Validating the CUIDARE Scale in Measuring the Impact on Patients and the Adaptation Process of their Family Caregivers.

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Research

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Abstract

Background: The family caregiving process requires adaptation and be evaluated to ensure a correct approach in supporting patients and their caregivers. The objective of the present study is to design and validate an instrument to determine the family caregivers’ adaptation to the caregiving process in relation to the care dependency of hospitalized patients. This paper presents CUIDARE, a validated scale based on the Nursing Outcomes Classification indicators and the Roy Adaptation Model, that evaluates the adaptation process of caregivers in hospital settings and its impact on hospitalized patients.

Methods: A cross-sectional and psychometric validation study was carried out in ten public hospitals in the Andalusian Healthcare System. Data collection was undertaken between May 2016 and February 2017 in medical and surgical units, included 432 family caregivers.

Results: The CUIDARE scale was shown to be internally consistent (Cronbach's alpha = 0.818). The Exploratory Factor Analysis grouped 4 items into a single component with a variance-explanatory power of 65.6%. The Confirmatory Factor Analysis tested the unidimensionality of the scale with good fit model (CMIN/DF = 2.152; AGFI = 0.975; NFI = 0.993; CFI = 0.996; RFI = 0.979; RMSEA = 0.052).

Conclusions: There is an association between the patients’ care dependency level and the family caregiver’s adaptation to caregiving (p-value <.001). Nursing professionals are encouraged to apply this instrument for the purpose of screening to facilitate the adaptation process of family caregivers and to improve the quality of care.

Background

The increase in life expectancy leads to an increase in disability and need of care in the subsidiary population [1]. The majority of care services (88%) are carried out by the family members, where women usually hold the role of primary or family caregiver [2]. The family caregiving process requires adaptation and may be evaluated to ensure a correct approach in supporting patients and their family caregivers. In this sense, instruments have been validated to assess caregivers of chronic patients or during end-of-life care [3, 4]. Other instruments have been validated taking into account other dimensions of caregivers such as emotional support or information-knowledge [5]. However, no tool has been validated in the hospital settings to evaluate family caregiver adaptation to the caregiving process in relation to the care dependency of hospitalized patients.

People over the age of 65 accounts for 8.5% of the world's population and it is estimated that this figure will double to 1.6 billion in the next 30 years. Chronic diseases, such as cardiovascular diseases, cancer, chronic obstructive pulmonary disease and type 2 diabetes are the most common health issues among older populations [6].

Age is the main cause of disability. One billion people, 15% of the world's population, experience some form of disability and the prevalence of disability is higher among developing countries [7]. The
implications of disability involve a specific approach to assure dignified care, which results in a complex healthcare process and increases the demand for medical assistance and care [8].

During the hospitalization process, there is a functional deterioration that negatively affects the quality of life of elderly patients, aggravating the decline in cognitive abilities with a deterioration that increases functional dependence [9]. The conditions in which care is provided is oftentimes a risk factor for the health of family caregivers, which is also exacerbated by the changes or interruption of their everyday roles due to the patient's hospitalization. The almost constant physical presence in the hospital of family caregivers, which can range from 6 to 24 hours each day, often disrupts their family, work, and social activities [10].

The Family Caregiver Alliance define informal and family caregivers as daughters, wives, husbands, sons, grandchildren, nieces, nephews who provide ongoing care and unpaid assistance. The terms ‘family caregiver’ and ‘unpaid caregiver’ are also used to differentiate from providers and other health care professionals who provide care [11].

Many studies have shown that the act of providing care has a direct impact on the physical, mental, and social well-being of family caregivers and, indirectly, on that of the patients [12]. This burden is likely to increase even further in the near future in Europe, which implies an increased risk of becoming a secondary patient and therefore another user of the healthcare system. Thus, interventions are needed to support family caregivers [13].

The family caregivers’ adaptation to the caregiving process has emerged as an important concept for determining the impact of the quality of family care on frail, older adults [14]. There are several tools for evaluating family caregivers in the hospital setting, like the most widely used being the Zarit Burden Interview and the Caregiver Strain Index [15]. However, the validation of these instruments is limited to specific contexts (home, elderly care facilities, day centers) and mainly to neurodegenerative diseases, such as dementia and Alzheimer’s disease [16]. The information gap is compounded by the fact that these instruments assess the effect of caregiving overload on family caregivers, while neglecting adaptation as the first phase of the caregiving process.

