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Transcultural adaptation and psychometric evaluation of the mainland China Version of Nursing Home Survey on Patient Safety Culture questionnaire: A cross-sectional survey based on 50 nursing homes in China

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Keywords: nursing homes; safety culture; aged; psychometrics

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Abstract

Objective: To provide a validated Chinese-language measurement of the Nursing Home Survey on Patient Safety Culture (NHSOPS) in mainland China. Thus, the primary aim is to carry out a transcultural adaptation into the Chinese of the NHSOPS questionnaire and to evaluate its psychometric properties.

Design: A psychometric evaluation study. Firstly, the “Translate-Back translate-Cultural adaption” and the pretesting procedure were followed to introduce the NHSOPS. Secondly, a cross-sectional survey was used to assess the psychometric properties of the mainland China version, and a test-retest survey was then also applied.

Setting and participants: The survey was carried out among 1397 nursing home staff from 50 nursing homes in South-western China.

Outcome Measures: Exploratory Factor Analysis (EFA) was used to assess the potential structure and Confirmatory Factor Analysis (CFA) was then applied. Reliability was assessed by Content validity index, Cronbach’s α and the test-retest value.

Results: Among the 1397 respondents, 1211 were included (86.7%). On the one hand, EFA was used and a 9-factor structure was explored. Five factors (Cronbach’s α > 0.6) were selected into the new structure for the mainland China version of the Nursing Home Survey on Patient Safety Culture (M-NHSOPS). Moreover, data showed that it was suitable for CFA, and Convergent validity and Discriminant validity were satisfying. On the other hand, M-NHSOPS contains five dimensions and 22 items.
The overall Cronbach's $\alpha$ value was 0.883; the values of each dimension ranged from 0.648-0.913. Additionally, Content validity showed significant performance. Finally, Test-retest reliability was 0.892, and for each dimension were 0.713, 0.809, 0.924, 0.795 and 0.859 respectively ($p<0.001$).

**Conclusions:** M-NHSOPS has acceptable reliability and satisfactory validity among staff in mainland nursing homes.

**Keywords:** nursing homes; safety culture; aged; psychometrics

**Strengths and limitations of this study:**
- Clarifying the inclusion of types of staff for the scale
- Representative and abundant sample
- Further verification among samples in other places in the Mainland is required

**Introduction**

Preventing incidents such as medication errors and misconducts are paramount goals in elderly care institutions, and Patient safety culture (PSC) refers to the prevailing attitudes, beliefs, values, and behaviors of employees formed by health institutions to achieve the goal of patient safety. The inverse association between PSC and adverse event occurrence was proved. Thus, PSC has been accepted as an essential quality indicator across all health care settings. For improvement, the most common approach which has been taken is to develop or introduce reliable PSC
assessment tools in specific countries and then survey the cross-sectional situation in the organizations.

As mentioned above, assessing the current situation and defining the weak aspects of organizations are regarded as the most challenging step. Correspondingly, a reliable tool is the premise for assessment. On the one hand, a significant concern in evaluating PSC at present is to continue to emphasize PSC in hospitals. Many tools were developed: Safety Attitudes Questionnaire (SAQ), Hospital Survey on Patient Safety Culture (HSOPS), and so on. SAQ and HSOPS have been widely introduced, such as in Norwegian, Greece, and China, etc. On the other hand, some pieces of evidence are recognized that nursing homes (NHs), are at high risk. Residents in NHs have multiple health problems and require complicated medications. Some of them even have cognitive impairments, which leads to more potential risks. However, there has been less previous research for PSC in NHs.

Though advocating PSC in NHs has increased in recent years, efforts in evaluating PSC in NHs, primarily available tools, are still lacking. In 2008, the Agency for Healthcare Research and Quality (AHRQ) developed a specific tool Nursing Home Survey on Patient Safety Culture (NHSOPS) for NHs, which had developed HSOPS before. Subsequently, NHSOPS has also been validated into different regions and cultures, including Norwegian, French, Swiss, Spain, etc. In mainland China, government categorizes NHs into three types: NHs hosted and managed by government party (in this research, it is named as type A), hosted by the government but managed by the non-government party (type B), and hosted and
managed by the non-government party (type C). Research suggests that the government-owned nursing homes still enjoy more benefits than private organizations in staffing, funding, and insurance. However, the same thing is that all kinds of NHs do face safety risks now and then. Since the Chinese nursing home industry is still under initial development, the qualities vary among different NHs, compared with NHs in developed countries.

Recently, two Chinese versions of NHSOPS were reported in 2016 and 2017. For Xiao’s version in mainland China, the sample size was small (N=322). Moreover, the proportion of the surveyed staff was not following staffing in Chinese NHs. Additionally, all staff types were included without considering the applicability of the scale content and some items. For another Taiwan, China version, there are numerous differences between mainland China and Taiwan: dialects, sub-cultures, functions, classifications of NHs, types of professionals in NHs, staffing proportions of professionals in different kinds of NHs, and different development levels of NHs, etc. Accordingly, NHs in mainland China are still in urgent requirement of a reliable assessment tool.

In this study, we focus on intercultural adaptation of NHSOPS into the mainland based on data from 50 NHs in South-western China and evaluating its psychometric properties.

**Methods**
This study was conducted in two phases: an initial phase involving the translation and cultural adaptation of the questionnaire, and a second phase in which the psychometric properties of the questionnaire were evaluated.

**Translation and transcultural adaptation of NHSOPS in mainland China**

The NHSOPS contains 42 items focused on 12 dimensions: teamwork, staffing, compliance with procedures, training and skills, non-punitive response to mistakes, handoffs, feedback and communication about incidents, communication openness, supervisor expectations and actions promoting patient safety, overall perceptions of patient safety, management support for patient safety, and organizational learning.\(^{14}\) Two overall rating questions are at the end of the scale. The total score ranges from 0 to 210; the higher scores represent a superior safety culture in the organization.

Copyright of the original scale (utilization and translation) was attained in October 2015 from AHRQ.

A cross-cultural adaptation procedure was conducted: translation, back-translation, cultural adjustment, and pretesting. The first step was to translate the original scale into Chinese by two independent native postgraduates who possess fluent vocal English. Both graduates are nurses and have well understandings on conceptions of PSC. Secondly, a professor from evidence-based medicine who has been concentrating on research of PSC synthesized the two Chinese versions into one. Two bilingual translators who with no medical backgrounds then translated it back to Chinese separately. Both of them were blind to the questionnaire. A geriatric nursing professor checked the equivalence of context and semantics by comparing the
back-translated versions with the original one and checked if it was translated in accordance.

The cultural adaptation process included 3 parts, with 3 rounds of group meetings, 2 rounds of expert consultations, and a pilot test. It is recommended by the User's Guide developed by AHRQ for international translators that group meetings focused on translation and adjustment should be used to make a better cultural-adaption.14

Participants in the group meetings were 3 Ph.D. students in geriatric nursing, 4 Master students in geriatric nursing and 2 Master students in evidence-based medicine. The criteria for inclusion of experts were that, (1) they have related experience as one of follows, safety culture, elderly care, elderly patient management, hospital management, nursing home management, and public health, etc.; (2) with more than 10 years of related experience; and (3) informed consent. Nineteen experts participated in 2 rounds of consultations, and all came from Sichuan Province. Their ages ranged from 40-60, and only one expert was above 60; 3 (15.8%) of them have worked for 10-19 years, 4 (21.1%) for 20-29 years and 12 (63.3%) ≥30 years; 3 (15.8%) graduated from Junior College, 9 (47.4%) were undergraduates, 4 (21.1%) have Master degrees, and 3 (15.8%) have doctoral degrees; 7 (36.8%) were head nurses in hospitals, 3 (15.8%) were deputy head nurse in hospitals, 1 (5.3%) was the management layer of the nursing department in a hospital, 3 (15.8%) were from Sichuan Association of Senior Services (SASS), 3 (15.8%) works as management layer of NHs, and 1 (5.3%) was a professor of nursing, 1 (5.3%) was a professor of statistics. Eventually, a pilot-test conducted by querying 200 care providers in the
nursing home to complete the survey, and no difficulty in understanding or responding was reported.

**Psychometric validation of mainland China version of the NHSOPS**

This cross-sectional study was conducted in Sichuan province, Southwest China, from 2016 to 2017. Primarily, we contacted one nursing home and pilot-tested a subgroup (N=200). We then reached each type of nursing home (A, B, C) from 20 administrative regions with detailed research information. Theoretically, at least 1 nursing home for each kind from each area should be extracted.

In this study, 50 NHs were enrolled, and 1397 staff were invited, while in which 186 questionnaires were excluded. Inclusion criteria were (1) personnel who provide direct care service to the elderly in NHs; (2) working full-time; (3) informed consent and participate voluntarily. Exclusion criteria were (1) staff who are absent or leaving the nursing home; (2) internship or trainee. Questionnaires were distributed by the research team and checked immediately after filling-in. If there were any incomplete questions, the members of the research team would remind the respondents to complete the items directly. Questionnaires were excluded as its missing value > 20% from this survey. To evaluate test-retest reliability, a subgroup (N=30) completed the survey again within a 0-14 days interval. This study was approved by the Institutional Review Board of West China Hospital, Chengdu, China.

**Statistical analysis**

Data were analyzed by SPSS24.0 and AMOS19.0, in SPSS24.0 and AMOS19.0, and $p<0.05$ was considered as statistically significant in two-tailed tests. The general
characteristics of our volunteer nursing homes and responded stuff were described by means (standard deviations, SD) or frequencies of categorical items.

Expert consultations were analyzed by the recovery rate and content validity index (CVI). This measurement includes item-level I-CVI and scale-level S-CVI. The S-CVI at the scale level also includes average S-CVI (S-CVI/Ave) and Universal agreement S-CVI (S-CVI/UA). Exploratory Factor Analysis (EFA) was applied to explore the potential structure. In EFA, KMO value, Bartlett's chi-square value, df value, etc. were used to indicate the properties of the new model. A further factor structure was developed with factors whose Cronbach's $\alpha > 0.6$. The Confirmatory Factor Analysis (CFA) was used to test if this factor structure was suitable, at the same time, Convergent validity and Discriminant Validity were explored. Pearson correlation coefficient was used to calculate the retest reliability. Cronbach's $\alpha$ coefficient was used to assess the reliability of the scale.

**Patient and public involvement**

Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

**Results**

**Translation and transcultural-adaptation**

The mainland China version of Nursing Home Survey on Patient Safety Culture (M-NHSOPS) contains 5 dimensions and 22 items. The original dimensions "employment" (A3, A8, A16, A17), "training and skills" (A7, A11, A13),
"non-punitve response to errors" (A10, A12, A15, A18) and "Communication Openness" (B7, B9, B11) were deleted from M-NHSOPS. Items such as A4, A9, B4, B5, B8, C1, C2, D3 were also deleted. The M-NHSOPS scale retains the Likert-5 response scale and "Does Not Apply or Don't Know" options as well as 2 overall evaluation items. More details are in Appendix 1.

We distributed 1397 questionnaires with 1211 completed. The 186 uncompleted questionnaires were excluded (missing data > 20%), and the recovery rate was 86.7%.

Characteristics of enrolled NHs and participants

Among the 20 administrative areas, 9 of them have all types of NHs. Eight districts have 2 types which contain at least a type A or a type B nursing home. Three areas have only 1 kind of nursing home in which 2 regions have only type C nursing home. The respondents from these facilities ranged from 17-224. More details are in Table 1.

Table 1 Characteristics of the Nursing homes (N = 50).

| Areas          | Type A (No. of NHs/ No. of staff) | Type B (No. of NHs/ No. of staff) | Type C (No. of NHs/ No. of staff) | Total of staff |
|----------------|----------------------------------|----------------------------------|----------------------------------|----------------|
| Qing Yang      | 1/70                             | 1/40                             | 1/10                             | 120            |
| Cheng Hua      | 1/24                             | -                                | 2/(14/17)                        | 55             |
| Jin Jiang      | -                                | -                                | 2/(19/13)                        | 32             |
| Jin Niu        | -                                | 1/19                             | 1/29                             | 48             |
| Wu Hou         | -                                | -                                | 1/17                             | 17             |
| Gao Xin        | 1/23                             | -                                | -                                | 23             |
Most staff were from type A NHs (42.6%), and 77.3% of them were females. The ages ranged from 18 to 80 (42.05±13.04), and those between 46-60 comprised the most significant part. Only 14.5% of them were undergraduates, and 1.7% of them had a Master's degree. Nursing assistant (54.4%) was the most prominent composition in NHs. More details are in Table 2.

Table 2 Characteristics of the respondents (N = 50).

| Characteristics | n(%) |
|-----------------|------|
| Du Jiangyan     | 1/57 |
| Shuang Liu      | 1/7  |
| Long Quan       | 1/51 |
| Xin Du          | 1/130|
| Pi Du           | 1/10 |
| Peng Zhou       | 1/17 |
| Chong Zhou      | 1/9  |
| Da Yi           | 1/48 |
| Qiong Lai       | 1/8  |
| Pu Jiang        | 1/5  |
| Jin Tang        | 1/12 |
| Qing Baijiang   | 1/9  |
| Wen Jiang       | 1/27 |
| Type of facility | Male  | Female |
|-----------------|-------|--------|
| A               | 275(22.7%) | 936(77.3%) |
| B               | 516(42.6%) | 322(26.6%) |
| C               | 373(30.8%) | 320(26.4%) |

| Sex | Male  | Female |
|-----|-------|--------|
| Male | 275(22.7%) | 936(77.3%) |
| Female | 936(77.3%) | 275(22.7%) |

| Age(years) | Male  | Female |
|------------|-------|--------|
| 18-40      | 497(41.0%) | 73(6.0%) |
| 40-60      | 572(47.3%) | 72(5.9%) |
| 60-80      | 142(11.7%) | 253(20.9%) |

| Education | Male  | Female |
|-----------|-------|--------|
| Illiteracy | 73(6.0%) | 201(16.6%) |
| Primary school | 201(16.6%) | 320(26.4%) |
| Middle school | 320(26.4%) | 95(7.8%) |
| High school | 95(7.8%) | 72(5.9%) |
| Technical secondary school | 72(5.9%) | 253(20.9%) |
| Junior College | 253(20.9%) | 176(14.5%) |
| Undergraduate | 176(14.5%) | 21(1.7%) |
| Master degree and above | 21(1.7%) | 198(16.4%) |

| Position | Male  | Female |
|----------|-------|--------|
| Management layer | 198(16.4%) | 176(14.5%) |
Validity

Structural validity

To explore the most suitable factor structure of the scale, we applied EFA. Principal component analysis and maximum variance method were used. Factors with
eigenvalues above 1 were selected, and items with the maximum factor loading value $< 0.5$ and those with double loading were deleted. The KMO value was 0.928, and the Barlett Test of Sphericity was significant (Chi square = 20882.645, df value was 861, $p < 0.001$), and it accounted for 58.096% of the variance. As a result, 9-factors were precipitated. More details are in Table 3.

