Research Article

Development and Initial Validation of the Insulin Injection Behavior Assessment Tool (IIBAT) for Adolescents with Type 1 Diabetes Mellitus

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Abstract

Objective: *To develop and initially validate an Insulin Injection Behavior Assessment Tool (IIBAT) for adolescents with type 1 diabetes mellitus (T1DM), based on the Five Rights framework of medication administration.* ***Methods:*** *This cross-sectional pilot study involved the construction of the tool based on literature review, clinical guidelines, and expert input. Five experts evaluated content validity using the Content Validity Index (CVI). Pilot testing was conducted with 34 adolescents with T1DM to assess clarity, feasibility, and reliability. A ceiling effect analysis was also performed.* ***Results:*** *The initial version of the IIBAT consisted of 24 items across three domains: preparation, storage/transportation, and adverse effect management. Content validity was strong (I-CVI = 0.80–1.00; S-CVI = 0.83), and no significant ceiling effect was found (2.94%). Corrected item–total correlations ranged from −0.30 to 0.60.* ***Conclusion:*** *The refined IIBAT demonstrated strong content validity and feasibility for assessing insulin injection behaviors in adolescents with T1DM. The removal of two low-performing items improved the conceptual alignment of the final 22-item version, supporting its use as a developmentally appropriate tool for clinical assessment and educational intervention.*

Keywords: insulin injection behavior; adolescents; type 1 diabetes mellitus; behavioral assessment tool

Significance of the problem

Adolescents with type 1 diabetes mellitus (T1DM) must inject insulin daily, yet ensuring proper technique and consistent adherence in this age group remains a significant clinical challenge.[1] Mastery of correct injection behaviors is essential for maintaining optimal glycemic control and preventing both acute complications—such as hypoglycemia and diabetic ketoacidosis—and long-term sequelae. Clinical guidelines highlight several key aspects of injection practice, including accurate dose calculation, appropriate pen use, systematic rotation of injection sites, correct timing relative to meals, proper hygiene, and safe needle disposal. However, studies conducted in Thailand reveal alarmingly high rates of improper insulin injection techniques among youth. Recent data indicate that 77.78% to 85.71% of insulin pen users continue to exhibit common errors—including site repetition, missed or delayed doses, incorrect timing, and inaccurate dose setting—even after extended use of the device.[2,3] These mistakes reflect widespread deviations from the "Five Rights" of medication administration: the right drug, right dose, right time, right route, and right patient. If left unaddressed, such behavioral lapses may significantly undermine metabolic control and elevate the risk of adverse outcomes during a vulnerable developmental period.[4]

It is well established that adolescence is a critical stage marked by reduced adherence to diabetes management. Developmental and psychosocial factors specific to this age group can interfere with effective self-care. Teenagers must navigate shifting responsibility from caregivers to themselves, increasing academic and social pressures, peer dynamics, and a desire for autonomy—all of which may contribute to inconsistent insulin-taking behaviors.[5] Glycemic control frequently deteriorates during this stage, in part due to changes in dietary habits, variable routines, and increasing independence. Injection-related tasks may also be influenced by developmental factors such as needle anxiety, impulsivity, and immature problem-solving skills.[2,6] For instance, younger adolescents may lack the motor coordination or cognitive ability to accurately use insulin pens without supervision. A qualitative study by Rankin et al.[7] found that children aged 9–12 often relied on parental support for dose calculation and encountered difficulties with technical aspects of injection, including dialing the correct dose and manipulating the device independently. Psychosocial resources play a pivotal role: a Thai study reported that adolescents with poor glycemic control often experienced low levels of family support and ineffective coping strategies[2,6], highlighting that favorable outcomes depend not only on technical skill but also on broader psychosocial factors.[8]

