

# TOBACCO 21: Policy Evaluation for Comprehensive Tobacco Control Programs



**Centers for Disease Control and Prevention** National Center for Chronic Disease Prevention and Health Promotion

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The following individuals from the Centers for Disease Control and Prevention, Office on Smoking and Health (OSH) helped contribute to the preparation of this publication:

Rene Lavinghouze, MA, Health Scientist

Nicole Kuiper, MPH, Health Scientist

Rebecca Fils-Aime, MPH, Evaluation Fellow

Megan Cotter, MPH, Evaluation Fellow

Tamara Crawford, DBH, MPH, ORISE Fellow

Yessica Gomez, MPH, Health Scientist

Nikki Hawkins, PhD, Lead Health Scientist

Monica Cornelius, PhD, MPH, Associate Service Fellow

Briana Oliver, MPH, ORISE Fellow

Cross-division workgroup members: Pamela Lemos, Sarah R. Lewis, Michael Tynan, and MaryBeth Welton

The following partners also contributed to the preparation of this publication:

Missouri University and the Missouri Department of Health and Senior Resources

California Department of Public Health

Hawaii State Department of Health

New York City Department of Health and Mental Hygiene

Maine Department of Health and Human Services

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#### Purpose

The Centers for Disease Control and Prevention's Office on Smoking and Health developed this guide to help state, local, territorial, and tribal health departments plan and implement evaluation of the federal law to raise the minimum legal sales age (MLSA) for tobacco products to 21 years (herein referred to as the T21 law). Guidance in this document can also support evaluation of state, local, territorial, and tribal T21 laws that may mirror or are more stringent than the federal T21 law (broadly referred to as T21 policies in this document).

On December 20, 2019, the Federal Food, Drug, and Cosmetic Act was amended to raise the MLSA for tobacco products from 18 to 21 years, effective immediately. The Food and Drug Administration (FDA) has 180 days to adopt a final rule for implementation and enforcement. Regulatory and enforcement elements for the national T21 law are unfolding and may have implications for the guidance provided in this document. Prior to the enactment of the national T21 law, nineteen states had already passed legislation to raise the MLSA for tobacco products to 21 years. This guide includes examples from Hawaii and California, the first two states to implement state T21 laws.

The evaluation approaches described in this guide can help assess the effects and impact of T21 laws to help advance the goals of the National Tobacco Control Program (NTCP) and to support NTCP awardee efforts in the following areas:

- Preventing initiation of tobacco use
- Eliminating nonsmokers' exposure to secondhand smoke
- Promoting quitting among adults and youth
- Identifying and eliminating tobacco-related disparities

#### Audience

The primary audiences for this guide consist of planners, program managers, and evaluators of state tobacco control programs. Users are encouraged to adapt the tools and resources in this guidance to meet program evaluation needs.

#### **Accessible Version**

https://www.cdc.gov/tobacco/stateandcommunity/tobacco\_ control\_programs/surveillance\_evaluation/tobacco-21-policyevaluation/index.html.

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## Introduction

Tobacco use is the leading cause of preventable and premature death in the United States (USDHHS, 2014).<sup>1</sup> Nearly all tobacco use begins during youth and young adulthood (USDHHS, 2012). People who begin smoking at a young age are more likely to become addicted, to progress to daily smoking, and to smoke more heavily in adulthood (USDHHS, 2012). In addition, the use of nicotine by adolescents and young adults can harm the developing brain, including the parts of the brain that control attention, learning, mood, and impulse control (USDHSS, 2016).

Policies to increase the MLSA for tobacco products have been shown to contribute to reductions in tobacco use and dependence among youth (Institute of Medicine, 2015). Increasing the MLSA for tobacco to 21 years could reduce the likelihood of high school students legally purchasing tobacco products for themselves, other students, and underage friends, thus reducing the secondary risks of harm on youth brain development and early addiction.

According to the Institute of Medicine's 2015 report (Institute of Medicine, 2015), once the MLSA for tobacco products increases to 21 years nationally, it is projected that:

- Tobacco use will decrease by 12 percentby the time today's teenagers become adults; smoking-related deaths will decrease by 10 percent.
- Smoking initiation will be reduced by 25 percent for 15–17-year-olds and by 15 percent for 18–20-year-olds.
- Nationwide, 223,000 premature deaths will be prevented among people born between 2000 and 2019, including 50,000 fewer deaths from lung cancer.

On December 20, 2019, the Federal Food, Drug, and Cosmetic Act was amended to reflect a change in the MLSA for tobacco products from 18 to 21 years of age, effective immediately. Prior to the enactment of the national T21 law, nineteen states had passed T21 laws: Arkansas, California, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, New Jersey, New York, Ohio, Oregon, Pennsylvania, Texas, Utah, Vermont, Virginia, and Washington. Guam and Palau had also raised the MLSA for tobacco products to 21 years. Many cities adopted city-wide T21 laws as well, such as New York, Washington D.C., Chicago, and St. Louis (Counter Tobacco, 2019).

Policy evaluation can help inform program efforts by identifying potential gaps or deficiencies within the policy, and the effects that those gaps can have on the policy's implementation or intended impact. Furthermore, policy evaluation can help assess support and compliance with the implemented policy, demonstrate the value of the policy, and can help inform the evidence for future policies at the state, local, territorial, tribal, and national levels. It also can provide accountability for resources appropriated. Evaluating the impact of the federal T21 law within a specific jurisdiction can help answer questions about impact in various domains, for example:

- To what extent does the policy prevent initiation?
- How does the policy affect youth access to tobacco products?
- How does the policy affect social norms on tobacco use?
- What is the economic impact of the policy?

Additionally, tobacco control programs can consider examining whether differences exist between T21 laws enacted in their jurisdictions and the national T21 law and the extent to which different provisions affect the implementation and effects of the law.

<sup>&</sup>lt;sup>1</sup>"Tobacco" in this document refers specifically to the use of manufactured, commercial tobacco products and not the sacred and traditional use of tobacco by American Indians and other groups.