The Roy adaption model provides a theoretical basis for studies on the adaptation processes, where patients interact with a changing environment and nurses facilitate their different modes of adaptation [17]. This process establishes four adaptive modes: physiological, self-concept, role mastery, and interdependence [18]. These dimensions, such as health-related behaviors or perceptions, are sensitive to nursing interventions and can be assessed using the Nursing Outcomes Classification (NOC). The NOC has recently become a reference framework for conducting research on health outcomes. The use of NOC indicators also reduces the time required to assess the outcomes and is sensitive to changes in the patient’s condition and facilitates the assessment and documentation of health outcomes [19].

Among the lines of research carried out on the basis of this trend, the development and validation of instruments is found with the use of NOC outcome indicators. In fact, among the scales that exist based
on NOC, the highlighted are INICIARE [20] INTEGRARE [21], Knowledge: Pain Management [22], CoNOCidiet [23, 24] with wide use and scientific evidence.

The objective of the present study is to design and validate an instrument based on NOC indicators and the Roy Adaptation Model to determine the family caregivers’ adaptation to the caregiving process in relation to the care dependency of hospitalized patients.

**Methods**

**Study Design**

A cross-sectional study was conducted to analyze the reliability and validity of a measuring instrument between May 2016 and February 2017. The present study was carried out in ten public hospitals in the Andalusian Healthcare System (part of the Spanish National Healthcare System), which provides universal, free coverage to 8 million citizens. These ten hospitals serve 3 million citizens, representing approximately 40% of the total coverage of the Andalusian Healthcare System.

The main type of hospital’s units were medical (Internal Medicine, Hematology Unit, Respiratory Unit) and surgical wards (Traumatology, Cardiac surgery, General surgery). The average length of stay of the patients was 4–8 days.

**Setting and Sample**

The family caregiver sample was taken from the sample of patients whose inclusion criteria were over 16 years of age, of both sexes, and admitted in medical-surgical hospital units. No exclusion criteria were established.

To calculate the sample size, the minimum sample size for structural validity of an instrument is at least 7 patients by the number of items and a minimum of 100 assessments according to the COSMIN checklist [25]. A minimum of 10 patients per items was established. Starting from the original 39 items on the scale, the minimum sample required was 390 family caregivers.

**Variables**

The following variables were grouped into sociodemographic and clinical. Sociodemographic variables were considered for both patients and caregivers, whereas clinical variables were only studied in patients.

Sociodemographic patients and family caregivers’ variables: gender (male, female); age (years); relationship between patient and family caregivers (couple, son/daughter, other) and co-residence (yes, no).

Clinical variables for patients: Admission unit (surgical or medical unit), hospital admission: the hospitals were classified by volume of patients, number of beds and geographical location in three hospital categories according to their level of specialization and reference population: Primary (> 500 beds and
large metropolitan areas), specialties (between 200 and 500 beds and small metropolitan areas), and tertiary hospitals (< 200 beds and rural areas).

Instruments: Barthel index, Pfeiffer's test, INICIARE scale, that measures of patient acuity and dependency.

**Barthel Index**

The autonomy to perform activities of daily living was measured using the Barthel Index. It consists of 10 items with five scoring intervals (total dependency, severe dependency, moderate dependency, mild dependency, independence), between 0 and 100: the lower the score, the greater the dependency in patients [26].

**Pfeiffer’s test**

Pfeiffer’s test is widely used to assess cognitive status and consists of 10 items. Cognitive impairment is suspected when the error score is equal to 3 or more in people who can read and write, or to 4 or more in people who cannot [27, 28].

**INICIARE scale**

It was used to assess nursing care dependency in patients. INICIARE is a recently created scale designed to evaluate nursing care dependency in patients with excellent psychometric properties (Intraclass Correlation Coefficient = 0.830–0.964; Internal Consistency total Cronbach's $\alpha = 0.98$, and by subscales between Cronbach's $\alpha = 0.92–0.98$). An exploratory factorial analysis identified three factors (Physiological, Instrumental and Cognitive-behavioural), which explained 74% of the variance. It consists of 55 items measured on a five-point Likert scale (5 reflects the most desirable patient's condition, and 1 reflects the least desirable). The scoring range is 55–275, with three cut-off points (four intervals) that indicate levels of dependency [20, 29].

