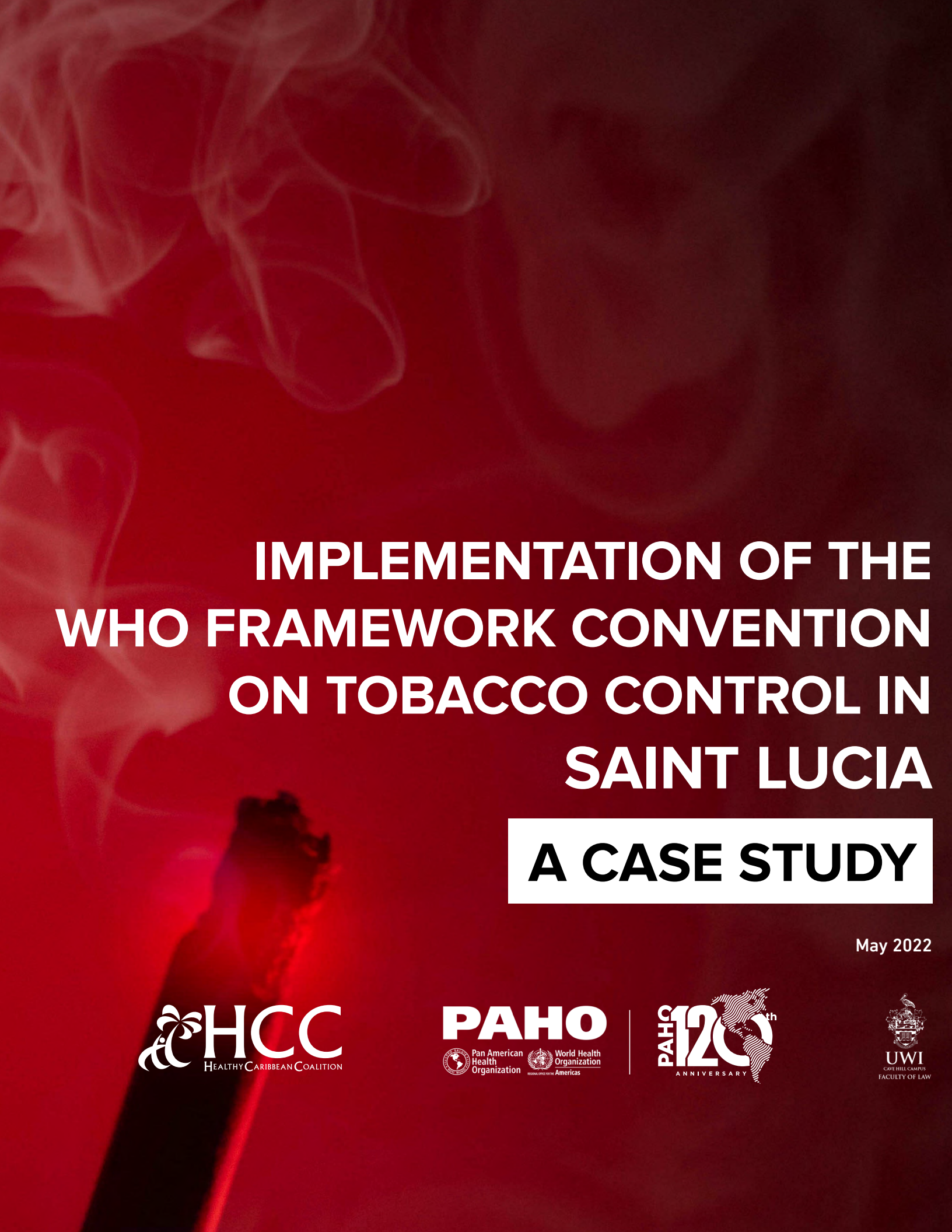


IMPLEMENTATION OF THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL IN SAINT LUCIA

A CASE STUDY

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List of abbreviations

Bureau	Saint Lucia Bureau of Standards
ECS	Eastern Caribbean States
FCTC	WHO Framework Convention on Tobacco Control
GATS	Global Adult Tobacco Survey
GSHS	Global School-based Student Health Survey
GYTS	Global Youth Tobacco Survey
NCDs	Noncommunicable diseases
PAHO	Pan American Health Organization
SDG	Sustainable Development Goals
SAACS	Substance Abuse Advisory Council Secretariat
STEPS	STEPS - STEPwise Approach to NCD Risk Factor Surveillance
UN	United Nations
WHO	World Health Organization



Executive Summary

Tobacco consumption and exposure is a serious global public health challenge. Although implementation of the World Health Organization Framework Convention on Tobacco Control (FCTC) can make an important contribution to countries' tobacco control efforts, there has not been uniform FCTC implementation globally, even though its commitments are time-bound. The Caribbean region is one of those where the pace of FCTC implementation is far slower than desired or required. This continues to be the case notwithstanding strong regional mandates from both CARICOM Heads of Government and CARICOM Health Ministers in the area.

As part of efforts to accelerate the Americas' tobacco control response, the Pan American Organization's (PAHO) Plan of Action and Strategy to Strengthen Tobacco Control in the Region of the Americas 2018 - 2022 identified implementation of smoke-free environments and adoption of effective measures on tobacco labelling and packaging as one of its strategic lines of action. To date, only 7 of the 14 CARICOM PAHO Member States that ratified the FCTC have smoke-free environments and strong health warnings on tobacco product packaging. Saint Lucia is one such country, having implemented graphic health warnings in 2017, followed by smoke-free environments in 2020.

This report is one of two case studies commissioned by PAHO to document the Caribbean region's experience with implementation of tobacco legislation such as smoke-free environments and graphic health warnings. The lessons learnt from Saint Lucia provide useful guidance to other CARICOM states who have not implemented smoke-free environments and/or graphic health warnings as yet and can act as a roadmap for accelerating their response. Saint Lucia's experience also provides a useful contrast to that of Antigua & Barbuda, the subject of the other case study, offering CARICOM Member States an alternate route to implementation. CARICOM Member states are encouraged to make full use of these case studies and create momentum for broader, accelerated implementation of their FCTC obligations. This can in turn make an important and meaningful contribution to CARICOM Member States' overall NCD prevention and control strategies and their efforts to achieve the Sustainable Development Goals.

About this case study

Objectives

This case study is intended to provide information to CARICOM policy makers and public health advocates on Saint Lucia's experience to date with implementation of its obligations under the WHO Framework Convention on Tobacco Control (FCTC) with special reference to Article 11 (graphic health warnings), and Article 8 (smoke-free environments). It is hoped that this experience will provide useful insights and guidance on how to accelerate FCTC implementation in the Caribbean sub-region, especially for those CARICOM States who are yet to advance their FCTC implementation. Saint Lucia's decision to use the approach of incremental FCTC implementation in the short to medium term, while working in parallel on a comprehensive tobacco control Act in the longer term, presents an interesting contrast to countries such as Antigua and Barbuda and Guyana which opted to enact a single, comprehensive tobacco control Act. It is hoped that this case study will also contribute to better public understanding and appreciation of Commonwealth Caribbean legislative processes thereby helping local public health advocates, as well as regional and international partners, to better identify potential useful points of entry and principal actors within these processes.

Methods and Materials

Research for this case study was conducted using systematic Internet searches complemented by semi-structured interviews with key stakeholders. The relevant legislation and related background information were sourced from the Saint Lucia Government websites while technical reports and data on the nature and extent of the tobacco epidemic in the Americas were sourced primarily from the PAHO and WHO websites and related databases complemented by information from other reputable public health organisations such as the US Centers for Disease Control and Prevention and the US National Cancer Institute. Broader grey literature and some peer reviewed articles were also reviewed to gather additional insights into country implementation experiences and processes. Peer-reviewed literature was identified using PubMed Central (U.S. National Library of Medicine, Bethesda, Maryland, United States), Science Direct (Elsevier, New York, New York, United States), and the *Revista Panamericana de Salud Pública*. Grey literature was identified by searching targeted websites of WHO, PAHO, the World Bank, the FCTC Secretariat, Campaign for Tobacco Free Kids and the Caribbean Public Health Agency.

