

TOBACCO HARM REDUCTION IN MEDICINE & PUBLIC HEALTH WHAT ARE THE PREREQUISITES FOR A POSITIVE CONTRIBUTION?

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At Imperial Brands we are committed to making a meaningful contribution to Tobacco Harm Reduction by offering adult smokers who would otherwise continue to smoke a range of potentially harm reduced alternatives to combustible cigarettes.

These products include E-cigarettes (myBLU®), Heated Tobacco (Pulze® & iD® sticks), Modern Oral Tobacco (Skruf®) and tobacco-free Nicotine Pouches (Zone X®).



There must be something about Tobacco Harm Reduction THR)...

Countries embracing Harm Reduction demonstrate accelerated decline in smoking prevalence



WHY IS TOBACCO HARM REDUCTION (THR) RELEVANT? CURRENT STRATEGIES ARE NOT HELPING ENOUGH ADULT SMOKERS

- Tobacco smoking is a cause of serious disease in smokers, including lung cancer, heart disease and emphysema.
- The best form of action adult smokers can take to improve their health is to stop all tobacco and nicotine use completely. This is in line with the current Guidelines for Tobacco Dependence Management. (Batra et al. 2021)
- Nevertheless, only 20% of smokers are interested or willing to quit smoking (Kotz et al. 2020). 80% of cessation attempts fail within the first week of quitting on your own (Caponetto 2013).
- Thus, in Europe around 25% of people still smoke cigarettes (with slow decline rates vs. faster decline in countries where Harm Reduction strategies have been endorsed by governments (e.g. UK) (Eurobarometer 2020).

Batra et al. S3-Leitlinie Rauchen und Tabakabhängigkeit: Screening, Diagnostik und Behandlung. 2021. AWMF. Kotz D et al. Rauchstoppversuche und genutzte Entwöhnungsmethoden - Eine deutschlandweite repräsentative Befragung anhand sozioökonomischer Merkmale in 19 Wellen von 2016–2019 (DEBRA-Studie). Deutsches Ärzteblatt | Jg. 117 | Heft 1–2 | 6. Januar 2020 4 | Caponetto P et al. Handling relapse in smoking cessation: strategies and recommendations. Intern Emerg Med. 2013 Feb;8(1):7-12.



WHAT ARE THE OPTIONS FOR PHYSICIANS? IS YOUR SMOKING PATIENT INTERESTED AND WILLING TO QUIT?

- <u>Option for Smokers interested in Smoking Cessation</u>: Nicotine Replacement Therapy (NRT) & Treatment Support Programs (depending on personal preference).
- Yet, only 13% of smokers use Nicotine Replacement Therapy (NRT) to stop smoking and when using NRT smoking abstinence is less than 7% after 12 months (Eurobarometer 2020, Farsanilos 2017).
- As a result, NRT is not helping enough adult smokers to transition away from combustible cigarettes quickly enough (i.e. smoking prevalence still remains high).

BUT: What if your patient is uninterested or unwilling to quit and would thus continue to smoke? **Mantras of "Quit or die!" or "Reduce smoking to reduce harm!" as an option?**

5 | Farsalinos K. Electronic cigarettes: an aid in smoking cessation, or a new health hazard? Ther Adv Respir Dis. 2018 Jan-Dec.



REDUCE SMOKING TO REDUCE HARM? WHAT IF THE PATIENT IS NOT WILLING TO QUIT?



- Smoking of even <5 cigarettes per day has been reported to be associated with accelerated lung function decline (Oelsner et al. 2020).
- Each cigarette smoked per day has been reported to elevate the odds of Respiratory & Circulatory diseases by 5-33% / 23% (King et al. 2020).
- Smoking cessation, but not reduction, has been reported to be associated with reduced CVD risk (Jeong 2021).

Oelsner EC et al. Lung function decline in former smokers and low-intensity current smokers: a secondary data analysis of the NHLBI Pooled Cohorts Study. Lancet Respir Med. 2020 King C et al. Mendelian randomization case-control PheWAS in UK Biobank shows evidence of causality for smoking intensity in 28 distinct clinical conditions. EClinicalMedicine. 2020. Jeong SM. 2021. Smoking cessation, but not reduction, reduces cardiovascular disease incidence. Eur Heart J. 2021.



WHAT IS HARM REDUCTION?

