TOBACCO CESSATION THROUGH USE OF ORAL HEALTH CARE PROVIDERS IN KENYA.

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**PROJECT SUMMARY**

**Background:** In addition to being a risk factor for non-communicable diseases such as diabetes, cardiovascular diseases and pulmonary pathology, tobacco’s oral effects vary from altered smell and taste sensation to dental staining, periodontitis, oral cancer and developmental defects due to maternal tobacco use. The World Health Organization (WHO) Global Oral Health Program has identified the implementation of tobacco use prevention and cessation (TUPAC) counseling guidelines as one of the priority goals in dentistry.

**Objectives:** The project aims at evaluating the effect of a training program in tobacco use prevention and cessation (TUPAC) on the uptake and participation of oral health care providers (OHCP) in tobacco control. After training and mobilization of OHCP with competence in tobacco use prevention and cessation (TUPAC) counseling, the number of patients abstaining from or reducing tobacco use will increase.

**Methods:** This will be an intervention study where OHCP will be trained in TUPAC, and changes in competence levels will be assessed before and after the intervention. The study population will be undergraduate Bachelor of Dental Surgery and Community Oral Health students in the clinical years, post-graduate Dental Students, Dental interns, Dentists and Community Oral Health officers in the 47 counties in Kenya.

**Perceived Benefits:** The study will form an evidence base for recommendation of the use of oral health care providers in reduction and control of tobacco, which in turn will lead to reduction in tobacco related morbidity and mortality.

**B1. OVERALL GOAL AND OBJECTIVES:**

**B1.1 MAIN OBJECTIVE:**

The project aims at evaluating the effect of a training program in tobacco use prevention and cessation (TUPAC) on the uptake and participation of oral health care workers in tobacco control. After training and mobilization of OHCP with competence in tobacco use prevention and cessation (TUPAC) counseling, the number of patients abstaining from or reducing tobacco use will increase.

**B1.2 SPECIFIC OBJECTIVES:**

1. **To conduct training of oral health educators in TUPAC (Training of Trainers):** There are currently no OHCP trained in TUPAC in the country. A core group of 8 representatives from various training institutions in the country will be trained on provision of education in tobacco cessation. Trainers will be expected to implement training using webinars and distance learning programs in addition to giving lectures and hands-on demonstrations.

2. **To train OHW in tobacco use prevention and cessation (TUPAC):** Training of OHCP will be based on evidence-based methods for stopping tobacco use. OHCP will also be

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1John J. Tobacco cessation counseling interventions delivered by dental professionals may be effective in helping tobacco users to quit. Evid Based Dent 2006;7(2):40–1.
given guidance in the use of pharmacological aids to assist patients in the quitting process. This client-based preventive campaign based on behavioral counseling and prescription of pharmacological aids by health professionals is an effective strategy in the management of nicotine dependence. Establishment of this program will provide a basis for advocacy for a national policy on TUPAC training for OHCP in Kenya and serve as a template for the training of other health profession cadres. Future integration of the TUPAC program into undergraduate curricula will ensure its sustainability.

3. **To identify and document best practices for TUPAC in a dental clinic setting:** There is currently no data concerning tobacco interventions in dental clinics in Kenya. Research in high income countries (HICs) has however shown that OHCP with tobacco cessation training perform more interventions and report increased self-efficacy, and they register higher levels of acceptability than those without training. A record of patients’ responses to OHCP trained in TUPAC will provide an evidence base for the translation of this research into clinical practice. Successful implementation of TUPAC in dental clinics within a low resource setting will also demonstrate its applicability for other sub-Saharan countries. Trainees will be empowered to conduct TUPAC within their dental practice. Successes, challenges and barriers will be documented.

