Multilevel Analysis of Individual, Organizational, and Regional Factors Associated With Patient Safety Culture: A Cross-Sectional Study of Maternal and Child Health Institutions in China

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Objectives: The aim of this study was to assess patient safety culture (PSC) in maternal and child health (MCH) institutions in China and its individual, organizational, and regional variations.

Methods: Using the PSC survey for MCH institutions (PSCS-MCHI), 2021 valid respondents from 25 participating institutions were investigated in three regions (Beijing, Zhejiang, and Jiangxi) of China. Patient safety culture and its subscale scores (1–5) and factors associated with PSC as revealed by multilevel modeling.

Results: The respondents had an average PSC score of 3.55 (SD = 0.35), with subscale scores ranging between 2.46 (“staffing and workload”) and 4.02 (“work commitment”). There were limited regional differences in PSC: a three-level regression model was only confirmed for the subscale “staff empowerment” (P = 0.006). However, significant organizational variations in PSC were evident: a two-level regression model was assumed for the PSC scale and nine subscales (P < 0.001). The fixed-effect models showed that male respondents, frontline workers, those who were in their mid-career (11–20 y), overloaded (299 hours), and had a masters or higher degree reported worse PSC. Frontline workers were less positive than managers in ratings on “managerial response to risks” (−0.11 [−0.20 to −0.02]), “management support” (−0.18 [−0.28 to −0.07]), and “staff empowerment” (−0.23 [−0.35 to −0.11]).

Conclusions: Patient safety culture in MCH institutions is shaped by organizational and individual characteristics. We observed a gap in perceived PSC between frontline worker, who are less positive, and managers. Actions for improving PSC should consider interventions on organizational management (such as appropriate staffing and workload management) and engagement of frontline workers in the development of management and training activities.

Key Words: patient safety culture, maternal and child health, multilevel analysis

(Original Article)
The mortality ratio of 19.9 per 100,000,22 a proud outcome in comparison with some of the developed nations such as the United States. The population health orientation of MCH institutions may set themselves apart from general hospitals in PSC.23 Indeed, we revealed some special features of PSC e.g., a long-term view of child health outcomes and preventive nature of services in MCH institutions in several studies.8,23,24 As a result, an adapted version of the PSC scale based on the HSOPSC established by the Agency for Healthcare Research and Quality was developed. In this study, we tested this scale and used this scale for determining regional, organizational, and individual determinants of PSC MCH institutions.

METHODS

Study Design and Setting
A cross-sectional survey was conducted in the following three regions of China: Beijing, Zhejiang, and Jiangxi. These regions were purposively selected. Beijing is a highly urbanized metropolitan region with a very high density of health resources. Health facilities in Beijing received patients across all regions of China.25 Zhejiang represents one of the most developed provinces in China but has great disparities in socioeconomic development within the region.26 Jiangxi is one of the least developed provinces in China, with gross domestic product per capita well below the average among all provinces in China.16

Sampling and Data Collection
All of the MCH institutions (n = 220) in the selected regions were invited and 25 (11.4%) agreed to participate in this study: 3 in Beijing, 14 in Zhejiang, and 8 in Jiangxi, accounting for 15.0%, 16.1%, and 7.1% of all MCH institutions in each region, respectively. These included one provincial MCH hospital, five municipal MCH hospitals, ten county MCH hospitals, and nine county MCH centers (The characteristics of the participating MCH institutions can be found in Appendix A, http://links.lww.com/JPS/A206). An MCH hospital delivers both individual-based specialist care and population-based preventive care. By contrast, MCH centers are much smaller, focusing on primary care (mostly population-based preventive care).

Data were collected from January 2016 to April 2017. Facility data such as resources and volume of services were provided by the facility managers. Individual experiences in patient safety and PSC were captured through a self-completed questionnaire. The questionnaire was distributed to all staff members who were approachable at the time of the survey, including managers, doctors, nurses, midwives, public health workers, technicians, pharmacists, and allied health workers. An informed consent statement was attached to the questionnaire. Return of the questionnaire was deemed consent, which was completely voluntary and anonymous. The questionnaire took approximately 10 to 15 minutes to complete. Participants were asked to return the completed questionnaire to a deposit box placed in the workplace within 2 weeks.

