Inferences beyond a claim: a typology of potential halo effects related to modified risk tobacco product claims

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ABSTRACT

When tobacco products are marketed with modified risk tobacco product (MRTP) claims, consumers may infer additional health benefits not directly stated in the claims. We propose a typology of seven potential ‘halo effects’ (ie, an unintended generalisation) that may occur with MRTP marketing. Evidence currently exists that some of these types of halo effects occur after exposure to MRTP claims. These generalisations are likely unavoidable in certain situations and may sometimes produce accurate inferences. However, some halo effects may be problematic if they mislead consumers into false inferences and result in unintended consequences that have a negative public health impact (eg, reinitiation, dual tobacco product use). To help mitigate unintended consequences and guide regulatory decisions about MRTP claims, we encourage researchers studying MRTP claims to test for halo effects. Regulatory agencies should include potential unintended consequences associated with halo effects when assessing individual-level and population-level health impacts of MRTP claims. Moreover, tobacco manufacturers should be required to report both premarket and postmarket surveillance of halo effects to relevant regulatory agencies. If MRTP claims are to play a role in tobacco harm reduction, it is imperative that they be communicated and interpreted in ways that minimise harms and maximise public health benefits.

INTRODUCTION

Many scientists and public health regulatory agencies across several countries have stated that the risks of different categories of tobacco products are not equal, but instead lie along a continuum.1–5 While combusted tobacco products (eg, cigarettes, cigars) are believed to present the greatest risks, non-combusted inhaled products, such as e-cigarettes, and smokeless products, such as snus, are believed to present lower risks.2 As such, public health groups, regulatory agencies and tobacco companies have begun using or proposing the use of claims that indicate a tobacco product poses ‘modified risk.’ In some countries, modified risk tobacco product (MRTP) claims are currently being used. For instance, in South Korea, IQOS, a new heated product, is being marketed with claims of reduced exposure (‘Harmful chemicals on average decreased by 90%—no solid ultrafine particles’).9 Canada has announced plans to allow modified risk labels for e-cigarettes.7,8 In the UK, e-cigarette manufacturers are permitted to make health claims.9 Further, public health organisations in the UK, such as Public Health England and Cancer Research UK, have stated that e-cigarettes are less-harmful than cigarettes.3,10

In the USA, MRTP claims can be authorised by the Food and Drug Administration (FDA) through a process outlined in the Family Smoking Prevention and Tobacco Control Act (TCA).11 12 Specifically, Section 911 of the TCA establishes criteria by which tobacco manufacturers may be authorised to market their tobacco products with MRTP claims. The TCA describes how both (1) risk modification (eg, reduced disease risk) and (2) exposure modification (eg, reduced user exposure to harmful chemicals or constituents) claims can be authorised by FDA. Tobacco manufacturers must submit evidence to FDA demonstrating that the potential MRTP would ‘reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products’, and that authorising the proposed claim would ‘benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.’12

In October 2019, FDA authorised Swedish Match’s proposed MRTP claim for eight of its General Snus products (claim: ‘Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema and chronic bronchitis’).13 FDA also authorised the claim ‘Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body’s exposure to harmful or potentially harmful chemicals’ (among other related language) in July 2020 for Philip Morris International’s (PMI) heated tobacco product IQOS.14 As of July 2020, MRTP applications have been accepted for review and made public by FDA for Camel Snus,15 Copenhagen moist snuff16 and 22nd Century’s very low nicotine (VLN) cigarettes.17

To help guide its decision making on whether to authorise MRTP claims, FDA is prioritising not only scientific evidence supporting the accuracy of the claim (eg, research assessing chemical exposure and biomarkers of harm), but also consumer perceptions and understanding of the claim to ensure that the public is not being misled. Specifically, FDA has expressed concerns that MRTP claims may produce halo effects, such that
Typology of halo effects

In this Special Communication, we catalogue potential halo effects that may result from advocating claims communicating relative risk (or exposure) information about tobacco products (eg, MRTP claims). The potential halo effects are extensively documented in the context of food claims. The potential for halo effects extends beyond the US regulatory environment, the typology of halo effects and examples detailed here may be most relevant to MRTP claims in the USA, the potential for halo effects extends beyond the US regulatory environment and can be studied wherever such claims are used.

