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Nurses' protocol-based care decision-making: a multiple case study

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Abstract

Aim: To describe and explain nurses' protocol-based care decision-making.

Background: Protocol-based care is a strategy to reduce variability in clinical practice. There are no studies looking at protocol-based care decision-making. Understand this process is key to successful implementation.

Method: A multiple embedded case study was carried out. Nurses' protocol-based care decision-making was studied in three inpatient wards (medical, surgical and medical-surgical) of a university hospital in northern Spain. Data collection was performed between 2015 and 2016 including documentary analysis, non-participant observations, participant observations and interviews. Analysis of quantitative data involved descriptive statistics and qualitative data was submitted to Burnard's method of content analysis (1996). The data integration comprised the integration of the data set of each case separately and the integration of the findings resulting from the comparison of the cases. The *following the thread* method of data integration was used for this purpose. The SRQR guideline was used for reporting.

Results: The multiple embedded case study revealed protocol-based care decision-making as a linear and variable process that depends on the context and consists of multiple interrelated elements, among which the risk perception is foremost.

Conclusion: This study has allowed progress in protocol-based care decision-making characterisation. This knowledge is crucial to support the design of educational and management strategies aimed at implementing protocol-based care.

Relevance to clinical practice: Strategies to promote protocol-based care should address the contexts of practice and the ability of professionals' to accurately assess the degree of risk of clinical activity. Hence, it will promote quality of care, patient safety and efficiency in healthcare cost.

KEYWORDS

case study research, decision-making, nursing, protocol

1 | INTRODUCTION

The variability of clinical practice refers to 'those differences in the care process and/or in the outcome of the care of a specific clinical problem, between different providers or oneself, once the demographic, sociocultural, and health-status factors are controlled' (Lorenzo et al., 2000, p. 460). There is great variability in clinical practice between hospital areas, units and even professionals (Karnon et al., 2016; Kennedy et al., 2010; Wennberg, 2002). The variability of clinical practice is one of the main quality problems in health care, since it reduces its effectiveness, efficiency, accessibility and safety (Karnon et al., 2013; Oliva et al., 2009). In the United States, it has been estimated that eliminating the variability of clinical practice between hospitals could save 3,000 lives annually (Werner & Bradlow, 2006) and 30 million dollars (Karnon et al., 2013).

Efforts to reduce the variability of clinical practice through standardisation have had limited effectiveness (Kennedy et al., 2010). In addition, the standardisation of clinical practice has been criticised for restricting clinical judgement and professional autonomy, amounting to a barrier to the individualisation of care (Rycroft-Malone et al., 2010). Protocol-based care (PBC) is an alternative strategy to classic interventions to standardise clinical practice that proposes a reasoned use of the tools of standardisation of care in a way that facilitates the balance between standardisation and individualisation of care (Rycroft Malone et al., 2009). Although its impact on patient outcomes is still unknown, Rycroft-Malone et al. (2010) point out that PBC has the potential to improve the autonomy of nurses.

To develop PBC, professionals need to gather, interpret and evaluate data in order to choose an individualised alternative of action as close to evidence-based standards as possible (Rycroft Malone et al., 2009). This selection process called PBC decision-making is best understood with a practical example. Evidence-based protocols for bedridden patients prescribe frequent postural changes to provide comfort and prevent the onset of pressure ulcers. The application of PBC decision-making to this clinical situation would involve gathering, interpreting and evaluating data about patients' general status, skin health, resting and sleeping patterns to individualise the decision of how strictly to apply the protocol. Indeed, to space out postural changes further than prescriptively recommended could be the most beneficial course of action for a patient who is resting after a sleepless night of distress or pain. Understanding PBC decision-making is key to designing training programmes and organisational strategies that facilitate the implementation of PBC. In the light of the above, a study aimed at describing and explaining PBC decision-making was carried out.

1.1 | Background

No studies have described or explained PBC decision-making, but there is theory and knowledge about similar phenomena, such as clinical decision-making and decision-making in the standardisation

What does this paper contribute to the wider global clinical community?

- This study provides in-depth understanding of the process and nature of PBC decision-making.
- PBC decision-making is characterised as a linear and variable process that depends on the context and nurses' risk perception.
- Nurse managers and lectures could use this knowledge to design educational and management strategies directed at implementing PBC and subsequently at reducing the variability of clinical practice, enhancing care quality safety and efficiency.

of care. Theories on clinical decision-making coincide in defining this type of decision-making as a process aimed at choosing a course of action among alternative approaches to a clinical situation (Benner, 1982; Hammond, 1980, 1996; Lee et al., 2006). This process includes four phases: information collection, interpretation of information, the risk of harm/benefit weighing of alternatives and choosing a course of action regarding the use of protocols (Hancock & Easen, 2006; Johansson et al., 2009). The cognitive continuum theory (Hammond, 1996) suggests that how these phases play out depends on the complexity of the clinical situation. Likewise, it notes that their sequence is iterative, and some phase may be reconsidered when new information appears (Hammond, 1996).

