



Study of chronic diseases from the perspective of health quality: methodological aspects

Estudo das doenças crônicas sob a ótica da qualidade em saúde: aspectos metodológicos

Thatiana Lameira Maciel Amaral¹, Aline Fernanda Silva Sampaio¹, Cledir de Araújo Amaral², Margareth Crisóstomo Portela³, Gina Torres Rego Monteiro⁴, Maurício Teixeira Leite de Vasconcellos⁵

¹ Centro de Ciências da Saúde e do Desporto. Programa de Pós-Graduação em Saúde Coletiva da Universidade Federal do Acre. Rio Branco (AC), Brasil.

² Campus Rio Branco. Mestrado Profissional em Educação Profissional e Tecnológica em Rede Nacional (PROFEPT) do Instituto Federal de Educação, Ciência e Tecnologia do Acre. Rio Branco (AC), Brasil.

³ Departamento de Saúde Pública. Programa de Pós-Graduação em Saúde Pública da Fundação Oswaldo Cruz, Escola Nacional de Saúde Pública Sérgio Arouca. Rio de Janeiro (RJ), Brasil.

⁴ Departamento de Saúde Pública e Meio Ambiente. Programa de Pós-Graduação em Saúde Pública e Meio Ambiente da Fundação Oswaldo Cruz, Escola Nacional de Saúde Pública Sérgio Arouca. Rio de Janeiro (RJ), Brasil.

⁵ Escola Nacional de Ciências Estatísticas Pesquisador da Fundação Instituto Brasileiro de Geografia e Estatística, Rio de Janeiro (RJ), Brasil.

*Corresponding Author: Thatiana Lameira Maciel Amaral – *E-mail*: thatianalameira27@gmail.com

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ABSTRACT

To describe the methodological aspects and sample design of the Study of Chronic Diseases from the perspective of quality in health (Edoc-Quali). The study consisted of surveys of four distinct populations: coordinators of Primary Health Care units, professionals from the Family Health Strategy (FHS) teams, arterial hypertension patients registered with the FHS, and type 2 diabetes mellitus patients registered with the FHS. Participants were 30 managers and 338 professionals who answered perceptions of the physical structure and work processes of the team using the PCATool-Brasil and data related to the care process for these patients. Interviews were also made with 672 people with arterial hypertension and 324 with DM2, who underwent physical assessment and electrocardiogram and had biological material collected. The assessment of the quality of care by managers and professionals and the results obtained from service users contribute to the control of complications.

Keywords: Diabetes mellitus. Chronic disease. Methodological study. Arterial hypertension. Quality of health care.

RESUMO

Descrever os aspectos metodológicos e desenho amostral do Estudo das Doenças Crônicas sob a ótica da qualidade em saúde (Edoc-Quali). O estudo é composto por pesquisas de quatro populações distintas: coordenadores das unidades da Atenção Primária em Saúde; profissionais das equipes da Estratégia de Saúde da Família (ESF); usuários cadastrados nas ESFs com hipertensão arterial; e usuários cadastrados nas ESFs com diabetes *mellitus* do tipo 2. Participaram 30 gestores e 338 profissionais, que responderam percepções sobre estrutura física e processo de trabalho da equipe, com aplicação do PCATool-Brasil, e dados relativos ao processo de cuidado a esses pacientes. Também foram entrevistadas 672 pessoas com HAS, e 324 com DM2, além de avaliação física, coleta de material biológico e realização do eletrocardiograma. A avaliação da qualidade do cuidado segundo os gestores e profissionais e dos resultados obtidos junto aos usuários do serviço favoreceu o controle de complicações.

Palavras-chave: Diabetes *mellitus*. Doenças crônicas. Estudo metodológico. Hipertensão arterial. Qualidade da assistência à saúde.



INTRODUCTION

The Study of Chronic Diseases (Edoc), started in 2014, evaluated the health conditions of two populations in Rio Branco (state of Acre): adults (18 to 59 years old) and elderly people (60 years old and over). For this, two independent household samples were selected, as described by Amaral¹. Their results showed a high prevalence of systemic arterial hypertension (AHT)² and type 2 diabetes mellitus (DM)³. For both adults and the elderly, there was a high frequency of chronic kidney disease^{4,5}, in addition to other comorbidities⁶⁻¹³. These data led to questions about the quality of services offered by the municipality's public network, the answers to which were beyond the limits of the data collected.

The search for knowledge about the quality of health offered to a population with permanent care needs and which has a direct impact on morbidity and mortality rates in the country – as is the case of hypertensive and diabetic patients, whose risk of cardiovascular complications is increasing – has become an interest important aspect of Edoc-Quali. We then sought to evaluate the quality of services offered by primary health care (PHC), the preferred gateway to the Unified Health System (SUS).

