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# Assessment of Legal Feasibility of Clinical Nursing Information System

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## Abstract

**Background and Objectives:** Legal considerations are essential to implement information system successfully. Therefore, the purpose of this study was to investigate the legal feasibility of clinical nursing information system (CNIS).

**Methods:** This research was a descriptive-cross sectional study. The instrument was developed through literature review. The psychometrics was confirmed by the CVR and CVI index based on comments of 15 experts. Reliability was approved by split method ( $\alpha=0.71$ ). The evaluation was done on nursing administrators through a questionnaire with 5 options Likert scale and face to face interview. Scores less than 30 were considered as weak and poor, scores of 30-70 were treated as middle and relatively desirable, and scores more than 70 stood in high and desirable levels. The data was analyzed using chi-square tests, *t* test and two-way analysis of variance (ANOVA).

**Results:** Definition and develop of low, access to information, informing and implementation and revision should be included in the legal feasibility of CNIS. The percentage of supplied needs to implement the CNIS was 60%. The average score of legal feasibility was 66.46 %.

**Conclusion:** Appropriate and comprehensive legislation to allow the use of the previous system in case of system failure or high volume of work and the accurate determination of the level of user access is required.

**Keywords:** Feasibility, Legal, Clinical nursing information systems, Nursing information system

## Background and Objectives

Legal considerations are necessary to implement clinical nursing information system (CNIS), because existing rules and regulations should be enacted to allow the development of the system. This requires analysis of the current rules or future requirements for legal issues governing the information systems and their possible consequences. The matters such as confidentiality laws and the copyright are included in this analysis.<sup>1,2</sup> A feasibility study in the development of systems identifies the systematic barriers and prevents costly errors in organization.<sup>3</sup> Also, this allows the beneficiaries to determine the evaluation criteria to measure the opportunity to achieve their goals. The main purpose of the feasibility is identifying appropriate solutions to

respond to the constraints of time, budget, rules, and regulations; and reduce the impact on the system.<sup>4,5</sup> One of the most important information systems is the nursing information system. This system enables nurses to collect, manipulate, store, retrieve, and display data associated with the management of nursing services and nursing performance management to improve patient care and increase nursing knowledge.<sup>6</sup> Nursing functions are useful when we can use and access to the health-related data. These systems capture and process data so that the establishment of medical records is possible throughout the individual's lifetime at any time and situation.<sup>7</sup> On the other hand, information systems can be employed as tools for evaluation, quality assurance, and training of nurses,<sup>8</sup> but the lack of coordination at the operational level, lack or limitation of imposed rules or standards deemed a threat to these systems.

Moreover, lack of coordination rules to improve the system, strict interpretation of existing laws, and lack

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of clear rules could support nurses well. Lack of specific contracts for developing the system, restart the system in case of absence of previous new system, the lack of clear rules and management and lack of attention to password lead to breach security and privacy,<sup>9-11</sup> especially if the users agree to share their information that ensures the security and protection of data will be respected by clinical staff, especially nurses.<sup>12</sup>

Conflict, political interference, lack of coordination in legislation, issues related to security and confidentiality of data, lack of supervision over the implementation of laws in the field of information technology are the legal obstacles to the development of information systems,<sup>13,14</sup> and show the priority of feasibility assessment of CNIS. For this reason, the influencing factors should be examined during the development of system lifecycle to provide the necessary knowledge for professionals.<sup>15</sup>

Compliance with security and data protection increases the efficiency and effectiveness of nursing information systems and patient satisfaction. The purpose of this study is to investigate the legal feasibility of implementing CNISs in general hospitals affiliated to Mazandaran Medical Sciences Universities, Iran in 2016.

## Methods

This research was done in 3 steps:

### Development of Instrument for Legal Feasibility of CNIS

The instrument was developed based on content analysis of related literature. The questionnaire was based on results of content analysis. Face validity of the questionnaire was confirmed by four experts in health information technology management, IT professionals, and nursing professors.

### Psychometric Testing of Instrument for Legal Feasibility of CNIS

To determine the validity of the content, the necessity of each question was confirmed by comments of 15 professors who were faculty members of health information technology management and nursing. CVR index was used as a criterion to determine the necessity of each question with three options: essential - helpful, but not necessary - not necessary.<sup>16</sup> CVI index of each question was obtained based on simplicity - relevance - clarity of the questions.<sup>17</sup> Options and scores of CVI questions included "exist with score 1" - "exist but need to main corrections by score 2" - "exist but need minor corrections with a score of 3," and "It is completely with score 4". Questions with CVI > 0.7 was acceptable and those with CVI < 0.7 were rejected or revised. Questions with CVR > 0.49 were confirmed and those with CVR < 0.49 were rejected or revised.

To determine the reliability of the data collection tools, questionnaires were distributed among the 15 members of the research community. Cronbach  $\alpha$  coefficient was obtained by split method ( $\alpha=0.71$ ).