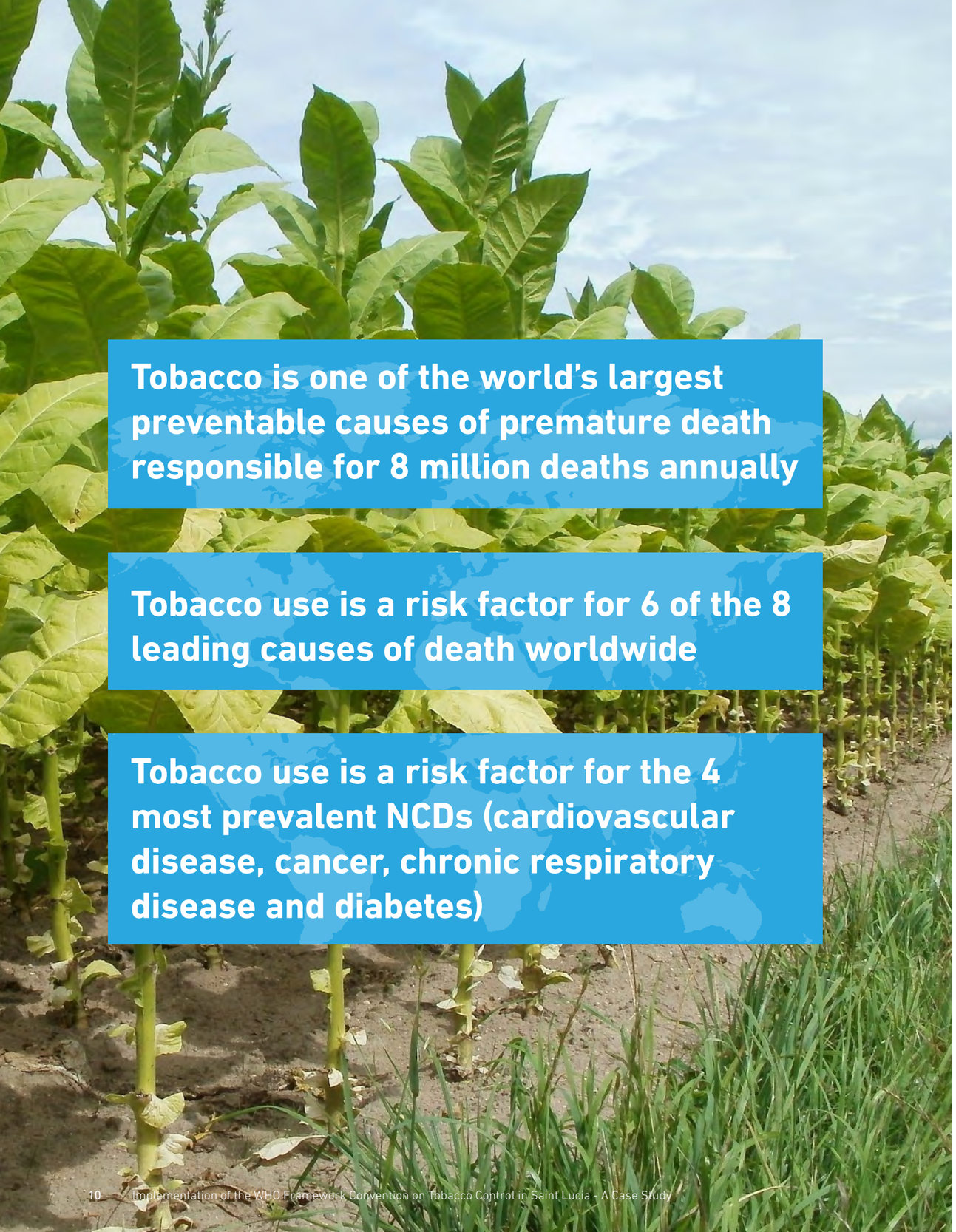
All searches were conducted during the period of September - October 2021 and included the following search terms: 'tobacco consumption and exposure in the Americas' 'tobacco consumption and exposure in the Caribbean', 'second hand smoke exposure in the Caribbean', 'tobacco control measures in the Caribbean', 'smoke-free environments', 'tobacco control best practices', 'CARICOM states and FCTC', 'implementation of FCTC Article 8', 'tobacco control legislative guide', 'tobacco control model legislation', 'the policy process', 'policy development in the Caribbean', 'Caribbean legislative process'.

The semi-structured interviews which complemented the Internet searches were conducted during the period of October/ November 2021 and were based on an interview guide, a copy of which is attached in Appendix I. These interviews were intended to gain deeper, first-hand understanding of the process for implementation of smoke-free environments in Saint Lucia from the stakeholders 'on the ground'. Interviewees were selected based on their involvement in the process of implementation of smoke-free environments and graphic health warnings in Saint Lucia. Follow up interviews were also conducted as needed during the drafting of the case study. A list of the interviewees, who were drawn from the Ministry of Health and Wellness, the (former) Saint Lucia NCD Commission, the Saint Lucia Bureau of Standards and the Saint Lucia Attorney General's Chambers, is set out in Appendix 2.

Limitations

The major limitation of this case study was the inability to reach and/or interview all of the key stakeholders in the process due to their unavailability and/or time constraints. Another limitation was the lack of availability of some pieces of Saint Lucia's standards legislation and some of the details on the country's parliamentary procedures relating to smoke-free environments.





Introduction

The Tobacco Epidemic in the Americas/Caribbean Sub-region

The tobacco epidemic has been described as "one of the biggest public health threats the world has ever faced".[1] Tobacco is one of the world's largest preventable causes of premature death and is responsible for 8 million deaths annually. Tobacco use is a risk factor for 6 of the 8 leading causes of death worldwide as well as for the 4 most prevalent chronic noncommunicable diseases (NCDs) cardiovascular disease, cancer, chronic respiratory disease and diabetes).[2]

Although recent years have seen important progress in global tobacco control such as the number of tobacco users declining despite population growth for the first time in 2018, the fact remains that "the tobacco epidemic is far from over. Progress reducing tobacco use everywhere in the world is uneven and some groups are getting left behind".[3] In fact, the world currently is not on track to achieve the target of 'a global 30% relative reduction in current tobacco use by 2025' set in the WHO Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013 - 2020.[3]

2005 was a landmark year for tobacco control as it was the year in which the historic WHO Framework Convention on Tobacco Control (FCTC) came into force. The FCTC obligates state parties to implement comprehensive tobacco control measures from both a demand and a supply perspective. Article 8 of the FCTC requires State Parties to provide effective protection from public and workplace exposure to tobacco smoke. Bearing in mind that there is no safe level of exposure to second-hand smoke, the FCTC Implementation Guidelines clarify that this Article 8 obligation requires 'the total elimination of smoking and tobacco smoke in a particular space or environment in order to create a 100% smoke free environment'.[4] Article 11 of the FCTC further requires State Parties to include graphic health warnings on the labelling and packaging of tobacco products with these warnings occupying a set minimum percentage of the package. In 2008, in an effort to promote effective country-level FCTC implementation, WHO launched the MPOWER initiative which includes implementation of 100% smoke-free environments under the banner 'P-rotect people from tobacco smoke' and graphic health warnings under the banner 'W-arning about the dangers of tobacco'.[5]

The Americas, including the Caribbean sub-region, is one region where tobacco consumption and exposure remains a serious regional public health threat. In the Americas mortality attributed specifically to tobacco is 16%,[6] and current tobacco consumption and exposure trends among the youth in the Caribbean sub-region are deeply concerning. The Caribbean has some of the highest levels of experimentation with cigarette smoking before age 10 in the Americas[6] and the second highest prevalence of current tobacco use among 13 - 15-year-olds in the Americas (21.3% vs regional

[1] WHO Tobacco Fact Sheet: https://www.who.int/news-room/fact-sheets/detail/tobacco

[2] WHO, 10 Facts on the Global Tobacco Epidemic; World Health Organization. WHO report on the global tobacco epidemic, 2008 - The MPOWER package. Geneva: World Health Organization; 2008.

[3] Foreword, WHO global report on trends in prevalence of tobacco use 2000 – 2025, third edition. Geneva: World Health Organization; 2019. In May 2021 the 74th World Health Assembly (WHA) instructed WHO to prepare an updated implementation roadmap for 2023 – 2030 in support of NCD prevention and control. This new roadmap will include updated actions for achievement of SDG Target 3.4, including action relating to reduction of tobacco use and will be submitted to the 75th WHA for consideration in May 2022.

[4] FCTC Article 8 Implementation Guidelines, Principle 1 (2011).

