Alternativprodukte zur Verbrennungszigarette

Ansätze der Risikoabschätzung

Prof. Dr. M. Storck
Direktor Klinik für Gefäß- und Thoraxchirurgie
Städt. Klinikum Karlsruhe gGmbH

Conflict of Interest

- Es bestehen keine Interessenskonflikte bezüglich der angesprochenen Thematik

Gliederung

- Warum braucht es eine Risikoabschätzung?
- Ansätze der Risikoabschätzung
- Wie bekannt sind Risikobewertungen?
- Fazit

Produktvielfalt

Eine Risikoabschätzung dient vor allem als Orientierungshilfe für Verbraucher, Politik und Ärzte

Rauchen und Herz-Kreislauferkrankungen

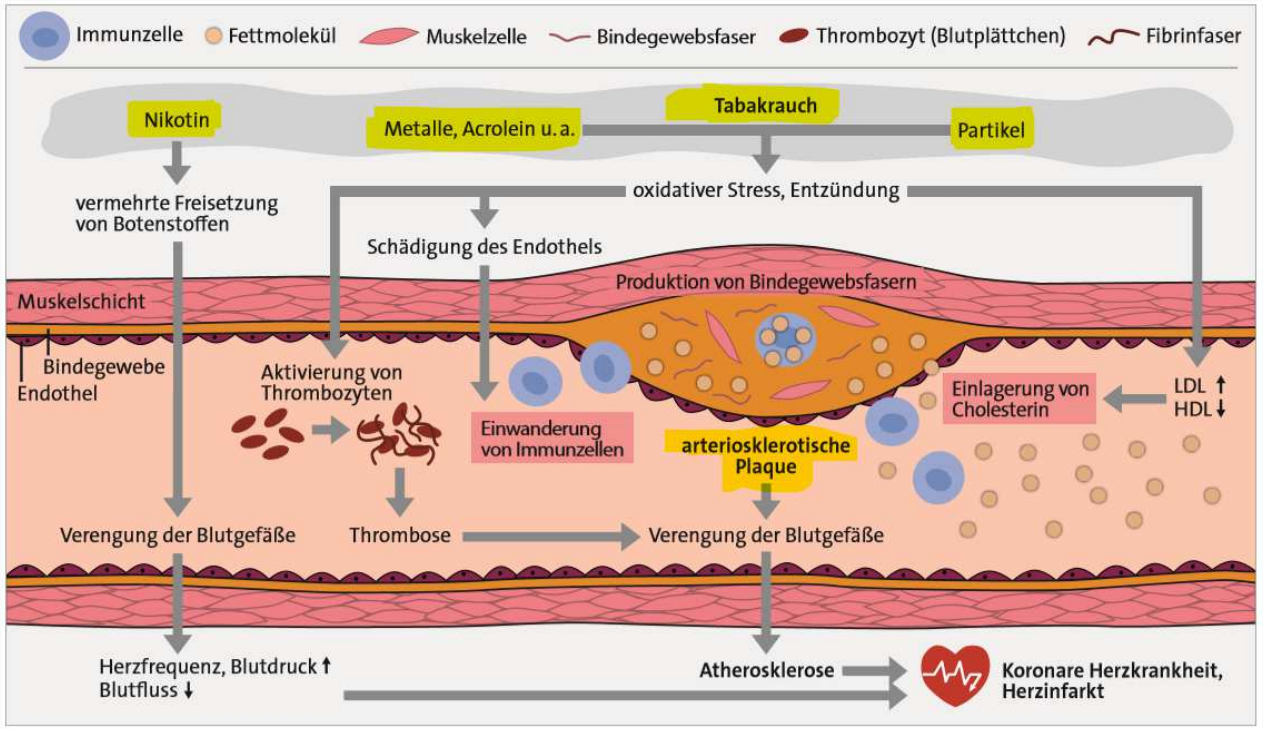


Abbildung 1: Mechanismen, über die Rauchen Herz-Kreislauferkrankungen verursacht[7,12]. Darstellung: Deutsches Krebsforschungszentrum, Stabsstelle Krebsprävention, 2018

DKFZ „Fakten zum Rauchen – Rauchen und Herz-Kreislaufsystem, 2018.
https://www.dkfz.de/de/tabakkontrolle/download/Publikationen/FzR/FzR_2018_Rauchen-und-Herz-Kreislaufsystem.pdf

Kritik am Fehlen von Langzeitstudien – ERS (2019)

ERS EUROPEAN RESPIRATORY SOCIETY
every breath counts

*"The **tobacco harm reduction strategy** is **based on incorrect claims** (smokers cannot or will not quit smoking), **undocumented assumptions** (alternative nicotine delivery products are highly effective as a smoking cessation aid and are generally harmless; smokers will replace conventional cigarettes with alternative nicotine delivery products)." [1]*

