# Development and content validation of the Pediatric Dizziness Index (PDI)

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#### Abstract

Introduction: Approximately, 3 million children are impacted by dizziness nationally, and are at high risk of intellectual and learning disability. Stark differences between children and adults in brain morphology, maturity, and perceptions of injury impact, valid, age-specific patient reported measures are important to capture the breadth of disability from dizziness post-concussion.

Objectives: To develop and examine content validity of the Pediatric Dizziness Index (PDI) to evaluate perceived disability due to dizziness.

Participants: Eight pediatric clinical and research experts participated in PDI development. PDI was developed in four steps: 1) Item development, 2) Item evaluation, 3) Content validity ratio and index calculation, and 4) Cognitive interviews to ensure face validity, and comprehension of the items. Content validation process followed the Consensus based Standards for the selection of health status Measurement Instruments (COSMIN) guidelines.

Main outcome measures: Content Validity Ratio (CVR) was calculated using Lawshe's formula CVR=(ne-N/2)/N/2 (ne=number of experts identified an item as essential; N=total number of experts). Finally, Content Validity Index (CVI) was calculated (CVI > 0.8 indicated good content validity).

Results: Following the modified Delphi process, the initial item bank of 33 items was condensed to 10 items in final version of PDI. Three items were revised post cognitive testing. The final version of PDI demonstrated good content validity (CVI=0.87).

Conclusion: PDI is the first comprehensive patient reported measure specific to dizziness and provides evidence of strong content validity. Further research to establish factor structure and construct validity is recommended.

Keywords: Validity, Children, Dizziness, Disability evaluation.

#### List of Abbreviations

PDI=Pediatric Dizziness Index; CI=Confidence Interval; PROM=Patient-Reported Outcome Measures; DHI=Dizziness Handicap Inventory; PVSQ=Pediatric Vestibular Symptom Questionnaire; DHI-PC=Vanderbilt Pediatric Dizziness Handicap Inventory for Patient Caregivers; DHI-CA=Dizziness Handicap Inventory-Children and Adolescents; COSMIN=Consensus based Standards for the selection of health status Measurement Instruments; ICF-CY=International Classification of Functioning, Disability, and Health: Children and Youth Version; CVR=Content Validity Ratio; CVR critical=Content Validity Ratio Critical Value; CVI=Content Validity Index.

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## Introduction

Dizziness is a broad term that includes sensations like vertigo, disequilibrium, presyncope and lightheadedness [1]. Dizziness has been reported in 3.5 (95% CI=3.1-3.9) million children with higher prevalence in the 15-17 years' age group [2,3]. Multiple factors including trauma, concussion, vestibular migraine, benign paroxysmal positional vertigo, peripheral vestibular syndromes, ear infections, and hemodynamic dysfunction can cause dizziness in children [3].

Dizziness significantly affects mobility and balance, function, participation in age-appropriate activities and health behaviors, and quality of life [4]. Moreover, dizziness has shown to increase anxiety and psychological stress in children and adolescents [5,6]. Children and adolescents with dizziness demonstrate a 6.6 times (95% CI=2.6-16.79) increase in likelihood of intellectual disability, 3.4 times increase in likelihood of learning disability (95% CI=2.18-5.45), and 1.76 times higher likelihood of attention deficit disorder (95% CI=1.06-2.81) as compared to those without vertigo [6].

Additionally, children with dizziness experience developmental delay, emotional difficulty, and behavioral difficulty and are 2.46 times (95% CI=1.48-4.10) times more likely to use special education services as compared to children without vertigo. If left untreated, dizziness can negatively affect child's recovery, independent functioning and participation in the age-appropriate activities [7].

Given the substantial impact of dizziness on activities of daily living, it is important to accurately assess dizziness to plan targeted rehabilitation intervention. Specifically, given the broad range of experiences a child can associate with dizziness, it is important to examine this problem from a patient perspective. Gathering self-report symptom information from the child is essential to capture true nature of perceived disability that allows for focused assessment and interventions to improve function [8]. This serves as a guide for directing further examination, goal setting and designing targeted rehabilitation interventions to effectively manage dizziness and consider the environmental and social contexts 1) Where the dizziness arises and/or 2) That children and adolescents avoid as a result of dizziness. This information will aid healthcare providers to include all relevant factors to support function.

