No significant difference in primary outcome for other age groups (age 15-24yrs, age 8-14yrs).</p> <p>In ≥25 year old age group, intervention group spent significantly more minutes in the target glucose range and significantly fewer minutes in the hyperglycemic range than the control group. There was no difference in mean minutes spent in the hypoglycemic range. There was no difference between intervention and control groups in the other two age ranges.</p> <p>There were very few severe hypoglycemic episodes in any age group, with no differences between intervention and control group.</p>	<p>Multicenter. Largest study to date; Intention to treat analysis; Adjusted significant p-value level (.0167) to analyze primary outcome.</p> <p>Adherence to sensor use was much higher in ≥25 year old age group (83% with at least 6 days/week of use) than in the 15-24 year old age group (30% with at least 6 days/week of use) or</p>

		with no severe hypoglycemic events, relative increase by $\geq 10\%$, absolute increase by $\geq 5\%$.	In secondary outcomes of relative decrease of HbA1C by $\geq 10\%$, absolute decrease by $\geq 5\%$, 26-week level $< 7.0\%$ with no severe hypoglycemic events, the intervention group (ages ≥ 25 and 8-14yrs) had significantly higher proportion achieve these goals than the control group. No differences for the 15-24 year old age group.	in the 8-14 year old age group (50% with at least 6 days/week of use).
Tanenberg 2004 ²⁴ Adults IDDM Medtronic MiniMed	N=128; all on insulin pumps or multiple injections / day with baseline HbA1C $> 7.9\%$. Intervention (N= 62/51 analyzed): CGM 3days/week x 12 weeks; Control (N=66; 54 analyzed): 4xdaily home blood glucose monitoring; 12-week study; at the end both groups with 3 days CGM for hypoglycemia measurement	Glycemic control HbA1C Number of hypoglycemic ($\leq 60\text{mg/dL}$) episodes per day. Mean minutes per hypoglycemic episode.	No difference in HbA1C change between intervention and control group at 12 weeks ($-.74\% \pm .95\%$ vs. $-.73\% \pm 1.17\%$; $p=.7$). No difference in number of hypoglycemic episodes per day (Intervention 1.4 ± 1.1 vs. control 1.7 ± 1.2 ; $p=.3$). Fewer mean minutes per hypoglycemic episode for intervention group (49.4 ± 40.9 vs. 81.0 ± 61.1 ; $p=.009$).	Multicenter Due to drop-out in both groups, study underpowered for primary HbA1C outcome.
Yates 2006 ²⁵ Children Type I Medtronic	N=36; all on insulin pumps or multiple injections / day. Intervention (N=19): CGM for 3 days every 3 weeks x 3 months; Control (N=17): 4-6x daily home blood glucose monitoring.	Glycemic control HbA1C	No difference in HbA1C change between intervention and control group at 12 weeks ($p=.83$) or at 6 months ($p=.87$).	Small trial Single site

DM: diabetes mellitus

HbA1c: hemoglobin A1C

IDDM: insulin dependent diabetes mellitus

CGM: continuous glucose monitor

TA Criterion 3 is met for non-pregnant adults.

TA Criterion 3 is not met for children or for pregnant women.

TA Criterion 4: The technology must be as beneficial as any established alternatives.

The standard of care for home glucose measurement is SMBG with a blood glucose meter and a lancet to collect a drop of blood for measurement. It is evident from the RCT's that the use of CGM devices is no worse than standard frequent SMBG measurement. Indeed it appears to have benefit above usual care for those non-pregnant adults who are able to adhere to continual use of CGM sensors and to change their insulin regimen in conjunction with their physician based on CGM data. However, the CGM devices all require regular calibration with blood glucose via SMBG. Thus, even patients utilizing CGM devices must use SMBG for calibration as well as for confirmation of alarm-triggering hypo- and hyper-glycemia. Most of the RCTs of children have been underpowered to detect a difference in benefit for CGM; and in the most recent and largest RCT,²³ while children did no worse, they did not benefit more from CGM use, in part because adherence to continual sensor use may be just too difficult in this population. There has not been an adequately powered RCT of pregnant women to draw conclusions of CGM devices compared to SMBG in this population.

TA Criterion 4 is met for non-pregnant adults.

TA Criterion 4 is not met for children and pregnant women.

TA Criterion 5: The improvement must be attainable outside of the investigational setting.

