Title: The impact of policies to reduce trans fat consumption: A systematic review of the evidence

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1 List of abbreviations:
TFA: Trans fatty acids
CHD: Coronary heart disease
CVD: Cardiovascular disease
EPHPP: Effective Public Health Practice Project
GRAS: Generally recognized as safe
LMIC: low- and middle-income country
MUFA: Monounsaturated fatty acid
NCD: Non-communicable disease
NYC: New York City
OECD: Organisation for Economic Co-operation and Development
PHO: Partially hydrogenated oil
PUFA: Polyunsaturated fatty acid
RCT: Randomized Control Trial
SFA: Saturated fatty acid
WHO: World Health Organization

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Abstract

Background: The consumption of industrially produced trans fatty acids (TFA) has been associated with an increased risk of heart disease. In recognition of this, countries, states and cities worldwide have implemented TFA policies aimed at reducing their availability in the food supply.

Objective: This paper aims to provide an update of the evidence of the effectiveness of policies aimed at reducing TFA in the food supply.

Methods: A systematic review of the literature from 2013 onwards was conducted, building on a previously published review that examined the evidence of the impact of TFA policies worldwide from 2000-2012. Studies that were 1) empirical, 2) examined a TFA policy and 3) examined the effect of the policy on TFA levels/availability pre and post policy intervention were included. Modelling studies examining the impact of TFA policies on cardiovascular, equity and economic outcomes were also included.

Results: A total of 18 articles from the updated search were combined with 14 articles from the previous review (total = 34 articles). All types of TFA policies led to its reduction; however, trans fat bans had a larger impact (TFA virtually eliminated) than voluntary (ranged from 20-38% reduction in TFA intakes) or labelling approaches (ranged from 30-74% reduction in TFA intakes, plasma serum or breastmilk concentrations) to reducing TFA levels in the food supply. Product reformulation to reduce TFA had variable effects on saturated fat (SFA) levels in these foods; however, the combined amount of TFA and SFA declined in most products. Overall, the modelling studies indicated that TFA bans would reduce heart disease risk, would benefit socioeconomically disadvantaged populations the most and would be cost saving.

Conclusions: Policies aimed at reducing TFA in the food supply are effective and will likely reduce the burden of diet-related disease, particularly among the most vulnerable socioeconomic
groups. Although all policy approaches lead to reductions in TFA in the foods, TFA bans are likely the most effective, economical and equitable policy approach to reducing TFA from the food supply.

**Keywords:** trans fatty acids; cardiovascular disease prevention; nutrition policy; bans
The impact of policies to reduce trans fat consumption: A systematic review of the evidence

Introduction

The consumption of trans fatty acids (TFA) has been associated with an increased risk of coronary heart disease (CHD) (1). Although there are small amounts of naturally occurring TFAs in ruminant animal products, the majority of TFA consumed is industrially produced (2). The main source of industrially produced TFA is partially hydrogenated oils (PHOs) often found in fried snacks and bakery products. Its removal from the food supply has been deemed one of the most straightforward public health interventions for rapid improvements in health (3) and is considered a best buy for tackling diet-related non-communicable diseases (NCDs) in low- and middle-income countries (LMICs) (4). Policy approaches to address the removal of TFA from the food supply are likely the most effective in terms of reducing consumption levels. Despite this, most countries worldwide have yet to introduce strong policy measures to limit TFA intakes and it continues to be widely consumed around the world (5).

The Global Burden of Disease study found a five-fold difference in TFA consumption between countries in 2010, ranging from 0.2 to 6.5% of energy intake, with the mean global TFA intake at 1.4% of total energy intake (5). This exceeds the WHO recommendations to limit consumption to less than 1% of total energy intake (6). The highest intakes were found in Egypt, Pakistan, Canada, Mexico and Bahrain (5). Even in countries like the United States, where there has been significant progress in terms of product reformulation after the introduction of mandatory TFA labelling, intakes remain above recommended levels among some pockets of the population (7).

Countries that have taken action to limit TFA levels in foods have generally adopted mandatory TFA labelling policies or set TFA limits (often referred to as bans). There have also been voluntary approaches to TFA reduction via product reformulation, often spearheaded by non-government stakeholders including industry and public health groups. Denmark was the first country to ban TFA in 2003 and a handful of other countries have since followed suit.
Although over the course of the past 20 years there has been a reduction in TFA in the food supply of the majority of countries that have measured it, in recent years there has been growing momentum for adopting TFA bans or limits in an effort to eliminate TFA from the food supply. In June 2015, the US Food and Drug Administration (FDA) made a final decision to remove the “generally recognized as safe” (GRAS) status from PHOs in the US, which will essentially act as a countrywide TFA ban once it comes into effect in June 2018. Canada also recently took steps to ban TFA which is planned to come into effect in September 2018, meanwhile the European Commission is considering setting a TFA limit.

This paper aims to provide an update of the evidence of policies aimed at reducing TFA in the food supply. A systematic review of the literature from 2013 onwards was conducted, building on a previously published review that examined the evidence of the impact of TFA policies worldwide from 2000-2012. This paper updates that review by examining the literature from 2013 to 2016 and compiles this with the evidence from the previously published review. Since the initial review, a number of studies examining the impact of TFA policies worldwide have been published. In order to better inform TFA policy development, updating the current state of the evidence is necessary.

Methods

A systematic literature search was conducted in August 2017 using the Medline, Embase and Cinahl databases to identify peer-reviewed articles that examined the impact of TFA policy. The main search terms were “trans fat” and “policy”. Additional search terms to represent TFA were: ‘trans fatty acids’, ‘hydrogenation’, ‘vanaspati’, ‘elaidic acid’ and ‘margarine’. Policy terms included ‘regulation’, ‘nutrition policy’, ‘health policy’, ‘legislation’, ‘ban’, ‘intervention’, ‘labelling’, ‘law’, ‘standards’ and ‘restriction’. Terms were included both as key words as well as free text searches in titles and abstracts, depending on the database being searched. The search terms and databases used were the same as the previously published systematic review. In
addition, the first 20 pages of Google were examined to identify additional studies published in
the grey literature.

**Inclusion criteria**

The inclusion criteria for the review were that the studies were 1) empirical, 2) examined a TFA policy (labelling, voluntary limits, bans, etc.) and 3) examined the effect of the policy on TFA levels/availability (in food, the blood, dietary consumption, breast milk, etc.). In addition to the aforementioned inclusion criteria, only studies that had pre and post data were included in the review. This differed from the previous review, which included studies even if they solely presented findings post policy intervention. Studies included in the previous review that did not present pre and post data were not included in this review. Moreover, unlike the previous review, modelling studies of TFA policies were included to enable the inclusions of studies that examined: 1) differences in policy impacts on specific segments of the population (e.g., lower socioeconomic groups) and 2) cost-effectiveness studies. Studies that modelled the potential impact of front-of-pack labelling (not specific to TFA) on TFA intakes were not included. Given that the previous review did not include modelling studies, the modelling studies published between 2000-2012 were added to the search conducted as part of the updated review.

**Overview of search**

The records identified through our searches were exported into EndNote, version X5 (Thomson Reuters, Philadelphia, PA, 2011) and duplicates were subsequently removed. The records were then imported into Covidence (Veritas Health Innovation, Deerfield, IL) – an online software to facilitate the systematic review process – to screen the records. Two researchers (SMD and MZB) independently reviewed the titles and abstracts of all records identified in our search. After removing records that did not meet the inclusion criteria, the full texts of the remaining articles were reviewed by both researchers to determine whether the studies met our inclusion criteria. In the event that the two researchers disagreed, a third researcher (JW) was
consulted and a decision reached by consensus. The reference lists of the full articles were also
examined in order to identify additional studies that met the inclusion criteria.

**Study extraction**

One researcher (MZB) extracted data from the full texts of the articles included in the review. The data extractions were then reviewed by a second researcher (SMD). The following data were extracted from each study: aim, location, design, type and year of intervention, data collection period, population, sample size, outcomes measured and their assessment method, results, summary of findings, conclusions, limitations, assumptions (for modelling studies) and source of funding.

**Study quality assessment**

In order to assess the overall quality of the studies that collected primary data (i.e., non-modelling studies) included in the review, the Effective Public Health Practice Project (EPHPP) Quality Assessment Tool was used (12). The tool was adapted to reflect the study designs included in the review. The tool is designed to assess study quality based on six domains: selection bias, study design, confounders, blinding, data collection method, and withdrawals/dropouts. Given the types of studies included in the review, blinding and withdrawals/dropouts were not included in our quality assessment. Each study was given a ranking of weak (score=1), moderate (score=2) or strong (score=3) for each of the remaining four domains based on the EPHPP Quality Assessment Tool’s dictionary (12, 13). An overall score was then generated by compiling the scores for each domain and assigning an overall study quality rating of weak, moderate or strong. If a study had two or more weak ratings it was considered weak, if it had only one weak rating it was considered moderate and if it had no weak ratings it was considered strong.
Results

Overview of included studies

Figure 1 depicts the search flow diagram of this review. We searched the full text of 43 articles (41 identified in our search (including one from the grey literature) and two modelling studies from 2000-2012). Eighteen articles (representing 17 distinct studies) met our inclusion criteria and were added to the 14 papers from the previous review. The main reasons for excluding articles based on the full text review were because they were: duplicates (n=3), included in previous review (n=5), had no TFA policy (n=3), were commentaries (n=3) or did not have a pre-post study design (n=11). Only one of the included studies was obtained from the grey literature search (14). The majority of the included studies were from high-income countries; only three were from LMICs (Argentina, Costa Rica and Iran).

