Working Paper Series

No. 49

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April 2013

Núcleo de Investigação em Microeconomia Aplicada

Universidade do Minho

Fundação para a Ciência e a Tecnologia
MINISTÉRIO DA EDUCAÇÃO E CIÊNCIA

The impact of regulatory compliance behavior on hazardous waste generation in European private healthcare facilities

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Abstract

Along with the increased provision of healthcare by private outpatient healthcare facilities within the EU countries, there is also an increase on waste generation from these facilities. A significant fraction of this waste is amongst the most hazardous of all wastes arising in communities, posing significant risks to people and the environment if inappropriately managed. The growing awareness that mismanagement of healthcare waste has serious environmental and public health consequences is reflected in the European waste legislation, aiming at waste prevention at the source and emphasizing the "management" aspects of the waste management process. Whether the increasingly large numbers of private healthcare facilities comply with the existing European waste legislation, and whether compliance with such legislation affects the fraction of healthcare waste classified as hazardous is an understudied subject. Using a large survey of private outpatient healthcare facilities, this study finds that although compliance with the law is far from ideal, it is the strongest factor influencing hazardous waste generation. These findings suggest that more public investments in monitoring healthcare facilities' compliance with the law in EU countries is warranted, along with increased efforts to raise the facilities' awareness of the cost savings brought about by compliance with the existing healthcare waste legislation.

1. Introduction

A significant fraction of healthcare waste (HCW) is amongst the most hazardous of all wastes arising in communities, posing significant risks to people and the environment if inappropriately managed (Pruss et al., 1999). The growing awareness that mismanagement of HCW not only results in huge disposal costs, but that it also has serious environmental and public health consequences is reflected in the recent regulations of HCW management at the EU level (Directive 2008/98/CE), and the required development of conforming waste legislation in all member states. The primary goal of the European waste legislation is *waste prevention and minimization at the source itself*, and to that end member states are to emphasize the "management" aspects of the waste management process. This process is not so much about technologies of waste treatment and disposal, but mainly about the implementation of proper segregation practices, good administration and organization, and, importantly, the active participation of trained and informed staff (WHO, 2005a) to ensure correct waste identification and segregation. Although it is generally believed that protection of the environment can be attained by compliance with existing regulations, little is known about the effects that compliance with these regulations has on hazardous waste generation by healthcare facilities (HCFs) within the EU countries. The relatively few existing studies on compliance behavior and waste generation tend to focus on segregation practices and are limited to a few EU hospitals (Muhlich et al., 2003; Blenkharn, 2006, 2007; Ferreira and Teixeira, 2010). The lack of information is, therefore, particularly intensified for "scattered" small private HCW producers such as outpatient clinics and physician's offices, as their large numbers make data collection, monitoring and government control of their compliance with legislative requirements problematic. However, the provision of healthcare by these facilities is expected to increase considerably in the future driven by the ageing of the population and the corresponding rise in chronic disease, coupled with the reconfiguration of the health sector towards smaller private clinical facilities (Bosanquet et al., 2010). Whether these HCFs comply with the existing European HCW management regulations, and whether compliance with such regulations affects the fraction of the hazardous HCW generated is, therefore, a matter of significant public concern. This study uses data collected by a large survey of over 700 small private HCFs distributed all over Portugal, a full member of the EU since 1986 where 50% of outpatient care is currently dominated by private operators, in order to assess compliance behavior with the existing regulatory framework and its impact on hazardous waste generation.