The Study of Chronic Diseases from the Perspective of Health Quality (Edoc-Quali) was then born in Rio Branco, a municipality with two districts, 44 PHC units, and a total of 68 Family Health Strategy (FHS) teams. It consists of surveys of four distinct populations: coordinators of PHC units; professionals from the FHS teams, arterial hypertension patients registered with the FHS, and type 2 diabetes mellitus patients registered with the FHS served by this program. For operational and cost reasons, Edoc-Quali was limited to the urban area of the municipality.

The objective of these studies was to describe the methodological aspects and sampling design of Edoc-Quali to contribute to the elucidation of the obstacles faced by FHS managers and professionals, aiming to improve PHC. Despite being independent, the four studies share part of the objectives and methods. For the population of coordinators and professionals working in the FHS during the period investigated, it was conducted a census survey. In the case of users with AHT or type 2 DM, probabilistic samples were selected with two selection stages: ESF unit and users.

The project relating to this research was approved by the Research Ethics Committee of the Federal University of Acre under approval opinions 2.753.401 and 2.574.391. All participants signed the Informed Consent (IC).

RESEARCH WITH MANAGERS AND PROFESSIONALS

The survey with managers was carried out between April and May 2019 to interview all coordinators of PHC units with at least four months of experience. Each unit has a coordinator (manager) and one or more FHS teams. Of the 44 units in Rio Branco, 38 were located in the urban area and formed the Edoc-Quali universe. Among the coordinators, two were on vacation during the study period, two were on leave, three had held the position for less than four months, and one refused to participate. As a result, 30 coordinators were interviewed.

Interviews were conducted in calm environments to provide conditions conducive to their development on previously scheduled days and times and with guaranteed confidentiality of responses. An electronic questionnaire composed of three parts was used:

- (1) sociodemographic data and data relating to the training and professional insertion of managers;
- (2) perceptions of the physical structure and work processes of the team using the PCATool-Brazil, version for health professionals, including 77 items divided into eight components: first-contact access - accessibility (9 items); longitudinality (13 items); coordination - integrated care (6 items); coordination - information system (3 items); Comprehensiveness - available services (22 items); Comprehensiveness - services provided (15 items); family orientation (3 items); and community orientation (6 items)¹⁴;
- (3) data relating to the initial care process for patients with hypertension or type 2 DM, including cardiovascular risk assessment, non-drug and drug interventions, and requests for complementary exams.

The survey with professionals from the FHS teams was carried out between April and May 2019, and those with a weekly workload of less than or equal to 20 hours, those who did not work in caring for patients with AHT and type 2 DM, and those who were away or on vacation were considered ineligible. Interviews were conducted in calm environments and with a commitment to the confidentiality of responses. Electronic questionnaires applied to coordinators were used after adding the following items or instruments:

- (1) information about the characteristics of the work process;
- (2) *Maslach Burnout Inventory – Human Service Survey* (MBI-HSS) (1986) questionnaire, whose validated translation into Portuguese was made by Benevides-Pereira (2001). The inventory is self-administered and assesses how the subject experiences their work according to the three dimensions established by Maslach's Theoretical Model: (a) emotional exhaustion (9 items); (b) personal accomplishment (8 items); and (c) depersonalization (5 items)¹⁵.

Participants were 338 health professionals, including community health agents (CHAs) (66.6%), nurses (10.7%), nursing technicians (9.8%), physicians (7.1%), and professionals belonging to other categories that make up an FHS team (5.8%).

RESEARCH WITH PATIENTS WITH AHT AND/OR DM

RESEARCH POPULATION

Two research populations were defined, which consisted of people aged 18 or over, served by and registered with an FSH team in the urban area of Rio Branco. The first was formed by people with hypertension, and the other, by people with type 2 DM. People with any impairment that made communication or understanding the questions unfeasible were excluded, as well as pregnant women and patients with type 1 DM.

To build the selection records for these populations in each FSH team, a prior check was made on the number of patients with AHT and type 2 DM. These patients were identified by surveying the family registration forms (File A) and the medical records and by checking with the CHAS about the patient's stay in the assigned area. In all 38 PHC units, 8,134 patients with hypertension and 2,492 with type 2 DM were identified.

SAMPLE DESIGN

The sampling plan used for each research population included two selection stages: FHS team and patient treated. The FSH teams were selected with a probability proportional to the number of registered patients in each population, using the Pareto principle^{16,17}. Patients from each population were selected with equiprobability in each selected FSH team. It is, therefore,

a complex probabilistic sample that requires special attention when estimating variances and dependent measures¹⁸.

