Assessing Compliance with Tobacco Packaging and Labeling Regulations

The Union
International Union Against Tuberculosis and Lung Disease
Health solutions for the poor

Campaign for Tobacco-Free Kids™

Johns Hopkins Bloomberg School of Public Health
Institute for Global Tobacco Control

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Glossary

Brand family: A marketing strategy that promotes a family of products under an umbrella brand name or trademark. Products are then differentiated from one another by the addition of a modifier (see definition of brand variant). Examples of well-known brand families are Philip Morris International's Marlboro and British American Tobacco's Camel.

Brand variant: The manifestation of a brand that is marketed as being sufficiently similar to, but also different when compared with, other variants in the same brand family. Color and name are key visual signifiers differentiating one variant from another. Variants are used to expand the type and availability of products. In some instances, brand variants have been falsely advertised to consumers, giving tobacco users the perception that a particular brand variant is less harmful than others in the same brand family. Examples of variants within the Marlboro family include Marlboro Red, Marlboro Gold, Marlboro Lights, Marlboro Menthol, and Marlboro Ice Blast, among others.

Heated tobacco products: Battery-operated electronic device that heat a stick (or plug) of compressed tobacco to a high enough temperature to produce an inhalable aerosol containing nicotine and other chemicals.

Illicit tobacco products: Tobacco products produced in either legal or covert manufacturing facilities that have not been declared to tax authorities, or tobacco products that are produced in one jurisdiction and illegally transported to another, avoiding applicable taxes.

Smoked tobacco products: Tobacco products designed to be consumed by inhalation. Nicotine, deadly toxicants and other chemicals are released through a process known as combustion and inhaled. Smoked tobacco products include cigarettes, cigars, cigarillos, little cigars, blunts, bidis, kreteks, cheroot pipes, and waterpipes.

Smokeless tobacco products: Tobacco products consumed by means other than inhalation, such as chewing, sniffing or placing the product between one's teeth and gum. Smokeless tobacco products include chewing tobacco, dipping tobacco, snuff, snus, gutka, khaini, betel quid, and dissolvable tobacco products.

Waterpipe tobacco: Tobacco that is smoked through a single or multi-stemmed instrument through which smoke passes through a water basin, often glass, before inhalation. Waterpipe tobacco is oftentimes flavored and, depending on the country, may be referred to as hookah, huqqah, shisha, sheesha, nargilah, narghile, arghlla, or qalyan.

Introduction

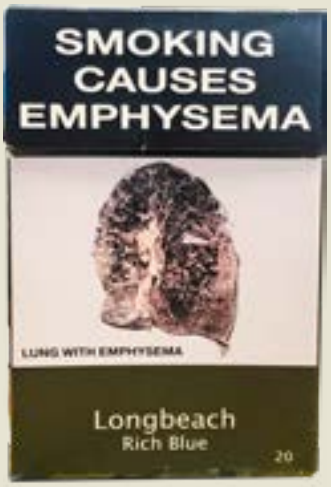
Tobacco companies use tobacco packaging as a way to promote and market their products and increase sales. In the absence of effective packaging and labeling requirements, the tobacco industry produces appealing packaging that creates brand recognition with the use of eye-catching colors, designs and trademarks. Tobacco companies exploit all elements of tobacco packaging to market their products including the outer film, tear tape, inner frame, pack inserts and onserts.

Article 11 of the World Health Organization Framework Convention on Tobacco Control (FCTC) requires Parties to adopt and implement effective packaging and labeling policies. The Guidelines for implementation of Article 11 (Article 11 Guidelines) recommend measures to increase the effectiveness of the Convention's requirements. These measures include:

- A ban on packaging and labeling that is false, misleading, deceptive, or likely to create an erroneous impression about a tobacco product's characteristics, health effects, hazards, or emissions;
- Large, rotating pictorial health warning labels (HWLs) printed on the principal display areas of the tobacco product package, carton and any outside packaging and labeling;
- Descriptive or qualitative information on relevant constituents and emissions of tobacco products; and
- Plain packaging.

Many countries have successfully implemented packaging and labeling measures pursuant to FCTC Article 11 and its Guidelines. These policy efforts have had measurable impacts in reducing tobacco use and consumer misperceptions. Australia, Uruguay and Nepal serve as examples of countries that have implemented comprehensive and effective packaging and labeling measures grounded in Article 11 of the FCTC.

Australia

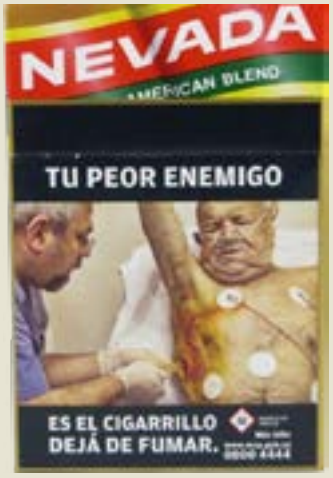


Front of pack

Back of pack

Australia has required tobacco products to be in "plain" packaging since December 2012. The Australian Department of Health released a Post-Implementation Review stating that between December 2012 and September 2015, after controlling for a range of variables, Australia's tobacco plain packaging, in combination with pictorial HWLs, accounted for approximately one quarter of the total decline in tobacco use prevalence during the period.[1]

Uruguay

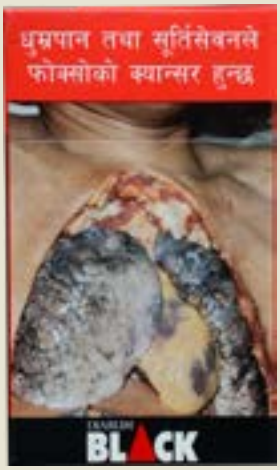


Front of pack

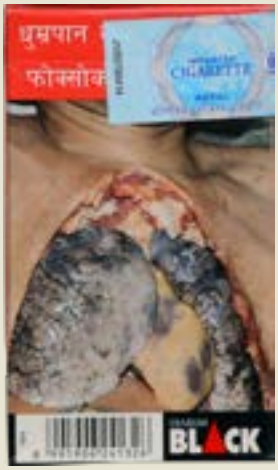
Back of pack

Uruguay's Ministry of Public Health Ordinance No. 514, effective in 2009, allows only a single pack presentation (i.e., only one family brand variant allowed) has had a positive impact on the perceptions and behaviors of smokers in Uruguay. For example, the percentage of smokers who incorrectly believed that "light" cigarettes are less harmful than regular cigarettes decreased from 29% of smokers before the single pack presentation policy was implemented to 15% afterward.[2]

Nepal



Front of pack



Back of pack

Nepal's Directive on Printing Warning Messages and Pictures on Tobacco Product Boxes, Packets, Cartons, Parcels and Packaging Materials (2014) requires a 90% pictorial HWL on the upper part of both sides of tobacco product packaging. These warnings have been effective at promoting quitting. One study found that 21.8% of respondents made a quit attempt attributed to pictorial HWL during the past 12 months.[3]

Conducting a compliance assessment is an important way to monitor packaging and labeling implementation in any country. The Johns Hopkins Bloomberg School of Public Health (JHSPH), the Campaign for Tobacco-Free Kids (CTFK), and the International Union Against Tuberculosis and Lung Disease (The Union) have developed this "how-to" guide to help civil society groups assess whether tobacco companies are implementing packaging and labeling requirements as specified by country laws and regulations.

This guide provides a step-by-step approach to conducting a compliance assessment on packaging and labeling. It takes into account the practical constraints that civil society groups may face when trying to conduct their own assessments and will present different options for how to conduct a compliance assessment given these constraints. The first option requires the least amount of resources, whereas subsequent options will reflect the availability of additional resources. Further sections will detail other packaging and labeling provisions advocates can assess using this guide such as constituents and emissions information and plain/standardized packaging. Importantly, this guide can be adapted for use with different types of tobacco products. The guide includes several appendices that provide additional information that can be used when conducting compliance monitoring.

Step 1

Know the Tobacco Packaging and Labeling Regulations in Your Country/ Jurisdiction

In order to decide the type of compliance study you need to conduct, you should first familiarize yourself with the existing packaging and labeling policies in your country or jurisdiction in order to understand how the polices apply to tobacco products. Sometimes packaging and labeling laws are not comprehensive (i.e., do not apply to all tobacco products or do not address all FCTC Article 11 provisions). See below.

Resources are available to help you identify the most current laws and regulations. Most government agencies, such as Ministries of Health, make their laws and regulations available to the public, and they are often accessible online. Additional resources are available through non-governmental organizations such as CTFK's Tobacco Control Laws database. The website is maintained by lawyers and provides country-specific tobacco legislative documents available for download in pdf format along with a detailed analysis of each country's packaging and labeling provisions in comparison to the WHO FCTC and its Guidelines, and summary fact sheets. A substantial number of countries have policy analysis available on the website (as of February 2020, laws from 208 countries and analysis of 123 countries). See Appendix A for more information.