May 2019

ERS Position Paper on Tobacco Harm Reduction

Statement prepared by the ERS Tobacco Control Committee

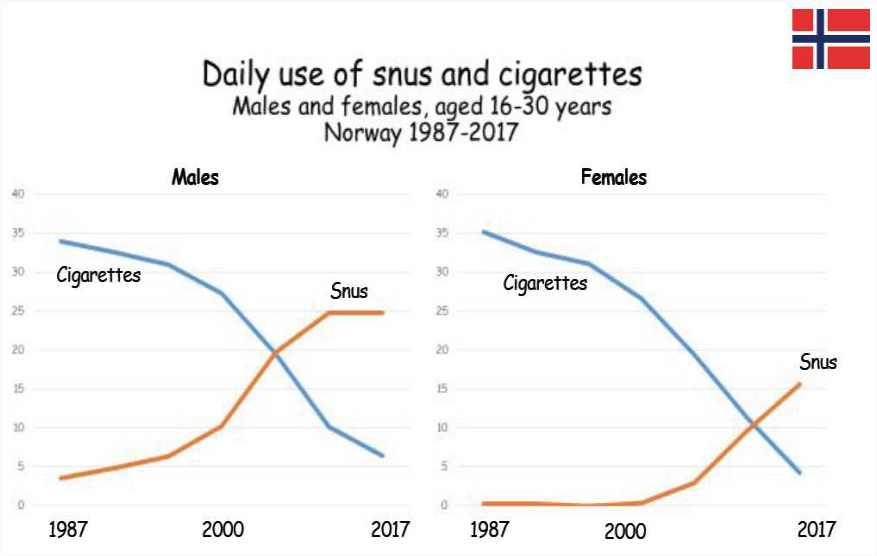
What is harm reduction?

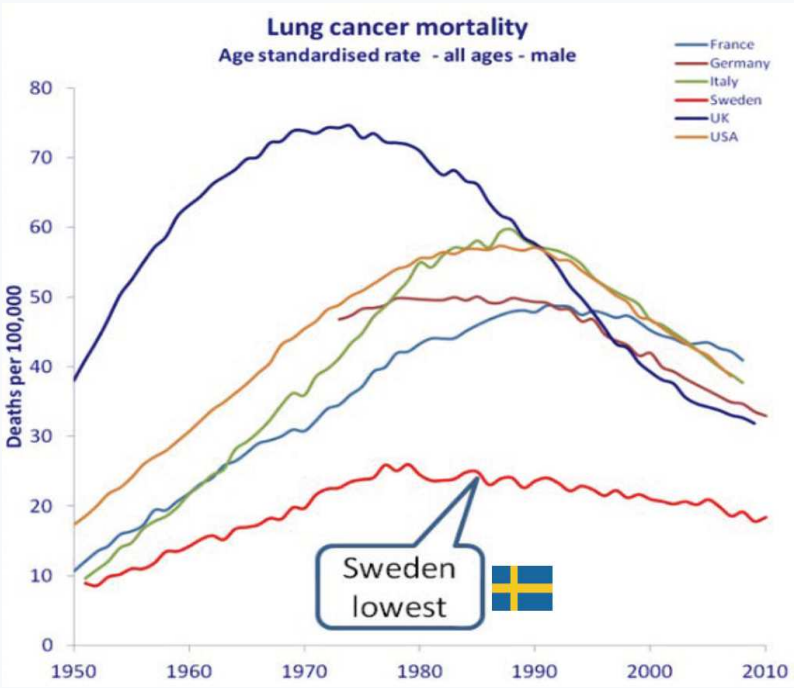
The International Harm Reduction Association, in line with the World Health Organization (WHO), defines harm reduction as "policies, programs and practices that aim primarily to reduce the adverse health, social and economic consequences of the use of psychoactive drugs without necessarily reducing drug consumption"[1,2]. Harm reduction began to be discussed after the threat of HIV spreading

*"most independent studies indicate potential harm, but **evidence is so far limited** and we have **no evidence on the long-term health effects of using e-cigarettes**." [2]*

(1) Loukides, ERS e-learning: ERS Position Paper on Tobacco Harm Reduction (June 2019). https://www.ersnet.org/professional-development/respiratory-digests/digest-ers-position-paper-on-tobacco-harm-reduction
(2) ERS Tobacco Control Committee: ERS Position Paper on Tobacco Harm Reduction (May 2019) https://pneumologie.de/fileadmin/user_upload/2019_Harm_reduction_position_paper_Final_2.pdf

