# Development and Preliminary Evaluation of Patient Perceptions on Safety Culture in a Hospital Setting Scale

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# ABSTRACT

**Objectives.** Majority of the existing patient safety culture tools are designed for healthcare workers. Despite the claims that this patient safety tools are patient-centered, limited attention was given to the patients' perspectives and cultural considerations in the development. Local studies are not available in extant literature that capture patient perspectives on being safe during hospitalization. The goal of the study was to develop and provide preliminary psychometric analysis on a tool that measures patients' perception of safety culture in a hospital setting.

**Methods.** The study was a quantitative methodological study. The instrument was developed in three phases, conceptualization and item generation through literature review, clinical observation, and focus group discussion, two rounds of expert panel review, and pilot testing. The tool was tested on 122 eligible patients admitted in a tertiary hospital. Factor analysis of the items was done to determine the underlying factor under each item. Cronbach's alpha



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**Results.** The Patient Perceptions on Safety Culture in Hospital Setting Scale consists of 25 items. The analysis yielded four factors explaining a total of 69.23% of the variance in the data. Items were grouped in four dimensions: Hospital workforce (4 items), Hospital Environment (5 items), Heath Management and Care Delivery (7 items), and Information Exchange (9 items). Each factor registered a Cronbach's alpha of 0.81, 0.78, 0.91, 0.94, respectively. The overall Cronbach's alpha of the scale is 0.95.

**Conclusion.** The study offers preliminary evidence on the psychometric properties of a newly developed tool that measures patient perceptions on hospital safety culture. Subsequent studies on larger samples need to be conducted to determine the reliability and validity of the tool when applied to different population and contexts as well as determining valid cut-off points in scoring and interpretation.

Keywords: patient safety, patient participation, surveys and questionnaire

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# **INTRODUCTION**

In 1999, the Institute of Medicine (IOM) published the report "To Err is Human", a literature report that called for an effort to provide a safer health care services to the patients.<sup>1</sup> It contains a report on the increasing number of deaths per year due to medical errors. According to the World Health Organization (WHO), the occurrence of adverse events due to unsafe care is likely one of the 10 leading causes of death and disability in the world.<sup>2</sup> This paved way to the development of another discipline in the health care system that focuses on reducing and preventing patient harm. Patient Safety is a health care discipline that emerged with the evolving complexity in health care systems and the resulting rise of patient harm in health care facilities. It aims to prevent and reduce risks, errors and harm that occur to patients during provision of health care.<sup>2</sup>

Throughout the years, patient safety became a fundamental aspect in the provision of health care globally. Numerous research was done to produce evidence-based action plans to improve the patient safety culture in the hospital setting. Most of the research conducted so far in the area of primary care patient safety is based on information supplied by health-care providers, and limited attention has been paid to patients' perspectives.<sup>3</sup>

Today, it is widely recognized that patient engagement can help improve outcomes and reduce the burden on health services and on patient safety. Indeed, partnering with patients for the sake of their own health and care is known to be a key component for developing the highest quality of healthcare.<sup>4</sup> To strengthen patient safety culture, it is necessary for management to act in a participatory manner and to realize that communication is the link between the needs of professionals, staff, and patients.<sup>5</sup>

Patients are the common element across the various settings, organizations and health professionals usually involved in their health care, and therefore, they are ideally suited to reflect on the health care they receive.<sup>3</sup> Despite the knowledge that we need to involve patients in strengthening the patient safety culture, there are still limited tools to assess how safe the patient feels while he/she is in the hospital. Measuring safety culture in the patient's point of view allows the identification of strengths and areas for improvement. It also enables the development of appropriate interventions to evaluate new safety programs by comparing results before and after implementation. Thus, this study aimed to develop a tool to measure the patients' perception of safety culture in a hospital setting, and evaluate its psychometric properties. Data driven from a standardized tool will help complement the patient safety perception and goals of healthcare workers and the hospital management, and to establish the baseline for the strengthening of patient safety in a hospital setting.

## OBJECTIVES

To contribute in achieving patient safety goals by the development and evaluation of tool that focuses on the patient's perceptions of patient safety culture in a hospital setting.

Specifically, the objectives of the study are:

- 1. Develop a standardized tool to measure patients' perception of patient safety culture in a hospital setting.
- 2. Conduct a preliminary psychometric study on the validity and reliability of the tool.