TFA interventions in the ‘real world’

Supplemental Table 1 provides an overview of the ‘real world’ studies included in the review, which combines the updated search with the before and after studies included in the previous review. The studies examined voluntary self-regulation (n= 4; Costa Rica, the Netherlands and the Americas) (15-18), mandatory labelling (n=8; South Korea and US) (3, 19-25), mandatory labelling in addition to voluntary TFA limits (n=6; Canada) (26-31), mandatory TFA limits in restaurants (n=4; NYC) (32-35), and mandatory TFA limits in PHOs (n=1; Iran) (14) and all foods (n=1; Denmark) (14, 36). In terms of the overall quality of the studies included in this review, nearly all were classified as weak. The main contributing factors to the studies being deemed weak by the EPHPP quality assessment tool were related to the weak study designs, high risk of selection bias and data collection methods that lacked strong validity and/or reliability.
The impact of different policy approaches on TFA

All of the studies examined reported a reduction in TFA levels in food, breastmilk, plasma serum or dietary intakes; however, there were differences based on the type of policy adopted as described below (Tables 1-3).

Voluntary approaches

The four studies that examined voluntary approaches to reducing TFA intakes found reductions in TFA intakes, levels in tissue and content in food. In addition, TFA levels in tissue were no longer associated with increased risk of myocardial infarction (MI) in Costa Rica post introduction of self-regulation; however, in some cases TFA intakes remained high (15-18). In Costa Rica, where there was industry self-regulation, the number of adolescents that exceeded the WHO recommendations (<1% of total energy intake from TFA) for TFA consumption declined by 32 percentage points between 1996 and 2006 in a population of urban and rural public school students; however, the number of adolescents exceeding the limit remained high (68% in 2006 vs 100% in 1996) (16). In comparison, there was a 20 percentage point reduction in TFA intakes in The Netherlands which coincided with average TFA intakes that were below the WHO recommendations (0.8% of energy intake).

TFA labelling

The majority of the studies looking at the impact of mandatory TFA labelling were conducted in the United States and Canada, with the exception of one study conducted in South Korea. Although the TFA labeling policies differed slightly among these three countries (e.g., TFA free foods were considered <0.2g of TFA per serving in South Korea and Canada as compared to 0.5g per serving in the US), all were associated with reductions in TFA levels in foods. However, it is important to note that TFA levels remained high in some product categories. For example, the TFA content in coffee whiteners was on average 38.3% of total fat in Canada (26). Moreover, in two product categories (coffee whiteners and lard/vegetable...
shortenings) the number of products meeting the voluntary TFA limits in Canada actually declined between 2005-09 and 2010-11(26). In addition to observing declines in TFA levels in foods, for the most part, all studies examining the impact of mandatory labelling policies in the US and Canada on biological outcomes found large reductions in TFA concentrations in serum plasma (ranging from 54 to 58%) (23-25) and breastmilk/dietary intakes (ranging from 30 to 74%) (27, 30).

Mandatory TFA limits in restaurants

Four studies (32-35) looked at the impact of the TFA limit in New York City (NYC) restaurants. Two of the studies examined the impact on MI and stroke, one of which found a 4.5% reduction in CVD mortality associated with the policy (35) and the second reporting a greater decline in stroke among younger age groups (who also consumed more restaurant foods) than would have been expected if the policy had not been enacted (34). However, it is important to note that the time lag between the introduction of the TFA policy and the analysis of hospital admissions due to MI or stroke was only three years. The two studies that examined TFA levels in foods found that nearly all (98%) of restaurants were using TFA free oils after the policy came into effect as compared to only 50% before its enactment (33). Moreover, the purchase of TFA free meals increased by 86% (32).

Mandatory TFA limits in food

Only two of the included studies examined the impact of TFA limits in foods/oils – one in Iran and another in Denmark. In Denmark, the 2% TFA limit led to the virtual elimination of TFA from the food supply (36). In Iran, where the TFA limit has been gradually reduced over time from 20% in 2005 to 10% in November 2007 there have been reductions in the quantity of TFA in edible oils (31.2% in 2004 as compared to 5.62% in 2008); however, TFA levels in oils remain high (14).

TFA free products
Table 2 synthesizes the evidence relating to the number of TFA free products in the food supply coinciding with mandatory and voluntary TFA limits as well as labelling regulation. Mandatory national bans have virtually eliminated TFA from the food supply while voluntary limits and labelling policies have led to an increase in the number of TFA free products; however, there is still further progress to be made.

Changes in fatty acid composition with product reformulation

There is often a concern that if TFA is removed from a product it will be replaced with saturated fatty acids (SFA) (37), decreasing the potential health benefits of product reformulation. Table 3 synthesizes the evidence related to changes in the fatty acid composition of foods after the implementation of TFA policies. Although all the studies that reported on the different fatty acids in products pre and post policy interventions found reductions in TFA levels in foods, there were mixed findings in terms of SFA levels in foods. Seven studies included information on mono- and poly-unsaturated fat (MUFA and PUFA) levels in foods (19,30,42,44,45,46,49), six of which found increases in either MUFAs or PUFAs (or both). Moreover, twelve studies examined the combined TFA and SFA content of foods before and after the introduction of a TFA policy, with all but one study (22), reporting a reduction post policy intervention.

Findings of modelling studies

Eight modelling studies were included in the review (Supplemental Table 2). The majority of the modelling studies were conducted in the UK (n=5), whilst other studies were conducted in Argentina, Denmark and the European Union. Six of these studies (38-41) examined the impact of hypothetical TFA policies and of these, three studies (38-40) examined several food policies simultaneously. In these cases, only results related to the TFA reduction were reported in this review.

Table 4 summarizes the findings of the studies modelling the impact of TFA policies on cardiovascular, equity and economic outcomes. All modelling studies reported a reduction in CHD/CVD deaths attributed to TFA policies. These ranged from 1.3% to 6.35% deaths averted.
Of the modelling studies conducted in the UK, annual cardiovascular deaths averted with TFA policies ranged from 112 deaths (with a 0.5% reduction in TFA) (40) averted in 2010 to between 2700 (38) and 3900 (41) deaths averted annually (with a 1% reduction in TFA) – the specific policy approaches taken to achieve these reductions were not always specified. For the UK modelling studies that examined CVD deaths averted over a longer time horizon, one study found that between 2006-2015, 3500-4700 CVD deaths would be averted (39), depending on whether there was a 0.5% or 1% reduction in TFA, and another found that 7200 deaths would be averted between 2015-2020 with a total TFA ban in processed foods as compared to TFA consumption remaining at its current level (42). The modelling studies (n=4) that included a cost-effectiveness component all reported that TFA policies would lead to net cost savings. However, the EU model found that a mandatory TFA labelling policy would not be cost-effective unless initial TFA intakes were quite high (43). For those studies that examined saving per year, health care saving ranged from 17 million US dollars per year (25) to 230 million British pounds per year (20). Two studies (41, 42) examined the effects of different TFA policy scenarios on different socioeconomic groups. Both studies were conducted in the UK and found TFA policies to have a greater effect on lower socioeconomic groups, regardless of type of policy examined (i.e., TFA labeling, ban in restaurants or total ban of processed foods). The first suggested that a TFA ban would reduce inequality in mortality from CHD by 15%, given the higher TFA intakes among lower socioeconomic groups (41, 42). The second study found that five times as many CHD deaths would be prevented in the lowest quintile of socioeconomic status with a 1% reduction in TFA intakes – in addition, they would also gain six times as many life years as compared to the most affluent group (41, 42).

Two modelling studies, one in Argentina (44) and another in Denmark (45), modelled the impact of the countries’ actual TFA policies, both showing positive impacts in terms of reducing CHD/CVD rates. Over the course of a ten-year period between 2004 and 2014 Argentina went from having a voluntary TFA labelling policy to having mandatory TFA limits in foods. This
study modelled several likely scenarios by linking different assumptions of the likely effect of TFA on CHD outcomes (e.g., based on individual data on CHD risk factors from a national prospective cohort study vs. effect of TFA on CHD blood lipid risk factors from RCTs) and baseline levels of TFA intake (mean=1.5% of total energy vs. lower bound of 1% and upper bound of 3% of total energy) (44). Across all the scenarios examined in the modelling studies, TFA regulation had a substantial impact leading to significant reductions in CHD deaths (301 to 1517) and CHD events (1066 to 5373), disability adjusted life years (5237 to 26 394) and health care-costs saved (US$17 to US$87 million) each year (44). In Denmark, a synthetic control group using CVD mortality data from the Organisation for Economic Co-operation and Development (OECD) countries without TFA policies was used to examine what the CVD mortality rate would have been if the country did not adopt a TFA ban in 2004 (45). They found that CVD mortality decreased by approximately 14.2 deaths per 100,000 people per year in Denmark with the TFA policy as compared to the counterfactual of not having a TFA policy. Supplementary Table 3 provides an overview of the main assumptions of the models included in the review. There were several limitations associated with the assumptions of the various models (e.g., time horizons, current TFA intakes, reductions in TFA due to policy, etc.) that have implications for their overall findings.

Discussion

This study compiles the evidence of the impact of TFA policies on its availability in the food supply, dietary intakes, concentrations in plasma serum and breastmilk, as well as changes in burden of disease due to TFA based on modelling studies. TFA policies coincide with reduction in TFA levels in foods as well as intakes. The evidence suggests that although all the policy approaches examined in the review will likely lead to reductions in TFA levels in foods and subsequent intakes, stronger policies (e.g., limits/bans) will have more pronounced effects (virtually eliminating TFA in the food supply) than voluntary (ranged from 20-38% reduction in intakes) or labelling approaches (ranged from 30-74% reduction in plasma serum/breastmilk...
concentrations) on reducing TFA levels in the food supply. Moreover, it is likely that they contribute to reductions in heart disease risk and there is some evidence to suggest that TFA bans are cost saving, as demonstrated in the modelling studies included in this review.

The studies that examined labelling policies found that although they had coincided with reductions in TFA levels in foods, foods high in TFA remained on the shelves. Given that high TFA foods tend to be cheaper than their low TFA counterparts (31, 46), these policy approaches may not deliver for the most disadvantaged pockets of the population. Lower income consumers are generally more sensitive to price differentials and thus more likely to purchase lower cost, higher TFA products. Moreover, in countries requiring mandatory labelling of TFA content in foods, consumers with lower nutrition knowledge and numeracy are less likely to understand or use nutrition labels (47), and thus may continue to purchase products with high levels of TFA.

