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Tougher than expected: insulin's surprising thermostability expands diabetes patients' hope in tropical countries

by Sara Pannilunghi [1] | PhD Student

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[1]: Institute of Pharmaceutical Sciences of Western Switzerland, University of Geneva, Geneva, Switzerland

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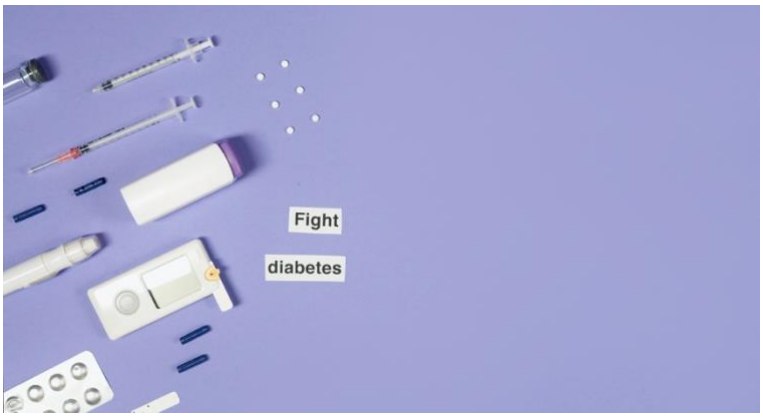
People increasingly suffer from diabetes in modern times. Safely delivering insulin, a life-saving drug, is challenging in some tropical, low-income countries because patients cannot afford cold storage at home. Despite this standard guideline, a new study suggests that patients can safely store insulins in hot environments.



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Today, people increasingly eat fast food and adopt sedentary habits by sitting long in an office and taking less exercise. This 'unhealthy' modern lifestyle has become a risk factor for common diseases such as obesity, cardiovascular disorders, and diabetes.

Diabetes is a chronic pathological condition characterized by high levels of blood sugar (glucose), the basic fuel that our body extracts from food and uses. The unusual blood sugar level in patients is caused by problems in the insulin-based system. In this system, insulin – a molecule secreted by the pancreas – circulates in the bloodstream and sends signals to the cells that allow them to intake sugar from the blood (thus decreasing blood sugar levels).

Diabetes is categorized into type 1 and type 2 diabetes. The "preventable" type 2 diabetes is often associated with an unhealthy lifestyle – while patients' pancreas produces insulin, their cells cannot properly respond to its signal to intake sugar from the blood. By contrast, type 1 diabetes is "unpreventable" as it is inherited, where patients show a defect in insulin production.

Diabetes patients show general symptoms such as fatigue, short breathing, and abnormally fast heartbeat. If untreated, this illness can lead to life-threatening complications, including blindness, stroke, cognitive impairment and coma. As insulin can be industrially synthesized, its daily injection provides effective treatment, especially for type 1 patients.

Safely delivering commercial insulin is a challenge in itself. According to standard guidelines, an

unopened vial of insulin must be stored between 2°C and 8°C. Once it is opened, patients can store it at room temperature (colder than 30°C) for up to 4 weeks.

However, while this may sound like an easy requirement, for patients living in low-income tropical countries – where temperatures can often reach higher than 30°C and people usually cannot afford a fridge at home – the standard guidelines still pose a difficulty. This puts an extra burden on patients, since they are obliged to daily visit the hospital near their home to get insulin injections. But what if they live in a rural area or have other disabilities that block relocating?

To find a solution to this problem, a team of researchers from Doctors without Borders and pharmacologists investigated how insulins respond to hot climate settings, like a refugee camp in Kenya. The researchers stored different commercially available insulins at hot temperatures and assessed how much their therapeutic ability declines over time.

They first monitored the degradation of insulin samples stored at temperatures fluctuating between 25° and 37°C, using the high-performance liquid chromatography (HPLC-UV), a widely-used approach for separating and measuring each component in a liquid mixture. Results demonstrated that insulins remained intact for 4 weeks, suggesting that the molecule's architecture is more stable in hot temperatures than previously thought. The researchers further confirmed this thermostability by analyzing the 3D structures of insulin molecules before and after the exposure to high temperatures, using a technique called circular dichroism.

Next, to understand how hot temperatures affect insulin's therapeutic activity, the researchers tested how cells cultured in the laboratory reacted to commercial insulin. These insulin samples were stored under different severe conditions – some kept for 4 weeks in a patient's home without a fridge in Kenya, and some left for 12 weeks at temperatures fluctuating between 25° and 37°C in the laboratory. The results showed that these insulin samples were as effective as the sample stored under ideal conditions (4°C). This indicates that high temperatures do not impair insulin's therapeutic activity.

Collectively, these findings illustrated that insulin stored at high temperatures (up to 37°C) was stable and lost only less than 1% of its therapeutic activity after 4 weeks. Since the regulation on pharmaceutical preparations accepts an activity loss of up to 5%, we can conclude that opened vial of insulin can be safely stored for at least 4 weeks at room temperature, even in tropical climate settings.

This breakthrough discovery paves the way for diabetes patients to manage their illness more independently and equitably. No matter where they live and how wealthy they are, they would have the opportunity to easily access this life-saving medication.