



TPackSS: Tobacco Pack Surveillance System

Smokeless and Bidi Tobacco Field Collection Protocol

10/23/2017

India

BACKGROUND

Johns Hopkins Bloomberg School of Public Health, Institute for Global Tobacco Control (IGTC) seeks to monitor whether required health warnings are being implemented as intended and rapidly identify pack design appeals that might violate or detract from country tobacco packaging laws. To this end, we have developed and are implementing a surveillance system of tobacco product packaging in the Bloomberg Initiative priority countries.

India is the second largest consumer of tobacco products in the world. According to the 2016-17 Global Adult Tobacco Survey (GATS), 21.4% (199.4 million) of the Indian adult population use smokeless tobacco, compared to 10.7% (99.5 million) of adults who smoke. Nearly twice as many smokeless tobacco users reside in rural areas than urban areas. Additionally, smokeless tobacco users are more likely to have no formal schooling, or have less than primary school education.

Smokeless tobacco data collection efforts will target rural areas in Indian states that have been identified as having a high prevalence of smokeless tobacco users.

STUDY DESIGN

States: Five (5) Indian states (Maharashtra, Rajasthan, Karnataka, Uttar Pradesh, and Assam) were identified based on smokeless tobacco user prevalence, geographic diversity and political relevance as identified by in-country partners.

Cities: Within each state, **five** (5) cities will be selected for sampling, totaling **twenty-five** (25) over all five states. Cities will be selected by first sorting every district within each state by total population. The top 5 most populous districts will then be selected (excluding districts that contain the state capital). From the top 5 most populous districts, two to three districts will be selected based on geographic proximity for pragmatic reasons. Within the selected districts, towns and villages will be identified and sorted from highest to lowest population and classified by Table 1. We will define tiers 1-3 as urban, and tiers 4-6 as rural. We will select one tier 3 city and two villages each in tiers 4 and 5. These five areas will be selected for sampling based on geographic diversity and practical purposes, such as travel time and distance.

Table 1: Indian city population tier, Census Bureau of India

Tier
Tier - 1 Population of 100,000 and above
Tier - 2 Population between 50,000 and 99,999
Tier - 3 Population between 20,000 and 49,999
Tier - 4 Population between 10,000 and 19,999
Tier - 5 Population between 5,000 and 9,999
Tier - 6 Population less than 5,000

Hubs: Five (5) hubs will be identified for sampling in tier 3 cities, and up to **five** (5), but a minimum of **three** (3), hubs will be chosen for sampling in tier 4 and 5 villages. All hubs are selected on the basis of geographic diversity within the city or town limits. Up to **twenty-five** (25) distinctive hubs in each state (up to **125** in total across India) will be identified.

Using Google Maps and Google Earth, a list of all primary hubs will be compiled that fell into the following categories: religious structures (temples, mosques, and churches) and educational institutions (primary and

secondary schools, universities, colleges, and madrassas). These primary hubs will be used to create an initial list of **five** (5) hubs for each city. Secondary, or backup hubs, consisting of banks (including ATMs) and post offices will be identified if any of the primary hubs cannot be found.

In the event that primary and secondary hubs alone cannot fulfill the five hub quota in each town, data collectors will identify any areas of commercial activity (i.e. markets or bazaars) and follow the walking protocol (Appendix E – Vendor Selection and Walking Protocol).

Vendors: In each previously identified hub, data collectors will follow the vendor selection and walking protocol (refer to Appendix E – Vendor Selection and Walking Protocol).

SAMPLING AND DATA COLLECTION METHODS

This study will employ two sampling methods, as described below. In India, smokeless tobacco (chewable, nasal and paste form), bidi, and cigarettes will be purchased. Only packaged tobacco products will be purchased (i.e. no individual sticks or unpackaged loose tobacco). In addition, no bulk items will be purchased (i.e. cartons of cigarettes or rolls of smokeless tobacco sachets).

Purchase Everything Sample

At the first vendor in each town, one of every uniquely different (any pack with at least one difference in an exterior feature of the pack including: stick count, size, brand name presentation, colors, cellophane, packaging material (i.e. hard, soft, tin), and inclusion of a promotional item) tobacco product (bidis, smokeless tobacco, and cigarettes) available in the store will be purchased.