Tobacco companies are responsible for complying with a country's tobacco product packaging and labeling policies. Tobacco companies regularly oppose comprehensive packaging and labeling regulations. Oppositional strategies include litigation and arguing that it is not possible to meet proposed regulations such as increasing the size of pictorial HWLs on their products. It is important that compliance studies are conducted to document any violations or weak interpretations of the law. If a tobacco control law/regulation is being misinterpreted, then documentation provides valuable evidence to governments who have the responsibility for enforcement.

Packaging and labeling policies encompass a number of different provisions. Before you design your compliance study, it is essential to familiarize yourself with four major packaging and labeling provisions:

Health warning labels

FCTC Article 11 Guidelines state that "Well-designed health warnings and messages on tobacco product packages have been shown to be a cost-effective means to increase public awareness of the health effects of tobacco use and to be effective in reducing tobacco consumption".[4] Scientific evidence proves that HWL effectiveness increases with size. The larger the warning the more effective it will be. Different design elements of HWLs include: type (pictorial vs. text-only), number (single vs. multiple), rotation system, location on pack (top vs. bottom; front and back vs. lateral sides), size (as a percentage of the principal display areas), message content, color, background, principal language(s), attribution, quit line, and textual typography (font, font size, font color).

Constituents and emissions information

FCTC Article 11 specifies that tobacco product packaging and labeling shall "contain information on relevant constituents and emissions of tobacco products defined by national authorities".[5] This information should be in the form of qualitative or descriptive messages or statements, and Guidelines recommend not displaying figures or emission yields. An example of a message in line with guideline recommendations is "Smoke from these cigarettes contains benzene, a known cancer-causing substance."

Misleading packaging and labeling

FCTC Article 11 requires that Parties prohibit packaging and labeling that promotes tobacco products by means that are "false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions".[5] This includes any term, descriptor, trademark, figure or other sign that directly or indirectly creates the false impression that particular tobacco products are less harmful than others. Examples include brand descriptors such as "light," "low tar," "organic," and "natural."

Plain or standardized packaging

FCTC Article 11 Guidelines urge Parties to consider "measures to restrict or prohibit the use of logos, colours, brand images, or promotional information on packaging other than brand names or product names in a standard colour and font style (plain packaging)".[4]

Step 2

Define the Purpose of Your Assessment

Compliance assessments should only be conducted if they serve a strategic purpose. It is essential to know why you are conducting a compliance assessment and ultimately how you intend to use the results.

There are many reasons why you might want to conduct a compliance assessment. Typically, compliance assessments have been useful tools for advocates to inform policy makers and enforcement agencies about the need to strengthen enforcement of existing tobacco control regulations. The purpose of these compliance studies is to identify noncompliance with the law or regulations. Results can then be used to identify gaps in implementation, provide evidence to show why loopholes or weak provisions of the law must be resolved and reveal areas for regulation expansion.

Bangladesh

Front of pack

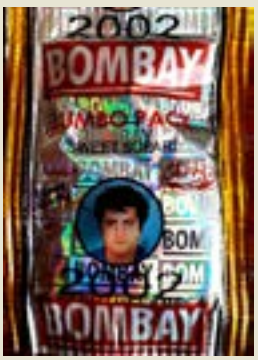
Back of pack
(tax stamp visible)


Side of pack

Bangladesh's Smoking and Tobacco Products Usage (Control) Act, 2013 requires that pictorial HWLs be displayed on the cigarette pack and outside packaging (e.g. carton), that the text be printed in the principal language of the country, and that stamps to not cover HWLs. The law, however, does not address qualitative constituents and emissions disclosures on the pack and only loosely defines prohibited misleading packaging and labeling descriptors (see "smooth taste" highlighted on side of pack).

Pakistan

Front of cigarette pack



Front of supari/ betelnut

Photo credit: Dr. Ziauddin Islam

Pakistan's law, SRO 127(KE)/2017, mandates that pictorial HWLs cover 60% of the package. However, this law only applies to smoked tobacco products, including manufactured cigarettes and bidis, and does not extend to smokeless tobacco products.

Nepal

Bottom of pack

Nepal's Directive on Printing Warning Messages and Pictures on Tobacco Product Boxes, Packets, Cartons, Parcels and Packaging Materials (2014) mandates a 90% pictorial HWL in the upper part on both sides of the package and prohibits misleading descriptors such as 'low,' 'light, 'ultra,' 'mild,' and 'extra'. It also prohibits distorting, damaging, hiding or covering the warning message and picture. The directive applies to all tobacco products. The display of figures for tar and carbon monoxide are prohibited. However, the law requires that manufacturers disclose the amount of nicotine on the tobacco product package.

Compliance studies are not restricted to the type of assessment outlined above. Other purposes for compliance studies might include:

- Assessing compliance with the law: Compliance monitoring can be conducted for different reasons. The most common is to assess whether tobacco product manufacturers are fulfilling the mandate of the law. When packs appear to feature the required health warnings, compliance assessments may nonetheless document inconsistencies in their appearance across manufacturers or the appearance of warnings in a manner unanticipated. In such cases, compliance monitoring also serves to identify "grey areas" and loopholes in the law. A common tobacco industry argument against packaging and labeling policies is that requirements are onerous and manufacturers will need more time than allotted by the government to meet them. In such cases, compliance monitoring that documents even some manufacturers ability to comply with the law can be used to demonstrate that, in fact, a law can be implemented.

- Educating policy makers and stakeholders: Compliance assessments can be used to educate policy makers, retailers, civil society, and/or the general public about the existence of packaging and labeling laws, the status of compliance, and areas for attention or improvement.

- Building the evidence base for legal action: In countries where tobacco companies are blatantly ignoring packaging and labeling policies, compliance studies can be used to document violations of the law. This evidence could be used to impose fines through a court of law or build a litigation case against the industry for not following the laws.

- Evaluating progress: Periodic compliance studies can be used to evaluate implementation progress of a packaging and labeling law by recording changes in compliance over a period of time.

Assess and Secure Resources

In order to carry out your compliance study, you must know which resources are readily available to you and those you need to obtain. It is important to consider any opportunities you might have to secure additional resources such as small "seed" or grant money from governments or universities to conduct local scientific studies. Key resources for a compliance assessment include labor, research materials and financial support.

Labor

When building your team consider the following positions:

- Project coordinator: Responsible for making sure that all study tasks occur according to the timeline and standards established for the study. The coordinator ensures that data collectors have all the necessary materials and training before the data collection phase. The coordinator serves as the "go to" person for data collectors should they encounter any difficulties when performing observations in the field.

- Data collectors: Can be paid staff or recruited volunteers. In both instances, data collectors need to be properly trained to collect data in the field.

- Technical experts & data analysts: Should be consulted to ensure that the sampling approach and data collection tools are appropriate. In some studies, these team members will conduct analyses of the collected data.

Compliance studies are most effective when you work with a team of people to conduct the assessment. It is important to consider partnerships with organizations or institutions that have the necessary technical skills. When building your research team, consider collaborating with local universities or a local policy, advocacy or research organization. Collaborations with these organizations can bring together individuals with diverse skill sets that will help make your assessment stronger.

Materials

Compliance studies are observational in nature. With this in mind, materials needed to conduct your study in the field may be minimal. Some materials you may need to consider purchasing include supplies such as data collection forms and plastic bags and stickers or address labels to identify packs. Consider saving money by storing your data electronically through online or mobile platforms, when appropriate, instead of printing hard copies of data collection forms.

Other materials you will need to consider later in your dissemination process include reports, fact sheets, or other printed materials. For the dissemination phase, it may be possible to share the cost of these materials with collaborators such as NGOs, advocacy organizations or academic institutions.

Field Costs

Costs to be considered include transportation costs for traveling to sampling areas, cash to pay for tobacco products and cost of time for your field staff. Be conscientious about the number of hours per day personnel can devote to data collection.

The costs associated with a compliance assessment are driven by the scope, time, materials and budget. If resources are a limitation, there are ways to make compliance studies more affordable without sacrificing rigor. As mentioned in this chapter, partnerships are an excellent way to share costs. A local university could be an excellent source of volunteers with technical expertise, as students may be required to engage in volunteer work to fulfill graduation requirements. Moreover, students are often familiar and comfortable using technology as part of the data collection process, thereby reducing the time needed to train volunteers on how to use data collection tools.

Step 4 Clarify the Scope

Based on the knowledge gathered in Step 1, you should now be familiar with the packaging and labeling policies in your country or jurisdiction. After you have defined the purpose of your compliance study in Step 2 and secured the resources outlined in Step 3, you now need to clarify the scope of your assessment. The scope of your study will greatly influence the timeline for completing it. You should consider the following two factors when determining the scope of your study.

Policy-Level Focus

What policy are you seeking to influence with your compliance study? Are you hoping to highlight the need for legislative amendments in order to close loopholes in the existing law? Or are you hoping to highlight lack of enforcement/compliance in a particular geographic area? A primary consideration when determining the scope of your study is to reconfirm how you intend to use your results. The purpose developed in Step 2 should align with your scope. If, for example, you believe that a local manufacturer may not be adhering to the national law, you may want to focus your study and compliance assessment on the sample of products in a local geographic scope.

