

## Methodological aspects of patient safety culture research: A scoping review

## Aspectos metodológicos da pesquisa de cultura de segurança do paciente: Uma revisão de escopo

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### ABSTRACT:

Investigating the safety culture has been relevant for more than two decades as a tool to improve the quality of patient care. This is a scope review of the last 20 years, whose objectives was to analyze the type and prevalence of methodological approaches to patient safety culture and climate research at hospital settings, and investigate the relationship between the approaches used and the diagnosis of the safety culture. The Cinahl, Medline, Lilacs, and Web of Science databases were used. A review protocol was registered. The results were reported according to reports of preferred items for systematic reviews and extension of meta-analyses for scope reviews (PRISMA-ScR). 107 studies were included. From the results, three major themes emerged for discussion, and the studies were classified into 1) Methodological approach and indeterminate use of concepts of climate and safety culture; 2) The isolated use of self-administered questionnaires in safety culture surveys and 3) A survey of the mixed methods approach in patient safety culture research. The quantitative approach was shown to be predominant, with the use of self-administered questionnaires for studies of the climate and culture of patient safety. The studies pointed out several limitations in the exclusive use of questionnaires, emphasizing the need to include multimethod research and the use of qualitative data collection techniques as an essential complement for the diagnosis of the patient safety culture.

**KEYWORDS:** Patient safety; Organizational culture; Health Services Research; Research Design.

### RESUMO:

Investigar a cultura de segurança tem sido relevante há mais de duas décadas como ferramenta de aprimoramento da qualidade do atendimento ao paciente. Trata-se de uma revisão de escopo dos últimos 20 anos, cujos objetivos foram analisar o tipo e prevalência de abordagens metodológicas das pesquisas de cultura e clima de segurança do paciente no contexto hospitalar, e investigar a relação entre as abordagens utilizadas e o diagnóstico da cultura de segurança. Foram utilizadas as bases de dados Cinahl, Medline, Lilacs e Web of Science. Foi registrado um protocolo de revisão. Os resultados foram relatados de acordo com os relatórios de itens preferidos para revisões sistemáticas e extensão de meta-análises para revisões de escopo (PRISMA-ScR). Foram incluídos 107 estudos. Dos resultados emergiram três grandes temas para discussão, e os estudos foram classificados em: 1) Abordagem metodológica e uso não especificado de conceitos de clima e cultura de segurança; 2) O uso isolado de questionários autoaplicáveis em pesquisas de cultura de segurança e 3) A relevância da abordagem de métodos mistos na pesquisa de cultura de segurança do paciente. A abordagem quantitativa mostrou-se predominante, com a utilização de questionários autoaplicáveis para estudos de clima e cultura de segurança do paciente. Os estudos apontaram várias limitações no uso exclusivo de questionários, ressaltando a necessidade de incluir a pesquisa multimétodo e a utilização de técnicas de coleta de dados qualitativos como complemento essencial para o diagnóstico da cultura de segurança do paciente.

**PALAVRAS-CHAVE:** Segurança do Paciente; Cultura Organizacional; Pesquisa sobre Serviços de Saúde; Projetos de Pesquisa.

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## INTRODUCTION

The patient safety culture in Health Organizations is, worldwide, a priority issue for evaluation and monitoring. Evaluating brings benefits to services and patients since it allows for improvements as well as to disclosures of future trends<sup>1</sup>.

The various studies on the theme deal with the quality of care and the aspects that determine the culture and safety of the patient, such as instruments for assessing the quality of care, the management style of the institutions, and differences in understanding on the subject within the Organization itself and cross-culturally<sup>2,3,4</sup>, among others.

Understanding the difference between assessing the safety culture and obtaining security perceptions and attitudes is important since the two concepts, despite complementing each other and contributing to the success of the protocols established, have different meanings.

The patient safety culture is the product of individual and group values that determine the commitment, style, and proficiency of running a healthy and safe Organization. The safety climate, on the other hand, is another component of the Organization culture, which in turn reflects the patient safety culture, which leads to the interchangeable use of terms in the literature<sup>5</sup>. The inaccurate use of these two terms is questionable since it connotes unrealistic analyzes of the patient safety culture in Health Organizations.

Therefore, it is justified to map the literature to analyze the profile of the methodologies and tools used to assess the patient safety culture since the most used terms represent different elements and meanings, and that demand specificity from the design and research question, choice of methodological component and description of its results. Inappropriately conducting evaluative culture research can result in biased results.

From the previous analysis of these concepts and the need to relating them to the methodologies used to assess the patient safety culture, the following research question was elaborated: What is the type and prevalence of methodological approaches used in studies of patient safety culture and how are they related to the analysis of Organizational safety culture?

The complexity of the hospital system and the influence of care processes in hospital institutions, reinforce the implementation of barriers to control and mitigate errors to ensure patient quality and safety. Thus, this review aimed to analyze the type and prevalence of methodological approaches to patient safety culture and climate research at hospital settings, and investigate the relationship between the approaches used and the diagnosis of safety culture.

## METHODS

### ***Guideline and aims***

A scoping review of the literature was conducted following Joanna Briggs Institute (JBI's) recommendations<sup>6</sup> and was registered in Open Science Framework (OSF)<sup>7</sup> in October 2020. The protocol followed the steps: 1) Title and question development; 2) Introduction; 3) Inclusion criteria; 4) Research Strategy; 6) Selection of the source of evidence; 7) Data extraction; 8) Analysis of the evidence; 9) Presentation of results. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for Scoping Reviews (PRISMA-ScR)<sup>8</sup> were applied to improve the quality of the reported results.

This scoping review aimed to analyze the type and prevalence of methodological approaches to patient safety studies based in the last 20 years, as it is the periodicity since the disclosure of the Institute of Medicine (IOM) document (To err is human: building a safer health system), in which research in the patient safety area started to be more encouraged and carried out. Besides, it sought to investigate the incidence of methods used in the last five years and the relationship between the methodology used and the diagnosis of the patient safety culture.

### **Study selection**

The research question utilized the acronym SPIDER. The descriptors originated from it are shown in chart 1:

**Chart 1:** Selection of descriptors

<b>Acronym</b>	<b>Description</b>	<b>Descriptors selection</b>
S	Sample	Patient Safety Culture evaluative studies/assessment
PI	Phenomenon of interest	Patient Safety Culture
D	Design	Surveys
E	Evaluation	Questionnaires and Interviews
R	Research Type	Quantitative and Qualitative studies

Source: The Authors.

