

Perceived Knowledge, Experiences, Concerns, and Attitudes to Regulations about Patient Confidentiality in a Maternity Setting: Development and Validation of a Confidentiality Self-Report Instrument

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ABSTRACT

Background: As patient's basic rights, privacy and confidentiality are paramount elements to establish a trusting and open doctor-patient relationship. Sometimes, however, there are situations when healthcare providers face some dilemma and fail to provide this to all patients, like in a maternity setting. Therefore, this study is an attempt to design a valid and reliable tool to assess patient's knowledge, experiences, concerns, and attitudes to regulations pertaining to confidentiality and disclosure of patient information in a maternity setting.

Methods: A comprehensive review of literature formed the basis for the design of the 28-item Self-Report Confidentiality Instrument which bridged the gap for the absence of a valid and reliable tool in a maternity setting. The said instrument comprised of four sections. The study was conducted in three phases: Inductive and deductive item generation process, theoretical analysis/ "content validity" or quantitative evaluation, and psychometric analysis/ "construct validity and reliability" or validation.

Results: The four dimensions and number of items for the scale are as follow: patient's knowledge about confidentiality (9 items), experiences with disclosure and confidentiality (4 items), effects of confidentiality concern on seeking care (3 items), and attitudes toward regulations pertaining to patient confidentiality (8 items). The said instrument has both an English and Arabic translations. All the questions were confirmed as valid and reliable. The final version of the Confidentiality Self-Report Instrument (CSRI) had 24 items after deleting four items. Scale reliability was assessed by Cronbach's Alpha, which is a measure of internal consistency and how closely a set of items are related as a group. The obtained result of the Cronbach's Alpha value of 0.71 in this study is greater than widely considered to be an acceptable level of 0.70.

Keywords

Attitudes, Concerns on Care-Seeking Behaviors, Confidentiality, Health Care Experiences, Maternity Setting Scale, Patient Information, Patients' Knowledge.

Introduction

Medical ethics is often defined as 'the disciplined study of morality

in medicine' [1] which explores the ethical issues utilizing the principles of moral philosophy and codes in the medical care of clients. The Oath of Hippocrates, "Wherever I may enter, in the course of my practice and whatever I may see or hear, I will keep as a secret" [2,3], is a famous saying about confidentiality governing medical practitioners in their day-to-day practice to provide safe and ethical care [4].

Health information is a critical component in the ethical care of clients which includes not only objective observations, diagnoses, and test results, however subjective ideas about the patient, their lifestyle, habits, and recreational activities. It includes all identifiable patient information that are written, computerized, visual, or audio, recorded, or simply held in the memory of health professionals [5]. Hence, all members of the team involved in their care are expected to be patient advocates in always safeguarding this confidential information in all settings [2]. Improper disclosure of such highly sensitive information is an infringement of the patient's basic right and could result to far-reaching negative consequences in patients' reputation or lead to lost opportunities, financial commitments, and even damage to one's name [6].

Confidentiality pertains to an individuals' basic right of data protection during its storage, transfer, and use to prevent unauthorized release of that information (Joint United Nations Programme on HIV/AIDS, UNAIDS, 2019). It is governed by legal and ethical safeguards to ensure trust between patients and health professionals by preserving any sensitive information entrusted to them unless there is a valid reason for its disclosure. Ensuring confidentiality is necessary not only for individual protection, more so, to protect the public by letting them have the confidence to seek appropriate treatment and share even embarrassing but potential medically important information to those involved in their care [7].

The concepts of privacy and confidentiality are critical and closely related elements of health care [8,9]. Privacy is about the right or expectation to be free from interference, surveillance, or more generally, a moral right to be left alone. Confidentiality, on the other hand, is about a person's right to keep personal, identifiable medical information out from other's reach. Practically speaking, privacy relates to the setting within which the patient's medical information is taken, that is, the "patient's body," while confidentiality focuses on the information collected from or about the patient, that is the "patient's information" [5].