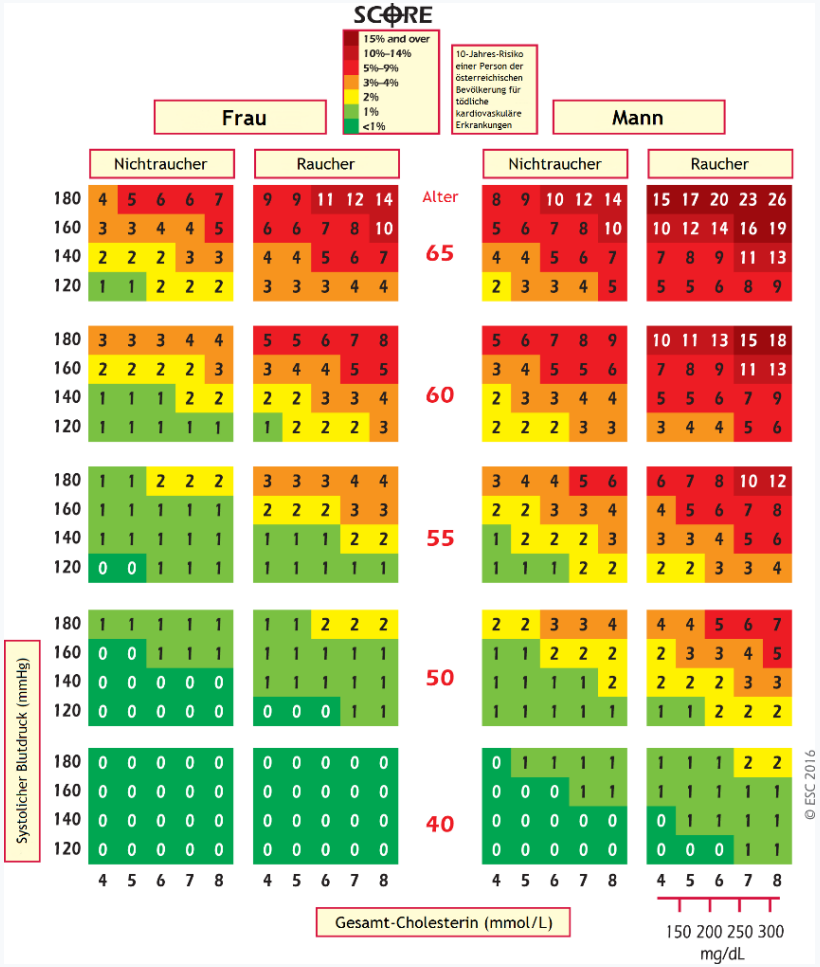
Beispiel Snus – Langzeitstudie





Lund KE, Future perspectives for reducing tobacco related harm — what have we learnt. Lisbon Addictions 2019. https://www.lisbonaddictions.eu/lisbon-addictions-2019/presentations/future-perspectives-reducing-tobacco-related-harm-%E2%80%94-what-have-we-learnt

Ansätze der Risiko-abschätzung: Scores



https://mein.sanofi.at/therapiegebiete/hypercholesterinaemie/risikofaktor-ldl-c-und-therapieoptionen/kardiovaskulaere-risikostratifizierung

Methode: Internationaler Expertenkonsens / MCDA (2014)

