

Möglichkeiten zur Risikoabschätzung von E- Zigaretten und Tabakerhitzern

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Interessenkonflikte

Keine

Warum Risiko-Bewertung?

- Pragmatische Ergänzung für Langzeitstudien (Minstdauer 20 Jahre)
- Vergleich des Schadenspotentials neuer mit herkömmlichen Produkten

Dilemma:

Ist die Empfehlung von stark Risiko-reduzierten (aber nicht: Risiko-freien) Produkten medizinisch/politisch vertretbar?
Müssen die Informationen Raucher die für eine Entwöhnung nicht erreicht werden können (80%) nicht verfügbar gemacht werden?



Risiko-Bewertung als Methode

Gründe für eine Risikobewertung?

Produktvielfalt, Orientierungshilfe, Fehlen von Langzeitdaten

Ansätze der Risikobewertung

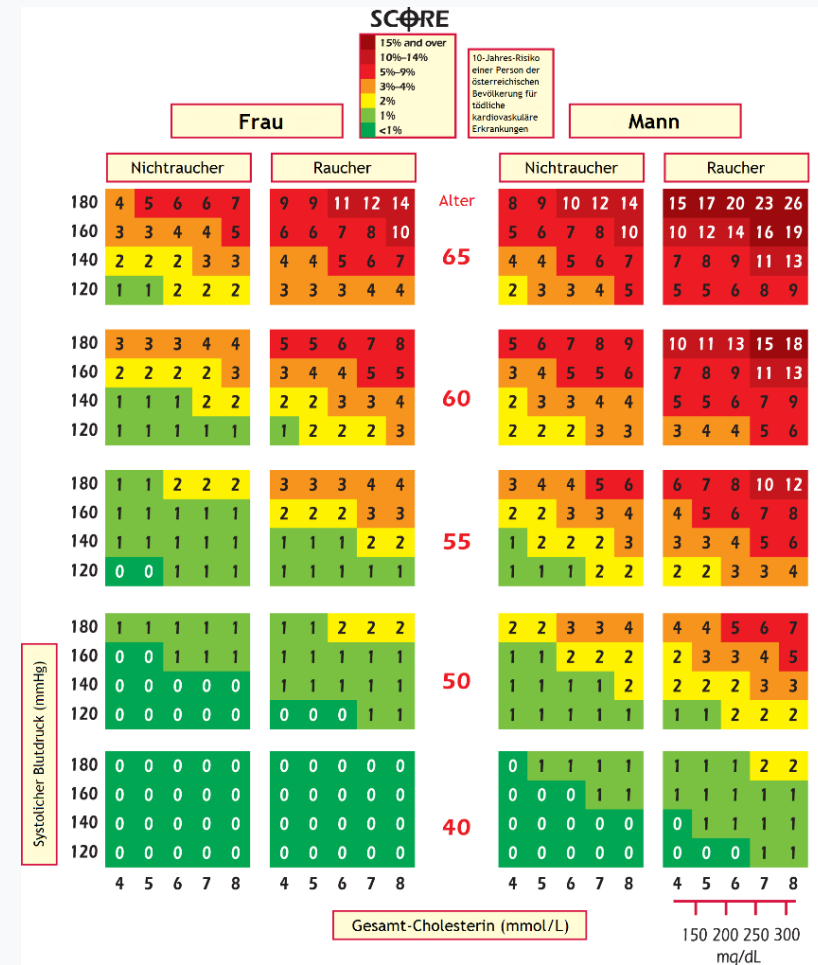
Toxikologische Analysen, Mathematische Verfahren

Zellkulturforschung, Literatur-Review, Marktbeobachtung

Wie bekannt sind Risikobewertungen?

Umfragen...

Rauchen ist in allen kardiovaskulären Risikoscores ein unabhängiger Risikofaktor...



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

Rauchen und Herz-Kreislaufkrankungen – Tabakrauch (nicht: Nikotin) ist das schädliche Agens

