TOBACCO PACK SURVEILLANCE SYSTEM (TPackSS), WAVE III: FIELD PROTOCOL

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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 14 Bloomberg Initiative priority countries. As the market for electronic cigarettes (e-cigarettes) and heated tobacco products (HTPs) grows, we are expanding to surveil these products as well.

STUDY DESIGN

Cities: Six data collection cities, Beijing, Shanghai, Chongqing, Guangzhou, Kunming and Shenzhen were determined by IGTC during the third round of data collection in consultation with the in-country partner. They consist of the most populated city, and five additional cities chosen based on geographic location and smoking and e-cigarette use prevalence. Data collection in Shenzhen will focus on e-cigarettes and heated tobacco products (HTPs), but not cigarette packs. Data collection will begin in the most populated city, Shanghai, and then proceed to the next five cities – the order will depend on pragmatic factors (distance, cost, and travel logistics). Data collection agenda may be changed to comply with local and national public health policies in response to COVID-19 pandemic in China.

Cigarettes, HTPs & E-cigarettes

Collection of cigarette packs, HTPs and e-cigarettes (disposable e-cigarettes and nicotine-containing e-cigarette refills [pods or pre-mixed liquids]) will follow the methods below:

Neighborhoods – Our sample of neighborhoods in each city will be based on identifying low, middle, and high socioeconomic (SES) areas. Four characteristically distinctive neighborhoods within each of the three socioeconomic strata will be chosen based on the following factors: geographic location; the makeup of who lives in the neighborhood (e.g. immigrants, religious group, ethnic group, professionals); or landmarks (e.g. university area, touristic area) for each socioeconomic area. Twelve distinctive neighborhoods in each city (72 across the six cities, country) will be identified.

Hubs – **One** hub will be identified in each neighborhood selected. Hubs will be used as a starting point for data collectors to follow a walking protocol (refer to Appendix F—Vendor Selection and Walking Protocol) and walk to vendors in each neighborhood. A hub is considered a central area in a neighborhood and can be a major transit point (bus terminal, train station), historical landmark, touristic attraction, major shopping center, large plaza, square, or major intersection and source of commerce, and tobacco vendors should be within walking distance from the hub.

Vendors – **Four** popular vendor types for cigarettes (independent small grocer, tobacco specialty, supermarket, hypermarket) and **one** vendor type for e-cigarette (vape store) were identified from Euromonitor data. For vape stores, two sub vendor types will be visited: (1) brand store (e.g., RELX, YOOZ, SNOWPLUS, MOTI, etc.), (2) non-brand name store. There is no vendor type data for HTP. HTPs and e-cigarettes will be looked for and purchased from the same vendors of cigarette sampling. Vendors will be selected via procedures in the field protocol. The first vendor visited will be selected from a middle SES neighborhood. Data collectors will follow the vendor selection and walking protocol (refer to Appendix F—Vendor Selection and Walking Protocol). In the case that unique packs are not found at the first vendor, data collectors will visit up to four cigarette vendors and two e-cigarette vendors in a given neighborhood until at least one unique pack is found.

Study Design Matrix

City	Venue types	Low (4 distinctive neighborhoods)	Middle (where initial vendor selection will happen) (4 distinctive neighborhoods)	High (4 distinctive neighborhoods)	Total vendors
Shanghai	Independent small grocer, tobacco specialty, street vendor, hypermarket	4-16 vendors	4-13 vendors*	4-16 vendors	12-45
	Vape store	4-8 vendors	4-7 vendors*	4-8 vendors	12-23
Beijing	Independent small grocer, tobacco specialty, street vendor, hypermarket	4-16 vendors	4-13 vendors*	4-16 vendors	12-45
	Vape store	4-8 vendors	4-7 vendors*	4-8 vendors	12-23
Chongqing	Independent small grocer, tobacco specialty, street vendor, hypermarket	4-16 vendors	4-13 vendors*	4-16 vendors	12-45
1	Vape store	4-8 vendors	4-7 vendors*	4-8 vendors	12-23
Guangzhou	Independent small grocer, tobacco specialty, street vendor, hypermarket	4-16 vendors	4-13 vendors*	4-16 vendors	12-45
ı	Vape store	4-8 vendors	4-7 vendors*	4-8 vendors	12-23
Kunming	Independent small grocer, tobacco specialty, street vendor, hypermarket	4-16 vendors	4-13 vendors*	4-16 vendors	12-45
	Vape store	4-8 vendors	4-7 vendors*	4-8 vendors	12-23
Shenzhen	Independent small grocer, tobacco specialty, street vendor, hypermarket	4-16 vendors	4-13 vendors*	4-16 vendors	12-45
	Vape store	4-8 vendors	4-7 vendors*	4-8 vendors	12-23
	-			Total vendors	144-408