## Significance of the Study

During a hospital stay, patients and relatives experience safety culture through observation and interaction, even if some aspects of safety culture may not be directly accessible to them. Thus, when aiming to provide a comprehensive assessment of safety culture, the perspective of patients and relatives may offer relevant information complementing the perspectives of staff and hospital management.<sup>6</sup> While there is little attention to research that focuses on patients' experience and perception of safety culture, existing tools are mostly qualitative and rely on patient interviews and focus group discussions as the data gathering method. It yields a relatively lower number of participants. An additional quantitative tool to measure patients' perception of patient safety culture that can be administered in a large-scale population can benefit to a better understanding of patients' perceptions and experiences of patient safety. Also, by using a tool that will quantify the patients' perception of patient safety, there will be an opportunity to evaluate and compare scores across time and different units in the hospital. This tool can be integrated into the routine collection of data on patient experience, thus helping administrators have a more comprehensive and balanced approach in measuring safety culture. Developing a patient-centred safety culture scale will help administrators assess the effectiveness and efficacy of future protocols implemented by comparing safety culture measures pre and post implementation.

#### **Scope and Limitations**

The study was a quantitative methodological study with several phases namely conceptualization and item generation; expert panel review and; pilot testing of the tool. The study had the following limitations: sample size - since this was a preliminary study and there were constraints in resources, a small sample size was recruited; the tool was validated in a tertiary hospital setting, to ensure universality of the tool, it should be tested in different hospital settings; the tool developed only underwent preliminary evaluation, further testing should be done to evaluate the validity, reliability, and usability of the tool.

# **METHODS**

## **Research Design**

This was a quantitative methodological study. A methodological design was used to provide the reliability and validity indices of a newly developed research tool. The design was appropriate to address the aims of the study which are to develop a scale that measures patient's perceptions on safety culture in a hospital setting, and evaluate its psychometric properties.

The pilot testing of the proposed instrument utilized a correlational design. Correlational design intends to establish the strength and direction of relationships between or among variables. In the study, items specified in the instrument was correlated to determine certain psychometric properties. Data collection strategy in this correlational design was cross-sectional. The study was conducted in three phases; conceptualization and item generation, expert review and pilot testing, and psychometric evaluation.

## Phase I. Conceptualization and Item Generation

The conceptualization of patient's perceptions on patient safety culture was done through review of existing instruments on patient safety, consultation with experts, review of related studies, and clinical observations. Initially, the researchers searched the electronic databases such as PubMed and Google Scholar for similar survey instruments that capture the patients' experience or perception on safety culture during their hospital stay published between January 2012 to April 2022 (10-year period). Boolean operators AND and OR were used to combine selected search items: patient safety, patient experience, patient satisfaction, patient involvement, safety culture, healthcare survey, safety climate, quality indicators. Exclusion criteria were disease-specific or hospital-specific survey questionnaires.

The researchers enlisted items without a lot of editing and critical review in order to capture a wide array for item selection in subsequent stages. However, the researcher was guided in observing clarity, avoiding jargons, avoiding double negatives, and double-barreled items when wording the scale items.<sup>7</sup>

The tool used a multiple item reflective scale using the traditional summated rating, Likert Scale. The assumption of the scale was based on classical test theory (CTT) which asserts that items are presumed to be more or less comparable indicators of the construct being measured.<sup>7</sup> Focus group discussion to eligible participants was also conducted to elicit items coming from the patients' perspective. A total of 35 participants were interviewed for the focus group discussions. Eligible respondents were those patients who are admitted in the hospital for at least three days; able to read and write. Excluded are those who are critically ill (i.e., intubated, unstable); problems in the level of consciousness/ neurologic conditions (i.e., comatose, lethargic); diagnosed with psychiatric or behavioral problems.

The scale item consists of a stem stated in a declarative form; and a response option. The stems were similar and fairly strongly worded as statements that lead to general universal acceptance or rejection were avoided. The traditional fivepoint Likert scale was utilized. Response option was stated in terms of frequency. Numerical score with corresponding descriptor were as follows: "strongly agree", "agree", "neutral", "disagree", "strongly disagree".

## Phase II. Expert Evaluation of Scale Items

External review by experts was conducted to evaluate the face/ content validity of the tool. The panel of experts consists of individuals with strong credentials and experience in patient safety research. It represents diverse perspectives from different disciplines. The initial phase included ten (10) experts in the field who underwent patient safety training and pioneers of patient safety in their respective fields.

