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Required Data Elements and Requirements of a Teleoncology System to Provide Treatment Plans for Patients with Breast Cancer

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Abstract

Background: Teleoncology refers to the use of telemedicine for remotely providing multiple specialized services in clinical oncology processes, including screening, diagnosis, treatment planning, consultation, supportive care, pathology, surgery, and follow-up services.

Objectives: The aim of this study was to identify the required data elements and elicitation of requirements for developing a telemedicine system that aims at providing treatment plans for patients with breast cancer.

Methods: In this study, the required data elements for the teleoncology system were identified through both the investigation of clinical guidelines and review of patients' medical records. Identified data elements were determined by breast cancer specialists through the questionnaire. Besides, an interview method was applied to elicit the requirements of this system.

Results: The identified data elements were categorized into 20 groups (e.g., clinical data, breast physical examinations, pathological results, tests, imaging results, etc.). From the 182 data elements included within the questionnaire, 125 were recognized to be necessary (n = 32, 100%). The lowest mean percentage were observed in magnesium blood test (Mg) (n = 21, 65.63%) and protein test (Pr) (n = 21, 65.63%). Other data elements with a minimum mean of 71.87% and a maximum mean of 100% were recognized necessary. In general, 2 major themes, 9 categories, and 45 related sub-categories were extracted from analyzing the findings of the interviews related to the system requirements.

Conclusions: The findings of the present study can be used as a basis for developing teleoncology systems that aim at providing treatment plans for patients with breast cancer.

Keywords: Telemedicine, Medical Oncology, Breast Neoplasm, Clinical Protocols

1. Background

As the most common type of cancer, breast cancer is one of the leading causes of cancer-related deaths in Iranian women (1, 2). Thus, it has a significant influence on public health and is a key concern of health policymakers (3, 4). In general, the global incidence of breast cancer will be increasing, particularly in regions with a low rate of incidence (5). In developing countries, in addition to the growing incidence of breast cancer in recent decades, patients are often diagnosed in advanced stages (6). Moreover, costs associated with different stages of the cancer treatment are rising rapidly, in such a way that even the rich countries are faced with financial restrictions in providing high-quality care equally accessible for all their residents (7). One of the most effective approaches to managing the treatment process of patients with breast cancer is suggested to be the use of multidisciplinary teams (8), which is not a new concept and is on the verge of becoming a medical standard of care (9). Telemedicine, a relatively new technique for healthcare delivery by using telecommunication technology, is one of the innovative and appropriate tools that can be applied to increase access to care services, overcome geographical barriers, and provide remote healthcare services for such areas (10). Telemedicine can make changes in processes of different domains of healthcare, including prevention, diagnosis, education, and treatment (11). Telepathology, teleophthalmology, teleradiology, and teleoncology are some of the subsets of telemedicine that have been employed in various medical specialties (12). Teleoncology refers to the use of telemedicine for remotely providing multiple specialized services in clinical oncology processes, including

screening, diagnosis, treatment planning, consultation, supportive care, pathology, surgery, and follow-up services (13). In this regard, many studies on the implementation of teleoncology have been performed for different types of cancers, including breast cancer in several countries (14-16).

The medical practice employs a combination of science and art to prevent, diagnose, and treat diseases. However, applying this approach without using appropriate guidelines will not guarantee the successful therapeutic and diagnostic outcomes (17). Recently, several clinical guidelines have been developed in the areas of prevention, diagnosis, and treatment for a wide range of medical specialties including oncology (18). Some of these clinical guidelines have been developed by professional organizations to provide up-to-date quality and specific evidence to assist clinicians in making decisions, better treatment options, and designing optimal care pathways for patients with breast cancer (19, 20). Therefore, it seems appropriate to employ the relevant identified clinical guidelines when a telemedicine system is used (21).

Every software system has requirements that should be identified before the development and implementation of the system because the success of a software system depends on how it meets the needs of its users (22). Therefore, determining the requirements of a software system, using the requirements engineering process, is the initial and fundamental stage in the design and development process of a system (23). The primary outcome of system requirements engineering is to determine the specifications of software systems achieved by investigating and analyzing the needs of its stakeholders (24). Healthcare environments have multiple stakeholders with several backgrounds and interests, including health professionals, patients, and managers. Moreover, software developed in the healthcare domain is more unique and specific than other software; so, the process of identifying the requirements of these software needs to be taken more seriously and comprehensively (25, 26).

Digital health technologies including telemedicine as a software system have considerably affected different aspects of healthcare delivery services by improving communication and facilitating data sharing between physicians and patients (27). However, many telemedicine projects have faced failure due to insufficient attention to the human, organizational, and other non-technological factors affecting these projects during the design and implementation phases, particularly in the requirements engineering phase (28). Therefore, the requirements engineering process for telemedicine projects, like any other software project, is crucial to identify its requirements (29).