## **Planning for Policy Evaluation**

## Step 1: Engaging Stakeholders

In identifying and engaging potential stakeholders for evaluating tobacco control policies, it is important to include participants from sectors in addition to those that are customarily involved in evaluation efforts. Promising groups include those involved in the policy

implementation and enforcement. Federal, academic, or national health organization partners represent stakeholders that may have an interest in evaluation of the T21 law. Examples of these and other potential stakeholders are shown in Table 1.

Stakeholder Categories	Examples of Stakeholders
Policy Experts	National/state/local/territorial/tribal legislators and staff
	National/state/local/territorial/tribal tobacco prevention and control program staff
	Relevant enforcement agency staff (e.g., Department of Health, Attorney General's Office, alcohol and tobacco boards, state enforcement agencies)
	State/national/local nonprofit organizations (e.g., American Cancer Society, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Public Health Law Center)
<b>Evaluation Experts</b>	State, federal, academic, or contract evaluation research partners
	Agency evaluation staff
Subject Matter Experts	State/local/territorial/tribal department of health and tobacco prevention and control program staff, SAMHSA-funded (Synar compliance) staff
	Legal support partners (e.g., legal technical assistance centers)
	State/national nonprofit organizations (e.g., Campaign for Tobacco-Free Kids, American Cancer Society, American Heart Association, American Lung Association, American Academy of Pediatrics, youth organizations)
	Local substance abuse agencies, local arms of the state alcohol and tobacco agency
	University research partners
	National Network representatives (e.g., National LGBT Cancer Network, National African American Tobacco Prevention Network)
	State and local partners of National Networks
Implementers	Inspection or enforcement agency staff (e.g., Department of Health, SAMHSA-funded staff such as Synar compliance staff, Alcohol and Tobacco boards/agencies, local law enforcement)
	Local enforcement agency staff (Department of Finance, Office of Consumer Affairs)
	City/county boards/workgroups responsible for enforcing laws
	Local advocates, coalition members, mobilized stakeholders
	Mayor's staff responsible for implementing new laws
	Attorney General's Office
	Military stakeholders
	Tribal stakeholders
	Business associations, retailers selling tobacco (engaged only in the context of implementation-related outcomes and only as appropriate)

#### Table 1. Examples of T21 Policy Stakeholders

## Step 2: Describing the Policy Being Evaluated

Evaluation of a T21 law requires a clear understanding of the policy. Stakeholders and evaluators should understand the policy content, including provisions, implementation, and enforcement guidance. FDA's guidance regarding the federal T21 law continues to emerge. Several key policy components are likely to affect implementation and enforcement and thus the evaluation. These components are highlighted below:

- Policy definitions (e.g., tobacco products covered)
- Enforcement authority
- Penalty schedule
- Dates for when the policy is effective and active enforcement begins.

Understanding the policy and its intended effects enables evaluators to graphically display the theorized pathways of change in a logic model. The logic model should be tailored to the policy components and a specific jurisdiction's evaluation priorities. A generic logic model that can be tailored to meet diverse evaluation needs is shown in Figure 1. In addition to standard logical model components, such as policyrelated inputs, activities, outputs and outcomes (CDC, 2008), environmental context and unintended consequences are important considerations that also should be tailored.

#### SHORT-TERM INTERMEDIATE LONG-TERM INPUTS ACTIVITIES OUTPUTS OUTCOMES OUTCOMES OUTCOMES Model T21 Policy Increased support for Reduced initiation of Policy T21 Policy tobacco use among Funding development individuals under 21 process Partners years Increased negative Networks social norms around **Finalize policy** underage tobacco Surveillance & Reduced tobacco use use components Monitoring Systems prevalence among **Cessation Resources** individuals under 21 Increased years Evaluation staff time compliance with T21 Ads placed Increased awareness and effort Develop media policy and understanding Earned media campaign of T21 policy Reduced tobacco-Press releases (general public, related morbidity Develop and retailers) and mortality Decreased distribute Communication availability communications materials developed of tobacco materials products to Education sessions individuals <21 held Develop and Increased distribute Decrease sales enforcement activity Signage distributed signage of tobacco related to T21 products Inspections protocol Train Compliance checks enforcement conducted Unintended Consequences personnel; • Increase in illicit sales (e.g., adults purchasing for minors outside the store) conduct Diminished political will for other evidence-based retail policies (e.g., flavored inspections sales restrictions) Reduced opportunities for implementation

#### Figure 1. Generic T21 Logic Model

#### **Environmental Context**

Rates of tobacco use, state/local tobacco control funding, existing state/local tobacco policy landscape, tobacco and e-cigarette industry spending neighborhood demographics, retail density, proximity to exempted areas (e.g., tribal, military) or borders with non-covered areas (other localities, states).

Evaluation of logic models specific to T21 policies passed in California (Figure 2) and Hawaii (Figure 3) illustrate state-specific tailoring of a generic logic model. California's model was designed to support process and outcome evaluations. The California T21 policy specified that "any person, firm, or corporation" who sells or gives away tobacco products is accountable for violating the policy and included an exemption for active duty military personnel (Cal. Bus. & Prof. Code § 22958)

#### Figure 2. California State T21 Policy Logic Model

#### INPUTS

Statewide Tobacco 21 Implementation Plan, Surveillance, of Tobacco-Related Attitudes and Behaviors, Surveillance of Tobacco Sales to Minors, Statewide Tobacco Cessation Quitline

