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Factors affecting patient safety culture in a university hospital under the universal health insurance system
A cross-sectional study from Japan

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Abstract

We conducted a cross-sectional study of patient safety culture aimed at examining the factors that influence patient safety culture in university hospitals under a universal health insurance system. The Hospital Survey on Patient Safety Culture developed by the Agency for Healthcare Research and Quality was used. The survey was distributed to 1066 hospital employees, and 864 responded. The confirmatory factor analysis showed a good fit of the results to the 12-composites model. The highest positive response rates were for "(1) Teamwork within units" (81%) and "(2) Supervisor/manager expectations and actions promoting patient safety" (80%), and the lowest was for "(10) Staffing" (36%). Hayashi's quantification theory type 2 revealed that working hours per week had the greatest negative impact on patient safety culture. Under a universal health insurance system, workload and human resources might have a significant impact on the patient safety culture.

Abbreviations: AHRQ = Agency for Healthcare Research and Quality, RMSEA = root mean square error of approximation, SRMR = standardized root mean square residual.

Keywords: cross-sectional study, factor, patient safety culture, universal health insurance system, university hospital

1. Introduction

Patient safety is an essential component of healthcare quality and safety that should be given the highest priority. However, a number of studies have shown that many opportunities exist for adverse events to occur in general healthcare environments. It is estimated that 98,000 Americans die each year as a result of medical errors that occur in hospitals.[1] Population-based data from the Colorado and Utah Medical Practices Study lead to estimates that preventable adverse events in outpatient settings in the U.S. cause 75,000 hospitalizations annually, with 4839 permanent serious illnesses and 2587 deaths.[2] A systematic review of reports on adverse events during hospitalization found that 9.2% of hospitalizations involved adverse events, of which 43.5% were preventable and 7.4% were fatal.[3] These unintended adverse events result in hospital admissions,[2] longer hospital stays,[4] increased medical expenditures,[4,5] and serious permanent injury or death,[4,6] which is a serious problem for individual patients, hospitals, and society.

A decisive factor in improving the quality and safety of healthcare is fostering an organization's patient safety culture.[7] The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management.[8] Many reports suggest that patient safety culture is positively correlated with healthcare quality and safety in facilities, including fewer medical incidents,[9] fewer surgical site infections,[10] less burnout among staff,[11] and reduced staff absenteeism and turnover intentions.[12] Therefore, in order to improve patient safety culture, healthcare organizations need to identify the factors that positively influence that culture.[13]

Several studies on factors affecting patient safety culture have been reported. A survey of nursing units in 8 North Carolina hospitals suggested that frequency of contact undergirds relationships between leaders and members and fosters a patient safety culture.[14] According to a systematic review conducted by Weaver et al, interventions such as executive walkrounds, interdisciplinary rounds, team training, or communication initiatives in acute care settings can nurture a patient safety culture.[7] A survey of hospitals with >300 beds and electronic medical record systems in Japan, excluding university hospitals, suggests that the number of days off, the presence of a hospital mission statement on patient safety, and the participation rate for in-hospital patient safety workshops are important factors in fostering a patient safety culture.[15] Because each of these individual studies is limited and heterogeneous in terms of the countries, hospitals, departments, or professions covered, further studies in various settings are needed to increase their generalizability.

In Japan, medical accidents were recognized only as issues of individual negligence, rather than those that concerned the entire organization, until 2000. From 1999 to early 2000, a series of serious medical accidents occurred in Japan, including an error regarding the surgical site due to a patient scheduled for heart surgery being mistaken for one scheduled for lung surgery and incidents where antiseptic solution rather than anticoagulants were administered intravenously to postoperative patients. In response to these medical accidents, in October 2002, hospitals in Japan were obliged to ensure that patient safety was being managed and maintained. In April 2003, university hospitals were required to establish dedicated patient safety managers and management departments. In April 2007, medical institution administrators were required to formulate guidelines that ensured patient safety, form safety management committees, provide training for employees, and assign a person who would be responsible for the safe use of drugs and medical equipment. In general, university hospitals are considered to have different regulations and resources related to patient safety management than other hospitals,[15] which calls for a university hospital-specific study. Furthermore, Japan has one of the few universal health insurance systems in the world. This is one of the most distinctive features of Japanese healthcare and may have a significant impact on the patient safety culture. The universal health insurance system guarantees all citizens a public medical insurance that allows them to freely choose medical institutions, and to receive advanced medical care at low costs, which might result in many patients and increased workload for medical personnel. Therefore, in this study, we quantitatively examined patient safety culture in university hospitals using a questionnaire for all departments to determine the factors that affect patient safety culture under a universal health insurance system.

