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# TITLE

Individualization process of the standardized care plan in acute care hospitalization units: Study protocol

## **RUNNING TITLE**

Study protocol of standardized care plan individualization process

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### **CONFLICT OF INTEREST**

No conflict of interest has been declared by the authors.

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Made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;	MC, PD, MEJ
Involved in drafting the manuscript or revising it critically for important intellectual content;	MC, PD, MEJ
Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content;	MC, PD, IA,MEJ
Agreed to be accountable for all aspects of the work in ensuring that questions related to the acuracy or integrity of any part of the work are appropriately investigated and resolved.	MC, PD, IA,MEJ

## Abstract

**Aim.** To understand the individualization process of the standardized care plan that nurses design for hospitalized patients.

**Background.** To apply the nursing process, it is advisable to use standardized care plans to standardize the diagnosis, planning and assessment stages. However, the fundamental element of this methodology is the individualization of the care plan.

**Design.** A qualitative study, framed within the constructivist paradigm and applying the Grounded Theory method, in accordance with Strauss and Corbin's approach.

**Methods.** Multicentre study. Theoretical sampling with maximum variation will be used. The data collection will consist of: in-depth individual interviews, participant observation, document analysis, focus group, and the questionnaires for Critical Thinking Assessment in relation to clinical practice and Nursing Competency Assessment for hospital nurses. The qualitative data will be analysed according to the constant comparative method of Strauss and Corbin's Grounded Theory, which involves performing open, axial and selective coding. The questionnaire results will be used to make a qualitative analysis that will consist of a triangulation between the level of critical thinking, level of expertise and record of the individualization process performed by the nurses. This protocol was approved in July 2015.

**Discussion.** By knowing the possible stages used in the individualization of a standardized care plan, together with the elements that facilitate or hinder said individualization and nurses' attitudes and experiences regarding this phenomenon, it could help direct improvement strategies in the standardization and individualization process. In addition to recommendations for teaching and research.

### **Summary Statement**

### Why this study is needed?

- To administer patient-centred care, it is necessary to individualise the care according to a patient's needs, values and wishes.
- If the clinical reasoning and instrumental procedure carried out by the nurses is defined in the information system for individualizing the Standardized Care Plan, it could help us understand the individualization process and establish its stages.

• Knowing which factors condition the individualization process and the nurses' experience in relation to this process could be useful for establishing improvement strategies in the future.

**Keywords:** grounded theory, hospital, individualized care plan, nursing, nursing process, qualitative research, standardized care plan.

### INTRODUCTION

The nursing process is structured into five phases: assessing, diagnosing, planning, implementing, and evaluating the care (Alfaro-Lefevre, 2014). The diagnosing, planning and evaluation phases are recorded by using nursing care plans (Ballantyne, 2016). To encourage the use of these plans, in the 1980s and 1990s some workplaces started to develop Standardized Care Plans (SCP) (Hall *et al.*, 1995; LeBoeuf & Greco-Gallagher, 1987; Slota, 1984). The purpose of these SCP is to administer evidence-based holistic care that ensures basic care that reflects professional responsibility, despite the nurses' level of experience (Ballantyne, 2016). In recent years, these SCP have been entered into the databases of information systems implemented by different hospitals to computerise records, making it easier to access and exploit data (Juvé-Udina, 2013; Svensson, Ohlsson & Wann-Hansson, 2012).

Plan standardization means that healthcare practice can be standardized, it speeds up the process and reduces variability (Contreras-Fernández, 2000; Juvé-Udina, 2013). However, administering patient-centred care implies being able to individualize the care according to a patient's needs and those of their family (Köberich, Feuchtinger & Farin, 2016). The way nurses individualise the care, record it in the information system, experience it and the context in which they do it are questions that this study aims to answer.

In the last 30 years, nursing documentation has undergone an evolution that probably reflects the development of the discipline itself. This change has consisted in going from using a chart to monitor vital signs and the activities performed, to recording the decision-taking process (Björvell, Thorell-Ekstrand & Wredling, 2000). The nursing process has turned nurses' work into a systematic method that follows the reasoning of scientific methodology. Its application makes it easier to provide individualized care to avoid basing it on routine tasks (Björvell *et al.*, 2000; Giménez-Maroto & Serrano-Gallardo, 2009). Alfaro-LeFevre (2014) defines this process in five phases: Assessment, Diagnosis, Planning, Implementation and Evaluation.

