Bol Med Hosp Infant Mex 2013;70(3):194-207

RESEARCH ARTICLE

Validation of an instrument for early detection of developmental problems in children under 5 years of age in Mexico

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ABSTRACT

Background. The "Evaluación del Desarrollo Infantil" (Infant Development Evaluation, IDE) test was developed as a screening tool for the developmental evaluation of Mexican children <5 years old. The objective of this study was to evaluate the psychometric properties of the IDE as a screening tool for children with developmental problems.

Methods. We carried out a cross-sectional study including patients from urban and rural areas in three locations: Mexico City, Yucatan and Chihuahua. The disease spectrum was defined according to biological risk, environmental risk or without risk for developmental problems. Patients with obvious neurological disabilities or genetic syndromes were excluded. The gold standards used were the Battelle Developmental Inventory 2 (BDI-2) (in Spanish) and Bayley-III. Each participant had two complete applications of the IDE test (questionned and observed) and the gold standard (Bayley-III only in Mexico City). Developmental delay was defined as a total development quotient ≤ 90.

Results. The study included 438 children <5 years old. Distribution according to location includes Mexico City (n =152, 34.7%), Yucatan (n =151, 34.5%), and Chihuahua (n =135, 30.8%); female gender (n =190, 43.4%). Classification by risk includes biological (n =197, 45%), environmental (n =137, 31.3%), and without risk (n =104, 23.7%). With the BDI-2 as the gold standard, the modified version of the IDE (questionned + observed) has a sensitivity of 0.81 (95% CI: 0.75-0.86), specificity 0.61 (95% CI: 0.54-0.67), and concordance 0.70 (95% CI: 0.66-0.74). The partial correlation between IDE and Bayley-III areas (n =87) was adjusted by test group: fine motor 0.468, gross motor 0.441, language 0.508, social 0.336 and adaptive 0.355 ($p \leq 0.001$).

Conclusions. The modified version of the IDE has similar properties as the various developmental screening tools available in the U.S. or Latin America and may be a good screening tool in Spanish.

Key words: validation, screening tool, child development evaluation.

INTRODUCTION

Screening tests designed to identify developmental problems must meet certain requirements that allow application to specific populations. The expected ratios of true and false positives and negatives should be determined so that the cost/benefit resulting from the detection and diagnosis of diseases they aim to identify justify the need for their application. Screening instruments designed to identify developmental problems in

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Received for publication: 1-24-13
Accepted for publication: 2-26-13

different populations require that they be validated before implementation.

Description of the usefulness of screening and diagnostic tests for any disease (sensitivity, specificity, positive and negative predictive value) must be preceded by a validation process. To validate the test infers to describe the extent that the study test results coincide with the diagnostic evaluations of the disease that the tool attempts to detect. The measure of the probability that a child who has a true developmental disorder is classified as suspicious by the screening test (sensitivity) and a child without any disorders is classified as normal by the test (specificity). Some examples of the developmental tests that have been validated are *Denver* (DDST and DDST II),[1,2] *Ages and Stages Questionnaries* (ASQ)[3,4] and *Child Development Inventory* (CDI).[5] In Chile, in 2009, the ASQ was validated using as standard reference the *Bayley Scale of Infant Development III* (Bayley-III). A correlation of 0.52 was found between the two tests with an ASQ sensitivity of 58.8% and specificity of 87.2%.[6]

Infantile development evaluation test (IDE)

The IDE is a screening test aimed at children 0–5 years old. This test measures, at pre-defined ages, different aspects of development (Table 1). It evaluates the areas of motor development, language, social, adaptive and cognitive, grouping them into four groups: gross motor, fine motor, language and social development. Additionally, it provides warnings and signs of alarm. It also uses the traffic light system: red for a probable developmental delay, yellow for a lag in development and green for normal, considering the presence of risk factors for development. Construct for validity and content was developed by Dr. Lourdes Schnaas-Arrieta. The main objective of the study was to perform a concurrent validation of the IDE against the Battelle Developmental Inventory, 2nd ed. (BDI-2), first to define based on the data obtained, the sensitivity, specificity and predictive values and second, to define the correlation coefficient between the areas of development of the Bayley III diagnostic test and the areas of development evaluated in the screening test (IDE).

SUBJECTS AND METHODS

We performed a cross-sectional, observational study in three entities of Mexico: Federal District (DF), Chihuahua and Yucatan, using as a standard reference the BDI-2.[7] In Mexico City, participants <42 months of age were also given the Bayley III diagnostic test.[8]

Included in the study were subjects from 1 month to 5 years of age, classified according to the type of risk. The population with biological risk factors were considered: children requiring care in intensive care units with a diagnosis of low birth weight, prematurity or respiratory distress; population with environmental risk factors: children in poverty, maternal age <18 years at birth, maternal education <12 years, and living in rural areas; and the population without risk factors (apparently healthy) children born at full-term without complications, and from middle and high socioeconomic levels. We excluded subjects with chronic diseases associated with developmental delay, known neurological diseases, metabolic diseases or genetic syndromes associated with mental retardation. Those cases that, after 30 days from discovery, had not yet completed a diagnostic evaluation were eliminated from the study.

The sample was divided into 14 age groups to follow the organization of the screening test, which includes 14

Table 1. Age groups of the IDE test

Strata of age in regard to the application of the IDE
• 1 month of birth until 1 day before completing 2 months
• 2 months until 1 day before completing 3 months
• 3 months until 1 day before completing 4 months
• 4 months until 1 day before completing 5 months
• 5 months until 1 day before completing 7 months
• 7 months until 1 day before completing 10 months
• 10 months until 1 day before completing 13 months or 1 year and 1 month
• 13 months until 1 day before completing 16 months or 1 year and 4 months
• 16 months until 1 day before completing 19 months or 1 year and 7 months
• 19 months until 1 day before completing 25 months or 2 years and 1 month
• 25 months until 1 day before completing 31 months or 2 years and 7 months
• 31 months until 1 day before completing 37 months or 3 years and 1 month
• 37 months until 1 day before completing 49 months or 4 years and 1 month
• 49 months until 1 day before completing 60 months or 5 years

IDE, Infant Development Evaluation.

subtests for well-baby visits.[9] For each group, children from each of the three categories were included in similar proportions.