Theories about clinical decision-making, as well as studies on decision-making in the standardisation of care, indicate that decision-making in relation to the use of protocols is influenced by the practical context (Hancock & Easen, 2006; Johansson et al., 2009; Thompson et al., 2004; Thompson & Dowding, 2009).

Studies on decision-making in the standardisation of care have further investigated the elements involved in this type of decision-making, suggesting that there are many elements that act in an interrelated way. Among these elements, the perceptions of knowing the patient and the risk of harming the patient seem to modulate decision-making regarding the standardisation of care (Dougherty et al., 2012; Hancock & Easen, 2006; Johansson et al., 2009).

1.2 | Aim of the study

The general objective of the study, to describe and explain PBC decision-making, was specified in four aims:

- Identify and describe the phases of PBC decision-making and their sequencing.
- Identify the elements that influence PBC decision-making.
- Examine the role played by each element in PBC decision-making.
- Explain how the elements that influence PBC decision-making are related.

TABLE 1 Protocol characteristics

Protocols	Frequency of use	Flexibility of application ^a	Degree of risk associated with their violation
Administration of blood products	++	–	++++
Prevention of falls	++++	+++	+++
Contact isolation	++	–	++
Hand hygiene	++++	–	++

Note: –: not possible; +: very low; ++: low; +++: moderate; and ++++: high.

^aPossibility of adaptation to different situations.

2 | METHOD

2.1 | Design

A multiple, embedded case study was carried out. This design allows the intensive research that is required for the clarification of complex and little-known phenomena, restricting the investigation to a small number of cases in which subunits of analysis can be observed, and using multiple sources of evidence. In addition, by promoting the analysis of phenomena in their real contexts, it allows to investigate their limits and their relationship with the different scenarios where they occur (Yin, 2014).

To conduct this study, theoretical propositions were established to guide the selection of the units and subunits of analysis and the collection, analysis, and integration of the data (Yin, 2014). These propositions can be reconsidered in light of the findings that emerge throughout the investigation to allow redirection if necessary. This is especially important when the phenomena investigated are novel and the propositions can only be elaborated based on tentative theoretical assumptions, as is the case with the present investigation. Specifically, three propositions were established based on the theory and available evidence on clinical decision-making and decision-making about the standardisation of care: (1) PBC decision-making depends on the organisational context and the type of protocol; (2) PBC decision-making is an iterative and variable process; and (3) PBC decision-making is made up of multiple interrelated elements. The formulation of these propositions was generic enough to allow the identification of new foci of inquiry but precise enough to facilitate the collection of data and allow inferences that considered the available knowledge.

Taking into account the focus and the limits of the phenomenon suggested by these propositions, the units and subunits of analysis were selected. The units of analysis consisted of three cases in which PBC decision-making could be investigated in various clinical and organisational contexts: PBC decision-making in a medical inpatient service (case A), in a surgical inpatient service (case B) and in a medical-surgical inpatient service (case C).

The selection of these cases also depended on their ability to enable the study of PBC decision-making with respect to four protocols: blood transfusion, prevention of falls, contact isolation and hand hygiene (Table 1). These protocols were selected for their disparity in terms of frequency of use, flexibility of application and

degree of risk associated with their violation. The establishment of these subunits of analysis in the different cases allowed us to examine to what extent variations in PBC decision-making were due to particularities of the protocols, other contextual factors or both.

The three hospital services where the selected cases were set were part of a private university hospital located in northern Spain. This hospital was selected as the study setting given its interest in the standardisation and individualisation of care and its size which was considered large enough to accommodate the units and subunits of analysis necessary to examine PBC decision-making.

2.2 | Sampling

Sampling, data collection and the first phase of data analysis (the individual analysis of the different groups of data of each case) occurred concurrently. The different sampling processes ran until data saturation was reached. Data saturation occurred when no new codes emerged from the data analysis performed by three researchers.

To identify and select relevant organisational documents, purposive and snowball sampling was used. This involved reviewing the Web and the institutional intranet as well as consultations with key informants. Nurses participating in the observations were selected by purposive sampling. To ensure they had had the opportunity to know and use the protocols investigated, the inclusion criterion was having worked at least 1 year in the hospital. Likewise, the nurses interviewed were selected by purposive and snowball sampling, with the same inclusion criterion of having worked at least 1 year in the hospital.

2.3 | Data collection

Data were collected between August 2015 and February 2016. The investigation of the selected cases, considering their subunits of analysis and contexts, required the collection of diverse data. As a result, documentary analysis, non-participant observations, participant observations and interviews were combined (see Table 2).

