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THE sensor report

ISSUE 1/2026

## WELCOME TO

# THE SENSOR REPORT, ISSUE 1, 2026

The use of CGM devices for people with diabetes was quickly shown to have significant benefits over self-monitored blood glucose (SMBG) for reductions in HbA1c and episodes of hypoglycemia.[1–4] A paradigm shift in the value of using CGM technology arrived in 2021 when the RELIEF study in France demonstrated that the application of the FreeStyle Libre system* for people with T1DM or T2DM significantly reduced hospital admissions for acute complications of diabetes (ADEs), such as severe hypoglycemia or diabetic ketoacidosis (DKA).[5] This pivotal research linked the use of CGM technology to reduce healthcare resource utilization (HCRU), which is one of the most significant direct costs associated with diabetes. Subsequently, numerous studies have shown the same impact of CGM on ADEs and hospital admissions or emergency room (ER) visits for people with T1DM or T2DM on insulin or non-insulin treatment regimens.[6–11]

Reductions in the frequency of DKA are an important part of this story, since DKA is responsible for more hospitalization and ER attendance than severe hypoglycemia for people with diabetes.[10,12] DKA is an acute complication of diabetes,[13,14] and is one of the most preventable causes of morbidity and mortality for individuals with diabetes.[15] The use of CGM technology can be expected to mitigate risks for DKA, given that visualization of elevated glucose levels will have an impact on user behaviors to limit or avoid hyperglycemia. However, despite the impact of using CGM technologies, particularly the FreeStyle Libre systems,[10,12] DKA rates for people with diabetes remain significant, with associated costs.

In this issue of the *Sensor Report*, we look at the pathophysiology of DKA and how diabetes technology can drive further reductions in the frequency and impact of DKA for people with diabetes. This is critical, since existing advice on self-monitoring of ketone levels at times of higher risk for DKA is poorly adhered to, such that people with diabetes do not know how to respond to elevated ketones or whether to seek emergency medical care.[16–18] With the anticipated introduction of continuous ketone monitoring (CKM) technology with regulatory approval for use as medical devices, expert recommendations have been authored that speak to the interpretation of CKM-detected ketonemia and what actions should be taken by people with diabetes and their healthcare professionals.[19] We take a look at what this means in clinical practice, and look at the opportunity to reduce DKA rates even further.

## IN THIS ISSUE



As part of this innovation in metabolic sensing technology, Abbott hosted a Spotlight session at the recent 61st European Association for the study of Diabetes (EASD) annual meeting, in which the real-world benefits and challenges of a combined glucose-ketone sensor were explored. This device combines the capability to provide both CGM and CKM functionality in a single sensor#. This minimizes additional burden for a person with diabetes and provides early awareness of rising ketone levels without the need for capillary fingerstick ketone testing or urine testing. A summary of this session is provided as part of our coverage of the EASD annual meeting.

In addition, we also report on several other outcomes presented at the EASD congress, including a separate Spotlight session that highlighted the urgent need for improved minimum standards for CGM accuracy and performance in the European medical technology marketplace. A CE mark is not a sufficient guarantee of CGM accuracy. Currently, only a small number of CGM devices including the FreeStyle Libre 2 and Libre 3 systems, meet the minimum standards for accuracy and performance as required by the US food and drug administration.

*Sale of the original FreeStyle Libre system has been discontinued in EU & UK markets. In these markets, the FreeStyle Libre 2 and 3 systems are for sale, providing the same benefits as the original FreeStyle Libre system, with the added functionalities of optional Real-Time Alarms.

# Product pending CE marking, not available for sale within the EU and UK.


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# Diabetic ketoacidosis, an underestimated and severe acute complication of diabetes

**Diabetic ketoacidosis (DKA) is an acute complication of type 1 diabetes (T1DM) or type 2 diabetes (T2DM),[1,2] and is one of the most preventable causes of morbidity and mortality for individuals with diabetes.[3] Episodes of DKA are a consequence of insufficient insulin action due to insulin deficiency leading to catabolism of muscle protein, releasing amino acids that are both gluconeogenic and ketogenic. Excessive lipolysis of endogenous triglycerides results in high levels of free fatty acids that are oxidized in the liver to ketone bodies. The sum total of these metabolic processes typically leads to an established diagnostic triad of hyperglycemia, metabolic acidosis and ketosis.**

Annual rates of hospitalization for DKA among children and adolescents with T1DM range from 5.0% to 7.1% across the UK, USA, Germany and Austria.[4] Hospital admission and registry data also report annual DKA rates of 1.9-2.8% in adults with T1DM and 0.5-0.9% for insulin-treated T2DM in the US,[5] Germany, Austria and Belgium.[6–8] DKA is also prevalent in at least 35% of hospital admissions for new-onset T1DM and is common at presentation for individuals with ketosis-prone T2DM.[9,10] Overall, rates of DKA for people with diabetes are increasing,[5,11] and it is important to note that admissions for DKA are much more common than for severe hypoglycemia in children and adults with T1DM.[12,13]

DKA is more common in younger individuals with T1DM and there are specific groups of people with diabetes at heightened risk for DKA,[14] including older and frail individuals, insulin pump users, young adults and teenagers with T1DM, rural populations, people with comorbid mental health disorders, pregnant women with T1DM, and people treated with sodium-glucose cotransporter 2 (SGLT2) inhibitors. Longitudinal studies show that experiencing a DKA episode is associated with significantly increased long-term risks for major adverse cardiovascular events (MACE), acute kidney injury and advanced kidney disease, neuropathy, retinopathy, recurrent DKA and all-cause mortality.[15–17] Recent data indicate that DKA can be associated with short-term and long-term neurocognitive effects, including reduced IQ scores and attention deficits.[18–20]

*Euglycemic diabetic ketoacidosis*

Not all episodes of DKA are accompanied by marked hyperglycemia. The phenomenon of euglycemic DKA in people with diabetes, with glucose below the 11.0 mmol/L (200 mg/dL) diagnostic threshold, was previously estimated to represent approximately 3% of cases in T1DM.[21] However, it is emerging as a more-common event in special populations at risk of DKA, including during pregnancy[22] and in treatment with SGLT2 inhibitors.[23] Cases of euglycemic DKA have also been reported in individuals with T1DM on insulin pump therapy.[24] Episodes of euglycemic DKA may also lack the typical symptoms of polydipsia and polyuria. For these reasons, ketone monitoring rather than glucose monitoring is the most reliable way to assess ketonemia and increased risk for DKA.

