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Integrating tobacco cessation into routine dental practice: protocol for a mixed-method qualitative study in Ahmedabad, India

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Title Page

Integrating tobacco cessation into routine dental practice: protocol for a mixed-method qualitative study in Ahmedabad, India

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KEYWORDS: Qualitative, Interview, Oral health professional, Dental patient, Protocol

ABSTRACT:

Introduction: Combined efforts encompassing different aspects of tobacco control have been in place for some time. Despite recognition of the need to offer support to the tobacco users to quit tobacco use, such support remains highly inadequate in India. However, little is known about the practice of oral health professionals (OHP) and the experiences and expectations of dental patients in context of tobacco cessation (TC) services. In this article, we describe the protocol of a doctoral research project that explores the OHP and their patients in an Indian city. The aims are (a) to understand functioning of oral health care system towards TC and what changes in it will be needed to benefit TC (b) to capture the views of dental patients on TC services provided by OHP .

Methods and analysis:

A cross-sectional qualitative study based on individual interviews with OHP and dental patients will be carried out in the city of Ahmedabad, Gujarat, India. The OHP will be stratified into two groups: general OHP (dentists practicing general dentistry irrespective to their qualification) and Prosthodontists (dentists with specialization in Prosthodontics).We would further divide these dentists into two categories based on the organization type they work in: (1) stand-alone dental clinics and (2) dental hospital attached to teaching institutions .We will sample dental patients through convenient sampling from a public teaching hospital and select private dental care facilities. The sampling will continue till we reach data saturatio. Interviews will be audio-recorded with prior written consent and transcribed verbatim. Thematic content analysis following the six-phase iterative process suggested by Braun and Clark will be applied.

Ethics and dissemination: Ethical approval for this research was granted by the Institutional Ethical Committee at the Government Dental College and Hospital, Ahmedabad. The findings will be disseminated through conference presentations and peer–reviewed publications.

ARTICLE SUMMARY

Strengths and limitations of the study

- Study will allow in-depth understanding of the challenges and possibilities of tobacco cessation (TC) in current dental practice of oral health professionals (OHP) working in different clinical set-ups.
- The study will generate knowledge that could inform practices of oral health care to bring about regulatory or institutional changes and will help in policy development and design resulting in tailored TC policy for OHP working in different types of set-ups.
- It will be useful in informing similar inquires in other settings and pave path for future research.
- The study site would limit the relevance of the findings to similar metropolitan areas as smaller towns are likely to present different organizational set-up and challenges.
- Convenient sampling of patients may not be representative of the patient community in the city at large.

BACKGROUND

What is Known

The need to provide tobacco cessation (TC) as a part of the primary health care is long acknowledged. Research has shown brief tobacco intervention by oral health professionals (OHP) has an impact on the quit

rates of tobacco users .There have been several studies in India exploring the role of OHP in TC that reveal that an overwhelming majority of them are willing to engage in TC .However this willingness does not readily translate into practice. The major barriers perceived for this include lack of training, lack of time, lack of financial incentives, and intriguingly, the fear of losing out on patient.

What This Paper Adds

To bridge the gap between willingness and practice, this research goes beyond the survey of individual OHP to an interview based study design .Guided by the WHO health system building blocks, the study will provide a deeper understanding of oral health care system as they operate today in the Indian scenario and not seeing TC as merely a technical intervention but something that might get affected and in turn get shaped by various building blocks of oral health system. In addition the study explores the perspective of dental patients in context of TC services. The overall goal is to improve TC integration in routine care by generating knowledge that could inform practices of oral health care and future research, and help in policy development and design resulting in tailored TC policy for OHP working in different types of set-ups.

INTRODUCTION

India is the second largest consumer of tobacco with 28.6 % of adults being current users of one or other tobacco products. [1] In 2010, tobacco use was estimated to have caused about 1.3 million adult deaths in India. [2] [3] Tobacco use is associated with several morbidities including oral diseases. India has one of the highest incidences of oral cancers in the world. [4] About 90% of these cancers are related to tobacco use. [5] Several tobacco control measures taken by Indian government, including a national legislation (Cigarette and Other Tobacco Products Act, 2003), a national program on tobacco control and ratification of the World Health Organization Framework Convention on Tobacco Control has pushed up the demand for TC services. The recent nation-wide survey suggests that 55.4% of the current smokers and 49.6% of current smokeless tobacco users are planning to quit tobacco use. [1]

Despite recognition of the need to offer support to the tobacco users to quit tobacco use as an important component of the tobacco control policy prescription (MPOWER) by the World Health Organization, such support remains highly inadequate in India. The Ministry of Health and Family Welfare (Government of India) with the support of the World Health Organization had started 19 tobacco cessation clinics in India. [6] However, majority of these centers are located in tertiary /super specialty hospitals. Hence, these centers often end up serving people who have already suffered from severe tobacco use related harms with very little scope of preventive and early interventions. Through the national tobacco control program, the government has attempted to organize counseling support in select districts across India. More recently, the national government has started a phone-based and mobile-phone app based support to tobacco users.

While these initiatives are very much needed, we are yet to fully optimize the potential that the formal healthcare services offer in terms of providing integrated TC services. At present only a half of the current smokers and only a third of the current smokeless tobacco users get some advice from healthcare providers for tobacco cessation. [7] Hence, there is room for integration of brief tobacco cessation intervention in general health care services, with oral healthcare services providing unique potential. The oral healthcare providers have an easy access to tobacco users in the early stages providing an opportunity to intervene. They often have more chair-side time with patients than other clinicians. Tobacco use prevention also enhances dental treatment outcomes. Some dental specialists, such as prosthodontists require spending longer time with patients and need several follow-ups providing them with opportunity to reinforce messages on cessation.

While, OHP are known to be very much willing to offer TC advice, they rarely put TC in practice. There seems to be several barriers that explain this gap between their willingness and practice with regard to TC. [8 9] There is a dearth of research on how to overcome these barriers and integrate cessation into routine dental care. In this paper, we present a protocol for a doctoral research that aims to better understand how TC could be integrated

into routine dental practice by general OHP and Prosthodontists working in public and private set-ups in Ahmedabad, India.

In order to better understand how to integrate TC into routine dental practice, we aim to address the following specific research questions:

- How current TC service (if at all) is organized in oral healthcare facilities in Ahmedabad city across major organization types (single-doctor practice and teaching-hospitals)?
- What are the suggestions by OHP with regard to feasibility of integrated TC support within routine dental practice?
- What are the needs and expectations of dental patients with regard to TC support?
- What sort of intervention protocols/prototypes can help in integrating TC in routine dental practice?

METHOD

Study Design and Setting

We propose to conduct a cross-sectional qualitative study based on individual interviews of OHP and dental patients. The study will be carried out in Ahmedabad, the largest city in the western Indian state of Gujarat with a population of over seven million. It is the sixth largest city and the seventh largest metropolitan area in India. The Ahmedabad urban population based cancer registry (PBCR) reports highest proportion of tobacco related cancer for both males (56.3%) and females (19.8%). [10] The incidence rate of mouth cancer among men from the urban population of Ahmedabad have increased markedly from 1985 to 2010. [11] The oral healthcare services available here are in the form of government and private care setup. With more than 1500 private oral health care set-ups, the city has two government and three private dental hospitals attached to teaching institutes.

Study Sampling

Oral Health Professional (OHP)

We will sample OHP, as in the study context, they are mostly owners and/or managers of dental care facilities. We will stratify them into two separate groups to be interviewed: general OHP (dentists practicing general dentistry irrespective to their qualification) and Prosthodontists (dentists with specialization in Prosthodontics practicing Prosthodontia). We would procure the list of general OHP and Prosthodontists in Ahmedabad through the dental directory (by Dental Health Foundation) and membership directory of the Gujarat Prosthodontic Forum (a state branch of the Indian Prosthodontic Society) respectively. We would further divide these OHP into two categories based on the organization type of dental care facilities they work in: (1) stand-alone dental clinics providing general and/or specialist dental care; and (2) specialist hospital (dentistry) attached to teaching institutions. These two set-ups present very different organization form. We will then start sampling OHP from these categories using computer-generated random numbers. The sampling will continue till we reach data saturation with specific groups. The broad inclusion criteria for OHP would be that they have a formal recognized qualification and registration with the Dental Council of India and are presently practicing dentistry in Ahmedabad city.

