1	Translation and cross-cultural adaptation to Portuguese of The Patient-
2	And Nutrition-Derived Outcome Risk Assessment Score (PANDORA)
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#### 2

### 21 Abstract

22

23 Introduction: Hospital malnutrition presents alarming rates and is characterized as an 24 independent risk factor for mortality. Hospital mortality has been studied as an important 25 indicator of the quality of care. In this sense, the Patient- And Nutrition-Derived Outcome 26 Risk Assessment Score (PANDORA) was created, seeking to associate the nutritional 27 status and in-patients' illness data with the risk of death within 30 days. The study aimed 28 to perform the translation, cross-cultural adaptation to Portuguese and application of an 29 instrument of identification of mortality risk in the hospital setting. Methods: A cross-30 sectional study was carried out in a university hospital in the city of Goiania-GO, Brazil, 31 in 2018. A translation and adaptation of the PANDORA instrument was carried out and 32 it was applied to hospitalized patients to evaluate their power to predict mortality. 33 **Results**: Fifty-four 54 patients were included in the study, most of them female and 33% 34 elderly. More than 16% of the sample presented low weight, which was positively 35 associated with the occurrence of death. The prevalence of cancer was almost 80% and 36 all patients who died had cancer. In the adjusted logistic regression analysis, it was 37 verified that there was no association between the PANDORA score and death in 38 hospitalized patients, however, there was a trend of association of sex and body mass 39 index with death in these patients. Conclusions: In this study, the PANDORA score was 40 not able to predict death in the patients in our sample, but found significant association 41 of low weight at admission with mortality. Further studies are needed for the validation 42 of PANDORA in Portuguese.

43

44 Keywords: Malnutrition, hospital mortality, BMI.

#### 3

# 46 Introduction

47

48 Hospital malnutrition has alarming rates despite therapeutic advances, especially 49 in emerging and industrialized countries. It affects almost 50% of adult patients in Latin 50 American countries, including Brazil. About 40% of in-patients are affected by this 51 condition, which represents an independent risk factor for mortality, besides favoring complications during hospitalization [1,2]. The influence of nutritional status on patient 52 53 prognosis has been reported in the literature some time ago. Correia and Waitzberg (2003) 54 found a 12.4% mortality rate in malnourished patients, three times higher than those considered well-nourished in the study (4.7%), showing that malnutrition is an 55 56 independent risk factor for the increase in hospital mortality [3].

According to Tsaousi et al. (2014), inadequate feeding can increase up to eight times the risk of hospital mortality, in addition to prolonged hospital stay [4]. This condition is often neglected and presents a high risk of developing other complications, such as surgical and infectious, pressure lesions, increase in length of hospitalization and depletion of the immune system. Its early identification is important to establish the most appropriate nutritional management aiming at better outcomes in these patients [5].

Hospital mortality has been identified for many years as an important indicator of the quality of care provided and has been extensively studied through the application of predictive instruments. One of the first predictive models of death within 30 days of hospital stay was for elderly patients with acute myocardial infarction [6]. These predictive models have been extensively used in emergencies and specific acute situations such as cerebral vascular accident (CVA), acute coronary syndrome (ACS), heart failure (HF), among others, in order to evaluate the quality of care provided [7].

4

In this sense, Hiesmayr et al. (2015) developed a simple punctuation system to
predict mortality in 30 days of hospitalized patients, with scores based on nutrition and
baseline disease. The instrument was named *The Patient- And Nutrition-Derived Outcome Risk Assessment Score* (PANDORA), and seeks to associate nutritional status
and in-patient disease data with the risk of death within 30 days [2].

From the above, evaluating the risk of hospital death related to nutritional status through a standardized questionnaire is important to assess the effectiveness of services provided in the hospital environment, and may contribute to the establishment of more effective therapeutic plans. Thus, this study aimed to perform the translation, crosscultural adaptation to Portuguese and application of a risk identification instrument for mortality in the hospital setting.

81

## 82 Methods

#### 83 Study design

A cross-sectional study was developed in a tertiary university hospital, throughthe application of the translated and adapted questionnaire.