OPTIONS TO REDUCE RATHER THAN ELIMINATE RISKS ENTIRELY

- Harm reduction is a range of policies, regulations and actions that either reduce health risks or encourage less risky behaviours.
- Objective is to reduce the risk associated with a substance or behaviour, rather than eliminate the behaviour or substance itself.
- Some current examples of everyday harm reduction:
 - > Road and Car Safety Measures (to reduce risk rather than prohibit driving)
 - Face-Masks and Hand Sanitizers (to reduce rather than fully prevent risk of infection)
 - Speed-Limits (to reduce risk rather than prohibit driving)
 - COVID19 vaccines (to prevent infection AND reduce risk of severe COVID19 course of disease despite inherent risks for Adverse Events)
 - Transition to E-Mobility (to reduce CO-Footprint rather inhibit driving)



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Photos by <u>Joshua Hoehne</u> and <u>Daniel Schludi</u> from <u>Unsplash</u> Art by Peter Nsanze of Spective Design



WHAT IS TOBACCO HARM REDUCTION?

OPTIONS FOR ADULT SMOKERS WHO WOULD OTHERWISE CONTINUE TO SMOKE

- The best action adult smokers can take to improve their health is to **stop all tobacco and nicotine use completely (i.e. eliminate risk)**.
- Complete transition to potentially risk-reduced products as an option for adult smokers who are neither interested nor willing to quit smoking and would otherwise continue to smoke (i.e. reduce risk).
- Objective of Tobacco Harm Reduction is to *reduce* risks, rather than *eliminate* risks.
- THR does not replace but **complements** conventional tobacco control strategies (WHO FCTC Art. 1-d).
- However, THR is not reflected in the **EU Beating Cancer Plan**.

(d) "tobacco control" means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke;

KEY PRINCIPLE: If you don't smoke - don't start. If you smoke - quit. If you don't quit - switch.



WHAT IS TOBACCO HARM REDUCTION?

COMBUSTION, NOT NICOTINE, IS THE MAJOR CAUSE FOR SMOKING RELATED DISEASES

- The primary cause of smoking-related diseases is burning tobacco and inhaling the smoke (not nicotine). (Stratton 2001).
- Tobacco smoke contains over 7000 chemicals around 100 of these are classified as causes or potential causes of smoking-related diseases.
- Avoiding combustion (i.e. decoupling nicotine from tobacco smoke) delivers fewer and substantially lower toxicants. Thus Nicotine products sit on a relative risk scale (Stephens 2018, Nutt 2014).
- Nicotine is addictive and not risk free; however, nicotine is not the primary cause of smoking-related diseases.
 (Even 90 % of physicians have misperceptions about nicotine according to Steinberg 2020.)



Stratton K et al.: Clearing the Smoke. Assessing the Science Base for Tobacco Harm Reduction. National Academy Pros; Washington 2001. Steinberg MB et al. Nicotine Risk Misperception Among US Physicians. J Gen Intern Med. 2020 Sep 1.

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Stephens W. Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke. Tob Control 2018 Nutt D J et al. Estimating the harms of nicotine-containing products using the MCDA approach. Eur Addict Res 2014; 20: (5) 218-225. 7000 Chemicals in Tobacco Smoke



TOBACCO HARM REDUCTION

NOT BURNING TOBACCO TRANSLATES INTO ...



...Reduced Emissions that translate into...

Rudd et al. Chemical Composition and In Vitro Toxicity Profile of a Pod-Based E-Cigarette Aerosol Compared to Cigarette Smoke. Applied In Vitro ToxicologyVol. 6, No. 1. 2020. Icon made by vectorsmarket15 from Flaticon: www.flaticon.com.



...reduced Biomarkers of Exposure that translate into...

Morris P. et al. Reductions in biomarkers of exposure to selected harmful and potentially harmful constituents following exclusive and partial switching from combustible cigarettes to myblu[™] electronic nicotine delivery systems (ENDS). 2021. Intern Emerg Med. 2021 Aug 26. Icon made by Freepik from Flaticon: www.flaticon.com.



TOBACCO HARM REDUCTION

TRANSITIONING TO EVP LEADS TO ...



Adjusted mean percentage change in forearm flow-mediated dilation with 95% confidence intervals for subjects on electronic cigarettes (EC), EC-nicotine, and ECnicotine-free.