A total of 2452 questionnaires were distributed (representing 29.4% of all staff members) and 2145 (87.5%) were returned. This resulted in a final sample size of 2021 (82.4% of distributed questionnaires) for data analyses (Fig. 1), after excluding the questionnaires containing more than 20% of missing items (≥8 items).

A repeated survey was undertaken to examine the test-retest reliability of the questionnaire in 135 respondents who volunteered to complete the second survey 10 to 14 days after the initial survey (Fig. 1).

Measures
Patient safety culture was measured using the PSCS-MCHI, an adapted version of HSOPSC tailored to the special context of MCHI. It has been validated through a vigorous process involving in-depth

FIGURE 1. Flowchart of sampling of respondents.
The PSCS-MCHI contains 37 items, measuring the following ten subscales of PSC: patient engagement (6 items), managerial commitment (4 items), patient safety (4 items), support (5 items), teamwork (4 items), job satisfaction (4 items), work overload (4 items), quality improvement (4 items), and organizational empowerment (4 items), staffing and workload (4 items), and reporting (4 items) (Appendix B, http://links.lww.com/JPS/A207). Respondents were asked to rate each item on a five-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = neither, 4 = agree, 5 = strongly agree; negative wording was scored reversely). An average score of all responded items in each PSC subscale as well as an average score of subscales were calculated, with a higher score indicating better PSC.

The questionnaire also collected data related to the demographic characteristics and work experience of the respondents, including age, sex, education, years of working in health industry, years of working with current employer, average daily workload, contact with patients, and job position.

**Statistical Analysis**

The reliability and validity of the PSCS-MCHI were further confirmed in this study (Appendix C, http://links.lww.com/JPS-A208), as indicated by the Cronbach’s α coefficients, intraclass correlations (test-retest reliability), and fitness of data into the confirmatory factor model (standardized root mean-square residual = 0.050, root mean square error of approximation = 0.039, comparative fit index = 0.914, Tucker-Lewis Index = 0.901).27,28

We performed multilevel linear regression modeling (iterative generalized least squares, IGLS) to identify individual, organizational, and regional factors associated with PSC. Measurements at the individual level (n = 2021) were nested in 25 organizations from three regions.

We started with an empty model to determine appropriate levels of modeling for the ten PSC subscales, which were treated as continuous variables. The variance components were considered as random effects and partitioned into the following three levels: with level-1 variance (σ²) indicating individual variance within an organization; level-2 variance (σ²) indicating organizational variance within a region; and level-3 variance (σ²) indicating regional variance. The significance of the impact of regional and organizational variations on PSC was assessed using intraclass correlation coefficient (ICC): ICC(υ) = σ²/(σ² + σ² + σ²) for the regional level; ICC(α) = σ²/(σ² + σ² + σ²) for the organizational level.29-32 A significant change in deviance [-2(\log-likelihood)] when eliminating a higher level from the empty model (e.g., from three- to two-level or from two- to one-level) indicates that the higher-level model has a better goodness of fit to the data.32,33 We then established two- or three-level fixed-effect models including all explanatory variables. The explanatory variables at the individual level were all entered as categorical variables, including age (≤34, 35–54, ≥55), sex (male, female), education (no university degree, bachelor degree, master or higher degree), years of working in health industry (≤10, 11–20, ≥21), average daily workload in the past week (≤8, 8–10, ≥10), patient contact (indirect, direct), and job position (manager, frontline worker). Data were entered and managed using Epidata 3.1. The confirmatory factor analysis was performed using Mplus 5.1. The multilevel linear regression models were established using MLwiN 2.1. The SPSS 20.0 software was used for group comparisons with analysis of variance tests.

**RESULTS**

Most respondents (52.7%) were younger than 35 years. The majority (82.9%) were women, frontline workers (91.5%), and had direct contact (85.8%) with patients. Approximately one-third did not have a university degree. Less than half had more than 10 years of work experience in the health industry (Table 1).