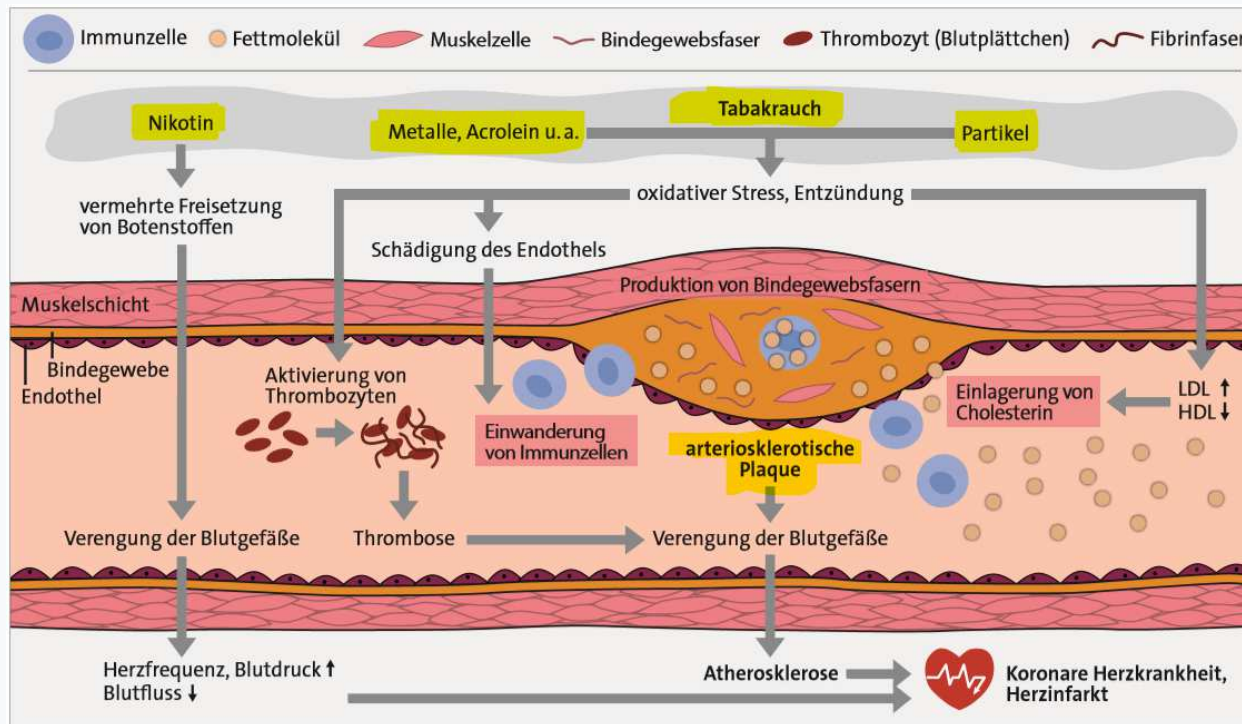


Abbildung 1: Mechanismen, über die Rauchen Herz-Kreislaufkrankungen verursacht^{7,12}. Darstellung: Deutsches Krebsforschungszentrum, Stabsstelle Krebsprävention, 2018

Moderators of real-world effectiveness of smoking cessation aids: a population study

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³Department of Clinical, Educational and Health Psychology, University College London, UK

Background/Aims—Understanding whether and how far smokers' characteristics influence the effectiveness of treatment may be important for tailoring recommendations on cessation aids to those most likely to help the user achieve abstinence. This study aimed to estimate the effectiveness of commonly-used smoking cessation aids and test whether their effectiveness differs according to cigarette addiction, socioeconomic status, age, or sex.

Design—Correlational design using cross-sectional survey data collected monthly between 2006 and 2018.

Setting—England.

Participants—18,929 adults (aged ≥ 16 y, 52.0% female) who had smoked within the previous 12 months and had made at least one quit attempt during that period.

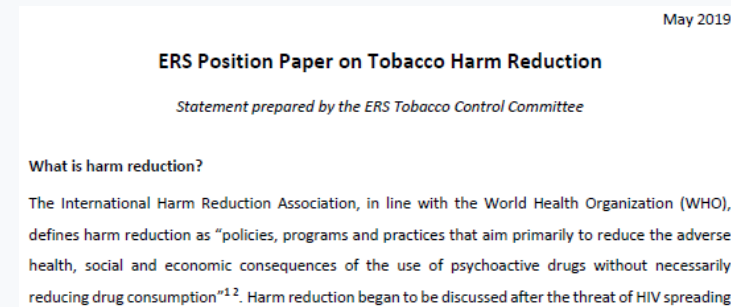
Measurements—The outcome was self-reported abstinence from quit date to survey. Independent variables were self-reported use during the most recent quit attempt of: prescription nicotine replacement therapy (NRT), NRT over-the-counter, varenicline, bupropion, e-cigarettes, face-to-face behavioural support, telephone support, written self-help materials, websites, and hypnotherapy. Moderators were cigarette addiction, social grade, age, and sex.

Findings—After adjustment for covariates and use of other cessation aids, users of e-cigarettes (OR=1.95, 95%CI:1.69-2.24) and varenicline (OR=1.82, 95%CI:1.51-2.21) had significantly higher odds of reporting abstinence than those who did not report use of these cessation aids. Use of prescription NRT was associated with increased abstinence in older (≥ 45 y) (OR=1.58, 95%CI: 1.25-2.00) but not younger (< 45 y) smokers (OR=1.09, 95%CI:0.85-1.42). Use of websites was associated with increased abstinence in smokers from lower (OR=2.20, 95%CI:1.22-3.98) but not higher social grades (OR=0.74, 95%CI:0.40-1.38). There was little evidence of benefits of using other cessation aids.

Kritik am Fehlen von Langzeitstudien – ERS (2019)



*“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*



*“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

Internationale Expertengruppe / MCDA (2014)

