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TRANS-FATTY ACID ACID (TFA) ELIMINATION IN PAKISTAN: A SITUATIONAL ANALYSIS

Heartfile

May 2019





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Executive Summary

Trans-fatty acids (TFAs) are unsaturated constituents of fat found in foods obtained from ruminants, such as dairy products and meat, and in industrially produced partially hydrogenated vegetable oils (PHOs). Since 1991, peer-reviewed research has accumulated that demonstrates the link between high intake of industrially produced trans-fatty acids (iTFAs) and a variety of non-communicable diseases (NCDs), including coronary heart disease. Pakistan's trans-fat intake is estimated to be the 2nd highest in the WHO-EMRO region after Egypt. In recent years, several countries around the world have implemented policies to eliminate industrially produced TFA from their diet, with remarkable degrees of success. The World Health Organization has called for the global elimination of TFA from the food by 2023 and has developed the REPLACE framework to remove and replace trans-fats from country diets. This report is a situational analysis of trans fatty acids (TFAs) in Pakistan that looks at the incidence and particular sources of TFA in the Pakistani diet, examines existing literature on TFA elimination from around the world and the policy and regulatory landscape in Pakistan to suggest possible steps to eliminate it from the Pakistani diet.

A wide variety of approaches for TFA elimination have been employed by governments around the world; these include mandatory labelling, mandatory limits, voluntary limits, bans on food products, TFA replacement initiatives and a combination of the above. The literature shows that mandatory limits backed by credible penalties are the most effective way of reducing TFA, with the remarkable success achieved by governments that have applied such limits. Mandatory labelling is also another key intervention that has the result of moving the industry toward reformulating TFA-heavy products. Successful TFA elimination policy efforts often tend to be characterized by strong stewardship of the process by key government institutions, extensive coverage by electronic and print media, multi-sectoral approaches that involve industrial, academic and civil society stakeholders, joint public-private research efforts for TFA replacement, strong monitoring capacity and the ability of governments to assess both TFA content in food and its intake by the population. In developing country contexts similar to Pakistan's, policymakers also face the added dilemma of ensuring a reduction in TFA while maintaining adequate calorie and fat intake among disadvantaged segments of society.

In Pakistan, the main dietary sources of TFA include vanaspati ghee, margarines, bakery shortenings and cooking oil. As these oils and fats are widely used for cooking and baking purposes in Pakistan, including widespread usage in homes, they lead to high TFA levels across a wide variety of food products, including biscuits, chocolates, pastries, breakfast foods, French fries, and breakfast cereals. The main industries that are the source of TFAs in the Pakistani context are edible oil, margarine, and the bakery and confectionary industry. The bulk of TFA consumed in Pakistan (about 98%) is produced within the country.

Pakistan's food regulation framework has historically been weakly enforced (owing to both lack of state capacity and flouting of regulations by food producers) and continues to suffer from a lack of enforcement capacity or institutional harmonization, with multiple laws, bodies and standards operating in different regions and tiers of governance. However, progress in food regulation has been made in recent years and some steps toward limiting TFA content in food have also been taken. The key institutions responsible for food safety regulation in the country include the provincial food authorities and the Pakistan Standards and Quality Control Authority (PSQCA). Authorities in Punjab and Khyber Pakhtunkhwa have enacted mandatory TFA limits for several food products, while PSQCA has adopted limits for vanaspati ghee only. However, with the exception of Punjab, none of the limits imposed are within WHO-recommended levels or cover the entire array of products high in TFA. The Punjab Food Authority (PFA) has also taken the added step of banning vanaspati ghee by 2020. Sindh and Balochistan have not yet enacted any policies or limits for TFA elimination and suffer from much more basic capacity constraints that inhibit their ability to regulate TFA within their jurisdiction. The PSQCA's standards are currently the most permissive out of all the standards bodies.

Other key government institutions relevant for the elimination of industrial TFA in Pakistan include the Ministry of National Health Services, Regulation and Coordination (NHSR&C), the provincial health departments, the Ministry of Commerce (Customs), the Pakistan Council of Scientific and Industrial Research (PCSIR), the Ministry of Planning, Development and Reform, the Ministry of National Food Security and Research (MNFSR) and the National Institute of Health (NIH) Pakistan.

A number of considerations need to be borne in mind by policymakers to achieve TFA elimination in Pakistan in the coming years. These include the existence of overlapping and contrasting standards across different provincial and

federal jurisdictions, maximum TFA limits, the need for uniform labelling and nutrition profiling requirements in compliance with WHO-recommended levels and legal loopholes for producers to circumvent regulations. Credible penalties need to be enacted and popularized for violation of TFA regulations. This needs to be tied to the clear definition of federal and provincial food regulation responsibilities to ensure an appropriate constellation of roles and effective enforcement across various tiers of governance.

There are a few capacity constraints among government institutions that hinder the fight against TFA. The capacity of provincial food authorities to assess TFA content needs to be strengthened; this includes both building laboratory capacity, recruitment and training of human resource personnel, and changes in rules of inspectors to monitor TFA in products and impose penalties for non-compliance. Data on TFA consumption has also never been collected at the population level in Pakistan, which hinders a more concrete understanding of the TFA intake for different sub-sections of the population; this needs to be collected (potentially as part of the National Nutrition Survey) both as a baseline to assess progress toward TFA elimination and to tailor policy interventions and public messaging appropriately.

A lack of awareness among the public, retailers and policymakers about the consequences of high TFA-intake remains a broader environmental concern that inhibits quicker action toward TFA elimination, pointing toward the need for targeted communication efforts to build public demand; such efforts must involve electronic, print and social media, and target population sub-groups with high TFA intakes. Research around TFA replacements and reformulation of TFA- rich products, such as vanaspati ghee, must be carried out in collaboration with academia and industry stakeholders to ensure a shift toward the production and consumption of heavier fats and oils. The federal and provincial government also need to take the lead to promote healthier alternatives through changes in procurement policies, nutrition guidelines and public messaging about healthier dietary habits

1. Introduction

Trans fatty acids (TFAs) are integral components of unsaturated fats found in foods obtained from ruminants, such as dairy products and meat, and in industrially produced partially hydrogenated oils. According to the WHO's definition, TFAs are fatty acids with at least one carbon–carbon double bond in the trans configuration.² For unprocessed natural food, the content of naturally occurring TFA is generally low (<0.3%) and so is its consumption by humans, with evidence to suggest that it does not adversely affect health.³ The same cannot be said for industrially produced TFA, which accounts for the bulk of contemporary trans-fat consumption, through the partial hydrogenation of vegetable oils such as palm, cottonseed, soybean or canola has been demonstrated to be immensely harmful to human health.

In recent decades, rigorous evidence-based research has accumulated to confirm the link between high intake of industrially-produced TFA (above 0.5% of total energy intake) and non-communicable diseases (NCDs), including increased risk of coronary heart disease, as well as infertility, endometriosis, gallstones, Alzheimer's disease, diabetes and some cancers. Globally, an estimated 537,000 deaths in 2010 were attributed to increased intake of TFA.⁴ TFA was responsible for 7.7% of coronary heart disease mortality, despite accounting for only 1.4% of global energy intake. Pakistan is a particularly high consumer of TFA; among the countries of WHO's EMRO region, TFA consumption in Pakistan was ranked highest after Egypt.⁵

The global food industry began using large amounts of partially hydrogenated oils in the 1960s, following public health campaigns aimed at decreasing animal fat use. The food industry favors these oils and resists their removal because they are cheap, have a long shelf-life, are semi-solid at room temperature (hence making them easier to use for baking), and can withstand repeated heating.⁶ This partly explains why voluntary industry efforts to remove trans-fat have been slow and insufficient for the most part in many countries.

Despite this, the elimination of TFA from diets has been deemed as a straightforward public health intervention for reducing the risk of non-communicable diseases (NCDs). The WHO has called for the elimination of trans-fat from the food supply and a core indicator adopted in WHO's Global Framework for United Nation's high-level meeting on NCDs in 2011 was the "adoption of national policies that virtually eliminate partially hydrogenated oils in the food supply and replace [them] with polyunsaturated fatty acids". TFA elimination was also identified as a priority in the draft 13th General Program of Work, which will guide the work of the World Health Organization (WHO) in 2019-2023. The WHO has developed the REPLACE framework as a roadmap for countries to implement actions to reduce and eliminate industrially produced TFA, which outlines six strategic action areas to support the elimination of industrially produced TFA from the

food supply.2

Elimination of industrially-produced TFA is an eminently achievable and large reduction in trans-fat intake at the population level have been achieved in high-income countries through a combination of policies, including mandated trans-fat labelling, public education campaigns, engagement with industry to reformulate products and imposing regulations and bans on high levels of trans-fats nationally and locally. However, that success required substantial political will sustained over a decade. Most other countries only have achieved voluntary TFAs limits, reflecting concerns about the feasibility and generally lower levels of public pressure for change. Many WHO member states that took part in consultations indicated "low (or no) support" for the inclusion of the removal of TFAs as a global monitoring target because of concerns about the feasibility, achievability and public health effect of removing them from the food supply.⁷

However, considerable progress has been achieved toward TFA elimination in recent years and it remains direly needed in countries like Pakistan with excessive TFA-intake and large NCD burdens. The purpose of this report is to undertake a situational analysis of TFA elimination for the Pakistani context. This will be done through the following steps.

- a) A review of literature on policies, actions and best practices for TFA elimination from around the world, with a view to understanding which combination of legislative, regulatory, administrative and advocacy initiatives can be most effective in eliminating TFA or reducing its intake to below recommended levels.
- b) A review of the policy and regulatory framework and key TFA-producing sectors in Pakistan, to understand which institutions, actors, policies, and actions will be relevant for TFA elimination in the Pakistani context.
- c) This review will also build on the results of the study commissioned by WHO-EMRO Pakistan on 'Assessment of Diet Associated Non-Communicable Disease Risk Factors in Pakistan and Strategies to Reduce their Burden' (WHO-EMRO, 2019), which provides a comprehensive account of the main dietary sources of TFA in Pakistan with a view to understanding the steps are needed for its elimination.

This report concludes with a discussion on the challenges and an outline of the steps needed for TFA elimination in Pakistan's context, in line with the REPLACE framework, with suggestions for target outputs and institutional responsibilities.

2. Methodology

The methodology for this assessment consisted of two parts: a review of academic and grey literature and interviews with key informants. The search strategy involved using Medline, Google Scholar, Embase, J Stor and Web of Knowledge, databases to identify peer-reviewed articles that examined TFA policy. In addition, the first 20 pages of Google searches were examined to identify articles from the grey literature. The main search terms were 'trans-fat' and 'policy'. Additional search terms related to trans-fat were: trans fatty acids, hydrogenation, vanaspati, and margarine. Additional search terms related to policy were regulation, health policy, legislation, ban, intervention, labelling, law, and standards.

Based on the information in the abstracts, those studies were selected for review that: a) were of an empirical nature; b) examined a TFA policy, for instance, labelling, voluntary limits or bans; c) examined a policy's effect on TFA levels in food products, for example, food, diet, blood or breast milk; and d) dated from 1991 to later, after the effects of TFA were discovered. The selected studies were reviewed and organized into categories of analysis informed by the REPLACE framework, as well as other categories that were refined based on the evidence emerging from the literature. Later, a specific search was undertaken for broader literature, including legislation and policy frameworks on nutrition and food regulation in Pakistan (for a more holistic understanding of Pakistan's policy frameworks and history with decentralization). In addition to the literature review, this assessment, in particular the section on Pakistan's context, was also informed by interviews and discussions with key federal and provincial government officials, non-government experts, academics and researchers.

3. TFA elimination around the world – the evidence

Several approaches have been employed by governments and public health organizations across different countries to reduce trans-fatty acid intake. These have ranged from nutrition recommendations on TFAs, awareness raising about the adverse effects of TFAs through nutrition and health claims, voluntary or mandatory labelling of the trans content of foods, legislated or voluntary reformulation by industry to remove TFAs, promotion of trans reductions through health

and agricultural policies that encourage the production of healthy alternatives to trans-fat and mandatory regulation of food standards. A few of the initiatives underway in selected industrialized and developing countries are detailed in this review, which can serve as models for countries like Pakistan to understand the considerations involved in their implementation in a variety of local conditions. The examples quoted cover both some of the most successful strategies adapted around the world, as well as relevant attempts and considerations from countries of a more similar socioeconomic structure to that of Pakistan.