2. Objectives

The aim of this study was to identify the required data elements (the data used by physicians to make decisions about presenting treatment plans to patients) and determine what requirements are needed and how to identify them for implementing a telemedicine system to provide treatment plans for patients with breast cancer.

3. Methods

3.1. Identifying the Required Data Elements

In this study, data elements required in the telemedicine system to provide treatment planning for patients with breast cancer were identified and determined in 3 stages. Firstly, validated clinical guidelines related to the provision of treatment plans for patients with breast cancer were examined and the related data elements were, then, extracted. Guidelines that were considered in this research were as follow:

1. Clinical Guidelines for the Management of Breast Cancer (West Midlands Expert Advisory Group for Breast Cancer) (30).

2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines) Breast Cancer (31).

3. St. Gallen/Vienna 2019: A Brief Summary of the Consensus Discussion on the Optimal Primary Breast Cancer Treatment (32).

4. Primary breast cancer: European Society for Medical Oncology (ESMO) Clinical Practice Guidelines for diagnosis treatment and follow-up (33).

5. 4th European School of Oncology-European Society for Medical Oncology (ESO-ESMO) International Consensus Guidelines for Advanced Breast Cancer (ABC 4) (34).

In addition to the clinical guidelines mentioned above, the clinical guidelines related to breast cancer in Iran, the clinical guideline for early detection of breast cancer developed by the Deputy of Treatment, Ministry of Health and Medical Education of Iran (35), was reviewed to identify the data elements associated with the diagnosis of breast cancer.

In the second step, several medical records of patients with breast cancer, receiving different treatment plans were examined. To meet the objectives of the study, the authors extracted the data elements, which were used by the physicians to develop the treatment plans.

In the third step, a questionnaire was designed based on the integration of data extracted from the previous steps. Then, the questionnaire was evaluated for reliability and validity (face and content validity). In doing so, reliability was evaluated, using Kuder Richardson 21 (KR-21).

However, the qualitative method was used to determine face validity, which was determined by forming a specialized panel comprised of 4 breast oncologists. In this panel, the difficulty level of questions, the use of common and relevant terms in the field, the amount of mismatch, the ambiguity of the concepts, phrases and expressions, and word meaning were appraised and discussed. Afterward, their comments were applied to the questionnaire.

Content validity was assessed through qualitative and quantitative methods. In the qualitative content validity method, 5 breast oncologists different from the mentioned 4-person panel were asked to propose their corrective opinion in written form after a careful study of the questionnaire. It was further emphasized that in assessing the quality of content validity, the following criteria were taken into account: the grammar, use of appropriate words, importance and relevance of questions, the order of questions, and the time needed to complete the questionnaire. The necessary changes were made to the questionnaire after collecting the experts' opinions. Then, the Content Validity Ratio (CVR) and Content Validity Index (CVI) were used to evaluate the content validity of the questionnaire by breast oncologists. In doing so, 8 copies of the questionnaire were given to radiation oncologists to rate each item of the questionnaire for measuring the CVR (based on 3-point scales: "necessary", "useful but not necessary", and "not necessary") and the CVI (based on 4-point scales: "an irrelevant item", "relevant but needs minor revision", "relevant but needs serious revision", and "extremely relevant item").

Responses to the items of the questionnaire were analyzed based on the CVR formula and were compared with the Lawshe table. Values above 75% were accepted for each item of the questionnaire (36). After measuring and determining CVR, the CVI of the survey was determined according to the Waltz and Basel content validity index. Then, based on the CVI results, each item in the questionnaire with a value above 79% was accepted (37). Ultimately, the final version of the questionnaire was distributed among 45 breast cancer specialists, who had at least 5 years of clinical experience for receiving their viewpoints and determining the data elements required to design treatment plans.

The final version of the questionnaire consisted of 2 parts with a total of 186 questions, including respondents' demographic information (4 questions) and required data elements for providing treatment plans (182 questions). The second part of the questionnaire was divided into 20 sub-categories according to the type of data included. To determine the required data elements based on the responses obtained from breast specialists, researchers of this study assigned two options of "necessary" (one point) and "unnecessary" (zero points) to each question. Additionally, a blank space was provided at the end of each subcategory for receiving comments and other required data elements from the perspective of respondents.

3.2. Requirements Elicitation

In this study, an interview method was applied to elicit the requirements of a teleoncology system to provide treatment planning for patients with breast cancer. Subsequently, both quantitative and qualitative data were obtained. Using this method made it possible to have a deeper analysis of stakeholders' feedback and needs.