**Study Protocol: Instrument validation**

The study had three distinct phases. A first phase of the conceptualization of instrument focused on a review of the literature, this resulted in a preliminary instrument. In the second phase, content validity by expert consensus and the preliminary instrument was tested in a sample of family caregivers, through an empirical validation process. The third phase consisted of fieldwork to validate the instrument in a hospital setting.

**First phase: Conceptualization of instrument**

The Roy Adaptation Model [17] was the conceptual foundation of the instrument, and the literature review was used to guide the selection of NOC indicators. The NOC taxonomy structure has five levels: domains, classes, outcomes, indicators and measures. Each outcome has a definition, a list of indicators that can be used to evaluate patient status in relation to the outcome, a target outcome rating and a scale to
measure patient status. Likert scale is used; indicators present five levels of response depending on the adequacy of its state: a value of 5, the highest value, reflects the patient’s most desirable condition, whereas a value of 1 reflects the least desirable condition [19].

From this conceptualization, the research team built a scale based on 39 indicators that belonged to the Domain VI Family Health "Outcome that describe status, behavior, or functioning of the family as a whole or of an individual as a family member", specifically, Classes W and Z.

Classes W (Family Caregiver Performance): "outcomes that describe the adaptation and performance of a family member caring for a dependent child or adult". Classes Z (Family Member Health Status): "outcomes that describe the physical, psychological, social, and spiritual health of an individual family member".

The NOC chosen were 2507 Caregiver Physical Health, 2210 Caregiver Role endurance and 2208 Caregiver Stressors. The NOC 2507 Caregiver Physical Health is defined as the "Physical Well-being of a family care provider while caring for a family member", it includes 16 indicators. The NOC 2210 Caregiver Role endurance is defined as "Factors that promote family care provider’s capacity to sustain caregiving over an extended period of time", includes 10 indicators. The NOC 2208 Caregiver Stressors is defined as "Severity of biopsychosocial pressure on a family care provider caring for another over an extended period of time", with 13 indicators.

Second phase: Content validity

The second phase focused on expert consensus and was conducted with a panel of 30 experts. The experts were selected from among clinical nurses, academic and research nurses, all of them highly trained, with extensive experience in nursing processes and use of Standardized Nursing Languages (SNLs), and proposed by the Nursing Directorate of the hospitals participating in the study. The panelists were also asked to propose new indicators if they considered them necessary. Face validity was not tested, as the wording of the indicators used for the instrument was directly extracted from the list of nearly 10,000 indicators included in the official version of the NOC, without modification or adaptation [19].

The profiles of the experts were as follows: clinical nurses (46.7%), academic and research nurses (20%), and nurse managers (33.3%). The mean age was 46.7 years old (range: 35–57). Eighteen panelists had a master's degree (54%), six panelists had a doctorate (20%), and the remaining experts were registered nurses (26%).

Each expert was asked to rate the relevance and clarity of each item, using a 5-point scale from 5 (reflects the patient’s most desirable condition) to 1 (reflects the least desirable condition).

Third phase: Data collection and fieldwork

The fieldwork was undertaken by interviewers trained by the principal investigator. The data collectors had a bachelor’s degree in Nursing and 10 years of clinical experience in medical/surgical care. Any
problem identified in the study questionnaire or the data collection were resolved through discussions between the data collectors and the principal investigator.

Nursing staff collected the data after the patients’ admission, the family caregiver was taken from the sample of patients. The interviews were conducted by the nurses to respective patients and family caregivers. Each data collector took between 5 to 10 minutes to complete the questionnaire.

The anonymity of the patients and caregivers was preserved at all times by using code numbers for their data, which were stored on a digital platform. A statistical analysis of the data was performed, confirming the validity and reliability of the instrument, which has been named CUIDARE.

**Data Analyses**

The SPSS statistical package for Windows (version 26.0) was used for statistical analysis (SPSS/IBM, Chicago, IL, USA). The results of the descriptive analysis are represented as measures of central tendency (mean, median) and dispersion (standard deviation) for quantitative variables, and as frequencies and percentages for qualitative variables.

An analysis of the normality of the data had been previously performed using the Kolmogorov-Smirnov test. The quantitative variables have not got a normal distribution. A bivariate analysis was carried out using the chi-square statistic for relationship between two qualitative variables (e.g. sex of family caregiver and co-residence). The Cramer’s V test was used to examine the magnitude of association; the Odds Ratio (OR) was calculated in 2 × 2 tables with 95% confidence intervals. In addition, non-parametric test was used such us Mann-Whitney U (e.g. sex of family caregiver and age of caregiver or patient) and Kruskal-Wallis test (e.g. dependency level according to INICIARE and CUIDARE score). The p-value significance of 0.05 was established.