We use the term 'halo effect' very broadly, and here it refers to generalisations made by heuristic thinking which involves use of simple rules and cognitive shortcuts, many of which result in inaccurate perceptions, and biased judgements and decisions. Generalisations made by heuristic thinking are likely unavoidable in certain situations, halo effects may be problematic if they mislead consumers into false inferences and decisions. Generalisations, the use of heuristics and cognitive shortcuts may be problematic if they mislead consumers into false inferences and decisions. Generalisations, the use of heuristics and cognitive shortcuts may be problematic if they mislead consumers into false inferences and decisions. Generalisations, the use of heuristics and cognitive shortcuts may be problematic if they mislead consumers into false inferences and decisions.

### Table 1: Typology of halo effects relevant to MRTP claims

<table>
<thead>
<tr>
<th>Type</th>
<th>Applies to</th>
<th>Claim generalised to</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure-to-exposure halo effect</td>
<td>Specific exposure claims.</td>
<td>Specific exposures not stated in claim.</td>
<td>Claim describing reduced exposure to carbon monoxide inferred to mean reduced exposure to formaldehyde.</td>
</tr>
<tr>
<td>Risk-to-risk halo effect</td>
<td>Specific risk claims.</td>
<td>Specific disease risks not stated in claim.</td>
<td>Claim describing reduced risk of lung cancer inferred to mean reduced risk of heart disease.</td>
</tr>
<tr>
<td>Exposure-to-risk halo effect</td>
<td>Exposure claims (specific or general).</td>
<td>Disease risks (specific or general).</td>
<td>Claim describing reduced exposure to carbon monoxide inferred to mean reduced risk of lung cancer.</td>
</tr>
<tr>
<td>Risk-to-exposure halo effect</td>
<td>Risk claims (specific or general).</td>
<td>Exposures (specific or general).</td>
<td>Claim describing reduced risk of lung cancer inferred to mean reduced exposure to carbon monoxide.</td>
</tr>
<tr>
<td>Exclusive-to-dual use halo effect</td>
<td>Claims describing benefits (exposure or risk) of completely switching from one product (eg, cigarettes) to the MRTP.</td>
<td>Partial switching/dual use.</td>
<td>Claim stating that switching completely from cigarettes to MRTP will reduce risk of lung cancer inferred to mean that partially switching also reduces lung cancer risk.</td>
</tr>
<tr>
<td>Similar product halo effect</td>
<td>Claims for a single product that has rival products in the same product category or similar products in a different category.</td>
<td>Competing brands within the same product category or similar products in a different category that have not been authorised to make the MRTP claim.</td>
<td>Claim describing reduced exposure benefits of IQOS inferred to mean that Glo, a competing heated tobacco product, also has reduced exposure benefits.</td>
</tr>
<tr>
<td>Brand halo effect</td>
<td>Claims for a single product that shares branding with products in other product categories, or the same product category.</td>
<td>Product with same brand name within a different product category or same product category that has not been authorised to make the MRTP claim.</td>
<td>Reduced risk claim for Camel Snus is inferred to mean that Camel cigarettes are also reduced risk.</td>
</tr>
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</table>

MRTP, modified risk tobacco product.
offers less exposure to formaldehyde. Such an inference would be indicative of what we refer to as the exposure-to-exposure halo effect.

With exposure-to-exposure halo effects, consumers’ evaluations may rely on an exposure reduction heuristic, where they assume that if one exposure is reduced, other exposures are reduced. Importantly, exposure-to-exposure halo effects occur with claims stating reductions in specific exposures (eg, carbon monoxide), and not with claims describing exposure reductions in more general claims (eg, ‘less exposure to harmful chemicals’). While general exposure claims are intended to communicate that many (or potentially all) exposures are reduced, specific exposure claims are intended to identify precise exposure reduction benefits. For instance, the three exposure claims submitted in the MRTP application for VLN cigarettes are specific, and all refer to reductions in exposure to nicotine (eg, ‘95% less nicotine’). Therefore, if a reduced nicotine claim (eg, ‘95% less nicotine’) caused consumers to infer that smoking VLN cigarettes will also reduce exposure to carbon monoxide, this would be indicative that an exposure-to-exposure halo effect has occurred. While we are unaware of any research evaluating perceptions of specific chemicals or constituents following exposure to a specific exposure claim, research has found that nicotine-free claims cause consumers to perceive that levels of tar and chemicals are reduced. Additionally, this halo effect may be similar to those observed in food labelling research where claims about the reduction of one exposure (eg, ‘no cholesterol’) are assumed to reduce exposure to another food component (eg, fat).

