Editorial

Challenges of assessing educational intervention in type 1 diabetes mellitus

In patients with Type 1 diabetes mellitus (T1DM), there is a continuous loss of pancreatic β-cell function and hence there is a need for life-long insulin treatment.[1] The biggest challenge for these patients is titrating insulin doses regularly to maintain target glucose levels.[2] Educating patients on diabetes self-management is essential for patients to achieve glycated hemoglobin (HbA1c) targets, decrease hypoglycemia, and improve quality of life (QoL). Educational programs such as Dose Adjustment for Normal Eating and the Diabetes Teaching and Treatment Programs have shown positive outcomes in diabetes control, minimizing hypoglycemia, and improving QoL in many studies.[1] It is desirable to assess the effectiveness before their widespread use in routine clinical practice.

In this issue of the journal, Ait-Taleb Lahsen *et al.* have reported a study of a structured therapeutic patient education (TPE) intervention in 100 T1DM Moroccan children and adolescents. Since there are no standardized structured TPEs, the authors developed their own TPEs. Two outcome measures were used in this study: (1) Clinical outcomes using the standard diabetic measurement, HbA1c and (2) QoL measurement using a validated questionnaire, Pediatric QOL Inventory PedsQL 3.0 at the end of 3 months. As the study was conducted in the center treating the patients, there was good recruitment, follow-up, and retention of patients. The authors have used a structured training curriculum with well-defined and specific educational objectives customized as per the individual needs of patients. The study found that TPE intervention was effective in improving patients' QOL. However, it did not show a statistically significant improvement in HbA1c.[3] The reason why statistically significant glycemic reduction was not found could be the short follow-up duration of 12 weeks.

This study was conducted in the same center as the one treating the patients so it was convenient for follow up and resulted in better recruitment and retention of patients. The authors have used a structured training curriculum with well defined and specific educational objectives. In line with the NICE recommendation, parents and careers of these participants also attended the three sessions.[3,4] Needs assessment for every patient was done in this educational program prior to customizing the training program as per the individual need of the patient and then delivered. This is good method of delivering the education.

In the above study, the authors have not specified if the educational intervention used in this study was validated. Before using any educational material, it is desirable to validate it. There are many forms of validity such as judgment and criterion validity. Judgmental validity refers to face, content, and consensual validity. Face validity is the direction, in which the variables are placed for the investigator so that he can measure it. Content validity is to verify if everything within the measure has been covered by the educational program. Consensual validity is to evaluate if the experts of the tool agree about the measures used. Criterion validity is the gold standard of all the validity tools. In addition, criterion validity can even be used to validate a program when the doctor and/or educator attempts to develop a shorter or more suitable version of a program by comparing it to a standard program.[5]

In research for evaluating educational training programs in T1DM, there are specific challenges in planning should be considered. As the clinical study would be conducted in juvenile patients which is a vulnerable group, ethical issues must be considered. These children are vulnerable as they are not able to make autonomous decisions regarding participation in research and have more likelihood of having additional and greater harm. Indian Council of Medical Research National Ethical Guidelines for Biomedical Research involving children recommends that specifies that an ethics committee reviewing and approving research. Children should have member/s or invited experts with pediatric expertise.[6]

Assent from the child and informed consent from the parent and legal guardian should be taken. The assent process should consider the children's developmental

level and capability of understanding which in turn would be affected by the cultural and social factors. The assent form should be developed based on the child's age and reading ability.[6] School-going children may not have the time to participate in clinical research and understanding of clinical research to give assent to participate. This can be addressed by conducting home visits or using virtual visits to collect data.[6]

In developing countries, the diabetologist may not have the time, skills, or resources to conduct clinical research. He or she would need to get the help of educators who can train in the local language, clinical research coordinators, statisticians, etc. to conduct a good clinical study to assess the effectiveness of the education program. In addition to time, there is a cost involved to conduct research (resources to develop the protocol, involvement of statistician, data collection, use of sensors/wearables, questionnaire-related cost, and analysis-related cost). Use of technology and use of educational aids such as posters, books, and apps would have its own challenges such as acceptance of the delivery and finding resources to deliver it, especially in rural places. It is tough to find funding for research in children. Compared to adults, the market for pediatric treatments is comparatively smaller hence pharmaceutical companies do not find it sufficiently remunerative to sponsor research in children.[6] During the study conduct, steps should be taken for the retention of the patients in the educational program since follow-up of the patient and/or family/caregivers is difficult in research involving children. Hence, widening the type of study visits would help. If there are study visits as defined in the protocol to measure study outcomes, these can be either conducted at home, by telephone, or by video call. The study protocol can predefine the minimum number of face-to-face visits.