For the psychometric analysis, internal consistency was calculated to determine whether the items of the same concept were homogeneous among them [27]. Using Cronbach’s alpha, internal consistency values can range from 0 to 1, where values close to 1 indicate increased instrument reliability. Structural validity was examined using an Exploratory Factor Analysis (EFA) after performing a Bartlett’s Test of Sphericity (p < 0.05) and a Kaiser-Meyer-Olkin test (range from 0 to 1). To construct validity, an EFA was carried out using Principal Component Analysis and Varimax rotation [31].

To assess the unidimensional aspect of the scale, a Confirmatory Factor Analysis (CFA) was carried for obtaining the level of goodness-of-fit of a factor model. AMOS v26.0 was used. Chi-square, Adjusted Goodness-of-Fit Index (AGFI), Normed Fit Index (NFI), Comparative Fit Index (CFI), Related Fit Index (RFI), and Root-Mean-Square Error of Approximation (RMSEA) were used to test the goodness-of-fit of the model. The fit was acceptable if the CFI, AGFI, RFI, and NFI ≥ 0.95 and the RMSEA < 0.06 [31, 32].

Finally, a Multiple Correspondence Analysis (MCA) was carried out. This method allows to investigate the relation between different categorical variables. The final figure provides a general view of relationships between variables.
Results

Sociodemographic characteristics: Characteristics of family caregivers and patients

The sample consisted of 432 family caregivers, that were selected from the 688 patients included in the study. The family caregiver’s profile is characterized by being female (76.4%) with a mean age of 56.4 years (SD = 13.6). The most common relationship that caregivers had with their patients is as their partners (52.8%) and as their sons/daughters (32.2%), with women standing out in both cases (39% wives, 25% daughters). In most cases, patients and caregivers live at home (77%).

The characteristics of the patients were 53.5% male, with a mean age of 62.42 years (SD = 16.56) and admitted mainly to surgical units (56.7%) and primary hospitals (51.6%). In terms of functional status, patients showed severe dependency (30.2%) according to the Barthel Index, and an oriented level of cognitive functioning (86%) according to Pfeiffer’s test. The most common level of care dependency was high care dependency (44.5%) according to INICIARE. The sociodemographic characteristics of family caregivers and patients are listed in Table 1.
<table>
<thead>
<tr>
<th>Variables</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>102 (23.6)</td>
<td>330 (76.4)</td>
<td>432 (100)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>58.2 ± 14.3</td>
<td>56.4 ± 13.6</td>
<td>56.8 ± 13.8</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Relationship</td>
<td>59 (13.8)</td>
<td>169 (39)</td>
<td>228 (52.8)</td>
<td>.42</td>
</tr>
<tr>
<td>Couple</td>
<td>31 (7.2)</td>
<td>108 (25)</td>
<td>139 (32.2)</td>
<td></td>
</tr>
<tr>
<td>Son/daughter</td>
<td>12 (2.8)</td>
<td>53 (12.2)</td>
<td>65 (15)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-residence</td>
<td>81 (19)</td>
<td>251 (58)</td>
<td>332 (77)</td>
<td>.48</td>
</tr>
<tr>
<td>Yes</td>
<td>21 (5)</td>
<td>79 (18)</td>
<td>100 (23)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender of patient</td>
<td>16 (3.7)</td>
<td>215 (49.8)</td>
<td>231 (53.5)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Male</td>
<td>86 (20)</td>
<td>115 (26.5)</td>
<td>201 (46.5)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>231 (53.5)</td>
<td>201 (46.5)</td>
<td>432 (100)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>62.42 ± 16.56</td>
<td>66.95 ± 17.08</td>
<td>64.53 ± 16.94</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Admission unit</td>
<td>215 (31.3)</td>
<td>175 (25.4)</td>
<td>298 (43.3)</td>
<td>.324</td>
</tr>
<tr>
<td>Medical</td>
<td>153 (22.2)</td>
<td>145 (21.1)</td>
<td>390 (56.7)</td>
<td></td>
</tr>
<tr>
<td>Surgical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td>188 (53)</td>
<td>167 (47)</td>
<td>355 (51.6)</td>
<td>.397</td>
</tr>
<tr>
<td>Primary</td>
<td>122 (56.7)</td>
<td>93 (43.3)</td>
<td>215 (31.2)</td>
<td></td>
</tr>
<tr>
<td>Specialties</td>
<td>58 (49.2)</td>
<td>60 (50.8)</td>
<td>118 (17.2)</td>
<td></td>
</tr>
<tr>
<td>Tertiary</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
### Family caregivers