2. Material and Methods

2.1. Regulatory Provisions

In line with the EU legislation, the legal provisions concerning the management of HCW in Portuguese law establish that the responsibility for its management belongs to the *producers* of such waste (Dec. Lei 178/2006). It also establishes that the treatment of HCW must be differentiated according to the type of waste produced. A classification system for HCW is established by law (Despacho 242/96, 13 August), separating HCW in four categories or groups: Group I – this waste is considered to be equivalent to urban waste, presenting no special requirements in its treatment; Group II – this is non-hazardous medical waste, not subject to specific treatments, and may be treated as urban waste; Group III – this is considered as biohazard medical waste, requiring incineration or other effective pre-treatment with a view to subsequent disposal as urban waste; Group IV – this group

comprises various types of hazardous waste subject to mandatory incineration. Thus, the first two groups of waste are deemed *non-hazardous* waste, while the last two are deemed *hazardous* waste. This waste classification can be linked to the 18th chapter (on HCW) of the European waste catalogue established by Commission Decision 2000/532/EC, which is a mandatory classification for all EU members.

In addition to this classification system, the same legal text establishes five specific requirements to handle HCW in order to minimize its negative impacts on the environment. In particular, is specifies that:

§0. Waste must be segregated at the point of generation;

§1. Waste must be stored at a temporary storage place in specific colored containers (black containers for Group I and II waste; white containers marked with a biohazard sign for Group III waste; red containers for Group IV waste);

§2. Group III and Group IV waste must be stored at a different place from the waste belonging to Groups I and II;

§3. The storage place must have a minimum storage capacity corresponding to 3 days of production, and, in case the collection period exceeds those 3 days, the storage place must be equipped with a refrigeration system. In any case, the period between collections cannot exceed 7 days;

§4. Each healthcare unit must have a waste management plan (WMP).

Under adverse circumstances where resources (financial, human and material) are limited, meeting these regulatory requirements may be difficult and expensive, but complete and documented compliance with the applicable regulations is thought essential to achieve the best environmental protection. In order to better achieve compliance with these requirements, the regulatory framework also contemplates a number of policy measures to be implemented at the facility level, namely that the HCFs shall provide E&T opportunities on waste handling issues to their staff; appoint an individual responsible for the management of the waste within the facility; and, implement regular internal audits.

2.2. Data Collection

A survey was designed and sent out to the HCFs based in continental Portugal, and registered at the office of the Portuguese Health Regulatory Entity (HRE). Answers to the survey were collected during March – May 2010 using an electronic survey platform developed by HRE. Rough estimates based on the HRE data indicate a response rate of about 20% from the private outpatient HCFs, a figure that is common in studies assessing compliance with environmental regulations (eg, Botelho et al., 2005, Marinkovic et al., 2008). In line with the figures for high-income countries, the estimated production of HCW by the largest producers (hospitals) in Portugal is about 7.0 Kg/(occupied bed.day), and the private outpatient HCFs account for at least 20% of the HCW produced at the national level (A.P.A, 2010; Almeida (2010)). The facilities in the sample indicate an average annual production of 444 Kg and 39 Kg of Group III and Group IV waste, respectively. This corresponds to an average weekly production of 9.3 Kg of Group III and Group IV waste, a figure that sits well with the production estimate for all small producers in Portugal (LPN, 2010). In addition, the average sample production of Group IV waste corresponds to 8% of the total production of Group III and Group IV waste as predicted by the Portuguese Environmental Agency (APA., 2010). Thus, the information provided by

the sampled facilities conforms to the predictions made by the relevant national entities concerning the population of HCFs.

The survey was composed of two broad parts. One part consisted on questions eliciting the HCFs' compliance with each of the legal requirements detailed above. It also included questions eliciting their use of the policy variables contemplated in the regulatory framework. In particular, policy variables elicited in the survey were whether the HCF has appointed a person responsible for waste management (*Responsible for WM*); whether internal waste audits have been regularly conducted (*Regular Audits*); and, whether training opportunities on waste handling issues have been provided to the HCF's staff (*Education and Training*). The other part of the survey consisted on questions concerning the amount of the various types of medical waste generated within the HCF, along with questions regarding a general characterization of the HCFs. The latter included the number of workers in the HCF, their region of location, and the type of services provided (*Type of Healthcare Facility* --each HCF could indicate several types of services) as previous studies have found these variables to be significantly associated with compliance behavior (eg., Botelho et al., 2005, Rahman et al., 2010, Rousseau, 2009). The policy variables and the variables pertaining to the general characterization of the HCF are included as control variables in the statistical analysis below assessing the impact of compliance behavior on hazardous waste generation.

