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Impact of the Dry Law on road traffic mortality in Brazilian states: an interrupted time series analysis

Impacto da Lei Seca sobre a mortalidade no trânsito nas unidades federativas do Brasil: uma análise de série temporal interrompida

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ABSTRACT: ***Objective:*** To assess the impact of 2008 Public Law number 11,705, also known as Dry Law (DL-08), on mortality from road traffic accidents (RTA), in each of the 27 Brazilian Federative Units (BFUs). ***Methods:*** Ecological study of interrupted time series with RTA data from 2002 to 2015, totalizing 168 months. Data were obtained from the Mortality Information System, the Brazilian Institute of Geography and Statistics, and from the National Traffic Department. Autoregressive integrated moving average (ARIMA) models were adjusted to assess the impact of DL-08 in each BFUs. ***Results:*** After the implementation of the DL-08, there was a significant decrease in mortality from RTA in the state of Santa Catarina (pre DL-08 = 2.60 ± 0.30 and post DL-08 = 2.32 ± 0.35; $p < 0.001$) and in the Federal District (pre DL-08 = 2.22 ± 0.40 and post DL-08 = 1.76 ± 0.35; $p = 0.002$), a significant increase in mortality in the states of Acre, Amazonas, Rondônia, Maranhão, Piauí, Ceará, Rio Grande do Norte, Paraíba, Pernambuco, Alagoas, Sergipe and Mato Grosso, and a stability in the other states. The sensitivity analysis conducted over a shorter time series with 24 months showed results similar to those obtained with the 168-month series for most of the 27 BFUs. ***Conclusion:*** The DL-08 had a heterogeneous impact on mortality from traffic accidents on BFUs.

Keywords: Interrupted time series analysis. Accidents, traffic. Time series studies. Ecological studies.

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RESUMO: ***Objetivo:*** Analisar o impacto da Lei 11.705, conhecida por "Lei Seca" (LS-08), sobre a mortalidade por acidentes de trânsito (AT) em cada uma das 27 unidades federativas (UF) do Brasil. ***Método:*** Estudo ecológico de séries temporais interrompidas com dados de AT entre 2002 a 2015, totalizando 168 meses. Os dados foram obtidos do Sistema de Informações sobre Mortalidade, do Instituto Brasileiro de Geografia e Estatística e do Departamento Nacional de Trânsito. Foram ajustados modelos auto-regressivos integrados de médias móveis (ARIMA) para analisar o impacto da LS-08 em cada UF. ***Resultados:*** Após a implantação da LS-08, a mortalidade por AT diminuiu significativamente no estado de Santa Catarina (pré-LS-08 = 2,60 ± 0,30 e pós-LS-08 = 2,32 ± 0,35; $p < 0,001$) e no Distrito Federal (pré-LS-08 = 2,22 ± 0,40 e pós-LS-08 = 1,76 ± 0,35; $p = 0,002$), aumentou significativamente nos estados do Acre, Amazonas, Rondônia, Maranhão, Piauí, Ceará, Rio Grande do Norte, Paraíba, Pernambuco, Alagoas, Sergipe e Mato Grosso e permaneceu estável nos demais. Análise de sensibilidade conduzida sob uma série temporal mais curta, com 24 meses, apresentou resultados semelhantes aos obtidos com a série de 168 meses para a maioria das 27 UF. ***Conclusão:*** A LS-08 exerceu impacto heterogêneo sobre a mortalidade por AT entre as UF.

Palavras-chave: Análise de séries temporais interrompida. Acidentes de trânsito. Estudos de séries temporais. Estudos ecológicos.

INTRODUCTION

Traffic accidents (TA) are a relevant public health problem. They account for about 1.35 million deaths per year worldwide, being the eighth leading cause of death in the general population and the leading cause of death among people aged 5 to 29 years[1]. Furthermore, most TAs occur in low- and middle-income countries, where their cost can reach 2.9% of the Gross Domestic Product (GDP)[2].

In Brazil, data from the 2013 National Health Survey show that 3.1% of the Brazilian population were involved in TAs with bodily injuries within a 12-month interval[3], which places TA as the second cause with the highest proportion of years of life lost due to external causes in Brazil[4].