Note: *Because an initial purchase in each city will always be conducted in a middle SES neighborhood, visiting up to 4 cigarette vendors and up to 2 e-cigarette vendors will not be required for that specific middle SES

neighborhood; yielding that only up to 13 cigarette vendors and 7 e-cigarette vendors in the middle SES neighborhoods will be visited.

SAMPLING AND DATA COLLECTION METHODS

Wave III will employ four different sampling methods, as shown below.

Tobacco product sampling – Cigarettes, HTPs, and e-cigarettes will be purchased at the vendor sites. Only packaged tobacco products will be purchased (i.e., no individual sticks or unpackaged loose tobacco). Only the package of nicotine containing HTP sticks will be purchased (i.e., no HTP devices). Only the package of nicotine containing e-cigarettes will be purchased (i.e., disposable e-cigarettes and nicotine-containing e-cigarette refills [pods or pre-mixed liquids]). In addition, no cartons of cigarettes, bidi, or smokeless products will be purchased.

The research collaborator will carry out unique pack and additional "purchase everything" sampling detailing below:

Unique Pack Sample:

In the first city, the first neighborhood visited will be a middle socioeconomic neighborhood. In this neighborhood, an "index store" for cigarettes and an "index store" for e-cigarettes will be selected by procedures in the field protocol to make an initial large purchase. One of every unique cigarette pack (any pack with at least one difference in an exterior feature of the pack including: stick count, size, brand name presentation, descriptor, colors, cellophane, packaging material [i.e., hard, soft, tin], and inclusion of a promotional item) available in the "index store" for cigarettes and one of every unique pack of e-cigarette products (any pack with at least one difference in an exterior feature of the pack including: volume, flavor, nicotine strength, brand name presentation, descriptor, colors, cellophane, and inclusion of a promotional item) available in the "index store" for e-cigarettes will be purchased.

After this initial purchase, in each of the remaining neighborhoods, one of every unique tobacco pack that was not already purchased will be purchased from a vendor. If the selected vendor, in a specific neighborhood, does not have any new packs (packs that were not purchased at another store), then until a new pack(s) is found, up to four cigarette vendors and up to two e-cigarette vendors in that same neighborhood will be visit. At the fourth cigarette vendor and the second e-cigarette vendor, if there are still no new packs found, then the data collectors should move on to the next neighborhood. The unique packs sample will be marked with a red sticker.

Additional "Purchase Everything" Sample:

At the first cigarette vendor and the first e-cigarette vendor in Beijing, Chongqing, Guangzhou, Kunming and Shenzhen, one of every unique pack (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 of cigarettes, nicotine containing HTP sticks and e-cigarettes available in the stores will be purchased. This is the same as for the unique pack purchase in the first city.

The packs from this collection should be kept separate from the unique packs sample. The additional "purchase everything" sample will be marked with a blue sticker. These packs from this collection that are duplicates of previous purchases should be physically kept separate from both the unique pack samples.

DATA COLLECTION PROCEDURES

Objective: Purchase cigarette packs, HTPs, and e-cigarettes within the two sampling methods correctly using resources and the appropriate procedures.

Resources

Data collection team:

Data collector 1: Will primarily interact with the vendor; will oversee systematically identifying the cigarette packs, HTPs and e-cigarettes for purchase; will oversee paying for the purchase and acquiring the receipt for purchase.

Data collector 2: Will primarily be responsible for management of the cigarette packs, HTPs and ecigarettes, packing, taking pictures of the packs and stores, and recording the price paid for each product.

Equipment: All equipment will be provided by Rising Sun. For a list of equipment needed for field collection, see below.