### Ketone monitoring in diabetes

Symptoms of DKA include nausea, vomiting, abdominal pain and fatigue, which may manifest at levels of ketonemia above 0.6 mmol/L of β-hydroxybutyrate.[2,25] As ketonemia increases, symptoms may also include confusion or difficulty paying attention, fruity breath, polydipsia, dry lips and difficulty breathing. Guidelines recommend that people living with diabetes should check their ketone levels if they are experiencing severe hyperglycemia or under certain conditions when they may be at higher risk of ketosis and acidosis or when they may be experiencing symptoms of DKA. These so-called 'sick day rules', also recommend that if a ketone test indicates a concentration of greater than 1.5 mmol/L, then the person with diabetes should call their healthcare provider for advice, and if a reading is 3.0 mmol/L or above, they should seek immediate medical attention.

Self-monitoring of ketones using capillary fingerstick test strips and meters or urine colorimetric dipsticks is well established. However, several surveys indicate that people with diabetes do not engage well with ketone testing. A US-based online survey, completed by 2,995 people in the T1D Exchange Clinic Registry, found that only 18% reported possessing a blood ketone meter and only 21% reported checking urine or blood ketone levels when nauseous or vomiting.[26] A survey of individuals with T1DM across Swiss and German outpatient diabetes clinics[27] revealed that 32% had no knowledge of DKA, almost half could not name a single symptom or potential cause of DKA, and 64% never tested for ketones. Notably, when surveyed, healthcare professionals overestimated the knowledge that people with diabetes, in their care, have regarding DKA.[27]

The reality of living with diabetes means that avoidance of DKA is a critical component of routine self-management. Yet this aspect of daily care is not well emphasized, with potentially serious consequences for people with diabetes that can be prevented with effective education and ketone self-monitoring behaviors.

### International guidelines for diagnosis of DKA in children and adults

| | Children and adolescents[2] | Adults[1] |
|---|---|---|
| Hyperglycemia | >11 mmol/L (>200 mg/dL) | ≥11.1 mmol/L (≥200 mg/dL) |
| Venous pH | <7.30 | <7.30 |
| β-hydroxybuyrate (BHB) | ≥3.0 mmol/L | ≥3.0 mmol/L |
| Serum bicarbonate | <18 mmol/L | <18 mmol/L |

### Possible symptoms of DKA

*Early symptoms – ketone concentrations >0.6 mmol/L*

Nausea/Vomiting · Abdominal pain · Fatigue

*Significant symptoms – ketone concentrations >1.5 mmol/L*

Nausea/Vomiting · Abdominal pain · Fatigue

Difficulty breathing · Fruity breath

Confusion/difficulty paying attention

Excess thirst · Frequent urination


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# **Insights** from EASD 2025 Annual Congress

## Continuous ketone monitoring: a glimpse into the near future

**In a scientific session at the 61st EASD annual meeting[1], chaired by Professor Ketan Dhatariya, two international experts on ketone monitoring and diabetic ketoacidosis (DKA) debated the potential benefits of continuous ketone monitoring (CKM). The benefits were explored by Dr Jennifer Sherr, Professor of Pediatrics at Yale School of Medicine, and the challenges were addressed by Professor Richard Bergenstal, Executive Director of the International Diabetes Center in Minnesota.**

DKA is a serious acute complication of diabetes and is a common presenting symptom of new-onset diabetes in youth, both in T1DM and in T2DM.[2] For people with established diabetes, DKA rates range from 5-10% annually,[3] and is associated with female sex, non-white status and above target HbA1c. Notably, DKA is also associated with insulin pump infusion set failures, a problem which is reported as a monthly occurrence by 41% of insulin pump users.[4] Costs for DKA-related hospital admissions vary depending on the national health service, but are significant.[5,6] Since each episode of DKA increases the risk of further DKA events, there is a currently unmet need to better prevent this acute diabetes complication.

Current methods to measure ketones for a person with diabetes include urine-stick colorimetric acetoacetate detection, which is not fully quantitative, or β-hydroxybutyrate (BHB) capillary blood fingerprick testing. Each of these methods have advantages and disadvantages but in reality the majority of people with diabetes do not actively test for ketones, even at times recommended by their healthcare provider.[7,8]

### Potential benefits of continuous ketone monitoring

A key benefit of CKM technology is that it provides passive, 24-hour feedback on BHB ketone levels in the interstitial fluid, in the same way that CGM devices measure glucose levels. By alerting users to elevated ketone levels, it prompts action to manage ketonemia before DKA can develop. The use of trend arrows to provide information on the rate and direction of ketone changes is an important part of CKM technology, adding additional information of value for the user.