The effects of alcohol consumption on the occurrence of TAs are well described in the literature. Alcohol is known to delay the reaction to a stimulus, alter alertness, visual acuity, performance in tasks that involve divided attention and the ability to judge[5-7]. Furthermore, studies show that alcohol intake is associated with a higher risk of injuries and death from TA[8,9]. In Brazil, Damacena et al.[10] showed that alcohol consumption is associated with TA even when the effects of age, sex, education, skin color and marital status are considered. Evidence of the harmful effects of alcohol presented in the world literature helps to understand why 45 countries currently have restrictive laws on alcohol and driving[1], including Brazil.

In Brazil, Law No. 11,705, of June 19, 2008, popularly known as Dry Law (DL-08), was one of the measures adopted by the Brazilian government to reduce morbidity and mortality from TA. In force since June 20, 2008, the DL-08 penalizes the driver caught driving under the influence of alcohol or any psychoactive substance with the suspension of the right to drive for 12 months across Brazilian territory, in addition to fines and administrative sanctions[11].

Several studies have investigated the impact of DL-08 on TA mortality in Brazil. Malta et al.[12] did this by comparing the overlapping confidence intervals of the standardized rate of mortality from TA before and after DL-08, using aggregated data from one year before and one year after the law implementation. The authors reported a significant reduction (-7.4%) in the standardized rate of mortality from TA in Brazil and also stated that this reduction occurred heterogeneously across states. Andreuccetti et al.[13] showed that DL-08 was responsible for a significant reduction in the rate of mortality from TA by 7.2% and 16.0% in the state of São Paulo and capital, respectively. Abreu et al.[14], in a descriptive study in the city of Rio de Janeiro, compared the months of July 2007 (pre-DL-08) and July 2008 (post-DL-08) and reported a reduction of 12.9% in mortality from TA. In 2017, Klabunde et al.[15] compared pre- and post-DL-08 TA mortality for the state of Santa Catarina and reported a significant reduction in the overall rate. More recently, Abreu et al.[16], in a segmented regression with yearly data for the state of Paraná between 1980 and 2014, observed a decrease in mortality among drivers in general and pedestrians after DL-08.

Despite the relevance of studies already carried out, the effect of DL-08 has not yet been evaluated by models that simultaneously incorporate autocorrelation, seasonality, confounders and cointerventions in all states. Thus, TA mortality described by closer-to-reality and regionalized models can provide more accurate estimates of the impact of DL-08, contributing to traffic management in the country. Therefore, the aim of this study was to assess the impact of DL-08 on mortality from TA in the 27 Brazilian Federation Units (UF), between January 2002 and December 2015.

METHODS

This study conducted an interrupted time-series analysis (ITSA) to assess mortality from TA that occurred monthly in each of the 27 Brazilian FUs between 2002 and 2015, in which 168 months were included, being 78 months before DL-08 (January 2002 to June 2008) and 90 after DL-08 (July 2008 to December 2015).

The studied outcome was the mortality coefficient due to TA observed monthly in each FU. Deaths whose underlying causes were coded in categories V01 to V89 were used for calculation, representing land transport accidents in Chapter XX (External Causes of Morbidity and Mortality) of the tenth revision of the International Classification of Diseases (ICD-10).

Three sources of information were used to collect data: Mortality Information System[17] for the monthly number of deaths from TA; Brazilian Institute of Geography and Statistics

(IBGE)[18] to collect the annual population projection; and the National Traffic Department (DENATRAN)[19] for information about the monthly vehicle fleet.

The intervention studied was DL-08, which was established in Brazil on June 20, 2008. Two co-interventions were also considered: the implementation of the Emergency and Emergency Medical Service (SAMU), according to Ordinance 5,055 of April 27, 2004 (SAMU-2004), and its reformulation according to Ordinance of the Ministry of Health 1,010 of May 21, 2012 (SAMU-2012).

Regressors considered were:

- seasonality, represented by 11 polychotomous variables, one for each month (from February to December) and assuming values of -1 for January (reference month), 1 for the current month and 0 otherwise;
- number of Saturdays and Sundays per month;
- state fleet of motor vehicles.

