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Development of a National Consensus Minimum Data Set for the Diagnosis and Treatment of Oral Cancer: Towards Precision Management

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Abstract

Background: Due to the complexity of prognosis, diagnosis, and treatment in the process of providing care for patients with oral cancer, a large amount of data elements have been processed. The present study was conducted to provide a minimum data set for managing the data generated in the diagnosis and treatment processes of oral cancer by reviewing the specialized literature, medical records and by gathering expert opinions.

Method: This research was a descriptive cross-sectional study with the following steps: reviewing texts and records, developing a draft of data elements, organizing a panel of experts, Delphi techniques, and creating a final pattern.

Results: The framework proposed in this study for managing the data generated in the diagnosis and treatment processes of oral cancer was divided into six sections: management data with four-axis, historical data with four-axis, paraclinical indicators with two-axis, clinical indicators, data related to the therapeutic measures, and mortality data.

Conclusion: The systematic collection of the data associated with the diagnosis and treatment of the patients with oral cancer could provide a good basis for identifying patients or those who are susceptible to this type of cancer in the community. These data can also be used in programs to prevent the development and/or emergence of the disease, thus the health of the community.

Keywords: Mouth neoplasms, Diagnosis, Therapeutics, Common data elements

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Introduction

Oral cancer is one of the top ten types of cancer in several parts of Iran.[1] Despite the significant advance in prevention strategies, diagnostic techniques, and therapeutic

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approaches, the survival of patients in developed countries is still a deep concern.[2]

The incidence of oral cancer has increased in many Asian countries. Therefore, developing national cancer surveillance programs, collecting data for the prevention and control of oral cancer through screening for early diagnosis, and helping to create a healthy society are essential, which improve people's living standards and resolve the weaknesses and limitations of the care system.[3]

Using artificial intelligence and machine learning techniques have greatly facilitated the diagnosis and treatment of the disease.[4-6]

Extensive data are produced in modern medicine, yet there is always a deep gap between data collection and their interpretation and the presentation of information is often overlooked. The existence of a systematic structure for collecting and processing data and distributing them as information, in other words managing the data related to the occurrence of the disease, using the most accessible data and models to provide timely and scientific information to make effective decisions could be an effective step towards promoting health care.

MDS is one of the most practical tools for improving the quality of data and making them comparable at the national and international levels.[7,8] The development of the MDS can lead to the standardization and operational management of data generated in the process of providing health care.[9,10] MDS refers to a series of defined data elements related to a specific issue. It creates uniformity in the process of data gathering in different institutions and provides a suitable basis for monitoring, managing, and evaluating performances.[11,12]

Numerous studies have pointed out the importance of MDS in improving the quality of care and disease control in different areas, such as delirium,[13] antimicrobial resistance management,[14] speech therapy,[15] cystic fibrosis,[16] and primary care optometry.[7]

In Iran, a model of essential data sets was created to standardize and manage the applied data in the field of burns.[9] Primarily, a minimum data set was developed for a drug poisoning registry system. It was divided into the administrative and clinical parts, including 32 data elements in three sections and 81 data elements in six sections, respectively. This MDS was used to collect, process, analyze, and report accurate information about drug poisoning.[17] WHO published its first MDS to be used in daily reports by the emergency medical team (EMT) when they face sudden events.[18] A nursing MDS was developed for managing data in nursing diagnoses, interventions, and activities in oncology hospital settings. This tool could be utilized to improve the care process of cancer patients who receive long-term care in nursing homes.[19] To improve oral health assessments in nursing homes in Canada, a Resident Assessment Instrument (MDS) was employed. This instrument could effectively monitor the clinical and functional characteristics on admission and subsequent quarterly intervals. Later, it was used in European countries.[20] Due to the complexity of the prognosis, diagnosis, and treatment in the process of providing care for patients with oral cancer, a large number of data elements have been processed. To date, no specific frameworks have been provided for recording these data elements. The efficient collection and management of these data elements in a specific framework, on top of increasing the accuracy of diagnosis, promoting the prognosis process, and improving early detection, would provide a good basis for planning national and international research. The present study aimed to provide a comprehensive model, as MDS, for managing the data generated in the diagnosis and treatment processes of oral cancer.

