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Patient's Attitude Towards Informed Consent

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ABSTRACT

Purpose: *Study of Patient Information within informed consent, in particular the "Not" category of the "Patient Information" variable.*

Methods: *This study collects data from hospitals in the University Hospital of Burgos, Spain, for two years, configuring a file with data with 647 cases and 23 variables, 21 of them referred to the attitude towards informed consent, Sex and Age. We will previously carry out a descriptive-exploratory and comparative analysis to have information on the variables that make up the classification/prediction model (Artificial Neural Network), how the data are distributed by category ("Yes" and "Not") of the variable "Patient Information". The study using the three-layer perceptron (input, hidden and output) will be carried out in three phases: Phase I, variables that have two categories; Phase II, variables that have three categories; Phase III, all variables (two and three categories).*

Results: *Tables 3 show the results of cross-referencing the variable "Patient Information" with the rest of the qualitative variables. The study on the variable "Age", the study of the difference in mean age, generated by the variables that have two categories (Table 4) and three categories (Table 5) leads us to know which difference in means is significant for a level of significance of 5%.*

The most efficient artificial neural network structure found in the classification of the categories of the variable "Patient Information" ("Yes" and "Not" categories) is the binomial hidden layer-output layer: hyperbolic tangent- softmax (Dependent variable: "Patient Information"; Partition: Training 60%, Testing 20% and Holdout 20%). Qualifying results are very low for the "Not" category.

Conclusions: *The information process, in order to obtain informed consent, has an essentially particular character for each patient, it must be away from any situation of overcrowding, bureaucratization and dehumanization and must be based on their self-determination and freedom.*

The study of the variable "Patient Information" using the artificial neural network, perceptron, offers us a low classification/prediction of the "Not" category. One of the factors why the classification of the "Not" category is very low in the variable "Patient Information" is mainly due to the limited data available for this category in the three phases.

Keywords
Informed Consent, Patient Information, Descriptive analysis, Exploratory analysis, t-Student, Crosstabs, Artificial Neural Network.

Introduction

Informed consent is a right of the patient that consists of the patient, before the medical intervention is carried out in his body, must express his consent that must be preceded by the due information that allows him to decide according to his interests. As a correlation of this right, the doctor's obligation to inform the patient and to obtain his consent before carrying out the medical act arises. Information and consent cannot be considered as specific issues, but must be considered as part of a process that promotes fundamental values in clinical relationships, which are communication between people, non-discriminatory treatment and respect for the right to decide according to one's own beliefs and values. Nowadays, it is essential that the physicians involved have internalized in their daily clinical practice the medical-legal concepts that govern health care, both to minimize the risks that patients may face during clinical practice and to avoid incurring defensive medicine.

Informed consent is a principle in medical ethics and medical law and media studies that patients must have sufficient information and understanding before making decisions about their medical care. Pertinent information may include risks and benefits of treatments, alternative treatments, the patient's role in treatment, and his right to refuse treatment. In most systems, healthcare providers have a legal and ethical responsibility to ensure that a patient's consent is informed. This principle applies more broadly than healthcare intervention, for example to conduct research and to disclose a person's medical information [1-8].

Informed consent forms are used by health and telehealth organizations to inform patients of the risks associated with a particular medical treatment and make them provide a signature to give their informed consent. To make the switch to telemedicine and collect e-signatures and informed consent online, there are models that facilitate this option [9]. The literature about informed consent is increasing due to the great impact in society [10-23].

In order to achieve the most efficient neural network structure (non-parametric technique) in data classification, the activation functions of the hidden layer and output layer have been modified, looking for the hidden layer-output layer binomial that provides the best results. The most efficient artificial neural network structure found in the classification of the categories of the variable "Patient Information" ("Yes" and "Not" categories) is the binomial hidden layer-output layer: hyperbolic tangent- softmax (Dependent variable: Patient Information; Partition: Training 60%, Testing 20% and Holdout 20%).

Material and Methods

Study database

The database consists of a representative sample of patients treated (who had undergone body intervention requiring informed consent) in the unit of the Orthopaedic Surgery and Traumatology Service of the University Hospital of Burgos, for two years. This database is made up of 647 cases and 23 variables, 21 of them referred to the attitude towards informed consent (Table 3) Sex and Age. The descriptive and exploratory analysis of data provides us with prior information on the distribution of the data, valuable for the rest of the analyses. The contingency tables (Variable x Patient Information) give us information on the number of cases per category (Yes and Not) of the variable "Patient Information" and the degree of dependence between them. The number of cases that differ from 647 in the analyses performed are missing values (the individual has not answered any question that has been asked).