Dental Patients

We will sample dental patients through convenient sampling from a public teaching hospital (government dental college and hospital, Ahmedabad where the first author is affiliated) and select private dental care facilities within the social networks of the authors in Ahmedabad city. We shall ensure that our sample represent patients from across categories of OHP and dental care organization types as discussed in the earlier section on sampling OHP. The broad inclusion criteria for patients would be that they are adults (aged 20 years or above) who are tobacco users and currently undergoing dental treatment or have undergone some dental treatment in last one year. We shall exclude patients with debilitating physical and mental conditions.

Data Collection

We will interview sampled OHP and patients using semi-structured interview guides. The interview guide for OHP [Supplementary 1] is shaped using the building blocks for health systems proposed by the World health Organization [8] as well as considering the known barriers for TC in dental practice reported in literature. [9] The purpose of these interviews is to understand how TC (if at all) is being practiced and organized and any suggestions by OHP in this regard. The interview guide for patients [Supplementary 2] is aimed at eliciting their TC support, needs and expectations as well as their prior experience in this regard within dental facilities. Both the guides will be field tested through interviewing a small sample of OHP and patients, and will be further refined for clarity and relevance. The first author will conduct all the interviews in any/mix of languages that the participants are most comfortable with.

Ethics and dissemination

This study has been approved by the Institutional Ethical Committee at the Government Dental College and Hospital, Ahmedabad. The first author will telephonically contact the sampled OHP explaining the purpose of the study and securing their appointments. After explaining the study purpose and the voluntary and anonymous nature of participation, the first author will seek their written informed consent. Interviews would be conducted at a place (that assures privacy and comfort) and time convenient to them. Similarly, after explaining and seeking informed consent, patients will be interviewed in a separate room (ensuring privacy and comfort) within healthcare facility and/or at their preferred place. The interviews will be audio-recorded following permission for the same from the participants. The first author, for further analysis, will then transcribe these records. These recordings and transcripts will be stored in a password-protected folder in a computer and back-up disk of the first author. The findings of the study will be shared with all stakeholders of this research and will be disseminated through conference presentations and peer–reviewed publications.

Data Analysis

We will use thematic content analysis following the six-phase iterative process suggested by Braun and Clarke: 1) familiarizing self with data 2) generating initial codes 3) searching for themes 4) reviewing themes 5) defining and naming themes and 6) providing the report. [12] [13] [14] We will do content coding using mix of inductive and deductive approach i.e. while we would look for coding material relevant to WHO health system building blocks themes, we would also openly code material that respond to our research questions. The data will be presented as dominant themes explaining research objectives.

Patient and Public Involvement

Our research question concerning integrating tobacco cessation in routine dental care is, in part, based on relative lack of proactive assistance offered by healthcare providers for tobacco cessation as reported by tobacco users and general public in a large scale survey in India. Our study design involves interviewing dental patients to better understand their expectations and experiences with regard to tobacco cessation by their dental care providers. We will seek informed written consent after providing and explaining a participant information sheet to the sampled patients. We plan to publish study results in an open access journal. A simple brief summarizing the study results and recommendations will be produced and disseminated to concerned stakeholders, including the study participants who opt for receiving one at the time of participation in the study.

DISCUSSION

Dentistry in current times is oriented more towards curative rather than preventive aspect. Studies show that OHP value preventive part of dentistry but find it difficult to practice and personally disreputable. [15] [16] [17] With the OHP being aware of the benefits and need of TC, the bridge between the willingness and practice is missing. This study will delve into the current practice and organizational set-up of OHP to understand the

possibilities and potential of integrating TC into routine care. The opinions of dental patients regarding TC will further shape the integration policies for the dental practice. Generating such data will help to make policy, regulatory or institutional changes that will be easily acceptable and make the preventive aspect of dentistry more effective.

Strength and Limitation

The selected study site would limit the relevance of findings to similar metropolitan areas in the state as smaller towns and rural areas are likely to present different organizational set-up and challenges with regard to TC practice. Convenient sampling of patients in our study may not be representative of the patient community in the city at large. However, the qualitative nature of the study allows for in-depth understanding of the challenges and possibilities of TC in dental practice. Beyond specific context of the study setting, such work is useful in informing similar inquiries in other settings but is not amenable to strict generalization possible in quantitative experiments.

CONCLUSION

The study explores the OHP, the system in which they work and their patients. Hence, at conclusion the study will lead to the designing of specific protocols for improving integration of TC in routine practice.

Authors' Contributions: R.S. and U.B. conceived the research idea and designed the study. R.S. wrote the initial draft of this paper. R.S., S.S. and U.B. edited and revised the paper.

Supplementary data:

Supplementary File 1 : Semi Structured Interview Guide for Oral Health Professionals (OHP)

Supplementary File 2 : Semi Structured Interview Guide for Dental Patient

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Conflicts of Interest: The authors declare no conflict of interest.

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Guide For Conducting Semi-Structured Interview With Oral Health Professional

[The purpose of this interview is to map organizational characteristics of the dental practice and the perspective of the dentist on tobacco cessation in Ahmedabad to understand possible health service interventions to improve tobacco control from dentists' perspective along with factors that may facilitate or hinder the same]

1. **Introduction**

Greet the doctor and thank him/her for giving appointment for interview.

Introduce yourself (interviewer) and Government Dental College and Hospital, if the interviewee is not already familiar with you.

Provide the interviewee with the leaflet on the study design and briefly explain about the study.

Explain about confidentiality and use of the study outcomes.

Introduce the consent form. Ask for consent to audio recording and note taking.

2. **Interview**

Start by asking some general questions that interviewee would be comfortable to answer….

So ,sir, tell me something about your practice….since how long are you practicing/working here? (In case of long practice)How different this area was when you had started the practice?

Collect the basic demographic data of participant (name, gender, age, religion , caste)

How many patients, who are also tobacco users, do you see in a month or in a week? Tell me about their general profile (age, education, economic background, occupation, etc)

Depending on the issue under conversation, a shift can be made to any relevant inquiry theme below. Ensure that all the themes are covered in the interview. Any new theme /concept brought in by the interviewee shall be accommodated and be probed if deemed relevant.

Information System

Please describe the kind of data/information you collect regarding tobacco use .How do you do this? (what kind of data: chewable or smoking tobacco, frequency, family history,…How: data remains with dentist/patient/both, on the case paper/diary/register/computer based system. If you are in doubt ,request him/her to show relevant paper/register)

How has been your experience with this system? What kind of challenges you face?

How these data help you? (If no data is collected) Do you see any use of collecting data/information of tobacco use by your patient?

(For what use: monitor treatment outcomes, shape ongoing practice, enhance person centered care, enable reminder services for patient follow-ups)

Health Workforce

Do you think it is the moral responsibility of a dentist to identify and provide brief tobacco interventions to every tobacco user who presents to your oral health care facility?

Please explain type of your practice (Individual / team), *who all work in this clinic/hospital with their qualification/ training, roles and responsibilities*. (ask details on doctors qualifications, year of graduation , experience etc.)

When a patient visits your clinic or hospital, what is the sequence of procedure and is done by whom? (inquire about who does the registration, history taking, examination, treatment procedure and post treatment advices)

How do you update your knowledge/skill regarding all the aspect of your practice? (probe specifically about tobacco related knowledge)

Did you or any of your team members undergo any specific training on tobacco control? If yes, please provide details.Are you aware of or following any guidelines for tobacco cessation?