ACTIVITIES —	- <b>)</b> OUTPUTS -	SHORT-TERM OUTCOMES	INTERMEDIATE     OUTCOMES	LONG-TERM OUTCOMES
<ul> <li>Distribute new age-of-sale warning signs to all CA tobacco retailers</li> <li>Develop and disseminate materials to educate retailers about increased age of sale and effective employee training</li> <li>Administer and promote a statewide tobacco use quitline to general public and 18-20-year-old users</li> <li>Display ads at point of sale to educate public about increased age of sale and quitline</li> <li>Conduct enforcement-related compliance checks of tobacco sales to minors under 21</li> <li>Educate American Indian communities about tobacco age of sale disparity</li> </ul>	<ul> <li>Warning signs posted at 100% of tobacco retailers</li> <li>Educational materials and training tools distributed to retailers</li> <li>Operational quitline promoted to diverse populations and 18-20-year- old tobacco users</li> <li>Advertisements notifying public about new law and quitline displayed at tobacco retailers</li> <li>Demand letters issued to violating retailers through compliance checks of tobacco sales to minors under 21</li> <li>Educational materials for American Indian communities</li> </ul>	<ul> <li>Increase awareness and support for new age-of-sale law among the general public and 18-20-year-olds</li> <li>Increased perception among youth that tobacco is difficult to obtain</li> <li>Increased awareness of new age of sale among retailers</li> <li>Increased compliance with new age-of-sale law</li> <li>Increased awareness of dangers of young adult smoking</li> <li>Increased call volume to quitline from diverse callers and 18-20-year-old tobacco users</li> <li>Increased awareness among American Indian leaders about disparity in age of sale and health consequences</li> </ul>	<ul> <li>Decreased illegal sales of tobacco to youth under 18 and young adults ages 18-20</li> <li>Decreased ability for minors under age 21 to obtain tobacco products</li> <li>Decreased sales of tobacco products</li> <li>Decreased susceptibility to experimentation with tobacco products</li> <li>Increased quit attempts among tobacco users age 18-20</li> <li>Increased quit attempts among all tobacco users</li> <li>Increased number of tribal compacts or tribal policies with age of sale as 21</li> </ul>	<ul> <li>Increased age of tobacco use initiation</li> <li>Decreased tobacco use initiation</li> <li>Decreased tobacco use prevalence among young adults ages 18-20</li> <li>Decreased youth and adult tobacco use prevalence</li> <li>Decreased tobacco consumption</li> <li>Decreased exposure to secondhand smoke/toxic aerosol</li> <li>Decreased tobacco-related morbidity and mortality</li> <li>Minimized tobacco-related disparities among American Indian population</li> </ul>

#### **Environmental Context**

State excise tax rates, rates of tobacco use, national media campaigns, state tobacco control funding, utilization of statewide quitline, tobacco cessation insurance coverage, tobacco and e-cigarette industry spending

Note: "Tobacco products" include electronic smoking devices"; "smoking" includes smoking tobacco and vaping electronic smoking devices; "smoke-free" and "secondhand smoke" include tobacco smoke and toxic aerosol emitted from electronic smoking devices; and "thirdhand smoke" includes residue from tobacco

The Hawaii T21 policy held "any person"—including the retailer making an illegal sale and the underage individual attempting to purchase a tobacco product accountable for violating the policy (Figure 3; Haw. Rev. Stat. Ann. § 712-1258). It specified that persons under age 21 years in violation of the policy are subject to a \$10 fine for the first offense and a \$50 fine or 48–72 hours of community service for subsequent offenses. Hawaii did not explicitly exempt the military; the Army, Marines, and Navy indicated that they would voluntarily follow Hawaii's T21 policy.<sup>2</sup>

<sup>2</sup> For more information: Army, http://governor.hawaii.gov/newsroom/usag-news-release-army-to-comply-with-hawaii-tobacco-law/; Marines, http:// www.marines.mil/News/Messages/Messages-Display/Article/897646/notice-of-hawaii-raising-smoking-age-to-21-effective-1-january-2016/; Navy, http://www.navy.mil/submit/display.asp?story\_id=92572

#### Figure 3. Hawaii State T21 Policy Logic Model

INPUTS	ACTIVITIES	OUTPUTS	SHORT-TERM OUTCOMES	INTERMEDIATE OUTCOMES	LONG-TERM OUTCOMES
Policy: Tobacco 21 Legislation	Enact State Law as of 1/1/16	# audience-tailored fact sheets developed (e.g.,	Increased awareness	Increased favorable public	Decreased smoking /ENDS
Funding: CDC Funds	Develop and distribute educational materials	military, POS locations) & distributed	and understanding of law (e.g., general public, tourists)	opinion of law (attitudes & beliefs)	use prevalence among minors (& military)
Coalition Funds Partners:	Educate key audiences	# education / training sessions held by group	Increased military base policies' consistency with	Increased compliance with law	Increased sustained cessation among minors
Dept. of Health/TPEP Coalition for a Tobacco-	<ul> <li>Military base commanders</li> <li>University staff/</li> </ul>	# meetings convened to discuss Tobacco	state law	Decreased tobacco & ENDS sales to persons	Improved health <ul> <li>Decreased tobacco/</li> </ul>
Free Hawaii (Coalition) CDC OSH	students <ul> <li>Public school teachers</li> <li>&amp; administrators</li> </ul>	21 implementation & enforcement (e.g., military, univ. campus	Increased awareness of location-specific policies around tobacco & ENDS	<21	nicotine exposure among minors • Decreased health
Campaign for Tobacco- Free Kids (CFTFK)	<ul> <li>Youth &amp; young adults</li> <li>&lt; 21</li> </ul>	security)	(e.g., universities, schools, military bases)	norms around underage smoking (descriptive,	effects b/c of smoking/ ENDS use
Cancer Center Univ. of Hawaii (Public Health Studies; Campus	<ul><li>Merchants</li><li>ENDS retailers</li></ul>	# and type of tobacco- related policy revisions / procedures developed and	Increased enforcement	injunctive, subjective) <ul> <li>Decreased smoking /</li> </ul>	Decreased health
Police; Student Affairs) Dept. of Education (DOE) Hawaii Police Dept. (HPD)	Create enforcement infrastructure • In schools	disseminated • ENDS-use at universities	Decreased commercial supply of tobacco/ nicotine to minors	ENDS use initiation <ul> <li>Decreased product switching</li> </ul>	disparities (e.g., tobacco/ nicotine access, use, and health and social consequences) Improved economic return on investment (ROI)
Networks: Military Base Commanders	<ul> <li>In universities</li> <li>On military bases</li> <li>With general public</li> <li>With visitors/tourists</li> </ul>	<ul> <li>military base tobacco policies for personnel &lt;21</li> <li>ENDS as drug</li> </ul>	Decreased social supply of tobacco/nicotine to minors	Decreased conversion from occasional to daily use	
Legislators Attorney General's Office Youth Coalitions	Train enforcement personnel in various sectors	paraphernalia in schools • tobacco possession in schools	Decreased intentions to start smoking/using ENDS	<ul> <li>Increased calls to Quitline from persons</li> <li>&lt;21</li> <li>Increased quit</li> </ul>	
Tourism & Hospitality Retailers & Grocers Chamber of Commerce	ity Create & distribute	<ul> <li>public possession</li> <li># / type signage developed and distributed</li> </ul>	Decreased intentions to product switch Increased quit intentions	attempts by underage smokers/ENDS consumers	
Tax Commissioner's Office HPPUD?/ADAD? Surveillance & Monitoring Surteme	<ul> <li>In retail establishments</li> <li>In point of sale locations</li> </ul>	(e.g., schools, retail establishments, point of sale locations)	Increased understanding about attitudes and knowledge of tobacco/		
Systems HYTS (Spring 2015) YRBS (Spring 2015)	Create & distribute media campaign	# calls to Quitline (tobacco and ENDS by age)	ENDS users Increased understanding of u		
BRFSS (e-cig module in 2016) SYNAR	Promote cessation resources	# ads in #/type of venues (featuring Quitline tag) # newsletter stories by	negative economic impacts,	illicit market)	
State Inspections of Tobacco Retailers Coalition's Public Opinion	Broaden and conduct underage enforcement activities	audience # press releases by audience (e.g., tourism, grocers)			
Polling Cessation Resources:	Monitor and evaluate	#/type of direct mass mailings			
Quitline	<ul> <li>Conduct periodic surveillance efforts</li> <li>Conduct focus groups on Quitline users</li> </ul>	Revised protocols & contracts (e.g., SYNAR, state inspections)			
	<ul> <li>Research vape shops' product lines</li> <li>Monitor tobacco revenue</li> </ul>	# focus groups & participants (e.g., ENDS cessation) Monthly tobacco sales revenue data/reports #/type surveys conducted & #/type of respondents			