Unique Cigarettes Packs Sample (each subsequent vendor, following the first purchase in each town)

A purchase will be made from a store if a smokeless or bidi pack is identified that has not been previously purchased. If the first selected vendor, in a specific hub, does not have any unique smokeless or bidi packs, then the Vendor Selection and Walking Protocol (Appendix F) will be followed. If at the fourth vendor at a hub, no additional unique packs are found, one of every bidi and smokeless product, will be purchased. After the initial *Purchase Everything Sample*, in each of the subsequent hubs when a purchase is made, one of every cigarette pack that was not already purchased will be purchased from a vendor.

All unique packs will be marked with a red sticker.

This data collection method will be repeated for each town (in tier 3, 4, 5) in every state.

DATA COLLECTION PROCEDURES

Objective: Purchase tobacco packs within the sampling method above using the correct procedures.

Resources

Data collection team:

Data collector 1: Will primarily interact with the vendor; will be in charge of systematically identifying the tobacco products for purchase; will be in charge of paying for the purchase and acquiring the receipt for purchase.

Data collector 2: Will primarily be responsible for management of the packs, packing and recording the price paid for each product.

Equipment: All equipment, except for the items marked below as “not provided”, will be provided by IGTC. For a list of equipment needed for field collection, see below.

Equipment:	
<input type="checkbox"/> Receipt book	<input type="checkbox"/> Pens
<input type="checkbox"/> Ziploc bags	<input type="checkbox"/> Bags or boxes to carry tobacco products (not provided)
<input type="checkbox"/> ID labels	<input type="checkbox"/> Cash/debit card (not provided)
<input type="checkbox"/> Smartphone	<input type="checkbox"/> Colored stickers (red, green, orange)
<input type="checkbox"/> Handheld GPS	<input type="checkbox"/> Rubber bands

PART I. IN-STORE COLLECTION PROCEDURES AT FIRST VENDOR IN EACH CITY

Procedures:

1. Purchase all unique tobacco packs available.
 - a. Face the tobacco product display and request to purchase one of each unique tobacco pack.
 - b. Capture the price of each pack. Place an orange sticker on the back of the pack and record the price on the sticker.
 - i. For retailers where the price is not given via bar code, do not request nor accept a reduced price if the vendor offers a discount due to the large quantity being purchased.
 - c. Ask the merchant to confirm that one of each tobacco pack they sell has been acquired and purchase any additional packs identified.
 - d. Place the packs in a box or bag. Pay for the entire purchase and retain a receipt that will be submitted for reimbursement.
 - i. Record on the receipt the neighborhood ID from doForms, number of packs purchased, total price of the purchase, and date.
 - ii. If the retailer does not provide receipts use the receipt book and record the information listed above.

2. Take a picture of the tobacco product display
 - a. After data collection and payment are complete, ask the merchant if it would be possible to take a photo of the retail display and if allowed use the smartphone to take the picture.
 - b. Take a picture of the receipt, with the recorded identifiers (neighborhood ID, # of packs purchased, total price, date) displayed, so that each retail display image is tied to its corresponding neighborhood and receipt.
 - c. Place the pictures into the “Point of Sale” photo album on the smartphone.

3. Record field data
 - a. After exiting the retail environment, open the doForms app on the smartphone and enter details about the purchase (refer to Appendix B—doForms Instruction Guide). **Important: The neighborhood # in Appendix A—Unique ID structure) given on doForms needs to match the neighborhood # written on the ID labels.**

4. Organize packs and record pack data
 - a. As soon as possible after purchase, place each pack into an individual plastic Ziploc bag and place a unique ID label at the bottom left hand front corner of the bag. Refer to Appendix A—Unique ID Structure Instruction Guide for how to fill in the unique ID label. While in the field, it is only necessary to fill in information up to Pack # (i.e. Country_City_Neighborhood #_Store #_Pack #). If necessary, refer back to doForms to confirm that the Neighborhood # matches the neighborhood entered in doForms.
 - b. In addition to the Unique ID, record the name, price, and date of purchase on the label.