3.1. Research, public awareness and a legislative ban – the case of Denmark

Denmark is often quoted as one of the early success stories for TFA elimination, as a country that achieved remarkable progress within a very short span of time due to the confluence of some key variables. In 2003, Denmark passed legislation to limit artificial TFA to 2 grams per 100 grams of fat or oil in all food in 2003. Section 1 of the legislation stated that it applied to "oils and fats, including emulsions with fat as the continuous phase which, either alone or as part of processed food stuffs are intended or likely to be consumed by humans." The limitation was not applicable to naturally occurring content of trans fatty acids in animal fats and was concerned solely to products sold to the final consumer. The legislation also specified that in products which claim to be 'free from trans fatty acids', the content of trans fatty acids in the finished product must be less than 1 gram per 100 grams of the individual oil or fat.

The Danish legislation also specified penalties and criminal liabilities for violation of the specified regulations, including fines for a first violation and prison for up to two years if the contravention was committed willfully or through gross negligence. Within three years of this legislation, TFA was virtually eliminated from the Danish diet, with nearly zero intake at the population and individual level by 2006.8

The rapid elimination of TFA in Denmark was due to several factors coming together involving science, economics, and politics. The course of events that led to TFA elimination was initially spurred by the publication of scientific research (by Willett et al, 1993)⁹ on TFA and its role in substantially increasing the risk of coronary heart disease. Prior to this, the Danish population was largely unaware of TFA and prompt, focused coverage by the media of this research spurred immediate action. Key to the eventual success response was the leadership by the Danish Nutrition Council (DNC), which immediately established a working group to produce a comprehensive report on the health effects of TFA. The research produced by the working group looked not just at the consequences of TFA and its average consumption, but also its impact and intake for specific sub-segments of the population. The DNC's report also received significant coverage, improving public awareness and prompting competition among Danish margarine producers to reduce TFA in their products.

This was followed by another round of research by the DNC in 2001 and 2003, which found still high levels of TFA in off-the-shelf products and fast food outlets, led to demands for action to establish mandatory limits through legislation, which was finally passed in June 2003, through the initiative of then Danish Minister of Food and Agriculture, Ritt BjerreGaard and her successor, Mariann Boel. Progress on the legislation was subsequently monitored both by the DNC as well as public and private electronic and print media outlets, to assess compliance, leading to action to take products off the shelves in case of non-compliance.¹⁰

The key ingredients for success in the Danish case include the publication of quality research tailored to the Danish context, the leadership of a steering institution like the DNC, evidence-based inquiry into consumptions habits among sub-sections of the population, focused multi-stakeholder planning by a working group on TFA, legislative action by key political leaders and focused, objective coverage of the research and reform measures around TFA by the print and electronic media throughout the process.

3.2. Mandatory TFA labelling and a trans-fat taskforce – the case of Canada

The Canadian case points to a different route to TFA elimination from Denmark. Canada, once one of the highest TFA-consuming countries in the world, became the first country to introduce mandatory labelling about TFA in the Nutrition Facts table of pre-packaged food, in 2002. To be labelled 'trans free', the Canadian labelling regulations required foods to not only contain <0.2 g of trans-fat but also be low in saturated fat (i.e., contain <2 g of saturated and trans-fat combined (per reference amount and per serving of stated size).^{11,12}

The labelling requirements, media attention, and increasing consumer concerns led to companies working to reduce TFA

in their products. Nevertheless, many argued that a government-imposed ban would hasten TFA reduction in the Canadian diet and affect a broader range of foods than those covered by the nutrition labelling regulations, which did not apply to foods consumed in restaurants or other places outside the home. This led to a parliamentary motion for the formation of a taskforce with Health Canada and the Heart and Stroke Foundation of Canada as co-chairs, whose mandate would be 'to provide the Minister of Health with concrete recommendations and strategies to effectively eliminate or reduce processed trans-fats in Canadian foods to the lowest level possible'.¹³

Members of the Task Force included individuals from the food manufacturing and foodservice sectors, the federal government, non-governmental health organizations, professional associations, academia, consumer groups, and oilseed producers and processors. In its recommendations, the task force called for foods purchased by retailers or food service establishments to be regulated on a finished product or output basis, and foods prepared on site by retailers or food service establishments to be regulated on an ingredient or input basis. This was because regulating the latter groups by using or employing limits on the finished product would have required the measurement of the nutrient content of foods served by thousands of individual retail bakeries, grocery stores, restaurants, fast food outlets and foodservice operations, who were not necessarily in a position to analyze their finished products. Thus, the burden of limiting TFA content in foods was placed higher up the food supply chain to simplify compliance and enforcement. The taskforce also limited total trans-fat content in vegetable oils and soft, spreadable margarine sold to consumers, retailers or food service establishments to 2% of total fat content.

On the basis of dietary intake modelling, using the recommended trans-fat limits above, the average daily intake of transfats for all age groups in Canada represented <1% of energy intake, consistent with WHO recommendations (WHO, 2003). The task force also recommended a '2+2' approach: two years to develop regulations and up to two years for implementation. It also drew up a list of healthful oils for a variety of food applications and recommended them to the industry as replacements.

The taskforce's recommendations were then put into place by Health Canada, which gave the industry two years to reduce trans-fats to the required levels, otherwise, the department would introduce regulations for limits. Health Canada also updated and released its revised 'Canada's Food Guide' in 2007, a tool to help Canadians make healthier food choices, which included explicit recommendations to reduce TFA and SFA intake and instructions for reading the Nutrition Facts table on food products. ¹⁴

This was accompanied by the establishment of a Trans-Fat Monitoring Programme to analyse trans-fat content in foods, with results posted every 6 months. Results from the monitoring program showed that the labelling requirements, task force recommendations, and public health awareness through media platforms resulted in significant reductions in TFA consumption in Canada within two years. However, the results were not as drastic as in Denmark; even after mandatory labelling led to 76% of foods meeting voluntary TFA limits, intake in the population still exceeded the WHO recommendation that less than 1% of daily dietary energy intake should come from consuming TFAs. More recently, in September 2018, Canada banned the use of partially hydrogenated oils in food products.

3.3. Multi-sectoral collaboration toward TFA regulations – the case of Argentina

Argentina followed a somewhat different trajectory, with multi-sectoral efforts to develop healthy fats and oils as replacements for TFAs. Work on TFA reduction was kicked off in Argentina by a baseline consumption study by La Plata University and the Buenos Aires Health Ministry, which revealed large levels of TFA in commonly consumed food items, including most sweet and salty food snacks.¹¹ The results of this scientific investigation were the starting point of a series of steps toward TFA elimination, starting with an assessment of whether the industry could ensure sufficient quantities of healthy fats and oils to replace TFAs.

This was done through collaboration between academia and industry; in 2001, La Plata National University and Dow Agrosciences signed a cooperative agreement to pool efforts to develop replacement oils. This collaboration came about as a result of a decision by industrial actors to move toward voluntary TFA reduction and pre-empt regulation. As a result of this, four years later, a variety of TFA-free sunflower oils with high oleic acid content were readily available on the Argentinean market. The properties of these oils, including very high heat resistance and relatively low price, were extremely important in allowing the food industry to replace partially hydrogenated oils.

Argentina eventually introduced regulations to enforce mandatory labelling of artificial TFAs in food in 2006. In 2008, with a push and support from the Pan American Health Organization (PAHO), the Argentine Ministry of Health formed the Argentine Commission for the Elimination of Trans-Fats, which brought together consumer groups, academia and the food industry, as well as the National Institute of Nutrition (part of the Ministry of Health), the National Institute of Industrial Technology (part of the Ministry of Economics), the Ministry of Agribusiness, and the Argentinian Association of Fats and Oils. The commission eventually recommended changes in the Argentinian food code (el Código Alimentario Argentino) and a new guide for small and medium businesses on how to replace industrially- produced trans-fats. The CAA amendments gave the industry two years to comply with the new regulations, namely that industrially produced TFAs in food must be limited to <2% of total fats in vegetable oils and margarine and <5% of total fats in other foods. This was accompanied by measures like a communication campaign to reduce TFA content in bakery goods and other foods in restaurants and public outlets. TFA information was also included in the nutritional guidelines for the Argentinian population issued by the Ministry of Health.¹⁶

Wide-ranging coverage of the TFA issue by the press was also a catalyst for change, as improved public awareness and demand led to the industry seeing trans-free reformulation as a commercial opportunity. The impact of these measures seems to have been substantial: in a very short time, Argentina was able to replace approximately 40% of the 30 000 metric tons of TFAs that were produced annually with other fats. A 2015 study published in the WHO Bulletin estimated that anywhere from 301 to 1517 cardiac deaths per year were averted by eliminating industrially-produced trans-fats in Argentina.¹⁷

Most studies in existing reviews of successful TFA elimination strategies tend to be located in industrialized, high-income countries. However, some case studies exist of developing and middle-income country contexts that have successfully enacted TFA elimination policies.

3.4. Evidence-based multi-sectoral collaboration to reduce consumption – the case of Iran

In the early 2000s, Iran was one of the world's top consumers of trans-fats (mostly through edible oils) and had seen a steady increase in cardiovascular disease (CVD). To address this situation in light of new research linking TFA consumption with CVD, the Iranian Ministry of Health and Medical Education (MOHME) decided to address the situation through an evidence-based approach. As the first step, a thorough situation analysis was done and evidence gathered regarding the prevalence of TFA in edible oils used in Iran. The research found extensive use of oils containing TFA among the Iranian public (up to 33% of fat in most oils) and found that replacement of TFA with cis-unsaturated fat could prevent 39% of CVD. Based on these findings, the MOHME came up with a national plan for the reduction of TFA and SFA in the Iranian diet.

The plan was composed of three main aspects: i) negotiations with food processing companies to restrict the percentage of TFA from >20% to <10% in their products; ii) a public education campaign with an emphasis on increasing the public's knowledge about the adverse health effects of TFA in processed food and edible oils; and iii) establishment of a national committee for TFA reduction with government agencies, civil society and industry, including the health and agriculture ministries, Iran Food and Drug Administration (FDA), oil manufacturers, nongovernmental organizations and oil importers.¹⁸

In 2005, the National Standards Organization of Iran mandated a 10% cap on trans-fats in corn oil, palm oil, frying oil and mixed liquid oils—a reduction from the previous 20%. Government organizations were mandated to use oils with less than 10% trans-fat content. In 4 years after the implementation of the policy on limiting the amount of TFA in edible oil to 10%, a dramatic decline was observed in TFA content of edible oils in Iran from 28.8% in 2003 to 5.62%. 18

More stringent changes were gradually phased in, in collaboration with industry. Trans-fat standards were reduced to less than 5% in fats and oils in 2011, and to less than 2% in 2013, with a 2016 compliance deadline. Recently, Iran's FDA Post Marketing Surveillance results showed that the average trans-fat of almost all of frying and liquid oils was below 1% and within the acceptable limit, according to a report on Iran's efforts by the International Fund for Agricultural Development (IFAD) and National Nutrition and Food Technology Research Institute (NNFTRI).¹⁹ While work remains to be done in reducing TFA levels in bakery products (for which the legal limit is still 5% rather than 2%), Iran's progress from one of the leading TFA consumers to a relatively safe position vis a vis TFA has been impressive and built on the back of evidence-based government action based on multi-sectoral collaboration and cooperation coupled with public

awareness to change consumption behaviour. Iran's stated goal is to limit trans-fats to less than 1% by 2019. According to the Iranian FDA, that target had already been reached by 2018.

3.5. Pioneering TFA elimination in developing country contexts – the case of South Africa

South Africa was faced with rising incidence of CVD mainly due to the increasing consumption of processed food, including many with high levels of iTFA. South Africa's push to control trans-fat started in 2008, with a call from Dr. Ruth Rabinowitz, an opposition member of Parliament, to outlaw industrially produced trans-fats. The South African National Department of Health (NDoH) decided to take on the question of trans-fat regulation as a priority on its own (separately from other nutrition requirements) and invited industrial stakeholders, academia and civil society for extensive consultations to develop a working document for regulation. This led to draft regulations in 2010 which were shared with the public and in media to elicit feedback and generate awareness around TFA intake and its health consequences. Following overwhelming public support for the draft regulation, the South African government introduced the Regulation 249: Regulation Relating to Trans-Fats in Foodstuffs in February 2011, to limit artificial trans-fat to 2 grams per 100 grams of fat in all food products and introduce mandatory labelling.²⁰ The industry was given 6 months to comply with the regulation.