### Evaluation of Legal Feasibility of CNIS

This step was done on all of the nursing administrators working in general hospitals in Mazandaran, Iran. Population study was 30 people with at least a bachelor degree of nursing and nursing management communiqué. The questionnaire consisted of 16 questions with the Likert scale with 5 options from very low=1 to very high=5. Data collection was done by face to face interview by the nursing administrators of all the general hospitals in Mazandaran province and necessary comments were explained. The average score is calculated for each question and multiplied by 5 to turn it into a base of 100. To better assessment of each item, the scores less than 30 were in weak and poor situation, scores 30-70 were in middle and relative desirable situation, and scores more than 70 were in high and desirable situation. The data was analyzed using chi-square tests, *t* test and two-way analysis of variance (ANOVA).

## Results

### Development of Instrument for Legal Feasibility of CNIS

The results of literature review showed four items including definition and development of law, how to access to information, how to inform and implementation and how to revised should be included in legal feasibility of CNIS.<sup>2,14,18,19</sup>

### Psychometric Measure of Instrument for Legal Feasibility of CNIS:

All the items extracted from literature review for legal feasibility of CNIS had a CVI score more than 0.7 and CVR more than 0.49 and accepted (Table 1).

### Evaluation of Legal Feasibility of CNIS in Mazandaran, Iran

Among a total of 30 senior managers of nursing research community, 23.3% were 35-39 years old, 50% were 40-44 years old and 26.6% were above 45 years old. 93.3% had bachelor degree and 53.3% had less than 19 years of work experience.

The results showed that the lowest frequency of legal feasibility of implementing CNIS was related to the items such as modify or remove items documentation 29.4%, to return to the previous 36%, system development rules 50.6%, the coordination to legislation were 54%. The most frequent items were requiring staff to observe rules by the

**Table 1.** CVI and CVR on Legal Feasibility of CNIS

Legal Feasibility Questions	CVI			CVR	Status
	Relevance	Simplicity	Clearly		
Rules and regulations for utilization of system.	1	0.93	0.93	0.87	Accepted
Coordination in law approval	0.93	0.87	0.93	0.87	Accepted
Definition of privacy	1	1	0.93	0.87	Accepted
Privacy laws	0.93	0.93	0.80	0.87	Accepted
Awareness staff about existence of laws	1	1	0.93	1	Accepted
Observance Information security by staffs	0.93	0.87	0.73	0.87	Accepted
There are Staff committal to Security Observance by Authorities	0.93	0.87	0.80	1	Accepted
Supervising the implementation of laws	0.93	0.93	0.93	0.87	Accepted
Penalties for violation of the rules	1	1	0.93	0.87	Accepted
System development rules	0.87	1	0.93	0.87	Accepted
Rules of processing and protection of data	0.93	1	0.93	0.87	Accepted
Determining of access level of employee	1	1	1	1	Accepted
Determine allow modification or delete documentations	0.87	0.87	0.87	0.73	Accepted
Guidelines access to information	0.93	0.93	0.93	0.87	Accepted
Security tactics for information access	0.80	0.87	0.87	0.73	Accepted
Allow return to the previous status	0.80	0.87	0.80	0.87	Accepted

authorities (90%) and observing security by employees (87.4%) (Table 2).

The results showed that the highest possibility of implementing of CNIS in terms of demographic characteristics included age group of 44-40 years old (66.7%), undergraduate education (60.7%) and work experience less than 19 years (68.8%) in all cases. Overall, legal feasibility was medium. Statistically, educational level, age, and experience of senior nursing managers were not significant (Table 3).

The mean score of legal feasibility was 66.46%.

## Discussion

The purpose of this study was to investigate legal feasibility of CNIS in all hospitals in the Mazandaran province, Iran in 2016. The research results showed that to develop a rule about modify or delete documents was 29.4%, agreement related to requiring the staff to observe rules by the authorities was 90% and regarding the security by employees was 87.4%.

Other studies show that access to password of the system under study was possible. Thus, lack of using the system as the user up to 15 minutes removed the user password automatically, users are allowed to determine the level of access to create, modify, or remove system documentation and are bound to implement the rules,<sup>14,20-25</sup> which is consistent with the results of this research. Also, in the present study, coordinating legislation 54%, rules and systems development 50.6%, to return to the previous status 36% indicated that the adoption and development

of the rules is not enough supplied.

