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Original Research

# Cost assessment of a program for laboratory testing of plasma trans-fatty acids in Thailand

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# ABSTRACT

*Objectives*: Intake of trans fatty acids (TFA) increases the risk of cardiovascular disease. Assessment of TFA exposure in the population is key for determining TFA burden and monitoring change over time. One approach for TFA monitoring is measurement of TFA levels in plasma. Understanding costs associated with this approach can facilitate program planning, implementation and scale-up. This report provides an assessment of costs associated with a pilot program to measure plasma TFA levels in Thailand. *Study design:* Cost analysis in a laboratory facility in Thailand.

*Methods*: We defined three broad cost modules: laboratory, personnel, and facility costs, which were further classified into sub-components and into fixed and variable categories. Costs were estimated based on the number of processed plasma samples (100–2700 in increments of 50) per year over a certain number of years (1–5), in both USD and Thai Baht. Total cost and average costs per sample were estimated across a range of samples processed.

*Results*: The average cost per sample of analyzing 900 samples annually over 5 years was estimated at USD186. Laboratory, personnel, and facility costs constitute 67%, 23%, and 10% of costs, respectively. The breakdown across fixed costs, such as laboratory instruments and personnel, and variable costs, such as chemical supplies, was 60% and 40%, respectively. Average costs decline as more samples are processed: the cost per sample for analyzing 100, 500, 1500, and 2500 samples per year over 5 years is USD1351, USD301, USD195; and USD177, respectively.

*Conclusions*: Laboratory analysis of plasma TFA levels has high potential for economies of scale, encouraging a long-term approach to TFA monitoring initiatives, particularly in countries that already maintain national biometric repositories.

### 1. Introduction

Intake of trans fatty acids (TFA) significantly raises the risk of cardiovascular disease (CVD) [1,2]. It has been estimated to contribute to hundreds of thousands of deaths from coronary heart disease each year in countries where its consumption is common [3]. Elimination of TFA in foods is a feasible approach to reducing CVD morbidity. While industrial use of TFAs in food production has been restricted or banned in many high-income countries, a large majority of low-and middle-income countries (LMICs) have not implemented mandatory restrictions to eliminate industrially produced TFAs in their food supply, thereby carrying a disproportionate health burden associated with TFA intake [1]. While data on the sources and magnitudes of TFAs in foods and humans have been existing in high-income countries [4,5], such

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data are lacking in most of the LMICs.

In 2018, the World Health Organization (WHO) launched the REPLACE action package as a roadmap for eliminating TFA from the global food supply [6]. The REPLACE package outlines six action steps that emphasize specific approaches for reviewing, regulating, monitoring of and enforcing limits on TFA in national food supplies. Of these, component "A" refers to "assess and monitor TFA content in the food supply and changes in TFA consumption in the population." This component prioritizes the surveillance of TFA content in food products and in dietary consumption [6]. TFA exposure can be assessed either by population-level food consumption surveys or by analysis of fatty acid in blood samples [6]. To understand the public health implications of TFA intake and to inform policies, it is essential to determine baseline TFA intake and subsequent changes over time. However, the surveillance objective of the REPLACE action package is challenged by limited or nonexistent data on TFA intake in many developing countries, where nutrition surveillance questionnaires may be outdated and not nationally representative [4]. Furthermore, tracking of TFAs in food products is hindered by the variability in the TFA content of foods within a food category, which complicates the assessment of TFA exposure when population exposure is calculated from food frequency questionnaires that rely on the groupings of similar foods.

An alternative approach to tracking population TFA exposure is laboratory measurement of TFA in blood plasma using methods developed and validated by the U.S. Centers for Disease Control and Prevention [7]. Such approach is implementable in countries that already collect biometric samples as part of national health examination surveys [8]. For instance, existing specimen collection for the WHO STEPwise Approach Surveillance System (STEPS) in more than 100 countries could be utilized to measure TFA intake levels through the analysis of TFA in plasma. Because this approach may require additional technical and scientific capacity, it is critical to understand the costs of conducting plasma TFA measurements in national and regional laboratories. An increased understanding of costs associated with the laboratory analysis of TFA in plasma can inform TFA monitoring programs in countries where knowledge about TFA surveillance is limited. Cost evaluation is also useful for scaling up existing TFA assessment initiatives at the national and regional levels.