3.2.1. Data Collection Tool

The initial interview guide was prepared based on the literature review (11, 12, 38, 39). Afterward, the final version of the interview guide was prepared, content and face validity of the interview questions were approved by using in-depth interviews with 3 experts in the field of health information management, medical informatics, and breast cancer treatment. The final interview guide included 2 main open questions about functional and non-functional requirements. In this regard, definitions and examples of such requirements were provided to learn more about these requirements in the interview guide. Two main open questions, used in our research, were as follow:

1. What do you think are the functional requirements of the telemedicine system to provide treatment planning for patients with breast cancer?

2. What do you think are the non-functional requirements of the telemedicine system to provide treatment planning for patients with breast cancer?

Furthermore, the questionnaire included requirements identified from studies in the field of telemedicine that were presented in the final interview guide to survey participants. To investigate the views of participants on the presented requirements, 2 options including "necessary" (one point) and "unnecessary" (zero points) were assigned to each question.

3.2.2. Data Collection Method

Face-to-face interviews were conducted with each of the participants according to the schedule agreed at the designated location by the researcher. A general explanation of the study and its objectives were given to all interviewees and written informed consent forms were obtained from all of them before the beginning of the interview. Moreover, the confidentiality of information gathered from the interviews was emphasized, and it was announced that the information extracted from the interviews would be presented to them for approval. The interviews were recorded in coordination with the interviewees, and important details were noted by the researcher

during the interview process. The interviews were continued until the data were saturated.

3.2.3. Data Analyzing Method

The information from the interviews was analyzed, using content analysis. For this purpose, all recorded audio files were transcribed and completed by taking notes written during the interviews. Subsequently, all documents and information extracted from the interviews in the form of text files were entered into the MAXQDA software to perform coding and qualitative analyses. Finally, the interviewee's suggestions and comments were extracted based on the themes, categories and sub-categories, and interpreted narratively.

4. Results

4.1. Results of Identifying the Required Data Elements

The results of the integration of data elements extracted from clinical guidelines and patients' medical records were presented as a questionnaire. Upon the development of the initial questionnaire, the reliability and validity were assessed and minor changes were applied. In addition to partial changes in the arrangement of the data elements, "ethnicity" was the only data element removed from the initial questionnaire. Concerning CVI and CVR, the total average score of 0.87 and a mean score of 0.89, respectively, was obtained. The total inter-item reliability of the questionnaire was measured by KR-21 ($\rho KR21 = 0.81$).

Overall, 45 questionnaires were distributed among radiation oncologists (n = 27), gynecologists (n = 6), specialists in blood and adult cancers (n = 6), and cancer surgeons (n = 6) working in hospitals and healthcare facilities. The total participation rate of specialists to fill out the questionnaire was 71.11%, including radiation oncologists (n = 19, 70.37%), gynecologists (n = 4, 66.66%), specialists in blood and adult cancers (n = 5, 83.33%), and cancer surgeons (n = 4, 66.66%). The mean age of specialists was 46.13 $\pm$ 5.41 years, and the meaningful work experience was 12.59 $\pm$ 6.08 years. The mean percentage of respondents regarding the required data elements to provide treatment plans for patients with breast cancer are shown in Tables 1-5.

Overall, form 182 data elements in the questionnaire, 125 were unconditionally considered necessary (n = 32, 100%) from the experts' point of view. Based on the data in Tables 1-5, the lowest mean percentages are related to the magnesium blood test (Mg) (n = 21, 65.63%) and protein test (Pr) (n = 21, 65.63%). Other data elements in these tables range from 71.87% to 100%, which was considered necessary by experts.

4.2. Results of the Requirements Elicitation

As mentioned earlier, one of the aims of the present study was to identify the requirements of the teleoncology system to provide treatment plans to patients with breast cancer by using the interview method. Overall, 15 qualified specialists in the field of breast cancer treatment (having at least 3 years of clinical experience in providing treatment plans for patients with breast cancer), as well as 10 qualified faculty members of health information management and medical informatics (having at least 3 years of faculty experience and familiar with software information systems) were invited to participate in the interview. The interviews continued until the saturation of the data were obtained, with 18 experts participating in the interview. The average interview time was 30 minutes.

In total, 18 interviews were conducted with experts in various disciplines, including health information management (n = 4), medical informatics (n = 2), radiation oncology (n = 8), pathology (n = 2), and cancer surgeon (n = 2). The mean age of the respondents was 44.11 $\pm$ 6.98 years and most of them were males (n = 12, 66.66%). Moreover, most of the interviewees were clinical specialists (n = 12, 66.66%), who were radiation oncologists (n = 8, 44.45%).

