Tobacco Harm Reduction in South Africa: Perceptions on alternative nicotine delivery products

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Dealing with perceptions of Governments and Regulators

- Are you saying Nicotine on its own is harmless
- Why spend so much money developing different ways of delivering Nicotine?
- Is this about glamourising smoking?
- Is this not a Gateway to ordinary smoking and access to harder drugs?
- Why do you resist regulation by Governments?
What is harm reduction?

- Harm reduction is about developing policies to try and minimize the negative health impact of a risky activity without stopping it entirely.
- For example, advocating the use of condoms reduces the spread of sexually transmitted diseases.
- For tobacco this means offering less risky alternatives to regular cigarettes for those smokers who cannot, or choose not to, give up.

Growing consensus among scientists and public health professionals that e-cigarettes are significantly less harmful than conventional cigarettes (95% less harmful than conventional tobacco products).

Smokers across the world are increasingly switching from conventional cigarettes to electronic cigarettes. (ASH UK survey estimates that nearly 2.1 million smokers and ex-smokers in the UK are using e-cigarettes as a cigarette substitute.)

Evidence indicates that ENDS present a relatively low risk of chronic disease for consumers compared to conventional cigarettes or alcoholic beverages.
Background: Prof. Nutt et al on Relative Harms of Nicotine Products


“...While nicotine is addictive, and not entirely harmless, e-cigarettes do not contain the extensive cocktail of cancer-causing chemicals found in tobacco. While the long term health consequences of e-cigarette use are uncertain, they are almost certainly far safer than tobacco cigarettes.” CRUK May 2014


“...it is very likely that average electronic nicotine device system use produces lower exposure to toxins than combustible products” WHO 2015/16
Growing body of evidence highlighting the harm reduction associated with ENDS
Explaining ENDS
**ENDS Category Overview**

**Tobacco Heating Products (THPs)**

THPs contain tobacco, but heat the tobacco at temperatures not high enough to cause combustion. THPs are smokeless tobacco products.

**Hybrids of THPs and ENDS**

Hybrids of THPs and ENDS. Pass vapour made as in ENDS through tobacco to release nicotine and flavour. Like THPs, hybrids are smokeless tobacco products.

**ENDS (e-cigarettes)**

Electronic Nicotine Delivery Systems (ENDS) deliver nicotine in a vapour that is inhaled. Contain no tobacco and produce no smoke. ENDS are not tobacco products.
Tobacco Heating Product (THP) - How it Works

- Redesigned the cartridge to incorporate a separate tobacco segment.

- The tobacco cartridge passes vapour through a tobacco segment.

- **Core principle**: nicotine containing solution crosses an atomiser and the resultant warm vapour is drawn through the tobacco segment, releasing a vapour with an authentic tobacco flavor.
E-Cigarette - How it Works

Diagram showing the components of an e-cigarette:
- Battery
- Electrical wire
- Microprocessor chip
- Wick
- Coil
- LED
- Wadding
- Mouthpiece
- Liquid container
- E-Liquid
- Vapour Heating Technology
Key Facts to Note About ENDS

- **Consumer product not medicinal approach**
  - ENDS are not a medicinal product but rather a consumer product that is enjoyed by adult consumers.
  - Consumers should have the freedom to choose ENDS instead of a conventional tobacco product, but the decision to use ENDS is at bottom not a medical one.

- **Avoidance of smoking cessation claims for ENDS**
  - In line with regulating ENDS as a consumer and not a medicinal, product - there is scientific evidence indicating that consumers use ENDS products as a substitute for conventional cigarette

- **ENDS regulation should not be modeled on tobacco product regulation**
  - Most jurisdictions have some codified form of tobacco product legislation or regulation. Such provisions typically address conventional cigarettes in detail due to their long-recognised health risks. ENDS products, however, are fundamentally different from conventional cigarettes or other tobacco-containing products.
Risks associated with different tobacco products

To help people understand the relative risks of different types of tobacco and nicotine products, they can be placed on a risk continuum based on exposure to toxicants as seen below:
Regulating ENDS - International
ENDS Regulation - Best Practice

EUTPD2 says ENDS are non-tobacco, but:
- Is not full harmonisation
- Member States delays in implementing
- Some gold plating, some not (UK)
- Additional laws still to be expected

New FDA regulations:
- Grandfather date 2007
- Pre-approval of ENDS (MRTP)
- Now high cost of doing business
- Further regulatory details expected

Main ENDS outcomes COP 7 Delhi Nov 2016:
- ENDS are not tobacco products
- Potential role in Harm Reduction
- Further monitoring and scientific evidence
- WHO support ongoing standards work
In 2015, the British Standards Institution (BSI) published specifications for vaping products, including e-cigarettes, focused on ensuring product quality to consumers.