Below are several types of evaluation studies that state or local tobacco control programs can conduct to understand the process and outcome of a T21 policy.

**Public Support.** These studies use focus groups and/ or surveys to assess public awareness of and support for a T21 policy. Public awareness/support studies can be used formatively to shape implementation or to document baseline public awareness and support for the policy and to measure changes over time.

**Retailer Implementation.** Telephone-based or inperson surveys of tobacco product retailers can be used to monitor implementation issues and unintended consequences (e.g., increases in purchases made on behalf of, or with the intent to sell to, underage consumers), as well as retailer support for or concerns about the policy.

Retailer Compliance. Assessments of T21 policy compliance by tobacco product retailers often rely on data gathered by the agency charged with enforcing the T21 policy, for example, tobacco purchase compliance checks. Such checks can be conducted by various agencies, depending on the jurisdiction, and may be part of routine retailer inspections for other purposes (e.g., FDA compliance, Synar compliance, state compliance). Data from compliance checks can be used to document policy compliance rates (i.e., proportion of retailers in a jurisdiction found to be in compliance with the policy), implementation of the enforcement regime, and/or types of venues and geographic regions that are more or less compliant with the T21 policy. This information can inform resource allocations for targeted retailer education, outreach, and enforcement efforts.

#### Behavior of Underage Youth and Young Adults.

Questions on behavioral outcomes (e.g., reported ease of access to tobacco products; ever or current use of tobacco products; quit attempts) can be developed for existing state- or locality-based surveys of youth and young adults within the jurisdiction being evaluated. Studies of behavioral outcomes are most effective if they include data from before and after the T21 policy goes into effect.

**Economic Impact.** These studies use economic data to assess the cost-benefit of a T21 policy on retailers and other stakeholders. For example, a study on the cost-effectiveness of raising the MLSA to 21 in California

used simulation models to generate estimates of benefits and costs (Ahmad, 2005). Substantial declines in youth initiation over 50 years with no net cost and a significant gain in guality adjusted life years were reported (Ahmad, 2005). Additionally, Ali et al. assessed the association between raising the MLSA to 21 with monthly sales of cigarette packs in California and Hawaii using difference-in-differences methods. Preand post-implementation estimates were obtained. The results showed that T21 policies were associated with a 13% reduction in cigarette pack sales in California and 18% reduction in cigarette pack sales in Hawaii (Ali, 2019). The costs, benefits, and methods included in these and similar studies may provide information that is helpful when planning studies of economic impact.

## Step 3: Focusing the Evaluation

Planning and implementing a T21 policy evaluation rely on having clearly articulated objectives and a sound plan for collecting and analyzing data. This section covers example evaluation questions across the domains of public awareness, compliance, health, and economic impact. Evaluation questions are organized by evaluation stage (Figure 4).

**Content evaluation** explores the process of identifying the problem and developing the policy.

#### Figure 4. Evaluation Planning and Implementation Flow

**Implementation evaluation** explores the policy enactment and implementation, including enforcement.

**Impact evaluation** examines the policy's impact on the intended short-, intermediate- and long-term outcomes, as laid out in the policy logic model.



#### **Evaluating Policy Content**

Evaluation of policy content is often included as a preliminary step of a comprehensive evaluation because it helps the evaluator properly interpret implementation and impact evaluation. Content evaluation of any policy, including T21 laws, takes an in-depth look at the policy's strengths and weaknesses when compared with a model policy. For example, national tobacco control organizations created guidelines for a strong MLSA policy and developed model language (see below).

According to these organizations (Public Health Law Center, 2019.), "A strong tobacco minimum legal sales age (MLSA) 21 ordinance will:

- Define tobacco products to include current and future tobacco products, including e-cigarettes.
- Prohibit the sale of tobacco products to persons under the age of 21.
- Require the tobacco retailer or their employer to verify the age of the purchaser prior to the sale.
- Require tobacco retailers to post signs stating that sales to persons under the age of 21 are prohibited.

