

# Development and Methodology of the 2024 and 2026 ISPAD Clinical Practice Guidelines

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## Keywords

Methodology · ISPAD clinical practice guidelines · Children · Adolescents · Diabetes

## Introduction

The International Society for Pediatric and Adolescent Diabetes (ISPAD) is the leading global organization dedicated to improving the lives of children and adolescents living with diabetes. With the mission to advance clinical and scientific knowledge, promote education, and advocate for better care and treatment, the ISPAD Clinical Practice Consensus Guidelines (CPCG), first released in 1995 [1] with subsequent updates in 2000, 2009, 2014, 2018, 2022, and 2024, have been a mainstay of pediatric diabetes care. The guidelines are

designed as a resource for health care practitioners with an interest in the care of children and adolescents with diabetes.

The guidelines align with the ISPAD declaration of Lisbon recommendations for improving care for children and adolescents with diabetes, particularly the calls to “prepare and disseminate written guidelines and standards for practical and realistic diabetes care, psychosocial care, monitoring, nutrition, education, and consistent goal-setting for young people with diabetes and their families” as well as to “advocate for inclusive policies and a safe environment in schools, non-academic activities, and work settings”[2].

The guidelines have evolved significantly over the years in scope and methodology, reflecting advances in

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diabetes technology, treatment strategies, and a commitment to inclusivity, engagement of individuals with diabetes, and rigorous evidence synthesis. Recent iterations have particularly emphasized the importance of social determinants of health and the use of technology in pediatric diabetes management [3]. As highlighted in a recent editorial [3], these changes are quantifiable. The 2022 guidelines included over twice as many references to diabetes technologies and a greater focus on health care disparities compared with 2018. Such measures may serve as useful benchmarks for assessing future progress in upcoming iterations of the ISPAD guidelines.

The need for transparent and comprehensive guidelines for children and adolescents authored by experts is underscored by a relative paucity of high-quality evidence in pediatrics compared to adult medicine [4]. This lack of evidence is attributed to factors including the relatively limited number of eligible pediatric patients available for clinical studies, the challenges inherent in translating adult clinical outcomes to children, and ethical concerns involving children's rights and safety. Additional considerations such as lower funding for pediatrics compared to adult research and barriers to enrolling children (particularly very young children) in clinical studies further contribute to gaps in evidence bases [5, 6]. Herein, we present the methodology used to develop the guidelines, with a focus on the 2024 process as well as the planned methodological changes to be introduced for the 2026 guidelines.

## Methodology

### *Governance and Editorial Team*

ISPAD guidelines development is initiated by ISPAD's executive board (EB), which includes international experts in pediatric diabetes. The board selects 1–2 lead editors for each guideline edition. The lead editors then propose to the EB an associate editor team. Editors are selected based on peer-reviewed publications in pediatric diabetes, clinical experience across diverse international health care systems, and prior guideline development expertise. Together, the editorial board, through a consensus process, invites experts in the field to contribute as authors in guideline development, with the aim of ensuring broad geographical, gender, age, career stage, and professional representation. Since 2022 there has been an intentional inclusion of persons with lived type 1 diabetes experience on each guideline chapter. Invitations to participate are also extended to experts from low and low-middle-income countries to ensure their perspectives are included in the guidelines.

### Editorial Team Members

For the 2024 and 2026 guidelines, the editorial team has been led by Dr. Linda DiMeglio (USA, ORCID ID: 0000-0002-8033-6078) and Dr. Farid Mahmud (Canada, ORCID ID: 0000-0002-3557-3584), and the associate editors are Dr. Carmel Smart (Australia, ORCID ID: 0000-0003-3104-8800), Dr. Klemen Dovc (Slovenia, ORCID ID: 0000-0001-9201-2145), Dr. Leena Priyambada (India, ORCID ID: 0000-0001-6004-576X) and Dr. Loredana Marcovecchio (Italy, ORCID ID: 0000-0002-4415-316X). One editor is assigned as the senior author for each guideline who guides and supervises the process. The whole editorial process is overseen and coordinated by the two senior editors. For the 2022 guidelines, a project officer/manager role was introduced (Dr. Leena Priyambada). Currently, the editorial efforts are supported by a pediatric endocrinologist (Dr. Yeray Nóvoa-Medina, ORCID ID: 0000-0002-9564-0654) who acts as project officer/manager, and helps coordinate the process, guide literature review and ensure homogeneity throughout the guideline development process.