Thus, this review had as a guiding question “What is the type and prevalence of methodological approaches used in studies of patient safety culture and how are they related to the analysis of Organizational safety culture?”. A previous literature search was carried out in October 2020 on the databases Lilacs, Cinahl, and Medline to identify the existence of similar research.

Search strategies were built following three phases. First, strategies were developed and piloted on Pubmed and Virtual Health Library (VHL) – Medline, with the descriptors and keywords “patient safety”, “organizational culture”, “evaluation”, and “questionnaires”. Based on this pilot search, one first search strategy was developed and applied on

Lilacs, Cinahl, Medline, and Web of Science databases. Then, in the second phase, we randomly screened studies of the Cinahl and Medline databases to pilot the extract process of the data and to verify keywords. The term “assessment” was added to the search strategy. Three authors (TAS, CSSB, ASF) conducted the pilot data charting process independently.

A second search using all identified keywords and index terms was undertaken across all included databases and is presented in Chart 2. In the third phase, all titles and summaries were screened by two reviewers independently (TAS, PCP). A third reviewer (KCF) was available to resolve any discrepancies.

**Chart 2:** Detailed search strategies and databases

Keyword and MeSH		
[MeSH] "Patient Safety"; "Organizational Culture"; "Corporate culture"; "Nursing assessment"; "Survey"; "Questionnaire"; "Survey Methods"; "Survey methodology"; "Interview"		
[Keyword] "Assessment"		
Search strategies		
[Search 1] "patient safety" AND ("corporate culture" OR "organizational culture") AND (("nursing assessment" OR ("Survey*" AND "questionnaire*") OR "survey methods" OR "survey methodology" OR "Survey" OR "Questionnaire" OR "Interview"))		
[Search 2] "patient safety" AND ("corporate culture" OR "organizational culture") AND (("nursing assessment" OR ("Survey*" AND "questionnaire*") OR "survey methods" OR "survey methodology" OR "Survey" OR "assessment" OR "Questionnaire" OR "Interview"))		
Databases	Search 1	Search 2
Cumulative Index to Nursing and Allied Health Literature (CINAHL);	202	389
Medical Literature Analysis and Retrieval System Online (MEDLINE);	301	380
Latin American & Caribbean Health Sciences Literature (LILACS);	72	75
Web of Science (WoS).	71	81

Source: The Authors.

### ***Inclusion and exclusion criteria***

Were included studies with full-text studies available in English, Portuguese, and Spanish, primary and secondary studies, theses, and dissertations that sought to verify the climate and/or culture of patient safety in public or private hospital services. Studies of construction and validation of instruments, cross-cultural adaptation, construction of short forms, letter to the editor, as well as studies that linked culture assessment to secondary factors were excluded.

### ***Data extraction***

The following data were extracted from a Microsoft Word spreadsheet: I) Title; II) First author's last name; III) Place; IV) Year; V) Objectives; VI) Professional categories; VII) Study design.

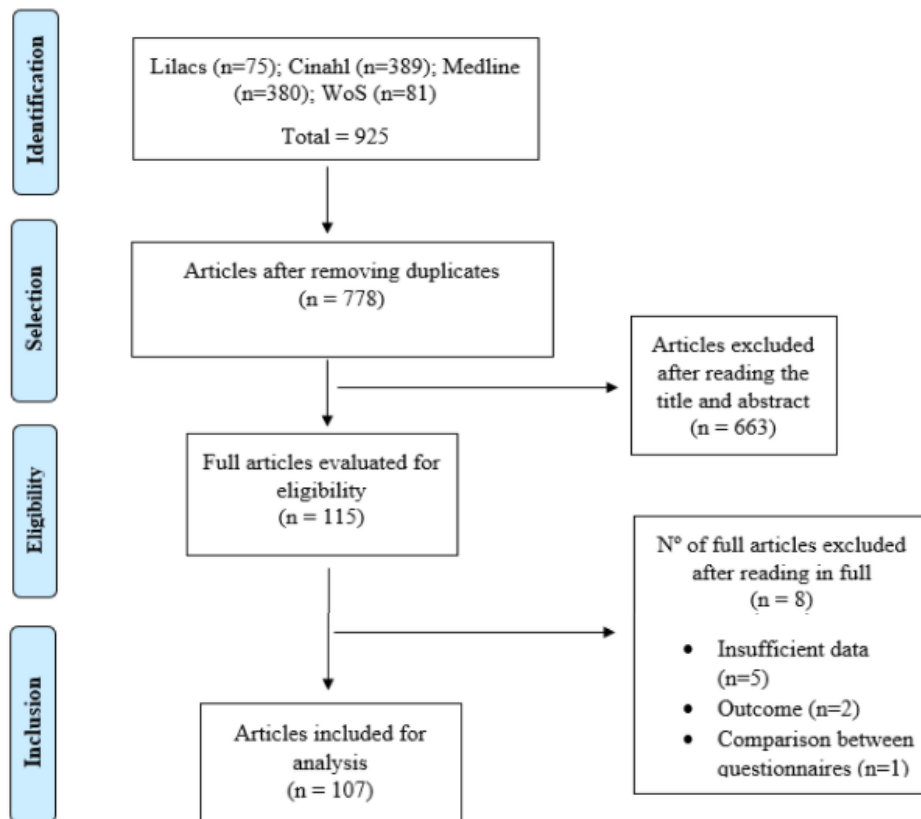
**Data synthesis**

The included studies were stratified according to the methodology used in (a) quantitative studies; (b) qualitative studies (c) quali-quantitative studies; (d) mixed methods studies; and (e) review studies. Then, they were grouped into I) Studies that sought to verify a safety climate and II) Studies that sought to verify a safety culture. The results were reported descriptively, taking into consideration the objectives that guided the scoping review.

**RESULTS**

A total of 925 studies were found and after removing the duplicates 778 remained. From these, 663 articles were excluded after reading titles and abstracts, resulting in 115 studies included for reading in full. Eight studies were excluded after full reading, for not having presented data from a data collection or not reporting data from the safety culture assessment. Also, one study was concerned with comparing two questionnaires. The final sample constituted of 107 studies. The Prisma flowchart (Fig 1) demonstrates a detailed selection of studies.

**Figure 1:** Flowchart of selection and inclusion of studies.



Source: Adapted from Tricco et al (2018)

Among all studies included in the sample, (n=52) were carried out in Brazil, followed by United States, and China with five studies each. Two studies<sup>9,10</sup> are cross-cultural performed both in Taiwan and in the United States. Most other locations have only one study per country, except for Spain (n=4), Taiwan (n=4), Australia, Japan, and the Netherlands with (n=3) each. Switzerland, Turkey, Sweden, Norway, and Palestine, computed two studies each. A representation of the distribution of studies around the world is presented in Figure 2.