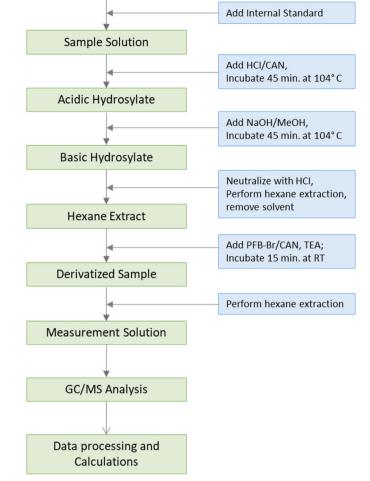
In 2017, a TFA surveillance project was initiated in several localities in Thailand [8]. The clinical chemistry lab in the Faculty of Medicine at Ramathibodi Hospital, Mahidol University, Thailand was selected as one of the sites to conduct a pilot study for the laboratory testing of plasma TFA. The pilot study was intended to: a) to build the country's capacity of conducting laboratory tests for TFAs in human plasma/serum; b) to generate preliminary data on TFA levels in plasma/serum in selected populations to guide design and selection of samples in large national or subnational surveys for estimating the baseline levels in the general population. At the time of program initiation, the program's capacity was established at processing of up to 900 samples per year. We conducted a cost evaluation to identify the major cost components of the program and to estimate operational costs. The aims of this study, thus, are identifying cost drivers and understanding the distribution of costs across fixed and variable to facilitate program planning, implementation and scale-up.

#### 2. Methods

#### 2.1. Study design

We conducted a cost accounting exercise for the TFA plasma assay program in Thailand. A flow chart of the analytical protocol for sample processing [7] is presented in Fig. 1.

# 2.2. Study variables



100 µL Plasma

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**Fig. 1.** Flow chart describing sample preparation process for fatty acid analysis. Source: Laboratory Protocol: Trans Fatty Acid in human serum or plasma, Centers for Disease Control and Prevention.

categories of the program. Next, we obtained purchasing costs for each category, and assigned these as either fixed or variable. Variable costs are costs that increase based on the number of unit samples processed. Fixed costs do not vary with the number of samples within a certain range of samples; however, these costs can grow in a stepwise manner as processing ranges expand. Finally, we formulated a model to estimate cost performance based on the annual number of samples processed within a one to five-year period. Based on current instrument capacity used for the program, the annual capacity baseline was 900 samples processed per year, within which fixed costs do not change.

Costs were categorized in three modules – laboratory costs, personnel costs, and facility costs. Laboratory costs included five components: i) supplies, ii) equipment, iii) chemicals, iv) standard solutions and quality control materials, and v) instruments. Each of these were further disaggregated into distinct cost elements: supplies - 18 elements; equipment - 14 elements; chemicals - 10 elements; standard solutions and quality control materials - 2 elements; and instruments - 12 elements (Appendix Table A1). Personnel costs included training and salary costs of technicians, researchers, and administrative staff. Facility costs included the cost of utilities, storage and office supplies. In this program, building costs were not incurred because the program was conducted in existing university facilities.

To assess relevant costs, we first identified applicable expenditure

# 2.3. Cost analysis

Specific program costs were classified as fixed and variable. Fixed costs included instruments, personnel, and facility costs. Fixed facility cost was assumed to be 5% of the fixed costs. Variable costs included costs of supplies, equipment, chemicals, and standard solutions and quality control materials. Variable facility cost and a cushion for consumables were assumed to be 20% and 2% of the variable costs respectively. Average annual costs were calculated based on the total number of samples analyzed during the time period.

