*Original Research Article*

*ANALYSIS OF CLINICAL OUTCOMES BEFORE AND AFTER VACCINATION AGAINST COVID-19 IN A GERIATRIC POPULATION: INVESTIGATION OF SOCIODEMOGRAPHIC FACTORS AND VACCINATION ADHERENCE IN A UNIVERSITY OUTPATIENT CLINIC IN TOCANTINS*

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ABSTRACT

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| **Aims:** The first confirmed case of SARS-CoV-2 in Brazil was registered in February 2020 in the State of São Paulo, and quickly spread throughout all 27 federative units in the country. Given the rapid global spread and high virus infectivity, with significant economic, humanitarian, and social impacts, it has become imperative to develop an efficient strategy to contain the spread of the disease. In this context, mass vaccination planning proved to be desirable and promising, aiming to reduce morbidity and mortality caused by the new coronavirus (SARS-CoV-2) and reduce hospitalizations resulting from the disease.  **Study design:** Descriptive quantitative cross-sectional epidemiological research with convenience sampling of patients treated at the geriatrics outpatient clinic of the University of Tocantins. **Place and Duration of Study:** Information was collected from 128 volunteer patients between August 2022 and July 2023. **Methodology:** Information was collected from 128 volunteer patients between August 2022 and July 2023. **Results:** Analyzing the distribution of cases and deaths by age group in Brazil, there was a higher incidence among adults, with 69.3% of deaths in people over 60 years of age, and 64% of these had at least one risk factor. **Conclusion:** Cases of pneumonia associated with COVID-19 were more likely to occur in older, male patients and with comorbidities, compared to milder cases. Following the guidelines of the World Health Organization (WHO), priority groups were established, including healthcare professionals due to high work exposure and elderly people due to their immunological vulnerability and prevalence of comorbidities. |

*Keywords: SARS-CoV-2; Immunization; Aged.*

1. INTRODUCTION

The first confirmed occurrence of SARS-CoV-2 in Brazil was in February 2020, in the State of São Paulo, and it quickly spread to all 27 federative units of the country (Candido et al., 2020; Coelho et al., 2020). By December 2023, the cumulative number of cases reached 38,201,864, with 708,638 reported deaths (Coronavirus Panel).

Given the rapid global spread and high virus infectivity, along with its significant economic, humanitarian, and social impact, an efficient strategy was required to curb the disease's progression (Lana et al., 2020). In this context, mass vaccination planning was considered both desirable and promising, aiming to reduce the morbidity and mortality caused by the novel coronavirus (SARS-CoV-2), as well as to decrease hospitalizations resulting from it.

Likewise, when analyzing the distribution of disease cases and deaths by age group in Brazil and worldwide, a higher incidence of the disease was observed in the adult population. However, mortality rates were higher among the elderly. In Brazil, 69.3% of deaths occurred in people over 60 years old, and among them, 64% had at least one risk factor (Andrade et al., 2020; Petrilli et al., 2019; Ortiz-Prado et al., 2021; Harrison et al., 2020).

Regarding risk factors for disease severity, cases that progressed to pneumonia were more likely to occur in older male patients with comorbidities than in milder cases (Galvão & Roncalli, 2020).

Thus, the National Immunization Program (PNI), a key branch of Brazil's Unified Health System (SUS), was responsible for the National Plan for COVID-19 Vaccination (Brazil, 2021). The plan followed the World Health Organization (WHO) guidelines, distinguishing priority groups, including healthcare professionals, due to their high occupational exposure, and the elderly, due to immunological factors associated with age and a higher prevalence of comorbidities (WHO, 2021).

Based on the previous information, the objective of the present study was to analyze the sociodemographic factors of a geriatric population attended at a university outpatient clinic and evaluate factors related to adherence to and the effectiveness of COVID-19 vaccination.

2. material and methods

The study consisted of descriptive quantitative cross-sectional epidemiological research with convenience sampling of patients treated at the geriatric’s outpatient clinic of the University of Tocantins.

Information was collected from 128 volunteer patients between August 2022 and July 2023. The data found on the participants were: gender, age, education, income, main means of information, municipality of residence, chronic diseases, daily use of medication, immunizer provided, quantity of vaccine doses, immunization data, post-vaccination symptoms, time of adverse occurrence, need for medical monitoring, previous COVID-19 infection, symptoms of infection, sequelae after the disease and medication use during COVID-19.

