

Development of a Clinical Data Model Addressing the Nursing Focus “Anxiety”

A Consensus Development Study

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Anxiety disorders are among the most prevalent mental disorders worldwide. However, anxiety is not exclusive to anxiety disorders. In fact, the nursing discipline approaches anxiety as a human response to health conditions/life processes. Health information systems should primarily contribute to improving the quality of care, patient safety, and the effectiveness of care delivery. Nevertheless, nursing information systems still fail to incorporate evidence-based clinical data models addressing the nursing focus “anxiety.” Thus, this study aimed to obtain consensus on the data to be included in a clinical data model addressing the nursing focus “anxiety,” its organization, and its interrelationships by using a brainstorming session and a modified e-Delphi technique with a panel of nurse experts from across Portugal. Eight experts participated in the brainstorming session. A total of 59 and 54 participants completed the survey in e-Delphi rounds 1 and 2, respectively. Consensus was achieved to all data presented to the participants, and these data were later included in the clinical data model. This evidence-based clinical data model, grounded on a nursing theory and with standardized nursing language, will substantially contribute to nursing documentation and, consequently, to nursing care targeted at patients with anxiety.

KEY WORDS: Anxiety, Consensus development, Nursing informatics, Nursing process, Nursing records

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The Institute for Health Metrics and Evaluation¹ reported in their flagship report “Global Burden Disease” that, in 2017, anxiety disorders were the most prevalent mental disorders worldwide, affecting 284 million people (approximately 3.8% of the global population). Consequently, in 2015, anxiety disorders led to a global total of 24.6 million years lived with disability.²

However, anxiety is not exclusive to anxiety disorders. For instance, a worldwide survey reported that 45.7% of individuals with lifetime major depressive disorder had a lifetime history of one or more anxiety disorders and, of the individuals with a primary depression diagnosis in the Netherlands Study of Depression and Anxiety, 67% had a current and 75% had a lifetime comorbid anxiety disorder diagnosis.^{3,4} Importantly, anxiety as a symptom is different from anxiety as a psychiatric disorder,⁵ the first being even more prevalent.

In the nursing discipline, anxiety is approached as a human response to health conditions/life processes.⁶ According to the most relevant nursing taxonomies (NANDA International Inc and International Classification for Nursing Practice [ICNP]), anxiety is defined as a vague and unsettling feeling of discomfort or threat accompanied by an autonomous response (the origin of which is often unspecific or unknown to the person), feeling of apprehension caused by anticipation of danger, a red flag that warns of imminent danger and allows the person to take action to deal with the threat,⁶ or a feeling of threat, danger, or distress.⁷ Anxiety is a normal reaction to many different kinds of life events, but when it becomes overwhelming or unmanageable, it can lead to a nursing diagnosis.⁶

Health information systems should primarily contribute to improving the quality of care, patient safety, and the effectiveness of care delivery.⁸ Backend data of nursing information systems, which refer to parts of those nursing information systems’ code that allow them to operate and that cannot be accessed by the user, should be based on the International Organization for Standardization (ISO) standard 18104:2014.⁹ However, the analysis of nursing information systems shows that this important standard for the quality of care is not always followed.¹⁰

In the nursing discipline, clinical data models provide evidence-based data elements related to nursing care¹¹ and

allow structuring all the information related to a given concept.¹² A nursing clinical data model allows the systematization of the connections between the elements of the nursing process - data, diagnoses and interventions - for a given nursing focus. The development of clinical data models might be highly beneficial to guarantee the adoption of the ISO standard 18104:2014 and enhance its potential usefulness based on a decision support system.¹³

It is well known that anxiety symptoms often co-occur with depression and other mental health disorders.¹ Moreover, there is a crescent need to better organize backend data of nursing information systems, following the ISO standard 18104:2014, but, most importantly, to improve the quality of care. In line with this impending reality, this study sought to develop a clinical data model addressing the nursing focus “anxiety.”

The nursing taxonomy/classification ICNP was used to develop this clinical data model because (1) it is in line with the ISO standard 18104:2014¹⁴; (2) it is integrated, as a related classification, in the World Health Organization Family of International Classifications¹⁵; and (3) it is the taxonomy that is currently used in nursing information systems in Portugal.¹⁶ Indeed, in Portugal, since 2005, nurses record nursing diagnoses and nursing interventions through the nursing information systems of the Ministry of Health, based on the nursing process and the ICNP standardized language. These information systems allow the identification of nursing diagnoses and nursing interventions addressing these diagnoses.¹⁷ Thus, Portuguese nurses, including clinical nurses, have more than 15 years of experience in using ICNP standardized language to document their practice in nursing information systems. In deciding on the best nursing theory to adopt, this study researchers examined the ISO standard 18104:2014—more directed to the concept of “potential”—¹⁴ and the Meleis' transitions theory¹⁸ that aids in early interventions (nursing therapeutics), addressing the personal conditions that may facilitate or hinder the processes of healthy transitions and focuses on ways to help patients cope with the new norm. Thus, the Meleis' transitions theory was found to best fit the purposes for developing of the clinical data model.