All of the studies included in this assessment had patients use the CGM device at home, with intermittent follow-up with study investigators. In order to ensure appropriate use of CGM devices patients must be taught how to apply and replace the sensors, how to respond to alarms, and the need to confirm glucose excursions using SMBG. All of this can be done in the non-investigational clinical setting. Certainly, it appears that adherence is a very important component of successful CGM device use, thus teaching and ongoing support will likely play a very important role in clinical use of CGM devices outside the investigational setting. The RCT's also all focused on patients already requiring multiple daily insulin injections or an insulin pump; this population is likely already

conducting SMBG multiple times per day (in the studies four to six times daily), and are the appropriate population in which to consider use of a CGM device in part because they are likely already receiving close follow-up for their diabetes. However, because CGM devices have not been proven in clinical trials to improve net health outcomes for children and pregnant women, that benefit also cannot be obtained outside the investigational setting.

TA Criterion 5 is met for non-pregnant adults.

TA Criterion 4 is not met for children and pregnant women.

CONCLUSION

In summary, the largest RCT to date of CGM devices for adults and children was well designed and analyzed, and it found conclusive benefit only for adults 25 years and older. While in this study, and in other smaller RCT's there is evidence that both children and adults spend less time in a hypoglycemic glucose range when using an CGM device compared to usual care frequent SMBG, there is little evidence that use of a CGM device confers an ultimate health benefit as measured by HbA1C a marker of overall glycemic control. It may be that for children and adolescents this is in large part due to difficulty with device adherence and not with the device itself. However, a health technology is only as good as its actual clinical application, and the evidence has not yet shown conclusive benefit for children, adolescents, and even young adults. Likewise, while the small studies that exist of pregnant women show the feasibility of CGM device use during pregnancy, they do not yet demonstrate conclusive benefit in this population either. Future study of these devices should incorporate more research on how the devices can be made more acceptable and user-friendly for children and adolescents with Type I diabetes in order to optimize potential clinical benefit for this population. Larger studies of pregnant women which are limited to those women requiring multiple insulin injections per day are needed in order to adequately assess potential benefit in this population.

DRAFT RECOMMENDATION

It is recommended that: continuous glucose monitoring devices *meet* CTAF criteria 1-5 for safety, effectiveness and improvement in health outcomes for the management of diabetes mellitus in non-pregnant adults requiring multiple (≥ 3) daily insulin injections and frequent (≥ 3) self-monitoring blood glucose checks.

It is further recommended that continuous glucose monitoring devices *do not* meet CTAF criteria 3-5 for safety, effectiveness and improvement in health outcomes for the management of diabetes mellitus in children, adolescents and pregnant women.

March 11, 2009

A previous assessment of this technology was reviewed by CTAF in October 2003.

RECOMMENDATIONS OF OTHERS

Blue Cross Blue Shield Association (BCBSA)

The BCBSA Technology Evaluation Center has not conducted a review of this technology since 2003 when it was determined that TEC criteria were not met.

Centers for Medicare and Medicaid Services (CMS)

CMS does not have a NCD specific to the use of this technology.

American Association of Clinical Endocrinologists (AACE)

The California Chapter of the AACE has been invited to provide an opinion and to have a representative at the meeting to provide testimony.

American Diabetes Association (ADA)

The ADA has been invited to have a representative at the meeting to provide testimony. The ADA Standards of Medical Care in Diabetes – 2009 were recently published in the January 2009 issue of Diabetes Care.

ABBREVIATIONS USED IN THIS REVIEW

CTAF	California Technology Assessment Forum
CGM	Continuous blood glucose monitoring
FDA	U.S. Food and Drug Administrations
RCT	Randomized controlled trials
HBA1C	Hemoglobin A1C
SMBG	Self-monitoring of blood glucose
DARE	Database of Abstracts of Reviews of Effects