Privacy and confidentiality are not just basic rights of the patients but also serve to warrant a trustworthy, frank, and open relationship with the doctor, thus improving patient care [10]. Privacy and confidentiality are just like a double-edged sword, [11,12] necessitating to safeguard client's details to a close contact unless permission has been given, and withholding confidential information to third parties (e.g., roommates, neighbors, family members) [13]. Both are needed to protect patient's well-being and ensure trust in the professional medical staff-patient relationship.

Furthermore, confidentiality is deeply emphasized in the legal and religious teachings of Islam and seen as sin and not acceptable [5].

A comparative review of the similarities and differences of confidentiality using the lenses of medical ethics and Islamic ethics emphasized that both views considered include both areas of personal and public discretion as imperative to win public trust while Islamic ethics considers religious confidentiality as an added dimension in tackling the issue [2].

However, the advent of massive developments in medical technology and informatics makes unauthorized access to one's secrets and disclosure of personal health information easier than ever. Healthcare providers in the maternity areas often encounter more situations of handling sensitive patient information, apart from endless the religious, social, and cultural challenges that create a dilemma in maintaining confidentiality. Therefore, laying the groundwork for a better understanding of patient views on medical confidentiality is paramount in this field of nursing practice. The aim of our study is to develop and validate a self-report instrument for perceived patient's confidentiality in a maternity care setting. This study carries with it presumed significance of shedding light about this topic in a conservative area on the field of bioethics – in Saudi Arabia, which is the gap to be spanned by this undertaking.

Methods

The study was conducted in six health settings (three governmental and three private hospitals in Al Ahsa). The target population for this study consisted of women who visited the outpatient department in the research locale and data were collected from March 25 to May 25, 2021. Inclusion criteria were as follows: those who are 18 years or older, has the willingness to participate in the study, and those who availed the maternity services in said health care settings.

The study was conducted in three phases: Inductive and deductive item generation process, theoretical analysis/ "content validity" or quantitative evaluation, and psychometric analysis/ "construct validity and reliability" or validation. This is shown in Figure 1 (Questionnaire Design/ Scale Development Process).

Questionnaire Design

The foundational phase was carried out through a comprehensive literature review as basis for the development of the research instrument and followed the steps for new scale development designed by Worthington and Whittaker [14]. Some related studies [15] and guidelines from several international associations like the British Medical Association [7] and General Medical Council [16] were reviewed and considered as the cornerstones of this study. A 28- item scale to measure self-report of patient confidentiality were selected from the pool of items generated to understand the acuity of confidentiality in care using a three-point Likert scale (with 3–agree, 2– unsure, 1–do not agree). The four dimensions and number of items for the scale are as follow: *patient's knowledge about confidentiality* (9 items), *experiences with disclosure and confidentiality* (4 items), *effects of confidentiality concern on seeking care* (3 items), and *attitudes toward regulations pertaining to patient confidentiality* (12 items). The said instrument has both an English and Arabic translations.

The previous related studies emphasized suitable scale instructions, an appropriate number of items, adequate display format, and appropriate item reduction (all items should be simple, clear, specific, variable response, and remain impartial, etc.) [17]. So, during this phase of instrument development, the researchers were

additionally concerned with some types of parameters and saw the need to adjust the location of some items and of the scale in its entirety.

The second phase, theoretical analysis/ "content validity" (pilot study) and expert opinion, intended to elicit feedbacks from participants and experts to allow for further refinement of the instrument and provide quantitative data to test for internal consistency by conducting Cronbach's alpha. This included administration of the instrument draft to a developmental sample of 62 women in two health settings. To determine its content validity, the researchers sought other's opinions about the operationalized items. The opinions were solicited from expert judges (in the development scales or in the target construct) and target population judges (potential users of the scale), which enabled the researcher to ensure that the study's hypothesis was appropriately elaborated and represented the construct of interest [17]. This phase emphasized instrument validation through expert review to determine the content validity of the tool.