These results of the research are consistent to results of Mbananga et al in the evaluation of hospital information system stated that the contract for development of the system has not been established, there are no laws to reboot if system failure is not possible to use the previous system.<sup>11</sup> Research results also are consistent to Prijaltj who studied nursing management role in the development of hospital information system in Slovenia and reported that there are no rules coordinating the development of the system.<sup>26</sup>

But with the results of other studies that there is harmony in the development of legislation, especially legislation back in case of failure of the system, the peak workload or possible flaws in the system have mentioned,<sup>20,27</sup> and research results Mbananga and colleagues in the evaluation of hospital information systems in Africa and Malaysia have been shown, because some users had not password, used others password, therefore individual recognition to access the system was not possible because some information was failed due to added or deleted by unauthorized users.<sup>11,21,28</sup>

Due to the lack of laws, strict interpretation or lack of coordination in the implementation of laws, the laws of development has been problematic,<sup>10</sup> and information systems cannot support the nurses at the operational level, because on one hand, the reduction commitments of interdisciplinary cooperation has led to the decline and on the other hand, to the lack of immediate access to patient information cause to the lack of security and privacy and

**Table 2.** Legal Feasibility Clinical Nursing Information System

Legal Feasibility Items		Scale					Mean	Status
		Very Low	Low	Moderate	High	Very High		
Definition and Develop of law	Definition of privacy	1 (3.3)	9 (30)	10 (33.3)	7 (23.3)	3 (10)	61.4	Semi-desirable
	Privacy laws	0	11 (36.7)	9 (30)	7 (23.3)	3 (10)	61.4	Semi-desirable
	Rules of processing and protection of data	0	2 (6.7)	8 (26.7)	17 (56.7)	3 (10)	74	Desirable
	Rules and regulations utilization system	1 (3.3)	9 (30)	11 (36.7)	6 (20)	3 (10)	60.6	Semi-desirable
	System development rules	3 (10)	15 (50)	8 (26.7)	1 (3.3)	3 (10)	50.6	Semi-desirable
	Coordination of laws	3 (10)	10 (33.3)	12 (40)	3 (10)	2 (6.7)	54	Semi-desirable
	Penalties for violation of the rules	3 (10)	4 (13.3)	13 (43.3)	7 (23.3)	3 (10)	62	Semi-desirable
	Security observance by staff	2 (6.7)	0	2 (6.7)	7 (23.3)	19 (63.3)	87.4	Desirable
Access to Information	Determining the level of employee access	0	1 (3.3)	4 (13.3)	9 (30)	16 (53.3)	86.6	Desirable
	Guidelines access to information	0	2 (6.7)	3 (10)	14 (46.7)	11 (36.7)	82.6	Desirable
	Security tactics for information access	2 (6.7)	5 (16.7)	3 (10)	12 (40)	8 (26.7)	72.6	Desirable
Informing and Implementation	Inform employees of law	0	2 (6.7)	4 (13.3)	13 (43.3)	11 (36.7)	82	Desirable
	Staff committal to security observance by authorities	0	1 (3.3)	3 (10)	6 (20)	20 (66.7)	90	Desirable
	Manner supervising of implementation laws	1 (3.3)	0	14 (46.7)	9 (30)	6 (20)	72.6	Desirable
Revised	Allow modification or delete documentations	18 (60)	10 (33.3)	2 (6.7)	0	0	29.4	Undesirable
	Allowed to return to the previous status	14 (46.7)	10 (33.3)	5 (16.7)	0	1 (3.3)	36	Undesirable

**Table 3.** Levels Legal Feasibility Clinical Nursing Information System in terms of the Demographic Status of Participants

Variable status		Moderate*	Upper*	P value
Age	35-39	5 (71.4)	2 (28.6)	0.349
	40-44	10 (66.7)	5 (33.3)	
	+45	3 (37.5)	5 (62.5)	
Education	BS	17 (60.7)	11 (39.3)	NS
	MS	1 (50)	1 (50)	
Job experience	Less than 19 years	11 (68.8)	5 (31.3)	0.457
	More than 20 years	7 (50)	7 (50)	

\* Weak: Less than 30%, Moderate: 30%-70%, High: more than 70%.

loss of patients data.<sup>9,29,30</sup>

So, given that detailed rules, clear and revise or amend these laws can play an important role in the development of the system, it is necessary to lay down clear rules as an important development indicator system to increase implementation, coordination of information security and privacy.

## Conclusion

Definition and develop of law, how to access to

information, how to inform and implementation and how to revised should be included in legal feasibility of CNIS. Possibility of implementing CNIS in legal aspect was relatively good. Due to constraints and the lack of clear rules, development and obligation to observe the laws by users is an important component in the nursing system. Appropriate and comprehensive legislation, determine the exact level of user access and permission to use the previous system in case of system failure or volume of work is necessary to increase willingness of nurses to use

the system to improve their performance and satisfaction.

## Abbreviations

(CNIS): Clinical nursing information system.

## Authors' Contributions

All authors contributed to the initial design of the research. FRJ, SE took part in data collection. Interviews were conducted by HA, SE and piloted by MAH, HA, SE. HA and SE led the analysis of the data. FRJ led the drafting of the article. All authors contributed to solve critical revisions. All of them approved the final manuscript.

## Competing Interests

The authors declare no competing interests.

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