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Manuscript title: Health and economic consequences of applying the United States' PM_{2.5} **automobile** emissions standards to other nations: a case study of France and Italy

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2 automobile emissions standards to other nations: a case study of France and Italy

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4
5

6 **Abstract**

7 Introduction: The US has among the world's strictest automobile emissions standards, but it
8 is now loosening them. It is unclear where a nation should draw the line between the
9 associated cost burden imposed by regulations and the broader societal benefits associated
10 with having cleaner air. Our study examines the health benefits and cost-effectiveness of
11 introducing stricter vehicle emissions standards in France and Italy.

12 Methods: We used cost-effectiveness modelling to measure the incremental quality-
13 adjusted life years (QALYs) and cost (EUR) of adopting more stringent US vehicle emission
14 standards for PM_{2.5} in France and Italy.

15 Results: Adopting Obama-era US vehicle emissions standards would likely save money and
16 lives for both the French and Italian populations. In France, adopting US emissions
17 standards would save €1,000 and increase QALYs by 0.04 per capita. In Italy, the stricter
18 standards would save €3,000 and increase QALYs by 0.31. The results remain robust in
19 both the sensitivity analysis and probabilistic Monte Carlo simulation model.

20 Conclusions: Adopting more stringent emissions standards in France and Italy would save
21 money and lives.

22

23

24 **Introduction**

25 Air pollution remains the primary environmental source of premature mortality in the
26 European Union (EU), causing about 400,000 deaths per year ¹. Transportation is responsible for
27 roughly half of all airborne pollutants in the EU. Regulations on transportation have led to
28 notable improvements in air quality in the region between 1990 and 2015 ¹. Nevertheless, the
29 United States (US) is relaxing vehicle emissions standards. The impact of incremental increases
30 or decreases in vehicle emissions standards on population health is roughly known, but less is
31 known about the trade-offs associated with such changes on macro-economic well-being relative
32 to health and health system costs.

33 This paper explores the trade-off between more stringent vehicle emissions standards and
34 regulatory costs. It does so by modeling the effect of applying more stringent standards to two
35 case study countries. We use the relatively stringent Obama-era standard for particulate matter
36 (PM) 2.5 as a reference because there are data on the macro-economic impacts of applying these
37 regulations over time in the US. Likewise, a number of studies have been conducted on the
38 relationship between vehicle emissions and air quality in France and Italy.

39 PM_{2.5} refers to air particles that are 2.5 microns in diameter or less. Particles of this size
40 can enter the circulatory system via the respiratory system, and thereby cause cardiovascular
41 disease, lung cancer, and premature mortality ²⁻⁸. While deaths associated with PM_{2.5} have
42 declined between 1990 and 2015 in the US and the EU overall, they continue to increase in Italy,
43 Greece, and Malta ⁹. The estimated number of Years-of-Life-Lost (YLL) from PM_{2.5} in 2014 was
44 852 per 100,000 inhabitants in the EU, 602 per 100,000 inhabitants in France, and 1024 per
45 100,000 inhabitants in Italy ¹. By contrast, YLLs in the US are small and limited mostly to the
46 greater Los Angeles area.

47 Cars and trucks contribute to about half of the total PM_{2.5} in the EU ¹. However, there is
48 considerable variation in the relationship between automobile emissions and PM_{2.5} by geographic
49 region, with some global cities being impacted to a greater extent by factories and power plants
50 ¹⁰.

51 Current Federal regulations for vehicle emission standards set in the US by the
52 Environmental Protection Agency ¹¹ are stricter than the EU's current Euro Six vehicle emission
53 standards for all major pollutants, except for carbon dioxide ¹. For PM_{2.5}, the target annual
54 exposure limit defined by the US EPA in 2012 is 12µg/m³ ^{12,13}.

