



Dr Sanjay Kalra
Dept. of Endocrinology,
Bharti Hospital,
Karnal, Haryana,
India; University
Center for Research &
Development,
Chandigarh University,
Mohali, Punjab, India



Dr Suneet Kumar Verma
Dept. of Internal
Medicine, Alchemist
Hospital, Panchkula,
Haryana, India;
Sparsh Clinic,
Zirakpur, Punjab,
India



Dr Rakesh Sahay
Dept. of
Endocrinology,
Osmania Medical
College, Hyderabad,
Telangana, India

Insulin is Essential: The National List of Essential Medicines, India, 2022

Insulin is essential for life. While most persons produce adequate amounts of insulin, not everyone is lucky enough. Persons living with type 1 diabetes, with pancreatic diabetes, and with severe or long-standing type 2 diabetes need exogenous insulin for survival.¹ Many persons with type 2 diabetes and comorbidities such as renal or hepatic impairment, severe sepsis or infection, also require insulin. It is the drug of choice for glycemic control during pregnancy. Unfortunately, insulin is expensive, and may be out of reach for many people who need it.² One way of ensuring affordable insulin is to declare it an essential drug.

INDIA'S NATIONAL LIST OF ESSENTIAL MEDICINES

The National List of Essential Medicines (NLEM), India reflects this thought process. Successive editions of the NLEM have included various preparations and strengths of insulin.^{3,4} This year, the NLEM lists four insulins: soluble, NPH (neutral protamine Hagedorn), premixed insulin and glargine, irrespective of delivery device.⁵ It is assumed that all strengths (40 IU/mL and 100 IU/mL for human insulin, and 100 U/mL for glargine) are included in the essential list. The 50:50 premixed insulin preparation is not included in NLEM, though it must be admitted that it is not as commonly prescribed as the 30:70 preparation.

The addition of insulin glargine in the Indian NLEM is a welcome development. This underscores the acceptance of the need to provide safe and effective medication to persons living with diabetes at an affordable cost. The updated NLEM highlights India's commitment towards providing world-class treatment to its citizens, and ensuring that the noncommunication

disease epidemic is addressed aggressively. The Indian pharmaceutical industry has contributed immensely to the production of economical and efficient insulin, not only for the domestic, but also for the global market.⁶ An Indian insulin glargine brand has received a label for interchangeability with originator brands from the United States Food and Drug Administration (US FDA).⁷

This implies the quality and robustness in clinical data and more importantly "a Make in India product to meet the global need" which addresses two key barriers, i.e., affordability and accessibility of insulin for all. US FDA defines Interchangeable if the biological product "is biosimilar to the reference product" and "can be expected to produce the same clinical result as the reference product in any given patient."⁸ The 'interchangeable' status can prompt faster and wider uptake of insulin biosimilars and keep the insulin expenditure under control, especially for patients who otherwise practice nonadherence or rationing of life-saving insulin.

NATIONAL LISTS OF ESSENTIAL DEVICES AND ESSENTIAL DIAGNOSTICS

Persons living with diabetes need much more, though. Just as insulin preparations are essential, so are the insulin delivery devices like syringes, pens and pumps.⁹ Insulin monitoring systems, such as glucose monitors, urine sugar strips, ambulatory/continuous glucose monitoring systems are equally essential to ensure safe and accurate therapy. Equal emphasis should therefore be placed on diabetes care in the National Lists of Essential Devices and Essential Diagnostics.

NONINSULIN MEDICATIONS

The 2022 NLEM contains a brief, yet comprehensive, list of noninsulin oral medications.⁵ Their listing reflects the increasing disease burden of diabetes, as well as the efficacy, safety and cost-effectiveness of the drug. Tenueligliptin, a dipeptidyl peptidase 4 (DPP-4) inhibitor has been added this year. The sulfonylurea glimepiride, and the insulin sensitizer, metformin, complete the list. No sodium-glucose co-transporter 2 (SGLT2) inhibitor or glucagon-like peptide 1 receptor agonists (GLP-1RA) figure in the list, however.

SUMMARY

As we work towards becoming the Diabetes Care Capital of the world (Prof BK Sahay, personal communication), each and every stakeholder's involvement is important. Diabetes care cannot be achieved without ensuring availability, accessibility and affordability of diabetes related diagnostics, drugs and devices. The NLEM 2022 demonstrates the commitment of the Indian government towards achieving this goal. Sustained and concerted efforts will be needed in the future as well, to accomplish our goals.

REFERENCES

1. Mathieu C, Martens PJ, Vangoitsenhoven R. One hundred years of insulin therapy. *Nat Rev Endocrinol*. 2021;17(12):715-25.
2. Zargar AH, Kalra S, Prasanna KMK, Murthy S, Negalur V, Rajput R, et al. Rising cost of insulin: a deterrent to compliance in patients with diabetes mellitus. *Diab Metab Syndr Clin Res Rev*. 2022;16(8):102528.
3. Kalra S, Bajaj S, Mithal A. Endocrinology and the essential list. *Indian J Endocrinol Metab*. 2012;16(Suppl 2):S133-5.
4. Kalra S. National List of Essential Medicines, 2015: Endocrinology perspective. *Indian J Endocrinol Metab*. 2016;20(3):412-3.
5. National List of Essential Medicines. Available at: <https://www.nppaindia.nic.in/en/utilities/national-list-of-essential-medicines/>. Last accessed September 14, 2022.
6. Sharma A, Kaplan WA. Insulin imports fail to meet many countries' needs. *Science*. 2021;373(6554):494-7.
7. Tanzi MG. FDA approves first interchangeable biosimilar insulin. *Pharmacy Today*. 2021;27(10):21.
8. Kim AP, Bindler RJ. The future of biosimilar insulins. *Diabet Spectr*. 2016;29(3):161-6.
9. Wahab MU, Raja UY, Kalra S. Essential diagnostics and devices in primary care diabetes. *J Pak Med Assoc*. 2021;71(9):2281-2.

■ ■ ■ ■

Medication-associated Changes in Hair Texture

Hair texture may alter as a side effect of medications, according to a study published in the *Journal of Drugs in Dermatology*.¹ Hair texture changes were most commonly associated with antineoplastic drugs.

Researchers carried out a review of 31 published articles involving 2,594 patients to characterize the changes in hair texture associated with medications and to also find out the most commonly implicated drugs. The articles were searched from PubMed and Cochrane databases. The average age of the study subjects was 48.4 years and about 42% of them were female.

Analysis of data revealed antineoplastic drugs (n = 97) were most commonly associated with hair texture changes. The antiepileptics (n = 56) were the second most common group. The other drug classes associated with hair texture changes were retinoids (n = 15), immunomodulators (n = 3) and antiretrovirals (n = 1).

The most common types of textural changes were *de novo* or exaggerated curling patterns, i.e., curling of straight hair or more curling of curly hair. Kinking, waving of hair were also seen. The changes occurred within 5 months following use of immunomodulator drugs, whereas with antiretrovirals, the hair texture changes took 17 months to appear. While most changes reversed in 3 week to 5 years after the therapy, the changes associated with the use of antiretrovirals, retinoids and antineoplastics were irreversible.

This study has correlated hair texture changes with five groups of drugs: antineoplastics, antiepileptics, retinoids, immunomodulators and antiretroviral therapy. Side-effects are undesired effects of medications and any change in the texture of hair may have psychosocial impact on the patient. Hence, clinicians should be aware of this potential side effect and communicate to the patient before initiating treatment with these drugs.

Reference

1. Phong C, et al. Systemic medications associated with hair texture changes. *J Drugs Dermatol*. 2022;21(9):989-96.