**Schedule A**

Title: A study exploring the extent and reasons of non-adherence of Cigarette and Other Tobacco Products Act (COTPA) in a district of Manipur, a Mixed method study Products Act (COTPA) in a district of Manipur, a Mixed method study

**Abstract:**

**Introduction and contex**t: According to the Global Adult Tobacco Survey (GATS) 2 findings there is rampant use of Tobacco or its product in Manipur. In spite of this the anti-Tobacco measures like the Cigarette and Other Tobacco Products Act implementation seems to be implemented in less effective manner as has been evident from the amount of challan collected.

## Research Question:

1. What is the extent of non-adherence of Cigarette and Other Tobacco Product Act(COTPA) in the District of Thoubal in Manipur?
2. What are the difficulties faced by the stakeholders in enforcing the COTPA act in the State?
3. What are the key areas to focus for the success of COTPA/Tobacco control?

**Research Design and Methods:** Mixed Method: Quantitative and Qualitative method will be used in concurrent manner. Mixing of the data will be done at the phase of data analysis.

The study will be done in a district of Manipur called Thoubal. In Quantitative methods: Schools will be selected randomly. The premises of the randomly selected school will be surveyed for violation of the COTPA Act and the school authority where COTPA violation is found will be interviewed in depth. Restaurants with more than 30 sitting capacity and point of sales will also be randomly selected for survey for violation of COTPA. In Qualitative methods, important stakeholders involved in the implementation of the COTPA like the Deputy Commissioners, the Superintendent of Police, Zonal Education Officers, Officers from Municipal Corporation, State Nodal officer/State Consultation for National Tobacco Control programme, police personnel involved in enforcement of COTPA, the Non- Government Organization Members working for Tobacco, Tobacco users.

**Results**: The findings will be depicted appropriately for quantitative and qualitative.

**Conclusion:** The study will give a picture of the extent of COTPA non-adherence and the reasons for non-adherence or difficulty of COTPA enforcement in the State.

Introduction

According to Global Adult Tobacco Survey (GATS) 2 which is regarded as the gold standard for systematically monitoring adult tobacco use and a nationally representative survey, the prevalence rates of Tobacco use in any form in Manipur is 55% i.e. a little more than every second person in Manipur is user of tobacco in any form while the overall Indian percentage is 28.6%. The percentage of male and female using Tobacco in any forms are 62.5% and 47.8 % respectively.1 Also 35.9% of men, 6.0% of women and 20.9% of all adults currently smoke tobacco. 50.2% of men, 45.2% of women and 47.7% of all adults currently use Smokeless Tobacco (SLT).1 Manipur occupies second rank in the use of Smokeless form (47.7%) of Tobacco after Tripura (48.5%). The common most form in the State is Betel Quid with Tobacco locally known as *Kwa Zarda*. Its users are ever increasing in number in the state of Manipur especially among the female population.1

Tobacco is the risk factor of major killer diseases like cancer, heart diseases, hypertension, lung diseases and many more affecting all system of the body but Tobacco is abundantly used in Manipur. Tobacco is used in various forms, it can be broadly categorised as smoking (e.g. cigarettes, bidi, hookah etc) and smokeless (SLT) forms (eg betel quid, khaini etc). 1

According to Indian Council of Medical Research (ICMR) report in 2016-17, in Manipur over a third (36.8%) of cancers in males and close to one-fifth (19.5%) in females are tobacco use related cancer sites. Among these, lung (18.9 % in males; 14.4% in females) followed by oesophagus (5.3% in males; 1.4% in females) constitute the leading sites. The cancer incidence rate and rise are higher for females than males. Among males, about two-third are current tobacco users, while 35.9% are current smokers. Nearly half of the females are current tobacco users.

The cancer attributable to Tobacco in India is that 45% of all cancers in males and 17% of all cancers in female while 80% of Oral cancer overall.

So, there is urgent need to control this particular situation. Various strategies are being designed for control of Tobacco, some of them as has been laid out by the Health Evidence Network(HEN) are as follows

Price increases.