The method we have followed to apply artificial neural networks to the study of the classification of the categories ("Yes" and "Not") of the variable "Patient Information" has been to set a constant seed (SPSS 26 program) and a partition variable to assign the training, test and reserve groups, in order to replicate the study. The classification/prediction of this variable by means of the artificial neural network, perceptron, offers us a low classification/ prediction of the "Not" category. The analysis of the data will be done with the IBM SPSS 26 program [24].

Results

Statistical Analysis

Before starting the actual analyses, we will perform descriptive and exploratory analysis (Tables 1 and 2) of data that will help us understand some of the results obtained later.

Table 1: Case Processing Summary.

		Patient Information		%	Mean (years)	Minimum (years)	Maximum (years)
		Yes	Not				
Sex	Man	246	19	42, 6	53,05	4	94
	Woman	304	53	57,4	62,48	10	95

Of the patients who answered the questionnaire, 42.6% were men and 57.4% were women. The mean age is 58.48 years with a standard deviation of 18.77 years, which represents a relatively high coefficient of variation of 32%.

Doing an analysis by age groups, we have:

Table 2: Case Processing Summary.

		Patient Information		Percentage "Yes" (%)	Percentage "Not" (%)
		Yes	Not		
Age	0-18	20	1	95,24	4,76
	19-28	22	5	81,48	18,52
	29-38	37	2	94,87	5,13
	39-48	71	10	87,65	12,35
	49-58	101	14	87,83	12,17
	59-68	103	20	83,74	16,26
	69-78	114	7	94,21	5,79
	79+	74	11	87,06	12,94

Table 2 shows that the response to the "Yes" category within the "Patient Information" variable exceeds 81% in all age groups and 4.5% for "Not".

An exploratory analysis of data from the variable "Age" to the variable "Sex" and "Patient Information" provides the following information:

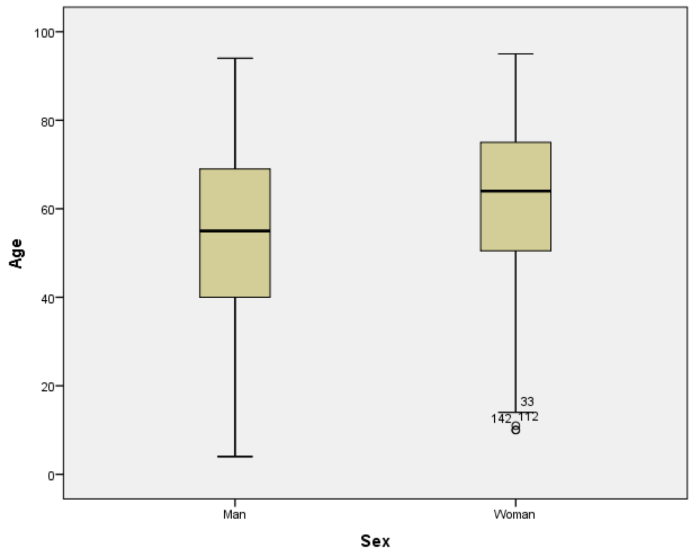

Figure 1: Box-Plot chart.

The box diagram (Box-Plot) collects, in a visual way, the distribution of the variable "Age" according to the category. For the variable "Sex" (Figure 1) the category "Man" has a mean of 53.05 years with a median of 55 years. This category does not have strange values. The "Woman" category has a mean age of 62.48 years and a median age of 64 years with anomalous values of 33 (11 years), 112 (10 years) and 142 (10 years). The interquartile range is 29 years for the "Man" category and 25 for the "Woman" category.

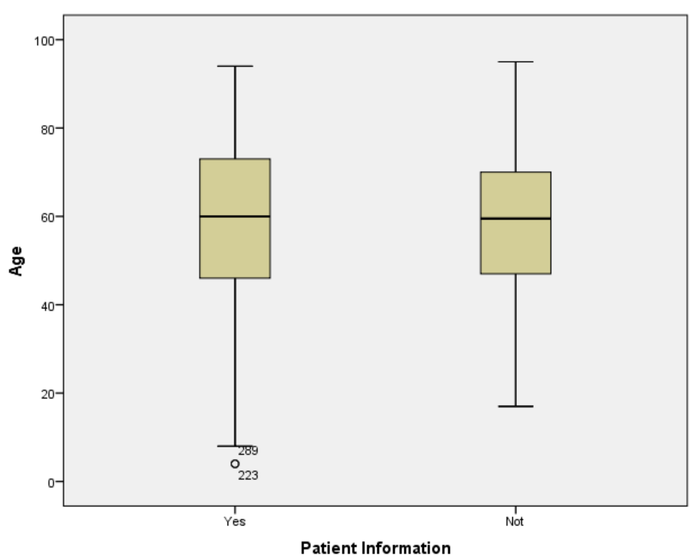

Figure 2: Box-Plot chart.