[5] World Health Organization. (2008). MPOWER: a policy package to reverse the tobacco epidemic. World Health Organization. Available at: https://apps.who.int/iris/handle/10665/43888

[6] Pan American Health Organization. Report on Tobacco Control in the Region of the Americas, 2018. Washington, D.C.: PAHO; 2018

estimate of 13.5%).[7] The use of e-cigarettes is also rising among Caribbean youth between 13 – 15 years with Antigua and Barbuda, Saint Lucia and Trinidad and Tobago all having prevalence rates for current use that surpassed that of conventional cigarettes.[6] Caribbean youth exposure to second-hand smoke is yet another growing area of concern. For example, in Saint Lucia's 2017 Global Tobacco Youth Survey, 26.8% of the 13 – 15-year-olds surveyed reported exposure to second-hand smoke at home and 42.7% reported exposure to second-hand smoke in public places.[8] These developments are particularly worrying given that the US Surgeon General has described nicotine as "brain poison for youth".[9] Specifically, nicotine exposure during adolescence can negatively affect learning, memory and attention.[9] Other health effects of nicotine exposure include addiction to nicotine, reduced lung function, reduced lung growth and early cardiovascular damage.[10] Adolescent smokeless tobacco users are more likely than non-users to become cigarette smokers[11] and nicotine use during adolescence can also act as a 'gateway' to other addictive drugs.[9]

Besides being a serious public health problem, tobacco control is also a sustainable development and human rights issue. The adverse health effects associated with tobacco consumption and exposure affect the quality of life of individuals and their families which in turn affects their ability to reach their full potential. The tobacco health and environmental burden also adversely affects countries' ability to grow and develop sustainably. Moreover, the socio-economic burdens associated with tobacco consumption and exposure are experienced disproportionately by low and middle-income countries and by those within these countries who are the most vulnerable.[12]

The connection between tobacco control and sustainable development is reflected in the fact that tobacco control is included among the targets for fulfilment of Sustainable Development Goal (SDG) 3 (health and wellness) and is linked to fulfilment of several other SDGs such as SDG 1 (end poverty), SDG 5 (gender equality) and SDG 10 (reduce inequality). From a human-rights specific perspective, tobacco consumption, exposure and production undermine the fulfilment of a range of rights, including the right to life, health, a healthy environment and children's right to development, survival and education. In fact, the Committee on the Rights of the Child's General Comment 15 on the right to health under the UN Convention on the Rights of the Child specifically mentions States' obligation to protect children from tobacco and the need for them to regulate advertising and sale of substances such as tobacco which are harmful to children's health.[13] Similarly, the Committee on Economic, Social and Cultural Rights' General Comment 14 on the right to health under the International Covenant on Economic, Social and Cultural Rights identifies states' "failure to discourage production, marketing and consumption of tobacco" as a violation of their obligation to protect the right to health.[14]

[7] Report on Tobacco Control for the Region of the Americas. WHO Framework Convention on Tobacco Control: 10 Years Later. Washington, DC: PAHO, 2016

[8] Global Tobacco Youth Survey 2017–Saint Lucia. Available at: https://extranet.who.int/ncdsmicrodata/index.php/catalog/475/related_materials

[9] Surgeon General's Advisory on E-cigarette Use Among Youth (2018)

[10] Smoking and Youth – CDC https://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/pdfs/fs_smoking_youth_508.pdf

[11] Preventing Tobacco Use Among Young People: A Report of the Surgeon General (1994)

[12] U.S. National Cancer Institute and World Health Organization. The Economics of Tobacco and Tobacco Control. National Cancer Institute Tobacco Control Monograph 21. NIH Publication No. 16-CA-8029A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; and Geneva, CH: World Health Organization; 2016

[13] UN Committee on the Rights of the Child (CRC), General comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health (art. 24), 17 April 2013, CRC/C/GC/15, para 65.

[14] UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant), 11 August 2000, E/C.12/2000/4 para 51. All CARICOM States have ratified the Convention on the Rights of the Child and Saint Lucia and St Kitts & Nevis are the only two CARICOM States that have not ratified the International Covenant on Economic, Social and Cultural Rights.

FCTC Articles 8 & 11 Implementation Status Quo in the Caribbean Sub-region

Currently of the 14 CARICOM States who are FCTC State Parties, only 7 (Antigua and Barbuda, Barbados, Guyana, Jamaica, Saint Lucia, Suriname and Trinidad & Tobago) have 100% smoke-free environments legislation.[15] This is particularly troubling, bearing in mind the existence of strong regional and sub-regional mandates on the issue such as the CARICOM Heads of Government July 2016 & 2018 Communiques and the PAHO Strategy and Plan of Action to Strengthen Tobacco Control in the Region of the Americas 2018 – 2022 (and related CARICOM Health Ministers Committment to a 100% smoke-free Caribbean by 2022) as well as the fact that the 3 year implementation period for FCTC Article 8 has long passed.

Different approaches have been adopted by those CARICOM States which do have smoke-free environments legislation with some such as Antigua and Barbuda and Guyana going the route of enacting a comprehensive tobacco control Act which includes smoke-free environments among its provisions. Others such as Barbados and Jamaica have opted for for smoke-free environments specific amendments to their Public Health Acts.[16] Saint Lucia, the most recent state to pass legislation on smoke-free environments, followed the latter approach of enacting amendments to its Public Health Act specific to 100% smoke-free environments.[17] Countries report lengthy processes spanning over 8 -12 years from ratification of the WHO FCTC to enactment of their current tobacco control laws and regulations. For Saint Lucia, this timeframe was approximately 15 years from ratification to passage of the relevant legislation.

There is a similar weak implementation picture in terms of graphic health warnings: of the 14 CARICOM States who are FCTC State Parties, only 5 (Barbados, Guyana, Jamaica, Saint Lucia and Trinidad and Tobago) have legislation with health warnings at the highest level of achievement. This is particularly disappointing since MPOWER 'W' measures, of all the MPOWER measures, are those that have seen the most progress globally since 2007 both in terms of countries acting and population covered by a best-practice policy.[18] There is therefore a compelling case to be made for urgent acceleration of tobacco control efforts within the region.

The Role of International Treaties within the Caribbean Domestic Sphere

Bearing in mind that the FCTC is an international treaty, it is useful to explain how treaties operate at the domestic level in the Commonwealth Caribbean. Saint Lucia, like the other members of the English-speaking Caribbean, follows a dualist tradition. As such, treaties are seen as part of a separate legal sphere, unconnected to the domestic legal sphere. Accordingly, the provisions of any treaty, including the FCTC, will not have the force of law in Saint Lucia until the treaty is 'transformed' into domestic law through a domestic legislative process. The principal justification for this approach is found in section 40 of Saint Lucia's Constitution which reserves to Parliament the exclusive power to 'make laws for the peace, order and good government of Saint Lucia'. Accordingly, although the FCTC became fully legally binding on Saint Lucia, *as a matter of international law*, from the date of its ratification on November 7, 2005, its provisions can only be enforced domestically within Saint Lucia following the passage of implementing legislation, in this case, the Saint Lucia Public Health (Smoking Control) Regulations, 2020.

[15] Noncommunicable diseases progress monitor 2020. Geneva: World Health Organization; 2020. Saint Lucia Public Health (Amendment Act 2019) (Act No. 19 of 2019). Saint Lucia Public Health (Smoking Control) Regulations 2020 (S.I No. 81 of 2020).

[16] Jamaica is currently well advanced in the process of implementing comprehensive tobacco control legislation. The draft Bill is currently before Parliament for deliberation.

[17] Saint Lucia Public Health (Amendment) Act 2019 and its accompanying Public Health (Smoking Control) Regulations 2020, S.I. No. 81 of 2020.

[18] WHO report on the global tobacco epidemic 2021: addressing new and emerging products. Geneva: World Health Organization; 2021

Implementing Graphic Health Warnings (FCTC Article 11) in Saint Lucia: Building From Regional Consensus

Implementing Graphic Health Warnings (FCTC Article 11) in Saint Lucia: Building From Regional Consensus

The Standards Act 1990 (No 14 of 1990), vests the Saint Lucia Bureau of Standards with the responsibility for developing and promoting standards and codes of practice for products and services for, *inter alia*, the protection of the health and safety of consumers and the environment. As such, although tobacco control is a public health matter, the implementation of FCTC Article 11 in Saint Lucia was the responsibility of the Saint Lucia Bureau of Standards ('the Bureau'), rather than the Ministry of Health and Wellness. Saint Lucia had a pre-existing mandatory standard in place for cigarettes labelling, 'Labelling of Retail Packages of Cigarettes' SLNS 27: 1992, but, rather than updating this standard on its own, Saint Lucia decided to contribute towards the creation of a regional tobacco labelling specification and then use that regional specification to update their pre-existing national standard. The decision to go the regional route first was influenced by the following considerations: a desire to maximise use of limited resources and avoid duplicating efforts as well as recognition that a regional standard made more sense from a trade perspective as it would have greater outreach and impact. On the other hand, the drawback of this decision is that the standard development process would necessarily take longer.

