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# Management of the essential data element in the differential diagnosis of oral medicine: An effective step in promoting oral health

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## Abstract:

**BACKGROUND:** Oral soft tissue diseases include a broad spectrum, and the wide array of patient data elements need to be processed in their diagnosis. One of the biggest and most basic challenges is the analysis of this huge amount of complex patient data in an increasing number of complicated clinical decisions. This study seeks to identify the necessary steps for collecting and management of these data elements through establishing a consensus-based framework.

**METHODS:** This research was conducted as a descriptive, cross-sectional study from April 2016 to January 2017, which has been performed in several steps: literature review, developing the initial draft (v. 0), submitting the draft to experts, validating by an expert panel, applying expert opinions and creating version v.i, performing Delphi rounds, and creating the final framework.

**RESULTS:** The administrative data category with 17 and the historical data category with 23 data elements were utilized in recording data elements in the diagnosis of all of the different oral diseases. In the paraclinical indicator and clinical indicator categories, the necessary data elements were considered with respect to the 6 main axes of oral soft tissue diseases, according to Burket's Oral Medicine: ulcerative, vesicular, and bullous lesions; red and white lesions of the oral mucosa; pigmented lesions of the oral mucosa; benign lesions of the oral cavity and the jaws; oral and oropharyngeal cancer; and salivary gland diseases.

**CONCLUSIONS:** The study achieved a consensus-based framework for the essential data element in the differential diagnosis of oral medicine using a comprehensive search with rich keywords in databases and reference texts, providing an environment for discussion and exchange of ideas among experts and the careful use of the Delphi decision technique.

## Keywords:

Clinical data management, dental informatics, differential diagnoses, oral medicine

## Introduction

“Oral medicine is a specialized discipline within dentistry that focuses on the provision of dental care for medically complex patients, and the diagnosis and management of medical disorders involving the mouth, jaws, and salivary glands.”<sup>[1]</sup>

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Oral soft tissue is affected by numerous pathological conditions with variable etiologies. Unfortunately, the clinical manifestations of many disease processes may be similar despite the great diversity in their etiology and pathology.<sup>[2]</sup> The overlap between the signs and symptoms of these diverse conditions results in significant issues in their diagnoses, which can only be resolved by the complete knowledge of the

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clinicopathologic characteristics of each condition and a systematic approach to diagnosis. Differential diagnosis is a necessary element in the process of diagnosis and includes the possible pathological information, ranked from the most to the least probable.<sup>[3]</sup> The speed and accuracy of access to the differential diagnosis list depends on collecting all of the data, including the medical history, the results of the patient examination, and the information obtained in consultations, as well as the knowledge of the dentists and their ability to match the clinical data with the manifestations related to one or more diseases.

Information is one of the most essential elements of diagnostic thinking. However, the limitations of human memory, variable disease manifestations, and factors such as biases and communication errors that influence clinical processes are a big challenge to ensuring a reliable and timely diagnosis.<sup>[4,5]</sup> Health information technology (HIT) tools and systems have great potential to enable clinicians to overcome or, at least, minimize human limitations. HITs can improve the diagnosis process by facilitating the gathering of a large volumes of clinical and nonclinical data and increasing the potential for complex management. According to previous studies, HIT methods, tools, and algorithms contribute to the different steps of a diagnosis by: (1) collecting data; (2) organizing and displaying information; (3) providing differential diagnosis; (4) weighing the diagnoses; (5) developing a diagnostic plan; (6) providing access to the information in diagnostic references; (7) facilitating patient follow-up; (8) screening asymptomatic patients for timely diagnosis; (9) shared diagnoses; and (10) facilitating the provision of diagnostic feedback to physicians.<sup>[6]</sup>