Before this study, we conducted a scoping review to map the literature on data, diagnoses, and interventions addressing the nursing focus “anxiety.”¹⁹ The findings of that scoping review pointed out, for example, that certain characteristics of anxiety, such as the cognitive and somatic data, should be assessed. Moreover, the findings indicated that some interventions seem to be particularly relevant for patients with anxiety, such as educational or music-based interventions. Thus, this study aimed to obtain consensus on the data to be included in a clinical data model addressing the nursing focus “anxiety,” its organization, and its interrelationships.

MATERIALS AND METHODS

Study Design

This study used a brainstorming session²⁰ and a modified e-Delphi technique.²¹ The Guidance on Conducting and Reporting Delphi Studies (CREDES checklist) was used to report the second stage of the study.²²

In a classical Delphi, round 1 starts with an open-ended set of questions, allowing free responses.²¹ However, because a scoping review¹⁸ and a brainstorming session were conducted before round 1, a structured questionnaire was used in the modified e-Delphi round 1.

Panel Selection and Eligibility

Regarding sample sizing, the brainstorming session followed the same recommendations of focus groups sessions.²³ According to those recommendations, the sample should include between five and eight experts on the topic. All the participants had to be mental health nurses; to analyze contrasting options, nurses of different ages were recruited, comprising a mix between nurses working in clinical settings and nursing professors.

Purposive sampling was used in this step of the study to ensure the abovementioned conditions were met. A list of 10 potential participants was prepared by the researchers. Oversampling was performed to compensate for expected experts' refusal to participate in the study.

There is still no consensus about the ideal sample size for Delphi studies, as it should be determined by the purpose of the study, selected design, and time frame for data collection.^{21,24,25} Thus, this study aimed to gather at least 50 panel members in each round.

All participants had to be mental health nurses, and purposive sampling was used in this step of the study to recruit participants from across Portugal. The inclusion criteria regarding registered nurses working in clinical settings were (1) having, at least, a master's degree; (2) a minimum of 5 years of professional experience; and (3) experience in nursing documentation using electronic health records (preference criterion). Criteria for nursing professors were (1) having, at least, a doctor's degree; (2) a minimum of 10 years of professional experience; and (3) experience of using or teaching contents related to the nursing process.

A list of 70 potential participants was compiled by the researchers. Oversampling was performed to compensate for expected experts' refusal to participate in the study.

Brainstorming Session

Due to the COVID-19 outbreak, the brainstorming session was held online on September 26, 2020, using the Zoom software, which lasted 120 minutes. The purpose of this session was to gather ideas about data addressing the nursing focus “anxiety,” its organization, and its interrelationships.

In the first half of the session, we used a questioning route composed of predetermined questions and related to three specific topics, namely, nursing diagnoses that derive from the focus “anxiety,” data that can lead to those diagnoses, and nursing interventions that can positively address nursing diagnoses in the anxiety domain. In the second half of the session, an analysis was performed on the findings of the scoping review¹⁸ that was previously carried out. According to that scoping review, whose aim was to map the body of literature on data, diagnoses, and interventions addressing the nursing focus “anxiety,” for instance, data that lead to nursing diagnoses in the anxiety domain can be divided into cognitive and somatic data, and some interventions, such as educational and music-based interventions, seem to be useful to address nursing diagnoses in the anxiety domain. The experts were asked to add the gathered ideas to the findings of the scoping review and organize and establish relations between data.

Round 1

The data collection of the modified e-Delphi round 1 was carried out between November 2 and November 16, 2020, using an online questionnaire. If eligibility criteria were met, experts were emailed a link to the URL for the first questionnaire.

The research team first drafted the clinical data model based on the findings of the scoping review and the ideas gathered in the brainstorming session. Afterward, round 1 was used to obtain consensus on the organization of the elements of data and established interrelationships regarding the nursing focus “anxiety.” The questionnaire consisted of 39 close-ended statements. Participants were asked to rate agreement through a 4-point Likert scale.²⁶ Although round 1 already aimed to obtain some consensuses, participants could use the free-text section to clarify their answers or to suggest changes. Three members of the research team (F.S., P.G., and C.S.) met and reviewed suggestions from the expert panelists. Suggested changes from the expert panel were entered into the list of statements and used in the subsequent round.

