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APPLICATION FORM FOR SUBMISSION OF RESEARCH PROPOSALS TO KMU-AS&RB

Serial No (for office use):_____ Date of submission:_____

Name of the Institute: Institute of Public Health & Social Sciences.

Date of Registration with institute: Jan-2016 Session: _____

Program/Specialty: PhD Semester: 5th Semester

Name: Dr. Fayaz Ahmad.

Fathers Name: Said Azam.

Contact No: 0341-9035750 Email dr.fayaz1980@gmail.com

Name & Designation of Supervisor: Assistant Professor. Dr. Nasim Khan.

Type of Participants: Humans ✓ Animals____ Others (specify):_____

Status of Submission: 1): Fresh ✓ 2): Revised:____ Duration of Data collection: 12 Months

Title of the project: Smokeless Tobacco control in Khyber pakhtunkhwa Pakistan (STOP): Mixed Method Research.

Please tick the following checklist before submission:

Work plan/Gantt Chart attached:			✓ Yes / No
Proposal attached as per format provided by KMU-AS&RB:			✓ Yes / No
Approved by Graduate Committee:			✓ Yes / No
Ethical Approval obtained:	Yes	No	In process ✓
KMU dues submitted and up to date:			✓ Yes / No
Covering Letter Attached:			✓ Yes / No
20 copies of proposals and all supplementary documents attached:			✓ Yes / No
Plagiarism Certificate attached			✓ Yes / No
Course Completion certificate attached			Yes / No

Candidate Signature:

Supervisor Signature and Stamp:

Dr. Muhammad Naseem Khan
Assistant Professor
KMU-IPH&SS

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Institute of Public Health & Social Sciences
Khyber Medical University

Ref: F-136/PhD F (15)/Vol-I/KMU-IPH&SS/ Dated: 25/01/2018

Director (ORIC)
Khyber Medical University
Peshawar.

Subject: COVERING LETTER

Dear Sir

With reference to the subject cited above; enclosed please find here with synopsis details of **Dr. Fayaz Ahmad S/o Mr. Said Azam** Student of **PhD Session Fall 2015** for onward submission to ASRB for approval.

Graduate Student Committee

1. Dr. Hamid Hussain (Member)	2. Dr. Ayaz Ayub (Member)
3. Dr. Muhammad Naseem Khan	4. Dr. Ayesha Imtiaz (Member)
5. Dr. Waqas Mohyddin (Member)	

Sincerely

Chairman
Graduate Student Committee

Cc:
1. Concerned student
2. Office Record

KMU-Acamedic Block, 1ST Floor, Phase-5, Hayatabad, Peshawar, Khyber Pakhtunkhwa
Phone #: 92-91-9217268/091-5892867