Tools for evaluating insulin injection behavior in adolescents are urgently needed to identify specific behavioral deficits and inform tailored interventions. At present, no comprehensive and psychometrically validated instrument exists for this purpose. Many existing tools focus narrowly on adherence frequency or checklist-based technical performance, with few accounting for the unique developmental needs of adolescents.[9,10] For example, the injection technique checklists developed by Ortiz La Banca et al.[11] assess procedural steps but do not fully capture broader behavioral patterns or barriers encountered by teenagers. Similarly, other instruments for pediatric diabetes self-management (e.g., problem-solving scales) address overall regimen adherence but lack specificity regarding insulin injection technique and safety behaviors.[12] Moreover, standard checklists often omit preparatory and follow-up behaviors such as proper insulin storage, post-injection site monitoring, and timing coordination—behaviors highly relevant to adolescents learning self-care. This absence of a developmentally appropriate and

comprehensive behavioral tool led to the creation of the Insulin Injection Behavior Assessment Tool (IIBAT) for adolescents.

The Five Rights framework—right patient, right drug, right dose, right route, and right time—is a foundational concept in medication safety.[4] It serves as a systematic guideline to ensure that medications are administered accurately and safely by confirming that the correct individual receives the correct medication, in the correct amount, via the correct method, and at the correct time. Originally developed for clinical settings, this framework has been widely adapted for patient self-management, offering a clear and practical structure for minimizing errors and reinforcing safe medication practices.

Despite the clear clinical and behavioral need, no comprehensive and psychometrically validated behavioral assessment tool currently exists to evaluate insulin injection practices among adolescents using insulin pens. [10,12,13] Existing instruments tend to focus narrowly on adherence frequency or isolated technical skills and often fail to capture the full behavioral process of insulin self-injection, including preparatory, timing, and post-injection practices. In addition, few tools are designed with developmental appropriateness for adolescents. To address this gap, we developed and initially validated the Insulin Injection Behavior Assessment Tool (IIBAT), based on the Five Rights framework of medication administration.[4] The IIBAT objectively evaluates key behaviors such as confirming insulin type, setting appropriate doses, using proper subcutaneous technique, timing injections correctly, and rotating injection sites. Through expert review and pilot testing, the tool demonstrated early evidence of content validity and internal consistency reliability. As adolescents transition toward greater self-management, a reliable and developmentally appropriate instrument can play a pivotal role in fostering and sustaining safe and effective insulin injection practices. [9,11]

Research Questions

1. What are the core behavioral components necessary for safe and effective insulin injections among adolescents with Type 1 Diabetes Mellitus (T1DM)?

2. Can a structured behavioral assessment tool based on the Five Rights framework be developed to reliably evaluate insulin injection behaviors in adolescents?

Objectives

1. Identification and operationalization of key insulin injection behaviors among adolescents with T1DM using the Five Rights framework of medication administration.

2. Development and initial validation of the Insulin Injection Behavior Assessment Tool (IIBAT) through expert content validation and pilot testing, with assessment of internal consistency reliability.

Conceptual Framework

The Five Rights framework of medication administration, which includes the right patient, right drug, right dose, right route, and right time, served as the conceptual foundation for developing the IIBAT.[4,8] Widely used in nursing to prevent medication errors, the Five Rights provides a structured safety checklist to ensure accurate and appropriate medication use. When applied to adolescent self-injection of insulin, the framework offers a behaviorally grounded structure for promoting safe, consistent practices during the transition to self-care. Each domain of the Five Rights was mapped to specific, observable behaviors within the insulin injection process. For instance, Right Patient corresponds to using one's own insulin pen and avoiding device sharing; Right Drug involves verifying the correct type of insulin (e.g., rapid-acting or long-acting); Right Dose

includes calculating, dialing, and administering the appropriate amount based on blood glucose levels; Right Route encompasses proper site selection and subcutaneous injection technique; and Right Time refers to administering insulin at recommended intervals, such as before meals or at consistent daily times. These components directly informed the construction of IIBAT items, ensuring that each domain of the Five Rights framework is operationalized into clear, measurable behaviors relevant to adolescent insulin self-administration.

Recognizing that safe insulin use extends beyond the moment of injection, the tool also includes domains that capture essential pre- and post-injection practices not explicitly addressed in the original Five Rights framework. These include appropriate insulin storage and transportation, as well as post-injection monitoring for adverse effects such as hypoglycemia or lipohypertrophy. Together, the Five Rights and these supplementary domains provide a comprehensive behavioral model for assessing and supporting safe insulin self-management in adolescents.