**Figure 2:** Concentration of studies of climate and/or culture of patient safety around the world.



Source: The Authors. World map designed by Layerace/Freepik.

Among the primary studies, the quantitative approach prevailed, with the application of at least one self-administered questionnaires (92.16%), followed by three studies of mixed methods (2.94%), three qualitative studies (2.94%) and two quali-quantitative studies (1.96%). The five secondary studies applied a qualitative approach (4.90%). All studies are identified from A1 to A107, available in supplementary material - Chart S1.

As for the prevalence of methodological approaches used in primary studies, it was found that in every 100 studies, 87.8 used exclusively self-administered questionnaires, 4,6 used questionnaires and interviews, and 2.8 studies used only interviews. The incidence was calculated for studies developed in the last five years (n=85) and for every 100 new studies, 84.7 apply a quantitative approach and 3.5 both qualitative and mixed methods approach.

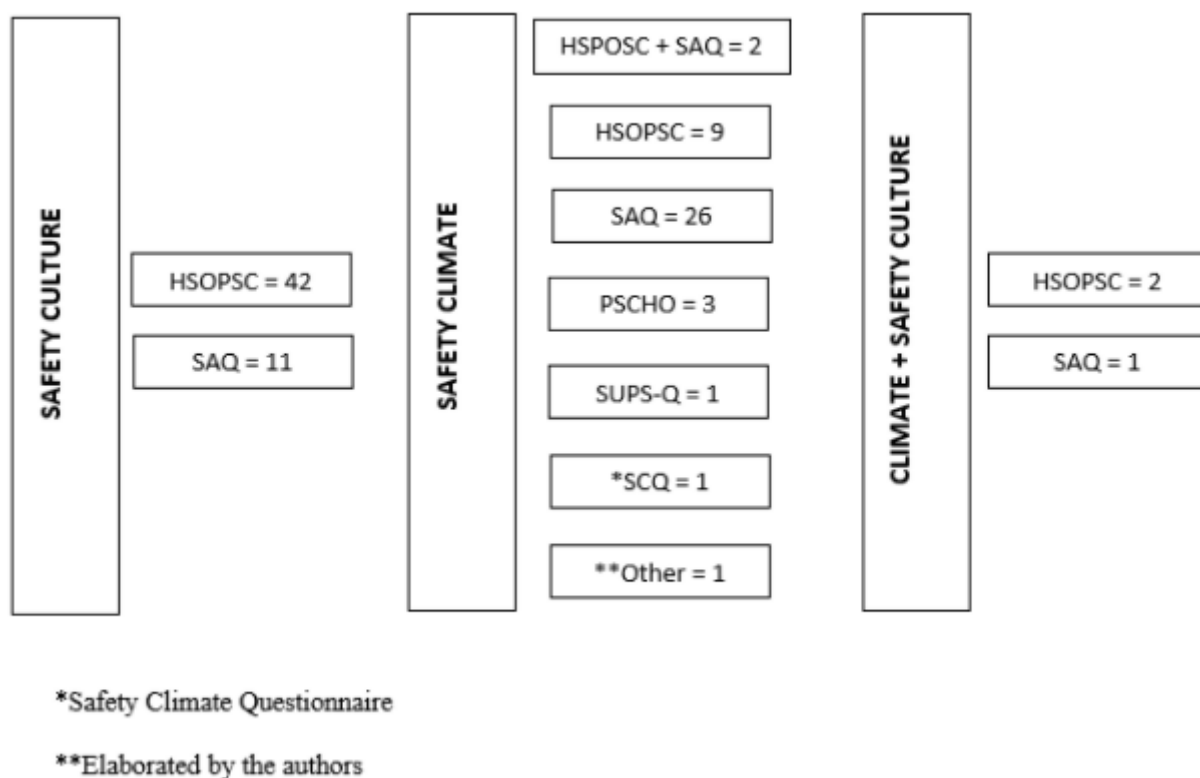
This review verified the presence of methodological characteristics directly related to the diagnosis of patient safety culture. Three thematic axes were formulated that present: 1) Methodological approach and unspecified use of climate and safety culture concepts; 2) The isolated use of self-administered questionnaires in safety culture surveys, and

3) The relevance of mixed methods approach in patient safety culture research.

Of all studies, 87.85% used the quantitative approach, demonstrating its prevalence with the use of questionnaires, in addition to (n=2) quali-quantitative studies and (n=3) studies of mixed methods with the use of a questionnaire in at least one phase of the research.

Primary and secondary studies were stratified according to the methodological approach used (Figure 3). The secondary studies were presented separately considering that they present different standards of literature review, however, their results are presented descriptively and no statistical analyzes were used, characterizing them as literature reviews with a qualitative approach. Three studies are master's theses<sup>11,12,13</sup>.

**Figure 3:** Stratification of primary quantitative, quali-quantitative, and mixed methods studies, according to the terminology and the questionnaire used.



Source: The Authors.

Among the secondary studies, an integrative literature review sought to identify, using the Safety Attitudes Questionnaire (SAQ), productions related to patient safety and organizational culture factors<sup>14</sup>. Two are systematic reviews<sup>15,16</sup> with similar objectives, but using the Hospital Survey on Patient Safety Culture (HSOPSC) questionnaire.

The literature review carried out by Pumar-Méndez et al. (2014)<sup>17</sup> sought to verify the methodological aspects of patient safety culture studies from 1999 to 2012, however, it does not specify the review standard used. Finally, a narrative

review of the literature sought to examine studies related to patient safety among intensive care units (ICUs) in Australia<sup>18</sup>.

In primary quantitative researches, the most used instruments were HSOPSC / HSPSC / HSPS (n=55) and SAQ/SAQ-short form and adapted versions (n=40) followed by (PSCHO) (n=3). One study<sup>19</sup> used the Safety Climate Questionnaire (SCQ), and another a self-made questionnaire<sup>20</sup>.

It stands out the fact that patient safety research uses the concepts of climate and patient safety culture without distinction. Of the primary studies, 49.53% aimed to verify patient's safety culture and 40.19% the safety climate. Studies that used the terminologies "perceptions" and "security attitudes" were included in the second group. Three studies<sup>21,22,23</sup> brought both concepts in the title and objective, however, they did not differ from the others regarding the data collection strategy. One study<sup>14</sup> did not specify the concept used in the research, using "patient safety" in composition with "organizational culture".

