

# Inter- and intra-interviewer reliability of Italian version of Pediatric Evaluation of Disability Inventory (I-PEDI)

M. Murgia<sup>1</sup>, A. Bernetti,<sup>2</sup> M. Delicata<sup>2</sup>, C. Massetti<sup>2</sup>, E. M. Achilli<sup>2</sup>,  
M. Mangone,<sup>2</sup> F. Ioppolo<sup>1</sup>, L. Di Sante<sup>1</sup>, V. Santilli<sup>1,2</sup>, G. Galeoto<sup>1</sup>,  
F. Agostini<sup>2</sup>, T. Venditto<sup>2</sup>

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*Parole chiave: Pediatric Evaluation Disability Inventory, affidabilità, paralisi cerebrale infantile, traduzione italiana e adattamento cross-culturale*

## Abstract

**Background.** Childhood disabilities determine a range of immediate and long-term economic costs that have important implications for the well-being of the child, the family and the society. The Pediatric Evaluation of Disability Inventory (PEDI) measures capability and performance in children aged between 6 months and 7.5 years. It contains three scales: Functional Skills Scales (FSS), Caregiver Assistance Scale (CAS) and Modifications Scale (MS). The present study evaluated the measurement properties of the Italian version of the PEDI (PEDI-I) in patients with spastic cerebral palsy (CP).

**Study design.** Reliability study.

**Methods.** The original PEDI was translated – including a cross-cultural adaptation - into Italian. Internal consistency and test-retest reliability were evaluated.

**Results.** Fifty-eight children with CP were recruited. According to inter-interviewer reproducibility, the FSS domain revealed intraclass correlation coefficient (ICC) values ranging between 0.94 and 1.00. CAS domain revealed ICC values ranging between 0.94 and 1.00. The SEM values ranged between 3.25 (SDD=8.98) for SF and 5.24 for SC (SDD=14.5).

According to intra-interviewer reproducibility, the FSS domain revealed ICC values ranging between 0.99 and 1.00. CAS domain revealed ICC values ranging between 0.92 and 0.99. The SEM values ranged between 3.44 (SDD=9.5) for SF and 3.75 for SC (SDD=10.36). The inter-interviewer and intra-interviewer reproducibility results showed very high ICC values for both FFS and CAS domains.

Cronbach's  $\alpha$  ranged between 0.94 and 0.99, indicating excellent internal consistency within each domain of the PEDI-I.

**Conclusions.** The inter-interviewer and intra-interviewer reproducibility results of PEDI-I showed very high ICC values for FFS and CAS domains. Therefore, we recommend its application to evaluate the effect of treatment in children with CP.

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<sup>1</sup> Department of Physical Medicine and Rehabilitation, Azienda Policlinico Umberto I, Rome, Italy

<sup>2</sup> Department of Physical Medicine and Rehabilitation. Board of Physical Medicine and Rehabilitation, Department of Anatomy, Histology, Forensic Medicine and Orthopedics, Sapienza University of Rome, Italy

## Introduction

Childhood disabilities determine a range of immediate and long-term economic costs that have important implications for the well-being of the child, the family, and the society (1). Cerebral palsy (CP) refers to a group of permanent motor disorders attributed to a non-progressive lesion that occurs in the immature brain. CP affects between 1,5 and 2,5 per 1,000 live births and is thought to be the most common cause of severe physical disability in childhood (2, 3).

CP can be classified by neurological subtype as well as by several functional classification systems (4) resulting in reduced activation of the central nervous system during the execution of movements (5, 6). Children with the spastic motor type (7) have postural problems that determine muscle weakness and impaired muscle coordination with difficulties in performing basic functional actions, such as sitting, standing and walking (8-11).

Therefore, multidisciplinary and multifaceted therapies can improve the quality of life of these people, bettering the ability to perform normal daily activities as primary therapeutic goal (12).

The focus of the assessment and treatment of children with CP has changed in response to the introduction of the International Classification of Functioning, Disability and Health (ICF). The ICF comprises four components: 1. body structures; 2. body functions; 3. activities and participation; and 4. environmental factors. The conceptualisation of disability in the ICF highlights its biopsychosocial nature and emphasises the need to support individuals to achieve optimal capacity and participation in all aspects of life.

Several outcome measures have been developed to assess functional performance in daily activities in children, such as the Gross Motor Function Measure (13), Functional Mobility Scale (14), Functional

Independence Measure for Children (WeeFIM) (15) and the Pediatric Evaluation of Disability Inventory (PEDI) (16).

