

Prathosh Gangadhar<sup>1</sup>, Gaurav Palikhe<sup>2</sup>

<sup>1</sup>IQRAA Hospital and Research Centre, Kozhikode, Kerala, India

<sup>2</sup>Paras Hospital, Panchkula, Haryana, India

# Do We Need Another Guideline on Managing Type 2 Diabetes in India?

## Why do we need guidelines?

According to World Health Organization, a guideline is “systematically developed statements to assist practitioners and patients in making decisions about appropriate health care for specific circumstances” [1]. Clinical practice guidelines are fundamental in improving patient outcomes and reducing healthcare costs by helping clinicians make the best evidence-based decisions for their patients. Numerous pieces of evidence suggest a reduction in practice discrepancy and a release of the tension between healthcare cost and quality using clinical practice guidelines [2]. Therefore, guidelines have an important place in evidence-based clinical practice. Type 2 diabetes (T2D) is a heterogeneous disease with varying clinical profiles, and general practitioners in India manage many T2D patients. A systematic guideline based on evidence can help to aid cost-effective, safe, and evidence-based treatment for people with T2D. Therefore, a clinical guideline on the management of newly diagnosed adults with T2D by the Association of Clinical Endocrinologists of India (ACE) is a welcome step [3].

## Current guidelines for managing T2D in Asian Indian

There are two major clinical practice guidelines or recommendations used in India that provide clinicians some guidance on managing T2D among Asian Indians;

### Address for correspondence:

Dr. Prathosh Gangadhar

IQRAA Hospital and Research Centre

Wayanad Rd, Malaparamba, Kozhikode

Kerala 673009, India

e-mail: prathosh@yahoo.com

Clinical Diabetology 2023, 12; 1: 4–5

DOI: 10.5603/DK.a2023.0002

Received: 2.02.2023

Accepted: 9.02.2023

a) ICMR (Indian Council for Medical Research) guidelines [4] that were published in 2018, and RSSDI-ESI (Research Society for the Study of Diabetes in India-Endocrine Society of India) Clinical Practice Recommendations published in 2020 which was updated in 2022 by RSSDI [5, 6]. The ICMR recommendations are an easy systematic approach to screening, diagnosing, and managing T2D in India. However, the ICMR recommendation lacks citations or references for each recommendation [4]. On the other hand, RSSDI is a comprehensive recommendation on screening, diagnosis, and management of T2D for Asian Indians, and recommendations are generated using more than 1300 publications [5, 6]. Considering the rapid change in evidence, guidelines must be updated, preferably yearly, and disseminated among clinicians on time to improve diabetes care. Unfortunately, both ICMR and RSSDI-ESI guidelines are not living documents and are not frequently updated.

## What is new in the Association of Clinical Endocrinologists guideline for managing newly diagnosed adults with T2D?

In the present issue of “Clinical Diabetology”, the Association of Clinical Endocrinologists working group from India comes with new guidance on managing T2D among Asian Indians [3]. What is new in the ACE guidelines?

First, it is a focused guideline addressing the approach to newly diagnosed adults with T2D, often neglected in a country like India, leading to a higher rate of diabetes complications and comorbidities. It is compact compared to previous guidelines; it contains 63 pages without references compared to 70 pages of ICMR guidelines and 99 pages of RSSDI-ESI guidelines. Second, it has graded recommendations based

on evidence, unlike previous guidelines. Grading gives readers more clarity about the level of evidence for each recommendation. Failure to contemplate the quality of evidence can lead to misguided recommendations [7]. Third, it used a modified Delphi method system for consensus. The modified Delphi method effectively addresses clinical issues when it is not easy to reach a consensus agreement. However, a limitation of the Modified Delphi method is the lack of anonymity during the voting process. Anonymity will help reduce the effect of dominant individuals and reduce manipulation or suppression to comply with certain viewpoints. However, face-to-face meetings in the modified Delphi method may help experts from exchanging important details, such as clarification of reasons for disagreements in consensus. Finally, consensus methods contain certain methodological issues, such as bias in selecting participants or that participants may feel compelled to abide by the group view [8]. Fourth, it included recent updates from the literature. According to the authors, it is an expert recommendation based on consensus amended and adopted by ADA (American Diabetes Association) 2022 and other well-recognized organizations' guidelines [9]. Certain new points highlighted in these guidelines include the assessment of C-peptide, the need for vitamin B12 estimation, strong dietary recommendations against current food faddism and dual PPAR agonist (Saroglitazar) as an option for hypertriglyceridemia treatment.

### What are the limitations of the ACE guideline?

ACE guideline is adapted from ADA standards of care and further modified based on the expert consensus achieved by the modified Delphi method. Though it is the first consensus recommendation from India with the grading of evidence, most of the evidence is based on western literature. One example is the CV risk score used was the ASCVD score, which was not validated for Asian Indians [10]. The strength of the evidence does not match with cited references, and the quality of studies in certain instances, for example, checking and replacing vitamin B12, which was a grade B recommendation, is not supported by cited references [11, 12]. Recommendations mention that 80 % concordance was not achieved for seven statements, which needed additional discussions in the guideline development process. These statements could suggest evidence gaps in the Indian context and could have been highlighted.