55 The World Health Organization (WHO) recommends that PM_{2.5} not exceed 10µg/m³ ¹⁴, a
56 stringent limit for which there are few case study nations. We chose the US as a comparator
57 rather than the WHO recommendation because there are extant data and at 12µg/m³, it is very
58 close to the WHO target. The 2008 EU legislation on ambient vehicle emissions sets vehicle
59 emissions limits for the entire EU and requires member states to place restrictions on harmful air
60 pollutants, including pollutants from on-road vehicles ¹⁵⁻¹⁸. Under this directive, the EU member
61 states are required to limit population exposure to PM_{2.5} to an annual average of 25µg/m³ by 2015
62 and 20µg/m³ by 2020 ^{1, 15-18}. In 2017, 6% to 7% of the EU urban population was exposed to
63 PM_{2.5} concentrations exceeding the EU limit and about 67% were exposed to levels exceeding
64 the WHO target ¹⁵.

65 Italy and France's PM_{2.5} emission exposure patterns are roughly similar to the range of
66 emissions for other European countries. According to the EEA, the annual mean PM_{2.5} emission
67 in 2015 was 13µg/m³ in France and 19µg/m³ in Italy ¹⁶, compared to an average of 13.9 µg/m³ for
68 all EU-28 countries ¹⁶. While France and Italy fall below the current EU limit of 25µg/m³, they
69 still exceed both the US's limit of 12 µg/m³ and the WHO's Air Quality Guidelines of 10µg/m³

70 ^{13,14,17}. Some eastern EU nations like Poland, Serbia, and Bulgaria have emissions averages that
71 are much higher than Italy ¹⁶.

72 In our analysis, we estimated health impacts in terms of premature deaths and years of life
73 lost due to PM_{2.5} emission exposure ^{1,18}. We also estimated economic costs associated with
74 morbidity related to road traffic pollution in the EU ^{18,19}. Using these inputs, we developed a cost-
75 effectiveness analysis to model the effect of applying the stricter US vehicle emissions standards
76 and enforcement to France and Italy.

77

78 **Methods**

79 Using a Markov model, we simulated relevant health and economic consequences of
80 reduced PM_{2.5} emissions associated with two scenarios in France and Italy: (1) “Keep the
81 standard as is;” and (2) “Adopt and enforce US emissions standards.” We estimated quality-
82 adjusted life years (QALYs), health system costs, regulatory costs, vehicle upgrade costs, and
83 fuel savings ¹³. All parameters were derived from the existing literature and are summarized in
84 Table 1.

85 We ran our model over the course of the lifetime of our standard cohort and discounted
86 future QALYs and costs at a discount rate of 3% ²⁰. Final estimates of incremental costs per
87 QALY were made in constant 2018 €. We conducted multiple one-way sensitivity analyses to
88 quantify the robustness of our estimates against broad changes in the core parameters and
89 assumptions of the model. Additionally, we performed a Monte Carlo simulation with 10,000
90 random samples to capture uncertainty in our model outcomes across all variables. We built our
91 model in TreeAge Pro 2016 software ²¹.

92

93 *PM_{2.5} Emissions Regulations: US vs. France and Italy*

94 In our model, we explored the potential impact of stricter regulations in two European
95 countries on health and costs. We limited the regulations to only light-duty vehicles, which are
96 defined as passenger cars for everyday use^{22,23} and account for more than 80% of registered
97 vehicles in France and Italy²⁴. We omitted light- and heavy-duty trucks from our analysis,
98 including commercial trucks, because there is limited data on upgrading costs and fuel savings.
99 Italy and France have a similar proportion of heavy vehicles on the road, extensive rail networks,
100 and while Italy imports a good deal of energy from France, 80% of this power comes from
101 nuclear power generation and hydropower^{25,26}. This allows for a natural control between the two
102 case study nations.

103

104 *Demographic Data*

105 We measured the impact of stricter vehicle emissions standards on all residents of France
106 and all residents of Italy as separate arms of the model. In our Markov model, the average age,
107 population size, and age-specific mortality rates for each country were retrieved from Eurostat
108 statistics²⁷. We also applied different regulatory standards in France, Italy, and the US to a
109 uniform, hypothetical cohort. This allows us to provide estimates of the impacts of regulatory
110 standards on health that are independent of socio-demographic differences between the three
111 nations.