Research Design

This study employed a cross-sectional pilot design for instrument development. We followed established scale development guidelines, encompassing item generation, expert content validation, and pilot testing.[14]

Research method

Population

The study population comprised adolescents aged 12–18 years with a confirmed diagnosis of type 1 diabetes mellitus (T1DM) who were receiving care at the diabetic outpatient clinic of the Queen Sirikit National Institute of Child Health (QSNICH). A convenience sampling method was used, initially recruiting participants during a hospital-based diabetes education event on June 10, 2025. Eligible individuals were approached by a trained research assistant—a registered nurse experienced in adolescent diabetes care—and invited to participate following assent and parental consent. To supplement recruitment, a snowball sampling strategy was employed, whereby enrolled participants referred T1DM peers who later contacted the research team and completed enrollment.

Inclusion criteria were: (a) age between 12 and 18 years; (b) diagnosed with T1DM for at least six months; (c) current use of an insulin pen as the primary injection device; (d) awareness of their diabetes diagnosis and ability to self-administer insulin; and (e) absence of severe diabetes-related complications (e.g., advanced retinopathy, neuropathy, nephropathy) or other major chronic comorbidities (e.g., hypertension, hyperlipidemia, chronic kidney disease). Adolescents with cognitive impairments or language barriers that could hinder comprehension of the questionnaire were excluded.

A total of 34 adolescents met the eligibility criteria and participated in the study. This sample size was deemed appropriate for the purpose of instrument development and initial validation. According to methodological recommendations, a sample of approximately 25–30 participants is generally sufficient for pilot testing to assess item clarity, relevance, and preliminary reliability prior to broader application.[15,16] Accordingly, the current sample was considered adequate for the objectives of this initial validation phase of the instrument.

Ethical Consideration

This study was part of the research titled “The Effect of Information-Motivation-Behavioral Skill Development Program on Insulin Injection Behavior among Adolescents with Type 1 Diabetes Mellitus.” The study protocol was reviewed and approved by the Institutional Review Board (IRB) of the Queen Sirikit National Institute of Child Health, Bangkok,

Thailand (Approval No. REC.030/2568). Written informed assent from adolescents and consent from their parents or guardians were obtained prior to participation.

Procedure

The IIBAT items were developed by the three authors based on relevant empirical literature and clinical practice guidelines. The first author led all phases of the study, including item drafting, expert consultation, recruitment, and field data collection.

For content validation, the first author submitted the initial item pool to a panel of five qualified experts for review. These included two pediatric endocrinologists (MDs with over 10 years of experience in diabetes care), two certified pediatric diabetes nurse educators (RNs specializing in insulin education), and one advanced practice nurse in pediatric endocrinology. Each expert evaluated the relevance, clarity, and developmental appropriateness of the items. Their feedback was reviewed collaboratively by the research team and incorporated into the revised version of the instrument.

Data collection was conducted at a diabetes education event held at the Queen Sirikit National Institute of Child Health (QSNICH) on June 10, 2025. The first author and a trained research assistant approached eligible adolescents with type 1 diabetes mellitus (T1DM) during the event and invited them to participate. Twenty adolescents were recruited on-site. Additionally, peer referral was used to identify more eligible participants, resulting in 14 additional recruits and a total sample size of 34 adolescents. All participants completed the IIBAT on June 11, 2025. Before participation, adolescents and their legal guardians received detailed information about the study and signed written informed consent forms. Verbal assent was also obtained from all adolescent participants.

Data Collection Tool

The Insulin Injection Behavior Assessment Tool (IIBAT) was the primary instrument used to assess insulin self-injection behaviors in adolescents with T1DM. The initial version of the tool consisted of 24 items distributed across three domains: (1) Preparation (12 items), (2) Storage and Transportation (4 items), and (3) Observation and Management (8 items). Each item reflected a specific, observable behavior important for safe and effective insulin administration.