This suggests that even in countries where the majority of products are TFA free – so long as products containing high industrial TFA remain available – TFA consumption will likely remain a public health problem and contribute to health disparities due to higher consumption by lower socioeconomic groups. In addition, the modelling study examining the impact of different TFA policy approaches in the European Union found that mandatory TFA labelling was unlikely to be cost-effective (43). TFA bans therefore remain the most effective, economical and equitable approach to reduce TFA consumption.

Although in most countries that have set limits of allowable TFA in foods the limit has been 2% of total fat – which is often described as a ban – in Iran the TFA limits were set high (initially 20%) and were reduced gradually over time. Additional progress is needed to bring TFA levels in edible oils down even further in LMIC settings. It is possible that TFA policies in LMICs will need to be adapted to local contexts and perhaps take place alongside additional interventions throughout the food supply chain given the large informal food sectors in many LMIC countries (48). For example, in India it is likely that the mandatory TFA limit of 5% in PHOs that came into effect in August 2016, will not reach the PHOs produced by small-scale
producers in the informal sector (48, 49). Providing incentives for these smaller scale producers to reformulate their products may be necessary in order to ensure that TFA levels in PHOs are aligned with the policy goal. Additional studies examining the impact of TFA policies in LMICs are needed.

In the past, there have been calls for a global TFA ban (50, 51); however, mandating a global ban would require significant stakeholder buy-in (including from non-governmental organizations and industry) and is unlikely to be feasible in the short term. However, as more and more countries and regions around the world adopt TFA policies, this buy-in may increase. The US FDA’s decision to revoke the GRAS status to PHOs sends a strong message globally. This may facilitate fresh impetus for the Codex Alimentarius to redefine the terms for the use of PHOs. LMICs in particular often look to Codex for guidance on issues of food safety and aim to comply with its standards (52). There may be potential for Codex to follow a similar approach to that used by the US and define PHOs as unsafe for consumption. If Codex were to take these steps it would essentially act as a pseudo global ban and prevent TFA regulation from being considered a technical barrier to trade. Although this could be a feasible approach to establishing a global TFA ban, vested interests are strong and the current policy environment (including stakeholder support) may not enable such a measure (53). In the meantime, countries will need to continue to use their own policy tools to improve the quality of fat that is available, affordable and acceptable in the food supply.

There is often a concern that reducing TFA levels in foods will lead to increases in SFAs (37). We found mixed evidence of increases in SFA post product reformulation to reduce/remove TFAs. It is likely that this will be quite dependent on product category. For example, it may be more difficult to reformulate bakery products with oils higher in MUFAs and PUFAs given that they are not semi-solid at room temperature; however, fried snack foods can more easily be reformulated with oils high in unsaturated fats. As palm oil, which is high in SFA, become more ubiquitous in the food supply and becomes the preferred substitute for PHOs, it is possible that
SFA levels will increase in foods – palm oil is now in approximately 50% of all products (54) – arguably an unintended outcome (55). It is likely that incentives for use of oils higher in MUFAs and PUFAs will be needed, particularly in LMICs (49). Substitution with oils high in unsaturated fats rather than palm oil is likely beneficial to heart health based on metabolic trials and observational studies (55), conversely there may be less demand for products that are both low in TFA and SFA. Therefore, understanding of consumer sentiment, technical and health impacts of specific fats and oils is paramount in product reformulation to reduce/remove TFAs.

The results of the modelling studies included in this review suggest that it is likely that policies that set TFA limits will be cost saving and have the greatest impact on lower socioeconomic groups. These are important considerations for policymakers in terms of deciding whether or not to move forward with a TFA policy. These findings suggest that TFA bans make sense from both an economic standpoint but also from an ethical perspective, given that they could help to reduce social inequities. Although there is often resistance to implementing regulation pertaining to food, from a public health ethics perspective regulating TFA in the food supply is an appropriate policy approach given that the benefits of the policy far outweigh any risk to individual liberties (56).

Limitations of included studies

One of the main limitations of this study is the lack of breadth in terms of the countries that have had studies examining the impact of their TFA policies. There is a substantial amount of evidence to support TFA labelling in both the US and Canada but fewer in countries beyond North America, particularly LMICs. In addition to the evidence compiled from this review, continued country level monitoring of TFA intakes over time can be used to indirectly assess the impact of different approaches to reducing TFA. Wanders et al. (8) examined trends in TFA intakes over time and found a reduction in TFA intakes in some European countries (e.g., Sweden, Iceland, Norway, etc.) coinciding with the adoption of voluntary TFA reduction measures but not in others (e.g., Spain, UK, France, etc.). These observations suggest that...
industry reformulated products to reduce TFA prior to mandatory measures coming into place in some but not all countries. By continuing to monitor trends in intakes over time across a wider range of countries, additional insight into the impact of different approaches to reducing TFA in the food supply may be possible.

The majority of the studies included in this review were from high-income countries with limited data from LMICs. Thus, the impact of TFA policies on intakes and cardiovascular outcomes in LMIC settings is less clear. Given that the global burden of disease estimates indicate that TFA intakes may be higher in many LMICs, particularly North Africa/Middle East and South Asia (5), there is a need for additional research examining the impact of policies in these settings.

There were several limitations to the assumptions used in many of the modelling studies included in the review that need to be considered. The time horizons used for the models were short, with the exception of the article by Martin-Saborido et al (43). In one study (40) the deaths averted were only examined for one year. Longer time horizons would be more appropriate as the implementation of a TFA policy would not result in instantaneous effects on CVD, using a lifetime approach as was used in the model examining the impacts of TFA policies in the European Union (43), would likely be more appropriate. Some of the modelling studies did not address current levels of TFA intake, which may in part be explained by limited data availability; however, this has significant implications for the model assumptions. For example, in the UK, average TFA intakes are already low (0.8% total energy) (57) so it may not be possible to reduce TFA intake by an additional 1% of total energy intake, as was examined in three of the models (38, 40, 41). TFA policies only apply to industrially produced TFA rather than all TFA given the lack of feasibility in terms of implementing a policy that addresses ruminant TFA levels in the food supply. It is therefore unlikely that TFA intakes can be reduced to 0% of total energy intake in the absence of avoiding all ruminant products. Moreover, another area of uncertainty in the models is the assumption that reducing ruminant TFA would have the same effect on CVD risk as
reducing industrially produced TFA – existing evidence on the cardiovascular effects of ruminant TFA remains mixed and uncertain (40-42). One of the main strengths of the European Union model is that they focused on reductions in industrially produced TFA levels in food, rather than total TFA (including ruminants), and they assessed three additional initial TFA levels in the sensitivity analyses thus giving a better indication of the potential costs and benefits of the different policy options examined.

Limitations in study design were not limited to modelling studies. The majority of the ‘real world’ studies included were weak. However, it is important to note that these studies were examining real policies that have been implemented in a number of countries and using more rigorous study designs, such as randomized control trials, to examine these policies in a ‘real world’ context is not possible. We only included studies with pre and post TFA policy implementation data to ensure that we included higher quality studies; however, these studies still had limitations. Despite these limitations, the totality of the evidence from both modelling studies as well as the studies conducted in ‘real world’ settings suggest that stronger TFA policies will have a larger impact on TFA levels in foods, their intake and CVD outcomes.

Conclusion

Policies aimed at reducing TFA in the food supply are effective and will likely reduce the burden of diet-related disease, particularly among the most vulnerable socioeconomic groups. Although only a handful of countries have adopted strict TFA limits or bans, these policies have dramatically reduced TFA levels in the food supply. Labelling policies have also led to reductions in the availability of TFA in the food supply; however, these reductions have not been across all product categories and high TFA products remain in the food supply. Moving forward, global, regional or country-level TFA bans should be adopted. TFA bans are likely the most effective, economical and equitable policy approach to reducing TFA from the food supply.

Additional studies need to be conducted to examine the impact of TFA policies in LMIC contexts. LMICs may require additional incentives and interventions alongside mandatory limits...
in order to reduce TFA levels in all foods in the food supply, including those manufactured by the
informal sector. Lastly, continued monitoring to ensure that progress in terms of reducing TFA
levels in the food supply over time will be necessary.

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Statement of Authors’ Contributions to Manuscript

J.H.W., J.B., L.V., and S.M.D. obtained funding, S.M.D and J.H.W. designed the research,
S.M.D and M.Z.B. reviewed articles and extracted data, S.M.D drafted the manuscript, all authors
had input into data interpretation and every author critically reviewed and approved the final
manuscript.
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## Tables

### Table 1. The impact of TFA policies on dietary intakes, concentrations in plasma serum and breastmilk and cardiovascular outcomes

<table>
<thead>
<tr>
<th>Policy Type</th>
<th>Authors, Year and Country/Region</th>
<th>Time period</th>
<th>Measurement</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voluntary self-regulation</td>
<td>Monge-Rojas et al. (16) Costa Rica</td>
<td>1996 to 2006</td>
<td>Dietary intake of TFA as a percentage of total fats</td>
<td>38% reduction</td>
</tr>
</tbody>
</table>
| | Colon-Ramos et al. (15) Costa Rica | 1994-99 to 2000-03 | TFA in subcutaneous adipose tissue and risk of MI | • Reduction in TFA in tissue of those that did not use PHVOs  
• TFA in tissue no longer associated with increased risk of MI |
<p>| | Temme et al. (18) The Netherlands | 2001 to 2009-10 | Dietary intake of TFA as a percentage of total fats | 20% reduction |
| Mandatory TFA labelling on packaged foods | Vesper et al. (24) USA | 2000 to 2009 | Plasma TFA concentration | 58% reduction |
| | Vesper et al. (23) &amp; Yang et al. (25) USA | 1999-2000 to 2009-10 | Plasma TFA concentration | 54% reduction |
| Mandatory TFA Labelling + Voluntary TFA limits | Friesen et al. (27) Canada | 1998 to 2004-06 | Breastmilk TFA concentration | 35% reduction |
| | Ratnayake et al. (28) Canada | mid 1990s to 2008 | %TFA of total fats | 30% reduction |
| | Ratnayake et al. (30) | 1992 to 2011 | Breastmilk TFA concentration | 74% reduction |</p>
<table>
<thead>
<tr>
<th>Mandatory TFA limits in restaurants</th>
<th>Canada</th>
<th>2000 to 2010</th>
<th>Stroke and MI rates</th>
<th>Greater decline in stroke than would have been expected based on temporal trends (for younger age group only)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Brandt et al. (34) NYC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Restrepo &amp; Rieger (35) NYC</td>
<td>1999 to 2013</td>
<td>CVD mortality rates</td>
<td>4.5% reduction in CVD mortality rates</td>
</tr>
<tr>
<td>Mandatory TFA limits in foods</td>
<td>Leth et al. (36) Denmark</td>
<td>1995 to 2005</td>
<td>Total amount of TFA in grams</td>
<td>TFA decreased from 1.5g/day in 1995 and were virtually eliminated in 2005</td>
</tr>
</tbody>
</table>
Table 2. The percentage of foods classified as TFA free post policy interventions (adapted from (11))