Opinions of seven experts (two associate professors from the medical field and five assistant professors from nursing) were requested to critique using an assessment form. The experts were asked to rate each item as "necessary," "need modification" or "unnecessary". The experts' opinions and evaluations were consolidated, and four items were excluded from the scale. All items were evaluated in terms of clarity and expression by considering the expert opinions, and relevant changes were made.

The last step, psychometric analysis/ "construct validity and reliability," is most directly related to the question of what the instrument intends to measure—what construct, trait, or concept underlies an individual's performance or score on a measure [18].

To ensure construct validity and reliability, the data was collected from a large and appropriately representative sample of the target population. It is a common rule of thumb that there should be at least 10-20 participants for each item of the scale, [19]. In this study, there was a total of 28 number of variables (p), and a total of 325 women-participants (N), which resulted in nearly 11 participants to one variable.

The final version of the Confidentiality Self-Report Instrument (CSRI) had 24 items after deleting four items from attitudes

toward regulations pertaining to patient confidentiality part. Scale reliability was assessed by Cronbach's Alpha, which is a measure of internal consistency and how closely a set of items are related as a group [20]. The obtained result of the alpha value of 0.71 in this study is greater than widely considered to be an acceptable level of 0.70.

Ethical Considerations

An ethical clearance was initially sought from the Institutional Review Board (IRB) of King Fahad Hospital of Hofuf (KFHH) No. 17-39-2021 showing that the patients will not be exposed to any risks during the duration of the study. The respondents' participation in the study would be strictly voluntary and completion of the questionnaire would be used to verify their consent to participate in the study. Respondents were likewise assured of the confidentiality of the data taken and will only be used solely for the purpose mentioned. Participants were asked to sign a verbal consent prior to enrollment in the study.

Results

Factor Analysis

Determining the dimensionality of a concept is an essential step in the scale development process. In this analysis, a Kaiser-Meyer-Olkin (KMO) Test value of 0.81 was used as the criterion for sampling adequacy. To produce scale uni-dimensionality and simplify the factor solutions, scree plot and parallel tests were used as criteria for factor extraction. Then, different kinds of validity, including face validity, content validity, content validity index (CVI), and content validity ratio (CVR) were calculated. These are shown in Table 1. Discriminant validity and factor analysis were used to confirm construct validity, and Cronbach's alpha was used to measure internal consistency.

Item loading (which refers to the degrees to which the original item scores correlate with the components), cross loading, and communalities were used as criteria for item deletion. If factors shared items that cross loaded too highly on more than one factor (e.g., > 0.32) or if factors shared items that cross-loaded and the difference in item loading from the highest was less than 0.15, it was rejected.

The KMO value for the scale was 0.81, indicating that there are components in the correlation matrix to uncover. Bartlett's test of sphericity, which was $\chi^2(4152) = 7365, p < 0.006$, indicated

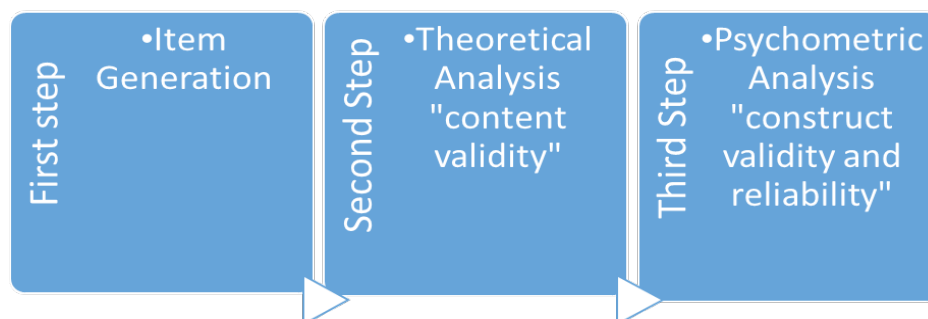


Figure 1: Questionnaire Design/ Scale Development Process.

Table 1: Content Validity Index of Confidentiality Self-Report Instrument (CSRI).