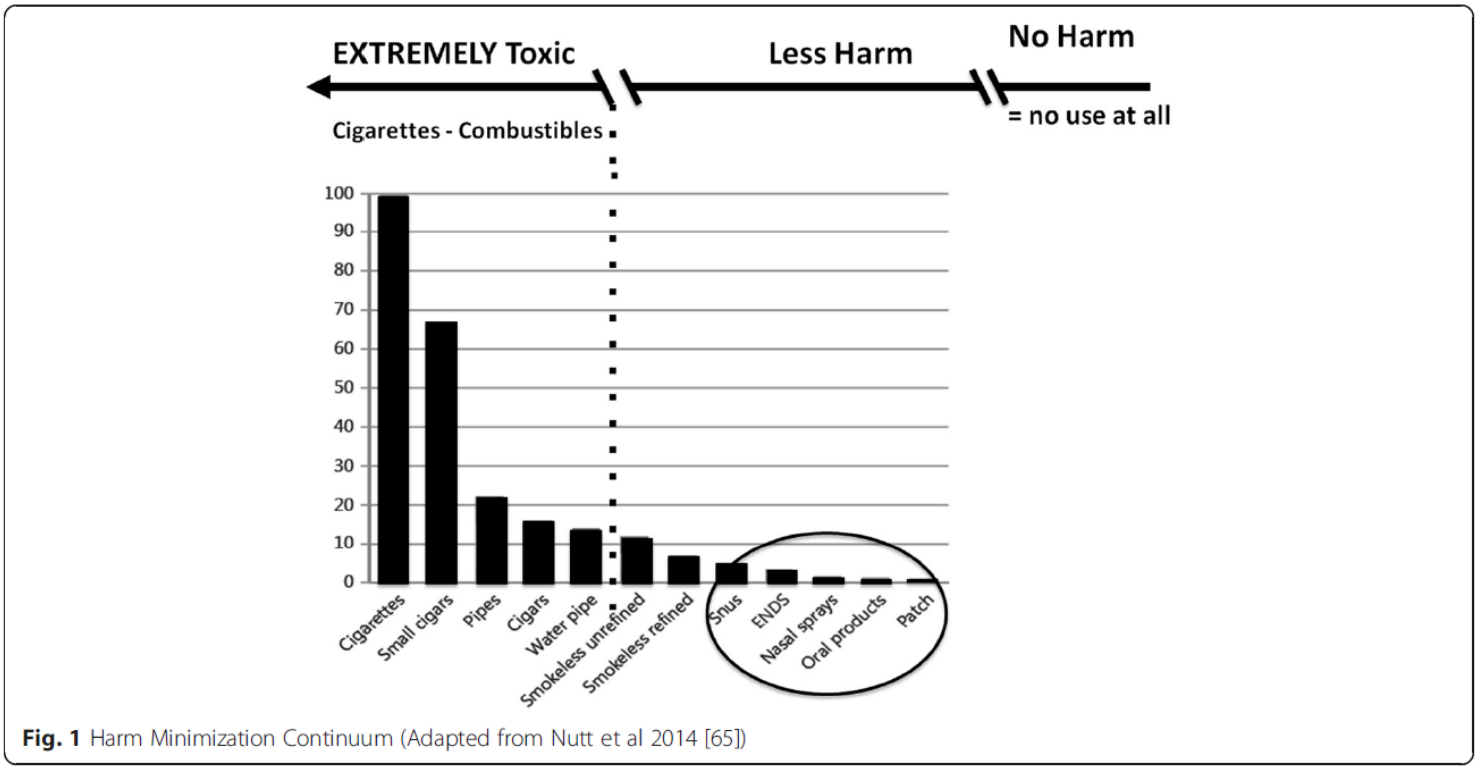
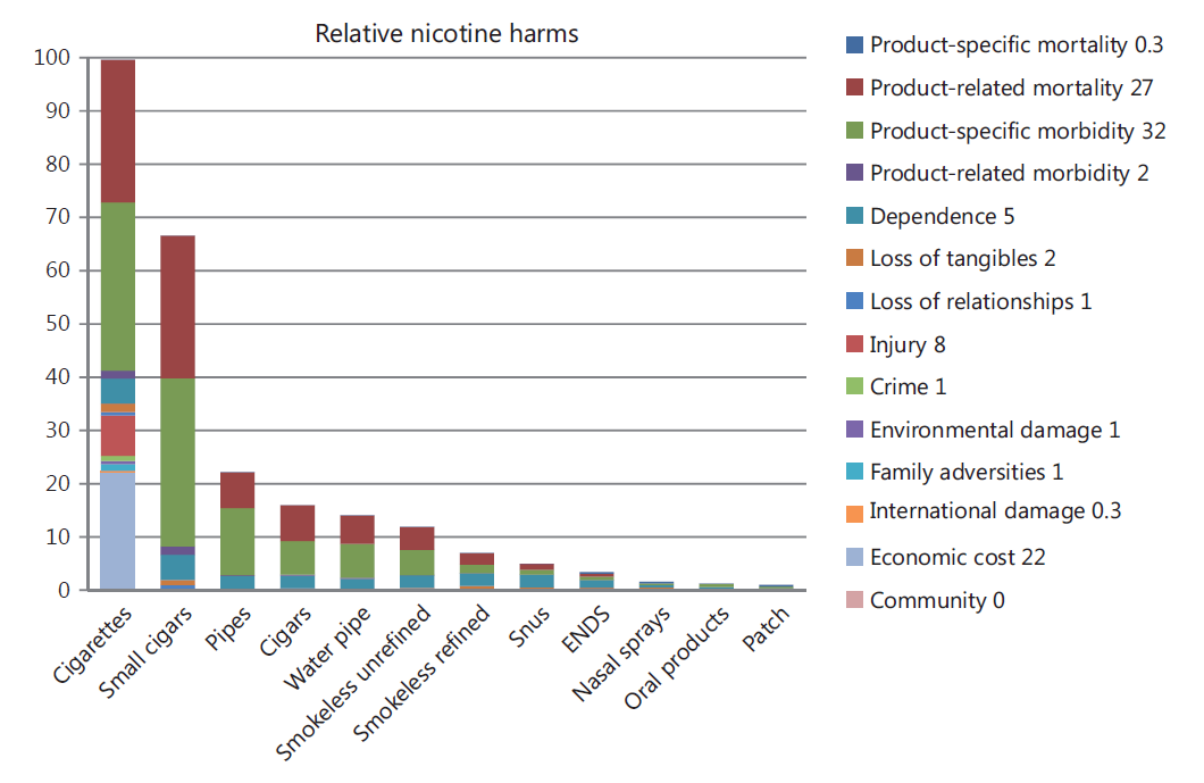


Fig. 1 Harm Minimization Continuum (Adapted from Nutt et al 2014 [65])

Kozlowski and Abrams. Obsolete tobacco control themes can be hazardous to public health: the need for updating views on absolute product risks and harm reduction. BMC Public Health (2016) 16:432. DOI 10.1186/s12889-016-3079-9

Methode: Internationaler Expertenkonsens / MCDA (2014)



Nutt et al. Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. Eur Addict Res 2014;20:218–225. DOI: 10.1159/000360220

Methode: Internationaler Expertenkonsens / MCDA (2014)