Oral soft tissue diseases include a broad spectrum, and the wide array of patient data elements need to be processed in their diagnosis. The abundance of data produced by an increasing number of novel supervision and diagnostic devices has created a huge dataflow that must be assessed for clinical decision-making. The review and analysis of the findings lead to diagnosis, determination of a treatment plan, and a plan for follow-up examinations in oral diseases. One of the biggest and most basic challenges is the analysis of this huge amount of complex patient data in an increasing number of complicated clinical decisions. So far, no specified framework has been presented for recording these data elements in oral diseases. The effective collection and management of these data elements in a consensus-based framework would not only increase diagnostic precision and accuracy but would also facilitate clinical risk assessment and case-mix adjustment, thus improving the reliability and validity of diagnostics in clinical practice. This framework can

also provide a platform for planning numerous national and international studies in the form of multivariable analyses and future meta-analyses. Finally, the use of data-mining algorithms for analyzing data elements to discover hidden patterns as well as the use artificial intelligence can also provide a foundation for the designing of an intelligent system to support clinicians in their clinical diagnoses.

The project of designing an intelligent system for the differential diagnosis of oral diseases is funded by Tehran University of Medical Sciences and incorporates three phases. This article reports Phase 1, which was conducted in order to reach an agreement on the draft of a consensus-based framework for essential data elements in the differential diagnosis of oral diseases. The present study can help clinicians by identifying the necessary steps for collecting the relevant medical history, performing an effective physical examination, and determining the best diagnostic strategy for differential diagnosis in a wide spectrum of oral diseases.

## Methods

In this study, we used Delphi decision-making technique to reach a consensus-based framework for essential data elements in the differential diagnosis of oral diseases. The following steps were performed before the Delphi rounds: literature review, developing the initial draft (v. 0), submitting the draft to experts, validating by an expert panel, applying expert opinions, and creating version v.i.

In literature review step, three major resources were considered. First, the main reference textbooks in the domain of oral medicine were reviewed in order to extract the essential data elements. Then, scientific databases, such as Science Direct, PubMed, and Web of Science, were searched using appropriate keywords, and all the relevant texts were evaluated based on inclusion and exclusion criteria. The inclusion criteria included literature in the English language: papers, guidelines, case reports, clinical studies, government publications, lectures, and other forms of research published in full text form, from valid sources with a clearly stated purpose. The exclusion criteria were non-peer-reviewed papers, reports and forms retrieved from personal weblogs, and abstracts without accessible full text. Then, the websites of WHO and dentistry associations in the pioneering countries such as the USA, the UK, and Australia were checked in order to access guidelines, manuals, and other relevant publications that had only been published on their websites. Finally, the printed and electronic records of oral diseases in Iran and other countries were examined.

The retrieved resources in the previous step that met the inclusion criteria were appraised in the next step,

and the initial draft (v. 0) of the necessary data elements in the diagnosis of oral diseases was developed. It is noteworthy that, in addition to clinical data elements, nonclinical data elements including administrative data, historical data, and paraclinical indicators were also extracted.

In order to formalize the extracted data elements, the initial draft was divided into clinical and managerial data elements and offered to the expert teams. The expert teams comprised the faculty members of Oral Diseases and Diagnostics Department of Tehran University of Medical Sciences for the clinical section and the faculty members of Health Information Management Department of Tehran University of Medical Sciences for the managerial section. Prior to filling in the questionnaires, they were sent an information package along with this draft to inform them of the goals of the study as well as the format of a Delphi study. All members of the expert teams studied the initial draft (v. 0) privately to familiarize themselves with the items before participating in the panel.

The panel provided the environment for discussion and the exchange of ideas on the necessity of various data elements. As a result, questionnaire items were clarified and amended when required. Moreover, the ambiguity in the wording of the questionnaire was resolved. In this section, the questionnaire was composed of three columns with “yes” (including required and optional) and “no” in front of each data element. At the end of each section, a blank row was included for adding necessary data elements by experts.

After taking the above-mentioned steps and reaching the final conclusions, the points agreed upon by the experts about data elements and their categorization were applied, and version (v.i) of the questionnaire was created. The reliability and validity of the questionnaire were assessed using test–retest and content validity methods, respectively. Finally, this questionnaire was used in Delphi rounds.