The respondents had an average PSC score of 3.55 (SD = 0.35), with subscale scores ranging between 2.46 (“staffing and workload”) and 4.02 (“work commitment”). Significant PSC scale

| TABLE 1. Characteristics of Respondents (N = 2021) |
|-----------------------------------------|-----------|-----------------|
| **Characteristics**                   | n (%)     |                 |
| **Region**                             |           |                 |
| Beijing                                | 425 (21.0)|                 |
| Zhejiang                               | 1236 (61.2)|                |
| Jiangxi                                | 360 (17.8)|                 |
| **Organization**                       |           |                 |
| Provincial hospital                    | 293 (14.5)|                 |
| Municipal hospital                     | 661 (32.7)|                 |
| County hospital                        | 740 (36.6)|                 |
| County center                          | 327 (16.2)|                 |
| **Individual characteristics**         |           |                 |
| Age, y                                 |           |                 |
| ≤34                                    | 1066 (52.7)|                |
| 35–54                                  | 866 (42.9)|                 |
| ≥55                                    | 76 (3.8)  |                 |
| Missing                                | 13 (0.6)  |                 |
| Sex                                    |           |                 |
| Male                                   | 284 (14.1)|                 |
| Female                                 | 1675 (82.9)|                |
| Missing                                | 62 (3.1)  |                 |
| Education                              |           |                 |
| No university degree                   | 675 (33.4)|                 |
| Bachelor degree                        | 1146 (56.7)|                |
| Master degree or higher                | 194 (9.6) |                 |
| Missing                                | 6 (0.3)   |                 |
| Years of working in health industry    |           |                 |
| 0–10                                   | 1081 (53.5)|                |
| 11–20                                  | 513 (25.4)|                 |
| ≥21                                    | 419 (20.7)|                 |
| Missing                                | 8 (0.4)   |                 |
| Years of working with current employer |           |                 |
| 0–10                                   | 1271 (62.9)|                |
| 11–20                                  | 431 (21.3)|                 |
| ≥21                                    | 311 (15.4)|                 |
| Missing                                | 8 (0.4)   |                 |
| Average daily workload, h              |           |                 |
| ≤8                                     | 1278 (63.2)|                |
| 9–10                                   | 572 (28.3)|                 |
| ≥11                                    | 161 (8.0) |                 |
| Missing                                | 10 (0.5)  |                 |
| Contact with patients                  |           |                 |
| Indirect                               | 162 (8.0) |                 |
| Direct                                 | 1735 (85.8)|                |
| Missing                                | 124 (6.1) |                 |
| Job position                           |           |                 |
| Manager                                | 158 (7.8) |                 |
| Frontline staff                        | 1850 (91.5)|                |
| Missing                                | 13 (0.6)  |                 |

Percentages may not add to 100 because rounding.
and subscale variations across regions (except for “management support” and “work commitment”) and organizations (except for “reporting of adverse events” and “work commitment”) were found (Fig. 2, Appendix D, http://links.lww.com/JPS/A209, and Appendix E, http://links.lww.com/JPS/A210).

In the empty models, the ICCs for PSC scores ranged from 0.0% to 5.3% at the regional level and from 0.5% to 9.1% at the organizational level. A three-level model was confirmed for the subscale “staff empowerment” (P = 0.006). Two-level models were selected for the rest of the PSC subscales and the overall PSC score (P < 0.001), except for “work commitment” (P = 0.113), for which a one-level model was assumed (Table 2).

The fixed-effect modeling revealed that PSC was associated with age, sex, work experience, workload, job position, and patient contacts (Table 3). Overall, male respondents, frontline workers, those who were in their mid-career (11–20 y), reported higher daily average work hours (≥29 hours) and had a masters or higher degree reported worse PSC. Older respondents (≥55 y) gave a higher score to “staffing and workload,” but lower scores to “work commitment” and “transfer and handoff” compared with their younger counterparts. Male respondents reported worse PSC in all subscales except for “staffing and workload” and “training.” Those with a higher degree were mainly concerned about “staffing and workload,” “reporting of adverse events,” and “training.” A longer working experience was associated with a higher score to “staffing and workload,” “managers response to risks,” “defensive medical practice,” and “transfer and handoff.”