#### 2.4. Analytical tool

An Excel model was used to assess the cost of analyzing different numbers of samples (100–900 in increments of 50) per year over a certain number of years (1–5), in both USD and Thai Baht using an exchange rate of 0.032. Salaries, prices of supplies, equipment, chemicals, internal standard solutions, quality control materials and cost of maintenance were adjusted using a 1% inflation rate beyond year one. Based on user specification of the number of samples processed per year and the number of program years, the model reports total cost, total fixed cost, total variable cost, total laboratory cost, total personnel cost, total facility cost, average cost, average laboratory cost, average personnel cost, and average facility cost. Where relevant, costs were estimated by multiplying cost per unit with the number of units required within a subcategory.

#### 3. Results

Table 1 summarizes costs by cost component based on processing 900 plasma samples per year over 5 years. The average cost per sample is \$185, with the largest share of costs driven by the cost of laboratory instruments (e.g., procurement and maintenance, 33%), personnel (e.g., salaries and training, 23%), and costs of internal standard solutions and quality control materials (13%). Table 2 illustrates the breakdown of cost components into fixed and variable. Fixed costs account for nearly 60% of overall costs and variable costs account for approximately 40%. Fixed costs primarily reflect the cost of laboratory instruments, personnel and some facility costs. Variable costs consist of most per-unit laboratory costs, most facility costs and a cost consumables cushion.

Table 3 describes how average costs for each category differ across different processing scopes. In addition to reporting average costs resulting from processing the baseline maximum capacity of 900 samples per year, it reports average cost estimates that correspond to doubling and tripling the maximum capacity to 1800 and 2700 samples per year. At 900 samples per year, the laboratory cost share is 67.5%, the personnel cost share is 22.9%, and the facility cost share is 9.6%. Increasing the annual processing capacity does not substantively alter this distribution of costs, though it slightly raises the share of personnel costs, which increase from 22.9% of the overall average cost at baseline

# Table 1

Summary of estimated costs of TFA laboratory analysis program, Thailand, based on 900 samples processed per year over 5 years.

	Total cost (USD)	Average cost (USD)	Share (%)
Laboratory costs			
Supplies	17,505	3.89	2.10
Equipment	57,699	12.82	6.92
Chemicals	96,234	21.39	11.54
Quality control materials/internal	109,388	24.31	13.11
standard solutions			
Instruments	278,247	61.83	33.36
Personnel costs	189,925	42.21	22.77
Facility costs	79,574	17.68	9.54
Cushion for consumables	5617	1.25	0.67
Overall	834,188	185.38	100.00

#### Table 2

Summary of estimated fixed and variable cost breakdown of TFA laboratory analysis program, Thailand, based on 900 samples processed per year over 5 years.

	Fixed cost (%)	Variable cost (%)
Laboratory costs		
Supplies	0	100
Equipment	0	100
Chemicals	0	100
Quality control materials/internal standard	0	100
solutions		
Instruments	100	0
Personnel costs	100	0
Facility costs	29	71
Cushion for consumables	0	100
Overall	59	41

# Table 3

Estimated average costs across a range of processed samples per year, over 5 years.

Samples per year	Average cost per sample				
	Overall	Laboratory	Personnel	Facility	
	(USD)	(% of overall cost)			
100	1350.7	63.8	28.2	8.0	
200	694.0	64.3	27.5	8.2	
300	478.3	64.9	26.6	8.5	
400	368.0	65.4	25.9	8.7	
500	301.0	65.8	25.4	8.8	
600	258.6	66.3	24.6	9.1	
700	227.9	66.8	24.0	9.3	
800	204.4	67.2	23.4	9.5	
900	185.4	67.5	22.9	9.6	
1000	223.1	67.8	23.6	8.6	
1100	262.5	63.2	27.7	9.0	
1200	251.6	63.3	27.6	9.1	
1300	242.0	63.4	27.5	9.1	
1400	233.8	63.6	27.2	9.2	
1500	226.2	63.7	27.0	9.2	
1600	219.4	63.9	26.8	9.3	
1700	212.4	64.0	26.7	9.3	
1800	205.6	64.1	26.6	9.4	
1900	200.8	64.3	26.3	9.4	
2000	185.5	64.7	25.8	9.6	
2100	181.2	64.8	25.6	9.6	
2200	177.2	64.9	25.4	9.7	
2300	173.0	65.0	25.3	9.7	
2400	169.0	65.1	25.1	9.7	
2500	194.6	65.6	25.3	9.1	
2600	190.0	65.7	25.2	9.1	
2700	186.5	65.8	25.0	9.2	