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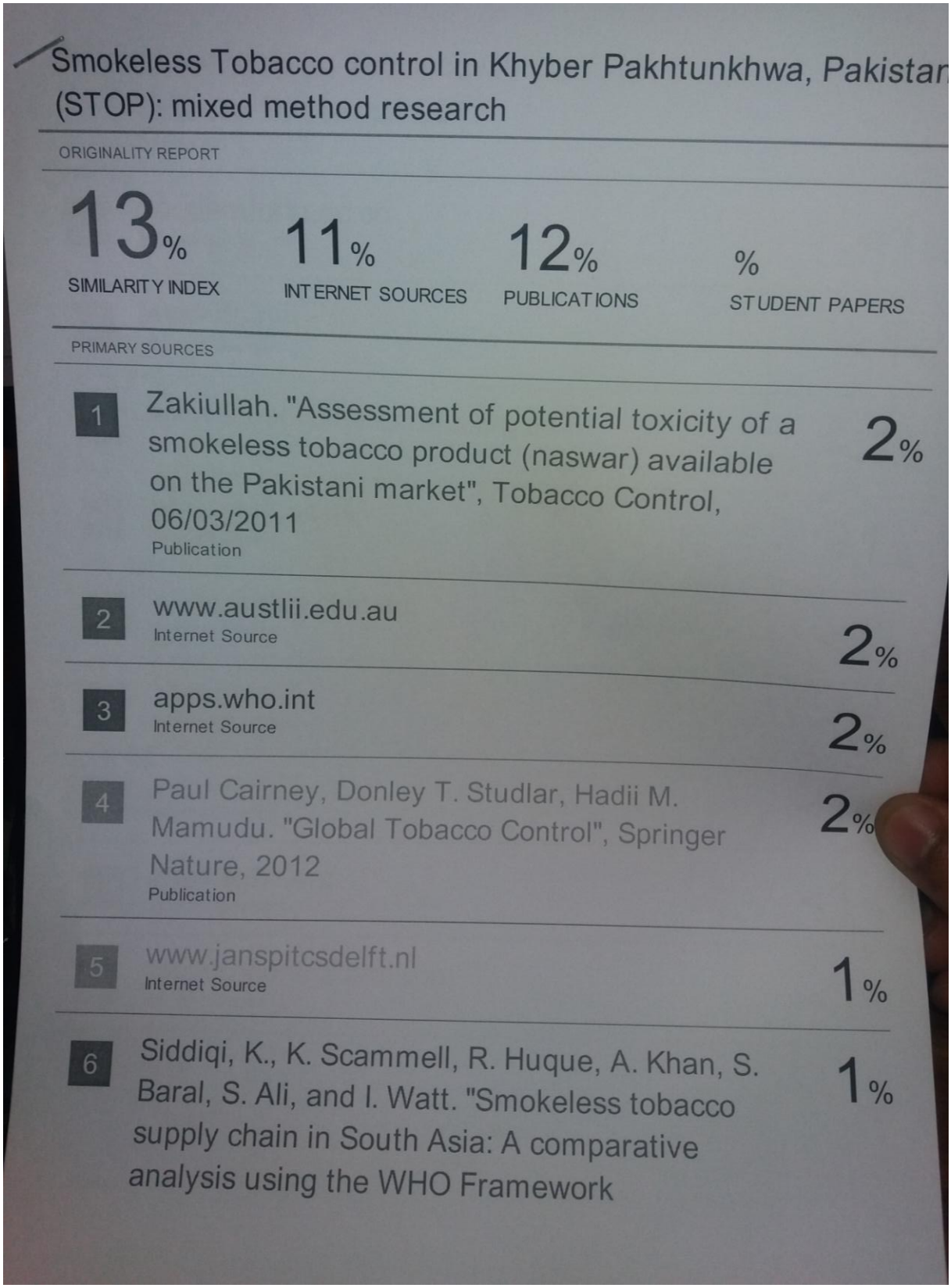

Smokeless Tobacco control in Khyber Pakhtunkhwa, Pakistar
(STOP): mixed method research

ORIGINALITY REPORT

13%	11%	12%	%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Zakiullah. "Assessment of potential toxicity of a smokeless tobacco product (naswar) available on the Pakistani market", Tobacco Control, 06/03/2011 Publication	2%
2	www.austlii.edu.au Internet Source	2%
3	apps.who.int Internet Source	2%
4	Paul Cairney, Donley T. Studlar, Hadii M. Mamudu. "Global Tobacco Control", Springer Nature, 2012 Publication	2%
5	www.janspitcsdelft.nl Internet Source	1%
6	Siddiqi, K., K. Scammell, R. Huque, A. Khan, S. Baral, S. Ali, and I. Watt. "Smokeless tobacco supply chain in South Asia: A comparative analysis using the WHO Framework	1%

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No: _____ **Date: _____**

RESEARCH PROPOSAL TEMPLATE

Title (not to exceed 50 words):

Smokeless Tobacco control in Khyber Pakhtunkhwa, Pakistan (STOP): mixed method research

Name of Candidate: Dr. Fayaz Ahmad

Name of Supervisor: Dr. Muhammad Naseem Khan

Co-Supervisors:

1. **Dr. Zohaib Khan**
2. **Dr. Zia-ul-Haq**

Duration of Project: **18 months**

Institute: **Institute of Public Health and Social Sciences (IPH&SS), Khyber Medical University**

Budget Required: **Funding Secured from German Academic Exchange Service (DAAD)**

Name & Signature of Student/Scholar: **Dr. Fayaz Ahmad**

Name & Signature of the Supervisor: **Dr. Muhammad Naseem Khan**

Name & Signature of Head of Institute: _____

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1. TITLE (not to exceed 50 words): Should reflect objective of the study.