2.3. Statistical Methods

In order to assess the impact of compliance with regulatory requirements on hazardous HCW generation, the analysis employs a likelihood function that is constructed to be appropriate for the type of data collected. First, not all the waste produced by these HCFs is deemed hazardous according to the regulatory definitions. Secondly, the amount of HCW classified as hazardous generated by some of these HCFs may be quite small and, therefore, not reported. Thus, the statistical analysis considers the process by which some HCFs generate zero or some positive fraction of hazardous HCW as separate from the process by which HCFs generate a specific positive fraction of hazardous HCW. The natural specification to capture these features of the collected data is a "hurdle model". This model is commonly used in health economics to capture the idea that seeking medical care is a "hurdle" that must be passed before positive medical expenditures set in (Duan et al., 1983; McDowell, 2003). In the present case, generating hazardous HCW is the "hurdle" that must be passed before positive fractions of hazardous HCW can be observed.

The likelihood function for the overall hurdle model is constructed as the product of two likelihoods. The first component is the likelihood that the HCF generates zero hazardous HCW or not, and uses a standard logit specification defined over a vector of explanatory variables x_i for HCF *i*, and associated parameter vector α. The second component is the *conditional* likelihood that the HCF generates a certain fraction of hazardous HCW (conditional on generating any positive amount of hazardous HCW). The latter likelihood function is constructed using the specification developed by Papke and Wooldridge (1996) for fractional dependent variables, since the dependent variable in this case is the fraction of hazardous HCW generated (the ratio of hazardous HCW to total HCW generated by the HCF). Using this estimation approach in the present analysis, the log-likelihood of observation *i* is specified as $l_i(\beta) = y_i \log[G(x_i\beta)] + (1-y_i)\log[1-G(x_i\beta)]$ for hazardous HCW fraction y_i, vector of explanatory variables x_i, parameter vector β, and some known function $G(.)$ satisfying $0 < G(z) < 1$

for all $z \in \Re$. Like in Papke and Wooldridge (1996), $G(.)$ is the logistic function in the present analysis. Thus, the overall likelihood function for the hurdle model requires the estimation of α and β, which is accomplished using the econometric package STATA® (version 11.1). Finally, because the conditional expectation functions in both components are nonlinear, the parameter values α_k and β_k do not directly measure the effect of a change in explanatory variable x_k on the mean of the dependent variable. In the present application, the marginal effect of x_k on the conditional expectation function is given by $g(x\gamma)\gamma_k$, where $g(z) = dG(z)/dz = \exp(z)/(1+\exp(z))^2$, and $\gamma_k = \alpha_k, \beta_k$.

3. Results and Discussion

3.1. Compliance rates and fraction of hazardous HCW

After discarding observations with missing values for the relevant questions asked in the survey, the working sample consists of 741 private outpatient HCFs. All of these HCFs indicate that the waste produced is segregated at the source as required by law. In addition, about 91% indicate that the waste is stored at a temporary storage place in the colored containers specified in the legislation. However, only 30% of the HCFs comply with the requirement of storing the hazardous waste in a different place from that used to store the non-hazardous waste. Compliance with the requirement that the period between collections is not to exceed 7 days is observed by only 23% of the HCFs. Finally, only 34% of the HCFs indicate having the WMP as required.

While all the HCFs comply with legal requirement §0, not all of them comply with legal requirements §1 - §4. Considering these 4 requirements only, some HCFs comply with none, some comply with all of them, and some comply with a fraction of them. Table 1 displays the compliance rate with these 4 requirements by the HCFs in the sample. As shown in the Table, only 4.99% of the HCFs comply with the four legal requirements simultaneously (a 100% compliance rate). The percentage of HCFs that do not comply with any of these requirements is smaller: 0.40%. About 39% comply with one of the requirements (a 25% compliance rate), 37% comply with two of the requirements (a 50% compliance rate), and 19% comply with three of the requirements (a 75% compliance rate).