Abbott is currently developing a CKM sensor that will be integrated with a CGM sensor in a dual glucose-ketone sensor*, which will provide the user with both real-time glucose and ketone values, as needed. This means that users will still only need to wear a single sensor. Published data shows that the ketone monitoring function is feasible.[9] Data from insulin suspension studies using the CKM sensor, presented by Dr Sherr during the session[10], shows that variability in ketone levels is not dependent on starting glucose levels or the duration of diabetes of the user. Notably, some individuals showed ketone profiles that became elevated faster than glucose, while others had ketonemia without any change in glucose levels. These observations are a clear indication of the phenomenon of euglycemic DKA and show that the need for ketone monitoring extends beyond people experiencing hyperglycemia.

**To watch an interview with Professor Ketan Dhatariya reviewing the EASD 2025 spotlight session "Continuous ketone monitoring: a glimpse into the near future", simply scan the QR code**

https://www.springermedicine.com/glucose-monitoring-and-insulin-delivery-devices/easd-2025/ketan-dhatariya-benefits-challenges-ckm/51471052

**Clinical scenarios that emphasize the value of CKM technology[1]**

- Monitoring for people with early-stage T1DM
- Reducing recurrent DKA
- Access to potentially ketogenic adjunctive therapies
- DKA avoidance during illness or other precipitating factors
- Identifying insulin pump infusion-set failures

### Potential challenges of continuous ketone monitoring

Before a CKM device can fulfil these promises it has to meet certain important standards. First among these is that it must be easy to apply and use, in the same way that CGM devices are proven to be. It must also have a name that describes its utility without confusing users or healthcare providers. Accuracy must be good enough for regulators to approve the device for use as a medical technology, including the trend arrows that accompany individual readings. The accuracy must also support the functionality of other digitally-connected devices, such as insulin pumps or AID systems, in order to manage both glucose and ketone homeostasis. The sensor must have a wear time that meets the needs of users, particularly those who are experienced with the FreeStyle Libre 2 and 3 systems, which have a 14-day wear time, or 15 days if using the 'plus' versions of the sensors. Data transfer capability for remote access by healthcare professionals is also a key challenge that must be addressed.

The wealth of data that will be generated by CKM devices, whether as part of a dual glucose-ketone sensor or as a stand-alone device, must be visualized effectively. To date, there are very few studies that have attempted to understand ketone profiles and there is no data that indicates what would be a 'normal' ketone profile for a person with diabetes on any of the various therapies used for glycemic management. The utility of CGM glucose data has been greatly enhanced by the development of the ambulatory glucose profile (AGP), which allows actionable decisions on diet, lifestyle and treatment adjustments. The same is true for the data that will be generated by CKM technology.

**Challenges for the application of CKM technology**

- Accuracy, for individual ketone readings and associated trend arrows
- Digital integration with digitally connected diabetes ecosystems
- Wear time must meet the needs of users with diabetes in daily life
- Data visualization that is actionable and empowers effective diabetes care and therapy adjustment


*Product pending CE marking, not available for sale within the EU and UK.

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# Minimum expectations for market authorization of CGM devices in Europe

**To a full audience in one of the scientific sessions at the 61st EASD annual meeting, chaired by Professor Tadej Battelino, three international experts on diabetes technologies explored the anomalous situation in which European regulators find themselves in need of minimum accuracy and performance standards for CGM devices.**

Professor Concetta Irace, from the University Magna Graecia in Catanzaro in Italy, guided the audience through the European Union (EU) medical devices regulatory landscape for CGM systems, which are designated as Class II medical devices. The most-recent Medical Device Regulation is MDR 2017/745, applicable in all EU member states, and requires clinical evaluation data to be generated by the device manufacturer and submitted to a Notified Body, which are private companies subject to EU oversight.

The main goals of MDR 2017/745 are to strengthen patient safety and increase transparency of the device approval process, including premarket approval, CE Marking and device registration, and post-market surveillance. Within this process, device manufacturers can choose which Notified Body they submit their Clinical Evaluation Assessment Report (CEAR). Although the CEAR should contain preclinical data on their own device, it is possible to make a submission using only published data on 'equivalent' devices, alongside unpublished in-house data on their own product. This creates a problem, since the final technical documentation is not publicly accessible to healthcare experts or payers, who have to recommend which CGM devices are provided to people with diabetes. A consequence of this has been that a CGM device, chosen through a cost-based tendering process, was provided to people with diabetes in the Campania region in Italy, which lacked accuracy and which physicians and people with diabetes refused to use. People with diabetes had to resort to fingerprick glucose monitoring and physicians could not intensify treatment, as necessary.

## MARD does not guarantee accuracy of CGM devices

The issue across Europe, highlighted by Professor Peter Adolfsson from Gothenburg University, is the effective medical evaluation of accuracy data. CGM is now established as the gold standard for care of children and adults with T1DM, and a shorthand for accuracy has become the mean absolute relative difference (MARD) of a CGM system. This refers to the difference between a CGM reading and a reading taken by a laboratory blood-glucose analyzer at the same time. A MARD of 10% or less is typically assumed to reflect a highly accurate system. If the data in a CEAR cannot be openly scrutinized by expert professionals, generating a MARD ≤10% for use in a CEAR can be achieved by so-called 'MARD doping'. This is the practice of testing a CGM in populations with low glucose variability and under controlled conditions that do not replicate the real-world daily living with diabetes. Similarly, MARD accuracy data can include only those days when performance is within the necessary range, ignoring periods when MARD was higher than the desired range. Such MARD doping is possible if the data is not published or open to review.

When transparency is lacking, the issue of trust becomes very important for a person with diabetes and their healthcare provider. This is further amplified when CGM is used in conjunction with insulin pumps in sensor-augmented insulin pump systems or automated insulin delivery (AID) systems. In digitally-connected diabetes ecosystems, the need for CGM systems with proven accuracy is critical, since insulin dosing calculations will be made by the connected system, based on glucose readings delivered by the CGM device. Currently, a CE Mark does not guarantee a CGM device can meet these needs, no matter what the MARD suggests.