capacity to 26.6% of the cost at double processing capacity.

Fig. 2 illustrates the expected trends in the program's total and average costs as more samples are processed annually up to the baseline maximum capacity of 900 samples. The average cost per sample declines rapidly with adding more samples, dropping from a high of USD1,350 per sample if only 100 samples are processed per year over 5 years, to a low of USD185 at the maximum capacity of 900 samples. For each quantity of samples processed per year, average costs are shown to decline if the program continues for more years. For example, the average cost per sample when the program is limited to a single year and 100 processed samples is more than three times higher than the average cost of processing the same number of samples every year over 5 years.

Fig. 3 depicts the total and average cost trajectory associated with scaling up the maximum processing capacity above 900 samples per year. Because of the added fixed costs at every 900-sample scale up, total costs show a distinct jump at each 900-sample increment, while average costs remain relatively stable above 900 samples per year.

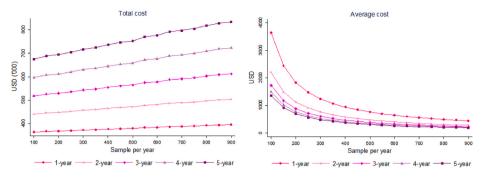


Fig. 2. Estimated total cost and average cost, up to baseline capacity of 900 samples per year.

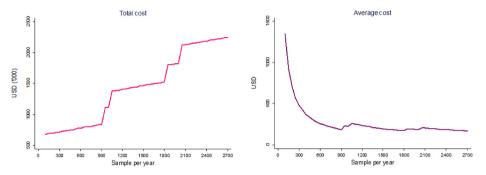


Fig. 3. Cost trajectory associated with scaling up laboratory processing capacity above 900 samples per year.

#### 4. Discussion

This study documents costs associated with a program for conducting analysis of TFA in plasma using preexisting blood specimens collected in previous National Health Examination Surveys in Thailand, and evaluates the expected change in costs in program scale-up scenarios. It has several strengths. First, it is the first, to our knowledge, to assess the costs associated with TFA laboratory surveillance in an international context. Despite recommendations for improved measurement of TFA globally, little evidence exists on the actual resources needed for advancing toward this objective [8]. This is especially true for lower-to-middle income countries, where data on costs is generally not available. Second, we show that considerable cost efficiencies can be obtained from economies of scale in the TFA laboratory surveillance process. Fixed costs, such as laboratory equipment procurement and maintenance costs, constitute a majority of program costs, indicating that opportunities exist for increasing program efficiency through increasing the number of samples processed. Economies of scale were found in terms of increasing both the quantity of samples processed per year and the number of program years. The average costs per sample decreases with processing more samples per year, up to the baseline maximum capacity of 900 samples per year; the average cost is further reduced if the program continues for more than one year. The average cost of processing 900 samples annually over 5 years was estimated at USD185 per sample. Although specific program costs may not be generalizable to other countries, the high proportion of fixed costs implies that programs can increase the efficiency of plasma TFA analysis by scaling up in countries that maintain national biospecimen repositories.

This report is subject to several limitations. First, generalizing the results of this report warrants some caution, as different countries are likely to incur different expenditures depending on differences in the purchasing prices of labor and capital equipment. Second, the costs analyzed in this report do not include expenses for specimen collection, transportation and storage. It is implicitly assumed that these costs are part of national health surveys where collected specimens could be used for studying multiple biomarkers. Third, program costs might be higher

in countries where external technical assistance is not available. Personnel cost and the educational investment needed for skilled lab personnel may vary across countries as well.