Work on development of a regional standard for labelling of tobacco products began in 2007 within the CARICOM Regional Organisation for Standards and Quality (CROSQ), CARICOM's standards development body. Once the CARICOM Regional Standard CRS 26:2013 Labelling of Tobacco Products was approved on December 11, 2012 at the 35th Meeting of CARICOM's Council for Trade and Economic Development, Saint Lucia began the work of translating this specification into a mandatory national standard.[19] As with all Saint Lucia national standards, this process was governed by the Standards Act 1990 and the Standards Regulations 2000 (S.I. No 10 of 2000) and began with wide-ranging consensus-building public consultations. These consultations took the form of in-person meetings hosted by the Bureau with stakeholders such as Ministry of Health and Wellness, regulators, consumers groups and civil society actors. Within the Bureau itself, the process of revision of SLNS27:1992 was overseen by the Bureau's Tobacco Subcommittee which was composed of the following interest groups: National Consumers Association, Saint Lucia Distillery, the Attorney-General's Chambers, the Saint Lucia Cancer Society, the Substance Abuse Advisory Council Secretariat (SAACS) of the Ministry of Health and Wellness, the Sir Arthur Lewis Community College, the Customs Department and the Saint Lucia Industrial and Small Business Association together with Bureau representatives. These consultations took place over a number of years in order to reach consensus (i.e. an absence of sustained opposition), which is one of the established goals of standards development.

Following the national consultations and disposal of all comments received, a few adjustments were made to the regional specification to bring it in line with Saint Lucia's specific local circumstances e.g. requiring that the labels had to be in English only and fine tuning the rotation of the labels to facilitate effective monitoring. The Bureau's Standards Council ultimately approved the revision of SLN27:1992 on March 4, 2016 and the Notice informing of the adoption of SLNS 27:16 as a Saint Lucia National Standard maintaining its mandatory status[20] (and the withdrawal of SLNS 27:1992) was gazetted on April 14, 2016.[21]

Saint Lucia's revised national standard SLNS 27:16 was implemented from August 16, 2017 with 90 days advance notice being given of this implementation date. During this period, the Bureau continued its outreach with various stakeholders to ensure the new standard was understood and could be effectively implemented. Initially, consignments containing tobacco products with a Bill of Lading dated prior to the August 16, 2017 implementation date were assessed based on the old standard SLNS 27: 1992. However, this allowance generated some problems for the Bureau as some dealers stocked up on tobacco products immediately prior to the end of the 90-day grace period which meant that there were large amounts of improperly labelled products in the market. Accordingly, after 2 years the Bureau decided to completely stop allowing the sale of any tobacco product not complying with the standard period regardless of the date of the Bill of Lading for the consignment.

To date, the Bureau has not experienced any problems with compliance with SLNS 27: 2016, even among those who initially asked for additional time before the new standard was implemented. Recently, they did receive some requests for delayed rotation of the various pictorial sets from some dealers due to the impact of COVID-19 which resulted in slower than usual trade. These persons wanted to be granted a grace period to try to deplete their stock of product with Set A pictorial warnings, before having to switch over to Set B pictorial warnings. However, these requests were refused since the standard is clear about the length of time that a particular set of pictorial warnings can be on the market.

[19] Section 18 of the Standards Act 1990 (No 14 of 1990) permits the adoption of specifications developed outside of Saint Lucia as a Saint Lucia national standard.

[20] The Standards Act 1990 (No 14 of 1990) vests the Minister of Commerce with the authority to declare a standard as a mandatory standard. Typically, this decision is based on an impact assessment which is used to determine what is in the country's best interests.

[21] The Standards Order 2000 (No. 230 of 2000) was amended to include SLNS 27:16 in the schedule of mandatory standards under the Act by the Standards (Amendment) (No.1) Order, 2018 (S.I No 91 of 2018) which was gazetted on October 29, 2018.

Overview of the Saint Lucia Standard SLNS 27: 2016

Key Elements

This new standard includes not just cigarettes, but also all tobacco products intended for retail in Saint Lucia. It also introduces requirements regarding health warning declarations and the display of pictorial warnings including how they should be displayed. The stated aim of the standard is to prevent fraud and/or deception arising from misleading labelling of individual packages of tobacco products intended for retail sale in Saint Lucia.

Scope
The revised standard applies to the labelling of individual packages and cartons of all tobacco products intended for sale in Saint Lucia i.e. extends to products such as cigarettes, cigars, e-cigarettes, smokeless tobacco etc. The standard does not apply to labelling of cases of such individual packages or cartons, irrespective of sizes, provided the cases are not displayed or used at the point of sale.

Select definitions
'*cigar*': any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco excluding items defined under sub-clause 2.6 (re cigarettes).

'*cigarette*': any roll of tobacco that is wrapped in paper or in any substance not containing tobacco or any roll of tobacco wrapped in any substance containing tobacco, which because of its appearance, the type of tobacco used in the filler, or, its packaging and labelling, is likely to be offered to, or purchased by, consumers as a cigarette described in Clause 1. Cigarettes specifically include products such as 'bidis', 'kretek' and products of a similar nature.

'*tobacco product*': product entirely or partly made of the leaf tobacco as a raw material which is manufactured to be used for smoking, sucking, chewing or snuffing.

General requirements
The standard applies to all manufacturers, importers, distributors, retailers and other entities.

Every package and carton of tobacco products intended for retail sale in Saint Lucia must bear labels which have, inter alia, a health warning in the prescribed form.

All point of sale materials and displays shall carry the prescribed health warning as set out in the standard.

Detailed requirements – Health warnings
The new health warnings consist of 16 high-definition graphic messages covering 50 percent of the top "front package" (principal display) and "back of package" surface.

The health warnings are in the form of text and pictures. The inclusion of pictures enhances the effectiveness of the health warnings and ensures that they reach those who cannot read.

The health warnings highlight various aspects of tobacco's adverse health and socio-economic effects and provide advice on cessation.

The standard requires that the health warnings be rotated with each form of packaging being assigned two sets of warnings (Set A and Set B) which are used exclusively for 8 months followed by a 4-month transition period where the first set is withdrawn and the second set is introduced. After the four months transition period, the second set is used exclusively for 8 calendar months. (This rotation is intended to maintain the impact of the messaging over time).

Health warnings are to be displayed on both the front and the back of the package and are not to be obscured in any way. These health warnings are to be clearly visible at point of sale displays of tobacco products.

There are to be no statements relating to smoking and or health other than the required health warnings on any package of tobacco products. The only exception is where the company wishes to advise the public of newly discovered health risks attributable to or associated with tobacco products; any such statement would need the approval of the Bureau.

The text of the health warning of products sold shall be in the English language and shall be printed on the package itself, and not on the cellophane or detachable outer packaging, or by adhesive labels or similar means.

The complete health warning and only the health warning is to occupy at least 50% of the front and back of the package.

The health warning shall not be permanently damaged when the package is opened.

The health warnings are to be subdivided into two distinct sets, Set A and Set B, and shall be used alternatively in rotation. No set of warnings shall be utilized in the market for more than 16 months.

A declaration stating "Smoke from this product contains extremely addictive nicotine and toxic substances such as tar and carbon monoxide. No safe level of consumption exists for this product" shall be printed on each package and carton of tobacco products.

For packages of cigars and smokeless tobacco, the health warning and the declaration may be affixed as stickers, provided that the stickers cannot be removed and are indelible.

Deceptive Labelling
No package or carton of tobacco products shall promote a tobacco product by any means that is false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates a false impression for any reason.

No package or carton of tobacco products shall depict: the terms light, mild, low tar, ultra, extra, slim, or similar terms, in any language; and a number to differentiate brands within a brand family or a number associated with a smoking machine yield, including use of such a number in a brand name.

Responsibility for labelling
Compliance with these labelling requirements is the responsibility of any person who sells or distributes tobacco products.

Approval of labels
All new and revised labels must be submitted for approval to the Saint Lucia Bureau of Standards or competent authority at the design stage.

Monitoring / Compliance
Monitoring and enforcement of SLNS27: 2016 is done through the Bureau's border control and market surveillance programs, in cooperation with the Customs and Excise Department. The Bureau has access to the Customs and Excise Department database (ASYCUDA World) and when consignment documents are submitted in ASYCUDA World, it identifies consignments with HS Codes of commodities that are to be reviewed and sends these consignments into the Bureau's red lane. Once a consignment is in the Bureau's red lane, it cannot be electronically released by Customs until the consignment is re-routed to the Bureau's green lane by Bureau officers. Typically the Bureau's Compliance Department would re-route a consignment after the importer or importer's agent makes arrangements for inspection.