Patient-Reported Outcome Measures (PROM) capture the impact of a disease and/or intervention on the patient and are important in implementation of patient-centered care model through integrated care in healthcare [9]. Studies suggest that 7-8 years old children demonstrate adequate cognitive skills to respond appropriately to systematic questioning as required in the PROM [10,11]. While PROMs to evaluate dizziness such as the Dizziness Handicap Inventory (DHI) exist in the adult population, the same measures have not been validated in children and have little clinical applicability in the pediatric population as the contextual factors are significantly different from adults. Existing measures to evaluate dizziness in children (Pediatric Vestibular Symptom Questionnaire (PVSQ), The vanderbilt pediatric Dizziness Handicap Inventory for Patient Caregivers (DHI-PC), and The Dizziness Handicap Inventory-Children and Adolescents (DHI-CA)) are either geared towards parents and caregivers, thereby limiting patient or showed questionable experience, validity comprehensiveness, thereby limiting their clinical applicability in this population of children with dizziness.

Hence, the purpose of this study was to develop and examine content validity of a new PROM *i.e.*, Pediatric Dizziness Index (PDI) to specifically evaluate activity limitation and participation restriction resulting from dizziness in children and adolescents.

#### **Materials and Methods**

Development and content validation of the PDI was completed in four steps: 1) Item development, 2) Item evaluation by content experts, 3) Content validity calculation, and 4) Cognitive testing *via* interviews to ensure readability and comprehension of the items on the PDI. Content validation was done according to the guidelines by the Consensus based Standards for the selection of health status Measurement Instruments (COSMIN) [12].

## Item development

The first step in developing a PROM is to identify the constructs intended to be assessed by the measure [11]. A literature search revealed three existing measures to assess dizziness in children, namely, 1) PVSQ, 2) DHI-PC, and 3) DHI-CA [13-15]. The PVSQ is an eleven-item self-report/ parent-caregiver assisted questionnaire which is primarily focused on the frequency of vestibular symptoms. Each item is scored on a 0-3 Likert scale (0=never, 3=most of the time) with a score ranging from 0-33 with higher scores indicating greater symptom severity [13]. DHI-PC is a parent/caregiver reported questionnaire that was designed to assess disability in children in the 5-12 year age group, whereas the DHI-CA was designed for children between 6-14 years of age [14,15]. DHI-PC contains twenty-one items and the DHI-CA twenty five items. Each item on both the measures is scored on a three-point Likert scale (0=no, 2=sometimes, 4=always) with a total score ranging from 0-84 (DHI-PC) and 0-100 (DHI-CA) with higher scores indicating higher perceived disability [14,15]. Content from these existing measures was evaluated to identify some potential items to be included on the PDI.

Additionally, a comprehensive pool of items related to activities and participation was further developed by the team following an exhaustive review of the International Classification of Functioning, disability, and health: Children and Youth version (ICF-CY) model [16]. The ICF-CY was created to facilitate an understanding of how a child's environment may influence their development and well-being [11]. The items were written in child-friendly language and kept at 3<sup>rd</sup> grade reading level [17]. As recommended by previous research, the items of the PDI were positively phrased to make the measure appropriate for children [18]. Each item on the PDI was scored on a 0-10 numeric rating scale (0=not difficult at all, 10=extremely difficult) with higher scores indicating higher perceived disability.

Linkage to the International Classification of Functioning, disability, and health: Children and Youth version (ICF-CY). To provide a comprehensive assessment regarding multiple facets of dizziness that impact function, the items on the PDI were constructed based on the ICF-CY model. The functioning and disability section of the ICF-CY model includes body functions and structures and activities and participation along with contextual factors (environmental and personal factors) [16]. ICF-CY classification is organized based on hierarchy and inter-relatedness of levels. Two research team members linked each item from the PDI to the ICF-CY categories.

