

**ORIGINAL ARTICLE** 

# Profile of Patients with Special Needs Assisted at a Brazilian University

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#### Abstract

Objective: To characterize the profile of patients with special needs assisted at a Dentistry School of a Brazilian University. Material and Methods: A retrospective and descriptive study was carried out through the analysis of 329 dental records from individuals with special needs assisted at the Dentistry for Special Needs Patients discipline between 2012 and 2017. Data on gender, age, race, monthly family income, schooling, medical diagnosis of the disabling condition, drug used and type of dental procedures performed were reviewed. Data were analyzed by descriptive and inferential statistics (Shapiro-Wilk and t-student tests) with 5% significance level. Results: There was higher prevalence of females (50.5%) aged 45-54 years (18.7%), low schooling (36.2%) and monthly income of 1 minimum wage (61.9%). Most special needs were chronic systemic diseases (67.2%) and endocrine-metabolic diseases (16.7%). Among patients investigated, 66.3% used anti-hypertensive (38.3%) and anti-inflammatory (20.6%) drugs. Of dental procedures performed, curative procedures were the most prevalent in the majority of patients (90.6%). Conclusion: The profile of most patients with special needs was characterized by females with chronic systemic diseases and mean age of 39.6 years, low schooling and monthly family income of up to 1 minimum wage, whose main reason for the visit was the search for curative dental treatment.

**Keywords:** Disabled Persons; Dental Health Services; Dental Care for Disabled.



### Introduction

The term "patients with special needs" (PSNs) refers to any individual who presents any loss or abnormality of structure and / or simple or complex psychological, physical, organic, social, intellectual, and emotional function, of acute or chronic nature, permanent or temporary, which determines lack of ability to perform essential activities of the daily living, originated or aggravated by the economic or social context in which they live, requiring special and multiprofessional approach [1,2].

Treatment for these patients requires specific care, which involves not only clinical procedures for oral health rehabilitation, but also knowledge in other areas, requiring multidisciplinary approach [3], which includes education and additional health instructions [1]. The demand for the care of this population increases with aging, since the number of chronic diseases and deficiencies increases according to age advancement [4].

It is important to know the patient's medical diagnosis, since approach must be differentiated for each disabling condition group, assessing risks, needs, opportunities and the cost / benefit ratio for treatment. The individual's health also includes the oral condition, which requires dental care for all [5].

The ability to understand and use the appropriate language in each situation is among the challenges faced by professionals working in this area [6]. Differentiated treatment should be dedicated in the management of patients whose general condition is often an aggravating factor for the oral condition, often impairing the introduction of adequate hygiene habits [7]. Factors such as poor brushing, unfavorable socioeconomic conditions, deleterious oral habits, occlusion, cariogenic diet and continuous use of some drugs may influence the onset of dental caries and periodontal disease, which require specific attention [8].

The oral health of these patients is often considered unsatisfactory, deficient or precarious, justified by intellectual and / or motor deficits, inability to correctly perform the procedures necessary for the mechanical removal of plaque associated to the lack of knowledge of correct hygiene techniques by caregivers and the delay in the referral of these patients to dental treatment [7]. Thus, they become more vulnerable to the onset of oral diseases when compared to the general population. This requires the commitment of the family and / or caregivers in the maintenance of oral health and daily care with the intent to improve life expectancies [8].

Individual well-being and general health should be considered in the environmental, behavioral and socio-cultural context, since precarious oral health can have socioeconomic, behavioral and even quality of life effects, negatively affecting self-esteem and self-image [6]. The quantification and qualification of PSNs are essential to characterize care services and offer the student quality learning, always seeking the prevention of problems and probable complications, and above all, creating beneficial habits for life [9].

Considering the scarcity of Brazilian studies describing the profile of PSNs that seek dental treatment in dental school clinics [3,5,8-10], the knowledge of the profile and diagnosis of these





patients are fundamental to minimize the oral problems of this population. Thus, it is of great importance to characterize this group and its main dental needs, so that professionals involved can develop adequate treatment plan, emphasizing the importance, in many cases, of a multidisciplinary team, and establish care protocols, providing Dentistry students a differentiated learning, not only in scientific and technical terms, but also in emotional terms and directed to the needs of this population, preparing them in the future to deal with the physical and emotional well-being of this population.

Thus, the present study aimed to know the clinical, sociodemographic and economic profile of patients assisted at the Dentistry for Special Needs Patients Discipline of a Brazilian university in the last 5 years (2012-2017).