External review was conducted into two rounds. The first round involved evaluation of items based on relevance. For the relevance of the item to the domain and construct, a four-point Likert was used in rating: 1= not relevant, 2= somewhat relevant, 3= quite relevant, 4= highly relevant. Low scoring items were eliminated in the tool. The remaining items underwent second round of expert review to evaluate the validity, clarity, and appropriateness of the items. Validity was rated as 1 = not necessary, 2 = useful but not essential, and 3 = essential.

Clarity and appropriateness were judged dichotomously (e.g., yes/no). If the expert rated the scale to be irrelevant, not clear or inappropriate, justifications and recommendations was provided in the remarks section.

# Phase III. Pilot Testing and Psychometric Evaluation

To ensure adequacy of sample, the researchers followed the ratio of 5-10 participants per variable. The revised instrument obtained from the external review by panel of experts was pilot tested to 122 participants to determine its psychometric adequacy. Due to time constraints, the researchers were only able to test the tool to 122 participants not meeting the target of 125 participants. For ease of understanding, questionnaire items were translated to Filipino by a linguist prior to testing to participants. The study utilized purposive sampling in recruiting respondents.

# Inclusion/ Exclusion Criteria

Eligible respondents are those (1) patients who are admitted in the hospital for at least one day, (2) able to read and write. Excluded are those who are (1) critically ill (i.e., intubated, unstable); (2) problems in the level of consciousness/ neurologic conditions (i.e., comatose, lethargic); (3) diagnosed with psychiatric or behavioral problems. Sample size was determined based on the total items of the scale.

Table 1. Patient Saf	ety Tools Selected for	Item Conceptualization
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Survey Instrument	Focus Population	Country and Year of Development
Hospital Survey on Patient Safety Culture (HSOPSC) <sup>8</sup>	Healthcare staff	United States, 2004
Manchester Patient Safety Framework (MaPSaF) <sup>9</sup>	Healthcare staff	United Kingdom, 2006
Safety Attitudes Questionnaire <sup>10</sup>	Healthcare staff	United States, 2004
Systematic Culture Inquiry on Patient Safety in Primary Care (SCOPE-PC) <sup>11</sup>	Healthcare staff	Netherlands, 2011
Primary Care Patient Measure of Safety (PC PMOS) <sup>12</sup>	Patients	Australia, 2015
Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) <sup>13</sup>	Patients	United Kingdom, 2016
Patient Perspective of Safety in General Practice (PPS-GP) <sup>14</sup>	Patients	Ireland, 2021

 Table 2. Structure of Initial Patient's Perception on Safety

 Culture Scale

Dimensione	Items in Scale	
Dimensions	Phase I	Phase II
Staffing and Workload	8	4
Teamwork	5	Items were integrated to Staffing and Workload
Physical Environment	13	6
Health Management and Care Delivery	11	5
Patient Autonomy	8	4
Communication and Information Sharing	21	6

#### Participant Recruitment

Trained research coordinators obtained permission from the chief nurses and unit head nurses prior to conduct of the study. The nature, purpose, and duration of the study and inclusion criteria was explained to prospective participants in the unit. Those who expressed interest to participate in the study were screened using the inclusion criteria. Participants were involved in the study for 10-15 minutes. Participant recruitment lasted for 10 days from September 28, 2022 to October 7, 2022

The study was conducted in a university tertiary hospital, a 1,500-bed capacity healthcare facility in the National Capital Region. Data collection was conducted in the general adult wards.

The questionnaire package consists of (1) Informed consent; (2) Basic socio-demographic and clinical profile, and (2) Patient Perceptions on Patient Safety Culture Scale in Hospital Setting. The research coordinator collected the answered questionnaire. No specific information linking to the participant was collected.

## **Psychometric Evaluation**

Since no theoretical framework was used as a basis, factor analysis using the principal components analysis with rotation was utilized. To show the correlation is strong enough to use this dimension reduction technique, Bartlett's test of Sphericity was examined. Kaiser Meyer Olkin (KMO) was also computed to determine plausibility of factor analysis.

## Validity

Level of agreement was computed by the formula number agreeing divided by the number of experts. Relevance was determined by computing item-level content validity index (I-CVI), the number giving a rating of 3 or 4, divided by the total number of experts. An I-CVI of 0.78 or higher was recommended. Items that registered lower than the desired I-CVI will be evaluated as feedback from the experts will be elicited. In the second round, a content validation of the scale was carried out from the same group of experts (n= 10).