#### Expert consultation

A measure has content validity if "it covers all parts of the universe of content and reflects the importance of each part" [19]. A modified Delphi process was used for content validation. Modified Delphi process is a technique to obtain the most reliable consensus from a group of experts [20]. The recommended number of experts for content validation should be a minimum of six and not more than ten [21]. Hence, eight experts in physical therapy were recruited *via* email to

participate in the modified Delphi process [19]. The expert panel comprised of clinicians and researchers with more than 5 years of work experience who had content, clinical, or research expertise in pediatrics and/or vestibular rehabilitation. The experts participated in two rounds of modified Delphi process [22,23]. A detailed explanation of the different items on the list and instructions on how to score the items was provided to assist the experts in their rating. Experts were asked to independently rate each item as "essential", "useful but not essential" or "not essential" as recommended previously by Lawshe [24]. The experts were requested to provide a rationale for their responses. The experts had three weeks to complete the first round and a reminder email was sent after two weeks. All responses were documented for the next step of content validation. The same procedure was followed for the second round of review.

#### Content validation

Two research team members completed all analysis. To determine content validity, the Content Validity Ratio (CVR) was calculated using Lawshe's formula CVR = (ne-N/2)/N/2 where "ne" is the number of experts identifying an item as "essential" whereas N is the total number of experts [23,25]. CVR values range from -1 to +1. A CVR value above zero indicated that over half of the experts agreed the item was "essential". Lawshe and Schipper's table of difficult values was used to determine the critical value of CVR (CVR critical) to eliminate chance agreement between experts. Items were

retained in their original form if the CVR values were above the CVR critical (Table 1) [24]. Based on the number of experts involved in the modified Delphi process (N=8), the CVR critical was set at 0.75 for item retention [24]. Once all rounds of review were complete, the Content Validity Index (CVI) was calculated to obtain a numeric value of the content validity of the measure [23,25]. The CVI was calculated as the mean of the overall CVRs for all the items included in the final measure. A CVI value of >0.8 was considered an indicator of good content validity [23].

# Cognitive interviewing

Approval from the institutional review board of the Simmons University was obtained (approval number #IRB 22-59). Children and adolescents aged 8-16 years' old who speak English as a primary language and currently experiencing dizziness or with a history of dizziness were recruited via a flyer posted to the researchers' social media accounts. After obtaining written consent from the parents and assent from the children, cognitive testing of the PDI was performed via purposive sampling. Parents were given the opportunity to stay with the child during the cognitive interview process. Cognitive interviewing is a form of qualitative interviewing used to obtain insights about a respondent's thought process as they read or hear an item, and as they respond to a question [26]. The purpose of cognitive interviewing and testing is to explore whether children understand the questions consistently in the way intended by the researchers. Cognitive interviewing was

| Item number | ICF-CY category          | Item details  | Content Validity Ratio (CVR) |
|-------------|--------------------------|---|------------------------------|
| 1           | Activity                 | Can do activities normally in a day   | 1                            |
| 2           | Body function            | Can focus on all classroom activities without feeling dizzy   | 0.75                         |
| 3           | Activity                 | Can stand/sit still comfortably   | 1                            |
| 4           | Activity                 | Can get in and out of bed without feeling dizzy.  | 0.75                         |
| 5           | Activity                 | Can stand up and sit down from a chair or couch without feeling dizzy.  | 1                            |
| 6           | Activity                 | Can ride a bike/scooter without feeling dizzy   | 0.75                         |
| 7           | Participation            | Can play with friends in gym class or an outdoor game of the choice (hopscotch, soccer, baseball, hockey etc.) without feeling dizzy. | 1                            |
| 8           | Activity, environmental  | Can use technology (TV, tablet, phone etc.) for as long as I like without feeling dizzy   | 0.75                         |
| 9           | Body structure, activity | Can look up/down/turn my head without getting dizzy.  | 0.75                         |
| 10          | Activity                 | Can walk up and down the stairs without getting dizzy   | 1                            |

Table 1. Content validity ratio values for individual items of the PDI after two rounds of modified Delphi process.

completed by two members of the research team using 1:1 interviews on zoom with children currently experiencing or with a history of dizziness. Recruitment was discontinued once saturation was attained. To control for bias (peer-pressure in a group setting), 1:1 interviews chosen instead of focus group interviews [11]. Additionally, it is difficult for the younger children to stay attentive to the questions in a focus group. All participants received a \$15 gift card for participating.