4. **To assess clinical practice of tobacco use prevention and cessation (TUPAC) in a dental clinic setting:** The Global Health Professions Student Survey (Warren, 2011) has reported that in general, dental students in Low to Middle Income Countries (LMICs) have limited exposure to TUPAC training, resulting in low levels of participation in tobacco control efforts in their subsequent clinical practice. Participation by OHCP as part of a multidisciplinary approach by clinicians in TUPAC increases abstinence rates more effectively than interventions delivered by health workers in a single specialty. Changes in levels of competence of OHCP will be monitored using a pre-test and post-test before and after training, and use of log books will enhance follow up.

5. **To increase the number of patients abstaining from and/ or reducing tobacco use.** Clients will be asked about tobacco use, assessed for nicotine dependence and motivation to quit, advised to quit and assisted in quitting. The trained OHCP will then

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arrange for follow up. Relevant pharmacotherapeutic aids shall be prescribed to reduce cravings and facilitate the quitting process.\(^8\) Assessment of self-reported quitting and/or reduction of tobacco use shall be done using mobile phones to enhance client follow up and test strips will be used to confirm patient compliance. An assessment of the efficiency of counseling supplemented by evidence based pharmacotherapy will be conducted.

6. **Advocacy for inclusion of TUPAC into both undergraduate and postgraduate curricula.** The validated training program can be used as an evidence base for recommendation of a national policy to include TUPAC into the training curricula for OHCP. The training modules may be used as a template for development of similar programs in other low and middle income countries (LMICs) as well as being applicable for other groups of health care students. Integration of such training programs into training curricula will ensure long term sustainability of this program.

**B2. TECHNICAL APPROACH:**

**B2.1 OPERATIONS RESEARCH IN TOBACCO CESSATION TRAINING:**

The purpose of this intervention study will be to gauge the level of knowledge, attitude, subjective norms and skills in a sample of OHCP on exposure to training on TUPAC.

**Enrollment of participants:** A descriptive cross sectional study will document the current practices of tobacco cessation counseling in Kenyan dental clinics. Clinicians (dentists and auxiliaries) who are active in provision of oral health care services and willing to give an informed consent will be included in the study.

**Study population:** Stratified random sampling will be used to select OHCP targeted for tobacco cessation training from the following Pre-service and In-service groups across Kenya:

- a. Dental interns (Ministry of Health).
- b. Undergraduate students (University of Nairobi and Moi University).
- d. Dental officers (Ministry of Health, all 47 Counties).
- e. Private dental practitioners and specialists.
- f. Post-graduate students (University of Nairobi only).

**Training sites:** The dental schools at University of Nairobi (SDS – Nairobi) and Moi Teaching and Referral Hospital (MTRH Eldoret/ Moi University) will serve as the main training venues. SDS is located in Nairobi, the capital city located in central Kenya, while MTRH Eldoret is in the western part of the country.

**B2.2 DATA MANAGEMENT AND ANALYSIS:**

**Data collection tools and techniques:** A combination of self administered questionnaires and participant interviews will be used to obtain personal background data and to assess current

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knowledge, attitudes and skills in pre-service and in-service groups. Possible barrier factors confronting oral health care providers in the intervention cohort in performing routine TUPAC will also be assessed. Data collection tools will be standardized and sample test data will be randomly gathered to establish authenticity, accuracy and validity.

**Data management and analysis:** Data will be entered using the Statistical Package for Social Scientists (SPSS) data entry program, Version 20.0 (IBM Corporation, New York, USA), supplemented by SAS software (SAS Institute, Cary, NC, USA), STATA (Statacorp LP, Texas, USA) and Excel (Microsoft Corp, USA) where necessary. Double entry will be carried out to improve validity of the data, with the second data entry carried out for purposes of verification and data cleaning prior to analysis. Descriptive statistics will be generated and McNemar test will be performed to compare data at the baseline, before and after intervention. Data will be presented in form of tables, graphs and charts.