Risk-to-risk halo effect

Similar to the exposure-to-exposure halo effect, the risk-to-risk halo effect may occur when a claim describing reduction in a specific disease risk(s) is generalised to other specific diseases not included in the claim. For instance, a claim stating ‘less risk of lung cancer’ may be inferred to also mean ‘less risk of heart disease.’ If such a generalisation has occurred, consumers may be relying on a disease risk reduction heuristic, where consumers infer that if one disease risk is reduced, other disease risks are also reduced. As with the exposure-to-exposure halo effect, risk-to-risk halo effects apply to claims stating reductions in specific disease risk (eg, less risk of lung cancer), and not general disease risk reduction (eg, less risk of tobacco-related diseases).

Evidence suggestive of a risk-to-risk halo effect was found in research by Swedish Match that was included in the company’s revised MRTP application to the US FDA for General Snus. Swedish Match proposed the following claim that lists six diseases: ‘Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema and chronic bronchitis.’ The proposed claim did not describe a reduced risk of ‘gum disease;’ however, Swedish Match found that the claim significantly reduced the perceived risk of gum disease associated with using General Snus. Thus, viewing an MRTP claim stating reductions in specific disease risks may cause consumers to infer risk of other diseases not stated in the claim are also reduced. Future research could explore whether claims that list a greater number of conditions are more vulnerable to unintended/inaccurate halo effects than those that only list one or two (eg, ‘IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer but not all other tobacco-related diseases’).

Exposure-to-risk halo effect

Consumers may also generalise between the two types of MRTP claims (ie, risk and exposure modification). For instance, MRTP claims describing reduced exposure to chemicals may be interpreted to mean reduced disease risk. We refer to this type of halo effect as the exposure-to-risk halo effect. The exposure-to-risk halo effect may be driven by a reduced exposure equals reduced risk heuristic, where a reduction in exposure is inferred to also reduce disease risk. For example, this type of halo effect would occur if an MRTP claim describing ‘reduced exposure to harmful chemicals’ is interpreted to mean ‘reduced risk of tobacco-related diseases.’

Unlike the exposure-to-exposure or risk-to-risk halo effects, the exposure-to-risk halo effect may occur with both general (reduced exposure to harmful chemicals interpreted to also mean reduced risk of smoking-caused diseases) or specific claims (reduced exposure to carbon monoxide interpreted to also mean reduced risk of lung cancer). The TCA (Section 911 (g) (2) (B) (iii) (I)) and FDA’s Draft Guidance for tobacco manufacturers both require that MRTP claims describing an exposure modification must not be misinterpreted as a risk modification. Thus, evaluating consumer perceptions for the exposure-to-risk halo effect is essential to FDA review and authorisation of MRTP claims describing reduced exposure.