The PEDI was developed at the New England Medical Centre Hospitals in Boston, USA, by Haley et al. (17). It was designed primarily to assess the capability, that is, what a person potentially may do, and the performance, that is, what a person actually does in his environment, in children aged between 6 months and 7.5 years (17). However, it may be used in older children whose functional performance falls below that expected for 7.5 year-old normally developing children.

Moreover, Schulze et al. (18) indicated the Functional Skill Scale and the Caregiver Assistance Scale of the German PEDI as reliable to evaluate activities of daily living in children with and without physical disability.

James et al. (19) performed a systematic review and evaluated the psychometric properties and clinical utility of measures of activities of daily living (ADL) for children with CP aged 5 to 18 years. The Authors observed that the PEDI is the best measure of ADL capability for elementary school-aged children according to reliability and validity results. Reliability concerns the extent to which an experiment, test or measuring procedure yields the same results in repeated trials. Validity refers to the degree to which evidence and theory support the interpretations of test scores entailed by the proposed uses of tests, describing how well one can legitimately trust the results of a test as interpreted for a specific purpose (20).

The identification and validation of specific outcome measures for children with CP appear crucial for the study of functional performance in daily activities.

The aim of the present study was to determine the measurement properties of the Italian version of PEDI (PEDI-I) in children with spastic CP.

## Methods

Guidelines developed by Guillemin et al. (21) and Beaton et al. (22) were used for the cross-cultural adaptation and validation of the Italian version of the PEDI.

### *Pediatric Evaluation of Disability Inventory*

PEDI contains three scales that may be used together or separately: i) the Functional Skills Scale (FSS) that identifies clinical patterns of deficiencies in functional skill attainment; ii) the Caregiver Assistance Scale (CAS), that is an indirect measure of capability and evaluates the actual performance by the extent of help a parent provides in daily functioning; and iii) the Modifications Scale (MS), which is a frequency count of the type and extent of environmental modifications that support functional performance. Each scale includes three domains: Self Care (SC), Mobility (M) and Social Function (SF).

PEDI scores reveal two types of information: normative standard scores (NSS) and scaled scores. NSS can be obtained for children from 6 months to 7.5 years. These are based on what children would typically be doing at a particular chronological age, providing an indication of the child's ability in relation to age expectations. NSS have a mean score of 50 for each age-band and a standard deviation of 10. The range 30-70, representing two standard deviations above and below the mean, is the area within which 95% of the children in each age-band are expected to fall. Scores outside the 10-90 range provide little normative meaning.

Secondly, scaled scores provide an indication of the child's performance along the continuum, from relatively easy to relatively difficult items in a particular domain, such as self-care. These do not take into account the age of the child. The scale is from 0 to 100, with higher scores

representing increasing levels of functional performance. These scores can be used for children whose chronological age is above 7.5 years, but whose capabilities fall below that of a 7.5-year-old subject.

In each domain of the FSS, the child is scored as either capable of doing or unable to do each of the items, which are listed in order of mastery. Capability indicates what the child can do without help, even if the child does not regularly perform these skills. CAS is measured on a 6-point rating scale from total assistance to complete independence.

### *Translation and cultural adaptation of the Pediatric Evaluation of Disability Inventory*

Translation and cross-cultural adaptation of the PEDI was performed according to international guidelines (22, 23). The original English version of the PEDI was independently translated into Italian by two bilingual translators, one of whom was a native English speaker and the second one was a physician whose native language was Italian. The two translations were analysed by a Healthcare Committee (four psychiatrists, one pediatrician, one physical therapist and one occupational therapist), which first ensured that the translations took Italian cultural characteristics into consideration. Then, the Committee selected a consensus version of these translations (version A) that was translated back into English by one other professional translator, whose native language was English and who had no medical background, being therefore unaware of the concepts being investigated.

At the end of this phase, a new consensus version was obtained and compared with the original PEDI to determine equivalence (version B). Version B was semantically and grammatically equivalent to the original PEDI. Therefore, a meeting was held with the Healthcare Committee that confirmed the equivalence of the original PEDI and the Italian version (PEDI-I).

### *Subjects and Procedures*

The PEDI-I was administered by a single physician (physician-interviewer-1) to parent/caregiver of normally developing children. Subjects were recruited from a nursery school and a pre-primary school of Rome from September to October 2014.

From January to June 2015 all children with CP who referred to our Physical Medicine and Rehabilitation outpatient service were screened for eligibility. Children were included if they were aged between 6 months and 7.5 years, or older than 7.5 years and below 12 years with functional abilities below those expected in 7.5 year-old children without disabilities.