Comprehensive ban on advertising and promotion of tobacco products

Strong restrictions on smoking and tobacco use in work places and public spaces Education and counter advertising campaign

Improved product warning

Increased access to cessation therapies3

The Cigarette and Other Tobacco Products Act (COTPA) which was first enacted on 18thMay 2003 is applicable to all products containing Tobacco in any form and extends to all over India.4

The COTPA include 33 Clauses for enforcement against Tobacco, of which the most important ones include Section 4 and 6. Section 4 is Prohibition of smoking in Public Places, Section 6 has two parts which are 6(a) and 6(b). 6a is prohibition of sale of Tobacco to minors and 6b is prohibition of sale of Tobacco within 100 yard of the school premises.4 Of these sections the one which will be feasible and that can be used as an indicator for enforcement of the act. So, in the quantitative part the schools will be surveyed for violation of section 4a and 4b.

## Context:

Most of these interventions are covered by COTPA. Monitoring of COTPA is to be done by the National Tobacco Control Program (NTCP). The NTCP has many thrust areas, some of the relevant ones to this study are training of law enforcers, monitoring of Tobacco Control Laws and setting up cessation clinic for Tobacco.5 Implementation and enforcement of COTPA is all the more challenging but there are places which made efforts overcome whatever issues that erupted.8,9 So it is pertinent that if COTPA and NTCP are implemented there will be effective Tobacco Control.

In Manipur, the National Tobacco Control Program (NTCP) was piloted in two districts which were Imphal West and Churachandpur from 2015-17. There are 16 sixteen districts in Manipur. Later NTCP was expanded to the rest of the districts in the state towards the end of 2018. The NTCP as given in its guidelines should be implemented through the State Tobacco Control Cell and at the District Levels through District Tobacco Control Cell. The programme also involves formation of State Level Co- ordination Committee involving various stakeholder departments with the Medical Minister as the chairman and heads of stakeholder departments include the Home, Education, Municipal Co-operation, PHED etc. The District Level Co-ordination Committee is a corresponding committee with members of the same departments as in The State Level with the Deputy Commissioner as the chairman.

All these are to function with a common aim to control the tobacco. The National Tobacco Control Program (NTCP) encompasses COTPA along with others strategies. The program requires involvement of various stakeholders and Multisectoral Collaboration. The Home Department and the Education sector are the two most important ones. It is the onus of the Health Department to implement the NTCP and so the Nodal department is the Health department for NTCP. Under the Health system lens, it comes under the Governance block which is software part of the Health system which is difficult to see or measure. Unfortunately NTCP implementation needs more push in Manipur. Discussion with few Program persons highlighted that seeking involvement from other sector is an important challenge. According to an information from the state NTCP division, the total Challan amount collected in the whole state from 2017 is very less.

After all these evidence of high use, prevalence of tobacco in the state and inspite of presence of effective legislature which is COTPA, there seems a lack of enforcement of COTPA in the state. As a Public Health Person and being involved in Health Programme have been vigilant about the non- adherence of the COTPA and it necessitates to ask the research question as follows.

## Research Question:

1. What is the extent of non-adherence of Cigarette and Other Tobacco Product Act (COTPA) in the District of Thoubal in Manipur?
2. What are the difficulties faced by the stakeholders in enforcing the COTPA in the State?
3. What are the key areas to focus for the success of COTPA/Tobacco control?

Here, by non-adherence of COTPA means any action or inaction that goes against the provisions mentioned in the clause of COTPA at individual and at the level of authority. By difficulties it means the operational problems faced by the stakeholders.

**Research Design:**

The study will adopt Mixed Method, involving both Quantitative and Qualitative method. It will be concurrent as both the quantitative and qualitative part will be done in parallel as quantitative will be done by recruited and trained data collector while the qualitative ones will be done by the Principal investigators and trained data collector. Mixing of the data will be done at the phase of data analysis. The study area selected is the district of Thoubal which is a prototype district with regards to implementation status of National Tobacco Control Programme. The implementation of NTCP is more or less the same in the all districts of Manipur. The total population of Thoubal is 422168. There are 210845 males and 211323 females in the district according to 2011 census.

The quantitative part will do a cross-sectional study for the presence of Tobacco sales within 100 yards of schools and other educational institution boundary, presence of signage against smoking and Tobacco at restaurant with sitting capacity of more than 30 and at point of sales for pictorial warning.

For this, list of schools in the district will be obtained from the Zonal Education Office (ZEO) of the District. The list will also include the address of the school, the level of classes, the number of students studying in the school. The schools will be assigned with a number for simple random sampling.