112

113 *Cost-Effectiveness Model*

114 Our Markov decision-analytic model had two arms: “Keep the standard as is” and “Adopt
115 US emissions standards.” Our hypothetical regulatory changes could reduce the risk of lung
116 cancer, stroke, asthma, and overall mortality^{18,19}. However, to ensure that our numbers are
117 conservative, we focused on two major health effects of ambient PM_{2.5}: asthma and

118 cardiovascular disease (CVD). Our model, therefore, assumes five health states: perfect health,
119 chronic asthma, chronic CVD, comorbid asthma and CVD, and death. Excluding other pollutants
120 also helps ensure that numbers are conservative on the benefits side of the cost-effectiveness
121 analysis.

122 Our Markov model simulates the impact of reduced PM_{2.5} levels on the risk of developing
123 new asthma, chronic CVD, and comorbid asthma, and CVD. We also modeled the risk of acute
124 exacerbations for people living with chronic asthma and the risk of acute CVD events such as
125 stroke or myocardial infarction among people living with chronic CVD. We ran the model from
126 2018 until 2050 to evaluate the impact of the policy over the lifetime of each standardized cohort.

127 We then conducted a one-way sensitivity analysis using the confidence intervals reported
128 in the literature to see how changing a given parameter would impact the incremental cost-
129 effectiveness ratio (ICER)²⁸. Finally, we developed a Monte Carlo simulation for probabilistic
130 sensitivity analysis using a normal probability distribution based on the reported standard errors
131 from the literature²⁸. We ran the simulation with a willingness-to-pay (WTP) threshold of
132 €46,000, referring to the European survey on willingness-to-pay for improved air quality in an
133 economic study²⁹ to assess the robustness of our analysis.

134

135 *Probabilities and Rates*

136 Model parameters for the incidence rates for asthma, CVD, exacerbations, and relapses,
137 was derived from the literature. The life tables and demographics for France and Italy were each
138 obtained from their national statistics bureaus^{30,31}. Where a country-specific value for a given
139 parameter was not available, we used the reported value for a demographically similar country.
140 Where co-morbid states are present, we adjusted health states to reflect independent probabilities

141 ^{32–35}. We averaged the reported values from as many meta-analyses and nationwide studies as
142 possible to improve the accuracy and generalizability of our findings.

143 The “Adopt US standards” scenario evaluates the economic costs and health benefits of
144 reducing PM_{2.5} in France and Italy to those currently seen in the US. We applied the drops in
145 PM_{2.5} levels to the relevant relative risks based on data from the literature ^{3,6,7,36}. We then
146 modified the baseline risk of health states in the control arm, “Keep the standard as is,” to inform
147 the corresponding probabilities in the intervention arm. For a complete list of parameters, see
148 Table 1.

149

150 *Costs*

151 We included health care-related costs, the costs of implementing new test facilities, and
152 fuel savings from stricter PM_{2.5} emissions standards as direct costs ¹¹. We quantified indirect
153 costs through health-related productivity gains associated with reduced PM_{2.5} levels ^{3,6,7,35}. All
154 the costs associated with this policy change were taken from the literature.

155 To determine the direct costs of introducing US standards to both France and Italy, we
156 used data from the US EPA’s 2014 Regulatory Impact Analysis ¹¹. Costs included a one-time
157 implementation cost for PM_{2.5} regulation test facilities, the unit cost of upgrading vehicles with
158 additional hardware, the indirect cost of additional labor, and the annual fuel savings after the
159 upgrade for gasoline vehicles ¹¹. To compute the total cost of vehicle upgrades, we multiplied the
160 unit costs per vehicle by the annual number of light-duty vehicles sold in each country. For each
161 health state, we included on-going costs of chronic asthma or CVD management ^{33,37–40}, costs of
162 asthma exacerbation ⁴¹, and costs of acute CVD events ^{37,40}.

