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 sub-category 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 (ρKR21 = 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 ± 5.41 years, and the meaningful work experience was 12.59 ± 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 ± 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 | The results of a physical examination of the breast (detectable mass?) | 100                   |
| 50       | Location of the mass in the left breast (1. upper-outer, 2. upper-inner, 3. lower-outer, 4. lower-inner, 5. central) | 100                   |
| 51       | Location of the mass in the right breast (1. upper-outer, 2. upper-inner, 3. lower-outer, 4. lower-inner, 5. central) | 100                   |
| 52       | Size of breast mass (cm)                                                     | 100                   |
| 53       | Fixation of the breast mass (yes, no)                                        | 100                   |
| 54       | Breast skin involvement (discoloration, scars, nodules, orange peel skin)    | 100                   |
| 55       | Area of breast skin involvement (less than 30%, between 30% and 50%, more than 50%) | 87.50                 |
| 4 Examination of the lymph nodes | The results of the examination of the lymph nodes (detectable mass?) | 100                   |
| 57       | Location of enlarged lymph nodes (axilla, supraclavicular, mammary internal) | 100                   |
| 58       | Fixation of the lymph nodes (yes, no)                                        | 100                   |
| 59       | Size of the lymph node (cm)                                                   | 100                   |
| 60       | Mattened lymph nodes                                                         | 100                   |
| 5 Examination of distant metastasis | Results of distant metastasis examination (bone tenderness, respiratory distress, ascites, organomegaly, etc.) | 100                   |
| 62       | 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) | Evidence of local recurrence (left side [at the surgical scar site, away from the surgical scar]) | 100                   |
| 68       | Evidence of local recurrence (right side [at the surgical scar site, away from the surgical scar]) | 100                   |
| 69       | Type of local recurrence (ulcer, mass, discoloration)                        | 100                   |
| 70       | Local recurrence size (cm)                                                    | 100                   |
| 71       | Fixation of local recurrence (yes, no)                                       | 100                   |

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 cancer.
| Category | Data Elements | Average (%) | Necessary |
|----------|---------------|-------------|-----------|
| 8 Pathology of breast and lymph node biopsy | Pathology of breast biopsy | 100 | |
| | Pathology of lymph node biopsy | 100 | |
| 9 IHC & FISH (or CISH) breast and lymph node biopsy | Date of biopsy | 100 | |
| | ER (negative or positive) (percent of + cells... Positivity: week, moderate, strong) | 100 | |
| | PR (negative or positive) (percent of + cells... Positivity: week, moderate, strong) | 100 | |
| | HER2 (-, +1, +2, +3) | 100 | |
| | Ki-67 | 100 | |
| | E-cadherin (negative or positive) | 84.38 | |
| | HER2 FISH (or CISH) (amplified, not amplified) | 100 | |
| | Other performed IHCs | 87.50 | |
| 10 Surgical pathology | Date of surgery | 100 | |
| | Pathology of breast surgery | 100 | |
| | Pathology of lymph node surgery | 100 | |
| | Surgery: breast (breast conservation surgery, total mastectomy, radical mastectomy, skin-sparing, nipple-sparing) | 100 | |
| | Surgery: axillary (sentinel: negative [number of nodes removed]) | 100 | |
| | Surgery: axillary (sentinel: positive [number of positive nodes and number of nodes removed]) | 100 | |
| | Surgery: axillary (dissection: negative [number of nodes removed]) | 100 | |
| | Surgery: axillary (dissection: positive [number of positive nodes and number of nodes removed]) | 100 | |
| | Surgery: breast reconstruction (time: immediate or delayed) | 100 | |
| | Surgery: breast reconstruction (type: prosthesis or autologous) | 100 | |
| | the number of tumor lesions | 100 | |
| | Size of the tumor (cm) | 100 | |
| | Skin involvement | 100 | |
| | Nipple involvement | 100 | |
| | LVSI | 100 | |
| | PNI | 100 | |
| | Extracapsular extension | 100 | |
| | Percentage of carcinoma in situ | 100 | |
| | Grade (1 or 2 or 3) | 100 | |
| | Margin status (R0, close, R1, R2) | 100 | |
| 11 IHC & FISH (or CISH) surgery | ER (negative or positive) (percent of + cells... positivity: week, moderate, strong) | 100 | |
| | PR (negative or positive) (percent of + cells... positivity: week, moderate, strong) | 100 | |
| | HER2 (-, +1, ++, +3) | 100 | |
| | Ki-67 | 100 | |
| | E-cadherin (negative or positive) | 100 | |
| | HER2 FISH (or CISH) (amplified, not amplified) | 100 | |
| | 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

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-
| 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 | Pft | 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 | CA15-3 | 87.50 |
| 166 | CEA | 75 |
| 167 | CA125 | 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; Bilr, bilirubin; Ca, calcium; CA125, cancer antigen 125; CA15-3, 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; Pr, 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 patient |
|             |            | 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 |
|             | Communication with other information systems | Ability to access the patient’s medical images through the system |
|             |            | Ability to access the patient’s lab results through the system |
|             | Security and privacy | Safe login to /logout from the system |
|             | 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 |

The National 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 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 sub-categories 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 re-search 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

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