To facilitate the implementation and recording of the diagnosis, planning and evaluation stages, it is recommended to standardize them by using Standardized Care Plans (SCP) (Ammenwerth *et al.*, 2001). According to Juvé-Udina (2012) a standardized care plan is: 'A structured summary of real problems and/or potential complications, together with the prescription of nursing interventions to achieve health results of a certain patient population (or groups)' (page 41).

SCP are used to establish common diagnoses for the same set of patients. For this reason, the selection of SCP is linked to the reason for admission (Ammenwerth *et al.*, 2001; Juvé-Udina, 2013).

It is advisable to use standardized nursing terminology for the elements that form the SCP structure. These terminologies are the structured representation of the phenomena that make up nursing knowledge and its use, and improve documentation content (Ammenwerth *et al.*, 2001; Carrington, 2012; Juvé-Udina, 2012).

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The individualization process is the fundamental element for working with SCP. This process consists in adapting the SCP to a patient's needs, according to the assessment on admittance and the subsequent re-evaluations required by their medical condition. The result is the application of an individualized care plan (Juvé-Udina, 2012). Failure to carry out this individualization can lead to the risk of only diagnosing expected, common problems (Carpenito, 2002). To facilitate individualization, it is convenient if the design of SCP in healthcare information systems (HIS) enables nurses to perform the process (Juvé-Udina, 2012).

Different studies show that nurses are satisfied with the use of SCP. They consider them manageable and, unlike free text, their structured content makes it possible to record the care planning in a more complete and relevant manner (Svensson *et al.*, 2012). However, some studies reveal difficulties or limitations in the SCP individualization process. These limitations can be at an organizational level, such as an unsuitable design of the HIS (Giménez-Maroto & Serrano-Gallardo, 2009; Harris, 1990) or a high patient-nurse ratio (O'Connell, Myers, Twigg & Entriken, 2000); at a professional level the limitations refer to a constant evolution of the patients' health condition (O'Connell *et al.*, 2000) and at an individual level, there are weaknesses in the nurses' diagnostic reasoning and care planning process (Giménez-Maroto & Serrano-Gallardo, 2009; Harris, 1990; Lee, Yeh & Ho, 2002; Müller-Staub, Lavin, Needham & Van Achterberg, 2006) combined with a lack of knowledge and professional experience (Fogelberg-Dahm & Wadensten, 2008) and insufficient skill for individualizing the SCP (Estrada & Dunn, 2012). Sometimes, the presence of these factors can lead to selecting the wrong SCP (Svensson *et al.*, 2012).

All stages of the nursing process require capacity of judgement or clinical reasoning. This judgement is a mental ability that enables a person to take the most appropriate decisions that help prevent and/or resolve problems in each one of the patients' situations. To develop it,

nurses need to be able to think critically, basing their thoughts on a series of skills and behaviours (Cerullo & Cruz, 2010). The more critical thinking evolves, the greater the ability will be to diagnose each person's specific problems (Bittencourt & Crossetti, 2013; Cerullo & Cruz, 2010; Giménez-Maroto & Serrano-Gallardo, 2009; Zuriguel-Pérez *et al.*, 2014a).

Benner (2004) transferred the model of adult skill acquisition developed by Stuart and Hubert Dreyfus to nursing practice (Dreyfus, 2004). This model consists in identifying and describing five levels of expertise based on experience and reflective practice that a nurse acquires through learning. The five levels are: novice, advanced beginner, competent, proficient, and expert (Benner, 2004). Experts are characterized by their high level of intuitive reasoning, coupled with a developed capacity for clinical judgement. An adequate combination of both enables nurses to make an accurate diagnosis, as well as plan and provide individualized care (Benner, 2000).

In their study, Papp *et al.* (2014) believe that the combination of advanced knowledge and expertise are probably associated to high level of critical thinking, which is necessary for acquiring different domains of competency. In this regard, no studies have been found that relate the level of critical thinking and professional expertise with the individualization of care.

Few studies propose or explain methods for individualizing SCP and they normally use a case study to make them easier to understand (Ammenwerth *et al.*, 2001; Castellà-Creus *et al.* 2011; Mayilvaganan, 2002). This study will provide new knowledge about how nurses individualize plans and explains which factors can influence the process.

### THE STUDY

### Aims

This research aims to understand the individualization process of standardized care plans carried out by nurses that care for hospitalized patients. The specific aims are:

- Describe the stages of the SCP individualization process used by nurses.
- Identify facilitators and barriers of the individualization process at an organizational, professional and individual level.
- Describe the meaning that nurses give to the individualization process of a standardized care plan.
- Explore the relationships between the record of the individualization process of a standardized care plan, degree of critical thinking and nurses' professional expertise.