163

164 *Utilities*

165 Health outcomes were measured in terms of QALYs, a measure of remaining life
166 expectancy, adjusted to reflect the average state of health of a cohort ⁴². The health state utility
167 value for chronic asthma was derived from literature ^{43,44}. We multiplied the distribution of
168 asthma health states, defined by the Global Initiative for Asthma ⁴⁵, by their corresponding utility
169 values ⁴⁶. For CVD, we compiled the health utility values from the literature based on the
170 EuroQol-5 Dimension (EQ-5D) scale ^{47,48}. All relevant asthma and CVD events were assigned a
171 disutility value based on literature, found in Table 1.

172 To measure the impact of an ambient PM_{2.5} decrease on quality of life, we used the
173 reported QALY gain/loss from the literature, and assumed a linear association between PM_{2.5} and
174 QALYs.

175

176 **Table 1. List of parameters used in the Markov Model**

177

178 [Insert Table 1 here.]

179

180 **Results**

181 In France, the added direct and indirect costs of not adopting and enforcing the US
182 regulations (keeping the status quo) amounted to €49,000 (95% CI €25,000, €90,000) while
183 adopting the US PM_{2.5} emission standards would cost €48,000 (95% CI €24,000, €88,000). The
184 number of QALYs associated with the status quo scenario was 19.63 (95% CI 18.47, 20.21),
185 while the number of QALYs associated with adopting US regulations was 19.67 (95% CI 18.50,
186 20.24). In Italy, the cost associated with not adopting stricter PM_{2.5} regulations was €39,000
187 (95% CI €6,000, €192,000), while adopting the standards was associated with a cost of €36,000

188 (95% CI €5,000, €175,000). The corresponding QALYs for the status quo and new emission
189 regulations were 27.38 (95% CI 26.15, 28.15) and 27.69 (95% CI 26.39, 28.45) respectively.
190 With incremental costs of -€1,000 for France and -€3,000 for Italy, as well as incremental
191 QALYs of 0.04 for France and 0.31 for Italy, adopting US emission standards saves costs and
192 lives for both French and Italian populations.

193
194 **Table 2.** Incremental costs, incremental quality-adjusted life years, and incremental cost-
195 effectiveness ratios for France and Italy for current vehicle emissions standards versus standards
196 set in the US.

197
198 [Insert Table 2 here]

199
200 The one-way sensitivity analysis indicated that the results of our model were robust to
201 changes to the parameter values, such as changes in the relative risk of CVD onset, ongoing cost
202 of chronic asthma, new CVD onset incidence rate, etc. (the full list of model parameters
203 subjected to the sensitivity analysis can be found in Appendix 1, Figure S1). The parameter that
204 affected our model the most was variability in the relative risk of asthma incidence due to an
205 increase in PM_{2.5} for France and ongoing cost of chronic CVD for Italy (Appendix 1, Figure S1).

206
207 [Insert Figure 1 Here.]

208
209 **Figure 1.** Incremental Cost-Effectiveness Scatter Plot with 95% Credibility Interval (defined as
210 inner space of the grey eclipse) falling within and outside of the willingness-to-pay (WTP)
211 threshold of €46,000 France and Italy.

212
213 From the probabilistic Monte Carlo simulation (Figure 1), 93.8% of randomly-generated
214 samples for France and 87.4% of samples from Italy were both cost- and life-saving for adopting
215 US PM_{2.5} emission standards compared to no change in air pollution policies. An additional
216 0.7% of French samples and 10.1% of Italian samples fell within a WTP of €46,000. Despite
217 excluding important benefits associated with regulatory changes, less than six percent of the
218 simulations for both France and Italy fell outside of the WTP threshold.

219 From the acceptability curve, with a WTP of €46,000, the intervention has 98.7%
220 acceptability for France and 96.0% acceptability for Italy. Within the confidence interval of
221 €27,000 - €110,000, the intervention maintained higher than 95% acceptability for both countries.
222 (Appendix 1, Figure S2)

223

224 **Discussion**

225 We set out to illustrate the changes in societal costs and health associated with changes in
226 PM_{2.5} regulations. We used two nations as case studies in order to illustrate the tradeoffs
227 associated with incremental regulatory changes. Cost-saving preventive health interventions are
228 very rare, and should be implemented so long as there are no overriding ethical concerns
229 associated with doing so^{20,49}. We find that improving vehicle emissions standards and
230 enforcement is one of those rare policies that could save both money and lives. The EU has not
231 kept pace with the US with respect to vehicle emissions standards set by the US EPA.
232 Enforcement of violations is also weak in many EU member states. As a result, the EEA reports
233 that about 400,000 deaths occur each year as a result of long-term exposure to excessive PM_{2.5}¹⁵.
234 This human toll also comes with an economic toll for the EU that hits health systems particularly
235 hard. This is striking for a block of nations that also offers near universal care to its occupants.