**Roles and responsibility for data collection and analysis:** The investigators drawn from the University of Nairobi, School of Dental Sciences will be responsible for the data collection, documentation of the findings and monitoring and evaluation of the intervention. 3 research assistants will be recruited to collect data and relay information from the main training centres, namely Moi Teaching and Referral Hospital (MTHR – Eldoret/ Moi University) and the School of Dental Sciences (SDS - Nairobi). The core team will have the responsibility of calibrating the research assistants, and processing the research in collaboration with the team statistician. The team will finally prepare scientific papers for publication in peer reviewed journals, as well as reports to be submitted to the Global Bridges management.

**B2.3 ETHICAL CONSIDERATIONS:**
The project proposal will be submitted to the Kenyatta Hospital and University of Nairobi Ethics and Standards committee for approval. Permission will be sought from University of Nairobi, Moi University, Kenya Medical Training College and the Ministry of Health for access to their premises and staff. All the participants meeting the inclusion criteria will have an equal chance to participate in the study. Only participants who give written informed consent will participate. Consent forms for the tobacco users will be available in English and Kiswahili. All information will be treated confidentially, and will be used for the welfare of society. Dissemination of results shall be by means of publications in peer reviewed journals and presentations in scientific conferences.

**B3. CURRENT ASSESSMENT OF NEED IN TARGET AREAS**
There are approximately a thousand registered dentists in Kenya, who practice in both public and private hospitals within a referral system that depends on dental auxiliaries at the primary

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health care level\textsuperscript{11}. However, the lack of participation of oral health care workers in tobacco use prevention and cessation (TUPAC) continues to be a missed opportunity in tobacco control. Although there is abundant data on the efficacy of smoking cessation programs in dental practice in other countries, the necessity and readiness for TUPAC amongst OHCP in Kenya remains unclear because there is no information on such interventions in dental clinics in this country.

In Kenya, it is estimated that the country uses three dollars to treat tobacco related diseases for every dollar that is collected as tobacco revenue\textsuperscript{12}. Non-communicable diseases (NCDs), for which tobacco is a major risk factor, currently account for more than 55% of the mortality in the country and approximately 50% of the public-hospital admissions\textsuperscript{13}. Kenya is a signatory to WHO's Framework Convention on Tobacco Control (FCTC), whose guidelines for comprehensive tobacco regulation provide a favorable environment for population based campaigns\textsuperscript{14}. Although legislative approaches such as taxation and prohibition of advertising have been effective, there is need for non-legislative and cost-effective approaches such as population-based preventive campaigns using health workers\textsuperscript{15}.

Tobacco use has been reported as the most important preventable contributor to global morbidity and mortality\textsuperscript{16}. It is the only legally available consumer product which kills people when it is used entirely as intended\textsuperscript{17}. Premature mortality affects a third to half of the users, with an average of 15 years’ loss of life, currently killing more than 5 million people a year. Unless urgent action is taken, tobacco’s annual death toll will rise to more than 8 million by 2030, and 70% of global deaths from tobacco will occur in LMICs\textsuperscript{18}. Tobacco use is associated with serious oral health problems such as oral cancer, oral cancer recurrence, adult periodontal diseases, and congenital defects such as cleft lips and palate in children\textsuperscript{19,20,21,22}. It is associated

\textsuperscript{11} Kenya Medical Practitioners and Dentists Board. \url{http://www.medicalboard.co.ke/}.
\textsuperscript{14} WHO. Updated status of the WHO Framework Convention on Tobacco Control. \url{http://www.who.int/tobacco/framework/countrylist/en/index.html}
\textsuperscript{15} John J. Tobacco cessation counseling interventions delivered by dental professionals may be effective in helping tobacco users to quit. Evid Based Dent 2006;7(2):40–1.
with gender-specific health problems including elevated risk of miscarriages, pre-term birth and low birth weight of babies in women who smoke. In men some of the consequences of smoking include impotence and infertility\textsuperscript{23}.