The exposure-to-risk halo effect is of concern because, in response to an exposure claim, consumers may infer disease risk reduction that has not been demonstrated, causing spurious consumer perceptions. This could happen through at least three scenarios. First, consumers may infer risk reduction of a disease that is unrelated to the exposure modification. For instance, if an MRTP claim describes ‘reduced exposure to nicotine’ (an exposure that causes addiction), consumers may falsely infer that risk of emphysema is reduced, even though emphysema development is not caused by nicotine exposure. Second, consumers may infer risk reduction for a disease that is associated with the exposure reduction claim, however, other exposures that are not reduced may maintain disease risk. For instance, over 70 carcinogenic compounds have been identified in cigarette smoke. Therefore, if switching completely from cigarettes to an MRTP reduces or eliminates exposure to one carcinogen, cancer risk may not appreciably be reduced if other carcinogens remain present. Third, once adequate scientific studies have been performed, it may be found that the amount of exposure reduction achieved by switching to an MRTP may not be large enough to reduce exposure below the ‘tipping point’ threshold for exposure-disease response. Thus, it is possible that a reduced exposure MRTP may expose consumers to levels of chemicals that are sufficient to cause disease, even though the exposure is reduced. In addition to these scenarios, consumers likely lack the complex understanding of exposure–risk relationships to correctly infer accurate risk reductions from exposure modification. After all, there are a multitude of tobacco-related diseases caused by smoking (eg, heart disease, cancer, emphysema), many physiological mechanisms of cigarette-induced harm, and thousands of chemicals in cigarette smoke.

To date, research evaluating responses to MRTP claims has found evidence of the exposure-to-risk halo effect. For instance, El-Toukhy et al found that experimental reduced
exposure MRTP claims for a heated tobacco product, e-cigarette and snus product were associated with lower perceived risks. Additionally, several studies have found that reduced nicotine claims, as well as additive-free claims, are misinterpreted to mean reduced disease risk. Finally, PMI’s own qualitative and quantitative studies submitted as part of the IQOS MRTP application indicated that consumers viewing exposure MRTP claims consistently reported reduced perceived risk beliefs.

However, FDA’s recent decision to authorise PMI’s proposed exposure claim (‘Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body’s exposure to harmful or potentially harmful chemicals’) for IQOS reveals that the presence of the exposure-to-risk halo effect does not automatically disqualify a proposed exposure claim. For instance, the Technical Project Lead document summarising FDA’s decision explains: ‘As noted above, although the studies in the applications were not sufficient to support the issuance of a risk modification order at this time, the totality of the evidence supports that risk reduction is reasonably likely to be demonstrated in subsequent studies. In other words, consumer understanding is in line with the relative health risks of the product that are reasonably likely.’ Thus, in the example of the IQOS MRTP application, FDA did not consider the exposure-to-risk halo effect problematic or misleading because reduced relative risks of IQOS (compared with cigarettes) are ‘reasonably likely.’

Risk-to-exposure halo effect

Similar to the exposure-to-risk halo effect, the reverse generalisation is also possible. Claims describing reduced disease risk may be interpreted to also mean reduced exposure to chemicals. We refer to this type of inference as the risk-to-exposure halo effect. For this type of halo effect, consumers may rely on a reduced risk equals reduced exposure heuristic.

Unlike the exposure-to-risk halo effect, the FDA has not publicly expressed concern about the risk-to-exposure halo effect in the USA, likely because risk reduction cannot be achieved without antecedent exposure reduction. However, the risk-to-exposure halo effect may still cause consumers to be misled if they infer reduced exposure to chemicals unrelated to the risk modification. For instance, a misleading risk-to-exposure halo effect may occur if an MRTP claim describing reduced risk of lung cancer is generalised to mean reduced exposure to carbon monoxide, an exposure that is not causally related to lung cancer. Experimental evidence of the risk-to-exposure halo effect has been found for claims about a heated tobacco product, e-cigarette and snus. For instance, researchers found that risk claims (e.g., ‘Suppose the FDA approves a label saying that Swedish snus is less harmful than cigarette’) resulted in significantly lower perceived chemical quantity compared with control.

Exclusive-to-dual use halo effect

The harm reduction potential of any MRTP relies on the assumption that smokers unable or unwilling to give up nicotine completely transition from cigarettes (or other combusted products) to the MRTP. Previous research suggests that partially switching from cigarettes to a non-combusted product (e.g., use of both e-cigarettes and cigarettes, or smokeless tobacco and cigarettes), also known as dual use, may not lead to a reduction in disease risk. Therefore, to realise the benefits described in an MRTP claim, smokers must become exclusive MRTP users. In many of the proposed MRTP claims that FDA is currently evaluating in the USA, switching language is included, such as ‘Smokers who switch completely...’ and ‘Switching completely...’ Other language implying complete switching has also been used, such as ‘Using General Snus instead of cigarettes...’