The future of diabetes care will become more dependent on the interoperability of separate technology components, working together and driven by artificial intelligence (AI) algorithms that can adapt to the input data. This cannot work if any component is not providing accurate data. This reality requires that the regulatory standards applied in Europe meet the most-rigorous standards required to guarantee the safety of people with diabetes under these rapidly evolving conditions.

## eCGM - going beyond MARD, and then further

Accepting that MARD is an insufficient measure of accuracy, the optimal scenario for ensuring and improving the glycemic health of people with diabetes in Europe, was outlined by Professor Stefano Del Prato from the Sant'Anna School of Advanced Studies at the University of Pisa. Because every single CGM reading matters when making self-treatment decisions, or as part of a connected insulin management system, the average of all glucose readings is of limited value.

This is why the US FDA iCGM requirements are so notable. These specify 12 separate performance criteria for CGM devices, which cover accuracy at 6 different glucose concentrations, including performance at high and low glucose levels, and under conditions of rapid glucose change. Meeting each of these separate performance criteria is essential, for each of the intended use populations. This means hitting these requirements for children and adolescents, adults with T1DM or T2DM and during pregnancy. The world of clinical diabetes management already needs these levels of accuracy for each component of diabetes technology. From a European perspective, the essential components of any regulatory decision must include data that shows that the system performs to the standards outlined in the box.

**Accuracy and performance requirements for CGM technology in Europe (eCGM)**

- Performance has been tested at each anatomical wear site claimed for the system.
- Clinical data must demonstrate consistent analytical performance throughout the sensor wear period.
- Accurate real-time glucose transmission is guaranteed at clinically meaningful time intervals to other connected devices.
- Glucose variability should reflect glucose changes in the intended use population.
- Changes in performance under different rates of change must be disclosed.
- Sensors must demonstrate acceptable performance in the presence of clinically relevant potential interfering substances.
- System design safeguards must ensure that disposable sensors cannot be used beyond their claimed sensor wear period.

**Watch a summary of the session with Professor Stefano Del Prato by scanning the code here**

https://www.springermedicine.com/glucose-monitoring-and-insulin-delivery-devices/easd-2025/del-prato-market-authorization-cgm-devices/514737302

Battelino T, et al. Minimum expectations for market authorization of continuous glucose monitoring (CGM) devices in Europe. Spotlight Stage, SP09, EASD 2025: 61st Annual Meeting. Vienna, Austria. 15-19 Sept 2025

# Diabetic ketoacidosis in T1DM: real-world data from the SFDT1 cohort in France

**The Suivi en France des personnes avec un Diabète de Type 1 (SFDT1) is a prospective study of people living with T1DM in France. This oral presentation at the EASD 2025 annual congress describes the prevalence and characteristics associated with diabetic ketoacidosis (DKA) in this study cohort.**

Data from 2,685 individuals with T1DM were collected between January 1, 2023, and December 31, 2024. 36.4% of the study cohort were on multiple daily injections (MDI), 21.7% were on automated insulin delivery (AID) systems and 41.9% were on non-AID insulin pump therapy. Annually, at least one DKA episode occurred in 4.5% of all participants. DKA was associated with younger age ($p<0.001$), shorter T1DM duration (<0.001) and higher HbA1c ($p=0.001$). DKA rates were highest in the 18-24 year age group, with annual prevalence of 10.3%.

Across insulin treatment regimens, DKA rates in AID users were 3.1%, compared to 4.5% in MDI therapy and 5.4% in non-AID pump users. Use of CGM systems, either alone or in combination with SMBG, was associated with annual DKA rates of 4.4%, compared to 8.1% for people using SMBG alone. 25.4% of the study cohort reported more than one DKA episode per year, and severe hypoglycemia events (SHEs) were much more common in this group compared to those with only one DKA event per year (27.0% vs 8.5%, $p<0.001$).

In summary, even with CGM use in at least 95% of the study cohort and AID use by 21.7% of people, annual DKA rates were 4.5%, indicating the need for further reduction in these groups. More-frequent DKA rates were associated with greater risk of SHEs, which indicates that further education is needed regarding symptoms of DKA and the need for ketone monitoring.

Riveline J-P, *et al.* Prevalence and Characteristics of Diabetic Ketoacidosis in Type 1 Diabetes: Real-World Data from the French SFDT1 Cohort. Late Breaking Abstract Oral Presentation 27, EASD 2025: 61st Annual Meeting. Vienna, Austria. 15-19 Sept 2025

# Analyzing real-world ketone testing behaviors and glucose levels in people with diabetes using the FreeStyle Libre systems

**People using the FreeStyle Libre systems with compatible handheld reader are able to test their ketone levels using the test-strip port on the reader. This study aimed to evaluate ketone testing frequency in relation to glucose levels among FreeStyle Libre reader users, and to understand the distribution of ketone levels.**

De-identified data was available from 165,108 FreeStyle Libre readers, recording 3,023,587 ketone tests between September 2014 and January 2025. Of all ketone tests performed, 4.6% recorded ketone concentrations ≥1.5 mmol/L, a level that indicates concern over impending diabetic ketoacidosis (DKA), and 1.8% of tests recorded ketone levels ≥3.0 mmol/L, which indicates users should seek immediate medical attention. Notably, 7.9% of separate FreeStyle Libre handheld readers had recorded ketone levels ≥3.0 mmol/L, suggesting that this proportion of users had at least one episode of ketonemia requiring immediate medical attention.