Research that sought to verify the safety culture used only HSOPSC (n= 42) and SAQ (n=11), while safety climate studies used in addition to HSOPSC (n=9) and SAQ (n=26), the instruments PSCHO (n=3), SUPS-Q (n=1) and SCQ (n=1). In addition, two studies used both the HSOPSC and SAQ questionnaires<sup>24,25</sup>. Three studies<sup>21,23,22</sup> brought both concepts without distinction. The first two used HSOPSC and the last one, the SAQ.

The stratification of the use of questionnaires among the primary studies in relation to the terminology used (Culture / Climate) is summarized in supplementary material - Figure S2. Results demonstrated the non-specific use of the terms climate and safety culture, which can generate research bias, since using self-administered questionnaires in isolation makes it impossible to deepen important variables, a necessary factor for the diagnosis of safety culture.

## DISCUSSION

Although the concepts "Climate" and "Culture" are complementary, they do not have the same meaning, the climate is the part that refers to the perception of employees about the values perpetuated in the Organization, acting as a transversal photograph. It is used as a form of evaluation in cross-sectional surveys to obtain data regarding perceptions concerning a specific moment in the local security culture<sup>26</sup>.

It is noted, however, that the questionnaires used in research that adopted the concept of "culture"<sup>27,28,29,30</sup> are the same ones used in research whose objective is to verify "perceptions" and "security attitudes"<sup>31,32,33</sup>, denoting the incipience of using both concepts in patient safety research.

These studies tend to generate diagnoses of patient safety culture, based on data obtained with the exclusive use of self-administered questionnaires. The results obtained from the statistical analysis are used to prove hypotheses and determine cultures as weak or strong<sup>34,35</sup> while identifying problematic variables in the different dimensions of the questionnaires<sup>1,3</sup>.



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However, they are not dedicated to investigating and proposing specific strategies for the place where the research was conducted<sup>36,37,38</sup>. Most of these studies are limited to providing recommendations to be adopted at the study site. In addition, these recommendations are provided when the study is published in the scientific community, and not directly in the places where the research was developed.

In addition to these important aspects, it is worth noting that culture permeates all hierarchical levels, as well as all the elements, influencing, and being influenced by them. It is up to the entire staff to play the role of the leaders, to commit to actions in favor of security<sup>39</sup>.

It was possible to prove the wide range of researches that use specific professional strata in “safety culture” surveys such as nurses/nursing staff<sup>28,40,41,42,43,44</sup> doctors<sup>45</sup>, or even these together<sup>39,46,47,48,49,50</sup>, without the presence of other cultural co-participants.

At first glance, the use of questionnaires explores, identifies, and assesses the Organization’s security issues, however, they become limited tools when used in isolation<sup>51</sup>. By adding the data collection techniques of the qualitative approach, the identified variables can be explored in-depth, so that not only the perceptions will be captured, but the Organizational factors associated with the genesis of the problems encountered.

Some studies declare the low reliability of responses due to internal inconsistencies in the dimensions of the questionnaires applied<sup>27,34</sup>, as well as recognizing that the simple evaluation of employees’ perceptions is not enough to promote significant evaluations<sup>13,52,53</sup>. These factors, in addition to limiting the generalization of results, should not be used to judge the state of the patient safety culture at the site. Also, cross-cultural adaptations of the questionnaire without consulting the developers of the original version may compromise its use<sup>50</sup>.

Pumar-Méndez et al. (2014)<sup>17</sup> recommend clarifying which dimensions of the questionnaires form the core of patient safety, which should be investigated in all safety culture research, as well as strengthening the psychometric properties of the questionnaires used for data collection.

Despite being widely used to measure attitudes and perceptions, compare sectors, Organizations and to obtain benchmarks, these questionnaires can leave behind underlying characteristics inherent to culture, from observable structural and managerial factors to elements of the unconscious that are pervaded by the workplace. It leads to a gap in reflection or intervention on them<sup>26</sup>. This could be translated as “here we always do things this way”.

Several studies highlight the need for more in-depth data to investigate factors such as: “Why are nurses and residents who work more hours a week the youngest and have negative perceptions of the safety culture when compared to other groups?”<sup>23</sup>, emphasizing the insufficiency of the isolated use of questionnaires to diagnose the culture of patient safety.

It is noted in a previous review<sup>17</sup> the need to expand the field of research using mixed methods of data aggregation to obtain real data from the safety culture. The benefit of using mixed methods in conducting patient safety research is

clear<sup>13,19</sup> and needs to be encouraged, as recommended by these studies.

The study conducted by Moretão (2019)<sup>13</sup>, because it is a master's thesis, brings in detail the contribution of the interviews in the research that aimed to analyze the safety culture under the view of professionals working in a teaching hospital. Among the results, it is possible to observe, for example, why the items concerning the communication dimension of the HSOPSC questionnaire were negatively evaluated. The statements reveal the behavior of doctors and nurses that hinder the establishment of a strong communication link, considering that such information was passed on between the two strata, excluding the other parts.

The execution of the research of mixed methods to evaluate safety culture can take place in different designs concerning the methodology. Studies that used mixed methods demonstrate the primary use of self-administered questionnaires, which are administered to a larger part of the employees, followed by interviews with a smaller part of the employees of the multi-professional team<sup>19</sup> or even carried out with a single professional stratum<sup>13,44</sup>.

This data corroborates the previous survey of the methodological approaches of patient safety studies<sup>17</sup>, which demonstrated that since the first decade of this century the quantitative approach has been prevalent, with the development of questionnaires and their respective adaptations. The researchers found that the only study that used a qualitative approach was not limited to capturing the perceptions of employees but made it possible to expand and illustrate several issues that relate to and compromise patient safety.

Culture is a complex phenomenon and requires robust techniques for conducting an adequate diagnosis, otherwise, poorly used methodologies can lead to an unreliable understanding of Organizational culture<sup>51</sup>. Organizational culture influences the way that professionals learn and share knowledge and directs the way of doing things in the Organization at three different levels<sup>54</sup>.

Organizational culture is sometimes compared to the figure of an Iceberg, divided into three levels. The first is the - artifacts (which you observe when entering an organization), the second - shared values (there are the goals, and objectives, that is, the reason that leads the person to do or not to do something). Finally, the third level concerns the necessary basic certainties and this is where the Organization's support is found, that is, the beliefs, values, principles, mission, and philosophies, which are present even if unconsciously in each component of the Organization<sup>54</sup>.

It is precisely for this reason that inserting into a local culture or being able to perceive it takes time. Professionals with less time in the Organization tended to evaluate more positively when compared to those who had more than five years of employment<sup>34</sup>.