#### **Material and Methods**

Study Design and Sample

In this cross-sectional study, all medical records of PSNs who sought dental care at the PSN Clinic of the School of Dentistry of Federal University of Amazonas (UFAM) from 2012 to 2017 were examined. This discipline was introduced in the pedagogical matrix of the Dentistry Course in 2012, being offered in the 9th period and, as the entry of students is annual, it is only offered in one semester of the year. In the even periods, part of patients (mainly those with chronic systemic diseases) is referred to the Integrated Clinics and to an extension project, which receives patients with difficult behavioral management.

This study included all dental records completely filled out and signed by PSNs or their caregivers.

# Data Collection

Data collection was performed by a single duly trained examiner. The following data were evaluated: gender, age, race, monthly family income, schooling, medical diagnosis of the disabling condition, pharmacological group of continuous use drugs and main reason for seeking dental treatment, recorded in standardized forms.

The medical diagnosis of the disabling condition was classified according to the type of disease and / or the areas compromised by the pathology included in medical reports, according to the International Association for Disability and Oral Health (IADH) [11] in: intelligence deviations, physical defects, congenital defects, behavioral deviations, psychic deviations, sensory and audiocommunication defects, chronic systemic diseases, endocrine-metabolic disorders, social deviations and special physiological conditions.

Dental procedures performed were grouped into 7 categories [8]: 1. Procedures for diagnosis (clinical examination of the oral cavity and radiographic examination); 2. Preventive procedures (oral hygiene and diet instruction, dental prophylaxis, seals of cracks and fissures, topical application of fluoride and chlorhexidine); 3. Periodontal procedures (supra and subgingival





mechanical cleaning, dental polishing, gingivectomy, gingivoplasty); 4. Restorative procedures (aesthetic and functional restorations); 5. Endodontic procedures (direct pulp protection, pulpotomy / pulpectomy of deciduous or permanent tooth, intracanal dressing, filling of coronary chamber and / or root canals, and re-treatment of root canals); 6. Surgical procedures (biopsy, excision of oral soft tissue lesions, extraction of deciduous, permanent or supernumerary teeth, extraction of residual and postoperative root); 7. Prosthetic procedures (confection and installation of fixed prosthesis, partial removable prosthesis and total prosthesis).

The classification of continuous use drugs was adapted from a previous study carried out in a School of Dentistry in Araraquara, Brazil [8].

#### Data Analysis

Data collected from medical records were tabulated in the Microsoft Excel Software, version 2013. Results were analyzed through descriptive statistics (absolute and relative frequencies). The hypothesis of normality was accepted using the Shapiro-Wilk test, mean and standard deviation (SD) were calculated and the t-student parametric test was applied. The software used in data analysis was the Epi Info version 7.2 for Windows and the significance level set in statistical tests was 5%.

## **Ethical Aspects**

This research was approved by the Ethics Research Committee of the Federal University of Amazonas under CAAE 67609717.9.0000.5020, according to requirements of Brazilian Resolution 466/2012.

#### Results

All dental records (N = 351) of the PSN discipline in the years from 2012 to 2017 were evaluated, of which 22 were excluded due to incomplete information, thus totaling 329 medical records. It was observed that, on average, after the initial treatment, 50% of patients returned annually for reevaluations and maintenance of the treatment performed.

Regarding the sociodemographic and economic profile of patients, it was observed that 50.5% were female, 73.9% were brown, 62% were born in Manaus (Brazil), 36.2% had incomplete elementary education, followed by complete high school (21.9%) and 61.9% had monthly family income of one minimum wage (Table 1).

Table 1. Frequency distribution of demographic characteristics of PSNs

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Variables	N	%	
Gender			
Male	163	49.5	
Female	166	50.5	
Schooling			
Illiterate	18	5.5	
Incomplete Elementary School	119	36.2	



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Complete Elementary School	12	3.6
Incomplete High School	48	14.6
Complete High School	72	21.9
Complete Higher Education	18	5.5
Incomplete Higher Education	42	12.7
Race		
White	47	14.3
Black	34	10.3
Brown	243	73.9
Indigenous	5	1.5
Place of Birth		
Manaus	204	62.0
Inner State of Amazonas	54	16.4
Other States	71	21.6
Income		
Up to One Minimum Wage	204	61.9
One to Two Minimum Wages	70	21.4
Two to Three Minimum Wages	24	7.2
Above Three Minimum Wages	31	9.5

Patients' age ranged from 3 to 88 years, with mean age of 39.6 ( $\pm$  20.4). Individuals were grouped into 8 age groups, and the most prevalent age ranged from 45 to 54 years (18.7%), those aged up to 12 years (15%), those aged 25-34 years (15%) and those aged 55-64 years (15%) (Figure 1).

