









Developing and validating an integrated instrument for nursing assessments in adult hospitalization units: Study protocol

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Abstract

Aims: To develop and validate an instrument that integrates functional capacity, risk of pressure ulcers and risk of falling with a more parsimonious approach towards nursing assessments in hospitalization units.

Design: Cross-sectional validation multicentre study.

Methods: Socio-demographic variables and assessments of Barthel Index, Braden Index and Downton Scale are included via electronic health records. Instrument's development process will include: (i) conceptual assessments; (ii) content validity; (iii) construct validity; (iv) internal consistency and (v) interobserver reliability. The analysis will consider possible differences in medical and surgical hospitalization units, hospitalization type or being a COVID-19 patient. This study was accepted for funding in November 2020 and approved by the Ethics and Research Committee in January 2021.

Results: An integrated instrument that lowers the administrative load of nursing assessments and allows at-risk patients to be detected with at least the same validity and reliability as the original instruments is expected to be obtained.

KEYWORDS

hospitalization, nurses, nursing, nursing assessment

1 | INTRODUCTION

Nurses working in hospitalization units are responsible for assessing, planning, implementing and re-assessing the care that patients require throughout the healthcare process, and for documenting all this in their electronic health records (EHR). Nevertheless, nurses perceive healthcare documenting as an administrative load owing to increasing quantities of data and duplicated items (Brown et al., 2020). In the meantime, the implementation of EHR has prolonged data-recording times, increased workloads (Dunn Lopez

et al., 2021; Walker et al., 2019), cut direct healthcare times (Cooper et al., 2021) and rendered nursing assessments incomplete, inconsistent and inaccurate (Charalambos & Goldberg, 2016). All these have negative repercussions on healthcare quality and on the development of adverse effects (Gasperini et al., 2021).

Some studies have centred on improving the workflow of nursing assessments in EHR (Lee et al., 2019; Swietlik & Sengstack, 2020). Others have focused on improving contents in nursing assessment templates, mainly vital signs and physical examinations (Muinga et al., 2021). Nonetheless, nurses employ several instruments to

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assess the risk of developing nursing-sensitive outcomes, such a loss of functional capacity, pressure ulcers or falls. These instruments share dimensions and items that make them redundant (Dante et al., 2015). Thus, developing an instrument that integrates them and takes a more parsimonious approach to nursing assessments is feasible (Palese et al., 2016).

1.1 | Background

Nursing assessments are the first step of the nursing process and can be defined as a planned, systematic, continuous and deliberate process of collection, classification and categorization of individualized information, for the purpose of recognizing individuals' responses to their health problems and real or potential needs (Kozier et al., 2005). These assessments are the basis for making diagnoses and performing interventions that match patient needs (Gray et al., 2018). Thus, any mistake, missing information or using unsuitable instruments can affect the next nursing process steps, and result in fragmented welfare and incomplete health care with repercussions on healthcare quality, user satisfaction and on the development of adverse effects (Gasperini et al., 2021).

The literature recommends arranging nursing assessments using a nursing-specific model or framework (Munroe et al., 2013), such as the 14 basic needs of Henderson (Morales-Asencio et al., 2015) or the 11 Functional Health Patterns of Gordon (Gengo E Silva Butcher & Jones, 2021). However, structured nursing assessments that are not based on a discipline-specific framework can be found (Gray et al., 2018). It is also necessary to determine the items or variables that nurses must assess as part of their competencies, in their knowledge area and according to user profiles (Douglas et al., 2016). Depending on the nature of this information, it can be obtained by holding interviews, making observations, performing physical examinations, reviewing medical records, running diagnosis tests or applying a wide range of questionnaires to assess the risk of suffering nursing-sensitive outcomes, such as loss of functional capacity (Buurman et al., 2011), pressure ulcers (Arndt & Kelechi, 2014) or falls (Aranda-Gallardo et al., 2013).

