ADHERENCE, BURDEN, AND MORBIDITY OF CHRONIC DISEASES IN AN OUTPATIENT CLINIC: A-CaMo I

Adherencia, carga y morbilidad de enfermedades crónicas en una clínica ambulatoria: A-CaMo I

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Abstract

Introduction: Chronic non-communicable diseases (NCDs) are a significant global health challenge due to their prolonged duration and varied progression rates, leading to increased noncompliance, especially in developing nations. Pharmacological adherence, defined by WHO, is crucial for maintaining patients' quality of life and reducing morbidity, yet it remains inadequate, with about 50% non-adherence in developed countries, 30% of which is unintentional. Understanding disease burden is vital, but research on medication adherence, burden, and morbidity in the Dominican Republic and Latin American countries is lacking, necessitating comprehensive studies.

Objectives: Ascertaining the degree of pharmaceutical adherence, disease burden, and morbidity amongst individuals with chronic illnesses were the study's primary endpoints.

Methodology: The project was a cross-sectional, prospective study that examined the sociodemographic data, past medical history, and medication regimens of a sample of 284 patients attending an outpatient clinic. Patients were selected using convenience sampling, to be later screened and interviewed after consultation for any of the diseases present on the MAR-Scale or the DBMA questionnaires. The screening sought only those individuals who met inclusion criteria (> 18 years old, diagnosed with a disease present on either scale) and did not meet exclusion criteria (not being able to fill the questionnaire due to language barrier). Data collected was stored using the KoboToolBox program and later summarized with mean and standard deviation for further processing using STATA BE. Statistical tests were programmed with an alpha of 5%, 95% CI, and $p < 0.05$ for statistical significance.

Results: The sample, comprising 133 individuals, had a mean age of approximately 58.4 years, with a majority of female participants. Most participants were married, Dominican, and of Hispanic Latino ethnicity, with Christianity being the predominant religion. Regarding past medical history, while a substantial portion had no prior respiratory or cardiovascular ailments, diabetes mellitus was prevalent, indicating potential implications for current health status and treatment adherence. Adherence, measured by daily and weeklyscores, ranged from 1.0 to 3.8, with the burden score per patient averaging 50.1 and per disease averaging 2.6. The analysis revealed that 16.9% of participants were monomorbid, while 83.1% were multimorbid, showcasing the complexity of health conditions within the cohort.

Conclusion: The study's key results reveal a significant portion of patients without a history of respiratory or cardiovascular diseases, suggesting a relatively healthy baseline. However, a notable proportion had diabetes, potentially impacting their current health status and treatment adherence. Furthermore, the study delves into factors influencing adherence, burden levels, and reasons for nonadherence. Findings indicate unmarried patients and those with lower education levels tend to exhibit higher burden levels and lower adherence scores. Mental health conditions like depression or anxiety, osteoporosis, and heart failure are associated with elevated burden levels. The study also assesses the reliability of adherence and burden measurement tools, emphasizing the importance of considering population variability in interpreting results. Limitations include challenges in patient selection and data collection, particularly regarding patients with multimorbidity. Overall, the study highlights the need for comprehensive exploration of adherence, burden, and morbidity to predict disease control, progression, and patient quality of life effectively in future research endeavors.

Keywords: Chronic diseases, adherence, burden, morbidity, reliability.

Resumen

Introducción: Las enfermedades crónicas no transmisibles (ENT) representan un desafío significativo para la salud global debido a su duración prolongada y tasas de progresión variadas, lo que conduce a un aumento en la falta de adherencia, especialmente en países en desarrollo. La adherencia farmacológica, definida por la OMS, es crucial para mantener la calidad de vida de los pacientes y reducir la morbilidad, sin embargo, sigue siendo inadecuada, con aproximadamente un 50% de no adherencia en países desarrollados, el 30% de los cuales es involuntario. Comprender la carga de enfermedad es vital, pero la investigación sobre adherencia a medicamentos, carga y morbilidad en la República Dominicana y otros países de América Latina es insuficiente, lo que hace necesarios estudios exhaustivos.

Objetivos: Determinar el grado de adherencia farmacológica, carga de enfermedad y morbilidad entre individuos con enfermedades crónicas fueron los objetivos principales del estudio.

Metodología: El proyecto fue un estudio transversal prospectivo que examinó los datos sociodemográficos, historias clínicas y regímenes de medicación de

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una muestra de 284 pacientes que asistieron a una clínica ambulatoria. Los pacientes fueron seleccionados mediante un muestreo por conveniencia, para luego ser evaluados e entrevistados después de la consulta para cualquiera de las enfermedades presentes en las escalas MAR o los cuestionarios DBMA. La selección buscó únicamente a aquellos individuos que cumplieran con los criterios de inclusión (> 18 años, diagnosticados con una enfermedad presente en alguna de las escalas) y no cumplieran con los criterios de exclusión (no poder completar el cuestionario debido a la barrera del idioma). Los datos recopilados se almacenaron utilizando el programa KoboToolBox y luego se resumieron con la media y la desviación estándar para su procesamiento adicional utilizando STATA BE. Las pruebas estadísticas se programaron con un alfa del 5%, IC del 95% y $p < 0,05$ para significación estadística.

Resultados: La muestra, compuesta por 133 individuos, tuvo una edad media de aproximadamente 58,4 años, con una mayoría de participantes femeninas. La mayoría de los participantes estaban casados, eran dominicanos y de etnia hispano-latina, siendo el cristianismo la religión predominante. En cuanto al historial médico previo, aunque una parte sustancial no tenía antecedentes de enfermedades respiratorias o cardiovasculares, la diabetes mellitus fue prevalente, lo que indica posibles implicaciones para el estado de salud actual y la adherencia al tratamiento. La adherencia, medida por puntajes diarios y semanales, osciló entre 1,0 y 3,8, con un puntaje de carga por paciente promedio de 50,1 y por enfermedad de 2,6. El análisis reveló que el 16,9% de los participantes eran monomórbidos, mientras que el 83,1% eran multimórbidos, lo que demuestra la complejidad de las condiciones de salud dentro de la cohorte.

Conclusión: Los principales resultados del estudio revelan una parte significativa de pacientes sin antecedentes de enfermedades respiratorias o cardiovasculares, lo que sugiere una línea de base relativamente saludable.

Sin embargo, una proporción notable tenía diabetes, lo que podría afectar su estado de salud actual y la adherencia al tratamiento. Además, el estudio analiza los factores que influyen en la adherencia, los niveles de carga y las razones de la falta de adherencia. Los hallazgos indican que los pacientes solteros y aquellos con niveles educativos más bajos tienden a exhibir niveles de carga más altos y puntajes de adherencia más bajos. Las condiciones de salud mental como la depresión o la ansiedad, la osteoporosis y la insuficiencia cardíaca están asociadas con niveles de carga elevados. El estudio también evalúa la confiabilidad de las herramientas de medición de la adherencia y la carga, enfatizando la importancia de considerar la variabilidad de la población en la interpretación de los resultados. Las limitaciones incluyen desafíos en la selección de pacientes y la recopilación de datos, especialmente en pacientes con multimorbilidad. En general, el estudio destaca la necesidad de una exploración exhaustiva de la adherencia, la carga y la morbilidad para predecir el control de la enfermedad, la progresión y la calidad de vida del paciente de manera efectiva en futuros proyectos de investigación.

Palabras clave: Enfermedades crónicas, adherencia, carga, morbilidad, confiabilidad.

Abbreviations

NCDs - Chronic non-communicable diseases
WHO – World Health Organization
COPD – Chronic Obstructive Pulmonary Disease
BRFSS - Behavioral Risk Factor Surveillance System
MAR-Scale – Medication Adherence Reasons Scale
DBMA - Disease Burden Morbidity Assessment
INTEC - Instituto Tecnológico de Santo Domingo
IRB – Independent Review Board

Introduction

Chronic non-communicable diseases (NCDs), which cause approximately 74% of deaths globally[1], are characterized by their prolonged duration, typically exceeding three months, and exhibit varying rates of progression, ranging from gradual to rapid. These conditions, such as diabetes mellitus or hypertension/cancer, typically lack curative treatments, making them a formidable challenge for both patients and healthcare providers. However, maintaining adherence to their therapeutic schedules ensures the patient's quality of life and a decrease in the probability of complications and

hospitalization, which is the goal when caring for people with chronic medical conditions.

