

Study shows a vial of insulin can be stored for 4 weeks after opening at up to 37C without losing efficacy

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Diabetes requires an extremely precise form of daily treatment, whereby patients inject themselves with several doses of insulin every day. Patients must therefore keep a supply of insulin which, according to pharmaceutical protocol, must respect the cold chain from production to injection. However, in some regions of the world like sub-Saharan Africa, not every household has a refrigerator.

This forces people living with [diabetes](#) to go to hospital on a daily basis. Faced with this issue, Médecins Sans Frontières (MSF) teamed up with the University of Geneva (UNIGE), Switzerland, to test [insulin](#) storage in real conditions, at temperatures ranging from 25 degrees C to 37 degrees C for four weeks. This corresponds to the time it usually takes a diabetic person to finish one vial of insulin. The findings published in the journal *PLOS ONE*, demonstrate that the stability of insulin stored under these conditions is the same as that of cold-stored insulin, with no impact on efficacy.

This allows people with diabetes to manage their illness without having to visit a hospital multiple times daily.

Type 1 diabetes is characterized by elevated blood sugar levels, which can have extremely serious consequences: coma, blindness, amputation or even death. Although it is now possible to treat type 1 diabetes well, it does require daily injections of insulin, which helps sugar enter the body's cells.

"The current pharmaceutical protocol requires insulin vials to be stored between 2 and 8 degrees C until opened, after which most human insulin can be stored at 25 degrees C for four weeks," explains Philippa Boule, a non-communicable diseases advisor at MSF. "This is obviously an issue in [refugee camps](#) in temperatures hotter than this, where families don't have refrigerators."

People with diabetes thus often have to travel to a hospital every day for their insulin injections, which can prevent them from working or force them to travel long distances. "We turned to Professor Leonardo Scapozza's team to undertake a detailed analysis of the temperature conditions under which insulin can be stored without a reduction in its efficacy," says Dr. Boule.

Real-life conditions

The MSF team in the Dagahaley refugee camp in northern Kenya found that the temperature in a home fluctuates between 25 degrees C at night and 37 degrees C during the day. The researchers then meticulously reproduced these conditions in laboratory setting, where they tested insulin storage. "As you can insulin vials can be used for four weeks after opening, we carried out our measurements over the same timeframe, first with vials kept at the temperatures found in Dagahaley,

and then with 'control' vials that were refrigerated," explains Leonardo Scapozza, a professor of the School of Pharmaceutical Sciences in UNIGE's Faculty of Sciences. The UNIGE team used high-performance liquid chromatography to analyze the insulin. "The risk is that insulin, a protein, precipitates under the influence of heat. In other words, it would begin to form 'flakes.'" Since the insulin is no longer in solution, it can't be injected."

No difference between the two storage methods

The research results show that all the insulin preparations stored at fluctuating temperatures, as encountered in the field, recorded a potency loss of no more than 1%, just like those kept in cold storage during the required four weeks. "The regulation on pharmaceutical preparations allow a loss of up to 5%, so we are well below that," says Professor Scapozza.

Crucially, the UNIGE researchers also observed that insulin activity was completely maintained. To verify this, they tested the action of insulin proteins on cells, compared with that of insulin that had been intentionally deactivated. "Finally, with the help of Professor Michelangelo Foti's group, we studied insulin vials that came directly from the Dagahaley camp, and always reached the same conclusion: the insulin was perfectly usable," adds Professor Scapozza.

Results that may change the daily lives of thousands of people

This scientific study has shown for the first time that insulin vials can be used for four weeks even in hot weather without being refrigerated. "These results can serve as a basis for changing diabetes management practices in [low-resource settings](#), since patients won't have to go to hospital every day for their insulin injections," states Dr. Boulle. In addition, people with diabetes would no longer be discriminated against and could lead normal lives and work. "Of course, this will have to go hand-in-hand with educating patients, as well as providing support and follow-ups," says Dr. Boulle, "so that people with diabetes can measure their blood sugar levels and inject the right amount of insulin. This will allow people to manage their illness correctly,

and more independently. In support of this goal, we hope that a consensus statement will be drawn up, focusing on the at-home use of insulin in hightemperature settings when there is no refrigeration available, and that it will be endorsed by the WHO."

More information: *PLOS ONE* (2021). [DOI: 10.1371/journal.pone.0245372](https://doi.org/10.1371/journal.pone.0245372)

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