Do you or any of your team member use tobacco? (if yes , how do you think will it affect the tobacco cessation practice ? if no, what is the effect of being a non-tobacco use role model) *Are you aware of any tobacco dependence treatment specialist in your city?*

Service Delivery

Do you see any patients who primarily come for tobacco de-addiction?When you treat a general patient using tobacco, do you point out (identify) their tobacco use habit? (ask if they talk of its ill effects and the advantages of quitting?, if yes how much time do they spend doing this and try to bring out the facilitators. if no, what are the barriers)

Do you have any material in your setup regarding tobacco control or de-addiction (Models, posters, documentary, self help materials, etc.)

How do you proceed if a patient demands tobacco de addiction service or wants to quit because of your advice? (counseling, support material, medication, referring to specialist)

What do you do for the patients who are tobacco users and not ready to quit? (probe further for future advice)

Do you think a team approach, where different roles and responsibilities are allotted to the team members, can help to promote tobacco control in your set-up? (ask if the barriers can be overcome by this way)

Governance And Leadership

Please describe all the regulatory requirements that you need to meet in order to practice. (practice license form municipal health department, registration with respective education council, certification from pollution control board..) *What are your views about these regulations? Do providers take them seriously?*

OHP can play an important role in tobacco cessation of their patients! do you agree to this statement? why?

Does government recognize your role in TC does it provide any support to you for this?(any guidelines, protocols, incentives etc)

Do you think incentives can motivate you more to provide cessation services for your patients?

What do you think will be the impact of making all the oral health care facilities tobacco free? (smoke free should be made tobacco free)*Can you tell me about any rules or guidelines (if any) that your staff has to follow in regards to tobacco control?*

What else in your opinion can the government do to curb the widespread use of tobacco products?

Medical Products And Technologies

Are you aware of any medications for tobacco cessation? (ask about NRTs, Non NRTs.. and its availability)*If yes, then how did you come to know about it? If no, do you think knowledge regarding these medications can help you provide TC service better?*

Do you think items such as TC guide, protocol, toolkit, posters, brochures, self-help materials, risk charts, motivational tools can help in providing TC services?

Financing

Do you think covering the cost of tobacco dependence treatment in health insurances can help providers as well as the patients?

What do you think about taxes levied on tobacco products?

Guide For Conducting Semi-Structured Interview With Dental Patients

[The purpose of this interview is to capture the attitude, knowledge and behavior of dental patients towards tobacco cessation in Ahmedabad to understand possible health service interventions to improve quality of care from patients' perspective along with factors that may facilitate or hinder the same]

1. **Introduction**

Greet the patient and thank him/her for giving the interview. Introduce yourself (interviewer) and Government Dental College and Hospital.

Provide the interviewee with the leaflet on the study design and briefly explain about the study.

Explain about confidentiality and use of the study outcomes.

Introduce the consent form. Ask for consent to audio recording and note taking.

2. **Interview**

Start by asking some general questions that interviewee would be comfortable to answer….

So please tell me something about yourself…. Collect the basic demographic data of participant (name, gender, age, religion , caste, education ,present occupation, marital status)

Please tell me which language do you speak at home? which languages can you read and understand?(interview can then be carried out in that language).

Since how long have you been coming to this hospital for your oral care? (in case of a long period)what is the reason you come here for your treatment?

2.1 Experiences and Practice of Tobacco Use

What form of tobacco products do you use? (smoking or chewing form)

Since how long have you been using it? Do you use it daily? if yes, on an average how many times a day do you use these products?

At what age did you start using tobacco products? How did you start using it? (peer, family, tradition, fun..)

Tell me something about the effects of tobacco on health? (try to bring out their views both positive and negative effects on general and oral health)

Do you see any effect of tobacco use on your health?

Have you ever thought of quitting? If yes, inquire about what happened then (what were the barriers and facilitators for the same) *if no, why so?*

What will be the effects of quitting on your health?

2.2 Patients' Perceived Quality of Care and Satisfaction

Have you been asked by OHP or their team about your tobacco use? when 1st ,2nd …visit?

Will you like to get advice from the OHP against the tobacco use? how frequently?

Have you been advised by OHP about the ill effects of tobacco use and the need to quit?

Have you ever expressed the desire to quit to the OHP? yes, how was the support from them to help you quit?

What support do you expect from the dentists?

Are you ready to pay for the tobacco cessation service provided to you?

Did you see any poster/video on tobacco in a language that you could easily read?

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ABSTRACT

Introduction: Combined efforts to encompass different aspects of tobacco control have been in place for some time. Despite the recognition of the need to offer support to tobacco users to quit tobacco use, such support remains highly inadequate in India. However, little is known about the practice of oral health professionals (OHP) and the experiences and expectations of dental patients in the context of tobacco cessation (TC) services. In this article, we describe the protocol of a doctoral research project that explores OHP and their patients in an Indian city. The aims are (a) to understand the functioning of the oral health care system towards TC and what changes to it will be needed to benefit TC and (b) to capture the views of dental patients on TC services provided by OHP.

Methods and analysis: A cross-sectional qualitative study based on individual interviews with OHP and dental patients will be carried out in the city of Ahmedabad, Gujarat, India. The OHP will be purposively selected from two major organisation types: (1) single-doctor dental clinics and (2) dental hospital attached to teaching institutions. The sample population will be divided into two subgroups: general OHP (dentists practicing general dentistry irrespective of their qualification) and Prosthodontists (dentists with a specialisation in Prosthodontics). We will sample dental patients through convenient sampling from a public teaching hospital and select private dental care facilities. The sampling of OHP and dental patients will continue until we reach data saturation. Interviews will be audio-recorded, transcribed verbatim and coded by hand. The interview transcript will subsequently be analysed using thematic content analysis.

Ethics and dissemination: The study received ethical approval from the Institutional Ethical Committee of the Government Dental College and Hospital, Ahmedabad. The findings will be disseminated through conference presentations, peer-reviewed publications and to the study participants.

ARTICLE SUMMARY

Strengths and limitations of this study

- The study will allow an in-depth understanding of the challenges and possibilities of tobacco cessation (TC) in the current dental practice of oral health professionals (OHP) working in different clinical set-ups.
- The study will generate knowledge that could inform practices of oral health care to bring about regulatory or institutional changes and will help in policy development and design resulting in a tailored TC policy for OHP working in different types of set-ups. It will be useful in informing similar inquiries in other settings and pave the way for future research.
- The study site will limit the relevance of the findings to similar metropolitan areas as smaller towns are likely to present different organisational set-ups and challenges.
- A convenient sampling of patients may not be representative of the patient community in the city at large.
- Self-reported data could vary from the participant's actual behaviour.

INTRODUCTION

India is the second largest consumer of tobacco, with 28.6 % of adults being current users of one or more tobacco products.[1] In 2010, tobacco use was estimated to have caused about 1.3 million adult deaths in India.[2,3] Tobacco use is associated with several morbidities, including many oral diseases. India has one of the highest incidences of oral cancers in the world.[4] About 90% of these cancers are related to tobacco use.[5] Several tobacco control measures taken by the Indian government, like national legislation (Cigarette and Other Tobacco Products Act, 2003), a national program on tobacco control and ratification of the World Health Organization Framework Convention on Tobacco Control, have pushed up the demand for TC services. The recent nation-wide survey suggests that 55.4% of current smokers and 49.6% of current smokeless tobacco users are planning to quit tobacco use.[1] The need to provide tobacco cessation (TC) as a part of primary health care is long acknowledged. Research has shown that brief tobacco intervention by oral health professionals (OHP) has an impact on the quitting rates of tobacco users. Despite

recognition of the need to offer support to stop tobacco use as an important component of the tobacco control policy prescription (MPOWER) by the World Health Organization, such support remains highly inadequate in India. The Ministry of Health and Family Welfare (Government of India) with the support of the World Health Organization has started 19 tobacco cessation clinics in India.[6] However, the majority of these centres are located in tertiary /super specialty hospitals. Hence, these centres often end up serving people who have already suffered from severe tobacco use-related harm with very little scope of preventive and early interventions. Through the national tobacco control program, the government has attempted to organise counselling support in select districts across India. More recently, the national government has started to provide phone-based and mobile-phone app-based support to tobacco users.