Materials and Methods

This research was carried out in a descriptive cross-sectional study in several steps. Initially, using appropriate keywords, the scientific databases were searched for the necessary data elements related to oral cancer and all the relevant texts, including books, articles, and guidelines, were evaluated based on the entry and exit criteria. Subsequently, the print and electronic records of oral diseases in Iran and other countries were considered. In this way, an initial draft of the

Table 1. Demographic data of the experts involved in the Delphi Decision Technique

Experts	Number	Age groups				Work experience			
		20-29	30-39	40-49	50-59	5-10	11-15	16-20	20<
Oral medicine	15	0	4	8	3	3	4	5	3
Health information management	5	0	2	2	1	1	2	1	1

essential data elements for the processes of diagnosis and treatment of oral cancer was developed and divided into two parts of clinical and non-clinical data elements. Afterward, an expert panel was formed to create a suitable space for discussing the necessity of the existence of different data elements. The panel of the clinical section consisted of the faculty members of the Oral Medicine Department and the panel of the management section consisted of the faculty members of the Health Information Management Department of Tehran University of Medical Sciences. The panel refined ambiguities in the wording of the questions and made the questionnaire as transparent as possible. To prioritize data elements, an online Delphi survey was conducted at a national level to facilitate the participation of experts living far away. At this stage, a targeted sampling method was used, through which the researchers selected particular participants consciously. In the targeted sampling, by choosing expert samples, the researchers collected data that are rich in information and have mastery of the research questions. In the present study, the experts with at least five years of teaching and clinical experience were selected among the faculty members of Oral Diseases and Health Information Management Departments of the medical universities of Iran. Two rounds of Delphi surveys were conducted to reach an agreement of over 75% among the respondents for each item. The data were analyzed with SPSS software version 20.0. Ethical approval for this study was obtained from Birjand University of Medical Sciences. (Approval number: IR.BUMS.REC.1396.108)

Results

Table 1 represents the demographic data of the experts participating in the Delphi decision technique.

The framework proposed in this study to manage the data generated in the diagnosis and treatment of oral cancer was divided into six sections, including management data with four-axis, history data with four-axis, paraclinical indexes with two-axis, clinical indicators, data related to therapeutic measures, and mortality data.

As shown in table 2, in the management data section, 37 elements entered the Delphi process consisting of 14 elements associated with demographic data, 9 elements related to the service provider, 10 elements related to the disease diagnosis, and 4 elements associated with patients' referral. In the first round, 8 elements were deleted because an agreement of below 50% was obtained and 15 elements won a collective agreement of over 75%. In the second round, out of the remaining 14 elements that had reached an agreement of 50% -75% in the first round, 7 were deleted and 7 were added to the final element set. Thus, the final model comprised 22 elements in the data management section.

In the section on historical data, a total of 25 elements were entered into the Delphi process, out of which 10 were related to the history of social habits, 4 were related to oral hygiene history, 4 were associated with family history, and 7 were related to the history of previous diseases. In the first round, a total of 2 elements with an agreement of below 50% were removed from the set of data elements and 19 elements gained a collective agreement of over 75%. In the second round, the 4 remaining elements that had reached an agreement of 50%-75% in the first round gained a collective agreement of over 75%; hence, they were added to the set of final elements. Overall, the final model had 23 historical data elements.