Information Scope

Consider the specific packaging and labeling provisions you want to assess for your compliance assessment. It is important to set a reasonable limit to the comprehensiveness of the data you intend to collect and analyze. For example, you may want to consider measuring packaging and labeling criteria that are culturally specific (colors, symbols, images, or language that denotes a certain meaning). A complete analysis of these characteristics would be costly and require more staff or volunteer support. Therefore, it would be important to narrow down the provisions to be assessed to a reasonable number, with consideration given to the resources you identified in Step 3.

In defining the scope of the information, it may help to write out SMART objectives. Your scope should be Specific, Measurable, Assignable, Relevant and Time-based (SMART). A hypothetical example of SMART criteria is provided in on the next page.

This guide recommends that you consider the following questions to determine the information you intend to collect:

- Which law/regulation requirement(s) are you interested in studying? For example, are you assessing the size of HWLs?

- What type of tobacco product? Is your focus on smoked and/or smokeless products? Do you want to study compliance with one type of tobacco product or all tobacco products (e.g. cigarettes, bidis, cigars, cheroot, waterpipe, smokeless tobacco) available for sale in your country?

- What tobacco brand do you want to study? Do you want to study a specific subset of tobacco brands?
    - You might select the most popular brand in your country or select brands based on other relevant criteria.
    - Other options could be a compliance study of international brands, local brands, or premium brands, etc. or a census of all brands on the market (all registered brands or via sampling).

- How will you treat illicit packs in your data collection and analysis processes and dissemination of findings?

Set a Timeline

An important component of your compliance assessment is developing a timeline that will enable you to adequately prepare for all of the practical steps involved. Good planning will also ensure that you are able to maximize the use of your results. See a sample timeline in Appendix B.

When developing a timeline, consider how you would like to use the results from your study. You may want to consider if there is an ideal time to release your results. For example, it may make the most impact on policy makers if you release your results during a legislative session or one year after a law's enactment. If there is a date on which you intend to release your results, this should be the end date of your timeline. You can work backward from this date to construct your sample, develop your protocol, obtain approval from authorities, secure your resources, train your research team and data collectors, conduct your data collection, analyze the data, write up results, prepare a policy brief and disseminate the results.

You should incorporate a few major tasks into your timeline. These tasks can be organized into three parts:

Pre-data collection: This is the planning phase. This occurs before any data are collected. When estimating how much time this stage will take to complete, consider how much time it will take you to secure the resources needed to conduct the study such as funding, staff and travel arrangements. Similarly, consider how long it will take to convene the relevant partners, construct a sample, and agree on data collection procedures. Lastly, you will need to pilot data collection procedures and tools before using them during your actual assessment. Consider how long it will take you to finalize these tools.

Training and data collection: This is the data collection phase. This involves the training of data collection staff and the data collection itself. Some considerations include whether or not data collectors have worked in the field before, and logistics for in the field, such as how long it will take to complete data collection in one geographic area with traffic. Are data collectors able to work several days consecutively or will they take time off in between data collection days? If this is a multi-jurisdiction study, how long will it take to travel from one jurisdiction to the next? Are there weather factors or holidays at this time of year that may delay data collection?

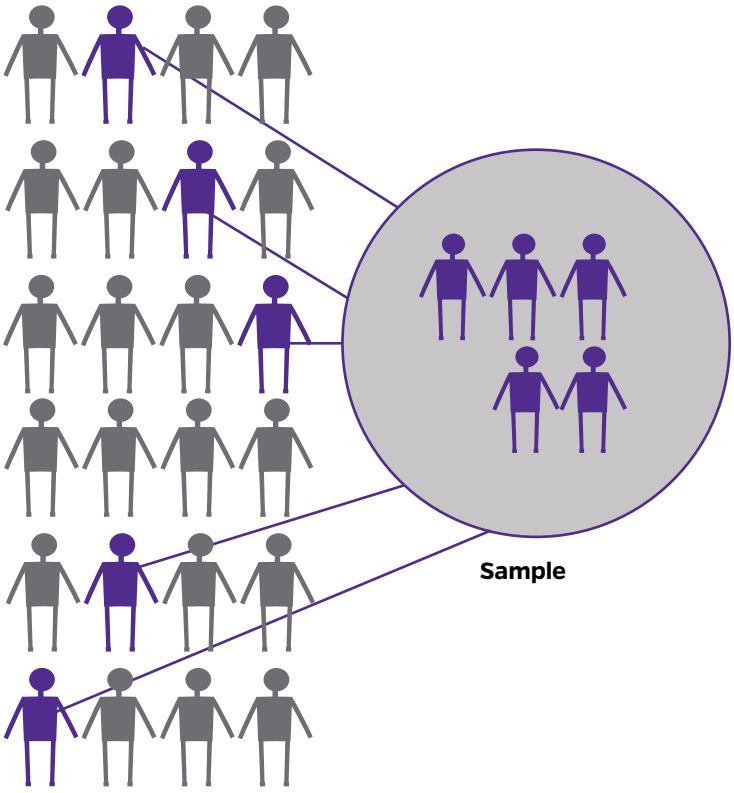
Post-data collection: This phase involves coding, analysis and dissemination of results. Some considerations include how much data you have to analyze and whether you have a team in-house to conduct analysis and create dissemination materials or if a third party will need to be brought on to complete this step.

Step 6 Construct Your Sample

Before beginning data collection, you will need to construct your sample. In research, a population is the entirety of units that are being examined, such as objects or humans. A sample is a part of the population that is selected to be observed and represent the entire group. A sampling unit is the individual unit that is observed.

In this instance, the population is all tobacco packs (specifically, the type/s of tobacco products you identified in Step 4 in clarifying the scope of your study) that are on the market for sale in the jurisdiction under study. However, it would be impossible to observe the entire population of tobacco packs. Thus, a sample must be selected. We will use the group of tobacco packs observed (sample) to draw inferences or conclusions about compliance of all tobacco packs available (population).

The sampling unit is the individual tobacco pack. As one pack of a brand variant (see Glossary, e.g. Marlboro Red) is expected to be identical to the others of the same brand variant, collecting one tobacco pack per brand variant could be expected to be indicative of compliance for that brand variant as a whole in that jurisdiction's market.



Monitoring will require selecting a subset of locations (e.g. cities, districts or neighborhoods) and tobacco vendors where tobacco packs will be observed or collected. Your selection will depend on the scope of your assessment and the resources that are available to you.

In this section, we will describe the methods most commonly used to construct a sample in tobacco pack monitoring, discuss considerations to take into account when choosing your methods, and provide guidance on the methods that may be the most appropriate based on the purpose of your assessment, scope, and different levels of resources.

Sampling Methods

There are two overarching categories of sampling methods- 1) probability sampling and 2) non-probability sampling. Probability sampling means that sampling units are chosen in such a way that all units in the population are at equal chance of being selected. Non-probability sampling means that units in the populations are not at equal chance of being selected. Non-probability sampling often relies on the subjective judgment of the research team.

In research where tobacco packs are the sampling unit, two sampling methods have primarily been used – 1) convenience sampling and 2) purposive sampling. Both of these methods are non-probability sampling methods. Convenience sampling relies on the selection of sampling units based on their accessibility to the research team. Purposive sampling relies on the expertise of the researcher to select the sampling units based on the researcher's knowledge of the literature and practice.

Convenience sampling

If your goal is to collect specific tobacco product brand variants, all tobacco product brand variants included on a list of registered tobacco products, or a pre-specified number of unique tobacco packs regardless of the brand variant, convenience sampling may suit your needs. In search of specific tobacco packs, the research team could navigate to any areas and/or tobacco vendors that are convenient to them and observe or collect tobacco packs. In the field, this could look like the research team navigating to one or multiple sampling areas or tobacco vendors surrounding their office until they have observed or collected the number of tobacco pack brand variants previously identified.

Purposive sampling

If your goal is to maximize breadth and observe or collect as many different tobacco brand variants as possible and/or if you are unable to obtain a list of all registered brand variants on the market, purposive sampling may be more suitable. From the literature on tobacco marketing, we know that the tobacco industry targets groups of people (e.g. by age, gender, race, income, education) using targeted marketing tactics. Given this information, different tobacco products and/or brands may be on sale in different locations based on the demographic that lives or works in the area. Therefore, you may want to consider several characteristics when selecting cities or towns (if more than one) and districts or neighborhoods. In the field, this could be reflected by the research team purposefully choosing to visit neighborhoods from different income strata (high, middle, low income), as well as a range of neighborhoods in terms of racial and ethnic diversity.

Selecting Locations in Your Country for Data Collection

Cities or towns

Depending on resources, time and other factors, one or more cities or towns can be selected in your country for data collection. If only one location can be chosen, we recommend choosing the capital or most populous city if possible. If you can select more than one location to visit, some characteristics to consider across a country are: geography, urban/rural status, culture, ethnicity, religion, and spoken language or dialect. We suggest choosing diverse cities or towns in order to maximize the chances that different tobacco packs will be observed. If you intend to capture data on the tobacco brands that are likely available to the vast majority of the population, choosing highly populated cities is recommended. In order to achieve results that are indicative of national compliance, you may consider collecting data from cities or towns in different sub-jurisdictions (e.g. states, provinces).