A model of the type $Z_t = \mu + w_0 I_t + X_t\beta + N_t$ was adjusted for each FU, with μ being a constant, Z_t the TA mortality coefficient in month t (t=1...168), w_0 the impact of DL-08, I_t a binary variable equal to 0 when $t \leq 78$ and equal to 1 when $t > 78$, X_t is the regressor matrix and N_t a residual series belonging to the autoregressive integrated moving average ARIMA (p,d,q). To identify the residual N_t series and to verify the assumptions of homoscedasticity and stationarity, the 78 pre-DL-08 observations were grouped into 13 clusters containing six observations in temporal sequence.

Homoscedasticity was verified with a scatter plot between means and standard deviations of the clusters. In the presence of heteroscedasticity, a Box-Cox transformation was applied to the data.

Stationarity was verified by comparing the series:

- of original (or transformed) data;
- of the first difference;
- of the second difference, in relation to the behavior displayed in the graphs of time series and the autocorrelation function (ACF), in which a decay of autocorrelations was observed.

In case of doubt about which of the three series was stationary, the increased Duckey-Fuller test was applied, and its regression equation was determined based on the number of significantly non-null partial ACF.

The orders p and q were determined by comparing models with different orders p and q in relation to the value of the Akaike information criterion (AIC). The need for a constant in the model was verified with the t test for H0: $\mu = 0$. The adequacy of the model was evaluated by graphic inspection of residuals using the ACF function, partial ACF function and residual histogram, and by the Ljung-Box test. Analyses were performed using the TSA, lmtest and AID packages of the R software, version 3.4.2.

RESULTS

Table 1 shows the estimates of the impact of DL-08 on traffic mortality, in each FU, based on the time series with 168 months, being 78 months before DL-08 and 90 months after DL-08, adjusted by cointerventions and regressors. A significant decrease in mortality from TA after DL-08 was observed only in the state of Santa Catarina ($\hat{w}_0$ = -0.08; $p < 0.001$) and in the Federal District ($\hat{w}_0$ = -0.08; $p = 0.002$). There was also a significant increase in mortality from TA after DL-08 in 12 Brazilian states: Acre ($\hat{w}_0$ = 0.22; $p = 0.005$), Amazonas ($\hat{w}_0$ = 0.08; $p = 0.030$) and Rondônia ($\hat{w}_0$ = 0.71 ; $p < 0.001$) in the North region; Alagoas ($\hat{w}_0$ = 0.31; $p = 0.008$), Ceará ($\hat{w}_0$ = 0.35; $p < 0.001$), Maranhão ($\hat{w}_0$ = 0.22; $p = 0.004$), Paraíba ($\hat{w}_0$ = 0.13; $p < 0.001$), Pernambuco ($\hat{w}_0$ = 0.30; $p < 0.001$), Piauí ($\hat{w}_0$ = 0.34; $p = 0.007$), Rio Grande do Norte ($\hat{w}_0$ = 0.25; $p < 0.001$) and Sergipe ($\hat{w}_0$ = 0.30; $p < 0.001$) in the Northeast region; and Mato Grosso ($\hat{w}_0$ = 0.41; $p < 0.001$) in the Mid-west region. In the other FUs, mortality from TA after DL-08 remained stable when compared to the pre-DL-08 period. The quality of adjusted models was evaluated using residuals and the Ljung-Box test, which did not indicate a failure in the white noise assumption for the residuals in all FUs.

Table 2 shows the sensitivity analysis performed to compare the results of the original 168-month time series with the results of the shorter 48-month time series, 24 months pre-DL-08 and 24 months post-DL-08. Among the 27 UF, the impact of DL-08 ($\hat{w}_0$) was significant, having presented the same direction in both time series of six UF (Santa Catarina, Federal District, Rondônia, Pernambuco, Sergipe and Mato Grosso), while $\hat{w}_0$ was not significant in both the time series of 10 UF (Amapá, Pará, Roraima, Bahia, Mato Grosso do Sul, Espírito Santo, Minas Gerais, Rio de Janeiro, São Paulo and Rio Grande do Sul), $\hat{w}_0$ had the same direction with significant p value only in the longer time series in five FUs (Acre, Ceará, Maranhão, Paraíba and Rio Grande do Norte), $\hat{w}_0$ presented opposite directions and significant p value only in the longer time series in three FUs (Amazonas, Alagoas and Piauí), $\hat{w}_0$ had the same direction and significant p value only in the shorter time series in two FUs (Goiás and Paraná) and, finally, $\hat{w}_0$ presented opposite directions between series and significant p value only in the shorter series in one FU (Tocantins).