For the variable "Patient Information" (Figure 2), the "Yes" category has a mean of 58.41 years, with a mean of 60 years, with anomalous values of 223 (4 years) and 289 (4 years). The "Not" category has a mean age of 58.44 years and a median age of 59.50 years, with no anomalous values. The interquartile range is 27 years for the "Yes" category and 23 years for the "Not" category.

A statistical study has been carried out on the independence of variables in relation to the variable "Patient Information", in order to use artificial neural networks as a classifier (predictor) of the categories "Yes" and "Not" that make up this variable, we have (Table 3).

Table 3: Crosstabs (Variable x Patient Information).

Variable / Category		Patient Information		(Phi/ Cramer's/ Contingency Coefficient) Approx. Sig. (Lower value)
		Yes	Not	
Sex	Man	246	19	0,003
	Woman	304	53	
Risk information	Yes	546	71	0,025
	Not	12	5	
Person to be informed	Patient	276	25	0,020
	Family	14	3	
	Both sides	269	49	
Information and fear	Yes	227	7	0,000
	Not	331	69	
Better non-Information	Yes	157	3	0,000
	Not	399	74	
Why do you think you're being informed?	The law obliges them	324	14	0,000
	Prevent the patient and Family Members	90	23	
	Information is a patient's right	145	37	
Enough time to explain	Yes	441	27	0,000
	Not	116	49	
Who informed	Traumatologist who diagnosed	487	48	0,001
	One of the traumatologists who intervened	67	19	
	The nurse of the plant	2	1	
How to give the information	Oral	235	53	0
	Written	16	5	
	Oral and written	307	14	
Understood the explanations	Yes	547	66	0,002
	Not	8	5	
He asked for clarification	Yes	423	41	0,002
	Not	131	28	
They clarified the doubts	Yes	445	55	0,002
	Not	25	10	
How they explained the risks	Generically	410	34	0,000
	With little detail	48	16	
	With a lot of detail	96	17	
Qualification information	Enough	515	49	0,000
	Insufficient	42	22	
The information enabled him to consent	Yes	548	67	0,000
	Not	6	7	
I would prefer the information to be given to a family member	Yes	107	9	0,124 (*)
	Not	446	66	

Who values more of the information?	Quality	271	26	0,124 (*)
	The quantity	7	2	
	Both	276	42	
How you would like informed consent to be in case of a new intervention?	Equal	464	42	0,000
	That they did not inform me	2	1	
	I would like more information	89	30	
Have you made the decision alone and freely?	Yes	508	67	0,032
	No, I have consulted with my family	41	4	
	No, I can't say who took it.	4	3	
He has been influenced by his family?	Yes	27	4	0,843 (*)
	Not	527	70	
You have signed a document?	Yes	471	59	0,569 (*)
	Not	79	12	
Considers the consent document important?	Yes	478	55	0,027
	No, I do not consider it necessary	42	9	
	No, it is pure procedure	31	9	

Tables 3 reference the crossings of variables (Variable x Patient Information) in which there is no dependency with an asterisk (*). For the rest of the variables (related variables) the approximate significance (Lower value) for the coefficients (Phi, Cramer's V and Contingency Coefficient) is between 0.000 and 0.032.

Taking "Patient Information" as a dependent variable and the independent "Age", the *eta* coefficient takes a value of 0.415, which represents a degree of dependence close to the mean.

In a study on the difference in mean age generated by the variables that have two categories (Table 4), we have:

Table 4: t-Student (Age x Variable).

Variable	t (sig.)
Sex	0,000 (*)
Patient Information	0,989
Risk information	0,454
Information and fear	0,054
Better non-Information	0,360
Enough time to explain	0,956
Understood the explanations	0,081
He asked for clarification	0,822
They clarified the doubts	0,419
Qualification information	0,618
The information enabled him to consent	0,605
I would prefer the information to be given to a family member	0,001 (*)
He has been influenced by his family?	0,589
You have signed a document?	0,134

In Table 4 we can see (*) that the variables "Sex" and "I would prefer the information to be given to a family member" are the ones that present significant differences in terms of the difference in their means for a significance level of 5%, that is, the mean age of the two categories that make up the variable are different.

