ABSTRACT
Objective: to generate evidence of validity of criteria of the General Test for the Evaluation of the Integral Development of Boys and Girls, between one month and six years of age (EDIN-II), in the Costa Rican population. Method: the EDIN-II and Battelle-2 tests were applied to 69 children, classified with: biological risk, environmental risks or apparently healthy, during 2019 and 2020. Through a Receiver Operating Characteristic curve model, sensitivity, specificity and efficacious discriminative efficacy of the test were determined, for differentiating “healthy” subjects versus those with delay or risk of delay. Results: the EDIN-II test presented a value below the curve of 0.7347 [95% CI = 0.6040 - 0.8647]; it reached a global sensitivity value of 0.688 and a global specificity of 0.642. Conclusion: nursing may use the EDIN-II test in the different pediatric care settings, favoring the timely detection of possible delays in child development.

DESCRIPTORS: Child Development; Validation Study; Child Health; Mass Screening; Primary Health Care.
INTRODUCTION

The existence of strong evidence in different areas of knowledge demonstrates the importance of early childhood, a stage between conception and eight years of age\(^1\), due to rapid growth, more intense brain development and greater sensitivity to external environmental influences such as family, community and society\(^{2,3}\). In addition, in this period the foundations for the physical, mental and emotional health of the girl or boy are built with great long-term impact in adult life\(^4\). Thus, development in early childhood becomes a social determinant of health, since the well-being and learning capacity of people throughout life will depend on this, which in turn will impact the degree of success of societies\(^2\).

However, around 43% of the child population under five years of age, in low- and middle-income countries, is at risk of not reaching their maximum development potential\(^5\). This data was obtained through indirect measures calculating the number of girls and boys in poverty and malnutrition at the global level, due to the lack of direct information regarding child development in different countries\(^6\). In Latin America, even with progress in the health and nutrition status of the child population, there are incipient data related to child development\(^7\).

Assessment of child development is critical. Since 2001, the American Academy of Pediatrics has promoted that every child be evaluated for the early identification of developmental disorders. During the first years of life, even girls and boys who show typical development may be at risk and need early intervention\(^8\). Also, early childhood is the best time to prevent and improve problems that could cause developmental difficulties and affect brain development throughout life.

On the other hand, having child development indicators has both individual and population implications. At the individual level, the timely identification of developmental delays or risks enables the implementation of early and appropriate interventions that benefit girls and boys at the most effective time to improve their child development\(^9\). At the population level, development indicators make it possible to evaluate public policies, programs and interventions aimed at children that promote child development, and identify who and where are the vulnerable populations that may need more care and resources\(^{10}\). Therefore, the timely measurement of the development situation in early childhood, using comparable methods, will allow societies to progress and achieve better levels of quality of life\(^{2,11}\).

In this context, it is imperative for Costa Rica to have a screening test, quick and easy to apply in the different scenarios of care for girls and boys throughout the country that allows identifying the situation of child development. Although the Comprehensive Development Assessment test for Boys and Girls, between zero months and six years of age (EDIN)\(^{12}\) was built in 1987, it was until 2010 that the validation processes began for its appearance and content\(^{13}\). The objective of this study was to generate evidence of criterion validity of the General Test for the Evaluation of the Integral Development of Boys and Girls, between one month and six years (EDIN-II) in the Costa Rican population.

METHOD

A methodological study was developed whose purpose was the validation of the criterion of the EDIN-II test. The universe of the study were all children from one month to 72 months of age, living within the Greater Metropolitan Area of Costa Rica. The population was obtained through a probabilistic sample of a deliberate or critical type\(^{14}\), for a total of 76 children over one month of age, which represented four minors per age group. Inclusion
criteria for each age group were: individuals who have a biological and/or environmental risk and those considered to be apparently healthy.

Subjects with biological risk are considered: children who required attention in intensive care units with a diagnosis of low birth weight, prematurity or respiratory difficulties; environmental or social risk: children in poverty, maternal age under 18 at the time of birth, maternal education under 12 years, rural; and población without risk factors (apparently healthy): children from full term pregnancy, without complications and of medium and high socioeconomic level.