Glucose readings within the 20 minutes prior to a recorded ketone test showed a median glucose level of 311 mg/dL (17.3 mmol/L), with 72% of ketone tests being associated with glucose levels >250 mg/dL (>13.9 mmol/L). This aligns with guidance to test ketones when glucose readings are elevated for any reason. Median ketone test frequency was one test per day, on days when a test was performed, but this rose to a median of two tests per day once ketone levels had tested at >0.5 mmol/L, indicating that user concern was elevated.

Overall, ketone testing behavior did reflect user concerns about high glucose among people using a CGM system with integrated ketone testing capability. Given that adherence to ketone monitoring guidance is low among people with T1DM, more-convenient ketone monitoring methods could improve rates of adherence.

Quadri F, *et al.* Analyzing real world ketone testing behaviors and glucose Levels in FreeStyle Libre readers. Oral Presentation 878, EASD 2025: 61st Annual Meeting. Vienna, Austria. 15-19 Sept 2025

# Clinical burden associated with T2DM in France: an update from the national insurance claim database

**Using data from the ESND national insurance claims database this study evaluated the burden of T2DM in France considering the new treatments and technologies available. The study was a cross-sectional analysis, comparing data from 2013 to those from 2022.**

The analysis covered 80,127 people with T2DM (mean age 68.4 years) and 237,607 propensity-score matched controls without T2DM from the ESND claims database, which has coverage of approximately 99% of the population in France. Relative rates (RR) of comorbidities and complications were significantly higher in people with T2DM compared to controls, with 77% increased RR for stroke, 115% increased RR of myocardial infarction, and 217% increased RR for heart failure. These increased rates of comorbid cardiovascular disease were similar to the rates described in 2013 for people with T2DM.

Glucose lowering treatment patterns remained largely unchanged between 2013 and 2022, despite the availability of new therapies, such as sodium-glucose cotransporter 2 (SGLT2) inhibitors and glucagon-like peptide 1 receptor agonists (GLP-1 RA). The use of CGM devices was also not extensive in the T2DM population.

The treatment inertia between 2013 and 2022 revealed in this analysis suggests that new treatment modalities and diabetes technologies, such as the FreeStyle Libre systems, can be more-widely applied in the management of people with T2DM in France.

Riveline J-P, *et al.* Clinical burden associated with Type 2 diabetes mellitus in France: an update from the national insurance claim database. Oral Presentation 365, EASD 2025: 61st Annual Meeting. Vienna, Austria. 15-19 Sept 2025

# Using CGM for people with T2DM not on Insulin is cost effective from a Medicaid perspective

**Medication reimbursement for use of CGM in people with T2DM currently covers only those on insulin therapies. This analysis considered the cost-impact of expanding access to CGM for all adult Medicaid beneficiaries with T2DM in the United States.**

The scenario projects market costs in Year 1, Year 2, and Year 3 of CGM for people with T2DM on multiple daily injections of insulin (MDI) or on basal insulin, compared to those for people not on insulin. The analysis compared the acquisition cost of CGM in each case, to the healthcare resource utilizations (HCRU) costs for all-cause inpatient hospitalizations and all-cause emergency room visits.

For people with T2DM on MDI regimens, addition of CGM results in potential annual cost savings of $13,035 per person. For a person with T2DM on basal insulin, the annual cost savings of providing access to CGM are $2,067 per person, and for people with T2DM not on insulin, access to CGM is associated with annual cost savings of $917 per person.

Calculating the three-year horizon cost savings for using CGM in people with T2DM on insulin or non-insulin therapy, the budget impact was a $1.9 Billion saving, driven by a $929 million reduction in direct HCRU costs for treating people with T2DM not on insulin. Even without consideration of indirect costs, providing access to CGM systems for all people with T2DM is financially beneficial for the Medicaid health insurance program.

Wright E, *et al.* CGM for People with T2DM not on Insulin—Budget Impact Analysis from a Medicaid Perspective. Oral Presentation 935, EASD 2025: 61st Annual Meeting. Vienna, Austria. 15-19 Sept 2025

# Use of CGM is associated with fewer acute diabetes events and reduced healthcare costs for people with T2DM on insulin in France

**Acute complications of diabetes, such as diabetic ketoacidosis (DKA) and severe hypoglycemia events, are a cause of considerable morbidity and mortality for people with diabetes. The objective of this study was to assess changes in acute diabetes events and hospital resource utilization one year before and after real-time CGM initiation for people with T2DM treated with any insulin regimen.**

Using data from the French SNDS national healthcare claims database, this retrospective analysis included acute diabetes outcomes, such as diabetic ketoacidosis and severe hypoglycemia, and healthcare resource utilization figures for 1,456 CGM users with T2DM treated with insulin, during the period from 1st January 2016 to 31st December 2022.

In the 12 months following initiation of CGM, the occurrence of acute diabetes events was reduced by -32% compared to the year before initiation (rate ratio 0.677, p=0.0146). This was associated with a -6.3% reduced use of inpatient resources (rate ratio 0.937, p=0.0119) driven by a reduced number of overnight hospitalization stays (rate ratio 0.827, p<0.0001).

These findings indicate that use of CGM technology is associated with improved diabetes outcomes for people with insulin-treated T2DM in France, with fewer acute diabetes events and lower healthcare resource utilization.

van Genugten M, *et al.* Impact of real-time continuous glucose monitoring (rt-CGM) devices among insulin-treated type 2 diabetes patients in France. Oral Presentation 949, EASD 2025: 61st Annual Meeting. Vienna, Austria. 15-19 Sept 2025

# Real world ketone profiles in people with T1DM using continuous ketone monitoring

**People living with T1DM are at increased risk of diabetic ketoacidosis (DKA). The aim of this study was to profile ketone levels in people with T1DM in daily life and in the absence of acute illness. Interstitial ketone profiles were assessed every 5 minutes with a subcutaneous continuous ketone monitoring (CKM) device as part of the PARTNER study.**

Study participants with T1DM (n=28), not using sodium-glucose cotransporter 2 (SGLT2) inhibitors, used the CKM device during a two-week observation period. 35.7% of the CKM users recorded a ketone level of ≥0.6 mmol/L during the study period. For every 10-year increase in diabetes duration, there was an increased 1.82 odds ratio of ketone levels ≥0.6mmol/L (p=0.046). Seven of the ten participants with ketones ≥0.6 mmol/L did not exceed 0.9 mmol/L. The other three had ketone levels that reached 1.0-1.5 mmol/L on up to 0.5% readings, with a highest level recorded at 1.4 mmol/L.