This section of the study consisted of a national multispecialty Delphi survey conducted via an online survey platform to allow the consultation of geographically distant experts in the ranking of the data elements. The questionnaire was then administered to the participants who had been selected through purposive sampling from among faculty members of the Oral Diseases and Diagnostics and Health Information Management Departments of Iranian Universities of Medical Sciences. All experts who participated in this study have extensive experience and knowledge in their own field. An electronic invitation was sent to selected experts requesting them to participate in our survey by

rating each diagnostic item in a number of subsequent rounds. Two rounds of surveys were used to gain over 75% consensus among the participants on each item.

### Round 1

In the first round, questionnaires were delivered to the experts individually by E-mail along with a cover note explaining the background of the study and a unique personal link to the online survey. During the first round, each item was rated separately for its degree of importance during the diagnostic workup. Experts were asked to rate each diagnostic item on a 9-point scale ranging from extremely unimportant ( $n = 1$ ) to extremely important ( $n = 9$ ). At the end of each section, a blank row was included for adding necessary data elements by the experts and they were given the opportunity to suggest the rewording of items, adding any missing items or offering essential explanations. The criteria for the acceptance of data elements in the final framework were gaining over 75% consensus among the participants on each item. Thus, the data elements with agreement levels more than 75% were accepted and with <50% were excluded in the first round; the 50%–75% agreement levels entered the second round. In the second round, an agreement level of 75% was also considered on each data element.

### Round 2

Based on the results of round 1, and reviewing the group’s average, the questionnaire was reviewed and items were rerated if no consensus was reached in the first round and/or had a median rating. If there was a suggestion by an expert to include an additional item, it was evaluated for relevance by the clinical experts in the research team, and if it was considered relevant, it was included in round 2. The revised questionnaire was submitted to the participants, in which they had access to both their previous rating and the experts’ feedback regarding details of the items. They were informed that the second round was the final round of the Delphi survey and the final instrument would only contain items for which consensus was reached after two rounds of the Delphi process.

### Data analysis

The IBM SPSS version 20.0 was used for data analysis. Eventually, in order to further improve the algorithm, it was submitted to the expert panel to give their final comments. In the end, the final data elements of the suggested framework for the differential diagnosis of oral medicine were found.

## Results

The demographic characteristics of experts participating in the Delphi decision technique are presented in Table 1.

The framework proposed in this study for recording the data elements in the diagnosis of oral diseases was divided into four categories including administrative data, historical data, paraclinical indicators, and clinical indicators.

Table 2 shows various sections of final data elements in the Delphi decision-making process.

From 186 data elements in the Delphi decision-making process, 168 data elements received over 75% of the votes (146 in the first and 22 in the second rounds). The experts reached a unanimous consensus (100%) on element 84. 18 elements that had received <50% of the votes in two Delphi decision-making rounds were removed from the data elements.

The administrative data category with 17 and the historical data category with 23 data elements were utilized in recording data elements in the diagnosis of all of the different oral diseases. The administrative data category includes three subsets: patient demographic

data (identification number, gender, marital status, etc.), care provider data (specialties name and date of acceptance, etc.), and diagnostic data (chief complaint and primary diagnosis, etc.). Furthermore, the historical data category includes four subsets: social history (number of alcoholic drinks per week, tobacco use, etc.), oral hygiene history (use a toothbrush, fluoride supplement, etc.), family history (genetic diseases, drug allergy, etc.), and past disease history (past previous malignancies, history of radiotherapy, etc.).

On the other hand, in the paraclinical indicator and clinical indicator categories, the necessary data elements were considered with respect to the 6 main axes of oral soft tissue diseases, according to Burket's Oral Medicine: ulcerative, vesicular, and bullous lesions; red and white lesions of the oral mucosa; pigmented lesions of the oral mucosa; benign lesions of the oral cavity and the jaws; oral and oropharyngeal cancer; and salivary gland diseases. The paraclinical indicator category includes two subsets: radiography data (extraoral radiographs, intraoral radiographs, etc.) and laboratory data (main group of test, tests results, etc.). Table 3 shows an overview of the final framework for the essential data element in differential diagnosis of oral medicine.