In each participating federal entity, a general practitioner was responsible for the administration of the screening test, anthropometry of the children, physical examination and clinical history interview as part of the administration of the screening test. A pediatrician administered the BDI-2 and was responsible for obtaining informed consent. None of the interrogators was aware of the results obtained from the other test.

Standardization of the application method was carried out, both with the general practitioners as well as the pediatricians prior to study initiation obtaining 100% interobserver concordance in the application. General practitioners were given the instruction to apply to each participant two screening tests: the first in which only the responses to the questions are captured, and a second where all questions are corroborated with the observation.

First we applied the screening instrument (IDE test) and then the diagnostic test (BDI-2) on the same day. The Bayley III test was applied no later than 7 days after the screening. Validation indicators considered for evaluating the IDE were sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV).

Diagnostic tests were scored by trained personnel who did not participate in the scoring of either of the other two tests. The entities within the country sent the tests weekly to the team coordination, with only the raw scores. General practitioners applied the screening test and scored it according to the traffic light system originally designed for the test. Data obtained from the tests administered to the children were sent to the neurodevelopmental project office in Mexico City where the reference tests were scored and the results placed in the project database. The evaluators were unaware of the results of the different tests. The study was approved by the research, biosafety and hospital ethics committees. Parents of all participants were asked to sign informed consent (registration number HIM/2011/056).

Statistical analysis

We performed a descriptive analysis of the population. For continuous variables we applied the Kolmogorov-Smirnoff test to evaluate the normal distribution fit. For numeric variables of normal distribution we used the mean and SD. In other cases we used the average and the interquartile range. For dichotomous or categorical variables we used the relative frequency. We calculated sensitivity, specificity, and predictive values with 95% CI. A sensitivity analysis according to different venues, nutritional status, and type of risk was carried out.

We performed a correlation analysis for categorical variables in the case of areas of development of the screening test with each of the diagnostic tests and a partially adjusted correlation according to the screening group. We used the receiver operator curve (ROC), taking as a cut-off point the developmental coefficient of the BDI-2 equal to 90, and the probability of having a delay (developmental quotient <90), taking as a positive result the result of the screening test in red as well as yellow, adjusted by site, type of risk and screening group. Statistical significance was considered at 0.05. Statistical analysis was performed using the IBM SPSS v.19 package.

RESULTS

Demographic characteristics

The test was administered in three Mexican states: Chihuahua, Mexico City and Yucatan. In total, it was administered to 438 children of whom 248 (56.6%) were male. There were no significant differences found according to gender distribution among sites (p =0.436). Mexico City ranked first in the recruitment of participants (34.7%, n =152) followed by the states of Yucatan (34.5%, n =151) and Chihuahua (30.8%, n =135). Table 2 describes the main demographic characteristics of the patients according to the participant's home.

Of the total group of participants, 45% (n =197) had biological risk factors, 31.3% (n =137) had environmental risk factors, and 23.7% (n =104) were without risk factors. Of the general characteristics of the participating children, risk type was the only statistically significant factor for evaluating the differences among locations (p <0.001).

In relation to the nutritional status of the participants evaluated by weight for height according to the Child

Growth Standards of the WHO and taking into consideration that these data were unknown in 23% of participants, one participant was classified with severe malnutrition (1.4%), 24 with mild malnutrition (7.1%) and 312 participants without malnutrition (92.6%), without statistically significant differences for nutritional status among locations (p =0.360).

With respect to the age distribution in accordance with the classification of predefined age groups, the group of 49- to 60-months of age was the one where most participants were registered (n =43), followed by the group of 37- to 48-months of age (n =39) and the group 19- to 24-months of age (n =36). The age group in which there were fewer participants was the 4-month age group (n =23) followed by the 3-month age group (n =27) (Table 3).

Regarding the patient distribution by type of risk according to the age group, 104 patients were identified without risk (23.7%), 137 with environmental risk (31.3%) and 197 with biological risk (45%) (Table 4). For biological risk, the age groups that maintained proportions >50% were the groups of 3-, 4-, 19–24, 25–30, 31–36 and 37–48 months of age. For environmental risk, none of the groups had ratios >50% nor were there patients without risk.

Distribution of the participants by group of total development quotient according to location

The rating of the Total Development Quotient (Battelle) per site showed the presence of significant delay in 43 patients (9.8%), mild delay in 72 patients (16.4) and a score in the low to average range in 91 patients (20.8%), whereas 232 patients were within the range of average development (162 patients, 37%) up to accelerated development (five patients, 1.1%). The higher proportion of patients with significant delay were from the Yucatan (16.6%), mild delay in patients from Mexico City (24.3%) and low average in the DF (26.3%), with statistical significance for differences among the three sites (p <0.001), and no significant differences between the DF and Yucatan (p =0.873) (Table 5).

Regarding the category of Total Developmental Quotient according to type of risk, of the 43 patients with significant delay, 32 (16.2%) had some biological risk, 33 patients with delay (24.1%) had an environmental risk and 42 patients with a low average score (21.3%) also had a biological risk. It is notable that in the group of patients with normal development that 71 subjects (36%) had average development even with biological risk factors with statistical significance for differences among risk types (p <0.001) (Table 6).

Assessment of Total Development Quotient and nutritional status of the patients was performed only in those patients with the available necessary data (weight and height). The patient reported with severe malnutrition had a significant developmental delay according to the Battelle assessment (Table 7).

Establishing the cut-off point for normality in the diagnostic test

According to the Battelle development scale, a patient is considered to have a clinically significant delay if a standardized score <80 is obtained. In this study we established a cut-off of 90. Although many patients had delay in one developmental domain, they attained an average score on the Total Development Quotient (Battelle) (Figure 1 and Tables 8 and 9).

General characteristics of the IDE

Tables 10 and 11 provide a comparison of the rating of IDE (both versions) vs. the total scaled Battelle score and sensitivities of both versions of the IDE. The overall sensitivity of the original version of the IDE is 90% (95% CI 0.86–0.94) and the modified version is 81% (95% CI .75–.86). The modified test shows marginally higher sensitivity values for moderate delay 86% (95% CI 0.76–0.93) and the original test for significant delay 95% (95% CI .84–.99).