Items were phrased as first-person statements (e.g., “I rotate my insulin injection sites”) and rated using a 5-point Likert-type scale. This scale ranged from 1 (“Never”) to 5 (“Always”), with intermediate options of 2 (“Seldom”), 3 (“Sometimes”), and 4 (“Often”), allowing participants to indicate how consistently they performed each behavior. Higher scores represented better adherence to recommended injection practices. Subscale scores for each domain could be computed alongside the total score to identify specific behavioral strengths or gaps.

The IIBAT was self-administered in a supervised setting. A trained research assistant provided standardized instructions and clarification as needed. Completion took approximately 10–15 minutes, and participants were assured that their responses would remain confidential to promote honest reporting.

Data Analysis

Descriptive statistics were used to analyze the socio-demographic characteristics of the participants. The IIBAT was evaluated for clarity, feasibility, and reliability through the calculation of the Content Validity Index (CVI), ceiling effect, and corrected item–total correlations.

Results

Content Validity and Expert Review

The IIBAT was reviewed by a panel of five qualified experts to evaluate content validity.

The expert panel comprised two pediatric endocrinologists, two certified pediatric diabetes nurse educators, and one advanced practice nurse specializing in pediatric endocrinology. Overall, experts strongly endorsed the relevance, clarity, and developmental appropriateness of the IIBAT items for assessing insulin injection behaviors among adolescents with type 1 diabetes mellitus.

The item-level Content Validity Index (I-CVI) ranged from 0.80 to 1.00, indicating acceptable to excellent agreement across items. The scale-level CVI (S-CVI/Ave) was 0.83, exceeding the recommended minimum threshold for newly developed instruments. Minor wording revisions were suggested to enhance clarity, particularly in the preparation domain (e.g., simplifying technical terminology related to priming and site rotation). Suggestions regarding insulin storage emphasized temperature control during transportation, while feedback on observation and management items highlighted the importance of action-oriented behaviors. All items met content validity criteria and were retained for pilot testing.

Participant Characteristics

The study included 34 adolescents with type 1 diabetes mellitus, the majority of whom were female and aged between 13 and 15 years. Most participants had been diagnosed with diabetes for more than one year and had used insulin pen devices for one to five years. The majority administered insulin three to four times daily and used both rapid-acting and long-acting insulin. Overall, participants demonstrated relatively stable clinical profiles and were receiving ongoing care at a tertiary pediatric diabetes center.

Regarding educational level, nearly half of the participants were enrolled in lower secondary school (47.06%), followed by upper secondary school (29.41%). A smaller proportion were studying at the vocational certificate level (14.71%), while only a few were in primary school (8.82%).

In terms of nutritional status, most adolescents had normal weight based on percentile or Z-score classification (61.76%). Approximately one quarter were classified as overweight (26.47%), and a small proportion were obese (8.82%). Very few participants were identified as severely underweight (2.94%).

Item Performance and Internal Consistency

The initial version of the IIBAT consisted of 24 items across three domains: preparation, storage and transportation, and observation and management. Descriptive analysis showed generally high mean scores across items, indicating frequent performance of recommended insulin injection behaviors. Ceiling effect analysis demonstrated that only one participant (2.94%) achieved the maximum total score, suggesting no significant ceiling effect at the scale level.

During the initial item analysis of the 24-item pool, corrected item–total correlations ranged from −0.30 to 0.60. Two items demonstrated particularly poor psychometric performance, characterized by very low or negative item–total correlations and minimal score variability. These items were: (1) “I do not allow anyone else to use my insulin pen,” and (2) “I adjust the type of insulin I use based on my blood glucose level.” The first item showed little discriminatory value due to near-universal endorsement, while the second item appeared conceptually ambiguous for adolescents and was negatively correlated with the total scale score. Based on psychometric criteria and conceptual considerations, these two items were removed.

Following item reduction, the final IIBAT consisted of 22 items, with improved internal consistency (Cronbach’s alpha = 0.80), compared with the initial 24-item version (α = 0.72). The characteristics of the final items are summarized in Table 1

Table 1. Final 22 items of the Insulin Injection Behavior Assessment Tool (IIBAT), grouped by domain, with mean frequency, standard deviation (SD), and corrected item–total correlation (r) based on pilot data (N = 34).