Despite their relevance, nurses perceive nursing assessments as an administrative load (Brown et al., 2020; Cooper et al., 2021; Dunn Lopez et al., 2021), which has increased with the implementation of EHR (Moore et al., 2020; Walker et al., 2019). In fact, different studies have evidenced that recording nursing assessments do not meet suitable information quantity and quality standards. For instance, Paans et al. (2010) found that nursing assessments had not been recorded in 20% of the health records audited in a sample of 10 Dutch hospitals. Lindo et al. (2016) reported how more than 60% of the health records audited in three Jamaican hospitals did not include complete nursing assessment data. Iula et al. (2020) indicated that assessments about pain and nutritional status were missing in a sample of 12,513 clinical records audited in an Italian hospital. Other studies inform about failing to complete records with

instruments that assess functional capacity (Asmirajanti et al., 2019), falls or pressure ulcers (Bååth et al., 2007; Bail et al., 2021; Redley & Raggatt, 2017).

Some factors that might justify this situation include increased patient complexity and heavy workload (Needleman, 2013), variety of nursing terminologies and classifications (De Groot et al., 2019), EHR developed in the traditional printed format and not considering nurses' views (Bail et al., 2021), increased data quantity, duplicated items and the diversity of assessment instruments (Brown et al., 2020). In fact, Palese et al. (2012) concluded that nurses routinely employ between 1 and 10 assessment instruments, which can vary depending on the clinical context, units and hospitals. In another study, Redley and Raggatt (2017) found that nurses in hospitalization units use from 8 to 27 assessment instruments.

The instruments employed to assess functional capacity (Buurman et al., 2011), risk of pressure ulcers (Arndt & Kelechi, 2014) and risk of falls (Aranda-Gallardo et al., 2013) are probably the most widely used by nurses in adult hospitalization units. In clinical practice, these instruments are independently employed, but share constructs, dimensions and items related to mobility, hygiene, eating or elimination of body waste (Palese et al., 2016; Palestini et al., 2012), which implies items becoming redundant and being duplicated (Brown et al., 2020). However, using redundant assessment instruments leads to certain scepticism and a perceived waste of time, which makes them being accepted and implemented in nursing very difficult (Dante et al., 2015). Therefore, nursing assessments can become an automatic and inaccurate task without much nurse engagement, which affects not only their validity but also the task of detecting at-risk patients (Palese et al., 2012). Consequently, combining nursing assessments of functional capacity, risk of pressure ulcers and risk of falls in a single instrument that integrates them, and one capable of assessing the risk of these nursing-sensitive outcomes with at least the same reliability and validity as the original assessment instruments, is deemed appropriate.

2 | THE STUDY

2.1 | Aims

To develop and validate an instrument that integrates functional capacity, risk of pressure ulcers and risk of falling with a more parsimonious approach towards nursing assessments in hospitalization units.

2.2 | Design

A cross-sectional validation multicentre study is underway. The study began in January 2021 and will end in December 2022. Figure 1 presents a general timeline of the study.

FIGURE 1 Timeline of the study

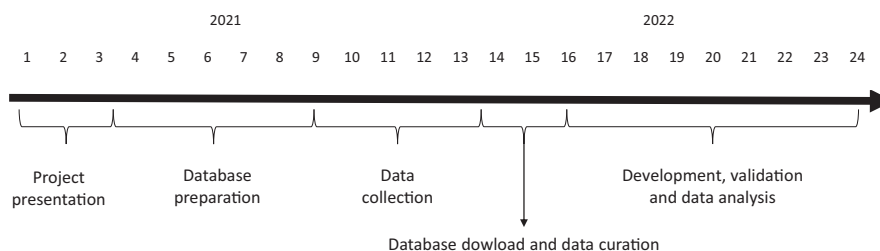


TABLE 1 Sample size estimation

Unit	Discharges in 2019	Mean monthly discharges	Estimated n (4 months)
Hospital Universitario Comarcal de Vinaroz			
Internal medicine A	1210	101	403
Internal medicine B	1032	86	344
Specialities A	1020	85	340
Specialities B	758	63	253
Surgery	966	81	322
Total hospital	4986	83	1662
Hospital Universitario de La Plana			
1 Trauma A–A&E	2023	169	674
Surgery 1B	1303	109	434
Cardiology 1D–digestion	1751	146	584
Neurology 2A–pneumology	1550	129	517
Surgery 2B	1397	116	466
Otorhino-Urology 2C	1760	147	587
Internal medicine 2D	1101	92	367
Total hospital	10,885	130	3628
TOTAL SAMPLE	15,871	106	5290

2.3 | Participants and sample

The study population is formed by assessments made of functional capacity, risk of pressure ulcers and risk of falls among the users of adult hospitalization units at two hospitals. Special services (intensive care, emergency, operating theatres or resuscitation), home hospitalization units, materno-infant and obstetric–gynaecology hospitalization units do not form part of this study due to differences in the type of care processes, in the organizational model of these units and in the assessment instruments used.