Districts or neighborhoods

When choosing districts or neighborhoods within a city or town, we suggest considering the same characteristics as those noted above, as well as socioeconomic status, to maximize breadth. A proxy measure can be used to estimate socioeconomic status – a proxy measure is an indirect measure of the desired outcome that is correlated with that outcome. In some cases, cities have data available on income, education, and occupation at the district or neighborhood level. However, these data may not be available. A proxy measure you could use might be the median value of housing.

Types of Tobacco Vendors

Gas Stations | Convenience Stores | Supermarkets

Selecting Tobacco Vendors for Data Collection

Common approaches for selecting vendors where data collection will take place are: 1) to identify types of vendors where tobacco users commonly purchase tobacco products, 2) to follow a walking protocol to select vendors, or 3) a combination of these approaches.

1. Common examples of types of vendors include convenience stores, gas stations, and supermarkets. To maximize diversity in terms of tobacco packs collected, you may wish to specify how many vendors in each category from which you will collect data, or ensure that data collectors visit at least one of each vendor type.
2. Different variations of walking protocols exist, but typically involve data collectors beginning at a central location in a pre-identified sampling area and following a systematic walking path to identify vendors from whom data will be collected. An example of a walking protocol is one that instructs data collectors to navigate to a pre-identified sampling area, select a starting location, and with their backs to that location, scan the surrounding area looking for a center of commercial activity. Navigating to the commercial activity to the most right (or left) direction, data collectors may be instructed to scan both sides of the street and walk to the nth tobacco vendor on their path.
3. Using a combination of the two approaches previously described is ideal and will involve using a walking protocol to navigate to pre-identified vendor types. Instead of collecting data at the nth tobacco vendor specified by the walking protocol regardless of vendor type, data collectors would collect data at the nth specified tobacco vendor type (e.g. the 3rd supermarket).

See Appendix C for a flow chart on decisions to be made when constructing your sample.

Develop Data Collection Procedures and Forms

Data collection procedures and tools must be developed in order to guide the data collectors in how to systematically collect tobacco packs. In this section, we describe the procedures that detail how data collectors can systematically observe or collect tobacco packs and the tools that can be developed to use during the data collection process.

Developing Procedures

As with your sampling strategy, data collection procedures will depend on the purpose of your assessment and available resources. In the literature, there are generally four types of procedures used to collect data on tobacco packs:

1. Purchasing packs
2. Observing packs at vendors
3. Collecting littered packs
4. A combination of these approaches.

Purchasing tobacco packs at vendors: This involves systematically identifying unique packs and purchasing the packs to be coded at a later time.

Systematically identifying unique packs

In countries that have not banned tobacco products display at the point-of-sale, tobacco packs most commonly will be displayed by the cash registers at a vendor or will sometimes occupy their own separate counter or cash register at a larger store (such as at some supermarkets). Tobacco packs might also be displayed on a power wall – a large display typically placed behind the cashier that displays many tobacco products and is typically decorated with tobacco brand logos, colors, and price information. In cases like this, a relatively easy procedure to implement is to instruct data collectors to face the product display and identify packs for purchase by scanning the rows of the display in a systematic way (e.g. bottom to top, left to right) and comparing the packs on display to what the protocol calls for in terms of purchase. It may be useful or necessary to compare packs available for sale to a list of packs already acquired. Using a photo archive on a mobile device can be very useful (see below). Data collectors should also ensure that they have viewed all tobacco packs on sale by asking the retailer if every unique pack that is available for purchase is on display.

In jurisdictions where retail settings are less formal or in non-chain establishments, the tobacco packs may not be displayed in such an organized fashion (or only some of the brands, for example the most popular brands, will be displayed). In such circumstances, it is important for data collectors to communicate with retailers to ensure that they have viewed all of the tobacco packs that are offered for sale.

In countries that have banned tobacco product display, vendors are only allowed to store tobacco packs in storage areas where they cannot be viewed by customers. In these cases, vendors sometimes can provide a printed list of the brand variants they sell. While a list can be helpful when it corresponds to a list that you are using for data collection, it can often be difficult to distinguish between different brand variants if you do not have a list to compare it to and are relying on the design of the packs to distinguish between brand variants. In this case, data collectors will need to interact with retailers to ask them to view the packs behind the counter to identify those they have not already purchased.

When thinking about how your data collectors will systematically identify unique packs, consider whether using a list versus using a picture archive would be easiest. If you are purchasing a few specific brand variants and have a list in hand, the process of purchasing tobacco packs may be simple. For example, a list could be used to check off the packs that have already been collected. If attempting to purchase all of the brand variants or unique packs available on the market, this may result in a collection of over a hundred packs and it may be difficult to quickly identify packs from a list. In this case, it may be useful to create a picture library that organizes the pictures of the packs that you have collected in order to make data collection simpler and limit the time data collectors spend in the store. A picture library of packs can be created by using a camera or any device with a camera (e.g. cellphone, tablet), taking pictures of the packs observed or collected, organizing the pictures into folders (optional, but it can be helpful to organize packs into folders by brand), and referring to these pictures at subsequent vendors to identify which packs data collectors have already purchased.

Making the purchase

It is often helpful to send data collectors out in a team of two people. After unique packs are systematically identified, one person can pay for the purchase while the other organizes the packs. For analysis purposes, it may be important for data collectors to collect information that corresponds to the purchase. If the data of interest are at the vendor level (e.g. type of vendor purchased from, date purchased, etc.), it may suffice to separate tobacco pack purchases into different bags or storage containers and record the corresponding information post-purchase. If the data of interest are at the pack level (e.g. price of pack), stickers placed on each pack with relevant data noted on them provide a quick and feasible way to record information in-store. If the vendor provides one, an itemized receipt can also be used at a later time to record pack level price data. For packs that are purchased, coding will be done at a later time.

Other considerations

One consideration when purchasing tobacco packs is the time that it takes to identify packs that have not already been purchased and the time it takes the retailer to pull these packs and ring them up as a purchase. In many cases, this process can take a substantial amount of time. Some retailers are very helpful and happy to help customers that are making a large purchase. Alternatively, some retailers may be too busy helping other customers to help data collectors for a lengthy amount of time. It can be helpful for data collectors to schedule visits to vendors during slow retail hours.

Another consideration is the reaction of the store owners, managers, and/or employees to the data collectors. Some retailers may be suspicious or have a negative reaction to data collectors. If asked to leave a vendor, data collectors should do so.

BENEFITS	CHALLENGES
• Not time-constrained in terms of coding – can code packs at a later time in office • Does not require as much time as observing packs at vendor • Retailer may be more willing to help if data collectors make a purchase at the vendor	• Requires money to purchase tobacco packs • May attract negative attention from retailer • Requires communication with the retailer (particularly if tobacco products are not on display)

2 Observing tobacco packs at vendors: This involves systematically identifying unique packs and coding them at the vendor.

Many of the same considerations that apply to purchasing packs apply to observation of packs and users should refer to the sections on Systematically identifying unique packs and Other considerations above for more information. Major differences between purchasing and observing tobacco packs is the lack of division between data collection and coding and the extra time data collectors are required to spend at vendors.

Observing the packs

Data collectors should record all of the packs at a vendor that are of interest to the study and ask retailers to pull these packs so that they can be further assessed inside of the vendor. Data collectors should stand out of the way of the cash register and other customers and code the packs using a short coding sheet. It is advised that data collectors also take pictures of the packs coded in order to conduct data quality checks at a later point in time.

While observing packs at point-of-sale presents its own challenges, there are some strategies that researchers may consider. The success of this research approach may depend on social norms and practices – in some settings, business owners or managers may be more supportive of aiding research efforts. If collecting data in a widespread geographic area, it can be helpful to deploy data collectors in areas where they work and live so they can capitalize on their local connections. You may also consider choosing data collectors who are knowledgeable of the tobacco control landscape and tobacco product packaging and labeling laws. It is also helpful to avoid business rush hours.

BENEFITS	CHALLENGES
• Does not require money to purchase tobacco packs • Data are available for quick analysis as coding is done at vendors	• Time-constrained in terms of coding; limits the amount of data that can be collected on each pack and increases potential for coding errors due to rushed process • Requires substantial amount of time at vendor (more so than if just purchasing packs) • May attract negative attention from retailer • Requires communication with the retailer (particularly if tobacco products are not on display)

3 Collecting littered tobacco packs: This involves visiting sampling areas and collecting packs that have been littered or discarded.

Picking up littered or discarded packs

Collecting littered tobacco packs involves different procedures than those already presented. A team of data collectors must be assembled to visit sampling areas and collect all of the packs that are littered in the street and/or discarded in trash receptacles. Data collectors may be deployed to collect all tobacco packs that they encounter or the research team may choose to specify criteria for the packs to be collected. For example, criteria may take into account the damage done to the tobacco pack and/or health warning displayed on the pack. If data collectors collect all tobacco packs regardless of damage or health warning, sorting packs can also be done at a later time. Coding of packs will take place after packs are collected and sorted to identify duplicate packs.