### The 2024 ISPAD Guidelines

The 2024 ISPAD guidelines introduced methodological enhancements to improve rigor, transparency, and global relevance [7]. Amongst 25 chapters (in the 2022 guidelines), 6 focusing on high impact areas were updated (Table 1). Topics were selected by the editorial team along ISPAD's EB input based on relevance and need for evidence update since 2022.

Updates were performed using a comprehensive and structured literature search methodology from 2021 to 2022 onwards. Search terms for each topic were initially proposed by the project officer based on recommendations from professional librarians, then further reviewed, complemented, and approved by the authors of each guideline to ensure coverage of relevant literature. All references were uploaded to Covidence for independent screening by two reviewers, with discrepancies resolved by a third. Recommendations were graded using the ADA evidence grading system [14].

Guidelines were written more concisely than in previous versions for ease of reference, with content and recommendations designed to address clinically relevant questions related to pediatric diabetes detection, prognosis, prevention, and management. There was emphasis on graphics and visualization to provide a clear guidance on the best practices for care of children and young people with diabetes, as well as input of persons with lived diabetes experience. As in the 2022 guidelines, all conflicts of interest (COI) and funding sources were

**Table 1.** 2024 and 2026 ISPAD guideline topics

2024 ISPAD guideline topics	2026 ISPAD guideline topics
Glycemic targets [8]	Exercise in children and adolescents with diabetes
Insulin and Adjunctive Treatments in Children and Adolescents with Diabetes [9]	Assessment and management of hypoglycemia in children and adolescents with diabetes
Screening, Staging, and Strategies to Preserve Beta-Cell Function in Children and Adolescents with T1D [10]	Diabetic ketosis, ketoacidosis and hyperglycemic hyperosmolar state
Type 2 Diabetes in Children and Adolescents [11]	Microvascular and macrovascular complications in children and adolescents with diabetes
Diabetes Technologies: Glucose Monitoring [12]	Nutritional management in children and adolescents with diabetes
Diabetes Technologies – Insulin Delivery [13]	Psychological care of children, adolescents and young adults with diabetes

transparently disclosed. Guideline methodology was published alongside each individual chapter [8–13].

After completing the guideline development, all authors were invited via email to participate in a survey comprising the unmodified AGREE II evaluation questionnaire [15]. Study data were collected and managed using REDCap electronic data capture tools hosted at Sickkids Hospital. REDCap (Research Electronic Data Capture) [16, 17] is a secure, web-based software platform designed to support data capture for research studies. Responses were collected anonymously. The purpose of the survey was to critically appraise the guideline development process across the following AGREE II domains: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence. The evaluation aimed to assess the strengths and areas for improvement in the process, thereby enhancing the quality and transparency of future guideline iterations. All items were scored on a scale of 1 (strongly disagree) to 7 (strongly agree). Since the survey was conducted as part of routine quality improvement, no formal ethics approval was required.

Of those invited, 30% responded (26/71 authors). Answers were summarized using descriptive statistics for each domain. Table 2 summarizes the average score for each domain.

### The 2026 ISPAD Guideline

In line with current best practice recommendations, the 2026 ISPAD guideline planned development aims to further standardize methodological rigor, emphasizing reproducibility, equity and integration of real-world data to bridge gaps between research and clinical practice.

The 2026 guidelines will maintain a limited number of updated guidelines [7] to facilitate an adequately rigorous and supervised process. The plan is to enrich the methodology used for the 2024 guidelines by adding:

- Population, interventions, comparators, and outcomes of interest (PICO) questions. A hybrid methodology will be employed, commencing with a wide topic relevant literature review to help capture all essential elements. Based on this review, the authors and the project officer will subsequently formulate the PICO questions, ensuring that the main guideline recommendations are developed with clarity and transparency.
- AGREE II tools. They will be used throughout the process as a benchmark and post hoc evaluation instrument to ensure high-quality, clinical implementable recommendations, and transparency.