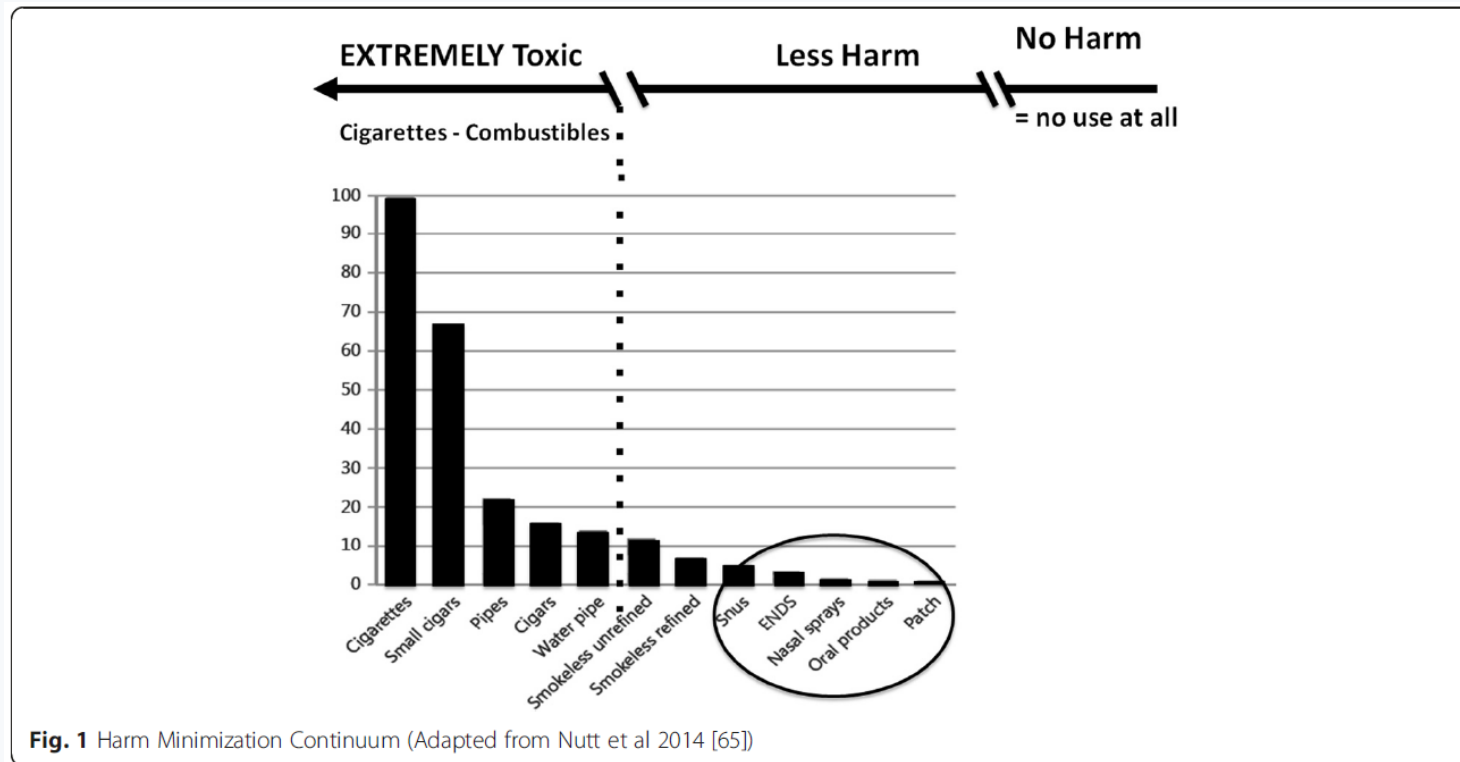
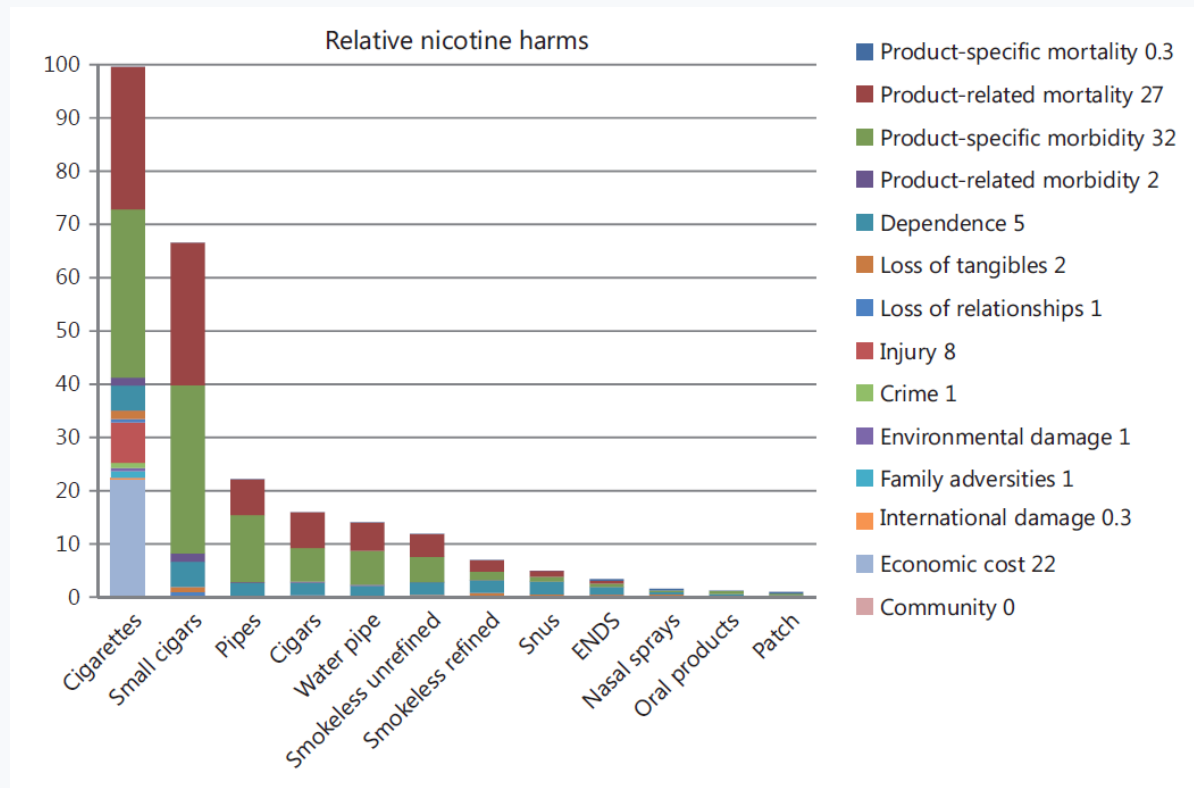