An exclusive-to-dual use halo effect would occur if MRTP claims, which are contingent on exclusive MRTP use, are incorrectly generalised to mean that partially switching to the MRTP (i.e., using cigarettes some of the time and the MRTP some of the time) will reduce risk or exposure. Such perceptions may be driven by a switching heuristic, where any amount of switching or product replacement/substitution is perceived to confer modified risk benefits. Past research by both tobacco companies and independent researchers has found that claims stating benefits from ‘switching completely’ are misinterpreted by some consumers to mean that partially switching from cigarettes to the MRTP offers benefits. Moreover, the exclusive-to-dual use halo effect is an issue that FDA has expressed concerns about. For instance, in briefing materials prepared for the Tobacco Product Scientific Advisory Committee (TPSAC) meeting to discuss the Camel Snus MRTP application, FDA researchers criticised the research included in the application for not providing ‘a robust assessment of perceptions of risk reduction from partially switching to Camel Snus.’

Similar product halo effect

If an MRTP claim is authorised for a single branded product within a product category, consumers may infer that the claim applies to all products within the product category, or possibly to similar products within a different product category. For instance, authorisation in the USA of the proposed MRTP claim for General Snus (‘Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema and chronic bronchitis’) may lead consumers to infer that the claim applies to all snus products. Moreover, consumers may generalise the claim to other types of smokeless tobacco products that resemble snus (e.g., pouch moist snuff). We refer to this type of generalisation as the similar product halo effect. Thus, membership into a product category (or similar product category) may serve as a heuristic.

While products within the same product category may have similar risks and exposures, such that some similar product halo effects may be accurate, this type of halo effect might be misleading in situations where significant product differences (e.g., constituent levels or other factors that affect product use) among products within the same category or similar products exist. For example, smokeless tobacco products sold in the USA have been shown to have significantly different product characteristics, including levels of free nicotine. Products containing higher levels of free nicotine may be more addictive for users compared with products that deliver lower levels of free nicotine. Varying levels of nicotine may affect frequency of product use, and these differences in product use behaviours may affect disease risks and exposures. Additionally, early monitoring of levels of tobacco-specific nitrosamines (TSNAs) in snus products sold in the USA revealed variation by brand, with at least one brand having levels of TSNAs comparable to that found in moist snuff.

Moreover, it seems plausible that an MRTP claim for snus may cause consumers to infer that the claim also applies to other portioned moist snuff products, due to their resemblance...
in appearance. Consumers may not yet understand important product differences between snus and moist snuff products. Snus and moist snuff products typically differ greatly with regard to levels of carcinogenic nitrosamines.\(^6\)

**Brand halo effect**

Most international tobacco manufacturers sell products spanning multiple tobacco product categories (eg, cigarettes, smokeless tobacco, e-cigarettes). Manufacturers frequently use similar branding across product categories. For instance, in addition to Marlboro branded cigarettes, Marlboro branded snus and heat sticks (used with the IQOS device) have been marketed. Similarly, Camel cigarettes and Camel Snus are available. The cross-marketing of brands across product categories may cause MRTP claims to be generalised across product categories to similarly branded products. Thus, a brand halo effect would occur if a claim is generalised to a product with the same brand name within a different product category. For instance, an MRTP claim made about Camel Snus (eg, reduced risk of disease) may be generalised to Camel cigarettes. In this example, once a brand name becomes associated with reduced risk or exposure, the brand name may become a heuristic.

Additionally, brand halo effects may occur for products within the same product category. For instance, while US Smokeless Tobacco (UST) submitted an MRTP application to FDA for Copenhagen Snuff Fine Cut, UST markets several other Copenhagen branded moist snuff products, which vary by flavour and cut. If authorised by FDA, the claim could only be used to market Copenhagen Snuff Fine Cut, and could not be used to market other varieties of Copenhagen. Evidence of the brand halo effect may occur if an MRTP claim for Copenhagen Fine Cut is generalised to other varieties of Copenhagen moist snuff. While we are not aware of research evaluating the brand halo effect for tobacco products, marketing research from other domains shows that perceptions of the central brand are easily transferred to brand extensions.\(^6\)\(^4\)\(^\)\(^1\)