**Table 1: Demographic characteristics of participants in the Delphi decision technique**

Participants	n	Gender	Age group	Education	Experience
Oral medicine specialists	15	Female: 9	20-29: 0	Specialist: 15	<5: 2
			30-39: 4		5-10: 2
		Male: 6	40-49: 8		11-15: 3
			50-59: 3		16-20: 5
					>20: 3
Health information management	5	Female: 3	20-29: 0	PhD: 5	<5: 1
			30-39: 2		5-10: 0
		Male: 2	40-49: 2		11-15: 2
			50-59: 1		16-20: 1
					>20: 1

## Discussion

The diagnosis of oral diseases is based on interviews, observations, and clinical examinations of the patient, including a patient history (previous diseases, family history, health and social habits, etc.), paraclinical examinations, and clinical investigations. An accurate picture of the patient's general health, oral/dental status, concerns, and requests forms the basis for an accurate and precise diagnosis by the clinicians.<sup>[1]</sup>

**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	4	8	2	0	2	10
	Provider ID	6	1	3	2	2	0	1	3
	Diagnostic	6	1	2	3	1	0	1	4
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	7	0	1	6	0	0	1	7
Para clinical indicators	Radiography	3	1	0	2	0	0	0	2
	Laboratory	11	4	4	3	2	0	2	5
Clinical indicators	Ulcerative, vesicular, and bullous lesions	15	0	1	14	0	0	1	15
	Red and white lesions of the oral mucosa	22	0	3	19	0	0	3	22
	Pigmented lesions of the oral mucosa	16	0	2	14	0	0	2	16
	Benign lesions of the oral cavity and the jaws	20	0	3	17	0	0	3	20
	Oral and oropharyngeal cancer	25	0	2	23	0	0	2	25
	Salivary gland diseases	23	0	1	22	0	0	1	23
Total		186	11	29	146	7	0	22	168

**Table 3: Final framework for the essential data element in differential diagnosis of oral medicine**

Data sections	Data elements	Variables	
Administrative data			
Demographic	Identification number		
	Gender	Male/female	
	Age group		
	Race		
	Marital status	Single/married	
	Education		
	Employment		
	Address		
Provider ID	Mobile		
	e-mail		
Diagnostic	Specialties		
	Date of acceptance		
	Record number		
Historical data	Chief complaint		
	Primary diagnosis		
	Differential diagnosis		
	Final diagnosis		
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, 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	
	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	
	Endocrine disorders such as diabetes	Yes/no	
	Immune system diseases such as HIV	Yes/no	
Para clinical indicator	Infection with human papilloma virus, HPV 16,18	Yes/no	
	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	
	Laboratory	Radiography result	
		Main group of test	Cytology, biochemistry, hormone tests, microbiology, pathology
		Tests results	
		Biopsy	
		Aspiration	
	Clinical indicator	Diascopy	

*Contd...*



Table 3: Contd...

