

## Human insulin less temperature-sensitive than previously thought

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A new article published in the *Cochrane Database of Systematic Reviews* has found that insulin can be kept at room temperature for months without losing potency, offering hope to people living with diabetes in



regions with limited access to health care or stable powered refrigeration. This affects millions of people living in low- and middle-income countries, particularly in rural areas, as well as people whose lives have been disrupted by conflict or natural disasters.

Human insulin is a hormone produced by the body that helps turn food into energy and controls blood sugar levels. People with diabetes cannot make enough insulin and those with type 1 diabetes have to inject insulin several times a day, typically before every meal. Insulin is an essential medicine for people with diabetes and current guidance states that before use it must be kept refrigerated to preserve its effectiveness.

For millions of people with diabetes living in low- and <u>middle-income</u> <u>countries</u>, however, the harsh reality is that electricity and refrigeration are luxuries that are unavailable to them. Vulnerable populations in wartorn areas, disaster-prone regions, and climate crisis-affected areas, including those enduring <u>extreme heat</u>, also need solutions that don't rely on powered fridges.

The new review summarizes results of different studies investigating what happens to insulin when stored outside of fridges, including previously unpublished data from manufacturers. The review found that it is possible to store unopened vials and cartridges of specific types of human insulin at temperatures of up to 25°C for a maximum of six months, and up to 37°C for a maximum of two months, without any clinically relevant loss of insulin activity.

Data from one study showed no loss of insulin activity for specific insulin types when stored in oscillating <u>ambient temperatures</u> of between 25°C and 37°C for up to three months. This fluctuation resembles the day-night temperature cycles experienced in tropical countries.

The research team, led by Bernd Richter from the Institute of General



Practice, Medical Faculty of the Heinrich-Heine-University in Düsseldorf, Germany, conducted comprehensive research to investigate insulin stability under various storage conditions. The review analyzed a total of 17 studies, including laboratory investigations of insulin vials, cartridges/pens, and prefilled syringes, demonstrating consistent insulin potency at temperatures ranging from 4°C to 37°C, with no clinically relevant loss of insulin activity.

Richter stressed the significance of this research, particularly for people living with type 1 diabetes, where "insulin is a lifeline, as their very lives depend on it. While type 2 diabetes presents its challenges, type 1 diabetes necessitates insulin for survival. This underscores the critical need for clear guidance for people with <u>diabetes</u> in critical life situations, which many individuals lack from official sources."

"Our study opens up new possibilities for individuals living in challenging environments, where access to refrigeration is limited. By understanding the thermal stability of insulin and exploring innovative storage solutions, we can make a significant impact on the lives of those who depend on insulin for their well-being."

These findings can help communities facing challenges in securing constant cold storage of insulin. They provide reassurance that alternatives to powered refrigeration of insulin are possible without compromising the stability of this essential medicine. It suggests that if reliable refrigeration is not possible, <u>room temperature</u> can be lowered using simple cooling devices such as clay pots for insulin storage.

The researchers have also identified uncertainties for future research to address. There remains a need to better understand insulin effectiveness following storage under varying conditions. Further research is also needed on mixed insulin, influence of motion for example when <u>insulin</u> pumps are used, contamination in opened vials and cartridges, and



studies on cold environmental conditions.

**More information:** Thermal stability and storage of human insulin, *Cochrane Database of Systematic Reviews* (2023). DOI: 10.1002/14651858.CD015385.pub2

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