The EDIN II test\(^{(13)}\) is an assessment test that allows measuring in 20 age groups from zero to 72 months, in different aspects of development in the following five areas: heavy motor, fine motor, language, cognitive and socio-emotional.

Its qualification is under the traffic light method, for each area of development is interpreted in the following way: Green: if the child succeeds in performing three of the items in her age group; Yellow: if the child succeeds in fulfilling only one of the items, the conducts of the previous age group must be applied, and two three items must be fulfilled; Red: if the child completes Only one or zero items of the previous age group.

The interpretation of the results according to the traffic lights should be used for the global evaluation: green determines normal development, the minor complies with the development achievements according to her age group; yellow is described as delay in development, since the child does not fulfill the expected hits for her age, but does achieve the conducts of the previous age; red denotes the risk of delay in development, given that the child has the one or more areas in red and does not comply with the successes of her age and neither achieves the conducts of the previous age.

Batelle-2 Development Inventory - is an instrument for the diagnostic evaluation of children’s development, it evaluates minors from birth to seven years of age, consisting of a manual and six independent application notebooks, with a total of 341 items distributed among following areas: personal/social, adaptive, motor, communication and cognitive\(^{(15)}\).

It was decided to use the Inventory of Development Battelle-2 as gold standard\(^{(16)}\), since 19% of the persons participating in the process of validation were Latin American\(^{(17)}\).

The data collection process was carried out between 2019-2020 within the Gran Metropolitan Area (GAM) of Costa Rica. The prueba EDIN II and Battelle-2 were applied to each minor on different days, with a maximum of seven days between them. Each instrument was applied by a different evaluator with the aim of reducing bias in the results obtained, and at the same time reaching inter-observer agreement. In all cases of children with prematurity, the age was corrected until two years of age, in both cases. The vacancy instruments corresponding to each of the tests were used, and a sheet of general data of the minor and Family was filled.

A logistic regression analysis was used, it seeks to quantify the importance of the relationship between each of the variables (sex, age group, initial education), as well as to classify individuals within the risk and no risk categories\(^{(18)}\); Through a model of ROC (Receiver Operating Characteristic) curves, the values of sensitivity, specificity and the discriminative effectiveness of the test were determined by differentiating “healthy” subjects versus those with delay or risk of delay\(^{(19)}\), taking as a point of cut the development quotient of the Battelle-II test equal to 110, and the probability of having a delay (development quotient less than 110); In the case of the EDIN-II size test\(^{(13)}\), the yellow and red results were considered at delay risk. A statistical significance in 0.05 was considered, and the statistical language package R was used.

The project was approved by the Scientific Ethical Committee of the University of Costa Rica under code B7-337. Furthermore, the informed consent of all the persons responsible for the children and children was filed.
The tests were applied to a total sample of 69 children under six years of age, of which 36 (52.17%) were boys and 33 (47.83%) girls. For each of the 19 age groups from one to 72 months, three to four participants were selected, one or two without risk, one with biological risk and one with social risk.

The tests were applied within the Greater Metropolitan Area (GAM) of Costa Rica, to a total of 69 children under six years of age, of which n = 36 (52.17%) were boys and n=33 (47.83%) were girls; The province of San José ranked first in the recruitment of participants n=38 (55.07%), followed by Cartago n=16 (23.19%) and third place Heredia n=11 (15.94%), from the province of Alajuela only three individuals participated; No significant differences were found for the distribution of the results by sex and place of origin.

The participating population is divided into three risk groups, 50.72% of the cases correspond to boys and girls without risk (n=35), 23.19% (n=16) had biological risk and 26.09% (n=18) social risk. It is important to emphasize that of the characteristics of the participants, risk was the only variable that presented a significant value (=0.020), that is, the associated risk or its absence predict differences in child development (Table 1).