236 Full quantification of the economic and health toll association with regional changes in
237 regulation would be a massive undertaking given the large national variations in emissions,
238 pricing of health goods, and other model inputs, and mean values for EU are of little use. Given
239 our finding that both nations would realize savings, it is likely that most EU nations would realize
240 similar gains. However, countries with tough regulations might experience increases in costs
241 without meaningful gains in health. Likewise, our predictions are not valid for countries with
242 weak regulations that might enact more radical changes that could produce unforeseen and
243 unintended macroeconomic consequences.

244 Our study also serves as a warning for US policy. Currently, the US is considering
245 relaxing environmental protections, and one EPA scientific advisor has indicated that the air in
246 the US is “too clean” to breathe for optimal health ⁵⁰. Relaxing standards, even to a small degree,
247 would likely lead to increases in deaths, disability, and costs. This is likely to be a bigger problem
248 in the US than in Europe not only because driving is more prevalent, but also because healthcare
249 costs are roughly twice those of France or Italy and growing much more rapidly over time ⁵¹⁻⁵³. A
250 recent study found that PM2.5 concentrations are highly predictive of Covid-19 deaths in the
251 United States ^{54,55}.

252 Our study has a number of limitations. First, we showed two case studies rather than
253 providing mean impacts in the EU. Some nations in the EU have much higher standards than
254 France or Italy, while others have much lower standards. Like the EU, US states vary with
255 respect to enforcement of EPA vehicle emissions standards. However, because the US
256 automobile market is somewhat monolithic, automobile emissions and fuel efficiency standards
257 in the US are driven more by the state with the toughest regulations than by EPA standards.

258 Another limitation is that our key model inputs—pollution-associated morbidity and
259 mortality—are not derived from randomized trials in humans (for ethical reasons). Rather, they

260 are derived from observational and quasi-experimental studies of humans backed by experimental
261 animal models. The health effects of pollution could be better or worse than those we present
262 here. We account for error in estimates of these and other model inputs by using a broad
263 sensitivity analysis and excluding potentially important pollutants from our estimates.

264

265 Conclusions

266 Most medical interventions cost well over \$100,000 per QALY gained ²⁸, however
267 broader social policies such as education interventions, can save both money and lives ⁵⁶⁻⁵⁹. We
268 show that titrating regulatory controls to optimize health could be added to the armament of
269 policies, including vaccines and education interventions ⁵⁶⁻⁵⁹, that improve health.

270

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272 Disclaimers: The research presented in this paper is that of the authors. All data is available in the
273 main text or the supplementary materials. The TreeAge model can be provided upon request. All
274 data collection and analysis were done in 2018, and the study is exempted from IRB approval.

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277 Competing interests: None declared