<table>
<thead>
<tr>
<th></th>
<th>Total dependence</th>
<th>Severe dependence</th>
<th>Moderate dependence</th>
<th>Low dependence</th>
<th>Independence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barthel Index</td>
<td>47 (6.8)</td>
<td>105 (15.3)</td>
<td>101 (14.7)</td>
<td>26 (3.8)</td>
<td>89 (12.9)</td>
</tr>
<tr>
<td>Total dependence</td>
<td>105 (15.3)</td>
<td>103 (15)</td>
<td>188 (27.3)</td>
<td>47 (6.8)</td>
<td>143 (20.8)</td>
</tr>
<tr>
<td>Severe dependence</td>
<td>101 (14.7)</td>
<td>87 (12.6)</td>
<td>21 (3.1)</td>
<td>54 (7.8)</td>
<td></td>
</tr>
<tr>
<td>Moderate dependence</td>
<td>26 (3.8)</td>
<td>21 (3.1)</td>
<td>47 (6.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low dependence</td>
<td>89 (12.9)</td>
<td>54 (7.8)</td>
<td>143 (20.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independence</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pfeiffer's test</td>
<td>323 (46.9)</td>
<td>269 (39.1)</td>
<td>592 (86)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oriented</td>
<td>45 (6.4)</td>
<td>51 (7.1)</td>
<td>96 (13.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disorientated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INICIARE</td>
<td>148 (21.5)</td>
<td>158 (23)</td>
<td>306 (44.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High care dependency</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate care dependency</td>
<td>95 (13.8)</td>
<td>75 (10.9)</td>
<td>170 (24.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk of care dependency</td>
<td>73 (10.6)</td>
<td>48 (7)</td>
<td>121 (17.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independence in care</td>
<td>52 (7.6)</td>
<td>39 (5.7)</td>
<td>91 (13.2)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Relationships between family caregivers and patients

There was a statistically significant difference between the sex of the family caregiver and the sex of the patient ($\chi^2(1) = 76.6; p < .001$), with a moderate effect size ($V = 0.421$). A woman is 10 times more likely to provide care for a man than the inverse (OR = 10; 95% CI [5.6, 17.9]). There are also significant differences with respect to kinship. There are significant differences between the sex of the patients and the sex of their spouses ($\chi^2(1) = 75.9; p < .001$), with a moderate relationship ($V = 0.419$), which indicates that a man is six times more likely to be cared for by his wife (OR = 6; 95% CI [3.9, 9]). There is also a significant relationship between the sex of the patients and being cared for by a son/daughter ($\chi^2(1) = 80; p < .001$), with a moderate relationship ($V = 0.430$). Data indicates that a woman is seven times more likely to be cared for by a son or daughter (OR = 7.5; 95% CI [4.7, 12]) than by her husband.

The dependency level and the fact of having a family caregiver available were related, with statistically significant differences between both ($\chi^2(1) = 66.6; p < .001$) and a moderate association ($V = 0.311$), indicating that individuals with dependency are 3.6 times more likely to have a family caregiver available (OR: 3.6; 95% CI: [2.5, 5]). The relationships between patients and family caregivers are listed in Table 2.
### Table 2
Relationships between patients and family caregivers.

<table>
<thead>
<tr>
<th>Family caregivers and patients’ relationships</th>
<th>X2</th>
<th>p-value</th>
<th>V</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>76.6</td>
<td>&lt; .001</td>
<td>0.421</td>
<td>10</td>
<td>5.6, 17.9</td>
</tr>
<tr>
<td>Female/Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relationship</td>
<td>75.9</td>
<td>&lt; .001</td>
<td>0.419</td>
<td>6</td>
<td>3.9, 9</td>
</tr>
<tr>
<td>Male/Spouse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female/Son_Daughter</td>
<td>80</td>
<td>&lt; .001</td>
<td>0.430</td>
<td>7.5</td>
<td>4.7, 12</td>
</tr>
<tr>
<td>Dependency level</td>
<td>66.6</td>
<td>&lt; .001</td>
<td>0.311</td>
<td>3.6</td>
<td>2.5, 5</td>
</tr>
<tr>
<td>Dependent patient/Caregiver</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Psychometric Validation

