beyond.
diagnostics

REAL-WORLD INSULIN STABILITY: THE HIDDEN CHALLENGE

INSPIRE
LAB

DCB Global Center for Technology Innovation in Diabetes

The Diabetes Center Berne (DCB) is a Swiss non-profit dedicated to accelerating diabetes technology for people living with diabetes. By bridging science, clinical care, and entrepreneurship, DCB supports groundbreaking ideas that improve daily life and long-term outcomes for the diabetes community.

INSPIRE LAB

IINSPIRE Lab is an interdisciplinary research platform founded at DCB to investigate the real-world stability and effectiveness of protein-based drugs – starting with insulin. Combining biochemical analysis, patient experience, and digital data, the lab seeks to redefine how medication quality is measured during treatment.

beyond. diagnostics

Beyond Diagnostics is a swiss medtech venture developing point-of-care tools to make medication quality visible. By empowering patients and providers with clarity at the moment of use, Beyond Diagnostics aims to reduce uncertainty, prevent medication waste, and build a new standard of confidence in therapy.

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Understanding Degradation: How Real-Life Conditions Undermine Insulin Stability

Insulin is a protein that degrades under physical and chemical stress. While manufacturers guarantee stability under label-compliant storage, the reality of daily use often introduces destabilizing factors that silently reduce effectiveness.

🔥 Heat Exposure

High temperatures >30 °C accelerate insulin degradation. This thermal stress can cause:

- Protein unfolding & loss of 3D structure.
- Aggregation and reduced receptor binding capacity.
- Chemical modification, such as deamidation or oxidation.

🔥 Pump Temperature & Body Heat

Insulin pumps worn by patients are exposed to continuous body heat (35–37 °C), significantly higher than recommended storage temperatures.

- Pumps worn close to the skin may accelerate degradation due to prolonged warmth and micro-vibrations.
- Studies suggest activity loss after just 24–48h at these conditions, especially in older insulin formulations.

"Storage recommendations do not account for the thermal environment of pump use." Delbeck et al., 2021

❄️ Freezing

Freezing can cause irreversible damage:

- Ice crystal formation leads to protein aggregation.
- Loss of biological activity, even after thawing.

📚 According to Braune et al. (2019), 24.8% of all monitored insulin vials experienced freezing at some point during home storage.

Currently, no point-of-care method exists to detect whether the insulin remains biologically active.

🔄 Mechanical Stress & Agitation

Shaking, jostling during travel, or frequent transport can induce:

- Air bubble formation.
- Protein denaturation from shear forces.
- Loss of uniformity in multi-dose pens and cartridges.

This is particularly relevant for Insulin carried in backpacks, purses, or sport belts.

A Silent Decline

Insulin degradation is rarely visible. Unlike spoiled food, degraded insulin looks normal – but behaves unpredictably. It may result in delayed onset, blunted glucose-lowering, or total failure. This variability makes degraded insulin difficult to identify based on glucose patterns alone.

Without tools to detect loss of activity, patients & providers are left guessing – and glucose levels become the only (late) signal.

📚 Key evidence:

Vimalavathini et al. (2009): Up to 18% activity loss when insulin was stored at 32–37 °C for 28 days.

Braune et al. (2019): 78.8% of insulin temperature logs showed excursions beyond the 2–8 °C storage range.

Sukumaran et al. (2020): In a rat model, insulin stored at 40 °C for just 24 hours showed reduced potency.

Delbeck et al. (2021): Structural degradation of insulin after storage at 37 °C for several weeks, misfolding correlated, suggesting structural instability with potential impact on activity.

Pryce R., BMJ Case Reports, 2009: An 11-year-old girl developed DKA after her insulin pump was exposed to heat and sunlight. Authors attributed the episode to insulin degradation in the reservoir.

REAL-WORLD INSULIN STABILITY: THE HIDDEN CHALLENGE

Bridging the gap between cold-chain and daily use for effective therapy.

Insulin is a protein drug with well-known stability limits – yet patients are expected to manage its stability without tools, standardized guidance, or real-world data to support decision-making. Regulators assume insulin is stored at 4 °C until treatment – and kept at room temperature (RT, typically 15–25 °C) during treatment. But in **daily life,** insulin is exposed to conditions far outside these assumptions: **body heat from pumps, summer travel, long commutes, storage in handbags or backpacks, and inconsistent access to refrigeration.**

These real-world situations are not rare – they're routine. While the degradation is often invisible, it can reduce insulin's effectiveness without any visible sign to the user.