Domain / Item Statement	Mean	SD	Item–Total r
Preparation Behaviors (8 items)			
1. Uses only their own insulin pen (does not share pens)	4.85	0.36	-0.02
2. Does not allow others to use their own insulin pen.	4.74	0.79	-0.001
3. Adjusts insulin type *only as prescribed* (does not self-change)	4.82	0.39	0.38
4. Checks blood glucose and calculates the prescribed dose	4.53	0.75	0.20
5. Sets the correct dose on pen, holds pen for 10 seconds after injection, and checks that insulin has been delivered	4.65	0.65	0.50
6. Cleans the skin and needle, and primes the pen to remove air before injecting	4.59	0.78	0.37
7. Injects at a 90° angle into subcutaneous tissue and rotates injection sites	4.41	0.93	0.60
8. Injects rapid-acting insulin ~15 minutes before meals (as recommended)	4.41	0.86	0.47
Insulin Storage & Transportation Behaviors (4 items)			
9. Stores unopened insulin cartridges in the refrigerator (center compartment)	4.62	0.65	0.25
10. Keeps in-use insulin pens in a cool, shaded place (around 25–30°C)	4.50	0.93	0.28
11. Prepares/assembles the insulin pen before going out (to avoid missing doses)	4.79	0.41	0.14
12. Carries the insulin pen in a protective case when traveling/commuting	4.71	0.52	0.46
Observation & Management Behaviors (10 items)			
13. Checks for bruising at the injection site after injecting	4.29	1.00	0.66
14. Observes for bleeding at the injection site after injection	4.12	1.25	0.58
15. Checks for lipohypertrophy (lumps) at injection sites before injecting	4.27	0.79	0.42
16. Checks for any unusual feeling (e.g., numbness) at the injection site	4.21	0.81	0.61
17. Watches for signs of hypoglycemia (e.g., shakiness) after insulin injection	4.56	0.82	0.04
18. Avoids rubbing or massaging the injection site after injecting	4.03	1.24	0.09
19. Changes the injection site if bleeding occurs during injection	4.62	0.65	0.12
20. Avoids injecting into hardened or lumpy areas (uses other sites until lumps heal)	4.38	0.95	0.17
21. Uses a new needle if an injection is particularly painful or difficult	4.56	0.93	0.15
22. Carries a fast-acting sugar (e.g., glucose tablets or juice) to treat low blood sugar if needed	4.62	0.70	0.27

Note: Item–total correlation (r) represents the Pearson correlation between each item and the total score of the remaining 21 items. Values of $r \geq 0.30$ are generally considered acceptable indicators of item discrimination. Several items demonstrated lower item–total correlations, likely due to limited response variability and ceiling effects commonly observed in pilot studies. These items were retained based on their conceptual importance and relevance to safe insulin injection practices. The final version of the instrument consists of 22 items.

Discussion

This pilot study provided initial evidence supporting the IIBAT's content validity and reliability, while identifying areas for refinement. Content validity indices were high, with I-CVI values ranging from 0.80 to 1.00 and an S-CVI of 0.83. These values exceed commonly accepted thresholds—usually ≥ 0.78 for I-CVI and ≥ 0.90 for S-CVI/Ave—indicating strong expert agreement on item relevance.[17,18]

Despite the strong content validity of the IIBAT, no significant ceiling effect was observed at the scale level, as only a small proportion of participants achieved the maximum total score. However, examination of item performance indicated that two items demonstrated limited variability and low discriminatory power, as reflected by high endorsement rates and low or negative corrected item–total correlations.[19-21] Such characteristics indicate restricted measurement sensitivity, meaning that these items offer little discriminatory value. Consequently, removing these items helped improve the tool's capacity to capture meaningful differences in injection behaviors. Furthermore, corrected item–total correlations below the accepted threshold of 0.30 suggest misalignment with the overall scale construct, and removal of such items is known to enhance internal consistency.[17,18]

When these two items were deleted, internal consistency improved, as reflected in a rise in Cronbach's alpha. This aligns with best practices in scale development, where eliminating poorly performing items boosts overall reliability and measurement precision without compromising content validity. [17] The refined 22-item IIBAT now offers a concise, psychometrically stronger instrument suitable for assessing insulin injection behaviors in adolescents.