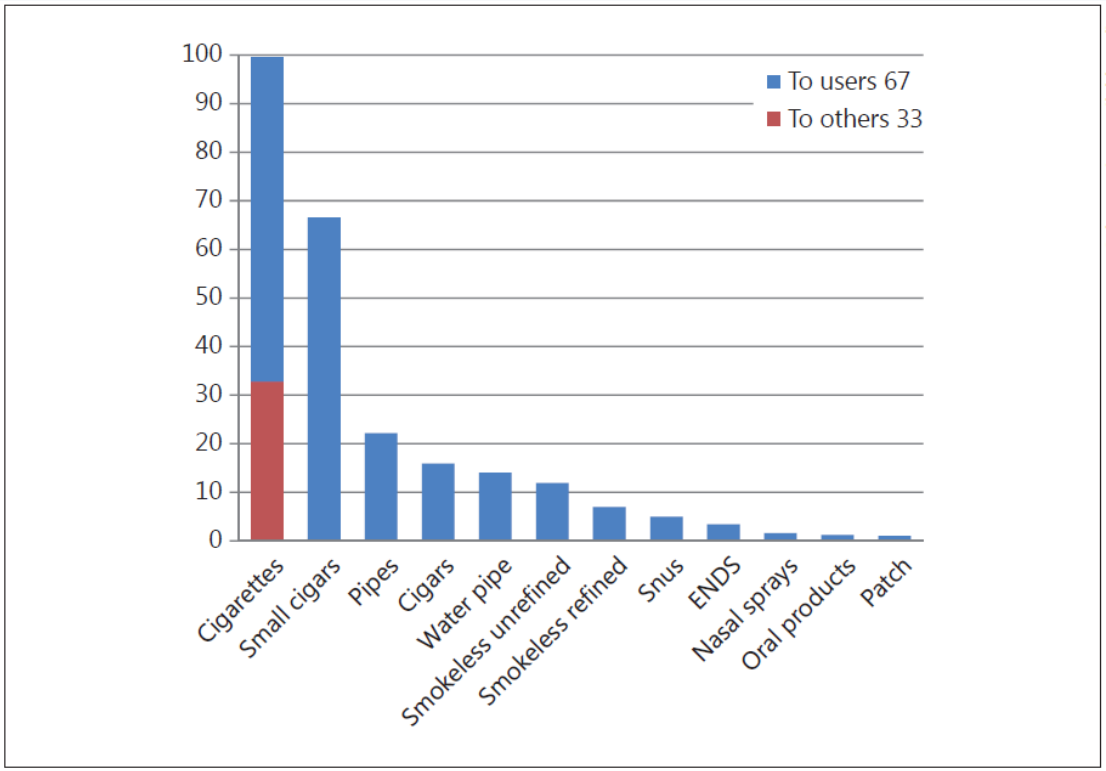
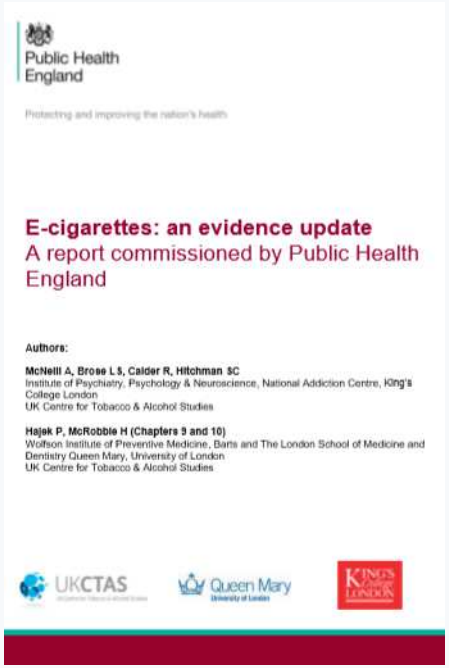


Fig. 3. The products ordered by their overall harm scores, with the stacked bar graphs showing the contribution to the overall score of harms to users and harm to others. The numbers in the legend show the sums of the normalized weights at each node.

Nutt et al. Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. Eur Addict Res 2014;20:218–225. DOI: 10.1159/000360220

Methode: Literatur-Review (PHE, UK, 2015) – E-Zigaretten

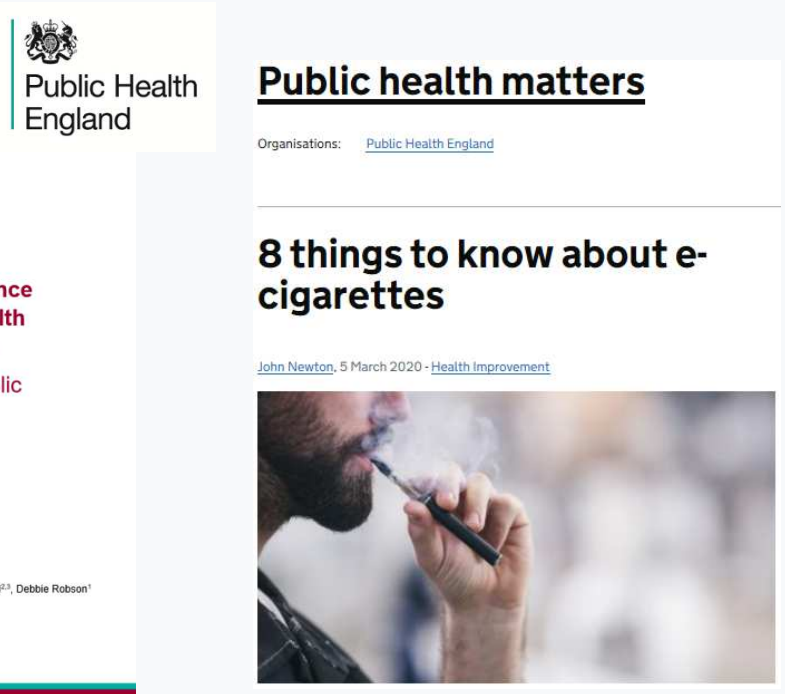
Public Health England



*"An <u>expert review of the latest evidence</u> concludes that **e-cigarettes** are around **95% safer** than smoked tobacco and they can help smokers to quit."*