The adherence to prescribed pharmacological regimens in patients with chronic diseases, herein referred to as pharmacological adherence, presents a substantial hurdle, with patients grappling with a heightened risk of noncompliance compared to those with non-chronic ailments[2]. As defined by the World Health Organization (WHO), pharmacological adherence reflects the extent to which patients adhere to treatment plans established in collaboration with healthcare professionals[3]. Beyond the significant personal burden borne by individuals afflicted by chronic diseases, pharmacological nonadherence is directly correlated with heightened morbidity stemming from their conditions.

The assessment of nonadherence in individuals coping with chronic diseases can be intricate, given the frequent necessity for multiple medications, often administered through diverse routes, including oral, topical, and injectable methods[3]. In its 2003 report on medication adherence, the WHO states that increasing the effectiveness of adherence interventions may have a far greater impact on the health of a population than any improvement in specific medical treatment, to which, by opposition, nonadherence leads to poor clinical outcomes, an increase in morbidity and mortality and unnecessary healthcare expenditure[4].

In developed countries, adequate pharmacological adherence is reported at approximately 50%, a figure that drops considerably in developing countries. Research indicates that 30% of instances of nonadherence are unintentional, and regularly originate from forgetfulness or insufficient skills to adhere to prescribed treatments, while the remaining 70% arise from deliberate patient decisions regarding treatment management[5]. This pervasive nonadherence poses an urgent and substantial challenge, leading to diminished health outcomes and escalated healthcare costs[3].

Parallel to pharmacological adherence, comprehending the disease burden emerges as a paramount concern. Disease burden serves as a metric for evaluating the impact of a disease can have on the daily lives of a particular population and encompasses a range of factors, with mortality, morbidity, and financial implications being prominent among them[6].

In the Dominican Republic, there is a lack of robust studies tackling medication adherence, burden, and morbidity in individuals living NCDs. However, is there a profile of all three characteristics (adherence, burden, and morbidity) with reliable externally validated data? The question denotes the lack of said data in the Dominican Republic and, regrettably, Latin American countries.

Consequently, a research proposal for a cross-sectional study was designed to assess pharmacological adherence and the primary causes of non-adherence among patients with NCDs in Santo Domingo, Dominican Republic, employing the Medication Adherence Reasons Scale (MAR-Scale), and to assess the impact of those diseases on daily activities using the Disease Burden Morbidity Assessment (DBMA). The clinical question for this proposal is: among individuals aged 18 and above with any of the chronic diseases listed in the MAR-Scale and/or the DBMA, and receiving care at the Dr. Evangelina Rodríguez Primary Care Center, Santo Domingo, Dominican Republic, what are the levels of oral, topical, and injectable pharmacological adherence, as well as burden and morbidity according to the MAR-Scale and the DBMA?

The secondary endpoints derived from this question are as follows: (1) to identify the 3 most frequent reasons for pharmacological nonadherence; (2) to assess the reliability of the MAR-Scale and the

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DBMA through Cronbach's alpha; (3) to evaluate the extent of the impact that various diseases have on patients' daily activities through the DBMA.

Materials and Methods

Design

The study as a cross-sectional project measured the adherence, burden, and morbidity rates related to chronic diseases in adults, using either the MAR-Scale or DBMA as evaluation tools. The research involved both descriptive and inferential analyses of collected data and followed the Strengthening of the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for reporting standards in observational studies.

Research site

Data collection took place at the Dr. Evangelina Rodriguez Primary Care Center, situated on the main campus of the Instituto Tecnológico de Santo Domingo (INTEC) in Santo Domingo, Dominican Republic, from March to August 2023, covering 5 months. Patients treated at this health center reside in the Constelación and Jardines del Norte areas, both of which are part of the Los Rios sector, located to the west of the Distrito Nacional in Santo Domingo.

Population, sample size, and sampling

The study included adults diagnosed with chronic diseases listed in the MAR-Scale or DBMA. However, it was challenging to establish a finite population due to the center's inability to determine the exact number of nearby patients. Therefore, the sample size determination used an infinite population approach.

The computation considered the following parameters: a 5% alpha (type 1 error), a 20% beta (type II error) corresponding to an 80% statistical power,

and an expected proportion of 50%. These parameters led to a required sample size of 384 patients. Participants were selected using a non-probabilistic convenience sampling method, due to the study population's specific characteristics and their access to healthcare services at the center.

Inclusion and exclusion criteria

Patients were screened based on the study's purpose, with inclusion and exclusion criteria outlined below. Inclusion criteria included: (1) age 18 or older, (2) residency between Constelación and Jardines del Norte, (3) diagnosis of at least one chronic disease from the MAR-Scale or DBMA, and (4) attendance at the primary care center Dra. Evangelina Rodríguez. Exclusion criteria encompassed: (1) individuals with mental disorders or learning disabilities preventing the autonomous completion of the forms, and (2) patients not proficient in English or Spanish.

Data tools: MAR-Scale, DBMA, and socio-demographic questionnaire

Patients were evaluated for potential inclusion immediately after their primary care consultation or when finishing their prescribed medication refill appointment. Afterward, a sociodemographic questionnaire, the MAR-Scale, and the DBMA, were used to assess each patient.

The variables measured in the study are subdivided into sociodemographic variables, adherence variables for the MAR-Scale, and burden and morbidity variables for the DBMA.

The MAR-Scale is designed to assess pharmacological adherence and primary causes of non-adherence and is tailored to each patient's specific medication and mode of use, covering the following 17 different diseases:: diabetes mellitus, rheumatoid arthritis, systemic lupus erythematosus (SLE), migraine, osteoporosis, chronic pain, inflammatory

bowel disease (IBD), gastroesophageal reflux disease (GERD), chronic constipation, irritable bowel syndrome (IBS), psoriasis, atopic dermatitis, multiple sclerosis, epilepsy, sleep disorders, depression, and overactive bladder[3].

To rate the impact of daily activities, the DMBA covers the following 22 chronic diseases: osteoarthritis, rheumatoid arthritis, chronic back pain, depression, circulation problems/intermittent claudication, hypertension, anxiety, osteoporosis, cancer, diabetes, heart failure, urinary tract problems (prostate, bladder), COPD/emphysema, stroke, memory disorder, gastric/duodenal ulcer, kidney disease, asthma, myocardial infarction, angina, and Parkinson's disease[7].

The sociodemographic questionnaire was created using published questionnaires from the literature, including the WHO Manual for Health and Disability Measurement and the CDC's Behavioral Risk Factor Surveillance System (BRFSS Questionnaire)[8]. It gathered various characteristics, including patient information, health status, medical history, healthcare use, and demographic details intending to capture the sociodemographic variables of the studied geographical areas.

Sociodemographic variables encompass age, sex, phone number, address, email, ethnicity, birthplace, marital status, religion, education, income, occupation, health insurance, toxic habits, and medical history. Questions about diagnosis timing were also included. KoboToolBox software was employed to consolidate DBMA, MAR-Scale, and sociodemographic questionnaire responses into a single, secure, and accessible database[9].

MAR-Scale: tool interpretation

The MAR-Scale, a self-reported twenty-item scale, was a key measurement parameter. The scale assesses drug adherence across three domains: top-

ical, oral, and injectable, for each disease. When patients undergo different forms of administration for the same disease using multiple drugs, multiple MAR-Scales are employed. For instance, a patient with diabetes mellitus receiving both metformin and injectable insulin completes separate questionnaires, one for oral administration and another for injectable administration[10].

The questionnaire measured adherence divided by questions of daily (7-day scale), weekly (4-week scale, i.e., monthly) adherence, and reasons for nonadherence per day and week. These measures of adherence can be summarized as follows:

Patient adherence (per last seven days amount score): asking the patient how many out of the last seven days they were able to adhere to their medication. Results could range from 0-7, where 0-2 indicates adherence and 3-7 indicates nonadherence.

Patient adherence (per last four weeks amount score): asking the patient for how many out of the last four weeks the patient was able to adhere to their medication. Results could range from 0-4, where 0-1 indicates adherence and 2-4 indicates nonadherence.