86

## 87 **Population**

The study sample consisted of adult patients hospitalized with any pathologies.
Patients older than 18 years, hospitalized in the Medical, Surgical, Tropical or Emergency
Clinics were included in the study. Patients under 18 years of age, in intensive care and
pregnant patients were excluded.

#### 5

# 93 Ethical aspects

94 The study was submitted to the HC-UFG / EBSERH Research Ethics Committee,
95 approved under No. 2,674,012. All participants were informed about the content of the
96 study and the risks involved, by means of a signed Free and Informed Consent Form.
97

## 98 Procedures for cross-cultural translation and adaptation

#### 99 adopted in the study

The methodology for translation and cross-cultural adaptation of the questionnaire
adopted in the study was based on the procedures suggested by Beaton et al. [8], American
Educational Research Association, American Psychological Association and National
Council on Measurement in Education [9] and reviewed by Muñiz, Elosua and
Hambleton [10], according to Fig. 1.

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Fig 1. Methodological procedures used in the translation and cross-cultural adaptation ofPANDORA into Portuguese

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In order to perform the translation and adaptation, the authors of the original instrument gave permission (Fig. 2) for its use, via e-mail. In addition, a committee was formed by the authors of the new version of PANDORA, to discuss concepts adjacent to the adapted test, considering the particularities of the target population. All translators in the study were unaware of the test to be adapted.

114

115 Fig. 2. Original PANDORA Questionnaire

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117	The applicability of the synthesis in Portuguese (2nd stage) was performed by
118	means of paraphrase, in which the interviewer asks the question and asks the respondent
119	to repeat it immediately. The synthesis in Portuguese was sent for retranslation, which
120	was then compared with the original one to validate its Portuguese version.

121

#### 122 Data collection

Data collection took place from June to December 2018 and was carried out by
previously trained nutritionists, using the instrument obtained from the final synthesis of
PANDORA.

PANDORA is composed of 7 items related to the general evaluation with
questions related to age, body mass index (BMI), physical activity level, hospitalizations,
in-patient group, disease, hydration, and dietary assessment (amount of food ingested on
the day of collection).

Each item quoted above generated a final score that was used to calculate the probability of death. The outcome (death or non-death) was followed up by searching the medical files of the hospital within 30 days of hospitalization.

133

#### 134 Statistical analysis

The collected data were stored in spreadsheets. A descriptive statistical analysis was performed, where the continuous data were presented in mean and average standard deviation. The normality of the data was tested by the Shapiro-Wilk test. In the presence of normality, an unpaired t-Student test was used to compare means. In the absence of normality, the U-Mann Whitney test was adopted. The relationship between the PANDORA score and hospital mortality at 30 days was assessed by the Logit formula

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141 (Logit = -6.72 + 0.1058 x PANDORA SCORE). From this result, the probability of death 142 was calculated ( $e^{logit} / 1 + e^{logit}$ ).

Data on categorical variables were presented in absolute (n) and relative (%) values. Fisher's exact test was performed to compare proportions between groups of categorical variables.

Logistic regression analysis (gross and adjusted) was performed using a death
outcome to verify the association and the magnitude with the PANDORA score. From
this analysis, the Odds ratio and its respective confidence interval were estimated.

Finally, a ROC curve analysis was performed to evaluate the predictive power of the scoreon the outcome (death versus non-death) and estimated the area under the curve and its

151 confidence interval.

152 The level of significance used for all tests was 5%. STATA® software version153 12.0 was used.

154

## 155 **Results**

The PANDORA questionnaire has been translated and adapted into Portuguese.
No operational difficulties were observed during the paraphrase and retranslation test,
allowing a reliable final Portuguese version (Fig. 3).

159

160 Fig. 3. Portuguese version of the PANDORA questionnaire

161

The study included 54 patients with a mean age of 50.63 (sd = 16.81), of which more than half were male and 33% were elderly (> 60 years). More than 16% of the patients presented low weight, that is,  $BMI < 18.5 \text{ kg} / \text{m}^2$  for adults or  $< 22 \text{ kg} / \text{m}^2$  for the elderly, which was associated with death in the evaluated patients (p = 0.008). Among

8

166	these low-weight patients, 12.5% reported that they did not eat anything on the day of
167	data collection, 37.5% were fasting, 37.5% were 100% food acceptance, and 12.5% ate a
168	quarter of what was offered on the day.

