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COMMENTARY

Investigating Real-World Stability and Sterility of in-Use Insulin-An Urgent Public Health Concern. In Sub-Saharan Africa

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Abstract: Insulin stability is a critical yet underexplored factor affecting diabetes outcomes in Sub-Saharan Africa (SSA). High ambient temperatures, unreliable refrigeration, and weak regulatory oversight may compromise insulin quality during storage and use. Patients often rely on traditional, non-validated methods that risk potency loss. This commentary highlights the urgent need for real-world studies on insulin stability and sterility in SSA to inform evidence-based practices and improve glycemic control among diabetic patients in resource-limited settings.

Keywords: diabetes, insulin stability, insulin sterility, glycemic control, Sub-Saharan Africa, SSA

Introduction and Discussion

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Type 2 diabetes mellitus (T2DM) constitutes over 90% of diabetes cases globally and poses a major public health burden, especially in low- and middle-income countries (LMICs) such as those in Sub-Saharan Africa (SSA).[1] According to the International Diabetes Federation (IDF), an estimated 24 million adults in the African region were living with diabetes in 2021, and this number is projected to increase to 55 million by 2045.[2] Alarmingly, more than 70% of people with diabetes in Africa are undiagnosed, and glycemic control remains suboptimal in the majority of those diagnosed.[2,3]

A 2019 meta-analysis on glycemic control in Africa reported that only 30.1% of patients achieved good glycemic control (defined as HbA1c <7%).[4] Several factors have been identified as contributors to poor glycemic control, including limited access to healthcare, low medication adherence, and socioeconomic constraints.[5] However, one underexplored but potentially significant contributor is the quality and stability of insulin products used by patients, particularly after distribution and during home storage.[6] According to a report by the World Health Organization (WHO), approximately 10% of medicines circulated in Africa may be substandard.[7]

Insulin remains a cornerstone of diabetes management, especially for patients with type 1 diabetes and for type 2 diabetes patients who fail to achieve target glycemic levels with oral agents alone.[2] In Africa, an estimated 10–15% of people with diabetes require insulin therapy.[8] Despite its critical role, access to high-quality insulin is limited, and improper storage practices due to poor infrastructure, high ambient temperatures, and irregular electricity supply may compromise insulin stability.[9] Many patients transport unopened insulin from health facilities to their homes in handbags

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or envelopes, often over long distances without cold chain support.[10] Once in use, insulin is typically stored using traditional methods such as clay pots, water-immersed charcoal setups, or household cabinets approaches not validated for preserving insulin potency.[9,11] Non-refrigerated insulin storage practices have often been recommended by healthcare workers in many developing countries due to infrastructural limitations.[12,13]

Proper insulin storage is a fundamental component of effective diabetes management. Most insulin products require cold-chain preservation, ideally between 2°C and 8°C before opening, and can be kept at room temperatures (25–30°C) for up to 28 days after opening, according to manufacturers' guidelines.[14–16] However, in SSA, where ambient temperatures frequently exceed 30°C and refrigeration is often unreliable or unavailable, these storage requirements are difficult to meet.[17,18]

Studies in SSA and other LMICs have reported widespread inappropriate storage practices at both community pharmacy and household levels.[18] Patients commonly use alternative methods such as clay pots or water-immersed containers, despite a lack of evidence supporting their efficacy in preserving insulin stability.[18] These practices raise concerns about potential degradation of insulin potency due to temperature fluctuations and microbial contamination.[17–19]

Data on the real-world impact of poor storage conditions on insulin quality are limited. Some laboratory-based studies have shown significant potency reductions up to 18% after insulin was exposed to temperatures as high as 37°C for one to four weeks.[20] Reported a loss in insulin potency after one month at 31°C, although other studies suggest minimal clinical significance under similar conditions.[21] These conflicting results highlight the need for further research, especially in real-life African settings where temperature regulation is often beyond patients' control. Our own findings from a recent work published in 2025 reinforce this, showing real concerns about the quality of insulin used by patients in Tanzania.[22]

Insulin degradation is not only a function of temperature but also of environmental stressors such as light, agitation, and pH. Structural alterations in insulin molecules can impair their ability to bind insulin receptors and exert therapeutic effects.[20] Although current pharmacopeia assays confirm insulin content and potency, they are not designed to detect structural or conformational changes.[23] This analytical gap may allow compromised insulin products particularly biosimilars or imported generics from regions with weaker regulatory oversight to enter the African market undetected.

Moreover, reuse of syringes is common among diabetic patients in SSA, due to limited access and affordability of medical supplies. This practice increases the risk of microbial contamination, which could further reduce insulin effectiveness or lead to infections.[19] While existing studies suggest minimal microbial contamination in opened insulin vials under standard conditions,[20] more robust investigations are needed in the African context, especially where sterility is harder to maintain.

The effect of climate change has further exacerbated the situation, with recorded temperatures in some SSA countries such as Sudan and Egypt reaching 40°C or higher.[24] These extreme conditions threaten the thermal stability of insulin throughout its supply chain from manufacturer to end-user. In countries where local insulin manufacturing is absent or minimal, reliance on imported insulin from countries with varying regulatory standards adds another layer of complexity.

This article highlights the need for research into the real-world stability, sterility, and structural stability of in-use insulin stored by patients under various conditions in SSA. It aims to draw attention to an overlooked aspect of diabetes care that may contribute to poor treatment outcomes and call for studies assessing insulin quality, particularly in resource-constrained settings. Moreover, there is a critical need for developing and validating low-cost, non-refrigerated insulin storage alternatives that are feasible for rural and peri-urban communities. Policymakers should also consider integrating cold-chain infrastructure improvements into national diabetes programs and enforcing stricter regulatory oversight on imported insulin products.

Conclusion

In conclusion, insulin stability is a critical concern in diabetes management, affecting millions of lives in Sub-Saharan Africa. Concerted efforts are necessary among medical researchers and health care professionals to investigate the insulin quality attributes in Sub-Saharan Africa supply chain in order to enable diabetic patients to achieve better glycemic control and ultimately improve their quality of life. To drive meaningful change, urgent collaboration is needed among

regulatory authorities, scientific communities, and local stakeholders to develop practical solutions that safeguard insulin integrity and promote equitable access to effective diabetes care.

Data Sharing Statement

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

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Disclosure

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