### Methodology

A qualitative study framed within the constructivist paradigm. (Guba & Lincoln, 2000; Jayasekara, 2012). From an ontological angle, reality is perceived in a relativistic manner, in such a way that people build local and specific realities according to the situation. This study analyses the different realities that are built upon the individualization process. From an epistemological perspective, the researchers will be subjective in their approach towards the phenomenon, establishing interactions between the participants so the findings emerge as the investigation progresses (Ruiz-Olabuénaga, 2012). The methodology will be based on dialectics and hermeneutics (Appleton & King, 1997; Ruiz-Olabuénaga, 2012), which will make it possible to interpret the dialectic exchange established between the researchers and the participants, to create constructions that help obtain in-depth understanding of the individualization process.

The Grounded Theory method according to Strauss and Corbin's approach (2002) will be used, which includes the interpretive description of data, thus enabling the researcher to become involved in the analysis by way of a flexible process. In regard to the phenomenon under study, the researchers acknowledge that they are unaware of the variety of coexisting methods for individualizing a standardized care plan and the factors that could influence the process.

#### **Participants**

The participants will be nurses working in any one of the three hospitals involved in the study, who fulfil the following characteristics: a) more than six consecutive months working in the same unit; b) they work with electronic care plans; c) they work in a medical, surgical or medical-surgical acute care hospitalization unit; d) they have the following years of experience working in hospitals: between 6 months - 10 years,  $\geq 11$  years,  $\geq 18$  years and  $\geq 25$  years.

Theoretical sampling with maximum variation will be used to select the participants. Bearing in mind the type of hospitalization unit and the years of professional experience working in hospitals, there are 12 nursing profiles and a sample of participants between 36-48 (3 or 4 nurses per profile). However, as expressed by Strauss and Corbin (2002), due to the fact that this kind of sampling is sequential and cumulative, the definitive size of the sample is determined by the theoretical saturation of the data. At the researchers' request and according to the defined criteria, the nursing supervisors or super user nurses of information systems will ask nurses to participate in the study and then put the researchers in contact with them.

#### Setting

A multicentre study conducted in medical, surgical and medical-surgical units for adult patients in two metropolitan tertiary hospitals and one basic general hospital. One of the metropolitan hospitals began implementing a hospital information system (HIS) for nursing in 2007 and it is the only one of the three centres that previously worked with a paper-based SCP. The basic general hospital implemented a HIS in 2009 and the other metropolitan hospital in 2010.

The three hospitals fulfil accessibility criteria for the principal investigator. She works in one of the metropolitan hospitals and can easily reach the other two; she has key people who will provide her with the selection of participants and access to the units for the participant observation.

### Data collection

Step one. Individual in-depth interviews will be conducted (Doody & Noonan, 2013; Mitchell, 2015; Valles, 2007). The place, date and time will be agreed with the participants and all effort will be made to ensure they are held in a peaceful atmosphere with few interruptions. The interviews will last approximately one hour. To facilitate the analysis, they will be recorded in audio and then transcribed. To validate the content of the interviews, the person interviewed will be sent a full copy of the transcription in case there is anything that needs to be clarified. The interview script will be validated by a pilot interview with a nurse who works in one of the hospitals participating in the study. Depending on the outcome of said interview and as the analysis progresses, the script may be modified.

Step two. To be able to observe the possible situations expressed in the interviews and to analyse the context in which the nurses work, a participant observation will be conducted (Spradley, 1980; Atkinson & Hammersley, 1994). The nursing supervisor of the units where

the observation is performed will inform the nurses of the researchers' presence; she will tell them the general purpose of the observation but will not enter into specific details. During the observation, the researchers will be allowed a certain degree of interaction with the participants. Five three-hour observations will be conducted that will include one and a half hours before and one and a half hours after the change of shift, as well as five observations that will include full morning, afternoon and night shifts. The observations will be recorded in field notes. These annotations will be made following Schatzman and Strauss' observational, theoretical and methodological note model (1973).

In two of these observations there will be a second observer who will also take field notes, which will be analysed with those taken by the principal investigator.