169 Considering the entire study population, the following data regarding food were 170 observed: 28.8% of the patients ate half of what was offered; 6.6% did not eat anything;

- 171 12.9% were fasted; and 8.8% ate a quarter of the offer.
- 172 The mean PANDORA score was higher than 32 points in the general sample,

173 however, with no significant difference in means in patients who died or not during

hospitalization (p > 0.05). The prevalence of death in the study population was 9.2%.

- 175 When evaluating the probability of death among patients, the mean was greater than 5%
- in the total sample (Table 1).
- 177

Table 1. Characterization of the study population and its relation with death / hospital
 discharge

Total	Death	No death	p-value
n=54	n=5(9.26)	n=49(90.74)	
50.63±16.81	48.6±9.29	50.84±17.44	0.780*
28(51.85)	1(20.00)	27(55.10)	0.184**
26(48.15)	4(80.00)	22(44.90)	
22.57±4.80	18.01±3.44	23.03±4.70	0.024*
9(16.67)	4(80.00)	5(10.20)	0.008**
32(59.26)	1(20.00)	31(63.27)	
10(20.41)	0	10(20.41)	
3(6.12)	0	3(6.12)	
32.13±9.66	37.20±11.75	31.61±9.41	0.221*
	n=54 50.63±16.81 28(51.85) 26(48.15) 22.57±4.80 9(16.67) 32(59.26) 10(20.41) 3(6.12)	n=54 n=5(9.26) 50.63±16.81 48.6±9.29 28(51.85) 1(20.00) 26(48.15) 4(80.00) 22.57±4.80 18.01±3.44 9(16.67) 4(80.00) 32(59.26) 1(20.00) 10(20.41) 0 3(6.12) 0	n=54n=5(9.26)n=49(90.74) $50.63\pm16.81$ $48.6\pm9.29$ $50.84\pm17.44$ $28(51.85)$ $1(20.00)$ $27(55.10)$ $26(48.15)$ $4(80.00)$ $22(44.90)$ $22.57\pm4.80$ $18.01\pm3.44$ $23.03\pm4.70$ $9(16.67)$ $4(80.00)$ $5(10.20)$ $32(59.26)$ $1(20.00)$ $31(63.27)$ $10(20.41)$ $0$ $10(20.41)$ $3(6.12)$ $0$ $3(6.12)$

9

Probability of death (%)	5.42±6.33	9.00±9.56	5.06±5.93	0.188‡
Classification of nutrition				0.144**
risk				
With risk	33(61.11)	5(100.00)	28(57.14)	
No risk	21(38.86)	0	21(42.86)	

Values presented in absolute values (relative values) or means ± standard deviation of the mean. p-value obtained by unpaired Student t-test or Fisher's exact test or Mann-Whitney test with 5% level of significance.

- 183
- 184

In the PANDORA questionnaire, only cancer disease is scored, with the other diseases classified as zero. It was verified that 83.3% (n = 45) of the studied population were diagnosed with some type of cancer, the most prevalent disease (79.62%), followed by Chronic Renal Disease, with a prevalence of 5.5%. Among the cancer patients, 17.7% had low weight, 100% presented nutritional risk. Of the ones who died, 100% were cancer patients.

191 In the adjusted logistic regression analysis, it was verified that there was no 192 association between the PANDORA score and death in hospitalized patients; however, 193 there was a trend of association of sex and BMI with death in these patients (Table 2). It 194 was not possible to perform the analyzes with the probability of estimated death from 195 PANDORA, due to the small sample size.

When verifying the predictive power of the PANDORA score on death in
hospitalized patients using the ROC curve (Fig. 4), it was possible to verify an area under
the curve of 0.66 considered adequate; however, when evaluating its range of confidence,
we found that its lower limit was below 0.5, making the PANDORA score inadequate to
predict death in patients in our sample.