Other considerations

Some unique considerations that pertain to collecting littered tobacco packs include time of day, weather, and a jurisdiction's cleaning schedule. Because collecting littered tobacco packs requires being outdoors, data collection hours should be limited to daylight hours or if done without daylight, the availability of street lighting should be considered. Weather is also an important consideration both the days of and days preceding data collection. For example, if it rains the day or even days before data collection is scheduled, it is very possible that the rain may wash away or damage littered packs. It can also be very uncomfortable for data collectors to collect littered packs in the rain or extreme weather conditions as they will be spending the majority of their time outside. The data collection schedule should also take into account the jurisdiction's cleaning schedule. For example, if street cleaning in a specific area takes place every Tuesday morning, data collectors will likely be able to collect more packs on the Monday preceding street cleaning than they would on a Tuesday or Wednesday.

BENEFITS	CHALLENGES
• Does not require money to purchase tobacco packs • Data collectors not limited by retailer in terms of time spent collecting packs • Familiar approach used in tobacco control monitoring and research	• Data collection reliant on time of day, weather, and jurisdiction's cleaning schedule • Tobacco packs may be in poor condition or damaged • Sample is limited to what has been littered or discarded by consumers in public spaces

4 A combination of approaches

A combination of the approaches described above can also be used. For instance, packs collected using one procedure can supplement packs collected using a different procedure. Two different procedures can also be used in order to balance out the benefits and challenges of each.

Developing Field Protocol and Data Collection Forms

Field protocol

A field protocol will need to be developed to guide data collectors. Data collectors will refer to this protocol during training and in the field so that data are collected in a standard way across study sites and/or by different data collectors.

The field protocol should include:

- A short overview of the purpose and scope of the study.
- A description of the sampling methods and what jurisdictions and sampling areas the data collectors will visit.
- The types of vendors that the data collectors will visit, a definition of each type of tobacco vendor, and walking protocol instructions, if these are applicable.
- A list of criteria for tobacco packs to be collected or observed. This should include definitions of different types of tobacco products (e.g. cigarettes, kreteks, bidis, smokeless tobacco, etc.) and if applicable, images of the mandated tobacco pack health warnings.
- The study procedures, including steps the data collectors should follow prior to entering the vendor, inside of the vendor, and following pack observation or collection. The procedures should also specify if data collectors should tell the retailer what they are doing, how much information they should provide to retailers, and what actions to take if the retailer responds negatively.
- Policies on safety. Data collectors should be instructed to leave locations where they do not feel comfortable and/or where their safety may be threatened. Safety is of the greatest importance and should be prioritized over all other aspects of the study.
- Instructions on how tobacco packs and data collection forms should be organized and stored after data collection is complete.

Data collection forms

Data collection forms are a helpful tool to capture neighborhood-, district-, and/or vendor-level data. You should consider utilizing data collection forms if you are interested in conducting an analysis that assesses compliance by vendor type or another neighborhood or vendor characteristic, want to return to the same data collection locations at a later time (e.g. for pictures or a second round of data collection), or want extra mechanisms in place to ensure adherence to the protocol.

A data collection form can be printed on paper or entered on an electronic device using a cellphone or tablet application. Some applications allow you to enter information into an electronic form offline and upload the data to a cloud at your convenience once internet can be accessed. Some examples of online data collection tools include Qualtrics, doForms, and Magpi. Refer to Appendix D for a sample in-field data collection form.

	Pros	Cons
Paper data collection form	• Low cost • Does not require data collectors to carry electronic devices	• Less discreet in places where phones and tablets are commonly carried around and used in public • Must be entered into a spreadsheet or electronic database manually at a later time, which can create delay and more opportunities for mistakes in data entry • Potential for forms to become lost or damaged
Electronic data collection form	• Discreet in places where phones and tablets are commonly carried around and used in public • Data are readily accessible; research team can track progress if internet access is available and data are uploaded to a cloud immediately or at the end of the day	• Possible costs associated with the electronic devices and survey applications • Potential for some electronic devices to attract unwanted attention in some settings

Create a Coding Sheet to Code Packs

Reflect on the scope of your study and utilize your earlier research on policies and possible loopholes to create a coding sheet that will be used to generate data on your sample of tobacco packs. Relevant variables might include:

- Required HWL (is the HWL one mandated in the country of purchase?)
- Rotation of HWLs (is the HWL from the current or past rotation/round?)
- Type of HWL (pictorial vs. text-only)
- Content of HWL
- Type of pictures
- Size of HWL (as a percentage of the principal display areas or a minimum size)
- Location of HWL on the pack (front, back, sides)
- Placement of HWL on the display area (top portion of front/back, bottom portion of front/back)
- Language/s of HWL
- Cessation information displayed (e.g. quit line, website)
- Placement of tax stamp (does it cover the HWL?)
- Display of descriptive or qualitative constituents and emissions messages
- Display of numbers for emissions yields (e.g. tar, nicotine, carbon monoxide)
- Presence of misleading descriptors (e.g. light, low tar, natural, organic)
- Number of sticks per pack (for example for cigarettes or little cigars) or quantity in grams per pack (for example for smokeless tobacco)
- If plain/standardized packaging: Use of colors, logos or brand images; product name displayed in standard font and color; shape and material of the pack

OPTIONAL additional variables can be used in analysis to evaluate compliance by different pack characteristics and might include:

- Manufacturer information
- Size of typography in text component of warnings (e.g. 12 pt. font)
- Color of typography and background in text component of HWL
- Ratio of pictures to text in HWL
- Presence of “for sale in [country]”
- Pack type (soft, hard)
- Brand family
- Flavor descriptors (e.g. menthol, strawberry, chocolate, etc.)

It is important that the coding scheme you create is valid. In research, validity refers to whether or not you are measuring what you intended to measure. One way to increase validity is to draw on the research that already exists and coding schemes that have already been developed and used. Refer to Appendix A for links to existing codebooks made available by the Tobacco Pack Surveillance System project and PhenX. Refer to Appendix E for a sample coding sheet.

Sample pack and coding questions: Brazil

1. Is there a HWL printed on the pack?
☒ Yes
☐ No

2. Does the HWL include a picture?
☒ Yes [combination of text and picture]
☐ No [text-only]

3. Is there a HWL on the front/back/side of the pack?
☒ Front
☒ Back
☒ Side

4. Is the front HWL on the top/bottom portion of the pack?
☐ Top
☒ Bottom

5. Does the front HWL cover 30% of the panel, side cover 100% of the panel, and back 100% of the panel?
☒ Yes
☐ No

6. Is a quit line displayed on the pack?
☒ Yes
☐ No

Key Principles for Creating a Coding Sheet

1. **It's an iterative process**
    a. While creating your coding sheet, look to existing packs on the market and in your sample to observe how packaging policies are put into practice and identify unanticipated coding challenges.
    b. Once you have created your coding sheet, see how well it works with a sub-sample of your sample. If discrepancies between coders come up or coding questions arise, REVISE! And keep revising until you have a coding sheet that captures what you need and can be implemented reliably (done consistently by coders and between coders). Don't be afraid to change the coding sheet multiple times before finalizing it.
2. **Be careful**
    a. Demonstrate objectivity in how you assess pack compliance and lean on the side of assessing policies conservatively as you may have to defend your decisions and/or definition of compliance to fellow tobacco control allies or opposition in the future.
    b. In cases where policies are not specific or are written ambiguously, the best action may be to consult with a lawyer and/or exclude these requirements from coding.

3. **Keep it simple**
    a. Depending on the time and other resources available to you, the simpler the coding the better. For example, if data collectors are coding packs at vendors, consider limiting your coding sheet to a few key questions that can be answered quickly. Coding is almost always more complicated than it appears at first.
    b. Consider using a standardized reference pack with which you can compare sample packs to estimate compliance assessment. For example, if the reference pack is the same size as a sample pack, you might decide that the best method for your assessment would be to quickly visually inspect them to assess whether the health warning label covers the mandated percentage of the pack rather than measuring the warning and pack and conducting a calculation.
4. **Keep notes on coding decisions**
    a. Keep detailed notes on the coding sheet decisions you make in case you are asked questions at a later time or want to write up your results for a more research focused publication.

Train Data Collectors and Collect Data

Training Data Collectors

The data collectors are essential to the study, and the research team should schedule an adequate amount of time to train them in the data collection procedures. Training should include a discussion of the purpose of the study, an overview of the study design, a detailed description of the procedures to be used for collecting or observing tobacco packs, and how to complete data collection forms. During training, it is helpful to use a projected presentation with images to illustrate procedures and to print copies of the field protocol and data collection forms for the data collectors so they can follow along and make notes. If electronic devices are to be used to capture photos or collect data, the training should also include a tutorial on how to use the devices and relevant applications.

Once the training materials have been reviewed and questions have been answered, training can be integrated into initial data collection activities.