In the paraclinical indicators section, a set of 16 elements were entered into the Delphi process consisting of 5 elements and 11 elements

Table 2. Data categories in the Delphi process

Data categories	Data sections	Number of data elements	First round of Delphi			Second round of Delphi			Final number of Data elements
			<50%	50–75%	75%<	<50%	50–75%	75%<	
Administrative data	Demographic	14	2	5	7	3	0	2	9
	Provider ID	9	2	4	3	2	0	2	5
	Diagnostic	10	3	3	4	1	0	2	6
	Referrals	4	1	2	1	1	0	1	2
Historical data	Social history	10	1	2	7	0	0	2	9
	Oral hygiene history	4	1	0	3	0	0	0	3
	Family history	4	0	1	3	0	0	1	4
	Past disease history	8	0	2	6	0	0	2	8
Para clinical indicators	Radiography	5	1	2	2	0	0	2	4
	Laboratory	11	4	4	3	2	0	2	5
Clinical indicators	oral and oropharyngeal cancer	32	3	7	22	1	0	6	28
Therapeutic measures		10	1	3	6	1	0	2	8
Mortality data		7	2	2	3	1	0	1	4
Total		128	21	37	70	12	0	25	95

respectively, associated with radiographic data and laboratory data. In the first round, a total of 5 elements were removed from the set of data elements with an agreement of below 50% and 5 elements had reached a collective agreement of over 75%. In the second round, out of the 6 remaining elements that had obtained an agreement of 50%-75% in the first round, 2 were removed and 4 were added to the final elements set. Thus, the final model had 9 elements related to the paraclinical Indicators.

In the clinical indicators section, a total of 32 elements related to oral cancer were introduced into the Delphi process. In the first round, 3 elements were removed from the set of data elements with an agreement of below 50% and 22 elements gained a collective agreement of over 75%. In the second round, out of the 7 remaining elements which had reached an agreement of 50%-75% in the first round, 6 were added to the set of final elements with a collective agreement of over 75%, and one was removed from the set of data elements.

In the therapeutic section, out of the 10 elements that had entered the Delphi process, 6 in the first round and 2 in the second round obtained the required collective agreement. In addition, one element in the first round and one in the second round, with an agreement of below 50%, were deleted from the set of data elements.

In the section on mortality data, out of the 7 data elements in the Delphi process, 3 in the first round and one in the second round were selected with a collective agreement of over 75%. Moreover, 2 elements in the first round and one in the second round were removed from the data element set.

Overall, about 128 data elements were surveyed, out of which 95 obtained a collective agreement of over 75% with 70 elements in the first round and 25 elements in the second round. In addition, 33 elements with an agreement of below 50% were deleted from the data element set in the two-round Delphi decision technique.

Table 3 depicts an overview of the MDS used for managing data generated in the diagnosis and treatment of oral cancer.

Discussion

Oral cancer is believed to be one of the most important life-threatening diseases. Several risk factors play roles in its incidence and severity.[21] Following a series of stages, including the review of texts related to the diagnosis and treatment of oral cancer, and the application of expert opinions through the Delphi decision-making process, herein, we developed a comprehensive model with six parts for managing the data generated in the diagnosis and treatment process of oral cancer. The model included management data with four sections, historical data with four sections, paraclinical indexes with two sections, clinical indicators, therapeutic proceedings-associated data, and mortality data.

Table 3. Minimum Data Set (MDS) for managing data generated in the diagnosis and treatment of oral cancer