This report informs approaches to support the TFA assessment component in the WHO REPLACE action package. The analysis of costs associated with the analysis of TFA in plasma in Thailand can support plans for expanding laboratory measurement of TFA in the country over time. This method can be similarly informative with respect to recently enacted TFA elimination policies in Thailand. In 2018, Thailand enacted a national ban on partially-hydrogenated oils, the primary source of TFA in food, and enforced a monitoring mechanism for mandatory TFA limits [1]. Tracking the change in population TFA exposure following the ban in Thailand can improve understanding of policy effects.

#### Author statements

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#### Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry. Use of trade names is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention, the Public Health Service and the US Department of Health and Human Services.

# Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

# Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhip.2021.100199.

# Appendix

# Table A1

Unit requirements and prices.

		Piece/sample	Piece/sample Pieces required per sample	Pieces per unit	Price per unit	
_					THB	USD
upp	lies					
••	Disposable glass pipettes (5 mL)	1 pc./20 test	0.05	1	118	3.8
2	Glass beakers (25 mL)	1 pc./200 test	0.005	1	64	2.1
;	Glass beakers (50 mL)	1 pc./200 test	0.005	1	64	2.1
	Glass beakers (100 mL)	1 pc./200 test	0.005	1	59	1.9
	Graduated cylinders (100 mL)	1 pc./200 test	0.005	1	321	10.3
	Capped 250 mL bottles, class A glassware	1 pc./200 test	0.005	1	128	4.1
	Pipette Tips 10 µL (1000/bag)	5 pcs.	5	1000	589	18.8
	Pipette Tips 100 µL (1000/bag)	5 pcs.	5	1000	482	15.4
		-	5			
	Pipette Tips 1000 μL (1000/bag)	5 pcs.		1000	642	20.5
0	2 mL cryovials with external thread (500/pack)	1 pc.	1	500	3852	123.3
1	Pyrex disposable glass culture tubes, (threaded, 11.5 mL, $16 \times 100$ mm) (250/pack)	1 pc.	1	250	5350	171.2
2	Pyrex disposable glass culture tubes (rimless,11.5 mL, $16 \times 100$ mm) (250/pack)	1 pc.	1	250	1070	34.2
3	GC vials 2-mL, Footed, Amber Glass (100/pack)	1 pc.	1	100	1017	32.5
4	Caps with septa, blue PTFE/Silicone/PTFE (100/pack)	1 pc.	1	100	1712	54.8
5	Insert glass vial with spring, 100/pk	1 pc.	1	100	1605	51.4
5	Syringe 5 mL for autopipette, 100/pk	1 pc./20 test	0.05	250	3745	119.8
7	Black phenolic screw caps, PTFE-faced rubber liner (250/pack)	1 pc.	1	250	1605	51.4
3	Disposable glass Pyrex Pasteur pipettes, 5 3/4 inch (250/pack)	3 pcs.	3	250	696	22.3
qui	oment	•				
1.1	Non-stick Fluorocarbon Liner Viton O-ring	1 pc./100 test	0.01	1	3980	127.4
	Ultra Inert, Split, Low Pressure drop, Glasswool Liner	1 pc./2000 test	0.0005	1	1605	51.4
	Fixed Tapered Needle Syringe 10 µL	1 pc./1000 test	0.0003	1	50722	1623.1
		1 pc./2000 test		1	126260	4040.3
	Capillary Column CP 7421 Select FAME 200 m $\times$ 250 $\mu m$ x 0.25 $\mu m$ (length, inner diameter, film thickness)	•	0.0005			