Smokeless Tobacco control in Khyber Pakhtunkhwa, Pakistan (STOP): mixed method research

2. INTRODUCTION: (must include problem statement, background information and rationale 250-300 words)

In 2005, Pakistan signed the World Health Organization's "Framework Convention on Tobacco Control (FCTC)"(1). The FCTC is an evidence-based global public health treaty, developed by countries in response to the globalization of the tobacco epidemic. It aims to tackle some of the causes of that epidemic, including complex factors with cross-border effects, such as trade liberalization and direct foreign investment, tobacco advertising, promotion and sponsorship beyond national borders, and illicit trade in tobacco products (2). Pakistan has made considerable progress in curbing the smoking epidemic in the country (3). However, the same cannot be said for the control of smokeless tobacco (SLT) (1), which is a socially acceptable habit in Pakistan (4). SLT is a form of tobacco that is used without burning the product (5). Recent evidence suggests that approximately 13% of the population in Pakistan use some form of smokeless tobacco (6). There is a distinct geographical difference regarding the consumption of different types of SLT products (7). While betel quid and its different variations are common in the southern parts of the country, Naswar is very common in the northern parts, particularly the north western province of Khyber Pakhtunkhwa (8). Naswar is a mixture of dried tobacco, ash and lime and has been historically used by the Pashtun tribes of Pakistan and Afghanistan and the Central Asian countries (9). More recently Naswar has also become available in countries where expats from the Naswar-using countries have relocated, i.e. in the United Kingdom (10).

SLT products have been labeled carcinogenic by the International Agency for Research on Cancer (IARC), and are associated with an increased risk of pre-malignant and malignant conditions of the upper aero digestive tract (11). SLT products have more than 30 cancer causing agents, of which the Tobacco Specific Nitrosamines (TSNAs) are the main group of carcinogens (5). There are marked differences in the amount of TSNAs present in SLT products used around the globe; hence there is a varying risk of disease associated with different SLT products. The SLT products used in Pakistan e.g. Naswar, Gutkha, and Betel quid with tobacco, have some of the highest levels of TSNAs (9).

Evidence from Pakistan points towards an elevated risk of oral cancer associated with SLT products used (7). Of particular interest is the very high risk of oral cancer associated with Naswar use, as indicated by our own epidemiologic research (7). The presence of lime and ash in Naswar leads to an increase of the pH of the oral cavity, which in turn leads to an enhanced formation of TSNAs, explaining the elevated risk of oral cancer with the use of Naswar (12-14).

Recent evidence from Pakistan has identified gaps in the smokeless tobacco control policies of the country, particularly those related to the lack of regulation and taxation of SLT products and the sale of these

products to minors (1, 3). Moreover, evidence gathered from the actors involved in the supply chain of SLT products suggests that most of the components of the FCTC (articles 6, 9-13, 15-17) applicable to the control of SLT are either absent or poorly implemented in Pakistan (15). SLT control has always taken a backseat to smoking control, both globally and in Pakistan (1, 16). This lack of emphasis on SLT control can be contributed to a variety of factors, including the perception of SLT being less harmful compared to smoking. This perception is illustrated in SLT being portrayed as a harm reduction substitute to smoking by some scientific quarters (17). Moreover, SLT use has been seen as a regional issue in comparison to smoking tobacco, which is used more extensively across the globe, and thus minimal resources have been allocated to research and advocacy related to SLT use (11). Additionally, the sheer diversity and complexity of SLT products and the difference in associated risk of disease with these different SLT products used across the world makes it challenging for tobacco control entities to effectively implement SLT control policies (1). The lack of emphasis on SLT control becomes more pertinent in the wake of the increasing prices of cigarettes, the lack of advocacy against the use of smokeless tobacco, and smokeless tobacco being advocated as a cheaper and less harmful alternative to smoking, as these can result in more people taking up smokeless tobacco products with potentially devastating consequences to their health (8).

The FCTC presents a valid and effective tool to regulate and control tobacco use, including SLT use (15). However, its effectiveness depends on the sustainable implementation of SLT control policies. To do so, information about potential facilitators and barriers for comprehensive implementation is needed. These factors are related to both supply and demand of SLT, as well as to policy formulation and implementation. Barriers can be in the form of a potential loss to the economy, through a decrease in demand and the resulting decrease in production of tobacco crop. The tobacco industry may reject any regulatory steps like taxation and pictorial warnings on the SLT products, as has been seen previously in the case of smoking (18). Another potential barrier could be fears of the SLT supply chain actors, who may revert to black market production and sale of the SLT products to avoid taxation.