Based on the concept of Organizational culture<sup>54</sup>, the patient's safety climate can be considered the most superficial, transversal, and perceptible part. The climate is clearly noticed by the members or even people outside the Organization. Culture, on the other hand, is the result of the philosophy adopted and the values passed on to the other levels, being essentially the basement of an Organization<sup>20,25,54</sup>.

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Thus, the premise is that to assess the safety culture, the researcher must provide theoretical and methodological knowledge for this purpose, to plan the necessary strategies depending on the level of safety culture that is to be diagnosed in a Health Organization, which includes patient safety culture as one of its components. The use of questionnaires can be taken as an example for conducting climate research, through obtaining internal and external benchmarking as well as monitoring patient safety interventions<sup>3</sup>.

The results of this review demonstrated a wide range of descriptive, cross-sectional studies with a quantitative approach<sup>11,12,52,59,60,61,62</sup> who sought to diagnose a safety culture using a questionnaire<sup>1,2,12,28,55,60,61,63</sup>. Demonstrating once again the conceptual indistinction of both terms culture and climate, since these results show safety climate data, however, are being reported as a patient safety culture.

The confusion between the concepts “climate” and “culture” can be perceived, for example, in relation to the objective “to evaluate the perceptions about the climate”<sup>11</sup>, since the perceptions are the climate itself, which demonstrates redundancy.

It is necessary to evaluate the climate as a strategy for monitoring actions to improve the patient safety component, however, it must be used with caution, since it represents an indirect measure of safety culture and does not represent it in its entirety<sup>64</sup>. This demonstrates that the non-specific use of questionnaires in cross-sectional research designs acts as a limiting factor for the diagnosis of the patient safety culture. The authors<sup>65</sup> emphasize that cross-sectional climate surveys do not capture the culture, serving as a snapshot of the perceptions at one point in time.

The climate results are obtained from the identification of positive or strong dimensions, such as the SAQ “Work Satisfaction” dimension<sup>58,62</sup>, “Work condition”<sup>59</sup>, or of weak dimensions<sup>11,32,56,66</sup>. They can also be used for comparative studies between teams, units, and services<sup>1</sup>. Dimensions that were considered weak in a climate study, such as teamwork within the units, open communication, non-punitive response to errors, and team adequacy, could have been better explored despite their causal factors with the application of interviews<sup>40</sup>.

The promotion of safety culture should be everyone’s responsibility, especially professionals who occupy managerial positions. They plan policies and set goals that aim to strengthen the value of “patient safety”<sup>1</sup>. Therefore, it is an essential part of the local security culture.

Studies carried out with only one professional stratum identified this as a limiting factor, as they assume the bias caused when assessing the safety culture<sup>22,28,65</sup>. Studies that used the SAQ<sup>34,57,67,68</sup>, had a prevalence of professionals from the nursing team.

Some studies does not specify the participation of professionals from the administrative sector<sup>55,59</sup>. Similarly, it was possible to verify the inclusion of only professionals that provide direct assistance in safety culture research<sup>29</sup>.

However, the simple inclusion of managers in the sample also does not mean that the safety culture was diagnosed<sup>1</sup>, but it serves as a starting point for the accurate investigation of the critical nodes found. This is since that

the transversal design prevalent in “culture” studies does not allow the establishment of cause-and-effect relationships<sup>62</sup>.

The qualitative technique of “problem-centered interview” is considered in the literature as the most appropriate technique to be applied with the multi-professional team to capture subjective aspects of the culture, and should be applied whenever possible to eliminate the bias brought by the single use of questionnaires<sup>51,69,70</sup>.

Therefore, it is recommended to use questionnaires that verify both the Organization’s values and Organizational practices, dimensions of culture and employee commitment, together with a qualitative approach, based on the application of interviews with employees, managers, and stakeholders, since the union of quantitative and qualitative methodological components applied with the Organization’s members are useful for the diagnosis of culture<sup>51</sup>.

## STRENGTHS AND LIMITATIONS

We conducted a systematic search that demonstrated a broad panorama of studies about patient safety worldwide in the past two decades. Many studies that sought to verify the patient’s culture were associated with secondary factors, demonstrating specific interests of the local service in analyzing the culture, and were not included in this sample due to the established criteria. It is important consider that there are a large number of studies that sought to assess safety culture, which was not included in this sample, but that demonstrated to follow the same methodological tendency represented by the results described here. There were few studies of other languages that can be considered in further research.

## CONCLUSION

The use of the same methodological strategy for climate and cultural research leads to the use of these terms as synonyms, which, in fact, are not. Therefore, they require different approaches and tools to be accessed. The high number of studies with a quantitative approach has its advantages due to the low cost of using the questionnaires as well as the speed of production of evaluation data. However, it was considered by most of the studies in this sample as a limiting issue for evaluating culture, due to its transversal characteristic capable of capturing only a specific moment, influenced by external and internal determinants of the Health Organization.

By properly analyzing the patient safety culture, it is possible to monitor quality indicators and implement actions such as strict monitoring of adverse event notifications, as these represent a concern in Health Organizations, directly interfering in the health of workers and patients.

Carrying out studies of mixed methods to diagnose the culture of patient safety shows to be a more assertive way to diagnose the patient safety culture, justified by its potential to fill the gaps that the isolated use of a single methodological component may cause. Based on the various methodological designs available in this approach, the methodology certainly corroborates for a more reliable culture diagnosis.

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## SUPPORTING INFORMATION – STUDY SAMPLE

Table S1. Stratification of studies according to the methodological approach adopted

Method	Studies	N	%
Quantitative 87,85	E1,E2,E3,E4,E5,E6,E6,E7,E9,E10,E11,E12,E13,E14,E15,E16,E17, E18,E19,E20,E22,E23,E24,E25,E26,E27,E28,E29,E30,E31,E32,E33, E34,E35,E36,E37,E38,E38,E41,E42,E45,E46,E47,E48,E49,E50,E51, E52,E54,E55,E57,E57,E59,E60,E61,E62,E63,E65,E66, E67,E68,E69 E70,E71,E72,E73,E74,E75,E76,E77,E78,E79,E81,E82, E83,E84,E85 E87,E89,E91,E92,E93,E94,E95,E96,E97,E98,E99,E100,E101,E102, E103,E105,E106	94	
Qualitative	E43,E80,E86	3	2,80
Quali-Quantitative	E40,E44	2	1,87
Mixed Methods 2,80	E21,E64,E107	3	
<b>Review studies</b>			
Integrative review	E53	1	0,93
Literature Review	E56	1	0,93
Narrative Review	E88	1	0,93
Systematic Review	E90,E104	2	1,87

Chart S1. Studies included and analyzed regarding the methodology and data collection strategy employed