> *"Patients are left to assume that their insulin is effective based solely on blood sugar levels and storage instructions."* (Braune et al., 2019)

Evidence: The Gap is Real

A landmark temperature tracking study by Braune et al. (2019) analyzed 400 sensors used by 338 patients in the US and Europe. The results showed:

- 78.8 % of insulin temperature logs showed excursions beyond the 2–8 °C safety storage range.
- 24.8 % of sensors recorded temperatures below 0 °C
- **50% of carried insulin logs exceeded the recommended 2–30 °C range**

These results show that storage reliability is routinely misaligned – even under "normal" living conditions.

Real-Life Scenarios: Daily Stress on Insulin

Insulin degradation is not rare. It's routine. From long-haul flights to summer commutes, patients report unexplained highs and insulin doubts in a multinational research survey by DCB, conducted across 21 countries:

- **75% of insulin users** said they had suspected their insulin had "gone bad" at least once.
- **85% said they would use a test if one existed.**
- Common topics: heat, travel, or inconsistent cooling.

Why This Matters

Pharma is measured on product quality but real-world use introduces uncontrolled variables.

HCPs adjust therapy assuming insulin efficacy – but may be responding to degraded insulin.

Regulators have strict rules for production, but few mechanisms for post-dispensing monitoring.

Patients shoulder the burden, guessing whether their insulin is still active.

This is where INSPIRE Lab and Beyond Diagnostics come in: by combining scientific analysis with patient experience and real-world stress testing, we aim to make insulin quality measurable at the point of use.

Braune et al., J Diabetes Sci Technol, 2019

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Patient Perspectives: The Human Impact of Unseen Insulin Degradation

While the science quantifies potency loss in percentages and degrees, patients experience the impact in very human terms. Loss of insulin potency can result in suboptimal glycemic control – often leading to confusion, anxiety, and avoidable health risks for the person with diabetes.

In a **multinational patient research study by DCB** 75% of insulin users reported having **suspected at some point that their insulin was less effective than normal.** As one might expect, this leads to a crisis of confidence: people are left wondering whether a vial is "bad" whenever their blood glucose swings unpredictably.

One survey respondent described the experience succinctly: *"I did everything the same, but my sugars were high – I couldn't help but think maybe my insulin had gone bad in the heat."* Such stories are common on diabetes forums, especially from those living in warm climates or who have traveled frequently.

Beyond the immediate health implications, there is also a **financial and practical burden**. Uncertain about their insulin's potency, patients often preemptively discard and replace insulin vials or pens, hoping a fresh supply will fix unexplained highs. This wastage can be significant – insulin is expensive, and in many regions not easily accessible. Yet when faced with erratic blood sugars, patients will sacrifice supplies for peace of mind, essentially treating insulin as "guilty until proven innocent."

This is not only costly but emotionally taxing: patients describe feeling helpless and worried that at any time, their vital medication could let them down.

Loss of trust in insulin undermines diabetes self-management. Without certainty, every dose becomes guesswork — some increase their dose "just in case," others delay switching vials. Both carry risks.

Degraded insulin may contribute to unexplained glucose variability. In such cases, patients risk being seen as non-adherent — when in fact, storage-related potency loss could be part of the picture.

The patient voices collected by DCB echo a clear message: there is a pressing need for a simple, real-time method to verify insulin potency in real-life conditions. In the same survey, over 85% of patients said they would use such a tool regularly if it were available.

"I started replacing my insulin every two weeks – not because I had to, but because I didn't trust it anymore." T1D patient, Africa

People with diabetes are asking for empowerment — not guesswork. They deserve the ability to know whether their insulin is still working, not to infer it retrospectively from glucose curves. This is a patient safety issue and restoring confidence in therapy is essential for effective chronic care.

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Spotlight: The INSPIRE Lab

Innovation for Stability & Patient-centred Research on Effectiveness

Founded at the Diabetes Center Berne (DCB), the INSPIRE lab brings together protein biochemistry, diagnostic development, and patient-centered research to investigate how everyday conditions affect the performance of biologic drugs – **starting with insulin.**

🔬 **Degradation Studies**
We simulate real-world stressors over time (heat, light, agitation) on protein drugs to detect critical thresholds and structural changes.

🧪 **Reference Method Development**
We develop robust, reproducible lab assays to quantify biologically active insulin – establishing a new reference for real-world effectiveness.