Fig. 1 Harm Minimization Continuum (Adapted from Nutt et al 2014 [65])

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

Internationale Expertengruppe / 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

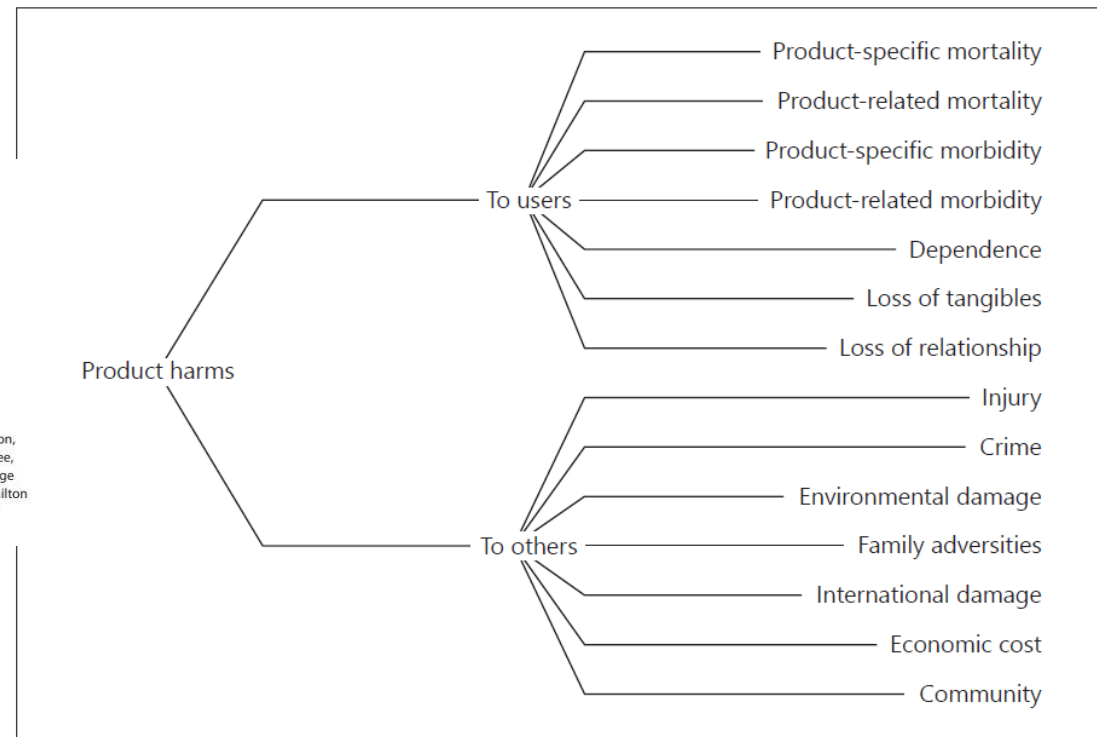
Internationale Expertengruppe / MCDA (2014)

Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach

David J. Nutt^a Lawrence D. Phillips^b David Balfour^f H. Valerie Curran^c
Martin Dockrell^d Jonathan Foulds^h Karl Fagerstromⁱ Kgosi Letlape^k
Anders Milton^j Riccardo Polosa^l John Ramsey^e David Sweanor^g

^aImperial College London, UK; ^bDepartment of Management, London School of Economics and Political Science, and Facilitations Ltd., UK; ^cUniversity College London, UK; ^dAction on Smoking and Health London, UK; ^eTICTAC Communications Ltd. at St. George's, University of London, London, UK; ^fUniversity of Dundee, Dundee, UK; ^gFaculty of Law, University of Ottawa, Ottawa, Canada; ^hPennsylvania State University, College of Medicine, Hershey Pa., USA; ⁱFagerström Consulting, Vaxholm, Sweden; ^jWorld Medical Association, Milton Consulting, Stockholm, Sweden; ^kWorld Medical Association, Johannesburg, South Africa; ^lCentre for the Prevention and Cure of Tobacco Use, University of Catania, Catania, Italy

Fig. 1. Evaluation criteria organized by harms to users and harms to others.