Also reported in Table 1 are descriptive statistics of the fraction of hazardous HCW stratified by compliance rates. Overall, waste classified as hazardous accounts on average for 69% of the total waste produced, a figure that substantially exceeds the 10%-25% predicted in the World Health Organization (WHO, 2005b) guidelines. Such high hazardous waste fractions, however, are not unheard of for the type of HCFs in this sample. For example, Da Silva et al., 2005, found hazardous waste accounting for 74.7% of the total waste produced in dental offices in the State of Rio Grande do Sul- Brazil. Importantly, the figures in Table 1 show that, on average, the fraction of hazardous waste tends to decline with increasing compliance rates, and the null hypothesis of no association between compliance rates and hazardous HCW fractions is easily rejected using a Pearson χ^2 test with a p-value less than 0.001.

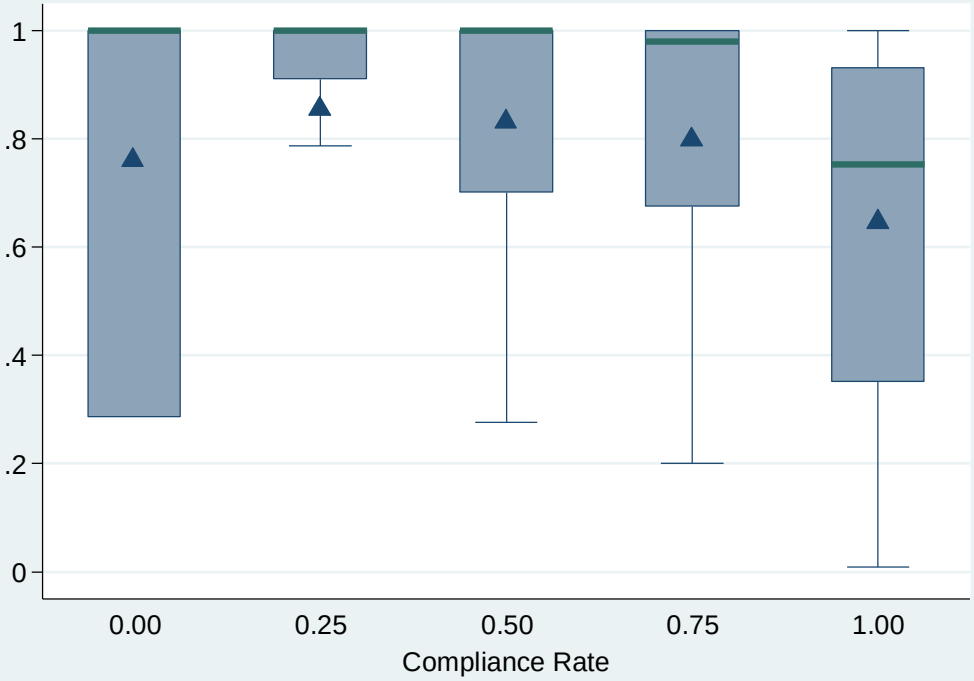
Table 1 – Compliance rate with legal requirements §1 - §4 and Fraction of hazardous HCW

Compliance rate	Percentage of HCFs in the sample	Fraction of hazardous HCW	
		Mean	Std. Dev
0.00	0.40	0.762	0.412

0.25	38.73	0.692	0.420
0.50	36.57	0.687	0.407
0.75	19.30	0.707	0.382
1.00	4.99	0.628	0.328