Characteristics of children (N=6) who participated in the cognitive interviews are reported in Table 2. Three out of six participants reported of experiencing dizziness within the last 12 months, one participant was experiencing dizziness currently, and two participants reported of having dizziness more than a year ago. Three participants were interviewed in the first round of cognitive interviews. A copy of the PDI was provided to participants for review prior to the interview. During the interview, a research team member read each item of the PDI to the participant. The participant also had the

written copy of PDI available for their reference if needed. The participant was then asked to think out loud and describe their thought process that they utilized to interpret the item and formulate a response [27]. Participants' input were sought to add/modify items in the PDI. Responses were audio recorded using a digital audio recorder, transcribed, and identified by a research team member.

After the first round of cognitive interviews, researchers reviewed the transcripts and agreed on the items that required modification. After revising the PDI based on results from the first round, three additional participants were interviewed in the second round. After fourth and fifth, minor modifications were made to three items (Table 3). Interviews were stopped after the sixth interview as data saturation point was reached, and no further modifications were recommended [28]. Cognitive interviews revealed that the survey items demonstrated face validity and were unambiguous and easy to understand for children.

| Participant number | Age | Gender | History of dizziness                                  |
|--------------------|-----|--------|---|
| 1                  | 16  | М      | Experienced dizziness more than a year ago            |
| 2                  | 10  | М      | Experienced dizziness 10-12 months prior to interview |
| 3                  | 15  | М      | Currently experiencing dizziness                      |
| 4                  | 10  | М      | Experience dizziness 7-8 months prior to interview    |
| 5                  | 11  | М      | Experienced dizziness 10-12 months prior to interview |
| 6                  | 8   | F      | Experienced dizziness more than a year ago            |

Table 2. Characteristics of children who participated in cognitive interviews.

| Item number | Item details   | Revised item after first round of cognitive interviews   | Revised item after second round of cognitive interviews                               |
|-------------|--|--|---|
| 1           | Can do activities in normally days when feeling dizzy                  | Can still do activities normally in a day when feeling dizzy.  | -   |
| 2           | Can still focus even though feeling dizzy                              | Can still focus on things such as classroom activities even when feeling dizzy.  | Can focus on all classroom activities without feeling dizzy                           |
| 3           | Can stand up and sit down and move around in bed without feeling dizzy | Can get in and out of bed without feeling dizzy.   | -   |
| 4           | Can use technology when feeling dizzy                                  | Can use technology (TV, tablet, smartphone) when feeling dizzy.  | Can use technology (TV, tablet, phone etc.) for as long as like without feeling dizzy |
| 5           | Looking up makes feel more dizzy.                                      | Can look up/down/turn head without getting dizzy.  | -   |
| 6           | Can play when feel dizzy   | Can play with my friends in gym class or<br>an outdoor game of my choice<br>(hopscotch, soccer, baseball, hockey<br>etc.) without feeling dizzy. | -   |
| 7           | While sitting or standing feel like falling because of dizziness.      | Can stand up and sit down from a chair or couch without feeling dizzy  | -   |

| 8  | Can drive (riding a bike, riding a scooter) when feeling dizzy | Can ride a bike/scooter without feeling dizzy        | - |
|----|--|--|---|
| 9  | Feel more dizzy when bend forward                              | Can look up/down/turn my head without getting dizzy. | - |
| 10 | Can able to keep body balanced while standing with eyes closed | Can stand/sit still comfortably                      | - |

Table 3. Item revision of Pediatric Dizziness Inventory (PDI) after two rounds of cognitive interviews.

## Results

Initial draft of the PDI comprised of thirty-three potential items (Appendix 1) Following two rounds of modified Delphi process and CVR calculation, ten items were retained. After the first round of the modified Delphi process, items with CVR < 0.75 but > 0.5 were modified and the items with CVR < 0.5 were removed. After the first round, twelve items were eliminated, and ten items were merged/modified resulting in 21 items underwent a second round of review. After completion of the second round, nine items were eliminated, and two items were merged with the other items of similar construct and PDI was revised to 10 items (Table 3). All ten items demonstrated CVI values equal to or higher than CVR critical (Table 1). The CVI of the items retained in the measure was calculated and was found to be 0.87 that indicated excellent content validity (CVI values >0.7 are considered acceptable) [23,29]. Minor changes to the final items were made following cognitive interviews to improve readability.