The specificity of both versions for all participants was 27% (95% 0.21–0.32) for the original version and 61% (95% CI 0.54–0.67) for the modified version. The modified version obtained a positive likelihood ratio (LR+) of 2.05 (95% CI 1.73–2.44), a positive predictive value (PPV) of 0.65 (95% CI 0.59–0.70) with a concordance of 0.70 (95% CI 0.66–0.74) compared with the original version that earned a LR+ of 1.23 (95% CI 1.13–1.35), a PPV of 0.52 (95% CI 0.47–0.57) and a concordance of 0.57 (95% CI 0.52–0.61) (Table 12).

The general characteristics of the original (Table 13) and modified (Table 14) versions of the IDE are observed according to age group, type of risk and location. Accord-

Table 2. Demographic characteristics of the participants according to location

Location *n* (%)	Sex[a] *n* (%)		Type of risk[b] *n* (%)			Nutritional status (weight/height)[c]* *n* (%)		
	Male	Female	Without risk	Environmental	Biological	No malnutrition	Mild malnutrition	Severe malnutrition
Federal District *n* =152 (34.7%)	92 (60.5)	60 (39.5)	36 (23.7)	48 (31.6)	68 (44.7)	65 (90.3)	6 (8.3)	1 (1.4)
Chihuahua *n* =135 (30.8%)	71 (52.6)	64 (47.4)	57 (42.2)	20 (14.8)	58 (43.0)	117 (92.1)	10 (7.9)	0 (0.0)
Yucatan *n* =151 (34.5%)	85 (56.3)	66 (43.7)	11 (7.3)	69 (45.7)	71 (47.0)	130 (94.2)	8 (5.8)	0 (0.0)
Total n =438 (100%)	248 (56.6)	190 (43.4)	104 (23.7)	137 (31.3)	197 (45.0)	312 (92.6)	24 (7.1)	1 (0.3)

[a]χ^2 for differences according to sex among the locations: $p = 0.436$; [b]χ^2 for differences according to type of risk among the locations: $p < 0.001$. [c]χ^2 for differences according to nutritional status among the locations: $p = 0.360$. *No records available for the nutritional status of 23% of the participants.

Table 3. Distribution of the participants according to age group and location

Location	*Age group (in months)*														*Total by age group n (%)*
	1	*2*	*3*	*4*	*5-6*	*7-9*	*10-12*	*13-15*	*16-18*	*19-24*	*25-30*	*31-36*	*37-48*	*49-60*	
Federal District	12 (34.3)	12 (41.1)	9 (33.3)	9 (39.1)	10 (33.3)	12 (42.9)	12 (36.4)	11 (35.5)	9 (31.0)	10 (27.8)	14 (48.3)	6 (23.1)	12 (30.8)	14 (32.6)	152 (34.7)
Chihuahua	11 (31.4)	9 (31.0)	10 (37.0)	10 (43.5)	11 (36.7)	9 (32.1)	10 (30.3)	10 (32.3)	9 (31.0)	9 (25.0)	8 (27.6)	9 (34.6)	10 (25.6)	10 (23.3)	135 (30.8)
Yucatan	12 (34.3)	8 (27.6)	8 (29.6)	4 (17.4)	9 (30.0)	7 (25.0)	11 (33.3)	10 (32.3)	11 (37.9)	17 (47.2)	7 (24.1)	11 (42.3)	17 (43.6)	19 (44.2)	151 (34.5)
Total *n* (%)	35 (7.9)	29 (6.6)	27 (6.2)	23 (5.3)	30 (6.8)	28 (6.4)	33 (7.5)	31 (7.1)	29 (6.6)	36 (8.2)	29 (6.6)	26 (5.9)	39 (8.9)	43 (9.8)	438 (100.0)

Table 4. Distribution of the participants according to age group and type of risk

Type of risk	*Age group (in months)*														*Total according to type of risk n (%)*
	1	*2*	*3*	*4*	*5-6*	*7-9*	*10-2*	*13-15*	*16-18*	*19-24*	*25-30*	*31-36*	*37-48*	*49-60*	
Without risk	7 (20)	4 (13.8)	6 (22.2)	5 (21.7)	11 (36.7)	6 (21.4)	11 (33.3)	6 (19.4)	5 (17.2)	8 (22.2)	5 (17.2)	6 (23.1)	9 (23.1)	15 (34.9)	104 (23.7)
Environmental	15 (42.9)	11 (37.9)	7 (25.9)	6 (26.1)	9 (30.0)	11 (39.3)	11 (33.3)	10 (32.3)	10 (34.5)	10 (27.8)	9 (31.0)	5 (19.2)	7 (17.9)	16 (37.2)	137 (31.3)
Biological	13 (37.1)	14 (48.3)	14 (51.9)	12 (52.2)	10 (33.3)	11 (39.3)	11 (33.3)	15 (48.4)	14 (48.3)	18 (50.0)	15 (51.7)	15 (51.7)	23 (59.0)	12 (27.9)	197 (45.0)
Total *n* (%)	35 (7.9)	29 (6.6)	27 (6.2)	23 (5.3)	30 (6.8)	28 (6.4)	33 (7.5)	31 (7.1)	29 (6.6)	36 (8.2)	29 (6.6)	26 (5.9)	39 (8.9)	43 (9.8)	438 (100.0)

Table 5. Distribution of the participants according to category of the Total Development Quotient (Battelle) and location

	Category of Total Development Quotient (Battelle) *n* (%)						
Location[a] *n = 438*	*Significant delay*	*Delay*	*Low average*	*Average development*	*High average*	*Advanced development*	*Accelerated development*
Federal District *n* =152	12 (7.9)	37 (24.3)	40 (26.3)	45 (29.6)	10 (6.6)	5 (3.3)	3 (2.0)
Chihuahua *n* =135	6 (4.4)	15 (11.1)	13 (9.6)	58 (43)	35 (25.9)	7 (5.2)	1 (0.7)
Yucatan *n* =151	25 (16.6)	20 (13.2)	38 (25.2)	59 (39.1)	4 (2.6)	4 (2.6)	1 (0.7)
Total	43 (9.8)	72 (16.4)	91 (20.8)	162 (37.0)	49 (11.2)	16 (3.7)	5 (1.1)

[a]Kruskal–Wallis test for differences among sites: p <0.001; Mann-Whitney U test for differences between the Federal District and Yucatan: p = 0.873.