McNeill et al., E-cigarettes: an evidence update. A report commissioned by Public Health England. 2015.
https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update

Update:
Literatur-Review (PHE, UK, 2020)
E-Zigaretten



"Vaping is not risk free but is far less harmful than smoking. ***Our advice remains*** *that people who smoke are better to switch completely to vaping but if you have never been a smoker, don't start to vape."* [2]

(1) McNeill et al., Vaping in England: an evidence update including mental health and pregnancy, March 2020. A report commissioned by Public Health England. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/869401/Vaping_in_England_evidence_update_March_2020.pdf
(2) 8 things to know about e-cigarettes. https://publichealthmatters.blog.gov.uk/2020/03/05/8-things-to-know-about-e-cigarettes/

Methode:
Schadstoff-Messung – Tabakerhitzer

Letter to the Editor, News and Views | Open Access | Published: 05 May 2018

Levels of selected analytes in the emissions of "heat not burn" tobacco products that are relevant to assess human health risks

Nadja Mallock, Lisa Böss, Robert Burk, Martin Danziger, Tanja Welsch, Harald Hahn, Hai-Linh Trieu, Jürgen Hahn, Elke Pieper, Frank Henkler-Stephani, Christoph Hutzler & Andreas Luch

Archives of Toxicology **92**, 2145–2149(2018) | Cite this article

Parameter	Unit	Stick variant 1		Stick variant 2		Combustible cigarettes (Counts et al. 2005)	Reduction
		Mean ± SD	*n*	Mean ± SD	*n*	Min–max (mean ± SD)	%
Puff count	Puff/stick	12 ± 0		12 ± 0		5.5 ± 0.3–13.6 ± 0.5	
TPM	mg/stick	52.6 ± 3.2	24	51.2 ± 3.2	24	27.5 ± 2.4–60.9 ± 3.3	
Nicotine	mg/stick	1.1 ± 0.1	24	1.1 ± 0.1	24	1.07 ± 0.06–2.70 ± 0.14	
Water	mg/stick	31.7 ± 5.5	24	28.5 ± 4.6	24	9.82 ± 1.42–21.35 ± 2.23	
NFDPM	mg/stick	19.8 ± 6.5	24	21.6 ± 5.9	24	16.3 ± 1.3–37.6 ± 2.1	
Acetaldehyde	µg/stick	179.4 ± 10.5	18	183.5 ± 10.1	14	930 ± 85–1540 ± 153	80.5–88.2
Acrolein	µg/stick	9.9 ± 1.2	18	8.9 ± 1.0	14	89.2 ± 7.3–154.1 ± 13.6	89.5–93.9
Formaldehyde	µg/stick	5.3 ± 0.4	18	4.7 ± 0.3	14	29.3 ± 3.8–130.3 ± 10.8	82.9–96.2
Crotonaldehyde	µg/stick	< 3.0	18	< 3.0	14	32.7 ± 1.5–70.8 ± 9.0	
1,3-Butadiene	µg/stick	0.22 ± 0.02	6	0.20 ± 0.02	6	77.0 ± 4.8–116.7 ± 14.3	99.7–99.8
Benzene	µg/stick	0.63 ± 0.07	6	0.54 ± 0.05	6	49.7 ± 7.7–98.3 ± 4.3	98.8–99.4
Isoprene	µg/stick	2.10 ± 0.35	6	1.82 ± 0.24	6	509 ± 41–1160 ± 65	99.6–99.8
Styrene	µg/stick	0.47 ± 0.06	6	0.49 ± 0.09	6	15.4 ± 0.8–33.3 ± 2.8	96.9–98.6
Toluene	µg/stick	2.15 ± 0.37	6	1.96 ± 0.23	6	86.2 ± 11.0–176.2 ± 15.7	97.6–98.8

BfR
Bundesinstitut für Risikobewertung

*„…**Tabakerhitzer** … **erhebliche Reduktion** von gesundheitsschädlichen Emissionen (**80–99 %**) im Vergleich zu … Tabakzigaretten“* [2]

*„Eine **Abschätzung und Bewertung** der verbleibenden Risiken für tabakassoziierte Erkrankungen ist derzeit noch nicht möglich und **erfordert** die **Entwicklung entsprechender Modelle**.“* [2]

(1) Mallock et al., Levels of selected analytes in the emissions of "heat not burn" tobacco products that are relevant to assess human health risks, Arch Toxicol (2018). https://doi.org/10.1007/s00204-018-2215-y

(2) Pieper et al., Tabakerhitzer als neues Produkt der Tabakindustrie: Gesundheitliche Risiken; Bundesgesundheitsblatt, 04 OKT 2018, https://doi.org/10.1007/s00103-018-2823-y

Methode: mathematische Modellierung des Krebspotenzials (2017)

Research paper

Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke FREE

William E Stephens

Correspondence to Dr William E Stephens, School of Earth & Environmental Sciences, University of St Andrews, Irvine Building, North Street, St Andrews, Fife KY16 9AL, Scotland, UK; Ed.Stephens@st-andrews.ac.uk