The inclusion criteria were all patients over 60 years of age, regardless of sex, color, and ethnicity treated at the institution's geriatrics outpatient clinic. As exclusion criteria, patients under the age of 60 and who did not show interest in participating in the study were considered.

The study was approved by the ethics and research committee in accordance with opinion number 5,439,034, which confirms the suitability of the study.

3. results and discussion

The sociodemographic analysis of the studied population showed that 67% of participants were female and 33% were male. The highest percentage among the female public highlights women's concern with self-care, in contrast to men. This scenario reveals the interference of cultural factors in reducing the demand for medical care by the male public, also cited by the Ministry of Health, with beliefs that they are less vulnerable, have better body composition, and play the role of family provider (Garcia et al., 2019). Furthermore, it is noted that the inclusion of men in health care occurs in specific situations such as chronic diseases and emergencies, which differs from female care, which has more actions aimed at the primary prevention of various diseases (Silva, 2016).

The age distribution of the sample was concentrated between 60 and 94 years old, with an average of 72 years old, with a standard deviation of 8.07. The distribution between the categories of family income and level of education was quite homogeneous, at up to 2 minimum wages and incomplete primary education, respectively. These social characteristics reflect the reality of the population that uses the public health service. The health policy implemented through the SUS, like all public policies, demonstrates the existence of great social inequality among users of the system about health plans, with a predominance of women (2:1), elderly people, black and brown people with low education and low concentration of family income per capita, without health insurance, being similar in all regions of the country. Corroborating that the strong socioeconomic problem and education are two factors of great importance and a strong probability of using SUS services and also of difficulty in access due to transportation and location of health units (Lima e Silva, 2023; Ribeiro, 2006; Guibu, 2017). In addition, there is a predominance of elderly women with low education, associated with a propensity for physical and mental disabilities, which generates a greater demand for the health system among this population (Silva et al., 2023).

Regarding the chronic disease factor, people were prevalent with hypertension, representing 66% of the total sample, and only 15% of the sample without any comorbidity. Associated with high blood pressure or other comorbidity, there was a prevalence of diabetes (29%), hypothyroidism (14%), heart problems (11%) and dyslipidemia (6%). Furthermore, it was analyzed during the research that this group has striking characteristics that justify the presence of some diseases, such as being overweight, a sedentary lifestyle, and an unbalanced diet. Despite hypertension appearing as frequent comorbidity, the data showed no interference of the disease in the prognosis of COVID-19 infection.

At the beginning of the vaccine's availability, a prioritization vaccination schedule was adopted, including people aged 60 years or over, people living in long-term care institutions, health workers, immunocompromised people, pregnant women, and women who have recently given birth, Indigenous populations, riverside dwellers, and quilombolas, people with permanent disabilities, population deprived of liberty and adolescents complying with socio-educational measures (Brazil, 2023). In addition to these groups, priority was given to people with comorbidities such as asthma, diabetes mellitus, Down syndrome, heart, hematological, hepatic, pulmonary, neurological, renal diseases, and obesity. These variables were selected by hospital teams observing the highest risk of hospitalization and death from COVID. In younger patients, the increased risk in the presence of obesity, diabetes mellitus, and kidney disease was also analyzed (Houvèssou, 2022).

It is known that obesity increases the risk of respiratory failure, due to mechanical and inflammatory processes, with higher concentrations of pro-inflammatory cytokines. Regarding underlying kidney diseases, results of immunological changes were associated with uremia, which hindered leukocyte function, thus increasing virulence capacity. In Diabetes Mellitus, increased expression of angiotensin-converting enzyme 2 in the lungs associated with inflammation, caused activation of endothelial cells and insulin resistance that worsened the inflammatory response of the disease, leading to dysfunction of the alveolar-capillary barrier (Houvèssou, 2022).

Due to the presence of comorbidities in the researched population, the prevalence of polypharmacy in prescriptions for this population was analyzed. Thus, it was observed that 70% of the population in this study was using three medications or more. The medications present a group of heterogeneous combinations with the frequent presence of antihypertensives (losartan), anti-glycemic agents (glibenclamide or insulin), thyroid hormones (Puran), antiaggregants (AAS), and antilipemic drugs (simvastatin). Therefore, patients with comorbidities and those who use a large number of medications may be more vulnerable, especially if they have pre-existing cardiovascular disease (Pietrantonio, 2023).