Study/Author	Local/Ano	Sample	Method
A1 Patient safety culture in three Brazilian hospitals with different types of management - Andrade et al	Brazil 2018	215 multiprofessional	Quantitative/HSOPSC
A2 Weaknesses in patient safety culture from the perspective of workers in a general hospital - Beck et al	Brazil 2018	109 multiprofessional	Quantitative/SAQ
A3 Cultura de segurança do paciente em centro cirúrgico: percepção da equipe de enfermagem - Bohomol et al	Brazil 2019	37 Nurses	Quantitative/HSOPSC
A4 Cultura de segurança do paciente em serviços de atenção obstétrica -Dissertação: Juliana Maria Almeida do Carmo	Brazil 2018	301 multiprofessional	Quantitative/HSOPSC
A5 Culture of patient safety in hospital units of gynecology and obstetrics: a cross-sectional study - Carmo et al	Brazil 2020	301 multiprofessional	Quantitative/HSOPSC
A6 Safety culture in the operating room of a public hospital in the perception of healthcare professionals - Carvalho et al	Brazil 2015	226 multiprofessional	Quantitative/SAQ
A7 Assessment of safety culture in a public hospital in the Federal District, Brazil - Carvalho et al	Brazil 2019	358 multiprofessional	Quantitative/SAQ
A8 Assessment of the culture of safety in public hospitals in Brazil - Carvalho et al	Brazil 2017	573 multiprofessional	Quantitative/SAQ
A9 Cultura de segurança entre profissionais de centro cirúrgico - Carvalho et al	Brazil 2015	132 multiprofessional	Quantitative/SAQ
A10 Cultura de segurança do paciente: percepção da equipe de enfermagem de um hospital pediátrico - Dissertação: Tavane Menezes Costa	Brazil 2016	55 Nursing team	Quantitative/SAQ
A11 Atitudes profissionais para cultura de segurança do paciente em unidade de transplante de medula óssea - Fermo et al	Brazil 2016	33 multiprofessional	Quantitative/SAQ
A12 Patient safety culture in a university hospital - Galvão et al	Brazil 2018	381 multiprofessional	Quantitative/HSOPSC
A13 Cultura de seguridad del paciente y factores asociados en una red de hospitales públicos españoles - Gama et al	Spain 2013	1.113 multiprofessional	Quantitative/HSOPSC
A14 Liderança e cultura de segurança do paciente: percepções de profissionais em um hospital universitário - Kawamoto et al	Brazil 2016	76 multiprofessional	Quantitative/HSOPSC
A15 Assessment of safety culture in organ donation - Knihs et al	Brazil 2020	185 multiprofessional	Quantitative/SAQ
A16 Clima de segurança do paciente entre trabalhadores de enfermagem: fatores contribuintes - Kolankiewicz et al	Brazil 2017	648 multiprofessional	Quantitative/SAQ
A17 Patient safety culture from the perspective of all the workers of a general hospital - Kolankiewicz et al	Brazil 2020	630 multiprofessional	Quantitative/SAQ
A18 Cultura de segurança do paciente em unidades cirúrgicas de hospitais de ensino - Lopez et al, 2020	Brazil 2020	381 multiprofessional	Quantitative/HSOPSC

A19 The culture of patient safety from the perspective of the pediatric emergency nursing team - Macedo et al, 2016	Brazil 2016	75 Nurses	Quantitative/HSOPSC
A20 A cultura de segurança do paciente na perspectiva do enfermeiro - Matiello et al	Brazil 2016	83 Nurses	Quantitative/SAQ
A21 A cultura de segurança do paciente em unidades cirúrgicas de um hospital de ensino da rede pública de saúde – Moretão - Dissertação	Brazil 2019	246 Multiprofessional + 21 interviews with Nurses	Quali-Quantitative (HSOPSC + semi-structured interviews)
A22 Safety culture of multidisciplinary teams from neonatal intensive care units of public hospitals - Notaro et al	Brazil 2019	514 multiprofessional	Quantitative/HSOPSC
A23 Health professional's perception of patient safety culture in a university hospital in São Paulo: A cross-sectional study applying the Hospital Survey on Patient Safety Culture - Okuyama et al	Brazil 2019	314 multiprofessional	Quantitative/HSOPSC
A24 Safety culture: perception of health professionals in a mental hospital - Oliveira et al	Brazil 2018	103 multiprofessional	Quantitative/SAQ
A25 Cultura de segurança do paciente: avaliação de enfermeiros - Pagani et al	Brazil 2019	68 Nurses	Quantitative/SAQ short form
A26 Patient safety culture in the maternal-child area of a university hospital - Pedroni et al	Brazil 2020	41 Nurses and Physicians	Quantitative/HSOPSC
A27 Percepción de la cultura de seguridad de pacientes en profesionales de una institución argentina - Ramos et al	Argentina 2017	203 multiprofessional	Quantitative/HSOPSC
A28 Clima de segurança do paciente: percepção dos profissionais de enfermagem - Rigobello et al	Brazil 2012	203 multiprofessional	Quantitative/SAQ short form
A29 Cultura de segurança do paciente na percepção de profissionais técnicos de enfermagem - Schmidt et al	Brazil 2017	345 Nursing technicians	Quantitative/SAQ
A30 Cultura de segurança do paciente em unidades de urgência/emergência - Schuh et al	Brazil 2020	112 Nurses	Quantitative/HSOPSC
A31 Avaliação da cultura de segurança do paciente em um hospital filantrópico - Serrano et al	Brazil 2019	209 multiprofessional	Quantitative/HSOPSC
A32 Cultura de segurança do paciente em organização hospitalar - Silva A et al	Brazil 2016	128 Nurses	Quantitative/HSOPSC
A33 Evaluation of the Patient Safety Culture in the Western Amazon - Silva et al	Brazil 2018	280 multiprofessional	Quantitative/HSOPSC
A34 Patient safety in organizational culture as perceived by leaderships of hospital institutions with different types of administration - Silva et al	Brazil 2016	103 administrative personnel	Quantitative/SAQ
A35 Clima de segurança em terapia intensiva para adultos: foco nos profissionais de enfermagem - Souza et al	Brazil 2018	27 Nurses	Quantitative/SAQ