5. Create image archive.
 - a. Create a photographic archive of packs purchased at the initial store to facilitate data collection at subsequent stores. Each tobacco product from the unique packs sample will be photographed and placed into a “brand family folder” on the iPod after each purchase (refer to Appendix E—Creating an Image Archive).

PART II. IN-STORE COLLECTION PROCEDURES AT ALL SUBSEQUENT VENDORS IN STATE

Procedures:

1. Approach the vendor. Face the tobacco product display and identify if any packs available were not already purchased.
 - a. When determining whether a pack was already purchased, look through the image archive on the smartphone to see if the pack exists. If there is a pack that does not exist in the image archive, every pack available within that vendor will be purchased.
2. Complete pack sample purchase.
 - a. Capture the price of each pack. Place an orange sticker on the back of the pack and record the price on the sticker.
 - i. For retailers where the price is not given via bar code, do not request nor accept a reduced price if the vendor offers a discount due to the large quantity being purchased.
 - b. Ask the merchant to confirm that one of each tobacco pack they sell has been acquired and purchase any additional packs identified.
 - c. Place the packs in a box or bag. Pay for the entire purchase and retain a receipt that will be submitted for reimbursement.
 - i. Record on the receipt the neighborhood ID from doForms, number of packs purchased, total price of the purchase, and date.
 - ii. If the retailer does not provide receipts use the receipt book and record the information listed above.
3. Take a picture of the tobacco product display
 - a. After data collection and payment are complete, ask the merchant if it would be possible to take a photo of the retail display and if allowed use the smartphone to take the picture.
 - b. Take a picture of the receipt, with the recorded identifiers (neighborhood ID, # of packs purchased, total price, date) displayed, so that each retail display image is tied to its corresponding neighborhood and receipt.
 - c. Place the pictures into the “Point of Sale” photo album on the smartphone.
4. Record field data
 - a. After exiting the retail environment, open the doForms app on the smartphone and enter details about the purchase (refer to Appendix B—doForms Instruction Guide). **Important: The neighborhood # in Appendix A—Unique ID structure) given on doForms needs to match the neighborhood # written on the ID labels.**
5. Organize packs and record pack data
 - a. As soon as possible after purchase, place each pack into an individual plastic Ziploc bag and place a unique ID label at the bottom left hand front corner of the bag. Refer to Appendix A—Unique ID Structure Instruction Guide for how to fill in the unique ID label. While in the field, it is only necessary to fill in information up to Pack # (i.e. Country_City_Neighborhood #_Store #_Pack #). If necessary, refer back to doForms to confirm that the Neighborhood # matches the neighborhood entered in doForms.

- b. In addition to the Unique ID, record the name, price, and date of purchase on the label.
6. Create image archive.
- a. Create a photographic archive of packs purchased at the initial store to facilitate data collection at subsequent stores. Each tobacco product from the unique packs sample will be photographed and placed into a “brand family folder” on the iPod after each purchase (refer to Appendix E— Creating an Image Archive).

PRODUCT INVENTORY, PHOTOGRAPHY, AND UPLOADING DATA

Objective: Generate a product inventory and high quality images of each tobacco pack in a uniform manner, save and label them, and secure them on an online database.

Resources

Equipment: All equipment and materials needed to complete this section, except for the ones marked below as “not provided”, will be supplied by IGTC. For a list of equipment needed for inventory and archival imaging, see below.

Equipment:		
<input type="checkbox"/> Canon camera	<input type="checkbox"/> N size battery charger	<input type="checkbox"/> Tobacco Packs (not provided)
<input type="checkbox"/> SanDisk 16G memory card	<input type="checkbox"/> Camera case	<input type="checkbox"/> Computer (not provided)
<input type="checkbox"/> Kingston memory reader	<input type="checkbox"/> 2 Canon N size batteries	<input type="checkbox"/> Internet access (not provided)
<input type="checkbox"/> 1 travel adaptor	<input type="checkbox"/> Passwords to Dropbox and RedCap	

Product Inventory

Procedures:

1. Ensure that all information on the unique ID label for the collected tobacco packs are filled in and accurate.
2. Complete an online data entry form for each tobacco pack collected, using REDCap, an online data collection tool (refer to Appendix C - REDCap Product Inventory Instruction Guide for instructions).