2. Methods

2.1. Setting

The Osaka Medical and Pharmaceutical University Hospital, the subject of this study, is a university hospital located in Takatsuki City (population: 350,000) in Osaka with 832 beds, 31 departments, and approximately 3000 staff members. The daily work of staffing in medical safety management is carried out by seven core members including the director of the medical safety department. The medical safety committee, which includes approximately 15 other members, meets monthly to review the incidents that have occurred and to conduct medical safety activities.

2.2. Design

In this study, cross-sectional research was conducted. Among 2949 staff members who were in our hospital from 2015 to 2016, staff members randomly selected from each group of experience period (1–5 years, 6–15 years, and 16 years or more) were included as survey subjects. Subjects were recruited using a list of employee numbers to equalize the number of years of experience groups. This cross-sectional research measured patient safety culture through questionnaires administered to employees at a university hospital, compared it to patient safety culture in the U.S., and further examined its relationship to employee background, such as job title and years of work experience.

2.3. Questionnaire

The Japanese version of the Hospital Survey on Patient Safety Culture, developed by the Agency for Healthcare Research and Quality (AHRQ), was authored and validated by 2 bilingual medical safety researchers with a good command of English in a previous study.[16] In this study, this Japanese version was used as a questionnaire to measure patient safety culture.[8,16] Furthermore, it has been reported that the patient safety culture in Japan fits well with the AHRQ's 12-composites model of patient safety culture.[17] The survey instrument consists of 42 items related to patient safety. All 42 items are either on a 5-point Likert scale (Strongly disagree = 1; Disagree = 2; Neither = 3; Agree = 4; Strongly agree = 5) or on a 5-point frequency scale (Never = 1; Rarely = 2; Sometimes = 3; Most of the time = 4; Always = 5), which are grouped into the following 12 composites of patient safety culture: teamwork within units; supervisor/manager expectations and actions promoting patient safety; organizational learning–continuous improvement; management support for patient safety; overall perceptions of patient safety; feedback and communication about error; communication openness; frequency of events reported; teamwork across units; staffing; handoffs and transitions; and nonpunitive response to error. The survey instrument also grades (E) respondents' perception for an overall grade on patient safety on a 5-point scale (Failing = 1; Poor = 2; Acceptable = 3; Very good = 4; Excellent = 5) and includes items related to the respondent's background, for example, job title, gender, age, and years of experience.

2.4. Data processing

Several items of the instrument were negatively worded. Disagreeing or responding "Never" to a negatively worded item indicates a positive response, and scores were reversed during analysis.[8,18]

2.5. Statistical analysis

Confirmatory factor analysis was used to examine whether responses to the questionnaire fit the AHRQ's 12-composites model of patient safety culture.[8] The model was estimated using the method of maximum likelihood estimation, and the goodness of fit of the estimated model was evaluated using the root mean square error of approximation (RMSEA) and standardized root mean square residual (SRMR). The RMSEA index was <0.06, or the SRMR index was <0.08, as the indicators of the fitness of the confirmatory factor analysis.[19] The positive response rate in the 12 composites was calculated as follows.[8] The positive response rate for each item was determined using the number of people who answered 4 or 5 as the numerator and the number of people who answered 1, 2, 3, 4, or 5 as the denominator. For each composite, the mean of the positive response rate for each item was calculated.

Category scores were obtained by applying Hayashi's quantification theory type 2[20–22] with the respondent's background as the explanatory variable and "(E) Overall grade on patient safety" as the objective variable to examine the impact of the respondent's background on patient safety culture. The range of scores defined as the difference between the maximum and minimum of the category scores obtained for each explanatory variable was calculated,[23] and the influence on patient safety culture was estimated. Hayashi's quantification theory type 2 is a linear discriminant analysis of categorical data. This method combines categorical and dummy variables (i.e., 0 or 1) to allow the analysis of quantitative relationships between objective and explanatory variables.[24] Statistical analysis was performed using R version 3.6.2.