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

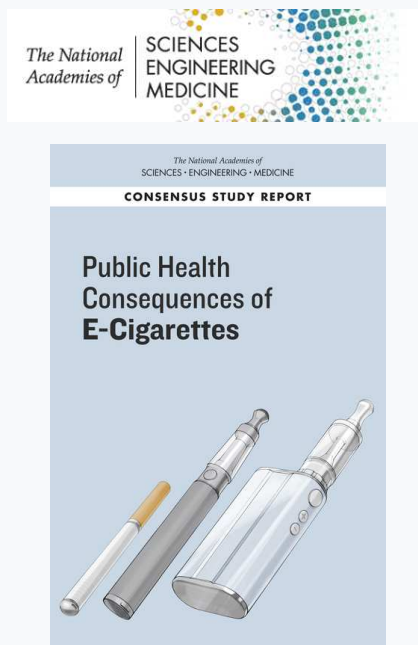


*“An expert review of the latest evidence concludes that **e-cigarettes** are around **95% safer** than smoked tobacco and they can help smokers to quit.”*

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>

Literatur-Review (NASEM, USA, 2018)

E-Zigaretten



Conclusion 5-3. There is **substantial evidence** that except for nicotine, under typical conditions of use, exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible tobacco cigarettes.

Conclusion 18-1. There is **conclusive evidence** that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.

Conclusion 18-2. There is **substantial evidence** that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems.

The **evidence about harm reduction** suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes.

Drogen- und Suchtbericht der Bundesdrogenbeauftragten, 05. NOV 2019: Unterscheidung zwischen Produkten MIT und OHNE Tabakverbrennung

	Tabakzigaretten	Wasserpfeifen	Tabakerhitzer	E-Zigaretten
Schadstoffgehalte im Rauch, bzw. in den Emissionen	Sehr hoch <i>Counts et al., 2005</i> (pro Zigarette)	Sehr hoch <i>Shihadeh et al., 2015</i> (pro Wasserpfeife)	Deutlich reduziert <i>Schaller et al., 2016</i> <i>Mallock et al., 2018</i> (pro Stick)	Stark reduziert <i>Goniewicz et al., 2014</i> (für 15 Züge)
Formaldehyd	29 - 130 µg	36 - 630 µg	4,5 - 5,5 µg	0,20 - 5,61 µg
Acetaldehyd	930 - 1.540 µg	120 - 2.520 µg	179 - 219 µg	0,11 - 1,36 µg
1,3-Butandien	77 - 117 µg	n.d.	bis zu 0,3 µg	n.d.
Benzol	50 - 98 µg	271 µg	0,64 - 0,65 µg	n.d.
Nikotin	1,1 - 2,7 mg	0,01 - 9,29 mg (bei Verwendung von Holzkohle zur Beheizung)	1,1 - 1,32 mg	variabel (u.a. abhängig vom Gerät und vom Gehalt im Liquid)
Suchtpotential	Sehr hoch	Sehr hoch	Sehr hoch	Vorhanden (nikotinhaltige Produkte)
		Wasserpfeifen werden von Jugendlichen oft nur zu besonderen Anlässen (Feiern) genutzt und eignen sich weniger für den täglichen Gebrauch		Nikotingehalte können ähnlich hoch wie im Tabakrauch sein, aber suchstverstärkende Pyrolyseprodukte treten nicht auf
Gesundheitliche Risiken	Sehr hoch	Hoch	Vorhanden	Vorhanden
		Tägliches Rauchen einer Wasserpfeife führt zu ähnlichen Gesundheitsrisiken wie ein moderater Zigarettenkonsum. (etwa zehn Zigaretten pro Tag) BfR-Stellungnahme 034/2016	Für eine zuverlässige Bewertung, inwieweit sich geringe Schadstoffgehalte auf gesundheitliche Risiken auswirken, fehlen noch geeignete Modelle.	Gesundheitsrisiken können weitgehend minimiert werden und hängen vom Gerät, den Inhaltsstoffen der Liquids und den Betriebsbedingungen ab. Zu den Risiken einer langfristigen Nutzung besteht Klärungsbedarf.

Quelle: BfR 2019, im Auftrag der Drogenbeauftragten der Bundesregierung

Drogen- und Suchtbericht der Bundesdrogenbeauftragten, (05. NOV 2019)
<https://www.drogenbeauftragte.de/presse/pressekontakt-und-mitteilungen/2019/iv-quartal/drogen-und-suchtbericht-2019-erschienen.html?L=0>

Chochrane-Review 14.10. 2020

The screenshot shows the Cochrane Library website interface. At the top, there is a search bar with the text 'Title Abstract Keyword' and buttons for 'Browse' and 'Advanced search'. Below the search bar is a navigation menu with options like 'Cochrane Reviews', 'Trials', 'Clinical Answers', 'About', and 'Help'. A banner below the menu says 'Explore new Cochrane Library features here.' Another banner below that says 'We noticed your browser language is German.' The main content area features the title 'Electronic cigarettes for smoking cessation' and a list of authors: Jamie Hartmann-Boyce, Hayden McRobbie, Nicola Lindson, Chris Bullen, Rachna Begh, Annika Theodoulou, Caitlin Notley, Nancy A Rigotti, Tari Turner, Ailsa R Butler, and Peter Hajek. A red arrow points to the 'New search' button.

50 Studien, 26 RCT'S, n=12430

Nicotine e-cigarettes probably do help people to stop smoking for at least six months. They probably work better than nicotine replacement therapy and nicotine-free e-cigarettes.

They may work better than no support, or behavioural support alone, and they may not be associated with serious unwanted effects.

However, we need more, reliable evidence to be confident about the effects of e-cigarettes, particularly the effects of newer types of e-cigarettes that have better nicotine delivery.