# Discussion

Dizziness has significant impact on child's ability to participate in age-appropriate activities and impedes social and community participation [4,7]. Its multifactorial nature and the wide variations in children's contextual and perceptual processes underscores the need for a comprehensive patient-reported assessment linking the symptoms to activities. Studies have reported that children older than 8 years of age can reliably use PROMs [30]. The current study aimed to develop and establish evidence of face and content validity of the PDI utilizing a systematic, evidence-based, and iterative approach. To our knowledge, this is the first PROM designed using robust methodology and incorporating the ICF-CY to evaluate the impact of dizziness on activity limitation and participation restriction in children.

# Face and content validity

Establishing content validity of a PROM is the first critical step and must be performed using rigorous methods prior to establishing other measurement properties [31]. Our study utilized a systematic and scientifically rigorous approach towards development of the PDI. The ICF-CY is a universally accepted theoretical framework and has been used extensively for content mapping of numerous PROM [16,32,33]. COSMIN guidelines were followed while developing and establishing the content validity (Appendix 2) along with a literature reviewof existing PROM assessing dizziness in children [12].

Additionally, every item on the PDI was refined to ensure child-friendly language and comprehensibility using cognitive interview.

## Advantages of the PDI

PDI offers several advantages over existing measures that assess dizziness in children. Of the two self-report measures (PVSQ and DHI-CA), PVSQ primarily focuses on symptom severity specific to vestibular function [13] unlike PDI. On the other hand, the DHI-CA demonstrated questionable validity due to concerns around valid factor structure, item difficulty levels, and construct validity which limits its clinical applicability [34,35].

DHI-PC is a parent reported measure and uses parents or caregivers as proxy to assess activity limitations due to dizziness [14]. It is noteworthy that the proxy measures may have response bias (over or underestimation) due to parent's/caregiver's unique perception, beliefs and attitudes about the child's impairments/activity limitation/participation restriction [36]. Additionally, both DHI-CA and DHI-PC include items that fall under the emotional and psychological domains [14,15]. There can be several other factors contributing to emotional and psychological issues apart from dizziness. Since these factors may not be addressed directly by physical therapy intervention, there is a potential for floor effect.

In terms of scoring an item on a PROM, children find it challenging to quantify subjective response categories like "most of the time", "sometimes", "often" etc., [37] (as seen in DHI-CA and DHI-PC) which may compromise the validity of responses obtained. In contrast, the numeric rating scale (0-10) has been documented to be valid, reliable, and easy to use for children [38]. Additionally, a response category of "don't know" (as seen in PVSQ) may reduce a child's ability to provide a valid response [39]. The "don't know" category may also be excluded as missing data during interpretation and analysis, and may result in misrepresentation of the data [40,41]. In terms of scoring categories, both DHI-PC and DHI-CA are scored using 3-point scale (4=yes, 2=sometimes and 0=No) which may limit quantification (as "sometimes" category may range anywhere between 1%-99%) and progress tracking leading to a potential ceiling effect [42-44].

## Limitations and future directions

PDI is a novel measure for the clinicians to assess activity limitation and participation restriction in children and adolescents. It is important to note that PDI must be tested in different diagnosis and population subsets to further consolidate

generalizability. Additionally, cognitive interviewing was limited to children who spoke English as their primary language and had unequal gender distribution (predominantly males) which may limit generalizability. Hence, cross cultural adaptation is recommended to broaden the application of the PDI. Lastly, future research on examining item-difficulty using robust statistical approaches like item-response theory is recommended to establish factor structure, internal consistency, test-retest reliability, construct and criterion validity and, responsiveness.

## Conclusion

PDI is a novel PROM that may fulfil a critical gap in assessment of activity limitation and participation restriction associated with dizziness in children. PDI will provide clinicians with meaningful information to identify specific functional limitations create individualized therapeutic goals and focused intervention strategies. Finally, to provide family centered care, it is important for the clinician to set goals in collaboration with the child and the family. For this purpose, creating goals that are valued by the child and are considered meaningful is critical to obtain improvements in function. In contrast to PVSQ and DHI-PC, item 7 of the PDI provides an opportunity to children to identify their activity of choice.