The questionnaire was pretested with an evaluation panel of three clinical nurses and three nursing researchers. The structure, content, and wording of the questionnaire were revised based on the panelists' feedback.

Round 2

The data collection of the modified e-Delphi round 2 was carried out between November 27 and December 11, 2020. The purpose was to obtain consensus on the organization of the elements of data and type of interrelationships regarding the nursing focus “anxiety.”

Data were collected using an internet-based questionnaire developed using the first-round results.²⁷ It consisted of 40 close-ended statements generated from the first-round data

analysis. Participants were asked to rate their level of agreement with the statements.²⁶

Data Analysis

Data from the brainstorming session were analyzed using the listing ideas technique. Thus, as recommended by this technique, the items that emerged from the brainstorming session were listed in a spreadsheet and were numbered and analyzed sequentially as they were generated (by two members of the research team [F.S. and P.G.]).²⁸ Later, three members of the research team (F.S., C.S., and T.L.C.) reviewed those ideas, converted them into ICNP standardized language following the Meleis' transitions theory, and combined them with the findings of the previously conducted scoping review. This aimed to guarantee that the experts' opinions were expressed using the ICNP standardized language and they could be embodied in Meleis' transitions theory (both premises for the development of the clinical data model). In addition, it aimed to guarantee that there were no inconsistencies between the experts' opinions and the findings of the scoping review.

After rounds 1 and 2, mean scores were obtained for each statement, and the participants' comments were reviewed by three members of the research team (F.S., P.G., and C.S.). In this study, a consensus was reached if more than 70% of the panel members' responses were rated within 2 points on the Likert scale (minimum level of agreement).²⁰ Consensus was assessed after rounds 1 and 2.

Ethical Considerations

This study was conducted under the principles of the Helsinki Declaration and subsequent amendments.²⁹ Approval for this study was obtained from the scientific committee (responsible for the ethical evaluation of research projects) of the Portuguese Society of Mental Health Nursing (ASPESM/030920).

RESULTS

Brainstorming Session

From the 10 potential professionals invited, eight accepted to participate in the brainstorming session. All the participants were mental health nurses; five worked in clinical settings, and three were nursing professors, aged between 31 and 55 years, with an average age of 42 years. Five of the participants held a master's degree, and three had a PhD. The years of professional experience ranged between 7 and 33 years, with an average of 19 years. All the participants had theoretical or practical experience in using the nursing process.

The ideas gathered from the brainstorming session were outlined as follows: (1) the manifestations of anxiety should be divided into cognitive, emotional, physical/somatic, and behavioral; (2) the data directly leading to the nursing diagnosis “anxiety” is “the person manifests cognitive or emotional

anxiety symptoms, accompanied by functional impairment”; (3) the additional data potentially leading to the nursing diagnosis “anxiety” are “the person manifests, either verbally or by observation, physical/somatic and behavioral anxiety symptoms” and “other data related to the person’s potentiality to manage anxiety”; (4) the clinical data model should comprise nursing diagnoses and interventions from two different domains: addressing anxiety as a problem the patient has no potential to address by himself or herself, and addressing anxiety as a problem the patient has the potentiality to address by himself or herself; (5) diagnoses related to the person’s potentiality should be included in the clinical data model (eg, “potentiality to improve anxiety self-control”); (6) interventions involving music, art, relaxation techniques, or spiritual support should be linked to the nursing diagnosis “anxiety”; (7) the use of cognitive-behavioral techniques are important interventions to address nursing diagnoses in the anxiety domain but should be specified.

Three members of the research team (F.S., P.G., and C.S.) reviewed all the gathered ideas. They made some considerations, mainly stressing the need to follow the principles of the Meleis’ transitions theory and the findings that emerged from the scoping review, which was previously carried out: (1) literature tends to divide anxiety symptoms into two domains—cognitive and somatic.^{30,31} However, emotional features are frequently included in the cognitive domain, and behavioral features are included in the somatic domain. Thus, the manifestations of anxiety were divided into cognitive/emotional and somatic/behavioral. (2) The data that can directly lead to the nursing diagnosis “anxiety” presented two different ideas—manifestations of anxiety and functional impairment. Thus, they were divided into two data: “the person verbalizes anxiety symptoms” and “functional impairment related to anxiety.” (3) The “additional data” concept would be difficult to manage in a clinical data model, as we found no literature that specified which data combination could lead to the nursing diagnosis “anxiety.” Therefore, data were converted into “data that characterize the diagnosis,” including cognitive/emotional and somatic/behavioral manifestations of anxiety. (4) To divide the clinical data model, at the level of the nursing diagnoses and interventions, in two domains: addressing anxiety as a problem the patient has no potentiality to address by himself or herself, and addressing anxiety as a problem the patient has the potentiality to address by himself or herself (transition process). This is totally in line with Meleis’ transitions theory, in which nursing care is different when approaching potential problems that individuals are likely to encounter if they are not properly prepared for a transitional experience (role insufficiency) and when they are prepared for the transition (role supplementation).¹⁸ (5) To include the nursing diagnoses “potentiality to improve the awareness about risk factors for