A three-level regression model was only confirmed for the subscale “staff empowerment” but lower scores in “staff empowerment,” “training,” “managers response to risks,” “defensive medical practice,” and “transfer and handoff” but a lower score in “staffing and workload.” Frontline workers reported lower scores in “managers response to risks,” “management support,” and “staff empowerment” than their managers (Table 3).

### DISCUSSION

**Challenges and Implications of PSC in MCH Institutions**

The PSCS-MCHI is an adapted version of HSOPSC tailored to the special context of MCH institutions in China. Its compositions draw a profile of PSC in MCH institutions, including the following ten subscales: “patient engagement,” “managers response to risks,” “management support,” “staff empowerment,” “staffing and workload,” “reporting of adverse events,” “defensive medical practice,” “work commitment,” “training,” and “transfer and handoff.”

A three-level regression model was only confirmed for the subscale “staff empowerment,” indicating limited regional differences in PSC of MCH institutions. This may be attributable to the strong

### TABLE 2. Variances, ICCs, and Significance Testing in Empty Models of PSC

| Parameter | PSC | 1-PE | 2-MRR | 3-MS | 4-SE | 5-SW | 6-RAE | 7-DMP | 8-WC | 9-TR | 10-TH |
|-----------|-----|------|-------|------|------|------|-------|-------|------|------|-------|
| Variance  |     |      |       |      |      |      |       |       |      |      |       |
| $\sigma^2_{\text{P}}$ | 0.000 | 0.000 | 0.003 | 0.000 | 0.023 | 0.008 | 0.004 | 0.000 | 0.000 | 0.000 | 0.005 |
| $\sigma^2_{\text{E}}$ | 0.007 | 0.003 | 0.006 | 0.036 | 0.007 | 0.022 | 0.002 | 0.038 | 0.001 | 0.041 | 0.010 |
| $\sigma^2_{\text{C}}$ | 0.115 | 0.210 | 0.255 | 0.359 | 0.403 | 0.448 | 0.313 | 0.408 | 0.201 | 0.553 | 0.252 |
| ICC(00) (%) | 0.0 | 0.0 | 1.1 | 0.0 | 5.3 | 1.7 | 1.3 | 0.0 | 0.0 | 0.0 | 1.9 |
| ICC(o) (%) | 5.7 | 1.4 | 3.4 | 9.1 | 6.9 | 6.3 | 1.9 | 8.5 | 0.5 | 6.9 | 5.6 |
| $-2 \log$-likelihood | 1455.797 | 2699.907 | 3025.379 | 3792.333 | 4002.365 | 4230.816 | 3417.299 | 4075.498 | 2496.937 | 4656.083 | 3051.099 |
| (1) one-level | 1403.548 | 2599.606 | 2997.354 | 3713.416 | 3935.630 | 4152.261 | 3404.694 | 3969.235 | 2494.419 | 4578.660 | 2982.551 |
| (2) two-level | 1403.548 | 2599.606 | 2996.790 | 3713.416 | 3928.019 | 4149.873 | 3402.330 | 3969.235 | 2494.419 | 4578.660 | 2981.406 |
| (3) three-level | 1.000 | 1.000 | 0.453 | 1.000 | 0.006 | 0.122 | 0.124 | 1.000 | 1.000 | 1.000 | 0.285 |
| P(3) versus (2), df = 1 | <0.001 | 0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | 0.113 | <0.001 | <0.001 | <0.001 |
| P(2) versus (1), df = 1 | <0.001 | 0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | 0.113 | <0.001 | <0.001 | <0.001 |