As mentioned earlier, the interview guide was designed in such a way that it included a basic framework involved requirements that were pre-identified by the researcher by reviewing related research and software projects. All of these requirements were considered necessary by all interviewees in the study as essential requirements for the teleoncology system. Subsequently, a total of 2 main themes, 9 categories, and 41 related sub-categories were extracted from analyzing the findings of the interviews (Table 6).

5. Discussion

According to the review of the studies, no research has been conducted in Iran regarding the implementation of telemedicine for oncology in breast cancer. However, many studies have been conducted on the use of telemedicine in oncology for a variety of cancers (40-42), including breast cancer in other countries (15, 43). In this regard, the results of studies show that healthcare professionals generally support the use of telemedicine technology in the field of oncology. Furthermore, the results of studies have shown that the quality of medical services provided to patients using this technology has been appropriate. Also, it is cost-effective and has reduced the cost of healthcare systems (15, 16, 44, 45). Therefore, in addition to using conventional methods (face to face) to manage breast cancer treatment in some countries, the facili-

Table 1. Patients' Demographic Information and Clinical Data

Category	Data Elements	Average (%) Necessary
1-Patients' demographic information		
1	Name	81.25
2	Family	81.25
3	National code	81.25
4	Age	100
5	Sex	100
6	Weight	100
7	Height	100
8	BSA	100
9	BMI	87.50
10	Marital status	87.50
11	Job	81.25
12	Residential address	87.50
13	Patient contact number	87.50
2-Clinical data		
14	The chief complaint	100
15	Symptoms other than the chief complaint	100
16	The first symptom leads to doubt	87.50
17	PS	100
18	Drugs in use	100
19	Drug used	100
20	Menstrual status	100
21	Age of first menstruation	87.50
22	Pregnancy status	100
23	Age of first pregnancy	87.50
24	Number of gravidities	81.25
25	Number of parities	75
26	Number of live births	75
27	Number of abortions	81.25
28	Menopause age	100
29	Lactation status	100
30	Contraception and its methods	100
31	Duration of diabetes (in years)	84.38
32	Medications used for diabetes (oral, insulin)	100
33	Cardiovascular disease	100
34	Hypertension	100
35	Immune deficiency disease	100
36	Patient's other comorbidities	100
37	History of surgery	90.62
38	Collagen and vascular diseases	100
39	Personal history of malignancy	100
40	History of hormone therapy and its type	100
41	History of chemotherapy	100
42	History of radiotherapy	100
43	Previous treatment plans	100
44	Duration of smoking (in years)	87.50
45	Daily cigarette consumption (pack of cigarettes per day)	87.50
46	History and level of alcohol consumption (low, medium, high)	90.62
47	Family history of malignancy	100
48	History of hepatitis	78.13
49	AIDS	87.50

Abbreviations: BSA, body surface area; BMI, body mass index; PS, performance status; AIDS, acquired immunodeficiency syndrome

Table 2. Examination of the Breast, Lymph Nodes, Distant Metastasis, and Chest Wall

Category	Data Elements	Average (%) Necessary
3-Physical examination of the breast		
50	The results of a physical examination of the breast (detectable mass?)	100
51	Location of the mass in the left breast (1. upper-outer, 2. upper-inner, 3. lower-outer, 4. lower-inner, 5.central)	100
52	Location of the mass in the right breast (1. upper-outer, 2. upper-inner, 3. lower-outer, 4. lower-inner, 5.central)	100
53	Size of breast mass (cm)	100
54	Fixation of the breast mass (yes, no)	100
55	Breast skin involvement (discoloration, scars, nodules, orange peel skin)	100
56	Area of breast skin involvement (less than 30%, between 30% and 50%, more than 50%)	87.50
4-Examination of the lymph nodes		
57	The results of the examination of the lymph nodes (detectable mass?)	100
58	Location of enlarged lymph nodes (axilla, supraclavicular, mammary internal)	100
59	Fixation of the lymph nodes (yes, no)	100
60	Size of the lymph node (cm)	100
61	Matted lymph nodes	100
5-Examination of distant metastasis		
62	Results of distant metastasis examination (bone tenderness, respiratory distress, ascites, organomegaly, etc.)	100
6-Breast examination (in case of the previous lumpectomy)		
63	Evidence of local recurrence (left side [at the surgical scar site, away from the surgical scar])	100
64	Evidence of local recurrence (right side [at the surgical scar site, away from the surgical scar])	100
65	Type of local recurrence (ulcer, mass, discoloration)	100
66	Local recurrence size (cm)	100
67	Fixation of local recurrence (yes, no)	100
7-Chest wall examination (in case of the previous mastectomy)		
68	Evidence of local recurrence (left side [at the surgical scar site, away from the surgical scar])	100
69	Evidence of local recurrence (right side [at the surgical scar site, away from the surgical scar])	100
70	Type of local recurrence (ulcer, mass, discoloration)	100
71	Local recurrence size (cm)	100
72	Fixation of local recurrence (yes, no)	100

ties and capabilities of telemedicine technologies are also used as a tool to improve service delivery to patients.