#### **Declarations**

Ethics approval and consent to participate: Approval from the Institutional Review Board of the Simmons University was obtained (approval number #IRB 22-59). Written informed consent from the parents and written assent was obtained from children before collecting data.

# **Consent for Publication**

Not applicable

# Availability of Data and Materials

Not Applicable

## **Competing Interests**

The authors report no competing interests or any conflict of interest.

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No funding was obtained for this study.

### **Authors' Contributions**

DT was responsible for the conceptualization, conducting cognitive interviews, development of the measure, manuscript writing and overall supervision of this project. BG, CS, MA and BS significantly contributed to conception, creation and refining of the PDI items, literature review and manuscript writing. MK significantly contributed to manuscript writing and refining of the PDI.

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Appendix 1: Initial draft of the Pediatric dizziness Index (PDI) with ICF-CY codes.

| Serial | ICF-CY   | Item details  |
|--------|----------|---|
| number | category |   |
| 1      | b1141    | I know where I am.  |
| 2      | b1142    | I know who and what is around me.   |
| 3      | b1144    | I can move around without bumping into things.  |
| 4      | b1252    | I can do activities I normally do in a day when I am dizzy.   |
| 5      | b134     | I can fall asleep even though I am dizzy.   |
| 6      | b1400    | I can still focus even though I am dizzy.   |
| 7      | b1440    | I forget things quickly.  |
| 8      | b1470    | I feel that I am slow or behind my peers while completing tasks.  |
| 9      | b2100    | I can tell how far things are from me.  |
| 10     | b176     | I have trouble planning how I would do a task with a lot of movement (eg. eating, brushing teeth, getting dressed). |
| 11     | b2100    | I can easily look at things when I am dizzy.  |
| 12     | b2350    | I am able to figure out how my arms and legs are positioned even without looking.                                   |
| 13     | b2352    | I am able to keep my body balanced when I am standing with my eyes closed.  |
| 14     | b2352    | I am able to figure out how and where my body is moving with my eyes closed and in the dark.                        |
| 15     | b2402    | When I am sitting or standing I feel like I am falling because I am dizzy.  |
| 16     | b5350    | I feel sick / nauseous when I am dizzy.   |
| 17     | b28010   | I feel pain in my head and neck when I am dizzy.  |
| 18     | d210     | I can understand how to complete tasks that my peers can do when I am dizzy.  |
| 19     | b770     | I can walk / move my body like normal when I am dizzy.  |
| 20     | b1252    | I can stand up and sit down and move around in bed without feeling dizzy.   |
| 21     | d475     | I can drive (riding a bike, riding a scooter) when I am dizzy.  |
| 22     | d880     | I can play when I am dizzy.   |
| 23     | d910     | I can interact with my community when I am dizzy.   |
| 24     | e115     | I can use technology when I am dizzy.   |
| 25     | e120     | I can use assistive devices to move around when I am dizzy.   |
| 26     | b2401    | Looking up makes me feel more dizzy.  |
| 27     | b152     | I am frustrated because I am dizzy.   |
| 28     | b152     | I feel sad because I am dizzy.  |
| 29     | b2401    | I am more dizzy when I bend forward.  |
| 30     | b152     | I worry about being dizzy.  |
| 31     | b2351    | I need to hold onto things to keep by balance.  |
| 32     | b152     | I can be on my own when I am dizzy.   |
| 33     | d450     | I can walk up and down the stairs when I am dizzy.  |

Appendix 2: COSMIN risk of bias checklist report for face and content validity of Pediatric Dizziness Index (PDI).

