Title of the article: Development and Validation of the Iranian Scale of “Patient Privacy and Confidentiality”

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Dear Editor of Indian Journal of Medical Ethics

We would like to submit our manuscript to your journal: Title: Title of the article: Development and Validation of the Iranian Scale of “Patient Privacy and Confidentiality”**.**

We declare that

• The manuscript, has not been published or submitted for publication elsewhere in any language,   
• All authors agreed to be listed and approved the content of the manuscript and have contributed significantly to research and involved in writing of the manuscript;  
• This study was granted Institutional Review Board (IRB) approval by Shaid Beheshti University of Medical Sciences and received ethics approval from the research ethics committee of the university. The research conforms to the provisions of the Declaration of Helsinki.  
• All participants gave informed consent for the research, and that their anonymity was preserved;   
• we also declare that no financial or personal matters that may pose a conflict of interest existed.

Abstract:

the aim of this study was developed and psychometrically validated the Iranian scale of patient privacy and confidentiality

This methodological study was conducted in two stages: First, the conventional content analysis was used to qualitatively identify concepts of privacy and confidentiality. In the second stage, face and content and construct validity were assessed. Internal consistency coefficient and total consistency were checked. Our scale consists of 26 items. KMO and Bartlett’s test were used to examine the questionnaire for factor analysis. EFA identified 7 factors that totally accounted for %55.252 of total variance in the questionnaire score. The total Cronbach’s α coefficient was 0.84 for the whole instrument. The Spearman reliability coefficient of the instrument was 0.91 using test-retest method. The final Persian version of “Patient Privacy and Confidentiality Scale” can be used as a valid and reliable instrument to measure the rate of observation of patient privacy and confidentiality.

Key-words: Privacy, confidentiality, secrecy, scale

Introduction:

Valuing human dignity is one of the most important components approved by human rights healthcare systems (1). Human dignity is an extensive multifaceted concept the major aspects of which have attracted the attention of researchers (2). Patient privacy and secrecy, defined as “any individual’s feeling towards their nature, position, independence, and private space”, is rendered as one of the most fundamental dimensions of patients’ dignity (3). Observing individuals’ privacy is of utmost significance so that it is included in human rights (4) and developed countries have passed a number of acts and legislations to support and protect this humane right (5). Moreover, WHO has clarified this concept in medical ethics and patient rights declaration to aid in observing patient privacy in therapeutic settings (6). Attendance of individuals in clinical setting encourages them to have greater inclination for protecting and controlling their privacy regardless of their position and health status (7).

This is a duty of various members of treatment team (4). Given that nurses have the round-the-clock responsibility of patient care, they have a greater role in observing patient privacy and secrecy (4). Paying attention to patient privacy is one of the most basic concepts of ethical care (2, 3) so that observing patient privacy is the first ethical code of nursing (8). On the basis of this code, the first professional responsibility of nurses is caring for patient needs and providing an atmosphere that respects human values, beliefs, rights, and dignity (8). Observation of patient privacy results in some consequences for the individual and the healthcare system (9). On the other hand, ignoring this phenomenon leads to loss of patient’s confidence in treatment team predisposing to reduced quality of care, prolonged hospital stay, delayed recovery, and increased costs (9, 10).

Despite the importance of patient privacy, few studies in Iran have focused on the issue (11) indicating that care-providers have little awareness of patient privacy and dignity and that their perception of the concept is different from that of patients (12). Tehrani et al. (2018) mentioned in their study that despite the importance given to privacy by nurses, observation of patient privacy in patients’ perspective and the level of patient satisfaction with the issue is very low (13). The results of the study by Adib Hajbagheri et al. (2014) on 330 elderly patients hospitalized in Isfahan and Kashan demonstrated that only in %16.4 of cases patient privacy was well observed (14). The probable cause of low number of studies in this field may be attributed to lack of a valid and reliable inventory for measuring the rate of observation of privacy (11). Özturk et al. believe that there is no valid and reliable instrument available for examining observation of patient privacy and secrecy (15). Evaluation of patient perspectives can exert some modifications in method of provision of services on the basis of standard health models. Presently, patient-centered approach is progressing and is fulfilled through continual feedback of patient expectations and steady improvement of processes and organizational care provision (8). Although a few inventories like “Privacy Attitude Questionnaire (RAQ)” (16), “Privacy Observation and Patient Satisfaction Scale” (7), “Observation of Pediatric Privacy in Pediatric Ward” (17), Scale of Professional Ethics Observation from Nurses’ and Patients’ Perspectives” (18), and the Privacy Model (19) have been published, they suffer from limitations such as great length, cultural dependence and bias, focusing on a specific population, lack of attention to various aspects of privacy, and lack of comprehensiveness.