While these initiatives are very much needed, we are yet to fully optimise the potential that the formal healthcare services offer in terms of providing integrated TC services. At present, only half of current smokers and only a third of current smokeless tobacco users get some advice from healthcare providers for tobacco cessation.[7] Hence, there is room for the integration of brief tobacco cessation intervention in general health care services, with oral healthcare services possessing a unique potential. Oral healthcare providers have easy access to tobacco users in the early stages; thus, providing an opportunity to intervene. They often have more chair-side time with patients than other clinicians. Moreover tobacco use prevention also enhances dental treatment outcomes. Some dental specialists, such as Prosthodontists, require spending even more time with patients and the need for several follow-ups providing them with an opportunity to reinforce messages on cessation.

While OHP are known to be very much willing to offer TC advice, they rarely put TC in practice. The major barriers perceived for this gap between their willingness and practice are a lack of training, a lack of time, a lack of financial incentives, and intriguingly, the fear that the patient might get annoyed and consequently stop seeking care from that dental office/facility.[8-12] There is a lack of research on how to overcome these barriers and integrate cessation into routine dental care. In this paper, we present a protocol for doctoral research that aims to better understand how TC

could be integrated into routine dental practice by general OHP and Prosthodontists working in single-doctor dental clinics and dental hospitals attached to teaching institutions in Ahmedabad, India.

In order to better understand how to integrate TC into routine dental practice, we aim to address the following specific research questions:

- How the current TC service (if at all) is organised in oral healthcare facilities in Ahmedabad city across major organisation types (single-doctor dental clinics and dental hospitals attached to teaching institutions)?
- What are the suggestions by OHP with regard to the feasibility of providing integrated TC support within routine dental practice?
- What are the perceived needs and expectations of dental patients with regard to TC support?
- What sort of intervention protocols/prototypes can be designed from this research for TC in routine dental practice?

METHOD

Study Design and Setting

We propose to conduct a cross-sectional qualitative study based on individual semi-structured interviews with OHP and dental patients. The interview topics for the OHP are guided by the WHO health system building blocks,[8] as well as considering the known barriers for TC in dental practice reported in the literature[8-12] (Supplementary file 1 and Supplementary file 2). The study will be carried out in Ahmedabad, the largest city in the western Indian state of Gujarat with a population of over seven million. It is the sixth largest city and the seventh largest metropolitan area in India. The Ahmedabad urban population-based cancer registry (PBCR)

reports the highest proportion of tobacco-related cancer for both males (56.3%) and females (19.8%).[13] The incidence rate of oral cancer among men from the urban population of Ahmedabad has increased markedly from 1985 to 2010.[14] The oral healthcare services available here are in the form of the government and private care set-up. With more than 1,500 private oral health care set-ups, the city has two government and three private dental hospitals attached to teaching institutes.

Study Sampling

Aligned with the qualitative nature of the study, a non-probability sampling approach will be adopted, and no sample size calculation will be done. As representativeness of the findings for an OHP and a dental patient spectrum that is as broad as possible is desired, we will use a variation sampling approach as a variant of purposive sampling.[15]

Oral Health Professional (OHP)

For the sampling of OHP, we will strive to attain respondents across gender, specialty and the organisational set-ups that OHP work in. This OHP spectrum composition will be purposively selected from the two major organisation types that most OHP work in; (1) single-doctor dental clinics and (2) dental hospitals attached to teaching institutions. The sample population will be divided into two subgroups: general OHP (dentists practicing general dentistry irrespective of their qualification) and Prosthodontists (dentists with a specialisation in Prosthodontics). General OHP and Prosthodontists from these two organisational set-ups will be conveniently sampled through the researcher's network and snowballing. The sampling will continue until we reach data saturation, the point when new data (interviews) will repeat information already expressed in the previous data.[16,17] We shall continue interviewing until we complete two interviews where data saturation is evident. The broad inclusion criteria for OHP would be that they have a formally recognised qualification and registration with the Dental Council of India and are presently practicing dentistry in Ahmedabad city.

Dental Patients

For the dental patients, we will cover age, gender and socio-economic background characteristics to obtain maximum variation within the spectrum. The patients will be sampled purposively from a public teaching hospital (Government dental college and hospital, Ahmedabad where the first author is affiliated) and select private dental care facilities within the social networks of the authors in Ahmedabad city, representing the two main organisation types. The patient spectrum composition will be selected conveniently from these two organisations. The sampling will continue until we reach data saturation, the point when new data (interviews) will repeat information already expressed in the previous data.[16,17] We shall continue interviewing until we complete two interviews where data saturation is evident. The broad inclusion criteria for patients would be that they are adults (aged 20 years old or above) who are tobacco users and currently undergoing dental treatment or have undergone some dental treatment in the last year. We will exclude patients with debilitating physical and mental conditions. The patient of the teaching institution will be selected and invited for the interview. As the researcher is herself a dentist working in this institute, patients receiving care from her will not be included in the study. The ones from the single-doctor dental clinics will be invited after permission from the OHP working in that clinic.

Data Collection

We will interview sampled OHP and patients using semi-structured interview guides. Both the guides will be field tested by interviewing a small sample of OHP and patients. It will be further refined for clarity and relevance. The first author will contact (by phone) the sampled OHP explaining the purpose of the study and securing their appointments. After explaining the study purpose and the voluntary and anonymous nature of participation, the first author will seek their written informed consent. The interviews, with duration of about 30-45 minutes, will be audio-recorded and conducted at a place (that assures privacy and comfort) and time convenient to them. Similarly, after explaining and seeking informed written or thumbprint consent, patients will be interviewed in a room (ensuring privacy and

comfort) within the healthcare facility of a teaching institute and in a room provided by OHP of the single-doctor dental clinic after verbal consent. The interviews, with duration of about 20-30 minutes, will be audio-recorded following permission from the participants. The first author, accompanied by a colleague, will conduct all the interviews in any/mix of languages that the participants are most comfortable with. Interviews will then be transcribed verbatim in the original language and subsequently translated into English. The data collection and analysis, including the report writing, are expected to be done from June 2019 to May 2021.

Ethics and dissemination

This study has been approved by the Institutional Ethical Committee at the Government Dental College and Hospital, Ahmedabad. As the researcher is a part of the institute from where the participants are going to be recruited, her position is bound to influence the data coproduced through interviews. The identity of the researcher as an OHP may bring in power dynamics, especially while interviewing patients. While it is not possible to fully eliminate such an influence, the researcher will ensure not to interview any patients with whom the researcher is associated as a caregiver and assure all the respondents that their responses will in no way impact their care and relationship with their OHP. We will also be vigilant of these dynamics while analysing data to identify any clear pattern that can be attributed to such power dynamics.

It is likely that the respondent might be semiliterate or illiterate, in which case, the researcher will read out and explain the consent form. If the respondent agrees to provide consent, their thumbprint will be taken on the consent form. Participants will remain anonymous; their names will be replaced by an ID number during the transcription and their identity will not be disclosed for the report and any subsequent publication. Secure electronic and paper-based filing systems for both the recordings and transcripts will be set-up. All the study related data will be kept for a minimum of five years after the end of the study. The findings of the study will be shared with all the stakeholders of this research and will be disseminated through conference presentations and peer-reviewed publications.

Data Analysis

Thematic content analysis will be carried out following the six-phase iterative process suggested by Braun and Clarke: 1) familiarising oneself with data, 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming themes and 6) providing the report, which will be used to analyse the qualitative data.[18-20] We will carry out content coding using a mix of the inductive and deductive approach, that is while we will look for coding material relevant to WHO health system building blocks themes, we will also openly code material that responds to our research questions. The data will be hand-coded by the researcher to bring out the themes. The data will be presented as dominant themes explaining research objectives and will explore new ideas to inform future research.