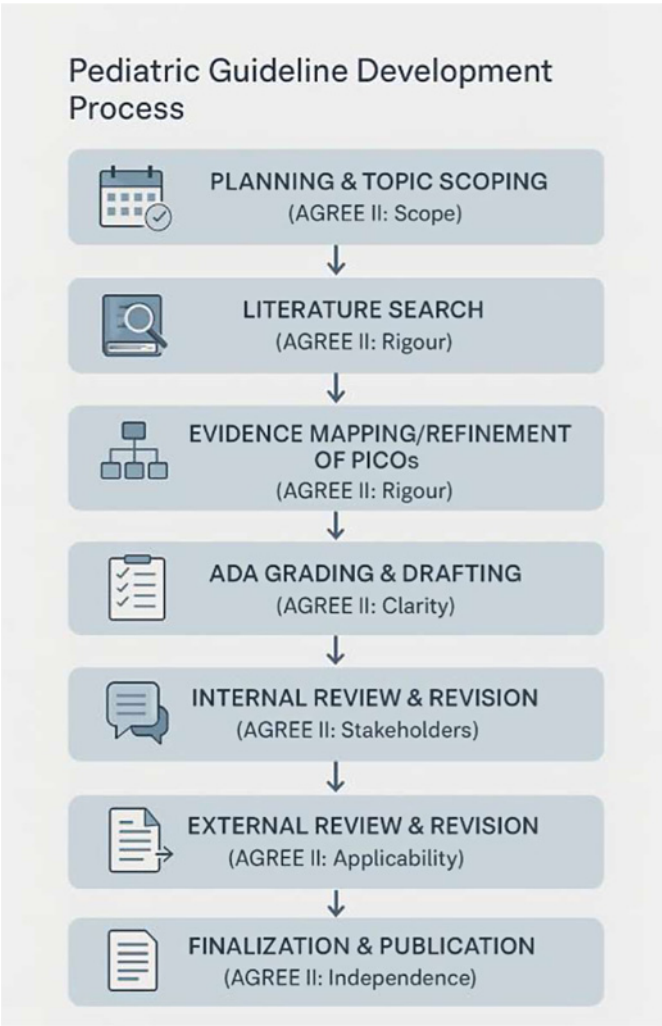
Figure 1 summarizes the 2026 planned ISPAD guideline development process incorporating PICO questions and AGREE II implementation steps throughout the process. Topics for the 2026 iteration of the guidelines are summarized in Table 1.

### Literature Search and Evidence Review

As was done in 2024, for the 2026 guidelines a literature search will be conducted to gather updated evidence, using a combination of relevant medical subject headings (MeSH, Emtree) and plain language keywords specific to each guideline's focus. Studies published from 2021 to 2022 onward (excluding non-English studies unless translated), related to children and adolescents, will be retrieved from Medline via PubMed, Ovid Embase and Cochrane Library. Other relevant international guidelines (American [American Diabetes Association],

**Table 2.** Summary of responses among 2024 guideline author

1. Scope and purpose	2. Stakeholder involvement	3. Rigor of development	4. Clarity of presentation	5. Applicability	6. Editorial independence	Overall quality of the guideline
6,37	5,76	5,86	6,32	5,73	6,41	6,23
Agree II questionnaire.						



**Fig. 1.** Summary of ISPAD 2026 guidelines development.

British [NICE], Canadian and Australian) will be reviewed to ensure all relevant aspects of the topic are covered and to enrich it with the specific pediatric needs.

The Project Officer, in collaboration with methodologists and librarians from SickKids Hospital, along with guideline leads and co-authors, will conduct the literature searches. The resulting articles will be up-

loaded to COVIDENCE for screening and review. Two authors/experts involved in drafting this guideline version will independently screen the articles. Any disagreements will be resolved by a third reviewer. Relevant articles suggested by the authors of each guideline not retrieved in the initial searches will be included. Search terms will be summarized and published as an Appendix/Supplementary material alongside each guideline.