Three rounds validation required were conducted using the Delphi consensus technique, 100% panel expert agreement for each indicator. From the first version of the questionnaire with 39 items, an expert panel decides to exclude 15 items and agreement in 2 items in the first round, obtaining a version of the questionnaire composes of 22 items. In the second round, 10 items were removed, and 1 were reassigned obtaining a version of the questionnaire composed of 12 items. In the third round, 11 items were excluded and 1 were reassigned. The experts agreed that the same four indicators were part of the last version scale: (250712) Perceived general health, (221002) Mastery of direct care activities, (221001) Mutually satisfying care recipient-caregiver relationship, (220801) Reported stressors of caregiving. The flowchart indicators over the successive rounds are described in Fig. 1.

### Reliability

Regarding internal consistency, an $\alpha$ value of 0.818 and an Interclass Correlation Coefficient of 0.788–0.844 were obtained. The total score of the Cronbach's $\alpha$ was not improved by the elimination of any of the items.

### Structural validity

Before the construct validation, KMO test was performed with a score of 0.803 and statistical significance ($p < 0.001$) was obtained. The EFA grouped the 4 items in a single component with a variance-explanatory power of 65.6%.

The Confirmatory Factor Analysis was carried out on the basis of the EFA and only one dimension was tested. The result of the test was a good fit of the model ($\text{CMIN/DF} = 2.152$; $\text{AGFI} = 0.975$; $\text{NFI} = 0.993$; $\text{CFI} = 0.996$; $\text{RFI} = 0.979$; $\text{RMSEA} = 0.052$) (Fig. 2.)

### Relationship between the family caregivers’ adaptation to caregiving and the patient characteristics
The relationship between the family caregivers’ adaptation process to care according CUIDARE and the dependency level according INICIARE, showed to be statistically significant (Kruskal-Wallis test = 36.089; p < .001). It was found that there are statistically significant differences between highly dependent patients and the rest of the groups (Fig. 3). There exists a relation between the caregiver care adaptation and the patient dependence. It is observed that the more independent the patients are, greater the adaptation to care is for the caregivers. Also, there was statistically significant with CUIDARE among the patients with less of 65 years and patients with 65 or more (U = 18686.5, p = .034).

In the correspondence analysis, it was found that a grouping of characteristics made it possible to identify some profiles in relation to dependency level. Thus, women are related to situations of high care dependency are aged 65 or over, have a primary family caregiver and are admitted in specialty hospitals.

**Discussion**

The objective of the present study was to design and validate the CUIDARE scale based on NOC indicators and the Roy Adaptation Model to determine the adaptation of family caregivers to the caregiving process in hospitals. The use of the NOC for wording scale items proved to have positive psychometric results, as is the case with INTEGRARE [21] or the Pain Level Outcome Scale [22] and others studies on validation of Nursing Outcomes [303.

The use of NOC indicators facilitates their easy cross-cultural adaptation because they have been translated into different languages, such as Chinese, German, and French, and because they are compatible with the Electronic Health Record or EHR [34]. These data confirm the appropriateness of Standardized Nursing Languages (SNLs) as a basis for the development of tools to assess and quantify health outcomes.

CUIDARE attained high reliability and validity, similar to or higher than other scales measuring different aspects of family caregivers, such as the Zarit Burden Interview and the Caregiver Burden Scale [35]. In terms of internal consistency, CUIDARE achieved high reliability (α = 0.818) and Interclass Correlation Coefficient (0.788, 0.844). To construct validity, the EFA grouped the four items into a single component with a variance-explanatory power of 65.6%. The Confirmatory Factor Analysis was carried out on the basis of the EFA and only one dimension was tested. In relation to feasibility, CUIDARE has a high usability, as it shows a unidimensional structure and is made up of only four items. Feasibility studies recommend that the number of items per factor do not exceed four. Having a higher number of items deteriorates the resulting factor structure by causing redundancies [36].

This study makes possible the empirical validation of a conceptual model, as it combines the theory base of the Roy Adaptation Model and NOC indicators. According to the Roy Adaptation Model, this model helps to prioritize care for caregivers and the nurse will be able to know what degree of adaptation they have. Other tools that have also been based on this model have turned out to be useful to assess
adaptation in other situations, highlighting the Coping and Adaptation Processing Scale (CAPS) - Short-Form that assesses the adaptation for people dealing with both, chronic and acute health condition [37].