Data sections	Data elements	Variables
Ulcerative, vesicular, and bullous lesions	Features	Isolated lesion, multiple lesions, persistent lesion, recurrent lesion
	Site	
	Size	
	Duration	
	Tendency/pain	Yes/no
	Predisposing factors	
	Associations/relieving factors	
	Previous treatment	
	Hemorrhage	Yes/no
	Description of margins	Regular, irregular, rolled
	Lymphadenopathy	Yes/no
	Depth	Superficial, deep
	Other features	Vesicle, bulla, plaque, papule, nodule, tumor solid
	Altered sensation	Yes/no
If yes, please describe the nature and distribution		
Red and white lesions of the oral mucosa	Features	Isolated lesion, multiple lesions, persistent lesion, recurrent lesion
	Color	Red lesions, white lesions, pigmented lesions
	Site	
	Size	
	Duration	
	Tendency/pain	Yes/no
	Predisposing factors	
	Associations/relieving Factors	
	Previous treatment	
	Hemorrhage	Yes/no
	Recent increase in size	Yes/no
	Description of margins	Regular, irregular, rolled
	Color nature	Homogeneous, heterogeneous
	Depth	Superficial, deep
	Other features	Vesicle, bulla, plaque, papule, nodule, tumor solid
	Ulceration	Yes/no
	If yes, describe appearance	
	Lymphadenopathy	Yes/no
	Discharge	Yes/no
	If yes, please describe the nature of discharge	
Altered Sensation	Yes/no	
If yes, please describe the nature and distribution		
Pigmented lesions of the oral mucosa	Features	Isolated lesion, multiple lesions, persistent lesion, recurrent lesion
	Color	Red lesions, blue lesions, brown lesions, black lesions, pigmented lesions
	Color nature	Homogeneous, heterogeneous
	Site	
	Size	
	Duration	
	Tendency/pain	Yes/no
	Predisposing factors	
	Associations/relieving factors	
	Previous treatment	
	Hemorrhage	Yes/no
	Description of margins	Regular, irregular, rolled
	Depth	Superficial, deep
	Other features	Vesicle, bulla, plaque, papule, nodule, tumor solid
	Altered sensation	Yes/no

Contd...

**Table 3: Contd...**

Data sections	Data elements	Variables
Benign lesions of the oral cavity and the jaws	If yes, please describe the nature and distribution	
	Features	Isolated lesion, multiple lesions, persistent lesion, recurrent lesion
	Color	Red lesions, colored tissue, white lesions, blue lesions, yellow lesions
	Site	
	Size	
	Duration	
	Tendency/pain	Yes/no
	Predisposing factors	
	Associations/relieving factors	
	Previous treatment	
	Hemorrhage	Yes/no
	Lesion process	Fast, slow
	History or evidence of infective etiology	Yes/no
	Shape features	Polypoid, sessile, Peduncalate, nodular, domed
	Surface	Smooth, papillary, verrucous, granulomatous
	Consistency	Soft, firm, hard, rubbery, cheesy
	Lymphadenopathy	Yes/no
	Ulceration of Surface	Yes/no
	If yes, describe appearance	
	Altered sensation	Yes/no
Oral and oropharyngeal cancer	If yes, please describe the nature and distribution	
	Site	Localized, generalized
	Number	Single, multiple lesion
	Margins	Coalescing, well defined
	Duration	
	Tendency/pain	Yes/no
	Predisposing factors	
	Associations/relieving factors	
	Previous treatment	
	Lymphadenopathy	Yes/no
	Lesion process	Fast, slow
	History or evidence of infective etiology	Yes/no
	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
	Depth of invasion	
	Perineural invasion	Yes/no
	Involved or close margins with measurements	Lengthxwidthxthickness in mm
	Tumor stage	Stage 0, Stage I, Stage II, Stage III, Stage IVA, Stage IVB, Stage IVC
	Shape features	Polypoid, sessile, Peduncalate, nodular, domed
	Surface	Smooth, papillary, verrucous, granulomatous
Consistency	Soft, firm, hard, rubbery, cheesy	
Lymphadenopathy	Yes/no	
Ulceration of Surface	Yes/no	
If yes, describe appearance		
Altered sensation	Yes/no	
If yes, please describe the nature and distribution		
Salivary gland diseases	Features	Isolated Lesion, Multiple Lesions, Persistent Lesion, Recurrent Lesion
	Color	Red lesions, colored tissue, white lesions, blue lesions, yellow lesions
	Site	
	Size	

Contd...