2.6. Ethical considerations

Respondents' information is treated in an anonymized state, and personal information is fully considered. All procedures involving human subjects were approved by the ethics committee of Osaka Medical and Pharmaceutical University (Approval ID: RIN-964, 2886).

3. Results

3.1. Study population

The questionnaires were distributed to 1066 staff members, and 864 responded (81.1% response rate).

3.2. Characteristics of the respondents

The professional backgrounds of the respondents are shown in Table 1. "Nurse" (40.3%) was the most common, followed by "Physician" (27.9%), "Medical staff" (15.5%), and "Unit assistant/clerk/secretary" (13.5%). "Female" (55.7%) was more common, while there was no significant difference in age. Asked how many years of occupational experience they had, 36.9% of respondents answered 1 to 10 years; 25.5% answered "11 to 18 years"; and 34.7% answered "≥19 years." Asked how many years of experience they had in their current facility, 34.6% answered 1 to 7 years; 24.7% answered "8 to 14 years"; and 39.2% answered "≥15 years." Asked how many years of experience they had in their current department, 34.8% answered 1 to 3 years; 19.9% answered "4 to 6 years"; and 43.5% answered "≥7 years." The most common working hours per week were "40 to 59 hours" (57.1%), followed by "20 to 39 hours" (16.8%), "60 to 79 hours" (13.5%), and "≥80 hours" (6.4%). Managers accounted for 25.8% of the respondents; 88.3% had the opportunity to interact with patients; and 70.0% had the opportunity to directly care for patients.

3.3. Results of confirmatory factor analysis

The confirmatory factor analysis results indicate the fitness of the proposed model[8] (RMSEA = 0.048; SRMR = 0.050). High standard partial regression coefficients (range: 0.471–0.920) were obtained (Table 2).

3.4. Percentage of positive scores of 12 patient safety culture composites

Figure 1 shows the positive response rate for the 12 composites of patient safety culture. The highest positive response rate was found in "(1) Teamwork within units" (81%), while the lowest was found in "(10) Staffing" (36%). Our results were generally comparable to those of a survey[25] of 447,584 respondents at 680 U.S. hospitals.

3.5. Effects of characteristics of respondents on an overall grade on patient safety

Regarding "(E) Overall grade on patient safety," 4.9% responded "Excellent," and 48.6% responded "Very good," with more than half of the positive evaluations (Table 3). Hayashi's quantification theory type 2 revealed the most negative impact of working hours per week on "(E) Overall grade on patient safety" (Fig. 2).

4. Discussion

Patient safety should be a top priority, and the development of an organization's patient safety culture is a critical factor in achieving this.[7] In the current study, we investigated the extent to which a patient safety culture was fostered in university hospitals under a universal health insurance system, and the factors that influence it. As a result, the confirmatory factor analysis showed that the results of this study were well suited to the AHRQ's 12-composites model of patient safety culture (Table 2).[8] According to the positive response rate results, patient safety culture in our hospital was comparable to the U.S. results from the AHRQ survey.[25] Hayashi's quantification theory type 2 showed that working hours per week had the most negative impact on "(E) Overall grade on patient safety" (Fig. 2).

The positive response rate for the 12 composites of patient safety culture in our hospital was similar to the survey result in the U.S. (Fig. 1).[25] Fujita et al found that patient safety culture in the U.S. was higher than in Japan and Taiwan.[26] These facts suggest that patient safety culture in our hospital is as high as it is in the U.S. According to a study by Hamdan et al in a Palestinian public hospital, patient safety initiatives and quality improvement programs were effective in fostering patient safety culture.[27] It is well recognized that patient safety training and education can improve patient safety attitudes and patient outcomes.[18] In our hospital, various patient safety initiatives have been ongoing for more than a decade under the leadership of the medical safety management department, such as patient safety slogan competitions in which patients participate, patient safety training camps, in-hospital patient safety workshops, and efforts to improve underreporting of incidents. The high level of patient safety culture in our hospital is largely because we have been honestly continuing these efforts. Furthermore, at least in Japanese university hospitals, it is mandatory to have a full-time patient safety staff consisting of three or more doctors, nurses, and pharmacists, while in other general hospitals, it is not.[15] This may also be a factor in the high patient safety culture in our hospital compared to the Japanese results.[26] The factor with the highest percentage of positive responses among the 12 composites was "(1) Teamwork within units" (81%). This was consistent with the U.S. (82%),[25] Japan (70%),[26] and Teleş et al's findings (85%).[28] In contrast, the lowest factors were "(10) Staffing" (36%), "(12) Nonpunitive response to error" (49%), and "(11) Handoffs and transitions" (51%). This was exactly the same in the U.S.[25] and in the Japanese study.[26] This suggests that perceptions of staffing shortages in the field, punitive responses to medical incidents, and patient safety issues during patient interdepartmental transfers and handovers are common across both cases. On the other hand, "(10) Staffing" was as low as 36% in our hospital, while it was 54% in the U.S., which was a large difference. This may be an indication of the perception that the staff of our hospital have more work and care for more patients than staff in the U.S. It is possible that Japan's universal health insurance system explains these differences. In fact, Stoyanova et al reported that the distribution of positive responses could be explained by the cultural, organizational, and healthcare system differences.[29] In addition, the survey results of Teleş et al[28] are significantly different from the results of our hospital and the U.S.[25] in that "(11) Handoffs and transitions" were higher (73%) and "(8) Frequency of events reported" was lower (32%). The fact that this study only included Turkey's general surgery departments may have