Regarding vaccination adherence in the researched group, seven patients did not take any dose of the vaccine and did not express a desire to be vaccinated, citing personal reasons or due to the influence of political speeches. Of this portion surveyed, aged between 64 and 87 years, two had COVID-19, with mild manifestations with symptoms such as asthenia, headache, cough, and sore throat, without seeking medical attention or sequelae. Such resistance can be conceptualized as “vaccine hesitancy”, which means the process of refusal or delay in accepting vaccines, despite their availability in health systems. Some studies indicate that the variables of trust, complacency, and population convenience interfered in different historical contexts of vaccination campaigns and influenced the acceptance of the anti-COVID vaccine. This social barrier was increased with the erroneous appropriation of epidemiology terms by the television media, such as “herd immunity”, as well as the dissemination of false or incorrect information on sociais networks, which generated noise in communication and compromised understanding. about vaccination, especially among the elderly (Souto, 2021).

Regarding those vaccinated, 121 of those interviewed were immunized with some dose of the anti-COVID vaccine with distribution to the number of doses shown in Graph 1.

**Graph 1.** Relationship between the number of vaccinated individuals and the number of vaccine doses received.

Source: copyright data

Some of the elderly people did not have their vaccination card at the time of the interview, however, the majority were able to report the manufacturer of the vaccine they received, however, they were unable to specify the date of their application, which made it impossible to quantify the time between doses. Thus, the vaccines received followed the distribution: 43.8% received the Coronavac vaccine, 26.4% AstraZeneca, 11.6% Pfizer, 0.8% Janssen, and 17.4% of people were unable to inform.

Among the adverse reactions after the administration of the immunizers, 30.3% of all those vaccinated reported having felt fever and flu-like symptoms, the latter considered in the research to be runny nose, cough, sore throat, and asthenia, in the average interval between 24 and 72 hours. Other symptoms with a lower percentage in this order of predominance were reported: myalgia, general malaise, headache, diarrhea, vomiting, and chills.

In the meantime, meta-analyses pointed out that the common adverse reactions caused by the administration of immunization agents were local and systemic, highlighting pain at the injection site, fever, fatigue, headache, myalgia, chills, and diarrhea, differing according to the vaccine administered. Among the most reported local reactions were pain, edema, redness, erythema, and swollen lymph nodes, in addition to muscular reactions such as myalgia and arthralgia. In systemic adverse reactions, the prevalence of fever, headache, chills, fatigue, gastrointestinal symptoms, palpitations, dyspnea, vertigo, and sleep disturbances was noted. Less common reactions are also noted, such as oral reactions, thrombosis, anaphylaxis, neurological reactions, hypotension, and hypertension (Correa, 2022). It can be observed that the most common local and systemic symptoms were mentioned among our interviewees, confirming a pattern among adverse reactions. However, in our study, the less common systemic reactions were not observed.

It was possible to quantify the number of elderly people who had COVID-19 infection before and after the vaccination schedule. Of the 121 individuals who took the vaccine, 25 had a previous viral infection and of these, one was asymptomatic (laboratory confirmation) and 24 were symptomatic, reporting flu-like symptoms, followed by headache and dyspnea. The number of elderly people who were infected after the vaccination schedule was 41 and of these, four were asymptomatic (laboratory confirmation) and 37 were symptomatic, in which the prevalence of flu-like symptoms, myalgia, headache, dyspnea, and fever was observed, as shown in graph 2 Although the increase in infected people post-vaccine is greater, the percentage of asymptomatic people pre- and post-vaccine increased from 4% to 9.7%, highlighting the role. of the vaccine in containing the disease and its vaccine effectiveness.

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**Graph 2.** Comparison between the symptoms reported by elderly people with COVID-19 infection before and after receiving the vaccine.

\*The following were considered flu-like symptoms: runny nose, cough, sore throat and asthenia.

Source: Data collected.

Concerning medical assistance, it was evident that 12 interviewees used medical assistance during virus infection before immunization, they received a median of 4 days of assistance. From this sample space, 9 patients used low and medium complexity services, that is, they requested care in basic health units or emergency care. In these places, nasal swab testing services were offered to identify the infection and guidance for social isolation and medication for symptomatic patients. Furthermore, the remaining 3 patients required assistance in highly complex units, with admission to the Intensive Care Unit (ICU).