anxiety,” “potentiality to improve the awareness about the relationship between self-control strategies and anxiety reduction,” “potentiality to improve the knowledge about anxiety,” “potentiality to improve the ability to use strategies for anxiety self-control,” and “potentiality to improve the meaning attributed to the threat” in the clinical data model. (6) To include

Table 1. Demographic Characteristics of the Participants

Characteristics	Round 1	Round 2
	n (%)	n (%)
Sex		
Female	37 (62.70)	32 (59.30)
Male	22 (37.30)	22 (40.70)
Academic degree (clinical nurses)		
Master’s degree	29 (85.30)	27 (90.00)
PhD	5 (14.70)	3 (10.00)
Academic degree (nursing professors)		
PhD	25 (100.00)	24 (100.00)
Professional setting		
Clinical practice	34 (57.60)	30 (55.60)
Education	25 (42.40)	24 (44.40)
Postgraduate training in the nursing process		
Yes	37 (62.70)	34 (63.00)
No	22 (37.30)	20 (37.00)
Experience in nursing documentation using electronic health records (clinical nurses)		
Yes	31 (91.20)	27 (90.00)
No	3 (8.80)	3 (10.00)
Experience in using or teaching contents related to the nursing process (nursing professors)		
Yes	25 (100.00)	24 (100.00)
	Mean (SD)	Mean (SD)
Age	45.17 (9.79)	44.65 (9.36)
Years of professional experience (clinical nurses)	17.50 (6.32)	17.07 (6.17)
Years of professional experience (nursing professors)	28.92 (9.43)	27.29 (8.26)
Years of professional experience as a mental health nurse (clinical nurses)	9.24 (5.15)	8.83 (4.88)
Years of professional experience as a mental health nurse (nursing professors)	20.56 (10.10)	19.13 (9.78)

Table 2. Results of Rounds 1 and 2

#	Statement	Round 1			Round 2		
		Level of Agreement, %	Mean	SD	Level of Agreement, %	Mean	SD
1	“The person verbalizes anxiety symptoms”—data potentially leading directly to the nursing diagnosis “anxiety” (round 1)	98.30		0.39	—	—	—
	“The person verbally expresses anxiety, spontaneously or when questioned”—data potentially leading directly to the nursing diagnosis “anxiety” (round 2)	—		—	98.10	3.74	0.48
2	“Functional impairment related to anxiety”—data potentially leading directly to the nursing diagnosis “anxiety” (round 1)	96.60	3.83	0.53	—	—	—
	“The person manifests a functional impairment related to anxiety”—data potentially leading directly to the nursing diagnosis “anxiety” (round 2)	—	—	—	100.00	3.94	0.23
3	“Cognitive and/or emotional signs and anxiety symptoms (eg, feeling worried, feeling scared, being close to panic, finding it difficult to relax, being afraid, feeling nervous)—data characterizing the nursing diagnosis “anxiety” (round 1)	100.00	3.88	0.33	—	—	—
	“Verbalization and/or observation of cognitive and/or emotional signs and anxiety symptoms (eg, impaired concentration, psychological suffering, anguish, feeling worried, feeling scared, being close to panic, feeling it difficult to relax) and its frequency”—data characterizing the nursing diagnosis “anxiety” (round 2)	—	—	—	98.10	3.89	3.89
4	“Somatic and/or behavioral signs and anxiety symptoms (eg, tension, difficulty breathing, shaking hands, resting difficulty, dry mouth, increased heart rate, and/or feeling the heart failing)—data characterizing the nursing diagnosis “anxiety” (round 1)	100.00	3.93	0.25	—	—	—
	“Verbalization and/or observation of somatic and/or behavioral signs and anxiety symptoms (eg, muscle tension, dyspnea/polypnea, tremor, resting/sleeping difficulty, xerostomia, tachycardia, palpitations) and its frequency”—data characterizing the nursing diagnosis “anxiety” (round 2)	—	—	—	100.00	3.93	0.26
5	“Severe cognitive impairment”—a condition potentially inhibiting the transition process	95.00	3.78	0.53	100.00	3.94	.23
6	“Severe concentration impairment”—a condition potentially inhibiting the transition process	96.60	3.73	0.52	98.10	3.70	.50
7	“Lack of motivation to change”—a condition potentially inhibiting the transition process	93.20	3.63	0.61	94.50	3.59	.66
8	“Severe positive symptoms”—a condition potentially inhibiting the transition process	94.90	3.61	0.64	96.30	3.70	.60
9	“Confusion state”—a condition potentially inhibiting the transition process	100.00	3.88	0.33	100.00	3.96	.19
10	“Psychomotor agitation”—a condition potentially inhibiting the transition process	95.00	3.75	0.54	100.00	3.89	.32
11	“Latent aggression”—a condition potentially inhibiting the transition process (round 1)	94.90	3.56	0.65	—	—	—