Collecting Data

It is helpful for the project coordinator to shadow the data collectors as they visit the first few vendors or sampling areas in order to answer questions that arise and ensure that the data collectors are following the data collection procedures, and to address questions and uncertainties that will arise in the field.

Once data collectors are ready to collect data independently, they should report to the project coordinator/s on a regular basis to provide updates on progress and address any issues that arise in the field. The project coordinator/s should be available to answer questions and troubleshoot problems during the course of data collection and if data are being collected in the field, ensure that they are being uploaded correctly or entered manually in a timely manner.

Special considerations for the data collection phase

As stated previously, safety is of the highest priority. People who are familiar with the areas in which you are working should be consulted during the planning stages, when appropriate, in order to ensure that sampling areas are safe for data collectors to walk around and collect data, as well as assist in the efficacy of data collection. Safety concerns in a jurisdiction may also dictate the mode of data collection used in the field – for example, it may be more appropriate for data collectors to use discreet electronic devices like a cell phone rather than a large electronic device like a tablet in some places.

If you are purchasing tobacco packs, consider how you will store the packs once they are in your possession. It is best practice to store tobacco packs in a locked storage cabinet that can only be accessed by the research team. In the case that tobacco packs are being purchased, at the end of each work day, data collectors should return to the project office, or a designated location (such as a hotel room, if conducting data collection remotely) in order to store tobacco packs in a secure location.

Labeling packs with unique ID

Following data collection and prior to coding, each tobacco pack should be assigned a unique identification number or name. This unique ID can be arbitrary or given to each pack based on important criteria about the pack. The unique ID will be entered during coding and used as a reference to identify packs throughout the research process. Some researchers find it helpful to store each tobacco pack in an individual plastic storage bag and label it with a sticker with the unique ID printed on it.

Unique ID Example

The unique ID structure for this example cigarette pack will include: the country abbreviation, city abbreviation, area number, and cigarette pack number. The country abbreviation, city abbreviation, and area numbers should be assigned beforehand. Packs can be numbered as they are labeled.

_ _ _ _ _ / _ _ _ _ / _ _ _ _ / _ _ _ _ _
Country City Area # Pack #

Pack purchased in USA, District of Columbia, Area #1, Pack #1
U S A / D C / 0 1 / 0 0 1
*Your unique ID system can be created to easily identify whatever information is most relevant to you. However, we do not recommend creating unique IDs longer than the example as it can become confusing and cumbersome to label the packs.

Step 10 Train Data Collectors and Collect Data

Decide on Single Coding vs. Double Coding

Coding may involve the coders' subjective judgment, meaning that answers to the same question about the same tobacco pack could potentially vary between different people. The quality of research depends on the uniformity of coding judgments. For a study examining health warning label compliance, inter-rater reliability could be described as the extent to which independent coders evaluate a characteristic of the tobacco pack and reach the same conclusion. See Appendix F for a brief summary on how to assess inter-rater reliability.

A robust research study may employ double coding and report inter-rater reliability for the full sample; however, it may only be feasible to employ single coding. If a sample is single-coded, it is helpful to have a second person code a sub-sample of the tobacco packs and examine agreement in order to ensure that the data are reliable.

Decide on Mode of Coding

Coding can be done using several different tools, including: 1) paper, 2) electronic spreadsheet, or 3) online database.

Method	Description	Pros	Cons
Paper	Print out coding sheet; coders complete one sheet per pack	• Feasible/low cost	• Potential to damage or lose paper forms • Will take extra time to manually enter data in a spreadsheet or database at a later time
Electronic Spreadsheet	Set up columns as questions/variable names and rows as individual pack observations; coders enter data into corresponding cells	• Feasible/low cost • Good option for managing small datasets • Widely accepted by statistical software	• Limited quality control can be built in
Online Database	Set up coding sheet as a form; coders enter data directly into database	• Data can easily be imported into statistical package • Allows for built-in quality control that limits data entry mistakes and missed data • Good for large datasets	• May not be feasible/may require purchase or subscription

Code Tobacco Packs

First, assemble the materials needed to code. This could include the physical tobacco packs, pictures of the tobacco packs, a tape measure or ruler (if measuring size of health warning labels or packs), paper coding forms, or a computer. Coders should carefully answer all questions included on the coding sheet as they pertain to each tobacco pack. Ideally, coders will all work through the items coding sheet in the same order, in as similar a way as possible.

Resolve Coding Discrepancies

If packs are double coded and answers do not correspond, a third party will need to re-evaluate the question and act as a judge to resolve the discrepancies.

Handling Illicit Tobacco Packs

Illicit tobacco packs (see Glossary) are often collected if the data collection is not targeting specific brand variants for collection. After data collection and before coding, it is important to distinguish between illicit and legal tobacco packs in your sample. Identifying illicit tobacco packs can be challenging. However, some common indicators used to identify illicit tobacco based on the packaging include:

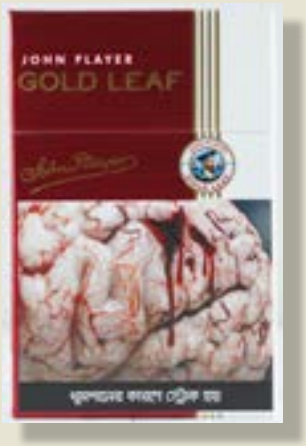
- → Health warning label: Is the health warning label on the pack one that is mandated by the country in which it was purchased?
- → Tax stamp: If the country in which the pack is purchased requires a tax stamp, is one affixed to the pack?

In many countries, the Tobacco Pack Surveillance System (TPackSS) has found that the display of the country's health warning label and tax stamp are highly correlated. Therefore, it may suffice to classify packs based on health warning label or tax stamp only. However, one limitation is that you may not capture all illicit packs – some illicit packs may display a counterfeit health warning label or fake tax stamp or if you are collecting littered packs, the tax stamp may have fallen off the pack.

If you detect illicit packs in your sample, you may want to report that illicit packs were detected within your overall sample, but exclude them from analysis if the purpose of your study is to assess compliance among legally sold products.

Whatever you choose to do with illicit packs, make sure to record how they were handled and what indicators were used to classify them so you can report this!

Legal Pack



Front of pack

Back of pack
(tax stamp visible)

Bangladesh, country's HWL and tax stamp on pack

Illicit Pack

Front of pack

Back of pack
(tax stamp visible)

Bangladesh, no HWL and out of country tax stamp on pack

Step 11 Analyze Your Results

Once tobacco packs are coded, the quality of the data must be checked and analyses then conducted.

Check Data Quality and Clean the Dataset

After coding is completed, several steps can be taken to assess the quality of the data:

- Check for missing data: Did data collectors answer all the questions that were relevant to the tobacco packs? Some electronic databases will allow you to program skip patterns (automatic programming of questions that appear based on responses to other questions that only apply under certain conditions) and will prompt the coder if they miss a relevant question.

- Check that data fall into the range of possibilities: If there are pre-determined answer options or a range within which a number is expected to fall, did a coder enter anything outside of these options/range? Some spreadsheets will allow you to program dropdown answers for each cell in a column where only one answer can be selected. The same is true of electronic databases where the data entry form can be programmed to display a dropdown menu or multiple choice options. These options will help coders avoid making accidental mistakes when coding.

- Look for outliers: If any of your questions involve measurement, do you see any numbers entered that are distant from most of the other numbers? Verify the outliers by referring to the physical packs or pictures of the packs.

- After these processes, you will have a 'Clean Dataset' that you feel confident does not include errors and is ready for analysis. This dataset should be clearly labeled and kept separate from the datasets used in its development.

Analyze Your Data

Analysis should be guided by the goals of your assessment. It can be helpful to create a visual representation of what you want to report, such as a table/tables, before conducting your analysis. Data analysis for health warning compliance will mainly utilize descriptive statistics such as frequencies and percentages.

Potential data analysis tools include Excel, SAS, Stata, SPSS, and R. Excel is a feasible option and is adequate for calculating descriptive statistics. Statistical packages like SAS, Stata, and SPSS are not free and require some knowledge of how to use the programs, but allow for more advanced analysis. R also allows for more advanced analysis and requires knowledge of how to use the program, but is free.

Present Your Data

Following analysis, present your outcome indicators. Examples include:

- Overall compliance (report on all variables, full sample)
- Compliance by specific indicators (e.g. presence of health warning label, size of health warning label, absence of misleading descriptors)
- Compliance results (overall or specific) by type of tobacco product or by tobacco manufacturer

In addition to results on overall compliance, results can also indicate weaknesses or loopholes in the law.

Step 12

Disseminate Your Results

After completing your compliance study, the final step is to disseminate your results in order to inform public health stakeholders, and possibly to support efforts towards compliance improvement or necessary policy changes. Remember, the discussion of your results should align with the purpose and scope of your assessment that you first defined in Steps 2 and 4. For example, if the purpose of your compliance assessment is to influence policy then your dissemination efforts should be targeted toward an audience that influences policy such as policy makers and government officials.