| Table 3. Fixed-Effect Models of Variables Associated With PSC: Regression Coefficients and Confidence Intervals (β [95% CI]) |
|---------------------------------------------|
| **Explanatory Variables** | **PSC (2-Level)** | **1-PE (2-Level)** | **2-MRR (2-Level)** | **3-MS (2-Level)** | **4-SE (3-Level)** | **5-SW (2-Level)** | **6-RAE (2-Level)** | **7-DMP (2-Level)** | **8-WC (1-Level)** | **9-TR (2-Level)** | **10-TIH (2-Level)** |
|---------------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|
| **Constant**              | 3.56 (3.48 to 3.65) | 3.77 (3.66 to 3.88) | 3.73 (3.64 to 3.86) | 3.39 (3.23 to 3.54) | 3.49 (3.46 to 3.92) | 2.87 (2.70 to 3.03) | 3.62 (3.40 to 3.75) | 3.22 (3.06 to 3.39) | 3.85 (3.75 to 3.96) | 3.69 (3.49 to 3.88) | 3.73 (3.60 to 3.86) |
| **Sex (male as reference)** | 0.19 (0.05 to 0.34) | 0.08 (0.02 to 0.14) | 0.07 (0.00 to 0.13) | 0.15 (0.07 to 0.22) | 0.00 (0.00 to 0.17) | 0.03 (0.05 to 0.12) | 0.14 (0.07 to 0.21) | 0.23 (0.15 to 0.32) | 0.06 (0.00 to 0.12) | 0.01 (0.08 to 0.11) | 0.11 (0.04 to 0.18) |
| **Years of working in health industry (≥10 y as reference)** | -0.10 (-0.16 to -0.03) | -0.03 (-0.11 to 0.06) | -0.02 (-0.12 to 0.08) | -0.20 (-0.32 to -0.08) | -0.27 (-0.39 to -0.14) | -0.05 (-0.15 to 0.06) | -0.09 (-0.21 to 0.03) | -0.00 (-0.08 to 0.09) | -0.20 (-0.34 to -0.06) | -0.05 (-0.15 to 0.04) | -0.01 (-0.12 to 0.13) |
| **Average daily workload (≥48 h as reference)** | -0.07 (-0.13 to -0.01) | 0.01 (-0.07 to 0.10) | -0.06 (-0.16 to 0.03) | 0.08 (-0.08 to 0.19) | -0.07 (-0.18 to 0.05) | -0.13 (-0.25 to -0.01) | -0.17 (-0.27 to -0.07) | -0.02 (-0.14 to 0.10) | 0.05 (-0.03 to 0.12) | -0.37 (-0.51 to -0.23) | -0.02 (-0.11 to 0.08) |
| **Years of working with current employer (≥10 y as reference)** | -0.10 (-0.16 to -0.03) | -0.03 (-0.11 to 0.06) | -0.02 (-0.12 to 0.08) | -0.20 (-0.32 to -0.08) | -0.27 (-0.39 to -0.14) | -0.05 (-0.15 to 0.06) | -0.09 (-0.21 to 0.03) | -0.00 (-0.08 to 0.09) | -0.20 (-0.34 to -0.06) | -0.05 (-0.15 to 0.04) | -0.01 (-0.12 to 0.13) |
| **Daily contacts (indirect as reference)** | -0.07 (-0.10 to -0.03) | -0.06 (-0.11 to -0.01) | -0.01 (-0.06 to 0.06) | -0.04 (-0.11 to 0.02) | -0.04 (-0.11 to 0.02) | -0.30 (-0.37 to -0.23) | 0.00 (-0.06 to 0.06) | -0.06 (-0.12 to 0.01) | -0.03 (-0.08 to 0.02) | -0.11 (-0.19 to -0.03) | -0.03 (-0.09 to 0.02) |
| **Job position (management as reference)** | -0.07 (-0.13 to -0.00) | 0.01 (-0.07 to 0.10) | -0.11 (-0.20 to -0.02) | -0.18 (-0.28 to -0.07) | -0.23 (-0.35 to -0.11) | -0.01 (-0.13 to 0.11) | 0.03 (-0.08 to 0.13) | -0.14 (-0.25 to 0.01) | 0.00 (-0.08 to 0.09) | -0.07 (-0.20 to 0.07) | -0.01 (-0.10 to 0.09) |