With this legislation, South Africa became the first developing country worldwide and the first African country to enact comprehensive trans-fat legislation. Concerns were raised by critics at the time of the legislation about their practicality and the government's lack of monitoring capacity, but they were largely unfounded. The legislation was followed by close monitoring of labels by NDoH of South Africa, which found that regulations were being complied with. The regulations spurred a technological evolution in the food industry and manufacturers of industrial fats managed to develop techniques of blending unsaturated and saturated fat to achieve the same functional properties previously generated by trans-fats. The legislation led to a domino effect as, to comply with the regulations and benefit from improved public awareness around trans-fats, major retailers and fast food also began to announce they were removing trans-fat from their product range, including Woolworth, Pick n Pay, McDonald's South Africa and Wimpy.²¹

3.6. Balancing TFA reduction and fat intake – the case of India

The challenges of TFA elimination in India, a country similarly placed to Pakistan in terms of income, diet and calorie consumption, are somewhat different from North American or European experiences. The major sources of TFA in India are vegetable oil products such as Vanaspati ghee, bakery fats and shortening made through partial hydrogenation methods. Cost, availability and stability of oils (which are often stored without refrigeration) are important considerations in India, as in Pakistan.

India also suffers from both chronic calorie deficiency (associated with low intakes of fat and diet-related chronic diseases (associated with excessive intakes). Fat intake in the Indian population is highly income dependent and therefore highly skewed, being low in rural and urban poor income groups. Thus, a major priority is to increase vegetable oil consumption from the present daily level of <13g per person to combat the widespread energy deficiency in low income groups.²² Thus, it is thought by experts in India that the goal to reduce TFA consumption by reducing the consumption or TFA content of vanaspati must be balanced against the current insufficient total fat intake among much of the population.

The Food and Safety Standards Authority of India established a trans-fat limit of 10% of total fat in vegetable oils,

vegetable fat and hydrogenated vegetable oil and further reduced it to 5% in 2017. This was also accompanied by the introduction mandatory nutrition labelling for trans-fats. India has committed to the WHO's stipulated deadline for trans-fat elimination by 2023. However, according to researchers, a trans-fat ban alone may not have the anticipated impact on TFA levels in the Indian food supply, given the scale and diversity of the country, lack of capacity for enforcement and the huge informal (and largely unregulated) food sector in India. (Downs et al, 2015)²³ Although ensuring that such policy measures are adequately enforced – and corruption minimized – could improve their

Box 1: Engaging vendors for healthier oil consumption in Singapore.

In Singapore, the Health Promotion Board (HPB) began an initiative in 2011 called the Healthier Hawker Program, which aimed to ensure that there was an affordable supply of healthier oils, by working with local manufacturing companies to increase the supply. In order to cut costs for vendors, they established cooperatives where manufacturers sold and vendors bought these healthier oils. By streamlining this supply chain, it reduced the price, making it a competitive option for vendors. In order to highlight those vendors using the healthier oil, they also adopted a healthier ingredients symbol program — which is part of the program — allows vendors to put up a sign to indicate use of healthier ingredients if trans-fat levels are less than 0.5 g/100 g and saturated fat levels are less than 38 g/100 g. (Downs et al, 2015)

effectiveness, additional, multi-sectoral measures may be needed in order to reduce trans-fat availability across the whole food supply.

Complementary measures that have been proposed for the Indian context include investment in the development and mass production of healthier and cost-effective bakery shortenings and frying oils, formulation of multi-stakeholder implementation frameworks for TFA-related regulations, investment in agricultural supply chains of healthier oils in order to allow manufacturers to replace PHOs with oils high in unsaturated fat (i.e. alternatives to palm oil), incentivizing food vendors to use healthier oils, and improving consumer awareness of health issues. Crucially, in contexts like India (and Pakistan), policies to improve the quality of fat being consumed need to take

place within the broader context of improving diet quality at the population level by tackling the double burden of diet related disease.8

4. Lessons from the literature

The literature shows that an increasing and wide array of similar policies have been employed around the world to eliminate trans-fats from country diets. Many of these strategies have met with success in achieving reduction; a review by Wanders (2017) found that the intake of trans-fat has substantially decreased over the past 20 years in almost all countries that have applied TFA elimination policies, while the average intake is below the recommended maximum intake of 1% of daily energy intake in 76% of the countries. This reduction is primarily attributable to a reduction in the use of industrial TFA.²⁴

However, this decline in TFA content is not uniform across countries. Most countries that have successfully minimized or eliminated TFA contents, are higher income, developed economies, while others like India, Egypt and Pakistan have not had either concrete policy efforts or measurable success. Even in some developed countries, statutory measures to reduce TFA contents are either non-existent or have only recently been instituted.

Mandatory limits on TFA are the most consistent and effective way to eliminate industrial TFA. While all types of TFA policies (voluntary limits on TFA, mandatory limits at the national level, local bans, and mandatory TFA labeling) reduce TFA levels in the food supply, mandatory TFA limits backed by credible penalties (like the ones implemented in Denmark, Argentina, Chile and South Africa) have led to drastic reductions or virtual elimination of trans-fats in some cases. However, the effectiveness of enacting TFA limits depends on the extent to which the bans are accompanied by complementary interventions aimed at both regulatory, industrial and behavioral change.

The enactment of mandatory labelling is another necessary measure on the road to TFA elimination that most countries have adopted with results. Labelling (in particular, front-of-pack labelling and nutrition profiling) is particularly important in that it can lead to product reformulation, as it helps consumers to understand the contents of their food and make demands of the industry for low-TFA products. However, catalyzing this change depends on high consumer awareness of TFA, which is often not the case in developing countries with lower literacy levels. Furthermore, labelling is an insufficient step to tackle high levels of TFA consumption in specific sub-sections of the population, for whom demand for certain food products may be price inelastic. Labelling can also lead to low-TFA products being marketed as a costlier alternative, leading to lower-income individuals continuing to choose the high-TFA products. Finally, in most lower income countries, most of the high-TFA food is consumed via street vendors in the informal sector and thus hard to regulate through labelling.

Stewardship for TFA elimination by a key government institution is a variable, visible in most successful strategies. TFA elimination is often led by a specific steering institution in the country that takes on the task – in some cases, it is the Ministry of Health or the national food standards body, while in others, it is led by subnational governments and government research institutions like the Danish Nutrition Council or temporary arrangements like the Working Group for TFAs in Canada. These institutions were often given responsibility for both reviewing the situation and planning and organizing the response along with other stakeholders.

Multi-stakeholder approaches, involving constructive partnerships with stakeholders from academia, media, producers and retailers tend to be a common feature of effective TFA reduction strategies. Electronic and print media has been central to TFA elimination strategies through focused coverage on research, industrial practices, government efforts and policy evaluation, which has been key in generating public awareness and consumer and citizen demand for TFA

Table 1: Regulations for TFA reduction/elimination in selected countries^{11,16,26}:

Country/Region	Policy	Details
Denmark	Mandatory limit and labelling	Mandatory limit of 2% of fat or oil for all foods Research on TFA intake through TFA working group
Argentina	Mandatory limits and replacement research and promotion	Industrially made TFA (iTFA) <2% of total fat content in vegetable oils and spreadable margarines iTFA <5% of total fat content in all other products. These regulations explicitly exclude all fats from ruminants
India	Mandatory limit and labelling	Mandatory limit of 5% of total fat in oils and fats Foods using hydrogenated fats or bakery shortenings must specifically declare this on the label, and mention that they contain trans-fat. India's food regulator has recently proposed to limit the maximum amount of trans-fat content in vegetable oils, vegetable fat and hydrogenated vegetable oil to 2 percent by weight as part of its goal to make India trans-fat-free by 2022
Brazil	Mandatory labelling, inter-sectoral collaboration for replacement	Prohibited the use of partially hydrogenated vegetable oil in 2018, to go into effect in 2021. Mandatory labelling in food products Inclusion of TFA information in the nutritional guidelines for the Brazilian population Development of consumer educational materials regarding TFA content in foods
Chile	Mandatory limits, campaigns, nutrition guidelines,	Limit of iTFA <2% of total fat content in all products Inclusion of TFA information in nutritional guidelines for the Chilean population Inclusion of TFA information in the national campaign 'Choose to Live Healthy' Inclusion of TFA information in consumer educational materials to adopt a healthy lifestyle Industry-led campaigns to educate consumers to choose TFA-free margarines, bakery products, sweets, French fries and other foodstuffs.
Peru	Limits and later ban	On 24 April 2014, the National Ministry of Health signed a resolution requiring fats, vegetable oils and margarines to not exceed 2 g TFA per 100 g/ml total fat; and all other processed foods and non-alcoholic drinks to not exceed 5 g TFA per 100 g/ml total fat. Within 36 months of entering into force, the use of TFA resulting from hydrogenation was to be discontinued completely.
Mexico		Recommendation to limit the maximum permitted level of TFA consumption. If there's a declaration with respect to the type of fatty acid or quantity of cholesterol: TFA (per 100 g/100 ml or per serving) should then be declared together with the MUFA and PUFA (g) and cholesterol (mg) quantities. TFA-free definition is not specified.

Continuous...

Country/Region	Policy	Details
Gulf Cooperation Council	Mandatory limits and labelling	Maximum trans-fat content of vegetable oils and soft spreadable margarines is 2% of the total fat, and for all other foods is 5% of the total fat content including ingredients sold to restaurants. The amount of TFA in food, including dietary supplements shall be included in the Nutrition Facts, expressed in grams and % Daily Value. Terms 'trans fatty acids' and 'trans-fat' can be used interchangeably. Label declaration of trans-fat content information is not required for products that contain less than 0.5 g of total fat per 100 g if no claims are made about cholesterol, saturated fats, monounsaturated fats, polyunsaturated fats and trans fats. Where a claim that a food product is 'trans-fat free' is made on the label or in an advertisement, the amount of trans-fat shall be less than 0.5 g of total fat in 100 g.
South Africa	Mandatory limits	The trans-fat content of any oils and fats cannot exceed two grams per 100 grams, as per legislation. Products with higher trans-fats levels are prohibited from entering or being sold in the country. The regulations also require any product labelled as 'transfat-free' to contain less than one gram of trans-fats per 100 grams.
China	Mandatory labelling	If any (partially) hydrogenated fat is used, the level of trans-fat has to be highlighted.
South Korea	Mandatory labelling	Mandatory nutrition labelling on foods covered by the nutrition labelling requirements (bread, chocolate, processed milk, sausage (mixed with fish), instant noodle (cup), fruit and vegetable juice, gimbab (prepackaged), hamburger, sandwich).
Malaysia	Mandatory labelling	Mandatory labelling of saturated fats, monounsaturated fats, polyunsaturated fats and trans fats if a claim is made regarding fatty acids.
Puerto Rico	Mandatory limits and restrictions on sale and use	No food that contains hydrogenated fats will be stored, distributed, used in preparation of any menu or served in any food establishment or mobile feeding units (except foods that are directed to the sponsors in sealed packages of the original manufacturer). No trans foods will be served in schools, centres of daycare and homes for the elderly.
Iran	Mandatory limits	Mandatory TFA limit of 2% in cooking oils and 5% of fats/oils in other food.
		Mandatory TFA limit of 2% in vegetable oils and spreadable margarines and 5% limit of total fat for other foods.
Singapore	Mandatory limits and labelling	Trans-fat limit of 2 g per 100 g product for edible fats and oils.

Country/Region	Policy	Details
		Mandatory nutrition labelling including TFA for retail packs of edible fats and oils.
Jordan	PHO ban	Ban on partially hydrogenated oil in dairy products, including imported produce.
Canada	Mandatory labelling and more recently, PHO ban	As of Sept. 15, 2018, made illegal for manufacturers to add partially hydrogenated oils to food products. Imported foods and menu items served in restaurants and institutional cafeterias are also included under the ban. Currently mandatory nutrition labelling of TFA plus voluntary measures by industry are in place.

reduction. Universities and research centers have been key in generating country-specific knowledge about the prevalence, sources and intake of trans-fats that has then been used to push for regulatory changes. Producers, including edible oil and margarine manufacturers, have played a constructive role in TFA elimination efforts in many countries, often partnering with governments to reformulate their products and supporting research for replacement oils. However, while many multinational companies have switched sources of fat to reduce TFA levels in products sold in high-income countries, they tend to resist making these changes in low- and middle-income countries. Consumer groups have been key in contexts like Canada, Argentina and others, to help build consumer demand for TFA replacement and help sustain the advocacy for the changes needed.¹⁶

Many countries have complemented regulations with concurrent research efforts for replacement of iTFA with healthier oils and reformulating TFA-heavy products, which has helped ensure the transition to TFA-free diets is seamless. Reformulation, rather than complete bans (like the proposed ban on vanaspati in Pakistan), can help ensure that the total TFA content in food remains acceptably low. However, it is important to bear in mind the direction which product reformulation takes, as some evidence exists to avoid the risk of replacing TFA with saturated fatty acids. Producers in some developing country contexts began replacing partially hydrogenated vegetable oils with palm oil, which increases the level of saturated fatty acids.²⁵ Progress in low and middle-income countries including Pakistan will have to be monitored to ensure that partially hydrogenated vegetable oils are not replaced exclusively with cheap oils high in SFA, such as palm oil, and work will have to be done to develop polyunsaturated (preferably) or mono-unsaturated oils as replacements. This may be easier for countries that grow crops rich in poly and mono unsaturated fats; however, for countries like Pakistan which rely on imports, the task will be more difficult to achieve.