278 Ethical approval: Not required (Quasi experimental study).

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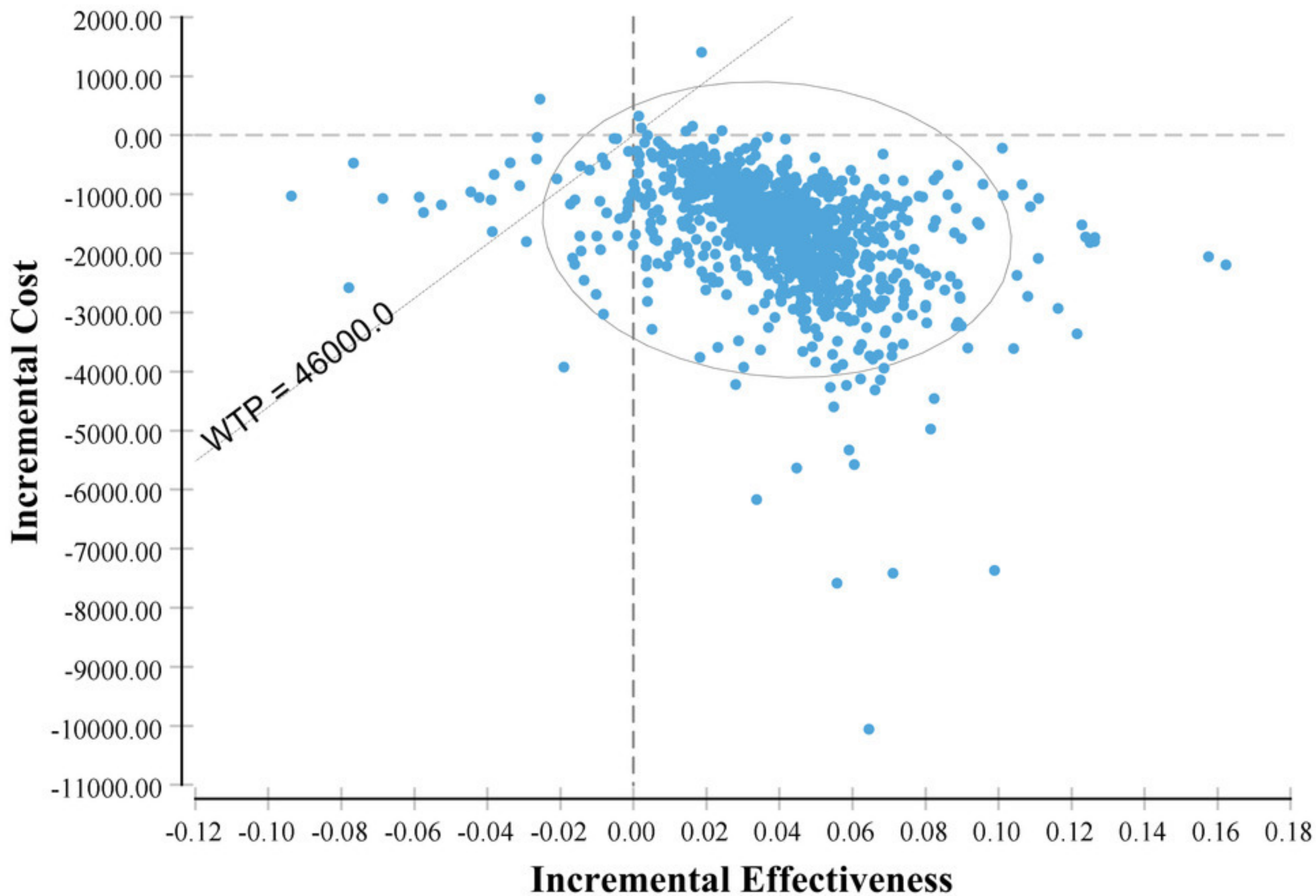