## Reliability

To test the degree of internal consistency of the scale, specifically to test the degree to which the set of items in the scale co-vary, relative to their sum score, Cronbach's alpha was used. An alpha coefficient of 0.70 was regarded as an acceptable threshold for reliability.

## **Ethical Considerations**

The universal ethical principles of respect for persons, beneficence and justice guide the ethical dimension of this study (Council for International Organizations of Medical Sciences, 2016). The study protocol adheres to the ethical principles outlined in the National Ethical Guidelines for Health and Health-related Research set forth by the Philippine Health Research Ethics Board (PHREB) (2017). These elements of research ethics are social value; informed consent; vulnerability; risk, benefit and safety, privacy, and confidentiality; justice; and transparency. The investigators obtained ethical review and clearance from the University of the Philippines Manila Review Ethics Board (REB) before the data collection procedure begins.

# RESULTS

The items generated in the tool was based on similar instruments (7 identified instruments as shown in Table 1 – Hospital Survey on Patient Safety Culture (HSOPSC), Manchester Patient Safety Framework (MaPSaF), Systematic Culture inquiry on Patient Safety in Primary Care (SCOPE-PC), Patient Safety Culture Scale for Chinese Primary Health Care Institutions, Primary Care Patient Measure of Safety (PC PMOS), Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC), Patient Perspective of Safety in General Practice (PPS-GP). Table 1 shows the different focus of the survey instruments.

The initial phase of the tool development yielded 66 items categorized into six dimensions namely Staffing and Workload, Teamwork, Physical Environment, Health Management and Care Delivery, Patient Autonomy, and Communication. Dimensions identified were extracted from review of existing patient safety scales, patient experience, and expert consensus.

After expert review, questionnaire items were reduced to 25 items as deemed relevant by the ten chosen experts. Redundant items and items that were not relevant as evaluated by experts were removed. Table 2 shows the difference in items of the scale from Phase 1 to Phase 2. Items under Teamwork retained only 2 items, the research team decided to merge the remaining items with Staffing and Workload. Tool development was conducted from June 2022 to September 2022.

The questionnaire was tested on 122 participants who are currently admitted in a tertiary hospital. All 122 questionnaires were accomplished completely. The participants consist of 48 (39.3%) male and 74 (60.6%) female. Majority (20.6%) of the participants were admitted in the Pay Patient wards that caters to medical-surgical patients, admitted for the first time (45%), and are on their 9<sup>th</sup> or more day (44%) in the hospital. The demographics of the participants is shown in Table 3.

Twenty-five items of the PPSC were factor analyzed after pilot testing, using principal components analysis with Varimax rotation. Using both scree plot and eigenvalue >1 to determine the underlying components, the analysis vielded four factors explaining a total of 69.23 percent of the variance of the data. Factor analysis yielded only four relevant dimensions. Items were regrouped based on their high loadings per category. The research team decided to rename the dimensions based on the underlying theme of the items. The first dimension explained 28.99% of the variance after the rotation. Items from Staffing and Workload was retained in this first dimension, this was labelled as Hospital Workforce. The second dimension explained 42.52% of the variance after the rotation, this included items from Physical Environment and Information Exchange. The second dimension was labelled as Hospital Environment. The third dimension explained 55.96% of the variance and retained its name as Health Management and Care Delivery. The fourth dimension was labelled Information Exchange as items from Patient Autonomy and Health Management and Care Delivery were grouped under this dimension. It explained 69.23% of the variance after the rotation.

The scale demonstrated high degree of internal consistency. The overall cronbach's alpha of the scale is 0.96. Each dimension also showed high internal consistency with cronbach's alpha of 0.81, 0. 78, 0.91 and 0.94, respectively, as shown in Table 4.

#### Table 3. Demographics of the Participants

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	n	%
Sex		
Male	48	39.3
Female	74	60.6
Religion		
Catholic	96	78.6
INC	6	4.9
Aglipay	1	0.8
Born again	16	13.1
Muslim	1	0.8
Christian	1	0.8
Adventist	1	0.8
Education		
No formal education	3	2.4
Elementary	11	9
Highschool	54	44.2
College	54	44.2
Work		
With work	42	34.43
Without work	80	65.57
Ward		
Medicine	1	0.8
Surgery	15	12
Pay Patient	40	32.7
Ob-Gyne	24	19.6
Neuro-rehab	14	11.4
Trauma	13	10.6
Cancer Institute	15	12.2
Frequency of admission		
1	55	45
2	32	26.2
3	10	8.1
4	13	10
5	5	4
6 or more	7	5
Hospitalization days		
1-2 days	7	3.6
3-5 days	37	3.1
6-8 days	24	19.6
9 or more days	54	44

