# **Original Research Article**

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# Tool development and validation of the oral cancer patient and diagnostic interval measure

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# ABSTRACT

**Background:** The poor survival rates observed in oral cancer can be improved if diagnosed early. A greater understanding of the patient and diagnostic interval in the diagnostic journey of oral cancer is vital for facilitating early diagnosis. The non-availability of a validated tool for measuring these intervals impedes early diagnosis research. The present study aimed to develop a tool to measure the patient and diagnostic intervals for early oral cancer diagnosis researchers.

**Methods:** To include appropriate questions to get the exact days, the researcher has first searched for published articles on the subject. This was followed by consultations with health care providers. The list of variables finalized through these iteration processes was circulated among the experts for establishing content validity. The face validity of the conceptually equivalent local language version of the tool was also assessed. The tool was developed as an interview schedule.

**Results:** The final tool had 16 symptom response categories and 14 other questions. Items with a content validity index of 0.8 or above were only included. The validated tool was further used in a cross-sectional study on patient interval. The most common initial symptoms recognized by the participants were non-healing ulcer with pain (n=97), tooth mobility (n=26), and non-healing ulcer without pain (n=25).

**Conclusions:** A tool was developed and validated for collecting various time points for measuring various time points in the diagnostic journey of oral cancer. To our knowledge, this is the first tool for measuring patient intervals and diagnostic interval in oral cancer.

Keywords: Diagnostic interval, Oral cancer, Patient interval, Tool development

# **INTRODUCTION**

Oral cancer is one of the most common cancers in South central Asia even though its incidence in other parts of the world is limited.<sup>1</sup> India alone reported more than one-third of total oral cancers in the world in the year 2020.<sup>1</sup> During the same period, India reported 8.5 lakh cancer-related deaths and of these, nearly one-tenth were contributed by oral cancer.<sup>1</sup> The cancer survival rate in India is much lower than that of European and North American countries. As per the national cancer registry program of India, only one-fourth of the head and neck

cancers were diagnosed in the early stages.<sup>2</sup> A systematic review on early oral cancer diagnosis concluded that long intervals from the first symptom to diagnosis as a risk factor for mortality from oral cancer.<sup>3</sup> Although delayed diagnosis and associated poor survival outcomes are well documented in the literature, there exists a dearth of information on the magnitude of patient interval and diagnostic interval in oral cancer.

There are no validated tools for examining the extent of delay in the diagnosis of cancer in general and oral cancer in particular.<sup>4</sup> The cancer-symptom interval measure (C-

SIM) tool developed by Neal et al is the only validated tool for measuring patient interval and diagnostic interval in the diagnostic journey of 11 common cancers in the United Kingdom.<sup>5</sup> Unfortunately, oral cancer was not one among them. Such a tool is necessary for conducting situational analysis before the planning and implementation of programs for early diagnosis.<sup>6</sup> It can also be used for evaluating the effectiveness of interventions promoting early oral cancer diagnosis. These circumstances necessitated developing a tool specific for oral cancer to identify patient and diagnostic intervals. The purpose of this paper was to report the development and validation of an interview schedule to measure the patient interval and diagnostic interval in oral cancer.

# **METHODS**

The following steps were taken for developing and validating the oral cancer patient and diagnostic interval measure (OC-PDIM) tool. The present exercise did not have a reliability aspect as the purpose was to develop a valid tool to measure the intervals from calendar dates. Moreover, the tool was administered as an interview schedule. This is the tool development process before data collection. The final tool was approved by the institutional ethical committee as per the guidelines.

# Step 1: Literature review

The current literature was searched primarily for identifying tools for capturing patient interval and diagnostic interval in oral cancer. For a literature search, the following keywords were used: "mouth neoplasms", "oral cancer", "patient interval", "patient delay", "presentation delay", "diagnostic interval", "diagnostic delay", "provider delay", and "professional delay". These keywords were used in various combinations using Boolean operations "AND" and "OR". Zotero reference management software was used for removing duplicates. The PubMed search could not find any existing tool for calculating the patient interval or diagnostic interval in oral cancer. The absence of a validated tool for estimating patient interval and diagnostic interval in oral cancer necessitated developing a new validated tool. Though the literature search did not fetch any relevant instrument for oral cancer, one validated instrument for measuring various time intervals in the diagnostic journey of 11 other types of cancers was identified. The instrument, named 'cancer symptom interval measure' (C-SIM), was developed by Neal et al in 2014. However, it did not include oral cancer.5