Of these more serious cases, we analyzed a hospitalization range of 15 to 90 days of medical care. One case that drew attention was that of a 70-year-old male patient with diabetes, hypertension, and atherosclerosis, who was hospitalized for 37 days in a hospital unit, however, he evolved without significant post-recovery sequelae. In addition to this, we identified another male patient, 63 years old, with hypertension and type 2 diabetes who was pre-immunizing infected and hospitalized for 3 months, with a tracheostomy, and a good prognosis. These two patients stood out because they were serious cases related to the same comorbidities: hypertension and diabetes. Furthermore, after the vaccination schedule, making a comparison, the first patient mentioned was reinfected but presented mild symptoms and the second did not suffer a new infection, which already demonstrates a good vaccine response given the severity of the cases.

On the other hand, 15 patients used medical care due to COVID after vaccination, making it clear that there was an increase in infected people, coinciding with the progression phase of the cases. Even with the increase in the number of cases, we noticed that there was a reduction in hospitalization cases in the country and a significant reduction in the sample, with only one patient hospitalized for 8 days in the ICU. This 75-year-old male patient was categorized as having a very high cardiovascular risk, presenting heart obstruction, kidney failure, diabetes, and hypertension. Therefore, the importance of vaccination for this patient is highlighted, as even with this severity he did not acquire significant sequelae, referring only to memory loss that we were unable to differentiate from common dementia diseases of his age.

In addition, only three were infected, also, pre and post-vaccine, which we detail below: Patient 1 - female, 69 years old, hypertensive, took 3 doses of the AstraZeneca vaccine. He acquired COVID pre-vaccine, presenting symptoms of dyspnea, and receiving care at the UBS. After the vaccination schedule, he acquired the virus with the same symptom, dyspnea, without the use of highly complex services, medications, or sequelae. Patient 2 - male, 70 years old, diabetic, hypertensive, and at cardiovascular risk. He took 3 doses of the AstraZeneca vaccine. He acquired the virus pre-vaccine with symptoms of dyspnea and cough, required highly complex medical assistance, being hospitalized for 37 days, with sequelae of memory loss and tinnitus. In post-vaccine COVID, he presented mild flu-like symptoms and was treated at the UPA, without the need for hospitalization, without using a highly complex health service, or after-effects. Patient 3 - female, 75 years old, hypertensive, diabetic, hypothyroidism, took 3 doses of Coronavac. During the pre-vaccine infection, she felt asthenia and was assisted at the UPA and used the anti-covid cocktail. Reports memory loss after infection. During the post-vaccine infection, she presented symptoms of dyspnea and asthenia, requiring hospitalization for 7 days. Reports memory loss as a sequel.

These cases showed that after the vaccination schedule, infected individuals generally required only low and medium-complexity services. Furthermore, the 12 elderly people who presented post-vaccine infection used the UPA service, as a screening to confirm the test and request a medical prescription.

About the medications used to treat pre- and post-vaccination infections, we noticed that in the first scenario, anti-COVID cocktails composed of Ivermectin, Azithromycin, and Hydroxychloroquine were used; in the post-vaccination period, antipyretics were more prominent than the cocktail. It was observed that the most common sequel, both pre and post-vaccination, was memory loss with a dominance of 75% and 61% respectively. Other less frequent symptoms were mentioned in infected individuals after immunization: headache, dyspnea, loss of appetite, and varicose veins. In this regard, some symptoms unrelated to the infection were noticed, such as the report of varicose veins, which may be more related to other previous pathologies of the individual, such as venous insufficiency, than necessarily viral sequelae.

Another important point was reports of memory loss, associated with the sequelae of COVID-19, indirect changes through inflammatory mechanisms in the central nervous system. Cognitive changes, headache, and sleep disturbances were also associated post-infection. These symptoms are linked to the recovery process and are similar to other diseases of viral etiology. There is the possibility of the disease also aggravating other etiologies of dementia in the elderly, such as Parkinson's and Alzheimer's, in addition to underlying chronic diseases, which are directly associated with cognitive loss, and the most obvious symptom would be memory loss. Therefore, more studies are needed to determine the correct association between memory loss and SARS-COV-2 infection, whether it is a direct consequence or just an aggravation of existing comorbidities (Lima, 2022). Therefore, we were unable to dissociate the cognitive loss bias from viral consequences in the elderly population studied.