<https://doi.org/10.1002/14651858.CD010216.pub4>

Schadstoff-Messung – Tabakerhitzer (2018)

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	93.0 ± 8.5–154.0 ± 15.3	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

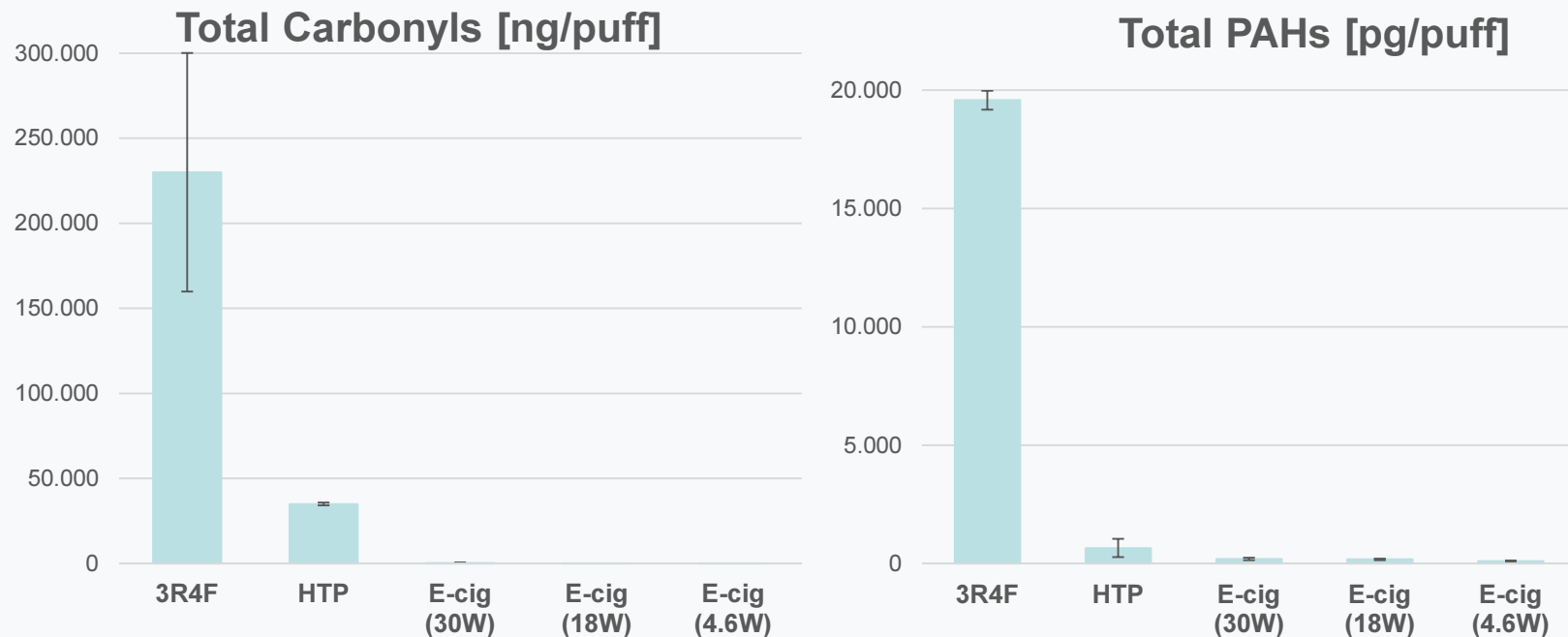
„...**Tabakerhitzer ... erhebliche Reduktion** von gesundheitsschädlichen Emissionen (**80–99 %**) im Vergleich zu ... **Tabakzigaretten**“ ²

„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).

(2) Pieper et al., Tabakerhitzer als neues Produkt der Tabakindustrie: Gesundheitliche Risiken; Bundesgesundheitsblatt, 04 OKT 2018, <https://doi.org/10.1007/s00204-018-2215-y>
<https://doi.org/10.1007/s00103-018-2823-y>

Schadstoffmessungen (pro Zug) im Vergleich Zigaretten vs. Vaping



Dusautoir et al., Comparison of the chemical composition of aerosols from heated tobacco products, electronic cigarettes and tobacco cigarettes and their toxic impacts on the human bronchial epithelial BEAS-2B cells, Journal of Hazardous Materials, Volume 401, 2021, 123417, ISSN 0304-3894, <https://doi.org/10.1016/j.jhazmat.2020.123417>

Carbonyle = Aldehyde (u.a. Formaldehyd, Acetaldehyd, usw.)

PAHs = Polyzyklische Kohlenwasserstoffe

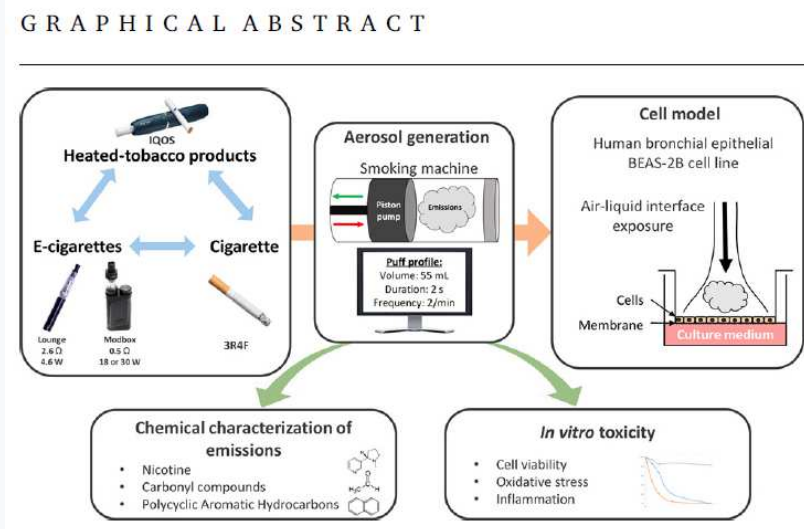
Effekt von Verbrennungszigaretten(3R4F) vs. Vaping auf humane Bronchial - Epithelzellen