Table 1 - Significance values by characteristics of the participants. San José, Costa Rica, 2019-2020

| Characteristics     | Estimate | Std. Error | z Value | Pr(>|z|) |
|---------------------|----------|------------|---------|---------|
| Sex                 | -0.035   | 0.621      | -0.056  | 0.955   |
| Age                 | 1.197    | 0.663      | 1.806   | 0.071   |
| Risk category       | -1.580   | 0.681      | -2.318  | 0.020   |
| Initial education   | -0.374   | 0.724      | -0.517  | 0.605   |

Source: Authors (2020).

Table 2 shows the distribution of participants by EDIN-II test result and risk category. For all risk categories, more than half of the girls and boys scored green and the fewest number scored red. On the other hand, in the distribution of participants by result of the Batelle-2 test and risk category, more than half of the girls and boys (59.4%) had an average result and the lowest percentage (1.5%) had a very high result.

Table 2 - Distribution of participants by result of the EDIN-II and Batelle-2 tests according to risk category. San José, Costa Rica, 2019-2020 (continues)
The findings, mainly with the EDIN-II screening test, indicate that having a social and biological risk can generate a greater probability of delay in development; As mentioned above, this variable presented a significant weight in the logistic regression analysis performed (=0.020) (Table 1).

In the Battelle-2 diagnostic test, used as the gold standard, a minor with a low average in its development is considered if she obtains a score lower than 90, and delayed when obtaining a score below 80. However, given the number of study participants, it was necessary to establish a cut-off point at 110 because, although many cases presented delay in some domain (area) of development, they reached an average global score.

The comparison between both tests is of utmost importance, since all the cases identified with green by the EDIN-II, that is, that do not have any development risk, are located in the Battelle-2 scores as average, high average and higher. For their part, those classified by the yellow color in EDIN-II, defined as delayed development, since the minors do not fulfill the tasks predisposed for their age group, but those of the previous age, are located in the Battelle-2 with low and average scores (Table 2).

However, in the classification of red in EDIN-II, which implies a risk of significant delay because it does not fulfill the tasks of the age or the previous one, in the Battelle-2 scale they are not located with any delay, that is, located in the diagnostic test as averages. It should be noted that the comparisons are made taking the global scores as a reference, despite the existence of domains (areas) with low average scores or delay, the general development quotient is not impacted (Table 3).

Table 3 - Comparison of the Battelle-2 Global Development Quotient and EDIN-II score. San José, Costa Rica, 2019-2020 (continues)

<table>
<thead>
<tr>
<th>Battelle-2 Development quotient</th>
<th>Qualification EDIN-II</th>
<th></th>
<th></th>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yellow n</td>
<td>%</td>
<td>Red n</td>
<td>%</td>
<td>Green n</td>
</tr>
<tr>
<td>Much higher</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Higher</td>
<td>1</td>
<td>9.1</td>
<td>0</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Average high</td>
<td>3</td>
<td>21.4</td>
<td>0</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>Average</td>
<td>7</td>
<td>17.1</td>
<td>3</td>
<td>7.3</td>
<td>31</td>
</tr>
<tr>
<td>Average low</td>
<td>1</td>
<td>6.2</td>
<td>1</td>
<td>5.6</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>100</td>
<td>18</td>
<td>100</td>
<td>35</td>
</tr>
</tbody>
</table>
According to the global results, the EDIN-II test presented an AUC value of 0.7347 [95% CI = 0.6040 - 0.8647], with a threshold point of 0.227 when comparing both ROC curves of EDIN-II and Battelle-2. Therefore, the screening test reaches a global sensitivity value of 0.688 and a global specificity of 0.642 (Figure 1).

This analysis was carried out for each of the developmental areas contemplated in the EDIN-II test, namely: gross motor, fine motor, language, cognitive and socio-affective. Table 4 describes the values for each of them, except for the cognitive area, since the results obtained are considered statistically unstable.