ITEMS	CVI
A. Patient's knowledge about confidentiality	
1. Confidentiality is one of the patient's rights.	0.859
2. Confidentiality means that healthcare providers are trusted to protect relevant information shared in confidence.	0.963
3. Confidentiality means personal health information is protected.	0.922
4. Healthcare providers should disclose any relevant, personal health information to anyone without the informed consent of the patient*	0.930
5. Healthcare providers are patients' representatives and are expected not to release any relevant, personal health information about a patient to a third party without the patient's informed consent.	0.888
6. Confidentiality should be always maintained between healthcare providers and patients without exception.	0.793
7. Healthcare providers should always ask permission from and/ or inform the patient before he or she breaks confidentiality.	0.885
8. Patient confidentiality should be broken if a client discloses information that places the patient at risk for injury, harm, or illness.	0.793
9. Confidentiality should be maintained whenever possible except for situations when there is a risk of harm to others.	0.830
B. Experiences with confidentiality and disclosure	
10. I heard conversations among healthcare providers giving personal information about other patients who are under their care. *	0.802
11. I saw or heard something that bothered me about the confidentiality of patient information while I was in healthcare settings. *	0.815
12. The healthcare provider has discussed with me the details and issues of confidentiality.	0.802
13. The healthcare provider has previously given my medical information to another person without my permission. *	0.945
C. Concerns about care-seeking behavior related to patient confidentiality	
14. Previously, I did not seek health care due to my negative experience/ concerns regarding the confidentiality of my health information. *	0.875
15. Previously I did not provide complete information to the healthcare providers due to my concerns regarding the confidentiality of the information. *	0.864
16. There were embarrassing but potential medically important information that I withheld from the healthcare provider because I fear that he/ she might share them to others not involved in my care. *	0.851
D. Attitudes toward regulations pertaining to patient confidentiality	
17. It is okay with me if a healthcare provider discusses my personal health information with other professionals (such as a consultant or laboratory technician).	0.815
18. It is okay with me if healthcare providers provide my personal medical information to my family members without my permission. *	0.793
19. I feel comfortable whenever people obtain medical information about their relatives without that person's permission. *	0.864
20. I feel it is proper that a healthcare provider be penalized if he/ she discloses patient's medical information to the other members of the patient's family without prior permission.	0.793
21. I want to be aware of the exceptions or situations pertaining to regulations about disclosure of information.	0.896
22. I feel confidentiality does not affect the patient in any way, so it is not a big deal if healthcare providers discuss patient information to others. *	0.898
23. I expect that healthcare providers will never divulge any personal health information without permission from the concerned individual.	0.793
24. I expect that any information discussed by a patient to a healthcare practitioner must remain confidential.	0.793

*Reversed Items

Table 2: Results of Factor Analysis of the Confidentiality Self-Report Instrument (CSRI) (i.e., Varimax Rotation).

	Factors loading				Cronbach's alpha
	Proposed guidelines Dimensions				
	1	2	3	4	
Experiences with Disclosure and Confidentiality					
I heard conversations among healthcare providers giving personal information about other patients who are under their care. *	.741	.577	.292	.785	0.705
I saw or heard something that bothered me about the confidentiality of patient information while I was in healthcare settings. *	.718	.611	.201	.803	
The healthcare provider has discussed with me the details and issues of confidentiality.	-.376	.764	.269	.547	
The healthcare provider has previously given my medical information to another person without my permission. *	.357	.142	.280	.547	
Concerns about care-seeking behavior related to patient confidentiality					
Previously, I did not seek health care due to my negative experience/ concerns regarding the confidentiality of my health information. *	.786	.830	-.725	.801	0.772
Previously I did not provide complete information to the healthcare providers due to my concerns regarding the confidentiality of the information. *	.871	.738	-.514	.614	
There were embarrassing but potential medically important information that I withheld from the healthcare provider because I fear that he/ she might share them to others not involved in my care. *	.769	.031	.167	.230	
Knowledge of Confidentiality					