Then, the PEDI-I was administered independently by two physicians (physician-interviewer-1 and physician-interviewer-2), interviewing the parent/caregiver (evaluation #1) to estimate inter-interviewer reproducibility. Two days later, the assessment was performed again (evaluation #2) by physician-interviewer-1 to examine intra-viewer reproducibility. Patients did not receive any treatment during these two days of interval to minimise the risk of short-term clinical change.

The Modification Scales were excluded for analysing the reliability of PEDI-I because the Modification scales mean a frequency count of type (17).

All parents agreed to participate in the study and signed an informed consent form in accordance with the Helsinki Declaration.

### *Sample size*

Power calculation was based on ICC value assuming a two tailed  $\alpha$  value of 0.05 (sensitivity 95%) and a  $\beta$  value of 0.20 (study power: 80%), a null hypothesis  $\rho_0$  of 0.3 and an alternative hypothesis  $\rho_1$  of 0.4. We determined that at least 58 patients were required (Power Analysis and Sample Size System software).

### *Data analysis*

After using a Kolmogorov Smirnov test to verify that the variables were normally distributed, we applied parametric tests. To ascertain whether the subjects' education levels affected the LEFS scores, we used a one-way ANOVA with education levels (elementary, secondary and university) as the between-subject factor, followed by a Tukey post hoc comparison when appropriate.

On the basis of the two-way random effects ANOVA, the intra-class correlation coefficient (ICCs), 95% confidence intervals (CIs), was calculated to assess reproducibility. The ICC (2,1) and ICC (2, k) were used to determine inter-interviewer and intra-interviewer reproducibility, respectively (15). The ICC, which is the most suitable statistical test for the assessment of reliability, ranges from 0 (no agreement) to 1 (perfect agreement) and was interpreted as follows: 0.00-0.25 = little, if any, correlation; 0.49 = low correlation; 0.50-0.69 = moderate correlation; 0.70-0.89 = high correlation; and 0.90-1 = very high correlation (24-26).

The agreement is the ability to achieve the same value with repeated measurements. It was calculated according to the standard error of measurement ( $SEM = SD \sqrt{1 - ICC}$ ) and the smallest detectable difference ( $SDD = 1.96 * \sqrt{2} * SEM$ ) that evaluates the minimal change falling outside the measurement error in the score of an instrument used to make a measurement.

Internal consistency of the PEDI-I was assessed by Cronbach's Alpha and 95% CIs, using data from the evaluation #1 of physician-interviewer-1. Values range from "0" (no internal consistency) to "1" (perfect internal consistency). It is considered acceptable when Cronbach's Alpha exceeds 0.7, although it has been said that values should not be above 0.9, as this suggests item redundancy (27).

Statistical tests were conducted using SPSS Release 18 for Windows.

## Results

Sixty normally developing children (34 males and 26 females) ranging in age between 14 months and 7.5 years (mean 51.2 months, SD 18 months) were included in the study.

Fifty-eight children with CP were eligible to participate in the study. The demographic information and subtype of CP are shown in Table 1.

The raw FSS and CAS scores of normally developing children and children with CP are shown in Table 2. We found significant differences between two groups according to each domain of PEDI-I ( $p < 0.001$ ).

No differences were found between the PEDI-I raw scores of parent/caregiver with different education levels ( $p = 0.824$ ).

### Reliability

The inter-interviewer and intra-interviewer reproducibility results showed very high ICC values for both FFS and CAS domains (Tables 3 and 4).

According to inter-interviewer reproducibility, FSS domain revealed ICC values ranging between i) 0.94 and 0.98 for SC; ii) 0.97 and 0.99 for M; iii) 0.98 and 1.00 for SF. The SEM values ranged between 3.45 (SDD = 9.5) for SF and 6.45 for SC (SDD = 17.82). CAS domain revealed ICC values

Table 1 - Characteristics of children with cerebral palsy (N=58)

Age, months, mean (SD)	57 (28.6)
Candidates	60 (34.2) males 34, females 26
Eligibles	58 (29.8)
Gender, male/female, n	33/25
Type of cerebral palsy	
Spastic:	
Quadriplegia	20
Triplegia	18
Diplegia	12
Hemiplegia	8

SD= standard deviation, N= number.

ranging between i) 0.94 and 1.00 for SC; ii) 0.96 and 1.00 for M; and iii) 0.95 and 1.00 for SF. The SEM values ranged between 3.25 (SDD = 8.98) for SF and 5.24 for SC (SDD = 14.5).