Step three. A document analysis will be performed in order to obtain in-depth understanding of the real status of the level of SCP individualization (Andréu, 2001; Del Rincón *et al.*, 1995). An analysis will be made of the electronic care plans and progress notes written by the nurses caring for patients admitted to the hospitals participating in the study. A data collection template based on the system proposed by Mayan (2009) will be created and the following data will be recorded: 1) Adaptation of the SCP, selecting the reason for admission, 2) Addition or deletion of an actual or risk diagnosis in the SCP, 3) Addition or deletion of an intervention in the SCP and 4) Coherence of the care plan content with the progress notes.

Step four. A focus group will be held to validate the results of the interviews, participant observation and document analysis to obtain further information about themes where it is considered that data saturation has yet to be reached (Callejo, 2001; Jayasekara, 2012; Then, Rankin & Ali, 2014; Traynor, 2015). The group will be made up of between 10 and 12 nurses from the three hospitals, who have not participated in the interviews but fulfil the same selection criteria. It will be held in a meeting room of the head office of the three hospitals, after agreeing on the date and time with the participants. It will be recorded in audio and then

transcribed. The transcription will be sent by email to the participants so they can validate it. The principal investigator will act as a moderator following a script specially written for the occasion. Another researcher will assume the functions of an observer and will take notes of the conclusions of the subjects discussed and write down all the details that refer to nonverbal aspects of communication.

Step five. The nurses participating in the interviews will be given the questionnaires for Critical Thinking Assessment in relation to clinical practice (initials in Spanish: CuePC-AC) which establishes three levels of critical thinking: low for scores of < 329, moderate for scores between 329 and 395, and high for scores of > 395. The total value of Cronbach's alpha is 0.96 and the content validity index is 0.85 (Zuriguel-Pérez, 2014b). The nurses participating in the interviews and their supervisors will be given the Competency Assessment questionnaire for hospital nurses (initials in Spanish: COM-VA) which determines nurses' level of competency according to the mean score of the questionnaire completed by the nurse and the one completed by the supervisor. The levels of competency are: expert for a score of 10, proficient between 8-9, competent between 6-7, novice for a score of 5, advanced beginner between 3-4 and very poor between 0-2 (Juvé-Udina, 2007). Both questionnaires will be sent by email and the recipients will be asked to complete them and send them back to the principal investigator.

### Data analysis

The data will be analysed following Strauss and Corbin's Grounded Theory method (2002) where the data are collected and analysed simultaneously using constant comparison. The analysis will begin with the open coding of the interview transcriptions, participant observation field notes, data recorded on the document analysis template and finally the focus group transcription. These will be analysed by way of micro-analysis in order to isolate

concepts according to their meaning or action (conceptualisation), thus being able to link the participants' account with the phenomenon under study. An analysis will be made of the similarities and differences between the codes that emerge, grouping them together in categories and subcategories. Continuing with constant comparison, the axial coding will then be performed. Sentences will be used to match the categories to their subcategories, based on their properties and dimensions. The different actions, conditions and strategies related to the phenomenon of the individualization process will also be identified and the analysis will be supported by diagrams. Finally, the selective coding will be developed. A central category will be established, which will be matched to the rest of the categories by means of sentences that provide a logical and consistent explanation. To favour and understand the matching process, the theme of the story will be described and a diagram will be designed that represents the theoretical framework. In addition, any unfinished categories will be completed by reviewing the data or, if necessary, extending the theoretical sampling. If any 'negative case' is identified during this stage of analysis, its explanation will be included. This stage of the analysis will consider the memorandums drawn up during the research. The theoretical sampling will end when the saturation of the categories is reached according to their properties and dimensions and there is no further matching between them. The QRS\_Nvivo\_10 program will be used to assist in the data analysis. A descriptive analysis that will include frequencies and percentages will be made of the results obtained in the two questionnaires. In addition, a qualitative analysis will be performed that will consist of a triangulation between the level of critical thinking, level of expertise and the record of the individualization process carried out by the nurses, according to the following criteria of coherence (Table 1):

### **Ethical considerations**

The nurses will be invited to participate in the study voluntarily. Prior to the interviews or the focus group, the principal investigator will inform the participants verbally and in writing about the aims and the reason they have been selected. They will be asked to sign an informed consent to their inclusion in the study and the confidentiality of the data will be guaranteed in writing. To ensure anonymity, the participants in the interviews will be assigned a code number. The people in the focus group will choose a pseudonym, with which they will be identified. The field notes of the participant observation and the clinical accounts reviewed in the document analysis will be identified with an alphanumeric code. The participants will be told that they can leave the study whenever they wish, without having to explain the reason and without prejudice, and the principal investigator will be informed by email. All recordings will be destroyed at the end of the study and the documents generated will be kept safely for five years. Due to the fact the interviews will be held outside working hours, the participants will be given a gift voucher to spend in a well-known cosmetics and perfume shop to thank them for their availability. The participants will know nothing about the voucher beforehand. This project has been authorised by the Nursing Directors and the Clinical Research Ethics Committee of the participating hospitals (PI-15-089) and (PR234/15), as well as the Academic Committee of the university's doctoral programme.