# Step 2: Development of an inventory

The C-SIM tool helped in conceiving the inventory for estimating patient and diagnostic intervals in oral cancer.<sup>5</sup> The main purpose of developing the tool was to identify the three-time points in the diagnostic journey of oral cancer. They include the 'date of symptom recognition by

the patient,' the 'date of presentation of the above symptom to a health care provider', and the 'date of histopathological diagnosis of cancer'. Identification of the date of initial symptom recognition is a challenge as it largely depends on the patient's oral cancer symptom awareness and interpretation of bodily changes. Considering this, all symptoms suggestive of oral cancer and oral pre-cancer were listed based on the existing literature. Apart from identifying these time points, the draft tool also had questions for identifying discussion intervals and routes to diagnosis. Discussion interval is the time taken by the participant for discussing the problems in their oral cavity with significant others before consulting a health care provider for the same. Routes to diagnosis is the number of health care providers consulted in the diagnostic journey of oral cancer, from initial consultation to final diagnosis. The inventory listed 12 symptoms suggestive of oral cancer/oral pre-cancer and nine other questions to identify routes to diagnosis and other characteristics of help-seeking concerning the current problem in the oral cavity.

# Step 3: Expert consultation

The newly developed inventory was discussed with practitioners in the field of oncology, dentistry, and medicine. Practitioners in these fields are directly involved in the diagnosis and management of oral cancer. The understanding and experience of these practitioners about the oral cancer diagnosis helped in modifying the Interview schedule. These discussions also helped to delineate various symptoms reported by the patient when they first report the disease condition to a health care provider. Sixteen practitioners participated in this exercise and gave their feedback. They include practitioners from surgical oncology (n=2), community oncology (n=2), oral medicine (n=4), otorhinolaryngology (n=2), general dentistry (n=4), and general medicine (n=2). They provided feedbacks either through face-to-face interviews or e-mail or telephone. Experts reviewed the adequacy and inclusiveness of the Interview schedule. They also identified the redundant questions. The interview schedule was modified based on their comments. Based on the expert consultation, some new questions were added, a few existing ones were removed and some were reframed. The modified inventory had 18 symptom response questions and 18 other questions.

# Step 4: Content validity

A ten-member expert panel reviewed the interview schedule to assess content validity. They reviewed each item for its relevance and appropriateness for the study. They also examined the grammar and appropriate usage of language for each of the items in the tool. They were requested to rate each item on a four-point ordinal scale as irrelevant (1), somewhat relevant (2), relevant (3), or very relevant (4).<sup>7</sup> The Content Validity Index (CVI) is an index that is estimated for each item in the tool by

computing the proportion of experts who have assigned either three (relevant) or four (very relevant) points to the item divided by the total number of experts who have participated.<sup>7</sup>

$$CVI = \frac{No. of experts scored 3 or 4}{Total number of experts}$$

CVI is the proportion of experts who agrees on the relevance of each item. Those items that received a content validity index of 0.8 or more were considered relevant and valid.<sup>8</sup> Only those items were included in the final tool.

#### Step 5: Translation and back translation

A conceptually equivalent version of the interview schedule in the local language 'Malayalam' was also prepared using the back-translation method.

#### Step 6: Face validity

The 'Malayalam' version of the interview schedule was administered to ten people as cognitive piloting. Participants include oral cancer patients (n=5) and other patients (n=5). They were requested to review the questions and provide suggestions concerning their meaning, clarity, comprehension, appropriateness of sentence structure, and difficulty for answering. The tool was modified based on the feedback received from the study participants.



# Figure 1: Steps in the development and validation of the tool for identifying the selected time points in the diagnostic journey of oral cancer.