Documentary analysis was used to collect information on the formal planning of the organisational contexts and the protocols where PBC decision-making would be examined (Yin, 2014). Given

TABLE 2 Propositions and data collection methods

Theoretical propositions	Documentary analysis	Non-participant observations	Participant observations	Interviews
PBC decision-making is an iterative and variable process	X	X	✓ (Reflection in action regarding PBC decision-making)	✓ (Reflection on the action regarding PBC decision-making)
PBC decision-making depends on the organisational context and the type of protocol	✓ (Formal planning of organisational contexts and protocols)	✓ (Daily organisational context and practice)	✓ (PBC and Reflection in action regarding PBC decision-making)	✓ (Reflection on the action regarding PBC decision-making)
PBC decision-making is made up of multiple interrelated elements	X	X	✓ (Reflection in action regarding PBC decision-making)	✓ (Reflection on the action regarding PBC decision-making)

Abbreviation: PBC, protocol-based care.

that health organisations are modulated by the social processes that are generated in them, understanding their contexts requires looking beyond their formal planning and noting how these prescriptions are translated into daily practice. Therefore, to complete the inquiry proposed in the proposition: *PBC decision-making depends on the organisational context and the type of protocol*, observations were made in daily practice. First, non-participant observations were made on the way in which clinical activity, management and leadership, planning, and communication and collaboration occurred in the medical, surgical and medical-surgical inpatient services where PBC decision-making was being studied. The researcher limited herself to observing the study phenomena without modifying them, that is, he adopted the role of 'complete observer' (Gold, 1958). An observation guide prepared *ad hoc* and piloted was used, and field notes were collected.

Second, participant observations were made of the way in which nurses from the three services developed PBC with respect to the protocols for administration of blood products, prevention of falls, contact isolation and hand hygiene. PBC was considered to have occurred when nurses made appropriate use of protocols that, depending on the situation, sometimes implied following the protocols and other times implied skipping a step or not following them. The researcher adopted the role of the 'participant observer' in this case (Gold, 1958). In these observations, in addition to collecting descriptions of the use of these protocols and thus completing the exploration of the proposition: *PBC decision-making depends on the organisational context and the type of protocol*, the nurses were asked to explain the decision-making process that accompanied their action immediately after it took place. Through this exercise of *reflection in action* (Schön, 2011), data were collected free of memory biases to examine the research paths proposed by the propositions: *PBC decision-making is an iterative and variable process*, and *PBC decision-making is made up of multiple interrelated elements*.

To deepen the investigation of the aspects suggested in the above propositions: *PBC decision-making is an iterative and variable process*, and *PBC decision-making is made up of multiple interrelated elements*, elaborated explanations were required for how the PBC decision-making process occurred and what elements intervened in it. These explanations could only arise from a *reflection on the action* by their authors, the nurses. This type of reflection consists of evaluating what has been done in light of what is prescribed, pausing to analyse the causes or motives that have guided such action (Schön, 2011). Their exploration was carried out through interviews (Yin, 2014). A semi-structured guide was used that facilitated covering the topics of interest: what phases make up PBC decision-making, what is its sequencing and degree of variability, and what elements intervene in this process.

2.4 | Ethical considerations

The study participants received oral and written information emphasising their free participation, the confidentiality and anonymity of

the data and the use of the data only for scientific purposes. Written informed consent was obtained from each participant before beginning the interview. The investigation was approved by the Research Ethics Committee (code 146/2014).

2.5 | Data analysis

An integration of the different groups of data collected on PBC decision-making was carried out to *expand* the research, that is, 'to extend the breadth and range of inquiry by using different methods for different inquiry components' (Greene et al., 1989, p. 259). The *following the thread* method of data integration was used for this purpose. This method consists of examining each data set in light of a 'thread', or specific area of study, to generate a set of interrelated results for each of them (Moran-Ellis et al., 2004, 2006). In this research, each of the propositions of the study was used as a starting point to develop the *threads*. Each data set was examined in light of the propositions to discriminate the relevant findings for its exploration. Once catalogued and regrouped, the complementarity of the different findings was analysed to add them and thus develop a more complete argument that responded to each aspect of the research. As a multiple case study, the data integration comprised two phases: (1) the integration of the data set of each case separately and (2) the integration of the findings resulting from the comparison of the cases. To facilitate the integration of data, for each case and for the three cases together, the data were tabulated in matrices.

To achieve the integration of the data, the different groups of data of each case were analysed first. Descriptive statistics were used to analyse participants' sociodemographic characteristics and the rest of the quantitative data collected through non-participants observations. Frequency measures were calculated for the discrete variables, while measures of central tendency and dispersion were calculated for the continuous variables, using the statistical programme SPSS VS. 21.0.

The qualitative data were subjected to a content analysis following the Burnard method of qualitative analysis (1996). The initial phases of the analysis included comprehensive readings of the data set and the development of a system of categories that would allow to describe the units of meaning identified in relation to the phenomenon studied. This system of categories was revised and refined based on the identification of common patterns in the data. In this way, categories were ordered and regrouped into broader topics that allowed to describe and explain PBC decision-making. The software NVivo VS. 20 was used.