This guide recommends that you work with experienced advocates and communications or public relations experts for guidance when disseminating your results. As discussed in Step 3, collaborations are a useful way to enhance the quality of your assessments. Similarly, collaborations with communications experts and advocates can assist in successfully disseminating your results and achieving the desired policy effect.

Three key steps can guide your dissemination efforts. First, identify your audience. Second, develop key messages tailored to reach the goals of your assessment. Third, disseminate your results in a way that will effectively reach your target audience.

Audiences

The section below describes different audiences you may want to target for your dissemination efforts. In some instances, you may want to target more than one audience. Common audiences include:

Policy makers: The primary targets for compliance assessment results are often policy makers. In the event that the purpose of your compliance study is to show weaknesses with packaging and labeling policies, your results should describe the current state of adherence with the law or lack thereof. In addition, exposing weak packaging and labeling policies provides an opportunity

to include an appeal for additional resources to improve compliance. Results could be presented in private briefings with legislators and senior government officials.

Media: The media can be a powerful tool to disseminate your results and gain the attention of key stakeholders, policy makers, and the public. You could choose to release the results of your study through a press conference, news story or other events. It is important to consider the timing of a media event to ensure that it does not conflict with other major stories, cultural events or holidays. In addition, consider whether dissemination through the media should be timed to take place before or coincide with the start of a legislative session or court case.

Enforcement agencies: Private briefings with government and/or enforcement agencies (including those designated for regulating finance, media and advertising) are a good practice prior to publicly releasing results. This will build trust and create capacity for building alliances, and may be more likely to result in action from the agencies.

Civil society: You might choose to present your assessment results to both primary and alternative parties that have an interest in tobacco packaging and labeling policies. By involving interested civil society members, these individuals or organizations could be future policy allies who may help in your efforts to strengthen existing laws and regulations. Civil society could include non-governmental organizations, advocacy organizations, youth organizations, community organizations, and health professionals.

Public: Multi-media communications efforts can inform the public about the levels of compliance among tobacco packaging and labeling laws. By exposing industry exploitation of loopholes, you can gain public support and call on the government for ongoing or increased enforcement of the law. Similarly, exposing the industry can create public demand for stronger tobacco control laws, which may motivate policy makers to act.

Academia: Your assessment might be of great interest to universities and researchers. It may be useful to disseminate your results to this target audience in the event that you think they might want to run a study to expand upon your packaging and labeling assessment. Such activities may create opportunities for future collaborations, and access to important research expertise.

Develop Key Messages

As you prepare to disseminate the results, revisit the purpose of your assessment. What did you want the compliance study to achieve? Structure your key messages with this purpose in the forefront.

Key messages might include:

- "The packaging and labeling law has been fully implemented." If you have a law with regulations specifying a number of requirements and you found compliance to be high across all provisions, this message should be emphasized.

- "Poor compliance shows a need for enforcement." This would be an appropriate message if you want to convince policy makers and government officials or the enforcement authority to take action.

- If you have information indicating that a company is not complying with the law while others are, you might say, "Most tobacco companies are complying with [country's] packaging and labeling law, while company [X] shows clear disregard for the law."

Working with a skilled communications team is useful for the dissemination of your results. Should you choose to collaborate with either a communications company or consultant, it is key that your research team work closely with the communications experts to ensure that the results are accurately reflected in the key messages.

Dissemination Strategies

Once you have identified the audience(s) that you want to target for your dissemination efforts, you should also consider your dissemination strategies. You will need to use more than one strategy to maximize the reach of your results. Common dissemination strategies include:

- **Fact sheets:** A useful resource to have on hand to disseminate your results to any target audience. These materials are particularly effective among policy makers and government officials. Fact sheets are a quick and simple way to highlight your main findings and advocate for policy change. As a general rule, try to make your fact sheet as simple as possible. Avoid using technical jargon and consider using graphs and tables to visually depict your results.

- **Press release:** Instead of releasing your results to one media channel, you could host a press conference where the media will come to you and ask you questions about your assessment and findings. A press release is particularly effective if the timing lines up with important legislative windows such as the start of a legislative session.

- **Tables and graphs:** Consider using eye-catching design (e.g. color, infographics, etc.) as a method to visualize your results. Use of effective tables and graphs not only organizes your data but also can attract attention to your dissemination materials and illustrate results.

- **Social media/Podcasts:** Use of social media is an effective way to further the reach of your dissemination efforts. Stakeholders such as advocacy organizations, youth organizations, community organizations, and health professionals could be helpful in drawing attention to and increasing support for your policy recommendations by tweeting about your assessment findings or posting them on their organization's social media platforms.

- **Scientific conferences:** Conferences can be a useful opportunity to disseminate your results in a formal setting among academics and stakeholders such as NGOs and advocacy organizations. Conferences can be a useful forum to share preliminary results and get feedback from scientists or expert parties on how to best move your assessment to the publication phase discussed below. A challenge for conferences can be one of timing, as they usually occur annually.

In the event, that you purchase or take pictures of tobacco packs during your compliance assessment, the Institute for Global Tobacco Control at Johns Hopkins University has a repository of cigarette packs from across the world available online. This web-based repository has detailed pictures of each pack collected by the Tobacco Pack Surveillance System (TPackSS) project. One option to further disseminate the data you collected is to archive and share your own collection of packs through images or submit pictures of packs at:

http://globaltobaccocontrol.org/tpackss/share-pack/

- **Journal articles:** Peer-reviewed, published evidence is part of the policymaking process. Policy makers and government officials often consider research that has undergone a rigorous process of review by outside parties when making policy decisions. If you feel your assessment was conducted systematically after following the steps in this guide, it may be worth considering writing up your results for publication in an academic journal.

Appendix A - Sources of Information

Campaign for Tobacco-Free Kids Tobacco Control Laws - https://www.tobaccocontrollaws.org/

Tobacco Control Laws is a website maintained by lawyers and provides easy access to tobacco control laws and court decisions from jurisdictions around the world, as well as fact sheets, summaries, and legal analysis. Most documents are available in the original and English language.

Global Adult Tobacco Survey (GATS) - https://www.who.int/tobacco/surveillance/survey/gats/en/

GATS is a nationally representative household survey on tobacco that has been implemented in over 25 low- and middle-income countries. Topics covered in GATS include tobacco use prevalence, second-hand tobacco smoke exposure and policies, cessation, knowledge, attitudes and perceptions, exposure to media and economics. GATS also collects data on the types of vendors where smokers purchase their tobacco.

List of registered tobacco brands

Some countries require tobacco manufacturers to register their products. Lists of registered products may be available to the public or you may need to contact local authorities to gain access to such lists.

Tobacco Pack Surveillance System (TPackSS) - https://www.globaltobaccocontrol.org/tpackss/

The Tobacco Pack Surveillance System is an ongoing surveillance project of tobacco packaging run by the Institute for Global Tobacco Control at the Johns Hopkins Bloomberg School of Public Health. The website offers a searchable database of over 5,600 tobacco packs collected from 14 low- and middle-income countries. There is also a feature (Share a Pack) whereby individuals can submit packs of interest for inclusion on the site. The TPackSS site also includes numerous data collection protocols and codebooks for health warning compliance and feature and appeals on its resource page. These are free to download, use, and adapt (https://www.globaltobaccocontrol.org/tpackss/resources).