A36 Patient safety culture at neonatal intensive care units: perspectives of the nursing and medical team - Tomazoni et al	Brazil 2014	141 Nurses and Physicians	Quantitative/HSOPSC
A37 Evaluation of the patient safety culture in neonatal intensive care - Tomazoni et al	Brazil 2015	141 multiprofessional	Quantitative/HSOPSC
A38 Cultura de segurança do paciente em instituições hospitalares na perspectiva da enfermagem - Toso et al	Brazil 2016	637 Nursing team	Quantitative/SAQ
A39 Predictors of perceptions of patient safety culture and frequency of event reporting by critical care nurses in Oman: a model-building approach - Ma'mari et al	Oman (Península Arábica) 2019	270 Nurses	Quantitative/HSOPSC
A40 Lessons learned from measuring safety culture: An Australian case study - Allen et al	Australia 2010	59 multiprofessional team + 15 interviews with managers, educators, consultants and specialists	Quali-Quantitative (SAQ + semiestrutred interviews)
A41 Improving patient safety culture in Saudi Arabia (2012-2015): trending, improvement and benchmarking - Alswat et al	Riyadh, Kingdom of Saudi Arabia 2017	2592 multiprofessional + administrative personnel	Quantitative/HSOPSC
A42 Measuring patient safety culture in Taiwan using the Hospital Survey on Patient Safety Culture (HSOPSC) - Chen e Li	Taiwan 2010	788 multiprofessional	Quantitative/HSOPSC
A43 Segurança do doente e os processos sociais na relação com enfermeiros em contexto de bloco operatório - Silva et al	Cabo-Verde Portugal 2016	6 Nurses	Qualitative/participant observation + 6 semiestrutred interviews
A44 Patient safety culture and associated factors: A quantitative and qualitative study of healthcare workers' view in Jimma zone Hospitals, Southwest Ethiopia - Wami et al	Ethiopia 2016	637 multiprofessional	Quali-Quantitative (HSOPSC + individual interviews)
A45 Patient Safety Culture Diagnosis - Ferreira and Melo	Brazil 2019	47 multiprofessional	Quantitative/SAQ
A46 Safety culture in two metropolitan Australian tertiary hospital intensive care units: A cross-sectional Survey - Dustan and Coyer	Australia 2020	206 multiprofessional	Quantitative/SAQ
A47 The current state of patient safety culture in Lebanese hospitals: a study at baseline - El-Jardali et al	Libano 2010	6807 multiprofessional	Quantitative/HSOPSC
A48 Safety Attitudes of the nursing team in the hospital environment - Barradas et al	Brazil 2019	74 Nurses	Quantitative/SAQ
A49 Perception of nursing regarding patient safety climate in public and private institutions - Gasparino et al	Brazil 2017	235 Nurses	Quantitative/SAQ
A50 An overview of patient safety climate in the VA - Hartmann et al	Unites States 2008	4547 multiprofessional	Quantitative/PSCHO

A51 Perceptions and Factors Affecting Patient Safety Culture of Employees in Pediatric Services - Karademirler e Malav	Uludağ 2020	461 multiprofessional	Quantitative/HSOPSC
A52 Variations in hospital worker perceptions of safety culture - Listyowardojo et al	2012 Netherlands	multiprofessional 5609	Quantitative/SAQ
A53 Culture of patient safety in the hospital setting: na integrative review - Meneghetti Baratto et al	2016 Brasil	16 publications	Integrative Review/SAQ
A54 Patient safety climate in general public hospitals in China: differences associated with department and job type based on a cross-sectional Survey - Zhou et al	China 2018	4753 multiprofessional	Quantitative/PSCHO
A55 Patient safety culture: health professional's perspective - Santos et al	Brasil 2019	242 multiprofessional	Questionnaire elaborated by the authors
A56 Methodological aspects in the assessment of safety culture in the hospital setting: A review of the literature – Pumar-Méndez et al	2014 Spain	43 publications	Literature Review
A57 Assessment of patient safety culture in intensive care from the health team's perspective. Minuzzi et al	Brazil 2016	59 multiprofessional	Quantitative/HSOPSC
A58 Assessment of patient safety culture in Saudi Arabian hospitals - Alahmadi	Saudi Arabia 2010	223 multiprofessional	Quantitative/HSOPSC
A59 How Does Patient Safety Culture in the Surgical Departments Compare to the Rest of the County Hospitals in Xiaogan City of China? - Wang and Tao	China 2017	1379 multiprofessional	Quantitative/HSOPSC
A60 Nurse safety culture in the services of a university hospital - Fassarella et al	Brazil 2019	195 Nurses	Quantitative/HSOPSC
A61 The characteristics of patient safety culture in Japan, Taiwan and the United States - Fujita et al	Japan, Taiwan and the United States 2013	308.323 multiprofessional	Quantitative/HSOPSC
A62 Survey on patient safety culture in the Republic of Moldova: a baseline study in three healthcare settings - Tereanu et al	Moldova 2018	929 multiprofessional	Quantitative/HSOPSC
A63 Assessing patient safety culture in hospitals across countries - Wagner et al	Netherlands, Taiwan 2013 and United States	210,387 multiprofessional	Quantitative/HSOPSC
A64 Nurses' perceptions of patient safety culture: a mixed-methods study – Granel et al	Catalunia 2020	109 Nursing team	Mixed Methods (convergent parallel design) HSOPSC + 9 interviews + non-participant observation
A65 Changes in patient safety culture after restructuring of intensive care units: Two cross-sectional studies - Vifladt et al	Norway 2015	302 + 289 Nurses	Quantitative/HSOPSC
A66 Attitudes towards patient safety culture in a hospital setting and related variables - Mir-Abellan et al	Barcelona 2017	211 multiprofessional	Quantitative/HSOPSC
A67 A safety culture training program enhanced the perceptions of patient safety culture of nurse managers - Xie et al	China 2017	67 Nurses	Quantitative/HSOPSC + SAQ