Patient and Public Involvement

Our research question concerning integrating tobacco cessation in routine dental care is, in part, based on a relative lack of proactive assistance offered by healthcare providers for tobacco cessation as reported by tobacco users and the general public in a large-scale survey in India. Patients were not involved in the study design, nor will they be involved in the recruitment and conduct of the research. They will be interviewed to better understand their perceived expectations and experiences with regard to tobacco cessation by their dental care providers. A simple brief summarising the study results and recommendations will be produced and disseminated to concerned stakeholders, including the study participants who opt for receiving one at the time of participation in the study.

DISCUSSION

Dentistry, in current times, is oriented more towards curative rather than preventive aspects. Studies show that OHP value the preventive part of dentistry but find it difficult to practice and personally disreputable.[21-23] With OHP being aware of the benefits and the need for TC, the bridge between the willingness and practice is missing. This study will delve into the current practice and organisational set-ups of OHP to understand the possibilities and potential of integrating TC into routine care. The opinions of dental patients regarding TC will further shape the integration

policies for the practice of dentistry. Generating such data will help to make policy, regulatory or institutional changes that will be easily acceptable and make the preventive aspect of dentistry more effective.

Strengths and Limitations

The selected study site would limit the relevance of the findings to similar metropolitan areas in the state as smaller towns and rural areas are likely to present different organisational set-ups and challenges with regard to TC practice. A convenient sampling of patients in our study may not be representative of the patient community in the city at large. Self-reported data could vary from the participant's actual behaviour. However, the qualitative nature of the study allows for an in-depth understanding of the challenges and possibilities of TC in dental practice. Beyond the specific context of the study setting, such work is useful in informing similar inquiries in other settings but is not amenable to the strict generalisation possible in quantitative experiments.

CONCLUSION

The study explores OHP, the system in which they work and their patients. Hence, in conclusion, the study will lead to the design of specific protocols for improving the integration of TC in routine practice.

Authors' Contributions: Rachana Shah and Upendra Bhojani conceived the research idea and designed the study. Rachana Shah wrote the initial draft of this paper. Rupal Shah, Sujal Shah and Upendra Bhojani edited and revised the paper.

Supplementary data:

Supplementary File 1: Guide for Conducting a Semi-structured Interview with Oral Health Professionals (OHP)

Supplementary File 2: Guide for Conducting a Semi-structured Interview with Dental Patients

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Guide for Conducting a Semi-Structured Interview with Oral Health Professionals (OHP)

[The purpose of this interview is to map the organisational characteristics of the dental practice and the perspective of the dentist on tobacco cessation in Ahmedabad to understand possible health service interventions to improve tobacco control from dentists' perspective along with factors that may facilitate or hinder the same.]

1. **Introduction**

Greet the doctor and thank him/her for attending the appointment for the interview.

Introduce yourself (interviewer) and the Government Dental College and Hospital, if the interviewee is not already familiar with you.

Provide the interviewee with the leaflet on the study design and briefly explain the study.

Explain about confidentiality and the use of the study outcomes.

Introduce the consent form. Ask for consent to record the audio and take notes.

2. **Interview**

Start by asking some general questions that the interviewee would be comfortable to answer….

So, sir/madam, tell me something about your practice … how long have you been practicing/working here? (In case of long practice) How different was this area when you started practicing here?

Collect the basic demographic data of the participant (name, gender, age, religion and, caste).

How many patients, who are also tobacco users, do you see in a month or in a week? Tell me about their general profile (e.g. age, education, economic background, occupation).

Depending on the issue being discussed, a shift can be made to any relevant inquiry theme below. Ensure that all the themes are covered in the interview. Any new theme/concept brought in by the interviewee shall be accommodated and be probed if deemed relevant.

Information System

Please describe the kind of data/information you collect regarding tobacco use. How do you do this? (what kind of data: chewable or smoking tobacco, frequency, family history. How data remains with dentist/patient/both, on the case paper/diary/register/computer-based system. If you are in doubt, request him/her to show a relevant paper/register.*)*

How has been your experience with this system? What kind of challenges do you face?

How does this data help you? (If no data is collected) Do you see any use of collecting data/information about tobacco use in your patients?

(For what use: monitor treatment outcomes, shape ongoing practice, enhance person-centered care, or enable reminder services for patient follow-ups.)

Health Workforce

Please explain the type of your practice (Individual/team), *who works in this clinic/hospital with their qualification/training, roles, and responsibilities*. (Ask details on doctors' qualifications, year of graduation, experience, etc.).

When a patient visits your clinic or hospital, what is the sequence of the procedure and is done by whom? (Inquire about who does the registration, history taking, examination, treatment procedure and post-treatment advice.)

How do you update your knowledge/skill regarding all the aspects of your practice? (Probe specifically about tobacco-related knowledge.)

*What in your opinion will be the effect on practice, if the OHP or their team members have undergone specific training on tobacco control? (*Ask if the OHP or their team members have undergone any specific training on tobacco control. If yes, try to get the details.)

*How effective can the use of guidelines for tobacco cessation be? (*Ask if the OHP is aware of or following any guidelines for tobacco cessation.)

*What do you think will be the effect on tobacco cessation practice if an OHP or any of their team members is a tobacco user? (*Ask if he or any of his team members uses tobacco. If no, what is the effect of being a non-tobacco user role model?)

*Are you aware of any tobacco dependence treatment specialist in your city? (*If yes, try to bring out details.*)*

Service Delivery

In your work experience to date, how many patients have come to you primarily for tobacco de-addiction? When you treat a general patient who is using tobacco, do you point out (identify) their tobacco use habit? (Ask if they talk about its ill effects and the advantages of quitting? If yes, how much time do they spend doing this and try to bring out the facilitators? If no, what are the barriers?)

Do you have any material in your set-up regarding tobacco control or de-addiction? (Models, posters, documentary, self- help materials, etc.)

How do you proceed if a patient demands a tobacco de-addiction service or wants to quit because of your advice? (Counselling, support material, medication, referring to the specialist)

What do you do for the patients who are tobacco users and not ready to quit? (Probe further for future advice.)

Do you think a team approach, where different roles and responsibilities are allotted to the team members, can help to promote tobacco control in your set-up? (Ask if the barriers can be overcome in this way.)

Governance and Leadership

Please describe all the regulatory requirements that you need to meet in order to practice. (Practice license from municipal health department, registration with respective education council, certification from pollution control board). *What are your views about these regulations? Do providers take them seriously?*

OHP can play an important role in tobacco cessation of their patients! Do you agree with this statement? Why?

*Does the government recognise your role in TC? Does it provide any support to you for this? (*Any guidelines, protocols, incentives, etc.)

Can incentives be a motivation to do more cessation work? Please elaborate. What do you think will be the impact of making all the oral health care facilities tobacco free? (Smoke-free should be made tobacco free.) *Can you tell me about any rules or guidelines (if any) that your staff has to follow in regards to tobacco control?*

What else in your opinion can the government do to curb the widespread use of tobacco products?

Medical Products and Technologies

Are you aware of any medications for tobacco cessation? (Ask about NRTs, non-NRTs and its availability.) *If yes, then how did you come to know about it? If no, do you think knowledge regarding these medications can help you provide TC service better?*

Do you think items such as a TC guide, protocol, toolkit, posters, brochures, self-help materials, risk charts and motivational tools can help in providing TC services?

Financing

How will it help the patients and providers if the cost of tobacco dependence treatment is covered in health insurance?

What do you think about taxes levied on tobacco products?

Guide for Conducting a Semi-Structured Interview with Dental Patients

[The purpose of this interview is to capture the attitude, knowledge and behaviour of dental patients towards tobacco cessation in Ahmedabad and to understand possible health service interventions to improve quality of care from patients' perspective along with factors that may facilitate or hinder the same.]

1. **Introduction**

Greet the patient and thank him/her for giving the interview. Introduce yourself (interviewer) and the Government Dental College and Hospital.