Table 6. Distribution of the participants according to category of the Total Development Quotient (Battelle) and type of risk

	Category of Total Development Quotient (Battelle) *n* (%)						
Type of risk[a] *n = 438*	*Significant delay*	*Delay*	*Low average*	*Average development*	*High average*	*Advanced development*	*Accelerated development*
Without risk *n* =104	2 (1.9)	9 (8.7)	12 (11.5)	45 (43.3)	26 (25.0)	7 (6.7)	3 (2.9)
Environmental risk *n* =137	9 (6.6)	33 (24.1)	37 (27.0)	46 (33.6)	7 (5.1)	4 (2.9)	1 (0.7)
Biological risk *n* =197	32 (16.2)	30 (15.2)	42 (21.3)	71 (36.0)	16 (8.1)	5 (2.5)	1 (0.5)
Total	43 (9.8)	72 (16.4)	91 (20.8)	162 (37.0)	49 (11.2)	16 (3.7)	5 (1.1)

[a]χ^2 test < 0.001; Spearman correlation = -0.249; p <0.001.

Table 7. Distribution of the participants according to category group of Total Development Quotient (Battelle) and nutritional status

Nutritional status	Category of Total Development Quotient (Battelle) *n* (%)						
(weight/height)[a] *n =337*	*Significant delay*	*Delay*	*Low average*	*Average development*	*High average*	*Advanced development*	*Accelerated development*
Severe malnutrition *n* =1 (0.3%)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0.0)	0 (0.0)
Mild malnutrition *n* =24 (7.1%)	7 (29.2)	7 (29.2)	3 (12.5)	6 (25.0)	1 (4.2)	0 (0.0)	0 (0.0)
Without malnutrition *n* =312 (92.6%)	30 (9.6)	51 (16.3)	69 (22.1)	112 (35.9)	38 (12.2)	10 (3.2)	2 (0.6)
Total by category	38 (11.3)	58 (17.2)	72 (21.4)	118 (35.0)	39 (11.6)	10 (3.0)	2 (0.6)

[a]Spearman correlation = 0.186; p = 0.001.

ing to age group the original version had a sensitivity of 85% (95% CI 0.78–0.91) with a specificity of 25% (95% CI 0.18–0.33) for children <16 months of age and a sensitivity of 97% (95% CI 0.93–1.00) with a specificity of 28% (95% CI 0.20–0.37) for the group >16 months of age (Table 13). In comparison, the modified version had a sensitivity of 74% (95% CI 0.65–0.82) and a specificity of 60% (95% CI 0.51–0.68) for children <16 months of age and a sensitivity of 89% (95% CI 0.82–0.95) with a specificity of 62% (95% CI 0.53–0.71) for the group >16 months of age (Table 14).

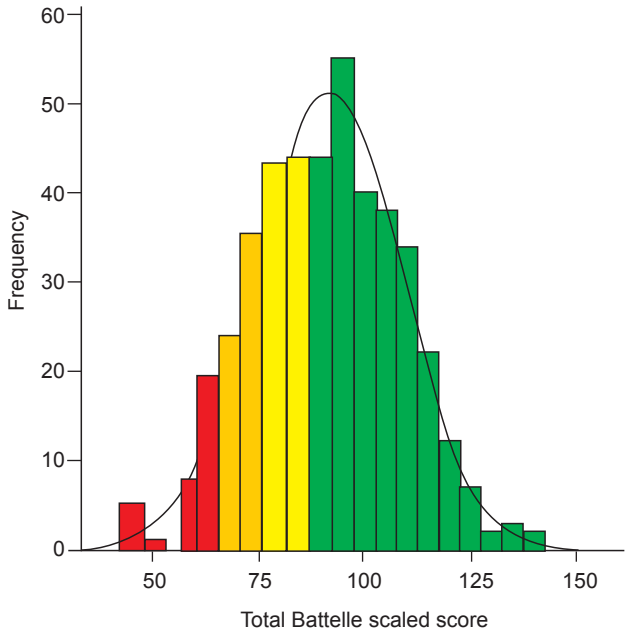

Figure 1. Histogram of the distribution of the total scaled score (Battelle) of the participants.

The sensitivity according to type of risk for the original version was 78% (95% CI 0.61–0.95) with a specificity of 44% (95% CI 0.34–0.55) for patients without risk, a sensitivity of 81% (95% CI 0.71–0.89) with a specificity of 41% (95% CI 0.29–0.54) for patients with environmental risk and a sensitivity of 100% (95% CI 0.99–1.00) with a specificity of 2% (95% CI 0.00–0.07) for patients with biological risk (Table 13). The modified version had a sensitivity of 70% (95% CI 0.51–0.88) with a specificity of 65% (95% CI 0.55–0.76) for patients without risk, a sensitivity of 78% (95% CI 0.69–0.88) with a specificity of 60% (95% CI 0.48–0.73) for patients with environmental risk and a sensitivity of 85% (95% CI 0.78–0.92) with a specificity of 57% (95% CI 0.47–0.67) for patients with biological risk (Table 14).

According to site, the original version had a sensitivity of 93% (95% CI 0.86–0.97) with a specificity of 14% (95% CI 0.06–0.25) for Mexico City, a sensitivity of 91% (95% CI 0.76–0.98) with a specificity of 28% (95% CI 0.18–0.37) for Chihuahua and a sensitivity of 87% (95% CI 0.77–0.93) with a specificity of 37% (95% CI 0.25–0.49) for Yucatan (Table 13). In comparison, the modified score had a sensitivity of 92% (95% CI 0.61–0.99) with a specificity of 52% (95% CI 0.40–0.65) for Mexico City, a sensitivity of 65% (95% CI 0.49–0.8) with a specificity of 66% (95% CI 0.57–0.76)

Table 8. Number of developmental areas with score <1 SD according to category of the Total Development Quotient (Battelle)

*Number of areas of development with score <1 SD**	*Category of the Total Development Quotient (Battelle) n (%)*							
	n	*Significant delay*	*Mild delay*	*Low average*	*Average development*	*High average*	*Advanced development*	*Accelerated development*
0	150	0 (0)	0 (0)	2 (1.3)	84 (56.0)	43 (28.7)	16 (10.7)	5 (3.3)
1	81	0 (0)	0 (0)	13 (16.0)	63 (77.8)	5 (6.2)	0 (0)	0 (0)
2	67	0 (0)	3 (4.5)	48 (71.6)	15 (22.4)	1 (1.5)	0 (0)	0 (0)
3	44	1 (2.3)	19 (43.2)	24 (54.5)	0 (0)	0 (0)	0 (0)	0 (0)
4	46	8 (17.4)	35 (76.1)	3 (6.5)	0 (0)	0 (0)	0 (0)	0 (0)
5	32	18 (56.2)	13 (40.6)	1 (3.1)	0 (0)	0 (0)	0 (0)	0 (0)
6	18	16 (88.9)	2 (11.1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Total by category		43 (9.8)	72 (16.4)	91 (20.8)	162 (37.0)	49 (11.2)	16 (3.7)	5 (1.1)

SD, standard deviation. *Spearman correlation = –0.890; p <0.001.