Table 1

Characteristics of the respondents to the questionnaire.

Characteristics (n = 864)	Frequency	Proportion (%)
Years of survey		
2015	440	50.9
2016	424	49.1
What is your staff position in this hospital?		
Physician	241	27.9
Nurse	348	40.3
Medical staff	134	15.5
Unit assistant/clerk/secretary	117	13.5
Other	18	2.1
Missing	6	0.7
Gender		
Male	370	42.8
Female	481	55.7
Missing	13	1.5
Age (yr)		
<20	2	0.2
20–29	184	21.3
30–39	221	25.6
40–49	229	26.5
≥50	212	24.5
Missing	16	1.9
How long have you worked in your current specialty or profession?		
1–2 yr	79	9.1
3–5 yr	99	11.5
6–10 yr	141	16.3
11–18 yr	220	25.5
≥19 yr	300	34.7
Missing	25	2.9
How long have you worked in this hospital?		
1–2 yr	95	11.0
3–4 yr	92	10.6
5–7 yr	112	13.0
8–14 yr	213	24.7
≥15 yr	339	39.2
Missing	13	1.5
How long have you worked in your current hospital work area/unit?		
1 yr	100	11.6
2 yr	100	11.6
3 yr	100	11.6
4–6 yr	172	19.9
≥7 yr	376	43.5
Missing	16	1.9
Typically, how many hours per week do you work in this hospital?		
<20 h	14	1.6
20–39 h	145	16.8
40–59 h	493	57.1
60–79 h	117	13.5
≥80 h	55	6.4
Missing	40	4.6
Are you a manager currently?		
Yes	223	25.8
No	626	72.5
Missing	15	1.7
In your staff position, do you typically have direct interaction or contact with patients?		
Yes	763	88.3
No	90	10.4
Missing	11	1.3
In your staff position, do you typically have direct care for patients?		
Yes	605	70.0
No	241	27.9
Missing	18	2.1

made a difference. These findings suggest that each country and department has a unique patient safety culture.

In order to foster a patient safety culture, healthcare policymakers and managers need to understand the factors that negatively influence patient safety culture and consider how to respond to them.[13] There have been reports that a work shift and occupational burnout negatively affect patient safety culture,[30] and that healthcare workers who work under 40 hours or >60 hours per week have lower patient safety culture scores than those who work 40–59 hours.[13] It has been reported that job satisfaction has the most positive impact on patient safety culture, whereas stress recognition has the most negative

Table 2

Results of confirmatory factor analysis for patient safety culture composites in the current hospital.