These guidelines, although not legally binding or incorporated into regulation, are a huge milestone for influencing the UK government and other governments in Europe to start looking seriously at product safety and quality standards in this important innovative category.
Global Snapshot of Fast-Changing Regulation of ENDS
The scale of the problem in South Africa

- 31,800 South Africans killed annually by tobacco-caused disease
- more than 343,000 children and 5,692,000 adults use tobacco each day.

-Tobacco Atlas
Smokeless oral tobacco use

6.6% of adults use smokeless tobacco
= 2,383,700 current users
Harm Reduction

- Policies, programs and practices that aim to reduce the harms associated with the use of psychoactive drugs in people unable or unwilling to stop.

- Complements approaches that seek to prevent or reduce the overall level of drug consumption.

- Based on the recognition that many people throughout the world continue to use psychoactive drugs despite even the strongest efforts to prevent the initiation or continued use of drugs.

- Many people who use drugs prefer to use informal and non-clinical methods to reduce their drug consumption or reduce the risks associated with their drug use.

- Well-known approach mainly after HIV spreading among injecting drug users.
Harm reduction for IV drugs

Total number of IV drug users
15.9 million

Value of harm reduction recognized by all countries, WHO, Red Cross, and other health organizations.

Source: The Lancet 2010; 376:551-563 (DOI:10.1016/S0140-6736(10)60928-2)
Harm reduction in daily activities
Harm Reduction in South Africa

- According to the World Health Organisation (WHO) smoking prevalence in South Africa stands at 16.2%, and 26.5% of men smoke and daily smoking amongst youth is 12.7% overall.

- Post 1994, South Africa established tax and regulatory measures that have reduced smoking prevalence by 7% from 31% to 24%.

- There are several strategies that exist that aim to deal with harm reduction in South Africa. Examples of these are the following:
  
  - The Prevention of Non-Communicable Diseases (NCD) Strategy 2013-2017 - Commitment to reduce tobacco consumption by 20% by 2020. To achieve that goal, the DoH in SA is currently in the process of amending the Tobacco Product Control Act 83, 1993.

  - The South African National Strategic Plan on HIV, TB and STIs 2017 - 2022 (NSP);

  - The National Health Promotion Policy and Strategy; and

  - The National Drug Master Plan 2013-2017 - Defines harm reduction as “the development of policies and programmes that focus directly on reducing the social, economic and health-related harm resulting from the use of alcohol and other drugs”.

DoH’s approach to regulating ENDS

- **Proposed amendments to the Tobacco Products Control Act 1993.**
- **Regulate e-cigarettes in the same manner as combustible cigarettes.**
- **The DOH is closing the door on one of the most promising innovations** in smoking cessation and harm reduction:
  - A complementary approach: Reduce the harm caused by tobacco smoking by making effective but less hazardous substitute products available to the smoker.
  - E-cigs deliver a nicotine vapor without the combustion of products that are responsible for nearly all of smoking’s damaging effects.
  - Scientists and commentators agree that complete tobacco cessation is the best outcome for smokers, any efforts to make available safer products need to be part of a comprehensive tobacco control strategy aimed at minimizing tobacco use through cessation and prevention.
  - Evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely.
  - There is a need for regulation to reduce direct and indirect adverse effects of e-cigarette use, but this regulation should not be allowed significantly to inhibit the development and use of harm-reduction products by smokers.
  - Technological developments and improved production standards could reduce the long-term hazard of e-cigarettes.
Summary of Preferred Regulatory Regulation

- **ENDS Regulation**
  - Stand-alone regulations for ENDS not part of tobacco or other product regulations
  - Public health harm reduction policy justifies subsidizing ENDS

- **THP Regulation**
  - A separate category for THPs within tobacco product regulations
  - Calculated using the weight of tobacco

- **ENDS and THP Regulation**
  - Marketing and distribution freedoms in line with the risk continuum
  - Mandatory quality and product standards
  - Regulation requiring scientific substantiation of reduced risk claims
Evidence-based policy, not policy-biased evidence seeking

- Assert importance of **scientific evidence**
  (above ideological motives)
- Balance: **Individual** & population-based sciences
- Ensuring the **independence** of scientists
- Proper handling of **uncertainty**
- Ensuring **transparency** of scientific advice
- Appropriate use of the **precautionary principle**
Conclusions: population effects

E-cigarette use is prevalent mostly in smokers or ex-smokers

- Minimal use by never smokers - mostly trial (experimentation)

Daily use and nicotine use are virtually non-existent among never smokers

- Gateway to smoking effect for never smokers unlikely

- Gateway to smoking effect for former smokers unlikely - could prevent relapse to smoking

- Effect on dual users depends on amount of smoking reduction (but added risk is unlikely)

Ever use or commonly-defined current use (past 30d use) can be misleading

- Surveys should evaluate
  - frequency of use and nicotine use
  - changes in smoking habit and consumption attributed to e-cigarette use
Thank You