Elements Impacting the Graphic Health Warnings Process

The process leading to implementation of FCTC Article 11 in Saint Lucia was influenced by a number of drivers and barriers that affected the content of SLNS 27: 2016 and the time it took to be approved and implemented as a mandatory national standard. Understanding some of the drivers and barriers experienced within Saint Lucia can offer useful guidance to those about to embark on this implementation journey.

Drivers

Political will
Interviewees highlighted the importance of political will if there is to be successful implementation of any legislative measures. As one interviewee put it, 'it was the right time for this action'. They noted that the work on graphic health warnings went through several different administrations but throughout, once the evidence as presented, the Bureau (and Ministry of Health and Wellness) got the necessary political support to proceed with the new standard.

Well-established procedures and institutional support
The Bureau stressed that the key to their success in terms of securing approval and implementation of the new standard was 'doing it by the books'. Since there was already a well-established and developed standards system in Saint Lucia pre-dating the work on graphic health warnings, it meant that there were clear procedures and guidance on how to undertake revision of the SLNS 27:1992. Ensuring compliance with these procedures, provided valuable protection from any challenges that opponents of the new standard might wish to raise. Benefits were also realised in terms of actual implementation and enforcement of the new standard as the Bureau already had a rigorous, well-functioning market surveillance programme in place where inspectors go out to retail outlets and examine labels etc as well as a pre-existing imports monitoring programme. This meant that effective monitoring and enforcement of SLNS 27: 2016 only required a slight modification of these existing programmes to include tobacco products. The process of effective implementation was also facilitated by the fact that the Bureau has a voluntary programme for label assessment in operation where dealers submit their labels to the Bureau in advance for feedback on the labels' compliance with the standard's requirements.

Pre-existing regional work / experience
Although going the regional route initially meant an extension of the period over which work on the new standard would take place, once the regional standard was agreed, it meant that much of the technical work and analysis on graphic health warnings was done and could simply be transferred to the national discussions. In addition, the high-resolution labels were accessible from CROSQ (rather than the individual country having to design them).

Industry competition
There are 3 main tobacco industry players in Saint Lucia who compete against each other. As such, different players may draw issues with a competitor's actions to the Bureau's attention for investigation and enforcement if necessary.

Barriers

Industry interference
Not surprisingly, industry interference was the principal challenge faced in trying to implement FCTC Article 11. This interference took different forms such as:

i. Delay tactics

   For example, in 2017 when the Bureau gave 90-day notice for implementation of the SLNS 27:2016, the tobacco industry players tried to argue for a grace period of perhaps another year to allow them to get the new labels organized. This was after they had already been engaged in the process for almost 7 years and had not indicated an objection to the implementation timeline when first proposed.

ii. Intimidation strategies

   Every time the Bureau's Tobacco Subcommittee met, the tobacco industry players flew in representatives from all over the world to attend. They also submitted copious comments throughout the consultations phase, some of which duplicated previous submissions, but still needed to be disposed of before the process could proceed.

iii. Lobbying politicians

   The industry leveraged their political access to reach politiicians and influence decision making in their favour. Demonstrating that the Bureaus's actions were required under the legislation and that there had been substantive consultation and due process were key in responding to concerns that were raised by politicians following on from tobacco industry lobbying.

The Bureau was able to counter this interference principally by carefully following the processes set out for standards development within Saint Lucia as well as ensuring consistent, accurate recording of the deliberations that took place between 2012 and 2017 when SLNS 27:2016 was implemented. This ensured that there was no room for anyone, particularly industry, to successfully challenge the new standard, how it had been arrived at and/or its implementation plan.

Implementing Smoke-Free Environments (FCTC Article 8) in Saint Lucia: The Subsidiary Legislation Route

Implementing smoke-free environments in Saint Lucia involved passage of new public health regulations and therefore fell under the responsibility of the Ministry of Health and Wellness. Specifically, FCTC Article 8 implementation involved amendment of Saint Lucia's Public Health Act Cap. 11.01 through the Public Health (Amendment) Act, 2019 (No. 19 of 2019) which includes a provision empowering the Minister of Health and Wellness to make regulations on smoke-free environments; and enactment of the Public Health (Smoking Control) Regulations, 2020. This legislative process took approximately 5 years to complete but that time frame is significantly shorter than if Saint Lucia had gone the route of single, comprehensive legislation (since that would have involved multiple additional areas).

It also involved going through the legislative procedures for both Acts (principal legislation) as well as for statutory instruments (subsidiary legislation). Smoke-free environments was just one of several amendments that were piloted by the former Saint Lucia Chief Medical Officer and included in the Public Health (Amendment) Act 2019. The key players in the process of the passage of smoke-free environments legislation were the Ministry of Health and Wellness, the Tobacco Control Working Group of the Saint Lucia NCD Commission (now defunct) and the Attorney-General's Chambers. **Figure 1** below summarises the key steps in the legislative processes and is followed by a brief description of these stages which in practice overlap and intersect.

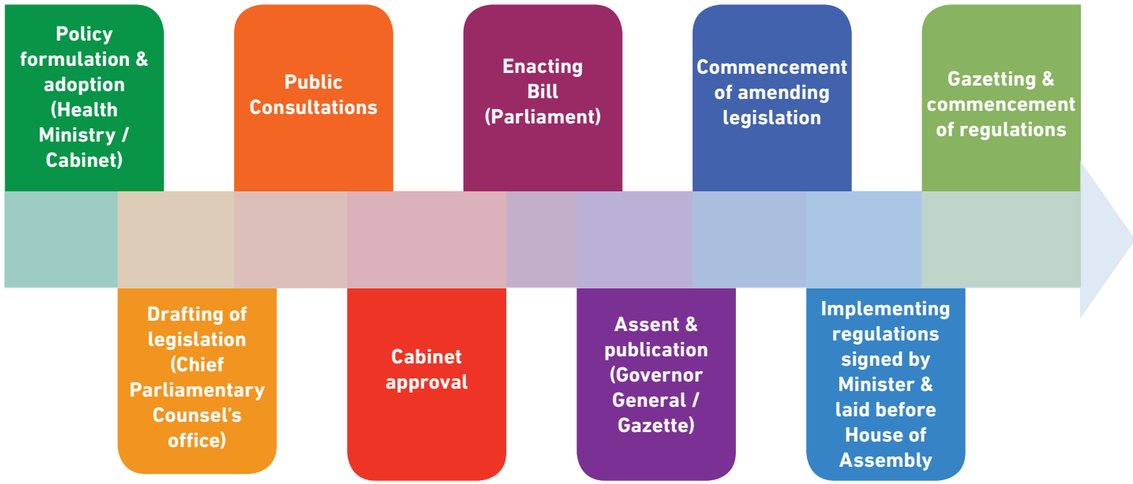


Figure 1: The Legislative Process

Policymaking:
Work on smoke-free environments started in 2015 with the drafting of a policy by the Ministry of Health and Wellness. The drafting of this policy was triggered by national and international considerations (high NCD prevalence rate, high level of youth exposure to second-hand smoke and Saint Lucia's FCTC obligations). As mentioned above, among the range of FCTC obligations, the Ministry of Health and Wellness felt that it was best to 'fast track' smoke-free environments since this was 'low hanging fruit'. This policy development work initially involved, *inter alia*, desk study and research building on data derived from national surveillance systems such as their WHO STEPwise Approach to NCD Risk Factor Surveillance (STEPS) reports and related policy documents such as the national NCD Prevention and Control policy. It also involved consultations with relevant stakeholders, governmental and non-governmental, who were going to be directly affected by the policy or have a role to play in implementation/enforcement of the resulting legislation e.g. the hotel sector, the Saint Lucia Cancer Society, Ministry of Education, the Royal Saint Lucia Police Force, as well as interested members of the public.

The Tobacco Control Working Group of the now defunct Saint Lucia NCD Commission (which was co-chaired by the NCD Commission Chair and the Deputy Director, SAACS/Tobacco Control Focal Point, Ministry of Health and Wellness) played a key role in driving this entire process. Once the smoke-free environments policy was completed, the Ministry of Health and Wellness prepared the relevant Cabinet paper submitting the policy to Cabinet for approval. Cabinet then approved the policy, clearing the way for instructions to be issued to the Chief Parliamentary Counsel to start the process of drafting the relevant legislation.