Data sections	Data elements	Variables
	Administrative data	
Demographic	Identification No.	-
	Gender	Male/female
	Age group	-
	Marital status	Single/married
	Education	-
	Employment	-
	Address	-
	Mobile	-
	e-mail	-
Provider ID	Specialties	-
	Surgeon	-
	Pathologist	-
	Date of acceptance	-
	Record number	-
Diagnostic	Chief complaint	-
	Primary diagnosis	-
	Date of primary diagnosis	-
	Differential diagnosis	-
	Final diagnosis	-
	Date of final diagnosis	-
Referrals	Date of primary referrals	-
	Origin of reference	Referral from a general practitioner Screening programs
	Historical data	
Social history	Number of caffeinated beverages you drink in a day	-
	Number of alcoholic beverages you drink in a week	-
	Number of carbonated beverages a day	-
	Have you ever used tobacco?	Yes/no
	If yes, what type	Cigarette, pipe/cigar, smokeless
	Do you currently use tobacco?	Yes/no
	If yes, the average number of uses per day	-
	For how many years?	-
	Exposure to sunlight?	Yes/no
Oral hygiene history	How often do you brush?	1/1>/1<
	How often do you floss?	Once per night, once per week, I do not use
	Do you take fluoride supplements?	Yes/no
Family history	Genetic Diseases	Yes/no
	Involvement of family members in infectious diseases	Yes/no
	Involvement of family members in cancer diseases	
	Food allergy	Yes/no
	Drug allergy	Yes/no
Past disease history	Past previous malignancies	Yes/no
	History of thyroid disorders	Yes/no
	History of radiotherapy	Yes/no
	History of liver disease	Yes/no
	History of skin disease	Yes/no
	Endocrine disorders such as diabetes	Yes/no
	Immune system diseases such as HIV	Yes/no
	Infection with human papillomavirus, HPV 16,18	Yes/no
	Paraclinical indicator	
Radiography	Extraoral radiographs	OPG/DPT, lateral Ceph, PA view, waters
	Intraoral radiographs	Bitewing radiographs, occlusal radiographs, periapical radiographs, full mouth series
	CT or CAT scan	-
	Radiography result	-
Laboratory	Main group of test	Cytology, biochemistry, hormone tests, microbiology, pathology
	Tests results	-
	Biopsy	-
	Aspiration	-
	Diascopy	-
	Clinical indicators	
Oral and oropharyngeal cancer	Site	Localized, generalized
	Number	Single, multiple lesion
	Margins	Coalescing, well defined

Table 3. Minimum Data Set (MDS) for managing data generated in the diagnosis and treatment of oral cancer

Data sections	Data elements	Variables
	Administrative data	
	Margins	Coalescing, well defined
	Involved or close margins with measurements	Length × width × thickness in mm
	Duration	-
	Tendency/pain	Yes/no
	Predisposing factors	Chewing areca nut, betel quid, oral snuff, cigarette smoking
	Associations/relieving factors	-
	Previous treatmen	Yes/no
	Lymphadenopathy	Yes (site, number, consistency, mobility and tenderness)/no
	Bleeding	-
	Lesion process	Fast, slow
	History or evidence of infective etiology	Yes/no
	Depth of invasion	-
	Perineural invasion	Yes/no
	type of lesion	ulcer/white or red or combination of them / exophytic
	Shape features	Polypoid, sessile, Peduncalate, nodular, domed
	Surface	Smooth, papillary, verrucous, granulomatous
	Consistency	Soft, firm, hard, rubbery, cheesy
	New primary cancer or recurrence	New primary, primary – secondary, recurrence, metastasis, not stated
	Histological grade	Grade 1: Well differentiated, Grade 2: Moderately differentiated, Grade 3: Poorly differentiated
	Tumor stage	Stage 0, Stage I, Stage II, Stage III, Stage IVA, Stage IVB, Stage IVC
	Ulceration of Surface	Yes/no
	If yes, describe the appearance	-
	Altered sensation	Yes/no
	If yes, please describe the nature and distribution	-
	Tumor type	Squamous cell carcinoma, Other
	Tumor subgroup	Conventional, Verrucous carcinoma, Basaloid squamous cell carcinoma, Papillary squamous cell carcinoma, Spindle cell carcinoma, Acantholytic squamous cell carcinoma, Adenosquamous carcinoma, Carcinoma cuniculatum, Undifferentiated (no or limited differentiation), Other
	Therapeutic measures	
Oral and oropharyngeal cancer	Surgery	Referred but not done/Yes/no
	Date of surgery	-
	Radiotherapy	Referred but not done/Yes/no
	Date of Radiotherapy	-
	Chemotherapy	Referred but not done/Yes/no
	Date of Chemotherapy	-
	Hormone therapy	Referred but not done/Yes/no
	Date of Hormone therapy	-
	Mortality data	
Oral and oropharyngeal cancer	Date of death	-
	The cause of death	-
	The patient's age at the time of death	-
	Place of deat	-