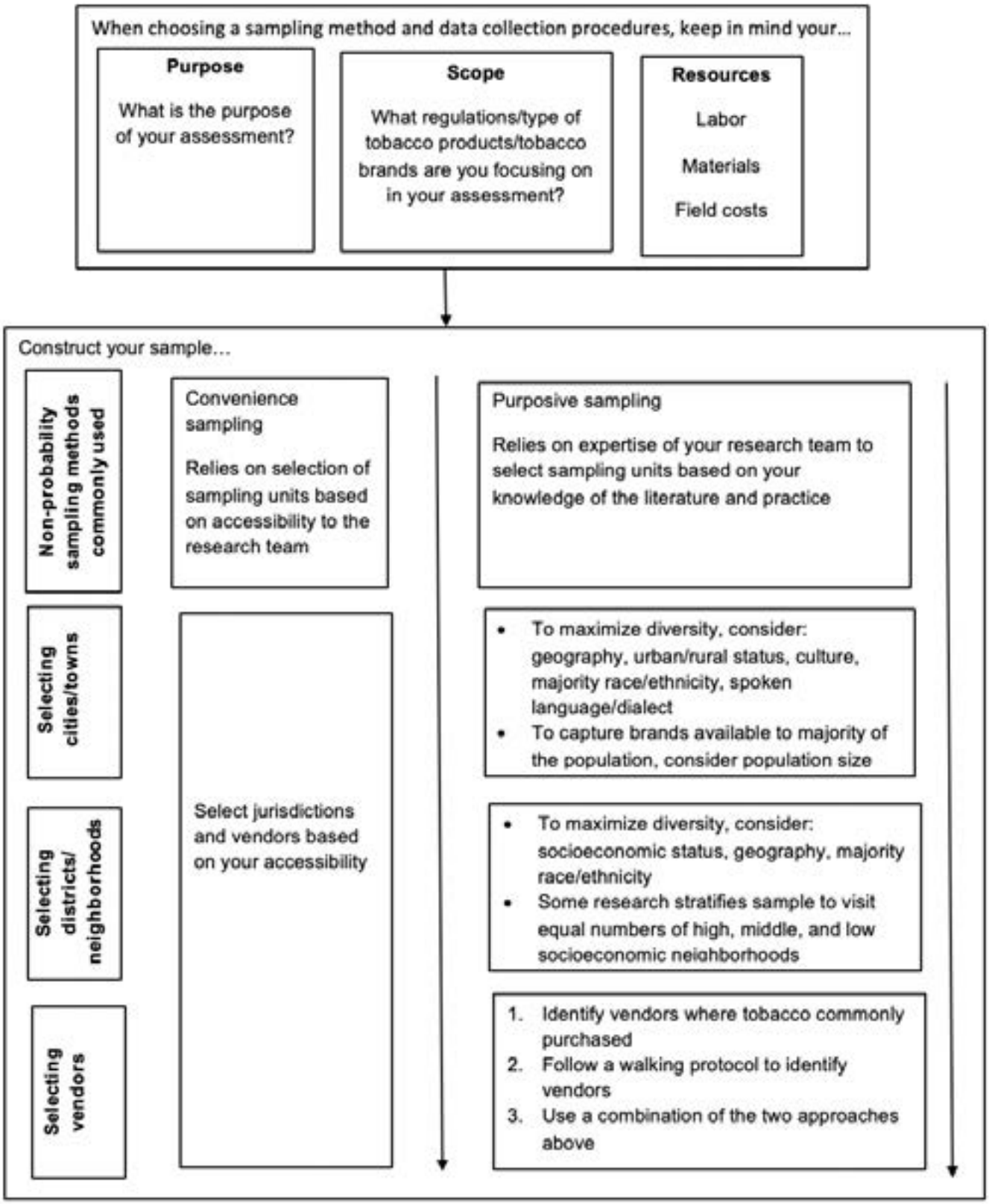
PhenX Toolkit - https://www.phenxtoolkit.org/

The PhenX Toolkit is an online catalog of standard measurement protocols. Most protocols are for use in biomedical research, but resources also include a protocol to examine tobacco packaging (https://www.phenxtoolkit.org/toolkit_content/PDF/PX750201.pdf) . PhenX is a collaboration of the National Human Genome Research Institute (NHGRI) of the National Institutes of Health (NIH) and RTI International.

Appendix B - Sample Timeline

TASKS	WEEK	PERSONS INVOLVED	PERSON RESPONSIBLE/ SUPERVISOR	DEADLINE FOR COMPLETION
Pre-data collection				
Familiarize yourself with existing laws				
Define purpose of your assessment				
Assess and secure resources				
Clarify the scope of your assessment				
Construct your sample				
Develop data collection procedures				
Develop data collection forms				
Pilot test procedures and forms				
Create coding sheet				
Training and data collection				
Train data collectors				
Collect data				
Post-data collection				
Code tobacco packs				
Check data quality				
Analyze your data				
Disseminate your results				

Appendix C – Choosing Your Sample



Appendix D – In-Field Data Collection Form

Date:
Data collector name:

Q1. City	What city or town are you in?	☐ [City 1] ☐ [City 2] ☐ [City 3]
Q2. District/neighborhood	What district or neighborhood are you in?	☐ [District X] ☐ [District Y] ☐ [District Z]
Q3. Vendor type	What vendor type are you visiting?	☐ [Vendor type 1] ☐ [Vendor type 2] ☐ [Vendor type 3] ☐ [Vendor type 4]
Q4. Number of packs collected	How many packs did you collect?	_ _
Q5. Comments	Comments (anything else of note)	

Appendix E – Sample Coding Sheet

Date:
Coder name:
Unique ID:
Date pack collected (if different from date observed):

Q1. City	What city or town was the pack collected in?	☐ [City 1] ☐ [City 2] ☐ [City 3]
Q2. District/neighborhood	What district or neighborhood was the pack collected in?	☐ [District X] ☐ [District Y] ☐ [District Z]
Q3. Vendor type	What vendor type was this pack collected from?	☐ [Vendor type 1] ☐ [Vendor type 2] ☐ [Vendor type 3] ☐ [Vendor type 4]
Q4. Health warning label	Is there a HWL printed on the pack?	☐ Yes ☐ No
Q5. Health warning label type	Does the HWL include a picture?	☐ Yes [combination of text and picture] ☐ No [text-only]
Q6. Health warning label content	Which HWL is printed on the pack?	☐ [Country specific warning 1] ☐ [Country specific warning 2] ☐ [Country specific warning 3] ☐ Other
Q7. Health warning label location	Is the HWL on the [front/ back/side] of the pack?	☐ Front ☐ Back ☐ Side
Q8. Health warning label placement	Is the HWL on the [top/ bottom] portion of the pack?	☐ Top ☐ Bottom
Q9. Health warning label size	Does the HWL cover [X%] of the pack? Refer to the reference pack.	☐ Yes ☐ No
Q10. Cessation information	Is [a quit line/quit website] displayed on the pack?	☐ Yes ☐ No
Q11. Tax stamp placement	Does the tax stamp cover the HWL?	☐ Yes ☐ No ☐ No tax stamp
Q12. Misleading descriptors	Identify any of the following terms that appear on the pack. [Select all that apply].	☐ [Low tar] ☐ [Light] ☐ [Ultra-light] ☐ [Mild] ☐ Other

Appendix E – Sample Coding Sheet (continued)

Q13. Constituents and emissions qualitative statement	Does the statement [on constituents and emissions] appear on the pack?	☐ Yes ☐ No
Q14. Constituents and emissions quantitative figure	Do any tar, carbon monoxide, or nicotine figures (e.g. 1.0 mg) appear on the pack?	☐ Tar ☐ Carbon Monoxide ☐ Nicotine
Questions on plain packaging (when applicable)		
Q15. Brand and product name	Does any promotional information, with the exception of the brand and product name in a standard color and font, appear on the pack?	☐ Yes ☐ No
Q16. Promotional features	If yes, what other promotional features appear on the pack?	☐ Brand logo ☐ Brand color ☐ Brand images
Q17. Comments	Comments (anything else of note)	

Appendix F – Assessing Inter-Rater Reliability

If more than one person codes the same content, you may consider assessing and reporting inter-rater reliability - the level of agreement between coders. There are several ways to assess inter-rater reliability. The methods described below assume that two coders have coded the same content independent of one another (i.e. they haven't discussed how they are coding, or consulted each other as they code). Your choice of method depends on the type of data you have and your audience. If you are assessing inter-rater reliability for internal purposes or including the results in a technical report, option 1 will likely suffice. If you are interested in publishing the results of your assessment in a peer-reviewed journal, you might want to consider options 2 or 3, and this may be an area where an academic partner might be valuable.

1. Percent agreement: This is the simplest method to use. Just count the number of ratings (or each question asked on the coding sheet) on which the coders agreed, divide this number by the total number of ratings (or total number of questions from the coding sheet answered), and convert to a percentage. This method typically works well unless the coders were asked to measure items.

2. Cohen's Kappa: This method is commonly used with categorical variables (a variable that can take on one of a limited number of possible values – for example, color e.g. red, blue, green or yes/no). We recommend using a software program or an online calculator through a university website to calculate this statistic. The prevalence and bias adjusted kappa (PABAK) can also be used and is similar to the Cohen's Kappa, but is adjusted for low prevalence observations and can be calculated by hand.

3. Krippendorff's Alpha: This method is commonly used with continuous variables (a variable that can take any numerical value). We recommend using a software program to calculate this statistic.

If you are conducting advanced statistical analysis, useful citations include:

- Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics.1977;33(1):159-174. http://www.ncbi.nlm.nih.gov/pubmed/843571.
- Hayes AF, Krippendorff K. Answering the Call for a Standard Reliability Measure for Coding Data. Commun Methods Meas. 2007;1(1):77-89. doi:10.1080/19312450709336664.
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3. Dhungel B, Basnet K. Prevalence of Smoking and Impact of Pictorial Health Warning on Quit Attempts Among Youths in Bhaktapur, Nepal. J Glob Oncol. 2018;(4_suppl_2):27s-27s. doi:10.1200/jgo.18.33400
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Contributors

AUTHORS

Campaign for Tobacco-Free Kids
Maria Carmona, M.Ed
Teresa DeAtley, MPH
Kaitlin Donley, JD
Ernesto Sebrie, MD

Institute for Global Tobacco Control, Johns Hopkins Bloomberg School of Public Health
Jennifer Brown, MPH
Joanna Cohen, PhD
Katherine Clegg Smith, PhD

International Union Against Tuberculosis and Lung Disease
Tara Singh Bam, PhD

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For more information, please contact:
Institute for Global Tobacco Control
2213 McElderry Street, 4th Floor
Baltimore, MD 21205
igtc@jhsph.edu

International Union Against Tuberculosis and Lung Disease

Health solutions for the poor

Institute for Global Tobacco Control