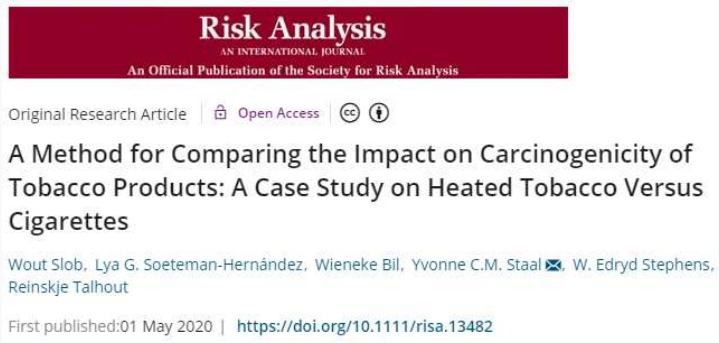
Mittleres lebenslanges Krebsrisiko
im Verhältnis zu Zigarettenrauch

- 1 Verbrennungszigarette
- 0,024 Tabakerhitzer (42-fach reduziert)
- 0,004 E-Zigarette (250-fach reduziert)

Stephens WE., Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke, *Tobacco Control* 2017;0:1–8, 2017. doi:10.1136/tobaccocontrol-2017-053808. https://tobaccocontrol.bmj.com/content/27/1/10

Modellierung: Krebspotenzial (2020) – Beispiel Tabakerhitzer

National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport



- 10- bis 25-fach reduzierte **Karzinogenität** geschätzt
- Deutlicher Gewinn an **Lebenserwartung** geschätzt bei Nutzung von erhitzten Tabakprodukten im Vergleich zu Verbrennungszigaretten

Slob et al. A Method for Comparing the Impact on Carcinogenicity of Tobacco Products: A Case Study on Heated Tobacco Versus Cigarettes. Risk Analysis. First published: 01 May 2020. https://doi.org/10.1111/risa.13482

Modellierung von Todesfällen (2017) E-Zigarette

USA

"Compared with the Status Quo, ***replacement of cigarette by e-cigarette use over a 10-year period*** *yields* ***6.6 million fewer premature deaths*** *with 86.7 million fewer life years lost in the* ***Optimistic Scenario****. Under the* ***Pessimistic Scenario****,* ***1.6 million premature deaths*** *are averted with 20.8 million fewer life years lost.*

Levy et al. Potential deaths averted in USA by replacing cigarettes with e-cigarettes. Tobacco Control 2017; https://tobaccocontrol.bmj.com/content/27/1/18

Methode: Marktbeobachtung (Deutschland, 2019)

Bundeszentrale für gesundheitliche Aufklärung

Rauchverhalten unter 12- bis 17-Jährigen

- 8,7 % Verbrennungszigarette*
- 5,1 % E-Zigarette**
- 0,1 % Tabakerhitzer**

*ständig/gelegentlich

**30-Tage-Prävalenz

BZgA: Rauchen bei Jugendlichen und jungen Erwachsenen in Deutschland - Ergebnisse des Alkoholsurveys 2018 und Trends (SEP 2019)
https://www.bzga.de/forschung/studien-untersuchungen/studien/suchtpraevention/rauchen-bei-jugendlichen-und-jungen-erwachsenen-in-deutschland-2018/

Marktbeobachtung: E-Zigaretten (UK)

STS Smoking Toolkit Study

ADDICTION SSA SOCIETY FOR THE STUDY OF ADDICTION

Research Report | Open Access

Association of prevalence of electronic cigarette use with smoking cessation and cigarette consumption in England: a time–series analysis between 2006 and 2017

Emma Beard, Robert West, Susan Michie, Jamie Brown

First published:16 October 2019 | https://doi.org/10.1111/add.14851 | Citations: 9

*„The **increase in prevalence of e-cigarette use** by smokers in England has been **positively associated with an increase in success rates of quit attempts and overall quit rates**"*

*With 7 million current smokers in 2017 and prevalence of current e-cigarette use at 18.5% in that **year…this would equate to 69 930 additional past-year smokers** who report that they are **no longer smoking** as a consequence of e-cigarettes **in 2017**."*

Beard et al. Association of prevalence of electronic cigarette use with smoking cessation and cigarette consumption in England: a time–series analysis between 2006 and 2017. Addiction. First published:16 October 2019 https://doi.org/10.1111/add.14851

Marktbeobachtung: Tabakerhitzer (Japan)

Research paper

PDF

Effect of IQOS introduction on cigarette sales: evidence of decline and replacement

Michal Stoklosa[1], Zachary Cahn[1], Alex Liber[1], Nigar Nargis[2], Jeffrey Drope[1]

Author affiliations

1. Economic and Health Policy Research, American Cancer Society, Atlanta, Georgia, USA
2. Economic and Health Policy Research, American Cancer Society, Washington, District of Columbia, USA