The majority of time spent with ketone levels ≥1.0 mmol/L occurred between 4-6 AM, and were associated with a median glucose level of 185 mg/dL (10.3 mmol/L), compared to a median glucose level of 140 mg/dL (7.8 mmol/L) in participants reporting ketone readings <1.0 mmol/L. Higher ketone levels were also associated with lower daily carbohydrate consumption. Insulin treatment modality was not associated with ketone concentrations between the participants.

The data in this small-scale study using CKM technology indicate that ketone levels in people with T1DM, who are not treated with ketogenic SGLT2 inhibitors, can rise significantly for a subset of individuals, particularly those with longer duration of T1DM or with lower daily carbohydrate intake.

Ngan J, *et al.* Ketone profiles in free-living people with type 1 diabetes using continuous ketone monitoring. Oral Presentation 877, EASD 2025: 61st Annual Meeting. Vienna, Austria. 15-19 Sept 2025

## Listen to the podcast with Ketan Dhatariya, on the newly published international consensus on continuous ketone monitoring in diabetes

The risk of diabetic ketoacidosis (DKA) remains a major problem for people with diabetes, particularly those on intensive insulin therapy. The anticipated availability of continuous ketone monitoring (CKM) technology has the potential to reduce this risk. The safe and effective use of CKM devices in reducing the occurrence of DKA requires that ketone thresholds are identified at which a CKM user can be made aware that action on their part is required. This interview provides important background and context for the recently published international consensus recommendations on CKM technology and ketone thresholds.

https://www.youtube.com/watch?v=enRWSwP4scM

Continuous ketone monitoring product is pending CE marking, not available for sale within the EU and UK.

# SGLT2 inhibitor associated diabetic ketoacidosis among older individuals with diabetes in France

**This study examined real-world cases of diabetic ketoacidosis (DKA) linked to SGLT2 inhibitors in adults with diabetes aged 65 and older using the French pharmacovigilance database.**

Researchers conducted a retrospective review of 55 validated cases of SGLT2 inhibitor associated DKA reported since 2020. Individuals were predominantly male (63.4%), with a median age of 74 years and high comorbidity burden (median Charlson index 8.0). Most cases were in T2DM (86.5%), or T1DM (5.8%), with no diabetes diagnosis recorded in 7.7% of cases. Polypharmacy was common, with a median of nine drugs per patient. Dapagliflozin was the most frequent SGLT2 inhibitor used (70.9%), followed by empagliflozin (27.3%).

All DKA cases required hospitalization, and 36.4% were admitted to intensive care units (ICU). Among ICU patients, one death occurred. Infections (36.4%), dehydration (20.0%), and fasting (18.2%) were leading precipitating factors. ICU admission was significantly associated with younger age (71 vs. 75 years, p=0.009), lower pH at admission (p=0.003), and infection as a trigger (p=0.007). Notably, symptoms of DKA were often atypical, such as falls or respiratory symptoms, which complicating diagnosis.

These findings emphasize the need for vigilance and patient self-monitoring of ketone levels when on SGLT2 inhibitors therapy, particularly in older, multimorbid patients during infections, dehydration, or surgery, when the risk of severe DKA and ICU admission is heightened.

Bassas Letissier N, *et al.* Ketoacidosis associated with type 2 sodium-glucose cotransporter inhibitors (SGLT2i) in patients aged 65 and older: Evidence from the French national pharmacovigilance database. *Diabetes Metab.* 2025; 51:101697. https://pubmed.ncbi.nlm.nih.gov/40829717

# Use of a continuous ketone monitoring system prevents potential DKA through early awareness of ketonemia

**This case report shows that a continuous ketone monitoring (CKM) device can provide early warning of increasing risk of diabetic ketoacidosis (DKA) in adults with T1DM.**

A 55-year-old man with T1DM (duration 53 years, HbA1c 6.9%) using an automated insulin delivery (AID) system was enrolled in a clinical trial (ACTRN12624000448549) and had initiated use of a CKM device. The device provided real-time interstitial fluid ketone readings with alarms set at ≥1.0 and ≥1.5 mmol/L, as part of the clinical trial protocol.

The CKM device issued a first alarm at 1.0 mmol/L, prompting monitoring and additional insulin administration. Despite this, ketones rose above 3.1 mmol/L within two hours, confirmed as 3.7 mmol/L by capillary blood ketone strip testing. Glucose reached 319 mg/dL (17.7 mmol/L). On investigation a dislodged automated insulin delivery (AID) pump cannula was replaced and insulin infusion re-established. The individual remained asymptomatic throughout and ketonemia and elevated glucose normalized within 4–5 hours, as confirmed by the CKM sensor and hospitalization was avoided.

This case illustrates the potential of CKM technology to act as an early-warning system, detecting ketone rises before symptoms develop and support timely interventions that may prevent DKA and hospital admissions.