This has led to limited use of these instruments. Hence, given the importance of patient privacy and secrecy and the role of this phenomenon in promotion of quality care and health services and also considering lack of a suitable scale for measuring observation of patient privacy, this study developed and psychometrically validated the Iranian version of “Patient Privacy and Confidentiality Observation Scale”.

**Subjects and Methods:**

**Methodology**

This methodological study was carried out in two stages during 2017-2019 in Tehran, capital of Iran.

**Item Generation**

First, to design items pool, the papers published during 2010-2019 were searched in Persian and English databases including PubMed, Ovid, Scopus, Science Direct, SID, Google Scholar, and Thomson Reuters using the keywords “privacy, confidentiality, secrecy” and other related English and Persian terms. The items in the scale were developed through a review of literature and texts on privacy and confidentiality and also the available questionnaires. Sixty studies (40 Persian and 20 English) were examined in this stage. The selected texts underwent conventional content analysis. The items pool including 93 items was designed on the basis of findings and codes extracted in review of literature. Then, a board of experts (one instrument developer, one bioethical specialist, one psychiatric nurse, two nursing ethics specialists, and one nurse) selected 64 out of 93 items as the first draft of the instrument. The 5-point Likert scale used, ranged from completely agree=1, agree, 2, indifferent=3, disagree=4, to completely disagree=5.

**Validity**

**Face and Content Validity**

To investigate content validity qualitatively, 10 experts familiar with privacy and pertinent concepts (bioethics, nursing ethics, instrument development, and psychiatric nursing) were asked to explore the inventory items regarding item sufficiency, literal and semantic structure, and writing problems and also to add more suitable items to the items pool. To examine content validity quantitatively, the experts were asked to investigate content validity of the instrument using content validity ratio (CVR) and content validity index (CVI). To assess CVR, the experts were asked to score the necessity of each item on a 3-point Likert scale ranging from necessary=1 to unnecessary=3. After calculating CVR of each item, the inclusion or exclusion of the item was determined on the basis of critical points of Lawshe table. Items with CVR<0.62 (critical point in Lawshe table for 10 experts) were excluded and the rest were maintained. The experts were asked to investigate the relevance of the items to assess CVI on a 4-point Likert scale. CVI of the whole instrument was examined with Kappa designating agreement on relevance. Moreover, to investigate face validity from the target group perspective, the questionnaire was read out separately for 15 patients by the first researcher who was familiar with the items and concepts in them. Patients’ perception of the items was explored. The items that were difficult or ambiguous for the patients were revised on the basis of the participants’ opinions.

**Construct Validity**

Construct validity was investigated with exploratory factor analysis (EFA). Considering the use of EFA in this study, 3-10 samples were required as per item in the questionnaire (20). In this questionnaire, 4 samples were selected for each item (46 items) so that sample volume was set at 200 samples after considering subject attrition. In so doing, 200 patients hospitalized in internal, neurology, ER, and orthopedic wards of Tehran hospitals (Shohadaye Tajrish Hospital, Imam Hussein Hospital, and Loqman Hospital) were selected with convenient sampling method and entered the study after signing informed written consent. Inclusion criteria were: orientation for time and place, lack of affliction with mental disorders, communicative ability, lack of emergency conditions, and passage of at least 48 h after hospitalization, age of 18+ years, literacy, and signing informed written consent. The exclusion criteria were lack of completion of questionnaire and interference of attendants in completing the questionnaire. KMO and Kervit Bartlett test were used to examine sampling sufficiency and investigate correlation coefficient matrix among the items. To extract the number of factors, the least factor loading of 0.35 and Eigen-value>1 were used. Varimax rotation was used to facilitate interpretability.