Table 5: ANOVA (Age x Variable).

Variable	F (sig.)
Person to be informed	0,001
Why do you think you're being informed?	0,088
Who informed	0,768
How to give the information	0,931
How they explained the risks	0,122
Who values more of the information?	0,155
How you would like informed consent to be in case of a new intervention?	0,299
Have you made the decision alone and freely?	0,063
Considers the consent document important?	0,377

In Table 5 we can see (*) that the variable "Person to be informed" is the only one that presents significant differences in terms of the difference in its means for a significance level of 5%, that is, the mean age of the categories (more than two) that make up this variable is different.

Analysis of the Variable "Patient Information" Using an Artificial Neural Network

The application of artificial neural networks (NN's) in the field of medicine in all its areas is increasing. Its implementation as another tool of artificial intelligence favors its growth [25-31].

Artificial Neural Network Modeling

The multilayer perceptron is composed of an input layer, an output layer and one or more hidden layers; although it has been shown that, for most problems, a single layer will suffice. In Figure 1, we can observe a typical perceptron formed by an input layer, a hidden layer and an output layer (N-H-M).

The inputs to the network are the variables: x_1, x_2, x_3, ..., x_N (independent variables), the wji weights (importance of the connections between the input layer-hidden layer neurons) and wkj (importance of the connections between neurons of the hidden layer-output layer) and the output variables: y_1, y_2, y_3, ..., y_M (dependent variables). In our case, we will only have a qualitative dependent variable (psychiatric disorder with two levels. When an input pattern p $X^p = (x_1^p, ..., x_N^p, ..., x_N^p)$ is presented, it is transmitted through the w_{ji} weights from the input layer to the hidden layer. The neurons in this intermediate layer transform the received signals by applying an activation function, thus providing an output value. This is transmitted through the w_{kj} weights to the output layer, where, applying the same operation as in the previous case, the neurons of this latter layer provide the output of the network. This process can be explained mathematically as follows: The total or net input received by a hidden neuron j is the

$$net_j^p = \sum_{i=1}^{N} w_{ji}(t)\, x_i^p(t) + \theta_j$$

where θ_j is the threshold of the neuron that is considered as a weight associated with a fictitious neuron.

The Hidden Neuron Output Value j, y_j^p, is obtained by applying a function f(.) about your net input: $y_j^p = f(net_j^p)$.

Similarly, the net input received by an output neuron k, is:

$$net_k^p = \sum_{j=1}^{H} w_{kj}(t)\, y_j^p(t) + \theta_k$$

Finally, the output value of the neuron k, y_k^p, is $net_k^p = f(net_k^p)$.

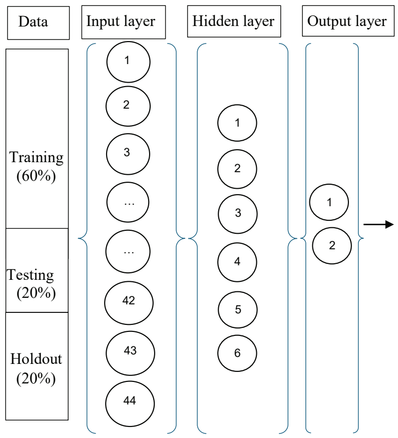

Figure 3: Multilayer Perceptron (44-6-2).

Table 6: Network Information.

Input Layer	Factors	1	Sex
		2	Risk information
		3	Person to be informed
		4	Information and fear
		5	Better non-information
		6	Why you think you're being informed
		7	Enough time to explain
		8	Who Informed
		9	How to give the information
		10	Understood the explanations
		11	He asked for clarification
		12	They clarified the doubts
		13	How they explained the risks
		14	Qualification information
		15	The information enabled him to consent
		16	How you would like informed consent to be in case of a new intervention?
		17	Have you made the decision alone and freely?
		18	Considers the consent document important?
	Number of Units[a]	44	
Hidden Layer(s)	Number of Hidden Layers	1	
	Number of Units in Hidden Layer 1[a]	6	
	Activation Function	Hyperbolic tangent	
Output Layer	Dependent Variables	1	Patient Information
	Number of Units	2	
	Activation Function	Softmax	
	Error Function	Cross-entropy	

[a]Excluding the bias unit

In this type of architecture, the connections between neurons are always forward, that is, they go from the neurons of a certain layer to those of the next one; there are no lateral connections, that is, between neurons belonging to the same layer, or backward connections, which go from one layer to the previous. Therefore, information is always transmitted from the input layer to the output layer.