Trans -fatty acid elimination also requires the robust monitoring mechanisms that involve periodic inspections of both labels and testing of food products to ensure strict adherence to governmental regulations. This is especially important, given studies on food products following the enactment of regulatory actions that have found still high levels of TFA in products covered by regulations. Where effective monitoring mechanisms have been deployed, accompanied by the imposition of penalties for violators and removal of products from the shelves for non-compliance with limits, compliance has been better. Successful elimination efforts have often featured the existence of technical institutions with the capacity for assessing TFA prevalence and consumption.

The generation of evidence on TFA intake, stratified by different population sub-groups, has been key in the strategies of countries that have established best practices in TFA elimination like Denmark, Austria and Iceland. This is an important variable for developing contexts like Pakistan, where large sections of the population suffer from under-nutrition and insufficient fat intake, and large informal sectors and weak state capacity make it difficult to assess how far regulations are being followed. TFA elimination policies in such contexts need to be designed to ensure certain strategies (such as bans) do not reduce any existing caloric deficiencies and cater to implementation issues specific to low enforcement capacity. Intake data is also necessary to be able to measure the health consequences of TFA elimination policies.

Overall, the review of the literature indicates that TFA reductions policies, in particular mandatory limits and bans, were positively associated with significant reductions in TFA levels in the food supply: such policies are feasible, achievable and

likely to be impactful for public health. However, further research is needed on TFA consumption and elimination policies in low-resource settings to identify context-specific challenges and appropriate policy responses. Encouraging and supporting producers and the agriculture sector to increase the supply of suitable alternative oils needs must be a key complement to limits and labelling requirements. Finally, it is important to note that reducing the TFA content of food is only one component of a multipronged strategy to improve diet and reduce the risk of diet-related chronic disease.

5. Trans-fats in the Pakistani context

5.1. Sources of trans-fats in Pakistan:

According to an assessment of diet-associated NCDs in Pakistan commissioned by WHO-EMRO (2019), Pakistan has the 2nd highest per capita intake of TFA in the WHO-EMRO region (even though it has one of the lowest per capita saturated fat consumption). Pakistan has also seen the largest increase in trans-fat intake between 1990 to 2010 (1.5%).¹¹ A review of research on TFA content in industrially-produced foods in Pakistan demonstrates that the major contributors to transfat consumption in Pakistan are vanaspati ghee, with TFA percentages of 14.2% to 34.3%; margarines, with TFA percentages of 11.5% to 34.8%; and bakery shortening, with TFA percentages of 7.3% to 31.7%.¹⁶ As these products are widely used for cooking and baking purposes in Pakistan, this leads to high trans-fat levels in multiple food items common

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Table-2: Major dietary sources of trans-fat in Pakistan²⁶.

 Source
 Average TFA range (%)

 Vanaspati ghee
 14.2% - 34.3%

 Margarines
 11.5% - 34.8%

 Shortenings
 7.3% - 31.7%

 Cooking oil
 0.4% - 1.8%

Table-3: Trans-fat levels in major food products⁵

Food product	Average TFA range (%)
Biscuits	9.3% - 34.9%
Chocolates	4.56% - 8.49%
Pastries	3.92% - 10.97%
Parathas	11%
Cakes	12%
French fries	0.11% - 24%
Breakfast cereals	14.4%

the Pakistani diet, ranging from biscuits, chocolates, pastries, breakfast foods, french fries, and breakfast cereals. 1,27

The bulk of trans-fat sources in Pakistan are locally produced (about 98%) and are concentrated in the edible oil, margarine and baking sectors.^{28,29} Research and knowledge about TFAs in the Pakistani diet is relatively new and government regulators have only recently begun to respond to the challenge, largely in Punjab and Khyber-Pakhtunkhwa and less so in other provinces. A brief overview of the key industries in which iTFA is produced in Pakistan (edible oil, margarine and bakery and confectionary) is provided below.

5.2. The edible oil industry:

Pakistan's edible oil industry has a market size of over PKR 500 billion, registering volumetric sales of ~4m tons in 2017. Pakistan is one of the leading consumers of edible oil in the world, averaging a per capita consumption of 23 kg/year compared to 3 kg/year in Europe. The predominant product in the industry is vanaspati ghee, accounting for over 70% of the market, with cooking oil accounting for 30% of sales. Most of the oil, about 2.5m tons, is consumed by retail consumers for cooking and baking a variety of food products that are a central part of Pakistan's food basket. Industrial consumers account for the remaining 1.5m tons per annum. Palm oil, which is cheaper and has a higher shelf life than soft oil (those that are liquid at room temperature, as opposed to solid or semi-solid oils), accounts for 65% of the market share.

The bulk of edible oil consumed in Pakistan – close to 2.9m tons - is imported. 0.4m tons of edible oil are produced domestically while domestic production of oil extracted from imported seeds amounts to 0.7m tons. Pakistan is the world's fourth largest edible oil importing country. Palm oil is the predominant import (about 94%), followed by soybean, sunflower and canola. Edible oil imports cost more than US\$ 3.1 billion annually, making it the country's second largest import after petroleum products. Pakistan imports crude and refined palm oil mainly from Malaysia (which accounts for 75% of total edible oil imports), as well as Indonesia and imports soybean oil from North America and Brazil. Pakistan's large edible oil import bill has been seen by policymakers as a major concern that adds to the country's large current account deficit and efforts are underway to expand domestic palm oil production. Edible oil imports into Pakistan are covered under Customs' tariff code 1516 ("Animal or vegetable fats and oils and their fractions, partly or wholly

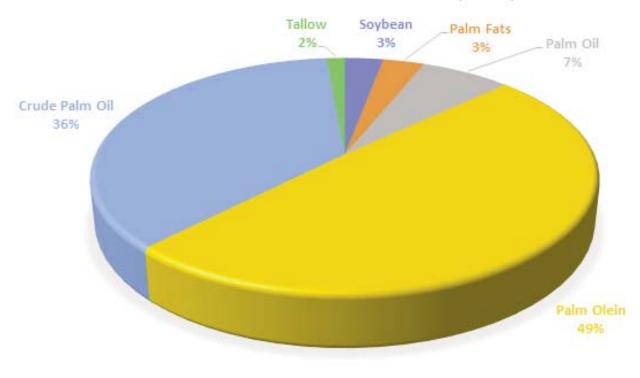


FIG 1. PAKISTAN EDIBLE OIL IMPORTS (TYPES)

Source: JCRVIS, (2018), 'Edible Oil Industry: Sector Update'.

hydrogenated, inter-esterified, re-esterified or elaidinised, whether or not refined, but not further prepared").

There are over 200 licensed cooking oil and ghee manufacturing companies in the country, including about 150 ghee manufacturing units, collectively producing 10,000 tons of oil and ghee daily. The Pakistani edible oil industry is characterized by competitive intensity due to market fragmentation and relatively low barriers of entry which results in limited pricing power and thin profitability. Major players in the organized segment (in order of descending market share) comprise Dalda Foods Limited (market share of ~8.1%), Habib Oil Mills Limited (market share of ~3.7%), Sufi Banaspati & Cooking Oil, Seasons Edible Oil, Mezan Cooking Oil & Banaspati, Punjab Oil Mills Limited and Kashmir Cooking Oil & Banaspati. Key producer entities include the Pakistani Vanaspati Manufacturing Association (PVMA) and Pakistan Edible Oil Refiners Association (PEORA).

5.3. Butter and margarine industry:

Pakistan is one of the top five milk producing countries in the world, producing 37-38 billion liters annually. The branded spreads category, including butter and margarine is a significant part of the dairy industry, valued at Rs. 2.5 billion. Nurpur is the market leader in branded butter with a "95% market share," according to Muhammad Tayab, GM Operations, Nurpur Foods, but there are also two other players: Millac Butter (a brand of Millac Foods, launched in 2008) and Adam's (a brand of Adam's Milk Foods).

The two most popular foreign brands are Lurpak (produced in Denmark) and Mumtaz (from the UAE). Local butter brands range in price from Rs 105-110 (for 200g) whereas the international brands retail at Rs 180 for the same stock-keeping unit (SKU).³⁰ Blue Band (made by Unilever Pakistan) is the biggest local player in the margarine category; international brands

include Flora (also a Unilever brand, but hasn't been distributed locally since 2010), "I Can't Believe It Is Not Butter", Mumtaz and Nawar. Margarine is much more popular than butter with a margarine-to-butter market share ratio of 70:30. This is principally because of cost: local margarine (e.g., Blue Band) is priced at Rs 84 for a 200g SKU (significantly less than butter) and is therefore more popular with consumers.

Pakistan imports US \$15 million worth of margarine annually, a figure that has grown by 88% over the last five years. Malaysia is the main source of imported margarine (40% in 2017-18), followed by Singapore (23% in 2017-18). Margarine imports into Pakistan are covered under Customs' Tariff code 1517 ("Margarine; edible mixtures or preparations of animal or vegetable fats or oils or of fractions of different fats or oils of this chapter, other than edible fats or oils or their fractions").

Another challenge relevant for the purposes of regulating margarine use is that people continue to believe butter and margarine are substitute products, despite margarine being produced with hydrogenated vegetable fat. Awareness raising of the differences between margarine and butter is key for behavioral changes regarding its consumption. It is also relevant to mention that much of the butter consumed in the country is of the unbranded variety.

5.4. Bakery and confectionary industry:

Pakistan's bakery and confectionary industry is one of the fastest growing economic sectors, averaging 6.5%-7.5% annual growth. The industry is divided into branded and generic segments. Independent, largely unorganized and unregulated retailers are still the largest contributors to the market, with sales being primarily generated via bakeries, shops, cafes, hotels and restaurants, which predominantly have a limited financial and banking history. Most businesses are family owned with members of one family performing different functions of business. However, there are a number of key bakery and confectionary brands that have gradually increased their market share in recent years.

The largest segment in the confectionery industry comprises plain biscuits, with a total of over 50 per cent share in volume. The biscuits sector has grown steadily in Pakistan in recent years, with a market size estimated at around PKR 60 billion in 2017. The bulk of biscuit consumption in the country is of the packaged variety; a Gallup Pakistan survey found that 62% of Pakistanis consume packaged biscuits while 31% consumed open bakery biscuits.

The market for the industry is quite competitive and price sensitive; an increase of Rs. 1 to Rs. 2 may mean sales volumes decreasing to one third. This has resulted in squeezed margins and emphasis on price points as all manufacturers compete to make the products available at lower prices as they are accessible to the bulk of the working-class majority. There is also an active informal manufacturing sector in biscuits, snacks and confectionaries with hundreds of players, which tends to respond if prices are increased. Bakery prices tend to be tied to prices of key raw materials, including sugar, flour and potatoes.

Domestic producers tend to dominate the bakery and confectionary market. The two main biscuit manufacturers are English Biscuits Manufacturers (EBM), which produces popular brands like Peak Freans Sooper Biscuits, Gluco Biscuits For Children, Marie Biscuits, Peanut Plus Biscuits, and Party Biscuits) and Continental Biscuits Limited (CBL) which produces brands like LU, TUC Biscuits, Bakeri Biscuits, Candy Biscuits, Tiger Biscuits, Prince Biscuits, among others. Other manufacturers of biscuits in Pakistan include Wafer Biscuits Pakistan, International Biscuits Limited, and United King Food Pakistan etc. Among bakeries, well-known names include Gourmet bakers, Nirala Sweets, Ideal Bakers, Copper Kettle and Sohni Sweets. The Pakistan Biscuit & Confectionery Manufacturers Association and Pakistan Food Association are two prominent trade groups of the bakery and confectionary industry.³¹

The informality of the sector means there are also mushroom industries sprouting in various areas of Pakistan producing counterfeit brands with low quality ingredients, which are often hazardous for consumers' health, besides being a revenue loss for the government. For TFA elimination purposes, this industry remains a key focal point for ensuring TFA-free food products at the retail level, by both monitoring it and encouraging and capacitating enterprises in the sector shift to toward healthier alternatives to TFA in production processes.