DISCUSSION

This study found that the DL-08 was not enough to reduce TA mortality in all FUs. After DL-08 implementation, mortality from TA decreased significantly in two states (Santa Catarina and Distrito Federal), decreased non-significantly in five states (Amapá, Rio de Janeiro, São Paulo, Paraná and Rio Grande do Sul), increased non-significantly in eight states (Roraima, Pará, Tocantins, Bahia, Goiás, Mato Grosso do Sul, Minas Gerais and Espírito Santo) and increased with statistical significance in 12 states (Amazonas, Acre,

Table 1. Estimates of the impact of the Dry Law (DL-08) on the monthly coefficient of mortality from traffic accidents in each federative unit in Brazil.

FU	Pre DL-08	Post DL-08	Nt*	DL-08	p value[&]
	(n = 78)	(n = 90)		w_0[#] (p[$])	
North					
Acre	1.22 ± 0.45	1.50 ± 0.57	ARMA (3,2)	0.22 (0.005)	0.345
Amapá	1.56 ± 0.62	1.42 ± 0.62	ARMA (2,2)	-0.16 (0.068)	0.191
Amazonas	0.91 ± 0.24	1.00 ± 0.23	MA (1)	0.08 (0.030)	0.231
Pará	1.10 ± 0.20	1.51 ± 0.31	AR (1)	0.07 (0.204)	0.195
Rondônia	1.96 ± 0.47	2.75 ± 0.67	ARMA (1,1)	0.71 (< 0.001)	0.691
Roraima	2.25 ± 0.99	2.53 ± 0.99	IMA (1,1)	0.08 (0.798)	0.677
Tocantins	2.51 ± 0.62	3.00 ± 0.68	ARMA (3,3)	0.18 (0.315)	0.645
Northeast					
Alagoas	1.61 ± 0.41	1.97 ± 0.43	ARMA (1,1)	0.31 (0.008)	0.771
Bahia	0.93 ± 0.19	1.37 ± 0.25	IMA (1,1)	0.01 (0.948)	0.216
Ceará	1.67 ± 0.23	2.08 ± 0.40	ARMA (1,1)	0.35 (< 0.001)	0.146
Maranhão	1.09 ± 0.25	1.85 ± 0.39	MA (1)	0.22 (0.004)	0.817
Paraíba	1.49 ± 0.32	1.95 ± 0.39	AR (1)	0.13 (< 0.001)	0.174
Pernambuco	1.41 ± 0.18	1.73 ± 0.23	ARMA (2,3)	0.30 (< 0.001)	0.252
Piauí	1.80 ± 0.44	2.93 ± 0.59	AR (1)	0.34 (0.007)	0.467
Rio Grande do Norte	1.20 ± 0.27	1.46 ± 0.28	MA (0,0,1)	0.25 (< 0.001)	0.994
Sergipe	1.77 ± 0.48	2.26 ± 0.47	ARMA (2,2)	0.30 (< 0.001)	0.163
Mid-West					
Distrito Federal	2.22 ± 0.40	1.76 ± 0.35	MA (1)	-0.08 (0.002)	0.326
Goiás	2.21 ± 0.33	2.52 ± 0.35	ARMA (1,1)	0.20 (0.085)	0.074
Mato Grosso	2.59 ± 0.46	3.02 ± 0.48	MA (2)	0.41 (< 0.001)	0.760
Mato Grosso do Sul	2.44 ± 0.42	2.59 ± 0.47	ARMA (1,1)	0.04 (0.741)	0.910
Southeast					
Espírito Santo	2.28 ± 0.38	2.34 ± 0.38	AR (2)	0.003 (0.972)	0.410
Minas Gerais	1.48 ± 0.22	1.75 ± 0.19	IMA (1,1)	0.01 (0.904)	0.503
Rio de Janeiro	1.55 ± 0.18	1.38 ± 0.19	ARIMA (2,1,1)	-0.10 (0.341)	0.256
São Paulo	1.46 ± 0.13	1.34 ± 0.15	ARMA (4,7)	-0.06 (0.627)	0.111

Continue...