201

Fig 4. ROC curve

	Gross		Mod	lel 1	Model 2		Model 3	
	OR (IC95%)	p-value	OR (IC95%)	p-value	OR (IC95%)	p-value	OR (IC95%)	p-value
PANDORA score	1.06(0.96-1.16)	0.224	1.10(0.99-1.23)	0.080	1.09(0.98-1.22)	0.119	0.97(0.83-1.12)	0.667
Age	0.99(0.94-1.05)	0.775	0.95(0.88-1.03)	0.219	0.95(0.87-1.03)	0.206	0.98(0.90-1.08)	0.754
Sex								
Male	1.00				1.00		1.00	
Female	4.91(0.51-47.16)	0.168			4.78(0.45-51.17)	0.196	28.97(0.98-851.81)	0.051
BMI (kg/m²)	0.71(0.52-0.98)	0.037					0.56(0.31-1.00)	0.051

203 Table 2. Association among PANDORA score, demographic variables and nutritional status of the study population

204 Logistic regression with Odds Ratio (OR) and 95% confidence interval (95% CI). Models: 1- Age-adjusted; 2 - Adjusted for age and sex; 3-Adjusted for age, sex, and BMI.

#### 11

# 205 **Discussion**

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207	PANDORA has been recently developed and validated in a large multinational in-
208	patient study, which included 2,480 patient care units in 32 countries. Its main advantage
209	is the simplicity and practicality in the application to predict hospital mortality in 30 days.
210	In addition, it is based on nutritional markers, and may be useful for stratification
211	of nutritional risk levels [11]. Another advantage found in the present study was the ease
212	of translation and cross-cultural adaptation, since it is an instrument with direct questions
213	and easy to understand.
214	The original PANDORA score had a high performance in predicting mortality in
215	hospitalized patients having three main facilitator points: it is based on data available at
216	any time of hospitalization; it is not necessary to spend much additional time collecting
217	data, since the items are part of the patient's history; and the model is public, international
218	and independent of national codification conventions [2].
219	The association between low weight (BMI $\leq 18.5 \text{ kg} / \text{m}^2$ ) and death in this study
220	corroborates other studies found in the literature. Hu et al. (2017) evaluated the
221	relationship between sarcopenic malnutrition syndrome and mortality in hospitalized
222	elderly. It was observed that individuals with BMI between 18.6 kg / $m^2$ and 19.5 kg / $m^2$
223	were twice as likely to die compared with individuals whose BMI was greater than 22 kg
224	/ $m^2$ [12]. Another study with elderly found similar results, and those with a mean BMI
225	of 21 kg / m <sup>2</sup> had a double risk of mortality [13].
226	A study conducted in the state of São Paulo, Brazil, observed that the presence of
227	low weight was independently associated with higher mortality rates in patients who

**228** underwent coronary intervention [14]. Other authors performed a prospective nutritional

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229 screening and verified a strong association between mortality and risk of malnutrition, 230 against our findings, in which 100% of the patients who died had nutritional risk [15]. 231 In order to analyze the association between BMI and mortality in critically ill 232 patients, a prospective multicenter study in France found that individuals with BMI <18.5 233  $kg/m^2$  had an independent association with higher mortality. The authors also suggested 234 that BMI may be a useful component in the development of future predictors of mortality. 235 [16]. Tremblay and Bandi (2003) found similar results, with low weight being associated 236 with a higher risk of mortality and worsening of functional status, delaying hospital 237 discharge [17].

238 Hospital malnutrition should be evaluated very carefully since it is a public health 239 problem, both in underdeveloped and in developing countries. The high prevalence of 240 this problem persists over the years and presents worrying data [5]. In 1998 a study 241 promoted by the Brazilian Society of Parenteral and Enteral Nutrition (BRASPEN) 242 evaluated more than 4,000 hospitalized patients nationwide and found a prevalence of 243 48.1% of malnutrition [3]. In a recent systematic review, this high prevalence of 244 malnutrition was confirmed [18]. All these findings reinforce the results found in our 245 study, showing the importance of nutritional status in the outcome of hospital admissions 246 [18].