Provide the interviewee with the leaflet on the study design and briefly explain the study.

Explain about confidentiality and use of the study outcomes.

Introduce the consent form. Ask for consent to record the audio and take notes.

2. **Interview**

Start by asking some general questions that the interviewee would be comfortable to answer…

So please tell me something about yourself… Collect the basic demographic data of participant (name, gender, age, religion, caste, education, present occupation and marital status).

Please tell me which language do you speak at home? Which languages can you read and understand? (The interview can then be carried out in that language.)

For how long have you been coming to this hospital/clinic for your oral care? (In case of a long period) *What is the reason you come here for your treatment?*

2.1 Experiences and Practice of Tobacco Use

What form of tobacco products do you use? (smoking or chewing form)

For how long have you been using it? Do you use it daily? If yes, on average how many times a day do you use these products?

At what age did you start using tobacco products? How did you start using it? (peer, family, tradition, fun)

Tell me something about the effects of tobacco on health? (Try to bring out their views on both the positive and negative effects on general and oral health.)

Do you see any effect of tobacco use on your health?

*Have you ever thought of quitting? (*If yes, inquire about what happened then. What were the barriers and facilitators for the same? If no, why so?)

What will be the effects of quitting on your health?

2.2 Patients' Perceived Quality of Care and Satisfaction

What did your OHP or their team ask about your habit when you visited them? During which visit 1st, 2nd…?

How will you feel if you get advice from the OHP against tobacco use? How often do you expect such advice?

Please share your experience of getting advice from an OHP about the ill effects of tobacco use and the need to quit?

*What support do you expect from the OHP if you wish to quit? (*Inquire if the patient has ever expressed a desire to quit to the OHP.*)*

What are your thoughts if the tobacco cessation service is made payable?

Did you see any poster/video on tobacco in a language that you could easily read? Where? How has this affected you?

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Integrating tobacco cessation into routine dental practice: protocol for a qualitative study in Ahmedabad, India

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Title Page

Integrating tobacco cessation into routine dental practice: protocol for a qualitative study in Ahmedabad, India

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KEYWORDS: Qualitative, Interview, Oral health professional, Dental patient, Protocol

ABSTRACT

Introduction: Combined efforts to encompass different aspects of tobacco control have been in place for some time. Despite the recognition of the need to offer support to tobacco users to quit tobacco use, such support remains highly inadequate in India. However, little is known about the practice of oral health professionals (OHP) and the experiences and expectations of dental patients in the context of tobacco cessation (TC) services. In this article, we describe the protocol of a doctoral research project that explores OHP and their patients in an Indian city. The aims are (a) to understand the functioning of the oral health care system towards TC and what changes to it will be needed to benefit TC and (b) to capture the views of dental patients on TC services provided by OHP.

Methods and analysis: A cross-sectional qualitative study based on individual interviews with OHP and dental patients will be carried out in the city of Ahmedabad, Gujarat, India. The OHP will be purposively selected from two major organisation types: (1) single-doctor dental clinics and (2) dental hospital attached to teaching institutions. The sample population will be divided into two subgroups: general OHP (dentists practicing general dentistry irrespective of their qualification) and Prosthodontists (dentists with a specialisation in Prosthodontics). We will sample dental patients through convenient sampling from a public teaching hospital and select private dental care facilities. The sampling of OHP and dental patients will continue until we reach data saturation. Interviews will be audio-recorded, transcribed verbatim and coded by hand. The interview transcript will subsequently be analysed using thematic content analysis.

Ethics and dissemination: The study received ethical approval from the Institutional Ethical Committee of the Government Dental College and Hospital, Ahmedabad. The findings will be disseminated through conference presentations, peer-reviewed publications and to the study participants.

ARTICLE SUMMARY

Strengths and limitations of this study

- The study will allow an in-depth understanding of the challenges and possibilities of tobacco cessation (TC) in the current dental practice of oral health professionals (OHP) working in different clinical set-ups.
- The study will generate knowledge that could inform practices of oral health care to bring about regulatory or institutional changes and will help in policy development and design resulting in a tailored TC policy for OHP working in different types of set-ups. It will be useful in informing similar inquiries in other settings and pave the way for future research.
- The study site will limit the relevance of the findings to similar metropolitan areas as smaller towns are likely to present different organisational set-ups and challenges.
- A convenient sampling of patients may not be representative of the patient community in the city at large.
- Self-reported data could vary from the participant's actual behaviour.

INTRODUCTION

India is the second largest consumer of tobacco, with 28.6 % of adults being current users of one or more tobacco products.[1] In 2010, tobacco use was estimated to have caused about 1.3 million adult deaths in India.[2,3] Tobacco use is associated with several morbidities, including many oral diseases. India has one of the highest incidences of oral cancers in the world.[4] About 90% of these cancers are related to tobacco use.[5] Several tobacco control measures taken by the Indian government, like national legislation (Cigarette and Other Tobacco Products Act, 2003), a national program on tobacco control and ratification of the World Health Organization Framework Convention on Tobacco Control, have pushed up the demand for TC services. The recent nation-wide survey suggests that 55.4% of current smokers and 49.6% of current smokeless tobacco users are planning to quit tobacco use.[1] The need to provide tobacco cessation (TC) as a part of primary health care is long acknowledged. Research has shown that brief tobacco intervention by oral health professionals (OHP) has an impact on the quitting rates of tobacco users. Despite

recognition of the need to offer support to stop tobacco use as an important component of the tobacco control policy prescription (MPOWER) by the World Health Organization, such support remains highly inadequate in India. The Ministry of Health and Family Welfare (Government of India) with the support of the World Health Organization has started 19 tobacco cessation clinics in India.[6] However, the majority of these centres are located in tertiary /super specialty hospitals. Hence, these centres often end up serving people who have already suffered from severe tobacco use-related harm with very little scope of preventive and early interventions. Through the national tobacco control program, the government has attempted to organise counselling support in select districts across India. More recently, the national government has started to provide phone-based and mobile-phone app-based support to tobacco users.

While these initiatives are very much needed, we are yet to fully optimise the potential that the formal healthcare services offer in terms of providing integrated TC services. At present, only half of current smokers and only a third of current smokeless tobacco users get some advice from healthcare providers for tobacco cessation.[7] Hence, there is room for the integration of brief tobacco cessation intervention in general health care services, with oral healthcare services possessing a unique potential. Oral healthcare providers have easy access to tobacco users in the early stages; thus, providing an opportunity to intervene. They often have more chair-side time with patients than other clinicians. Moreover tobacco use prevention also enhances dental treatment outcomes. Some dental specialists, such as Prosthodontists, require spending even more time with patients and the need for several follow-ups providing them with an opportunity to reinforce messages on cessation.

While OHP are known to be very much willing to offer TC advice, they rarely put TC in practice. The major barriers perceived for this gap between their willingness and practice are a lack of training, a lack of time, a lack of financial incentives, and intriguingly, the fear that the patient might get annoyed and consequently stop seeking care from that dental office/facility.[8-12] There is a lack of research on how to overcome these barriers and integrate cessation into routine dental care. In this paper, we present a protocol for doctoral research that aims to better understand how TC

could be integrated into routine dental practice by general OHP and Prosthodontists working in single-doctor dental clinics and dental hospitals attached to teaching institutions in Ahmedabad, India.

In order to better understand how to integrate TC into routine dental practice, we aim to address the following specific research questions:

- How the current TC service (if at all) is organised in oral healthcare facilities in Ahmedabad city across major organisation types (single-doctor dental clinics and dental hospitals attached to teaching institutions)?
- What are the suggestions by OHP with regard to the feasibility of providing integrated TC support within routine dental practice?
- What are the perceived needs and expectations of dental patients with regard to TC support?
- What sort of intervention protocols/prototypes can be designed from this research for TC in routine dental practice?