### Rigour

This study will follow Guba and Lincoln's criteria for trustworthiness and authenticity (2000). In relation to credibility, the data collection and interpretation stages will be constantly alternated, and the latter will be explained with specific examples. As regards transferability, the results will describe the contexts where the phenomenon will be studied, and an explanation will be given of the participants' characteristics. For dependability, the

data collection and analysis will be explained in detail. To increase the rigour and richness of the study, a triangulation of researchers, data and data collection techniques will be employed. Regarding confirmability, in addition to the recordings of the interviews and focus group, memorandums will be recorded to help interpret the data, establish relationships between concepts and support the emergence of the central category. The content will include the researchers' thoughts, reflections and observations. In addition, the data will be validated by sending the transcriptions to the participants and checking the results with the participants of the focus group (Houghton, Casey, Shaw & Murphy, 2013; Koch, 1994).

The researchers will endeavour to maintain negotiated relationships throughout the whole process, without exercising any authority and applying crystallisation processes in the analysis so that the interpretation of the results reflects the plurality of all the voices, without omitting any participant (Moral-Santaella, 2006).

Likewise, as indicated by Calderón (2002), reflexivity will be applied to the entire analytical process to ensure that the researchers' knowledge and experience influence the results as least as possible.

### DISCUSSION

By knowing the possible stages used in the individualization of a standardized care plan, together with the elements that facilitate or hinder said individualization and the nurses' attitudes and experiences regarding this phenomenon, it would be possible to direct improvement strategies in the standardization and individualization processes and it would lead to the emergence of the need for specific training related to this process and establish improvement actions in the use of healthcare practice.

An improvement in the content of care plans, in such a way they reflect patients' problems, with care adapted to their individual needs, could help demonstrate nurses' healthcare

practice, articulate the decision-making process, improve communication between professionals and the continuity of the care. In addition, it would provide reliable data for care provision management and would be a good source of information for clinical research. Without forgetting that an appropriate plan individualization could improve the quality and safety of the patients' care.

### Limitations

This study is centred on three hospitals that share the same Information System and the same corporate model of nursing knowledge management. For this reason, the study covers hospitals with different healthcare levels with the aim of trying to find maximum variability within these characteristics. We will try to minimise the effects of the exclusion of the day hospitals where care plans are employed by carrying out a maximum variation sampling between hospitalization units and nurses, in order to explore the phenomenon from a diverse perspective. The nursing supervisors and super user nurses of information systems will have a key role as regards the participants' access to the study. Despite the fact that they will be given very precise instructions about the characteristics of the nurses that make up the sample, it must be borne in mind that they could possibly exercise some control over the selection of the participants.

## CONCLUSION

Within the Health Sciences, and nursing in particular, it is considered increasingly necessary to include patients when taking health-related decisions. Besides this characteristic, there is another that gives added value to the care we provide, which is caring for people in an individualized manner. This is the work philosophy that this project aims to study. Analyse the individualization of care by recording it will enable us to know how said individualization is carried out, to become aware of the resources and limitations nurses encounter when they devise it and to know what they think and their experiences of it. The results of this research could provide new knowledge about person-centred care models and improve patients' healthcare processes.

Author Contributions:

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE\*):

1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;

2) drafting the article or revising it critically for important intellectual content.

\* http://www.icmje.org/recommendations/

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TABLE FOR DEFINING QUALITATIVE COHERENCE				
LEVEL OF CRITICAL THINKING	LEVEL OF PROFESSIONAL EXPERTISE	INDIVIDUALIZATION RECORD	QUALITATIVE COHERENCE	
HIGH	PROFICIENT	YES	HIGH +++	
MEDIUM	PROFICIENT	YES	HIGH ++	
MEDIUM	COMPETENT	YES	HIGH +	
LOW	COMPETENT	YES	LOW +	
MEDIUM	COMPETENT	NO	LOW -	
MEDIUM	PROFICIENT	NO	LOW	
HIGH	PROFICIENT	NO	LOW	
LOW	COMPETENT	NO	HIGH -	

Accepted