**Reliability**

Internal consistency coefficient was estimated with Cronbach’s α coefficient. Test-retest was used to establish the reliability coefficient of the instrument. Since the questionnaires were anonymous, the patients were asked to willingly write their file number on the questionnaires. Then, 30 questionnaires were selected from among those with a file number. Test-retest was administered with a 2-week interval and consistency of the instrument was established using intra-class correlation coefficient. If a patient was discharged or did not complete the questionnaire for any reason, another questionnaire with a file number on it was substituted. The data were gleaned via self-report. To complete the questionnaires, the researcher first explained the research topic, goals, and procedures to the patient in a private room (examination room). After obtaining informed consent, the questionnaire was given to the patient to be completed after the researcher left the room and cast in the questionnaires box.

**Ethical Considerations**

Approval of research proposal was conferred by Committee of Ethics in Human Research at Shahid Beheshti University of Medical Sciences under code: IR.SBMU.PHARMACY.REC.1397.183 dated 2018. The patients were assured of anonymity and information confidentiality and they could leave the study at any stage.

**Data Analysis**

The data were analyzed with SPSS16 using descriptive statistics. Kolmogorov-Smirnov test was used to examine normal distribution of data. Spearman correlation coefficient was used to measure correlation between scores of the two tests. Cronbach’s α coefficient and ICC were used to investigate reliability. Given the abnormal distribution of data, principal axis factoring or PAF along with varimax rotation were used to extract items in the Iranian “Patient Privacy and Confidentiality Scale” by considering the least factor loading of 0.35 (P=0.05).

**Results:**

**A. Face and Content Validity**

To establish content validity qualitatively, expert opinion was used to modify and revise the wording and grammar of most items to simplify and objectify them. For instance, the item “How far do ward staff provide suitable conditions for your prayer and worship?” was converted to “Treatment staff provides the required facilities for my prayers and worship”. Also, the item “Access to phone or paging attendant if necessary” was changed to “The treatment staff helps me to access phone or page my attendant if required”. The CVR ranged between 0.6 and 0.8 for each item. The 12 items with CVR<0.62 were omitted. CVI was estimated between 0.3 and 1 for individual items in relation to relevance leading to omission of 6 more items. CVI was estimated at 0.89 for the whole instrument using Kappa designating agreement on relevance. During content validation stage, 18 items were eliminated and 46 items were maintained. Demographics of the samples in the construct validation phase and other information are displayed in Table 1. On this basis, %57 of the participants was male. The mean age of patients was 53.12±17.93 years with hospitalization time of 5.53±5.72 days.

Table 1: Demographic information of the study units

|  |  |  |  |
| --- | --- | --- | --- |
| Variable | | Frequency | Percentage |
| Gender | Female | 114 | 57 |
| Male | 86 | 43 |
| Marital  status | Single | 22 | 11 |
| Divorced | 12 | 6 |
| Married | 166 | 83 |
| Employment  status | Student | 16 | 8 |
| House-keeper | 76 | 38 |
| Employed | 27 | 13.5 |
| Unemployed | 13 | 6.5 |
| Free job | 68 | 34 |
| Education  level | Primary school | 42 | 24 |
| Sub-diploma | 40 | 20 |
| High school diploma | 68 | 34 |
| Academic degree | 50 | 25 |
| Residence | Urban | 165 | 82.5 |
| Rural | 35 | 17.5 |
| Satisfaction with  care provision | Complete | 40 | 20 |
| Relative | 134 | 67 |
| Dissatisfied | 26 | 13 |
| Variable | | Mean | SD |
| Age | | 53.12 | 17.93 |
| Hospitalization stay | | 5.53 | 5.72 |

**B. Construct Validity**

In this stage, 46 items entered the model, of which 20 items were omitted due to lack of loading onto the extracted factors, and thus, reducing the number of items to 26. KMO and Bartlett’s test were used to examine capability of the questionnaire for factor analysis. KMO indicated sufficiency of sample volume (0.823). Bartlett’s test demonstrated that the correlation matrix among the questionnaire items fits for analysis (X2=2212.534, P<0.001). Factor analysis resulted in 7 factors that accounted for %55.252 of total variance in the score of the Iranian version of “Patient Privacy and Confidentiality Scale” developed in this study (Table 2 and Table 3, Figure 1).