**CONCLUSIONS**

Previous research has found that cigarettes marketed with claims of lower levels of tar\(^6\)\(^3\) and nicotine,\(^40\) absence of additives,\(^41\) and cigarettes made with organic tobacco\(^41\) create a false perception of reduced harm. These findings suggest that claims for these products are misleading consumers into making inaccurate inferences (ie, halo effects). In 2016, nine cigarette manufacturers and two tobacco industry trade organisations in the USA were found liable for violating the Racketeer Influenced and Corrupt Organisation Act, largely based on deceptive ‘low-tar’ cigarette marketing.\(^44\) Additionally, false consumer perceptions linked to tobacco company marketing practices are a major component to the TCA’s Findings, section 2 (eg, subsections (36–46)).\(^12\) While MRTP claims are intended to communicate reduced risk or exposure information, consumers may similarly overgeneralise the stated benefits by use of heuristics. Consequently, a variety of potential halo effects may be created by marketing with MRTP claims. While these generalisations are likely unavoidable in certain situations, halo effects have the potential to mislead consumers and promote biased judgements and decisions, which may result in unintended consequences.

Some halo effects may be more problematic than others with regards to promoting and sustaining tobacco risk behaviours. For instance, because it may substantially hinder consumers from taking steps to reduce their risk, the exclusive-to-dual use halo effect, which has potential to encourage dual-use, may be more concerning than the exposure-to-exposure halo effect. Further, the presence of halo effects should not automatically disqualify any proposed MRTP claim. Instead, regulatory agencies (such as FDA) should consider whether any resulting halo effects are likely to be inaccurate and misleading and include potential unintended consequences associated with halo effects as part of the overall evaluation when assessing individual and population-level health impact of MRTP claims. Consumer perceptions and potential behavioural responses caused by halo effects should be considered, along with research on exposure assessment and biomarkers of harm, to fully evaluate MRTP claims.

To help mitigate unintended consequences and guide regulatory decisions about MRTP claims, we encourage researchers studying MRTP claims to test for halo effects. Although research is needed to develop psychometrically sound measures for halo effects assessment, the use of common terms to describe halo effects will help align this burgeoning area of research and will allow for easier comparison across multiple studies.

Finally, tobacco manufacturers making use of MRTP claims should be required to report both premarket and postmarket surveillance of halo effects to relevant regulatory bodies in their country of use (eg, FDA in the US context) to determine whether consumers understand these claims in the context of total health and in relation to the myriad of diseases associated with tobacco products. By doing so, these agencies will be better equipped to make regulatory decisions about relative risk and exposure communication that will maximise public health benefits and reduce potential unintended consequences.

**What this paper adds**

- Marketing tobacco products with modified risk tobacco product (MRTP) claims may cause consumers to infer additional health benefits not directly stated in the claim (ie, halo effects).
- We propose a typology of seven types of halo effects that may be caused by MRTP claims and describe the regulatory significance of and evidence for each type of halo effect.
- While these generalisations are likely unavoidable in certain situations and may sometimes produce accurate inferences, halo effects may be problematic if they mislead consumers into false inferences and result in unintended consequences that have a negative public health impact (eg, reinitiation, dual tobacco product use).
- As more countries begin to allow MRTP claims, we encourage researchers to measure halo effects and regulatory agencies to require tobacco manufacturers to conduct premarket and postmarket surveillance of halo effects to help minimise unintended consequences of MRTP claims and maximise potential benefits.

**Contributors**

AS conceptualised the paper and wrote the manuscript’s first draft. LP, DLA and OAW helped draft and revise the manuscript.

**Funding**

AS is supported by National Institute on Drug Abuse of the National Institutes of Health under Award Number F31DA045424. Contributions by LP were supported by the National Cancer Institute of the National Institutes of Health and the Food and Drug Administration under Award Number R00CA187460. Contributions by OAW were supported by the National Cancer Institute of the National Institutes of Health under Award Number R37CA222002.

**Disclaimer**

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

**Competing interests**

None declared.


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