Bold numbers indicate that the regression coefficients are significant (P < 0.05).
top-down governance and administration of MCH services. For the last few decades, the central government of China has set MCH as a priority in the health care system development, serving as a foundation for sustainable human development. A series of legislations, regulations, and policies have been put into place, giving clearly defined instructions to the funding, workforce, and services arrangements for MCH institutions. Empirical evidence shows that these measures have significantly improved regional equality of MCH care and MCH outcomes in China.\(^\text{21,34,35}\) Furthermore, the significant variation of “staff empowerment” in both regional and organizational level also reveals that the top-down MCH system is a double-edged sword for PSC. It should be necessary to make a priority of optimizing frontline workers’ engagement in decision-making, through creating a work environment with an informal power structure, developing the decision-making capabilities of frontline workers by training or educational programs, and ensuring their participation in decision-making processes by policies and regulations, etc.\(^\text{36–40}\)

There are significant organizational variations in PSC. The PSC scale and its nine subscales presented significant heterogeneity across MCH institutions in this study, suggesting a two-level regression model. This result is consistent with the findings of other studies. Indeed, PSC is rooted in the context of organizational arrangements.\(^\text{9,14,41,42}\) In the Chinese context, it seems that the size of MHC institutions matters. Those in the medium to large range (e.g., 500–999 health workers or 500–999 beds) seemed to have better PSC, but a further increase in the size may not necessarily bring benefits in PSC (Appendix E, http://links.lww.com/JPS/A210). Further studies are warranted to explore the underlined reasons and mechanisms. For those huge institutions in the size, it may be reasonable to compose into various target groups of the interventions with different purposes, because an inherently hierarchical structure exists in an organization where culture is often deeply embedded within different levels and subgroups.\(^\text{43}\)

Management can make a difference to organizational PSC. However, they have to realize that individual variations in PSC always exist in an organization. This study revealed that MCH institutions in China share similar individual determinants of PSC in comparison with other health institutions,\(^\text{1,2,39,43}\) which indicate that management actions for improving PSC need to consider age, sex, educational background, work experience, and workloads of their staff members. This study presents the worse perceived PSC among respondents who are male, in their mid-career, or having a master or higher degree, which is consistent with the findings of previous studies, possibly because of neglect, arrogance, or burnout of patient safety.\(^\text{39,44}\) It is worth noting that a gap in perceived PSC exists between managers and frontline workers. This is a common finding across several studies\(^\text{43–46}\) that has some implications on the development of PSC training and management programs. Frontline workers usually hold a less positive perception on PSC than their managers. Therefore, staff participation and engagement in training and management decision-making are extremely important in driving effective cultural changes.\(^\text{39,47,48}\)

Managers themselves should be made accountable for PSC. Of the PSC subscales, “staffing and workload” was rated as a particular concern by the study participants in comparison to those of studies undertaken in other countries.\(^\text{39–55}\) Previous studies of hospitals in China conveyed similar concerns.\(^\text{39,42,43,52}\) Interestingly, China has already had a MCH workforce of 2.8 per 10,000 population,\(^\text{16}\) higher than the recommended standard (1:10,000) from the national health authority.\(^\text{31}\) However, 36.3% of respondents in this study still reported overloading (>8 h/d). This is not uncommon in MCH institutions in China.\(^\text{34,54,55}\) In October 2015, China abandoned its one-child family policy, allowing each family to have two children. The baby boom has not happened as expected, but with a cut of 630 thousand births from 17.86 million in 2016 to 17.23 million in 2017. However, an increasing of pregnant women with advanced age has emerged undoubtedly,\(^\text{36,57}\) with higher risks of pregnant complications and adverse birth outcomes,\(^\text{58,59}\) imposing greater pressure on MCH services. Therefore, it should be the urgent matter to improve the efficiency, capacity, and quality of MCH services.

**Limitations and Further Studies**

The study sample is not representative of the entire country of China. Because of limitations in sample size and availability of data, we were not able to further analyze PSC scores across units and wards as was done in some previous studies.\(^\text{3,13,33,66}\) Further studies are needed to establish representative benchmarking for MCH institutions. There is also a need to explore the underlying mechanisms of organizational variations in PSC.

**CONCLUSIONS**

The PSCS-MCHI is a reliable instrument for measuring PSC in MCH institutions. In China, regional differences in PSC in MCH institutions are limited. However, great organizational variations in PSC exist. Actions for improving PSC should consider interventions at the organizational level (such as appropriate staffing and workload management) as well as at the individual level (such as training). Furthermore, it is important to engage frontline workers in the development of management and training activities.

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