Patient adherence per daily reasons (7 days reasons score): asks 19 different reasons to determine the cause of nonadherence. Results could range from 0-133, where 30 was the cut-off point between adherence (<30) and nonadherence (>30).

Patient adherence per weekly reasons (4 weeks reasons score): asks 19 different reasons to determine the cause of nonadherence. Results could range from 0-76, where 20 was the cut-off point between adherence (<20) and nonadherence (>20).

DBMA: tool interpretation

The DBMA, also a self-reported questionnaire, was used to estimate the disease burden experienced by

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patients living with the diseases mentioned before, as well as any other chronic disease that might be added. It evaluates the impact of chronic conditions on daily activity, therefore measuring disease severity. Patients were questioned on the presence of the 23 conditions foretasted. All conditions not present were scored 0. Those that the patient did affirm having were subjectively ranged on a descriptive five-point scale, based on how much the condition limits their daily activities, one being "not at all" and five "a lot". The total score is the sum of the limitations from all conditions[7].

The questionnaire was standardized in Spanish, English, and French, so the validity of the original construct was not impacted when using the questions in Spanish.

Data collection and procedures

The study was conducted in three phases: (1) preparation of the research proposal, (2) information and data collection, and (3) data analysis. The research proposal and design were prepared over approximately 3 months. While the recollection of information and data was done in 5 months, it was limited by the flow of patients in the primary care health center and the reasons stipulated in the discussion section.

For said recollection, a non-probability sampling was carried out for convenience, to incorporate patients who came to the care center, where the researchers and data collectors were present.

Data was collected by conducting interviews mornings and evenings, Monday through Friday. The recruiters were previously trained on how to approach patients and conduct interviews and were accompanied by 3rd, 4th, and 5th year medical students. Each interviewer was part of the research team and the answers collected from the patients were verified by the medical student and the attending physician on call at the primary care center. In addition, they obtained training on in-

formed consent, compilation of sociodemographic variables, and evaluation of patients against the parameters established by the MAR-Scale, and the DBMA. The primary care center consists of three offices and a common waiting area, where patients are approached once their consultation or prescription process is completed.

Statistics

Descriptive statistics

To summarize the dataset, central tendency measures, specifically the mean, and median, were employed for continuous variables, distinguishing between normal and non-normal distributions. The assessment of distribution normality was ascertained through the application of the Shapiro-Wilk's test, with a significance threshold of $p < 0.05$.

To distinguish between normal and non-normal distributions in the data analysis, central tendency measures such as the mean and median were utilized for continuous variables, as previously mentioned. Additionally, the Shapiro-Wilk test was employed to assess the normality of the distribution. The use of this test is widely supported in the scientific literature and is suitable for detecting deviations from normality, especially in samples of moderate size as used in this study (n = 133). The significance threshold was set at $p < 0.05$, implying that the null hypothesis of normality is rejected if the p-value is less than this threshold.

The differentiation between normal and non-normal distributions is crucial due to the need to ensure the validity of parametric statistical tests that assume data normality.

Inferential statistics

No inferential statistics were performed in the study.

Missing data

The analysis for missing data encompassed a complete case analysis (CCA), meaning that patients with missing values were excluded from the study analysis.

Ethics

The study underwent a comprehensive series of regulatory evaluations before securing ethical approval from an independent review board (IRB). Firstly, the BioINTEC research committee meticulously assessed and granted approval for the project. Subsequently, a formal letter of intent was submitted to the administrative coordinators of the clinic, seeking their endorsement for the utilization of their facilities within the study. In the final regulatory review, the study proposal was submitted to the Research Center of Hospital Pediátrico Dr. Hugo de Mendoza, where it received approval as a project that fully complies with the requisites stipulated by both national and international ethical guidelines. It is crucial to underscore that the study maintains strict adherence to the principles delineated in the Declaration of Helsinki and the Nuremberg trials, thereby ensuring unwavering commitment to all ethical procedures governing research involving human subjects (see attachment D and E for supplementary ethical approval documents).

Each of the 284 study participants received formal written consent forms, necessitating their official endorsement, along with the inclusion of the interview date. These consent documents were meticulously elucidated by the study's data collectors, who also conveyed a comprehensive explanation of the study's objectives and its overarching aim. This approach was undertaken to ensure that participants achieved a thorough grasp of the project's purpose, thereby upholding principles of transparency and fostering informed consent.

Results

Table #1 also quantifies the relationship between non-adherence to medical treatments and age distribution in a representative sample of patients, to identify the age group in which non-adherence is most prevalent which represents that the age group of patients non-adherent to medical treatment is between 58–59 years old.

The mean age of the participants is approximately 58 years old, with a standard deviation of around 13 years. The most common gender is female, comprising approximately 72.7% of the total participants. The most common marital status is single, with around 35.6% of the participants falling into this category. The most common nationality is Dominican, making up approximately 96.2% of the participants. The most common ethnicity is Hispanic Latino, accounting for around 90.2% of the participants. The most common religion is Christianity, with approximately 75% of the participants identifying as such. The most common occupation is public/private service, with around 45.5% of the participants working in this sector. The most common level of education is preschool, with approximately 38.6% of the participants having attained this level. The most common past medical history within the respiratory category is none, representing approximately 90.9% of the participants. Within the cardiovascular category, the most common past medical history is hypertension, with around 10.6% of the participants having this condition. Finally, within the endocrinology category, the most common past medical history is none, with approximately 83.3% of the participants having no reported endocrine disorders.

Based on the data presented in Table 1, the study encompasses various sociodemographic variables and past medical history of the patients. Out of the total sample, which comprised 133 individuals,

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Table 1. Sociodemographic variables according to medication adherence and disease burden

	Adherent, n(132), per weekly reason score	Adherent, n (35), per weekly amount score	Non adherent, n (1), per weekly reason score	Non adherent, n(32), per weekly amount score	Burden < 5, n (144)	Burden ≥ 5, n (170)
Age, mean ± SD* (years)	58.4±13.2	57.9 ± 13.4	58 ± 2.8	59.7 ± 12.3	55.6 ± 13.6	56.8 ± 15.2
Gender:						
Male, n (%)	36(27.3)	5(14.3)	0	5(15.6)	48 (42.1)	46 (27.0)
Female, n (%)	96(72.7)	30(85.7)	1(100)	27(84.4)	66 (57.9)	124 (72.9)
Marital Status:						
Single, n (%)	47(35.6)	14(40)	1(100)	12(37.5)	35 (30.7)	69(40.5)
Married, n (%)	34(25.8)	7(20)	0	6(18.8)	32 (28)	37 (21.7)
Divorced, n (%)	7(5.3)	2(5.7)	0	2(6.3)	10 (8.8)	8 (4.7)
Widowed, n (%)	25(18.9)	7(20)	0	7(21.9)	10 (8.8)	20 (11.7)
Free-partnership, n (%)	19(14.4)	5(14.3)	0	5(15.6)	27 (23.7)	36 (21.1)
Nationality:						
Dominican, n (%)	127(96.2)	34(97.1)	1(100)	31(96.9)	110 (96.5)	164 (96.4)
Foreign citizen, n (%)	5(3.8)	1(2.9)	0	1(3)	4 (3.5)	6 (3.5)
Ethnicity:						
Hispanic Latino, n (%)	119(90.2)	33(94.3)	0	30(93.8)	96 (84.2)	144 (84.7)
Afro-latino, n (%)	12(9.1)	2(5.7)	1(100)	2(6.2)	18 (15.8)	25 (14.7)
White Caucasian, n (%)	1(0.8)	0(0)	0	0(0)	0 (0)	1 (0.5)
Religion:						
Christianity, n (%)	99(75)	25(71.4)	0	23(71.9)	75 (65.8)	127 (74.7)
Judaism, n (%)	0(0)	0(0)	0	0(0)	1 (0.9)	0 (0)
Agnostic, n (%)	7(5.3)	1(2.9)	0	1(3.1)	11 (9.6)	8 (4.7)
Atheism, n (%)	2(1.5)	1(2.9)	0	1(3.1)	5 (4.4)	7 (4.1)
Not specified, n (%)	24(18.2)	8(22.8)	1(100)	7(21.9)	22 (19.3)	28 (16.4)

Table 1. Sociodemographic variables according to medication adherence and disease burden (*continued*)