Table 9. Number of developmental areas with a score <2 SD according to category of Total Development Quotient (Battelle)

*Number of developmental areas with score <2 SD**	*Category of Total Development Quotient (Battelle) n (%)*							
	n	*Significant delay*	*Mild delay*	*Low average*	*Average development*	*High average*	*Advanced development*	*Accelerated development*
0	319	0 (0)	25 (7.8)	70 (21.9)	155 (48.6)	48 (15.0)	16 (5.0)	5 (1.6)
1	65	4 (6.2)	34 (52.3)	20 (30.8)	7 (10.8)	0 (0)	0 (0)	0 (0)
2	30	16 (53.3)	12 (40.0)	1 (3.3)	0 (0)	1 (3.3)	0 (0)	0 (0)
3	14	13 (92.9)	1 (7.1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
4	3	3 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
5	1	1 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
6	6	6 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Total by category *n* (%)		43 (9.8)	72 (16.4)	91 (20.8)	162 (37.0)	49 (11.2)	16 (3.7)	5 (1.1)

SD, standard deviation. *Spearman correlation = –0.677; p <0.001.

Table 10. Comparison of the Total Development Quotient and IDE classification

IDE classification	*Category of Total Development Quotient (Battelle) n (%)*				
	Significant delay n =43 (%)	*Delay n =72 (%)*	*Low normal n =91 (%)*	*Normal n =232 (%)*	*Total n =438 (%)*
			Original version		
Red	25 (58.1)	26 (36.1)	27 (29.7)	58 (25.0)	136 (31.1)
Yellow	16 (37.2)	42 (58.3)	50 (54.9)	112 (48.2)	220 (50.2)
Green	2 (4.7)	4 (5.6)	14 (15.4)	62 (26.7)	82 (18.7)
			Modified versión		
Red	27 (62.8)	35 (48.6)	27 (29.7)	24 (10.3)	113 (25.8)
Yellow	9 (20.9)	27 (37.5)	41 (45.1)	67 (28.9)	144 (32.9)
Green	7 (16.3)	10 (13.9)	23 (25.3)	141 (60.8)	181 (41.3)

IDE, Infant Development Evaluation.

Table 11. Sensitivity of the original IDE vs. modified IDE in the total participants

Sensitivity	*Original*		*Modified*	
	Value	*95% CI*	*Value*	*95% CI*
Normal/Low	0.85	0.75-0.91	0.75	0.64-0.83
Moderate delay	0.94	0.86-0.98	0.86	0.76-0.93
Significant delay	0.95	0.84-0.99	0.84	0.69-0.93
Total	0.90	0.86-0.94	0.81	0.75-0.86

IDE, Infant Development Evaluation; CI, confidence interval.

Table 12. Comparision of the specificity, likelihood ratios and predictive values of the two versions of the IDE test in all the participants

Property	*Original*		*Modified*	
	Value	*95% CI*	*Value*	*95% CI*
Specificity	0.27	0.21-0.32	0.61	0.54-0.67
LR+	1.23	1.13-1.35	2.05	1.73-2.44
LR-	0.36	0.23-0.58	0.32	0.24-0.43
PPV	0.52	0.47-0.57	0.65	0.59-0.70
NPV	0.76	0.66-0.85	0.78	0.72-0.84
Concordance	0.57	0.52-0.61	0.70	0.66-0.74

IDE, Infant Development Evaluation; LR+, positive likelihood ratio; LR-, negative likelihood ratio; PPV, positive predictive value; NPV; negative predictive value; CI, confidence interval.

for Chihuahua and a sensitivity of 81% (95% CI 0.72–0.89) with a specificity of 60% (95% CI 0.49–0.72) for Yucatan (Table 14).

Tables 15 and 16 show the general characteristics of both versions of the IDE in patients <16 months of age according to age group. Tables 17 and 18 show the same characteristics for patients >16 months of age by corresponding age group.

A ROC was performed by taking as a cut-off point the developmental quotient of the BDI-2 equal to 90 and the probability of having a delay (developmental quotient <90), taking as a positive result the result of the screening test, in the red as well as yellow, adjusted by site, type of risk and screening group. It was found that the area under the curve of the probabil-

Table 13. General characteristics of the original IDE according to age group, type of risk and location

Original version	Age group		*Classification by risk*			Location		
	1-15 months	*16-60 months*	*Without risk*	*Environmental risk*	*Biological risk*	*DF*	*Chihuahua*	*Yucatan*
Sensitivity	0.85 (0.78-0.91)	0.97 (0.93-1.00)	0.78 (0.61-0.95)	0.81 (0.71-0.89)	1.00 (0.99-1.00)	0.93 (0.86-0.97)	0.91 (0.76-0.98)	0.87 (0.77-0.93)
Specificity	0.25 (0.18-0.33)	0.28 (0.20-0.37)	0.44 (0.34-0.55)	0.41 (0.29-0.54)	0.02 (0.00-0.07)	0.14 (0.06-0.25)	0.28 (0.18-0.37)	0.37 (0.25-0.49)
LR+	1.13 (1.00-1.29)	1.35 (1.19-1.53)	1.41 (1.05-1.88)	1.38 (1.01-1.76)	1.02 (0.99-1.05)	1.09 (0.97-1.22)	1.26 (1.08-1.48)	1.37 (1.12-1.68)
LR-	0.61 (0.36-1.03)	0.11 (0.03-0.35)	0.49 (0.22-1.10)	0.46 (0.27-0.79)	0.00 (0.00-0.00)	0.47 (0.18-1.26)	0.32 (0.10-0.98)	0.36 (0.19-0.68)
PPV	0.50 (0.43-0.57)	0.55 (0.48-0.63)	0.29 (0.17-0.40)	0.65 (0.56-0.75)	0.53 (0.46-0.60)	0.61 (0.52-0.69)	0.30 (0.21-0.39)	0.63 (0.54-0.71)
NPV	0.65 (0.52-0.79)	0.91 (0.81-1.00)	0.88 (0.78-0.98)	0.62 (0.46-0.77)	1.00 (1.00-1.00)	0.60 (0.35-0.85)	0.90 (0.80-1.00)	0.69 (0.54-0.84)
Concordance	0.74 (0.66-0.82)	0.61 (0.54-0.68)	0.52 (0.42-0.62)	0.72 (0.64-0.80)	0.54 (0.46-0.61)	0.60 (0.52-0.69)	0.44 (0.35-0.52)	0.64 (0.56-0.72)

IDE, Infant Development Evaluation; LR+, positive likelihood ratio; LR-, negative likelihood ratio; PPV, positive predictive value; NPV, negative predictive value.