5.1. Identifying the Required Data Elements

Teleoncology is a potential solution in the management of breast cancer worldwide. It can establish effective and systematic collaboration among healthcare providers in multiple oncology centers for improving cancer care services (46). Given that the development of such a system is in its early stage in Iran, identifying required data elements is the first step in developing a telemedicine system that aims at providing treatment plans for patients with breast cancer. There are various treatment plans available for patients with breast cancer and people suffering from this type of cancer often receive more than one treatment plan (47). Furthermore, selection of a treatment plan for patients with breast cancer is based on many factors, including the extent and location of the tumor (number and extent of lymph node involvement, number of lesions, size and location of the primary tumor), as well as age, patient's general health status, and patient's preferences (33). Therefore, the required data elements for the telemedicine system were identified by investigating the clinical guidelines and reviewing the medical records of patients with breast

Table 3. Pathology of the Breast, Surgical, and Lymph Node Biopsy

Category	Data Elements	Average (%) Necessary
8-Pathology of breast and lymph node biopsy		
73	Pathology of breast biopsy	100
74	Pathology of lymph node biopsy	100
9-IHC & FISH (or CISH) breast and lymph node biopsy		
75	Date of biopsy	100
76	ER (negative or positive) (percent of + cells… Positivity: week, moderate, strong)	100
77	PR5 (negative or positive) (percent of + cells… Positivity: week, moderate, strong)	100
78	HER2 (-, +1, +2, +3)	100
79	Ki-67	100
80	E-cadherin (negative or positive)	84.38
81	HER2 FISH (or CISH) (amplified, not amplified)	100
82	Other performed IHCs	87.50
10-Surgical pathology		
83	Date of surgery	100
84	Pathology of breast surgery	100
85	Pathology of lymph node surgery	100
86	Surgery: breast (breast conservation surgery, total mastectomy, radical mastectomy, skin-sparing, nipple-sparing)	100
87	surgery: axillary (sentinel: negative [number of nodes removed])	100
88	surgery: axillary (sentinel: positive [number of positive nodes and number of nodes removed])	100
89	surgery: axillary (dissection: negative [number of nodes removed])	100
90	surgery: axillary (dissection: positive [number of positive nodes and number of nodes removed])	100
91	surgery: breast reconstruction (time: immediate or delayed)	100
92	surgery: breast reconstruction (type: prosthesis or autologous)	100
93	the number of tumor lesions	100
94	Size of the tumor (cm)	100
95	Skin involvement	100
96	Nipple involvement	100
97	LVSI	100
98	PNI	100
99	Extracapsular extension	100
100	Percentage of carcinoma in situ	100
101	Grade (1 or 2 or 3)	100
102	Margin status (R0, close, R1, R2)	100
11-IHC & FISH (or CISH) surgery		
103	ER (negative or positive) (percent of + cells… positivity: week, moderate, strong)	100
104	PR (negative or positive) (percent of + cells… positivity: week, moderate, strong)	100
105	HER2 (-,+1,+2,+3)	100
106	Ki-67	100
107	E-cadherin (negative or positive)	100
108	HER2 FISH (or CISH) (amplified, not amplified)	100
109	Other performed IHCs	87.50

Abbreviations: CISH, chromogenic in situ hybridization; ER, estrogen receptor; FISH, fluorescence in situ hybridization; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; LVSI, lymphovascular space invasion; PNI, perineural invasion; PR, progesterone receptor

cancer in this study.