As noted above, however, not all the HCFs in the sample report producing any positive amounts of waste classified as hazardous. In fact, all the waste produced by about 16% of the HCFs is deemed non-hazardous, generating a mode at the zero value for the distribution of the fraction of hazardous HCW generated by all the HCFs in the sample. Considering only the sub-sample of HCFs that generate positive amounts of hazardous waste, this type of waste accounts on average for 82% of their total waste. This fraction is noticeably higher than that found for the overall sample. The association between compliance rates and hazardous HCW fractions depicts the same pattern as for the overall sample, however. A boxplot depicting the distribution of the fraction of hazardous waste produced by HCFs with positive production of hazardous waste, stratified by compliance rates, is presented in Figure 1. The vertical lines demarcate the minimum and maximum sample values. The upper and lower limits of the boxes represent the lower and upper quartiles of the fraction. The median fraction of hazardous HCW for each compliance rate is represented by thick horizontal lines within each box, and mean values are indicated with triangular markers. The data summarized in Figure 1 clearly suggests a significant difference in the fraction of hazardous waste produced between highly compliant HCFs and less compliant HCFs.

Figure 1: Fraction of Hazardous HCW by Compliance Rate



3.2. Statistical determinants of hazardous HCW generation

Table 2 provides maximum likelihood estimates of the hurdle model for the data collected. All estimates for the α parameter represent the computed marginal effect of the associated explanatory variable on the probability of generating positive fractions of hazardous HCW. The reported estimates for the β parameter represent the marginal effects in terms of the positive fraction of hazardous HCW generated.

The focus variable is the compliance rate as it measures the strength of compliance with the relevant regulatory provisions. It clearly has no effect on the probability of generating (or reporting) positive amounts of hazardous waste or not, but it does have a large and significant effect on the fraction of hazardous waste produced, conditional on producing any. In fact, all else the same, a unit *increase* in the compliance rate leads to a *decrease* in the fraction of hazardous HCW by 16.3 percentage points. Although in an ideal world, compliance with environmentally sound HCW management regulations would mean reducing the generation of hazardous wastes to zero, in practice it means reducing hazardous waste streams to small quantities, mainly when compared to total HCW produced. The results herein reported provide strong empirical evidence that environmentally sound management in compliance with the European waste legislation significantly contributes to hazardous waste prevention at the source, thereby reducing the risks posed by HCW and their associated disposal costs.

Table 2 – Maximum likelihood estimates of the hurdle model of hazardous waste generation

Parameter	Variable	Estimate	SE	p-value	95% CI	
α	*Compliance Rate*	0.046	0.049	0.348	-0.050	0.142
	Education and Training	0.019	0.053	0.721	-0.084	0.122
	Responsible for WM	0.131	0.027	0.000	0.078	0.183
	Regular Audits	0.004	0.032	0.900	-0.059	0.067
	≥Median number of Workers	0.062	0.023	0.008	0.016	0.107
	Type of Healthcare Facility					
	Dental Clinic	0.195	0.031	0.000	0.133	0.256
	Medical Office	-0.027	0.028	0.330	-0.081	0.027
	Nursing Office	0.072	0.023	0.002	0.027	0.118
	Region of location					
	North	-0.008	0.024	0.725	-0.055	0.039
	Alentejo	0.002	0.037	0.950	-0.069	0.074
	Algarve	0.010	0.036	0.790	-0.061	0.080
β	*Compliance Rate*	-0.163	0.052	0.002	-0.264	-0.062
	Education and Training	-0.097	0.061	0.112	-0.216	0.022
	Responsible for WM	-0.019	0.025	0.443	-0.067	0.029
	Regular Audits	0.081	0.024	0.001	0.034	0.128
	≥Median number of Workers	-0.065	0.026	0.012	-0.115	-0.014
	Type of Healthcare Facility					
	Dental Clinic	0.015	0.026	0.563	-0.035	0.065
	Medical Office	0.006	0.027	0.836	-0.048	0.059
	Nursing Office	0.009	0.039	0.816	-0.068	0.086
	Region of location					
	North	-0.055	0.027	0.042	-0.108	-0.002
	Alentejo	0.021	0.041	0.604	-0.060	0.103
	Algarve	0.023	0.051	0.656	-0.077	0.122

Note: Marginal effects for α and β parameters; N=741 in estimating the α parameter; N=622 in estimating the β parameter.