Table 1. Continuation.

FU	Pre DL-08	Post DL-08	Nt*	DL-08	p value&
	(n = 78)	(n = 90)		w_0# (p$)	
South					
Paraná	2.43 ± 0.30	2.46 ± 0.33	IMA (0,1,2)	-0.01 (0.894)	0.119
Rio Grande do Sul	1.58 ± 0.18	1.52 ± 0.19	IMA (1,1)	-0.18 (0.060)	0.295
Santa Catarina	2.60 ± 0.30	2.32 ± 0.35	ARMA (2,2)	-0.08 (< 0.001)	0.921

*Residual series adjusted by models of the autoregressive integrated moving average (ARIMA); #estimate of the impact of DL-08 seasonally adjusted, co-interventions SAMU-2004, SAMU-2012, state vehicle fleet and number of Saturdays and Sundays in the month and autocorrelation; $p regarding the impact of DL-08 on mortality from TA; &p referring to the Ljung-Box test on residuals of adjusted models.

Rondônia, Maranhão, Piauí, Ceará, Rio Grande do Norte, Paraíba, Pernambuco, Alagoas, Sergipe and Mato Grosso).

Although interventions that regulate and penalize drinking and driving are among the most effective to reduce mortality from TA[20], this study pointed out a significant decrease in mortality from TA after DL-08 in only two of the 27 FUs.

To explain this divergence, factors associated with TA deaths should be considered, particularly vehicle fleet, behavior of drivers, functioning of the national traffic system and traffic engineering interventions, traffic municipalization process and adherence to health policies and actions, which may have evolved differently between states.

As for the vehicle fleet, the study showed a direct linear correlation between the fleet growth rate and the magnitude of the DL-08 effect ($\hat{w}_0$) between FUs ($r = 0.55$; $p = 0.003$; Spearman's correlation). Thus, FUs with high positive variations in the number of automotive vehicles between 2002 and 2015 had higher values of $\hat{w}_0$, which indicates that the effect of DL-08 may have lost strength in FUs whose population acquired more vehicles. The high interest in purchasing vehicles is described in the literature. Carvalho and Pereira[21] showed that families spend, on average, five times more on private transportation than on public transportation. Public transport has been increasingly ignored and this has an impact on urban mobility. From 1992 to 2012, commuting time between residence and workplace increased on average by 6.4% in Brazil[22].

With regard to behaviors associated with mortality from TA, such as those described by Nascimento and Menandro[23]—alcohol and drug consumption, high-speed driving, disobedience to traffic rules and overestimation of driving skills—, the prevalence may have evolved differently depending on state during the period of this study. The same may have occurred with non-behavioral factors associated with mortality from TA, such as those mentioned by Almeida et al.[24] and Lima et al.[25]—age of the fleet, degree of urban development, traffic engineering conditions and meteorological conditions—, which may also have evolved differently between UFs.

Table 2. Results of the sensitivity analysis assessing the impact of DL-08 based on the longest original time series (168 months) and on a shorter time series (48 months).