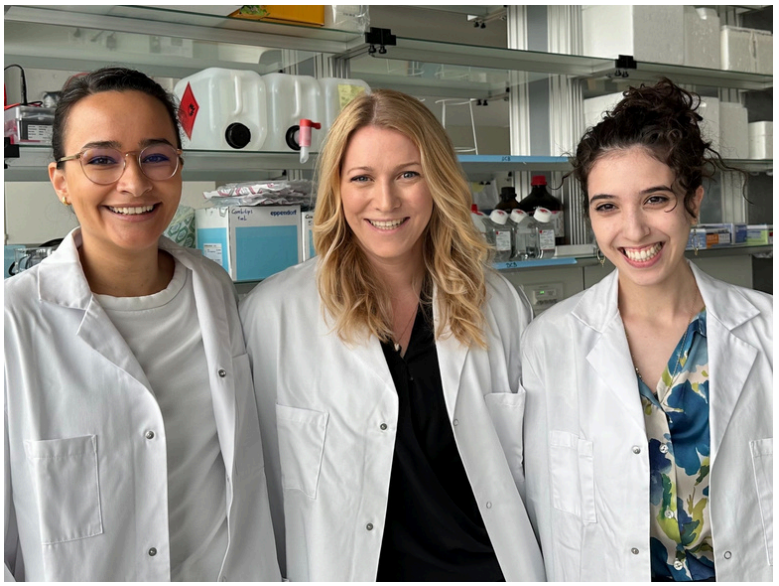
👩‍⚕️ **Real-World Data & Patient Input**
We analyse CGM data, insulin use patterns and temperature exposure – combined with perceived insulin effectiveness – to identify invisible therapy gaps.

🫀 **In-vivo Functional Studies**
We aim to validate biochemical degradation through preclinical studies that explore clinically relevant thresholds of effect loss.

From Biochemistry to Breakthroughs
INSPIRE applies cutting-edge molecular diagnostics to develop both a reference method for real-world insulin activity and a point-of-care test that brings protein drug quality directly to the user.

Funded by: Diabetes Center Berne Foundation, Innosuisse

A Lab That Listens
But science is only part of the story. INSPIRE is also a space for listening. Through interviews, surveys and co-creation with people living with diabetes, we translate their insights into study protocols, ensuring our findings address real concerns and lead to meaningful, practical solutions.



> *We aim to create a new gold standard for assessing protein drug effectiveness – one that reflects real-life conditions, not just lab shelf stability.*

Our Patient Board plays a vital role – not as a formality, but as a core partner in shaping our research. They help us:

- Identify gaps: Where insulin trust breaks down (e.g. heat, travel, erratic highs)
- Design studies: Co-creating use cases, digital solutions and study formats
- Interpret results: Validating findings with real-life meaning and relevance

🌍 The board includes voices from Europe, Africa, USA and Asia from pump users, people looping, MDI to caregivers, T1D and T2D ensuring a global, inclusive perspective.

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From Uncertainty to Insights:

Rethinking Protein Drug Stability in the Real World

INSPIRE Lab is an interdisciplinary research platform founded at the Diabetes Center Berne (DCB). Our goal is to uncover how real-world conditions affect the stability and effectiveness of protein-based drugs – starting with insulin.

Why It Matters

- Biologic drugs like insulin are temperature-sensitive
- But once they leave the pharmacy, they enter uncontrolled environments: heat, body temperature, travel, daily wear.
- These deviations are common – but current systems offer no visibility into drug integrity during treatment

Patients report:

- Rising glucose levels despite correct dosing
- Compensating with extra doses or early cartridge replacements
- A loss of confidence in therapy
- Discarding unused insulin due to fear of reduced potency (up to 30–40 % of insulin may be wasted globally before expiry – NGO estimates)

Our Approach

We are building a platform that combines:

- Protein analytics
- Real-world degradation models
- Patient-generated data (CGM, usage patterns, lived experience)
- Point-of-care diagnostics for real-time stability feedback

INSPIRE aims to establish a new reference standard for protein drug effectiveness under real-life conditions.

Why it matters for PwD:

- Empowers PwD to verify the potency of their insulin
- Reduces insulin waste while boosting confidence
- Enables more accurate dosing, improved glucose control, and potentially fewer medical emergencies

Together with NGOs, Ministries of Health, and frontline actors, we aim to ensure equitable access to medication certainty.

Let's Partner Up! We're looking for:

- Real-world experiences in hot climate regions or during humanitarian crisis
- NGO perspectives on insulin waste
- Pilot project opportunities with global health actors

Let's explore together how to make invisible loss visible – and transform uncertainty into measurable trust.

We're open to early feedback, collaboration ideas, or future partnerships for pilots.

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