#### Step 7: Modified protocols for calculating 'pseudoexact' dates from 'estimated dates'

"Exact date" and "estimated date" are the two types of dates provided by the patient in response to questions on patient interval and diagnostic interval. "Exact date" is the actual date of occurrence of an event. Estimated date is an indicative date of occurrence of an event provided by the patient which is not the actual date. "Pseudo exact date" is a date closer to the exact date derived from the estimated date with the help of the protocol. Patients often fail to provide the exact date for various time points in the diagnostic journey of cancer such as the 'date of symptom recognition, the 'date of first reporting of symptoms to a health care provider'. They generally provide an estimated time for the occurrence of the above-mentioned time points. In cases where the patient forgets the exact dates of events, the only alternative left is to identify a pseudo exact date of occurrence of an event from the estimated date provided by the patient. A protocol for calculating pseudo exact dates from the estimated dates was given by Neal et al.<sup>5</sup> If the patient reported an estimated date of six months, then according to the protocol six months must be counted back from the completion date to identify the pseudo exact date. Similarly, if the patient reported a 'few months', then 'three months' may be counted back from the completion date. If the patient reported a range of months or years, then we should calculate the midpoint of that range and then count back that from the completion date to get the pseudo exact date. For example, if the patient reported the estimated date as four to five years ago, then count 4.5 years from the completion date to get the pseudo exact date.<sup>5</sup> Instances where the patient reports incomplete dates like 'year only' or 'month only', then consider the middle of the year /month as the pseudo exact date. To illustrate this, let's consider some estimated dates like "in 2009" or "in June 2010". The pseudo exact dates for the above-estimated dates were "1<sup>st</sup> July 2009" and "15<sup>th</sup> June 2010". Patients often report estimated dates using the adjectives 'early' or 'late'. The pseudo exact dates for the estimated dates like "early 2020", "late January", "beginning of March", and "end of 2009" are 15<sup>th</sup> February 2020, 23<sup>rd</sup> January, 1<sup>st</sup> March and 31<sup>st</sup> December 2009 respectively.<sup>5</sup> Changes were made in the protocol by incorporating seasons and festivals specific to our country and state.<sup>5</sup>

 Table 1: Protocol for calculating 'pseudo-exact' dates from estimated dates to calculate time intervals in the diagnostic journey of oral cancer.

Text for an estimated date	Rule	Example text	Example recode
Seasons and holidays			
'Summer or pre-monsoon season- search March to May	15.04.xxxx	'Summer 2019	15.04.2019
'Early Summer	15.03.xxxx	'Early Summer 2019'	15.03.2019
'Late summer'	15.05.xxxx	'Late summer 2019'	15.05.2019
Monsoon or rainy season- search June to August	15.07.xxxx	'Monsoon 2019'	15.07.2019
'Early Monsoon'	15.06.xxxx	Early Monsoon 2019'	15.06.2019
'Late Monsoon'	15.08.xxxx	'Late monsoon 2019'	15.08.2019
Post-monsoon- search September to November	15.10.xxxx	'Autumn 2019'	15.10.2019
'Early Autumn'	15.09.xxxx	'Early Autumn 2019'	15.09.2019
'Late Autumn'	15.11.xxxx	'Late Autumn 2019'	15.11.2019
Winter- search December to February	15.01.xxxx	'Winter 2019'	15.01.2019
'Early Winter'	15.12.xxxx	'Early Winter 2019'	15.12.2019
'Late Winter'	15.02.xxxx	'Late Winter 2019'	15.02.2019
Republic day	Recode to exact date	Republic day 2019	26-01-2019
Sivarathri	Recode to exact date	Sivarathri 2019	04-03-2019
Vishu	Recode to exact date	Vishu 2019	15-04-2019
'Good Friday'	Recode to exact date	'Good Friday 2019'	19.04.2019
Easter	Recode to exact date	'Easter 2019'	21.04.2019
Id ul Fitr	Recode to the exact date	Id ul Fitr	05-06-2019
Independence day	Recode to exact date	Independence day 2019	15-08-2019
Thiruvonam	Recode to exact date	Thiruvonam 2019	11-09-2019
Xmas	Recode to exact date	'Xmas 2019'	25.12.2019
Before Xmas	15.12.xxxx	Before Xmas 2019	15.12.2019
After Xmas	31.12.xxxx	After Xmas 2019	31.12.2019

Adapted from the Protocol for calculating 'pseudo-exact' dates from estimated dates to calculate time intervals.<sup>5</sup>

# RESULTS

The final tool had 16 symptom response categories. For each of the symptom response categories, the patient was asked to provide the exact day/closer day of recognizing that symptom. They were also asked about their initial thoughts about that symptom. The symptom response categories help to identify the date of symptom recognition for measuring the patient interval and the question 'when did you first meet a health care provider for discussing the symptom in your oral cavity?' will provide the 'date of symptom reporting'. Subtracting the date of symptom recognition from the date of symptom reporting will give the patient interval.