<table>
<thead>
<tr>
<th>Policy intervention</th>
<th>Countries/Regions</th>
<th>Food categories</th>
<th>% TFA free$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>National bans</td>
<td>Denmark</td>
<td>Overall</td>
<td>Virtually eliminated</td>
</tr>
<tr>
<td>Local bans (48)</td>
<td>NYC</td>
<td>All fast-food purchases</td>
<td>59%</td>
</tr>
<tr>
<td>Mandatory labelling + voluntary limits (26, 29)</td>
<td>Canada</td>
<td>Margarines/spreads</td>
<td>0-85%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bakery Products</td>
<td>25-100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Restaurant food (including restaurants in institutions)</td>
<td>50-100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Overall</td>
<td>76-97%</td>
</tr>
<tr>
<td>Mandatory labelling (26, 29, 58)</td>
<td>USA, South Korea</td>
<td>Potato chips</td>
<td>98%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Restaurant foods</td>
<td>80%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Supermarket foods</td>
<td>85-95%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cookies</td>
<td>89%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Spreads (all)</td>
<td>86%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Spreads (stick)</td>
<td>46%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Spreads (tub or spray)</td>
<td>99%</td>
</tr>
<tr>
<td>Voluntary TFA limits (18)</td>
<td></td>
<td>Restaurant frying oil</td>
<td>45%</td>
</tr>
</tbody>
</table>

$^a$Studies conducted in the United States classify <0.5g/serving as TFA free whereas other countries classify products <0.2g/serving as TFA free. In Canada, additional requirements include a combined TFA + SFA ≤15% of energy.
<table>
<thead>
<tr>
<th>Policy Intervention</th>
<th>Authors</th>
<th>Country</th>
<th>TFA</th>
<th>SFA</th>
<th>MUFA and/or PUFA</th>
<th>TFA + SFA*</th>
<th>Total Fat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory TFA Labelling</td>
<td>Lee et al. (20)</td>
<td>South Korea</td>
<td>↓</td>
<td>↑</td>
<td>↑ bakery products</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td></td>
<td>Mozaffarian et al. (3)</td>
<td>USA</td>
<td>↓</td>
<td>↑</td>
<td>↑ supermarket foods</td>
<td>--</td>
<td>↓</td>
</tr>
<tr>
<td></td>
<td>Van Camp et al. (22)</td>
<td>USA</td>
<td>↓</td>
<td>↑</td>
<td>↑ bakery products</td>
<td>↑ oils high in PUFA &amp; MUFA in chips</td>
<td>NC</td>
</tr>
<tr>
<td></td>
<td>Storey &amp; Anderson (21)</td>
<td>USA</td>
<td>↓</td>
<td>↓</td>
<td></td>
<td>NC</td>
<td>NC</td>
</tr>
<tr>
<td></td>
<td>Garsetti et al. (19)</td>
<td>USA</td>
<td>↓</td>
<td>↑</td>
<td></td>
<td>↑ PUFA</td>
<td>↓</td>
</tr>
<tr>
<td>Mandatory TFA limits</td>
<td>Angell et al. (33)</td>
<td>NY, USA</td>
<td>↓</td>
<td>↓</td>
<td></td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>Angell et al. (32)</td>
<td>NY, USA</td>
<td>↓</td>
<td>↑</td>
<td></td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>Peymani et al. (14)</td>
<td>Iran</td>
<td>↓</td>
<td>↑</td>
<td></td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Mandatory TFA Labelling + Voluntary Limits</td>
<td>Ricciuto et al. (31)</td>
<td>Canada</td>
<td>↓</td>
<td>NC</td>
<td>↑ PUFA</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td></td>
<td>Ratnayake et al. (28)</td>
<td>Canada</td>
<td>↓</td>
<td>↓</td>
<td>↑</td>
<td>NC</td>
<td>NC</td>
</tr>
<tr>
<td></td>
<td>Ratnayake et al. (29)</td>
<td>Canada</td>
<td>↓</td>
<td>↑</td>
<td>↑ crackers, cookies, and garlic spreads &amp; donuts</td>
<td>↑</td>
<td>↓</td>
</tr>
</tbody>
</table>

Table 3. Changes in the fatty acid composition of foods after the introduction of a TFA policy (adapted from (11))
| Voluntary TFA Self-regulation | Temme et al. (18) | The Netherlands | NC | NC↓ in biscuits | NC |

*Change in TFA + SFA calculated by adding fatty acids when the sum not reported by authors; in these cases, significance was not assessed.
MUFA – Monounsaturated fatty acids; PUFA – Polyunsaturated fatty acids; SFA – Saturated fatty acids; TFA – Trans fatty acids; NC – No change
Table 4. An overview of the modelling studies included in the systematic review

<table>
<thead>
<tr>
<th>Policy Type</th>
<th>Authors, Year and Country/Region</th>
<th>Stroke deaths</th>
<th>CHD/CAD deaths</th>
<th>CVD deaths</th>
<th>CHD/CVD events</th>
<th>DALYs</th>
<th>QALYs/LYs gained</th>
<th>Costs to health system/society</th>
<th>Reduces inequalities in CVD death (Y/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conservative policy scenario</td>
<td>O’Keeffe et al. (22) Republic of Ireland</td>
<td>▼</td>
<td>▼</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>O’Flaherty et al. (21) United Kingdom</td>
<td>▼</td>
<td></td>
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<tr>
<td></td>
<td>Pearson-Stuttard et al. (23) England and Wales</td>
<td>▼</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y</td>
</tr>
<tr>
<td>Voluntary limit on TFA</td>
<td>Martin-Soborido et al. (43) European Union</td>
<td>▼</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>TFA labelling</td>
<td>Allen et al. (24) England</td>
<td>▼</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td>Martin-Soborido et al. (43) European Union</td>
<td>▼</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Not cost effective</td>
<td></td>
</tr>
<tr>
<td>Legislative ban</td>
<td>O’Keeffe et al. (22) Republic of Ireland</td>
<td>▼</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>O’Flaherty et al. (21) United Kingdom</td>
<td>▼</td>
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<td></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Barton et al. (20) England</td>
<td>▼</td>
<td></td>
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<td></td>
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<tr>
<td>Wales</td>
<td>Pearson-Stuttard et al. (23)</td>
<td>England and Wales</td>
<td>Allen et al. (24)</td>
<td>England</td>
<td>Martin-Soborido et al. ((43)</td>
<td>European Union</td>
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<td>Y</td>
<td>Y</td>
<td>Y</td>
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<td></td>
</tr>
</tbody>
</table>

**Modeling of enacted real-world policies**

<table>
<thead>
<tr>
<th>Real</th>
<th>Rubinstein et al. (25)</th>
<th>Argentina</th>
<th>Restrepo &amp; Rieger (26)</th>
<th>Denmark</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y</td>
</tr>
</tbody>
</table>

\[ TFA = \text{trans fatty acid}, \text{CVD} = \text{cardiovascular disease}, \text{CHD} = \text{coronary heart disease}, \text{CAD} = \text{Coronary Artery Disease}, \text{QALY} = \text{quality adjusted life year}, \text{SEC} = \text{socio-economic circumstances}, \text{DALY} = \text{disability adjusted life year}, \text{TC/HDL-C} = \text{total cholesterol/high density lipoprotein} \]

\[ a \text{Article did not provide detailed information about what the policy entails. It solely provided the estimated reduction in TFA intakes.} \]

\[ b \text{Modelled policy was improved labelling or TFA limits in restaurants} \]
Figure 1. Systematic review flow chart
Figure 1.
Supplemental Data for Publication

Supplemental Figure 1. The countries around the world with TFA policies
### Supplemental Table 1. Overview of the ‘real world’ TFA policy studies included in the systematic review