In the management data section, in addition to the patients' demographic data, the data related to care providers were considered. Early diagnosis of malignant and disposable lesions is of great necessity for achieving a good prognosis. Furthermore, delays in diagnosis generally make treatment difficult or impossible. General dentists are among the first groups who can deal with patients with oral cancer.[22] If they diagnose it correctly, they can refer patients to specialists

and surgeons for efficient administration and treatment using the referral system. Thus, governments should acknowledge the benefits of using referral systems for cancer treatment and ensure their quality improvement.[23]

To extract these data elements, numerous forms, including acceptance, registration, satisfaction, referral, and follow-up forms, were used in the dental care centers.

The history data section includes social behavior and habits, as well as the history of the previous diseases. The etiology of oral cancer is multifactorial and occurs in a multistage process. The suspected cases of oral cavity cancer are normally detected by assessing the patients' demographic data and examining their specific habits. A complete history data should include the history of oral hygiene and exposure to any other carcinogens. Family history should also be considered in examining the presence of any syndrome that may increase the risk of developing oral cancer.[24]

In the Oral Cancer Screening Program in Taiwan, which aimed to reduce mortalities, in addition to the demographic data of the participants, other characteristics, such as smoking and drinking alcohol, were also considered.[25]

Moreover, in the study on the HPV Knowledge gap and search of information by oral cancer patients, the demographic data section included gender, age, race, ethnicity, marital status, annual income, current employment status, and educational level.[26]

In addition to the patients' demographic data, other studies have considered several other factors that are effective in delaying the various stages of the disease, such as psychiatric disorders, social factors, lack of awareness, family problems, various cultural experiences,[27] and occasionally, the inability of diagnosing and interpreting symptoms or fear of consulting with physicians.[28]

The paraclinical data section includes the processes and techniques mainly used to diagnose oral cancer and its treatment process. A wide range of diagnostic tests was used in the diagnosis of chronic diseases. The most prevalent techniques utilized to diagnose oral cancer are magnetic resonance imaging, computed tomography, and positron emission tomography; however, tissue biopsy remains the gold standard for oral cancer diagnosis.[29,30]

The data elements in the clinical data section have been extracted from a complete review of the section on oral cancer in Burket's oral medicine book.[31] To facilitate the differential diagnosis, pathological conditions that alter the soft tissue of the mouth have been categorized into three main groups in previous studies, including the change in color, change in level, and mass or swelling.[32] This categorization was applied in the present study.

In chronic diseases, the choice of appropriate treatment depends on several factors; for instance, certain factors influencing the choice of treatment in oral cancers are tumor type and size, tumor, node, and metastasis (TNM) stage, tumor location, patient preferences[33] as well as marginal status, invasion depth, lymphosuction invasion (LVI) , and perineural invasion (PNI).[34] In the therapeutic measures section, a variety of treatment methods has been considered.[35]

The Taiwan Cancer Registration Database contains the history of the first treatments, including chemotherapy, surgery, radiation therapy, hormone therapy, and the history of relapse.[25]

Supplying the parameters that can predict the outcome of the treatment is fundamental in selecting the best therapeutic strategy among the available options. Recording mortality data could also play an important role in managing oral cancer along with other essential data elements.

Conclusion

The systematic collection of data related to the diagnosis and treatment of patients with oral cancer could provide a good basis for identifying the patients or even those who are susceptible to oral cancer. These data could also be utilized in programs for preventing the development or emergence of the disease, thus the health of the community.

This research was conducted to organize and manage the flow of the data created in the process of diagnosis and treatment of oral cancer.

Researchers hope that the proposed model would be used for planning and intervening through the systematic collection of relevant data, as well as cleaning and upgrading the quality of the existing data in this field to improve the health of the community.

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Conflict of Interest

None declared.

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