Table 3 Factors and factor loadings explored by EFA.

| Factor number | Items included | Factor loadings |
|---------------|----------------|-----------------|
| 1             | D6             | 0.808           |
|               | D5             | 0.774           |
|               | D8             | 0.770           |
|               | D9             | 0.755           |
|               | D10            | 0.734           |
|               | D1             | 0.727           |
|               | D7             | 0.703           |
|               | C3             | 0.644           |
|               | D4             | 0.603           |
|               | D2             | 0.569           |
| 2             | B3             | 0.801           |
|               | B1             | 0.779           |
|               | B2             | 0.776           |
|               | B10            | 0.680           |
|               | B6             | 0.513           |
Convergent validity and Discriminant Validity

Based on EFA, a new 5-factor structure was formed, of which all factors' Cronbach’s $\alpha$ were above 0.6. To test the new structure, we used CFA, with results of

CMIN/DF=2.631, RMR=0.026, GFI=0.967, AGFI=0.952, NFI=0.965,
RFI=0.955, IFI=0.978, TLI=0.971, CFI=0.978, RMSEA=0.037. All items were

| Factor | Item | Loading |
|--------|------|---------|
| 3      | A2   | 0.844   |
|        | A1   | 0.838   |
|        | A5   | 0.690   |
| 4      | A11  | 0.699   |
|        | A7   | 0.653   |
|        | A9   | 0.505   |
| 5      | B5   | 0.840   |
|        | B8   | 0.815   |
| 6      | A6   | 0.761   |
|        | A14  | 0.693   |
| 7      | A18  | 0.658   |
|        | C1   | 0.541   |
| 8      | B9   | 0.703   |
|        | A17  | 0.566   |
| 9      | A10  | 0.766   |
|        | A8   | 0.626   |
identified to have a 5-dimensional construct with 22 items. More details are in Table 4 and Table 5, respectively.

Table 4   Convergent validity analysis table (CV).

| Factor No. | Items | Factor loading | Reliability coefficient | Measuring error | Composite reliability | Average Variance Extracted |
|------------|-------|----------------|-------------------------|----------------|----------------------|------------------------------|
| 1          | D1    | 0.724          | 0.524                   | 0.476          | 0.917                | 0.527                        |
|            | D2    | 0.588          | 0.346                   | 0.654          |                      |                              |
|            | C3    | 0.661          | 0.437                   | 0.563          |                      |                              |
|            | D4    | 0.614          | 0.377                   | 0.623          |                      |                              |
|            | D5    | 0.792          | 0.627                   | 0.373          |                      |                              |
|            | D6    | 0.826          | 0.682                   | 0.318          |                      |                              |
|            | D7    | 0.703          | 0.494                   | 0.506          |                      |                              |
|            | D8    | 0.785          | 0.616                   | 0.384          |                      |                              |
|            | D9    | 0.792          | 0.627                   | 0.373          |                      |                              |
|            | D10   | 0.733          | 0.537                   | 0.463          |                      |                              |
| 2          | B1    | 0.772          | 0.596                   | 0.404          | 0.854                | 0.543                        |
|            | B2    | 0.829          | 0.687                   | 0.313          |                      |                              |
|            | B3    | 0.795          | 0.632                   | 0.368          |                      |                              |
|            | B6    | 0.577          | 0.333                   | 0.667          |                      |                              |
|            | B10   | 0.685          | 0.469                   | 0.531          |                      |                              |
| 3          | A1    | 0.867          | 0.752                   | 0.248          | 0.826                | 0.621                        |
Table 5  Convergent validity(CV) and Discriminant Validity(DV).

| Factor number | 1   | 2   | 3   | 5   | 6   |
|---------------|-----|-----|-----|-----|-----|
| 1             | 0.527 |     |     |     |     |
| 2             | 0.375 | 0.543 |     |     |     |
| 3             | 0.180 | 0.082 | 0.621 |     |     |
| 5             | 0.073 | 0.158 | 0.019 | 0.748 |     |
| 6             | 0.080 | 0.156 | 0.023 | 0.009 | 0.491 |

Reliability

Expert consultation related indicators and content reliability

Two rounds of expert consultations were used to localize the scale, and recovery rates of 2 rounds were 100%. The CVI was used to assess the fitness between the content to be measured and the content actually measured. In this study, except for A6 and B10 (both I-CVI values were 94.7%), all values of the rest items were 100%. The S-CVI/UA was 95.2%, and S-CVI/Ave was 99.4%.
**Reliability analysis**

Reliabilities values were calculated on the 9 factors extracted by EFA, and Cronbach's $\alpha$ ranged from 0.360-0.911. The overall Cronbach's $\alpha$ value of the mainland China version scale was 0.883. More details are in table 6.

| Factor number | Included items | Number of items | Cronbach's $\alpha$ |
|---------------|----------------|-----------------|---------------------|
| 1             | D1/D2/C3/D4/D5/D6/D7/D8/D9/D10 | 10              | 0.913*              |
| 2             | B1/B2/B3/B6/B10          | 5               | 0.851*              |
| 3             | A1/A2/A5                | 3               | 0.797*              |
| 4             | A7/A9/A11               | 3               | 0.565               |
| 5             | B5/B8                   | 2               | 0.851*              |
| 6             | A6/A14                  | 2               | 0.648*              |
| 7             | A18/C1                  | 2               | 0.393               |
| 8             | B9/A17                  | 2               | 0.422               |
| 9             | A8/A10                  | 2               | 0.366               |

Cronbach's $\alpha>0.6$ were signed with "*".

**Test-retest reliability**

The Pearson correlation coefficient was applied to calculate test-retest reliability. We retested 30 employees in a nursing home after a 0-14 interval. It showed that the test-retest reliability was 0.892, in which each dimension were 0.713, 0.809, 0.924, 0.795 and 0.859 separately ($p<0.001$).
Discussion

In the translation period, there were 42 items, which was similar to the Xiao’s study,\textsuperscript{22} Taiwan, China version,\textsuperscript{12} and French version,\textsuperscript{16} compared with the Norwegian version with 43 items.\textsuperscript{15} Quality of translation and cultural-adaption were guaranteed by translation, back-translation and cultural adaption process. Additionally, we used the data from the expert consultations to explore content validity. The recovery rates of 2 rounds were high, indicating the active participation of experts in this study. All the I-CVI data were higher than 0.78 for three and more experts.\textsuperscript{26} The values of S-CVI/UA and S-CVI/Ave were $\geq 0.8$ and $\geq 0.9$, respectively, indicating excellent levels.\textsuperscript{27} All indicators above showed that the M-NHSOPS has good content validity.

Considering the recovery rate, it was much higher than French version 58.4\%,\textsuperscript{16} Norwegian version 69\%\textsuperscript{15} and Swiss version 66\%,\textsuperscript{17} however it was lower than Xiao’s study 92.3\%\textsuperscript{22} and Taiwan, China version 100\%.\textsuperscript{12} In this study, the average age of participants was (42.05±13.04), and staff aged from 60-80 accounted for 11.7\%, while in French version,\textsuperscript{16} only 7.2\% of respondents were $\geq$ 56 years. In Taiwan, China version the average age was (37.7±10.5).\textsuperscript{12} This result addresses that respondents in this survey are considerably senior than respondents in other studies. Illiteracy accounted for 6.0\% and staff whose educational background from primary school to high school comprised 50.9\%. However, in Taiwan, China version,\textsuperscript{12} there were no illiteracy staff. Individuals who graduated from elementary and high school were 36.6\% and those who have diplomas, bachelor and higher degrees were 62.4\%. In brief, staff in Chinese NHs were lower educated than staff in other studies.\textsuperscript{28}
Additionally, the number of working years in NHs < 1 year was 12.1%, while in Cappelen's study it was 6.3%. Staff whose working hours ≥ 40 h/week was 91.2%, while in Cappelen's study > 35.5 h/week was 16.1%. These indicate that staff in this study have less working experience but always work over-loaded than in other places.

EFA explored a 9-factor structure with 31 items included. The value of KMO indicates sufficient inter-correlations and the Barlett Test of Sphericity demonstrates that the data was ideal for factor analysis. Moreover, the cumulative contribution rate of this study > 40% indicates good construct validity. Compare the 9-factor structure with the original US scale, 4 original dimensions (9 items) were deleted (staffing, Non-punitive Response to Mistakes, Communication openness and Training and Skills). The deletion of "staffing" may be due to the proportion of staffing and the educational background of employees: 54.4% of the respondents were nursing assistants, and 62.8% of the employees have lower education than secondary/high school. Briefly, most of them have less/no management-related knowledge/work experience, and the connotation of employee competence has not been formed, which prevents them from participating in the promotion and construction of the management of the nursing home. Besides, due to the general management culture in China, there is some leadership hierarchy between superiors and subordinates. Management layers tend to be in charge of such kind of management matters. However, most employees do not regard that they have the right/responsibility to intervene in the management stuff. The removal of "Non-punitive Response to Mistakes" and "Communication openness" may be related to the fact that the "learn
from error" climate and "open communication" have not been well developed in domestic organizations. Original dimension "Training and Skills" was deleted which encloses the fact that most staff in NHs have received little training in elderly care. China is also in urgent need of good-quality and well-structured training courses for all types of staffs. To check the performance of the new 5-factor structure of M-NHSOPS, CFA was applied. All values of GFI, AGFI, NFI, RFI, IFI, TFI and CFI were higher than 0.9, CMIN/DF was less than 3, RMSEA was less than 0.08, and RMR was less than 0.05, which indicates the 5-factor structure fits excellently. All values of Composite Reliability (CR) of the five dimensions were higher than 0.6 which means they achieved the required level. All values of Average Variance Extracted (AVE) were more than 0.5, indicating excellent construct reliability and adequate convergent validity. However, for factor 6, even though its AVE value was less than 0.5, its other indicators were satisfying—factor loadings of the two items were 0.658 and 0.741 separately, and CR value was 0.658, so it was kept in the M-NHSOPS scale. The correlation between the respective constructs was less than the square root of AVE for the construct achieved the discriminant validity of M-NHSOPSC.

In M-NHSOPS, factor 1 was named "Perceptions of resident safety and related administrative support" including 10 items (D1/D2/C3/D4/D5/D6/D7/D8/D9/D10). Its Cronbach's α value was 0.913, and item loading ranged from 0.569-0.808. It was a combination of 3 original dimensions "Overall Perceptions of Resident Safety", "Management Support for Resident Safety" and "Organizational Learning". This
combination of dimensions is consistent with the composition of factors in the Norwegian version. However, there was a little difference: in M-NHSOPS, item C3 replaced D3 in the Norwegian version. The composition of the 3 dimensions in both studies indicates that there is some homogeneity between "Organizational learning" and "Management Support for Resident Safety" in some cultures. Factor 2 was named "Handsoff" containing 5 items (B1/B2/B3/B6/B10). Its Cronbach’s α value was 0.851, and item loading ranged from 0.577-0.829. Items B1/ B2/ B3/ B10 belong to the original dimension "Handoffs" while B6 "Staff tell someone if they see something that might harm a resident" belongs to the original dimension "Feedback & Communication About Incidents". It can be explained by that staff hands over potential hazards, and staff think this is essential and valuable to share with colleagues and to keep patients safe. Factor 3 was named "Teamwork", it contains three items(A1/A2/A5). Its Cronbach's α value was 0.797, and item loading ranged from 0.570-0.887. In the original dimension "Teamwork", it contained all three items above and item A9 "When someone gets really busy in this nursing home, other staff help out". However, in M-NHSOPS, A9 was deleted since, in Chinese cultures, it is not one's responsibility both in terms of work regulations or ethics to help colleagues, merely a favor. Moreover, factor 5 was named "Feedback & Communication About Incidents" and included two items (B5/B8). Its Cronbach's α value was 0.851, and item loading ranged from 0.815-0.912. In the original dimension "Feedback & Communication About Incidents", it included 4 items, B5, B8, B4 "When staff report something that could harm a resident, someone takes care of it", and B6 "Staff
tell someone if they see something that might harm a resident”. B6 was merged into factor 2 "Handsoff" while B4 was deleted automatically from the original 9-factor structure. Eventually, factor 6 was named "Compliance With Procedures", and it contained two items (A6/A14). Its Cronbach's $\alpha$ value was 0.648, and item loading ranged from 0.658-0.741. In the original dimension "Compliance With Procedures", A4 "Staff follow standard procedures to care for residents" was included. The deletion may be related to there is no national/provincial standard for determining the quality of care in nursing homes.\(^37\) Accordingly, there are no standard procedures in Chinese nursing homes right now.

In this study, the value of Cronbach's $\alpha > 0.6$ was considered reliable,\(^38\) Cronbach's $\alpha$ ranges from 0.7-0.8 was deemed to be acceptable, and Cronbach's $\alpha > 0.8$ was considered adequate.\(^39\) The overall Cronbach's $\alpha$ of the scale was 0.883. It was close to Xiao's study\(^22\) but lower than Taiwan, China version.\(^12\) The Cronbach's $\alpha$ value of dimensions of M-NHSOPS ranged from 0.648-0.913, illustrate excellent reliability and satisfying internal consistency. The recovery rate of the test-retest experiment was 100%, and all the values of the total scale and each dimension were all greater than 0.7, indicating that the test-retest survey has satisfying performance on validity.\(^40\)

M-NHSOPS has 5 dimensions and 22 items, while Taiwan, China version has 4 dimensions with 29 items.\(^12\) There exist 17 same items between versions above, but they have different compositions of dimensions. This result confirms the differences between mainland China and Taiwan, which were mentioned in the introduction.\(^23-25\)
Moreover, Lin's study was applied among 309 staff in 30 long term care facilities, and the sample size was smaller than in this study. Similarly, significant differences was shown between M-NHSOPS and Xiao's version (1) 23 items were included in Xiao's result, and 22 items were included in M-NHSOPS; (2) in Xiao's study, it only has 13 same items with items included in M-NHSOPS; (3) there are 6 dimensions in Xiao's research while 5 dimensions in M-NHSOPS. What's more, the compositions of each dimension are entirely different. These differences can be explained by the various inclusions of participants between these 2 studies: (1) the sample size in Xiao's research was too small and it only included 6 NHs and 322 respondents; (2) in the pilot study, we found that the employees, for instance, support staff, securities, canteen staff who do not directly provide care service to the elderly, have insufficient understanding and integration of PSC as they do not take part in daily care routine; (3) the scale contains a large number of items related to the care for the elderly, which makes it difficult for the non-direct care provider to respond; (4) sampling in Xiao's study was that medical staff took the most significant proportion (professional medical staff was 67.7% while the nursing assistant was 25.8%). However, in Chinese NHs, nursing assistants are the largest workforce. In brief, the inclusion of all staff types in Chinese NHs is not practical and applicable at present, even though the original developer suggested otherwise. Regarding this, both the Taiwan, China version and this study only included direct care providers in organizations. In conclusion, sample size in this study is comparatively adequate, and M-NHSOPS is more suitable for NHs in mainland China.
Sampling was based on both geographic locations and types of NHs. Researchers tried to include all possible types of nursing home in each area unless there exists no exact sort of nursing home, or the only nursing home in this type refuses to participate. Thus, a total of 50 NHs were enrolled, of which 17 (34.0%) were type A organizations, 12 (24.0%) were type B, and 21 (42.0%) were type C. It shows that the sampling in this study was evenly distributed and relatively representative. Similarly, as for staffing in NHs, the average number of employees in type A was 30.4 people per institution, in type B was 26.8 per institution, and in type C was 17.8. The staffing in private organizations is comparatively insufficient than the other two types of NHs, and this result is consistent with previous literature reviews in the introduction.20 However, our study also has some limitations: initially, the sample was only from NHs in southwestern China. Further verification of M-NHSOPS on a large sample size in elsewhere in China is recommended. Secondly, this study only used quantitative research to explore the PSC in NHs in mainland China. However, qualitative research methods are also recommended to be combined in further research to complete the connotations of PSC in Chinese NHs.