Equipment:	
☐ Receipt book	☐ Pens
☐ Ziploc bags	☐ Bags or boxes to carry tobacco products
☐ ID labels	☐ Cash/debit card
☐ Smart phone	☐ Colored stickers (red, blue, orange)
☐ Handheld GPS	☐ Rubber bands

PART I. IN-STORE COLLECTION PROCEDURES AT FIRST VAPE SHOP, AND FIRST VENDOR **Procedures**

- 1. Complete unique packs sample by purchasing all unique tobacco packs available.
 - a. Face the tobacco product display and request to purchase one of each unique 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. If you are unable to place a sticker on pack while in store, and an itemized receipt is provided, then keep the packs organized by sectioning off every 5-10 consecutive packs with a rubber band and organize the packs in a bag or box in the order they are rung up on the cash register so they can be matched with the price on the itemized receipt.
 - ii. 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.
- 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 to use the smart phone 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 smart phone.

3. Record field data

- a. After exiting the retail environment, open the Kobo Toolbox app on the smart phone and enter details about the purchase and store location (refer to Appendix B—Kobo Toolbox Instruction Guide). Important: The provided SES/neighborhood # (refer to Appendix A—Unique ID structure) given with the name of the neighborhood on Kobo Toolbox needs to match the SES/neighborhood # written on the ID labels.
- 4. Organize packs and record pack data
 - d. As soon as possible after purchasing, separate the packs according to product type (i.e., cigarette, HTP, or e-cigarette) and place each pack into an individual plastic Ziploc bag. 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_SES/Neighborhood #_Store #_Pack #). The remaining identifier (i.e. Unique/Duplicate_Brand/Cost) will be completed when the packs are being prepared for product inventory. If necessary, refer back to Kobo Toolbox to confirm that the SES/Neighborhood # matches the neighborhood entered in Kobo Toolbox.
 - e. In addition to the Unique ID, record the name, price, and date of purchase on the label. Place a red-colored sticker in the top right hand corner on the inside of the Ziploc bag so that the color of the sticker is clearly visible when viewing the bag from the front if the pack is part of the unique packs sampling.
- 5. Create an image archive.
 - f. Create a photographic archive of packs purchased at the initial store to facilitate data collection at subsequent stores. Each product from the unique packs sample will be photographed and placed into a "product type" and "brand family folder" on the smart phone after each purchase (refer to Appendix E—Creating an Image Archive).

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

Procedures

- 1. Complete **unique packs sample** by purchasing one of every unique pack that was not already purchased.
 - a. Face the tobacco product display and identify any packs that were not already purchased.
 - i. When determining whether a pack was already purchased, look through the image archive on the smart phone to see if the pack exists. If the pack matches a pack in the image archive, do not purchase the pack. If the pack does not exist in the image archive, it will be purchased as part of the unique packs sample.
 - 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. If you are unable to place a sticker on pack while in store, and an itemized receipt is provided, then keep the packs organized by sectioning off every 5-10 consecutive packs with a rubber band and organize the packs in a bag or box in the order they are rung up on the cash register so they can be matched with the price on the itemized receipt.

- ii. 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.
- 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 to use the smart phone 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 smart phone.

3. Record field data

- a. After exiting the retail environment, open the Kobo Toolbox app on the smart phone and enter details about the purchase (refer to Appendix B—Kobo Toolbox Instruction Guide). Important: The provided SES/Neighborhood # (refer to Appendix A—Unique ID structure) given with the name of the neighborhood on Kobo Toolbox needs to match the SES/Neighborhood # written on the ID labels.
- 4. Organize packs and record pack data
 - a. As soon as possible after purchasing, separate the packs according to product type (i.e., cigarette and HTP) and place each pack into an individual plastic Ziploc bag. 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. While in the field, it is only necessary to fill in information up to Pack # (i.e. Country_City_SES/Neighborhood #_Store #_Pack #). The remaining two identifiers (i.e. Unique/Duplicate_Brand/Cost) will be completed when the packs are being prepared for product inventory. If necessary, refer to Kobo Toolbox to confirm that the SES/Neighborhood # matches the neighborhood entered in Kobo Toolbox.
 - b. In addition to the Unique ID, record the name, price, and date of purchase on the label. Place a red sticker in the top right hand corner on the inside of the Ziploc bag so that the color of the sticker is clearly visible when viewing the bag from the front if the pack is part of the unique packs sampling.