Patient interval = Date of symptom reporting – Date of symptom recognition

The two-time points required for calculating diagnostic interval are 'date of symptom recognition' and 'date of diagnosis'. The date of diagnosis was identified as per the directions given by the European Network of Cancer Registries.<sup>9</sup>

Diagnostic interval = 'Date of diagnosis' - 'Date of symptom reporting'

A new concept called 'discussion interval' can also be calculated through this tool. Discussion interval is the time taken by the patient for discussing their health problem with significant others.

Discussion interval= 'Date of symptom recognition' – 'Date of discussion with others'

Apart from these intervals, the tool also helps in identifying the number of health care providers consulted in the diagnostic journey, the type of health care provider first consulted for the present oral problem and the compelling reason for initial HCP consultation, etc.

# Table 2: Symptom response categories included in the oral cancer patient and diagnostic interval measure (OC-PDIM) tool.

S. no.	A. Symptom response categories	Yes /No	If yes, please give an exact/closer date
1	A non-scrapable white patch or plaque		
2	A non-scrapable red patch or plaque		
3	A non-healing oral ulcer with pain		
4	A non-healing oral ulcer without pain		
5	Burning sensation in the oral cavity		
6	Dryness in the oral cavity		
7	Inability to take hot or spicy food		
8	Restricted mouth opening		
9	The difficulty for tongue movements		
10	An abnormal growth without pain		
11	An abnormal growth with pain		
12	Difficulty in swallowing		
13	Un explained tooth mobility		
14	Un explained bleeding from the oral cavity		
15	Un explained the change of sensation in the oral cavity		
16	Mucosal erosions in the oral cavity		
17	Any other change you observed in the oral cavity		
В	If your answer to categories 1 to 16 is "No", then how did y cavity?	ou come to	know about the problems in your oral
	(open-ended response)		

# Table 3: Questions about patient interval, diagnostic interval, and routes to diagnosis.

С	What was your first response to the symptom you recognized in your oral cavity?	
	1. Attributed symptoms as minor 2. Waited to see whether it will be resolved spontaneously 3. Tried some home	
	remedy 4. I prayed to god 5. Consulted a doctor 6. Tried herbal medicine 7. Others	
п	Did you mention or discuss the problems in your mouth with anyone else before meeting a Health Care Provider	
D	for the first time for discussing the same?	
	1. Yes, 2. No	
Е	If yes, what did the person you talked to suggest? (open-ended response)	
F	If yes, how much time do you take to discuss the same with that person? (open-ended response)	
G	What is this person's relationship with you?	
	1. Spouse 2. Son 3. Daughter 4. Father 5. Mother 6. Brother 7. Sister 8. Relative 9. Friend	
	10.Colleague 11.Others	
тт	When did you first meet a health care provider for discussing the symptom in your oral cavity? (Please give an	
п	exact date/ closer date) (open-ended response)	
Ι	Which type of Health Care Provider did you meet first?	
	1. General practitioner 2. Dental surgeon 3. ENT surgeon 4. General surgeon 5. Other medical specialists 6.	
	Cancer specialist 7. Ayurveda practitioner 8. Homeopathy practitioner 9. Other AYUSH Practitioner 10.	

	Traditional healers 11. Other
J	What was the first advice you received from that health care provider?
	1. Ignored the symptom as minor 2. Asked for review 3. Advised biopsy 4. Referred to higher center 5. Others
K	What prompted you to see a Health Care Provider?
	1. Pain 2. Discomfort 3. Increase in size 4. The insistence by family 5. The insistence by friends 6. Affected normal routine 7. Others
L	Please describe the important incidents/ events/ occasions that happened in your life in the period after you recognize the above-mentioned problem in your oral cavity? (open-ended response)
М.	So far, how many Health Care Providers were consulted for the above-mentioned problem in your oral cavity? (open-ended response)
N.	Date of diagnosis (open-ended response)
0.	Stage of disease at the time of diagnosis (from patient case file)

The tool was used to conduct a cross-sectional study among 261 oral cancer patients to identify the various time points in the diagnostic journey of oral cancer. The findings of the study including patient interval, discussion interval, and other factors contributing to it were published elsewhere.<sup>10</sup> The most common initial symptoms reported by the study participants were nonhealing ulcer with pain (n=97), tooth mobility (n=26), non-healing ulcer without pain (n=25), difficulty in swallowing (n=23), white patch (n=18), abnormal growth with pain (n=17), abnormal growth without pain (n=16), and burning sensation (n=11). Nearly half of the participants (46%) considered the initial symptom as a usual mouth ulcer or an ulcer from cheek or tongue bite. or as tooth or denture-related trauma. Just 3.8% of the participant considered their initial symptom as abnormal or suggestive of cancer. Trivialization of the symptoms. relating it to a pre-existing condition or attributing it to a previous history of trauma, or attributing to the existing habits were the other thoughts on their initial oral cancer symptom. Some people attributed the symptom as a sequel to their existing dental problem.