The Kenya Global Youth Tobacco Survey of 2001 estimated that the prevalence of smoking among children aged 12 to 15 years for males was 15.8\%, while that among females was 10\%, which was consistent with data reported in a regional survey conducted in seven African countries\textsuperscript{24}. A similar survey done in 2007 indicated an increase of 43\% for the whole population of children reported to be using any form of tobacco. The greatest increase was among females from the 2001 level of 10\% to 18.2\% in 2007, an increase of 82\%\textsuperscript{25}. The mean age of smoking commencement has been report to be 19.7 years\textsuperscript{26}. Furthermore, the Joint National Capacity Assessment on the Implementation of Effective Tobacco Control Policies in Kenya identified gaps in the technical capacity for implementation of tobacco control in the country\textsuperscript{27}.

Although 70\% of patients who smoke want to quit, only 7.9\% are able to do so without help\textsuperscript{28}. Oral health care professionals can contribute significantly to increasing tobacco cessation rates when tobacco use prevention and cessation (TUPAC) counseling is effectively integrated into the context of routine diagnosis, advice/treatment and referral of patients\textsuperscript{29,30,31}. WHO Global Oral Health Program identified TUPAC counseling as a priority goal in

\textsuperscript{23} https://www.asrm.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/smoking.pdf
\textsuperscript{28} Bates RC, Bueltel LM. Creating a comprehensive smoking cessation program. AARC Times. 1999;23:46-53.
\textsuperscript{31} Monaghan N. What is the role of dentists in smoking cessation? Br Dent J 2002;193:611-2.
dentistry. However, it has been reported that dentists are less active than other health professionals in counseling patients on tobacco cessation, mainly due to perceived lack of skills and training in TUPAC.

The Global Health Professions Student Survey (GHPSS) reported that in general, dental students in LMICs have limited exposure to TUPAC training, and most of them practice in hospitals that do not implement smoke-free policies. This in turn translated to oral health care providers with inadequate knowledge and skills in TUPAC. Professional training for oral health care workers should include courses detailing the harmful health effects of tobacco use and exposure to SHS, and effective tobacco counseling in combination with evidence-based pharmacotherapeutics. Group education, which will be used in this project, is a cost-efficient and effective method of training in TUPAC. Tobacco use cessation in dentistry is critical to ensure multidisciplinary participation of all health cadres in anti-tobacco efforts.

B2.2 INTERVENTION DESIGN AND METHODS:
The OHCP educators will undergo Training of Trainers on TUPAC methods. Four of the trainers will be from University of Nairobi and the other four will be from other institutions involved in training of OHCP in Kenya. Training materials will be developed by the core team from SDS, with technical support from the regional WHO office. This core team of SDS trainers will then coordinate a baseline survey to assess the knowledge, attitudes, practices and subjective norms of OHCP regarding TUPAC, followed by 3 intensive, hands-on workshops to train a total of 100 participants organized in collaboration with other training institutions. All trainees will participate in a post-workshop evaluation to measure the change in competence in TUPAC related knowledge and skills. Each OHCP will be trained practically in the use of a clinical log.

book providing an easy check-list system for the motivational steps to be taken in the 5A’s for clients willing to quit and the 5R’s for those who are not willing to quit\textsuperscript{40,41}. The log book will contain an annex of recommended evidence-based pharmacotherapeutic aids for tobacco cessation in a tabulated prescription format. An immediate uptake evaluation of the TUPAC methodologies will be recorded and trainees at two centers (SDS - Nairobi and MTRH – Eldoret) will undergo on-site follow ups for three months after training.

**B2.3 EVALUATION DESIGN:**

**Evaluation of outcomes:** Assessment of changes in competence and engagement of the target group of OHCP after the intervention shall be based on reviews of pre-and post-test questionnaires, analysis of clinical logbooks and on-site observational evaluations of OHCP by the core team of trainers for six months following the training. OHCP will be required to follow up clients and reinforce quitting messages through mobile telephone contact and face-to-face reviews. Mobile phone penetration in Kenya is currently at 77.2\%\textsuperscript{42}. The trainees shall use their logbooks to record number of counseling sessions, telephone interactions, time spent with clients, cessation methods, prescriptions used and patient progress. Our target is an increase of at least 80\% from the baseline in levels of competence and participation in TUPAC counseling amongst the trained oral health workers.