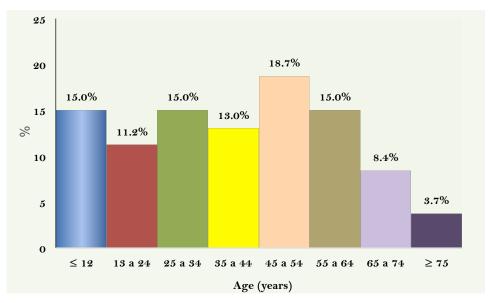


Figure 1. Distribution according to the age of PSNs.

Regarding the reason for seeking treatment in dental reports, 48.6% sought routine dental treatment, 19.7% sought service due to the presence of pain and 18.6% were referred, either for indication or reevaluation (Figure 2), with mean of 3 consultations / patient (61.8%), regardless of conclusion or not of the proposed treatment.





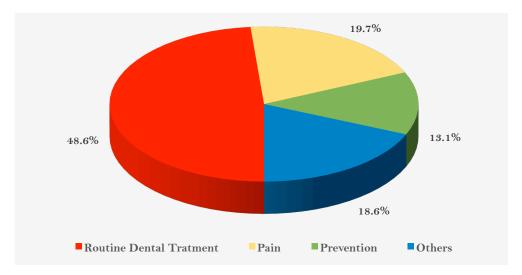


Figure 2. Distribution according to the frequency of the main complaint of PNEs.

Considering the IADH classification, the majority of patients belonged to Group 7, referring to chronic systemic diseases (67.2%), followed by Group VIII in which endocrine-metabolic diseases (16.7%) were included, as shown by Table 2.

Table 2. Frequency of IADH classification.

IADH Classification	N	%
Intelligence Deviations	21	6.4
Physical Defects	43	13.1
Congenital Defects	28	8.5
Behavioral Deviations	28	8.5
Psychic Deviations	9	2.7
Sensory and Audio-Communication Defects	6	1.8
Chronic Systemic Diseases	221	67.2
Endocrine-Metabolic Disorders	55	16.7
Social Deviations	3	0.9

The most prevalent disabling conditions corresponded to the diagnoses of systemic hypertension (35.8%), diabetes mellitus (15.9%), heart disease (11.3%), epilepsy (10.3%), systemic lupus erythematosus - SLE (10.3%), chronic kidney diseases (9.3%), congenital abnormalities (8.4%), among them cleft lip and palate (3.7%) and Down's Syndrome (1.9%), ASD (7.5%), mental deficiency (6.5%) and cerebral palsy (6.5%) (Table 3). It was also observed that of the 329 patients investigated, 200 (60.8%) had only one medical condition and 129 (39.2%) had more than one, simultaneously.

Table 3 Distribution of the sample according to the medical diagnosis

IADH Classification	Condition		Total
			(%)
Intelligence Deviation	Mentally Impaired	6.5	6.5
Physical Defects	Amputation	0.9	13.1
	Limb Defects	5.6	
	Cerebral Palsy	6.5	
Congenital Defects	Moebius Sequence	0.9	8.4
	Mowat Wilson Syndrome	0.9	



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	Down Syndrome	1.9	
	Reye's Syndrome	0.9	
	Cleft Lip and Palate	3.7	
Behavioral Deviations	Autism Spectrum Disorders (ASD)	7.5	9.3
	ADHD	1.9	
Psychic Deviations	Schizophrenia	0.9	2.8
	Depression	0.9	
	Bipolar Disorder	0.9	
Sensory and Audio-Communication Defects	Hearing Impairment	0.9	1.9
•	Deaf-Mute	0.9	
	Hypertension	35.8	
	Heart Murmur	1.9	
	Fallot's Tetralogy	0.9	
	Cardiac Arrhythmia	2.9	
	Acute Myocardial Infarction	2.9	
	Valvopathy	2.7	
Chronic Systemic Diseases	Chronic Kidney Disease	9.3	93.6
•	Anemia	4.7	
	Epilepsy	10.3	
	Neoplasias	6.3	
	Asthma	2.8	
	Systemic Lupus Erythematosus	10.3	
	Rheumatoid Arthritis	2.8	
Endocrine-Metabolic Disorders	Diabetes	15.9	16.8
	Hyperthyroidism	0.9	
Social Deviations	Alcoholist	0.9	0.9

ADHD: Attention Deficit Hyperactivity Disorder

The majority of patients presented continuous drug use (66.3%), with anti-hypertensive, steroidal anti-inflammatory, anticonvulsants and antipsychotic drugs as the most frequently used; it should be noted that a large number (37.4%) used two or more types of drugs (Table 4).