**Table 3: Contd...**

Data sections	Data elements	Variables
	Duration	
	Tendency/pain	Yes/no
	Predisposing factors	
	Associations/relieving factors	
	Previous treatment	
	Hemorrhage	Yes/no
	Milking	Normal, parotid, submandibular, sublingual
	Pooling	Yes/no
	Salvia nature	Clear, turbid
	Dry mouth	Yes/no
	Period	Night, day, both
	Dry other parts of the body (eyes, skin, throat, vagina, etc.)	Yes/No
	Swallowing difficulties	Yes/no
	Opening mouth difficulties	Yes/no
	Speaking difficulties	Yes/no
	The amount of salivation	Little, a lot, normal
	Skull – pink disorders	Yes/no
	Intraoral symptoms	Severe decay, severe abrasion, candidiasis, enamel hyperplasia, atrophy of the oral mucosa
	History of fill and empty	Yes/no

CAT=Computed axial tomography, CT=Computed tomography, OPG/DPT=Orthopantomogram/Dental Panoramic Tomogram, PA=It's not acronym

The absence of an agreed-upon framework for recording the dataflow in the differential diagnosis of oral diseases was a challenge. Therefore, with a comprehensive view of this complex process, the suggested framework in this study divided data elements into managerial and clinical sections and four categories including administrative data, historical data, paraclinical indicators, and clinical indicators.

Various studies have been performed to determine the minimum data set in different domains.

In the study of determining the minimum data set for lung cancer, after performing 3 Delphi rounds, the final model consisted of 74 data elements across 8 domains (patient demographics, risk factors, biopsy data, staging, timeliness, treatment, follow-up, and patient selection). This consensus agreement can be used for optimal treatment recommendations and to evaluate team performance.<sup>[7]</sup>

Dominique *et al.* conducted a research for establishment of an internationally agreed minimum data set for acute telestroke in 2020. The final pattern was obtained after an initial scoping review of variables, an international expert panel of clinicians, researchers, and managers from the Australasia Pacific region, USA, UK, and Europe and a modified-Delphi technique via online questionnaires, teleconferences, and E-mail. The consensus model included 110 variables in three themes (service configuration, consultations, and patient information) and 12 categories: details about

telestroke network/program, details about initiating hospital, telestroke consultation, patient characteristics, presentation to hospital, general clinical care within first 24 h, thrombolysis treatment, endovascular treatment, neurosurgery treatment, processes of care beyond 24 h, discharge information, postdischarge, and follow-up data.<sup>[8]</sup>

Here, we point to some evidence for the selection of the data elements in various parts of the suggested framework in this study.

In administrative data section, many data elements were proposed after reviewing the dental claim form, authorization form, dental registration and history, and referral pro forma. In order to facilitate the provision of effective clinical care and ensure the continuity and comprehensiveness of oral/dental health services, it is essential to have a complete chart and record documenting of all the aspects of patient care.<sup>[9,10]</sup> The necessity for clear, accurate, and uniform data collection has been examined in various studies for the comparison of the data extracted from different analyses, system assessment, comparison in national and international research, policy-making, planning and its effects on the comprehensiveness of care plan, and improvement of care and life quality.<sup>[11,12]</sup>

On the other hand, the information about serious illnesses, conditions, or adverse reactions that might impact the provision of safe health care in oral diseases is very important and many recommendations have been



made in order to collect medical history information in a systematic manner. This medical history should include details of past hospitalization and/or serious illnesses, conditions or adverse reactions, cancer/radiation treatment/chemotherapy, drug or alcohol dependency, any known allergies, and any other conditions or problems that the clinician should be aware of. For example, tobacco use, alcohol use, past history of oral-pharyngeal cancer, immunodeficiency, oral infection with human papilloma viruses 16 or 18, sun exposure, and age are known as risk factors for some of the oral diseases, such as oral cancer.<sup>[13]</sup> In this section, data elements are proposed with a comprehensive view of the aforementioned points.

Furthermore, in many oral diseases, diagnosis is made based on a review of data collected through clinical examination along with necessary radiographs, diagnostic study models, and/or the results of any tests or consultations. Oral soft tissue biopsy and imaging techniques, e.g., computed tomography, magnetic resonance imaging, positron emission tomography, and ultrasonography, are utilized in the diagnosis of diseases such as oral cancer.<sup>[14,15]</sup> Therefore, the inclusion of the paraclinical indicator in the suggested framework is essential.