Identification of the specific barriers and facilitators to the regulation of SLT and the assessment of the knowledge, attitudes, practices, and fears of the SLT supply chain actors is, therefore, an important step in devising and implementing a national/regional SLT control policy in Pakistan. Through this proposed project and the evidence generated, we intend to identify the perceived barriers and possible facilitators, fears, and reservations of the SLT supply chain actors regarding SLT regulation. Building on these findings, in-depth interviews with policy makers will be conducted, focusing on the barriers and facilitators to SLT regulation policy. Interviews will explore how such a policy can address the reservations of the supply chain actors.

The study aims to inform policy through a consultative process guided by the results of our survey and interviews. Findings are intended to support SLT control in Khyber Pakhtunkhwa and in Pakistan by raising awareness for SLT control. SLT control may ultimately lead to a decrease in the burden of head and neck cancers associated with SLT use in the country, the second most prevalent cancers in Pakistan, and contribute to the economic and social development of Pakistan in a sustainable manner.

Rationale

An implemented regulatory policy for SLT is missing in Pakistan. Knowledge on specific barriers and possible facilitators to SLT control policy formulation and implementation has not yet been sufficiently explored (9, 10). The "STOP" study aims to identify these barriers amongst the target groups, specifically supply chain actors and policy makers, and to elicit information on necessary actions to facilitate policy implementation.

3. OBJECTIVE(S): (must be stated in measurable terms and starting with an action verb)

1. To identify barriers and facilitators to the formulation and implementation of an SLT control policy in Khyber Pakhtunkhwa, Pakistan.
2. To explore the fears, knowledge, attitudes and beliefs of the smokeless tobacco (Naswar) supply chain actors regarding SLT regulation (Naswar) in Khyber Pakhtunkhwa, Pakistan.
3. To formulate recommendations to inform SLT regulation policy for Khyber Pakhtunkhwa, Pakistan.

4. OPERATIONAL DEFINITIONS: (All key variables of study must be clearly defined in detectable terms)

Following are the operational definitions to be used in this study.

- **Smokeless Tobacco (SLT)**
  Any product of NICOTIANA TABACUM that is not smoked but is either inhaled through the nose, chewed, or stored in cheek pouches.

- **Frame work Convention on Tobacco Control (FCTC)**
  The WHO Framework Convention on Tobacco Control (WHO FCTC) is the first treaty negotiated under the auspices of the World Health Organization. The WHO FCTC represents a paradigm shift in developing a regulatory strategy to address addictive substances; in contrast to previous drug control treaties, the WHO FCTC asserts the importance of demand reduction strategies as well as supply issues. The WHO FCTC was developed in response to the globalization of the tobacco epidemic.(2)

- **Supply Chain actors**
  All those people involved in the business of SLT and availability of SLT for the consumption of general population. This chain includes point of sale vendors, wholesale retailers, manufacturers, raw tobacco retailers and farmers.(15)

- **Naswar (a smokeless tobacco)**
  Naswar is an SLT widely used in Pakistan, Afghanistan, Iran and the Central Asian Republics, and in South Africa. It is a mixture of mainly sundried, powdered local tobacco (Nicotina rustica), ash, slaked lime, and in some areas flavouring agents (e.g. cardamom, menthol) and colouring agents (indigo). It is consumed by placing it in the mouth cavity, usually between the oral mucosa and gingival cavity or sometimes under the tongue (floor of the mouth). After about half an hour it is then spat out. (15)

- **Focus Group Discussion (FGD)**
  It is a form of qualitative research consisting of interviews in which a group of people are asked about their perceptions, opinions, beliefs, and attitudes towards a product, service, concept, advertisement, idea, or packaging.

5. HYPOTHESIS (If required): (only the alternate hypothesis must be clearly stated aligned with objective)

NA

6. MATERIALS AND METHODS:

6a. Study Design:

The STOP project will have four components within a mixed methods design over a period of 2 years:

1. Focus groups with SLT supply chain stakeholders to develop topics for the questionnaire.
2. Broadly disseminated questionnaires on the topic of SLT supply chains, barriers, and facilitators.
3. Semi-structured interviews with policymakers about barriers and facilitators.
4. Dissemination workshop and development of policy brief.