Table 4. Distribution of the sample according to the type of drug used.

Variables	N	%
Use of Drugs		
None	111	33.7
Only One Type	95	28.9
More Than One Type	123	37.4
Type of Drug		
Vasodilator Antihypertensive	55	25.2
Anti-Inflammatory	45	20.6
Other Antihypertensive	32	14.7
Anticonvulsant	30	14.0
Hypoglycemic	24	11.0
Antipsychotic	22	10.1
Diuretic Antihypertensive	16	7.3
Antidepressant	14	6.4
Immunosuppressant	10	4.6
Anticoagulant	4	1.8
Antibiotic	4	1.8
Anxiolytic	4	1.8
Erythropoietin / Alfapoetin	2	0.9
Others	20	18.7





In the five-year period, most dental procedures were curative (90.6%), with periodontal procedures prevailing (30.6%), as well as restorative and surgical procedures (27.5%) (Table 5).

Table 5. Distribution of the procedures performed.

Type of Procedure	N	%
Periodontal	650	30.6
Restorative	583	27.5
Surgical	583	27.5
Preventive	200	9.4
Endodontic	84	4.0
Prosthetic	21	1.0
Total	2121	100.0

There was no significant association between medical diagnosis and the gender of patients treated, unlike age, which showed strong association with some chronic systemic diseases, mental deficiency and present conditions at birth such as syndromes, autism spectrum disorders and cerebral palsy (Table 6). When sociodemographic variables were associated with the main complaint of patients investigated and with types of procedures performed, no statistical significance was observed.

Table 6. Comparison of the mean age in relation to the medical diagnosis.

•		A	ge		
Diagnostic	Posi	tive	Nega	ntive	
	Mean	SD	Mean	SD	p-value*
Cardiovascular Diseases	52.2	16.6	31.1	18.4	< 0.001
Epilepsy	24.1	16.8	41.3	20.1	0.007
Cleft Lip and Palate	15.2	10.7	40.5	20.2	0.014
Hemopathy	41.0	16.7	39.5	20.7	0.874
Limitation of Movements	31.0	21.3	40.1	20.4	0.292
Lupus	37.4	7.6	39.8	21.4	0.707
Nephropathy	43.4	8.6	39.2	21.3	0.536
Malignant Neoplasm	48.8	9.3	39.0	20.8	0.255
Cerebral Palsy	16.4	14.2	41.2	19.9	0.002
Syndrome	9.6	3.8	41.0	19.8	< 0.001
Autism Spectrum Disorders	17.0	8.9	41.4	20.0	< 0.001
Pneumopathy	24.0	20.8	40.0	20.3	0.182
Others	43.2	18.7	38.9	20.7	0.445

SD = Standard Deviation; \*Shapiro-Wilk test and t-student test.

#### Discussion

With the aim of knowing the profile of patients with special needs who sought and received treatment at the Dental Clinic for PSNs of the School of Dentistry of a Brazilian Public Higher Education Institution, information of great relevance on the profile of these patients was verified, thus guiding teaching and research of the Dentistry student, in addition to resulting in valuable information for the improvement of the dental service provided.





There are few studies in literature on the profile of PSNs that seek dental treatment in university dental clinics [3,5,8-10], which makes it difficult to estimate the percentages in each of the variables described.

It was found that, in relation to gender, the percentage of female PSNs was higher in relation to males, disagreeing with other studies published in scientific literature performed in dental specialties centers, university dental clinics and dental outpatient clinics of hospitals and pediatric rehabilitation centers of Feira de Santana (Bahia) [4], São Paulo (São Paulo) [5], Porto Alegre (Rio Grande do Sul) [9], Niterói (Rio de Janeiro) [10], Natal (Rio Grande do Norte) [7,12] and Madrid (Spain) [13]. The greater demand of women for dental treatment seems to be related to their greater concern with general and oral health [3,14,15]. According to data from the 2010 Census conducted by the Brazilian Institute of Geography and Statistics, up to 2010, 26% of the female population (25 million) had some disability, compared to 21% of the male population (19 million).