 
 Table 4. Number of Items and Reliability of Patient's Perception on Safety Culture Scale

	Number of items	Cronbach's alpha
Hospital Workforce	4	0.81
Hospital Environment	5	0.78
Health Management and Care Delivery	7	0.91
Information Exchange	9	0.94
Overall scale		0.96

## DISCUSSION

The Patient Perceptions on Safety Culture in a Hospital Setting Scale (PPSC) aims to measure the patient's perception of safety while admitted in hospital settings. This study explains the detailed development of a questionnaire that will assess the level of safety as reported by the patient. The tool aims to aid in measuring and monitoring safety practices. Being one of the first local tool developed, this captures perspectives of patients that is different from patients from other countries, with different population and totally different health care set up. Most tools are developed in UK and USA, and instruments valid for other countries are very much needed<sup>15</sup> as some of items in the tools available in the literature may not be applicable in the local health care setting.

Similar themes identified with existing tools include concerns on staffing adequacy and competency, patient autonomy, and ease of communicating with health care staff regarding their treatment and concerns. Themes of patient safety concerns identified were similar to other tools, but patients were able to identify specific measures of patient safety that are important to them. Among those identified were cleanliness of environment, protection from infection, presence of safety warnings, signages and grab bars at bathrooms. Patients also expressed the importance of proper patient identification, timely delivery of care, and prevention of harm through monitoring of side effects and complication after receiving treatment. Security from unsafe equipment and personnel were also highlighted. Competence of health care staff, properly working equipment, and introduction of healthcare staff during patient interaction were identified as important component of patient safety.

Patients have always had minimal participation in developing measure on how to ensure their safety. Key strategies in patient safety involves utilizing patient generated information in promoting their own safety. Patient reported outcomes should also be emphasized in promoting patient safety, as they provide valuable feedback and a different perspective in incident reporting, in which most of the time gathered from health care professionals, which usually suffers underreporting.<sup>16</sup> It is clear that patient can identify contributory factors within the hospital setting with ease.<sup>16</sup> Increasing evidence suggests that patients can be involved in improving patient safety as they are acute observers of their own care, actively and consistently collecting observations about their health care experience.<sup>15</sup> Evident in the tool development how patient can identify contributory factors in the hospital setting that affects their perspective of patient safety. Involving patient in their own safety is both a promising and policy driven area for study, with the potential for delivering real changes to patient safety outcomes.<sup>17</sup>

The PPSC can also be used in the unit level to aid decision makers in identifying weaknesses in their patient safety mechanism in a unit level. Use of psychometrically evaluated tools will help evaluate effectiveness of patient safety interventions. This will help them provide more clientcentered interventions that is responsive to the needs of the patients at the unit. Outcomes reported from this can be utilized in quality improvement strategies that can be implemented in the organizational level. The PPSC can also be used in adjunct to other patient safety tools and other incident reporting mechanism to further improve safety in a unit level and in the organizational level over time. This will help evaluate and monitor changes in safety practices over time. Patient and staff feedback and other data sources, will together provide a more comprehensive picture of patient safety.<sup>12</sup>

## Limitations

The development of the tool did not utilize any theoretical framework, and only used existing patient safety scales, clinical observations, and data from focus group discussions. It does not capture all possible contributory factors of patient safety thus it should be used with other safety measurement tools. The use of the tool is limited to hospital setting and may not be applicable to measure patient safety perception in other healthcare setting.

#### Recommendations

Further research is recommended prior to use of tool. Subsequent studies on larger samples should be conducted to determine reliability and validity of the tool when applied to different population and context. Face validity of the tool should also be tested in the subsequent studies. Cut off points and methods of interpratation of scores should be developed. Future studies are also needed to compare levels of patient safety as measured by PPSC against other measures of the concept to support the validity of the tool.

#### CONCLUSION

The Patients Perception Safety Scale is a new tool developed to measure patients' perception of patient safety culture in a hospital setting. Results of the psychometric analysis support its internal consistency. The PPSC provides data than can be used in a more comprehensive assessment of patient safety, thus allowing stakeholders to plan and implement quality and responsive patient safety measures.

#### **Statement of Authorship**

All authors certified fulfillment of ICMJE authorship criteria.

#### **Author Disclosure**

All authors declared no conflicts of interest and all authors are in agreement with the content of the manuscript.

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