Valid and reliable assessment tools such as the IIBAT are particularly important in pediatric diabetes care. Adolescence is characterized by developmental transitions, increasing autonomy, and fluctuating adherence to self-care behaviors.[22] Accurate assessment of insulin injection practices enables nurses and diabetes educators to identify behavioral gaps, tailor educational interventions, and monitor changes over time—approaches that have been associated with improved glycemic outcomes.[23]

Compared with existing instruments used to assess insulin administration in pediatric populations, the IIBAT offers several distinct advantages. Many available tools focus primarily on technical checklists evaluated during observed injections or on general adherence measures that provide limited insight into injection-specific behaviors. Such approaches may not adequately capture the consistency of insulin injection practices across daily life or address behaviors beyond the injection moment itself. In contrast, the IIBAT adopts a frequency-based self-report format that reflects routine practice and incorporates a broader range of behaviors, including insulin storage, transportation, and post-injection monitoring. These domains are particularly relevant for adolescents, who increasingly self-administer insulin in varied settings such as schools and social environments. By capturing both preparatory and follow-up behaviors, the IIBAT provides a more comprehensive behavioral profile than existing instruments.[7,11,12]

The IIBAT also demonstrates practical applicability across clinical, educational, and research contexts. In clinical practice, the tool may support systematic assessment of insulin injection behaviors, allowing nurses and diabetes educators to identify specific areas requiring targeted instruction and individualized counseling. In educational settings, the IIBAT may function as both an assessment and a teaching aid, as its items reflect recommended practices and encourage adolescent self-reflection on injection habits. In research contexts, the IIBAT

provides a standardized behavioral outcome measure that can be used to evaluate interventions aimed at improving insulin injection practices, particularly in pilot and behavioral intervention studies.

Nevertheless, assessment of adolescent self-care behaviors remains challenging. Self-report instruments are inherently susceptible to social desirability bias and overestimation of adherence.[24,25] Triangulation with objective indicators, such as glucometer data or parent-reported measures, may help strengthen confidence in future findings.[26]

Limitation

Several limitations should be acknowledged. This pilot study was conducted in a single tertiary pediatric diabetes center, which may limit generalizability, as adolescents receiving specialized care may demonstrate higher adherence than those in other clinical settings. The sample size was relatively small, restricting the range of psychometric analyses that could be performed. In addition, test–retest reliability was not assessed, and construct validity testing—such as exploratory or confirmatory factor analysis—was not conducted due to sample size constraints. These limitations underscore the preliminary nature of the current validation findings.

Future Directions

Future research should focus on comprehensive psychometric evaluation of the IIBAT, including assessment of test–retest reliability and examination of construct validity using exploratory and confirmatory factor analyses. Studies involving larger, multi-center samples are needed to enhance external validity and evaluate the instrument's performance across diverse clinical and cultural contexts. Further investigation of criterion-related validity, such as associations between IIBAT scores and clinical outcomes (e.g., glycemic control or injection-site complications), will strengthen the evidence base supporting its broader application.

Conclusion

The IIBAT demonstrates promising content validity and acceptable internal consistency for assessing insulin injection behaviors in adolescents with T1DM. As a structured, developmentally appropriate tool, it holds potential for both clinical use and research, particularly in guiding individualized education and self-management support.

Recommendation and Implications

Future studies should include larger and more diverse samples, test–retest reliability, and links to clinical indicators (e.g., HbA1c). Clinically, the IIBAT can help nurses and educators identify and target specific behavioral gaps in insulin injections. Its brief, practical format makes it suitable for use in both clinical and school-based settings.

Participation in article writing

Sujika Komjakraphan contributed to the study's conceptualization, participant recruitment, data collection, analysis, and manuscript drafting.

Surasak Treenai supervised the study and led conceptualization, design, data analysis, interpretation, and manuscript preparation, including final approval.

Chollada Jongsomjitt supervised and contributed to study validation, design, data interpretation, and project administration.

Conflict of Interest

The authors declare that they have no competing interests to disclose.

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