(continues)

Table 2. Results of Rounds 1 and 2, Continued

#	Statement	Round 1			Round 2		
		Level of Agreement, %	Mean	SD	Level of Agreement, %	Mean	SD
12	“Hostility”—a condition potentially inhibiting the transition process (round 1)	93.2	3.53	0.68	—	—	—
	“Aggressive behavior”—a condition potentially inhibiting the transition process (round 2)	—	—	—	98.1	3.76	0.55
13	“Awareness about the risk factors for anxiety”—data characterizing the transition process	100.00	3.93	0.25	100.00	3.94	0.23
14	“Awareness about the relationship between self-control strategies and anxiety reduction”—data characterizing the transition process	100.00	3.97	0.18	100.00	3.93	0.26
15	“Knowledge about anxiety”—data characterizing the transition process	100.00	3.78	0.42	100.00	3.81	0.39
16	“Ability to use anxiety self-control strategies”—data characterizing the transition process	100.00	3.92	0.28	100.00	4.00	0.00
17	“Meaning attributed to the threat”—data characterizing the transition process	100.00	3.76	0.43	100.00	3.87	0.34
18	“Anxiety” should be the nursing diagnosis when selecting an intervention that aims to reduce/solve the problem	98.30	3.86	0.47	100.00	3.98	0.14
19	“Potentiality to improve the awareness about risk factors for anxiety”—a potential nursing diagnosis when selecting an intervention aimed at empowering the person to be able to function to his or her full capacities	100.00	3.88	0.33	100.00	3.93	0.26
20	“Potentiality to improve the awareness about relationship between self-control strategies and anxiety reduction”—a potential nursing diagnosis when selecting an intervention aimed at empowering the person to be able to function to his or her full capacities	98.30	3.85	0.41	100.00	3.93	0.26
21	“Potentiality to improve the knowledge about anxiety”—a potential nursing diagnosis when selecting an intervention aimed at empowering the person to be able to function to his or her full capacities	98.30	3.80	0.45	100.00	3.87	0.34
22	“Potentiality to improve the ability to use anxiety self-control strategies”—a potential nursing diagnosis when selecting an intervention aimed at empowering the person to be able to function to his or her full capacities	100.00	3.93	.25	98.20	3.94	0.30
23	“Potentiality to improve the meaning attributed to the threat”—a potential nursing diagnosis when selecting an intervention aimed at empowering the person to be able to function to his or her full capacities	98.30	3.69	0.50	100.00	3.85	0.36
24	“Performing distraction activities (eg, music, art, spiritual)—an intervention potentially useful to address the nursing diagnosis “anxiety” (round 1)	96.60	3.73	0.58	—	—	—
	“Planning distraction activities (eg, music, art, reading, cinema, spiritual)—an intervention potentially useful to address the nursing diagnosis “anxiety” (round 2)	—	—	—	100.00	3.85	0.36
25	“Performing relaxation techniques (guided imagery, diaphragmatic breathing, muscle relaxation)—an intervention potentially useful to address the nursing diagnosis “anxiety”	100.00	3.93	0.25	98.20	3.94	0.30
26	“Performing active listening”—an intervention potentially useful to address the nursing diagnosis “anxiety” (round 2)	—	—	—	100.00	3.87	0.34

(continues)