American Cancer Society®

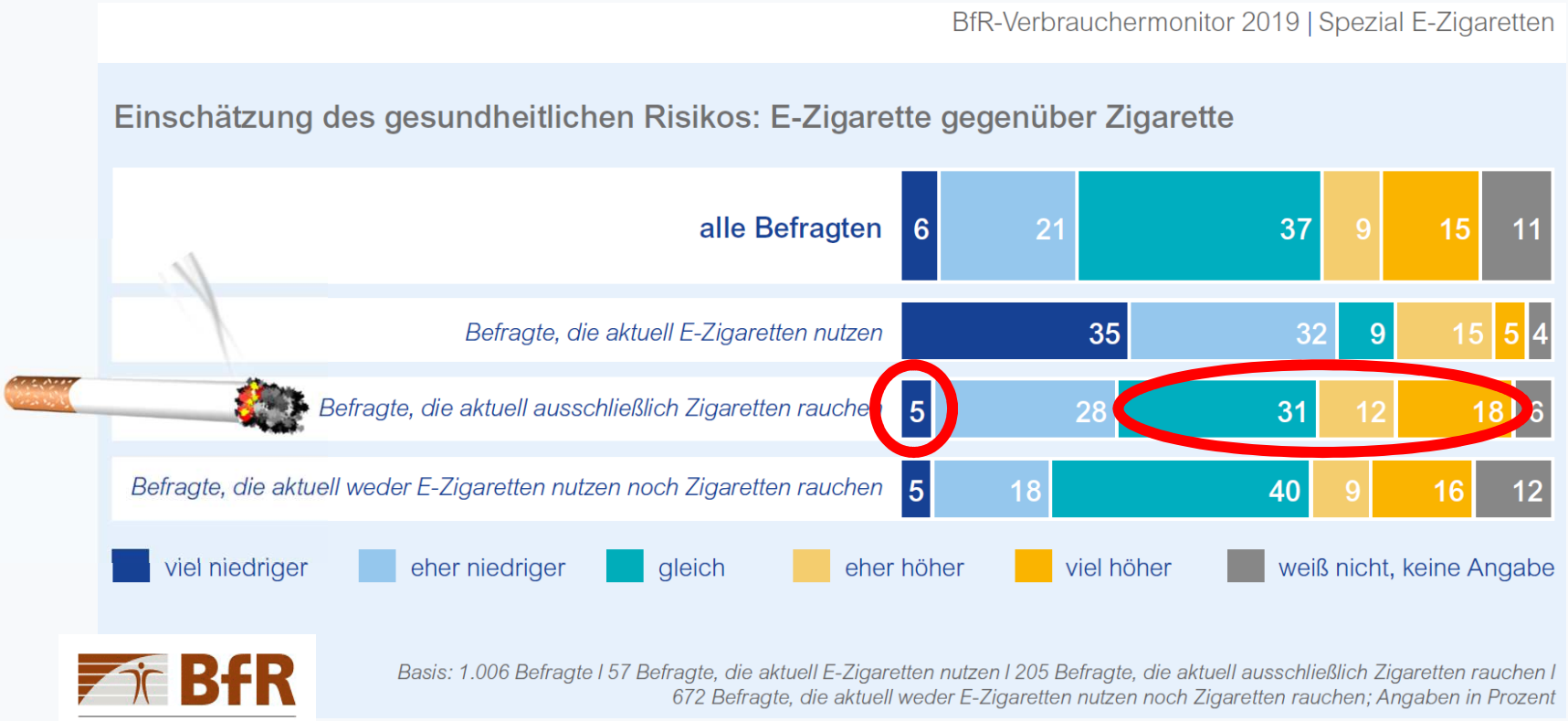
„Cigarette sales begin to substantially decline at the time of the introduction of IQOS in each of 11 Japanese regions."

*"The introduction of **IQOS likely reduced cigarette sales in Japan**."*

Stoklosa et al., Effect of IQOS introduction on cigarette sales: evidence of decline and replacement. *Tobacco Control* Published Online First: 17 June 2019. https://doi:10.1136/tobaccocontrol-2019-054998

Wie bekannt sind diese Risikobewertungen?

Kommt der aktuelle Stand der Risikobewertung an? Umfrage BfR



BfR Bundesinstitut für Risikobewertung

BfR-Verbrauchermonitor 2019 | Spezial E-Zigaretten (veröffentlicht im APR 2020)
https://www.bfr.bund.de/cm/350/bfr-verbrauchermonitor-2019-spezial-e-zigaretten.pdf

Fazit

- **Langzeitdaten** zu E-Zigaretten und Tabakerhitzern stehen aus und werden so schnell nicht verfügbar sein
- **Risikoabschätzung** kann einen wesentlichen Teil der Wissenslücken schließen
- Verschiedene Methoden der Risikoabschätzung für **E-Zigaretten** und **Tabakerhitzer** bestätigen deren Potenzial für Risikoreduktion
- **Differenzierte Risikokommunikation** an Raucher – ob durch Behörden der öffentlichen Gesundheit, durch Ärzte oder die Politik – sollte diese Ergebnisse berücksichtigen

Diskussionspunkte

- E-Zigaretten und Tabakerhitzer sind nach aktueller Risikoeinschätzung weniger schädlich als fortgesetztes Rauchen und daher schon jetzt geeignet, einen Beitrag zur Risikoreduktion beim Rauchen zu leisten.

- Das heute schon vorhandene Wissen zur Risikoabschätzung sollte Teil einer umfassenden Tabakkontrollstrategie werden.

- *kontakt: martin.storck@klinikum-karlsruhe.de*