The results also uncover important patterns associated with policy variables that can be manipulated at the HCF level. The results show that, ceteris paribus, HCFs that designate a staff member to manage or coordinate waste management are, on average, 13 percentage points more likely to report positive amounts of hazardous waste than HCFs that do not do so, which might reflect greater knowledge from the former concerning what is categorized as hazardous waste (and, eventually, more precise measurements of their values). Other control variables also exhibit significant effects on the probability of reporting positive amounts of hazardous HCW. As expected, larger HCFs (ie, those having a number of collaborators equal to or higher than the median number (4) of collaborators in the sampled facilities) are more likely to report positive amounts of hazardous HCW than smaller HCFs. Likewise, dental clinics and nursing offices are more likely to report positive amounts of hazardous HCW than other types of private outpatient HCFs included in the sample.

Turning to the analysis of the effects of these variables on the fraction of hazardous HCW, the results show that, all else the same, HCFs that provide regular (ie, at least once a year and lasting for more than 2 hours) education and training opportunities (E&T) on waste handling issues to their staff generate lower fractions of hazardous HCW than those HCFs that do not provide such E&T opportunities. Ceteris paribus, provision of E&T opportunities reduces the fraction of hazardous HCW produced by about 10 percentage points, an effect that is statistically significant at the 0.056 significance level (one-tailed test). This result is in line with Botelho (2012)'s finding that provision of E&T on HCW management improves waste separation procedures thereby contributing to smaller amounts of misclassified "hazardous" waste and, as a consequence, to enhanced environmental protection. Surprisingly, conducting internal waste audits regularly contributes to higher fractions of hazardous HCW. All else the same, conducting these audits increases the fraction of hazardous HCW produced by about 8 percentage points, suggesting that they fail to contribute to the improvement of waste management practices. Other control variables having an effect on the fraction of hazardous HCW are the dimension of the HCFs and their location. Ceteris paribus, the fraction of hazardous HCW produced by larger HCFs is 6.5 percentage points lower than that produced by smaller HCFs. Likewise, the fraction of hazardous HCW produced by HCFs located in the North region of Portugal is, on average, 5.5 percentage points lower than that of HCFs located in the Center and Lisbon regions of Portugal (the omitted category).

4. Conclusions

Along with the increased provision of healthcare by private outpatient healthcare facilities within the EU countries, there is also an increase on waste generation from these facilities. A significant fraction of this waste is amongst the most hazardous of all wastes arising in communities, posing significant risks to people and the environment if inappropriately managed. The growing awareness that mismanagement of healthcare waste has serious environmental and public health consequences is reflected in the European waste legislation, aiming at waste prevention at the source and emphasizing the "management" aspects of the waste management process. Whether the increasingly large numbers of private healthcare facilities comply with the existing European waste legislation, and whether

compliance with such legislation affects the fraction of healthcare waste classified as hazardous is an understudied subject. Using a large survey of private outpatient healthcare facilities, this study finds that although compliance with the law is far from ideal, it is the strongest factor influencing hazardous waste generation. These findings suggest that to ensure a system that is economically sustainable, and protects human health and the environment, more public investments in monitoring healthcare facilities' compliance with the law in EU countries is warranted, along with increased efforts to raise the facilities' awareness of the cost savings brought about by compliance with the existing healthcare waste legislation.

Acknowledgments

The author acknowledges the pivotal input of Professor Lígia Pinto and the Portuguese Health Regulatory Entity (PHRE) in the collection of data. The author alone is responsible for the analysis and views expressed in this paper, and they do not represent the policies or views of the PHRE. This research was partially funded by FCT through the Applied Microeconomics Research Unit (NIMA), and completed while the author was on sabbatical leave at the Water Science and Policy Center, University of California, Riverside, and University of Arizona, Tucson.