	Adherent, n(132), per weekly reason score	Adherent, n (35), per weekly amount score	Non adherent, n (1), per weekly reason score	Non adherent, n(32), per weekly amount score	Burden < 5, n (144)	Burden ≥ 5, n (170)
Occupation:						
Public/private service, n (%)	60(45.5)	16(45.7)	1(100)	13(40.6)	70 (61.4)	72 (43.3)
Housekeeping, n (%)	30(22.7)	8(22.9)	0	9(28.1)	20 (17.5)	47 (27.6)
Student, n (%)	5(3.8)	0(0)	0	1(3.1)	4 (3.5)	9 (5.2)
Retired, n (%)	21(15.9)	7(20)	0	6(18.8)	11 (9.7)	22 (12.9)
Other, n (%)	16(12.1)	4(11.4)	0	5(15.6)	9 (7.9)	20(11.7)
Insurance:						
Government/ contributive, n (%)	48(36.4)	8(22.9)	0	8(25)	45 (39.5)	52 (30.5)
Government/ subsidized, n (%)	69(52.3)	20(57.1)	1(100)	19(57.4)	42 (36.8)	85 (50)
Private insurance, n (%)	13(9.8)	4(11.4)	0	2(6.3)	18 (15.8)	24 (14.1)
International insurance, n (%)	0(0)	0(0)	0	0	2 (1.8)	0
Without insurance, n (%)	1(0.8)	0(0)	0	0	4 (3.5)	6 (3.5)
Retirement insurance, n (%)	1(0.8)	3(8.6)	0	2(6.3)	3 (2.6)	3 (1.76)
Education:						
Pre-school, n (%)	51(38.6)	14(40)	1(100)	12(37.5)	39 (34.2)	65 (38.2)
High school, n (%)	33(25)	8(22.9)	0	7(21.9)	35 (30.7)	46 (27.0)
College, n (%)	33(25)	9(25.7)	0	8(25)	29 (25.5)	44 (25.8)
None of the above, n (%)	15(11.4)	4(11.4)	0	5(1.6)	11 (9.6)	15 (8.8)

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Table 1. Sociodemographic variables according to medication adherence and disease burden (*continued*)

	Adherent, n(132), per weekly reason score	Adherent, n (35), per weekly amount score	Non adherent, n (1), per weekly reason score	Non adherent, n(32), per weekly amount score	Burden < 5, n (144)	Burden ≥ 5, n (170)
Past medical history**:						
Respiratory:						
Asthma, n (%)	6(4.5)	1(2.9)	0	1(3.1)	4 (2.7)	14 (8.2)
COVID-19, n (%)	0(0)	0(0)	0	0	2 (1.3)	0 (0)
Allergic rhinitis, n (%)	0(0)	0(0)	0	0	1 (0.69)	0 (0)
Tuberculosis, n (%)	1(0.8)	0(0)	0	0	1 (0.69)	0 (0)
Pneumonia, n (%)	1(0.8)	0(0)	0	0	0 (0)	4 (2.3)
Sinusitis, n (%)	2(1.5)	0(0)	0	0	0 (0)	1 (0.5)
Pulmonary edema, n (%)	2(1.5)	1(2.9)	0	1(3.1)	1 (0.69)	1 (0.5)
None, n (%)	120(90.9)	33(94.2)	0	30(93.8)	105 (72.9)	148 (87.0)
Cardiovascular:						
Hypertension, n (%)	14(10.6)	1(2.9)	0	1(3.1)	5 (4.4)	26 (15.2)
MI, n (%)	2(0.8)	0(0)	0	0	1 (0.9)	3 (1.7)
Unstable angina, n (%)	3(2.3)	0(0)	0	0	1 (0.9)	2 (1.1)
Stroke, n (%)	0(0)	0(0)	0	0	1 (0.9)	0 (0)
Ischemic heart disease, n (%)*	1(0.8)	1(2.9)	0	1(3.1)	1 (0.9)	1 (0.5)
Valvular disease, n (%)	1(0.8)	0(0)	0	0	1 (0.9)	0 (0)
Patent foramen ovale, n (%)	2(1.5)	1(2.9)	0	1(3.1)	0 (0)	1 (0.5)
Thrombotic event, n (%)*	0(0.8)	0(0)	0	0	0 (0)	1 (0.5)
Beri Beri, n (%)	1(0.8)	0(0)	0	0	0(0)	2 (1.1)
Unspecified arrhythmia, n (%)	1(0.8)	0(0)	0	0	1 (0.9)	3 (1.7)
Aortic aneurysm, n(%)	0(0)	0(0)	0	0	1 (0.9)	0 (0)
Peripheral vascular disease, n (%)	0(0)	0(0)	0	0	2 (1.8)	3 (1.7)
None, n (%)	107(81.1)	32(91.4)	0	29(90.7)	101 (88.4)	128 (75.2)

(*continued*)

Table 1. Sociodemographic variables according to medication adherence and disease burden (*continued*)

	Adherent, n(132), per weekly reason score	Adherent, n (35), per weekly amount score	Non adherent, n (1), per weekly reason score	Non adherent, n(32), per weekly amount score	Burden < 5, n (144)	Burden ≥ 5, n (170)
Endocrinology:						
Diabetes mellitus, n (%)	18(13.6)	1(2.9)	1(100)	1(3.1)	2 (1.8)	12 (7.0)
Pre-diabetic, n (%)	0(0)	0(0)	0	0	0 (0)	2 (0.5)
Hyperthyroidism, n (%)	1(0.8)	0(0)	0	0	1(0.9)	2 (1.1)
Hypothyroidism, n (%)	2(1.5)	1(2.9)	0	1(3.1)	2 (1.8)	6 (3.5)
Unspecified thyroid disease, n (%)	0(0)	0(0)	0	0	0 (0)	3 (1.7)
Thyroid nodule, n (%)	1(0.8)	1(2.9)	0	1(3.1)	2 (1.8)	6 (3.5)
PCOS, n (%)**	0(0)	0(0)	0	0	1 (0.9)	1 (0.5)
None, n (%)	110(83.3)	32(91.4)	0	29(90.7)	106 (92.8)	138 (81.1)

*SD= standard devia+tion.
**Possible multimorbodity: patients with more than one condition (% sum could be greater than 100%).

the mean age was approximately 58.4 years. The gender distribution showed a majority of female participants. Regarding marital status, the highest proportion was married individuals, while Dominican nationality and Hispanic Latino ethnicity were predominant.

Concerning religion, Christianity was the most prevalent. In terms of occupation, a significant portion of the participants were involved in public/private service. Government/contributive insurance was the most common type of insurance among the patients. Education-wise, a notable number had either completed pre-school or high school education.

Regarding the past medical history, the data sheds light on the patient's past medical history, a crucial aspect in understanding the health profile of the study participants. Notably, a substantial portion of the patients reported no prior history of respiratory or cardiovascular ailments, signifying a relatively healthy baseline. However, a noteworthy percentage had a history of diabetes mellitus, which could have potential implications for their current health status and treatment adherence.

Moreover, while the prevalence of certain cardiovascular conditions such as hypertension was relatively low, the data indicated a scattered presence of other cardiovascular issues like myocardial infarction and unstable angina among a small subset of patients. Additionally, there were some reported cases of endocrine disorders, including hyperthyroidism, hypothyroidism, and thyroid nodules, suggesting a varied spectrum of endocrine health within the cohort.

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Table 2 summarizes data on three key aspects: levels of adherence, burden, and the presence of multiple chronic conditions (multimorbidity). Adherence was measured using daily and weekly scores, with mean scores ranging from 1.0 to 3.8. The burden score per patient averaged 50.1, while the score per disease was 2.6. Morbidity analysis showed that 16.9% of participants were monomorbid, while 83.1% were multimorbid.

Table 3 reflects the most frequent reasons why the patients surveyed with the MAR-Scale, representing a total of 133 patients of which only 117 answered. When highlighting the 3 most frequent reasons; we can observe that the one that predominates is "they didn't have the money to pay for the medicine" in 13.53% of 18 patients. Followed by "would have used it but simply forgot about it" in 9.02% of 12 patients. At last, "didn't feel comfortable using it for personal reasons" with 9.02% equivalent to 12 patients.