Table 2. Results of Rounds 1 and 2, Continued

#	Statement	Round 1			Round 2		
		Level of Agreement, %	Mean	SD	Level of Agreement, %	Mean	SD
27	“Assessing anxiety progress”—an intervention potentially useful to address the nursing diagnosis “anxiety”	94.90	3.83	0.56	98.10	3.93	0.33
28	“Assisting the patient to identify risk factors for anxiety”—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the awareness about risk factors for anxiety”	98.30	3.88	0.38	100.00	3.94	0.23
29	“Assessing the progress of the awareness about risk factors for anxiety”—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the awareness about risk factors for anxiety”	96.60	3.83	0.53	98.10	3.89	0.37
30	“Contracting the adoption of anxiety self-control strategies”—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the awareness about relationship between self-control strategies and anxiety reduction”	91.50	3.61	0.74	98.20	3.89	0.46
31	“Assessing the progress of the awareness about the relationship between self-control strategies and anxiety reduction”—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the awareness about the relationship between self-control strategies and anxiety reduction”	93.30	3.73	0.69	100.00	3.87	0.34
32	“Performing psychoeducational intervention”—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the knowledge about anxiety”	96.60	3.90	0.48	98.10	3.91	0.45
33	“Teaching anxiety self-control strategies (eg, music, art, exercise)—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the knowledge about anxiety” (round 1)	93.20	3.81	0.60	—	—	—
	“Teaching anxiety self-control/distraction strategies (eg, music, art, reading, cinema, spiritual, exercise, relaxation techniques)—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the knowledge about anxiety” (round 2)	—	—	—	100.00	3.83	0.38
34	“Assessing the progress of the knowledge about anxiety”—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the knowledge about anxiety”	96.70	3.78	0.56	98.10	3.89	0.37
35	“Performing cognitive behavioral techniques (eg, systematic desensitization, implosion)—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the ability to use anxiety self-control strategies” (round 1)	93.30	3.71	0.65	—	—	—
	“Performing behavior modification technique (eg, time management planning)—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the ability to use anxiety self-control strategies” (round 2)	—	—	—	98.10	3.83	0.51
36	“Instructing about relaxation techniques”—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the ability to use anxiety self-control strategies”	98.30	3.88	0.38	100.00	3.94	0.23

(continues)

Table 2. Results of Rounds 1 and 2, Continued

#	Statement	Round 1			Round 2		
		Level of Agreement, %	Mean	SD	Level of Agreement, %	Mean	SD
37	“Training relaxation techniques”—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the ability to use anxiety self-control strategies”	98.30	3.92	0.34	100.00	3.98	0.14
38	“Assessing the progress of the ability to use anxiety self-control strategies”—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the ability to use anxiety self-control strategies”	96.60	3.80	0.55	98.10	3.89	0.37
39	“Performing cognitive-behavioral techniques (eg, cognitive restructuring)—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the meaning attributed to the threat” (round 1)	93.30	3.73	0.64	—	—	—
	“Performing cognitive restructuring”—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the meaning attributed to the threat” (round 2)	—	—	—	98.20	3.85	0.49
40	“Assessing the progress of the meaning attributed to the threat”—an intervention potentially useful to address the nursing diagnosis “potentiality to improve the meaning attributed to the threat”	95.00	3.76	0.60	98.10	3.85	0.41

the interventions “planning distraction activities (eg, music, art, spiritual)” and “performing relaxation techniques (guided imagery, diaphragmatic breathing, and muscle relaxation)” addressing the nursing diagnosis “anxiety,” as well as teaching, instructing, and training those activities or techniques addressing nursing diagnoses in the domain of the person’s potentiality. (7) To specify cognitive-behavioral techniques that can be useful to address the “potentiality to improve the ability to use strategies for anxiety self-control”—“performing cognitive-behavioral techniques (eg, systematic desensitization)—and the “potentiality to improve the meaning attributed to the threat”—“performing cognitive-behavioral techniques (eg, cognitive restructuring)”.

Rounds 1 and 2

From the 70 potential participants invited, 59 accepted to participate in round 1. A total of 54 participants were included in round 2 (attrition rate, 8.47%). The demographic characteristics of the participants are displayed in Table 1.

All the statements presented in the round 1 questionnaire obtained consensus (>70% of panel member responses falling within scores “3” or “4” on the Likert scale). All the suggestions made by the panelists in round 1 that were in line with the clinical data model to be developed (eg, framed by Meleis’ transitions theory) were included in the questionnaire of round 2. These results are shown in Table 2.

Differences between statements were settled by including the statements with the highest level of agreement in

the clinical data model. After reaching consensus on the modified e-Delphi study, the final version of the clinical data model addressing the nursing diagnosis “anxiety” was drafted, as depicted in the flowchart (Figure 1).