References

Almeida, J.C.N. (2010). *A Cost Optimization Model for Hazardous Medical Waste Management in Portugal*. Instituto Superior Técnico, Universidade Técnica de Lisboa, Portugal.

A.P.A. (2010). *Plano Estratégico dos Resíduos Hospitalares 2010-2016.* Agência Portuguesa do Ambiente – Direcção Geral Saúde, Lisboa, Portugal.

Blenkharn, J. I. (2006), "Standards of clinical waste management in UK hospitals", *Journal of Hospital Infection*, 62, 300-303.

Blenkharn, J. I. (2007). "Standards of clinical waste management in hospitals – second look", *Journal of Hospital Infection*, 121, 540-545.

Bosanquet, N., Cawston, T., Haldenby, A., Nolan, P., Seddon, N., (2010). *Fewer hospitals, more competition*, Reform, London.

Botelho, A. (2012). "The impact of education and training on compliance behavior and waste generation in European private healthcare facilities". *Journal of Environmental Management*, 98, 5-10.

Botelho, A., Pinto, L. M. C., Rodrigues, I. (2005). "How to Comply with Environmental Regulations? The Role of Information". *Contemporary Economic Policy*, 23(4), 568–577.

Da Silva, C.E., Hoppe, A.E., Ravanello, M.M., Mello, N. (2005). "Medical wastes management in the south of Brazil". *Waste Management*, 25(6), 600–605.

Duan, N., Manning, W., Morris, C., Newhouse, J. (1983), "A Comparison of Alternative Models for the Demand for Medical Care", *Journal of Business and Economic Statistics*, 1(2), 115-126.

Ferreira, V., Teixeira, M. R. (2010). "Healthcare waste management practices and risk perceptions: Findings from hospitals in the Algarve region, Portugal". *Waste Management*, 30(12), 2657-2663.

LPN (2010). *Parecer- Plano Estratégico de Resíduos Hospitalares 2010-2016*. Liga para a Protecção da Natureza. Portugal. http://www.lpn.pt/LPNPortal/ (26.04.10).

Marinkovic, N., Vitale, K., Holcer, N. J., Dzakula, A., Pavic, T. (2008). "Management of hazardous medical waste in Croatia". *Waste Management,* 28, 1049-1056.

McDowell, A. (2003), "From the help desk: hurdle models", *Stata Journal*, 3(2), 178-184.

Muhlich, M., Scherrer, M., Daschner, F.D. (2003). "Comparison of infectious waste management in European hospitals". *Journal of Hospital Infection*, 55, 260–268.

Papke, L.E., Wooldridge, J. M. (1996). "Econometric Methods for Fractional Response Variables with an Application to 401(K) Plan Participation Rates", *Journal of Applied Econometrics*, 11, 619-632.

Pruss, A., Giroult, E., Rushbrook, P. (1999). *Safe Management of Wastes from Health Care Activities*. World Health Organization, Geneva.

Rahman, T.; Kohli, M.;Megdal, S.; Aradhyula, S.; Moxley, J. (2010). "Determinants of Environmental Noncompliance by Public Water Systems". ***Contemporary Economic Policy*, 28(2), 264-274.**

Rousseau, S. (2009). "Empirical Analysis of Sanctions for Environmental Offenses". *International Review of Environmental and Resource Economics*, 3, 161-194.

Silva, C.E., Hoppe, A.E., Ravanello, M.M., Mello, N. (2004). "Medical wastes management in the south of Brazil". *Waste Management,* 25 (6), 600–605.

StataCorp. (2009). *Stata Statistical Software: Release 11*. College Station, TX: StataCorp LP.

WHO (2005a). *Healthcare Waste Management.* Geneva: World Health Organization.

WHO (2005b). *Management of solid healthcare waste at primary healthcare centres: a decision-making guide*. Geneva: World Health Organization.