Table 14. General characteristics of the IDE modified according to age group, type of risk and location

Modified version	Age group (months)		*Classification by risk*			Location		
	1-15	*16-60*	*Without risk*	*Environmental risk*	*Biological risk*	*DF*	*Chihuahua*	*Yucatan*
Sensitivity	0.74 (0.65-0.82)	0.89 (0.82-0.95)	0.70 (0.51-0.88)	0.78 (0.69-0.88)	0.85 (0.78-0.92)	0.92 (0.61-0.99)	0.65 (0.49-0.81)	0.81 (0.72-0.89)
Specificity	0.60 (0.51-0.68)	0.62 (0.53-0.71)	0.65 (0.55-0.76)	0.60 (0.48-0.73)	0.57 (0.47-0.67)	0.52 (0.40-0.65)	0.66 (0.57-0.76)	0.60 (0.49-0.72)
LR+	1.82 (1.43-2.31)	2.35 (1.82-3.03)	2.01 (1.34-3.01)	1.98 (1.41-2.77)	1.97 (1.54-2.52)	1.82 (1.38-2.38)	1.92 (1.33-2.78)	2.03 (1.49-2.78)
LR-	0.44 (0.31-0.62)	0.18 (0.10-0.33)	0.47 (0.25-0.88)	0.36 (0.22-0.57)	0.27 (0.17-0.44)	0.26 (0.14-0.46)	0.53 (0.33-0.86)	0.32 (0.20-0.52)
PPV	0.61 (0.53-0.70)	0.68 (0.60-0.76)	0.36 (0.22-0.51)	0.73 (0.63-0.82)	0.69 (0.61-0.77)	0.72 (0.63-0.80)	0.39 (0.26-0.52)	0.71 (0.62-0.80)
NPV	0.72 (0.63-0.81)	0.86 (0.78-0.94)	0.88 (0.80-0.96)	0.67 (0.55-0.80)	0.77 (0.67-0.87)	0.73 (0.60-0.86)	0.85 (0.77-0.93)	0.72 (0.60-0.84)
Concordance	0.66 (0.60-0.72)	0.75 (0.69-0.81)	0.66 (0.57-0.76)	0.70 (0.63-0.79)	0.72 (0.65-0.78)	0.72 (0.64-0.80)	0.66 (0.56-0.74)	0.72 (0.64-0.79)

IDE, Infant Development Evaluation; LR+, positive likelihood ratio; LR-, negative likelihood value; PPV, positive predictive value; NPV, negative predictive value.

ity of having a delay using the original version was 0.781 (95% CI 0739–0824) and on the modified version, which was greater, 0.838 (95% CI: 0801–0875) (Figure 2).

In the analysis by areas, a moderate and highly significant correlation was found that was better in most cases in the questionnaire version and corroborated on the examination (modified), both in the BDI-2 test as well as with the Bayley III test (Table 19).

DISCUSSION

In the original version, all test points are queried to the child's guardian. If the child met all the expected developmental areas for age and had no signs of alarm or biological risk factors, it was considered (and classified) that the child is experiencing normal development. If the child meets all areas of expected development for age but has signs of alarm or one or more factors of biologi-

Table 15. General characteristics of the original version of the IDE in patients <16 months of age

Original version	Screening groups (age <16 months)							
	1 month	*2 month*	*3 month*	*4 month*	*5-6 months*	*7-9 months*	*10-12 months*	*13-15 months*
Sensitivity	0.79 (0.54-0.94)	0.82 (0.57-0.96)	0.90 (0.55-1.00)	1.00 (0.69-1.00)	1.00 (0.40-1.00)	0.77 (0.46-0.95)	0.82 (0.56-0.96)	0.85 (0.62-0.97)
Specificity	0.25 (0.07-0.52)	0.25 (0.05-0.57)	0.29 (0.10-0.56)	0.23 (0.05-0.54)	0.23 (0.09-0.44)	0.33 (0.12-0.62)	0.25 (0.07-0.52)	0.18 (0.02 -0.52)
LR+	1.05 (0.73-1.52)	1.10 (0.74 -1.63)	1.28 (0.88-1.85)	1.30 (0.97 1.75)	1.30 (1.05-1.60)	1.15 (0.72-1.84)	1.10 (0.77-1.57)	1.04 (0.74-4.21)
LR-	0.84 (0.25-2.84)	0.71 (0.172.92)	0.34 (0.05-2.51)	0.00 (0.00-0.00)	0.00 (0..00-0.00)	0.69 (0.20-2.35)	0.71 (0.19-2.67)	0.83 (0.16-0.52)
PPV	0.56 (0.37-0.74)	0.61 (0.41-0.81)	0.43 (0.22-0.64)	0.50 (0.28-0.72)	0.17 (0.02-0.32)	0.50 (0.28-0.72)	0.54 (0.35-0.73)	0.65 (0.47-0.84)
NPV	0.50 (0.15-0.85)	0.50 (0.10-0.90)	0.83 (0.54-1.13)	1.00 (1.00-1.00)	1.00 (1.00-1.00)	0.63 (0.29-0.96)	0.57 (0.20-0.94)	0.40 (0.05-0.85)
Concordance	0.54 (0.37-0.71)	0.59 (0.39-0.76)	0.52 (0.32-0.71)	0.56 (0.34-0.77)	0.33 (0.17-0.53)	0.53 (0.34-0.72)	0.54 (0.36-0.72)	0.61 (0.42-0.78)

IDE, Infant Development Evaluation, LR+, positive likelihood ratio; LR-, negative likelihood ratio; PPV, positive predictive value; NPV, negative predictive value.