In addition, there is scientific evidence that identifies how Roy Adaptation Model has been extended as a conceptual framework to meet changing global needs. Therefore, using a tool that has been validated by following this model guarantees the rapid detection of patient's needs change. Thus, caregivers were approached and treated by the nurse as soon as possible, improving the adaptation to care [38, 39].

The use of a theoretical model for the validation of an instrument has already been carried out with the validation of the INICIARE scale, which was based on the Henderson Model for measuring nursing care dependency in hospitals, obtaining good results in its validation and implementation in hospital units [20, 29].

As for the characteristics of the sample, the patients had a family caregiver on six out of ten occasions. The family caregiver profile in this study can be described as women majority (76.4%), who were related to the patients as their spouses or daughters. These data are consistent with other studies conducted worldwide. Jang, Avendano, & Kawachi (2012) showed that the prevalence of female family caregivers is higher in different countries, especially in the Mediterranean and Asian countries [40]. The family relationship also coincides with other publications in which spouses and daughters are abundant [41].

The dependency level of the patient has been shown to have a statistically significant relationship to the family caregiver’s adaptation process to care. This indicates that as the dependency level of the patient increases, the adaptation of the family caregiver to the caregiving process decreases. Higher dependency levels are related to higher levels of burden and lower quality of life and self-perceived health [42].

The incorporation of the new scale CUIDARE to hospital settings, serves as a screening tool for family caregivers, to attend any hospitalized relative with any dependency level. This scale is for clinical use, since the presence of a patient with high levels of care dependency is a risk factor for the health of the family caregiver. Faced with this scenario, nursing professionals are encouraged to act preventively by initiating a rapid screening of their adaptation to caregiving, using the most appropriate tool for each situation instead of their systematic choice. The use of nursing outcomes classifications and have highlighted the important role that cares have in promoting the health and well-being of their relatives.

However, further research is needed along these lines. It is necessary a longitudinal study (to understand the state of the patient and the family caregiver before they arrive to the hospital to understand the history of caregiving and conditions under which it is done). It is also necessary to identify what other factors are related to the adaptation process of a family caregiver and triangulate with other methods. Therefore, hospital data could be combined with the community data to make a much stronger study.

The patients and family caregiver’s assessment in this study were conducted upon admission. As a result, the dependency level of patients prior to their admission is unknown, as is the family caregivers’ adaptation to caregiving process before hospital admission. In addition, as these are acute care
hospitals, in many cases the patients’ care dependency may be temporary due to the nature of the condition leading to their admission.

Furthermore, the event leading to the admission may be severe enough to trigger a chronic, degenerative, or disabling condition that causes the family to start the caregiving activity. In any of these situations, the family caregivers’ adaptation to caregiving at the time of admission may not be necessarily affected, and there would therefore be a distortion between the patient’s care dependency level and the family caregivers’ adaptation to caregiving.

In this line of reasoning, we also do not know if hospitalization could mean a break for family caregivers who take advantage of the patient's admission to the hospital to be able to rest while the nurses perform care in the hospital. Another important limitation of this study is that it was not possible to determine the convergent validity of the instrument with a gold standard.

**Conclusions**

CUIDARE is a scale for clinical use, with reliable and valid instrument to measure the family caregiver's adaptation to caregiving in hospital settings. There is an association between the patients’ care dependency level and the family caregiver's adaptation to caregiving. The results highlighted that health professionals should use a validated tool for each situation to improve the quality of patient care, as well as the well-being of family caregivers.

**Abbreviations**

AGFI: Adjusted Goodness-of-Fit Index

CAPS: Coping and Adaptation Processing Scale

CFA: Confirmatory Factor Analysis

CFI: Comparative Fit Index

EFA: Exploratory Factor Analysis

EHR: Electronic Health Record

MCA: Multiple Correspondence Analysis

NFI: Normed Fit Index

NOC: Nursing Outcomes Classification

OR: Odds Ratio
Declarations

Ethics approval and consent to participate

The study protocol was approved by the ethics committee at the Andalusian Healthcare System (Code:1967). All patients and family caregivers participated voluntarily and signed a consent form. The anonymity of patients and family caregivers was preserved at all times by using code numbers for their data for storage purposes and subsequent statistical analyses. The participating nurses whom collected the data signed a confidentiality agreement consent and were aware of their right to withdraw from the study at any time.

Consent for publication

Patient consent for publication was not required as all data are anonymized.