The study includes the assessments made of patients aged more than 18 years in the first 24 h after being admitted to a hospitalization unit that include the three instruments studied (Braden Index, Barthel Index and Downton Scale) to ensure that data related to the time of admission are obtained for all patients. Assessments made of patients transferred from other units at the same hospital or from other hospitals are excluded because their healthcare process is

already underway and their assessments when hospitalized do not correspond to the initially made assessment.

The literature recommends a sample size between 5 and 10 subjects per item for developing and validating assessment instruments (Anthoine et al., 2014). All the items of each instrument considered in the project come to 21, which means that 210 nursing assessments will be necessary. However, no specific recommendations about sample size were found when combining or unifying several instruments. Notwithstanding, Palese et al. (2016) used a sample with 1446 assessments for a theoretical work with a similar objective. Therefore, by considering that the maximum representativeness of the users of these services is sought and the analysis strategy requires working with different subsamples, all the nursing assessments are included in this study, which complies with the selection criteria and was made during a 4-month period (September 2021–January 2022). By considering the mean of the monthly hospital discharges in hospitalization units in 2019, the final study sample was estimated to include 5290 nursing assessments (Table 1).

2.4 | Variables and instruments

The study includes socio-demographic variables (age and gender) and variables related to the healthcare process, such as process type (medicine, surgical), hospitalization type (scheduled, emergency), main and secondary diagnoses, Charlson Index score and being a COVID-19 patient (yes/no). Nursing assessment-related variables are also included, such as pressure injury detected when admitted to hospital (yes/no), hospitalized due to a fall (yes/no) and Barthel Index, Braden Index and Downton Scale scores when admitted to hospital. The scores of all the items making up these questionnaires are also incorporated.

2.5 | Data collection

Initially, the data collection was planned between March and June 2021 using EHR. However, the research team was forced to postpone this period and collect the data between September 2021 and January 2022 for various reasons. On the one hand, the initial period coincided with a wave of COVID-19 and nurses stopped using the assessment instruments included in this study at the instruction of nursing managers,

with the intention of reducing work overload. On the other hand, after this initial period the summer season began, with high recruitment and staff turnover that could affect the validity of the data.

The nurses working in the hospitalization units herein included carried out data collection prospectively, as part of their normal work through the EHR. When the data collection period ended, the pseudonymized database was requested from the documentation service of both hospitals, along with the variables to be studied, but without including any personal data that could identify patients. A consensus was reached beforehand with the documentation services about the structure of this database. The documentation service of each hospital will keep the original database with patients' identification details.

We ought to mention that both hospitals have a nursing assessment protocol. This protocol indicates that nursing assessments must be made for all patients in the first 24 h after being admitted to hospitalization units. This protocol also specifies the use of assessment instruments herein considered (Barthel Index, Braden Index and Downton Scale). These tools are completed in the EHR available at both hospitals, which allows data to be exported and pseudonymized.

2.6 | Ethical considerations

The project has been accepted by the management of both the participating centres and positively evaluated by the Ethics and Research Committee in January 2021. This project complies with the Organic Law 3/2018, of 5 December, about Personal Data Protection and Guaranteeing Digital Rights, as specifically indicated by its additional 17th disposition, section d, which considers the lawful use of pseudonymized personal data for health research purposes, particularly for biomedicine. This was why requesting informed consent was waived. This means that, in accordance with the legislation currently in force in the country where this study will be conducted, the technical and functional separation between the research team and the documentation services that will perform pseudonymization will be ensured. This will avoid possible re-identifications by third parties and will ensure re-identification by healthcare centres in the event of a real specific hazard existing for the health and safety of someone or of a group of people.

2.7 | The development, validation and data analysis procedures

A descriptive analysis will be performed of the sample in accordance with the nature of the variables. The existence of significant differences in the nursing assessment results will be studied by considering the hospital and hospitalization units, as well as the process kind (medical or surgical), hospitalization type (urgent or scheduled) and the main diagnosis.