| Category   | Method utilized  |
|--|--|
| General design requirements  |  |
| Is a clear description provided of the construct to be measured?   | Introduction section includes the incidence and functional impact of dizziness in children.  |
| Is the origin of the construct clear: was a theory, conceptual framework or disease model used or clear rationale provided to define the construct to be measured? | Introduction section highlights the need to develop PDI.   |
| Is a clear description provided of the target population for which the PROM was developed?   | PDI aimed to examine activity limitation and participation restriction in children due to dizziness.   |
| Is a clear description provided of the context of use  | PDI aimed to examine activity limitation and participation restriction in children due to dizziness.   |
| Was the PROM development study performed in a sample representing the target population for which the PROM was developed?  | Yes. Cognitive interviews were completed for children ranging between 8-18 years.  |
| Was an appropriate qualitative data collection method used to identify relevant items for a new PROM?  | Comprehensive literature search along with the review of the ICF-CY model was performed to identify relevant items for PDI.  |
| Were skilled group moderators/<br>interviewers used?   | Research team members with expertise in cognitive interviews, conducted the interviews.  |
| Were the group meetings or interviews based on an appropriate topic or interview guide?  | A semi-structured interview guide was utilized to conduct the cognitive interviews.  |
| Were the group meetings or interviews recorded and transcribed verbatim?   | Interviews were recorded using digital audio recorder, transcribed and deidentified.   |
| Was an appropriate approach used to analyze the data?  | Data from the interviews was digitally recorded and transcribed. Standardized measurement i.e., Content validity ratio and content validity index were used to establish content validity. |
| Was at least part of the data coded independently?   | Two research team members independently coded the data.  |
| Was data collection continued until saturation was reached?  | Data saturation point was reached after two rounds of cognitive interviews.  |
| Cognitive interview  |  |
| Was a cognitive interview study or other pilot test conducted?   | Two rounds of cognitive interviews were completed with children between 8-18 years of age.   |
| Was the cognitive interview study or other pilot test performed in a sample representing the target population?  | Two rounds of cognitive interviews were completed with children between 8-18 years of age.   |
| Were patients asked about the comprehensibility of the PROM?   | Children were asked questions related to comprehensiveness and comprehensibility of the measure.   |
| Were all items tested in their final form?   | A second round of cognitive interview was conducted with the final version of the measure. No areas of further modifications were identified.  |

| Was an appropriate qualitative method used to assess the comprehensibility of the PROM instructions, items, response   | Yes. A semi-structured cognitive interview method was used to assess comprehensibility of the PROM instructions, items and response options.   |
|--|--|
| options, and recall period?  Was each item tested in an appropriate  | Yes. Each item was tested in 6 children between the age of 8-18  |
| number of patients?  Were skilled interviewers used?   | Research team members who were experienced in conducting cognitive interviews, conducted the interviews.   |
| Were the interviews based on an appropriate interview guide?   | Yes. A semi-structured interview guide was used to conduct the cognitive interviews.   |
| Were the interviews recorded and transcribed verbatim?   | Yes. Interviews were recorded using digital audio recorder, transcribed and deidentified.  |
| Was an appropriate approach used to analyze the data?  | Each item was scrutinized and revised based on the results from the cognitive interviews.  |
| Were at least two researchers involved in the analysis?  | Yes. Two researchers reviewed the data extracted from the cognitive interviews.  |
| Were problems regarding the comprehensibility of the PROM instructions, items, response options, and recall period appropriately addressed by adapting the PROM? | Items were scrutinized and revised to improve comprehensibility and response options based on the results from the cognitive interviews.   |
| Were patients asked about the comprehensiveness of the PROM?   | Children were asked questions related to comprehensiveness and comprehensibility of the PDI.   |
| Was the final set of items tested?   | A second round of cognitive interview was conducted with the final version of the measure. No areas of further modifications were identified.  |
| Asking patients about relevance, comprehe  | nsiveness, and analyses methods  |
| Was an appropriate method used to ask patients whether each item is relevant for their experience with the condition?  | During cognitive interviews, children were asked if they felt whether each item is important to them and is relevant. Also, children were provided an opportunity to add items which they felt were important and were not already in the measure. |
| Was each item tested in an appropriate number of patients?   | Yes. Each item was tested in 6 children between the age of 8-18 years.   |
| Were skilled interviewers used?  | Research team members, who were experienced in conducting cognitive interviews, conducted the interviews.  |
| Were the group meetings or interviews based on an appropriate topic or interview guide?  | Yes. A semi-structured interview guide was used to conduct the cognitive interviews.   |
| Were the group meetings or interviews recorded and transcribed verbatim?   | Yes. Interviews were recorded using digital audio recorder, transcribed and deidentified.  |
| Was an appropriate approach used to analyze the data?  | Each item was scrutinized and revised based on the results from the cognitive interviews.  |
| Were at least two researchers involved in the analysis?  | Yes. Two researchers reviewed the data extracted from the cognitive interviews.  |
| Asking professionals about relevance, comp   | rehensiveness and analysis   |
| Was an appropriate method used to ask professionals whether each item is relevant for the construct of interest?   | Yes. A modified-Delphi process was utilized to ask professionals about the relevance of items.   |
| Were professionals from all relevant   | Physical therapists and occupational therapists were   |