Questionnaires used in these studies can be generic such as Short Form 12, Short Form 36, and Euro QoL or diabetes-specific such as Diabetes QoL and Diabetes Impact Measurement scale. The choice of which one to use would depend on (a) age and education of the patients and/or parents and (b) delivery method-paper or electronic. (a) Fee for use of questionnaire in addition, for the questionnaires used in the study. The QoL e questionnaires in English require cultural adaptation and validation in the translated local language. With the development of technology, smartphones, smart wearables, and/or sensors can be used (1) To monitor insulin dose, diet and physical activity, and glycemic control, (2) To deliver educational training, (3) To send reminders regarding the educational training sessions and study visit, and (4) To record data. While using technology, validation of the devices/wearables, questionnaires as well as data privacy and security, and the cost involved with using this should be considered.[7]

Diabetologists planning studies to study the efficacy of educational in T1DM should consider (a) Challenges of research in the developing country pediatric population, (b) Issues in the selection of culturally appropriate validated educational tools, (c) Training in communication skills, (d) Complexity of technology use for patients and parents, and (e) Methods of validation of QoL scales and digital technology. It is important for diabetologist researchers to remember that just as patient education is important, so is clinical research in assessing the long-term effectiveness and impact of the education.

Disclosure

The insights stated in this article are the author's personal opinion and does not reflect those of the current and previous employers.

Financial support and sponsorship

The insights stated in this article are author's personal opinion and does not reflect those of the current and previous employers.

Conflicts of interest

Deepa Chodankar is an employee of Sanofi India and might be shareholders of Sanofi.

Deepa Chodankar

Heading Genesis Unit, Sanofi, Mumbai, India

Address for correspondence: Dr. Deepa Chodankar, Sanofi House, L and T Business Park, Saki Vihar Road, Powai, Mumbai - 400 072, Maharashtra, India.
E-mail: deepa.chodankar@sanofi.com

REFERENCES

1. Xie Y, Liu F, Huang F, Lan C, Guo J, He J, *et al.* Establishment of a type 1 diabetes structured education programme suitable for Chinese patients: Type 1 diabetes education in lifestyle and self adjustment (TELSA). BMC Endocr Disord 2020;20:37.
2. Chiang JL, Kirkman MS, Laffel LM, Peters AL, Type 1 Diabetes Sourcebook Authors. Type 1 diabetes through the life span: A position statement of the American Diabetes Association. Diabetes Care 2014;37:2034-54.
3. Ait-Taleb Lahsen H, Ragala ME, El Abed H, Zarrouq B, Halim K. Effects of therapeutic patient education program on glycemic control and quality of life among children and adolescents with type 1 diabetes mellitus in Fez city, Morocco. Perspect Clin Res 2024;15:24-30.

4. Type 1 Diabetes in Adults: Diagnosis and Management. National Institute for Health and Care Excellence (NICE) Guideline [NG17]; 2022. Available from: https://www.nice.org.uk/guidance/ng17/resources/type-1-diabetes-in-adults-diagnosis-and-management-pdf-1837276469701. [Last accessed on 2023 Dec 09].
5. Kisokanth G, Prathapan S, Indrakumar J, Ilankoon IM. Validation of educational material for diabetes self-management education: Judgemental and criterion validity. Biomed Res 2018;29:2290-5.
6. National Ethical Guidelines for Biomedical Research Involving Children. Indian Council of Medical Research; 2017. Available from: https://ncdirindia.orgICMR_National_Ethical_Guidelines.pdf. [Last accessed on 2023 Dec 16].
7. Smuck M, Odonkor CA, Wilt JK, Schmidt N, Swiernik MA. The emerging clinical role of wearables: Factors for successful implementation in healthcare. NPJ Digit Med 2021;4:45.

Access this article online

Quick Response Code:	Website: www.picronline.org
	DOI: 10.4103/picr.picr_331_23

How to cite this article: Chodankar D. Challenges of assessing educational intervention in type 1 diabetes mellitus. Perspect Clin Res 2024;15:1-3.

Received: 25-12-23, **Accepted:** 27-12-23, **Published:** 09-01-24.