<table>
<thead>
<tr>
<th>Authors, Year and Region</th>
<th>Study design</th>
<th>Study population and sample size</th>
<th>Aim of study</th>
<th>TFA policy</th>
<th>Main outcomes assessed</th>
<th>Main findings</th>
<th>Study quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monge-Rojas et al. (1)</td>
<td>Pre-post cross-sectional</td>
<td>Adolescents aged 12 to 17 years living in San Jose, Costa Rica in 1996 (n=276) and 2006 (n=133)</td>
<td>To identify how dietary intake and food sources of SFA, PUFA and TFA in the diet of Costa Rican adolescents changed from 1996 to 2006</td>
<td>Voluntary industrial modification of partially hydrogenated soybean oil</td>
<td>Total fat, SFA, TFA, PUFA and MUFA</td>
<td>Changes in TFA: In 1996, 100% of adolescents exceeded the WHO TFA recommendations (&lt;1% of total energy intake from TFA). By 2006, 68% of adolescents exceeded the limit. TFA intakes were significantly lower in adolescents in 2006 (1.3% of total fatty acids) as compared to 1996 (2.1% of total fatty acids).</td>
<td></td>
</tr>
<tr>
<td><strong>Costa Rica</strong></td>
<td></td>
<td><strong>Voluntary self-regulation</strong></td>
<td></td>
<td></td>
<td></td>
<td>Changes in other fatty acids: Total fat was higher (25.6% vs 31.1% of energy intake) in 2006 as compared to 1996. SFAs were significantly lower in 2006 (9.5% of total fatty acids) as compared to 1996 (12.1% of total fatty acids). MUFAs (8.2% to 10.6%) and PUFAs intakes increased from 1996 to 2006 (5.5% to 7.5%).</td>
<td>Weak</td>
</tr>
<tr>
<td>Colon-Ramos et al. (2)</td>
<td>Case-control</td>
<td>1797 case control pairs from metropolitan Costa Rica in 1994-99 (before industrial modifications of TFA) and in 2000-</td>
<td>To assess the risk of nonfatal acute MI before and after the TFA reduction in the food supply</td>
<td>Voluntary industrial modification of partially hydrogenated soybean oil</td>
<td>Subcutaneous adipose tissue sample for fatty acid, FFQ + questions about oils and fats used (confirmed by</td>
<td>Changes in TFA: Median values for quintiles of TFA were higher in 1994-99 as compared to 2000-03. There was a decrease over time of TFA in the tissue of those who</td>
<td>Weak</td>
</tr>
</tbody>
</table>
Changes in disease risk: Prior to self-regulation total TFA content in adipose tissue was associated with increased risk of MI, after controlling for several confounders; this relationship was not seen in the period 2000-03.

| Monge-Rajos et al. (3) Americas | Pre-post test | Self-reported surveys by corporations (n=12) that had signed “trans-fat-free Americas” declaration. 3 provided all data requested; the remaining companies completed portions of the survey or refused to provide data (n=6) | To assess progress towards the goal of achieving a “trans-fat-free Americas” | Voluntary reformulation of products; 12 major companies in the Americas signed a declaration of their intentions to help achieve a “trans-fat-free Americas” | % and type of fats/oils used to replace TFA; current and past (2006) TFA amounts in specific foods; description of obstacles | Changes to TFA: Of the 3 companies that provided data, some progress had been made to reduce TFA however high quantities remained in cookies/crackers and seasonings/sauces. PepsiCo had virtually eliminated TFA in cookies/crackers sold in Mexico and the Caribbean but in North America those products still contained 11-28g TFA/100g. The Brazilian Association of Food Industries reported reductions ranging from 25-92% in oils and fats to 100% in breakfast cereals; TFA in seasonings and sauces averaged 11.5g TFA/100g. McDonalds reported 100% reductions in TFA in the oils used in Brazil. Other companies reported that they had made efforts to reduce TFA but did not provide specific data. |

Weak
<table>
<thead>
<tr>
<th>Reference</th>
<th>Country</th>
<th>Study Design</th>
<th>Participants</th>
<th>Study Details</th>
<th>Changes in TFA</th>
<th>Changes in other fatty acids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temme et al. (4)</td>
<td>The Netherlands</td>
<td>Pre-post test</td>
<td>750 Dutch participants aged 19-30 years</td>
<td>To estimate the impact of reformulations in task force food groups by estimating intakes of TFA in young Dutch</td>
<td>Usual intakes of fatty acids before and after task force activities</td>
<td>TFA decreased from 1.0% of energy intake before to 0.8% after reformulation. Contribution of task force foods to TFA consumption declined from 45% to 29% after reformulation. Pastry, cakes, biscuits and snacks contributed the most to the decrease in TFA. The TFA intakes from fats and margarines were not different.</td>
</tr>
<tr>
<td>Lee et al. (5)</td>
<td>Korea</td>
<td>Pre-post test</td>
<td>21 food products within 7 different categories of food from local markets and fast food restaurants in both 2005 and 2008</td>
<td>To examine the impact of mandatory TFA regulation on TFA levels in food products</td>
<td>Fatty acid composition of food products sampled in 2005 (pre-regulation) and 2008 (post-regulation)</td>
<td>TFA levels significantly (p&lt;.05) decreased with the exception of 1 breakfast cereal and fried chicken. TFA levels were &lt;1% in breakfast cereals, French fries and fried chicken in 2008. Cream filled biscuits and cakes had TFA levels ranging from...</td>
</tr>
</tbody>
</table>

**Mandatory TFA labelling on packaged foods**

- **Lee et al. (5)**
- **Korea**

21 food products within 7 different categories of food from local markets and fast food restaurants in both 2005 and 2008.

To examine the impact of mandatory TFA labelling on packaged foods, TFA content <0.2g/serving labelled as TFA free.

Fatty acid composition of food products sampled in 2005 (pre-regulation) and 2008 (post-regulation).

Changes in TFA levels: TFA levels significantly (p<.05) decreased with the exception of 1 breakfast cereal and fried chicken. TFA levels were <1% in breakfast cereals, French fries and fried chicken in 2008. Cream filled biscuits and cakes had TFA levels ranging from...
Mozaffarian et al. (6) USA

| Pre-post test | 83 reformulated products (58 supermarket foods and 25 restaurant foods) identified based on consumer magazines, health newsletters, a non-profit organisation database and FDA food composition databases | To assess the levels of TFA and SFA in major brand name US supermarket and restaurant foods reformulated to reduce TFA from 1993 to 2006 and 2008 to 2009. | Mandatory TFA labelling on packaged foods; TFA content <0.5g/serving labelled as TFA free | TFA, SFA and total fat content pre- and post-reformulation | Changes in TFA: TFA was reduced to <0.5g/serving in 95% of supermarket foods. Average reductions were 1.8g/serving (84%) in supermarket foods. TFA was reduced to <0.5g/serving in 80% of restaurant foods. Average reductions were 3.3g/serving (92%) in restaurant foods. Changes in other fatty acids: 65% of supermarket products and 90% of restaurant products had SFA levels that were lower, unchanged or only marginally (< 0.5g) higher than before reformulation. The average SFA content in supermarket foods increased slightly (< 0.5g; attributed to 1/3 of weak
non-detectable to 5.4%. TFA content in French fries decreased by 91-98% and fried chicken by 50-96%. TFA reduction ranged from 69-89% in cream filled biscuits and 88-97% in cream filled cakes but Changes in other fatty acids: SFA significantly increased by up to 29-135% in biscuits and 48-69% in cakes respectively (p<.05). Unsaturated fatty acids increased by 35-185% in French fries and 17-76% in fried chicken. | Weak
Reduction in TFA nearly always exceeded any increase in SFAs. Overall, the content of both fats combined was reduced in 90% (average reduction of 1.2g/serving) of supermarket foods and 96% (average of 3.9g/serving) of restaurant products.

### Van Camp et al. (7) USA

**Pre-post test**

5012 chip and cookie products in 2001-02 and 2008-09

**Aim:** To assess the impact of mandatory TFA labelling on packaged foods; TFA content <0.5g/serving labelled as TFA free

**Mandatory TFA labelling on US snack foods**

**TFA media citations, changes in lipid ingredients used, change in reported TFA & SFA content and use of ‘0g TFA’ declaration**

**Changes in TFA:** A 45% reduction in PHVO use in chips and (sunflower oil main replacement). Only 1% of chip introductions reported >0g TFA. A 42% reduction in PHVO use in cookies (palm oil main replacement). Cookie introductions containing palm and palm kernel oil increased by 41% and 5% respectively. 9% of cookie introductions reported >0g TFA.

**Changes in other fatty acids:** No difference in SFA levels in chips. On average, increase of 0.49g SFA/30g serving of cookies but no increase in total fat.

### Vesper et al. (8) USA

**Pre-post test**

229 non-Hispanic white participants in 2000 and 292 from 2009

**To assess the possible impact of TFA regulation on TFA levels in the blood**

**Mandatory TFA labelling on packaged foods; TFA content <0.5g/serving labelled as TFA free**

**TFA in the blood in 2000 vs 2009, LDL, HDL cholesterol and triglycerides**

**Changes in TFA:** TFA levels in the blood decreased from 43.7 μmol/L in 2000 to 19.4 μmol/L in 2009 (58% decrease)

**Changes in cholesterol/triglycerides:**
<table>
<thead>
<tr>
<th>Study</th>
<th>Study Design</th>
<th>Study Population</th>
<th>Methods</th>
<th>Energy and fatty acid intake</th>
<th>Changes in TFA</th>
<th>Changes in other fatty acids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storey &amp; Andersen (9) USAa</td>
<td>Interrupted time series (2005-6, 2007-8, 2009-10)</td>
<td>Children aged 6-11y, adolescents aged 12-18y and adults aged ≥19y. Pregnant and lactating women were excluded. 2005-6: children (n=1009), adolescents (n=1853), adults (n=4367) 2007-8: children (n=1117), adolescents (n=999), adults (n=5411) 2009-10: children (n=1147), adolescents (n=1097), adults (n=5784)</td>
<td>To examine the trend in energy and fat intakes as well as SFA and TFA intakes from French fries among children, adolescents, and adults using the 3 most recent waves of NHANES.</td>
<td>Mandatory TFA labelling on packaged foods; TFA content &lt;0.5g/serving labelled as TFA free</td>
<td>Energy and fatty acid intake. Intakes of SFAs and TFAs from fried French fried potatoes</td>
<td>Changes in TFA: Intakes of TFAs from fried French fried potatoes decreased significantly between 2005–2006 and 2009–2010 among children (0.4g/d vs 0.01 g/d), adolescents (0.6g/d vs 0.01 g/d), and adults (0.3g/d vs 0.01 g/d). Changes in other fatty acids: Intakes of SFAs from fried French fried potatoes decreased significantly between 2005–2006 and 2009–2010 among children (0.3g/d vs 0.2g/d), adolescents (0.5g/d vs 0.2g/d), and adults (0.3g/d vs 0.1g/d). Intakes of total energy, total fat, SFAs, and monounsaturated fatty acids (MUFAs) decreased significantly between 2005–2006 and 2009–2010 among children and adolescents; however, PUFA intakes did not change. Among adults, intakes of total fat, SFAs, and MUFAs decreased; moderate.</td>
</tr>
</tbody>
</table>
Vesper et al. (10) & Yang et al. (11) USA

Pre-test (1999-2000, 2009-2010) Nationally representative US adults aged ≥20 years (48% men, 67% non-Hispanic White (NHW), 11% non-Hispanic Black (NHB), 6.4% Mexican American (MA))

1999-2000 (n=1613); 2009-2010 (n=2462)

To examine plasma TFA concentrations in a representative sample of the US population using NHANES samples from 1999-2000 and 2009-2010 and to assess the association between TFA intake and serum lipid and lipoprotein concentrations.