Table 4 provides key insights into the burden caused by 6 of the diseases included within the DBMA on a patient's daily life. Even though the majority of patients recruited for this investigation show a lower average burden on their daily routines, those being patients with hypertension with an average burden of 1.66 ± 1.18, it is those patients with depression or anxiety problems that lead in burden levels with 3.52 ± 1.65, osteoporosis with 2.94 ± 1.35 and heart failure with 2.80 ± 1.83.

Table 5 provides valuable insights into the questionnaire reliability, measured through Cronbach's alpha. specifically focusing on the MAR-Scale and DBMA. The MAR-Scale, consisting of 68 items, demonstrates an average inter-item covariance of 0.3179353, which indicates a moderate level of consistency within the scale. The scale reliability coefficient, computed at 0.7829, further confirms a strong internal consistency, suggesting that the items within the MAR-Scale are reliably measuring the intended construct.

On the other hand, the DBMA, comprising 22 items, exhibits a notably lower average inter-item covariance of 0.0288156, proposing a weaker degree of correlation among the items in the scale. Consequently, the scale reliability coefficient for the DBMA is calculated to be 0.4265, indicating a moderate level of internal consistency.

These findings emphasize the need for careful interpretation of the results from the DBMA, considering its comparatively lower scale reliability coefficient and inter-item covariance. However, the robust reliability coefficient for the MAR-Scale underscores the high internal consistency of the questionnaire, implying its efficacy in accurately capturing and assessing the relevant parameters.

Table 2. Adherence, burden, and morbidity in patients with chronic diseases

Adherence*, n (133), mean +/- SD****	
Adherence by daily reasons score (0-49)	3.8 ± 9.2
Adherence by daily amount score (0-7)	1.8 ± 2.7
Adherence by weekly reasons score (0-52)	2.2 ± 7.6
Adherence by weekly amount score (0-4)	1.0 ± 1.5
Burden*, n (284), mean +/- SD**	
Score per patient (1-70)	50.1 ± 4.5
Per disease*** (1-5)	2.6 ± 0.6
Morbidity, n (284), n (%)	
Monomorbid	48 (16.9%)
Multimorbid	236 (83.1%)

Table 3. Most frequent reasons for non-adherence (n = 133)

Reasons for weekly non-adherence	Patients, n (%)
I didn't have the money to pay for the medicine.	18 (13.53%)
I would have used it but simply forgot about it.	12 (9.02%)
I have not felt comfortable using it for personal reasons.	12 (9.02%)
Concerns about long-term effects from the medicine	11 (8.27%)
I would have used it, but I forgot because I was too busy, or because of a change in routine.	9 (6.77%)
I didn't have the medication because the pharmacy or provider ran out of it.	8 (6.02%)
I worry about possible side effects of the medication.	8 (6.02%)
I don't think I need the medicine anymore.	6 (4.51%)
I would have used it, but I have difficulty remembering things in my daily life.	6 (4.51%)
I sometimes skip using the medication to see if I still need it.	5 (3.76%)
The medication is not a high priority in your daily routine.	4 (3.01%)
I have had side effects from the medicine.	4 (3.01%)
I think the medicine is not working for me.	4 (3.01%)
Difficulty opening container/getting the injection ready to use.	3 (2.26%)
I didn't have the medicine because I didn't have a way to get to the pharmacy or provider.	3 (2.26%)
Difficulty swallowing/difficulty injecting the medicine.	3 (2.26%)
Problems managing all prescribed medications.	1 (0.75%)
I have not felt comfortable using it for social reasons.	0
Not sure how to take the medicine.	0

Table 4. Burden per disease affecting patients (n = 284)

Chronic Disease	Number of Patients *, n(%)	Burden, mean ± SD
Depression or anxiety problems	33 (11.62%)	3.52 ± 1.65
Osteoporosis	17 (5.99%)	2.94 ± 1.35
Heart failure	5 (1.76%)	2.80 ± 1.83
Heartburn or peptic ulcer	31 (10.92%)	2.77 ± 1.58
Cancer**	8 (2.82%)	2.75 ± 1.64
Hypertension	203 (71.48%)	1.66 ± 1.18

* Percentage exceeds 100% due to multimorbidity.** Within the last 5 years (including melanoma, but excluding all other skin cancers).

Table 5. Questionnaire reliability by Cronbach's alpha

	MAR-Scale	DBMA
Average inter-item covariance	0.3179353	0.0288156
Number of the items in the scale	68	22
Scale reliability coefficient (Cronbach's alpha)	0.7829	0.4265

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Conclusion

Key results

Notably, a significant portion of patients reported no history of respiratory or cardiovascular disease, indicating a relatively healthy baseline. However, a notable proportion had a history of diabetes, which could have a potential impact on their current health status and treatment adherence.

It has been demonstrated that patients who are non-compliant with medical treatment are between 58 and 59 years old. Careful interpretation of DBMA results, based on relatively lower scale reliability coefficients and inter-item covariance. However, the high-reliability coefficient of the MAR scale highlights the high internal consistency of the questionnaire, implying its effectiveness in accurately capturing and assessing relevant parameters.

Discussion

As indicated above, a slight majority of single patients presented with burden levels above 5 (indicating both multimorbidity and elevated burden per disease) and were less adherent per weekly reason and amount score, which is not surprising due to the published literature highlighting that unmarried individuals have an excess risk of elevated burden, mortality, and the possibility that economic burden in single patients could affect pharmacological adherence[11]. Also, education showed the same pattern as unmarried patients with those with only a preschool education having higher adherence scores (i.e. less adherent) and the majority being at a burden above 5, detailing the importance of education to understand patterns of adherence and disease burden, which has been studied extensively with similar findings[12 13]. Patients with asthma, arterial hypertension, and diabetes mellitus reported higher nonadherence

and higher burden than those with other respiratory, cardiovascular, and endocrine diseases. However, the low frequency of patients with other diseases and the fact that these three pathologies were the most commonly found in each category could also explain the said finding.

Regarding the most frequent reasons for nonadherence, "I didn't have the money to pay for the medicine" was frequently cited as a reason for nonadherence. As said before, the economic status of unmarried patients could be a factor. However, adjusted models have also shown that both extremes (low-income and high-income) are associated with poor and good pharmacological adherence, respectively[14 15]. The other two most frequent reasons were "I would have used it but simply forgot about it" and "I have not felt comfortable using it for personal reasons". For the first reason, pharmacological education and factors leading to poor recognition of of when to take the medication need to be explored. Regarding the possible personal reasons, the study did not ask whether these were related to possible side effects (although there are options that ask about concern over long-term side effects) that the patient might've presented during the current treatment.

Exploring burden as a measure of the patient's inability to cope with daily activities, it's found that depression or anxiety problems (without differentiating both), osteoporosis, and heart failure had the highest mean burden levels. These findings, alongside those of Santomauro et al., show that mental health is rapidly transitioning as a debilitating factor in patients with chronic diseases in the modern age[16]. Osteoporosis's elevated burden could be related to poor adherence, leading to disease progression. Another fact to consider is osteoporosis being part of a larger disease process that could also impact the patient self-reported burden. Heart failure, its chronicity, and complex treatment create a difficult sce-

nario for patients to maintain an adequate quality of life with a manageable disease burden. However, more data from disease processes, drug adherence, and disease burden from developing countries such as the Dominican Republic, is needed for diseases such as heart failure[17].

Both the DBMA and the MAR-Scale were assessed for reliability in the Dominican population. Having already been tested in different populations[10], seeking to test reliability would give a more robust view of the findings of A-CaMo I and the feasibility to be used for later interactions of the study. Cronbach's alpha results for the MAR-Scale were higher than the DBMA, possibly, due to the MAR-Scale having more items in the scale, it provides for testing pharmacological adherence with a broader margin. In comparison, the DBMA has fewer items to test for disease burden, and as such, less reliability coefficient. By stating the number of items per test and the questionnaire's alpha, it is not implying that both values are correlated positively, but stating that the more items per scale, the more accurate the measure can be. Another factor to weigh in is the study population. The reliability of an instrument is also linked to the variability of the study population, the pattern of response, and even the way the sample is selected. Therefore, all the aforementioned elements need to be taken into consideration when evaluating the study's Cronbach's alpha results.