| Composites	Codes	Items	Standard partial regression coefficients
1. Teamwork within units	A1	People support one another in this unit.	0.774
	A3	When a lot of work needs to be done quickly, we work together as a team to get the work done.	0.764
	A4	In this unit, people treat each other with respect.	0.768
	A11	When one area in this unit gets really busy, others help out.	0.581
2. Supervisor/manager expectations and actions promoting patient safety	B1	My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures.	0.602
	B2	My supervisor/manager seriously considers staff suggestions for improving patient safety.	0.701
	B3*	Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts.	0.614
	B4*	My supervisor/manager overlooks patient safety problems that happen over and over.	0.672
3. Organizational learning–Continuous improvement	A6	We are actively doing things to improve patient safety.	0.649
	A9	Mistakes have led to positive changes here.	0.662
	A13	After we make changes to improve patient safety, we evaluate their effectiveness.	0.506
4. Management support for patient safety	F1	Hospital management provides a work climate that promotes patient safety.	0.639
	F8	The actions of hospital management show that patient safety is a top priority.	0.625
	F9*	Hospital management seems interested in patient safety only after an adverse event happens.	0.718
5. Overall perceptions of patient safety	A10*	It is just by chance that more serious mistakes don't happen around here.	0.471
	A15	Patient safety is never sacrificed to get more work done.	0.575
	A17*	We have patient safety problems in this unit.	0.591
	A18	Our procedures and systems are good at preventing errors from happening.	0.614
6. Feedback and communication about error	C1	We are given feedback about changes put into place based on event reports.	0.723
	C3	We are informed about errors that happen in this unit.	0.767
	C5	In this unit, we discuss ways to prevent errors from happening again.	0.754
7. Communication openness	C2	Staff will freely speak up if they see something that may negatively affect patient care.	0.666
	C4	Staff feel free to question the decisions or actions of those with more authority.	0.706
	C6*	Staff are afraid to ask questions when something does not seem right.	0.658
8. Frequency of events reported	D1	When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?	0.714
	D2	When a mistake is made, but has no potential to harm the patient, how often is this reported?	0.920
	D3	When a mistake is made that could harm the patient, but does not, how often is this reported?	0.730
9. Teamwork across units	F2*	Hospital units do not coordinate well with each other.	0.706
	F4	There is good cooperation among hospital units that need to work together.	0.558
	F6*	It is often unpleasant to work with staff from other hospital units.	0.587
	F10	Hospital units work well together to provide the best care for patients.	0.704
10. Staffing	A2	We have enough staff to handle the workload.	0.535
	A5*	Staff in this unit work longer hours than is best for patient care.	0.407
	A7*	We use more agency/temporary staff than is best for patient care.	0.610
	A14*	We work in "crisis mode" trying to do too much, too quickly.	0.646
11. Handoffs and transitions	F3*	Things "fall between the cracks" when transferring patients from one unit to another.	0.693
	F5*	Important patient care information is often lost during shift changes.	0.671
	F7*	Problems often occur in the exchange of information across hospital units.	0.738
	F11*	Shift changes are problematic for patients in this hospital.	0.544

(*Continued*)

(Continued)

Composites	Codes	Items	Standard partial regression coefficients
12. Nonpunitive response to error	A8*	Staff feel like their mistakes are held against them.	0.685
	A12*	When an event is reported, it feels like the person is being written up, not the problem.	0.677
	A16*	Staff worry that mistakes they make are kept in their personnel file.	0.574