Mandatory TFA labelling on packaged foods Plasma TFA concentration, LDL, HDL, total cholesterol, and triglycerides

Changes in TFA: Plasma TFA concentrations were 54% lower in 2009-2010 (geometric mean=37.4µmol/L, 95% CI: 36.1, 38.8) as compared to 1999-2000 (geometric mean=80.9µmol/L, 95% CI: 75.7, 86.5). The largest change among the four isomers of TFA measured (vaccenic, elaidic, linolelaidic, palmitelaidic) was in concentrations of elaidic acid which declined from 40.5% to 36% of total TFAs. TFA concentrations declined consistently in different population subgroups with the exception of different age groups where individuals aged 20y had a higher decline (57%) than those aged 80 years (49%).

Changes in cholesterol/triglycerides: TFA concentrations continued to be associated with serum lipid and lipoproteins even after significant reductions in plasma TFA concentrations. At both time points, higher TFA
concentrations were associated with a higher prevalence of unfavourable lipid profiles. Levels of LDL-C were lower in 2009-10 (123/dL) compared to 1999-2000 (114 mg/dL). Levels on HDL-C were higher in 2009 (47mg/dL) as compared to 1999-2000 (51mg/dL). Triglyceride levels were higher (121mg/dL) in 1999-2000 as compared to 2009-10 (104mg/dL).

**Garsetti et al. (12)**

**USA**


**Fat composition of spreads sold in 2013 (n=37) representing >80% of the market sales volume and 2010-11 (n=44) representing >75% of the sales volumes as compared to the fat composition of spreads (as described in the literature) in 2002 (n=7)**

**To assess the fat composition of vegetables oil spreads and margarines in 2013 and to evaluate changes in the fat composition of spreads over the previous decade.**

**Mandatory TFA labelling on packaged foods**

**Total fat, MUFA, PUFA, SFA, TFA**

**Changes in TFA:** From 2002 to 2013, TFA in a 14g serving of spreads declined by an average of 1.5g (1.7g in 2002 vs 0.5g in 2011 vs 0.2g in 2013) and 16 percentage points of total fatty acids (19.2% in 2002 vs 6.7% in 2011 vs 3.2% in 2013).

**Changes in other fatty acids:** Over this time period, the proportion of total fat from solid fat (SFA & TFA) declined from 39% to 30% and unsaturated fat increased from 61% to 70% of total fatty acids. From 2002 to 2013, the total fat of a 14g serving of spreads declined by an average of 2.2g (9.3g in 2002 vs 7.4g in 2011 vs 7.1g in 2013). SFAs remained stable on a per serving basis but increased as a percentage of total fatty acids.
acids (19.5% in 2002; 24.6% in 2011; 26.7% in 2013). PUFAs varied slightly on a per serving basis (2.8g in 2002; 3.2g in 2011; 3.0g in 2013) but increased as a percentage of total fatty acids from 31.1% in 2002 to 29.9% in 2013. Over this time period, MUFAs declined on a per serving (2.7g in 2002; 1.7g in 2011; 1.8g in 2013) and percentage of total fatty acid (30.2% in 2002; 23.6% in 2011; 25.9% in 2013) basis. By 2013, 86% of spreads were TFA free. In 2013, compared to branded spreads, private label spreads contained more total fat (8.6 vs. 7.1g/serving) and more TFA (10% vs 3.2% of total fatty acids).

<table>
<thead>
<tr>
<th>Mandatory TFA Labelling + Voluntary TFA limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Friesen et al. (13)</td>
</tr>
<tr>
<td><strong>Canada</strong></td>
</tr>
<tr>
<td>Breast milk samples from women (n=103) collected in 1998</td>
</tr>
<tr>
<td>To compare TFA in the breast milk before (1998) and after (2004-05) the Canadian TFA regulation</td>
</tr>
<tr>
<td>TFA content &lt;0.2g/serving and TFA+SFA combined &lt; 2g/10g (≤ 15% of energy) serving labelled as TFA free. Voluntary limit of 2% total fat from TFA in fats, oils and spreads and 5% total fat from in foods.</td>
</tr>
<tr>
<td>TFA in the breast milk of women in 2004-05 as compared to samples taken from women in 1998</td>
</tr>
<tr>
<td>Change in TFA levels: TFA was 35% lower in 2004-06 than 1998. TFA levels progressively decreased in 3 time points at 5 month intervals between 2004 and 2006. The estimated intake of TFA (using breast milk) was 4.0g/person/day in 1998 as compared to 2.2g/person/day in 2005</td>
</tr>
<tr>
<td>Weak Changes in other fatty acids: MUFA and PUFA did not change but SFA were slightly higher.</td>
</tr>
<tr>
<td>Ricciuto et al. (14)</td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Ratnayake et al. (15)</td>
</tr>
</tbody>
</table>
products, margarines, etc.)

total fat from in foods.

more than once to assess reformulation, none had an increase in SFA or TFA; 1 had no change but all others had lower TFA + SFA and increased cis-unsaturated fat content. Average TFA + SFA was reduced from 53% to 12% to 30% to 19%. Average absolute change in total fat content was 0.8 %.

| Ratnayake et al. (16) | Interrupted time series | 1120 Samples in 31 different food categories were collected from 2005-2009 from major grocery stores, fast food chains and cafeterias across Canada. Foods collected had previously been identified as having high quantities of TFA. 2004 Canadian Community Health Survey data on TFA and SFA intakes (n=33,000) | To provide results of the TFA monitoring program for the period 2005-2009 | TFA content <0.2g/serving and TFA+SFA combined < 2g/10g (≤ 15% of energy) serving labelled as TFA free. Voluntary limit of 2% total fat from TFA in fats, oils and spreads and 5% total fat from in foods. | Fatty acid composition of selected foods | Changes in TFA: TFA decreased from 8.4g/day in the mid 90s to 3.4g/day in 2008 (still above WHO recommendations). On average, there was a 30% decrease in TFA intakes between 2004 and 2008. From 2005-2009, of the 1120 samples analysed 76% met the recommended TFA limits. In 2005 and 2006 only 58% of samples met the limits, in 2007 68%, in 2008 77% and 2009 78% met the limit. Only 45% of brownies, 43% cakes, 25% of croissants, 45% of Danishes, 55% of garlic breads, 36% pies, and 67% of tarts contained TFA <5%. Only 29% of donuts sampled between 2005 and 2008 contained <5% TFA. 100% of pizzas, 79% of French fries and chicken products, 83% of fish products, 89% of muffins and 75% of onion rings | Weak |
sampled <5% TFA. 62% of tub margarines, 0% of print margarines and 50% of vegetable shortenings met the recommended limits. TFA in margarines between 2005-07 were on average 39.3%. Most (70%) of the products sold in cafeterias met the limit with the exception of some products (margarines, onion rings and fish products).

Changes in other fatty acids: SFA intakes did not increase during the study time period. TFA reductions were achieved in most products without increasing SFA but with increasing MUFA and PUFAs. However, in crackers, cookies, frozen chicken products and garlic spreads TFA reductions were associated with an increase in SFA and unsaturated fatty acids. The sum of TFA + SFA in these products did not increase. Reformulated donuts that reduced TFA had SFA levels nearly double to those with TFA levels >5%.

<table>
<thead>
<tr>
<th>Ratnayake et al. (17)</th>
<th>Pre-post cross sectional study (1992, 2009, 2010, 2011)</th>
<th>TFA content in breast milk samples collected in 2009 (n=153), 2010 (n=309), and 2011 (n=177) from</th>
<th>To assess the impact of the efforts in Canada to reduce industrial TFAs in foods, the concentration of</th>
<th>Mandatory TFA labelling + voluntarily TFA limits (2% for oils/fats and 5% for packaged food) in</th>
<th>TFA intake of breastfeeding women and TFA content of breast milk</th>
<th>Changes in TFA: TFA contents of total milk fat were 2.8% in 2009, 2.3% in 2010 and 2% in 2011 as compared to 7.2% found previously for Canadian milk</th>
</tr>
</thead>
</table>

Weak
breastfeeding mothers in 10 major Canadian cities. These were compared to breastmilk samples in 1992 (n=198). TFAs in human breast milk samples was measured.

Arcand et al. (18) Canada

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Databases Used</th>
<th>Methods</th>
<th>Foods and Change in TFA</th>
</tr>
</thead>
</table>
| Pre-post cross-sectional study | 3 databases were used.  
Packaged foods: 1) Foods (n=5544) from 3 grocery stores in Toronto 1 in Calgary (2010-11) and 2) foods from the Trans Fat Monitoring Program (TFMP) database (2006-9) of foods that contribute the most to the Canadian diet.  
Restaurant foods: 4272 foods from 85 Canadian restaurants with >20 outlets nationwide (2010). | To conduct an updated assessment of TFA levels in the food supply and to determine whether they have been replaced by SFAs.  
Mandatory TFA labelling + voluntarily TFA limits (2% for oils/fats and 5% for packaged food) in foods.  
Foods that met recommended limits for TFA and TFA in foods. | Changes in TFA: In 2005-06, 75% of foods met the TFA limits as compared to 95.4% of packaged foods and 96.1% of restaurant foods in 2010-11. Foods with the greatest improvements were: croissants (25% to 100%), pies (36% to 98%), cakes (43% to 90%), garlic spreads (33% to 100%), and garlic bread (55% to 91%). However, the number of products meeting the TFA limits decreased in 3 product categories: coffee whiteners (53% to 33%) and lard (100% to 75%) and vegetable (50% to 40%) shortenings.  
Foods that exceeded the recommended TFA limits were: dairy free cheeses (100%), frosting (72%), coffee whiteners (66.7%), Mexican meal kits (62.5%), lard and shortening (55.5%), shortbread cookies (41.7%) and refrigerated dough (50%). Many packaged foods that exceeded the TFA limits. |
contained very high mean quantities of TFA as a % of total fat: coffee whiteners (38.3%), yeast doughnuts (35%), popcorn (33.9%), frosting (28.6%), cake doughnuts (27.7%), dairy-free cheese and spreads (27.5%) and sugar wafer cookies (25.0%). Biscuits and scones (47.4%) and cookies (14.7%) were categories with the highest proportion of foods exceeding the TFA limits.