| disciplines included?   | included as part of the expert panel.   |
|---|---|
| Was each item tested in an appropriate number of professionals? | Eight professionals were included in the modified Delphi process.   |
| Was an appropriate approach used to analyse the data?           | Cutoff scores based on Lawshe's Content Validity Ratio was used to retain items and Content validity index were used to examine overall content validity. |
| Were at least two researchers involved in the analysis?         | Two research team members were involved in the analysis.  |

# STROBE Statement—Checklist of items that should be included in reports of cross-sectional studies.

| Title and abstract           | Item<br>No | Recommendation  | Page No           |
|------------------------------|------------|---|-------------------|
|                              | 1          | (a) Indicate the study's design with a commonly used term in the title or the abstract  | 1                 |
|                              |            | (b) Provide in the abstract an informative and balanced summary of what was done and what was found   | 01-02             |
| Introduction                 |            |   |                   |
| Background/rationale         | 2          | Explain the scientific background and rationale for the investigation being reported  | 03-04             |
| Objectives                   | 3          | State specific objectives, including any prespecified hypotheses  | 4                 |
| Methods                      | 1          |   |                   |
| Study design                 | 4          | Present key elements of study design early in the paper   | 4                 |
| Setting                      | 5          | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection   | 05-08             |
| Participants                 | 6          | (a) Give the eligibility criteria, and the sources and methods of selection of participants   | 06-08             |
| Variables                    | 7          | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable  | Not<br>Applicable |
| Data sources/<br>measurement | 8*         | For each variable of interest, give sources of data and details of methods of assessment (measurement).  Describe comparability of assessment methods if there is more than one group | 06-08             |
| Bias                         | 9          | Describe any efforts to address potential sources of bias   | 8                 |
| Study size                   | 10         | Explain how the study size was arrived at   | 06-08             |
| Quantitative variables       | 11         | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why  | 7                 |
| Statistical methods          | 12         | (a) Describe all statistical methods, including those used to control for confounding   | 7                 |
|                              |            | (b) Describe any methods used to examine subgroups and interactions   | Not<br>Applicable |

|                   |     | (c) Explain how missing data were addressed  | Not<br>Applicable |
|-------------------|-----|--|-------------------|
|                   |     | (d) If applicable, describe analytical methods taking account of sampling strategy   | Not Applicable    |
|                   |     | (e) Describe any sensitivity analyses  | Not               |
|                   |     |  | Applicable        |
| Results           | 1   |  | T                 |
| Participants      | 13* | (a) Report numbers of individuals at each stage of study —eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed           | 9                 |
|                   |     | (b) Give reasons for non-participation at each stage   | Not<br>Applicable |
|                   |     | (c) Consider use of a flow diagram   | Not<br>Applicable |
| Descriptive data  | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders   | 18                |
|                   |     | (b) Indicate number of participants with missing data for each variable of interest  | Not<br>Applicable |
| Outcome data      | 15* | Report numbers of outcome events or summary measures   | Not<br>Applicable |
| Main results      | 16  | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | Not<br>Applicable |
|                   |     | (b) Report category boundaries when continuous variables were categorized  | Not<br>Applicable |
|                   |     | (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period   | Not<br>Applicable |
| Other analyses    | 17  | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses   | Not<br>Applicable |
| Discussion        |     | · · ·  | 11                |
| Key results       | 18  | Summarise key results with reference to study objectives   | 10-12             |
| Limitations       | 19  | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias   | 12                |
| Interpretation    | 20  | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence                                   | 10-12             |
| Generalisability  | 21  | Discuss the generalisability (external validity) of the study results  | 13                |
| Other information | 1   | •  |                   |
| Funding           | 22  | Give the source of funding and the role of the   | Not               |

|  |  | funders for the present study and, if applicable, for the original study on which the present article is based | Applicable |
|--|--|--|------------|
|--|--|--|------------|

**Note:** An explanation and elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org. \*: Give information separately for exposed and unexposed groups.