- Designate an enforcement agency and establish a clear enforcement protocol.
- Create a tobacco retail licensing program if the jurisdiction has the authority to do so under state law.
- Dedicate funding to fully cover enforcements costs, either through licensing fees or as a provision in a state statute or local ordinance.
- Provide authority for the state, county, or municipality to inspect tobacco retailers for compliance with MLSA 21 and a mandated minimum number of annual compliance checks for every tobacco retail establishment.
- Provide penalties focused on the tobacco retailer, or licensee rather than the youth purchaser or the non-management employee. This would mean eliminating Purchase, Use, and Possession (PUP) penalties where they exist in current tobacco sales laws or polices.
- Establish a civil penalty structure for violations rather than a criminal penalty structure to avoid unintended consequences that disproportionately impact marginalized communities and undermine the public health benefits of the policy.

• Where state legislation is pursued, ensure that local jurisdictions have the authority to enact more stringent regulations for tobacco products than state or federal law."

Nineteen states and over 540 localities passed T21 laws prior to the passage of the federal law, and two additional states have enacted T21 laws since passage of the federal law (Campaign for Tobacco-Free Kids, 2020). Jurisdictions may continue to adopt their own MLSAs for tobacco products to help bolster compliance with the federal T21 requirements or to raise the MLSA higher than 21 years. If a state, local, territorial, or tribal law is not as strong as federal law, retailers still must comply with the federal law. Differences among these policies may be relevant for assessing and comparing the strengths of the various laws as well as any other relevant, existing state or local policy elements that are still being enforced. This can help inform future MLSA policy development, as well as other retail-oriented policies.

Examples of specific questions for a T21 policy content evaluation are listed below:

- Is there support for the policy components? Is there opposition?
- Is the policy consistent with gold standard policies?
- Are enforcement activities, retailer education, and penalties delineated?
- How are key components defined in the policy (e.g., tobacco products, restrictions, and signage)?
- Did economic considerations or interests strengthen or weaken the policy?
- Does the policy state the evidence about the expected economic impact?
- If there are multiple local policies, how do they differ along these key components?
- How did local education efforts affect policy adoption at the local level?

#### **Evaluating Policy Implementation**

A T21 implementation evaluation explores the activities involved in communicating about the policy, policy monitoring, and policy enforcement. For example, an implementation evaluation may

examine media and other communications efforts (e.g., distributing signage) about the policy to the public and retailers. Implementation also covers the training, protocol development, and activities related to retailer inspections that make up compliance monitoring. For the federal T21 law, the FDA has not yet issued its final regulation, but has said that its enforcement will generally be carried out using the same process as when the federal MLSA was 18, and that it has begun using older underage persons in its compliance checks. (FDA, 2020).

Implementation evaluation questions could include:

- Were education activities conducted, including addressing any concerns? Were they well-received?
- Were education efforts effective at increasing awareness of the policy?
- Were compliance checks performed according to the policy, or if not, how were they performed?
- Are there geographic pockets of retailers who are non-compliant?
- Were the right stakeholders involved in implementation?
- Was the policy implemented uniformly across states?

As part of an evaluation of policy implementation, evaluators should examine all aspects of the policy. This includes the activities, actions, and the multiple perspectives for raising the MLSA for tobacco products to 21 years (for an expanded discussion, see Morian & Malek, 2017). A comprehensive evaluation will address all viewpoints by providing evidence of the policy's impact and equipping policymakers and implementers with available data to mitigate any unintended consequences.

#### **Evaluating Policy Impact**

T21 policy impact evaluations can explore a variety of topics including changes in policy awareness and support, enforcement activities and compliance, retail sales, and underage tobacco access and use. Comprehensive impact evaluations intend to answer questions about whether the policy is having its intended effect, such as:

• How has public and retailer support for the policy changed since its enactment?

- Did T21 policy enactment affect public or decision-maker support for other evidence-based tobacco control policies?
- Did negative social norms about underage tobacco use change?
- Has retailer non-compliance changed over time as enforcement activities have continued?
- Did quitline call volume change?
- Did young adult tobacco use change?
- Did retail tobacco product sales change?

- Did cessation activity of underage youth or young adults change?
- Did retailer revenues and employment change after the policy went into effect?

Impact evaluations can employ quantitative and qualitative methods and a variety of data sources, including focus groups; public opinion polls; surveys of adults, youth, and retailers; enforcement agency reports; and retail sales data.

Table 2 presents example evaluation questions, study designs, indicators, and data sources for evaluation of T21 policy content, implementation, and impact.

#### Table 2. Evaluation Planning Matrix – T21 Policy Evaluation

#### **PUBLIC AND RETAILER SUPPORT**

#### Content Evaluation

Example Evaluation Questions	Example Evaluation Designs	Example Meaningful Indicators	Example Data Source
Is there support for the elements of the policy under consideration (e.g., penalties)?	Qualitative (content analysis of news media) Quantitative (analysis of opinion poll/survey data)	Level of support for specific policy components	News media Survey or opinion poll
Is there opposition to any of the elements?	Qualitative (content analysis of legislative history, testimony, news media)	Expressions of opposition in legislative history, news media	Legislative history News media
Is the policy consistent with gold standard policies?	Qualitative (analysis of policy language, model policy language)	Presence of policy content in alignment with gold standard	Legal documents; published and grey literature
Does the policy apply to more products than the federal law?	Qualitative (analysis of policy language)	Presence of definitions	Legal documents

#### Implementation Evaluation

Example Evaluation	Example Evaluation	Example Meaningful	Examtple Data Source
Questions	Designs	Indicators	
Were efforts made to educate the public, retailers, decision makers, or other stakeholders about the policy?	Qualitative (analysis of administrative records, stakeholder interviews, focus groups)	Number and types of communication with stakeholders (e.g., in-person meetings, phone calls, emails, press releases, educational materials distributed)	Administrative records, press releases, stakeholder websites, stakeholder interviews, focus groups Telephone or in-person retailer interviews