In some studies, identifying required data elements for telemedicine systems has been performed by reviewing the literature and designing a researcher-made ques-

Table 4. Recurrent Pathology and Pathology of Metastatic Biopsy and Staging by Tumor-Node-Metastasis (T-N-M)

Category	Data Elements	Average (%) Necessary
12-Recurrent pathology		
110	Pathology of breast recurrence	100
111	Pathology of lymph node recurrence	100
13-IHC & FISH (or CISH) recurrence		
112	ER (negative or positive) (percent of + cells… positivity: week, moderate, strong)	100
113	PR (negative or positive) (percent of + cells… positivity: week, moderate, strong)	100
114	HER2 (-, +1, +2, +3)	100
115	Ki-67	100
116	HER2 FISH (or CISH) (amplified, not amplified)	100
117	Other performed IHCs	87.50
14-Pathology of metastatic biopsy		
118	Pathology of distant metastasis	100
119	Pathology of lymph node metastasis	100
15-IHC & FISH (or CISH) metastasis		
120	ER (negative or positive) (percent of + cells… positivity: week, moderate, strong)	100
121	PR (negative or positive) (percent of + cells… positivity: week, moderate, strong)	100
122	HER2 (-, +1, +2, +3)	100
123	Ki-67	100
124	HER2 FISH (or CISH) (amplified, not amplified)	100
125	Other performed IHCs	87.50
16-Staging by T-N-M		
126	T (TX, Tis, T0, T1, T2, T3, T4 (T4a, T4b, T4c, T4d))	100
127	By which modality the T was determined? (CT, MRI, Sonography, PET-Scan, Mammography, Pathology, Examination)	100
128	N (NX, N0, N1, N2, N3)	100
129	By which modality the N was determined? (CT, MRI, Sonography, PET-Scan, Mammography, Pathology, Examination)	100
130	M (M0, M1)	100
131	Metastasis location (bone, lung, liver, lymph nodes, brain, etc.)	100
132	Metastasis detection method (imaging (CT, MRI, Sonography, bone scan, PET-Scan) or biopsy)	100
133	The final result of staging (T-N-M)	100

Abbreviations: CT, computerized tomography; MRI, magnetic resonance imaging; PET-Scan, positron emission tomography-scan; T-N-M, tumor-nodes-metastasis

tionnaire for receiving the users' opinions (11, 12, 48, 49). However, for identifying the required data elements, this study scrutinized the latest clinical guidelines related to breast cancer and reviewed the medical records of patients with breast cancer, who received different treatment plans. Due to the multidisciplinary approach of the teams for optimally managing patients with breast cancer, knowledge, and views of healthcare providers with various specialties in oncology, including radiation oncologists, gynecologists, blood and adult cancer specialists, and cancer surgeons were considered (8).

Similar studies in the field of teleoncology for breast cancer have focused on the final clinical results and comparison of these systems with face-to-face models. To our knowledge, identifying the required data elements have not been addressed in those studies (15, 16, 44). In our study, experienced breast cancer specialists actively participated in the identification of required data elements for the teleoncology system, and their views and opinions were applied.

It is worth noting that there was no consensus on some data elements, which were identified necessary with a low average percentage and due to patients' clinical conditions. For example, the existence of some data elements including some tests (Mg, Pr), imaging (PET scan, simple X-ray), and consultations (genetic counseling, psychiatric counseling) did not appear to provide a treatment plan for all patients.

Rudnisky et al. applied the clinical guidelines related to imaging, presentation, and diagnostic grading in a teleophthalmology system designed for diabetic retinopathy (50). Furthermore, in the study conducted by Hazin and Qaddoumi to investigate the current and future state of teleoncology, the authors noticed that the Mexican Na-

Table 5. Tests, Imaging, Patient Preferences, and Consultations

Category	Data Elements	Average (%) Necessary
17-Assess PD-L1 biomarker		
134	Assess PD-L1 biomarker status for triple-negative breast cancer	78.13
18-Tests		
135	WBC	100
136	Neut	100
137	Lymph	90.63
138	Hb	100
139	Plt	100
140	Urea	90.63
141	Cr	100
142	AST	100
143	ALT	100
144	ALKP	100
145	Bill (total)	100
146	Bill (direct)	100
147	T3	75
148	T4	75
149	TSH	78.13
150	Uric acid	75
151	ESR	81.25
152	LDH	100
153	FBS	100
154	Na	84.38
155	K	84.38
156	Ca	81.25
157	P	75
158	Mg	65.63
159	Alb	75
160	Pr	65.63
161	β-HCG	87.50
162	FSH	87.50
163	LH	87.50
164	Estradiol	87.50
165	CA_{15-3}	87.50
166	CEA	75
167	CA_{125}	75
19-Imaging		
168	CT (neck, chest, abdomen, pelvis, brain, spine, etc.)	100
169	MRI (neck, chest, abdomen, pelvis, brain, spine, breast, etc.)	75
170	Sonography (abdomen, pelvis)	100
171	Sonography (breast)	100
172	Mammography	100
173	Bone scan	100
174	PET Scan	71.87
175	Simple X-ray (chest, spine, pelvis, etc.)	71.87
176	Important findings of imaging	87.50
20-Patient preferences and consultations		
177	Fertility counseling	100
178	Cardiovascular counseling	100
179	Images of cardiovascular counseling	84.38
180	Genetic counseling	87.50
181	Psychiatric counseling	81.25
182	Patient preferences	100