*Recommendation Development and Grading*

Recommendations will be graded as per the ADA evidence grading system for “Standards of Medical Care in Diabetes” [14]. This hierarchical A-E grading system sets A as having the highest level of evidence, and E having the lowest (Table 3). We will take into account resource limitations, with resource-stratified recommendations.

*Drafting, Review, and Dissemination*

After initial meeting(s) to divide work, each co-author will collaborate in the development of a specific area of their topic. Once sections are drafted, the manuscript will be reviewed internally by the whole authorship group and guideline editor. After an initial manuscript is finalized by the writing group, external review by the 2 lead editors will be conducted, with suggestions incorporated to create a final manuscript. The resulting draft guideline will be posted on the ISPAD forum for a period of 2–4 weeks, to allow feedback from the greater ISPAD membership. Modifications will be made with authorship consensus, with the guideline receiving endorsement from the ISPAD editorial team.

The final guidelines will be published in Hormone Research in Pediatrics, the Society’s official journal since 2024, under open access. The guidelines are free and will be available on the ISPAD website in addition to HRP. Translation to other languages will also be available as soon as possible (currently, the 2022 guidelines are available on ISPAD’s website in English, French, Hindi, Portuguese, and Spanish). The content will be shared in international meetings (ISPAD, Advanced Technologies & Treatments for Diabetes [ATTD], ADA).

**Table 3.** Adapted from ADA evidence grading system [14]

Level of Evidence	Description
A	Strong and consistent findings from well-designed, sufficiently powered randomized controlled trials (RCTs), including: <ul style="list-style-type: none"> <li>• Results from multicenter RCTs with broad applicability</li> <li>• Meta-analyses that incorporate quality assessments of included studies</li> </ul> Also includes supportive evidence from well-executed RCTs conducted at single or multiple sites and meta-analyses with quality considerations
B	Evidence derived from well-conducted observational studies, such as: <ul style="list-style-type: none"> <li>• Prospective cohort studies or registries with sound methodology</li> <li>• Meta-analyses of cohort studies</li> </ul> Additionally, well-designed case-control studies providing supportive data
C	Evidence based on studies with methodological limitations or less rigorous designs, including: <ul style="list-style-type: none"> <li>• RCTs with significant flaws that may affect validity</li> <li>• Observational studies prone to bias, such as case series compared to historical controls</li> <li>• Case reports or series</li> </ul> Also includes situations where evidence is conflicting, but the majority supports the recommendation
E	Recommendations primarily based on expert opinion, clinical experience, or consensus in the absence of strong empirical evidence

### *Funding of the Guidelines and COI*

The 2026 Consensus guidelines are supported by unrestricted grants from Abbott Diabetes Care, Dexcom, Medtronic, and Sanofi. These companies do not take part in any aspect of the development of these guidelines. Funds are allocated to cover the project officer's salary, graphic design services, and open-access fees. These funds are managed independently by ISPAD's EB to ensure no influence on the guideline development process. Members of the editorial and authorship team, except for the project officer, do not receive any remuneration for their participation in the development of these guidelines.

All participants involved in the development of these guidelines will disclose any COI at the start of guideline development, which will be published alongside the final guideline. Authors with COI will be recused from voting on relevant topics.

### **Discussion**

Clinical guidelines have become indispensable tools for health care providers, offering much-needed guidance and distilling complex evidence into actionable recommendations. When developed and endorsed by respected National or International societies, they provide clear and trusted updates that inform clinical decisions, shape policy, and support advocacy efforts worldwide [18, 19].

To ensure that guidelines are evidence-based, reliable, and globally applicable to clinical practice, their development process must follow a structured, transparent, and systematic approach. The National Academy of Medicine (formerly the Institute of Medicine, IOM) identified eight standards for developing guidelines [18]. They include attention to: transparency, COI, guideline development group composition, systematic reviews, articulation of recommendations and rating their strength, external review and updating. Our updated development process includes these recommendations:

1. Topic Selection and Scope Definition: Topics are chosen based on clinical importance, practice variability, and available evidence, using the PICO(TS) framework, which includes population, intervention, comparator, outcome, timing, and setting, to ensure focused and answerable clinical questions [20, 21].
2. Multidisciplinary Guideline Development Group: Our panel includes clinicians, methodologists, and people with lived experience, ensuring diverse perspectives [21, 22].
3. Systematic Evidence Review: A comprehensive literature search is conducted to gather evidence, assisted with the use of Covidence, a platform that streamlines systematic review workflows [23].
4. Development of Recommendations: Recommendations are graded using the ADA evidence grading system, balancing rigor, and feasibility [14].