Comparison of the chemical composition of aerosols from heated tobacco products, electronic cigarettes and tobacco cigarettes and their toxic impacts on the human bronchial epithelial BEAS-2B cells

Romain Dusautoir^a, Gianni Zarcone^a, Marie Verrièle^b, Guillaume Garçon^a, Isabelle Fronval^b, Nicolas Beauval^a, Delphine Allorge^a, Véronique Riffault^b, Nadine Locoge^b, Jean-Marc Lo-Guidice^a, Sébastien Anthérieu^{a,*}

^a Univ. Lille, CHU Lille, Institut Pasteur de Lille, ULR 4483, IMPECS - IMPact de l'Environnement Chimique sur la Santé humaine, F-59000, Lille, France
^b IMT Lille Douai, Univ. Lille, SAGE, F-59000, Lille, France



Romain Dusautoir, Gianni Zarcone, Marie Verrièle, Guillaume Garçon, Isabelle Fronval, Nicolas Beauval, Delphine Allorge, Véronique Riffault, Nadine Locoge, Jean-Marc Lo-Guidice, Sébastien Anthérieu, Comparison of the chemical composition of aerosols from heated tobacco products, electronic cigarettes and tobacco cigarettes and their toxic impacts on the human bronchial epithelial BEAS-2B cells, Journal of Hazardous Materials, Volume 401, 2021, 123417, ISSN 0304-3894, <https://doi.org/10.1016/j.jhazmat.2020.123417>

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](#)

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Mittleres lebenslanges Krebsrisiko im Verhältnis zu Zigarettenrauch

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



Krebs-Risiko und kardiovasukäres Risiko / EC / HTP vs. Zigaretten

$$\text{Cancer potency}_i = \sum_{j=1}^n IUR_j C_{ij},$$

$$\text{Lifetime cancer risk}_i = \frac{DAI_i}{DBV} \times \text{cancer potency}_i,$$

For cigarettes and stick-type HTPs, DAI was determined as follows:

$$DAI_i = \text{puff volume} \times \text{puff number}_i \times DC_i,$$

IUR
inhalation unit risk
1 $\mu\text{g} / \text{m}^3$ lifetime exposure

DAI
daily aerosol intake

DBV
daily breathed volume

DC
daily consumption

Krebs-Risiko EC / HTP vs. Zigaretten

Logarithmische Darstellung!!

Archives of Toxicology

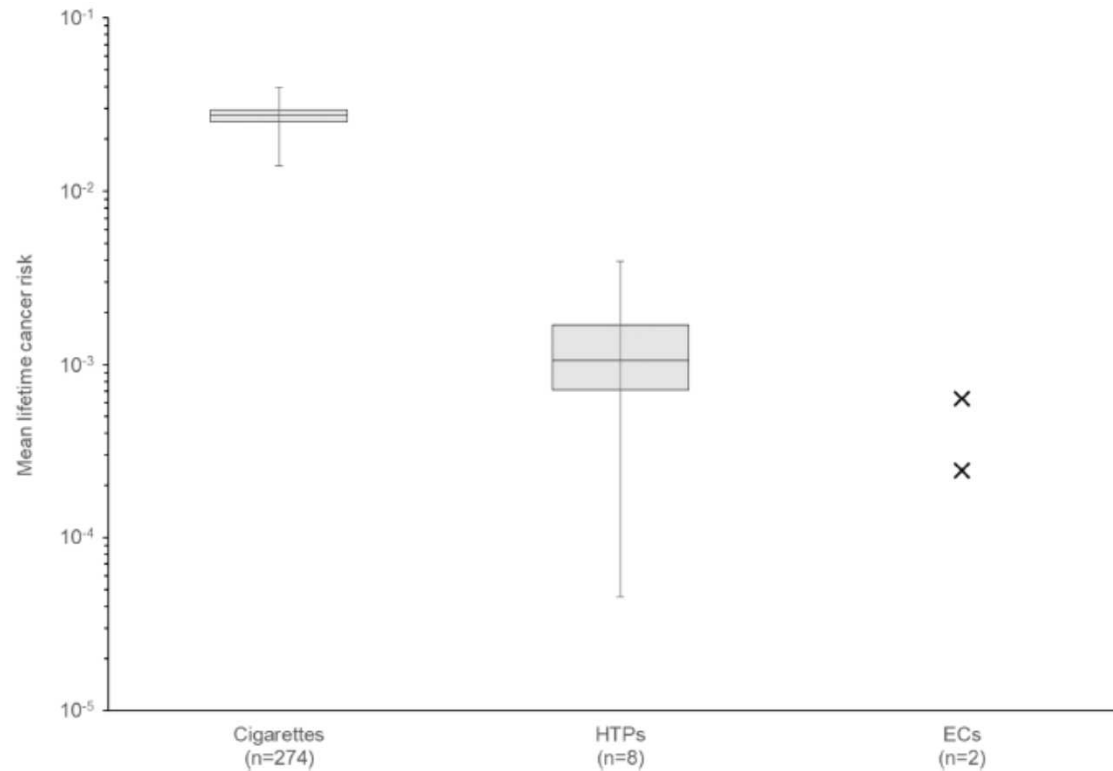
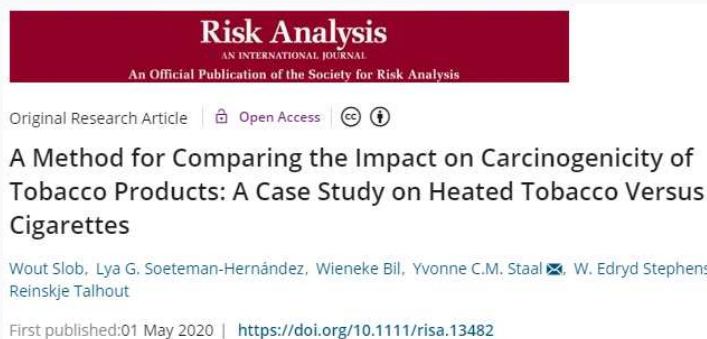