Table 2: Special value and variance determined by factors extracted by the final version of Iranian “Patient privacy and Confidentiality Scale”

|  |  |  |
| --- | --- | --- |
| Factor | Special value | Variance accounted  for by each factor |
| Factor 1 (5 items) | 6.542 | 10.409 |
| Factor 2 (4 items) | 3.130 | 8.149 |
| Factor 3 (4 items) | 1.919 | 8.094 |
| Factor 4 (4 items) | 1.731 | 7.689 |
| Factor 5 (3 items) | 1.509 | 7.078 |
| Factor 6 (3 items) | 1.255 | 6.990 |
| Factor 7 (3 items) | 1.213 | 6.843 |
| Total factors | 55.252 | |

The extracted subscales were named on the basis of item content and review of literature.

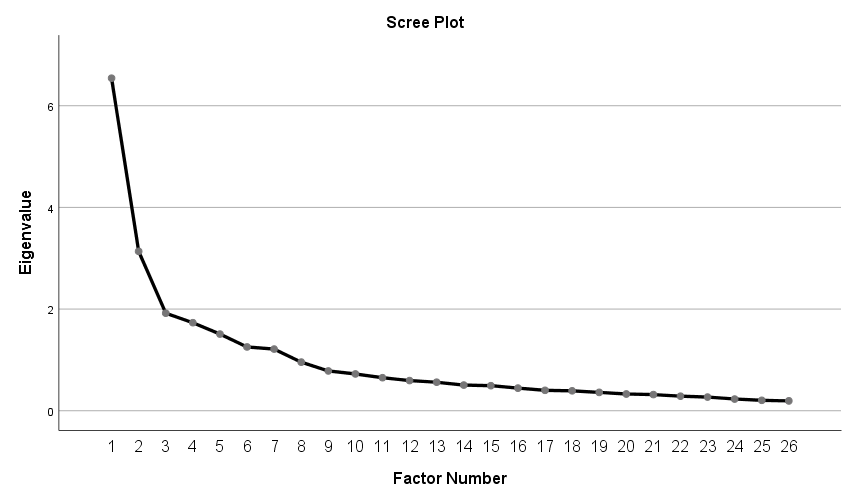


Figure 1: The scree plot of Persian version of “Patient Privacy and Confidentiality Scale”

**factor**

Special value

Table 3: Factorial coefficients, items of extracted factors in factor analysis in the final Persian version of “Patient Privacy and Confidentiality Scale”