	GC advance Green non-stick 11 mm septa	1 pc./100 test	0.01	1	1605	51.4
	MS filament	1 pc./500 test	0.002	1	2675	85.6
	Ferrule and nut for GC fitting	1 pc./1000 test	0.001	1	2675	85.6
	Hydrogen gas, purity 99.999%	1 pc./200 test	0.005	1	3745	119.8
	Trap for hydrogen gas	1 pc./2000 test	0.0005	1	12198	390.3
0	Methane gas, purity 99.99%	1 pc./200 test	0.005	1	8025	256.8
1	Trap for methane gas	1 pc./2000 test	0.0005	1	16050	513.6
2	CI gas regulator	1 pc./2000 test	0.00005	1	15500	496.0
		-				
3	CI gas cylinder	1 pc./2000 test	0.0005	1	5500	176.0
4	Hydrogen gas cylinder	1 pc./2000 test	0.0005	1	8500	272.0
hen	nicals					
	Sodium Hydroxide 10 N solution, 1L	10mL/20 test	0.5	1000	1284	41.1
	Acetonitrile	100 ml/20	5	1000	1552	49.6
	Hydrochloric Acid 6 N solution, 1L	10mL/20 test	0.5	1000	2675	85.6
	Methanol 2.5L	100 ml/20test	5	2500	482	15.4
	Pentafluorobenzyl Bromide (PFB–Br) 5 ML	0.5 mL/50 test	0.01	5	6869	219.8
	Triethylamine (TEA) 99.7% 100 ML	10 µl	0.01	100	899	28.8
	Hexane 1L	10 ml	10	1000	2108	67.5
	Toluene 2.5L	1 ml	1	2500	749	24.0
	Acetone, 1L	1 ml	1	1000	1070	34.2
0	Mixed internal standard (100 ml)	0.1 ml	0.1	1000	541447	17326
		0.1 III	0.1	100	341447	17520
and	lard Curve and Control	1 (06 ) .	0.007770		10410	400.0
	Calibration curve	1 curve/36 test	0.027778	1	13412	429.2
	Quality control material	1 set/36 test	0.027778	1	13393	428.6
istr	uments					
	GC/MS with EI/CI capabilities	900 cases/1 year	0.001111	1	5300000	16960
	GC maintenance	900 cases/1 year	0.001111	1	50000	1600.0
	Vortex mixer	10,000 cases/1 year	0.0001	1	10165	325.3
	Multi-Tube Vortex mixer, speed range 50–2500 rpm	10,000 cases/1	0.0001	1	59000	1888.0
	Evaporation System (centrifugal or nitrogen)	year 5000 cases/1	0.0002	1	2256000	72192
		year				< <b>1</b> 00 .
	Convection Oven, temperature range from up to 325 $^\circ\text{C}$	5000 cases/1	0.0002	1	200000	6400.0
	Convection Oven, temperature range from up to 325 °C Fixed-Speed Reciprocal Shaker	5000 cases/1 year	0.0002	1	200000 50000	6400.0 1600.0

#### Table A1 (continued)

		Piece/sample	Pieces required per sample	Pieces per unit	Price per unit	
					THB	USD
		5000 cases/1 year				
8	Centrifuge with A-4-62 rotor	10,000 cases/1 year	0.0001	1	520000	16640.0
9	Analytical Balance, with printer	2000 cases/1 year	0.0005	1	10000	320.0
10	Positive Displacement Pipettes (10–100 µL)	3000 cases/1 year	0.000333	1	12500	400.0
11	Positive Displacement Pipettes (100–1000 µL)	3000 cases/1 year	0.000333	1	12500	400.0
12	Repeater Pipette Adapter	3000 cases/1 year	0.000333	1	10000	320.0
Pers	onnel					
1	Project director	1000 cases/1 year	0.001	1	720000	23040.0
2	Researcher	900 cases/1 year	0.001111	1	420000	13440.0
3	Training	900 cases/1 year	0.001111	1	120000	3840.0

Note: Detailed protocol components can be found in the WHO Laboratory Procedure Manual for the REPLACE package, https://www.who.int/docs/default-source/ documents/replace-transfats/a-blood-analysis-lab-protocol.pdf?sfvrsn=e7113973\_2.

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