Changes in other fatty acids: Most food categories did not have increases in SFA between those foods that met the TFA limit. Packaged food exceptions included: chocolate chip, chocolate-covered and sandwich cookies, brownies, squares, cakes with pudding/mousse, dessert toppings and lard/shortening. Restaurant food exceptions included: cookies and desserts and other baked goods.
<table>
<thead>
<tr>
<th>Study Authors</th>
<th>Design</th>
<th>Pre-post</th>
<th>NYC</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brandt et al. (19)</td>
<td>Pre-post</td>
<td>NYC</td>
<td>Used Census data from 2000 and 2010 for hospital admissions. 2004 NYC HANES data were used to examine restaurant usage per week. To assess MI and stroke rates before and after the TFA limits in New York City restaurants.</td>
<td>Changes in disease risk: After 2007, younger age groups (25-34 and 35-44) experienced an additional decline in stroke, but not MI, that was greater than would have been expected based on temporal trends. Younger age groups also reported higher mean restaurant use in NYC HANES.</td>
</tr>
<tr>
<td>Restrepo &amp; Rieger (20)</td>
<td>Pre-post</td>
<td>NYC</td>
<td>CDC Wonder panel data of annual mortality rates from NYS counties between 1999-2013. To examine the impact of TFA limits in restaurants on mortality rates in NYS county residents with and without a TFA policy.</td>
<td>Changes in disease risk: When comparing mortality rates in NYS counties with and without a TFA limit in restaurants, the results indicated that the policy was associated with a 4.5% reduction in CVD morality rates or 13 fewer CVD deaths (11 from HD and 2 from stroke) per 100,000 persons per year.</td>
</tr>
<tr>
<td>Angell et al. (21)</td>
<td>Interrupted time series</td>
<td>NYC</td>
<td>478 restaurants in 2005, 1021 restaurants in 2006, 996 food establishments in 2007 (after passage but prior to effective date). Fast food nutrition (n=12) information of major chains pre and post regulation. To examine the effectiveness of NYC TFA restrictions.</td>
<td>Changes in TFA: 98% of restaurants were not using oils/spreads containing TFA in November 2008 compared to 50% in 2005. Changes in other fatty acids: On average, French fries in fast food chains decreased SFA by 10.5%, TFA by 97.9% and total TFA + SFA grams by 54%.</td>
</tr>
<tr>
<td>Angell et al. (22)</td>
<td>Pre-post test</td>
<td>NYC</td>
<td>6969 purchases in 2007 and 7885 purchases in 2009 at 168 randomly selected NYC restaurant locations of 11 fast-food. To examine the effect of NYC TFA restriction on the TFA and SFA content of fast-food purchases.</td>
<td>Changes in mean grams of TFA, SFA, TFA + SFA and TFA/1000kcal overall and by fast-food chain type. Changes in TFA: Mean TFA/purchase decreased by 2.4g (2.9g vs 0.5g; p&lt;.001) and mean TFA/1000kcal decreased by 2.7g/1000kcal. TFA/purchase.</td>
</tr>
</tbody>
</table>
chains in 2007 and 2009 significantly decreased in 3 of 5 chain types and increased in one (0.2g vs 0.3g). Purchases with 0g of TFA increased by 86% from 32% to 59%. The maximum TFA content of a single purchase decreased from 28g to 5g.

**Changes in other fatty acids:** SFA increased by 0.6g (p=.011) and mean TFA + SFA decreased by 1.9g (p<.001). The maximum TFA + SFA content in a single purchase decreased from 96g to 60g.

### Mandatory TFA limits in foods

| Peymani et al. (23) | Interrupted time series: (2002, 2003, 2004, 2005, 2006, 2007, 2008) | Samples of edible oils from local manufacturers and retail markets: 2002 (n=30), 2003 (n=36), 2004 (n=36), 2005 (n=19), 2006 (n=33), 2007 (n=38), 2008 (n=19) | To assess TFA and SFA levels in oils before and after TFA limits in edible oils were implemented in Iran | Mandatory limit of 20% TFA in edible oils (2005-Oct 2007) and limit of 10% TFA beginning Nov 2007 | TFA and SFA levels in edible oils | Changes in TFA: Average TFA levels prior to the implementation of the 20% TFA limit were: 27% in 2002, 28.8% in 2003, 31.2% in 2004. Average TFA levels after the 20% limit (but prior to 10%) were: 31.2% in 2005, 18.2% in 2006 and 13.7% in 2007. Following the implementation of the 10% TFA limit, average TFA levels were further reduced to 5.62% of total fat. | Changes in other fatty acids: Average SFA levels were 20% in 2002, 21.5% in 2003, 22.2% in 2004, 24.5% in 2005, 26.1% in 2006, 24.1% in 2007 and 26.68% in 2008. | Weak |

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Mandatory TFA limits in foods
### Denmark

| Leth et al. (24) | Pre-post test | 253 samples of both imported and domestically produced products at the end of 2002 to early 2003 (pre-ban) | To assess the effectiveness of Denmark’s TFA ban | TFA limit on all foods sold in the country; a maximum of 2% total fat from TFA in both 2002-03 and 2004-05 | TFA content of food samples known to be high in TFA in both 2002-03 and 2004-05 | Changes in TFA: TFA decreased from 4.5g/day in 1976, to 1.5g/day in 1995 and were virtually eliminated in 2005 (post-ban). Fewer samples had levels of TFA >2% post regulation. Those that did have levels >2% ranged between 2-6% TFA, some with milk ingredients (meaning some of the TFA was likely naturally occurring TFA). In a couple potato and cake products higher levels of TFA were found and steps have been taken by authorities to correct this. | Weak |

| **PHVO** – Partially hydrogenated vegetable oils | **MUFA** – Monounsaturated fatty acids | **PUFA** – Polyunsaturated fatty acids | **SFA** – Saturated fatty acids | **TFA** – Trans fatty acids | **MI** – Myocardial Infarction |

- Voluntary industrial modification of partially hydrogenated soybean oil (began in 2000)
- Voluntary reformulation of products; 12 major companies in the Americas signed a declaration of their intentions to help achieve a “trans-fat-free Americas” (began in 2007)
- 2004 Product Board for Margarine, fats and oils set up the Task Force for Responsible Fatty Acid Composition to reduce use of PHVOs setting limit of 5% TFA in frying oils
- Mandatory TFA labelling (began in 2006). TFA content <0.2g/serving labelled as TFA free
- Mandatory TFA labelling (began in 2006). TFA content <0.5g/serving labelled as TFA free
- Mandatory TFA labelling (began in 2005). TFA content <0.2g/serving labelled as TFA free TFA content <0.2g/serving and TFA+SFA combined < 2g/10g (≤ 15% of energy) serving labelled as TFA free. Voluntary limit of 2% total fat from TFA in fats, oils and spreads and 5% total fat from in foods.
- Ban (<0.5g/serving) of artificially produced TFAs in all licensed food establishments. First phase – oils and spreads, second phase – all products including bakery items.
- Ban of TFA in all foods sold in the country; a maximum of 2% total fat from TFA.
### Supplemental Table 2. An overview of the modelling studies included in the systematic review

<table>
<thead>
<tr>
<th>Authors, Year and Country/Region</th>
<th>Model type</th>
<th>Study population</th>
<th>Aim of study</th>
<th>TFA reductions/policy</th>
<th>Outcomes assessed</th>
<th>Main findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>O’Keeffe et al. (22) Republic of Ireland</td>
<td>Validated IMPACT Food Policy Model</td>
<td>Population of Ireland aged 25-84y</td>
<td>To estimate the potential reduction in CVD mortality by decreasing salt, trans fat and saturated fat consumption, and by increasing fruit and vegetable consumption in Irish adults aged 25-84 years in 2010</td>
<td>Conservative policy scenario: reductions in TFA by 0.5% of energy intake</td>
<td>CHD and stroke deaths averted</td>
<td>Conservative TFA policy scenario: 88 of the total of 241 CHD deaths averted are attributable to TFA policy (36.5% of the total CHD deaths). 24 of the 154 stroke deaths averted are attributable to TFA policy (15.6% of the total stroke deaths prevented).</td>
</tr>
<tr>
<td>O’Flaherty et al. (21) United Kingdom</td>
<td>Spreadsheet model</td>
<td>Population of UK aged 25-84y</td>
<td>To estimate how much more CVD mortality could be reduced in the UK through more progressive nutritional targets from 2006 to 2015</td>
<td>Conservative policy scenario: reductions in TFA by 0.5% of energy intake</td>
<td>Total CVD deaths averted</td>
<td>Conservative TFA policy scenario: Reduction of 3500 deaths (min 1820, max 6820) attributable to TFA policy. More substantial TFA policy scenario: Reduction of 4700 deaths (min 2500, max 8800) attributable to TFA policy</td>
</tr>
<tr>
<td>Barton et al. (20) England and Wales</td>
<td>Spreadsheet model</td>
<td>Population of England and Wales aged 40-79y at time of intervention</td>
<td>To estimate the potential cost effectiveness of a population-wide risk factor reduction program aimed at preventing CVD</td>
<td>Legislative TFA ban to reduce current iTFA intakes (0.8% of total energy) by approximately 0.5% of total energy content</td>
<td>CVD events avoided, QALYs gained, and savings in healthcare costs for a given effectiveness</td>
<td>More substantial TFA policy scenario: Reduction of 4700 deaths (min 2500, max 8800) attributable to TFA policy</td>
</tr>
<tr>
<td>Pearson-Stuttard et al. (23) England and Wales</td>
<td>Validated IMPACT-SEC model (named IMPAC-TFA)</td>
<td>Population of England and Wales aged ≥25y stratified</td>
<td>To quantify the potential benefits of population level reductions of TFA</td>
<td>Conservative policy scenario: reductions in TFA by 0.5% of energy intake</td>
<td>CHD deaths prevented or postponed, life years gained and hospital</td>
<td>Conservative policy scenario: 1,900 fewer CHD deaths, 4,900 fewer hospital admissions and 19,000 life years gained</td>
</tr>
</tbody>
</table>

DOI: 10.3945/cdn.117.000778 on November 14, 2017 - First published online on November 13, 2017 in Current Developments in Nutrition.
To determine health and equity benefits and cost effectiveness of policies to reduce or remove trans fatty acids (TFA) from processed foods, compared with consumption remaining at the most recent TFA levels in England from 2015 to 2020.