	Impact of DL-08	
	48-month series	168-month series
	w_0* (p value#)	$w_0$$ (p value&)
$\hat{W}_0$ in the same direction and significant p value in both time series		
Santa Catarina	-0.09 (< 0.001)	-0.08 (< 0.001)
Distrito Federal	-0.07 (0.005)	-0.08 (0.002)
Rondônia	0.60 (0.001)	0.71 (< 0.001)
Pernambuco	0.19 (< 0.001)	0.30 (< 0.001)
Sergipe	0.28 (< 0.001)	0.30 (< 0.001)
Mato Grosso	0.51 (< 0.001)	0.41 (< 0.001)
Stable TA mortality after DL-08 in both time series		
Amapá	0.03 (0.806)	-0.16 (0.068)
Pará	0.19 (0.202)	0.07 (0.204)
Roraima	-0.13 (0.400)	0.08 (0.798)
Bahia	0.002 (0.983)	0.01 (0.948)
Mato Grosso do Sul	0.01 (0.892)	0.04 (0.741)
Espírito Santo	-0.21 (0.222)	0.003 (0.972)
Minas Gerais	0.02 (0.757)	0.01 (0.904)
Rio de Janeiro	-0.14 (0.165)	-0.10 (0.341)
São Paulo	-0.06 (0.634)	-0.06 (0.627)
Rio Grande do Sul	-0.22 (0.053)	-0.18 (0.060)
$\hat{W}_0$ in the same direction and significant p value only in the longer time series		
Acre	0.15 (0.123)	0.22 (0.005)
Ceará	0.08 (0.480)	0.35 (< 0.001)
Maranhão	0.22 (0.051)	0.22 (0.004)
Paraíba	0.06 (0.138)	0.13 (< 0.001)
Rio Grande do Norte	0.10 (0.189)	0.25 (< 0.001)
$\hat{W}_0$ in opposite directions and significant p value only in the longer time series		
Amazonas	-0.09 (0.153)	0.08 (0.030)
Alagoas	-0.03 (0.780)	0.31 (0.008)
Piauí	-0.09 (0.631)	0.34 (0.007)

Continue...

Table 2. Continuation.

	Impact of DL-08	
	48-month series	168-month series
	w_0* (p value#)	$w_0$$ (p value&)
$\hat{W}_0$ in the same direction and significant p value only in the shorter time series		
Goiás	0.29 (<0.001)	0.20 (0.085)
Paraná	-0.26 (0.017)	-0.01 (0.894)
$\hat{W}_0$ in opposite directions and significant p value only in the shorter time series		
Tocantins	-0.63 (0.009)	0.18 (0.315)

* Impact estimate of seasonally adjusted DL-08, SAMU-2004, SAMU-2012 cointerventions, state vehicle fleet and number of Saturdays and Sundays in the month and autocorrelation, based on the original time series of this study, with 168 months; #p regarding the impact of DL-08 on TA mortality, based on the original series of this study, with 168 months; $estimate of the impact of DL-08 adjusted for state vehicle fleet and number of Saturdays and Sundays in the month and autocorrelation, based on a shorter time series of 48 months; &p regarding the impact of DL-08 on TA mortality, based on a shorter time series of 48 months.

Another possible explanation for the variability of estimates $\hat{w}_0$ is the complexity of the National Traffic System (NTS). In each UF, the NTS is composed of a State Traffic Council (CETRAN), a Traffic Department (DETRAN), a Roads and Highways Department (DER), military police and an administrative appeals and infractions board (JARI)[26]. Each of these bodies has complex structures made up of directors, superintendencies and management boards. Thus, it is possible that the quality of intra- and inter-organizational integrations is not the same in all 27 FUs.

Another factor that can explain the heterogeneity of values is the process of municipalization of traffic, which has been occurring at an unequal speed between the states. DENATRAN data reveal that, in the state of Tocantins, 5% of the municipalities are integrated into the NTS, while in Rio Grande do Sul this percentage reaches 97%. Many managers resist the idea of municipalizing the traffic of their municipalities for financial reasons[27], even though it is something positive[28].

The different degrees of adherence of FUs to health policies and actions can also explain the heterogeneity in values. The SAMU—a relevant component of the National Emergency Care Policy—represents an important advance in the fight against morbidity and mortality associated with emergencies in Brazil[29]. Despite its relevance, Machado et al.[30] show that the scope of SAMU varies from state to state. In July 2009, the proportion of the population covered by SAMU ranged from 21% (in Espírito Santo) to 100% (in the Federal District and Santa Catarina). Other important policies in the fight against TA, such as the National Policy for the Reduction of Morbimortality from Accidents and Violence of 2001 and the National Policy for Health Promotion of 2006, may also have been conducted differently between FUs.

Finally, differences in road structures, in the operationalization of traffic engineering and in the assertiveness of works over the years between FUs can also contribute to the variability observed.