Drafting & Public Consultation:
The work on drafting of the amendments to the Public Health Act Cap. 11.01 together with the relevant implementing regulations was done by the Chief Parliamentary Counsel's Office, Attorney-General's Chambers based on instructions from the Ministry of Health and Wellness. The draft legislation was discussed extensively within the Tobacco Control Working Group and revised as needed by the Drafting Section. Once the draft legislation was finalised, public consultations were conducted on it. This process was led by SAACS of the Ministry of Health and Wellness. Next the final draft legislation in the form of the Public Health (Amendment) Bill 2019 and the draft Public Health (Smoking Control) Regulations were certified by the Attorney-General as being fit for submission to Cabinet and then approved by Cabinet.

Enacting the Bill:
Following Cabinet approval, the Public Health (Amendment) Bill 2019 was introduced into the House of Assembly for 3 readings. The Bill went through all its stages and was approved by the House of Assembly on June 11, 2019. This process was then repeated in the Senate on June 13, 2019. At this point, the Bill became an Act of Parliament, the Public Health (Amendment) Act 2019.

Assent and Publication:
The Governor General assented to the Public Health (Amendment) Act 2019 on July 2, 2019. It was then published in the Gazette.

Commencement:
The Public Health (Amendment) Act 2019 came into effect on July 3, 2019, the commencement date specified in the legislation. With its coming into effect, the next step was for the Government to implement the Act.

Implementation/Monitoring / Enforcement:
Implementation of section 9 of the Public Health (Amendment) Act, 2019 dealing with smoke-free environments required enactment of the Public Health (Smoking Control) Regulations 2020. The draft regulations received Cabinet approval and were signed by the Minister of Health on February 7, 2020. Since regulations under the Public Health Act Cap 11.02 are subject to a negative resolution of the House of Assembly, after being signed by the Minister of Health and Wellness, the regulations were then laid before Parliament to permit the House of Assembly to annul the regulations if desired, which was not the case. The Public Health (Smoking Control) Regulations 2020 were therefore gazetted on June 2, 2020 and took effect from that date. Persons were granted a 6-month grace period to comply with the Regulations.[22]

SAACS of the Ministry of Health and Wellness has responsibility for monitoring and evaluation of implementation of the smoke-free environments legislation. This plan is currently very general, but the Secretariat intends to refine and update it as implementation of the legislation progresses. Compliance and enforcement matters are the responsibility of the Environmental Health Unit (as is the case with all enforcement of all public health regulations) with assistance, as needed, from the Royal Saint Lucia Police Force. Unfortunately, the Environmental Health Unit has not been able to fully engage on this matter since they are currently overwhelmed, especially with COVID-19 related matters. The Environmental Health Unit has, however, completed the first step of getting their staff trained on the legislation's requirements but the development of the enforcement protocols for the legislation is still outstanding.

[22] Saint Lucia Public Health (Smoking Control) Regulations, 2020 s. 10.

Overview of the Public Health (Smoking Control) Regulations 2020

Key Elements

Section 2: Definitions

- "smoke": means inhaling or exhaling the emissions of tobacco, other product and substance and includes handling an ignited or heated tobacco product, other product and substance that it produces smoke or other emissions by any means, including by electronic means;
- "tobacco": includes a tobacco product;
- "tobacco product" means tobacco in any form including by electronic nicotine delivery in which it is used or consumed and includes the tobacco leaf, tobacco in cigarettes and any product entirely or partly made from the leaf of the tobacco plant as raw material and which is manufactured for use in smoking, sucking, chewing or snuffing tobacco or a by-product;
- "tobacco smoke" means the smoke or other emissions released from tobacco;
- "workplace" includes vehicles used in the course of employment or work purposes, connected, annexed places or common areas, and residences used for commercially operated child care facilities.

Section 3: Prohibition on smoking in public places

- It is an offence to smoke or hold 'a lit or electronic tobacco product' within a 10-metre radius of an enclosed public place, enclosed workplace or public conveyance including the following places:
    - a health facility;
    - a sports, athletics or other similar facility, for the public use;
    - an educational institution of all levels and a childcare institution;
    - a bus stop, public transport terminal;
    - an area specifically for use by children;
    - a beach or outdoor market (except where an outdoor smoking area has been established consistent with the Regulations' requirements);
    - a cinema, theatre, concert hall, casino or other place used for indoor public entertainment.
- Owners of bars, restaurants, clubs etc are permitted to create outdoor smoking areas in open spaces but these outdoor smoking areas must be:
    - open-sided;
    - located at least 15 metres from any structure or area where smoking is prohibited;
    - located in an area where access by persons, other than those smoking, is not necessary;
    - physically separated and structurally unconnected to, areas where smoking is prohibited;
    - inspected by an environment health officer.
- Distribution, promotion, branding or sale of tobacco products or entertainment organized by the proprietor is not permitted within an outdoor smoking area.
- Children are not permitted to enter or stay in an outdoor smoking area.
- Users of outdoor smoking areas are to be advised that staff do not serve in the area.
- Smoking is prohibited in the outdoor smoking area when it is being cleaned.

Section 4: Prominent display of no smoking signs

- 'No smoking' signs must be prominently displayed in businesses and must be at least 216 mm x 279 mm and posted at eye level.

Section 5: Prohibition of sale of tobacco products in certain places

- The sale of tobacco products within a 10-metre radius of educational facilities, health facilities, sports, athletic or other similar facilities for public use, religious institutions or Government occupied buildings is prohibited.
- A person violating this rule is liable on summary conviction to a fine not exceeding ECS$5000 (or ECS$10,000 in the case of a corporate entity).

Section 8: Protection of employees

- An employer who retaliates against an employee who testified against them in an action brought under the Regulations commits an offence.

Section 9: Penalties

- The general penalty for offences under the Regulations is in the case of an individual, on summary conviction, a fine not exceeding ECS$5000 (or ECS$10,000 in the case of a corporate entity, tourist establishment, club, bar, restaurant and other businesses other than small shop owners, itinerant vendors and pedlars).

Strengths

Broad scope based on definitions of 'tobacco product', 'smoke' 'tobacco smoke' etc.

- Even though novel and emerging nicotine products, e-cigarettes etc are not mentioned in the FCTC itself, they are now an important dimension of the tobacco epidemic and tobacco control (as the statistics re youth usage of e-cigarettes in Saint Lucia clearly demonstrate). The current definitions allow for these products to be addressed in addition to conventional tobacco products.

Comprehensive coverage of designated smoke-free locations

- There are complete indoor smoke-free environments for 8 places (health-care facilities, educational facilities other than universities; universities; government facilities; indoor offices and workplaces not considered in any other category; restaurants or facilities that serve mostly food; cafes, pubs and bars or facilities that serve most beverages and public transportation).
- The regulation also protects beaches which stands out in the Caribbean where not all of the smoke free legislation extends to beaches.
- Public transport was a major source of second-hand smoke for youth in Saint Lucia and this coverage should have a definite positive impact in this area. The legislation also restricts the sales of tobacco products within a certain perimeter of various facilities including childcare and schools.
- The legislation's overall emphasis on protection of children is a definite strength.

'Whistleblower' protection

- The protection offered to employees who testify against their employers should help persuade employees to report breaches of the regulations without fearing retaliation.

Provision for penalties

- The Regulations impose penalties on patrons and business owners thereby increasing the probability of compliance. The level of the penalties is also such as to have a deterrent effect.