6. The food regulation framework in Pakistan

Pakistan does not have an integrated legal framework for food regulation but has a set of different laws which deal with varying aspects of food safety. While food laws have existed since the early decades of the country, their implementation

has been sparse and has led to periodic crises of food safety and public health. Part of the reasons relate to the lack of enforcement capacity historically and disinterest of authorities in antagonizing business interests. However, there are also longstanding institutional problems; the country's peculiar history of authoritarian centralized rule, followed by wideranging legislative and administrative decentralization to provincial governments in 2010 has led to a degree of institutional instability across multiple areas of governance, including those related to food regulation and safety. However, some provinces, in particular Punjab and KP, have also managed to develop provincial capacities and standards for food regulation since 2010.

While there have been visible advances in food safety regulations in some areas in recent years, it has been uneven and non-uniform across provinces. A number of key questions continue to beset the development of a coherent and well-enforced food regulation regime including continued weaknesses in regulatory and enforcement capacity, the issue of varying provincial standards, unresolved overlapping jurisdictions between federal and provincial bodies, and separate licensing and certification regimes, among others.

6.1. The Pure Food Laws:

The Pure Food Ordinance 1960 was the first piece of legislation pertaining to food safety in Pakistan and governed the safety and purity of the preparation and sale of foods for several decades after. Over the years, as governance has been decentralized, most provinces and federating units have adopted and updated versions of this law, including the Punjab Pure Food Regulations 2011 and 2018 and the Khyber Pakhtunkhwa Food Safety and Halal Food Regulations 2018. Food regulation in the military-managed 'cantonments' in Pakistan's cities and towns is governed by an adaptation of the same ordinance, namely the Cantonment Pure Food Act 1966. The content of the CPFA 1966 is very similar to the PFO 1960, including the rules of operations (the difference is in the enforcing institutions).

The Pure Food Laws, in their various provincial incarnations, cover food items under nine broad categories:

Dairy and dairy products, edible oils and fat products, beverages, food grains and cereals, starchy food, spices and condiments, sweetening agents, fruits and vegetables and miscellaneous food products. The General Provisions of the laws cover several areas including the prohibition of mixing food, selling mixed food, sale, and preparation, manufacture or export of unwholesome, adulterated, misbranded or low quality food, sale of prepacked food, licensing and registration of manufacture, storage and sale of goods, and sale of margarine, edible oils and vanaspati. The Act also includes provisions for food analysis, including appointment of analysts and inspectors, enforcement authorities, sampling methods and rights, and powers and certification of analyses. Procedures for complaints and penalties for violations are also outlined under the Act, most of which have been adapted by provincial authorities for their food authorities.

6.2. Pakistan Standards and Quality Control Authority (PSQCA):

The Pakistan Standards and Quality Control Authority (PSQCA) prescribes standards for food products and food grade materials (as well as other items) at the national level. The PSQCA was established under the Ministry of Science and Technology through the PSQCA Act of 1996; the function of the PSQCA is to provide advice to the government on standardization policies, programs and activities to promote industrial efficiency and development, as well as consumer protection. PSQCA standards cover both domestic products and imports. Domestic manufacturers and exporters are required to be registered with the authority to ensure compliance. The PSQCA's food standards are aligned with Codex and WHO and cover a mandatory list of 37 products under the Compulsory Certification Mark License Scheme ³². These items, whether imported or domestically produced, must carry a certification mark from PSQCA to be sold on the market. PSQCA also serves as the focal point in Pakistan for engagement with regional and international organizations such as ISO, IEC, Codex and WTO and serves as the National Inquiry Point for the WTO Agreement on Technical Barriers to Trade.

Food safety requirements under the PSQCA can be broadly categorized under two areas: i) Food premises and Machinery safety and; ii) Food processing safety. The former covers standards pertaining to facilities location and design, machinery and production line design, pest control, waste management, cleaning, maintenance, personal and environmental hygiene, handling, storage and transport and staff training. Food processing safety relates to food additives, preservatives, flavoring, antioxidants, processing equipment, covering and packaging.

The PSQCA also accredits certain bodies for food safety certification in Pakistan namely, Bureau Veritas Certification (BV Certification), SGS Pakistan (Pvt) Limited, Systems and Servicer Certification, Moody International (Pvt) Limited, Pakistan Systems Registrar, RICCI Pakistan and CeSP (Certification Services Pakistan). While PSQCA has the mandate to inspect and test food products and services, most stakeholders are of the view that it does not possess adequate capacity to carry this out on a national scale, and various federal and provincial departments and authorities are involved in the regulation, testing and analysis of food products to ensure quality and standards.

6.3. Provincial food authorities:

The principal responsibility for enforcing food regulations in the country lies with the provincial food authorities. Following the wide-ranging devolution of legislative and administrative powers to the provinces through the 18th constitutional amendment, provinces began to establish their own food authorities. Currently, the provincial authorities are in varying states of policy and operational readiness; some are still in the process of establishing their institutions while others have expanded their footprint and enforcement capacity considerably in recent years. The bulk of the focus of the activities of food authorities has been around issues of food safety and hygiene, but some authorities like Punjab Food Authority (PFA) are gradually expanding into broader enforcement around food composition, labelling and nutrition-related interventions.

The first of the provincial authorities to be established was the Punjab Food Authority (PFA), created through the Punjab Food Authority Act 2011, to 'ensure availability of safe and wholesome food for human consumption' in Punjab. The purpose of the Authority is to lay out standards for food articles and regulate their manufacturing, storage, distribution, sale and import. The PFA has several main functions, including formulating standards, procedures, processes and guidelines in relation to any aspect of food including labelling, business, and additives and specify appropriate enforcement systems for the same. It is also empowered to establish laboratories, set up procedures and guidelines for their accreditation and utilize them for sampling, analysis and reporting.

The PFA is also empowered to license producers and vendors (through a separate licensing regime from the PSQCA's), carry out food surveillance, issue emergency prohibition orders, recall substandard food products, issue improvement notices and prosecute violators. It is also mandated to provide scientific advice and technical support to the provincial government on food matters, collect and analyze relevant data, establish a network of food operators and consumers to facilitate food safety and quality control.

The PFA is Pakistan's most well-established and functional food regulation authority. It started off its operations in Lahore, which was the first district to come under the operational jurisdiction of the Punjab Food Authority. Later, it expanded to Faisalabad, Gujranwala, Rawalpindi and Multan and thereafter, to the whole of the Punjab. In 2018, the authority conducted 43,689 inspection visits across the province, shut down 747 centres due to various violations, served 25,000 improvement notices to various food businesses and penalized thousands with heavy fines for violations.³³ In December 2018, the Authority also declared 61 ghee and cooking oil brands unfit for human consumption.³⁴ Unsurprisingly, given its zeal in the pursuit of its duties, it has come under legal and political attack from those associated with the food industry; In April, 2019 some lawmakers in the Punjab Assembly, including the Speaker, called for legislation to 'rein in' the PFA.³⁵

PFA also has a food testing laboratory, which processed 6419 food samples out of 13716 in 2018, indicating considerable strains on existing testing capacity. It has also been active in capacity building for food safety, training 28,890 food workers in a Level 1 food safety course in 2018.³⁶ PFA has also recently established nutritional clinics in all 36 districts of the province, staffed with nutritional experts to provide guidelines to citizens on their diet, lifestyle and eating plans for nutritional awareness. Its Public Relations department has made effective use of media coverage and social media outreach to improve awareness and compliance around food safety and taken steps toward engendering a culture of citizen-led accountability.

The PFA has developed and updated its food regulations from the Punjab Pure Food Rules of 2011 to the current Pure Food Regulations 2018, which encompass regulations on trans fat. The PFA's regulations for trans-fats are currently the most stringent in the country and the only ones that meet WHO's specifications (details in Table 4 below). However, there are still no TFA-specific penalties. Regulations can be amended through the recommendations of the PFA's scientific panel, which consists of food safety, science and technology experts.

Table-4: Existing national and provincial trans-fat regulations

Food Article	PSQCA National Standards	Punjab Food Authority (Punjab Pure Food Regulations 2018)	KP Food Safety and Halal Food Authorit (KP Food Regulations 2018)	Sindh Food Safety Authority	Balochistan Food Safety Authority
Vanaspati	Trans-fat not more than 10%	Shall not have more than 0.5% trans-fat and transfat percentage shall be mentioned on the label. After July 2020, there shall be complete ban on any form of Vanaspati.	It shall not have more than 5% trans-fat and industry will be given a grace period of three years from the implementation of these regulations to conform to these standards. During this grace period, trans-fats shall be not more than 15%. (mentioned in product description) Trans-fat percentage shall be mentioned. Trans Fatty acid content not more than 10% (mentioned in product characteristics table)	Trans-fat not more than 10%	Trans-fat not more than 10%
Shortening	NA	Trans-fat not more than 0.5%	Trans-fat not more than 5%	NA	NA
Cream analogue	NA	All cream analogues shall mention trans- fat contents on the label. The label shall also mention source of vegetable oil(s) used in their descending order. Partially hydrogenated vegetable oil shall not be used in the production of these analogue products.	NA	NA	NA
Margarine	NA	It shall be clearly defined on the label in Urdu "ye makhan nahi hai" ("this is not butter"). This label shall be 15% of the total package area and it shall be mentioned on both sides of the label, in two colors only. The Transfatty acid percentage must be mentioned on the label.	NA	NA	NA

Continuous...

Food Article	PSQCA National Standards	Punjab Food Authority (Punjab Pure Food Regulations 2018)	KP Food Safety and Halal Food Authorit (KP Food Regulations 2018)	Sindh Food Safety Authority	Balochistan Food Safety Authority
Table Margarine	NA	Trans-fat not more than 0.5%	Trans-fat not more than 5%	NA	NA
Industrial Margarine	NA	Trans-fat not more than 0.5%	NA	NA	NA
Margarine Spread	NA	Trans-fat not more than 0.5%	NA	NA	NA
Spread	NA	Trans-fat not more than 0.5%	NA	NA	NA
COils/Fats During Fry	i ng NA	Any oil/fats or emulsions used for frying of any food shall conform to following standards when sample is taken during frying: Trans-fats not more than 5%	Any oil/fats or emulsions used for frying of any food shall conform to following standards when sample is taken during frying. Trans-fatty acids: Not more than 24 %	NA	NA
Infant formulae	NA	The content of trans-fatty acids shall not exceed 3% of total fatty acids provided 100 percent milk fat is used in the formula. Plant oils and fats intended to be used in infant formula should be virtually trans-fat free and the maximum allowance level for trans fatty acids shall be proportionately decreased with increasing level of plant oils and fats in the formula	The content of trans-fatty acids shall not exceed 3% of total fatty acids provided 100 percent milk fat is used in the formula. Plant oils and fats intended to be used in infant formula should be virtually trans-fat free and the maximum allowance level for trans fatty acids shall be proportionately decreased with increasing level of plant oils and fats in the formula.	NA	NA

Food Article	PSQCA National Standards	Punjab Food Authority (Punjab Pure Food Regulations 2018)	KP Food Safety and Halal Food Authorit (KP Food Regulations 2018)	Sindh Food Safety Authority	Balochistan Food Safety Authority
Follow-up formulae					
	NA	The content of trans-fatty acids shall not exceed 3% of total fatty acids provided 100 percent milk fat is used in the formula. Plant oils and fats intended to be used in infant formula should be virtually trans-fat free and the maximum allowance level for trans fatty acids shall be proportionately decreased with increasing level of plant oils and fats in the formula	The content of trans-fatty acids shall not exceed 3% of total fatty acids provided 100 percent milk fat is used in the formula. Plant oils and fats intended to be used in infant formula should be virtually trans-fat free and the maximum allowance level for trans fatty acids shall be proportionately decreased with increasing level of plant oils and fats in the formula	NA	NA
Dried Ice Cream Mix/Dried Frozen Dessert/Confectionar	NA y	The type of frozen confection shall be clearly indicated on the label otherwise, standards of frozen dessert/frozen confection shall apply and every package of frozen dessert / frozen confection shall bear proper label declaration as per regulations including trans-fat % per serving bases.	The type of frozen confection shall be clearly indicated on the label otherwise, standards of frozen dessert/frozen confection shall apply and every package of frozen dessert / frozen confection shall bear proper label declaration as per regulations including trans-fat % per serving bases.	NA	NA

Source: Punjab Pure Food Regulations 2018, KP Food Regulations 2018, Sindh Draft Food Regulations 2018, WHO-EMRO assessment of diet associated risk factors of NCDs 2019

The Khyber Pakhtunkhwa Food Safety and Halal Food Authority (KPFSHFA) is the principal food regulation authority for Khyber Pakhtunkhwa province. It is relatively newly-established, through the Khyber Pakhtunkhwa Food Safety and Halal Food Authority Act 2014 and became operational even more recently in 2017. Its purpose is to 'ensure availability of safe and healthy food for human consumption' in KP; the responsibilities of the Authority under the Act are similar to the PFA's, with the added responsibility of regulating the 'Islamic authenticity of food being prepared or sold' in the province. Like PFA, it also has the responsibility of licensing, surveillance and enforcement. The authority passed its own food regulations, adapted from the Pure Food Ordinance in 2018, called the the Khyber Pakhtunkhwa Food Safety and Halal Food Regulations 2018. In the past year, KPFSHFA has expanded its operations to multiple districts in Khyber Pakhtunkhwa and begun the process of establishing laboratory capacity. Since becoming operational, it has carried out 23,016 inspections across the province, issued licenses to 3500 vendors, issued notices to 7705 vendors and imposed fines worth Rs. 50 million. However, the authority faces severe deficits in assessing regulatory compliance owing to a lack of laboratories, which forces it to rely on other public and private laboratories for testing purposes. The KPFSHFA has established trans-fat regulations, which are less stringent than Punjab and WHO recommendations (details in Table 4 below). Similar to the PFA, the KPFSHFA also has a scientific panel for establishing and amending regulations.