2.6 | Rigour of the study

The procedures used to ensure the rigour of the study were selected based on the criteria proposed by Riege (2003) (see Table 3). The Standards for Reporting Qualitative Research (O'Brien et al., 2014) guideline was used for reporting (Appendix S1).

3 | RESULTS

To frame the findings of the study, the characteristics of the sample and the context of the cases are provided. Then, the findings resulting from the integration of the data generated in the three cases for each proposition are presented, accompanied by the data source from which they emerged and illustrative citations. The documents and quotations data are codified by Doc with their correlative numbering; and by the case letter with the number assigned to the interviewed nurse, respectively.

3.1 | Sample characteristics

The documentary analysis included 21 documents (see Table 4). Non-participant observations involved 267 h of fieldwork (91 h, 88 h and 88 h in cases A, B and C, respectively), while participant observations reached 280 h (104 h and 358 events, 96 h and 333 events, and 80 h and 236 events in cases A, B and C, respectively). The 46 nurses involved in the observations, all women, had a mean experience in the service of 15 years (SD 6.2; 6–26 years) in case A ($n = 19$), 23.3 years (SD 4; 18–34 years) in case B ($n = 15$) and 16.15 years (SD 5.4; 8–24 years) in case C ($n = 12$). Interviews were conducted with 30 of the nurses who had been observed (data saturation was achieved after 13 interviews in case A, 8 in B and 9 in C).

3.2 | The contexts of the cases

In the institution in which the three cases are set, the two key aspects for the development of PBC were promoted: standardisation and individualisation of care (Doc1). The standardisation of care was one of the objectives of the strategic plan of the organisation to increase patient safety (Doc1) and had mechanisms for its implementation (Doc6, Doc7, Doc17, Doc18). The institutional strategy also advocated the individualisation of care (Doc1, Doc2).

Despite having a common strategic framework, both the local context and the development of PBC were different in the selected cases. In Table 5, the main characteristics of the cases' local contexts are summarised and confronted to reveal existing dissimilarities in terms of human resources, workload, supervisors' practices regarding monitoring or coaching and organisational climate issues, such as teamwork and the level trust in protocols.

Differences in the level of PBC development among the three cases become evident when comparing the pie charts included in Figure 1, where the events observed regarding the use of four protocols in each inpatient service have been graphically summarised. Pie charts illustrating the use of protocols in the medical inpatient service (case A) show that PBC was commonly developed in relation to all the investigated protocols (88 - 100% of events) but the one promoting hand hygiene (30.6% of events). In the surgical inpatient service (case B), pie charts describing the use of protocols regarding the administration of blood products and the prevention of falls also

TABLE 3 Procedures used for enhancing case study rigour

Criteria	Procedures
Confirmability Logical and impartial interpretation of data	<ul style="list-style-type: none"> • Use of multiple sources of evidence • Monitoring the chain of evidence and careful storage of data • Detailed and explicit description of research methods and procedures
Credibility Veracity of the results	<ul style="list-style-type: none"> • Supervision and discussion of data analysis, after reading the transcripts and individual identification of key topics. Presentation of the results to the relevant audiences • Performing semi-discovered participant observations, without the nurses knowing the protocols on which they were observed • Use of textual quotes from the transcripts to support the arguments • Systematic use of propositions to relate the elements
Transferability Applicability of results to similar contexts	<ul style="list-style-type: none"> • Use of the logic of replication, where the same propositions are supported in more than one case examined in another context • Detailed description of the study contexts and results so that transferability to other contexts can be evaluated
Trust Stability and consistency of the data	<ul style="list-style-type: none"> • Development of a protocol for the case study (pilot case study) • Development of a database for the case study • The use of clear research questions and proposals consistent with the characteristics of the study design • <i>Verbatim</i> recordings of the interviews • Peer review of data analysis and supervision of data analysis and integration. Discussion of methodological decisions

Source: Riege (2003), pp. 78–79.

point to an extensive development of PBC (77%–100% of events). However, PBC exercise decreased not only in observed events regarding the use of the hand hygiene protocol (41% of events) but also in the ones related to contact isolation (39% of events). In cases A and B, nurses followed PBC, usually individualising only actions related to protocols with flexibility of application and moderate degree of risk associated with their violation.

Finally, in case C, the development of PBC occurred only in situations in which the violation of protocols implied a severe risk for patients. Pie charts illustrating the use of protocols in the medical-surgical inpatient service show a drastic decrease of PBC events regarding the use of all protocols: the practice of PBC in the administration of blood products sinks by 50%, while, in the case of contact isolation and hand hygiene protocols, PBC events only represent the 14% and 2% of the total observed events, respectively. In these few PBC events, no instance of care individualisation was observed (see Figure 1).