The concentration of PSNs in the age range between 3 and 80 years in the present study is explained by the fact that care is provided in a discipline that includes children, adolescents, adults and the elderly, unlike many researches carried out in pediatric hospitals [7,11] or pediatric dental clinics of educational institutions [3]. Mean age similar to that found in this study (39.6 years) was found by other authors [9,13], when analyzing the profile of PSNs in university dental clinics of Rio Grande do Sul (Brazil) and Madrid (Spain), respectively. Also, regarding the age group, it was observed that the youngest individuals in this study were those who presented medical conditions from birth. These results may represent shorter life expectancy for individuals with syndromes when compared to normoreactive individuals [5,16]. Individuals with chronic systemic diseases were the oldest in the study population, since these conditions are more representative in the age group over 40 years of age [4,15].

A large part of our sample was born in the capital of the state of Amazonas (62.2%) and was in agreement with findings of another study [3], which evaluated the profile of PSNs treated at the Pediatric Dentistry Clinic of the Federal University of Pará, where 86.2% were also born in Belém, the capital of the state of Pará. Perhaps this fact is due to the difficulty of access of individuals living in the inner state of Amazonas, largely made by waterway, which would justify that only 16.4% of the sample was not born in the state capital.

Regarding monthly family income, 61.9% of patients earned up to 1 minimum wage and 45.3% had low schooling. In similar studies in Northeastern, Southeastern and Southern regions of Brazil [9,10,12], the monthly family income of most of the sample was up to one minimum wage and low level of schooling. The granting of continued care and disease-aid benefits by Social Security to 40.2% of patients investigated due to the impossibility of patients to work considering their physical, emotional or mental limitations, or the caregiver, due to the need for permanent care to patients investigated, may explain the precarious economic conditions found [9].

Pain was reported as one of the reasons for seeking dental treatment by 22.6% of PSNs who received dental treatment at a private higher education institution in São Paulo [5], a percentage



similar to that found in this study (19.7%). This reason is not common only among these patients, but for this population, the caregiver is often who reports this condition, who may underestimate, in some cases, the patient's symptoms. Perhaps the greatest demand for routine dental treatment in our sample (48.6%), similar to a previous study that evaluated dental records of 1455 individuals attended at the Dental Care of Patients with Special Needs Discipline of the School of Dentistry of the Federal University of Rio Grande do Sul from January 2007 to December 2015 [9], may be a reflection of the ongoing work to raise awareness of the importance of oral health maintenance by teachers and students of UFAM through educational lectures to PSNs and their caregivers in the waiting room. It was observed that there is a demand for the implementation of public oral health policies that contemplate the promotion, prevention and improvement of specialized services for PSNs.

The number of appointments for dental treatment of most investigated patients was up to 3 sessions (61.8%), disagreeing with previous study where the majority of patients (63%) attended up to ten appointments for dental treatment and a considerable portion of them (37%) had greater number of sessions [8]. This may have occurred because the patient had little need for treatment, for presenting more complex health conditions, with non-cooperative behavior, making outpatient care unfeasible, being referred to hospital treatment, lack of financial resources for commuting and the cost of prosthetic treatment, or the non-return after medical referral for the request of a medical report or complementary examinations. The need for medical reports, complementary examinations, and patient / caregiver adherence are factors that interfere in the continuity and finalization of dental treatment in university dental clinics [5].

Regarding the classification of medical conditions, according to IADH, in our study, chronic systemic diseases were present in 67.3% of patients, especially cardiovascular diseases [7,12,14,15], LES, epilepsy and chronic kidney disease followed by endocrine-metabolic diseases (16.8%), differing from other studies [4,6,8-10,12], where mental deficiency, cerebral palsy and Down syndrome were the most frequent conditions. The higher demand for dental care by patients in the present study was due to the high prevalence of patients over 44 years of age (45.8%) and also to the existence of the "Getúlio Vargas" University Hospital and "Araújo Lima" Outpatient Clinic, both of UFAM and annexes to the school of dentistry building, the existence of special programs aimed at this population, with a multidisciplinary care, directing them to dental treatment aiming at the adequacy of the oral environment prior to surgeries, consequently improving quality of life.