APPENDIX I: Detailed search criteria

Pubmed Search

Search	Most Recent Queries	Time	Result
#22	Search #21 OR #18	16:47:41	<u>87</u>
#18	Search #11 AND SYSTEMATIC REVIEW*	16:46:42	<u>2</u>
#21	Search #12 NOT (REVIEW[PT] OR EDITORIAL[PT] OR LETTER[PT] OR NEWS[PT] OR NEWSPAPER ARTICLE[PT])	16:46:13	<u>85</u>
#12	Search #11 AND (CONTINUOUS[TI] OR CGMS[TI] OR CGM[TI] OR CHMG[TI])	16:26:46	<u>95</u>
#11	Search #9 NOT #10	16:26:14	<u>143</u>
#10	Search #9 Limits: Animals	16:26:02	<u>6</u>
#9	Search #7 OR #8	16:24:08	<u>149</u>
#8	Search #6 Limits: Research Support, N I H, Extramural, Research Support, N I H, Intramural, Research Support, Non U S Gov't, Research Support, U S Gov't, Non P H S, Research Support, U S Gov't, P H S	16:21:37	<u>130</u>
#7	Search #6 AND (CLINICAL TRIAL OR CLINICAL TRIALS AS TOPIC[MH] OR RANDOMIZED CONTROLLED TRIAL*)	16:18:22	<u>65</u>
#6	Search #2 AND #3 Limits: Publication Date from 2003 to 2008	16:17:57	<u>261</u>
#5	Search #2 AND #3 Limits: English	16:17:15	<u>326</u>
#3	Search CONTINUOUS GLUCOSE MONITOR* OR CONTINUOUS GLUCOSE MEASUR* OR CONTINUOUS BLOOD GLUCOSE MONITOR* OR CONTINUOUS BLOOD GLUCOSE MEASUR* OR CONTINUOUS SUBCUTANEOUS GLUCOSE MONITOR* OR ("CONTINUOUS HOME MONITORING" AND GLUCOSE[TIAB]) OR CONTINUOUS GLUCOSE SENSOR* OR CGMS[TIAB] OR CGM[TIAB] OR CHMG[TIAB]	16:11:16	<u>803</u>
#2	Search DIABETES MELLITUS, TYPE 1[MH] OR DIABETES MELLITUS[MAJR:noexp] OR TYPE 1 DIABETES OR TYPE I DIABETES OR JUVENILE DIABETES	16:08:19	<u>100003</u>

Embase Search

No.	Query	Results
#12	'continuous *4 monitor' OR 'continuous *4 monitors' OR 'continuous *4 monitoring' OR 'continuous *4 measurement' OR 'continuous *4 measurements' OR 'continuous *4 sensor' OR 'continuous *4 sensors' OR cgms:ti,ab OR cgm:ti,ab OR chmg:ti,ab	14,311
#13	'insulin dependent diabetes mellitus'/de OR 'diabetes mellitus'/mj OR ((diabetes:ti,ab OR diabetic:ti,ab) AND ('type 1' OR 'type i')) OR 'juvenile diabetes'	139,780
#14	#12 AND #13	584
#15	#14 AND ('clinical trial'/exp OR 'clinical study'/de OR 'major clinical study'/de OR 'controlled study'/de OR random*:ti,ab)	297
#16	#15 AND [english]/lim	275

#17 #15 AND [english]/lim AND [animals]/lim	7
#18 #16 NOT #17	268
#19 #16 NOT #17 AND [2003-2008]/py	204
#20 #16 NOT #17 AND ([editorial]/lim OR [letter]/lim OR [review]/lim OR [short survey]/lim)	38
#21 #19 NOT #20	175
#22 #21 AND (continuous*:ti or cgms:ti or cgm:ti or chmg:ti)	122

Cochrane Search

ID	Search	Hits	Edit	Delete
#1	<u>(TYPE 1 NEAR DIABET*) OR (TYPE i NEAR DIABET*) OR JUVENILE DIABETES OR JUVENILE DIABETIC OR "INSULIN DEPENDENT" and (CONTINUOUS NEAR MONITOR*) OR (CONTINUOUS NEAR MEASUR*) OR (CONTINUOUS NEAR SENSOR*) OR CGMS OR CGM OR CHMG</u>	47	edit	delete
#2	<u>(TYPE 1 NEAR DIABET*) OR (TYPE i NEAR DIABET*) OR JUVENILE DIABETES OR JUVENILE DIABETIC OR "INSULIN DEPENDENT" and (CONTINUOUS NEAR MONITOR*) OR (CONTINUOUS NEAR MEASUR*) OR (CONTINUOUS NEAR SENSOR*) OR CGMS OR CGM OR CHMG and (CONTINUOUS* OR CGMS OR CGM OR CHMG):ti, from 2003 to 2008</u>	26		

Search Results

Show Results in:

[Cochrane Reviews \[1\]](#) |
 [Other Reviews \[0\]](#) |
 [Clinical Trials \[23\]](#) |
 [Methods Studies \[0\]](#) |
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Please note: exported CLINICAL TRIALS [23 REFS] & TECHNOLOGY ASSESSMENTS [2 REFS] only; COCHRANE REVIEWS [1 ref] not relevant.

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