The results of the sensitivity analysis obtained over the shorter time series of 24 months suggest that, in the states of Santa Catarina, Distrito Federal, Rondônia, Pernambuco, Sergipe and Mato Grosso, there was a significant decrease or increase in mortality from TA after DL-08 in the short term and extended to the long term. In the states of Acre, Ceará, Maranhão, Paraíba and Rio Grande do Norte, a possible effect of the time series size on the power of the tests in adjusted models must be considered. In the states of Amazonas, Alagoas and Piauí, the effect of DL-08 may have been important only in the short term, with the historical trend of increased mortality from TA prevailing, while in the state of Paraná, DL-08 may have lost efficiency over time. However, the possibility that DL-08 has maintained its long-term efficiency in the state of Paraná cannot be ruled out, but other factors associated with mortality from TA have increased in the long-term.

The possible biases of this study were discussed using the instrument Risk Of Bias In Non-randomised Studies of Interventions (ROBINS-I)[31].

We believe that the risk of confounding bias is low because DL-08 is a federal law, which submits any driver to its rules regardless of their predictors of mortality from TA.

In this study, for selection bias, one would need:

- an association between intra- and inter-regional migrations and DL-08, in such a way that the demographic composition would be different in pre- and post-DL-08 phases;
- a change in demographic composition accompanied by a change in behavioral and non-behavioral factors associated with mortality from TA. As the probability of these two conditions having occurred is subjectively small, we believe that the risk of bias is low.

As for the risk of bias in the classification of interventions, we believe that this risk is null because there was no possibility that the inhabitants of all 27 states were classified as not exposed to DL-08 when it was in force, nor they were considered exposed to DL-08 before its validity.

In this study, with aggregated data from all FUs, the problem of missing data is discussed in the context of international emigration. Data from the 2010 Demographic Census indicate that the percentage of people who moved to other countries ranged from 0.06% in Piauí to 0.57% in Goiás. Therefore, the percentage of people who leave Brazil is insufficient to impact the estimates of monthly mortality coefficients for TA. Thus, we believe the risk of bias due to lost data is low or null.

In addition, this study has advantages over previous work on the impact of DL-08[12-16]. This is the first study to investigate the effect of DL-08 in all FUs using a statistical intervention model that simultaneously considers ACF in monthly observations, seasonality and the following confounding variables: number of Saturdays and Sundays per month, evolution of vehicle fleet in each UF and co-interventions that represent the implementation of SAMU, according to Ordinance 5,055 of April 27, 2004 (SAMU-2004), and its reformulation in the Ministry of Health Ordinance 1,010 of 21 of May 2012 (SAMU-2012).

Time limits for pre- and post-DL-08 periods were determined based on Penfold and Zhang[32], who recommend at least eight observations before and eight observations after an intervention. However, considering that our model would include several regressors and that the TA mortality time series showed great variability in some FUs, we decided to expand our time limit from January 2002 to December 2015 (n = 168 months), expanding the recommended by Penfold and Zhang[32].

However, this study has some limitations:

- other co-interventions could have been considered, including the National Traffic Policy of September 2004 and its reformulation, approved in December 2014;
- alternative transfer functions for the impact of DL-08 could have been tested;
- evolution covariates of behavioral and non-behavioral factors associated with TA could not be considered due to lack of secondary data;
- alcohol consumption may also have evolved differently between FUs.

Unfortunately, data on the annual prevalence of alcohol consumption were not found for all 27 FUs. One possibility would be to use data from the Surveillance of Risk Factors and Protection for Chronic Diseases by Telephone Survey (Vigitel), which provides an estimate of proportion of the number of adults who abused alcohol. However, the first edition of Vigitel is from 2006 (therefore, it does not cover the period of our study—2002 to 2015). Also, these data represent the capitals of each UF only, not the UF as a whole.

In summary, after DL-08 there was a significant decrease in mortality from TA only in the state of Santa Catarina and in the Federal District. This heterogeneity may stem from factors associated with death from TA such as change in vehicle fleet, change in behavior of vehicle drivers, functioning of the national traffic system, municipalization of traffic management and variable adherence to health policies and actions, which evolved unevenly between the FUs.

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