Kong YW, *et al.* Preventing diabetic ketoacidosis with continuous ketone monitoring: insights from a clinical research case. *Diabetes Technol Ther.* 2025; Online ahead of print. https://pubmed.ncbi.nlm.nih.gov/40711834/

# The FreeStyle Libre system* is associated with real-world benefits for people with T1DM or T2DM on insulin or non-insulin therapy

**The FRONTIER study evaluated the impact of the FreeStyle Libre system* on HbA1c and hospital use in people with diabetes on intensive insulin or basal insulin therapy, and with or without glucagon-like peptide 1 receptor agonist (GLP-1 RA) therapy.**

This study used Ontario's IC/ES health database to conduct retrospective longitudinal analyses of adults initiating the FreeStyle Libre system between September 2019 and August 2020. The study cohort were then followed for 24 months. Outcomes were compared for the 12 months before and after initiation. One part of the study focused on intensive insulin users,[1] including 10,510 with T1DM, and 12,668 with T2DM. A second part included adults with T2DM treated with basal insulin, with or without GLP-1 RA, or on non-insulin therapy with GLP-1 RA or oral therapy alone.[2]

For people on intensive insulin therapy, HbA1c decreased significantly across all subgroups after starting the FreeStyle Libre system. In T1DM, reductions were –0.8% in people aged <25 years, –0.5% in ages 25–65, and –0.1% in those >65 years (p<0.0001 in all cases). In the T2DM treatment group, HbA1c fell by –0.6% (≤65 years of age) and –0.3% (>65 years of age; both p<0.0001). Emergency department visits and hospitalizations for diabetic ketoacidosis and hypoglycemia fell in younger people with T1DM and across all people with T2DM.

In people with T2DM on basal insulin, those not treated with GLP-1 RA showed mean reductions in HbA1c from baseline of -0.7% (≤65 years) and -0.5% (>65 years) after initiating the FreeStyle Libre system. For those on basal insulin and on GLP-1 RA therapy, mean reductions in HbA1c from baseline were –0.8% (≤65 years) and –0.6% (>65 years) after starting the Freestyle Libre system (p<0.0001 in all cases). For people with T2DM not on basal insulin but treated with GLP-1 RA, using the FreeStyle Libre system was associated with mean reductions in HbA1c of –0.8% (≤65 years) and –0.6% (>65 years). For individuals on oral glucose-lowering therapy only, mean HbA1c fell by 0.6% (≤65 years) and 0.3% (>65 years) (p<0.0001 in all cases).

In the 12 months after initiation of the FreeStyle Libre system, hospitalizations for DKA and hypoglycemia fell in the T2DM groups on basal insulin without GLP-1RA, and for non-insulin treated people with T2DM on GLP-1 RA or oral glucose-lowering therapy.

The FRONTIER study confirms the impact of using the FreeStyle Libre system for people with T1DM or T2DM on insulin or non-insulin therapies, including treatment with GLP-1 RA or oral glucose-lowering treatments. The improvements in glycemia and reduced healthcare resource utilization support wider access to this technology.

* Sale of the original FreeStyle Libre system has been discontinued in EU & UK markets. In these markets, the FreeStyle Libre 2 and 3 systems are for sale, providing the same benefits as the original FreeStyle Libre system, with the added functionalities of optional Real-Time Alarms.

1. Ratzki-Leewing A, *et al.* FRONTIER—FreeStyle Libre system use in Ontario among people with diabetes mellitus in the IC/ES database: Evidence from real-world practice, patients using intensive insulin. *Diabetes Technol Ther.* 2025;27(6):449–459. https://pubmed.ncbi.nlm.nih.gov/39970010/

2. Ratzki-Leewing A, *et al.* FRONTIER—FreeStyle Libre system use in Ontario among people with diabetes mellitus in the IC/ES database: Evidence from real-world practice, patients using basal insulin. *Diabetes Obes Metab.* 2025; 27(5):2637-2646. https://pubmed.ncbi.nlm.nih.gov/40117297/

# The Glycemia Risk Index – what is it?

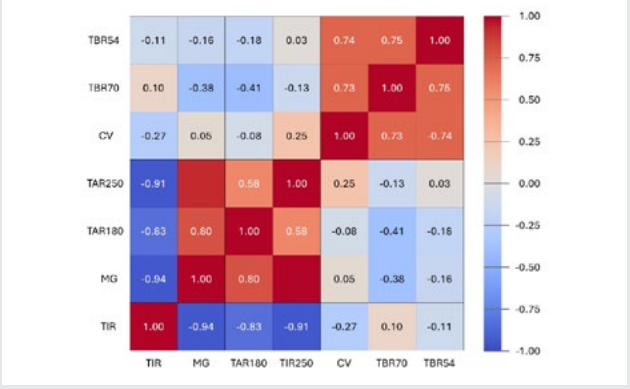
**When using an ambulatory glucose profile (AGP)[1,2] a clinician must simultaneously interpret several CGM-derived metrics to determine the glycemic health of a person with diabetes and decide on any potential changes to treatment. These CGM metrics are: time in range (TIR) 70-180 mg/dL (3.9-10.0 mmol/L), time below range (TBR) with low glucose <70 mg/dL (<3.9 mmol/L) or very low glucose <54 mg/dL (<3.0 mmol/L), time above range (TAR) >180 mg/dL (>10.0 mmol/L) and >250 mg/dL (>13.9 mmol/L), coefficient of variation (CV) – a measure of glycemic variability, and mean glucose.**

However, these metrics are highly interdependent, such that attempts to target one metric for improvement might worsen another. For example, increasing the percentage of TIR towards the consensus clinical target of >70% of time each day[3] might also increase the TBR with low or very low glucose. This makes treatment optimization a complex and unpredictable task. In 2023, a group of expert diabetes clinicians and researchers set out to identify a single composite metric, derived from the CGM data parameters described above, that describes both the risk for hypoglycemia and for hyperglycemia. This is the glycemia risk index (GRI).