From the list a random sample of around 50 schools will be taken considering the feasibility of the study period. All the selected schools and its premises of 100 yards will be surveyed for compliance with COTPA using a checklist. The checklist for school will include information like the presence of signage, presence of points of sales for Tobacco, anyone found smoking etc. School authority (may be a principal or a teacher of those schools which were not compliant with the act) will be interviewed at the end of each week. The survey will be done in such that 10 schools which are in proximity for journeying are covered per week and at the end of each week the total number of schools found not adhering to the act will be recorded and appointments of prominent authority of the school will be taken for an in-depth interview. The transcript and analysis has to, be completed before the end of the next week,

From this we will record the number or percentage of schools not adhering to the Tobacco Law ei., Cigarette and Other Tobacco Act(COTPA) under which sales of Cigarette and other Tobacco products to children below 18 years of age and sale in the vicinity of the school of 100 yard is prohibited.

As the investigator travel from one to school to another for survey, he/ she will also check for display of pictorial warning at points of sale located nearest to the schools. A total of around 50 sales point may be checked in the localities situation in the vicinity of the schools.. Since the district has two blocks ei Lilong and Thoubal, the sale points will be those situated in these blocks.

For checking the signage at restaurant the list of restaurants will be obtained from the District Food Safety department along with their contact numbers. After verifying the number of sitting capacities.

Ten percent of those with more than 30 sitting capacities will be visited randomly for checking of signage and non-adherence of the act.

**Qualitative Method:**

The qualitative method employed will be in-depth interviews of the major stakeholders using an interview guide developed appropriately for the concerned stakeholder. The major stakeholders who will be interviewed in depth will include Deputy Commissioner, the Superintendent of Police, the Zonal Education Officer, School Principal or a senior teacher of the schools which violated COTPA, Non- Government Organisation, members active in Tobacco Control, 4 vendors or salesman of Tobacco and 4 Tobacco users. The reasons for selecting these stakeholders is because they are the key actors involved in the Tobacco control especially the enforcement of the Cigarette and Other Tobacco Act (COTPA). The enforcement mainly involves smoking in public places, sale under 18 years of age and within 100 metres of the schools and educational institutes. For violations of this acts there is fine and challan has to be issued by the enforcers. The interview will be carried out after prior appointment and will be done at a venue appropriate/convenient to the stakeholders. All the interviews will be recorded with consent of the interviewee for better analysis.

There are 7 police stations in the district of Thoubal. At least 2 Officer in Charge and 2 Sub inspectors of the police station will be interviewed for knowledge of COTPA and its implementation.

**Analysis Plan:**

Quantitative data will be entered in Excel sheet. The data will be analysed for presence or absence of violations in the form of presence of sales of Tobacco within 100 yards of school boundary, absence of signage at schools, restaurants, important government offices, pictorial warning at point of sales etc.

**Qualitative:**

The in depth interviews will be transcribed for thematic analysis.

If required there will be mixing of data during analysis.

**Result:**

The quantitative result will be mostly as percentage, depicted in tabular and graphic form as required like the percentage of schools violating the COTPA. Further stratification of schools in the form of government and private schools will be done.

The qualitative data will be presented in the form of themes like the barriers or difficulties faced by the stakeholders especially the COTPA enforcers and NTCP implementers at the State level and the district level in running the programme.

A short History of NTCP in Manipur will also be obtained.

**Expected impact:**

The study is expected to show evidence for generating awareness about the alarming situation of the state to the various stakeholders. The evidence will also bring alertness among the various stakeholders and give them insight indirectly that may bring about improvement in the Tobacco Control in the State which will be of high policy relevance.

It may affect the affect the utilisation of Tobacco and its products.

**Ethical considerations:**

These principles of ethical consideration including voluntary participation, informed consent, anonymity, confidentiality, potential for harm, and results communication will be maintained throughout the research.

**Limitations:**

Due to the limited time period other districts of the state will not be covered. The Principle investigator is an employee of the Health Department and is working for the National Tobacco Control Programme at the District Level. So, an Assistant Professor from a local Medical College is being involved as Co Principle Investigator.

**Dissemination plans:**

The result will be disseminated to all the stakeholder department at the District level by holding Dissemination Workshop. The results will be shared as a report to all the concern departments, and will be presented in the relevant Conferences if possible.