**Conclusion**

We introduced the NHSOPS scale into mainland China and firstly clarified the inclusion of types of staff in NHs for use of the scale. M-NHSOPS has 5 dimensions and 22 items. It has excellent reliability and validity, making it acceptable and useful. However, further verification among samples in other
places in the Mainland is required

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Patient consent for publication Not required.

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Appendix 1  M-NHSOPS
中文版养老机构患者安全文化量表（M-NHSOPSC）

左侧方框里给出的句子，在右侧方框里选择您对这句话是“完全不同意”、“不太同意”、“中立”、“比较同意”、“完全同意”、“不适用或不知道”并在对应的方框里打上“√”（或“从不”、“偶尔”、“一半时间”、“大部分时间”、“总是”、“不适用或不知道”）。

### A. 您所在养老机构

| 句子                                                                 | 完全不同意 | 不太同意 | 中立 | 比较同意 | 完全同意 | 不适用或不知道 |
|----------------------------------------------------------------------|-------------|----------|------|----------|----------|----------------|
| 1. 您与同事相互尊重                                                 |             |          |      |          |          |                |
| 2. 您与同事相互支持                                                 |             |          |      |          |          |                |
| 3. 您觉得您是这个集体中的一员                                     |             |          |      |          |          |                |
| 4. 您为了将工作快速完成，常会简化标准流程                          |             |          |      |          |          |                |
| 5. 为了使工作更简化，您经常忽略标准流程                              |             |          |      |          |          |                |

### B: 沟通

| 句子                                                                 | 从不 | 偶尔 | 一半时间 | 大部分时间 | 总是 | 不适用或不知道 |
|----------------------------------------------------------------------|------|------|----------|-------------|------|----------------|
| 1. 您在服务新照护对象前，会被告知所需照护对象的相关信息            |      |      |          |             |      |                |
| 2. 当您负责的照护对象的照护计划改变时，您会立即得到通知            |      |      |          |             |      |                |
| 3. 照护对象从医院转来时，您能获得所需的相关信息                     |      |      |          |             |      |                |
| 4. 当您发现机构或者照护对象存在安全隐患时，会及时告知相关人员     |      |      |          |             |      |                |
| 5. 您服务照护对象时，能获得所需的相关信息                           |      |      |          |             |      |                |
| 6. 您和同事会讨论如何避免意外再次发生                               |      |      |          |             |      |                |
| 7. 您和同事会讨论如何有效避免照护对象受到伤害                       |      |      |          |             |      |                |

### C: 关于您所在的养老机构

|                              |           |           |           |           |       |                 |
|------------------------------|-----------|-----------|-----------|-----------|-------|-----------------|
|                               | 完全不同意 | 不太同意 | 中立 | 比较同意 | 完全同意 | 不适用或不知道 |
|-------------------------------|------------|--------|-----|---------|----------|----------------|
| 1. 照护对象在此机构内能够得到很好的照护 |            |        |     |         |          |                |
| 2. 此机构在保障照护对象安全上一直做的很好 |            |        |     |         |          |                |
| 3. 此机构对照护对象来说是安全的 |            |        |     |         |          |                |
| 4. 管理者向机构员工征求提高照护对象安全的建议 |            |        |     |         |          |                |
| 5. 管理者听取机构员工有关提高照护对象安全的建议或想法 |            |        |     |         |          |                |
| 6. 管理者经常巡视照护对象的照护情况 |            |        |     |         |          |                |
| 7. 您的上级重视照护对象的安全问题 |            |        |     |         |          |                |
| 8. 改善照护对象安全的措施在机构中容易开展 |            |        |     |         |          |                |
| 9. 此机构一直致力于提高照护对象的安全 |            |        |     |         |          |                |
| 10. 改善照护对象安全的措施一旦开始实施,检查就会跟进 |            |        |     |         |          |                |

D: 綜合评分

1. 您会告诉朋友这是个安全的养老机构吗？ □ 会 □ 可能会 □ 不会
2. 请对此养老机构的安全做一个综合性的评价。 □ 非常差 □ 不太好 □ 中等 □ 良好 □ 非常好
STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

| Item No | Recommendation |
|---------|----------------|
| **Title and abstract** | 1 | *(a)* Indicate the study’s design with a commonly used term in the title or the abstract  
  *(b)* Provide in the abstract an informative and balanced summary of what was done and what was found |
| **Introduction** | 2 | Explain the scientific background and rationale for the investigation being reported |
| **Methods** | 3 | State specific objectives, including any prespecified hypotheses |
| **Participants** | 4 | Present key elements of study design early in the paper |
| **Setting** | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection |
| **Variables** | 6 | *(a)* Give the eligibility criteria, and the sources and methods of selection of participants  
  *(b)* Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable |
| **Data sources/measurement** | 7 | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group |
| **Bias** | 8 | Describe any efforts to address potential sources of bias |
| **Study size** | 9 | Explain how the study size was arrived at |
| **Quantitative variables** | 10 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why |
| **Statistical methods** | 11 | *(a)* Describe all statistical methods, including those used to control for confounding  
  *(b)* Describe any methods used to examine subgroups and interactions  
  *(c)* Explain how missing data were addressed  
  *(d)* If applicable, describe analytical methods taking account of sampling strategy  
  *(e)* Describe any sensitivity analyses |
| **Results** | 12 | *(a)* Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed  
  *(b)* Give reasons for non-participation at each stage  
  *(c)* Consider use of a flow diagram |
| **Descriptive data** | 13 | *(a)* Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders  
  *(b)* Indicate number of participants with missing data for each variable of interest |
| **Outcome data** | 14 | Report numbers of outcome events or summary measures |
| **Main results** | 15 | *(a)* Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included  
  *(b)* Report category boundaries when continuous variables were categorized  
  *(c)* If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period |
| **Other analyses** | 16 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses |
### Discussion

| Key results | 18 | Summarise key results with reference to study objectives |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results |

### Other information

| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based |

*Give information separately for exposed and unexposed groups.*

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.
Transcultural adaptation and psychometric evaluation of the mainland China Version of Nursing Home Survey on Patient Safety Culture questionnaire: A cross-sectional survey based on 50 nursing homes in China

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Transcultural adaptation and psychometric evaluation of the mainland China Version of Nursing Home Survey on Patient Safety Culture questionnaire: A cross-sectional survey based on 50 nursing homes in China

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Keywords: nursing homes; safety culture; aged; psychometrics

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Abstract

Objective: To provide a validated Chinese-language measurement of the Nursing Home Survey on Patient Safety Culture (NHSOPS) in mainland China. Thus, the primary aim is to carry out a transcultural adaptation into the Chinese of the NHSOPS questionnaire and to evaluate its psychometric properties.

Design: A psychometric evaluation study. Firstly, the “Translate-Back translate-Cultural adaptation” and the pretesting procedure were followed to introduce the NHSOPS. Secondly, a cross-sectional survey was used to assess the psychometric properties of the mainland China version, and a test-retest survey was then applied.

Setting and participants: The survey was carried out among 1397 nursing home staff from 50 nursing homes in South-western China.

Outcome Measures: Exploratory Factor Analysis (EFA) was used to assess the potential structure and Confirmatory Factor Analysis (CFA) was then applied. Reliability was assessed by the Content validity index, Cronbach’s α, and the test-retest value.

Results: Among the 1397 respondents, 1211 were included (86.7%). EFA was used and a 9-factor structure was explored. Five factors (Cronbach's α > 0.6) were selected into the new structure for the mainland China version of the Nursing Home Survey on Patient Safety Culture (M-NHSOPS). Moreover, data showed that it was suitable for CFA, and Convergent validity and Discriminant validity were satisfying. On the other hand, M-NHSOPS contains five dimensions and 22 items. The overall Cronbach's α value was 0.883; the values of each dimension ranged from 0.648-0.913. Additionally,
Content validity showed significant performance. Eventually, Test-retest reliability was 0.892, and each dimension was 0.713, 0.809, 0.924, 0.795, and 0.859 respectively \((p<0.001)\).

**Conclusions:** M-NHSOPS has acceptable reliability and satisfactory validity among staff of nursing homes in southwestern China, and further verification among samples in other places in the mainland China is required.

**Keywords:** nursing homes; safety culture; aged; psychometrics

**Strengths and limitations of this study:**

- Well applied translation and cultural adaptation process
- Clarified inclusion criteria for different staff of the scale
- Relatively abundant sample size
- Further verification among samples in other regions in mainland China is required
- Further explorations of patient safety culture connotations in nursing homes in mainland China are recommended

**Introduction**

Preventing incidents such as medication errors and misconducts are paramount goals in elderly care institutions,\(^1\) and Patient safety culture (PSC) refers to the prevailing attitudes, beliefs, values, and behaviors of employees formed by health
institutions to achieve the goal of patient safety.\textsuperscript{2} The inverse association between PSC and adverse event occurrence was proved.\textsuperscript{3} Thus, PSC has been accepted as an essential quality indicator across all health care settings.\textsuperscript{4} For improvement, the most common approach been taken is to develop or introduce reliable PSC assessment tools in specific countries and then survey the cross-sectional situation in organizations.

As mentioned above, assessing the current situation and defining the weak aspects of organizations are regarded as the most challenging steps.\textsuperscript{5} Correspondingly, a reliable tool is the premise for assessment. On one hand, a significant concern in evaluating PSC at present is to continue to emphasize PSC in hospitals.\textsuperscript{6} Many tools were developed: Safety Attitudes Questionnaire (SAQ), Hospital Survey on Patient Safety Culture (HSOPS), and so on. SAQ and HSOPS have been widely introduced, such as in Norwegian,\textsuperscript{7,8} Greece\textsuperscript{9}, and China,\textsuperscript{10,11} etc. On the other hand, some pieces of evidence showed that nursing homes (NHs) are at high risk.\textsuperscript{12} Residents in NHs have multiple health problems and require advanced medications. Some of them even have cognitive impairments, which leads to more potential risks.\textsuperscript{13} However, there has been less previous research for PSC in NHs.\textsuperscript{4}

Though advocating PSC in NHs has increased in recent years, efforts in evaluating PSC in NHs, primarily available tools, are still lacking.\textsuperscript{12} In 2008, the Agency for Healthcare Research and Quality (AHRQ) developed a specific tool-Nursing Home Survey on Patient Safety Culture (NHSOPS) for NHs,\textsuperscript{14} which had previously developed HSOPS. Subsequently, NHSOPS has also been validated into different regions and cultures, including Norwegian,\textsuperscript{15} French,\textsuperscript{16} Swiss,\textsuperscript{17} and Spain,\textsuperscript{18} etc. In
mainland China, NHs is categorized by government into three types: NHs hosted and
managed by government party (named as type A in this research), hosted by the
government but managed by the non-government party (type B), and hosted and
managed by the non-government party (type C). Research suggests that the
government-owned nursing homes still enjoy more benefits than private organizations
in staffing, funding, and insurance. However, the same thing is that all kinds of NHs
do face safety risks now and then. The Chinese nursing home industry is under initial
development, therefore, the quality varies among different NHs, compared with NHs
in developed countries.

Recently, two Chinese versions of NHSOPS were reported in 2016 and 2017. For Xiao’s version in mainland China, the sample size was insufficient (N=322). Additionally, all included staff types did not consider the applicability of the scale content and some items. Furthermore, there are numerous differences between mainland China and Taiwan version including dialects, sub-cultures, functions, classifications of NHs, types of professionals in NHs, staffing proportions of professionals in different kinds of NHs, and different development levels of NHs, etc.

Accordingly, NHs in mainland China are still in urgent need for a reliable and validated Chinese version of assessment tool to evaluate their psychometric properties so as to have a baseline data on Patient Safety Culture of NHs in mainland China.

In this study, we focus on intercultural adaptation of NHSOPS into the mainland based on data from 50 NHs in South-western China and evaluate its psychometric properties.
Methods

The NHSOPS contains 42 items focused on 12 dimensions: teamwork, staffing, compliance with procedures, training and skills, non-punitive response to mistakes, handoffs, feedback and communication about incidents, communication openness, supervisor expectations and actions promoting resident safety, overall perceptions of resident safety, management support for resident safety, and organizational learning. Two overall rating questions are at the end of the scale. The total score ranges from 0 to 210; the higher scores represent a superior safety culture in the organization.

Copyright of the original scale (utilization and translation) was attained in October 2015 from the Agency for Healthcare Research and Quality (AHRQ).

This study was conducted in two phases: an initial phase involving the translation and cultural adaptation of the questionnaire, and a second phase in which the psychometric properties of the questionnaire were evaluated.

Translation and transcultural adaptation of NHSOPS in mainland China

A cross-cultural adaptation procedure was conducted: translation, back-translation, cultural adjustment, and pretesting. The first step was to translate the original scale into Chinese by two independent native postgraduates who possess fluent vocal English. Both graduates are major in nursing and have well understandings of conceptions of PSC. Secondly, a professor from evidence-based medicine who has been focusing on research of PSC synthesized the two Chinese versions into one. Two bilingual translators with no medical backgrounds then translated it back to Chinese separately. Both of them were blind to the questionnaire. A geriatric nursing professor
examined the equivalence of context and semantics by comparing the back-translated versions with the original one and checked if it was translated in accordance.

The cultural adaptation process included 3 parts, with 3 rounds of group meetings, two rounds of expert consultations, and a pilot test. It is recommended by the User's Guide developed by AHRQ for international translators that group meetings focused on translation and adjustment should be used to make a better cultural-adaptation.14

The research team members included three Ph.D. students, and four Master students in geriatric nursing, and two Master students in evidence-based medicine. The criteria for inclusion of experts were that, (1) they have relevant experience as follows, safety culture, elderly care, elderly patient management, hospital management, nursing home management, and public health, etc.; (2) with more than 10 years of relevant experience; and (3) informed consent. Nineteen experts participated in 2 rounds of consultations, and all were from Sichuan Province of China. Their age ranged from 40-60, and only one expert was above 60; 3 (15.8%) of them have worked for 10-19 years, 4 (21.1%) for 20-29 years, and 12 (63.3%) ≥ 30 years; 3 (15.8%) graduated from Junior College, 9 (47.4%) were undergraduates, 4 (21.1%) have Master degrees, and 3 (15.8%) have doctoral degrees; 7 (36.8%) were head nurses in hospitals, 3 (15.8%) were deputy head nurse in hospitals, 1 (5.3%) was the management layer of the nursing department in a hospital, 3 (15.8%) were from Sichuan Association of Senior Services (SASS), 3 (15.8%) works as management layer of NHs, 1 (5.3%) was a professor of nursing, and 1 (5.3%) was a professor of statistics. Finally, a pilot test was conducted by querying 200 care providers in nursing homes to complete the
survey (3 nursing homes in Xindu district of Sichuan Province), and no difficulty in
understanding or responding was reported. The figure for the translation and
adaptation process is shown in Figure 1.

