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European Regulatory Science on Tobacco- Policy implementation to reduce lung disease

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European Network for Smoking and Tobacco Prevention (ENSP)
Single most important cause of preventable morbidity and premature mortality worldwide.
4 “Classical” stages of the tobacco epidemic: Prevalence-death “categorization”

Figure 1. 4 Stages of the Tobacco Epidemic


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Hypothesis: Different “virus” – different epidemiology

Nicotine containing products have evolved over the past few years:

✓ Epidemiology (spatial, geographical)
✓ susceptible populations/high risk groups
✓ modes of transition
✓ risk-benefit,
✓ “infectivity” (addictive potential)
✓ social contagion

Just as different viruses effect different target organs, cells due to a number of factors: susceptibility, proximity,

Different tobacco types effect different “cells” and “organs” within a society.
Evolution of the global tobacco epidemic

Type 1
Oral tobacco and Cigarettes

Type 2
Dual use

Type 3
Non combustible products

Hypothesis of 3 epidemic phenotypes

Type 1
Smokeless and Cigarettes
Still increasing prevalence
Regional production/use
Traditional TC initiatives
S+E Asia, Middle East, African Region
LMIC

Type 2
Dual Infectivity
Located in countries with developing TC initiatives
An environment potentially interested in other products but still at the apex of the epidemic
Steady cigarette sales/consumption
Growing awareness of the harm caused by tobacco
Eastern and Southern Europe*

Type 3
Novel Tobacco Products
Advanced TC
Steady reductions in cigarette sales/consumption
Greater awareness
Multiple product use
Consumer pressure
Examples: USA, Canada, Northwestern Europe,

The window of opportunity

• Efforts to reduce the devastation of tobacco-related deaths and illness include, the Tobacco Products Directive (TPD), and the implementation of the WHO Framework Convention on Tobacco Control (FCTC).
• These two instruments provide the EU Member States with the framework of actions.
• Unique window of opportunity to be able to evaluate this large natural experiment.
• As tobacco control policies are formulated and implemented, it is important that policies undergo rigorous evaluation.
Birth of the idea

- Hypothesis
- Opportunity
- Framework

eurestplus
European Regulatory Science on Tobacco: Policy implementation to reduce lung diseases (EUREST-PLUS)

- Funded by H2020-HCO-2015-681109
- Global Alliance for Chronic Diseases (GACD) call
- Duration of 36 months,
- Budget approx. 2.7M
- 13 partners
- 64 researchers
- Coordinated by ENSP

✓ Network of regional NGOs and stakeholders with representation in almost all EU MS.
✓ FCTC observer status
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<th>Organization</th>
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<td>European Network on Smoking and Tobacco Prevention (ENSP)</td>
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<tr>
<td>Institut Català d’Oncologia (ICO)</td>
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<td>Kings College London (KCL)</td>
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<td>Smoking or Health Hungarian Foundation (SHHF)</td>
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<td>German Cancer Research Center (DKFZ)</td>
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<td>Health Promotion Foundation (HPF)</td>
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<td>University of Maastricht (UniMaas)</td>
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<td>University of Crete (UoC)</td>
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<td>University of Athens (UoA)</td>
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<td>TNS Opinion Europe (TNS)</td>
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<td>Aer Pur Romania (APR)</td>
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<td>European Respiratory Society (ERS)</td>
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<td>University of Waterloo (UW)</td>
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Engagement of Civil Society

“To achieve political progress in a modern and democratic society, it is vital to have the support of active and committed citizens and their organisations” European Economic and Social Committee

- European Network for Smoking and Tobacco Prevention
- European Respiratory Society
- Polish Health Promotion Foundation
- Smoking or Health Hungarian Foundation
- European Lung Foundation
- International Society for the Prevention of Tobacco Induced Diseases
- European Federation of Allergy and Airways Diseases Patients' Associations
- Engagement with the Framework Convention Alliance (FCA)
Main objective

- To monitor and evaluate the impact of the TPD within the context of FCTC ratification at a European level.
  - To evaluate the psychosocial and behavioral impact of TPD implementation and FCTC implementation, through the creation of a cohort of adult smokers in 6 EU MS
  - To assess support for TPD implementation through secondary dataset analyses of the Special Eurobarometer on Tobacco Survey (SETS).
  - To document changes in e-cigarette product parameters following implementation of Article 20 of the TPD.
  - To enhance innovative joint research collaborations on chronic, non-communicable diseases (NCDs) in low- and middle-income countries (LMICs) and in vulnerable populations in high-income countries (HICs), a key priority of the Global Alliance for Chronic Disease (GACD).
WP1: Coordination and Management