Documentation of the clinical data is essential for the continuity of care, the development of clinical knowledge, the establishment of a base for judgment, a guarantee of security, the management of care,<sup>[16]</sup> a reduction in the number of claims,<sup>[17]</sup> and research purposes.<sup>[18]</sup>

Different data are regarded in the types of oral diseases, and various guidelines were prepared for each type. In this section, the data elements were proposed with a comprehensive consideration of the six main axis of oral soft tissue diseases, according to Burket's Oral Medicine: ulcerative, vesicular, and bullous lesions; red and white lesions of the oral mucosa; pigmented lesions of the oral mucosa; benign lesions of the oral cavity and the jaws; oral and oropharyngeal cancer; and salivary gland diseases.<sup>[1]</sup> During examination, the characteristics of the lesion, e.g., the number, location, size, margins, color, tissue, and consistency, are inspected. In order to facilitate the challenging task of differential diagnosis, different pathological conditions that alter oral soft tissues are scrutinized and divided into three categories: changes in color, surface alterations, and masses or swellings. Based on clinical manifestations, surface alterations in oral lesions are divided into ulcerative, vesiculobullous, and papillary, papular, or polypoid lesions.<sup>[3]</sup> Many soft tissue diseases of the oral cavity include a wide range of lesions with different etiology and the same pathogenesis that sometimes have quite the same histologic and clinical features in a way that

makes them difficult to detect. Thus, a more accurate record of detailed clinical data is required to provide a diagnosis algorithm. The proper management of patients includes diagnosing the lesions of the oral mucosa, which is a cognitive process based on logic and knowledge. The initial differential diagnosis is made based on exclusion, followed by ordering tests and procedures that narrow the diagnosis based on the probability of lesions that have not been removed. In order to increase the accuracy of the diagnosis and assist clinicians by organizing the knowledge of oral pathology, ADA Continuing Education Recognition Program designed a decision tree which simulates the clinical appearance of oral lesions and makes a logical conclusion possible through step-by-step decisions.<sup>[19]</sup>

A range of tests, systems, guides, and equipment are available to dentists to aid in diagnostic decision-making. In the era of information technology, the development of evidence-based clinical practice has led to an interest in early diagnosis based on quantifiable methods to assess the value of such diagnostic procedures. Different studies have been carried out to design a method to give appropriate weight to the results in clinical decision-making and to understand the effectiveness of the procedures.<sup>[20-22]</sup> Recording of data in a structured framework can make these studies more effective.

Administrative data, past medical history, sign and symptoms, physical examinations, and laboratory tests in similar studies are also an important part of MDS.<sup>[23,24]</sup>

This study presents a consensus-based framework for the essential data elements in differential diagnosis in oral medicine, in order to ensure that the necessary steps are taken for effective diagnosis. To our knowledge, this is the first attempt at the objective of structuring the essential data elements in differential diagnosis in oral medicine. The high level of agreement (close to 95%) between experts shows a high degree of unanimity and reflects a considerably uniform professional criterion. A limitation in our study is the selection of participants that all came from Iran, and there may have been a geographic bias. A large-scale and representative study of other countries is required to validate this suggested framework.

## Conclusions

The study achieved close to full agreement in the suggested framework (tool) for structuring the essential data elements in differential diagnosis in oral medicine using a comprehensive search with rich keywords in databases and reference texts, providing an environment for discussion and exchange of ideas among experts and the careful use of the Delphi decision technique.

Embedding this tool in future clinical trials will promote the consistency and transparency in recording data elements in diagnosis process. The tool provides a way of controlling data variance and diagnostic reliability as well as interrater reliability and intertrial reproducibility. It is also useful for clinicians and health information managers in organizing the floating data in the process of diagnosis and proposes a set of quality criteria for future research on the validity of diagnostic methods, thus providing a suitable opportunity for planning national and international studies.

This framework can be used as a foundation for the designing of an intelligent system and for evaluation in a cross-sectional diagnostic or quasi-experimental study in our institution.

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### Conflicts of interest

There are no conflicts of interest.

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