Figure 1. Translation and cultural adaptation process

Psychometric validation of mainland China version of the NHSOPS

This cross-sectional study was conducted in Sichuan Province, Southwest China
from 2016 to 2017. Initially, we contacted three nursing home and pilot-tested a
subgroup (N=200). We then accessed each type of nursing home (A, B, C) from 20
administrative regions with detailed research information. Theoretically, at least one
nursing home for each kind from each area should be extracted.

In this study, 50 NHs were enrolled, and 1397 staff were invited. Inclusion criteria
were (1) personnel who provide direct care service to the elderly in NHs; (2) working
full-time; (3) informed consent and participation voluntarily. Exclusion criteria were
(1) staff who are absent or leaving the nursing home; (2) internship or trainee.

Questionnaires were distributed by the research team and checked immediately after
filling-in. In case the respondents failed to complete the items, members of the
research team would remind them for completion. Questionnaires were excluded as
their missing value > 20% from this survey. To evaluate test-retest reliability, a
subgroup (N=30) completed the survey twice on day 0 as well as on day 14. This
study was approved by the Institutional Review Board of West China Hospital,
Chengdu, China.
Statistical analysis

Data were analyzed by SPSS24.0 and AMOS19.0, in SPSS24.0 and AMOS19.0, and $p<0.05$ was considered statistically significant in two-tailed tests. The general characteristics of our volunteer nursing homes and responded stuff were described by means (standard deviations, SD) or frequencies of categorical items.

Expert consultations were analyzed by the recovery rate and content validity index (CVI). This measurement includes item-level I-CVI and scale-level S-CVI. The S-CVI at the scale level also includes average S-CVI (S-CVI/Ave) and Universal agreement S-CVI (S-CVI/UA). Exploratory Factor Analysis (EFA) was applied to explore the potential structure. In EFA, KMO value, Bartlett's chi-square value, df value, the value of variance, eigenvalues, and factor loading were calculated which were used to indicate the properties of the new model. A further factor structure was developed with factors whose Cronbach's $\alpha > 0.6$. The Confirmatory Factor Analysis (CFA) was used to test if this factor structure was suitable, at the same time, Convergent validity and Discriminant Validity were explored. Pearson correlation coefficient was used to calculate the retest reliability. Cronbach's $\alpha$ coefficient was used to assess the reliability of the scale.

Inclusion criteria of items and dimensions of the M-NHSOPS

In this study, EFA was firstly applied to explore the original structure of the data set, and a preliminary factor structure was obtained, and the validity of each factor was explored. Factors whose Cronbach’s $\alpha > 0.6$ and item loading $>0.5$ were then selected as the new structure for M-NHSOPS.
Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

Results

Translation and transcultural-adaptation

The mainland China version of the Nursing Home Survey on Patient Safety Culture (M-NHSOPS) contains 5 dimensions and 22 items. The original dimensions "staffing" (A3, A8, A16, A17), "training and skills" (A7, A11, A13), "non-punitive response to mistakes" (A10, A12, A15, A18), and "communication openness" (B7, B9, B11) were deleted from M-NHSOPS. Items such as A4, A9, B4, B5, B8, C1, C2, D3 were also deleted. The M-NHSOPS scale retains the Likert-5 response scale and "Does Not Apply or Don’t Know" options as well as 2 overall evaluation items. More details are in Appendix 1 and 2.

Of the 1397 questionnaires distributed, 187 questionnaires were excluded since over 20% of items were missing, resulting in a total of 1211 responses (86.7% response rate).

Characteristics of enrolled NHs and participants

Among the 20 administrative areas, 9 have all types of NHs, 8 have 2 types which contain at least a type A or a type B nursing home, and 3 areas have only 1 kind of nursing home in which 2 regions have only type C nursing homes. The respondents from these facilities ranged from 17-224. Additional details are shown in Table 1.
Table 1: Characteristics of the Nursing homes (N = 50).

| Areas         | Type A (No. of NHs/ No. of staff) | Type B (No. of NHs/ No. of staff) | Type C (No. of NHs/ No. of staff) | Total of staff |
|---------------|----------------------------------|-----------------------------------|----------------------------------|---------------|
| Qing Yang     | 1/70                             | 1/40                              | 1/10                             | 120           |
| Cheng Hua     | 1/24                             | -                                 | 2/(14/17)                        | 55            |
| Jin Jiang     | -                                | -                                 | 2/(19/13)                        | 32            |
| Jin Niu       | -                                | 1/19                              | 1/29                             | 48            |
| Wu Hou        | -                                | -                                 | 1/17                             | 17            |
| Gao Xin       | 1/23                             | -                                 | -                                | 23            |
| Du Jiangyan  | 1/57                             | -                                 | 2/(12/10)                        | 79            |
| Shuang Liu    | 1/7                              | 1/40                              | 1/20                             | 67            |
| Long Quan     | 1/51                             | 1/44                              | 1/39                             | 134           |
| Xin Du        | 1/130                            | 1/68                              | 1/26                             | 224           |
| Pi Du         | 1/10                             | -                                 | 2/(36/24)                        | 70            |
| Peng Zhou     | 1/17                             | -                                 | 1/9                              | 26            |
| Chong Zhou    | 1/9                              | -                                 | 1/12                             | 21            |
| Da Yi         | 1/48                             | 1/8                               | 1/11                             | 67            |
| Qiong Lai     | 1/8                              | 1/8                               | 1/10                             | 26            |
| Pu Jiang      | 1/5                              | 1/12                              | -                                | 17            |
| Xin Jin       | 1/9                              | 1/17                              | 1/9                              | 35            |
| Jin Tang      | 1/12                             | 1/12                              | -                                | 24            |
| Qing Baijiang | 1/9                              | 1/26                              | 1/6                               | 41            |
Most staff were from type A NHs (42.6%), and 77.3% of them were females. The age ranged from 18 to 80 (42.05±13.04), and those between 46-60 comprised the primary part. Only 14.5% of them were undergraduates, and 1.7% of them had a Master's degree. Nursing assistant (54.4%) was the most prominent composition in NHs. Additional details were shown in Table 2.

Table 2 Characteristics of the respondents (N = 1211).

| Characteristics          | n(%)   |
|--------------------------|--------|
| Type of facility         |        |
| A                        | 516(42.6%) |
| B                        | 322(26.6%)  |
| C                        | 373(30.8%)  |
| Sex                      |        |
| Male                     | 275(22.7%)   |
| Female                   | 936(77.3%)   |
| Age(years)               |        |
| 18-40                    | 497(41.0%) |
| 40-60                    | 572(47.3%) |
| 60-80                    | 142(11.7%) |
| Education                |        |
| Education Level                  | Number of Participants | Percentage |
|----------------------------------|------------------------|------------|
| Illiteracy                       | 73                     | 6.0%       |
| Primary school                   | 201                    | 16.6%      |
| Middle school                    | 320                    | 26.4%      |
| High school                      | 95                     | 7.8%       |
| Technical secondary school       | 72                     | 5.9%       |
| Junior College                   | 253                    | 20.9%      |
| Undergraduate                    | 176                    | 14.5%      |
| Master degree and above          | 21                     | 1.7%       |

| Position                          | Number of Participants | Percentage |
|-----------------------------------|------------------------|------------|
| Management layer                  | 198                    | 16.4%      |
| Doctor                            | 138                    | 11.4%      |
| Nurse                             | 186                    | 15.4%      |
| Nursing assistant                 | 659                    | 54.4%      |
| Others                            | 30                     | 2.5%       |

| Professional licenses              |                        |            |
|-----------------------------------|------------------------|------------|
| Paramedical staff                 |                        |            |
| Yes                               | 271                    | 22.4%      |
| No                                | 940                    | 77.6%      |

| Elderly care assistant staff      |                        |            |
|-----------------------------------|------------------------|------------|
| Yes                               | 357                    | 29.5%      |
| No                                | 854                    | 70.5%      |

| Number of years in Nursing home   |                        |            |
|-----------------------------------|------------------------|------------|
Working hours per week

|                   | <40h         | ≥40h         |
|-------------------|--------------|--------------|
| <1 year           | 147 (12.1%)  |              |
| ≥1 year           | 1064 (87.9%) |              |

Validity

Structural validity

To explore the most suitable factor structure of the scale, we applied EFA. Principal component analysis and maximum variance method were used. Factors with eigenvalues above one were selected, and items with the maximum factor loading value < 0.5 and those with double loading were deleted. The KMO value was 0.928, and the Barlett Test of Sphericity was significant (Chi square = 20882.645, df value was 861, p < 0.001), and it accounted for 58.096% of the variance. As a result, 9-factors were precipitated. Additional details are shown in Table 3.

Based on EFA, a new 5-factor structure was formed, of which all factors' Cronbach’s α was above 0.6. To test the new structure, we used CFA, and the results were CMIN/DF = 2.631, RMR = 0.026, GFI = 0.967, AGFI = 0.952, NFI = 0.965, RFI = 0.955, IFI = 0.978, TLI = 0.971, CFI = 0.978, and RMSEA = 0.037. All items were identified to have a 5-dimensional construct with 22 items. Additional details are displayed in Table 4 and Table 5, respectively.

Table 3 Factors and item loadings explored by EFA.

| Factor number | Items included | Item loadings |
|---------------|----------------|---------------|

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|   |   |                       |
|---|---|-----------------------|
| 1 | D6 | 0.808                 |
|   | D5 | 0.774                 |
|   | D8 | 0.770                 |
|   | D9 | 0.755                 |
|   | D10| 0.734                 |
|   | D1 | 0.727                 |
|   | D7 | 0.703                 |
|   | C3 | 0.644                 |
|   | D4 | 0.603                 |
|   | D2 | 0.569                 |
| 2 | B3 | 0.801                 |
|   | B1 | 0.779                 |
|   | B2 | 0.776                 |
|   | B10| 0.680                 |
|   | B6 | 0.513                 |
| 3 | A2 | 0.844                 |
|   | A1 | 0.838                 |
|   | A5 | 0.690                 |
| 4 | A11| 0.699                 |
|   | A7 | 0.653                 |
|   | A9 | 0.505                 |
| 5 | B5 | 0.840                 |
| Factor No. | Items | Factor loading | Reliability coefficient | Measuring error | Composite reliability | Average Variance Extracted |
|-----------|-------|----------------|------------------------|----------------|----------------------|---------------------------|
| 1         | D1    | 0.724          | 0.524                  | 0.476          | 0.917                | 0.527                     |
|           | D2    | 0.588          | 0.346                  | 0.654          |                      |                           |
|           | C3    | 0.661          | 0.437                  | 0.563          |                      |                           |
|           | D4    | 0.614          | 0.377                  | 0.623          |                      |                           |
|           | D5    | 0.792          | 0.627                  | 0.373          |                      |                           |
Table 5  Convergent validity(CV) and Discriminant Validity(DV).

| Factor number | 1  | 2  | 3  | 5  | 6  |
|---------------|----|----|----|----|----|
| 1             | 0.527 |    |    |    |    |
| 2             | 0.375 | 0.543 |    |    |    |

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Reliability

Expert consultation related indicators and content reliability

Two rounds of expert consultations were used to localize the scale, and recovery rates of 2 rounds were 100%. The CVI was used to assess the fitness between the content to be measured and the content measured. In this study, except for A6 and B10 (both I-CVI values were 94.7%), all values of the rest items were 100%. The S-CVI/UA was 95.2%, and S-CVI/Ave was 99.4%.

Reliability analysis

Reliabilities values were calculated on the 9 factors extracted by EFA, and Cronbach's $\alpha$ ranged from 0.366-0.913. The overall Cronbach's $\alpha$ value of the mainland China version scale was 0.883. Additional details are displayed in table 6.

Table 6  Cronbach's $\alpha$ values of the nine factors.

| Factor number | Included items     | Number of items | Cronbach's $\alpha$ |
|---------------|--------------------|-----------------|---------------------|
| 1             | D1/D2/C3/D4/D5/D6/D7/D8/D9/D10 | 10              | 0.913*              |
| 2             | B1/B2/B3/B6/B10    | 5               | 0.851*              |
| 3             | A1/A2/A5          | 3               | 0.797*              |
| 4             | A7/A9/A11         | 3               | 0.565               |
| 5             | B5/B8             | 2               | 0.851*              |
### Test-retest reliability

The Pearson correlation coefficient was applied to calculate test-retest reliability. We retested 30 employees in a nursing home after a 0-14 interval. The test-retest reliability was 0.892, in which each dimension was 0.713, 0.809, 0.924, 0.795 and 0.859 ($p<0.001$).

### Discussion

In the translation period, there were 42 items, which was similar to Xiao's study, Taiwan, China version, and French version, compared with the Norwegian version with 43 items in which it split item B3, “We have all the information we need when residents are transferred from hospital” into two items. Quality of translation and cultural-adaptation were guaranteed by translation, back-translation, and cultural adaptation process. Additionally, we used data from the expert consultations to explore content validity. The recovery rates of 2 rounds were high, indicating the active participation of experts in this study. All I-CVI data were higher than 0.78 for 3 and more experts. The values of S-CVI/UA and S-CVI/Ave were $\geq$
0.8 and $\geq 0.9$, respectively, indicating exceptional levels. All indicators above showed that the M-NHSOPS has satisfactory content validity.

The recovery rate was significant higher than French version 58.4%, Norwegian version 69%, and Swiss version 66%. However, it was lower than Xiao's study 92.3% and Taiwan, China version 100%. The recovery rate in this study is relatively satisfying. In this study, the average age of participants was (42.05±13.04), and staff aged from 60-80 accounted for 11.7%, while in the French version, only 7.2% of respondents aged above 56. In Taiwan, China version the average age was (37.7±10.5). This result emphasize that respondents in this survey are considerably senior to respondents in other studies. Illiteracy accounted for 6.0% and staff whose educational background from primary school to high school comprised 50.9%. However, in Taiwan, China version, there was no illiterate staff, and individuals who graduated from elementary and high school were 36.6% and those who have diplomas, bachelor and higher degrees were 62.4%. In brief, staff in Chinese NHs were lower educated than those in other studies. Additionally, the number of working years in NHs < 1 year was 12.1%, while in Cappelen's study it was 6.3%. Staff whose working hours $\geq 40$h/week was 91.2%, while in Cappelen' s study $>35.5$ h/week was 16.1%. These indicate that staff in this study have less working experience while experience more overtime work than in other places.