In the present study, 39.2% of patients presented simultaneously more than one medical condition, being in agreement with a previously published study [14], where of the 832 patients with medical conditions who sought routine dental care in the Department of Oral Medicine and Radiology of the University of Surendera and at the Sri Ganganagar Research Institute (India), only 270 (32.4%) had on average two to five systemic conditions. The presence of comorbidities may be explained by the high prevalence of chronic systemic diseases found in this population, demonstrating the direct or indirect repercussion of the involvement of one organ in the other



systems of the organism. The knowledge by the dentist of the multiple systemic conditions presented by this population is fundamental, since they can interfere in the necessary dental treatment and drug prescription, and a detailed investigation of the patient's history and clinical examination is essential.

The indication of continued drug use is directly related to the treatment of the patient's medical condition. However, there is a strong trend in prescribing these drugs to PSNs [5]. In the present study, 66.3% of patients continuously use one or more types of drug, a result similar to that found in other studies in literature involving the profile of PSNs [7,13,14]. The drugs most frequently prescribed in this study were antihypertensive drugs [15], mainly used by patients with heart disease; steroidal anti-inflammatory drugs, used by systemic lupus erythematosus and chronic kidney disease patients; anticonvulsants, commonly used by epileptic patients and those with cerebral palsy; and antipsychotic drugs, used by those affected by behavioral and psychic deviations. It is important to emphasize that many patients present reduced salivary flow and pH due to the systematic and continuous use of drugs such as those described above, among others. Hyposalivation caused by these drugs leads to changes in the electrolytic and organic composition of saliva, reducing its buffer capacity, with consequent increase in the mineral loss of the dental structure and remineralization impairment, which may increase the risk of dental caries [8]. Some of these drugs may also promote gingival increase that, together with poor oral hygiene, leads to inflammation and development of early periodontal disease, which may lead to postural hypotension or altered blood crasis. Thus, the knowledge by the dentist regarding the possible adverse effects on the oral cavity related to interactions between these drugs and local anesthetics and / or drug therapy is fundamental [9].

Although UFAM Dental Clinics prioritize dental caries and periodontal disease prevention, the study showed that most patients received curative procedures, with periodontal, restorative and surgical procedures being the most prevalent, which is directly related to the late search for dental treatment. The importance of preventive behavior is indisputable not only for PSNs, but for all individuals. It should be emphasized that in view of the difficulties found for dental restorative, surgical and endodontic treatment in these individuals, prevention is essential [5]. The interpretation of these results reflects the difficulty of management and the lack of collaboration of PSNs for the accomplishment of the endodontic treatment. Data also showed that despite the concern about adopting and encouraging preventive measures for these individuals and their caregivers, adequate success rate is very difficult to achieve. This is mainly due to the lack of collaboration and difficulties inherent to each type of disability. In addition, the main barriers to access to dental services, low schooling and low income, lead to the accumulation of oral diseases, which is reflected in the high tooth loss index [17]. Low socioeconomic status, overprotection given to the patient with special needs, lack of knowledge regarding the importance of dental care and oral hygiene are factors that could justify the late search for dental treatment [18,19]. Therefore, these results indicate the need for an early approach to these patients, since it is known that they are prone





to oral complications because they present limitations due to their physical and systemic condition. Knowing the reality of diseases related to oral conditions is of great importance for the adoption of preventive strategies that result in improvements with respect to oral health and, thus, resulting in better quality of life for these patients. Scientific evidence shows that not all dentists are able to identify different groups with special needs, which may constitute one of the barriers to access to dental treatment. The number of universities that include the PSN discipline in their undergraduate and graduate programs is still small considering the need in Brazil [15,16,20].

The knowledge of the social, demographic and economic profile, as well as the medical diagnosis of patients with special needs can be used to improve the quality of the planning of clinical care offered to the population that annually seeks university dental clinics, directing it to the real needs of the public seeking them. This knowledge will facilitate, in subsequent studies, the elaboration of care protocols aimed at this population, providing managers of institutions the qualification of the educative process developed, as well as the formulation of tools to improve the dental care provided [5,19].

One of the limitations of this study was the lack of computerization of the medical records system of School of Dentistry - UFAM, which led to the loss of several medical records, as well as the lack of filling of some fields of dental records, leading to the loss of relevant information, with consequent difficulty in understanding the real situation of patients by the various professionals, which impairs the care provided.

### Conclusion

The profile of the majority of patients with special needs was characterized by the presence of chronic systemic diseases, mostly females with mean age of 39.6 years, low schooling and monthly family income of up to 1 Brazilian minimum wage, whose main reason for the visit was the search for curative dental treatment.

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**Conflict of Interest:** The authors declare no conflicts of interest.

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