In addition, the research team represented the interrelationships between identified concepts using Unified Modeling Language and the ISO 18104:2014 base elements, instantiating the general classes with the main elements and value sets relevant to the anxiety clinical data model (see Supplemental Digital Content 1, <http://links.lww.com/CIN/A139>) for accommodating the diagnosis and action concepts following a similar approach to Chow et al.¹¹

DISCUSSION

These study results make a unique contribution to the body of literature identified in the scoping review, which was previously carried out.¹⁹ Data presented in Table 2 shows a high level of agreement with the statements, leading to the development of a clinical data model addressing the nursing focus “anxiety.”

Importantly, the developed clinical data model is entirely evidence based, but it comprises different levels of evidence. For example, the efficacy of some interventions deriving from the scoping review has been assessed through randomized controlled trials (eg, music-based interventions).^{32,33} Other interventions (eg, “performing active listening”) derived from the experts’ consensus because these interventions were suggested by experts during the brainstorming session and/or the modified e-Delphi study.³⁴

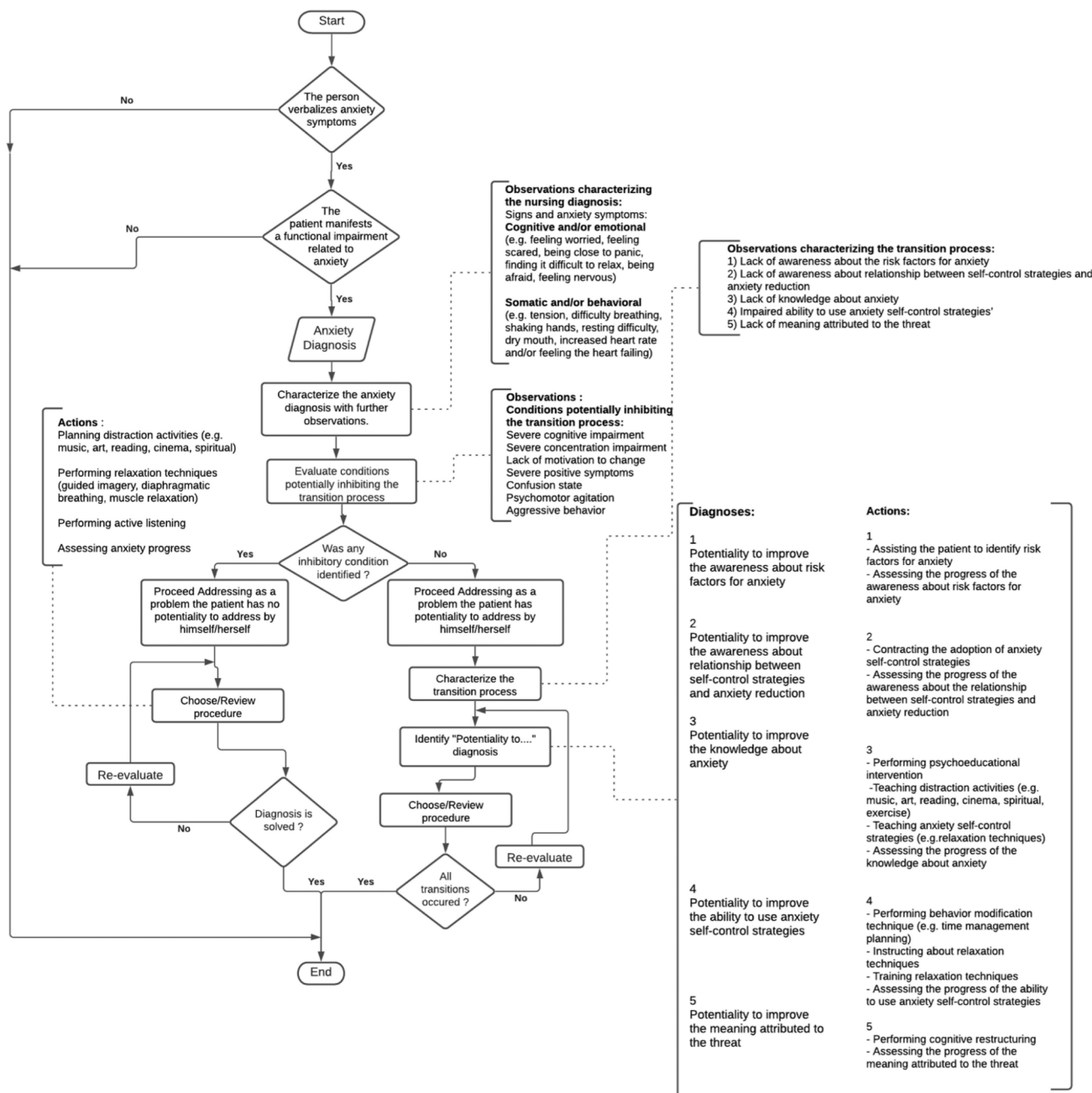


FIGURE 1. Flowchart depicting the decision process and conceptual data model for the nursing focus “anxiety.”