Limitations

Though the majority of patients reside in the Constelacion and Jardines del Norte neighbourhoods, the lack of a patient recording system within the primary care center resulted in the inclusion of patients who live in other neighborhoods. Compounded with the low patient flow, the data collection process was prolonged beyond the established time frame, leading to the conclusion of the investigation with a total of 284 patients due to difficulty in gathering an adequate amount of data. Also, patients with multiple health conditions (multimorbidity) posed a challenge in data analysis due to the variability of treatment and medication administration patterns. Another key aspect that could impact the study's generalizability is that patients were selected based on a convenience sampling, which could introduce selection bias and decrease the study's external validity.

The study excluded patients with mental disorders and learning disabilities due to their impairment to be able to accurately complete the study's data collection process, however it could also lead to decreased generalizability of the study's findings.

To conclude, the study sought to measure three different components of a patient's health profile: adherence, which has become a challenge for both patients and clinicians to maintain adequately; burden, which could reflect to a degree, the amount of debilitation the patient attributes to their disease affecting their daily life; and morbidity, the current state of health measured as a single-disease or multi-diseased patient. The study's findings need to be analyzed and compared with other published data, with consideration that several cultural characteristics can account for both similarities and differences. All three variables need to be explored both individually and as co-dependent in future studies to understand how their behavior could predict disease control, disease progression, and a patient's quality of life.

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Attachments

A. Socio-demographic form

Número de registro: _____

1. Edad: ____
2. Teléfono: _____
3. Correo electrónico: _____
4. Dirección: _____
5. Sexo (Es la identidad sexual genital y biológica)
    1. Masculino
    2. Femenino
    3. Otros (Especificar tipo de estado inter-sexual) _____

6. Género (La forma en la cual el sujeto se identifica a sí mismo y se expresa hacia su prójimo)
    1. Hombre
    2. Mujer
    3. Otro: _____

7. Estado civil
    1. Soltero/a
    2. Casado/a
    3. Unión libre
    4. Divorciado/a
    5. Viudo/a

8. Lugar de nacimiento
    1. Dominicano/a
    2. Extranjero/a

9. Etnia
    1. Asiaticos
    2. Afrolatinos
    3. Hispanos latinos
    4. Blanco caucasico
    5. Otros: _____

10. Religión
    1. Cristianismo
    2. Judaísmo
    3. Hinduismo
    4. Islam
    5. Ateísmo

6. Agnóstico
7. Otra: _____

11. Ocupación
    1. Estudiante
    2. Trabajador/a
    3. Amo/a de casa
    4. Otra: _____

12. Seguro médico
    1. Sí
    2. No

13. Si la respuesta fue sí, ¿Cubre su seguro médico el costo parcial o total de sus medicamentos?
    1. Sí
    2. No

14. Nivel educativo
    1. Primaria
    2. Bachiller
    3. Superior
    4. Ninguna de las anteriores

15. Ingreso económico (mensual)
    1. Menos de 6,000RD$
    2. 6,000-15,000 RD$
    3. 15,000-75,000 RD$
    4. Más de 75,000 RD$

16. Enfermedad que padece: _____

17. Tiempo de diagnóstico de la enfermedad: _____

18. ¿Qué tiempo lleva tomando la medicación? _____

Antecedentes patológicos

19. ¿Tiene usted algún antecedente patológico respiratorio?
    1. Sí
    2. No

20. Si su respuesta fue sí, ¿cuál es el antecedente patológico? _____

21. ¿Tiene usted algún antecedente patológico cardiovascular?
    1. Sí
    2. No

22. Si su respuesta fue sí, ¿cuál es el antecedente patológico? _____

23. ¿Tiene usted algún antecedente patológico endocrinológico?
    1. Sí
    2. No

24. Si su respuesta fue sí, ¿cuál es el antecedente patológico? _____

25. ¿Tiene usted algún antecedente patológico quirúrgico?
    1. Sí
    2. No

26. Si su respuesta fue sí, ¿cuál es el antecedente patológico? _____

27. ¿Tiene usted algún antecedente patológico relacionado con transfusiones sanguíneas?
    1. Sí
    2. No

28. Si su respuesta fue sí, ¿cuál es el antecedente patológico? _____

29. ¿Tiene usted algún antecedente patológico infeccioso (VIH, Hepatitis, enfermedad de transmisión sexual)?
    1. Sí
    2. No

30. Si su respuesta fue sí, ¿cuál es el antecedente patológico? _____

B. MAR-Scale Adherence Level Form

ESCALA DE MOTIVOS DE CUMPLIMIENTO DEL TRATAMIENTO FARMACOLÓGICO (MAR-SCALE, MEDICATION ADHERENCE REASONS SCALE)

Ha indicado que actualmente usa un medicamento o más de venta con receta para **<afección>**. Ahora nos gustaría hacerle algunas preguntas más sobre cómo usa el (los) medicamento(s).

(P1) En las siguientes preguntas, piense en su(s) medicamento(s) **DE USO DIARIO** para **<afección>** (es decir, medicamentos recetados para ser usados todos los días). Estos medicamentos incluyen:

En los últimos **7 días**, ¿por cuáles de los siguientes motivos **NO** ha usado el (los) medicamento(s) indicado(s) anteriormente cómo se le había(n) recetado?

(P2) Ha indicado que **NO** pudo usar el (los) siguiente(s) medicamento(s) **DE USO DIARIO** para **<afección>** como se le habían recetado:

En los últimos **7 días**, ¿cuántos días **NO** pudo usar el (los) medicamento(s) indicado(s) anteriormente como se le habían recetado, por cada uno de los siguientes motivos?

		Sí (Me he saltado el (los) medicamento(s) debido a este motivo **durante los últimos 7 días**)	No (No me he saltado el (los) medicamento(s) debido a este motivo **durante los últimos 7 días**)
1	He sufrido efectos secundarios del medicamento.		
2	No tenía dinero para pagar el medicamento.		
3	No me he sentido cómodo(a) usándolo por motivos personales (p. ej., cansado(a) de tomar el medicamento, demasiado enfermo(a), mis creencias religiosas).		
4	No me he sentido cómodo(a) usándolo por motivos sociales (p. ej., estaba con mis amigos).		
5	Creo que ya no necesito el medicamento.		
6	Creo que el medicamento no está funcionando en mi caso.		
7	A veces me salto el uso del medicamento para ver si todavía me hace falta.		
8	Me preocupan los posibles efectos secundarios del medicamento.		
9	Me preocupan los efectos a largo plazo del medicamento.		
10	He tenido dificultad para abrir el envase, o he tenido dificultad para preparar la inyección (p. ej., abrir el paquete, mezclar los contenidos, sacar el medicamento).		
11	He tenido dificultad para tragar, aplicar, inhalar o inyectar el medicamento (p. ej., miedo a las agujas, problemas físicos o sensoriales).		
12	No tenía el medicamento porque a la farmacia o al proveedor se les había acabado, a mí no me quedaban repuestos o el pedido por correo no llegó a tiempo.		
13	No tenía el medicamento porque no tuve cómo desplazarme hasta la farmacia o el proveedor.		
14	No estoy seguro(a) de cómo se usa este medicamento.		
15	Tengo problemas para gestionar todos los medicamentos que tengo que usar.		
16	Lo habría usado, pero tengo dificultad para recordar cosas en mi vida cotidiana.		
17	Lo habría usado, pero se me olvidó porque estaba muy ocupado(a), o debido a un cambio de rutina.		
18	Lo habría usado, pero sencillamente se me olvidó.		
19	No considero que usar el medicamento tenga una prioridad alta en mi rutina cotidiana.		