3.3 | PBC decision-making is a linear and variable process

In the three cases when the instances of PBC analysed corresponded to routine clinical situations or during the application of protocols with high degree of risk associated with their violation, the PBC decision-making process was limited to three phases: gathering information, interpreting information and choosing a course of action. In cases A and B, the decision-making process regarding the use of protocols with flexibility of application and moderate degree of risk associated with their violation incorporated a fourth phase: the risk of harm/benefit weighing of alternatives. The PBC decision-making

process varied, expanding to incorporate the possibility of modifying the application of a protocol when the safety and well-being of the patient suggested it.

In these patients who (...) a postural change involves pain, alteration of the constants, anxiety (...) sometimes you decide to space the postural changes more, but then (...) hydrate more, put other measures to replace the postural change because sometimes (...) it is necessary to modify the protocol for the good of the patient, due to their circumstances.

(AE1)

In case C, it was not possible to observe whether the PBC decision-making process varied depending on the type of protocol, since PBC only occurred if the violation of protocols implied a severe risk to the patients. Moreover, the constant emergence of data discarding the iterative sequencing of the PBC decision-making phases advised the revision of the theoretical proposition set in the study to guide the examination of the PBC decision-making process. Its final modification as *PBC decision-making is a linear and variable process* enabled the research to progress in the direction suggested by the data.

In fact, whether the PBC decision-making process included three or four phases, these were said to follow each other linearly. Nurses' *reflection in action* and *on the action* brought up during participant observations and interviews revealed consistent explanations of the PBC decision-making process that commenced with the phase of data gathering. The latter was repeatedly qualified as extensive, foremost and catalytic for the remaining phases, which were described as occurring consecutively and in an orderly fast-paced sequence.

TABLE 4 Documents included in the documentary analysis

Code	Document	Source
Doc1	Hospital Strategic Plan (2011–2014)	Intranet
Doc2	Hospital presentation	Web
Doc3	Reception Process in a Department	Human Resources Department
Doc4	Job description of the Nurse Manager, Advanced Practice Nurse, and Clinical Nurse	Human Resources Department
Doc5	Leadership of the Organisation	Quality Department
Doc6	Quality Plan	Intranet
Doc7	Safety Plan	Intranet
Doc8	Programme for Risk Management	Intranet
Doc9	Methodology for continuous quality improvement	Intranet
Doc10	Annual goals of the service	Nurse Manager
Doc11	Nursing Staffing by services	Nursing Board
Doc12	Procedure to elaborate Procedures	Intranet
Doc13	Falls Prevention Protocol	Intranet
Doc14	Blood Products Transfusión Protocol	Intranet
Doc15	Hand Hygiene Protocol	Intranet
Doc16	Isolation Precautions Protocol	Intranet
Doc17	Surveillance and Control Plan for Nosocomial Infections	Intranet
Doc18	Annual Professional Development Plan	Intranet
Doc19	Performance Review Process	Human Resources Department
Doc20	Clinical activity record of the service	Admission Service
Doc21	Length of service record of the personnel of the service	Human Resources Department

TABLE 5 The local context of the cases

	Case A	Case B	Case C
Local context characteristics	Medical inpatient service	Surgical inpatient service	Medical-surgical inpatient service
Human Resources	Satisfactory	Sufficient	Insufficient
Workload	Satisfactory	Satisfactory	Overload
Supervision practices			
Monitoring of compliance with protocols	Timely Supported by a APN	Exhaustive Supervisor act as role model	Scarce and unmethodical
Coaching on the use of protocols	Delegated on a APN	By supervisor	Inexistent
Organisational climate			
Teamwork	Satisfactory	Satisfactory among nurses, conflictive with physicians	Inexistent
Trust in protocols	Generalised trust	Scepticism reinforced by lack of coordination with physicians	Distrust and contempt reinforced by peer pressure

Abbreviation: APN, Advanced Practice Nurse.

3.4 | PBC decision-making depends on the organisational context and the type of protocol

In the previous section, when detailing the findings regarding the variability of PBC decision-making, it has been explained how in cases A and B, it was observed that the type of protocol modulated

this phenomenon. In addition, in all three cases, data were obtained on how PBC decision-making was conditioned by the local context in which it took place. The way of performing coaching, the style of supervision and the organisational climate influenced the development of the PBC decision-making process and the elements that intervened in it.

In case A, the coaching exercised by the APN (Advanced Practice Nurse), contributed to improving the PBC decision-making process, allowing the improvement of the collection and interpretation of information and the risk of harm/benefit weighing of alternatives. In this way, coaching helped nurses to distinguish clinical situations in which individualisation or standardisation should have more prominence.

The advanced-role nurse (...) helps us understand each situation and that in that patient it is better to decide to follow the protocol, adapt it... or even not follow it.

(AE6)

Likewise, in cases A and B, where coaching was offered and a positive attitude towards protocols and a good relationship between nurses prevailed, the perception of risk was broader and more useful for PBC decision-making. The nurses not only appreciated risks that could cause severe and immediate damage to the patient but also considered those that could trigger moderate, mild or less explicit damage.