4. Conclusion

It was found that the anti-COVID vaccine can significantly reduce the symptoms of SARS-CoV-2 virus infection in elderly people who have been vaccinated. Therefore, it is up to the medical profession itself and the authorities to develop preventive strategies based on evidence to effectively offer the vaccine, requiring constant research due to mutations and the emergence of new strains.

Furthermore, it is extremely important to combat misinformation regarding methods of preventing and eradicating diseases. Since fake news can hinder the population's adherence to vaccine models.

References

ANDRADE CARLA LOURENÇO TAVARES, ET AL. COVID-19 HOSPITALIZATIONS IN BRAZIL’S UNIFIED HEALTH SYSTEM (SUS). PLOS ONE, 15:E0243126, SÃO FRANCISCO, 2020.

BRAZIL. MINISTRY OF HEALTH. NATIONAL PLAN FOR THE OPERATIONALIZATION OF VACCINATION AGAINST COVID-19. 2021. AVAILABLE AT: HTTPS://WWW.GOV.BR/SAUDE. ACCESSED ON: JANUARY 15, 2021.

BRAZIL. MINISTRY OF HEALTH. FIND OUT WHY EACH PERSON IN THE PRIORITY GROUPS NEEDS TO GET VACCINATED WITH THE BIVALENT BOOSTER DOSE AGAINST COVID-19. 2023. AVAILABLE AT: HTTPS://WWW.GOV.BR/SAUDE. ACCESSED ON: 05 NOV. 2023.

CANDIDO DARLAN S, ET AL. EVOLUTION AND EPIDEMIC SPREAD OF SARS-COV-2 IN BRAZIL. SCIENCE, WASHINGTON, 369:1255-60, JUL. 2020.

COELHO FLÁVIO C, ET AL. ASSESSING THE POTENTIAL IMPACT OF COVID-19 IN BRAZIL: MOBILITY, MORBIDITY AND THE BURDEN ON THE HEALTH CARE SYSTEM. PLOS ONE, SAN FRANCISCO, 18;15(9), SEP. 2020.

CORREA, ISABELA, ET AL. ADVERSE REACTIONS AFTER COVID-19 VACCINATION: AN INTEGRATIVE REVIEW. RESEARCH SOCIETY AND DEVELOPMENT, 11(13), SÃO PAULO, OCT.2023.

DE LEON, CRISTIANO DO AMARAL; ET AL. HOW SOCIAL MEDIA CAN DEMYSTIFY COVID-19 VACCINATION: A LITERATURE REVIEW. MEDICAL SCIENCE SCIENTIFIC DISCOVERIES FOR TRANSFORMATIVE HEALTH. SÃO JOSÉ DOS PINHAIS: SEVEN EDITORA, 2023.

GALVÃO, MARIA HELENA RODRIGUES; RONCALLI, ANGELO GIUSEPPE. FACTORS ASSOCIATED WITH A HIGHER RISK OF DEATH FROM COVID-19: SURVIVAL ANALYSIS BASED ON CONFIRMED CASES. BRAZILIAN JOURNAL OF EPIDEMIOLOGY, 23: 200106, SÃO PAULO, 2020.

GARCIA, LUIS HENRIQUE COSTA, ET AL. SELF-CARE AND ILLNESS IN MEN: A NATIONAL INTEGRATIVE REVIEW. JOURNAL OF PSYCHOLOGY AND HEALTH, V. 11, N. 3, P. 19-33, CAMPO GRANDE, 2019.

GUIBU, IONE AQUEMI, ET AL. MAIN CHARACTERISTICS OF USERS OF PRIMARY HEALTH CARE SERVICES IN BRAZIL. JOURNAL OF PUBLIC HEALTH, 51: 17S, SÃO PAULO, 2017.

HARRISON STEPHANIE L, ET AL. COMORBIDITIES ASSOCIATED WITH MORTALITY IN 31,461 ADULTS WITH COVID-19 IN THE UNITED STATES: A FEDERATED ELECTRONIC MEDICAL RECORD ANALYSIS. PLOS MED, 17:E1003321, SÃO FRANCISCO, 2020.

HOUVÈSSOU, GBÈNANKPON M, ET AL. RISK FACTORS FOR INTENSIVE CARE UNIT ADMISSION AND DEATH FROM COVID-19 IN FULLY VACCINATED PATIENTS HOSPITALIZED FOR SEVERE COVID-19, BRAZIL, 2021–2022. REVISTA PANAMERICANA DE SALUD PÚBLICA, 46:E203, WASHINGTON, 2022.