Abbreviations: Alb, albumin; ALT, alanine transaminase; ALKP, alkaline phosphatase; AST, aspartate transaminase; Bill, bilirubin; Ca, calcium; CA_{125}, cancer antigen 125; CA_{15-3}, cancer antigen 15-3; CEA, carcinoembryonic antigen; Cr, creatinine; ESR, erythrocyte sedimentation rate; FBS, fasting blood sugar; FSH, follicle-stimulating hormone; Hb, hemoglobin; K, potassium; LDH, lactate dehydrogenase; LH, luteinizing hormone; Lymph, lymphocytes; Mg, magnesium; Na, sodium; Neut, neutrophils; P, phosphorus; Plt, platelet; Pr, protein; WBC, white blood cell; T3, triiodothyronine; T4, thyroxine; TSH, thyroid-stimulating hormone; β-HCG, beta-human chorionic gonadotropin

Table 6. Main Themes, Categories, and Sub-Categories of Extracted Requirements

Main Themes	Categories	Sub-Categories
Functional	Basic operational requirements for all users	Ability to register users in the system
		Existence of user profile for each user in the system
		Ability to edit user information registered in the system
		Ability to verify the identity of users who register in the system
		Ability to print documents and report in the system
		Ability to support standard devices such as laptops and tablets
		Ability to access the system through web browsers without the need to install on a specific platform or operating system
		Help for users to learn how to work with the system
		Ability to search in the system
	Operational requirements special for physicians involved in providing patient's treatment planning	Ability to create audio and video communication to discuss and consult with other physicians involved in the treatment process
		Ability to create audio and video communication with the patient
		Ability to access to information and medical history of the patient through the system
		Ability to access to patient's medical images through the system
		Ability to access to patient's lab results through the system
		Ability to access the results of the consultations and patient preferences through the system
		Ability to provide comments and suggestions by physicians involved in providing a treatment plan to the patient
	Operational requirements special for residents	Ability to create medical records for the patients
		Ability to send patient medical records for specialists
		Residents' ability to access clinical information and provide treatment plans for educational purposes
		Ability to send the provided treatment plan to the patient
		Ability to record and access information and medical history of the patient through the system
		Ability to record and access to patient's medical images through the system
		Ability to record and access to patient's lab results through the system
		Ability to record and access to results of the consultations and patient preferences through the systems
	Operational requirements special for patients	Ability to access patients' medical records and provide treatment plans
		Ability to access the patient's medical images through the system
		Ability to access the patient's lab results through the system
	Communication with other information systems	Ability to connect to the Electronic Health Record (EHR) system for sending and receiving patient medical records
		Ability to connect to the Health Information System (HIS) for sending and receiving patient medical records
		Ability to connect to information systems such as laboratory information systems or radiological information systems if these information systems are separate from the hospital information system for sending and receiving patient medical records
		Ability to connect to the Personal Health Record (PHR) system for sending and receiving patient medical records
Non-functional	Security and privacy	Safe login to /logout from the system
		Defining the access level of users
	Usability	User-friendly system
		Easy training and learning of the desired operation in the system
		The availability of the system for all users
	Efficiency	Appropriate response time for processing operations, communication, reporting, and data storage in the system
	Reliability and supportability	Ability to change and develop, configure and service the system
		Appropriate response time when encountering an error
		Appropriate response time to repair and update the system
		Minimize the number and severity of system errors

tional Center for Health Technology Excellence has proposed comprehensive clinical guidelines in the Spanish language to be used in their telemedicine projects (46). The results of studies indicate that applying the clinical

guidelines in telemedicine programs is important and valuable to provide quality healthcare services. In this regard, the use of clinical guidelines for the development of telemedicine systems has also been emphasized by prominent telemedicine associations including the American Telemedicine Association (ATA) in various fields of medicine (51). In addition to investigating the latest clinical guidelines related to the treatment of breast cancer and reviewing the patients' medical records, the added value of the present study aimed at identifying the required data element is in applying the comments and suggestions of breast cancer specialists at all stages. Finally, the required data elements, identified by experts, were confirmed. Therefore, all the processes were performed scientifically and by applying experts' opinions in the field of breast cancer treatment, thereby covering all aspects in this regard.