The effects can be terrifying if you do not do it, and that conditions you when deciding (...) If I leave my patient with a high bed and no bars (...) you see the effect that is so immediate and disastrous. On the other hand, if I do not wash my hands, nothing happens visibly (...) you do not see the bad effect that it can have from one patient to another (...) although we believe that there is risk...

(BE13)

3.5 | PBC decision-making consists of multiple interrelated elements

In the three cases, the interrelation of several elements in the development of PBC decision-making was observed, which underscores its multifactorial nature. Among them, the perception of risk is directly involved in PBC decision-making. This element was influenced by previous experiences of medical errors and the perception of personal responsibility for medical errors (see Figure 2).

The beliefs of the nurses about the possibility of exposing the patient to a risk as a result of not following the protocols and about the magnitude of the effect of that exposure decisively intervened in their PBC decision-making. When nurses perceived risk to the patient, they prioritised safety, opting to prioritise standardisation and leaving little room for individualisation.

What influences me the most when deciding (...) are (...) the consequences that it may have for the patient. The more serious you foresee the consequences to be if you stop doing something or do it wrong (...) the

more you decide for the patient's safety to follow the protocol 100%.

(AE3)

If you are going to do a cure or something sterile, you do decide to wash your hands (...) [because] it implies a risk of infection. (...) However, if you are going to give some pills, you don't wash yourself, because you're not going to touch the tubes nor to do cures, nor are you going to do anything in which (...) there could be a risk of infection.

(BE3)

In all three cases, the nurses explained that their previous experiences of medical errors associated with the misuse of protocols led them to be more aware of the risks and the importance of applying the protocols correctly.

We have lived here situations in the past... of not doing things...there were mistakes and confusion... in which we have had to rush with a transfusion, this also makes you aware (...) of taking extreme caution in those protocols because, the consequences can be fatal, it truly happens and we have to be cautious about it. Now it is inconceivable that you decide to transfuse blood without having verified many things...

(BE7)

In cases A and C, the perception of personal responsibility for medical errors was also identified as a factor that modulated the perception of risk. When nurses believed that the harm caused to the patient depended solely on their actions, they felt a greater responsibility for medical errors and thus a greater perception of risk. However, when they considered that the risks and damages to which patients were exposed could be generated by the actions of different professionals, nurses perceived less responsibility for them, and their risk assessment seemed to be attenuated.

If something important happens to the patient because I do not check the blood (...) it is directly because of me. There, you are more aware that if I do not check the blood (...) the patient can die....

(CE9)

I think that we are less aware of the bad effect it may have if you do not wash your hands between patients when it does not only depend on you (...), it depends on the actions of others (...), of the health workers who come to bathe him, of the assistants who lift him to the chair, of the doctor who comes to examine him.

(AE13)