A68 Is culture associated with patient safety in the emergency department? A study of staff perspectives - Noord et al	Netherlands 2014	658 multiprofessional	Quantitative/HSOPSC
A69 Staff perceptions of patient safety culture in general surgery departments in Turkey - Teleş	Turquia 2019	124 multiprofessional	Quantitative/HSOPSC
A70 Patient safety culture in kidney transplant patients in western Santa Catarina - Pavan et al	Brazil 2019	33 multiprofessional	Quantitative/SAQ
A71 Survey on patient safety climate in public hospitals in China - Zhou et al	China 2015	1,272 multiprofessional	Quantitative/PSCHO
A72 Organizational culture and climate for patient safety in Intensive Care Units - Santiago et al, 2015	Brazil 2015	197 multiprofessional	Quantitative/SAQ and HSOPSC
A73 Speaking up about patient safety in psychiatric hospitals - a cross-sectional survey study among healthcare staff - Schwappach and Niederhauser	Switzerland 2019	817 multiprofessional	Quantitative/SUPS-Q
A74 Evaluation of the patient safety climate in hospitalization units: a cross-sectional study - Silva et al	Brazil 2019	50 Nurses	Quantitative/SAQ Short form
A75 How to improve patient safety culture in croatian hospitals? - Sklebar et al	Croatia 2016	576 multiprofessional	Quantitative/HSOPSC
A76 Assessment of patient safety culture among healthcare providers at a teaching hospital in Cairo, Egypt - Aboul-Fotouh et al	Cairo 2012	510 multiprofessional	Quantitative/HSOPSC
A77 A cross-sectional survey on patient safety culture among healthcare providers in the Upper East region of Ghana - Akologo et al	Ghana 2019	406 multiprofessional	Quantitative/HSOPSC
A78 Baseline assessment of patient safety culture in public hospitals in Kuwait - Ali et al	Kuwait 2018	12871 multiprofessional	Quantitative/HSOPSC
A79 A nation-wide transition in patient safety culture: a multilevel analysis on two cross-sectional surveys - Noord et al	Netherlands 2015	314 multiprofessional	Quantitative/HSOPSC
A80 Attitudes of doctors and nurses toward patient safety within emergency departments of two Saudi Arabian hospitals - Alzahrani et al	Saudi Arabia 2018	10 Médicos and 10 Physicians	Qualitative/individual interviews
A81 Turkish surgical nurses' attitudes related to patient safety: A questionnaire study - Bahar e Onler	Turquia 2020	231 Nurses	Quantitative/SAQ
A82 Study of safety culture in healthcare institutions: case of an Algerian hospital - Boughaba et al	Algeria 2019	114 multiprofessional	Quantitative/HSOPSC
A83 Comparing Trainee and Staff Perceptions of Patient Safety Culture - Bump et al	United States 2017	1,426 Intern Physicians + 18,815 multiprofessional	Quantitative/HSOPSC
A84 The patient safety culture as perceived by staff at two different emergency departments before and after introducing a flow-oriented working model with team triage and lean principles: a repeated cross-sectional study - Burström et al	United States 2014	859 multiprofessional	Quantitative/HSOPSC
A85 Safety culture perceptions of pharmacists in Malaysian hospitals and health clinics: a multicentre	Malaysia 2015	117 Pharmaceutics	Quantitative/SAQ



assessment using the Safety Attitudes Questionnaire - Samsuri et al			
A86 The professional culture among physicians in Sweden: potential implications for patient safety - Danielsson et al	Sweden 2018	28 Physicians	Qualitative/16 interviews
A87 Patient safety culture lives in departments and wards: multilevel partitioning of variance in patient safety culture – Deilkås and Hofoss	Norway 2010	1400 multiprofessional	Quantitative/SAQ
A88 Safety culture in intensive care internationally and in Australia: A narrative review of the literature - Dunstan et al	Australia 2018	36 Publications	Narrative Review
A89 Patient safety culture in a large teaching hospital in Riyadh: baseline assessment, comparative analysis and opportunities for improvement - El-Jardali et al	Riyadh 2014	2572 multiprofessional	Quantitative/HSOPSC
A90 Status of patient safety culture in Arab countries: a systematic review -Elmontsri et al	Arab countries 2017	18 Publications	Systematic Review
A91 Revealing and Resolving Patient Safety Defects: The Impact of Leadership WalkRounds on Frontline Caregiver Assessments of Patient Safety - Frankel et al	United States 2008	790 + 741 multiprofessional	Quantitative/SAQ
A92 Characteristics of unit-level patient safety culture in hospitals in Japan: a cross-sectional study - Fujita et al	Japan 2014	8,700 multiprofessional	Quantitative/HSOPSC
A93 Assessment of patient safety culture in clinical laboratories in the Spanish National Health System - Giménez-Marín et al	Spain 2015	740 multiprofessional	Quantitative/HSOPSC
A94 Interprofessional team assessments of the patient safety climate in Swedish operating rooms: a cross-sectional Survey - Göras et al	Sweden 2017	332 Nurses and Physicians	Quantitative/SAQ OR
A95 Assessment of patient safety culture in Palestinian public hospitals - Hamdan	Palestina 2013	2852 multiprofessional	Quantitative/HSOPSC
A96 Measuring safety culture in Palestinian neonatal intensive care units using the Safety Attitudes Questionnaire - Hamdan	Palestina 2013	305 Nurses and Physicians	Quantitative/SAQ UTI
A97 Challenging patient safety culture: survey results - Hellings et al	Belgium 2007	3940 multiprofessional	Quantitative/HSOPSC
A98 The perceptions of patient safety culture: A difference between physicians and nurses in Taiwan - Huang et al	Taiwan 2018	774 Nurses and Physicians	Quantitative/SAQ
A99 A cross-sectional survey on patient safety culture in secondary hospitals of Northeast China - Jiang et al	China 2019	665 multiprofessional	Quantitative/SAQ
A100 Improvement of teamwork and safety climate following implementation of the WHO surgical safety checklist at a university hospital in Japan - Kawano et al	Japan 2014	177 + 162 Nurses and Physicians	Quantitative/SAQ OR
A101 Strengthening leadership as a catalyst for enhanced patient safety culture: a repeated cross-sectional experimental study - Kristensen et al	Dinamarca 2016	358 + 325 multiprofessional	Quantitative/SAQ-DK
A102 Assessing patient safety culture in Tunisian operating rooms: A multicenter study - Mallouli et al	Tunisia 2017	368 multiprofessional	Quantitative/HSOPSC

A103 Patient safety climate profiles across time: Strength and level of safety climate associated with a quality improvement program in Switzerland-A cross-sectional survey study - Mascherek & Schwappach	Switzerland 2017	1193 multiprofessional	Quantitative/SAQ
A104 Healthcare Professional's Perception of Patient Safety Measured by the Hospital Survey on Patient Safety Culture: A Systematic Review and Meta-Analysis) Okuyama et al	Brazil 2018	59 Publications	Systematic Review
A105 Safety climate in 5 intensive care units: a nationwide hospital survey using the Greek-Cypriot version of the safety attitudes questionnaire - Raftopoulos et al	Cyprus 2013	132 Nurses	Quantitative/SAQ-UTI
A106 Patient safety culture among nurses at a tertiary government hospital in the Philippines - Ramos and Calidgid	Philippines 2018	292 Nurses	Quantitative/HSOPSC
A107 (Comparing safety climate for nurses working in operating theatres, critical care and ward areas in the UK: a mixed methods study - Tarling et al	United Kingdom 2017	319/23 Nurses	Mixed Methods (sequential explanatory design)

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