Example Evaluation	Example Evaluation	Example Meaningful	Examtple Data Source
Questions	Designs	Indicators	
Were efforts made to address or alleviate concerns about the policy? Were efforts well received?	Qualitative (analysis of stakeholder interviews, focus groups) Quantitative (analysis of opinion poll/survey data)	Number and types of communication with stakeholders (e.g., in-person meetings, phone calls, emails, press releases, educational materials distributed) Public awareness of outreach Percent of public who felt concerns were addressed	Stakeholder interviews, focus groups, newspaper coverage Opinion poll data

### Impact Evaluation

Example Evaluation Questions	Example Evaluation Designs	Example Meaningful Indicators	Example Data Source
How has public support changed since the policy was enacted?	Qualitative (focus groups, content analysis of news media) Quantitative (time-series)	Level of community awareness Level of support for T21 policy Level of support for policies, and for enforcement of policies, to decrease availability of tobacco to young people	Focus groups (before and after policy enactment) Adult tobacco survey, public opinion polls, news media
Did policy enactment change support for other policies to prevent initiation of tobacco use?	Quantitative (time-series)	Level of support for other tobacco use initiation policies	Public opinion polls
Did negative social norms about underage tobacco use change?	Quantitative (time-series)	Level of support for norms about underage tobacco use	Adult tobacco survey, public opinion polls

### COMPLIANCE

#### Content Evaluation

Example Evaluation Questions	Example Evaluation Designs	Example Meaningful Indicators	Example Data Source
Are retailer, public education and enforcement activities explicitly referenced, delegated, and funded in the policy?	Qualitative (analysis of policy language)	Presence of policy components relevant to education and enforcement	Legal documents
Were penalties for non- compliance specified in the policy for retailers and customers? Are the penalties evidence-based?	Qualitative (analysis of policy language, literature)	Presence of T21 penalties Evidence from the literature supporting T21 penalties	Legal documents, grey and published literature

### Implementation Evaluation

Example Evaluation Questions	Example Evaluation Designs	Example Meaningful Indicators	Example Data Source
To what extent were the public and businesses aware of the	Qualitative (analysis of stakeholder interviews, focus	Knowledge of specific policy components	Stakeholder interviews (including retailers)
policy?	group data)		Focus groups
	Quantitative summary analysis		Public opinion polls
To what extent were compliance checks and enforcement actions	Qualitative (analysis of stakeholder interviews)	Description of compliance checks in alignment with policy	Stakeholder interviews (including retailers)
performed according to the policy?	Quantitative summary analysis (post-intervention)	Documentation of compliance checks	Enforcement data
Are there pockets of non- compliance that need additional enforcement?	Quantitative summary analysis (post-intervention)	Number of T21 violations by geographic area, store type	Enforcement data

### Impact Evaluation

Example Evaluation Questions	Example Evaluation Designs	Example Meaningful Indicators	Example Data Source
Has non-compliance changed over time as enforcement activities have continued?	Quantitative (post-intervention time series)	Number of violations as proportion of inspections	Enforcement data
How does observed retailer compliance compare to other states or localities without their own T21 policies?	Quantitative (post-intervention time series; strengthened with comparison)	Number of violations as proportion of inspections	Enforcement data
Has reported retail access changed for youth under 18? Have reported usual sources for tobacco changed for youth under 18?	Quantitative (time-series, strengthened with comparison)	Proportion of young people who report having purchased a tobacco product from a retailer in the previous 30 days Proportion of youth who report that they were refused sale of tobacco products because of their age during the previous 30 days Locations where youth purchased cigarettes	Youth tobacco survey

#### **YOUTH BEHAVIOR**

#### Content

Example Evaluation	Example Evaluation	Example Meaningful	Example Data Source
Questions	Designs	Indicators	
Is policy consistent with evidence base to eliminate harms to health and not increase disparities among population groups?	Qualitative (literature review)	Evidence supporting policy content regarding health and disparities	Grey and published literature

### Implementation

Example Evaluation	Example Evaluation	Example Meaningful	Example Data Source
Questions	Designs	Indicators	
To what extent was policy enacted uniformly in all communities affected by the policy?	Quantitative summary analysis (post-intervention) Qualitative (stakeholder interviews)	Proportion of stores inspected in affected jurisdiction(s) Perception of uniform implementation Number of people affected	Enforcement data Stakeholder interviews

### Impact Evaluation

Example Evaluation Questions	Example Evaluation Designs	Example Meaningful Indicators	Example Data Source
How did quitline call volume change as a function of the policy?	Quantitative, time-series	Number of quitline calls (per week/month)	Quitline data
How did rates of youth tobacco use change as a function of the policy?	Quantitative (time-series, strengthened with comparison)	Proportion of young people who have never tried smoking or using any other tobacco products	Youth tobacco survey
		Proportion of young people who have smoked or used some type of tobacco product at least 1 day during the previous 30 days	
How did rates of young adult tobacco use change as a function of the policy?	Quantitative (time-series, strengthened with comparison)	Cigarettes: Proportion of adults aged 18-24 years old who have smoked at least 100 cigarettes in their lifetime and who now report smoking cigarettes every day or some days	Adult tobacco survey
How did overall tobacco consumption change as a function of the policy?	Quantitative (time-series, strengthened with comparison)	Retail unit sales of tobacco products	Retail scanner data
How did rates of tobacco use cessation actions (quit attempts, quits) by young adults change as a function of the policy?	Quantitative (time-series, strengthened with comparison)	Proportion of tobacco users who stopped using a tobacco product for 24 hours in a quit attempt	Adult tobacco survey
		Proportion of former tobacco users who last used tobacco 6 months to 1 year ago	
		Proportion of former tobacco users who have sustained abstinence from tobacco use for 6 months or longer	

### **ECONOMIC IMPACT**

### Content

Example Evaluation Questions	Example Evaluation Designs	Example Meaningful Indicators	Example Data Source
To what extent did economic considerations or interests strengthen or weaken the policy?	Qualitative (content analysis of legislative history, testimony)	Evidence of economic considerations in legislative history	Legislative history
Did the policy state the evidence about the expected economic impact?	Qualitative (content analysis of legislative history, testimony)	Presence of economic impact considerations in policy language	Legislative history