LANA, RAQUEL MARTINS, ET AL. EMERGENCY OF THE NEW CORONAVIRUS (SARS-COV-2) AND THE ROLE OF TIMELY AND EFFECTIVE NATIONAL HEALTH SURVEILLANCE. PERSPECTIVAS: CADERNOS SAÚDE PÚBLICA, 36, 3, RIO DE JANEIRO, 2020.

LIMA, INGRID NASCIMENTO, ET AL. MEMORY LOSS ASSOCIATED WITH SARS-COV-2 VIRAL INFECTION: LITERATURE REVIEW. RESEARCH, SOCIETY AND DEVELOPMENT, 11, 4, VARGEM GRANDE PAULISTA, 2022.

LIMA E SILVA, VANESSA. KNOWLEDGE, ATTITUDES AND PRACTICES FOR PREVENTING COVID-19 IN COMMUNITY-DWELLING ELDERLY IN A CAPITAL IN NORTHEAST BRAZIL. INTERDISCIPLINARY STUDIES ON AGING, 28, PORTO ALEGRE, 2023.

OLIVEIRA, VICENTINA MARIA GASPAR; SILVA HENRIQUE SALMAZO. DIGITAL TECHNOLOGIES AND THE ELDERLY: A STUDY ON THE USE OF SMARTPHONES DURING COVID-19. INTERDISCIPLINARY STUDIES ON AGING, 29, PORTO ALEGRE, 2024.

ORTIZ-PRADO ESTEBAN, ET AL. EPIDEMIOLOGICAL, SOCIO-DEMOGRAPHIC AND CLINICAL FEATURES OF THE EARLY PHASE OF THE COVID-19 EPIDEMIC IN ECUADOR. PLOS NEGLECTED TROPICAL DISEASES, 15:E0008958, SAN FRANCISCO, 2021.

PETRILLI CHRISTOPHER M, ET AL. FACTORS ASSOCIATED WITH HOSPITAL ADMISSION AND CRITICAL ILLNESS AMONG 5279 PEOPLE WITH CORONAVIRUS DISEASE 2019 IN NEW YORK CITY: PROSPECTIVE COHORT STUDY. BMJ, 369:M1966, LONDON, 2020.

PIETRANTONIO, FILOMENA, ET AL. POLYPHARMACY MANAGEMENT IN A GENDER PERSPECTIVE: AT THE HEART OF THE PROBLEM: ANALYSIS OF MAJOR CARDIAC DISEASES, SARS-COV-2 AFFECTION AND GENDER DISTRIBUTION IN A COHORT OF PATIENTS IN INTERNAL MEDICINE WARD. INTERNATIONAL JOURNAL OF ENVIRONMENTAL RESEARCH AND PUBLIC HEALTH, 20, 9, P. 5711, GLENDALE, 2023.

RIBEIRO, MANOEL CARLOS SAMPAIO DE ALMEIDA, ET AL. SOCIODEMOGRAPHIC PROFILE AND PATTERN OF USE OF HEALTH SERVICES FOR USERS AND NON-USERS OF SUS-PNAD 2003. CIÊNCIA & SAÚDE COLETIVA, 11, P. 1011-1022, RIO DE JANEIRO, 2006.

SILVA, ELAINE ANDRADE LEAL, ET AL. PROMOTING MEN'S HEALTH IN PRIMARY HEALTH CARE: AN EXPERIENCE REPORT. REVISTA DE PHC, 19, 4, JUIZ DE FORA, 2016.

SILVA, MARIANE COIMBRA; ET AL. USER PROFILE AND PLANNING OF RESOLVING PUBLIC POLICIES: HEALTH CARE FOR THE ELDERLY IN BELO HORIZONTE/MG. MANAGEMENT & PLANNING-G&P, 24, SALVADOR, 2023.

SOUTO, ESTER PAIVA; KABAD, JULIANA. VACCINE HESITATION AND THE CHALLENGES IN DEALING WITH THE COVID-19 PANDEMIC IN ELDERLY IN BRAZIL. BRAZILIAN JOURNAL OF GERIATRICS AND GERONTOLOGY, 23, E210032, RIO DE JANEIRO, 2021.