**Policy model**

*Entire population of Argentina*

To estimate the impact of Argentine policies to reduce TFA on CHD, DALYs and associated healthcare costs from 2004 to 2015.

**Progressive TFA policies actually implemented** (voluntary labelling (2004), mandatory labelling (2006), 2% TFA limit in fats (2012) and 5% TFA limits in all foods (2014-15):

- Three scenarios:
  - Scenario 1: Based only on the effect of TFA
  - Scenario 2: Based on projected changes in lipid profile, 301 deaths, 1066 acute CHD events and 5237 DALYs would be averted. US$17 million in health-care costs annually would be avoided. Based on the adverse effects of TFA intake reported in prospective cohort studies, 1517 deaths, 3500 acute CHD

**Deaths from CHD prevented or postponed; life years gained; QALYs; policy costs to government and industry; policy savings from reductions in direct health care, informal care and productivity loss.**

**Total ban would prevent or postpone about 7200 deaths from CHD between 2015-2020. This would reduce inequality in mortality from CHD by ~3000 deaths (15%).**

**Improving labelling or removing trans fatty acids from restaurants/fast food could save between 1800 and 3500 deaths – inequalities would be reduced by 600 (3%) to 1500 (7%). A total ban would have the greatest net cost savings of about £265 million as compared to £80-147m for the other policies.**

**Rubinstein et al. (25)**

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replacements on the ratio of TC/HDL-C._scenario_2: Scenario 1 plus the effects of TFA replacements on other CHD biomarkers in controlled trials. Scenario 3: Based on the observed relationship of TFA replacements with clinical CHD events in prospective cohort studies. 6 events and 26,394 DALYs would be averted annually. US$ 87 million in health-care costs annually would be avoided.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Model</th>
<th>Country/Region</th>
<th>Methodology</th>
<th>Objectives</th>
<th>Policy Scenarios</th>
<th>Outcome Measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restrepo &amp; Rieger (26)</td>
<td>Empirical model</td>
<td>Denmark</td>
<td>To assess whether Denmark’s trans fat policy reduced deaths caused by CVD using synthetic control methods to simulate the CVD mortality trajectory (using that of other OECD countries) that Denmark would have witnessed in the absence of the policy</td>
<td>Trans fat ban (2% upper limit) in all products</td>
<td>CVD mortality in Denmark, with and without the TFA policy. Mortality attributed to CVD.</td>
<td>Before the trans fat policy was implemented, CVD mortality rates in Denmark closely tracked those of a weighted average of other OECD countries (i.e., the synthetic control group). In the years before the policy, the annual mean was 441.5 deaths per 100,000 people in Denmark and 442.7 in the synthetic control group. In the 3 years after the policy was implemented, mortality attributable to CVD decreased on average by about 14.2 deaths per 100,000 people per year in Denmark relative to the synthetic control group.</td>
<td></td>
</tr>
<tr>
<td>Martin-Soborido et al. (25)</td>
<td>Markov Model</td>
<td>European Union</td>
<td>To assess the value and cost-effectiveness of 3 possible EU-level TFA reduction policies</td>
<td>Scenario 1: Do nothing beyond current state (reference situation) Scenario 2: Mandatory TFA labelling of pre-packaged foods Scenario 3: Voluntary agreements to reduce iTFA content of foods Scenario 4: Legislative limit for iTFA content of foods</td>
<td>CAD related DALYs and costs in yearly cycles for 85 years; ICERs</td>
<td>Legislating an EU-level legal limit may avoid the loss of 3.73 million DALYs and save &gt;51 million Euros when compared to the current state. A voluntary limit may lead to 2.19 million DALYs and save &gt;23 billion euros compared to the reference situation. A TFA labelling policy may save 0.98 million DALYs; however, it would not be cost effective in less in cases in which initial iTFA intakes are relatively</td>
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using 4 initial iTFA intake estimates: 0.3% of total energy (base case), 0.15% of total energy (scenario 1), 0.45% of total energy (scenario 2), and 0.7% of total energy (scenario 3). high.

TFA = trans fatty acid, iTFA = industrially produced trans fatty acid, CVD = cardiovascular disease, CHD = coronary heart disease, CAD = Coronary Artery Disease, QALY = quality adjusted life year, SEC = socio-economic circumstances, DALY = disability adjusted life year, TC/HDL-C = total cholesterol/high density lipoprotein, ICER = incremental cost effectiveness ratio
### Supplemental Table 3. The underlying assumptions of the included modelling studies

<table>
<thead>
<tr>
<th>Authors, Year and Country</th>
<th>Model Assumptions</th>
</tr>
</thead>
</table>
| O’Keeffe et al. (26)      | Republic of Ireland  
|                           | • Combined changes in RR for individuals are multiplicative.  
|                           | • Changes between current food component consumption and the expected two scenarios examined will be made by all individuals within the population changing consumption by the same amount.  
|                           | • Reductions in unit change in RR refer to a unit change in food component consumption or proximal risk factors following a dose-response relationship (i.e. a change in consumption of fruit and vegetables from 2 to 3 portions a day has the same effect on RR as a change in consumption from 8 to 9 portions a day). |
| Allen et al. (27)         | England  
|                           | • Future consumption would remain constant  
|                           | • Continuing declines in incidence of and mortality from CHD  
|                           | • The policies modelled varied in assumed coverage: 100% coverage for a total ban, at most 49% for labeling, and at best 40% for a restaurant/fast food ban |
| O’Flaherty et al. (28)    | United Kingdom  
|                           | • Effects of food policies would be quantitatively similar to those in other countries.  
|                           | • Assumed trans fat could be replaced by an equal mixture of good MUFAs and PUFAs, not by saturated fat.  
|                           | • Assumed changes in dietary variable would be similar across all age groups.  
|                           | • Effects of dietary changes on mortality would wane with increasing age, as with cholesterol and blood pressure. |
| Barton et al. (29)        | England and Wales  
|                           | • Benefits apply consistently for men and women across age, social and risk groups  
|                           | • No attempt to consider recurrent events or subsequent deaths  
|                           | • Assumes that CVD rates would remain constant if there was no intervention |
| Rubinstein et al. (30)    | Argentina  
|                           | • 80% of sudden deaths were due to CHD  
|                           | • The reduction in CHD deaths was proportional to the difference in estimated CHD risk  
|                           | • Baseline consumption of 1.5% of total energy intake as TFA in 2004 |
| Restrepo & Rieger (31)    | Denmark  
|                           | • Assumed that OECD countries were all similar when creating synthetic Denmark |
| Pearson-Stuttard et al. (32)| England and Wales  
|                           | • Used an area level categorization of socioeconomic status. This may be sub-optimal for analyzing trends within individuals.  
|                           | • The value for the 85+ age group was extrapolated using the reducing mortality reduction figures from the younger age groups.  
|                           | • Mortality reduction for a 0.25% reduction in TFA intake was estimated using linear extrapolation.  
|                           | • Assumed also that the elimination of ruminant TFA would not be feasible.  
|                           | • Assumed no future decline in case fatality, which is a conservative estimate when modeling a 2030 scenario. |
| Martin-Soborido et al. (25) | European Union  
|                           | • Estimated current iTFA intakes based on literature; however, examined 3 alternative scenarios of initial iTFA levels  
|                           | • Assumed a continuous decrease in iTFA content of foods that leads to their complete removal from the food supply over a 10-year period, even in the absence of policy (i.e., reference situation)  
|                           | • Assume the total removal of iTFA from the food supply within 5 years with a voluntary agreement  
|                           | • The TFA mandatory labelling policy scenario assumes that the removal of iTFA in pre-packaged, but not in non-packaged, foods is faster than the reference situation (no action). It assumes population TFA intakes are similar to the reference situation for the first 2 years (until pre-packaged foods are labelled) then a faster reduction in TFA which is assumed to contribute to 50% of population TFA intake initially and decrease to 0% in 3 years. This policy scenario assumes that reduction in iTFA in non-packaged food will remain the same as the reference
situation.

- The legislative TFA limit policy assumes the total removal of iTFA in 2 years.

RR = relative risk, CHD = coronary heart disease, MUFA = monounsaturated fatty acid, PUFA = polyunsaturated fatty acid, CVD = cardiovascular disease, TFA = trans fatty acid, iTFA = industrially produced trans fatty acid, OECD = Organisation for Economic Cooperation and Development
References

2. Colón-Ramos U, Baylin A, Campos H. The relation between trans fatty acid levels and increased risk of myocardial infarction does not hold at lower levels of trans fatty acids in the Costa Rican food supply. The Journal of Nutrition 2006;136:2887-2892.