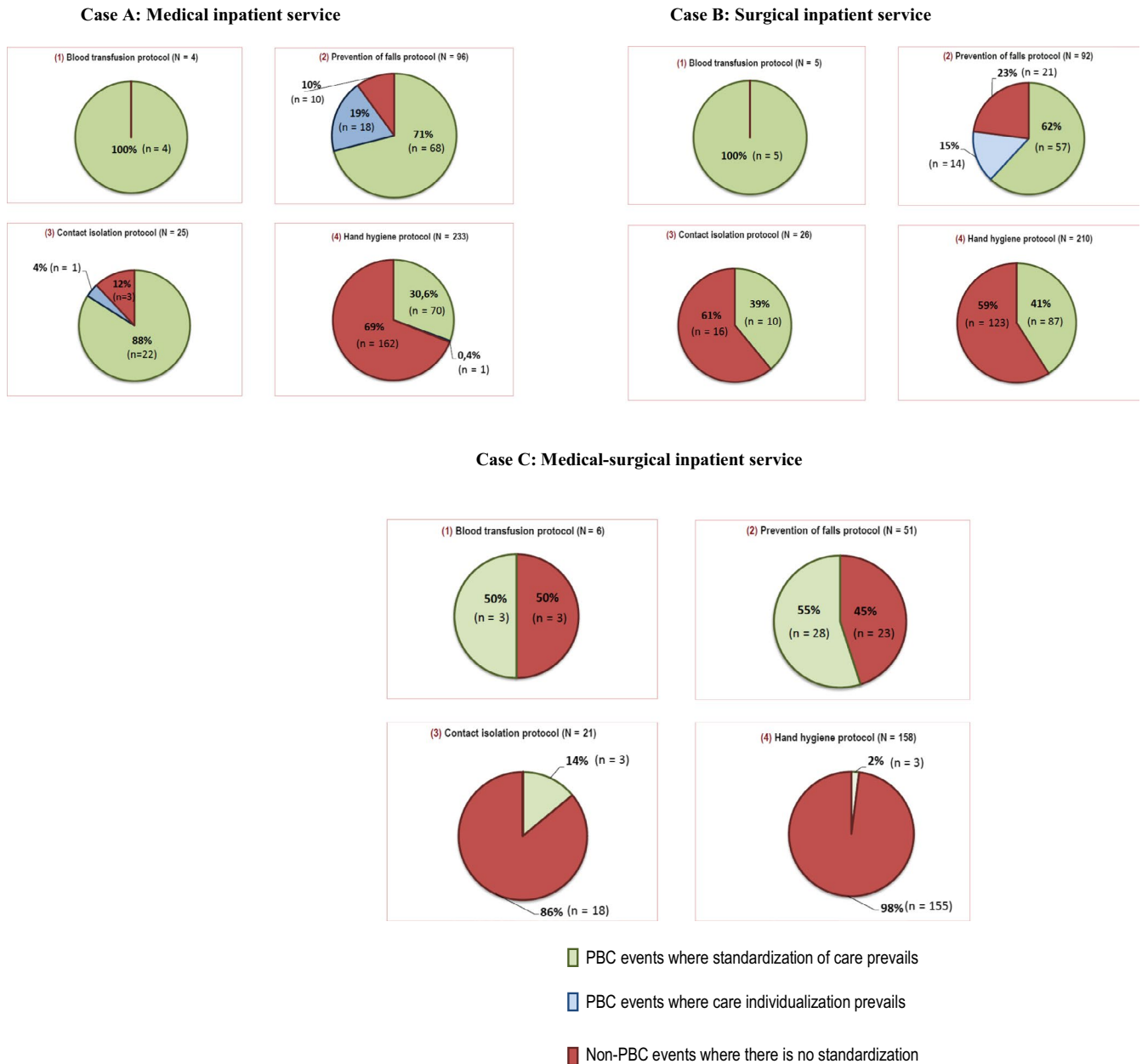


FIGURE 1 Events observed regarding the use of four protocols

4 | DISCUSSION

To the best of the authors' knowledge, this study is the first to generate knowledge about the process and nature of PBC decision-making. Its analysis in different contexts has characterised PBC decision-making as a linear and variable process that depends on the context and the perception of risk.

The linearity of this process has been reflected in the no repetitive sequencing of the phases and its variability in the incorporation of three or four phases. Thus, in situations that do not involve risk and the modification of protocols can result in greater well-being for the patient, the risk of harm/benefit weighing of alternatives is added to the phases of gathering information, interpreting information and

choosing a course of action. These findings partially coincide with the assumptions that defend clinical decision-making theories that can be classified as hypothetical-deductive (Lee et al., 2006). These theories defend the linearity of the process, but they also defend the invariable presence of four phases: gathering of information, interpretation of the information, the risk of harm/benefit weighing of alternatives and choosing a course of action. In this last aspect, the findings of the study are more assimilated to the decision-making scheme proposed in the cognitive continuum theory, where it is argued that health professionals extend and introduce more variables in decision-making when the clinical situation is not urgent and accurate information is available (Hammond, 1996). The findings of this study do not entirely coincide with any of the theories probably

because the approach from which decision-making is examined is PBC. PBC aims to simplify as much as possible the decision-making process regarding the use of protocols and incorporates a new decision criterion: individualisation (Rycroft-Malone et al., 2004; 2009).

These findings have interesting implications for the teaching of PBC decision-making. According to them, educators should make nurses aware of the variables that modulate the process: the degree of risk of a clinical activity and the availability of clues about how to optimise the patient's well-being. The training aimed at nurses who work in clinical contexts where care does not involve life-threatening choices should also dedicate an extraordinary space to learning the risk of harm/benefit weighing of possible alternatives, since the situations where the need to go through this phase will be more frequent.

In addition to helping to clarify the PBC decision-making process, the study investigated its context-dependent nature. Three contextual aspects especially relevant to the process of PBC decision-making were identified: the organisational climate, coaching and the type of protocol. The finding that suggests that the organisational climate shapes the predisposition of nurses to focus their decision-making from the perspective of PBC is in line with previous studies that reveal the influence of the organisational climate on the way nurses work (Aiken et al., 2013; Moreno-Casbas et al., 2018). The influence of particular aspects of the organisational climate, such as the attitude towards protocols and inter- and intra-professional relationships in the predisposition of professionals to balance the standardisation and individualisation of care, also echoes previous findings (Johansson et al., 2009; Manias & Street, 2000; Parker & Lawton, 2000).