Results will be synthesized and applied to develop a set of recommendations to inform SLT control policy for the region of Khyber Pakhtunkhwa during a series of consultative workshops with regional policy makers, researchers, representatives of the SLT supply chain and tobacco control experts.

6b. Study Settings:

In Khyber Pakhtunkhwa province of Pakistan, major administrative districts will purposively be selected on the basis of high levels of consumption and large scale manufacture, distribution, and sale of SLT products. These will include Peshawar, Mardan and Bannu districts.

6c. Study Duration:

18 months.

6d. Sample Size: (with justification of its calculations and reference used):

- 2-3 Focus groups with SLT supply chain stakeholders to develop topics for the questionnaire and number of participants in each focus group will be 6-10.
- The in-depth interviews with policy makers will follow thematic saturation and at this stage it is estimated to be 10-15 respondents.
- For quantitative component, the survey part, to calculate the sample size a pilot study will be carried out in two enumeration blocks of district Peshawar; one each from both the urban and rural blocks. This will give us the exact number of Naswar point of sale vendors at block level. The number of blocks for all the 3 districts of our study will be obtained from Bureau of Statistics (BOS) where each block consists of 250-300 households. This process will give us our sampling frame. The pilot will give us an estimate of population, the sale points here. If Peshawar has 2000 enumeration block and each one has 1 sales point, then we have a 2000 point of sale vendors/city. So for three major cities, we have a P of 6000. Keeping the margin of error at 5% we have a sample size of 362. If we increase the number to 4 points/block then the sample size for a frame of 24000 "P" increases to 379.

6e. Sampling Technique:

As the target group, the supply chain actors is highly specific and difficult to get access to, a snowball sampling and purposive sampling scheme will be used to recruit the study participants in three phases.

In the first phase, 2-3 focus groups will be conducted with supply chain actors and with tobacco control experts. Each focus group will consist of 6-10 participants criterion-selected based on their occupation and expertise. This will be purposive sampling to get the maximum information from the relevant participants.

In the second phase, the survey part does not aim to be representative of a population, but rather to include a typical case. Based on the numbers required and the response rate of the participants, all the three approaches of snow ball sampling; chain referral, Exponential Non-Discriminative and Exponential Discriminative methods will be used for recruitment during the different stages. Stage one will include interviews with point-of-sale vendors and wholesale dealers. The vendors will subsequently be asked to identify the commercial producers and wholesale retailers of the SLT products, who will then be interviewed in stage 2. The commercial producers will be asked to identify farmers, who will be interviewed in stage 3.

In the third Phase, sampling strategy will be guided by a preliminary qualitative case selection plan and aims for thematic saturation. The exact number of interviews to be conducted will, therefore, be adapted throughout the data collection period, in line with recommendations for qualitative research approaches.(19, 20)

7. SAMPLE SELECTION:

7a. Inclusion criteria: (What type of subjects or material is to be included in the study)

Only those participants will be included in the study that consented to take part.

8. DATA COLLECTION PROCEDURE: (Detailed inclusion of subjects and data collection plan, including briefs about laboratory procedures, surgeries etc. Must clearly explain how the researcher will flow his data collection plan right from start till finishing the follow up on subjects or material.

Focus groups with SLT supply chain stakeholders

To elicit information on key issues that need to be addressed in a quantitative survey, 2-3 focus groups will be conducted, one with supply chain actors and one with tobacco control experts. Each focus group will consist of 6-8 participants criterion-selected based on their occupation and will be moderated by a trained researcher and observed by a second researcher who takes notes (21). A preliminary topic guide for the questionnaires, designed by the research team based on a review of the SLT policy literature, will be presented to the focus group participants and their opinions elicited.