	Factors loading				Cronbach's alpha
	Proposed guidelines Dimensions				
	1	2	3	4	
Experiences with Disclosure and Confidentiality					
Confidentiality is one of the patient's rights.	.567	.174	.260	.277	0.701
Confidentiality means that healthcare providers are trusted to protect relevant information shared in confidence.	.527	.095	.404	.523	
Confidentiality means personal health information is protected.	-.557	-.750	-.645	.523	
Healthcare providers should disclose any relevant, personal health information to anyone without the informed consent of the patient*	-.383	-.214-	.615	.065	
Healthcare providers are patients' representatives and are expected not to release any relevant, personal health information about a patient to a third party without the patient's informed consent.	-.543	.684	.776	.625	
Confidentiality should be always maintained between healthcare providers and patients without exception.	.604	.627	.725	.547	
Healthcare providers should always ask permission from and/ or inform the patient before he or she breaks confidentiality.	.557	.687	.555	.724	
Patient confidentiality should be broken if a client discloses information that places the patient at risk for injury, harm, or illness.	-.587	.625	.774	.528	
Confidentiality should be maintained whenever possible except for situations when there is a risk of harm to others.	-.658	.715	.596	.715	
Attitudes toward regulations pertaining to patient confidentiality					
It is okay with me if a healthcare provider discusses my personal health information with other professionals (such as a consultant or laboratory technician).	.702	.745	.244	.615	0.703
It is okay with me if healthcare providers provide my personal medical information to my family members without my permission. *	.331	.323	.505	.274	
I feel comfortable whenever people obtain medical information about their relatives without that person's permission. *	.714	-.214	-.235-	.542	
I feel it is proper that a healthcare provider be penalized if he/ she discloses patient's medical information to the other members of the patient's family without prior permission.	.151	.796	.443	.648	
I want to be aware of the exceptions or situations pertaining to regulations about disclosure of information.	-.499-	.144	-.085	.619	
I feel confidentiality does not affect the patient in any way, so it is not a big deal if healthcare providers discuss patient information to others. *	.129	.328	.217	-.251-	
I expect that healthcare providers will never divulge any personal health information without permission from the concerned individual.	.157	-.251-	-.458-	-.304-	
I expect that any information discussed by a patient to a healthcare practitioner must remain confidential.	.274	.535	.336	.294	

that correlation between the items was sufficiently large for Confidentiality Self-Report Instrument CSRI. The two tests indicated that use of CSRI was appropriate.

Analysis of inter item consistency showed good internal correlation with Cronbach's alpha of 0.71.

The 24-item Confidentiality scale's mean score for the developmental group was 44.4 with standard deviation of ± 4.67 . The mean and standard deviation for each component were 8.9 ± 1.8 , 2.57 ± 0.74 , 7.0 ± 1.5 , 20.7 ± 2.5 .

Discussion

This study is an attempt to design a valid and reliable tool to assess patient's knowledge, experiences, concerns, and attitudes to regulations pertaining to confidentiality and disclosure of patient information in a maternity setting. This was decided after an extensive literature review of confidentiality and disclosure of patient's information rules and regulations was done and revealed that, no relevant and valid tool exists. Through the process

of instrument design, experts' feedbacks and developmental sample's critique were solicited. The instrument was continuously reviewed and revised accordingly by the research team based on the necessity of inclusion of all the questions was confirmed.

The review and revision of the draft tool by a panel of health experts improved the content coverage as well as the relevance of items in identified dimensions to local contexts and ensured the face validity and content validity of the scale. Evidence of construct validity of the scale was obtained through factor analysis, which showed stability of the four components of the scale and good internal consistency. The observed reliability falls in the range of acceptable internal consistency as described by DeVellis [21].

Limitation

For this study, the developmental groups were selected from governmental and private hospitals in one town in Saudi Arabia. To use this tool, additional studies need to be conducted by including more hospitals and health centers. This calls for further exploratory work in the scale using a different sample and setting.