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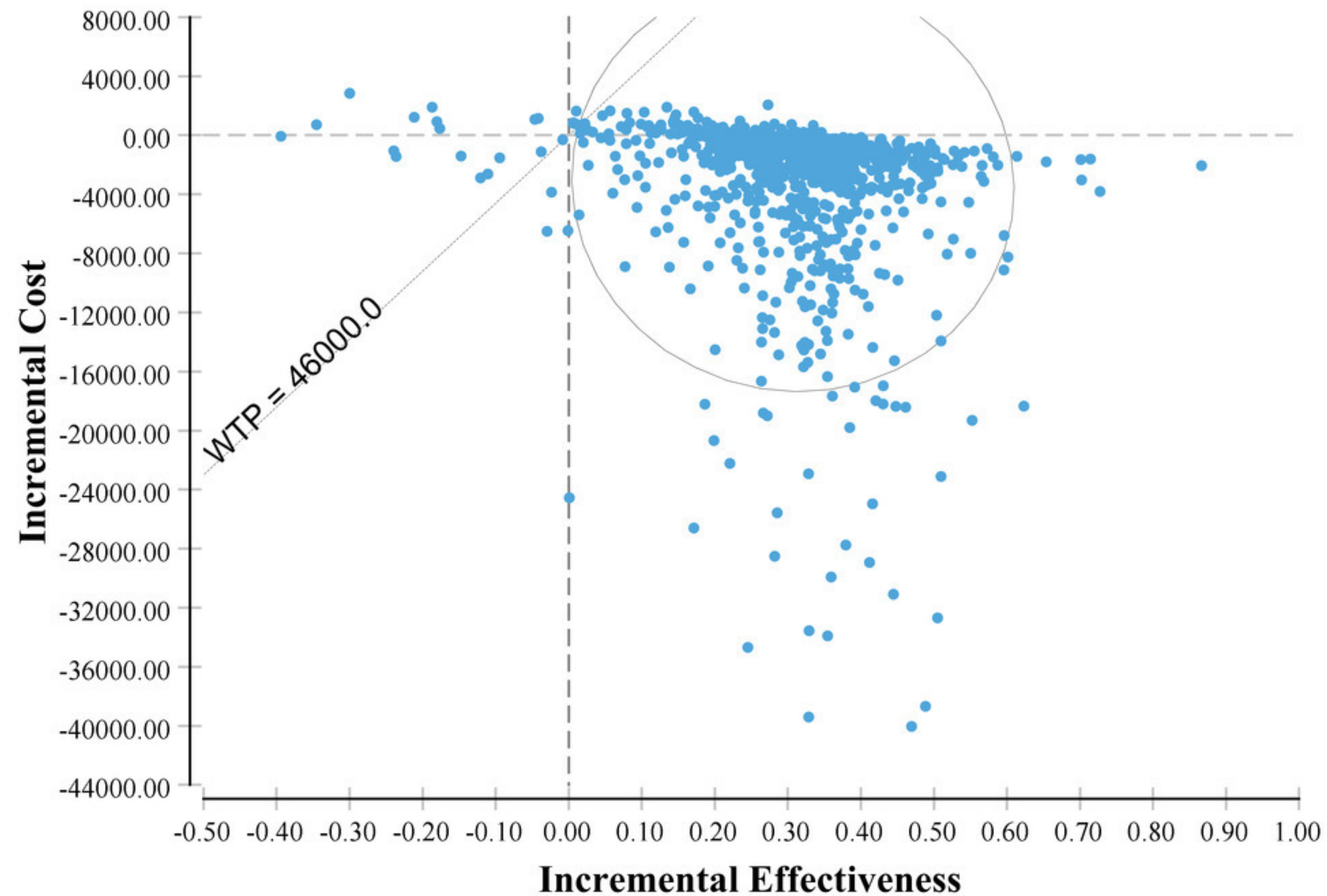
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Incremental Cost-Effectiveness Scatter Plot - FRANCE