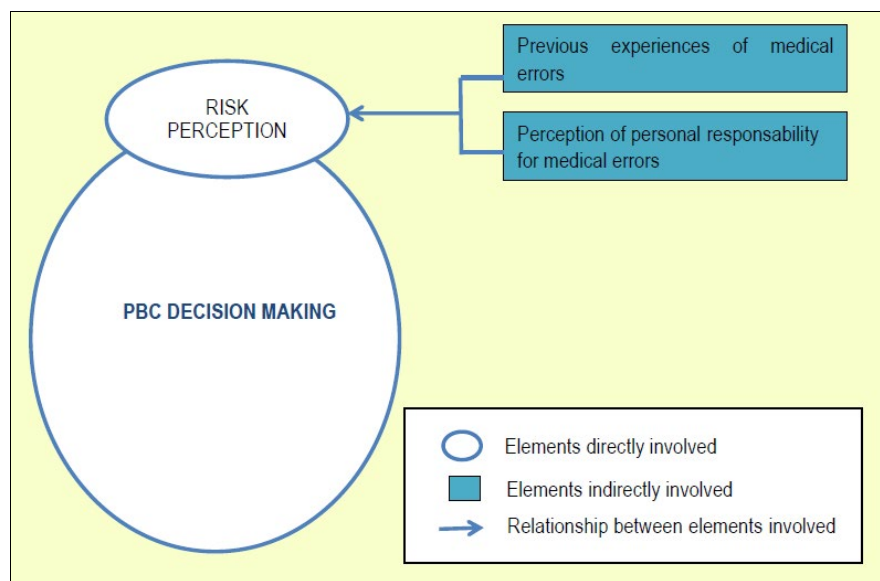
The finding that the provision of coaching in the practice environment favours that decision-making follow PBC is not surprising. Coaching facilitates self-reflection on the way work is done,

fostering a critical attitude. This critical attitude is fundamental for encouraging professionals to consider different alternatives of action and not to act automatically (Duff, 2013; Wallker-Reed, 2016). In the present study, coaching when offered by an APN was more effective. Previous studies have described the effectiveness of the APN's coaching when aimed at developing critical thinking and other skills for evidence-based nursing practice (Ervin, 2005; LaSala et al., 2007). The results of this study broaden this notion because for the first time, they relate the coaching offered by the APN to the improvement of decision-making processes that combine standardisation and individualisation of care.

The last contextual aspect that the present study identified as influential in the development of PBC decision-making, the type of protocol, is an especially novel finding. Decision-making regarding the use of protocols has not been examined from the perspective of PBC nor with respect to multiple protocols with varied characteristics.

In short, the findings on the context dependence of PBC decision-making imply that to design effective strategies for the promotion of PBC, the context in which it is applied must be taken into account. Specifically, they recommend intervening on the contextual aspects that influence PBC decision-making that can be modified, such as the organisational climate and coaching. The organisational climate should be characterised by the existence of positive attitudes towards the protocols, co-responsibility for their development and effective intra-/inter-professional work.

A final noteworthy finding of this study is the characterisation of PBC decision-making as a multifactorial phenomenon, in which the perception of risk is a central element. According to the findings of the study, the perception of risk decisively modulates PBC decision-making, directing it towards greater or less standardisation. White et al. (2015) report findings consistent with these, although



PBC: Protocol-Based Care

FIGURE 2 Elements involved in PBC decision-making and their relationship

with reference to a single protocol. In their telephone survey on nursing decision-making regarding the hand hygiene protocol, 2,378 nurses from 50 hospitals in Australia found that the perception of risk significantly predicted the decision to wash (White et al., 2015). White et al. (2015) and other authors (Dougherty et al., 2012; Johansson et al., 2009) who have theorised about the influence of risk perception in decision-making regarding the use of protocols have not delved into how the risk perception is configured. The later has been investigated for the first time in this study. This advance in the characterisation of the elements that modulate PBC decision-making is crucial to support the design of programmes for the introduction of PBC. For example, one aspect to consider to ensure their effectiveness is the way in which the two identified precursors of risk perception, previous experiences of medical errors and the perception of personal responsibility for the errors, will be handled to make them work in favour of PBC decision-making.

4.1 | Limitations

Given that this study was conducted in a Spanish hospital, the results are circumscribed by the corresponding cultural and health context. However, taking into account that the phenomenon has been examined in clinical contexts with different and detailed characteristics, the knowledge generated has sufficient depth to be compared with other similar contexts, which opens the door to analytical generalisation (Yin, 2014). To minimise possible subjectivity biases in data collection and analysis, the researchers systematised these processes by applying multiple control measures as can be seen in Table 3.

5 | CONCLUSION

This study has provided evidence on the linearity, variability, multifactorial and context dependence of the nursing PBC decision-making process, which has allowed progress in its characterisation. This knowledge, fundamental to support the design of educational and management strategies aimed at implementing PBC, should be reinforced with new case studies in disparate contexts. Preliminarily, it is proposed to develop multicomponent strategies, which simultaneously address the contexts of practice and the ability of professionals to accurately assess the degree of risk of a clinical activity and the availability of information on how to optimise the well-being of the patient.

CONFLICT OF INTEREST

The authors have no conflict of interest to declare.

AUTHOR CONTRIBUTIONS


MV-C; CO; LP; and MJP-M made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; involved in drafting the manuscript or revising it critically for important intellectual content; given final approval of the version to

be published and each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any of the work are appropriately investigated and resolved.

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