EFA explored a 9-factor structure with 31 items included. The value of KMO indicates sufficient inter-correlations and the value of the Barlett Test of Sphericity demonstrates that the data was ideal for factor analysis. Moreover, the cumulative
contribution rate of this study > 40% indicates good construct validity. Comparing the 9-factor structure with the original US scale, 4 original dimensions (9 items) were deleted (staffing, non-punitive response to mistakes, communication openness and training, and skills). The deletion of "staffing" may be due to the proportion of staffing and the educational background of employees: 54.4% of the respondents were nursing assistants, and 62.8% receive lower education than secondary/high school. In brief, most of them have less/no staffing or management relevant knowledge/experience, and the connotation of employee competence has not been formed, which prevents them from participating in the staffing/management of the nursing home. Besides, due to the general management culture in China, there is some leadership hierarchy between superiors and subordinates: management layers tend to always be in charge of such kind of staffing matters, and most employees perceive themselves not being in the position to intervene the upper management. The removal of "non-punitive response to mistakes" and "communication openness" may be related to the fact that the "learn from error" climate and "open communication" have not been well developed in domestic organizations. Original dimension "training and skills" was deleted which encloses the fact that most staff in NHs have received little training in elderly care. China is in urgent demand of good-quality and well-structured training courses for all types of staff. To check the performance of the new 5-factor structure of M-NHSOPS, CFA was applied. All values of GFI, AGFI, NFI, RFI, IFI, TFI and CFI were higher than 0.9, while CMIN/DF was less than 3, RMSEA was less than 0.08, and RMR was less than 0.05, which indicates the 5-factor structure.
fits excellently. All values of Composite Reliability (CR) of the five dimensions were higher than 0.6 which means they achieved the required level.\textsuperscript{35} All values of Average Variance Extracted (AVE) were more than 0.5, indicating excellent construct reliability and adequate convergent validity.\textsuperscript{36} However, for factor 6, despite its AVE value was less than 0.5, its other indicators were satisfying—factor loadings of the two items were 0.658 and 0.741 separately, and CR value was 0.658, hence it was kept in the M-NHSOPS scale. The square between the respective constructs was less than the square of AVE for the construct that achieved the discriminant validity of M-NHSOPSC.\textsuperscript{35}

In M-NHSOPS, factor 1 was named "perceptions of resident safety and related administrative support" including 10 items (D1/D2/C3/D4/D5/D6/D7/D8/D9/D10). Its Cronbach's $\alpha$ value was 0.913, and item loading ranged from 0.569-0.808. It was a combination of 3 original dimensions "overall perceptions of resident safety", "management support for resident safety", and "organizational learning". This combination of dimensions is consistent with the composition of factors in the Norwegian version.\textsuperscript{15} However, there was a little difference: in M-NHSOPS, item C3 replaced D3 in the Norwegian version. The composition of the 3 dimensions in both studies indicates that there is some homogeneity between "organizational learning" and "management support for resident safety" in some cultures. Factor 2 was named "handoff" containing 5 items (B1/B2/B3/B6/B10). Its Cronbach's $\alpha$ value was 0.851, and item loading ranged from 0.513-0.801. Items B1/ B2/ B3/ B10 belong to the original dimension "handoffs" while B6 "Staff tell someone if they see something that
might harm a resident" belongs to the original dimension "feedback & communication about incidents". It can be explained by that staff hands over potential hazards, and staff thinks this is essential and valuable to share with colleagues and to keep patients safe. Factor 3 was named "teamwork", it contains three items (A1/A2/A5). Its Cronbach's $\alpha$ value was 0.797, and item loading ranged from 0.690-0.844. The original dimension "teamwork" contained all three items above and item A9 "When someone gets really busy in this nursing home, other staff help out". However, in M-NHSOPS, A9 was deleted since in Chinese cultures, it is not one's responsibility both in terms of work regulations or ethics to assist colleagues, merely a favor. Moreover, factor 5 was named "feedback & communication about incidents" and included two items (B5/B8). Its Cronbach's $\alpha$ value was 0.851, and item loading ranged from 0.815-0.840. The original dimension "feedback & communication about incidents" included 4 items, which were B5, B8, B4 "When staff report something that could harm a resident, someone takes care of it", and B6 "Staff tell someone if they see something that might harm a resident". B6 was merged into factor 2 "handoff" while B4 was deleted automatically from the original 9-factor structure. Eventually, factor 6 was named "compliance with procedures" and contained two items (A6/A14). Its Cronbach's $\alpha$ value was 0.648, and item loading ranged from 0.693-0.761. In the original dimension "compliance with procedures", A4 "Staff follow standard procedures to care for residents" was included. The deletion may be due to lack of standard procedures to care for residents in most of the nursing homes.
in mainland China neither national/provincial standard for determining the quality of care in nursing homes.\(^{37}\)

In this study, the value of Cronbach's \(\alpha > 0.6\) was considered reliable,\(^ {38}\) Cronbach's \(\alpha\) ranges from 0.7-0.8 were deemed to be acceptable, and Cronbach's \(\alpha > 0.8\) was considered adequate.\(^ {39}\) The overall Cronbach's \(\alpha\) of the scale was 0.883. It was close to Xiao's study\(^ {22}\) but lower than Taiwan, China version.\(^ {12}\) The Cronbach's \(\alpha\) value of dimensions of M-NHSOPS ranged from 0.648-0.913, illustrating exceptional reliability and satisfactory internal consistency. The recovery rate of the test-retest experiment was 100%, and all values of the total scale and each dimension were all above 0.7, indicating that the test-retest survey has satisfactory performance on validity.\(^ {40}\)

M-NHSOPS has 5 dimensions and 22 items, while Taiwan, China version has 4 dimensions with 29 items.\(^ {12}\) There exist 17 identical items between versions above, but they have different compositions of dimensions. This result confirms the differences between mainland China and Taiwan, which were mentioned in the introduction.\(^ {23-25}\) Moreover, Lin's study was applied among 309 staff in 30 long-term care facilities, and the sample size was smaller than in this study. Similarly, significant differences were shown between M-NHSOPS and Xiao's\(^ {22}\) version (1) 23 items were included in Xiao's result, and 22 items were included in M-NHSOPS; (2) in Xiao's study, it only has 13 identical items with items included in M-NHSOPS; (3) there are 6 dimensions in Xiao's research while 5 dimensions in M-NHSOPS. Moreover, the compositions of each dimension are entirely different. These
differences can be explained by the various inclusions of participants between these 2 studies: (1) the sample size in Xiao's research was too small and it only included 6 NHs and 322 respondents; (2) in the pilot study, we found that the employees, for instance, support staff, securities, canteen staff who do not directly provide care service to the elderly, have insufficient understanding and integration of PSC as they do not take part in daily care routine; (3) the scale contains a large number of items related to the care for the elderly, which makes it difficult for the non-direct care provider to respond; (4) sampling in Xiao's study was that medical staff took the most significant proportion (professional medical staff was 67.7% while the nursing assistant was 25.8%). However, in Chinese NHs, nursing assistants are the largest workforce. In brief, there still lacks of enough evidence that the inclusion of all staff types in Chinese NHs is practical and applicable at present, even though the original developer suggested otherwise. Regarding this, both the Taiwan, China version and this study only included direct care providers in organizations. Comparatively, in this study, the inclusion criteria of staff fit the staffing situation in mainland China better, and the sample size is relatively adequate.

Sampling was based on both geographic locations and types of NHs. Researchers tried to include all possible types of nursing homes in each area unless there exists no exact sort of nursing home or the only nursing home in this type refuses to participate. Thus, a total of 50 NHs were enrolled, of which 17 (34.0%) were type A organizations, 12(24.0%) were type B, and 21(42.0%) were type C. It shows that the sampling in this study was evenly distributed and relatively representative. Similarly,
as for staffing in NHs, the average number of employees in type A was 30.4 per institution, in type B was 26.8, and in type C was 17.8. The staffing in private organizations is comparatively insufficient than the other two types of NHs, and this result is consistent with previous literature reviews in the introduction.\(^{20}\) However, our study also has some limitations: initially, the sample was only from NHs in southwestern China. Further verification of M-NHSOPS on a large sample size elsewhere in China is recommended. Secondly, this study only used quantitative research to explore the PSC in NHs in mainland China. However, qualitative research methods are also recommended to be combined in further research to complete the connotations of PSC in Chinese NHs.

**Conclusion**

We introduced the NHSOPS scale into mainland China with well-applied cultural adaptation process and validated it in relatively adequate sample size. This study firstly clarified the inclusion of types of staff in NHs for use of the scale. M-NHSOPS has 5 dimensions and 22 items, it has excellent reliability and validity, making it acceptable and useful. However, further verification among samples in other places in mainland China is recommended.

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collected the data. YQL and YFC were involved in data entering and analyzing. YQL drafted the manuscript. YFC, LHZ and XYH revised the manuscript. All authors have read and approved the final manuscript. XYH and LHZ are correspondence authors.

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**Competing interests** None declared.

**Patient consent for publication** Not required.

**Ethical approval** This study was supported by the Institutional Review Board of West China Hospital, Sichuan University (Chengdu, China), and the approval number is [2017-268]. Informed consent was obtained. And data in this study were all anonymous and used exclusively for academic purposes.

**Data availability statement** No additional data are available.

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Figure 1. Translation and Cultural adaptation process

827x440mm (96 x 96 DPI)
# Appendix 1  English version M-NHSOPS

The mainland China version of the Nursing Home Survey on Patient Safety Culture (M-NHSOPS)

Please choose whether you agree with this sentence or not in the box on the right side.

| A. Working in This Nursing Home | Strongly Disagree | Disagree | Neither Agree nor Disagree | Agree | Strongly Agree | Does Not Apply or Don’t Know |
|---------------------------------|------------------|---------|---------------------------|-------|----------------|-----------------------------|
| 1. Staff in this nursing home treat each other with respect |                  |         |                           |       |                |                             |
| 2. Staff support one another in this nursing home |                  |         |                           |       |                |                             |
| 3. Staff feel like they are part of a team |                  |         |                           |       |                |                             |
| 4. Staff use shortcuts to get their work done faster |                  |         |                           |       |                |                             |
| 5. To make work easier, staff often ignore procedures |                  |         |                           |       |                |                             |

| B: Communications | Never | Rarely | Sometimes | Most of the time | Always | Does Not Apply or Don’t Know |
|-------------------|-------|--------|-----------|------------------|--------|-----------------------------|
| 1. Staff are told what they need to know before taking care of a resident for the first time |       |         |             |       |                             |
| 2. Staff are told right away when there is a change in a resident’s care plan |       |         |             |       |                             |
| 3. We have all the information we need when residents are transferred from the hospital |       |         |             |       |                             |
| 4. Staff tell someone if they see something that might harm a resident |       |         |             |       |                             |
| 5. Staff are given all the information they need to care for residents |       |         |             |       |                             |
| 6. In this nursing home, we talk about ways to keep incidents from happening again |       |         |             |       |                             |
| 7. In this nursing home, we discuss ways to keep residents safe from harm |       |         |             |       |                             |
## C: Your Nursing Home

| Statement                                                                 | Strongly Disagree | Disagree | Neither Agree nor Disagree | Agree | Strongly Agree | Does Not Apply or Don’t Know |
|---------------------------------------------------------------------------|-------------------|----------|-----------------------------|-------|----------------|-----------------------------|
| 1. Residents are well cared for in this nursing home                      |                   |          |                             |       |                |                             |
| 2. This nursing home does a good job keeping residents safe               |                   |          |                             |       |                |                             |
| 3. This nursing home is a safe place for residents                        |                   |          |                             |       |                |                             |
| 4. Management asks staff how the nursing home can improve resident safety |                   |          |                             |       |                |                             |
| 5. Management listens to staff ideas and suggestions to improve resident safety |                   |          |                             |       |                |                             |
| 6. Management often walks around the nursing home to check on resident care |                   |          |                             |       |                |                             |
| 7. My supervisor pays attention to resident safety problems in this nursing home |                   |          |                             |       |                |                             |
| 8. It is easy to make changes to improve resident safety in this nursing home |                   |          |                             |       |                |                             |
| 9. This nursing home is always doing things to improve resident safety    |                   |          |                             |       |                |                             |
| 10. When this nursing home makes changes to improve resident safety, it checks to see if the changes worked |                   |          |                             |       |                |                             |

## D: Overall Ratings

| Statement                                                                 | Yes | Maybe | No |
|---------------------------------------------------------------------------|-----|-------|----|
| 1. I would tell friends that this is a safe nursing home for their family |     |       |    |
| 2. Please give this nursing home an overall rating on resident safety     |     |       |    |
### Appendix 2  M-NHSOPS in Mandarin

中文版养老机构患者安全文化量表（M-NHSOPSC）

左侧方框里给出的句子，在右侧方框里选择您对这句话是“完全不同意”、“不太同意”、“中立”、“比较同意”、“完全同意”、“不适用或不知道”并在对应的方框里打上“√”（或“从不”、“偶尔”、“一半时间”、“大部分时间”、“总是”、“不适用或不知道”）。

#### A. 您所在养老机构

| 句子                                                                 | 完全不同意 | 不太同意 | 中立 | 比较同意 | 完全同意 | 不适用或不知道 |
|---------------------------------------------------------------------|-------------|----------|------|----------|-----------|----------------|
| 您与同事相互尊重                                                   |             |          |      |          |           |                |
| 您与同事相互支持                                                   |             |          |      |          |           |                |
| 您觉得您是这个集体中的一员                                       |             |          |      |          |           |                |
| 您为了将工作快速完成，常会简化标准流程                           |             |          |      |          |           |                |
| 为了使工作更简化，您经常忽略标准流程                               |             |          |      |          |           |                |

#### B. 沟通

| 句子                                                                 | 从不 | 偶尔 | 一半时间 | 大部分时间 | 总是 | 不适用或不知道 |
|---------------------------------------------------------------------|------|------|----------|-------------|------|----------------|
| 您在服务新照护对象前，会被告知所需照护对象的相关信息             |      |      |          |             |      |                |
| 您服务照护对象时，能获得所需的相关信息                            |      |      |          |             |      |                |
| 您和同事会讨论如何避免意外再次发生                               |      |      |          |             |      |                |
| 您和同事会讨论如何有效避免照护对象受到伤害                       |      |      |          |             |      |                |
### C: 关于您所在的养老机构

|  | 完全不同意 | 不太同意 | 中立 | 比较同意 | 完全同意 | 不适用或不知道 |
|---|------------|----------|------|----------|----------|----------------|
| 1. 照护对象在此机构内能够得到很好的照护 | 1 | 2 | 3 | 4 | 5 | 6 |
| 2. 此机构在保障照护对象安全上一直做的很好 | 1 | 2 | 3 | 4 | 5 | 6 |
| 3. 此机构对照护对象来说是安全的 | 1 | 2 | 3 | 4 | 5 | 6 |
| 4. 管理者向机构员工征求提高照护对象安全的建议 | 1 | 2 | 3 | 4 | 5 | 6 |
| 5. 管理者听取机构员工有关提高照护对象安全的建议或想法 | 1 | 2 | 3 | 4 | 5 | 6 |
| 6. 管理者经常巡视照护对象的照护情况 | 1 | 2 | 3 | 4 | 5 | 6 |
| 7. 您的上级重视照护对象的安全问题 | 1 | 2 | 3 | 4 | 5 | 6 |
| 8. 改善照护对象安全的措施在此机构中容易开展 | 1 | 2 | 3 | 4 | 5 | 6 |
| 9. 此机构一直致力于提高照护对象的安全 | 1 | 2 | 3 | 4 | 5 | 6 |
| 10. 改善照护对象安全的措施一旦开始实施，检查就会跟进 | 1 | 2 | 3 | 4 | 5 | 6 |