Any significant differences in the assessment results for positive COVID-19 patients will also be analysed. To do this, first, the application conditions of the parametric tests (normality with the Shapiro–Wilk test and homoscedasticity with the Levene test) will be verified. If the application conditions are met, the parametric tests will be used depending on the number of groups (Student's T for two groups or ANOVA for three or more groups). If the application conditions are not met, the non-parametric tests will be used (Mann–Whitney U for two groups or Kruskal–Wallis for three or more groups). The categorical variables will be analysed by Chi-squared (χ^2) (Fisher's exact test as a non-parametric test) and correlations by Pearson's (Spearman's test as non-parametric test) correlation tests. Three multivariate regression analyses will be carried out, one with each evaluation instrument (Barthel, Braden and Downton) as a dependent variable, to determine the influence of the independent variables type of process, type of hospitalization, age and sex on the results of the evaluation. This initial analysis can determine if, for example, it will be necessary to develop a specific assessment instrument for medical units and another for surgical units in the next phase.

After this initial analysis, the procedure to develop and validate the new instrument will be performed by adapting the proposal by Palese et al. (2016). Firstly, a conceptual evaluation will be made to obtain a representative battery of items from the original instruments. To this end, a nominal group made up of researchers and clinical nurses will assess the conceptual similarities and redundancies of both dimensions and items. The correlation between items and dimensions will also be studied, and linear regressions will be made to verify them. The Rasch technique will be applied to examine the opportunity of reducing items.

Secondly, the new instrument's content validity will be determined. A group of 20 experts will be formed. It will include clinical nurses with at least 10 years' experience, as well as university nursing teachers with a PhD degree and at least 10 years' teaching experience in fundamental nursing or medical-surgical nursing. This group will assess the suitability of the proposed items and dimensions. To do so, it will follow the methodology of Polit and Beck (2006) and will apply the Content Validity Index calculation (suitable validity if I-CVI ≥ 0.78).

Thirdly, the new instrument's construct validity will be established. For this purpose, the sample will be randomly divided into two subgroups, whose homogeneity will be verified by an inferential analysis (Efron & Tibshirani, 1997). With subgroup 1, an explanatory factor analysis will be run initially with varimax rotation in accordance with the maximum likelihood hypothesis. However, the technique with the best fit will be sought. Feasibility will be confirmed by the Kaiser–Meyer–Olkin (KMO) test and by Bartlett's test of sphericity. The theoretical structure of the instrument derived from the previous phase is expected to be replicated. Factorial loadings over 0.3 will indicate a good fit of the items in their dimensions. Next with subgroup 2, a confirmatory factor analysis will be carried out initially by the maximum

likelihood estimation technique. The goodness of fit will be evaluated by χ^2 (low values suggest a good fit), root mean square error of approximation (RMSEA, where <0.05 indicates a good fit) and the comparative fit index (CFI ≥ 0.97 denotes a good fit). The research team will also establish theoretical relations between the new instrument's different dimensions and items, which will be confirmed by structural equations models.

Fourthly, the new instrument's internal consistency will be verified with Cronbach's alpha ($\alpha < 0.7$ will be cautiously considered when removing items) (Ponterotto & Ruckdeschel, 2007). Finally, two researchers will pilot a sample of 50 patients to determine interobserver reliability by the intraclass correlation coefficient (suitable ICC values reach >0.61). The statistical analysis will be performed with software R, EQS and SPSS and significance level will be $p < 0.05$.

2.8 | Limitations, validity and reliability

The main study limitation lies in lacking a methodology for which a consensus has been reached to combine different assessment instruments as a single one. Notwithstanding, the proposal put forward is based on the scarce literature about the present research subject (Palese et al., 2016).

Another aspect to bear in mind is that this study is based on the recorded data taken from EHR, which means that data validity cannot be considered per se. This is due to a possible data bias related to the quality of nursing assessments, just as the literature points out (Asmirajanti et al., 2019; Bail et al., 2021; Charalambous & Goldberg, 2016). Thus, in the early project phase, meetings were organized to diffuse the project and informative posters were designed with a set message: REMEMBER, YOUR ASSESSMENT COUNTS!. Here, the objective is to remind nurses about the importance of making nursing assessments using the available instruments and encouraging them to avoid making incomplete, inconsistent or inaccurate assessments to get valid and reliable data.

Finally, limiting this project to two hospitals restricts the generalization of its outcomes. However, the risk of a selection bias is low because a large sample of participants is included, and the database is debugged by an atypical case study and by controlling the outcomes according to the different variables, such as process kind, hospitalization type or diagnosis, age and gender and being a positive COVID-19 patient.