5. Drafting and Review: Drafts undergo internal and external review, including open feedback from the ISPAD membership, to ensure broad input [24, 25].
6. Finalization and Publication: The final recommendations are approved by the guideline development group. The guidelines are then published in a peer-reviewed journal (in our case, *Hormone Research in Pediatrics*) and made available online to ensure wide dissemination [25, 26].

Among our quality control initiatives, it is worth highlighting the use of the AGREE II instrument and the feedback it provides. In the evaluation of the 2024 guidelines, the responses from the author group were overall very positive. However, the limited response rate represents a potential limitation. To help mitigate this bias and enhance representativeness, we plan to disseminate the questionnaire more broadly by uploading it to the ISPAD website, thereby enabling participation from members beyond the authorship group.

Increasingly, international societies are more transparent in the methodology used for the development of their guidelines. The American College of Physicians [27], American Association of Clinical Endocrinologists [20], American Diabetes Association (ADA) [14], European Association for the Study of Diabetes (EASD) [28], and other professional groups adhere to these rigorous processes to develop trustworthy and actionable clinical guidelines.

A key distinction among organizations is the choice of evidence grading system. While GRADE is increasingly used for its transparency and nuance, ISPAD and ADA have traditionally used the ADA grading system. We have decided to maintain ADA grading for several reasons:

1. Standardization and consistency with ADA. Using the same system ensures consistency and comparability between ISPAD and ADA guidelines, which is especially important for practitioners who rely on both.
2. Clarity and Practicality. The ADA grading system is simple, clear, and easy to apply. This makes the guidelines accessible and actionable for a broad clinical audience.
3. Efficiency. The ADA system is less resource- and time-intensive, facilitating timely updates while offering a practical balance between rigor and feasibility.

## Conclusion

Rigor, transparency, and inclusivity are essential components of high-quality guideline development. The methodological changes introduced in this initiative over

the last years, including the publication of this methodological paper, are designed to enhance the reach, transparency, reproducibility, and validity of the ISPAD guidelines. By prioritizing a systematic approach, inclusive collaboration and patient engagement, we aim to involve experts from diverse geographic and professional backgrounds. This commitment ensures that ISPAD guidelines reflect a truly global perspective and meet the needs of the international diabetes community.

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## Conflict of Interest Statement

F.H.M.: research support from the Canadian Institute for Health Research (CIHR), Physicians Services Incorporated, Heart and Stroke Foundation, Diabetes UK and Breakthrough Diabetes (formerly JDRF). K.D.: received honoraria for participation in the speaker's bureau of Abbott, Eli Lilly, Medtronic, Novo Nordisk A/S, and Pfizer and advisory board for Medtronic and Novo Nordisk. C.E.S.: speaker honoraria from Medtronic and Eli Lilly and advisory boards for Abbott. M.L.M., Y.N.-M., L.P.: no conflicts of interest to declare. L.A.D.: research support from the NIH, JDRF, and the Helmsley Charitable Trust. Her institution has received research support from Dompe, Lilly, Mannkind, Medtronic, Provention Bio, Sanofi, and Zealand. Dr DiMeglio has consulted for Abata, Tandem, Biomea Fusion, and Vertex. She also received payment from Sanofi for a CME talk (content independently developed by her). "Prof. Assoc. Klemen Dovč and Dr. M. Loredana Marcovecchio and Dr. Leena Priyambada and Dr. Carmel E. Smart and Dr. Linda A. DiMeglio and Dr. Farid H. Mahmud were members of the journal's Editorial Board at the time of submission."

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## Author Contributions

F.M. and L.A.D. co-directed the guideline methodology development process. Y.N.-M. prepared the first draft of the manuscript. J.C., F.M., L.A.D., K.D., M.L.M., C.E.S., and L.P. critically revised the draft and subsequent versions and approved the final manuscript.



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