*Negatively worded items that have points for answers were reversed as follows: 1 to 5, 2 to 4, 4 to 2, 5 to 1; six respondents with missing values in 21 or more of the 42 items and 175 respondents who answered "Not applicable" in at least one item were excluded. After these exclusions, the remaining missing values were assigned mean values for each item before the data analysis was conducted; root mean square error of approximation (RMSEA), 0.048; standardized root mean square residual (SRMR), 0.050; n = 683.
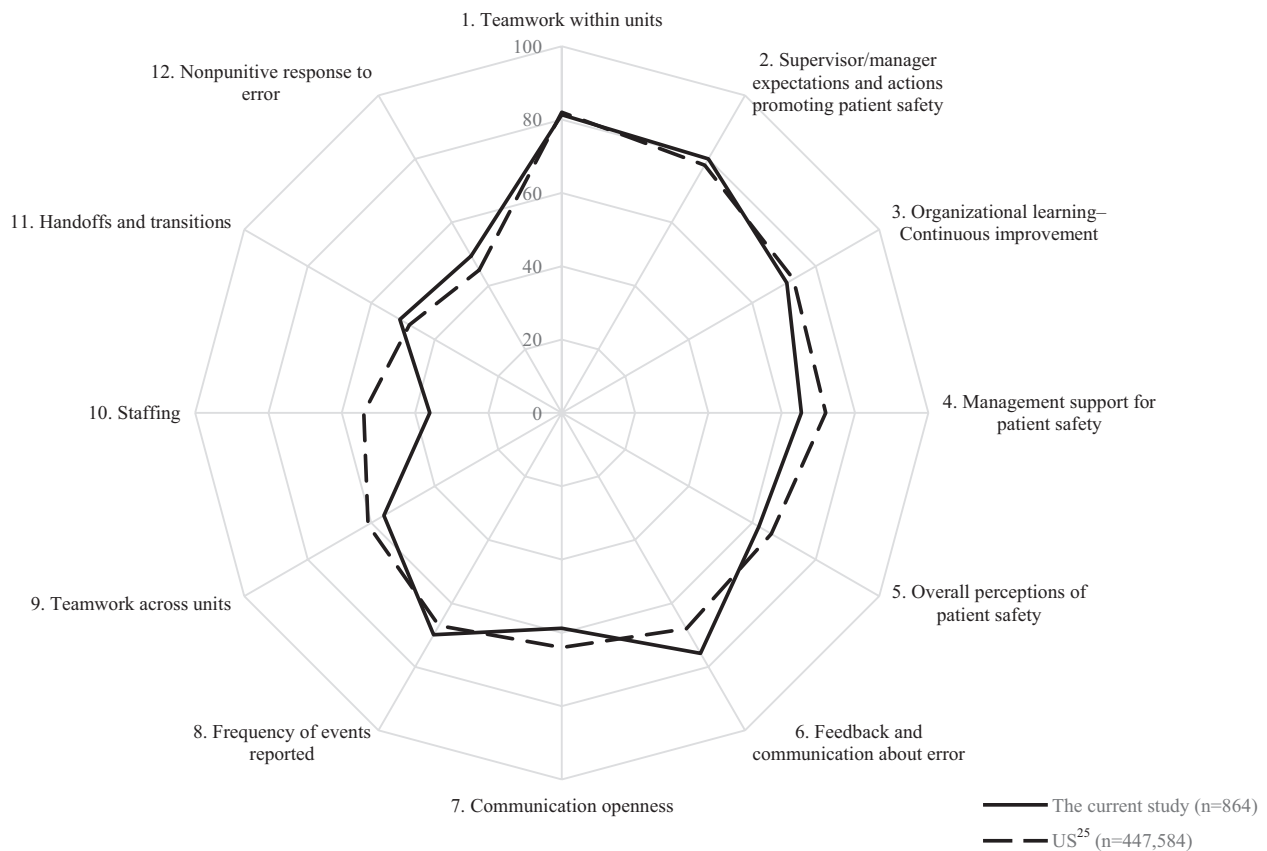
**Figure 1.** Percentage of positive scores for 12 patient safety culture composites.

Table 3			
"(E) Respondents' perception for an overall grade on patient safety."

Codes	Items	Frequency	Proportion (%)
E	Please give your work area/unit in this hospital an overall grade on patient safety.		
	Excellent	42	4.9
	Very good	420	48.6
	Acceptable	365	42.2
	Poor	21	2.4
	Failing	1	0.1
	Missing	15	1.7

n = 864.