### Implementation

Example Evaluation	Example Evaluation	Example Meaningful	Example Data Source
Questions	Designs	Indicators	
How did events or activities in surrounding jurisdictions impact policy implementation (e.g., such that these may have encouraged or discouraged cross-border sales by young people)?	Qualitative (content analysis of stakeholder interviews, legal documents) Quantitative (time-series, adjacent jurisdictions)	Summary of policy and/or environmental context of surrounding jurisdiction(s) Retail unit sales of tobacco products	Stakeholder interviews, legal/ news documents, scanner data

#### Impact Evaluation

Example Evaluation Questions	Example Evaluation Designs	Example Meaningful Indicators	Example Data Source
How did quitline call volume change as a function of the policy?	Quantitative, time-series	Number of quitline calls (per week/month)	Quitline data
How did rates of youth tobacco use change as a function of the policy?	Quantitative (time-series, strengthened with comparison)	Proportion of young people who have never tried smoking or using any other tobacco products	Youth tobacco survey
		Proportion of young people who have smoked or used some type of tobacco product at least 1 day during the previous 30 days	
How did rates of young adult tobacco use change as a function of the policy?	Quantitative (time-series, strengthened with comparison)	Cigarettes: Proportion of adults aged 18-24 years old who have smoked at least 100 cigarettes in their lifetime and who now report smoking cigarettes every day or some days	Adult tobacco survey
How did overall tobacco consumption change as a function of the policy?	Quantitative (time-series, strengthened with comparison)	Retail unit sales of tobacco products	Retail scanner data

Example Evaluation Questions	Example Evaluation Designs	Example Meaningful Indicators	Example Data Source
How did rates of tobacco use cessation actions (quit attempts, quits) by young adults change as a function of the policy?	Quantitative (time-series, strengthened with comparison)	Proportion of tobacco users who stopped using a tobacco product for 24 hours in a quit attempt	Adult tobacco survey
		Proportion of former tobacco users who last used tobacco 6 months to 1 year ago	
		Proportion of former tobacco users who have sustained abstinence from tobacco use for 6 months or longer	

## Steps 4-5: Gathering Credible Evidence and Justifying Conclusions

In addition to the standard considerations around data selection and analyses, there are other considerations specific to the logistical, social, and political context of T21 policies that should be considered carefully when planning an evaluation. When looking at state, local, territorial, or tribal-level policies, the logistical and contextual considerations below can vary significantly between policies. While the national T21 law may dissipate much of the variability among state, local, territorial, or tribal laws, it will still be important to understand how the law is structured, the environmental context in which it is taking place, as well as the historical context, which will vary between jurisdictions.

**Compliance Checks:** In addition to compliance activities conducted to enforce state, local, territorial, or tribal T21 laws, compliance checks for the federal T21 law occur at both state and federal levels. The Synar Amendment to the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 requires states to enact and enforce laws prohibiting the sale or distribution of tobacco products to individuals under the age of 18 years to be eligible to receive substance abuse funding (Substance Abuse and Mental Health Administration, 2017). Under the Synar Amendment and other T21 laws enacted prior to the national T21 law, compliance was assessed by using underage decoys to determine if retailers were selling to underage persons. When the national T21 law was enacted, the Synar Amendment was also updated to reflect the new MLSA of 21. The federal agency that administers the Synar program has not yet provided

guidance for states to conduct those compliance checks, and FDA has not yet finalized its regulations related to federal enforcement of the federal law.

**Baseline Data Collection:** States or jurisdictions should consider collecting baseline information when using pre-post designs to evaluate T21 policies. However, the rapid nature in which the national T21 law was passed presents challenges for having baseline data. This makes it difficult to measure changes in public opinion over time and, thus, policy impact. In such cases, existing data sources may offer opportunities for estimating baseline rates. Examples include, examining previous tobacco use among 16-17-year-old survey respondents, underage retail sales rates from Synar inspections, data collected related to more locally based T21 policies prior to the national T21 law, and retail scanner sales data (which is typically available retrospectively for several years). If information was not previously collected, a prepost comparison will not be possible. However, other designs could be used to assess impact.

**Comparative Assessments:** When baseline measures are impossible to obtain, quasi-experimental designs using comparison groups could be helpful, since this design allows for comparisons of samples similar in all aspects except for the characteristic of interest. For example, this design can be used to assess how contextual factors and variation in enforcement and compliance can have an impact on policy outcomes and impact (Coly & Parry, 2017).

**Environmental Context:** As with any policy evaluation, policies, campaigns, initiatives, or other environmental changes concurrent to the policy under review must be considered when designing and analyzing a T21 evaluation. This attention to the environmental context is especially important given that point-of-sale campaigns, increases in tobacco taxes, and other strategies may be enacted independent of T21 policies. Evaluators should consider both new and existing tobacco control policies and other interventions that may contribute to the outcomes being measured. In addition, evaluators can use evaluation designs that maximally control sources of invalidity (Campbell & Stanley, 1966).

## Step 6: Applying Policy Evaluation Results

T21 policy evaluation results can be useful for stakeholders at multiple levels. Evaluation results can be used to inform ongoing national, state, and local implementation and enforcement, assess the level of public awareness and support for the policy, and provide meaningful indicators of success for stakeholders and the public.

Some examples of how evaluation findings can be used by various audiences, are highlighted below (Table 3).

Evaluation Findings	Type of Information to be Disseminated
Content/implementation evaluation results	Potential enforcement gaps to inform policy/enforcement modifications
Impact evaluation results	Policy outcomes and the effect on the population, including intended and unintended effects
Lessons Learned	Recommendations for future T21 and other retail policy implementation and evaluation

#### Table 3: Types of Information Disseminated from Policy Evaluation Results

Evaluators should consider tailoring communication of evaluation findings to the needs and interests of different stakeholders, while packaging the evaluation results in a manner that is appropriate for the type of stakeholder. For example, a report describing policy impact may be of interest to T21 implementers, enforcement agencies, and policy and evaluation experts. Scientific manuscripts detailing the methods to evaluate the policy and the findings may be of greater interest to policy and subject matter experts. Similarly, "lessons learned" reports and straightforward documents or publications describing recommendations for implementation may be a better fit for staff members in jurisdictions that exhibit problems with effective implementation of the T21 law.