**Reference:**

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2. Indian Council of Medical Research-National Centre for Disease Informatics and Research. Profile of Cancer and Health Related Indicators in the North east Region of India. 2021. Available at: https://ncdirindia.org/All\_Reports/Report\_2020/default.aspx. Assessed: October 1, 2022.
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4. Government of India The Cigarettes and Other Tobacco Products (Prohibition of Advertisement and regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003. Available at: [http://legislative.gov.in/sites/default/files/A2003-34.pdf.](http://legislative.gov.in/sites/default/files/A2003-34.pdf) Published May 18, 2003. Accessed October 2, 2022.
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6. Census of India (2011). Office of the Registrar General & Census Commissioner, New Delhi, 27- 12-2013. Available at https://[www.census2011.co.in/census/district/375-imphal-](http://www.census2011.co.in/census/district/375-imphal-) west.html#:~:text= Imphal%20West%20District%20Urban%2FRural%202011&text=In%20total%20322%2C879%2

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1. Census of India (2011). Office of the Registrar General & Census Commissioner, New Delhi, 27- 12-2013. Available at https://[www.census2011.co.in/census/district/](http://www.census2011.co.in/census/district/) 374 -thoubal.html. Accessed October 3, 2022.
2. Surbhi Tripathi, Palanivel Chinakali, Bijaya Nanda Naik, Sitanshu Sekhar Kar.COTPA implementation status: An observational study in South Indian city. Indian J Med Res 156, September 2022, pp 508-515, DOI 10.4103/ijmr\_2376\_20.
3. Dharmashree Satyarup , Manish Kumar , Radha Prasanna Dalai , Sourav Chandra Bidyasagar Bal , Sailaja Panda. Tobacco control in India: Enforcement strategies and challenges. Journal of Global Oral Health.Volume 5, Issue 2 , July-December 2022 |p119

**Gannt Chart**

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| Tasks | Time(Weeks | 1w | 2w | 3w | 4w | 5w | 6w | 7w | 8w | 9w | 10w | 11w | 12w | 13w | 14w | 15w | 16w | 17w | 18w | 19w | 20w | 21w | 22w | 23w | 24w | 25w | 26w | 27w | 28w | 29w | 30w | 31w | 32w | 33-38w | 39-43w | 44-47w | 48-52w |
| ROL | 12 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| RL Report | 4 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Advertisement for Data  Collector | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Interview/  Result | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Data Collector  training | 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Vehicle Hiring  Advertisement | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Vehicle Hiring  Advertisement | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Data  Collection | 12 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Data Entry | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Quant Data  analysis |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Transcript | 8 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Translate | 12 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Report |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Planning and preparation for  dissemination | 4 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Dissemination  Workshop | 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Attending  Conference |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Publication in scientific  journal |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Submission of  final report | 8 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**Budget**

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| --- | --- | --- | --- | --- | --- |
|  | Resource Required | Units | Time | Unit cost | Amount |
| ROL | Laptops | 1 | NA | 60000 | 60000 |
|  | Printer | 1 | NA | 25000 | 25000 |
| Data Collection | Recruitment Process | 1 | 1week | 20000 | 10000 |
|  | DC/RA salary | 2 | 4months | 15000 | 120000 |
|  | Local Travel /Transport | 1 | 4months | 26000 | 104000 |
|  | Training | 1 | one time | 20000 | 20000 |
|  | Mobile/Recorder | 1 | NA | 20000 | 20000 |
|  | Dissemination Workshop | 1 | 1day | 50000 | 50000 |
|  | Review Meeting | 2 | 4 | 10000 | 80000 |
|  | Publication | |  |  | 30000 |
|  | Institutional Ethical Committee fees | |  |  | 10000 |
|  | Overhead expenses | |  |  | 71000 |
| Total |  |  |  |  | 600000 |

**Compensation**

The Consultant will be paid a total amount of **INR 6,00,000** (Inclusive of all indirect taxes). The payments will be released only on the completion of deliverables as per the terms of payment and raising an invoice in the given format*.*

**Terms of Payment:**

●        **Instalment 1** – 50% advance upon signing contract and **on the receipt of NOC or Self Declaration (Schedule B or C) as applicable.**

●        **Instalment 2** – 30% upon completion of data collection & analysis

●        **Instalment 3** – 20% upon submission of final research project

**Term**

This engagement shall commence upon execution of this Agreement. The Agreement shall continue in full force and is effect from **October 01, 2023** to **March 31, 2024.**

**Note: All expenses to be claimed as actuals within the approved budget. Supporting financial documents including invoices, receipts etc must be submitted.**