effect.[31] A study of healthcare workers in a Tunisian center's intensive care unit reported that a significantly lower patient safety culture was associated with a higher workload.[32] The current study also showed that the number of working hours per week had the most negative impact on the overall assessment of patient safety (Fig. 2). These facts clearly suggest the existence of a positive relationship between maintaining an appropriate workload and work–life balance and patient safety culture. While years of service at the hospital had a positive impact on patient safety culture, patient safety culture scores decreased
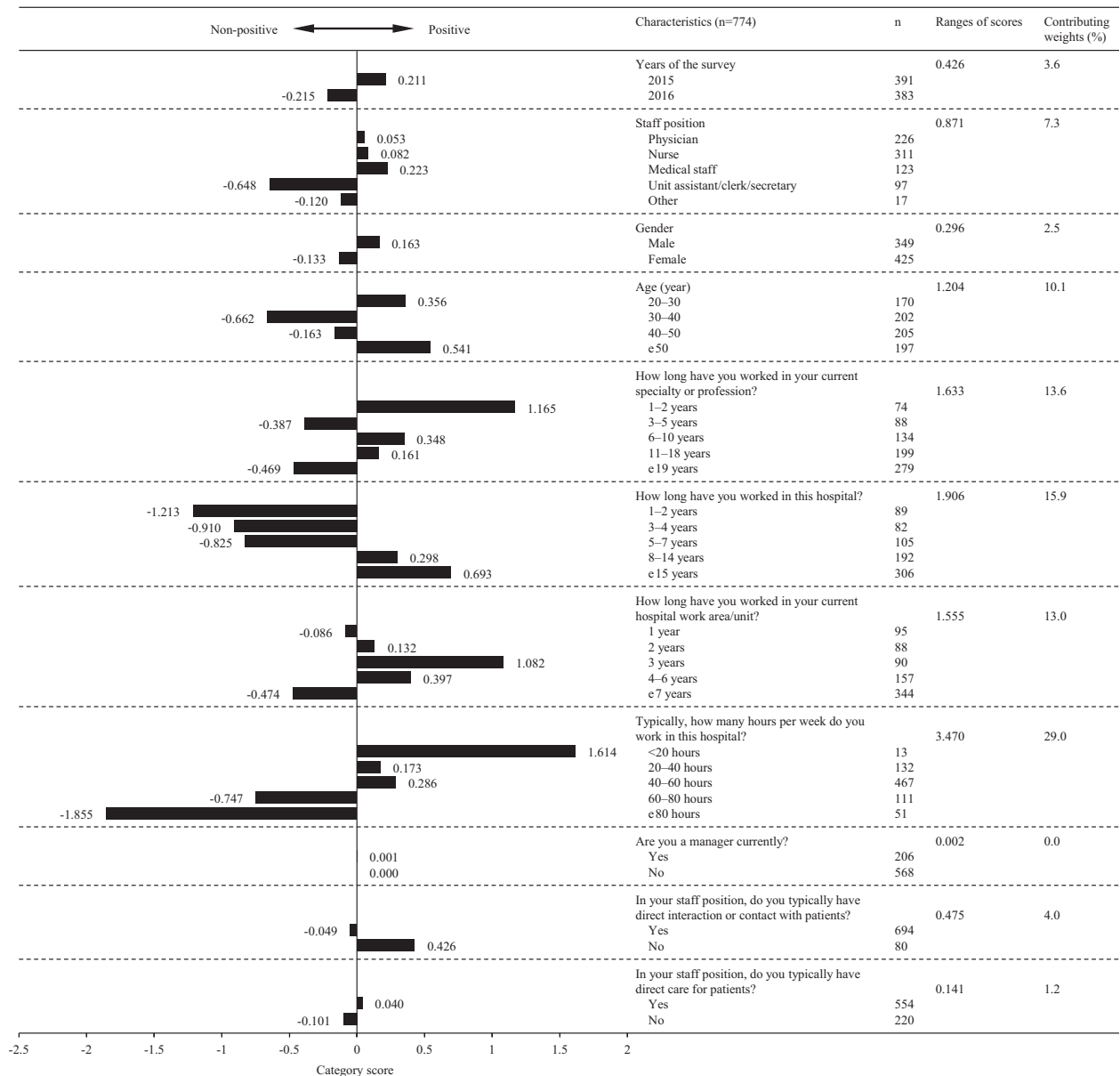
Figure 2. Category scores of characteristics of respondents regarding an overall grade on patient safety in current hospital. Two respondents under 20 years of age and 88 respondents with missing values in at least one item were excluded; n = 774.

when the number of years of intra-departmental experience was greater than 7 years (Fig. 2). Departmental transfers to avoid staying in the same department for too long may be effective in preventing a decline in patient safety culture. No clear tendency was found in the number of years of occupational experience. From the above, healthcare policymakers and managers need to foster a patient safety culture in consideration of workload, work–life balance, and reassignment.

The current study has several limitations. First, this study is a cross-sectional study. Because of its design, in which the temporal precedence of the explanatory variables analyzed as causes over the objective variables was unknown, we were not able to identify these causal relationships. Second, the questions in the Japanese version of the Hospital Survey on Patient Safety Culture used in this study were not validated by back-translation.

5. Conclusion

In this study, we have shown that working hours are the factor that has the most negative impact on patient safety culture.

Under a universal health insurance system, workload and human resources might have a significant impact on the patient safety culture. It is important to continue regularly monitoring and maintaining patient safety culture. Future studies should be conducted in various settings. Furthermore, it is desirable to consider the decisive factors that negatively affect the patient safety culture of working hours and how to deal with them.

Author contributions

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