The number of questions in the questionnaire (186 questions) was one of the limitations of the present study; as the results of some studies show, using long questionnaires may reduce the accuracy of participants' responses and their willingness to participate in the study (52, 53). However, reducing the number of questions might have hindered us in achieving the main purpose of the study. Therefore, we decided to decrease the effect of this limitation by organizing the questions into several sections based on the content and relevance of the items. Moreover, sufficient time was given to the participants, if they needed, to complete the questionnaire. According to the arrangements made with the participants, a text message to complete the questionnaire was sent to them one day before the visit.

5.2. Requirements Elicitation

As mentioned earlier, the interview method with end-users was employed to determine the requirements of the teleoncology system. Moreover, the questionnaire containing pre-identified requirements was used during the interview process. Considering the interviewees of the study did not have practical experience of working with telemedicine systems; the use of the questionnaire, by which we had already identified some requirements, helped guide the interviewees and identify the requirements by them. Similarly, interviews, questionnaires, or a combination of these two methods have been applied in various studies to identify the requirements of telemedicine systems (11, 54-56). Generally, the software requirements are divided into 2 main categories, which are functional and non-functional requirements (57). In this regard, the requirements identified in the present study were divided into two main functional and non-functional themes, and each of these themes was classified and subcategories based on the analysis of the results of the interviews.

Since health information systems are more complex than other information systems and have multiple users with different levels of expertise and knowledge, one of the best approaches to identify such systems require to engage the users (28). Given that one of the aims of the present study was to identify the requirements of the telemedicine system to provide treatment plans for patients with breast cancer, and typically a multidisciplinary team consisting of various specialists is used to provide treatment plans for breast cancer, they should be involved to identify the requirements of such system. Indeed, one of the strengths of the present study was the fact that the users participating in the interview process were from the different specialized disciplines, leading to a comprehensive examination of the requirements of the system from different perspectives.

The results of the present study in the functional requirements section show that all participants remarked that they needed to register in the system and have their profiles to securely access the system and perform their duties. In this regard, our results are in line with other studies, in which web-based telemedicine programs have been applied (58, 59). In similar studies conducted in the field of telemedicine, capabilities, and features such as the ability to upload medical images, search and report in the system have been identified as the main requirements of such systems (11, 12). According to the findings of the present study, most of the interviewees mentioned that depending on the patient's condition, special medical images, which could be uploaded, were needed. It is also necessary to provide the ability to search and report in the system for all users of the system with different roles.

Some studies have shown that human error is one of the major factors, leading to errors commonly observed in telemedicine systems. This could be due to the inability of users to use these systems. This problem can be resolved by providing a help section to train users of telemedicine systems (60, 61). Similar to other studies in this area (62-64), providing a help section for users of the teleoncology system is necessary to get informed about the capabilities of the system and to learn how to work with the system. There is evidence to suggest that connecting telemedicine systems to other clinical information systems provide positive outcomes such as easy access to various types of patients' medical information and minimizing the repetition of unnecessary tests and procedures (65, 66). Likewise, the results of our study show that communicating the teleoncology system with other clinical information systems is one of the requirements recommended by the

interviewees.

The results of Alencar et al.'s systematic mapping research on non-functional requirements in health information systems show that the interview method is the most widely used instrument to identify the non-functional requirements in this area. The result of their research also showed that security and privacy were observed more than other non-functional requirements in studies (39). Some of the non-functional requirements identified in health care software systems include communicativeness, confidentiality, integrity, efficiency, privacy, reliability, safety, security, traceability, and usability (67). In this regard, the non-functional requirements resulting from the analysis of interviews in our study were divided into 4 categories, including security and privacy, reliability and supportability, usability, and efficiency.

5.3. Conclusions

Based on the results of this study, identifying the required data elements for teleoncology systems is a key step for implementing such systems. In this regard, as clinical guidelines provide up-to-date and evidence-based information, it is recommended to use them to identify the required data elements of telemedicine systems. Besides, the data elements that are recorded in the patients' medical records for providing treatment plans in the conventional model should also be examined. Finally, applying the opinions and knowledge of medical professionals to improve the process of identifying the required data elements is suggested.

Since the healthcare providers in various fields of oncology are potential users of such systems, developers should consider users' requirements and needs when designing and developing telemedicine systems to increase its acceptance and use. In this regard, the findings of the present study can provide a fairly comprehensive view for determining the requirements of teleoncology systems for developers and researchers in their future research.

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Footnotes

Authors' Contribution: Farahnaz Sadoughi and Kambiz Novin designed and directed the project and performed the critical revision. Taleb Khodaveisi has involved in data acquisition and statistical analysis and wrote the first draft of the manuscript. Farahnaz Sadoughi, Kambiz Novin, and Taleb Khodaveisi contributed to interpretation of the results and discussion of the manuscript. All authors read and approved the manuscript.

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