The Sindh Food Authority (SFA) is also newly established, through the Sindh Food Authority act of 2016 and currently has operations in three major urban centres of Sindh, Karachi, Hyderabad and Larkana. Its enforcement capacity is as yet undeveloped - it only recently recruited food safety officers for inspections and is in the process of establishing a food testing laboratory. The Authority has drafted its own food safety regulations, which are awaiting notification; in the

interim, is following PSQCA and Codex Alimentarius Commission standards, including for trans-fat (which only cover Vanaspati). The draft 'Sindh Food Authority Regulations 2018' cover licensing and registration, sampling and seizure procedures, and regulations for a wide variety of food products. The SFA currently faces considerable challenges in terms of fiscal and human resources for surveillance, enforcement and assessment, and has a need for capacity-building support, as well as advocacy for its strengthening and fiscal consolidation.

The Balochistan Food Authority (BFA) is the newest provincial food authority, established through the Balochistan Food Authority Act, passed in 2014, but which remained un-operationalized for years since. The BFA has only recently begun operations in February 2019 and is in the process of framing its rules and regulations, while adhering to PSQCA and Codex Alimentarius Commission standards in the interim. A food authority for the Capital Islamabad is in the process of being established while Gilgit-Baltistan and Azad Jammu Kashmir do not currently have dedicated institutions responsible for regulating food.

6.4. Existing regulations for trans-fat in Pakistan:

Currently, varying standards are in place for trans-fat regulation across the federal and provincial levels (See Table 4 below). PFA regulations target the main food products associated with high levels of trans-fat and have TFA limits within (and even lower than) the limits prescribed by WHO. The PFA has also undertaken the step of banning Vanaspati in the province, with the industry given until July 2020 to comply with the ban. However, most other standards in place do not target all sources of TFA and do not meet WHO recommendations for TFA limits. In the case of PSQCA standards (also followed in Sindh and Balochistan), no standards are mentioned for food articles other than Vanaspati (and that too at 10%, much higher than the WHO recommendation of 2% in foods. The Sindh Food Authority's (draft) Regulations do not yet contain TFA-specific limits; however, the newly-constituted scientific panel for the authority is currently considering including TFA limits for Vanaspati, margarines and bakery fats. Currently, there are no penalties specific to non-compliance with TFA regulations.

6.5. Other institutions:

Beyond the main food regulatory institutions, there are also some other key institutions that are of central importance to the overall effort for TFA elimination.

6.5.1. Federal health ministry and provincial health departments:

The federal health ministry and provincial health departments are key institutions for bringing about TFA elimination. Pakistan devolved responsibility for health to the provincial level in 2010, but after the emergence of several institutional challenges in health governance, the former Federal Ministry of Health was reconstituted as the Ministry of National Health Services Regulation and Coordination (NHSR&C) in 2013, and given the charge of national health sector coordination, oversight for regulatory bodies in the health sector, coordination of population welfare programs, drug laws and regulations, health sector training and coordination of preventive programs.

The Ministry has developed a federal level nutrition strategy aligned with the Pakistan Vision 2025 that involves health, education, social protection and civil society actors. To assess the current state of nutrition, the National Nutrition Survey has recently been released to provide insight into nutrition data down to the district level. The federal NHSR&C and its Nutrition wing is an important stakeholder that could steer the TFA elimination process and bring together provincial, industrial, civil society, and academic stakeholders in this regard. Further, the National Nutrition Survey should also be used to gather information on trans-fats at the local level.

The provincial health departments bear principal responsibility for health and nutrition policy, planning and service delivery in the country and are hence, crucial stakeholders in the process. The prevention of NCDs through minimizing dietary risk factors is a key strategic priority in all provincial health strategies. Nutrition at the provincial level is integrated in one programme with Maternal Neonatal and Child health (MNCH) and family planning (FP). Nutrition focal persons in the integrated programme are key to TFA elimination in the areas of campaigns for improved awareness of TFA, developing and promoting content on TFA in dietary guidelines, and the national nutrition survey,

6.5.2. Ministry of Commerce (Pakistan Customs):

Food imports in Pakistan are regulated by the federal government, through the Ministry of Commerce which houses the Customs Department. Pakistan Customs employs Codex Alimentarius Commission standards and guidelines as well as certain US Food and Drug Administration standards in its regulation of imported food products. The department's function for the food sector is to ensure imported food items meet Pakistan's labelling and shelf-life requirements, are not on the banned items list and are assessed for appropriate tariffs.

A list of permissible food colors is kept and updated annually. Halal certifications are required for import of animal products. The relevant tariff codes which govern the imports that are the main dietary sources of TFA in Pakistan are tariff code 1516 ("Animal or vegetable fats and oils and their fractions, partly or wholly hydrogenated, inter-esterified, reesterified or elaidinised, whether or not refined, but not further prepared") and tariff code 1517 ("Margarine; edible mixtures or preparations of animal or vegetable fats or oils or of fractions of different fats or oils of this chapter, other than edible fats or oils or their fractions"). Examples of products covered by these tariff codes includes vegetable oils, vanaspati ghee, shortening, table spreads including table margarine, and confectionary fats. While only a small proportion (2 percent) of dietary sources of TFA are imported, all updates in TFA limits will also have to be reflected in standards applied to imports by Pakistan Customs.

6.5.3. Ministry of Planning, Development and Reform:

The Ministry of Planning, Development and Reform is responsible for financial and public policy planning in the country. It carries out research for evidence-based policy and brings together federal and provincial public and private stakeholders to formalize a development framework. The Ministry's area sections for policy research and action include agriculture and food, devolution and area development, education, environment, governance, health, information and communication, industries and commerce, manpower, media and culture, nutrition, physical planning and housing, population and social planning, science and technology, social welfare, transport, and water. In December 2018, the Nutrition section of the Ministry in collaboration with the Food and Agriculture Organization (FAO), released the Pakistan Dietary Guidelines for Better Nutrition (PDGN) to encourage better eating practices and prevent and reduce the risk of infectious and chronic diseases. The guidelines call for limiting the consumption of edible oil and fat in cooking to 1% of total daily energy intake from oils to reduce risk of NCDs.³⁷

6.5.4. Pakistan Council of Scientific and Industrial Research (PSCIR):

PCSIR was originally established in 1954 as an autonomous research organization under the Societies Act to promote science and technology and was later incorporated through an Act into the government under the Ministry of Science and Technology in 1973. The council includes bureaucrats (the governing body), laboratory directors, directors of industry from the provinces and representatives of industries, with a chairman appointed by the federal government. The council has eleven laboratories and five human resource development (HRD) centers established throughout the country, which are staffed by over 500 scientists and close to 900 technicians and technical support staff.³⁸ The multi-functional laboratories of PCSIR carry out research in several areas of industry, including textile, oil and gas, agriculture, minerals and edible oil. The PSCIR will be key for working with the edible oil industry for the development of healthier replacements for TFAs and PHOs.

6.5.5. Ministry of National Food Security and Research (MNFSR):

The Federal Ministry of National Food Security & Research was created in 2011 after the devolution of the prior Ministry of Food and Agriculture to the provincial governments. It is mainly responsible for policy formulation, economic coordination and planning with respect to food grains and agriculture. It also includes procurement of food grains, fertilizer, import price stabilization of agriculture produce, international liaison, economic studies for framing agricultural policies. The Ministry formulated a National Food Security Policy in 2018, which calls for promotion, cultivation and utilization of oilseeds as alternative crops for import substitution. The MNFSR could support the process of research on trans-fat consumption in Pakistan.

6.5.6. National Institute of Health, Pakistan (NIH):

The National Institute of Health, Pakistan is a research, advisory and capacity-building institution established under the NHSR&C which is responsible for public health initiatives in laboratory diagnosis, investigation of epidemics, disease

prevention, biological manufacturing, food and drug quality control and research and development. The Nutrition division of the NIH conducts research for the control of malnutrition and participates in the development and up-dating of food policies and standards and monitors quality control of both processed and unprocessed foods and water samples. The NIH could serve an important role in the generation of research into TFA consumption in various sub-sections of the population.

7. Discussion – key considerations for TFA elimination in Pakistan

Considering the above facts surrounding dietary sources of trans-fat and the relevant policy and regulatory context in Pakistan, there are a number of key issues that require attention for TFA elimination in the Pakistan context. These pertain to harmonization, product bans, labelling, federal-provincial responsibilities, assessment, enforcement, data, public demand and TFA replacement, and are discussed below.

7.1. Harmonizing mandatory limits with penalties:

Research tells us that enacting mandatory TFA limits by law has by far been the most effective method for TFA elimination and that much is understood by key stakeholders in the country. Such limits have already been put in place through regulations in Punjab, and KP, and to some extent at the federal level. The first concern in this respect is the question of variations and gaps in the limits set. Punjab has by far the most stringent regulations, with trans-fat limits of 0.5% of total fat for margarine and vanaspati ghee. KP's TFA standards in contrast, are less stringent; 10% for Vanaspati and a high 24% for margarine. The Sindh Food Authority has thus far adapted the federal PSQCA standards, in which the only TFA-specific limit in the PSQCA is for Vanaspati (at 10%). Balochistan, whose food authority has only been operationalized in February 2019, is yet to adopt any standards, facing an altogether different set of priorities regarding basic food safety and several capacity and resource constraints.

In the first place, limits need to be harmonized across provinces and territories in order to be effective. For this purpose, KP, Sindh, Balochistan, and PSQCA need to enact trans-fat limits to WHO-recommended levels (less than 2% of fats and oils in foods). However, for limits to be effective in the first instance, penalties need to be in place to enforce compliance and none are currently specified for TFA violations. The most straightforward way to achieve this is by adding products with TFA levels beyond established limits in the adulterated food category, in order to apply penalties for violations and empowering provincial officials to impose such penalties. According to provincial food authority officials, rather than legislation, this can be done through a recommendation of the scientific panels of the respective food authorities.

7.2. The question of vanaspati ghee:

The question of Vanaspati ghee is of central concern for TFA elimination in Pakistan given its high trans-fat content and high level of consumption of edible oils in the country – at 18 kg/year compared to 3kg/year in Europe. The Punjab Food Authority has chosen to address this situation by banning the industrial production of vanaspati ghee in the province, while giving producers up until July 2020 to comply with the ban. The scientific panel of the KP Food Authority is currently considering a similar ban, while Sindh and Balochistan have yet to formulate a response on this issue.

The Vanaspati ban has been contested by the Vanaspati ghee industry in the courts, the media as well as through lobbying efforts with the government. The Pakistan Vanaspati Manufacturers Association (PVMA) has claimed that vanaspati ghee is a key source of nutrition for the poor and have invoked fears of WTO fines and trade retaliation by major edible oil exporting countries like Malaysia and Indonesia, whose edible oil exports to Pakistan will be significantly affected on technical grounds by this decision as they constitute a key input for Vanaspati production.³⁹ However, it is worth remembering that countries have the right to legislate to protect public health without it constituting an infringement of international trade law if the measure is applied the same to local and foreign companies (principle of Fair and Equitable Treatment / Non-Discrimination and if the measure is legitimate and proportionate to the aim it tries to achieve.