## **Appendix: Accessible Explanations of Figures**

Figure 1 Generic T21 logic model. Evaluators can use this model as a quide and tailor it to best fit the evaluation needs of each state and jurisdiction. Provided are examples of points to include in a T21 logic model. This model covers six categories: inputs, activities, and outputs, as well as short-term, intermediate, and long-term outcomes. The inputs for this T21 model are the T21 law, funding, partners, networks, surveillance and monitoring systems, cessation resources, and the evaluation of staff efforts and time. Activities for this model can involve policy development and finalizing its components, development and distribution of media campaigns, communication materials and signage, and training personnel on enforcement and inspections. Outputs can include advertisements and press releases, educational sessions for the T21 law, signage distribution, inspection protocols, and compliance checks. Short-term outcomes in this model can encompass increased awareness and understanding of T21 law, as well as increased enforcement of activities related to the law. Intermediate outcomes can be an increase in support for T21 law, increased change in social norms for underage tobacco use, increased compliance with T21 law, decreased availability of tobacco products to youth under 21, and decreased sales of tobacco products. Long-term outcomes can include reduction of the following: tobacco use initiation, tobacco use prevalence, and tobacco-related morbidity and mortality for youth under 21. This logic model also covers sections for both unintended consequences and an environmental context that gives states and jurisdictions an opportunity to discuss specific issues related to implementation of the T21 law in their area. (Page 3)

**Figure 2** California's T21 logic model. It uses six categories: inputs, activities, and outputs, as well as short-term, intermediate, and long-term outcomes. California's inputs are the statewide implementation of their T21 law and cessation quitline, as well as surveillance of the public's attitudes/behaviors of the law and surveillance of tobacco sales to youth. Activities in this model involve distribution of warning signs and educational materials to retailers and employees about T21 law, promoting quitline to youth tobacco users, educate public about T21

law and guitline, conduct compliance checks, and educating American Indian communities about age of sale disparity. Outputs in this model include warning signs posted in all tobacco retailers, distribution of training materials to retailers, promotion of guitline to underage tobacco users, advertisements notifying the public of T21 law, demand letters to retailers who violate the law, and educational materials to American Indian communities. Short-term outcomes in this model cover increased awareness and support for the T21 law among the public and underage tobacco users, increased perception to youth that tobacco use is dangerous and difficult to obtain, increased awareness and compliance of T21 law to retailers, increased call volume to guitline for tobacco users, and increased awareness among American Indians of disparity in age of sale and health consequences. Intermediate outcomes in this model include decreased illegal sales and ability to obtain tobacco products for youth under 21, decreased sales of tobacco products, decreased susceptibility of experimentation of tobacco products, increased guit attempts for all tobacco users, and increased number of tribal compacts or policies with age of sale as 21. Long-term outcomes for this model involve increased age of tobacco use initiation, decreased tobacco use initiation and tobacco use prevalence for youth and adults, decreased tobacco consumption, decreased exposure to secondhand smoke, decreased tobacco-related morbidity and mortality, and minimized tobacco-related disparities among American Indian population. California utilized the environmental context section and highlighted state excise tax rates, rates of tobacco use, national media campaigns, state tobacco control funding, utilization of guitline services including cessation insurance coverage, and spending on tobacco products. They also make note that references to tobacco products and use include that of e-cigarettes and other electronic smoking devices. (Page 4)

**Figure 3** Hawaii's T21 logic model. This model covers six categories: inputs, activities, and outputs, as well as short-term, intermediate, and long-term outcomes. The inputs for Hawaii's logic model are as follows: T21 law, funding from CDC and other coalitions, external partnerships with public health departments and organizations, state-based networks like military bases and youth coalitions, surveillance and monitoring systems (HYTS, YRBS, BRFSS, SYNAR, etc.), and cessation guitline services. Activities in Hawaii's logic model involves enacting the T21 law, developing and distributing educational materials, educating the public and those who work with youth about the T21 law, creating enforcement infrastructure, training enforcement personnel, creating and distributing signage, promotion of cessation resources, broadening underage enforcement activities, and monitoring the following: evaluation, research, and surveillance efforts on guitline users and sales of tobacco products. The outputs for Hawaii's model include fact sheets tailored to every audience about the law, training sessions to discuss implementation and enforcement of the T21 law, dissemination plan for tobaccorelated procedures, development and distribution of signage, number of calls to guitline, advertisements to promote the T21 law and guitline services, revised protocols and contracts, and focus groups. Short-term outcomes for this model cover increased awareness and understanding of T21 law, increased consistency between tobacco-related military policies and T21 law, increased enforcement, decreased commercial supply of tobacco products to minors, decreased intention to start smoking or switch to a different product, increased guit intentions, and increased understanding about the attitudes of tobacco users. Intermediate outcomes include increased favorable public opinion and compliance of T21 law, decreased tobacco product sales to persons under 21 years, increased change in social norms around underage smoking, decreased smoking initiation and tobacco product switching, decreased daily smoking, and increased calls to cessation resources and guit attempts for youth under 21. Long-term outcomes in the model encompass decreasing tobacco use prevalence among minors and military, increased sustained cessation for youth under 21, decreased tobacco product exposure among youth, decreased health effects of tobacco use, decreased tobacco-related health disparities, and improved economic return on investment. Hawaii also provided a space to discuss an increased need to understand the unintended consequences when a T21 law is implemented. (Page 5)

**Figure 4** Evaluation Planning and Implementation Flow. The flow starts with content evaluation which consist of Problem identification, policy analysis, and strategy and policy development. It then moves to implementation evaluation which consist of policy enactment. The flow ends with impact evaluation which consist of the policy implementation. (Page 7)

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