Fig. 1 Mean lifetime cancer risk index for cigarettes and HTPs based on ISO intense smoking regime emissions and for closed-system ECs based on CRM 81/ISO 20,768 aerosol emissions

Archives of Toxicology

<https://doi.org/10.1007/s00204-020-02924-x>

Modellierung: Krebspotenzial (2020) – Beispiel Tabakerhitzer



- 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



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Research paper

Potential deaths averted in USA by replacing cigarettes with e-cigarettes 

David T Levy¹, Ron Borland², Eric N Lindblom³, Maciej L Goniewicz⁴, Rafael Meza⁵, Theodore R Holford⁶, Zhe Yuan⁷, Yuying Luo⁷, Richard J O'Connor⁴, Raymond Niaura⁸, David B Abrams^{1, 8}

Article Text

Article info

Citation Tools

PDF

Aufsummierte Langzeiteffekte bis 2100, wenn alle Raucher auf EZ umsteigen würden.

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/Umfragen (Deutschland, 2019)



Rauchverhalten unter 12- bis 17- Jährigen / 30 Tage-Prävalenzen

- 7,7 % Wasserpfeife
- 6.6% Tabakzigarette
- 4,1 % E-Zigarette
- 0,1 % Tabakerhitzer

Marktbeobachtung: E-Zigaretten (UK)



ADDICTION SSA SOCIETY FOR THE STUDY OF ADDICTION

Research Report | Open Access | CC | i

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

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



Michal Stoklosa¹, Zachary Cahn¹, Alex Liber¹,
Nigar Nargis², Jeffrey Drope¹

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American Cancer Society, Washington,
District of Columbia, USA



*„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.“*

Kommt der aktuelle Stand der Risikobewertung an?

BfR-Verbrauchermonitor 2019 | Spezial E-Zigaretten

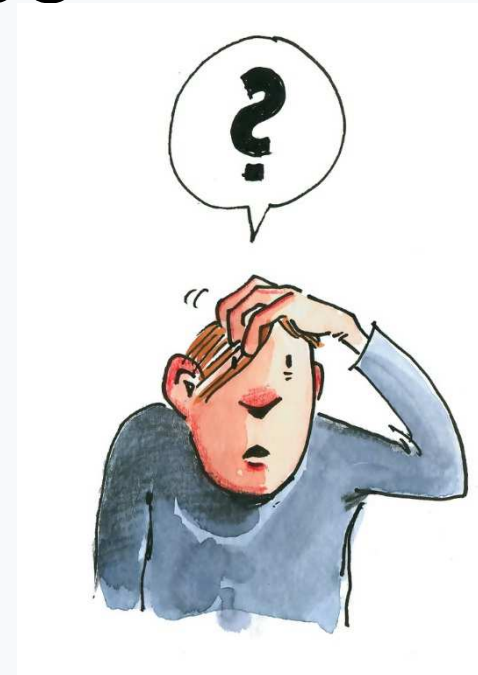
Einschätzung des gesundheitlichen Risikos: E-Zigarette gegenüber Zigarette



Fazit

- ▶ **Langzeitdaten** zu E-Zigaretten und Tabakerhitzern sind naturgemäß nicht vorhanden, dies darf aber Innovationen nicht verhindern.
- ▶ **Risikoabschätzung** inkl. Marktanalysen können einen Teil der Wissenslücken schließen
- ▶ **Toxikologische Messungen und mathematische Modelle** erlauben die Berechnung von Krebsrisiken anhand standardisierter Verfahren
- ▶ **EC und HTP** sind mit einem ca 90-99% Risikoreduktion für Krebserkrankungen in diesen Modellen assoziiert
- ▶ EC sind in **klinischen Studien** ein geeignetes Hilfsmittel zur Rauchentwöhnung (Cochrane Review 2020).

Wie bekannt sind diese Risikobewertungen?



Eine **differenzierte Risikokommunikation** an Raucher – ob durch Behörden der öffentlichen Gesundheit, durch Ärzte, Fachgesellschaften oder Gesundheitsspolitiker – sollte diese Erkenntnisse unbedingt berücksichtigen