Weaknesses

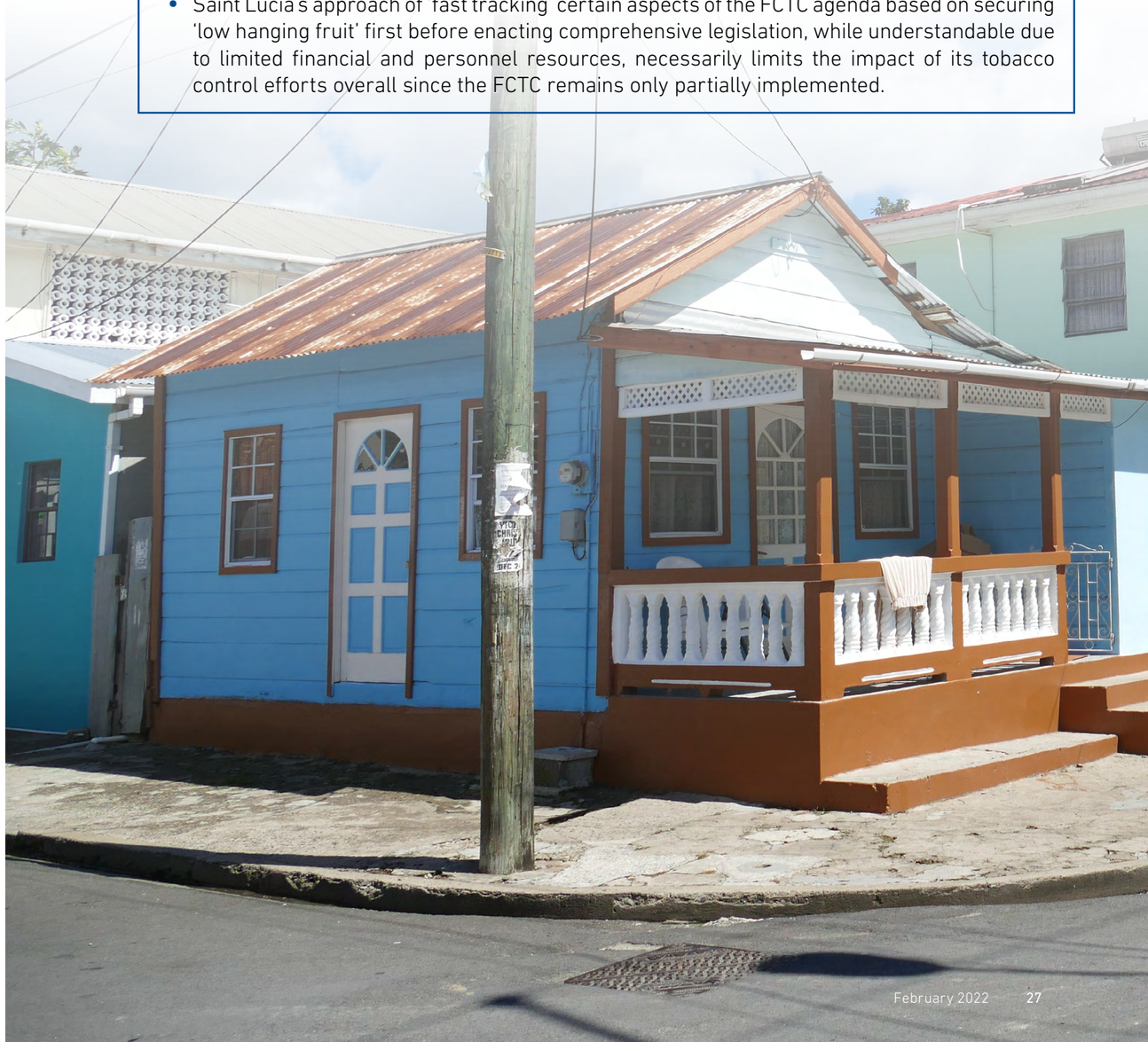
No dedicated funds and/or human resources for monitoring and enforcement

- Human and financial resource to effectively monitor and enforce the regulations (as well as continue the public education programme more generally) is a significant challenge. Monitoring and evaluation together with enforcement are key elements of successful implementation.

No provision for citizen complaints and investigations

Partial FCTC implementation

- Saint Lucia's approach of 'fast tracking' certain aspects of the FCTC agenda based on securing 'low hanging fruit' first before enacting comprehensive legislation, while understandable due to limited financial and personnel resources, necessarily limits the impact of its tobacco control efforts overall since the FCTC remains only partially implemented.



Elements Impacting the Smoke-free Environments Process

As was the case with graphic health warnings, the process leading to implementation of FCTC Article 8 in Saint Lucia was also influenced by a number of drivers and barriers that affected the content of Saint Lucia's Public Health (Smoking Control) Regulations, 2020 and the time it took to be passed and implemented. Understanding some of these drivers and barriers (in addition to offering useful guidance to those about to embark on this implementation journey), also provides a useful comparison to graphic health warnings since smoke-free environments were implemented through a different legislative process.

Drivers

Strategic, incremental strategy/approach
The interviewees generally felt that Saint Lucia had benefitted from adopting an incremental approach to FCTC implementation. One interviewee commented that the (financial and personnel) resource challenges they have experienced with smoke-free environments confirmed that the wisdom of approaching implementation step by step. Another interviewee commented that the incremental approach meant that they were able to learn (and benefit) from what had been achieved previously (and potentially advance quicker with later work on remaining elements).

Champions / Political support
Interviewees highlighted the importance of champions of the particular policy or legislation. In particular, the members of the Tobacco Control Working Group were identified as key in driving and selling the policy within their respective Ministries and organisations, which helped keep the momentum going. The Tobacco Control Working Group was a multi-sectoral group with representatives drawn from the Ministry of Health and Wellness (SAACS, NCD Office, Environmental Health Unit, Community Nursing, National Mental Wellness Centre (psychiatric hospital) representatives), the Bureau, the Ministry of Education, the Ministry of Finance, the Ministry of Social Transformation and Equity, the Saint Lucia Police Force, the Attorney-General's Chambers, Turning Point (rehabilitation centre) and the Saint Lucia Cancer Society.

Public support
Interviewees reported that they got relatively strong public support for the move to implement smoke-free environments and this support was quite helpful. It also had the added benefit of providing greater encouragement to those working directly on the legislation as they did not necessarily expect that level of support. This public support was communicated in-person at the various meetings held with the main stakeholders. Feedback provided orally in the consultations. Support for the move to smoke-free environments included support from persons living with NCDs (through the Cancer Society which was as member of the NCD Commission Tobacco Control Working Group but also through Faces of Cancer, a NGO which includes cancer survivors). Notably, the hotel industry was among those supporting smoke-free environments. An interviewee explained this based on the hotel industry perhaps being a little more advanced than some other areas of the private sector and the fact that many of their guests originate from countries such as the United Kingdom and US that already have very strong tobacco control and they therefore expected a similar level of protection while on holiday.

Institutional support
In addition to the pivotal role played by the Saint Lucia NCD Commission's Tobacco Control Working Group, mention was made of the benefit of the person(s) working on the implementation of new policies or legislation being well versed in the government's systems and procedures. In Saint Lucia's case the consultant working on smoke-free environments with the Ministry of Health and Wellness and the Tobacco Control Working Group was a former civil servant who was well acquainted with the government's systems and procedures.

Experiences of other countries
The experiences of other CARICOM countries such as Antigua & Barbuda with drafting legislation for smoke-free environments, while not very influential, did provide useful local experiences to learn from, especially what to prepare for in terms of general opposition and interference from the tobacco industry.

Grounding in scientific evidence
Having a strong evidence base facilitated introduction of smoke-free environments as it provided a sound basis for informed decision making. In developing its legislation, Saint Lucia was able to benefit from the large body of international evidence regarding smoke-free environments and their economic and health effects, as well as from data collected as part of their NCD national policy, already established national surveillance systems such as the STEPS reports, the Global School-based Student Health Survey (GSHS) and Global Youth Tobacco Survey (GYTS).

Barriers

Industry interference
Unlike what obtained with implementation of graphic warnings on tobacco products, industry interference was not a factor in Saint Lucia for implementation of smoke-free environments. One interviewee thought this might be because Saint Lucia no longer produces cigarettes locally and there was therefore less of a vested industry interest. On the other hand, another interviewee felt that the lack of industry interference had more to do with the nature of the issue itself as opposed to the lack of local cigarette production. This contrasted, for example, with the earlier implementation of graphic warnings on cigarette packages, which did see significant industry push back and interference. In addition, as mentioned above, the hotel industry was among those supporting implementation of smoke-free environments since this was something many of their guests were demanding.

Implementation processes (scheduling and attendance at meetings)
The number of meetings needed to support successful development of the legislation was particularly challenging because of personnel constraints. Meetings were often very long and took away from the other parts of persons' portfolios that they had to deal with. One interviewee indicated that they found that some of the meetings could have been usefully replaced by giving persons a well-constructed questionnaire to complete rather than having to sit through hours of meetings.

Lack of resources (financial & personnel)
The lack of human and financial resources was the most significant barrier encountered. The individuals from the Ministry of Health and Wellness had other portfolios they were responsible for, and it was therefore very difficult to focus on the policy development the way they would have liked to. In addition, financial resources were very limited and in fact some aspects of the policy development had to be supported by grant funding from Bloomberg Philanthropies. PAHO has also been an important source of support for WHO FCTC implementation in St Lucia.

Conclusion

Conclusion

Saint Lucia's experience to date with implementation of graphic health warnings and smoke-free environments provides some useful lessons for other CARICOM territories seeking to implement the FCTC:

- The first lesson is that legislative change involves deployment of significant financial and personnel resources and may therefore call for strategic decisions to be made about the scope and pace of implementation to ensure its realisation. Even then, resource constraints may still require complementary grant funding from international partners.
- Saint Lucia's decision to opt for gradual, incremental implementation while continuing to work on comprehensive tobacco control legislation seems to have been the correct choice for them, particularly when one considers that Antigua and Barbuda's comprehensive tobacco control Act, although completed since 2018, has not come into force as yet.
- Saint Lucia's experience also illustrates the importance of a sound evidence base for proposed work and gives some insights into how to prepare for and counter tobacco interference even in the face of limited resources.
- A final lesson that can be drawn from Saint Lucia's experience is that political support and policy champions more broadly are critical for successful legislative reform.