Table 16. General characteristics of the modified version of the IDE in patients <16 months of age

Modified version	Screening groups (age <16 months)							
	1 month	2 months	3 months	4 months	5-6 months	7-9 months	10-12 months	13-15 months
Sensitivity	0.84 (0.60-0.97)	0.76 (0.50-0.93)	0.80 (0.44-0.97)	0.70 (0.35-0.93)	1.00 (0.40-1.00)	0.69 (0.38-0.91)	0.59 (0.33-0.81)	0.70 (0.46-0.88)
Specificity	0.94 (0.70-1.00)	0.58 (0.28-0.85)	0.53 (0.28-0.77)	0.61 (0.31-0.86)	0.42 (0.23-0.63)	0.60 (0.32-0.84)	0.62 (0.35-0.85)	0.54 (0.23 -0.83)
LR+	13.47 (2.00-90.78)	1.84 (0.89 -3.77)	1.70 (0.94-3.07)	1.82 (0.82-4.04)	1.73 (1.25-2.41)	1.73 (0.84-3.55)	1.57 (0.74-3.31)	1.54 (0.76-3.13)
LR-	0.17 (0.06-0.48)	0.40 (0.15-1.08)	0.38 (0.10-1.41)	0.49 (0.17-1.38)	0.00 (0.00-0.00)	0.51 (0.21-1.28)	0.66 (0.33-1.30)	0.55 (0.23-1.30)
PPV	0.94 (0.83-1.00)	0.72 (0.52-0.93)	0.50 (0.26-0.75)	0.58 (0.30-0.86)	0.21 (0.03-0.39)	0.60 (0.35-0.85)	0.63 (0.39-0.86)	0.74 (0.54-0.93)
NPV	0.83 (0.66-1.00)	0.64 (0.35-0.92)	0.82 (0.26-0.75)	0.73 (0.46-0.99)	1.00 (1.00-1.00)	0.69 (0.44-0.94)	0.59 (0.35-0.82)	0.50 (0.22-0.78)
Concordance	0.89 (0.73-0.97)	0.69 (0.49-0.85)	0.63 (0.42-0.80)	0.65 (0.43-0.84)	0.50 (0.31-0.69)	0.64 (0.44-0.81)	0.61 (0.42-0.77)	0.64 (0.45-0.81)

IDE, Infant Development Evaluation; LR+, positive likelihood ratio; LR-, negative likelihood ratio; PPV, positive predictive value; NPV, negative predictive value.

cal risk, the child will be considered as having normal development with risk factors and is considered as yellow in the original version. If a child does not meet with some or various areas of expected development for age, it is possible that the child may experience developmental delay. In this case it will be necessary to assess the areas in which the child failed with the corresponding reactions to the previous age. If the child does have the expected behaviors for the previous age, it may be suspected that the child is possibly developing slower than expected development for age and is classified as having a possible developmental delay.

Finally, if a child fails to meet one or more of the areas of development for their age group and does not meet any area of a prior age group, has an abnormal neurological assessment, or has at least two signs of alarm, the child will probably be considered as experiencing a developmental delay and should be referred

Table 17. General characteristics of the original version of the IDE in patients >16 months of age

Original version	*Screening groups (age >16 months)*					
	16-18 months	*19-24 months*	*25-30 months*	*31-35 months*	*36-47 months*	*48-60 months*
Sensitivity	1.00 (0.78-1.00)	0.95 (0.74-1.00)	1.00 (0.83-1.00)	1.00 (0.79-1.00)	0.94 (0.71-1.00)	0.88 (0.52-1.00)
Specificity	0.21 (0.04-0.51)	0.12 (0.01-0.36)	0.11 (0.00-0.48)	0.30 (0.06-0.65)	0.42 (0.17-0.59)	0.38 (0.22-0.56)
LR+	1.27 (0.97-1.67)	1.07 (0.88 -1.32)	1.13 (0.89-1.42)	1.43 (0.95-2.14)	1.48 (1.06-2.07)	1.44 (0.01-2.04)
LR-	0.00 (0.00-0.00)	0.45 (0.04-4.51)	0.00 (0.00-0.00)	0.00 (0.00-0.00)	0.16 (0.02-1.17)	0.29 (0.04-1.94)
PPV	0.58 (0.39-0.77)	0.55 (0.38-0.72)	0.71 (0.55-0.88)	0.70 (0.51-0.88)	0.53 (0.35-0.71)	0.28 (0.11-0.44)
NPV	1.00 (1.00-1.00)	0.67 (0.09-0.99)	1.00 (1.00-1.00)	1.00 (1.00-1.00)	0.89 (0.52-1.00)	0.93 (0.66-1.00)
Concordance	0.62 (0.42-0.79)	0.55 (0.38-0.72)	0.72 (0.53-0.87)	0.73 (0.52-0.88)	0.61 (0.45-0.77)	0.49 (0.33-0.64)

IDE, Infant Development Evaluation; LR+, positive likelihood ratio; LR-, negative likelihood ratio; PPV, positive predictive value; NPV, negative predictive value.

Table 18. General characteristics of the modified version of the IDE in patients >16 months of age

Modified version	Screening groups (age >16 months)					
	16-18 months	19-24 months	25-30 months	31-35 months	36-47 months	48-60 months
Sensitivity	1.00 (0.78-1.00)	0.84 (0.60-0.97)	0.90 (0.68-0.99)	0.87 (0.62-0.98)	0.82 (0.56-0.96)	0.88 (0.52-1.00)
Specificity	0.71 (0.42-0.92)	0.65 (0.38-0.86)	0.66 (0.30-0.92)	0.70 (0.35-0.93)	0.64 (0.41-0.83)	0.53 (0.35-0.70)
LR+	3.50 (1.53-8.00)	2.39 (1.22 -4.67)	2.70 (1.06-6.88)	2.92 (1.11-7.65)	2.26 (1.25-4.14)	1.89 (1.24-2.89)
LR-	0.00 (0.00-0.00)	0.24 (0.08-0.73)	0.15 (0.04-0.60)	0.18 (0.05-0.69)	0.28 (0.09-0.81)	0.21 (0.03-1.37)
PPV	0.79 (0.61-0.97)	0.73 (0.54-0.91)	0.86 (0.64-0.97)	0.82 (0.64-1.00)	0.64 (0.44-0.84)	0.33 (0.14-0.52)
NPV	1.00 (1.00-1.00)	0.79 (0.57-1.00)	0.75 (0.35-0.97)	0.78 (0.40-0.97)	0.82 (0.64-1.00)	0.95 (0.74-1.00)
Concordance	0.86 (0.68-0.96)	0.75 (0.58-0.88)	0.83 (0.64-0.94)	0.81 (0.61-0.93)	0.72 (0.55-0.85)	0.60 (0.44-0.75)

IDE, Infant Development Evaluation; LR+, positive likelihood ratio; LR-, negative likelihood ratio; PPV, positive predictive value; NPV, negative predictive value.