According to intra-interviewer reproducibility, FSS domain revealed ICC values ranging between i) 0.99 and 1.00 for SC; ii) 0.98 and 0.99 for M; and iii) 0.99 and 1.00 for SF. The SEM values ranged between 3.44 (SDD=9.5) for SF and 3.75 for SC (SDD=10.36). CAS domain revealed ICC values ranging between i) 0.92 and 0.99 for SC; ii) 0.94 and 1.00 for M; and iii) 0.90 and 1.00 for SF. The SEM values ranged between 3.70 (SDD=10.23) for SF and 5.27 for SC (SDD=14.57).

Table 2 - Differences between cerebral palsy subjects and normally developing children according to mean values of raw scores of Functional Skills and Caregiver Assistance

	Normally developing children	Cerebral Palsy children	p-value
FunctionalSkills			
Self-care	60.02 ± 11.62	34.47 ± 18.68	<0.001
Mobility	54.26 ± 4.35	30 ± 18.19	<0.001
Social Function	56 ± 6.33	33.74 ± 17.17	<0.001
Caregiver Assistance			
Self-care	30.63 ± 8.9	13.88 ± 13.17	<0.001
Mobility	31.5 ± 4.06	14.85 ± 11.61	<0.001
Social Function	22.48 ± 2.46	11.94 ± 8.27	<0.001

SD = Standard Deviation

Table 3 - Inter-operator reproducibility

	ICC	SEM	SDD	Internal consistency (Cronbach's)
<b>Functional Skills</b>				
Self-care	0.97 (CI: 0.94-0.98)	6.45	17.82	0.96
Mobility	0.98 (CI: 0.97-0.99)	5.10	11.39	0.99
Social Function	0.99 (CI: 0.98-1.00)	3.45	9.5	0.99
<b>Caregiver Assistance</b>				
Self-care	0.96 (0.94-1.00)	5.24	14.5	0.94
Mobility	0.98 (0.96-1.00)	3.25	8.98	0.98
Social Function	0.97 (0.95-1.00)	2.81	7.78	0.99

ICC = intraclass correlation coefficient; SEM=standard error of measurement; SDD= smallest detectable difference

Table 4 - Intra-operator reproducibility

	ICC	SEM	SDD	Internal consistency (Cronbach's)
<b>Functional Skills</b>				
Self-care	0.99 (CI: 0.99-1.00)	3.75	10.36	0.99
Mobility	0.99 (CI: 0.98-0.99)	3.62	10	0.98
Social Function	0.99 (CI: 0.99-1.00)	3.44	9.5	0.99
<b>Caregiver Assistance</b>				
Self-care	0.96 (0.92-0.99)	5.27	14.57	0.94
Mobility	0.97 (0.94-1.00)	3.94	10.91	0.95
Social Function	0.95 (0.90-1.00)	3.70	10.23	0.97

ICC = intraclass correlation coefficient; SEM=standard error of measurement; SDD= smallest detectable difference

Cronbach's  $\alpha$  ranged between 0.94 and 0.99, indicating excellent internal consistency within each domain of the PEDI-I.

## Discussion

The aims of the present study were to cross-culturally adapt the PEDI questionnaire and determine the measurement properties of the Italian version produced in patients with spastic CP.

No difficulties were encountered in translating the questionnaire, and the back translation corresponded very well to the original version.

According to Cacchio et al. (28), we used the interview rather than self-reporting

for the PEDI questionnaire in this study because Italian patients are rarely required to complete questionnaires in clinical practice, although they are becoming accustomed to being interviewed by a physician or a physiotherapist.

The Cronbach alpha coefficient for PEDI-I indicated an excellent internal consistency. As for reliability, measurements provided by the PEDI-I showed very high correlation values for both inter and intra-interviewer reproducibility, according to FSS and CAS domains.

Soyeon Park et al. (29) examined the reliability of Korean-PEDI (PEDI-K) in 104 (62 males and 42 females) school-aged children with CP by calculating the internal consistency of Cronbach's  $\alpha$ . The Authors

found good internal consistency, with values above 0.90 for all domains of the PEDI-K. The Cronbach's  $\alpha$  was 0.98 for each FSS domain and 0.97 for each CAS domain (self-care, mobility and social function).

Kuan-Lin Chen et al. (30) examined the reliability and validity of a Chinese version of the PEDI (PEDI-C) in children with CP, showing excellent internal consistency and test-retest reliability. Cronbach's  $\alpha$  ranged between 0.90 and 0.99. The PEDI-C was administered independently by two physicians twice, 2 weeks apart, interviewing the parent/caregiver, to estimate inter-interviewer reproducibility. All the ICC<sub>2,1</sub> values ranged from 0.98 to 0.99.