In the area of smoke-free environments specifically, Saint Lucia is still in the early days of enforcement and monitoring of its legislation. Continued study of its national experiences will therefore be necessary to gain full insight into what works. Of particular interest will be the full roll-out of its implementation and enforcement programmes which are still very much in their infancy.

Saint Lucia is to be commended for its efforts to continue to advance the tobacco control agenda and encouraged to forge ahead with its full FCTC implementation.



In 2021 the World Health Organization (WHO) awarded the Saint Lucia's Ministry of Health and Wellness the 2021 World No-Tobacco Day Award in recognition of achieving key advances in tobacco control efforts namely the implementation of their tobacco regulations. Saint Lucia was among only six (6) winners in all of the Americas.

The country's' experience will hopefully illustrate to others within the region that progress is still possible even where resources are quite limited and/or the legislative agenda is already quite full. With 2022 being the last year of the current Strategy and Action Plan to Strengthen Tobacco Control in the Region of the Americas 2018 - 2022, it is hoped that more CARICOM territories will urgently take the necessary steps to implement their binding and time-bound FCTC obligations, particularly those on smoke-free environments. In so doing, they will be taking an important step towards securing the health and human rights of their respective populations, young and old alike as well as contributing towards the sustainable development of their territories.

Appendix 1: Interview Guide

The aim of this interview is to gain an understanding of the development and implementation of the Public Health (Smoking Control) Regulations in Saint Lucia and to gain some insights into current efforts to devise comprehensive tobacco control legislation. This understanding will facilitate an accurate mapping of the existing policy and legislative landscape in the Caribbean Community ("CARICOM") and assist in the development of policy and legislative guidance for implementing effective tobacco control measures across CARICOM.

This interview has six (6) sections – you are only expected to provide responses to the questions relevant to your work/which you have the knowledge base to address. The sections are:

i. Background Information
ii. Policy Environment and Policy Development
iii. Legislative Process and Overview
iv. Implementation Status
v. Monitoring and Evaluation Status
vi. Concluding Questions

BACKGROUND INFORMATION:

1. How would you describe your role in relation to bringing the Public Health (Amendment) Act 2019 and its associated Public Health (Smoking Control) Regulations 2020 into existence?
2. What has been the most striking and/or challenging aspect of your role in these processes to date?

POLICY ENVIRONMENT & DEVELOPMENT:

3. What prompted or influenced the government's decision to introduce smoke-free environments?
4. What was the policy development process for smoke free environments?
5. Were any special steps taken to protect the policy development space from conflict of interest?
6. What challenges, if any, have been encountered in developing the policy which informed the smoke free environments legislation. How were they managed or overcome?
7. Who were the key stakeholders in the policy development process (both supporters and opponents, as applicable)?
8. Has there been opposition from the tobacco industry to the introduction of smoke free environments? If so, how has this opposition been managed or overcome?
9. Who were the key stakeholders/informants for the policy? Were there any Ministries/ agencies or civil society actors who played a particularly important role in the process?
10. What international, regional and or national policy/policies were considered in the development of the policy?
11. What are some key lessons learnt from the policy development process?
12. With the benefit of hindsight, is there anything you would do differently if you had to start the process over?

LEGISLATIVE PROCESS AND OVERVIEW

13. Once the policy was finalized by the relevant Ministry, what was the process to move from a policy to passage of the Public Health (Amendment) Act and its associated Public Health (Smoking Control) Regulations?
14. 1What are the key features/elements of the legislation? Does it cover novel and emerging tobacco products?
15. What are the legislation's strengths and/or weaknesses?

IMPLEMENTATION STATUS

16. What aspects of the legislation, if any, have been challenging to implement or have not been fully implemented as yet?
17. What are some key lessons learnt from implementation of the legislation to date?

MONITORING AND EVALUATION STATUS

18. Describe the monitoring and evaluation plan for the Public Health (Smoking Control) Regulations 2020.
19. What are the challenges faced, if any, in effectively monitoring and evaluating the legislation?
20. What are some of the key lessons learnt from monitoring and evaluation of the legislation to date?

CONCLUDING QUESTIONS

21. What would be your advice to anyone seeking to create model legislation in this area for CARICOM?
22. Is there anything else that you would like to add that we have not already discussed?

I truly appreciate the time you took to answer these questions. If you have any further points or any questions, please do not hesitate to contact me at nicole.foster@cavehill.uwi.edu or on Whatsapp at + (246) 256-5966. Thank you!

Appendix 2: List Of Interviewees Re Implementation of Smoke-Free Environments / Graphic Health Warnings In Saint Lucia

Ministry of Health and Wellness

Dr. Shana Cyr-Philbert, Senior Medical Officer (Chronic Diseases) & NCD Coordinator/Focal Point

Mrs Joanna Joseph-Henry, Deputy Director, Substance Abuse Advisory Council Secretariat / Tobacco Control Focal Point / Co-Chair, Tobacco Control Working Group, Saint Lucia NCD Commission

Attorney-General's Chambers

Mrs Rochelle John-Charles, Crown Counsel II

Saint Lucia Standards Bureau

Mrs Tzarmallah Haynes-Joseph, Director

Mr Hubert Reynolds, Head, Compliance Department

Mrs Gilian King-Portland, Standards Development Officer & Technical Secretary, Tobacco Sub-Committee

Appendix 3: Smoke-Free Environments Legislation Checklist

- ✓ defines all key terms in accordance with FCTC Article 1 and Guidelines definitions [and also includes novel and emerging tobacco products;]
- ✓ applies a ban on smoking in all indoor public places and workplaces, on all means of public transport, and in specified outdoor spaces;
- ✓ imposes legal duties on compliance on persons in charge of those premises and means of transport, and on smokers;
- ✓ specifies inspection and enforcement authorities, duties, and powers, and the places falling within each ministry's area of responsibility when more than one ministry has these responsibilities;
- ✓ provides a range of deterrent penalties that are proportionate to the seriousness of the violation and the degree of responsibility of the violator;
- ✓ empowers and enables civil society to make complaints and take legal action to compel compliance with the law;
- ✓ requires the appropriate ministry to evaluate the effectiveness of implementation and enforcement of the smoke-free legislation and of the legislative provisions; and
- ✓ provides the appropriate ministry with regulatory authority to address implementing details and any other matter necessary or appropriate for effectual implementation of the legislation.

Source: Campaign for Tobacco-Free Kids, Essential Elements of Smoke-Free Legislation https://www.tobaccocontrollaws.org/files/Essential%20Elements%20of%20Smoke%20free%20legis%2012%2027%2010.pdf

For general tobacco control legislative guidance see also: Tools for advancing tobacco control in the 21st century - Tobacco control legislation: an introductory guide D. Douglas Blanke and Vera da Costa e Silva Editors World Health Organization 2004; and Pan American Health Organization. Manual for Developing Tobacco Control Legislation in the Region of the Americas. Washington, DC: PAHO, 2013.

Appendix 4: Some Key Elements of Tobacco Labelling Legislation

- ✓ Provide clear legislative objectives
- ✓ Define key terms
- ✓ Ensure comprehensive application of labelling measures including by:
  - Prohibition of false, misleading, or deceptive packaging and labelling including through use of terms such as "low tar," "light," "ultra-light," or "mild.
  - Prohibit misleading packaging and labelling both inside and out.
  - Guard against packaging innovations that undermine legislation.
  - Include required content and other details for health warnings and messages including their placement and size.
  - Include pictorial warnings and messages.
  - Make provision for rotation of warnings.
  - Include required content and other details for constituents and emissions information.
  - Impose legal duties of compliance
- ✓ Provide for a single supply deadline after which manufacturers, importers, wholesalers, and retailers may only supply products that comply with the new requirements.
- ✓ Provide effective enforcement mechanisms.
- ✓ Provide a range of deterrents and proportionate penalties.
- ✓ Provide a role for civil society e.g. to submit complaints or denounce noncompliance with the law.
- ✓ Require evaluation and public dissemination of results.
- ✓ Grant broad regulatory power to the appropriate authority to address implementation details.

Source: Pan American Health Organization. Manual for Developing Tobacco Control Legislation in the Region of the Americas. Washington, DC: PAHO, 2013.

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