		1 día	2 días	3 días	4 días	5 días	6 días	7 días (me salté el uso del medicamento en la totalidad de los 7 días debido a este motivo)
1	He sufrido efectos secundarios del medicamento.	1	2	3	4	5	6	7
2	No tenía dinero para pagar el medicamento.	1	2	3	4	5	6	7
3	No me he sentido cómodo(a) usándolo por motivos personales (p. ej., cansado(a) de tomar el medicamento, demasiado enfermo(a), mis creencias religiosas).	1	2	3	4	5	6	7
4	No me he sentido cómodo(a) usándolo por motivos sociales (p. ej., estaba con mis amigos).	1	2	3	4	5	6	7
5	Creo que ya no necesito el medicamento.	1	2	3	4	5	6	7
6	Creo que el medicamento no está funcionando en mi caso.	1	2	3	4	5	6	7
7	A veces me salto el uso del medicamento para ver si todavía me hace falta.	1	2	3	4	5	6	7
8	Me preocupan los posibles efectos secundarios del medicamento.	1	2	3	4	5	6	7
9	Me preocupan los efectos a largo plazo del medicamento.	1	2	3	4	5	6	7
10	He tenido dificultad para abrir el envase, o he tenido dificultad para preparar la inyección (p. ej., abrir el paquete, mezclar los contenidos, sacar el medicamento).	1	2	3	4	5	6	7
11	He tenido dificultad para tragar, aplicar, inhalar o inyectar el medicamento (p. ej., miedo a las agujas, problemas físicos o sensoriales).	1	2	3	4	5	6	7

12	No tenía el medicamento porque a la farmacia o al proveedor se les había acabado, a mí no me quedaban repuestos o el pedido por correo no llegó a tiempo.	1	2	3	4	5	6	7
13	No tenía el medicamento porque no tuve cómo desplazarme hasta la farmacia o el proveedor.	1	2	3	4	5	6	7
14	No estoy seguro(a) de cómo se usa este medicamento.	1	2	3	4	5	6	7
15	Tengo problemas para gestionar todos los medicamentos que tengo que usar.	1	2	3	4	5	6	7
16	Lo habría usado, pero tengo dificultad para recordar cosas en mi vida cotidiana.	1	2	3	4	5	6	7
17	Lo habría usado, pero se me olvidó porque estaba muy ocupado(a), o debido a un cambio de rutina.	1	2	3	4	5	6	7
18	Lo habría usado, pero sencillamente se me olvidó.	1	2	3	4	5	6	7
19	No considero que usar el medicamento tenga una prioridad alta en mi rutina cotidiana.	1	2	3	4	5	6	7

(P3) En los últimos **7 días, ¿cuántos días pudo** usar su(s) medicamento(s) **DE USO DIARIO** para **<afección>** exactamente como se le habían recetado? Estos medicamentos incluyen:

0 días (no he usado el (los) medicamento(s) en los últimos 7 días)	1 día	2 días	3 días	4 días	5 días	6 días	7 días (he usado el (los) medicamento(s) en la totalidad de los últimos 7 días)
0	1	2	3	4	5	6	7

Over the last 4 weeks were you NOT able to take XXX as prescribed for each of the following reasons?
- 0 week (this was not a reason for missing the medicine)
- 1 week
- 2 weeks
- 3 weeks
- 4 weeks (Missed taking the medicine on all 4 weeks due to this reason)

Over the last 4 weeks, how many weeks were YOU ABLE TO take XXX exactly as prescribed?
- 0 week (have not taken the medicine or medicines in the last 4 weeks)
- 1 week
- 2 weeks
- 3 weeks
- 4 weeks (took the medicine or medicines on all of the 4 weeks)

DBMA Morbidity and Burden Form

Additional file 1
English version of the questionnaire

QUESTIONNAIRE ABOUT YOUR HEALTH
CONDITION
INSTRUCTIONS

This questionnaire evaluates your health condition. It contains a list of 22 chronic health problems. Please, answer to the best of your knowledge. If you have a health problem; you must think about how the problem affects your daily activities. Note: you should be as specific as possible.

Do not forget to include treated diseases or those that are controlled for. It could

be helpful to think of the medications that you currently take or treatments that

you have received.

NB. The expression "daily activities" refers to the activities that a person of your age takes part in every day.

Thanks for your collaboration.

1. Do you suffer from **hypertension** (high blood pressure)?: ☐ NO ☐ YES
If yes, how much is this problem limiting you in your daily activities?
Limitation:
☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

2. Do you suffer from a **cholesterol problem**?: ☐ NO ☐ YES
If yes, how much is this problem limiting you in your daily activities?
Limitation:
☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

3. Do you suffer from **asthma**? ☐ NO ☐ YES
If yes, how much is this problem limiting you in your daily activities?
Limitation:
☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

4. Do you suffer from a **pulmonary problem** (**chronic bronchitis or emphysema**)?:
☐ NO ☐ YES
If yes, how much is this problem limiting you in your daily activities?
Limitation:
☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

5. Do you suffer from **diabetes**?: ☐ NO ☐ YES
If yes, how much is this problem limiting you in your daily activities?
Limitation:
☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

6. Do you suffer from **thyroid disorder**? ☐ NO ☐ YES
If yes, how much is this problem limiting you in your daily activities?
Limitation:
☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

2

Questions 7 to 11 refer to diseases that affect the spine (vertebral column) and joints.

The disease has to have been diagnosed by a doctor to answer YES to a question.

Note: Be careful not to answer YES to more than one question to indicate one disease

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7. Do you suffer from **osteoarthritis**?: ☐ NO ☐ YES

If yes, how much is this problem limiting you in your daily activities?

Limitation:

☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

8. Do you suffer from **rheumatoid arthritis**? ☐ NO ☐ YES

If yes, how much is this problem limiting you in your daily activities?

Limitation:

☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

9. Do you suffer from persistent **back pain or sciatic pain** (excluding osteoarthritis)?:

☐ NO ☐ YES

If yes, how much is this problem limiting you in your daily activities?

Limitation:

☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

10. Do you suffer from **osteoporosis**? ☐ NO ☐ YES

If yes, how much is this problem limiting you in your daily activities?

Limitation:

☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

11. Do you suffer from **ANOTHER illness that affects the members or**
the articulations for more than 6 months (example: **tendonitis, bursitis,**
fibromyalgia, lupus, etc.)?

☐ NO ☐ YES

If yes, how much is this problem limiting you in your daily activities?

Limitation:

☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

12. Do you suffer from reflux or **heartburn or peptic ulcer**? ☐ NO ☐ YES

If yes, how much is this problem limiting you in your daily activities?

Limitation:

☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

13. Do you suffer from an **intestine problem (example: irritable bowel syndrome, Crohn disease, ulcerative colitis, diverticulosis, etc.)**?

☐ NO ☐ YES

If yes, how much is this problem limiting you in your daily activities?

Limitation:

☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

14. Do you suffer from a **circulatory problem in your legs**? ☐ NO ☐ YES

If yes, how much is this problem limiting you in your daily activities?

Limitation:

☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

15. Do you suffer from **overweight**? ☐ NO ☐ YES

If yes, how much is this problem limiting you in your daily activities?

Limitation:

☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

16. Do you suffer from an **audition problem (hard of hearing)?** ☐ NO ☐ YES

If yes, how much is this problem limiting you in your daily activities?

Limitation:

☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

4

17. Do you suffer from a **vision problem even though you wear glasses**? ☐ NO ☐ YES
If yes, how much is this problem limiting you in your daily activities?
Limitation:
☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

18. Do you suffer from **cardiac illnesses (e.g.: angina, infarction, dilation, artery bypass, angioplasty, etc.)**?
☐ NO ☐ YES
If yes, how much is this problem limiting you in your daily activities?
Limitation:
☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

19. Did you suffer from a **CVA (cerebrovascular accident)?** ☐ NO ☐ YES
If yes, how much is this problem limiting you in your daily activities?
Limitation:
☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

20. Do you suffer from **heart failure (diagnosis confirmed by your doctor)?** ☐ NO ☐ YES
If yes, how much is this problem limiting you in your daily activities?
Limitation:
☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

21. Did you suffer from a **cancer in the 5 last years (including melanoma, but excluding all other skin cancers)?**
☐ NO ☐ YES

If yes, how much is this problem limiting you in your daily activities?
Limitation:
☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

22. Do you suffer from **depression or anxiety problems**?
☐ NO ☐ YES
If yes, how much is this problem limiting you in your daily activities?
Limitation:
☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot
Do you suffer from ANOTHER or MANY OTHER chronic health problems
That weren't mentioned above?
☐ NO ☐ YES

If yes, name them and indicate how much each problem is limiting you in your daily activities:
1. _____

☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

2. _____

☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

3._____

☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ A lot

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C. Consent form

<div align="center">

CONSENTIMIENTO INFORMADO
INSTITUTO TECNOLÓGICO DE SANTO DOMINGO
"ADHERENCIA FARMACOLÓGICA, CARGA Y MORBILIDAD EN PACIENTES CON ENFER-MEDADES CRÓNICAS EN SANTO DOMINGO, REPÚBLICA DOMINICANA DURANTE EL PERIODO FEBRERO- ABRIL 2023"

</div>

Asesor: Dr. Ramón Romano, doctor en medicina
Coordinador(es): Br. Shamelle López; Br. Michael Richardson
Subcoordinador(es): Br. Isabella Gutiérrez; Br. Génesis Vegazo; Br. Laura Reyes
Colaboradores: Br. Arthur Leyba; Br. Juan Espaillat; Br. Laura Díaz; Br. Ruben Bleubar; Br. Erika Alcántara; Br. Rosaliz Piña

Ha sido invitado a participar en una investigación acerca de la adherencia farmacológica, carga y morbilidad en pacientes con enfermedades crónicas incluidas en la MAR-Scale y el DBMA, en un centro de atención primaria de Santo Domingo, República Dominicana.