WHO. WORLD HEALTH ORGANIZATION. WHO CORONAVIRUS (COVID-19) DASHBOARD. AVAILABLE AT: <HTTPS://COVID19.WHO.INT/>. ACCESSED ON: 27 DEC. 2021.

APPENDIX

UNIVERSITY OF GURUPI – UNIRG

FREE AND INFORMED CONSENT TERMS – TCLE

You are being invited to participate in a research carried out at the University of Gurupi (UNIRG), in partnership with the UNIRG community health clinic.

To enable you to decide whether or not to participate in the research, the following information was provided:

• The title of the project is: Clinical outcomes in elderly patients immunized against SARS-CoV-2: a study in an outpatient center in Gurupi.

• The project is quantitative research and was submitted for approval by the Research Ethics Committee of the University of Gurupi, which aims to protect the subject of this research.

• The responsible researcher is Dr. Samara Tatielle Monteiro Gomes, professor at the Department of Medicine at the University of Gurupi (Campus Gurupi), who can be contacted at any time by phone (91) 98239-0560 to clarify questions regarding the research and provide support

• Any assistance, whether immediate or comprehensive, will be provided by the project's technical team and questions regarding the objectives, methodology and relevance of the study can be directed to the responsible researcher through the contacts mentioned above.

• The objective of the research is to investigate the effectiveness and adverse effects in patients immunized with COVID-19 vaccines treated at the outpatient center of the University of Gurupi (UNIRG) in Gurupi, of geriatric age.

• The participant's name will not be used on any study forms or in any records resulting from this study. At the beginning of the study, the participant will receive an identification number (code from the outpatient identification form), which will be used on the forms.

• Any information obtained through this study will be kept strictly confidential. Only members of the study team (doctors, students and researchers) will have access to the information, linking their name to their number in the study.

• The decision not to participate or to withdraw from participation will not influence the care you receive in the clinic. If you agree to become a study participant, you may withdraw from the study at any time (verbally).

• A semi-structured questionnaire will be applied with open and closed questions on the research theme.

• Data collection will be carried out by research volunteer academics, supervised by doctor Diego Lorenzi Agnolin, responsible for the specialty outpatient clinic, at the place of care.

• After the end of the service, the patient will be informed about the risks and benefits of the research and if they become a volunteer for the study, the data will be collected in the treatment room to preserve the confidentiality of the research.

• The research data will be tabulated in the Excel 2019® program and subsequently cataloged in statistical analyzes using specific software.

• During the study you can choose not to answer any particular question.

• There are no direct benefits or risks to you in participating in the study. When the results of the study are known, they will be able to help understand the factors related to vaccination for Covid-19.

• There will be no monetary compensation for participating in the study.

• The result of this work will be a benefit to basic science, public health and the geriatric community with a better future understanding of how some types of vaccines work in the body of the elderly.

• There is no potential harm caused by this research to the elderly, considering that there is no direct intervention in the elderly's habits, usual drugs and there is no need to administer any drugs to the group.

• Volunteers will not suffer financial loss as the research is completely free, with the pen and forms provided by the researchers. Participation is voluntary and free.

• Responses to the questionnaire will preferably be made in an interview format (open answers) in order to minimize any social, moral, intellectual or religious harm in this vulnerable age group.

• Researchers and institutions involved in the research are responsible for providing comprehensive assistance to research participants with regard to complications and damages arising from the research, as well as compensation and material coverage to repair damage caused by the research to the research participant

• Study data will be kept de-identified and secure for at least 15 years after the end of the study and may be destroyed or kept for an indefinite period, only in electronic format.

Gurupi-Tocantins, \_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_

**Declaration of participation**

I have been informed verbally and in written form about the study and understand what is involved. I also know who to contact if I need more information. I understand that confidentiality will be preserved. I understand that I am free to withdraw from the study at any time without it affecting the care I would normally receive in the clinic. I agree to participate in this study as a volunteer and a copy of this informed consent will be provided for me to keep.

Participant’s signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Investigator's statement**

I, the undersigned, defined and explained to the volunteer, in the language they understand, the procedures of this study, the objectives and the risks and benefits associated with their participation. I informed the volunteer that confidentiality will be preserved, that he is free to withdraw from the study at any time, without this influencing the care he will receive in the clinic. Following my definitions and explanations, the volunteer agrees to participate in this study.

Investigator’s signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_