### Future directions

Guidance needs to be a living document (constant yearly update rather than once a few years update)

considering rapidly changing evidence. One option is to start appraisal and update plans of the guidelines in the implementation stage. Moreover, guidance needs to be Asian Indian specific from studies conducted in this population. The guidance also needs to provide what is unknown and what needs to be focused on (in terms of research) to generate more evidence. The guideline development process should include end-users – decision-makers (specialists or general practitioners), policymakers, and patients. Finally, guidelines must operate considering a specific healthcare system's social, ethical, legal, and cost constraints.

### Conflict of interests

None declared.

### REFERENCES

- Guidelines in health care practice. Report on a WHO Meeting, Schloss Velen, Borken, Germany 26–28 January 1997. [https://www.euro.who.int/\\_data/assets/pdf\\_file/0011/118379/E53492.pdf](https://www.euro.who.int/_data/assets/pdf_file/0011/118379/E53492.pdf) (4.02.2023).
- Guerra-Farfan E, Garcia-Sanchez Y, Jornet-Gibert M, et al. Clinical practice guidelines: The good, the bad, and the ugly. *Injury*. 2022 [Epub ahead of print], doi: [10.1016/j.injury.2022.01.047](https://doi.org/10.1016/j.injury.2022.01.047), indexed in Pubmed: [35135686](https://pubmed.ncbi.nlm.nih.gov/35135686/).
- Erukulapati RS, Ganguri M, Menon AS, et al. Approach to a Newly Diagnosed Adult with Type 2 Diabetes in the Indian Context: Recommendations by Association of Clinical Endocrinologists Consensus Group. *Clin Diabetol*. 2023; 12(1), doi: [10.5603/DK.a2022.0061](https://doi.org/10.5603/DK.a2022.0061).
- ICMR Guidelines for Management of Type 2 Diabetes 2018. [https://main.icmr.nic.in/sites/default/files/guidelines/ICMR\\_Guidelines-Type2diabetes2018\\_0.pdf](https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Guidelines-Type2diabetes2018_0.pdf) (15.01.2023).
- Chawla R, Madhu SV, Makkar BM, et al. RSSDI-ESI Clinical Practice Recommendations for the Management of Type 2 Diabetes Mellitus 2020. *Int J Diabetes Dev Ctries*. 2020; 40(Suppl 1): 1–122, doi: [10.1007/s13410-020-00819-2](https://doi.org/10.1007/s13410-020-00819-2).
- RSSDI Clinical Practice Recommendations for the Management of Type 2 Diabetes Mellitus 2022. *International Journal of Diabetes in Developing Countries*. 2022; 42(S1): 1–143, doi: [10.1007/s13410-022-01129-5](https://doi.org/10.1007/s13410-022-01129-5).
- Guyatt GH, Oxman AD, Vist GE, et al. GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*. 2008; 336(7650): 924–926, doi: [10.1136/bmj.39489.470347.AD](https://doi.org/10.1136/bmj.39489.470347.AD), indexed in Pubmed: [18436948](https://pubmed.ncbi.nlm.nih.gov/18436948/).
- Eubank BH, Mohtadi NG, Lafave MR, et al. Using the modified Delphi method to establish clinical consensus for the diagnosis and treatment of patients with rotator cuff pathology. *BMC Med Res Methodol*. 2016; 16: 56, doi: [10.1186/s12874-016-0165-8](https://doi.org/10.1186/s12874-016-0165-8), indexed in Pubmed: [27206853](https://pubmed.ncbi.nlm.nih.gov/27206853/).
- American Diabetes Association Professional Practice Committee. Summary of Revisions: Standards of Medical Care in Diabetes-2022. *Diabetes Care*. 2022; 45(Suppl 1): S4–S7, doi: [10.2337/dc22-Srev](https://doi.org/10.2337/dc22-Srev), indexed in Pubmed: [34964881](https://pubmed.ncbi.nlm.nih.gov/34964881/).
- Kumar A, Shariff M. Atherosclerotic cardiovascular disease risk score: Are Indians underestimating the risk of cardiovascular disease? *Indian Heart J*. 2019; 71(4): 364–365, doi: [10.1016/j.ihj.2019.08.002](https://doi.org/10.1016/j.ihj.2019.08.002), indexed in Pubmed: [31779868](https://pubmed.ncbi.nlm.nih.gov/31779868/).
- Singla R, Garg A, Surana V, et al. Vitamin B12 Deficiency is Endemic in Indian Population: A Perspective from North India. *Indian J Endocrinol Metab*. 2019; 23(2): 211–214, doi: [10.4103/ijem.IJEM\\_122\\_19](https://doi.org/10.4103/ijem.IJEM_122_19), indexed in Pubmed: [31161105](https://pubmed.ncbi.nlm.nih.gov/31161105/).
- Nand L, Mahto S, Garg D, et al. Vitamin B12 deficiency in patients of type 2 diabetes mellitus treated with metformin: a cross section observational study from a tertiary care centre in Sub-Himalayan region of North India. *International Journal of Research in Medical Sciences*. 2020; 8(4): 1248, doi: [10.18203/2320-6012.ijrms20200997](https://doi.org/10.18203/2320-6012.ijrms20200997).