Favor leer este consentimiento con detenimiento antes de aceptar participar en este estudio.

Este estudio está dirigido para personas mayores o iguales a 18 años que padezcan alguna enfermedad crónica presente en la *MAR-Scale* o el *DBMA*, residentes entre Constelación y Los Jardínes del Norte, que asisten a una Unidad de Atención Primaria (UNAP) en Santo Domingo, República Dominicana. Si acepta ser parte de este estudio, se le pedirá que responda a varios cuestionarios digitalizados con diversas preguntas. El **primer cuestionario** consistirá de 10 preguntas sobre su información sociodemográfica, las cuales engloban los siguientes aspectos: número de registro, edad, sexo, seguro médico, religión, tiempo de diagnóstico de la enfermedad, nivel de escolaridad y nacionalidad. El **segundo cuestionario** consiste de preguntas relacionadas con el grado de cumplimiento a los medicamentos que toma para la enfermedad y, por último, un **tercer cuestionario** de 22 preguntas relacionadas con las condiciones de salud. En cada cuestionario usted tendrá la posibilidad de contestar las preguntas, seleccionando las opciones que representen a su persona. De presentar dudas, se encuentra en el derecho de hacer preguntas y podrá retirarse en cualquier momento sin que sea perjudicado, y sin que sus datos sean utilizados en la investigación; de sentirse incómodo con alguna de las preguntas o por cualquier otro motivo, tiene derecho de indicar al investigador para que pueda recibir asistencia. Al finalizar, usted es libre de retirarse.

La confidencialidad de sus datos e información será protegida en todo momento y no se colocará su nombre en la investigación. En cambio, se le colocara un ID al inicio de su formulario y si usted desea recibir un email con las respuestas que dio, este se le será proporcionado. Sin embargo, es importante destacar que la información recolectada en esta investigación puede ser compartida con otros investigadores que sean parte del estudio, pero no se compartirá ninguna información que pueda revelar su identidad. La información recolectada será eliminada 8 meses después del inicio de esta.

La protección más importante de su información, es que los miembros del equipo de investigación no pueden ser forzados a revelar o proporcionar ninguna de sus informaciones privadas e identificables en ningún procedimiento federal, estatal, civil, criminal, administrativo, legislativo o de cualquier otra índole a no ser que usted provea su consentimiento.

Si usted tiene alguna duda sobre esta investigación, favor contactar al Dr. Ramón Romano, autor, al correo anthonyromanop@icloud.com (o a su número telefónico 809-860-5326).

Al firmar este documento, usted acepta formar parte del estudio presente. Asegúrese de haber comprendido de qué se trata la investigación antes de firmar. Se guardará otra copia para los archivos del estudio. Si tiene alguna pregunta sobre el estudio después de haber firmado, puede contactar al equipo de estudio usando la información dada anteriormente.

Si desea participar en la investigación por favor firme a continuación. Gracias.

He leído el procedimiento descrito anteriormente. Voluntariamente acepto participar en el proceso de este estudio.

Nombre legal: _____

Cédula: _____

Firma: _____

Fecha (dd/mm/aa): _____

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D. Ethics committee approval of the study

HOSPITAL
PEDIÁTRICO DR. HUGO MENDOZA
RNC. 4-30-13509-7

PREMIO IBEROAMERICANO DE LA CALIDAD
FUNDIBEQ
PREMIO ORO 2019

Gran Premio Nacional a la Calidad 2017

Comité de Ética de la Investigación

CERTIFICA

Que el proyecto de investigación titulado **"ADHERENCIA FARMACOLÓGICA, CARGA Y MORBILIDAD EN PACIENTES CON ENFERMEDADES CRÓNICAS EN SANTO DOMINGO, REPÚBLICA DOMINICANA"**, cuyo investigador principal en la República Dominicana es el **Dr. Ramon Romano.**

El proyecto no implica investigación en seres humanos, se encuentra ajustado a las Pautas Éticas Internacionales para la Investigación Biomédica en Seres Humanos preparadas por el Consejo de Organizaciones Internacionales de las Ciencias Médicas (CIOMS) en colaboración con la Organización Mundial de la Salud, así como también los principios de la Declaración de Helsinki de la Asociación Médica Mundial aprobada en su 18ª Asamblea General.

La categoría de riesgo a los seres humanos que ofrece la propuesta pertenece a la de <nula>. Sobre el posible impacto en el medio ambiente, el comité conceptúa que, por la naturaleza de la investigación, el proyecto no tiene efectos negativos sobre el medio ambiente dada la naturaleza de la investigación y en cumplimiento con las normas establecidas y en la cual se tiene previsto actividades de análisis de datos.

Con base en lo expresado anteriormente, el Comité de Ética de la Investigación conceptúa que el proyecto cumple con todos los requisitos de calidad exigidos y en consecuencia otorga su aprobación. El respectivo concepto se consigna en el acta de la correspondiente sesión.
Se expide esta certificación el 10 de febrero del 2023 en la ciudad de Santo Domingo, República Dominicana por el Comité de Ética de Investigación representado por:

Dr. Demian Herrera

Av. Konrad Adenauer (Pról. Charles de Gaulle), Ciudad Sanitaria Dra. Evangelina Rodríguez, Santo Domingo Norte, R.D. | 809-568-8222 | info@hhm.gob.do

INTECO
CERTIFIED MANAGEMENT SYSTEM
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METROPOLITANO SRS

Premio a los Derechos Humanos

E. Letter from the clinic approving the study

Dr. Fernando Santa María
Instituto Tecnológico de Santo Domingo (INTEC)

08 de febrero del 2023

Dr. Demian Arturo Herrera Morban

Centro de Investigación Dr. Hugo Mendoza
Hospital Pediátrico Dr. Hugo Mendoza
Santo Domingo, República Dominicana

Distinguido Dr. Herrera Morban, saludos cordiales.

Nos comunicamos por esta vía para hacer constancia del proyecto de investigación *"Adherencia farmacológica, carga y morbilidad en pacientes con enfermedades crónicas en Santo Domingo, República Dominicana - estudio A-CaMo"* se realizará en el Centro de Atención Primaria Dra. Evangelina Rodríguez. El proyecto A-CaMo obtuvo la aprobación otorgada por el comité de investigación del proyecto BioINTEC, y una vez presentado a los coordinadores del centro de atención primaria, fue aprobado para su realización. El estudio está en autoría del Dr. Ramón Romano, la Dra. Gabriella Anzani, la Dra. Ana Lebrón, y los bachilleres Michael Stevens Richardson, Shamelle López, Isabella Gutiérrez, Génesis Vegazo, Laura Reyes, Juan Espaillat, Arthur Leyba, Ruben Bleubar, Erika María, Rosaliz Piña, y Laura Díaz.

Esta investigación se procederá utilizando la escala **Medication Adherence Reasons Scale (MAR-Scale,** por sus siglas en inglés**)** para medir adherencia farmacológica y el **Disease, Burden, Morbidity Assessment** (**DBMA**, por sus siglas en inglés) para medir la carga y morbilidad, ambas en enfermedades crónicas. El proyecto BioINTEC por igual se comunicó con el centro para solicitar la asistencia de estudiantes de medicina con fin de recolectar los datos, la cual por igual, fue aprobada.

Quedo a la orden ante cualquier duda, se despide,

Dr. Fernando Santamaría
Coordinador académico de la carrera de Medicina
Instituto Tecnológico de Santo Domingo (INTEC)