Availability of data and materials

All data generated or analysed during this study are included in this published article. Requests for data should be made to Professor Ana María Porcel Gálvez.

Competing Interest

The authors declare no competing interest.

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Authors’ Contributions


References

   https://doi.org/10.1016/j.cnur.2014.10.014
   https://doi.org/10.1111/jocn.12543


25. COSMIN Study Design checklist for Patient-reported outcome measurement instruments. 
   17 Jan 2019.
    99. https://doi.org/10.1097/NNR.0000000000000072
27. Martínez-Iglesia J, Herrero RD, Vilches MCO, Taberné CA, Colomer CA, Luque RL. Adaptación y
    validación al castellano del cuestionario de Pfeiffer (SPMSQ) para detectar la existencia de deterioro
    https://doi.org/10.1016/s0025-7753(01)72040-4
28. Pfeiffer E. A short portable mental status questionnaire for the assessment of organic brain deficit in
29. Barrientos-Trigo S. Validez externa y convergencia de la escala INICIARE 2.0 y Care Dependency
    Scale: Estudio multicéntrico (Tesis doctoral). University of Seville, Nursing Department, Spain. Date
    of completion: 6/05/2015.
    https://doi.org/10.5116/ijme.4dfe.8df
31. Rennie KM. Exploratory and Confirmatory Rotation Strategies in Exploratory Factor Analysis. Instit
32. Schreiber JB, Stage FK, King J, Nora A, Barlow EA. Reporting structural equation modeling and
33. Emidio S, Dias F, Moorhead S, Deberg J, Oliveira-Kumakura A, Carmona EV. Conceptual and
    operational definition of nursing outcomes regarding the breastfeeding establishment. Rev Lat Am
34. Stifter J, Yao Y, Lodhi MK, Lopez KD, Khokhar A, Wilkie DJ, Keenan GM. Nurse Continuity and
    Hospital-Acquired Pressure Ulcers: A Comparative Analysis Using an Electronic Health Record "Big
35. Flynn-Longmire C, Knight BG. Confirmatory Factor Analysis of a Brief Version of the Zarit Burden
    https://doi.org/10.1093/geront/gnr011
    D. How to reduce the number of rating scale items without predictability loss? Scientometrics.
    2017;111:581–593. https://doi.org/10.1007/s11192-017-2283-4
37. Roy C, Bakan G, Li Z, Nguyen TH. Coping measurement: Creating short form of Coping and
    Adaptation Processing Scale using item response theory and patients dealing with chronic and acute
    https://doi.org/10.1016/j.apnr.2016.06.002
38. Barone SH, Roy CL, Frederickson KC. Instruments used in Roy adaptation model-based research: 


**Figures**

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Delphi Panel

Round 1

Preliminary Scale version (n=39 indicators)
2507 Caregiver Physical Health (16 indicators)
2210 Caregiver Role Endurance (10 indicators)
2208 Caregiver Stressors (13 indicators)

Agreement (n= 2 indicators)
Excluded (n=15)

Round 2

Re-assessment (n= 22 indicators)

Agreement (n= 1 indicators)
Excluded (n= 10)

Round 3

Re-assessment (n= 12 indicators)

Agreement (n= 1 indicators)
Excluded (n= 11)

Final agreement (n= 4 indicators)
```
Figure 1

Description of the Delphi process.

Figure 2

Confirmatory Factor Analysis of CUIDARE

<table>
<thead>
<tr>
<th>Average CUIDARE</th>
<th>HIGH</th>
<th>MODERATE</th>
<th>RISK</th>
<th>INDEPENDENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>( \bar{x} = 15.3 ) IC [14.7-16]</td>
<td>( \bar{x} = 17.1 ) IC [16.4-17.8]</td>
<td>( \bar{x} = 17.9 ) IC [17.1-18.7]</td>
<td>( \bar{x} = 18.1 ) IC [17.1-19.1]</td>
</tr>
<tr>
<td>Female</td>
<td>( \bar{x} = 16.6 ) IC [16.1-17.1]</td>
<td>( \bar{x} = 17.8 ) IC [17-18.7]</td>
<td>( \bar{x} = 17.7 ) IC [16.2-19.2]</td>
<td>( \bar{x} = 18.7 ) IC [17.9-19.5]</td>
</tr>
</tbody>
</table>

Dependence Care INICIARE
Figure 3

 Relationship between the degree of adaptation and levels of dependence in the care of hospitalized patients.

Figure 4

Correspondence analysis