A couple of key considerations need to be borne in mind by policymakers for effectively eliminating the risk to health from TFA in Vanaspati ghee. Firstly, there is the capacity of the industry to circumvent the ban by appealing to the existence of different standards at the federal level or in other provinces. One of the legal arguments employed by the PVMA in its appeal against the ban is that they are already following the (more lenient) standards adopted by the PSQCA.⁴⁰ This serves as a reminder of the need to harmonize federal and provincial standards to ensure discrepancies cannot be exploited as

legal loopholes.

Secondly, there are the implications of the extremely high share of Vanaspati ghee in edible oil consumption in Pakistan (80% by some estimates) to consider. This is principally because of two reasons; one, Vanaspati ghee is cheaper as its main ingredient, palm oil, is significantly less expensive than popular vegetable oils like canola and sunflower; and two, there is a popular perception about ghee being a healthier and more organic alternative to cooking oils. To prevent continued proliferation of vanaspati despite the ban, the development and popularization of ghee substitutes and reformulated varieties needs to be a central part of the effort to remove it from the Pakistani diet.

7.3. Making labelling effective:

Labelling has been a central component of successful TFA elimination strategies around the world and has also been employed as a regulatory strategy by the Punjab and KP food authorities. However, labelling requirements for TFA in Pakistan are currently specific to certain products and far from uniformly categorized. The PFA requires trans-fat content to be mentioned on the label for cream analogues, and trans fatty acid percentage to be mentioned on the label for margarine and frozen confections. KPFSHFA requires TFA content to be labelled for Vanaspati only, while Sindh and Balochistan have no labelling requirements. The key regulatory priority in this area is developing and harmonizing mandatory nutrition labeling that includes the percentage of both TFA and SFA in overall fat across all food products.

However, as the literature confirms, labelling is only likely to be effective as a means to reduce TFA consumption when the population is aware of the health consequences of TFAs and able to accurately interpret nutrition labels, which is a reason labelling is not considered a sufficient intervention for low- and middle income countries such as Pakistan, where literacy levels are low. The harmonization of mandatory nutrition labeling (including ingredient lists and nutrient declaration) must be complemented with advocacy efforts aimed at improving public knowledge about the harmful effects of TFA and how to interpret nutritional labels on food products. Nutrition labeling also need to be standardized in Urdu to ensure the majority of the population can read them.

7.4. Improving assessment capacity:

The effectiveness of policies like TFA limits, labelling and bans on TFA-heavy products hinge on the ability of regulators to assess TFA content in food products and monitor compliance. Currently, this is a key capacity gap, as none of the provinces have adequate laboratory capacity to assess TFA content in food products. Sindh and KP are still in the process of establishing food laboratories while Punjab has one functional laboratory – however, even Punjab's laboratory is overstretched and ill-equipped to deal with the scope of provincial testing needs. Assessment needs in all provinces are currently being fulfilled with the help of third-party public and private sector laboratories. Possible techniques that laboratories can be equipped with to assess TFA levels include attenuated total reflection-Fourier-transform infrared (ATR-FTIR) spectroscopy and gas chromatography with flame ionization detection (GC-FID), two methods used in official methods by regulatory agencies around the world. This will require both the requisite equipment and skilled human resource, for which budgetary resources will have to be allocated.

7.5. Generating data on TFA intake:

A key constraint in the way of effective monitoring and elimination of fat in the Pakistani diet is the near-complete lack of data on TFA consumption. While some studies on consumption exist, they consist of small sample sizes and there has never been a population-level survey of TFA consumption. This means that while there is research knowledge on dietary sources of TFA, there is little information on how the TFA is being consumed, where it is being consumed the most, and the differences in TFA consumption among different age, class, gender, and ethnic groups. According to Nutrition officials in the federal Ministry of Health, the cost-intensiveness of such exercises is the major reason such a survey has not yet been commissioned. However, as efforts for TFA elimination in Pakistan take off, conducting a comprehensive representative assessment of TFA consumption is critical to be able to create a baseline against which progress will be measured. As per WHO recommendations, this can either be done through population-level food consumption surveys, the more recently developed plasma assay⁴¹ which can be used as a part of ongoing population surveys, or through breast milk samples. This process should be steered by the Nutrition wing of the Ministry of Health in collaboration with provincial nutrition wings of Health Departments, university nutrition departments, research organizations and provincial food authorities.

7.6. Strengthening monitoring and enforcement:

A lack of implementation of otherwise well-drafted policies has long been a key governance challenge in Pakistan. Historically, food regulations in Pakistan have been weakly-enforced, due to lack of resources for monitoring and enforcement, lobbying by the food industry to circumvent regulatory measures, and the existence of a large informal network of food production and distribution. In recent years, particularly with the provincial decentralization following the 18th amendment, this has started to change, with food authorities in Punjab in particular (and to a lesser extent, Khyber Pakhtunkhwa), modernizing their regulations, expanding their surveillance apparatuses across the province and strengthening their enforcement mechanisms. Sindh and Balochistan still require significant work to build enforcement capacity in areas under their jurisdiction. However, across provinces, the priority for food regulatory enforcement thus far is food safety and hygiene rather than disease consequences or NCDs.

For strengthening enforcement capacity for TFA in particular, there is a need to include trans-fat assessment in the rules and terms for food authority inspectors and improving their knowledge and skills to enable them to monitor TFA levels. According to provincial officials from Punjab and KP, this can be done through a recommendation of the scientific and technical panels of the provincial food authorities. For Sindh and Balochistan, fiscal and human resource allocations are required to enhance the budgetary, technical and human resource capacity of the food authorities and create an effective food regulatory infrastructure that can also effectively monitor and enforce TFA limits.

7.7. Streamlining federal and provincial roles in food regulation:

As with many other areas of governance in Pakistan, a key challenge in food regulation has been the lack of a clear demarcation of roles and responsibilities between federal and provincial authorities, particularly since the passage of the devolutionary 18th Amendment to the constitution in 2010. Thereafter, provincial authorities have asserted that food regulation is now an entirely provincial domain in which the federal government (including the PSQCA) should not interfere, particularly in the domain of enforcement, while the federal government has argued for the need for a central body to harmonize standards and regulate international commitments. The PSQCA argues that it is mandated to certify items under the Compulsory Certification Mark Scheme, under which 105 items, including 40 food items have been notified. The Punjab Food Authority holds, however, that food has always been a provincial subject and that its own regulations are much more stringent than the PSQCA's. While the other provinces have adopted some of PSQCA's standards for some food items, they also agree that food regulation, particularly enforcement, should lie with the provinces.

In practice, this conflict has led to the formulation of varying standards in different regions of government, including in the edible oil and dairy industry, both important for TFA elimination. There is also the issue of separate federal and provincial licensing regimes for food products, which forces producers to obtain multiple licenses to operate in different provinces, hampering inter-provincial trade. Further, food producers, including the edible oil industry, have attempted to use the PSQCA's more lax standards to try to circumvent stricter regulations in Punjab.

Currently, the matter of center-province mandates and responsibilities in food is the subject of an ongoing dispute being mediated by the Council of Common Interests (CCI), a constitutional body that addresses conflicts between different tiers of government. Negotiations are currently underway in a technical committee constituted by the CCI which includes representatives from the Ministry of Science and Technology, Ministry of National Food Security & Research, Ministry of Inter Provincial Coordination, Ministry of Industries and Production, Ministry of Health, Board of Investment (BoI), PSQCA and secretaries of all the provincial food departments including Azad Jammu & Kashmir (AJ&K) and Gilgit-Baltistan (GB). The purpose is to develop a consensus on one uniform standardization system for all food products, to be known as Pakistan Standard.² If the federal and provincial authorities manage to come to a consensus on Pakistan Standard, it would also serve as the key arbiter of acceptable TFA levels in food products.

Provincial demands to retain enforcement authority at the provincial level must be supported, both for reasons of constitutional propriety and given provincial capacity for enforcement of food regulation, both in terms of resources and institutional infrastructure, far outstrips that of any federal institution. PSQCA should retain a role at the federal level as a focal point for coordination, harmonization, and management of international food trade in a consultative arrangement

with provincial authorities. However, for the purposes of TFA elimination, it is essential also that TFA limits under the Pakistan Standard framework are harmonized to the stricter levels established by the Punjab Food Authority and updated to ensure legal loopholes for non-compliance are closed. Another important role for the federal government is food research support through the Pakistan Council of Scientific and Industrial Research (see 7.9).

7.8. Creating public demand for TFA elimination and alternatives:

The literature on TFA elimination highlights the centrality of building public knowledge and awareness of the harmful effects of TFA which can in turn pressure industries to move more rapidly toward healthier alternatives. Efforts to eliminate TFA from the Pakistani diet are currently hampered by the fact that public knowledge about its health consequences are minimal and some of the main sources of TFA – particularly vanaspati ghee – are viewed by the public as healthy and nutritious. Thus, communication campaigns to increase overall public knowledge about the dangers of high TFA consumption, the main dietary sources of TFA and possible replacements are essential. Mobilizing consumer groups and civil society in this process will be key, while producers could also be encouraged to highlight the importance of TFA-free products in their own marketing.

7.9. Enabling replacement and reformulation:

One of the key measures that have contributed to TFA reduction or elimination in other county contexts is the generation of knowledge on replacements for partially hydrogenated oils and methods for reformulating products with high levels of TFA. In Pakistan, the question of replacement or reformulation of TFA-heavy products is especially critical, given that TFA consumption in Pakistan is rooted in products like vanaspati central to the population's diet. While authorities like PFA have resolved to support a move toward a total liquid oil diet, the viability of such a move has not really been adequately considered in the absence of data on consumption. Furthermore, similar to India, Pakistan has a problem of low overall calorie intake among lower-income segments, which needs to be assessed and considered in the case of impending bans on vanaspati ghee which is a major source of fat intake. There is low knowledge of the need for reformulating products among SMEs and street vendors.

WHO guidelines on TFA and SFA intake suggest the use of polyunsaturated fatty acids (preferably) or monounsaturated fatty acids as TFA replacements. The Malaysian Palm Oil Association has offered research and capacity-building assistance for reformulation of edible oils to ensure TFA-free products. However, this process cannot be left to industry stakeholders or the private sector; the federal and provincial governments should lead the process, preferably with a single stewarding institution such as the Ministry of Health (Nutrition Wing), Ministry of Science and Technology (particularly the PCSIR), or Ministry of National Food Security & Research. University research departments (such as Aga Khan University), academics and relevant organizations for food research should be partnered with for this purpose. The research should be accompanied with an agreed set of actions by government and industry stakeholders to replace all trans-fat sources with healthier alternatives. Critically, SMEs and street vendors also need to be supported with technical assistance for reformulation, either from government or via knowledge transfer from large food manufacturers.

7.10. Stewardship and coordination:

Most successful strategies of TFA reduction around the world have relied on government-formed multi-stakeholder task forces or coordination committees that have steered the process forward. This is particularly important in the case of Pakistan, a country with multiple overlapping regulatory frameworks that can often be in direct contradiction with each other, a situation that can easily be taken advantage of by industry actors seeking to circumvent strict regulations imposed. Therefore, the formation of a TFA elimination taskforce or working group with representation from all provincial authorities and other federal institutions (such as the Ministry of Science and Technology and PCSIR) and stewardship from a federal institution (such as the Nutrition wing of the Ministry of Health) is an essential need of the hour. This working group/task force needs to include representatives from academia, research institutions, civil society⁴³ and if and when the time is appropriate, representatives of the food industry, to ensure TFA levels can be sustainably reduced and replaced.

8. The route to TFA elimination in Pakistan

Literature from around the world as well as an analysis of the context in Pakistan demonstrate that TFA elimination is both

necessary and completely achievable. Listed below are a series of steps required, in light of the evidence, to achieve TFA elimination by the 2023 deadline. The steps are based broadly around the REPLACE framework for TFA elimination and are listed in order of their feasibility in the current Pakistani context.

Short-term objectives (1-6 months):

LEGISLATE or enact regulatory actions to eliminate industrially-produced trans-fats

1. Form multi-stakeholder working group to steer trans-fat elimination process, with representatives from provincial food and health authorities, PSQCA, National Ministry of Health Services Regulation and Coordination, WHO, academia, civil society representatives and edible oil, dairy and bakery industry representatives (while ensuring avoidance of conflict of interest and ensuring, through clear terms of references, industry representatives do not encroach on the policymaking process). The group should be coordinated by a representative of the federal government with the objective of overseeing the implementation of a workplan for TFA elimination, harmonizing TFA limits to WHO-recommended levels across food products, generating knowledge on TFA intake, coordinating implementation of the regulations, monitoring compliance and progress and steering research on replacement and reformulation.