A questionnaire on the topic of SLT supply chains, barriers, and facilitators

The survey component of the project will be based on a study carried out among supply chain stakeholders. A structured questionnaire will be administered in a face-to-face interview with the various actors of the SLT supply chain. The face-to-face design allows people with low literacy to participate as they can fill in the questionnaire verbally together with the researchers. Broadly, the questionnaire will comprise questions pertaining to issues raised in the focus groups, and likely the SLT related FCTC articles i.e. Article 6: Price and tax measures to reduce the demand for tobacco, Article 9: Regulation of the contents of tobacco products, Article 10: Regulation of tobacco product disclosures, Article 11: Packaging and labelling of tobacco products, Article 12: Education, communication, training and public awareness, Article 13: Tobacco advertising, promotion and sponsorship, Article 15: Illicit trade in tobacco products, Article 16: Sales to and by minors, Article 17: Provision of support for economically viable alternative activities. The final design of the questionnaire will be pilot tested in a small sample of supply chain stakeholders (3-5 persons) using verbal probing techniques of cognitive interviewing (22, 23), and adapted as needed.

Interviews with policy makers

Qualitative semi-structured interviews with a purposive sample of policymakers will be conducted to identify barriers to and facilitators of the regulation of SLT products in Pakistan generally and in Khyber Pakhtunkhwa specifically. Potential interview participants include representatives of the Provincial Ministry of Health, Ministry of Agriculture, Provincial Health Department, Tobacco Control Cell, Pakistan Tobacco

Board, Excise and Taxation department, and the National Ministry of Health Services Regulation and Coordination.

The sampling strategy will be guided by a preliminary qualitative case selection plan and aims for thematic saturation. The exact number of interviews to be conducted will, therefore, be adapted throughout the data collection period, in line with recommendations for qualitative research approaches (19, 20). At this stage, an estimated sample of 10-15 interviews is expected to lead to thematic saturation (24, 25). The interview guides will be based on topics drawn from the SLT-related FCTC articles and the findings of the quantitative survey on implementation barriers. All interviews will be carried out by trained researchers, audio-recorded and transcribed verbatim. Transcripts will be analysed using a qualitative content analysis approach in NVIVO-11 software.

Dissemination workshop and development of policy brief

Findings will be presented at a consultative workshop with those policymakers who participated in the focus groups or interviews. Additional policymakers interested in the topic are invited to attend. The aim of the workshop is to engage relevant actors in guided discussion to identify potential action points for future policy development. An interactive format for the workshop will be selected with input from local partners in order to adhere to local customs. Results of the workshop will be synthesized together with overall study findings and written up into a policy brief.

Ethics

Ethics approval for the study will be sought from the “Ethical Review Board" of KMU in Pakistan. The researchers will all adhere to Good Scientific Practice as outlined by the German Research Foundation (DFG). The project gathers information from experts and professionals on their occupation-related views and does not collect sensitive information. The main expected burden of this research project on participants is the required time to participate in a focus group, survey or interview. The research team will take care to minimize the time needed from participants in the design of data collection instruments.

All participants will be informed about the aims of the project, the time required, data handling and that they are participating voluntarily and may withdraw from the study at any time without negative consequences. Participants will be asked to sign informed consent forms prior to data collection.

9. DATA ANALYSIS PROCEDURE: Detailed description of type of analysis plan according to type of variables and study design, statistical tests (if required), stratification of confounders/effect modifiers, presentation of results etc. must be clearly mentioned.

Expected Outcomes

Through the proposed research we expect to identify the barriers to SLT control in Pakistan with a particular emphasis on those measures required by the FCTC: taxation, health warnings, manufacturing, and composition of SLT products. Results of the study components will be triangulated to explore issues common to both policy makers and supply chain actors from all phases of the empirical research, while potentially coming up with solutions to address these points of concern among both groups. Eventually, the core issues identified in the research phase will be aimed to inform the draft formulation of an SLT regulation policy in the consultative meeting.