**Project Coordinator**  
**European Commission**

**Project Secretariat**

**Steering Committee**  
(All Partners leads)

**General Assembly**  
(All Partners reps)

**External Advisory Group**

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**WP2: Cohort Study on Tobacco Control in the EU: Wave 1**  
Lead: UW

**WP3: Cohort Study on Tobacco Control in the EU: Wave 2**  
Lead: UoA

**WP4: Cross-country analysis among ITC cohorts: EU and non-EU pooled analyses**  
Lead: KCL

**WP5: Secondary analyses of the Special Eurobarometer on Tobacco Surveys**  
Lead: UoA

**WP6: Assessing e-cigarette product compliance to the TPD**  
Lead: DKFZ

**WP7: Maximizing impact through communication and dissemination**  
Lead: ERS
WP 2 and WP3: The 6E ITC cohort

• To evaluate the psychosocial and behavioral impact of TPD implementation and FCTC implementation, through the creation of a cohort of adult smokers in 6 EU MS (n=6000) in a pre- vs. post-TPD study design (WP2-WP3),

• The study design is ideal for addressing the structural interventions or policies designed to promote improved health outcomes such as monitoring the potential effects of such policies if adopted and implemented.

• Use of the International Tobacco Control (ITC) methods and approach as a proven effective tool.

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<thead>
<tr>
<th>Participating MS</th>
<th>GINI</th>
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<tr>
<td>Germany</td>
<td>134%</td>
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<tr>
<td>Greece</td>
<td>60%</td>
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<tr>
<td>Hungary</td>
<td>37%</td>
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<td>Poland</td>
<td>38%</td>
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<tr>
<td>Spain</td>
<td>82%</td>
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<td>Romania</td>
<td>27%</td>
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The ITC Project (Univ of Waterloo, Canada)

1. Only international research project that focuses on evaluating the impact of tobacco control policies at the population level

2. World’s largest tobacco control research program: 150 researchers across 28 countries (>50% of the world’s population and >70% of the world’s tobacco users)

3. ITC recognized by International Agency for Research on Cancer for best practices in evaluating tobacco control policies.

4. Existing surveillance systems (e.g., Eurobarometer, GATS) do not have the extensive measures nor the study design for evaluating policies. (Eurobarometer & other surveillance: cross-sectional, but ITC is the first-ever international cohort study of tobacco use).

5. Over 400 scientific articles – most joint collaborations

6. Extensive history of working with governments to promote stronger, evidence-based approaches to tobacco control.
## Tobacco Epidemic Evidence Systems

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<td></td>
<td>FCTC Reports, GTCR, Civil Society</td>
<td>ITC Project</td>
<td>GATS, STEPS, country systems</td>
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<table>
<thead>
<tr>
<th>Systems</th>
<th>Central Question</th>
<th>Evidence Source</th>
<th>Measures &amp; analysis</th>
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<tbody>
<tr>
<td></td>
<td>What policies have been implemented?</td>
<td>Legislation, reports from stakeholders</td>
<td>Legislative analysis of strength/weakness</td>
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<tr>
<td></td>
<td>What is the impact of the policies?</td>
<td>Individuals from the population</td>
<td>Measures of tobacco use, SHS exposure, policy-relevant measures of impact, mediators of behavior</td>
</tr>
<tr>
<td></td>
<td>What is tobacco prevalence?</td>
<td>Individuals from the population</td>
<td>Measures of tobacco use, SHS exposure</td>
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**Tobacco-Related Morbidity and Mortality**
The International Tobacco Control Policy Evaluation Project (the ITC Project)

Canada  United States  Australia  United Kingdom
Ireland  Thailand  Malaysia  South Korea
China  Uruguay  Mexico  New Zealand
France  Germany  Netherlands  Bangladesh
Brazil  Mauritius  Bhutan  India
Zambia  Kenya  Abu Dhabi  Greece

Greece  Hungary  Poland  Romania  Spain
WP4 – Cross Country analyses

• Aim: To enhance innovative joint research collaborations on chronic, non-communicable diseases (NCDs) in low- and middle-income countries (LMICs) and in vulnerable populations in high-income countries (HICs).

• We will specifically address these cross-country analyses through the pooling and comparisons across both other EU countries of the ITC Project (UK, France, Netherlands), and other non-EU countries from LMICs and HICs from the global ITC Project.