### D: 综合评分

|  | 会 | 可能会 | 不会 |
|---|----|-------|------|
| 1. 您会告诉朋友这是个安全的养老机构吗? | 1 | 2 | 3 |
| 2. 请对此养老机构的安全做一个综合性的评价。 | 1 | 2 | 3 | 4 | 5 | 6 |

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### STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

| Item No | Recommendation                                                                                     | Page No. | Relevant text from manuscript |
|---------|----------------------------------------------------------------------------------------------------|----------|-------------------------------|
| **Title and abstract** | 1. (a) Indicate the study’s design with a commonly used term in the title or the abstract | 1        | 1-4                           |
|         | 2. (b) Provide in the abstract an informative and balanced summary of what was done and what was found | 2-3      | 28-55                         |
| **Introduction** | 2. Explain the scientific background and rationale for the investigation being reported | 3-5      | 68-112                        |
| **Objectives** | 3. State specific objectives, including any prespecified hypotheses | 5        | 113-115                       |
| **Methods** | 4. Present key elements of study design early in the paper | 6        | 126-128                       |
|         | 5. Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 8-9      | 166-182                       |
|         | 6. (a) Give the eligibility criteria, and the sources and methods of selection of participants | 8-9      | 172-182                       |
| **Variables** | 7. Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 9        | 183-199                       |
| **Data sources/measurement** | 8* For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 9        | 183-199                       |
| **Bias** | 9. Describe any efforts to address potential sources of bias | 10       | 166-182                       |
| **Study size** | 10. Explain how the study size was arrived at | 8-9      | 166-182                       |
| **Quantitative variables** | 11. Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 9        | 183-199                       |
| **Statistical methods** | 12. (a) Describe all statistical methods, including those used to control for confounding | 9        | 183-199                       |
|         | 13. (b) Describe any methods used to examine subgroups and interactions | 9        | 183-199                       |
|         | 14. (c) Explain how missing data were addressed | 9        | 183-199                       |
|         | 15. (d) If applicable, describe analytical methods taking account of sampling strategy | 9        | 183-199                       |
|         | 16. (e) Describe any sensitivity analyses | 9        | 183-199                       |
| **Results** | 13* (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 10       | 219-221                       |
|         | 14* (b) Give reasons for non-participation at each stage | 8        | 178-179                       |
|         | 15* (c) Consider use of a flow diagram | 8        | 178-179                       |
|         | 16* (d) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 10-14    | 222-235                       |
|         | 17* (b) Indicate number of participants with missing data for each variable of interest | 10-14    | 222-235                       |
Outcome data 15* Report numbers of outcome events or summary measures 10 211-218

Main results 16

(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included

(b) Report category boundaries when continuous variables were categorized

(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

Other analyses 17 Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Discussion

Key results 18 Summarise key results with reference to study objectives 19-20 280-290

Limitations 19 Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias 26 423-429

Interpretation 20 Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence 19-26 280-429

Generalisability 21 Discuss the generalisability (external validity) of the study results 26 432-437

Other information

Funding 22 Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based 27 445-446

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.
Transcultural adaptation and psychometric evaluation of the mainland China Version of Nursing Home Survey on Patient Safety Culture questionnaire: A cross-sectional survey based on 50 nursing homes in China

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Transcultural adaptation and psychometric evaluation of the mainland China Version of Nursing Home Survey on Patient Safety Culture questionnaire: A cross-sectional survey based on 50 nursing homes in China

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Keywords: nursing homes; safety culture; aged; psychometrics

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Abstract

Objective: To provide a validated Chinese-language measurement of the Nursing Home Survey on Patient Safety Culture (NHSOPS) in mainland China. The primary goal is to carry out a transcultural adaptation of the NHSOPS questionnaire into Chinese, and evaluate its psychometric properties.

Design: A psychometric evaluation study is constructed. Firstly, the “Translate-Back translate-Cultural adaptation” and the pretesting procedure were followed to introduce the NHSOPS. Secondly, a cross-sectional survey was used to assess the psychometric properties for the mainland China version of the NHSOPS, and a test-retest survey was then applied.

Setting and participants: The survey was carried out among 1397 nursing home staff from 50 nursing homes in Southwestern China.

Outcome Measures: Exploratory factor analysis (EFA) was used to assess the potential structure and confirmatory factor analysis (CFA) was then applied. Reliability was assessed by the content validity index, Cronbach’s α, and the test-retest value.

Results: Among the 1397 respondents, 1211 were included (86.7%). EFA was used and a 9-factor structure was explored. Five factors (Cronbach’s α > 0.6) were selected into the new structure for the mainland China version of the Nursing Home Survey on Patient Safety Culture (M-NHSOPS). Moreover, data showed that it was suitable for CFA, and convergent validity and discriminant validity were satisfactory. On the other hand, M-NHSOPS contains five dimensions and 22 items. The overall
Cronbach's \( \alpha \) value was 0.883; the values of each dimension ranged from 0.648-0.913.

Additionally, content validity showed significant performance. Eventually, test-retest reliability was 0.892, and each dimension was 0.713, 0.809, 0.924, 0.795, and 0.859 respectively (\( p<0.001 \)).

**Conclusions:** M-NHSOPS has acceptable reliability and satisfactory validity among staff of nursing homes in Southwest China, and further verification among samples in other regions of mainland China is required.

**Keywords:** nursing homes; safety culture; aged; psychometrics

**Strengths and limitations of this study:**

- Well applied translation and cultural adaptation process
- Clarified inclusion criteria for different staff of the scale
- Relatively abundant sample size
- Further verification among samples in other regions of mainland China is required
- Further explorations of patient safety culture connotations in nursing homes in mainland China are recommended

**Introduction**

Preventing incidents such as medication errors and misconducts are of paramount importance in elderly care institutions,\(^1\) and Patient safety culture (PSC) refers to the
prevailing attitudes, beliefs, values, and behaviors of employees formed by health institutions to achieve the goal of patient safety.\textsuperscript{2} The inverse association between PSC and adverse event occurrence was proved.\textsuperscript{3} Thus, PSC has been accepted as an essential quality indicator across all health care settings.\textsuperscript{4} For improvement, the most common approach has been to develop or introduce reliable PSC assessment tools in specific countries and then conduct cross-sectional surveys in organizations.

As mentioned above, assessing the current situation and identifying the weak aspects of organizations are regarded as the most challenging procedures.\textsuperscript{5}

Correspondingly, a reliable tool is a prerequisite for reliable assessment. On one hand, up to now research on the evaluation of PSC has largely been confined to hospitals.\textsuperscript{6} Numerous tools such as Safety Attitudes Questionnaire (SAQ), Hospital Survey on Patient Safety Culture (HSOPS) were developed. SAQ and HSOPS have been widely introduced, such as in Norway,\textsuperscript{7} Greece\textsuperscript{9}, and China,\textsuperscript{10} etc. On the other hand, some pieces of evidence showed that nursing homes (NHs) are at high risk.\textsuperscript{12} Residents in NHs have multiple health problems and require advanced medications. Some of them even have cognitive impairments, which leads to increased potential risks.\textsuperscript{13} However, previous research for PSC on NHs has been lacking.\textsuperscript{4}

Despite increased advocacy of use of PSC in NHs in recent years, efforts in evaluating PSC in NHs, primarily available tools, are still lacking.\textsuperscript{12} In 2008, the Agency for Healthcare Research and Quality (AHRQ) developed a specific tool-Nursing Home Survey on Patient Safety Culture (NHSOPS) for NHs,\textsuperscript{14} which had previously developed HSOPS. Subsequently, NHSOPS has also been validated.
into different regions and cultures, including Norway, France, Switzerland, and Spain, etc. In mainland China, NHs is categorized by the government into three types: NHs hosted and managed by government party (named as type A in this research), hosted by the government but managed by the non-government party (type B), and hosted and managed by the non-government party (type C). Research suggests that the government-owned nursing homes still enjoy more benefits than private organizations in staffing, funding, and insurance. However, at the same time NHs are still occasionally associated with safety risks. The Chinese nursing home industry is under initial development, and the quality varies among different NHs in comparison with developed countries.

Recently, two Chinese versions of NHSOPS were reported in 2016 and 2017. For Xiao’s version in mainland China, the sample size was insufficient (N=322), and it lacked consideration of staff classification, content of scale, and applicability of certain items. Furthermore, there are numerous differences between mainland China and Taiwan versions including: dialects, sub-cultures, functions, classifications of NHs, types of professionals in NHs, staffing proportions of professionals in different kinds of NHs, and different development levels of NHs, etc. Accordingly, NHs in mainland China are still in urgent need of a reliable and validated Chinese version of an assessment tool to evaluate their psychometric properties to have baseline data on the Patient Safety Culture of NHs in mainland China.
In this study, we focus on the intercultural adaptation of NHSOPS into the mainland based on data from 50 NHs in South-western China and evaluation of its psychometric properties.

Methods

The NHSOPS contains 42 items focused on 12 dimensions: teamwork, staffing, compliance with procedures, training and skills, non-punitive response to mistakes, handoffs, feedback and communication about incidents, communication openness, supervisor expectations and actions promoting resident safety, overall perceptions of resident safety, management support for resident safety, and organizational learning. Two overall rating questions are at the end of the scale. The total score ranges from 0 to 210; the higher scores represent a superior safety culture in the organization.

Copyright of the original scale (utilization and translation) was attained in October 2015 from the Agency for Healthcare Research and Quality (AHRQ).

This study was conducted in two phases: an initial phase involving the translation and cultural adaptation of the questionnaire, and a second phase in which the psychometric properties of the questionnaire were evaluated.

Translation and transcultural adaptation of NHSOPS in mainland China

A cross-cultural adaptation procedure was conducted: translation, back-translation, cultural adjustment, and pretesting. The first stage was to translate the original scale into Chinese by two independent native postgraduates with fluency in English. Both graduates majored in nursing and had sufficient understandings on PSC. Secondly, a professor from evidence-based medicine who had been focusing on the research of...
PSC synthesized the two Chinese versions into one. Two bilingual translators with no medical backgrounds then translated it back to Chinese separately. Both of them were blind to the questionnaire. A geriatric nursing professor examined the equivalence of context and semantics by comparing the back-translated versions with the original one and check if it was translated in accordance.

The cultural adaptation process included 3 parts, with 3 rounds of group meetings, two rounds of expert consultations, and a pilot test. It is recommended by the User's Guide developed by AHRQ for international translators that group meetings focused on translation and adjustment should be used to make a superior cultural adaptation. The research team members included three Ph.D. students, four Master students in geriatric nursing, and two Master students in evidence-based medicine. The criteria for inclusion of experts were that, (1) they have relevant experience of safety culture, elderly care, elderly patient management, hospital management, nursing home management, or public health, etc.; (2) with more than 10 years of relevant experience; and (3) informed consent. Nineteen experts participated in 2 rounds of consultations, and all were from the Sichuan Province of China. Their age ranged from 40-60, and only one expert was above 60; 3 (15.8%) of them have worked for 10-19 years, 4 (21.1%) for 20-29 years, and 12 (63.3%) for over 30 years; 3 (15.8%) of them were graduated from Junior College, 9 (47.4%) were undergraduates, 4 (21.1%) have Master degrees, and 3 (15.8%) have doctoral degrees; 7 (36.8%) of them were head nurses in hospitals, 3 (15.8%) were deputy head nurse in hospitals, 1 (5.3%) was the management layer of the nursing department in a hospital, 3 (15.8%) were from
Sichuan Association of Senior Services (SASS), 3 (15.8%) was the management layer of NHs, 1 (5.3%) was a professor of nursing, and 1 (5.3%) was a professor of statistics. Eventually, a pilot test was conducted by querying 200 care providers in nursing homes to complete the survey (3 nursing homes in Xindu district of Sichuan Province), and no difficulty in understanding or responding was reported. The translation and adaptation process is shown in Figure 1.

**Figure 1. Translation and cultural adaptation process**

**Psychometric validation of mainland China version of the NHSOPS**

This cross-sectional study was conducted in Sichuan Province, Southwest China from 2016 to 2017. Initially, we contacted 3 nursing homes and pilot-tested a subgroup (N=200). Based on the research information, we then accessed each type of nursing home (A, B, C) from 20 administrative regions. Theoretically, at least one type of nursing home (A, B, C) should be extracted for each area.

In this study, 50 NHs were enrolled, and 1397 staff were invited. Inclusion criteria were (1) personnel who provide direct care service to the elderly in NHs; (2) working full-time; (3) informed consent and voluntary participation. Exclusion criteria were (1) staff who are absent or leaving the nursing home; (2) internship or trainee.

Questionnaires were distributed by the research team and checked immediately after completion by respondents. In case of failed completion for certain items, members of the research team would remind them for completion. Questionnaires were excluded as their missing value >20% from this survey. To evaluate test-retest reliability, a
180 subgroup (N=30) completed the survey twice on day 0 as well as on day 14. This
181 study was approved by the Institutional Review Board of West China Hospital,
182 Chengdu, China.

183 **Statistical analysis**

184 Data were analyzed by SPSS24.0 and AMOS19.0, and \( p < 0.05 \) was considered
185 statistically significant in two-tailed tests. The general characteristics of our volunteer
186 nursing homes and responded stuff were described by means (standard deviations, SD)
187 or frequencies of categorical items.

188 Expert consultations were analyzed by the recovery rate and content validity index
189 (CVI). This measurement includes item-level I-CVI and scale-level S-CVI. The
190 S-CVI at the scale level also includes average S-CVI (S-CVI/Ave) and Universal
191 Agreement S-CVI (S-CVI/UA). Exploratory factor analysis (EFA) was applied to
192 explore the potential structure. In EFA, the KMO value, Bartlett's chi-square value, df
193 value, the value of variance, eigenvalues, and factor loading were calculated to
194 indicate the properties of the new model. A further factor structure was developed
195 with factors whose Cronbach's \( \alpha \) > 0.6. The confirmatory factor analysis (CFA) was
196 used to test if this factor structure was suitable and at the same time, convergent
197 validity and discriminant validity were explored. Pearson correlation coefficient was
198 used to calculate the retest reliability. Cronbach's \( \alpha \) coefficient was used to assess the
199 reliability of the scale.

200 **Inclusion criteria of items and dimensions of the M-NIISOPS**
In this study, EFA was firstly applied to explore the original structure of the data set, and a preliminary factor structure was obtained, and the validity of each factor was explored. Factors whose Cronbach’s α > 0.6 and item loading > 0.5 were then selected as the new structure for M-NHSOPS.

Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

Results

Translation and transcultural-adaptation

The mainland China version of the Nursing Home Survey on Patient Safety Culture (M-NHSOPS) contains 5 dimensions and 22 items. The original dimensions "staffing" (A3, A8, A16, A17), "training and skills" (A7, A11, A13), "non-punitive response to mistakes" (A10, A12, A15, A18), and "communication openness" (B7, B9, B11) were deleted from M-NHSOPS. Items such as A4, A9, B4, B5, B8, C1, C2, and D3 were also deleted. The M-NHSOPS scale retains the Likert-5 response scale and "Does Not Apply or Don’t Know" options as well as 2 overall evaluation items.

Further details are shown in Appendix 1 and 2.

Of the 1397 questionnaires distributed, 187 questionnaires were excluded since over 20% of items were missing, resulting in a total of 1211 responses (86.7% response rate).

Characteristics of enrolled NHs and participants
Among the 20 administrative areas, 9 have all types of NHs, 8 have 2 types which contain at least a type A or a type B nursing home, and 3 areas have only 1 kind of nursing home in which 2 regions have only type C nursing homes. The respondents from these facilities ranged from 17-224. Additional details are shown in Table 1.

Table 1  Characteristics of the Nursing Homes (N = 50).

| Areas        | Type A (No. of NHs/ No. of staff) | Type B (No. of NHs/ No. of staff) | Type C (No. of NHs/ No. of staff) | Total of staff |
|--------------|----------------------------------|----------------------------------|----------------------------------|----------------|
| Qing Yang    | 1/70                             | 1/40                             | 1/10                             | 120            |
| Cheng Hua    | 1/24                             | -                                | 2/(14/17)                        | 55             |
| Jin Jiang    | -                                | -                                | 2/(19/13)                        | 32             |
| Jin Niu      | -                                | 1/19                             | 1/29                             | 48             |
| Wu Hou       | -                                | -                                | 1/17                             | 17             |
| Gao Xin      | 1/23                             | -                                | -                                | 23             |
| Du Jiangyan  | 1/57                             | -                                | 2/(12/10)                        | 79             |
| Shuang Liu   | 1/7                              | 1/40                             | 1/20                             | 67             |
| Long Quan    | 1/51                             | 1/44                             | 1/39                             | 134            |
| Xin Du       | 1/130                            | 1/68                             | 1/26                             | 224            |
| Pi Du        | 1/10                             | -                                | 2/(36/24)                        | 70             |
| Peng Zhou    | 1/17                             | -                                | 1/9                              | 26             |
| Chong Zhou   | 1/9                              | -                                | 1/12                             | 21             |
| Da Yi        | 1/48                             | 1/8                              | 1/11                             | 67             |
| Qiong Lai    | 1/8                              | 1/8                              | 1/10                             | 26             |
Most staff were from type A NHs (42.6%), and 77.3% of them were females. The age ranged from 18 to 80 (42.05±13.04), and those between 46-60 comprised the majority. Merely 14.5% of them were undergraduates, and 1.7% of them had acquired a Master's degree. Nursing assistant (54.4%) was the most prominent composition in NHs. Additional details were shown in Table 2.

Table 2  Characteristics of the respondents (N = 1211).

| Characteristics          | n(%)        |
|--------------------------|-------------|
| Type of facility         |             |
| A                        | 516 (42.6%) |
| B                        | 322 (26.6%) |
| C                        | 373 (30.8%) |
| Sex                      |             |
| Male                     | 275 (22.7%) |
| Female                   | 936 (77.3%) |
| Age (years)              |             |
| Education |   |   |
|-----------|---|---|
| Illiteracy | 73 (6.0%) |
| Primary school | 201 (16.6%) |
| Middle school | 320 (26.4%) |
| High school | 95 (7.8%) |
| Technical secondary school | 72 (5.9%) |
| Junior college | 253 (20.9%) |
| Undergraduate | 176 (14.5%) |
| Master’s degree and above | 21 (1.7%) |

| Position |   |   |
|----------|---|---|
| Management layer | 198 (16.4%) |
| Doctor | 138 (11.4%) |
| Nurse | 186 (15.4%) |
| Nursing assistant | 659 (54.4%) |
| Others | 30 (2.5%) |

| Professional licenses |   |   |
|-----------------------|---|---|
| Yes | 271 (22.4%) |
| No | 940 (77.6%) |
Elderly care assistant staff

|       | Yes          | No          |
|-------|--------------|-------------|
|       | 357(29.5%)   | 854(70.5%)  |

Number of years in nursing home

|       | <1year       | ≥1year      |
|-------|--------------|-------------|
|       | 147(12.1%)   | 1064(87.9%) |

Working hours per week

|       | <40h         | ≥40h        |
|-------|--------------|-------------|
|       | 107(8.8%)    | 1104(91.2%) |

Validity

Structural validity

To explore the most suitable factor structure of the scale, we applied EFA.

Principal component analysis and the maximum variance method were used. Factors with eigenvalues above one were selected, while items with the maximum factor loading value < 0.5 and those with double loading were deleted. The KMO value was 0.928, and the Barlett Test of Sphericity was significant (Chi square=20882.645, df value was 861, p <0.001), and it accounted for 58.096% of the variance. As a result, 9-factors were precipitated. Additional details are shown in Table 3.

Based on EFA, a new 5-factor structure was formed, of which all factors' Cronbach’s α was above 0.6. To test the new structure, CFA was used for which CMIN/DF=2.631, RMR=0.026, GFI=0.967, AGFI=0.952, NFI=0.965,
RFI=0.955, IFI=0.978, TLI=0.971, CFI=0.978, and RMSEA=0.037. All items were identified to have a 5-dimensional construct with 22 items. Additional details are displayed in Table 4 and Table 5, respectively.

| Factor number | Items included | Item loadings |
|---------------|----------------|---------------|
| 1             | D6             | 0.808         |
|               | D5             | 0.774         |
|               | D8             | 0.770         |
|               | D9             | 0.755         |
|               | D10            | 0.734         |
|               | D1             | 0.727         |
|               | D7             | 0.703         |
|               | C3             | 0.644         |
|               | D4             | 0.603         |
|               | D2             | 0.569         |
| 2             | B3             | 0.801         |
|               | B1             | 0.779         |
|               | B2             | 0.776         |
|               | B10            | 0.680         |
|               | B6             | 0.513         |
| 3             | A2             | 0.844         |
|               | A1             | 0.838         |
| Factor No. | Items | Factor loading | Reliability coefficient | Measuring error | Composite reliability | Average variance extracted |
|-----------|-------|----------------|-------------------------|----------------|-----------------------|---------------------------|
| 1         | D1    | 0.724          | 0.524                   | 0.476          | 0.917                 | 0.527                     |
|           | D2    | 0.588          | 0.346                   | 0.654          |                       |                           |
|           | C3    | 0.661          | 0.437                   | 0.563          |                       |                           |
|           | D4    | 0.614          | 0.377                   | 0.623          |                       |                           |

Table 4 Convergent validity analysis table (CV).
Table 5  Convergent validity (CV) and discriminant validity (DV).

| Factor number | 1     | 2     | 3     | 5     | 6     |
|---------------|-------|-------|-------|-------|-------|
| D5            | 0.792 | 0.627 | 0.373 |       |       |
| D6            | 0.826 | 0.682 | 0.318 |       |       |
| D7            | 0.703 | 0.494 | 0.506 |       |       |
| D8            | 0.785 | 0.616 | 0.384 |       |       |
| D9            | 0.792 | 0.627 | 0.373 |       |       |
| D10           | 0.733 | 0.537 | 0.463 |       |       |
| B1            | 0.772 | 0.596 | 0.404 | 0.854 | 0.543 |
| B2            | 0.829 | 0.687 | 0.313 |       |       |
| B3            | 0.795 | 0.632 | 0.368 |       |       |
| B6            | 0.577 | 0.333 | 0.667 |       |       |
| B10           | 0.685 | 0.469 | 0.531 |       |       |
| A1            | 0.867 | 0.752 | 0.248 | 0.826 | 0.621 |
| A2            | 0.887 | 0.787 | 0.213 |       |       |
| A5            | 0.570 | 0.325 | 0.675 |       |       |
| B5            | 0.815 | 0.664 | 0.336 | 0.855 | 0.748 |
| B8            | 0.912 | 0.832 | 0.168 |       |       |
| A6            | 0.658 | 0.433 | 0.567 | 0.658 | 0.491 |
| A14           | 0.741 | 0.549 | 0.451 |       |       |
Reliability

Expert consultation related indicators and content reliability

Two rounds of expert consultations were used to localize the scale, and recovery rates of 2 rounds were 100%. The CVI was used to assess the fitness between the content to be measured and the content measured. In this study, except for A6 and B10 (both I-CVI values were 94.7%), all values of remaining items were 100%. The S-CVI/UA was 95.2%, and S-CVI/Ave was 99.4%.

Reliability analysis

Values of reliability were calculated on the 9 factors extracted by EFA, and Cronbach's $\alpha$ ranged from 0.366-0.913. The overall Cronbach's $\alpha$ value of the mainland China version scale was 0.883. Additional details are displayed in Table 6.

| Factor number | Included items     | Number of items | Cronbach's $\alpha$ |
|---------------|--------------------|-----------------|---------------------|
| 1             | D1/D2/C3/D4/D5/D6/D7/D8/D9/D10 | 10              | 0.913*              |
| 2             | B1/B2/B3/B6/B10    | 5               | 0.851*              |
| 3             | A1/A2/A5          | 3               | 0.797*              |
| 4             | A7/A9/A11         | 3               | 0.565               |
|   |   |   |   |
|---|---|---|---|
| 5 | B5/B8 | 2 | 0.851* |
| 6 | A6/A14 | 2 | 0.648* |
| 7 | A18/C1 | 2 | 0.393 |
| 8 | B9/A17 | 2 | 0.422 |
| 9 | A8/A10 | 2 | 0.366 |

Cronbach's α > 0.6 were signed with "*"

**Test-retest reliability**

The Pearson correlation coefficient was applied to calculate test-retest reliability. We retested 30 employees in a nursing home after a 0-14 interval. The test-retest reliability was 0.892, in which each dimension was 0.713, 0.809, 0.924, 0.795, and 0.859 (p<0.001).

**Discussion**

In the translation period, there were 42 items, which was similar to Xiao's study, Taiwan, China version, and French version, compared with the Norwegian version with 43 items in which it split item B3, “We have all the information we need when residents are transferred from hospital” into two items. Quality of translation and cultural-adaptation were guaranteed by translation, back-translation, and cultural adaptation process. Additionally, we used data from the expert consultations to explore content validity. The recovery rates of 2 rounds were high, indicating the active participation of experts in this study. All I-CVI data were higher
than 0.78 for 3 and more experts. The values of S-CVI/UA and S-CVI/Ave were ≥ 0.8 and ≥ 0.9, respectively, indicating exceptional levels. All indicators above showed that the M-NHSOPS has satisfactory content validity.

The recovery rate was significant higher than the French version of 58.4%, the Norwegian version of 69%, and the Swiss version of 66%. However, it was lower than Xiao's study of 92.3% and the Taiwan, China version of 100%. The recovery rate in this study is relatively satisfactory. In this study, the average age of participants was (42.05±13.04), and staff aged from 60-80 accounted for 11.7%, while in the French version, only 7.2% of respondents were aged above 56. In Taiwan, China version the average age was (37.7±10.5). This result emphasize that respondents in this survey are considerably senior than those in other studies. Illiteracy accounted for 6.0% and staff whose educational background ranging from primary to high school comprised 50.9%. However, in Taiwan, China version, there was no illiterate staff, and individuals who have graduated from elementary to high schools were 36.6% and those who have diplomas, bachelor or higher degrees were 62.4%. In brief, staff in Chinese NHs were lower educated than those in other studies. Additionally, staff who worked in NHs for less than a year comprised 12.1%, while in Cappelen's study it was 6.3%. Staff who worked at least 40h/week comprised 91.2%, while in Cappelen's study those worked at least 35.5 h/week comprised 16.1%. These indicate that staff in this study have less working experience while experience greater overtime than in other regions.
EFA explored a 9-factor structure with 31 items included. The value of KMO indicates sufficient inter-correlations and the value of the Barlett Test of Sphericity demonstrates that the data was ideal for factor analysis. Moreover, the cumulative contribution rate of this study which was over 40% indicates satisfactory construct validity. Comparing the 9-factor structure with the original US scale, 4 original dimensions (9 items) were deleted (staffing, non-punitive response to mistakes, communication openness and training, and skills). The deletion of "staffing" may be due to the proportion of staffing and the educational background of employees, for which 54.4% of the respondents were nursing assistants and 62.8% received lower education than secondary/high school. In brief, the majority of them have less/no staffing or management relevant knowledge/experience, and the concept of workplace competition has not appeared to be instilled, which prevents them from participating in the staffing/management of the nursing home. Besides, due to the general management culture in China, there exists strict leadership hierarchy between superiors and subordinates in which management layers tend to be exclusively in charge of such kind of staffing matters, and most employees perceive themselves not being in the position to intervene the upper management. The removal of "non-punitive response to mistakes" and "communication openness" may be related to the fact that the "learn from error" climate and "open communication" have not been well developed in domestic organizations. The original dimension "training and skills" was deleted which indicates that most staff in NHs have received little training in elderly care. China is in urgent demand of good-quality and well-structured training
schemes for all types of staff. To check the performance of the new 5-factor structure of M-NHSOPS, CFA was applied. All values of GFI, AGFI, NFI, RFI, IFI, TFI, and CFI were above 0.9, while CMIN/DF was less than 3, RMSEA was less than 0.08, and RMR was less than 0.05, which indicates the 5-factor structure fits excellently. All values of composite reliability (CR) of the five dimensions were higher than 0.6 which means they achieved the required level. All values of average variance extracted (AVE) were above 0.5, indicating satisfactory construct reliability and adequate convergent validity. For factor 6, despite its AVE value being less than 0.5, its other indicators were satisfactory—factor loadings of the two items were 0.658 and 0.741 respectively, and CR value was 0.658, hence it was kept in the M-NHSOPS scale. The square between the respective constructs was less than the square of AVE for the construct that achieved the discriminant validity of M-NHSOPSC.