Wassenberg-Severijnen et al. (31) evaluated the reliability of the Dutch version of the PEDI (PEDI-D). In testing the PEDI-D, the Authors interviewed parents of children with disabilities (n=53) and without any known disabilities (n=63). Cronbach's alpha was computed on the sample of non-disabled children, showing  $\alpha$  values of 0.89, 0.74 and 0.87 for self-care, mobility and social function domains, respectively. Inter-interviewer (Researcher-1/Researcher-2), test-retest (First interview/Second interview) and inter-respondent (Mother/Father) reliability were established using scores from both disabled and non-disabled children. They found ICC values ranging between 0.91 and 0.99 for FSS and CAS domains.

There were some limitations in the present study. We did not compare the PEDI-I with a general health questionnaire and we included only subjects with CP.

Reliability is a generic term used to indicate both reproducibility (test and retest reliability) of scores and homogeneity (internal consistency) of a scale. The ICC is the method of reliability analysis recommended that does not produce the problems relating to systematic bias experienced by other statistical tests (32). Based on the results of our study, we found inter-interviewer and intra-interviewer reproducibility values that

appear similar to the other cross-cultural adaptation studies of the original version of the PEDI. However, the PEDI-K reliability was only evaluated according to Cronbach and PEDI-C reliability established only inter-interviewer reproducibility.

The modern interpretation of reproducibility studies is the determination of cut-off values based on which clinically relevant change or smallest real difference would be determined. Indeed, unlike the ICC, which is a relative measure of reliability, the SEM provides an absolute index of reliability. In our study, we found low SEM values that could be attributed to a satisfactory test design and could be useful for monitoring change over time. Indeed, a greater SEM corresponds to lower reliability and a greater variance in observed scores.

## Conclusions

The PEDI-I is a reliable instrument that may be used to evaluate functional performance in self-care, mobility and social function in Italian children with CP. Moreover, it can be used in further research to establish validity.

For editorial reasons, the appendix was not included in the text. To get it, contact the corresponding author.

## Riassunto

### *Affidabilità inter e intra-esaminatore della versione italiana della Pediatric Evaluation of Disability Inventory (PEDI-I)*

**Introduzione.** Le disabilità nei bambini comportano elevati costi socio-sanitari nel lungo periodo. La Pediatric Evaluation of Disability Inventory (PEDI) è uno strumento di valutazione clinica globale utilizzato per valutare e misurare le capacità funzionali e le performances nei bambini di età compresa tra i 6 mesi e i 7,5 anni. Tale scala si compone di tre domini che valutano il livello funzionale, l'assistenza fisica dei caregiver e le modifica-

zioni adattative. Il presente studio ha valutato le proprietà psicometriche della versione italiana della PEDI (PEDI-I) nei pazienti con paralisi cerebrale infantile (PCI).

**Disegno dello studio.** Studio di affidabilità.

**Metodi.** La versione originale della PEDI è stata tradotta in lingua italiana. Sono stati valutati la consistenza interna e l'affidabilità inter e intra-intervistatore.

**Risultati.** Sono stati reclutati 58 bambini con PCI. In accordo con i risultati di riproducibilità inter-intervistatore, il livello funzionale ha mostrato coefficienti di correlazione intraclasse (ICCs) che variavano da 0,94 a 1, l'assistenza fisica ha mostrato coefficienti di correlazione intraclasse (ICC) che variavano da 0,94 a 1. I valori dell'errore medio standard (SEM) variavano tra 3,2 (SDD –la più piccola differenza significativa- 8,98) e 5,24 (SDD=14,5).

In accordo con la riproducibilità intra-intervistatore, il livello funzionale ha mostrato ICCs che variavano da 0,99 a 1, l'assistenza fisica ha mostrato coefficienti di correlazione intraclasse (ICC) che variavano da 0,92 a 0,99.

Il Cronbach  $\alpha$  variava tra 0,94-0,99, mostrando valori eccellenti di consistenza interna all'interno dei singoli domini della PEDI-I.

**Conclusioni.** La versione italiana della scala PEDI (PEDI-I) ha mostrato elevati valori di riproducibilità inter e intra-intervistatore. Sugeriamo, quindi, l'utilizzo di tale scala nella valutazione dell'effetto del trattamento nei bambini con PCI.

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Corresponding author: Teresa Venditto, Department of Physical Medicine and Rehabilitation. Board of Physical Medicine and Rehabilitation, Department of Anatomy, Histology, Forensic Medicine and Orthopedics, Sapienza University of Rome, Piazzale Aldo Moro 5, 00185 Rome, Italy  
e-mail: [teresa.venditto@hotmail.it](mailto:teresa.venditto@hotmail.it)