Cancer is among the most common non-communicable diseases and injuries that cause death worldwide [19] and was the most prevalent disease in this study. According to the National Cancer Institute, the estimated incidence of the disease in 2018 was more than 300,000 new cases in Brazil [20]. Cancer patients are 1.7 times more likely to present malnutrition or nutritional risk than other hospitalized patients, both for physiological effects and for side effects to treatment [21]. A study of more than 2,000 cancer patients

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found that 19.7% of the individuals presented malnutrition, similar to our findings, where
17.7% of the cancer patients were underweight [22].

In this context, malnutrition in individuals with cancer is favored by low food intake, which was highlighted in this study, since most accepted only 50% of what was offered on the day. Ferreira, Guimarães and Marcandenti (2013) evaluated the acceptance of hospital diets of cancer patients admitted to a tertiary hospital and observed a high rate of rest ingestion among cancer patients and especially among the malnourished ones. The main associated factors were inappetence, xerostomia, constipation, dysgeusia, nausea related to smells and early satiety [23].

Another study based on Nutrition Day data collected between 2012 and 2015 evaluated the determinants of reduced food intake in colorectal cancer patients and concluded that being women, with advanced cancer, hospitalization longer than four days, and weight loss were the main determinants for the reduction of dietary intake of these patients. That study highlighted the need for the early identification of patients with nutritional risk for effective therapeutic measures [24].

268 Our study found no positive association between the PANDORA score and death, 269 which makes it inadequate to predict death in the sample considered. This result can be 270 justified by the limiting factor of the small sample size. The PANDORA score was 271 already used in other studies and presented positive results as a tool to predict hospital 272 death. Nakayama (2018), in an analytical cohort, evaluated whether the PANDORA score 273 was associated with the mortality of patients in Intensive Care Units (ICU) compared with 274 APACHE II. The authors concluded that the PANDORA score was strongly associated 275 with mortality and that it can be compared to APACHE II for predicting mortality in 276 critically ill patients [11].

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Therefore, in the present study, the PANDORA score was not able to predict death in the patients in our sample, but found a significant association of low weight at admission with mortality.

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281

# 282 **Conclusions**

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The PANDORA questionnaire was translated and adapted to Portuguese without any operational difficulties, allowing a final version that is reliable to the original one. It was not possible to predict death in patients in our sample using the PANDORA score. However, low weight had significant association with mortality, and may be an independent factor for predicting death.

In addition, a high prevalence of cancer in the studied population and association of the disease with the occurrence of low weight were observed, which highlights the need for studies that allow early identification of the nutritional risk factors in these patients, in order to obtain effective therapeutic plans.

Although some studies have shown positive results in relation to the PANDORA
instrument, we suggest further studies for the Portuguese validation of PANDORA in
hospitalized patients.