3 | DISCUSSION

One of the main causes of adverse effects in hospitalization units is not having a suitable assessment (Levinson, 2010). Loss of functional capacity, pressure ulcers or falls are nursing-sensitive outcomes that depend on the availability of valid, reliable and sensitive assessment instruments and must also be accepted by nurses (Zega et al., 2014).

The administrative load that nursing assessments involve (Dunn Lopez et al., 2021) and the redundancy of these instruments lead to nurses' scepticism (Dante et al., 2015), which affects data quality, shortens the time spent on direct healthcare (Cooper et al., 2021) and influences the development of adverse effects (Gasperini et al., 2021).

Recent studies confirm that it is possible to reduce assessment times by revising the workflow of EHR (Karp et al., 2019; Swietlik & Sengstack, 2020). However, this does not appear to be sufficient and improving assessment contents is necessary (Guo et al., 2017; Topaz et al., 2017). Some authors have developed nursing assessments by expert consensus. For example, Zega et al. (2014) developed a nursing assessment to support the NANDA nursing diagnosis selection. However, it did not specify which patient type it targeted, and no later studies were found with its psychometric properties or about its repercussion on nursing assessment quality. Gray et al. (2018) developed a nursing assessment interRAI Acute Care with a nominal group. It showed good interobserver reliability (Boscart et al., 2020) and favourable results about the quality of the collected data. Nonetheless, there is no proof of it working any better than the original instruments for detecting risks and more than half of the interviewed nurses did not support the continuous use of this instrument (Peel et al., 2021).

These studies deal with a relevant problem by attempting to reach a consensus about the dimensions and items that a nursing assessment must contain. However, their authors consider neither the administrative load it represents for nurses nor the consequences of redundant and systematic assessments for patients. Palese et al. (2016) cover this problem using a theoretical exercise and a secondary analysis of the Italian ESAMED database. Its results suggest that it is possible to combine several assessment instruments. Nevertheless, its study population was formed by patients aged 65 years or older who were admitted to medical units. Thus, it did not reflect the real casuistics of hospitalization units. Despite these limitations, the methodology put forward by Palese et al. (2016) is useful for making progress in developing this type of assessment instruments, which was why it was considered for our project.

Furthermore, the appearance of a new disease caused by SARS-CoV-2 means that it had to be adequately considered while this project was performed. With every passing day, more characteristics and properties are known of not only this virus, but also of the disease that it causes. Nonetheless, no studies were found that have dealt with its relation to the appearance of adverse effects linked with hospitalization or care quality. For this reason, the present study will include a specific analysis to deal with any possible differences in the results obtained from the initial assessment about the risk of pressure ulcers, falls and functional capacity between positive and negative COVID-19 patients.

Finally, the intention of this project is to develop this new instrument and to study its psychometric properties (content validity, construct validity, reliability and intra- and interobserver reliability).

This study did not include a phase to assess the ability of the new instrument for the identification of patients at risk for functional decline or for clinical outcomes such as pressure ulcers or falls. It will also be necessary to determine its sensitivity, specificity and predictive capacity on different risks in future studies. It also opens up new research lines in relation to nursing assessments in hospitalization services and preventing adverse effects, which will also be applied to other areas, like home hospitalization or intensive care units once the appropriate modifications have been made. Other possible research lines are related to the time spent on care or nursing assessment quality. Bureaucracy is expected to be cut, which will allow nurses to spend more time on direct care, but future studies will have to confirm this.

4 | CONCLUSION

The nursing assessment is the first step of the nursing process and a fundamental one to detect patients' care needs and at-risk situations. Nurses use several different instruments to assess the risk of nursing-sensitive outcomes, such as loss of functional capacity, pressure ulcers or falls. These instruments share dimensions and items, which increase the administrative load and result in redundant and systematic assessments. We expect to obtain an instrument that reduces the administrative load of nursing assessments and allows at-risk patients to be detected, at least with the same validity and reliability as the original instruments.

AUTHOR CONTRIBUTIONS

All authors participated in the writing of the initial draft and in the review of the article. Likewise, all authors agree with the final version of this article.

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CONFLICT OF INTEREST

No conflict of interest is declared by the authors.

DATA AVAILABILITY STATEMENT

No data is available on this protocol.

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