An important finding on data leading to the diagnosis is that the diagnosis is identified only when the person verbalizes he or she presents anxiety symptoms. This consensual option, accepted by the experts, is likely related to the need to avoid value judgments in nursing care³⁵ and, consequently, avoid legal issues related to the identification of the nursing diagnosis. Furthermore, data that characterize the nursing diagnosis are tendentially in line with the literature,^{36,37} presenting cognitive/emotional and somatic/behavioral signs and anxiety symptoms.

Consensus on the conditions that inhibit the transition process corroborate the usual exclusion criteria of any psychotherapeutic approach.³⁸ This is explained by the fact that psychotherapy, as a transition process, is also a process of change.³⁹

The potential diagnoses that achieved consensus if anxiety is considered a problem the patient has the potentiality to address by himself or herself (transition process) are totally in line with the theoretical framework of the clinical data model (Meleis' transitions theory). Thus, awareness,

knowledge, ability, and meaning are central concepts of the theory.¹⁸

Finally, consensus was achieved regarding some interventions, mostly emerging from the scoping review previously carried out.¹⁹ Hence, interventions based on music or art were included in the clinical data model, such as exercise and relaxation techniques.

The ISO 18104:2014 structures provide valuable hints for modeling the concepts identified in this study and bring them closer to the information system. It is considered a relevant instrument for integrating nursing terminologies into computerized information systems.⁴⁰

However, to explore fully the potential of clinical data models and translate this knowledge base into evidence, their incorporation should also follow a common information model to preserve meaning and context. For this purpose, their mapping to structured, detailed information models that allow the development and promotion of systems interoperability at the semantic and syntactic levels is another important step. Initiatives like openEHR⁴¹ provide an archetype-based model and an open specification based on a multilevel (or dual) model, in which the clinical knowledge is represented by constraints on a common and generic reference model.

On the other hand, to overcome information silos, standard communication approaches are also necessary. As such, initiatives like fast healthcare interoperability resources (FHIR) should be strongly considered. The FHIR provides a strong foundation for information communication by offering a set of base resources and providing a set of constructs that allow developers to create profile and extensions in a regulatory fashion. FHIR resources also incorporate constructs for terminology bindings, allowing for increased semantical interoperability. For this particular case, the natural progression would be to identify a consensual mapping between the purposed clinical data model and the available resources provided by the FHIR.

Limitations

This study had an important limitation, common to consensus development studies, such as the use of nonrandomized samples, bias imposed by the composition of the expert panels, and the absence of concrete recommendations regarding the number of participants, the number of rounds, or how consensus might be defined.²¹

Another limitation had to do with the fact that the study was limited to the Portuguese healthcare context. Extending the results to countries with dissimilar health services and resources must be regarded with caution because one has to decide whether these study findings are applicable to other contexts.

Finally, there is a gap between nursing as a discipline (theoretical/scientific domain) and as a profession (practical domain), which seems more evident in psychiatric and men-

tal health nursing. This gap was not fully bridged by the developed clinical data model, so that it can be regarded as a limitation of the present study. Nonetheless, the integration of clinical data models in the backend of nursing information systems may promote clinical nurses' critical thinking and clinical reasoning, which are crucial for improving the quality of care and, consequently, minimize the gap between nursing theory and practice.

CONCLUSIONS

Importantly, this study can serve as a catalyst for the development of other nursing clinical data models. In the future, the results of this study—the clinical data model addressing the nursing focus “anxiety”—are projected to be used at the backend of nursing information systems and, therefore, enable clinical nurses to easily document their practice. The development of clinical data models to be inserted at the backend of nursing information systems is increasingly relevant for improving the quality of care.

Clinical data models are entirely evidence based, which is a significant upgrade to the data currently inserted in nursing information systems. Moreover, the preestablished relations between data, which is a characteristic of clinical data models, allow these data to be used as a decision support system. Finally, this clinical data model is grounded on a nursing theory (theoretical framework), and this is an important differentiation from the traditional nursing taxonomies/classifications. Thus, future work should consider the development of clinical data models addressing other nursing focuses.

The evidence of this clinical data model would greatly benefit from studies assessing the feasibility of its integration in nursing information systems. Future studies are recommended mainly to examine the efficacy of the interventions included in the clinical data model to solve or improve the nursing diagnosis under study.

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