#### 15

# 297 **References**

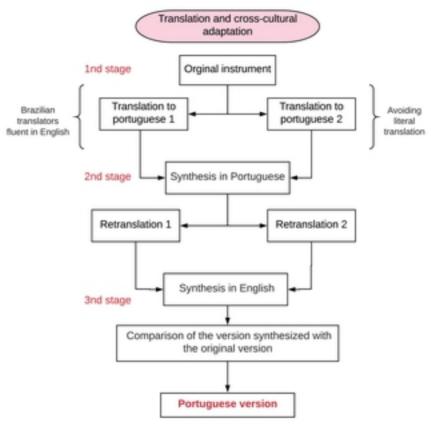
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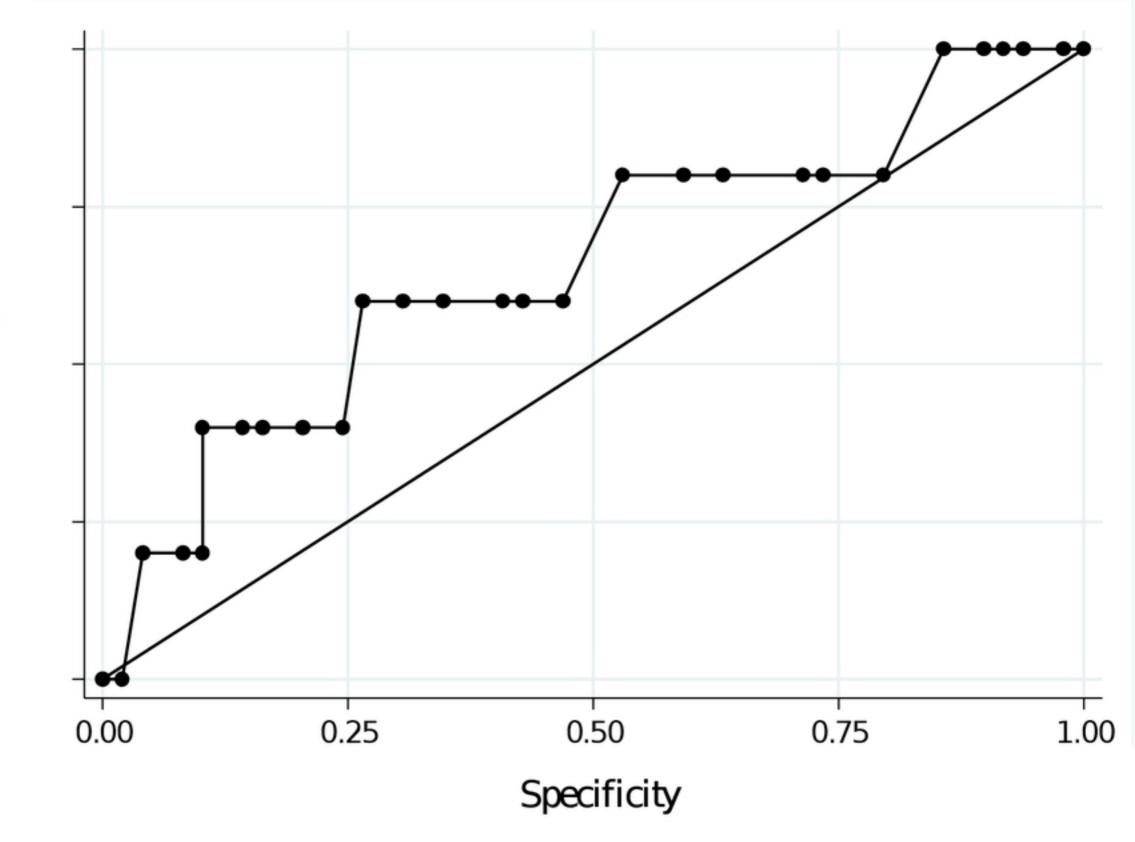
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Variable	Groups	Score
Age	40	0
	40-50	6
	50-60	8
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	70–80	11
	80-90	14
	>=90	17
Body Mass Index (BMI)	<18.5	9
	18.5-25	6
	25-30	2
	30-35	0
	35-40	0
	>40	3
Canyouwalk?	Walk without assistance	0
	Only with assistance	6
	I stay in bed	11
What did you eat today?	All	0
	Half	3
	Quarter	9
	Nothing, Allowed	12
	Nothing, Notallowed	7
Main patient group admitted Internal	Internal	7
	Surgery	0
	Geriatrics	5
	Neurology	3
	Others	6
DiseasedOrgan	Cancer	9
Fluid status	Dehydrated	7
	Normal	0
	Overload	10
PANDORA score	Sum	

Variável	Grupos	Escore
Idade	40	0
	40-50	6
	50-60	8
	60-70	10
	70-80	11
	80-90	14
	>=90	17
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	18.5-25	6
	25-30	2
	30-35	0
	35-40	0
	>40	3
É capaz de andar?	Ando sem assistência	0
	Ando com assistência	6
	Estou acamado	11
O que comeu hoje?	Tudo	0
	Metade	3
	M etade da metade	9
	Nada. Permitido	12
	Nada. Não permitido	7
Grupo principal de internação do	Clínico	7
paciente	Cirurgia	0
	Geriatria	5
	Neurologia	З
	Outros	6
Doença	Câncer	9
Condição de hidratação	Desidratado	7
	Normal	0
	Excessivo (edema)	10
Pontuação PANDORA	Soma	



Sensibility