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| No. | Item | Factor 1 | Factor 2 | Factor 3 | Factor 4 | Factor 5 | Factor 6 | Factor 7 |
| Q.3 | The treatment staff obtains my permission for care-giving or training. | 0.748 |  |  |  |  |  |  |
| Q.4 | The treatment staff obtains my permission for displacing my private materials. | 0.707 |  |  |  |  |  |  |
| Q.1 | The treatment staff familiarizes me with ward setting. | 0.683 |  |  |  |  |  |  |
| Q.2 | The nursing students obtain my permission for care-giving or training. | 0.680 |  |  |  |  |  |  |
| Q.11 | The treatment staff pays attention to what I say to them. | 0.471 |  |  |  |  |  |  |
| Q.27 | The treatment staff introduces itself to me. |  | 0.856 |  |  |  |  |  |
| Q.26 | Nursing students of the ward are introduced to me. |  | 0.701 |  |  |  |  |  |
| Q.28 | The treatment staff responds to my requests as quickly as possible. |  | 0.635 |  |  |  |  |  |
| Q.29 | The treatment staff respects my clinical needs. |  | 0.483 |  |  |  |  |  |
| Q.36 | My information remains confidential in the hospital electronic file system. |  |  | 0.824 |  |  |  |  |
| Q.37 | The treatment staff is confidant and reliable regarding my information. |  |  | 0.813 |  |  |  |  |
| Q.40 | My personal information remains confidential by the treatment staff. |  |  | 0.664 |  |  |  |  |
| Q.39 | The treatment staff attaches importance to my personal information. |  |  | 0.428 |  |  |  |  |
| Q.21 | The treatment staff values me. |  |  |  | 0.721 |  |  |  |
| Q.20 | The treatment staff understands my concerns. |  |  |  | 0.662 |  |  |  |
| Q.19 | The treatment staff avoids disturbing my rest and sleep. |  |  |  | 0.520 |  |  |  |
| Q.23 | The treatment staff supports me psychologically at the time of fear. |  |  |  | 0.435 |  |  |  |
| Q.34 | The treatment staff explains to me the follow-up care such as subsequent appointments. |  |  |  |  | 0.734 |  |  |
| Q.35 | The treatment staff guides me correctly at discharge. |  |  |  |  | 0.689 |  |  |
| Q.33 | The treatment staff explains to me any therapeutic intervention. |  |  |  |  | 0.674 |  |  |
| Q.16 | In this ward, male staff gives care to male patients and female staff gives care to female patients. |  |  |  |  |  | 0.756 |  |
| Q.18 | The treatment staff provides the required facilities for patient praying. |  |  |  |  |  | 0.727 |  |
| Q.24 | The treatment staff aids me to access phone or page my attendants if necessary. |  |  |  |  |  | 0.576 |  |
| Q.9 | The treatment staff partitions my bed with shades on examination or care-giving like wound dressing, injection, etc. |  |  |  |  |  |  | 0.782 |
| Q.8 | The treatment staff closes the door on examination or other care-giving like wound dressing, injection, etc. |  |  |  |  |  |  | 0.642 |
| Q.10 | The treatment staff drapes me on examination or care-giving like injection, wound dressing, etc. |  |  |  |  |  |  | 0.622 |
| Factors extracted from themes of the items on which they were loaded were named as follows:   1. Factor 1 including items “3, 11, 4, 1, 2”, independence in decision-making. 2. Factor 2 including items “27, 26, 28, 29”, accessibility and responsiveness. 3. Factor 3 including items “36, 37, 40, 39”, confidentiality and secrecy. 4. Factor 4 including items “21, 20, 19, 23”, valuing and mental security. 5. Factor 5 including items “34, 35, 33”, care-giving and follow-up. 6. Factor 6 including items “16, 18, 24”, respecting beliefs. 7. Factor 7 including items “9, 8, 10”, observation of privacy and secrecy. | | | | | | | | | |

**C. Internal Consistency and Instrument Reliability**

Internal consistency was estimated for each item using Cronbach’s α coefficient >0.72 and the reliability coefficient of the whole instrument was 0.84. Regarding instrument consistency, test-retest reliability coefficient was 0.91 using Spearman correlation coefficient (P<0.0001, ICC=0.71, P<0.0001) (Table 4).

Table 4: Reliability coefficients of the final Iranian version of “Patient Privacy and Confidentiality Scale”

|  |  |  |
| --- | --- | --- |
| Subscale | Cronbach’s α | Intraclass correlation  coefficient |
| Independence in decision-making | 0.832 | 0.792 |
| Accessibility and responsiveness | 0.800 | 0.751 |
| Confidentiality and secrecy | 0.784 | 0.730 |
| Valuing and mental security | 0.729 | 0.786 |
| Care-giving and follow-up | 0.853 | 0.658 |
| Respecting beliefs | 0.757 | 0.810 |
| Observation of privacy | 0.778 | 0.709 |
| Total instrument | 0.842 | 0.710 |

Discussion:

This study developed and psychometrically validated the Iranian version of “Patient Privacy and Confidentiality Scale”. To perform the validation of the scale, first 64 items were identified on the basis of codes. Of these, 46 items were selected by experts leading finally to 26 items in the final version. In the first stage, the face validity of the instrument was assessed by experts. Ultimately, the questionnaire was completed by the target group. The content was modified and clarified if necessary. The items with CVR>0.62 on the basis of 10 experts’ opinion were omitted. Then, 12 items with CVR less than the expected value in Lawshe table were eliminated and 52 items were maintained for the following stages. Thus, it can be said that the presence of all items is necessary in this instrument. The CVI of each item for relevance fell between 0.8 and 1 and the total CVI was >0.9. Six items with CVI<0.70 were omitted and 46 items were maintained for subsequent analysis. A CVI <0.70 is not acceptable and the item ought to be revised or omitted. Regarding CVI of the whole instrument, values >0.86 are acceptable (21-23). Therefore, the Iranian version of “Patient Privacy and Confidentiality Scale” possessed acceptable content validity. “Determination of face validity of the questionnaire qualitatively from the target group perspective” indicated the changes applied to this instrument by the research team during qualitative face validation. The changes applied were more concerned with the appearance, credibility, and realization resulting in the target group’s better perception of it on the basis of local culture and context (24). Content validation of the developed scale on the basis of expert opinions was mostly concerned with simplicity, clarity, perceptibility, and intelligibility in wording and writing of the items. In this stage, most items were revised and reworded to make it more understandable by patients. The rate of variance determined by extracted factors during EFA is one of the most important parameters used in judging the construct validity of an instrument so that Polit (2012) states that the factors identified in factor analysis should account for at least %60 of total variance of scores and each identified factor ought ot account for at least %5 of total variance in scores (21). Many sources, furthermore, assert that the identified factors should account for at least %50 of total variance of scores (25-27). EFA suggested that the final version of the scale developed in this study is a 7-factor instrument that has construct validity. The following factors were identified by the developed questionnaire indicating that in ethical patient care, “the patient enjoys independence in decision-making (28-30), the patient’s care-givers are accessible and responsive (31), confidentiality and privacy are observed in patient care, the patient has feelings of value and mental security (32, 33), the patient is cared for and followed-up (34), their beliefs are respected (35), and their privacy and secrecy are respected (36, 37). Özturk et al. (2014) provided the “Patient Privacy in Nursing Scale” in which some aspects resemble those designed in the present study (privacy, secrecy, confidentiality, and respect for beliefs) and account for >%61 of total variance. On the other hand, the aspects of physical privacy (10), dynamism of privacy, bodily privacy, and spiritual and religious privacy (6), and also respecting beliefs, secrecy, and confidentiality (38) were similar to those in the Iranian version of Patient Privacy and Confidentiality Scale. Cronbach’s α for the whole instrument was 0.84. Ebadi et al. believe that an acceptable and reliable α ranges between 0.7 and 0.9. An instrument with α<0.7 will not be reliable and α>0.9 indicates confounded items so that the similar items need to be reduced. Hence, the scale developed in this study enjoys suitable reliability (23). The α coefficient was 0.93 for Özturk et al.’s questionnaire, 0.81 for “Privacy Observation Scale”, 0.84 for “Privacy Observation and Patient Satisfaction Scale”, and 0.89 for “Nurses’ Privacy Observation from Elderly Perspective Scale”. The Spearman’s test-retest consistency coefficient of the instrument was 0.91. Schneider (2003) renders correlation coefficient >0.7 as acceptable (39). The correlation coefficient between scores of test and retest examines the consistency and repeatability of a test (23, 40). Given the correlation coefficients obtained in this study, it may be asserted that the instrument enjoys appropriate consistency and repeatability and is, therefore, suitably reliable. The ICC of the whole instrument and its factors was >0.7. In interpreting ICC, ICC<0.5 is weak, ICC between 0.50 and 0.75 is moderate, ICC between 0.75 and 0.90 is good, and ICC>0.90 is excellent. The ICC of the scale developed here was between 0.47 and 0.71 with acceptable consistency.

**Limitations of the Study**

The most important limitation of the present study was exclusion of illiterate patients that jeopardized the generalizability of the results and thus, reducing external validity of the study.

**Conclusion**

The findings showed that the scale developed and validated in this study enjoys high validity and reliability and thus, it can be used to investigate the patient privacy and secrecy in Iranian hospitals and medical centers. The use of the Persian version of “Patient Privacy and Confidentiality Scale” in educational curriculum of medicine and allied health can familiarize university students with the aspects and components of patient privacy, secrecy, and confidentiality.

**Suggestions for Further Research**

It is recommended that future studies use this questionnaire to measure rate of observation of privacy in state and private hospitals.

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