The analysis used 14-day CGM profiles from 225 adults with diabetes, who had participated in one of four randomized clinical trials: DIAMOND,[4] DIAMOND-T2D,[5] REPLACE-BG,[6] and DCLP3[7] studies. The profiles included equal numbers of individuals with T1DM using multiple daily injections (MDI), insulin pumps or hybrid closed-loop devices and people with T2DM on MDI therapy. These CGM profiles were reviewed by 330 diabetologists experienced with AGP profiles and ranked from best to worst in terms of the quality of glycemia and which CGM metrics were most interdependent.

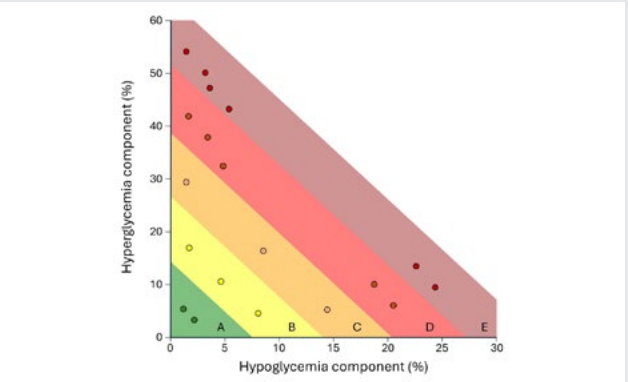
The analysis showed the seven key CGM metrics can be divided into two distinct highly correlated clusters: a hypoglycemia-related group, and a hyperglycemia-related group (**Fig 1**). TIR shows a strong inverse correlation with TAR, but not TBR, whereas TBR shows a strong correlation with glycemic variability as measured by CV. Based on the 14-day profiles, risk profiles were assigned GRI scores from zero to 100, where zero equals no risk and 100 equals maximum risk for adverse hypoglycemic or hyperglycemic outcomes, such as severe hypoglycemia or DKA.

**Figure 1.** Correlation between CGM metrics. A value of 1.0 indicates a strong positive correlation, -1.0 means a strong inverse correlation.




Each person with diabetes using CGM can be assigned a GRI score for their hypoglycemia risk and one for their hyperglycemia risk. These can be plotted on a GRI grid that identifies five risk zones, A-E (**Fig. 2**). In zone A, a person is low risk for both hypoglycemia or hyperglycemia events, and has a stable treatment profile. As risks escalate, the CGM profile moves into progressively higher risk zones, typically emphasizing higher risks for hypoglycemia or hyperglycemia.

**Figure 2.** GRI grid showing risk zones A-E. Each circle is an individual person with diabetes, with differential risks for adverse hypoglycemia or hyperglycemia events.




The use of the GRI grid also allows for an individual's risk profile to be monitored over time, ideally with reduced risks depending on their treatment adjustment. For people with T1DM, the most stable profiles (zones A or B) may be expected on hybrid closed-loop therapy,[8,9] and the highest risk profiles seen in people on MDI therapy. People with T2DM are likely to have higher risk profiles on MDI therapy, in the hyperglycemia region of zone C.[8]

Overall, GRI correlates well with other CGM-derived indicators and has demonstrated relevance in various settings, including the management of individuals using hybrid closed-loop systems and individuals with HbA1c≤7%, where it can capture risks for hypoglycemia not evident in the TIR for an individual.

1. Danne T, *et al.* International Consensus on Use of Continuous Glucose Monitoring. *Diabetes Care* 2017; 40: 1631–1640. https://pubmed.ncbi.nlm.nih.gov/29162583/

2. Bergenstal RM, *et al.* Recommendations for Standardizing Glucose Reporting and Analysis to Optimize Clinical Decision Making in Diabetes: The Ambulatory Glucose Profile. *J Diabetes Sci Technol* 2013; 7: 562–578. https://pubmed.ncbi.nlm.nih.gov/23567014/

3. Battelino T, *et al.* Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. *Diabetes Care* 2019; 42: 1593–1603. https://pubmed.ncbi.nlm.nih.gov/31177185/

4. Beck RW, *et al.* Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. *JAMA* 2017; 317: 371–378. https://pubmed.ncbi.nlm.nih.gov/28118453/

5. Beck RW, *et al.* Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections. *Ann Intern Med* 2017; 167: 365–374. https://pubmed.ncbi.nlm.nih.gov/28828487/

6. Aleppo G, *et al.* REPLACE-BG: A Randomized Trial Comparing Continuous Glucose Monitoring With and Without Routine Blood Glucose Monitoring in Adults With Well-Controlled Type 1 Diabetes. *Diabetes Care* 2017; 40: 538–545. https://pubmed.ncbi.nlm.nih.gov/28209654/

7. Brown SA, *et al.* Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes. *New Engl J Med* 2019; 381: 1707–1717. https://pubmed.ncbi.nlm.nih.gov/31618560/

8. Klonoff DC, *et al.* A Glycemia Risk Index (GRI) of Hypoglycemia and Hyperglycemia for Continuous Glucose Monitoring Validated by Clinician Ratings. *J Diabetes Sci Technol* 2023; 17: 1226–1242. https://pubmed.ncbi.nlm.nih.gov/35348391/

9. Hoogendoorn CJ, *et al.* Glycemic Risk Index Profiles and Predictors Among Diverse Adults With Type 1 Diabetes. *J Diabetes Sci Technol* 2024; 18: 1070–1078. https://pubmed.ncbi.nlm.nih.gov/36999215/

## Tell us what you think!

The team at the *Sensor Report* is always keen to hear your feedback and suggestions.
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https://www.surveymonkey.com/r/QT88KVR