Incremental Cost-Effectiveness Scatter Plot - ITALY



1 **Table 1. List of parameters used in the Markov Model**

Description	France		Italy		Probabilistic Distribution ^a
	Base Value	Standard Error	Base Value	Standard Error	
General parameters					
Average age of target population ²⁷	41.4	-	45.9	-	-
Total number of target population ²⁷	66989083	-	60589445	-	-
Chronic asthma prevalence ³³ (2010)	0.06	-	0.04	-	-
Chronic CVD prevalence ^{32,34,35}	0.054	-	0.045	-	-
Annual discounting rate ²⁰	0.03	-	0.03	-	-
Ambient PM2.5 base level ($\mu\text{g}/\text{m}^3$)	13.00	-	19.00	-	-
Ambient PM2.5 benchmark level ($\mu\text{g}/\text{m}^3$) ⁶⁰	7.65	-	7.65	-	-
Number of gasoline passenger cars sold in year 2017 ^{61,62}	777645	-	599752	-	-
Number of diesel passenger cars sold in year 2017 ^{61,62}	1089403	-	1061004	-	-
Total passenger vehicles on road ^{61,62}	32326000	-	37080753	-	-
Costs (2018 Euro)					

Cost of acute asthma ED visit or hospitalization ^{41,63}	399	-	1,225	-	γ
On-going cost of chronic asthma	1,230	6,076	1,407	118	γ
Cost of acute CVD attack ^{37,40,63}	19,279	-	23,053	20,929	γ
On-going cost of chronic CVD ^{37,40,63}	9,358	-	5,282	8,539	γ
One-time facility set-up cost ¹¹	1,077,089	-	8,616,711	-	γ
Unit cost per vehicle for new vehicle hardware ^{11,b}	70.77	-	47.75	-	γ
Annual fuel savings per vehicle ^b (Gasoline vehicles only) ¹¹	1.51	-	1.30	-	γ

Probabilities, Rates, and Relative Risk

(RR)

Asthma ED visit or hospitalization rate ⁶⁴	0.356	-	0.356	-	β
Acute cardiovascular attack rate ^{32,34,35}	0.009	0.001	0.014	0.001	β
New asthma onset incidence rate ⁶⁵	0.006	-	0.004	-	β
New CVD onset incidence rate ⁶⁵	0.015	-	0.012	-	β
Case fatality rate of asthma hospitalization or ED visit ⁶⁶	0.015	-	0.015	-	β
Case fatality rate of acute CVD attack ³²	0.079	-	0.062	-	β

RR of all-cause mortality due to PM2.5 increase ³⁶	1.06	0.01	1.06	0.01	γ
RR of asthma hospitalization or emergency department visit by PM2.5 ⁷	1.023	0.004	1.023	0.004	γ
RR of new asthma onset due to PM2.5 increase ³	1.04	0.10	1.04	0.10	γ
RR of new cardiovascular disease onset due to PM2.5 increase ⁶	1.11	0.05	1.11	0.05	γ
RR of asthma emergency department visit or hospitalization rate association with CVD comorbidity ⁶⁶	2.16	0.78	2.16	0.78	γ
RR of cardiovascular attack with prior history ⁶⁷	1.97	0.17	1.97	0.17	γ

Utilities used to Calculate Quality-Adjusted Life Years (QALY)

Annual utility of healthy resident in QALYs ⁴²	1.00	-	1.00	-	β
Annual utility decrement attributable to asthma ED visit or hospitalization in QALYs ³⁹	-0.016	0.015	-0.016	0.015	β

Annual utility decrement

attributable to acute CVD attack in QALYs ⁴⁸	-0.283	0.013	-0.283	0.013	β
Utility of chronic asthma ^{33,39,68}	0.808	0.211	0.747	0.214	β
Utility of chronic cardiovascular disease ⁴⁸	0.844	0.010	0.844	0.010	β
Utility of chronic cardiovascular disease and asthma ^{43,46,47}	0.789	0.002	0.728	3.077 E-06	β

2

3 a: Probabilistic distribution of parameters. β denotes beta-distribution and γ stands for gamma
4 distribution.

5 b: Different cost values used per calendar year. Values in the table is the initial cost at year 2019.

1 **Table 2.** Incremental costs, incremental quality-adjusted life years, and incremental cost-effectiveness ratios for France and Italy for
 2 current **vehicle emission** standards versus standards set in the United States. (Numbers are rounded to reflect the high degree of
 3 uncertainty in the estimates.)

France				
Arm	QALY	Incremental QALY	Cost (EUR)	Incremental Cost (EUR)
Maintain Current	19.63		49,000	
PM2.5 Emissions Standard	(18.47, 20.21)	-	(25,000, 90,000)	-
Adopt U.S. PM2.5 Emissions Standard	19.67 (18.50, 20.24)	0.04	48,000 (24,000, 88,000)	-1,000

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Italy				
Arm	QALY	Incremental QALY	Cost (EUR)	Incremental Cost
Maintain Current	27.38		39,000	
PM2.5 Emissions Standard	(26.15, 28.15)	-	(6,000, 192,000)	-
Adopt U.S. PM2.5 Emissions Standard	27.69 (26.39, 28.45)	0.31	36,000 (5,000, 175,000)	-3,000

16

a: Quality of Life

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