METHOD

Study Design and Setting

We propose to conduct a cross-sectional qualitative study based on individual semi-structured interviews with OHP and dental patients. The interview topics for the OHP are guided by the WHO health system building blocks,[8] as well as considering the known barriers for TC in dental practice reported in the literature[8-12] (Supplementary file 1 and Supplementary file 2). The study will be carried out in Ahmedabad, the largest city in the western Indian state of Gujarat with a population of over seven million. It is the sixth largest city and the seventh largest metropolitan area in India. The Ahmedabad urban population-based cancer registry (PBCR)

reports the highest proportion of tobacco-related cancer for both males (56.3%) and females (19.8%).[13] The incidence rate of oral cancer among men from the urban population of Ahmedabad has increased markedly from 1985 to 2010.[14] The oral healthcare services available here are in the form of the government and private care set-up. With more than 1,500 private oral health care set-ups, the city has two government and three private dental hospitals attached to teaching institutes.

Study Sampling

Aligned with the qualitative nature of the study, a non-probability sampling approach will be adopted, and no sample size calculation will be done. As representativeness of the findings for an OHP and a dental patient spectrum that is as broad as possible is desired, we will use a variation sampling approach as a variant of purposive sampling.[15]

Oral Health Professional (OHP)

For the sampling of OHP, we will strive to attain respondents across gender, specialty and the organisational set-ups that OHP work in. This OHP spectrum composition will be purposively selected from the two major organisation types that most OHP work in; (1) single-doctor dental clinics and (2) dental hospitals attached to teaching institutions. The sample population will be divided into two subgroups: general OHP (dentists practicing general dentistry irrespective of their qualification) and Prosthodontists (dentists with a specialisation in Prosthodontics). General OHP and Prosthodontists from these two organisational set-ups will be conveniently sampled through the researcher's network and snowballing. The sampling will continue until we reach data saturation, the point when new data (interviews) will repeat information already expressed in the previous data.[16,17] We shall continue interviewing until we complete two interviews where data saturation is evident. The broad inclusion criteria for OHP would be that they have a formally recognised qualification and registration with the Dental Council of India and are presently practicing dentistry in Ahmedabad city.

Dental Patients

For the dental patients, we will cover age, gender and socio-economic background characteristics to obtain maximum variation within the spectrum. The patients will be sampled purposively from a public teaching hospital (Government dental college and hospital, Ahmedabad where the first author is affiliated) and select private dental care facilities within the social networks of the authors in Ahmedabad city, representing the two main organisation types. The patient spectrum composition will be selected conveniently from these two organisations. The sampling will continue until we reach data saturation, the point when new data (interviews) will repeat information already expressed in the previous data.[16,17] We shall continue interviewing until we complete two interviews where data saturation is evident. The broad inclusion criteria for patients would be that they are adults (aged 20 years old or above) who are tobacco users and currently undergoing dental treatment or have undergone some dental treatment in the last year. We will exclude patients with debilitating physical and mental conditions. The patient of the teaching institution will be selected and invited for the interview. As the researcher is herself a dentist working in this institute, patients receiving care from her will not be included in the study. The ones from the single-doctor dental clinics will be invited after permission from the OHP working in that clinic.

Data Collection

We will interview sampled OHP and patients using semi-structured interview guides. Both the guides will be field tested by interviewing a small sample of OHP and patients. It will be further refined for clarity and relevance. The first author will contact (by phone) the sampled OHP explaining the purpose of the study and securing their appointments. After explaining the study purpose and the voluntary and anonymous nature of participation, the first author will seek their written informed consent. The interviews, with duration of about 30-45 minutes, will be audio-recorded and conducted at a place (that assures privacy and comfort) and time convenient to them. Similarly, after explaining and seeking informed written or thumbprint consent, patients will be interviewed in a room (ensuring privacy and

comfort) within the healthcare facility of a teaching institute and in a room provided by OHP of the single-doctor dental clinic after verbal consent. The interviews, with duration of about 20-30 minutes, will be audio-recorded following permission from the participants. The first author, accompanied by a colleague, will conduct all the interviews in any/mix of languages that the participants are most comfortable with. Interviews will then be transcribed verbatim in the original language and subsequently translated into English. The data collection and analysis, including the report writing, are expected to be done from June 2019 to May 2021.

Ethics and dissemination

This study has been approved by the Institutional Ethical Committee at the Government Dental College and Hospital, Ahmedabad. As the researcher is a part of the institute from where the participants are going to be recruited, her position is bound to influence the data coproduced through interviews. The identity of the researcher as an OHP may bring in power dynamics, especially while interviewing patients. While it is not possible to fully eliminate such an influence, the researcher will ensure not to interview any patients with whom the researcher is associated as a caregiver and assure all the respondents that their responses will in no way impact their care and relationship with their OHP. Similarly, there could be dynamics while interviewing participants of opposite gender from that of the interviewer's. This is more likely to be of consequence in case of the interviewed patients compared to the interviewed OHP. We will also be vigilant of these dynamics while analysing data to identify any clear pattern that can be attributed to such power dynamics.

It is likely that the respondent might be semiliterate or illiterate, in which case, the researcher will read out and explain the consent form. If the respondent agrees to provide consent, their thumbprint will be taken on the consent form. Participants will remain anonymous; their names will be replaced by an ID number during the transcription and their identity will not be disclosed for the report and any subsequent publication. Secure electronic and paper-based filing systems for both the recordings and transcripts will be set-up. All the study related data will be kept for a minimum of

five years after the end of the study. The findings of the study will be shared with all the stakeholders of this research and will be disseminated through conference presentations and peer-reviewed publications.

Data Analysis

Thematic content analysis will be carried out following the six-phase iterative process suggested by Braun and Clarke: 1) familiarising oneself with data, 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming themes and 6) providing the report, which will be used to analyse the qualitative data.[18-20] We will carry out content coding using a mix of the inductive and deductive approach, that is while we will look for coding material relevant to WHO health system building blocks themes, we will also openly code material that responds to our research questions. The data will be hand-coded by the main researcher to bring out the themes which will then be discussed with other researchers. The data will be presented as dominant themes explaining research objectives and will explore new ideas to inform future research.

Patient and Public Involvement

Our research question concerning integrating tobacco cessation in routine dental care is, in part, based on a relative lack of proactive assistance offered by healthcare providers for tobacco cessation as reported by tobacco users and the general public in a large-scale survey in India. Patients were not involved in the study design, nor will they be involved in the recruitment and conduct of the research. They will be interviewed to better understand their perceived expectations and experiences with regard to tobacco cessation by their dental care providers. A simple brief summarising the study results and recommendations will be produced and disseminated to concerned stakeholders, including the study participants who opt for receiving one at the time of participation in the study.

DISCUSSION

Dentistry, in current times, is oriented more towards curative rather than preventive aspects. Studies show that OHP value the preventive part of dentistry but find it difficult to practice and personally disreputable.[21-23] Available

evidence suggests that brief interventions increase tobacco abstinence rates.[24] With OHP being aware of the benefits and the need for TC, the bridge between the willingness and practice is missing. This study will delve into the current practice and organisational set-ups of OHP to understand the possibilities and potential of integrating TC into routine care. The opinions of dental patients regarding TC will further shape the integration policies for the practice of dentistry. Generating such data will help to make policy, regulatory or institutional changes that will be easily acceptable and make the preventive aspect of dentistry more effective.

Strengths and Limitations

The selected study site would limit the relevance of the findings to similar metropolitan areas in the state as smaller towns and rural areas are likely to present different organisational set-ups and challenges with regard to TC practice. A convenient sampling of patients in our study may not be representative of the patient community in the city at large. Self-reported data could vary from the participant's actual behaviour. A single coder approach that we propose to use may introduce bias in coding data compared to independent coding by two or more researchers. However, the qualitative nature of the study allows for an in-depth understanding of the challenges and possibilities of TC in dental practice. Beyond the specific context of the study setting, such work is useful in informing similar inquiries in other settings but is not amenable to the strict generalisation possible in quantitative experiments.