• Always in collaborative partnership
ITC Evaluation of FCTC Policies (Partial List)

**Warning labels**
- UK (2003): Text
- India (2009): Graphic
- UK (2008), France (2011): Graphic on front
- Australia (2006): Graphic
- Canada (2010): Graphic, Round 2
- China (2008): Text; (2015): Larger font text
- Mexico (2008): Graphic
- Uruguay (2006,09): Graphic
- Brazil (2008/09): Graphic, Round 3
- Malaysia (2008): Graphic
- Mauritius (2009): Graphic
- New Zealand (2008): Graphic

**Advertising/Promotion**
- UK (2003): Comprehensive
- Canada (2003): Last part of Comp.
- Thailand (2006): POS bans
- Mexico (2008): Comprehensive
- Canada (2008+): Re-emergence of “descriptive” ads & possible new ban
- China (2011): Comprehensive
- Many other countries: Partial

**Smoke-free**
- Ireland (2004)
- Scotland (2005)
- Mexico (2008+)
- Brazil (2008+)
- Bangladesh
- Uruguay (2006)
- Bhutan (2009+)
- France (2007/08)
- India (partial)
- Germany (2008+)
- Mauritius (2009)
- China (2008/09 + Olympics)
- Netherlands (Part 2–2008/09)

**Taxation**
- All countries

**Product policies**
- EU: 10-1-10 regulation, TPD (2016)
- US/Canada: Reduced ignition propensity
- All countries: product; product x behavior

**Illicit trade / Cross-Border**
- China (2008): prevalence
- EU: Cross-border shopping
- Bhutan (2009+): total ban on sales in country
Examples of ITC Project Evaluation

1. **Smoke-free:** Ireland’s comprehensive smoke-free law (2003-04) and in Scotland (2006), France (2008), Germany (2007-8), Netherlands (2008), China’s partial laws, 20 other countries

2. **Health Warnings:** Evaluation of graphic warnings in Canada, Australia, Thailand, Malaysia, Mauritius, Brazil, Uruguay, UK, France, New Zealand

3. **Tax/Price:** Impact of price/tax on demand for tobacco products across 20+ countries; Impact of tax structure on effectiveness of tax increases in 17 countries; New research on affordability

4. **E-Cigarettes:** Extensive global research program: what is the impact of e-cigarettes on cigarette smoking? Does this differ across countries depending on policies on e-cigarettes/tobacco control?

5. **Govts defending policies:** Provided evidence supporting Australia in defending plain packaging at WTO and Uruguay defending large pictorial warnings being challenged by PMI via a bilateral investment treaty
WP5: Eurobarometer analyses

- To perform population based assessment of policies support for TPD implementation through secondary dataset analyses of the 2015 Special Eurobarometer on Tobacco Survey (SETS),
- Trend analyses to monitor progress in FCTC implementation in the EU over the past years through merged dataset analysis with a special focus on vulnerable populations (youth, minorities, unemployed, etc.)
  - Price and tax measures: Based on FCTC-Art 6,
  - Protection from exposure to SHS (FCTC-Art 8)
  - Tobacco advertising promotion and sponsorship (FCTC Art 13)
  - Issues of tobacco dependence and cessation (FCTC- Art14)
  - Tobacco packaging and labelling: TPD-Art 8-14 and FCTC Art 9
  - Tobacco product design characteristics: (TPD Art 6,7,13):
  - E-cigarettes (TPD Art 20)
WP6: E-cigarette product evaluation

Why?
- Art 20 of the TPD
- Commission implementing decisions

How?
- Evaluation of the top 5 companies in each MS
- Evaluation of all products and tactics
- Purchase of sample of products
- Pre vs. Post design

What?
- Technical design features
- Safety features
- Labelling/packaging
- Composition
Integrating results into policy actions

- Results disseminated through civil society to policymakers and the public in Europe. (WP7)
  - Website, Journals, Conferences, Sessions at the EP
  - Policy “bites” for press releases

- Results to FCTC will be disseminated via the Framework Convention Alliance

- The results will be provided to the FCA, which in turn will disseminate the information to delegates at the next COP

- This is a unique opportunity to provide voting delegates at FCTC with the scientific evidence of the impact of tobacco control policies at a global level. (COP 2016, COP 2018)

- The impact of the EUREST-PLUS Project will be an essential element of this, both because of the demographic weight of the European Union and the impact EU directives typically have on non-EU countries, especially LMIC.
In conclusion

- Monitoring the impact and effects of TPD on population indexes, is of significant interest to public policy makers at both the central EU and MS level.
- Moreover, we envisage that if our results indicate that the TPD is a successful tobacco prevention strategy then it will most likely set the stage for the adoption of its articles in other jurisdictions under the FCTC implementation umbrella.

Contribute to the expansion/adaptation of the “cure” to the epidemic
Thank you

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