**Table 4 - AUC values, sensitivity, specificity and threshold point by areas of EDIN-II development. San José, Costa Rica, 2019-2020**

<table>
<thead>
<tr>
<th>EDIN-II areas</th>
<th>AUC [IC 95%]</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross motor</td>
<td>0.846 [0.62-1]</td>
<td>0.667</td>
<td>0.712</td>
<td>0.058</td>
</tr>
<tr>
<td>Fine motor</td>
<td>0.809 [0.63-0.98]</td>
<td>0.600</td>
<td>0.719</td>
<td>0.070</td>
</tr>
<tr>
<td>Language</td>
<td>0.8731 [0.78-0.95]</td>
<td>0.778</td>
<td>0.800</td>
<td>0.136</td>
</tr>
<tr>
<td>Socio-affective</td>
<td>0.880 [0.70-1]</td>
<td>0.750</td>
<td>0.738</td>
<td>0.059</td>
</tr>
<tr>
<td>Global</td>
<td>0.734 [0.60-0.86]</td>
<td>0.688</td>
<td>0.642</td>
<td>0.227</td>
</tr>
</tbody>
</table>

Source: Authors (2020).
The objective of this study was to generate evidence of criterion validity of the General Test for the Evaluation of the Comprehensive Development of Boys and Girls, between one month and six Years of age (EDIN II) in the Costa Rican population. The Sustainable Development Goals (SDGs) include a target on early childhood development, which justifies the need for local resources and assessment measures, to be able to effectively measure the progress of children in a variety of cultures and contexts\(^{10}\). Therefore, the EDIN-II is a local screening instrument with optimal properties to classify the individuals evaluated as: normal development for their age, with a delay in their development or with risk of delay in development and It complies with the characteristics of easy and fast application, with a low-cost and accessible equipment for professionals in the health and education area.

This was confirmed in the logistic regression analysis, in which the ROC curve model was used to present the discriminatory capacity of the test to classify minors who have some delay as delay -true positives- [sensitivity] and the people without delay as without delay -false positives- [specificity]\(^{19}\).

Likewise, the parameter evaluated area under the curve (AUC), which indicates the degree of reliability that a classifier has to adequately discern between the possible states studied; the AUC will always have a value between 0.5 - 1, where 1 represents the perfect diagnostic value, so that when obtaining a value of 0.7347 [95% CI = 0.6040 - 0.8647], above 0.7 is considered an acceptable level of discrimination.

Therefore, the EDIN II is capable of detecting in a timely manner possible delays in development, which will allow achieving short, medium and long-term benefits for the child, their family, and the community in social, political and economic terms\(^{20}\). It is an advantage to have a screening test for the Costa Rican child population, since health care and well-being of children at an early age are issues of global interest, it is known through research that countries that prioritize the promotion of child health and development will achieve a higher human development index\(^{21-22}\).

The assessment appointments became empathetic spaces in which counseling and health promotion activities were carried out for the pediatric population and other family members; which in turn highlights the work of the nursing professional within the process of child growth and development, since the role of nursing care allows to provide timely interventions, guidance on many issues and facilitates interrelation with other professionals, services or sectors\(^{23}\).

Within the limitations of the study, it was found that the participating families did not have complete availability to attend appointments, they also had difficulties to go to the university, where the evaluations of the boys or girls were done, reasons why there were groups of age who did not meet the quota of four assessments; as well as the small number of the sample and having participants located geographically in the Greater Metropolitan Area.

Anyone who will use the EDIN II test who has experience in caring for children is recommended to receive prior training to master the way in which the statements are applied, the use of standardized materials and the use of the score sheet according to the traffic light method; Compliance with this will avoid bias in the evaluation, and become the basis for having qualified professionals who will be part of a child development surveillance system\(^{24}\).

CONCLUSION
The EDIN-II test is a screening instrument with optimal properties to classify evaluated individuals with normal development for their age, with a delay in their development or with a risk of delay in development.

The EDIN-II meets the necessary characteristics of screening tests, it is simple, easy to apply, has safe materials, is accepted by the evaluated population, and has a good cost-effectiveness ratio. Nursing will be able to use the EDIN-II test in the different pediatric care scenarios, favoring the timely detection of possible delays in child development.

There is a need to develop future studies in which it is extended to other geographical regions, and even to carry out cultural adaptations in areas where the child population does not use Spanish as an official language.

REFERENCES