# DISCUSSION

The development of a tool for identifying the length of diagnostic journey in oral cancer is highly relevant owing to its association with disease prognosis and survival. Apart from that, the availability of such instruments will help in evaluating the effectiveness of interventions for the early diagnosis of oral cancer.<sup>4</sup> The role of early diagnosis in cancer survival is well documented in the literature but our understanding of various processes and factors influencing early diagnosis is limited.<sup>9</sup> This is of particular importance as survival rates of various cancers in different countries and regions within the country vary considerably. Developing and developed countries differ in cancer survival rates, highlighting the role of access and utilization of diagnostic and treatment facilities.<sup>11</sup> A thorough examination of the early cancer diagnosis research by a group of researchers observed the poor detailing of the methodology and instrument development process.9 The definitions for patient interval and diagnostic interval used in the instrument conform with the Aarhus statement.<sup>9</sup> Walter's refinement of the

Andersen Model of Total Patient Delay and the World Health Organization's guide to Early Cancer Diagnosis provided the necessary guidelines for conceptualizing the tool.<sup>6,12</sup> The cancer symptom interval measure (C-SIM) was the only available validated tool for measuring patient interval and diagnostic interval in cancer.<sup>5</sup> The C-SIM version for colorectal cancer consists of four symptom response categories specific to colorectal cancer whereas, in our tool, we have 16 symptom response categories mainly due to the anatomic and functional complexities of the oral cavity.<sup>5</sup> One of the challenges in determining the patient interval in oral cancer or any other cancer is the difficulty in obtaining the exact date of initial symptom onset. Several factors influence the recollection of that date by the patient, most importantly patients' symptom awareness level and symptom interpretation process.<sup>13</sup> To overcome this limitation to an extent, the tool has an exhaustive list of symptoms reported by oral cancer patients during their initial consultations. For this, consultations were made with health care practitioners who are primarily involved in managing diseases of the oral cavity to list the common symptoms reported by oral cancer patients. This helped in preparing a comprehensive list of all possible oral cancer symptoms. Another challenge is arriving at a date closer to the exact date of symptom occurrence from the estimated date provided by the patient. The protocol used by Neal for their C-SIM tool is a valuable protocol for arriving at a pseudo exact date.<sup>5</sup> The same protocol was followed for identifying the date of symptom reporting to a health care provider. Many times patients provide documentary proof of their initial consultation in the form of a referral letter or medical prescription. The date of diagnosis was determined by following the Hierarchy for defining the date of diagnosis provided by European Network of Cancer Registries.<sup>9</sup> The term 'discussion interval' in the diagnostic journey of cancer was first described in our study. Other relevant questions like compelling reason behind first consultation, routes to diagnosis, and type of health care provider first consulted were also included in the tool.14

Cancer patients generally experience anxiety during the course of cancer treatment and follow-ups.<sup>15</sup> Patient anxiety is a challenge in studies involving cancer patients.

Studies that recruit cancer patients should explore ways to reduce anxiety among them. A previous study has shown that the method of data collection has a direct bearing on patients' anxiety levels and the findings favoured an interviewer-administered questionnaire over a self-completed one for reducing patient anxiety.<sup>5</sup> Moreover, there are limits on the validity of the responses of self-completed questionnaires in early diagnosis research.<sup>14</sup> Considering these observations, the newly developed 'oral cancer patient and diagnostic interval measure' (OC-PDIM) tool is developed as an interview schedule.

# CONCLUSION

A tool was developed and validated for collecting various time points for measuring patient interval, discussion interval, and diagnostic interval in the diagnostic journey of oral cancer. The tool was further used in a study and established its feasibility and acceptability for use in early diagnosis research. To our knowledge, this is the first tool for measuring patient interval and diagnostic interval in oral cancer. Researchers from countries where oral cancer pose significant public health problem can use this tool for identifying the length of the diagnostic journey in oral cancer. This tool can also be used to assess the effectiveness of programs for promoting the early diagnosis of oral cancer.

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