**Preliminary impact assessment:** The desired impact of this study is an increase in number of smokers committing to tobacco cessation. Due to the two year duration of the project, a full impact evaluation (long-term follow up of clients) is not feasible as recommended by the Russell Standard\textsuperscript{43}. However, a preliminary cessation/ tobacco use reduction analysis will be conduction at two practice monitoring centers (SDS - Nairobi and MTRH - Eldoret). Self-reported cessation shall be biochemically validated by semi-quantitative measurement of cotinine presence in unstimulated saliva with saliva dipsticks\textsuperscript{44,45}. The sampled patients shall be evaluated at baseline (first visit) and after one and three months with the test strips. The entire group of educators from different institutions involved in training of OHCP will also be interviewed to provide an overview of the perceived successes and challenges of implementing the training.

\textsuperscript{41} Lai DTC, Cahill K, Qin Y, Tang JL. Motivational interviewing for smoking cessation. Cochrane Database Syst Rev. 2010; CD006936.
\textsuperscript{42} http://www.cck.go.ke/news/2013/Mobile_penetration.html.
\textsuperscript{44} Montalto NJ and Wells WO. Validation of Self-Reported Smoking Status Using Saliva Cotinine: A Rapid Semiquantitative Dipstick Method. Cancer Epidemiol Biomarkers Prev 2007; 16(9): 1858-1862.
Minimising errors and biases: The questionnaires will be pre-tested among 10 dentists, 10 community oral health workers, and 10 dental students in Nairobi to assess the suitability and un-ambiguity of items. None of the persons included in the pre-test will be included in the study. Data from the pre-test will be analyzed to check whether the information obtained is suitable for achievement of the study objectives. The questionnaires will be tested for temporal stability, test-retest reliability and clarity before being duly corrected. Participant recruitment will be on the basis of their work stations, with stratified random sampling used for selection and an invitation register maintained to avoid double participation.

Strategy for dissemination of project outcomes: The training program will include the use of eLearning, webinars on the Global Bridges website and social media to facilitate access to teaching materials. The team proposes to present a paper entitled “Attitudes, subjective norms and intention to do tobacco cessation counseling amongst oral health care providers in Kenya” at the WCTOH meeting in March 2015. A policy makers’ workshop involving the Ministries of Health and Higher Education at the end of the project will ensure adequate national and regional sensitization on the benefits of training OHCP in TUPAC.

B4. DETAILED WORKPLAN AND DELIVERABLES SCHEDULE:

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<th>YEAR</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
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<td>QUARTERS</td>
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<td>Phase I: Project planning</td>
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<td>Training of the core team of trainers (5 days)</td>
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<td>Development of research/training tools</td>
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<td>Recruitment and calibration of 3 research assistants</td>
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<td>Stratified sampling of study participants</td>
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<td>Enrollment of study participants</td>
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<td>Baseline survey on TUPAC practice without training</td>
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<td>Analysis of baseline data</td>
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<td>Piloting of questionnaires, analysis and adjustment</td>
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<td>Phase II: Implementation, monitoring and evaluation</td>
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<td>Presentation of baseline data at WCTOH (March)</td>
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<td>Pre-test immediately before training</td>
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<td>Training workshops (3 in number – 3 days)</td>
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<td>Post-test immediately after training</td>
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<td>Survey six months after training</td>
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<td>Phase III: Reporting</td>
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<td>Data analysis, report writing</td>
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<td>Report submission to IGLC</td>
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<td>Policy makers’ workshop (2 days)</td>
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NB: The Principal investigator is tasked to deliver a weekly report to the Dean, SDS and University of Nairobi administration concerning progress on the project deliverables.