Photography

Procedures:

1. Generate two images of each tobacco pack purchased, then save, label, and upload the images to the shared Dropbox account (refer to Appendix D – Photography Protocol for instructions).
2. After all data collection is complete, upload to the shared Dropbox account all of the tobacco pack images from the brand family image archive and the Point of Sale images found on the iPod. Place images into the *iPod Images* folder and inside the *iPod Collection Archive Images* or the *Point of Sale Images* folder.

REPORTING GUIDELINES

Objective: Report on progress of TPackSS project.

PART I: REPORTING ON CREATING PRODUCT INVENTORY

1. After the first 50 packs have been entered into REDCap, email Research Program Manager **Michael Iacobelli** (miacobelli@jhu.edu).
 - a. **Michael** will review the product inventory entered in REDCap and provide feedback.
 - b. After feedback is provided, update the existing product inventory if needed and proceed with completing the product inventory.
2. After all packs have been entered into REDCap, email **Michael** and report that the product inventory data entry is complete.

PART II: REPORTING ON ARCHIVAL IMAGING AND UPLOADING

After uploading the two tobacco pack images, and the smartphone tobacco pack archival images and the Point of Sale images, send an email to **Michael Iacobelli** (miacobelli@jhu.edu) stating that the photographs have been uploaded.

1. Each day that packs are photographed and uploaded to Dropbox, email Michael and provide a summary of work completed.
 - a. In the email, include the photographs taken and which folders they were uploaded to (Ex: Today, India > Uttar Pradesh > Gola, packs 001-049 were uploaded.), the total number of packs that were collected in the city whose packs are being photographed, and the total number of packs that have been photographed for that particular city (ex: 49 packs of a total of 156 packs collected in Gola have been photographed to date.). These packs will be reviewed daily for image quality by IGTC staff, and changes or approval of the images will be given.
2. Email **Michael Iacobelli** (miacobelli@jhu.edu) once the tobacco pack archival images and the Point of Sale images are uploaded.
3. After all photography is uploaded email Michael Iacobelli and report that the photography activities are complete

PACKAGING AND SHIPPING

Objective: Properly package tobacco packs for shipment and support shipping logistics.

Resources

Equipment: All of the paperwork noted below will be provided by IGTC. All of the shipping materials needed to ship the equipment and tobacco packs will need to be purchased. Save the receipts in order to submit for reimbursement. For a list of equipment needed for packaging and shipping, see below.

Equipment:	
<input type="checkbox"/> Tobacco packs	<input type="checkbox"/> Packing List Envelope
<input type="checkbox"/> Standard shipping boxes	<input type="checkbox"/> "Pro Forma Invoice" Form (5 copies)
<input type="checkbox"/> Packaging tape	<input type="checkbox"/> Waybill
<input type="checkbox"/> Packaging popcorn foam or bubble wrap	<input type="checkbox"/> FDA and FTC letters
<input type="checkbox"/> Product inventory list	

PART I: PACKAGING AND SHIPPING OF THE EQUIPMENT SUITCASE AND THE TOBACCO PACKS

Procedures:

1. Confirmation of acceptable product inventory entry and photography upload, and preparation for shipment.
 - a. After receiving an email from Michael Iacobelli that the product inventory entry and photography upload is acceptable; then Senior Research Coordinator **Sejal Saraf** (ssaraf3@jhmi.edu) will send an email with instructions for how to prepare shipment of the equipment suitcase and the tobacco packs.
2. Purchase materials required to ship the equipment suitcase and the tobacco packs.
 - a. Visit a packaging/shipping store and purchase the appropriate size box for shipping the equipment suitcase and for shipping the tobacco packs. Purchase protective material for each box. The equipment suitcase and the tobacco packs should be placed in separate boxes.
3. Sejal will email a pick-up date for when the shipping carrier will retrieve the boxes. **Have the boxes ready for the specified pick-up date.**
4. Email Michael and Sejal once the boxes are picked up by the shipping carrier and provide any confirmation or tracking documentation from the shipper.