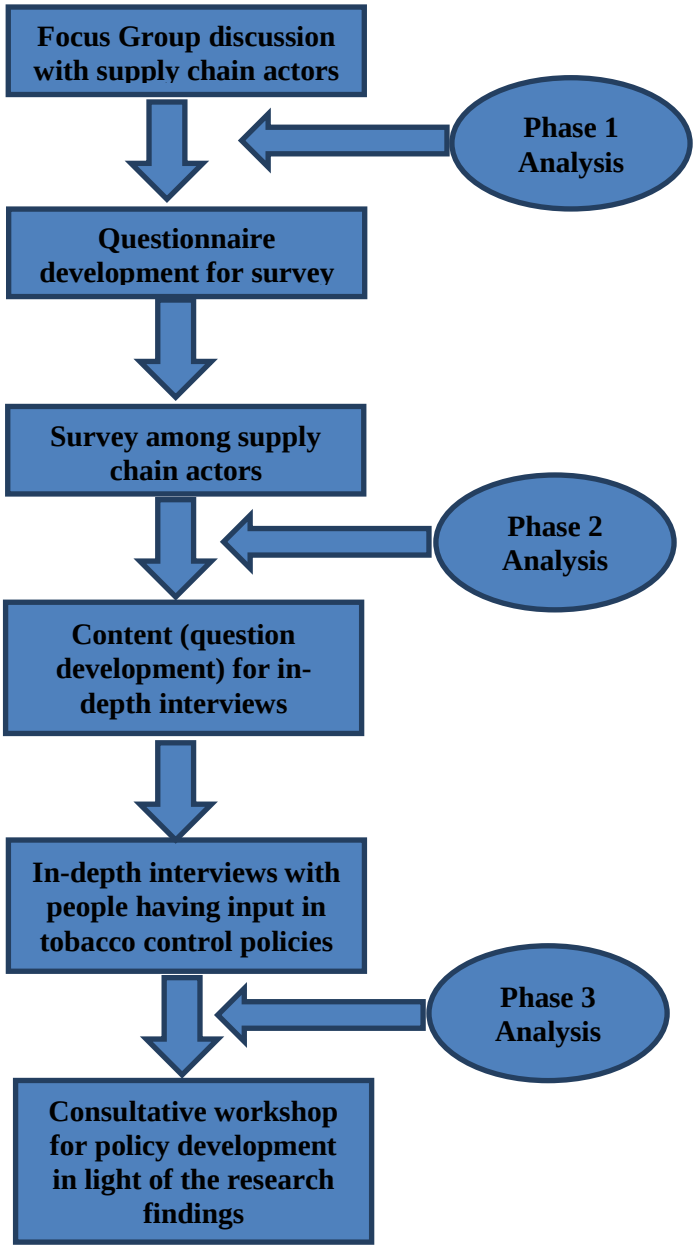
The project will take an iterative form, where findings of FGDs will help in the development of topics for the quantitative survey and the quantitative survey among the SLT supply chain actors will inform the qualitative interviews with the different players involved in policy formulation and implementation, followed by the consultative policy formulation meeting. The final 6 months of the project duration will be used to publish and further disseminate results.

A preliminary topic guide for the questionnaires, designed by the research team based on a review of the SLT policy literature, will be presented to the focus group participants and their opinions elicited. Focus group discussions will be audio-recorded, transcribed verbatim and transcripts analysed using qualitative content analysis. Identified themes will be synthesized into topic guidance for the subsequent survey.

The questionnaire will comprise questions pertaining to issues raised in the focus groups, and likely the SLT related FCTC articles i.e. Article 6, 9-13 and 15-17. Data from the paper-based questionnaire will be entered and analysed in STATA version 14. Translations, if required, will be performed on the basis of the verbatim interviews. The data analysis will include descriptive statistics, comprising response frequencies, mean values and cross tabulations for different variables on barriers and facilitators to SLT regulation and supply chain.

All interviews with relevant stakeholders will be carried out by trained researchers, audio-recorded and transcribed verbatim. Transcripts will be analysed using a qualitative content analysis approach in NVIVO-11 software. Data will be pseudonymised and kept confidential. However, considering the small community of policymakers, absolute anonymity cannot be guaranteed as policymakers may recognize points of views of their peers in subsequent publications.

Data collection and analysis flow diagram:



10. BIBLIOGRAPHY: In Vancouver style.

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Gantt chart for Smokeless Tobacco control in Khyber Pakhtunkhwa Pakistan (STOP): mixed method research

S.NO	TASK	May 2018	July 2018	Sep, 2018	Nov, 2018	Jan, 2019	March, 2019	May, 2019	Aug, 2019	Nov, 2019
1	Focus Group Discussion with supply chain actors									
2	Phase 1 Analysis									
3	Questionnaire Development for survey									
4	Survey among supply chain actors									
5	Phase 2 Analysis									
6	Content (questions development) for In depth interview									
7	In-depth interviews with people having input in tobacco control policies									
8	Phase 3 Analysis									
9	Consultative Workshop									