The notation we will use will be to consider w_{ji} as the connection weight between the input neuron i and the hidden j, and w_{kj} as the connection weight between the hidden neuron j and the output k.

For the analysis of the data we will create a partition variable: training, test and reservation samples. The training sample comprises the data records used to train the neural network; a certain percentage of cases in the data set must be assigned to the mentioned above sample in order to obtain a model. The test sample (validation) is an independent set of data records used to track errors during training, in order to avoid an excess of it. It is highly recommended to create a training sample. Network training will generally be more efficient if the test sample is smaller than the training sample. The reserve sample (test) is another independent set of data records used to evaluate the final neural network; the error of the reserve sample offers an estimate of the predictive capacity of the model, because reserved cases are not used to create such a model. For example, specify 6, 2 and 2, as relative numbers of the training, test and reservation (holdout) samples, it is equivalent to list 60%, 20% and 20%. In our case we have created a partition variable that includes these percentages.

The input variables to the artificial neural network (perceptron) are those that are related to the variable under study: "Patient Information". This analysis is carried out in three phases. In all of them, "Age" is taken as a covariant variable. The structure of the most efficient artificial neural network found in the classification of the categories of the "Patient Information" variable ("Yes" and "Not" categories) is the binomial Hidden layer-Output layer: Hyperbolic tangent-Softmax (Dependent variable: "Patient Information"; Partition: Training 60%, Testing 20% and Holdout 20%). The result we take is the percentage of classification for the "Yes" and "Not" category in the Holdout (Percent Correct) phase.

Table 7: Classification.

Sample	Observed	Predicted (Phase I: 10 variables)		
		Yes	Not	Percent Correct
Holdout	Yes	82	1	98,8%
	Not	11	1	8,3%
		Predicted (Phase II: 8 variables)		
Holdout	Yes	95	4	96,0%
	Not	11	1	8,3%
		Predicted (Phase III: 18 variables)		
Holdout	Yes	78	2	97,5%
	Not	10	2	16,7%
Dependent Variable: Patient Information				

Phase I

Only independent variables are introduced into the model that have 2 categories (total 11 = 10 factors (variables) + 1 covariant variable (Age)). The result obtained for the "Yes" category is 98.8% and 8.3% for the "Not" category. The difference between the classification of the "Yes" and "Not" categories is 90.5%.

Phase II

Only independent variables are introduced into the model that have more than 2 categories (total 9=8 factors (variables) + 1 covariant variable (Age)). The result obtained for the "Yes" category is 96.0% and 8.3% for the "Not" category. The difference between the classification of the "Yes" and "Not" categories is 87.7%.

Phase III

All independent variables are introduced into the model (Table 6, total 19 = 18 factors (variables) + 1 covariant variable (Age)). The result obtained for the "Yes" category is 97.5% and 16.7% for the "Not" category. The difference between the classification of the "Yes" and "Not" categories is 80.8%.

In all phases of the study, applying the artificial neural network, a low percentage of classification for the "Not" category is observed [10,11]. The difference between the classification of the "Yes" and "Not" categories decreases in phases: I (90.5%), II (87.7%) and III (80.8%) due to the number of categories included in each phase.

In all phases of the study, a large difference is observed between the classification of the "Yes" and "Not" categories, above 80%. This is largely due to the few data we have in the sample for the "Not" category. The average data for the "Not" category is 22.37 data, i.e. "Holdout" corresponds to 22.37 · 20%=4.47 data.

Conclusions

The information process, in order to obtain informed consent, has an essentially particular character for each patient, it must be away from any situation of overcrowding, bureaucratization and dehumanization and must be based on their self-determination and freedom.

Among the main conflicts that arise in the process of obtaining Informed Consent are issues related to the ownership of the right to clinical information, the ability of patients to understand, information to people linked to the patient, the refusal of treatment and the situation of minor patients. Most patients are aware of the existence of a legal rule that obliges the physician to inform in order to obtain consent. Patients show total awareness of the right they have to be informed, evidence the desire to know, affirm their right to their family and most deny that the information provided by the doctor has caused them a state of fear or anxiety.

In all phases of the study, applying the artificial neural network, a low percentage of classification for the "Not" category is observed due to the low number of cases for this category and the fact that only one covariant variable, "Age", has been used. Therefore, the artificial neural network (perceptron) is not a good classifier of the "Not" category and therefore for the prediction (classification) of the variable "Patient Information".

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