In M-NHSOPS, factor 1 was named "perceptions of resident safety and related administrative support" which included 10 items (D1/D2/C3/D4/D5/D6/D7/D8/D9/D10). Its Cronbach's α value was 0.913, and item loading ranged from 0.569-0.808. It was a combination of 3 original dimensions "overall perceptions of resident safety", "management support for resident safety", and "organizational learning". This combination of dimensions is consistent with the composition of factors in the Norwegian version. However, there was a minor difference: in M-NHSOPS, item D3 was replaced by C3 in the Norwegian version. The composition of the 3 dimensions in both studies indicates that there exists homogeneity between "organizational learning" and "management support for
resident safety” in some cultures. Factor 2 was named “handoffs” containing 5 items (B1/B2/B3/B6/B10). Its Cronbach’s α value was 0.851, and item loading ranged from 0.513-0.801. Items B1/ B2/ B3/ B10 belong to the original dimension “handoffs” while B6 "Staff tell someone if they see something that might harm a resident" belongs to the original dimension "feedback & communication about incidents". This can be viewed and explained such that the staff would closely and actively communicate with each other on any potential safety hazards, for which they consider such in-time communication is essential and valuable. Factor 3 was named "teamwork" and contained 3 items(A1/A2/A5). Its Cronbach's α value was 0.797, and item loading ranged from 0.690-0.844. The original dimension "teamwork" contained all 3 items above and item A9 "When someone gets really busy in this nursing home, other staff help out". However, in M-NHSOPS, A9 was deleted since in the context of Chinese cultures, assisting colleagues is merely a favor and not an individual’s responsibility in terms of workplace regulation or ethics. Moreover, factor 5 was named "feedback & communication about incidents" and included two items (B5/B8). Its Cronbach's α value was 0.851, and item loading ranged from 0.815-0.840. The original dimension "feedback & communication about incidents" included 4 items, which were B5, B8, B4 "When staff report something that could harm a resident, someone takes care of it", and B6 "Staff tell someone if they see something that might harm a resident". B6 was merged into factor 2 "handoffs" while B4 was deleted automatically from the original 9-factor structure. Eventually, factor 6 was named "compliance with procedures" and contained 2 items (A6/A14). Its Cronbach's α value
was 0.648, and item loading ranged from 0.693-0.761. In the original dimension "compliance with procedures", A4 "Staff follow standard procedures to care for residents" was included. The deletion may be due to lack of standard procedures to care for residents in most of the nursing homes in mainland China as well as lack of national/provincial standard for determining the quality of care in nursing homes. In this study, the value of Cronbach's $\alpha > 0.6$ is considered reliable, $\alpha$ ranges from 0.7-0.8 are deemed to be acceptable, and Cronbach's $\alpha > 0.8$ is considered adequate. The overall Cronbach's $\alpha$ of the scale was 0.883. It was close to Xiao's study but lower than Taiwan, China version. The Cronbach's $\alpha$ value of dimensions of M-NHSOPS ranged from 0.648-0.913, illustrating exceptional reliability and satisfactory internal consistency. The recovery rate of the test-retest experiment was 100%, and all values of the total scale and every dimensions were above 0.7, indicating that the test-retest survey has satisfactory performance on validity.

M-NHSOPS has 5 dimensions and 22 items, while Taiwan, China version has 4 dimensions with 29 items. There exist 17 identical items between versions above, however they have different compositions of dimensions. This result confirms the differences between mainland China and Taiwan, which is mentioned in the introduction. Moreover, Lin's study was applied among 309 staff in 30 long-term care facilities, and the sample size was smaller than that in the present study.

Similarly, significant differences were shown between M-NHSOPS and Xiao's version (1) 23 items were included in Xiao's result, and 22 items were included in
M-NHSOPS; (2) in Xiao's study, it merely has 13 identical items with items included in M-NHSOPS; (3) there are 6 dimensions in Xiao's research while 5 dimensions in M-NHSOPS. Moreover, the compositions of each dimension are entirely different. The differences can be explained by the various inclusions of participants between these 2 studies: (1) the sample size in Xiao's research was too small and merely included 6 NHs and 322 respondents; (2) in the pilot study, we found that the employees such as support staff, securities, and canteen staff who do not directly provide care service to the elderly, have insufficient understanding and integration of PSC as they do not participate in daily care routine; (3) the scale contains a large number of items related to the care for the elderly, which makes it difficult for the non-direct care provider to respond; (4) sampling in Xiao's study showed that medical staff accounted for most significant proportion (professional medical staff was 67.7% while the nursing assistant was 25.8%). However, in Chinese NHs, nursing assistants comprise the largest workforce. In brief, there still lacks sufficient evidence that the inclusion of all staff types in Chinese NHs is practical and applicable at present, even though the original developer suggested otherwise. Regarding this, both the Taiwan, China version, and this study merely included direct care providers in organizations. Comparatively, in this study, the inclusion criteria of staff fit the staffing situation in mainland China better, and the sample size is relatively adequate.

Sampling was based on both geographic locations and types of NHs. Researchers attempted to include all possible types of nursing homes in each area except in case no exact sort of nursing home exists or the only nursing home in this type refuses to
participate. Thus, a total of 50 NHs were enrolled, of which 17 (34.0%) were type A
organizations, 12(24.0%) were type B, and 21(42.0%) were type C. It shows that the
sampling in this study was evenly distributed and relatively representative. Similarly,
as for staffing in NHs, the average number of employees in type A was 30.4 per
institution, in type B was 26.8, and in type C was 17.8. The staffing in private
organizations is comparatively insufficient than the other two types of NHs, and this
result is consistent with previous literature reviews in the introduction. However, our
study also has some limitations: initially, the sample was only from NHs in Southwest
China. Further verification of M-NHSOPS on a large sample size elsewhere in China
is recommended. Secondly, this study merely used quantitative research to explore the
PSC in NHs in mainland China. However, qualitative research methods are also
recommended to be combined in further research to complete the connotations of PSC
in Chinese NHs.

Conclusion

We introduced the NHSOPS scale into mainland China with a well-applied cultural
adaptation process and validated it with a relatively adequate sample size. This study
firstly clarified the inclusion of types of staff in NHs for use of the scale. M-NHSOPS
has 5 dimensions and 22 items, with excellent reliability and validity, making it
acceptable and useful. However, further verification among samples in other regions
of mainland China is recommended.

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**Competing interests** None declared.

**Patient consent for publication** Not required.

**Ethical approval** This study was supported by the Institutional Review Board of West China Hospital, Sichuan University (Chengdu, China), and the approval number is [2017-268]. Informed consent was obtained. And data in this study were all anonymous and used exclusively for academic purposes.

**Data availability statement** No additional data are available.

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Figure 1. Translation and Cultural adaptation process

827x440mm (96 x 96 DPI)
# Appendix 1  English version M-NHSOPS

The mainland China version of the Nursing Home Survey on Patient Safety Culture (M-NHSOPS)

Please choose whether you agree with this sentence or not in the box on the right side.

## A. Working in This Nursing Home

|   | Strongly Disagree | Disagree | Neither Agree nor Disagree | Agree | Strongly Agree | Does Not Apply or Don’t Know |
|---|-------------------|----------|-----------------------------|-------|----------------|-----------------------------|
| 1. Staff in this nursing home treat each other with respect | | | | | | |
| 2. Staff support one another in this nursing home | | | | | | |
| 3. Staff feel like they are part of a team | | | | | | |
| 4. Staff use shortcuts to get their work done faster | | | | | | |
| 5. To make work easier, staff often ignore procedures | | | | | | |

## B: Communications

|   | Never | Rarely | Sometimes | Most of the time | Always | Does Not Apply or Don’t Know |
|---|-------|--------|-----------|------------------|-------|-----------------------------|
| 1. Staff are told what they need to know before taking care of a resident for the first time | | | | | | |
| 2. Staff are told right away when there is a change in a resident’s care plan | | | | | | |
| 3. We have all the information we need when residents are transferred from the hospital | | | | | | |
| 4. Staff tell someone if they see something that might harm a resident | | | | | | |
| 5. Staff are given all the information they need to care for residents | | | | | | |
| 6. In this nursing home, we talk about ways to keep incidents from happening again | | | | | | |
| 7. In this nursing home, we discuss ways to keep residents safe from harm | | | | | | |
**C: Your Nursing Home**

| Strongly Disagree | Disagree | Neither Agree nor Disagree | Agree | Strongly Agree | Does Not Apply or Don’t Know |
|-------------------|----------|-----------------------------|-------|---------------|-----------------------------|
| 1. Residents are well cared for in this nursing home |
| 2. This nursing home does a good job keeping residents safe |
| 3. This nursing home is a safe place for residents |
| 4. Management asks staff how the nursing home can improve resident safety |
| 5. Management listens to staff ideas and suggestions to improve resident safety |
| 6. Management often walks around the nursing home to check on resident care |
| 7. My supervisor pays attention to resident safety problems in this nursing home |
| 8. It is easy to make changes to improve resident safety in this nursing home |
| 9. This nursing home is always doing things to improve resident safety |
| 10. When this nursing home makes changes to improve resident safety, it checks to see if the changes worked |

**D: Overall Ratings**

| 1. I would tell friends that this is a safe nursing home for their family | □Yes □Maybe □No |
| 2. Please give this nursing home an overall rating on resident safety | □Poor □Fair □Good □Very good □Excellent |
## Appendix 2  M-NHSOPS in Mandarin

中文版养老机构患者安全文化量表（M-NHSOPSC）

左侧方框里给出的句子，在右侧方框里选择您对这句话是“完全不同意”、“不太同意”、“中立”、“比较同意”、“完全同意”、“不适用或不知道”并在对应的方框里打上“√”（或“从不”、“偶尔”、“一半时间”、“大部分时间”、“总是”、“不适用或不知道”）。

| A. 您所在养老机构 | 完全不同意 | 不太同意 | 中立 | 比较同意 | 完全同意 | 不适用或不知道 |
|-------------------|------------|---------|-----|----------|----------|----------------|
| 1. 您与同事相互尊重 |            |         |     |          |          |                |
| 2. 您与同事相互支持 |            |         |     |          |          |                |
| 3. 您觉得您是这个集体中的一员 |            |         |     |          |          |                |
| 4. 您为了将工作快速完成，常会简化标准流程 |            |         |     |          |          |                |
| 5. 为了使工作更简化，您经常忽略标准流程 |            |         |     |          |          |                |

| B. 沟通 | 从不 | 偶尔 | 一半时间 | 大部分时间 | 总是 | 不适用或不知道 |
|---------|------|------|----------|-------------|------|----------------|
| 1. 您在服务新照护对象前，会被告知所需照护对象的相关信息 |      |      |          |             |      |                |
| 2. 当您负责的照护对象的照护计划改变时，您会立即得到通知 |      |      |          |             |      |                |
| 3. 照护对象从医院转来时，您能获得所需的相关信息 |      |      |          |             |      |                |
| 4. 当您发现机构或者照护对象存在安全隐患时，会及时告知相关人员 |      |      |          |             |      |                |
| 5. 您服务照护对象时，能获得所需的相关信息 |      |      |          |             |      |                |
| 6. 您和同事会讨论如何避免意外再次发生 |      |      |          |             |      |                |
| 7. 您和同事会讨论如何有效避免照护对象受到伤害 |      |      |          |             |      |                |
C: 关于您所在的养老机构

|  | 完全不同意 | 不太同意 | 中立 | 比较同意 | 完全同意 | 不适用或不知道 |
|---|---|---|---|---|---|---|
| 1. 照护对象在此机构内能够得到很好的照护 |  |  |  |  |  | |
| 2. 此机构在保障照护对象安全上一直做的很好 |  |  |  |  |  | |
| 3. 此机构对照护对象来说是安全的 |  |  |  |  |  | |
| 4. 管理者向机构员工征求提高照护对象安全的建议 |  |  |  |  |  | |
| 5. 管理者听取机构员工有关提高照护对象安全的建议或想法 |  |  |  |  |  | |
| 6. 管理者经常巡视照护对象的照护情况 |  |  |  |  |  | |
| 7. 您的上级重视照护对象的安全问题 |  |  |  |  |  | |
| 8. 改善照护对象安全的措施在此机构中容易开展 |  |  |  |  |  | |
| 9. 此机构一直致力于提高照护对象的安全 |  |  |  |  |  | |
| 10. 改善照护对象安全的措施一旦开始实施，检查就会跟进 |  |  |  |  |  | |

D: 综合评分

|  |  |  |  |  |  |  |
|---|---|---|---|---|---|---|
| 1. 您会告诉朋友这是个安全的养老机构吗? | □会 | □可能会 | □不会 |
| 2. 请对此养老机构的安全做一个综合性的评价。 | □非常差 | □不太好 | □中等 | □良好 | □非常好 |
STROBE Statement—Checklist of items that should be included in reports of cross-sectional studies

| Item No | Recommendation | Page No. | Relevant text from manuscript |
|---------|----------------|----------|------------------------------|
| **Title and abstract** | (a) Indicate the study’s design with a commonly used term in the title or the abstract | 1 | 1-4 |
| | (b) Provide in the abstract an informative and balanced summary of what was done and what was found | 2-3 | 28-56 |
| **Introduction** | Explain the scientific background and rationale for the investigation being reported | 3-5 | 69-113 |
| **Objectives** | State specific objectives, including any prespecified hypotheses | 6 | 114-116 |
| **Methods** | Present key elements of study design early in the paper | 6 | 127-129 |
| | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 8-9 | 166-182 |
| | (a) Give the eligibility criteria, and the sources and methods of selection of participants | 8-9 | 172-182 |
| **Variables** | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | | |
| **Data sources/ measurement** | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 9 | 183-199 |
| **Bias** | Describe any efforts to address potential sources of bias | | |
| **Study size** | Explain how the study size was arrived at | 8-9 | 166-182 |
| **Quantitative variables** | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 9 | 183-199 |
| **Statistical methods** | (a) Describe all statistical methods, including those used to control for confounding | 9 | 183-199 |
| | (b) Describe any methods used to examine subgroups and interactions | | |
| | (c) Explain how missing data were addressed | | |
| | (d) If applicable, describe analytical methods taking account of sampling strategy | | |
| | (e) Describe any sensitivity analyses | | |
| **Results** | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 10 | 219-221 |
| | (b) Give reasons for non-participation at each stage | 8 | 178-179 |
| | (c) Consider use of a flow diagram | | |
| **Descriptive data** | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 11-14 | 223-236 |
| | (b) Indicate number of participants with missing data for each variable of interest | | |
| Outcome data                                                                 | 15* | Report numbers of outcome events or summary measures | 10 | 211-218 |
|-----------------------------------------------------------------------------|-----|-----------------------------------------------------|----|---------|
| Main results                                                                 | 16  | *(a)* Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included *(b)* Report category boundaries when continuous variables were categorized *(c)* If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | 10-19 | 209-276 |
| Other analyses                                                              | 17  | Report other analyses done—e.g. analyses of subgroups and interactions, and sensitivity analyses | | |

**Discussion**

| Key results                                                                 | 18  | Summarise key results with reference to study objectives | 19-20 | 278-289 |
|----------------------------------------------------------------------------|-----|--------------------------------------------------------|-------|---------|
| Limitations                                                                | 19  | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 26    | 424-430 |
| Interpretation                                                             | 20  | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 19-26 | 278-430 |
| Generalisability                                                           | 21  | Discuss the generalisability (external validity) of the study results | 26    | 432-438 |

**Other information**

| Funding                                                                     | 22  | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 27    | 446-447 |

*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at [http://www.plosmedicine.org/](http://www.plosmedicine.org/), Annals of Internal Medicine at [http://www.annals.org/](http://www.annals.org/), and Epidemiology at [http://www.epidem.com/](http://www.epidem.com/)). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).