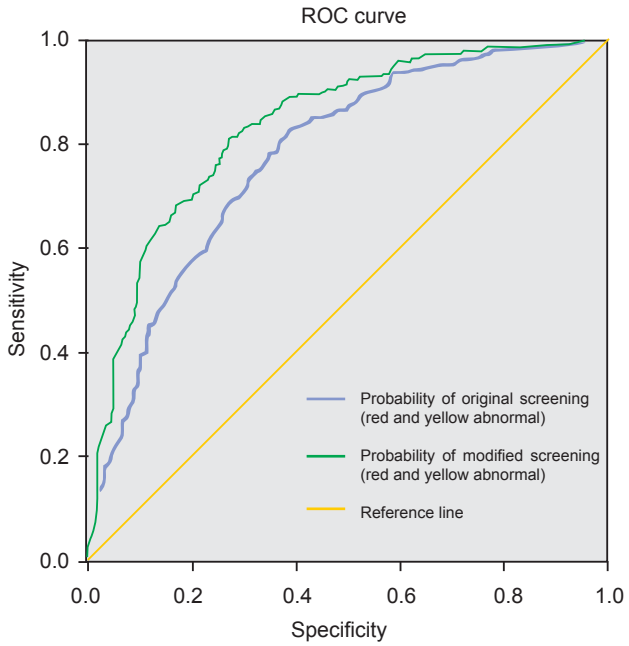

Figure 2. Receiver-operator curve (ROC) of the probability of developmental delay according to the results of the screening test in both versions.

for specialized consultation for a more comprehensive evaluation.

The modified version included the questions of all test reactions as well as corroboration by observation or exploration thereof. For all the scores except behavioral, a greater weight was given to that which was observed during consultation. The scoring system was as follows:

- Green (considered normal development): Meets all areas of development corresponding to age, and has no warning signs or neurological disorder. In case of appropriate development (green areas) and risk or warning signs, a more frequent application of the screening test is required
- Yellow (developmental delay): Does not perform the activities corresponding to age but does meet those of the preceding screening group
- Red (probable developmental delay): Does not meet the questions of development of the corresponding applicable age group or the one immediately pre-

Table 19. Correlation by developmental area between the screening test applied in both versions: questionned (original) or questionned and corroborated by exploration (modified) and diagnostic tests (Battelle-2 and Bayley III)

Test used	Correlation between diagnostic tests and screening test (IDE)										Total sample
	Developmental areas										
	Fine motor		Gross motor		Language		Social		Adaptive		
	Questionned	Questionned and corroborated with exploration	Questionned	Questionned and corroborated with exploration	Questionned	Questionned and corroborated with exploration	Questionned	Questionned and corroborated with exploration	Questionned	Questionned and corroborated with exploration	
Battelle Developmental Inventory 2nd. Edition	Bivariate correlation										*n* = 438
	0.099*	0.170**	0.355**	0.360**	0.364**	0.386**	0.078	0.163*	0.165*	0.265**	
	Partial correlation adjusted according to screening group										
	0.173**	0.256**	0.380**	0.391**	0.412**	0.427**	0.105	0.205**	0.228**	0.306**	
Bayley Infant Neurodevelopmental 3rd ed.	Bivariate correlation										*n* = 87
	0.294**	0.383**	0.454**	0.448**	0.350*	0.411**	0.003	0.265*	0.182	0.331*	
	Partial correlation adjusted by screening group										
	0.396**	0.468**	0.465**	0.441**	0.430**	0.508**	0.103	0.336**	0.115	0.355**	

IDE, Infant Development Evaluation. *p <0.05. **p <0.001.

Table 20. Comparison of the properties of the different developmental screening tests available in the Americas

Developmental screening test	*Language*	*Application time (min)*	*Age range (months)*	*Sensitivity*	*Specificity*
Ages & Stages Questionnaires (USA)	English	10-15	4-60	0.70-0.90	0.76-0.91
Battelle Developmental Inventory Screening 2nd ed (USA)	English and Spanish	10-30	0-95	0.72-0.93	0.79-0.88
Bayley Infant Neurodevelopmental Screen (USA)	English	10	3-24	0.75-0.86	0.75-0.86
Denver-II	English and Spanish	20-30	0-71	0.56	0.80
Evaluation of Psychomotor Development Scale (Chile)	Spanish	20	0-24	NR	NR
PRUNAPE (Argentina)	Spanish	10-15	0-60	0.80	0.93
IDE Test (México)	Spanish	10-15	0-15 16-60 TOTAL	80.5 76.1 88.5	60.5 59.1 62.3

IDE, Infant Developmental Evaluation; NR, not reported; PRUNAPE, Prueba Nacional de Pesquisa.

ceding or has neurological deficits or has signs of alarm.

The IDE in the version that examines and confirms the items (as amended) is an appropriate screening test for developmental problems in children from 1 month to the day before their fifth birthday in Mexico, with properties similar to those reported in the other screening tests available on America[10] (Table 20) and with the advantage of quick and easy administration.

Conflict of interest

The authors declare that there are no conflicts of interest.

Funding

The study received financial support from the Convenio CPSS/ART.1°/128/2011 carried out between the Hospital Infantil de México Federico Gómez (HIMFG) and the Comisión Nacional de Protección Social en Salud (CNPSS).

ACKNOWLEDGMENTS

To Elías Hernández Ramírez, Ana Alicia Jiménez Burgos, Ana Lilia González Camacho, Lizbeth Robles Ochoa, Juan Garduño Espinosa, Jennifer Ruíz Cano, Rocío Del Carmen Córdoba García, Edgar Flores Pérez, Amalia Reyes Peón and Judith Torres Mujica.

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