Table 3: Total correlation for the final of Confidentiality Self-Report Instrument (CSRI).

Items	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
Experiences with Disclosure and Confidentiality				
I heard conversations among healthcare providers giving personal information about other patients who are under their care. *	42.1201	19.315	.291	0.697
I saw or heard something that bothered me about the confidentiality of patient information while I was in healthcare settings. *	41.9974	19.317	.284	0.708
The healthcare provider has discussed with me the details and issues of confidentiality.	42.7337	21.725	-.067-	0.705
The healthcare provider has previously given my medical information to another person without my permission. *	41.7415	19.512	.390	0.706
Effect of confidentiality concern on seeking care				
Previously, I did not seek health care due to my negative experience/ concerns regarding the confidentiality of my health information. *	41.7781	19.524	.299	0.696
Previously I did not provide complete information to the healthcare providers due to my concerns regarding the confidentiality of the information. *	41.7937	19.484	.295	0.696
There were embarrassing but potential medically important information that I withheld from the healthcare provider because I fear that he/ she might share them to others not involved in my care. *	41.8068	18.711	.409	0.681
Knowledge of Confidentiality				
Confidentiality is one of the patient's rights.	43.5170	20.800	.298	0.702
Confidentiality means that healthcare providers are trusted to protect relevant information shared in confidence.	43.4125	21.170	.384	0.705
Confidentiality means personal health information is protected.	43.4543	21.359	.176	0.700
Healthcare providers should disclose any relevant, personal health information to anyone without the informed consent of the patient*	44.1514	22.118	-.108-	0.689
Healthcare providers are patients' representatives and are expected not to release any relevant, personal health information about a patient to a third party without the patient's informed consent.	43.4883	20.737	.358	0.702
Confidentiality should be always maintained between healthcare providers and patients without exception.	43.6371	20.740	.234	0.685
Healthcare providers should always ask permission from and/ or inform the patient before he or she breaks confidentiality.	43.4909	20.769	.343	0.681
Patient confidentiality should be broken if a client discloses information that places the patient at risk for injury, harm, or illness.	43.6658	21.019	.154	0.701
Confidentiality should be maintained whenever possible except for situations when there is a risk of harm to others.	43.5457	20.982	.217	0.707
Attitudes toward regulations pertaining to patient confidentiality				
It is okay with me if a healthcare provider discusses my personal health information with other professionals (such as a consultant or laboratory technician).	41.6606	20.131	.261	0.703
It is okay with me if healthcare providers provide my personal medical information to my family members without my permission. *	42.1384	20.413	.089	0.687
I feel comfortable whenever people obtain medical information about their relatives without that person's permission. *	41.8381	19.942	.218	0.686
I feel it is proper that a healthcare provider be penalized if he/ she discloses patient's medical information to the other members of the patient's family without prior permission.	41.9399	20.324	.165	0.692
I want to be aware of the exceptions or situations pertaining to regulations about disclosure of information.	41.4935	20.722	.310	0.661
I feel confidentiality does not affect the patient in any way, so it is not a big deal if healthcare providers discuss patient information to others. *	41.7311	19.988	.246	0.682
I expect that healthcare providers will never divulge any personal health information without permission from the concerned individual.	41.9034	20.161	.242	0.663
I expect that any information discussed by a patient to a healthcare practitioner must remain confidential.	41.6084	20.296	.353	0.656

Conclusion

The 24-item CSRI scale had shown a substantial and solid degree of validity and reliability to measure the patient's perception and experiences related to confidentiality received during their health care. The CSRI scale had four sections: patient's knowledge about confidentiality (9 items), experiences with confidentiality and disclosure of personal information (4 items), concerns about care-seeking behavior related to patient confidentiality (3 items), and attitudes toward regulations pertaining to patient confidentiality (8 items); and had an English and Arabic translations. We proposed that health care settings use the CSRI scale to ascertain patient's confidence in sharing sensitive personal medical information to healthcare providers.

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