...improved Clinical Endpoints like pulmonary and cardiovascular health in former smokers. (i.e. Reduced Toxicants > Reduced Biomarkers > Improved clinical endpoints)

George J et al. Cardiovascular Effects of Switching From Tobacco Cigarettes to Electronic Cigarettes. J Am Coll Cardiol. 2019 Dec 24;74(25):3112-3120. Polosa R et al. COPD smokers who switched to e-cigarettes: health outcomes at 5-year follow up. Ther Adv Chronic Dis. 2020 Oct 10;11:2040622320961617. Polosa R et al. Health outcomes in COPD smokers using heated tobacco products: a 3-year follow-up. Intern Emerg Med. 2021 Apr;16(3):687-696. Icons made by Freepik from Flaticon: www.flaticon.com.



TOBACCO HARM REDUCTION AS A <u>PUBLIC</u> HEALTH STRATEGY PREREQUISITES - THE HARM REDUCTION EQUATION

On public health level, three important criteria need to be considered:

- (1) Scientifically substantiated as reduced risk compared to combustible cigarettes (i.e. on a Relative Risk Scale they need to show fewer and lower levels of toxicants compared to cigarettes)
- (2) Accepted by adult smokers (maximising adult smoker transitioning) (i.e. adult smokers must find the alternative appealing and satisfying, so they ultimately transition away from combustible cigarettes)

(3) Not appealing to non-smokers and youth (minimising unintended use)

(i.e. THR may be compromised if significant numbers of unintended users –like youth and never smokers– begin using them).



TOBACCO HARM REDUCTION AS A PUBLIC HEALTH STRATEGY MAXIMISING ADULT SMOKER TRANSITIONING

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Caitlin Notley, Nancy Version published: 14 Sep						ka Theodoulou,

"There is moderate-certainty evidence that ECs with nicotine increase quit rates compared to NRT and compared to ECs without nicotine. Evidence comparing nicotine EC with usual care/no treatment also suggests benefit, but is less certain. More studies are needed to confirm the effect size." DORDERAND YOURNAL OF MEDICINE DORIGINAL ARTICLE CONCONTRACTOR DORDERATION DORD

"E-cigarettes were more effective for smoking cessation than nicotinereplacement therapy, when both products were accompanied by behavioral support."

"The rate of continuing e-cigarette use was fairly high. This can be seen as problematic if e-cigarette use for a year signals ongoing long-term use, which may pose as-yet-unknown health risks. On the positive side, ongoing ecigarette use may ameliorate withdrawal symptoms."

Potentially risk-reduced nicotine products may play an important role in transitioning more adult smokers away from cigarettes.



TOBACCO HARM REDUCTION AS A PUBLIC HEALTH STRATEGY MINIMIZING UNINTENDED USE



- **Low prevalence of vaping amongst neversmokers in Germany** compared to current and former smokers.
- Lower prevalence of vaping amongst former smokers in Germany compared to current smokers.

Call for responsible manufacturers and marketing as well as appropriate regulation.

Drogen- und Suchtbericht der Bundesregierung. Germany. 2019



TOBACCO HARM REDUCTION AS A PUBLIC HEALTH STRATEGY POPULATION LEVEL HARM REDUCTION POTENTIAL





TOBACCO HARM REDUCTION IN MEDICINE & PUBLIC HEALTH SUMMARY & KEY MESSAGE

- The best action adult smokers can take to improve their health is to stop all tobacco and nicotine use completely. Complete transitioning to potentially risk-reduced alternatives as an option for adult smokers who would otherwise continue to smoke combustible cigarettes.
- Nicotine is addictive and not risk free; however, it is not the primary cause of smoking-related diseases.
 Nicotine can be delivered in less harmful ways if decoupled from combustion.
- To fulfill the **THR potential on Public Health Level** Products need to:
 - (1) Exhibit a scientifically substantiated reduced exposure / reduced risk
 - (2) Maximise adult smoker transitioning
 - (3) Minimise unintended use (esp. youth and non-smokers)
 - (4) Be better understood by users, media, regulators, health bodies and physicians.
- There is a need for a wider debate amongst regulators, policy makers and physicians and fact based, informed education to adult smokers to maximise THR potential.

THE BASIS OF THE PUBLIC HEALTH CONCEPT OF THR:

If you don't smoke - don't start. If you smoke – quit. If you don't quit – switch.



THANK YOU!

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