5. Create image archive

a. Create a photographic archive of each product from the unique packs sample to facilitate data collection at subsequent stores. Place the photograph of the pack into a "product type" and "brand family folder" on the smart phone after each purchase (refer to Appendix E—Creating an Image Archive).

PRODUCT INVENTORY, PHOTOGRAPHY, AND UPLOADING DATA

Objective: Generate product inventory and high-quality images of each pack in a uniform manner, code packs for health warning label compliance, save and label them, and secure them on an online database.

Resources

Equipment: All equipment and materials needed to complete this section will be supplied by Rising Sun. Password to Dropbox will be provided by IGTC.

Equipment:	
☐ Canon camera	☐ Promaster mini tripod
☐ N size battery charger	☐ Password to Dropbox
☐ Camera case	☐ Tobacco and Nicotine Product
	Packs (not provided)
☐ 1 travel adaptor	☐ Computer (not provided)
☐ 2 Canon N size batteries	☐ Internet access (not provided)

Product Inventory

Procedures

- Fill in the missing information (i.e. the unique/duplicate and brand identifiers) on the unique ID label for the collected packs. The other identifiers (i.e. Country_City_SES/Neighborhood #_Store #_Pack #) should have been completed during in-field collection.
 - a. All the packs in the unique packs sample, with red stickers, will be designated with the code of 0, and the remaining packs, with only an individual blue sticker, will be designated as duplicates with the code of 1 (refer to Appendix A—Unique ID structure).
- 2. Complete an online data entry form for each pack collected, recording descriptive data, using REDCap, an online data collection tool (refer to Appendix C REDCap Product Inventory Instruction Guide).

Photography

Procedures

- 1. Generate a set of images of each 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 in a given city, upload to the shared Dropbox account all of the pack images from the smart phone. Place images into the *Smartphone Images* folder and inside the *Pack 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 Jane Doe.
 - a. Jane Doe 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 form.
- 2. After all packs have been entered into REDCap, email Jane Doe and report that the product inventory data entry is complete.

PART II: REPORTING ON ARCHIVAL IMAGING AND UPLOADING

After uploading the smart phone pack archival and the Point of Sale images send an email to Jane Doe, stating that the photographs have been uploaded. In the email, include the city, product types, and number of packs of each product type uploaded.

- 1. Each day packs are photographed (for the standard 0 and 180 degree shots) and uploaded to Dropbox, email Jane Doe, and provide a summary of work completed.
 - a. In the email, include the photographs taken and which folders they were uploaded to (Ex: Today, China>Shanghai, cigarette packs 001-049 were uploaded, HTPs 001-004 were uploaded, e-cigarette packs 001-029 were uploaded), the total number of packs that were collected in the city which packs are being photographed, and the total number of packs that have been photographed for that particular city (e.g., 49 out of 156 cigarette packs, 4 out of 10 HTP packs, and 19 out 34 e-cigarette packs collected in Shanghai 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 Jane Doe once the tobacco pack archival images and the Point of Sale images were uploaded.
- 3. After all photography is uploaded, email Jane Doe and report that the photography activities are complete.

PACKAGING AND SHIPPING

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

Resources

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

Equipment:	
☐ Cigarette and HTP product packs	☐ Packing List Envelope
☐ Standard shipping boxes	☐ Pro Forma Invoice Form (5 copies)
☐ Packaging tape	☐ Waybill
☐ Packaging popcorn foam or bubble wrap	☐ FDA and FTC letters (provided by IGTC)
☐ Product inventory list	

PART I: PACKAGING AND SHIPPING OF THE PACKS

Procedures

- 1. Confirmation of acceptable product inventory entry and photography upload, and preparation for shipment.
 - a. After receiving an email from Jane Doe that the product inventory entry and photography upload is acceptable, Jane Doe will send an email with instructions on how to prepare shipment of the packs.
- 2. Purchase materials required to ship the tobacco packs.
 - a. Visit a packaging/shipping store and purchase the appropriate size box for shipping the packs. Purchase protective material for each box.
 - b. Place the packs in boxes according to product types
- 3. Jane Doe 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 Jane Doe once the boxes are picked up by the shipping carrier and provide confirmation or tracking documentation from the shipper.