CONCLUSION

The study explores OHP, the system in which they work and their patients. Hence, in conclusion, the study will lead to the design of specific protocols for improving the integration of TC in routine practice.

Authors' Contributions: Rachana Shah and Upendra Bhojani conceived the research idea and designed the study. Rachana Shah wrote the initial draft of this paper. Rupal Shah, Sujal Shah and Upendra Bhojani edited and revised the paper.

Supplementary data:

Supplementary File 1: Guide for Conducting a Semi-structured Interview with Oral Health Professionals (OHP)

Supplementary File 2: Guide for Conducting a Semi-structured Interview with Dental Patients

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Guide for Conducting a Semi-Structured Interview with Oral Health Professionals (OHP)

[The purpose of this interview is to map the organisational characteristics of the dental practice and the perspective of the dentist on tobacco cessation in Ahmedabad to understand possible health service interventions to improve tobacco control from dentists' perspective along with factors that may facilitate or hinder the same.]

1. **Introduction**

Greet the doctor and thank him/her for attending the appointment for the interview.

Introduce yourself (interviewer) and the Government Dental College and Hospital, if the interviewee is not already familiar with you.

Provide the interviewee with the leaflet on the study design and briefly explain the study.

Explain about confidentiality and the use of the study outcomes.

Introduce the consent form. Ask for consent to record the audio and take notes.

2. **Interview**

Start by asking some general questions that the interviewee would be comfortable to answer….

So, sir/madam, tell me something about your practice … how long have you been practicing/working here? (In case of long practice) How different was this area when you started practicing here?

Collect the basic demographic data of the participant (name, gender, age, religion and, caste).

How many patients, who are also tobacco users, do you see in a month or in a week? Tell me about their general profile (e.g. age, education, economic background, occupation).

Depending on the issue being discussed, a shift can be made to any relevant inquiry theme below. Ensure that all the themes are covered in the interview. Any new theme/concept brought in by the interviewee shall be accommodated and be probed if deemed relevant.

Information System

Please describe the kind of data/information you collect regarding tobacco use. How do you do this? (what kind of data: chewable or smoking tobacco, frequency, family history. How data remains with dentist/patient/both, on the case paper/diary/register/computer-based system. If you are in doubt, request him/her to show a relevant paper/register.*)*

How has been your experience with this system? What kind of challenges do you face?

How does this data help you? (If no data is collected) Do you see any use of collecting data/information about tobacco use in your patients?

(For what use: monitor treatment outcomes, shape ongoing practice, enhance person-centered care, or enable reminder services for patient follow-ups.)

Health Workforce

Please explain the type of your practice (Individual/team), *who works in this clinic/hospital with their qualification/training, roles, and responsibilities*. (Ask details on doctors' qualifications, year of graduation, experience, etc.).

When a patient visits your clinic or hospital, what is the sequence of the procedure and is done by whom? (Inquire about who does the registration, history taking, examination, treatment procedure and post-treatment advice.)

How do you update your knowledge/skill regarding all the aspects of your practice? (Probe specifically about tobacco-related knowledge.)

*What in your opinion will be the effect on practice, if the OHP or their team members have undergone specific training on tobacco control? (*Ask if the OHP or their team members have undergone any specific training on tobacco control. If yes, try to get the details.)

*How effective can the use of guidelines for tobacco cessation be? (*Ask if the OHP is aware of or following any guidelines for tobacco cessation.)

*What do you think will be the effect on tobacco cessation practice if an OHP or any of their team members is a tobacco user? (*Ask if he or any of his team members uses tobacco. If no, what is the effect of being a non-tobacco user role model?)

*Are you aware of any tobacco dependence treatment specialist in your city? (*If yes, try to bring out details.*)*

Service Delivery

In your work experience to date, how many patients have come to you primarily for tobacco de-addiction? When you treat a general patient who is using tobacco, do you point out (identify) their tobacco use habit? (Ask if they talk about its ill effects and the advantages of quitting? If yes, how much time do they spend doing this and try to bring out the facilitators? If no, what are the barriers?)

Do you have any material in your set-up regarding tobacco control or de-addiction? (Models, posters, documentary, self- help materials, etc.)

How do you proceed if a patient demands a tobacco de-addiction service or wants to quit because of your advice? (Counselling, support material, medication, referring to the specialist)

What do you do for the patients who are tobacco users and not ready to quit? (Probe further for future advice.)

Do you think a team approach, where different roles and responsibilities are allotted to the team members, can help to promote tobacco control in your set-up? (Ask if the barriers can be overcome in this way.)

Governance and Leadership

Please describe all the regulatory requirements that you need to meet in order to practice. (Practice license from municipal health department, registration with respective education council, certification from pollution control board). *What are your views about these regulations? Do providers take them seriously?*

OHP can play an important role in tobacco cessation of their patients! Do you agree with this statement? Why?

*Does the government recognise your role in TC? Does it provide any support to you for this? (*Any guidelines, protocols, incentives, etc.)

Can incentives be a motivation to do more cessation work? Please elaborate. What do you think will be the impact of making all the oral health care facilities tobacco free? (Smoke-free should be made tobacco free.) *Can you tell me about any rules or guidelines (if any) that your staff has to follow in regards to tobacco control?*

What else in your opinion can the government do to curb the widespread use of tobacco products?

Medical Products and Technologies

Are you aware of any medications for tobacco cessation? (Ask about NRTs, non-NRTs and its availability.) *If yes, then how did you come to know about it? If no, do you think knowledge regarding these medications can help you provide TC service better?*

Do you think items such as a TC guide, protocol, toolkit, posters, brochures, self-help materials, risk charts and motivational tools can help in providing TC services?

Financing

How will it help the patients and providers if the cost of tobacco dependence treatment is covered in health insurance?

What do you think about taxes levied on tobacco products?

Guide for Conducting a Semi-Structured Interview with Dental Patients

[The purpose of this interview is to capture the attitude, knowledge and behaviour of dental patients towards tobacco cessation in Ahmedabad and to understand possible health service interventions to improve quality of care from patients' perspective along with factors that may facilitate or hinder the same.]

1. **Introduction**

Greet the patient and thank him/her for giving the interview. Introduce yourself (interviewer) and the Government Dental College and Hospital.

Provide the interviewee with the leaflet on the study design and briefly explain the study.

Explain about confidentiality and use of the study outcomes.

Introduce the consent form. Ask for consent to record the audio and take notes.

2. **Interview**

Start by asking some general questions that the interviewee would be comfortable to answer…

So please tell me something about yourself… Collect the basic demographic data of participant (name, gender, age, religion, caste, education, present occupation and marital status).

Please tell me which language do you speak at home? Which languages can you read and understand? (The interview can then be carried out in that language.)

For how long have you been coming to this hospital/clinic for your oral care? (In case of a long period) *What is the reason you come here for your treatment?*

2.1 Experiences and Practice of Tobacco Use

What form of tobacco products do you use? (smoking or chewing form)

For how long have you been using it? Do you use it daily? If yes, on average how many times a day do you use these products?

At what age did you start using tobacco products? How did you start using it? (peer, family, tradition, fun)

Tell me something about the effects of tobacco on health? (Try to bring out their views on both the positive and negative effects on general and oral health.)

Do you see any effect of tobacco use on your health?

*Have you ever thought of quitting? (*If yes, inquire about what happened then. What were the barriers and facilitators for the same? If no, why so?)

What will be the effects of quitting on your health?

2.2 Patients' Perceived Quality of Care and Satisfaction

What did your OHP or their team ask about your habit when you visited them? During which visit 1st, 2nd…?

How will you feel if you get advice from the OHP against tobacco use? How often do you expect such advice?

Please share your experience of getting advice from an OHP about the ill effects of tobacco use and the need to quit?

*What support do you expect from the OHP if you wish to quit? (*Inquire if the patient has ever expressed a desire to quit to the OHP.*)*

What are your thoughts if the tobacco cessation service is made payable?

Did you see any poster/video on tobacco in a language that you could easily read? Where? How has this affected you?