Output(s): Working Group on TFA elimination formed, TORs for WG formulated

Main responsibility: Federal Ministry of Health (MHSRC)

Other stakeholders: Provincial food authorities, PSQCA, WHO, civil society, academia, research institutions, provincial departments of health (nutrition wings), edible oil, margarine and bakery industry representatives

2. Harmonize mandatory limits for trans-fat to <1% of total fats in products across all provincial food authorities and the PSQCA. In Khyber Pakhtunkhwa, this will involve reducing from the 5% current limit; at the federal level, it will involve reduction of the limit from the current level of 10% for vanaspati ghee, while introducing a limit for other products, while in Sindh and Balochistan, this will involve introducing TFA limits for all food products (including, but not limited to margarines, shortening, spreads, cooking oils, biscuits, confectionaries, infant formulae, and dried frozen desserts). Along with limits for TFA percentage, effective penalties for non-compliance will also have to be specified in the regulations, including fines for first time violations and imprisonment for multiple violations.

Output(s): Mandatory TFA limits enacted with penalties for non-compliance across provincial and federal levels

Main responsibility: Technical panels of provincial food authorities/PSQCA

Other stakeholders: TFA Working Group

Extend the phased ban on Vanaspati to other provinces and at the federal level for it to be effective. This will require placing vanaspati into the list of unsafe and harmful food items in Khyber Pakhtunkhwa, Sindh, Balochistan and at the federal level, and imposing strict penalties for violators. However, the imposition of such a ban will have to be complemented with efforts at preparing and popularizing replacements for vanaspati (see below), closely monitoring it to prevent the emergence of a black market for vanaspati and working with the industry to push for reformulation.

Output(s): Vanaspati ban extended in all provinces and at federal level.

Main responsibility: Technical panels of provincial food authorities/PSQCA

Other stakeholders: Enforcement officials in provincial food authorities, MHSRC, TFA Working Group

4. Harmonize mandatory nutrition labeling with ingredient lists and nutrient labels across all food products in all provincial food authorities and at the federal level. This must ensure that the TFA percentage of total fats is mentioned prominently. Labelling regulations must also specify the conditions for a product to be

termed 'trans-fat free': to contain <0.2 g of trans-fat and also be low in saturated fat (i.e., contain <2 g of saturated and trans-fat combined (per reference amount and per serving of stated size). For margarine, labelling regulations must include stating that it is not butter.

Output(s): Enactment of mandatory labelling of TFA in nutrient profiling for all food products

Main responsibility: Technical panels of provincial food authorities/PSQCA

Other stakeholders: Enforcement officials in provincial food authorities, TFA Working Group

CREATE awareness of the negative health impact of TFA among policy-makers, producers, suppliers, and the public

Build awareness about trans-fat among policymakers, producers, suppliers and retailers in order to create an enabling environment for changes in regulations and consumption patterns. This must involve a concerted advocacy campaign with key decision makers, including policymakers and industry representatives, that convinces them of the need to eliminate TFA from the Pakistani diet and take necessary steps for its replacement. Parliamentarians must be engaged through policy roundtables and targeted individual advocacy to create political support for TFA elimination. Suppliers and retailers must also be sensitized and capacitated on TFA to support a shift away toward healthier fats and oils.

Output(s): Advocacy strategy for policymakers, producers, suppliers and retailers

Main responsibility: Federal Ministry and Provincial Departments of Health (Nutrition wings)

Stakeholders: TFA Working Group, provincial food authorities, civil society, Parliamentarians, food producers, suppliers and retailers.

6. Engage electronic, print and social media for TFA elimination to improve public awareness around the need for TFA elimination and replacement. This must involve the design of a communications strategy to popularize the health consequences and economic costs of TFA intake, the main dietary sources of TFA, the availability of healthier alternatives, how to interpret product labels and information about existing regulations around TFA, with the overall purpose of encouraging a shift in production, retail and consumption behaviours. Government institutions pertaining to health and information must be engaged to incorporate TFA-related information in public health messaging and publicly-available nutrition guidelines. Specific prominent journalists, including prime time TV anchors and popular op-ed writers, must be engaged and sensitized to discuss trans-fat on their electronic and print media platforms. Youth engagement is also critical given that young people are often the main consumers of products with high TFA; social media can be an important tool for this purpose, and prominent social media influencers can be engaged to popularize awareness about TFA. Food companies must also be encouraged to build awareness of the importance of trans free products through their advertising (however, this must be coupled with close monitoring of advertising and labelling to ensure any misrepresentations about the health consequences of the product can be avoided). Consumer groups, while weak in Pakistan, can also be made part of this process to build consumer awareness and action on trans-fats.

Output(s): Communication strategy, public health messaging, media advertisements about TFA, journalists and influencers sensitized about TFA

Main responsibility: Ministry and Provincial Departments of Health (Nutrition wings)

Stakeholders: TFA Working Group, print and electronic media, consumer groups, civil society, provincial food authorities, ministry and departments of information, producers

Medium term objectives (6-24 months):

ASSESS and monitor trans-fat content in the food supply and changes in trans-fat consumption in the population

7. Undertake a comprehensive population level food consumption survey that assesses, among

other facets of nutrition, TFA consumption in the Pakistani population and serves as a baseline for assessing the effectiveness of TFA elimination policies. The survey must be stratified by region, age, gender, socio-economic class, and other key variables to paint a detailed picture of TFA consumption in Pakistan that can enable effective targeting of interventions. Other options for assessment, if resources allow, include a recently-developed plasma assay, which allows for the use of biomarkers rather than dietary surveys to determine total TFA intake levels, and the use of breast milk samples. The process of assessing TFA intake could be stewarded by the nutrition wing of the federal Ministry of Health in collaboration both public and private sector institutions. The federal government needs to be pushed to allocate resources for this purpose, the Ministry for Food Security and Research and National Institute of Health should be engaged and WHO-EMRO, bilateral and multi-lateral donors and other stakeholders working in nutrition and NCDs should also be asked to support this process as part of a collective effort to generate data for nutritional improvement.

Output(s): Food consumption survey, budgetary allocations for TFA intake assessment

Main responsibility: Federal Ministry of Health (MNHRSC),

Stakeholders: Ministry of Food Security and Research, Provincial Health Departments, the National Institute of Health, universities, research organizations, TFA Working Group

8. Strengthen the TFA assessment capacity of provincial food authorities to enable them to effectively monitor compliance. This must involve both improving the equipment available in laboratories as well as improving the numbers and skills of laboratory human resources to carry out assessments of nutrient profiles in food products. In the case of provinces other than Punjab, this needs to involve building functional provincial laboratories from scratch. Provincial governments (specifically the Departments of Finance) will have to be pushed to make budgetary allocations for this purpose and civil society and food and nutrition organizations can be engaged to support technical training workshops on food content analysis and TFA assessment.⁴⁵

Output(s): Provincial budgetary allocations for laboratory equipment and staff recruitment, laboratory staff training workshops

Main responsibilities: Provincial food authorities, provincial governments

Stakeholders: Provincial finance departments, food and nutrition organizations

ENFORCE compliance with policies and regulations

9. Strengthen the monitoring and enforcement capacity of provincial food authorities in order for the regulations to have the desired effect. While authorities in Punjab (and to a lesser extent, Khyber Pakhtunkhwa) have built enforcement capacity over time, Sindh and Balochistan have a great deal of work to do in this area. This will require the recruitment and capacity-building of food inspectors in TFA levels at production and retail units. Responsibilities for assessing TFA levels and imposing penalties for violation will also be added to the rules of service for provincial food authority inspectors and other officials, through the recommendation of the authorities' technical panels.

Output(s): Provincial budgetary allocations for food inspectors, rule changes to incorporate TFA assessment for inspection staff

Main responsibilities: Provincial food authorities, provincial governments

Stakeholders: Provincial finance departments, food and nutrition organizations, academia, CSOs.

PROMOTE the replacement of industrially produced trans-fats with healthier fats and oils

10. Undertake multi-stakeholder research on healthier replacements for TFA and PHOs, including those containing polyunsaturated (preferably) and mono-unsaturated fats, that are tailored to Pakistan's context. A priority in this regard must be the replacement of vanaspati ghee, which accounts for the vast majority of

edible oil consumption and is central to the population's dietary preferences. Industry stakeholders should be involved in this process, to both support the research and capacitate their own staff for reformulation purposes. This research must also be undertaken in tandem with the food consumption survey to enable targeted interventions for ensuring sufficient levels of caloric intake among disadvantaged segments of the population. Research on replacement must also generate evidence on ways to enable small and medium enterprises, including those in the informal sector, to replace TFA in their products.

Outputs: Replacement oils and fats for TFAs/PHOs, research on TFA replacement by SMEs

Main responsibilities: Ministry of Science and Technology

Stakeholders: Edible oil, dairy and bakery industry, small and medium enterprises, food companies

11. Promotion of replacement fats and oils by federal and provincial governments through their own messaging and procurement processes, to set an example on TFA consumption and strengthen effective demand for TFA-free fats and oils. Procurement rules need to be changed at the federal and provincial levels for this purpose, to make food products with high TFA-levels ineligible for public procurement. Further, nutritional guidelines issued by federal and provincial governments need to include information on reducing and replacing TFA intake and make people aware of its consequences for NCDs.

Outputs: Changes in procurement rules, changes in nutrition guidelines

Main responsibilities: Federal and provincial procurement authorities, Ministry of Planning, Development and Reform, Ministry and Provincial Departments of Health

Stakeholders: Provincial and federal governments, TFA Working Group

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Acronyms

Acron	yms		
AJ&K	Azad Jammu & Kashmir	МОНМЕ	Ministry of Health and Medical Education
CAA	Argentinian food code (el Código Alimentario Argentino)	NHSR&G	Ministry of National Health Services, Regulation and Coordination
BVC	Bureau Veritas Certification	NCD	Non-Communicable Disease
Bol	Board of Investment	NCDA	Non-Communicable Disease Alliance
CBL	Continental Biscuits Limited	NDoH	National Department of Health
CCI	Council of Common Interests	NIH	National Institute of Health
CeSP	Certification Services Pakistan.	NNFTRI	
CVD	Cardiovascular Disease	DALLO	Institute
DNC	Danish Nutrition Council	PAHO	Pan American Health Organization
EBM	English Biscuits Manufacturers	PCSIR	Pakistan Council of Scientific and Industrial Research
EMRO	Eastern Mediterranean Regional Office	PDGN	Pakistan Dietary Guidelines for Better Nutrition
FAO	Food and Agriculture Organization	PEORA	Pakistan Edible Oil Refiners Association
FDA	Food and Drug Administration	PFA	Punjab Food Authority
FP	Family Planning	PHOs	Partially Hydrogenated Oils
GB	Gilgit-Baltistan	PSQCA	Pakistan Standards and Quality Control Authority
GC-FID	Gas Chromatography with flame ionization	PVMA	Pakistani Vanaspati Manufacturing Association
	detection	REPLAC	E REview, Promote, Legislate, Assess, Create, Enforce
IFAD	International Fund for Agricultural Development	SFA	Saturated Fatty Acids
ISO	International Organization for Standardization	SKU	Stock-Keeping Unit
iTFA	Industrially produced Trans Fatty Acids	SME	Small and Medium Enterprise
KPFSHF	A Khyber Pakhtunkhwa Food Safety and	TFA	Trans-Fatty Acid
	Halal Food Authority	UAE	United Arab Emirates
MNCH	Maternal Neonatal and Child health	WHO	World Health Organization
MNFSR	Ministry of National Food Security and Research	WTO	World Trade Organization

Abstract

The guidelines for management of traumatic brain injury (TBI) are based largely on measures to maintain an optimum internal milieu for prevention of secondary brain injury and enhancing recovery. One of the most common reasons for worsening outcomes following TBI is expanding intracranial haematoma compounded by the fibrinolytic physiology that follows TBI. Tranexamic acid (TXA) has a time tested role in preventing poor outcomes linked to excessive haemorrhage in trauma patients. Historically, patients with isolated head trauma were excluded from TXA use due to a theoretical increased risk of thrombosis. Recent evidence that redefines the beneficial role of early TXA administration in preventing mortality amongst patients with TBI is now at hand and offers a real prospect of a pharmacological intervention that would be adopted as a recommendation based on Class I evidence.

Keywords: Tranexamic Acid, Brain Injuries, Traumatic, Randomized Controlled Trial.

Introduction

It is estimated that 69 million people suffer from traumatic brain injury (TBI) each year all over the world with more than 10 million deaths or hospital admissions. This number is on the rise with increasing motorization in the developing countries. Estimates from Canada put the economic cost of TBI at a staggering \$945 million. A disproportionate number of individuals who suffer from such injuries are in the productive age group (young to