SAMPLE SIZE DETERMINATION

Sample sizing was guided by Edoc-Quali budget parameters and the team's experience in similar surveys. For the population of patients with AHT, a minimum proportion of 5% ($P_{\min} = 0.05$) was specified, for which the relative margin of error in estimation should be a maximum of 50% ($d_r = 0.5$) with a confidence coefficient of $(1-\alpha) = 95\%$. These parameters indicate that proportions of 5% have a 95% confidence interval, ranging from 2.5% to 7.5%. According to Cochran¹⁹ and assuming simple random sampling without replacement (SRS), the sample size necessary to estimate a prevalence P_{\min} with relative error d_r , at confidence level $1-\alpha$, is given by:

$$n_{\text{SRS}} = \frac{z_{\alpha/2}^2 \times P_{\min} \times (1 - P_{\min})}{d_r^2} \quad (1)$$

However, the present research did not use SRS, as described above. To consider its effects on sizing, Pessoa and Silva¹⁸ recommend multiplying the sample size obtained by expression (1) by an estimate of the effect of the sampling plan (Deff) referring to the sizing variable. Due to the lack of previous studies on this population, it was decided to set an Deff at 1.5. Setting an arbitrary Deff value greater than 1 is preferable to the alternative of not making any adjustment to the sample size for cluster effects expected with the sampling plan used.

With these parameters, the sample size for people with AHT, represented by n_{AHT} , was defined by:

$$n_{\text{AHT}} = \frac{z_{\alpha/2}^2 \times P_{\min} \times (1 - P_{\min})}{d_r^2} \times \text{Deff} = \frac{1.96^2 \times 0.05 \times (1 - 0.05)}{0.5^2} \times 1.5 = 438 \quad (2)$$

Setting the number of patients to be selected per FHS team at 25 leads to the need to select 16.8 teams. Thus, 17 teams were selected to sample the population of patients with AHT.

In the case of people with type 2 DM, the parameters set for calculating the sample size, represented by n_{DM} , were: minimum proportion of 7% ($P_{\min} = 0.07$), with a relative margin of

error in estimation at most 50% ($dr = 0.5$) with a confidence coefficient of $(1-\alpha) = 95\%$ and $Deff = 1.5$. Thus,

$$n_{DM} = \frac{1.96^2 \times 0.07 \times (1-0.07)}{0.5^2} \times 1.5 = 308 \quad (3)$$

Setting the number of patients to be interviewed per FHS team at 18 indicates 17.08 teams to be selected, which is approximately 17 teams.

PROBABILISTIC SAMPLE DESIGN

The probabilities of inclusion of FHS teams and patients are different for each research population because of different sample sizes. In Figure 1, these inclusion probabilities are defined for each population, as well as the basic sampling weights.

1.b Patients with AHT

The probability of inclusion of the FHS_i team in the sample of AHT patients, represented by $P(\text{FHS}_i)$ is indicated in expression 4, below:

$$P(\text{FHS}_i) = E_i \times \frac{N_{hi}}{\sum_i^M N_{hi}}, \text{ where} \quad (4)$$

N_{hi} is the number of patients with AHT registered with the FHS_i team, according to a previous registration survey;

E_i is the number of FHS teams to be selected, i.e., 17;

M is the total number of FHS teams; therefore, $\sum_i^M N_{hi}$ corresponds to the total number of patients with AHT registered with all FHS teams in the urban area of Rio Branco.

The probability of inclusion of the AHT_j patient from the FHS_i team, represented by $P(\text{PH}_{ij}|\text{FHS}_i)$, is shown in expression 5.

$$P(\text{PH}_{ij}|\text{FHS}_i) = \frac{n_{\text{AHT}}}{N_{hi}} = \frac{25}{N_{hi}}, \text{ where} \quad (5)$$

n_{HAS} is the sample size of patients with AHT to be selected per FHS team, i.e., 25.

The probability of inclusion of any patient with AHT, represented by $P(\text{PH}_{ij})$, is given by the product of the probabilities of inclusion in each selection stage (expressions 4 and 5, above), as indicated below:

$$P(\text{PH}_{ij}) = E_i \times \frac{N_{hi}}{\sum_i^M N_{hi}} \times \frac{n_{\text{AHT}}}{N_{hi}} = \frac{25 \times n_{\text{AHT}}}{\sum_i^M N_{hi}} \quad (6)$$

As a result, the natural sample weight (or basic weight) of the sample of AHT patients, represented by wh_{ij} and defined as the inverse of the product of the probabilities of inclusion in each selection stage, is given by:

$$wh_{ij} = \frac{\sum_i^M N_{hi}}{25 \times n_{\text{AHT}}} \quad (7)$$

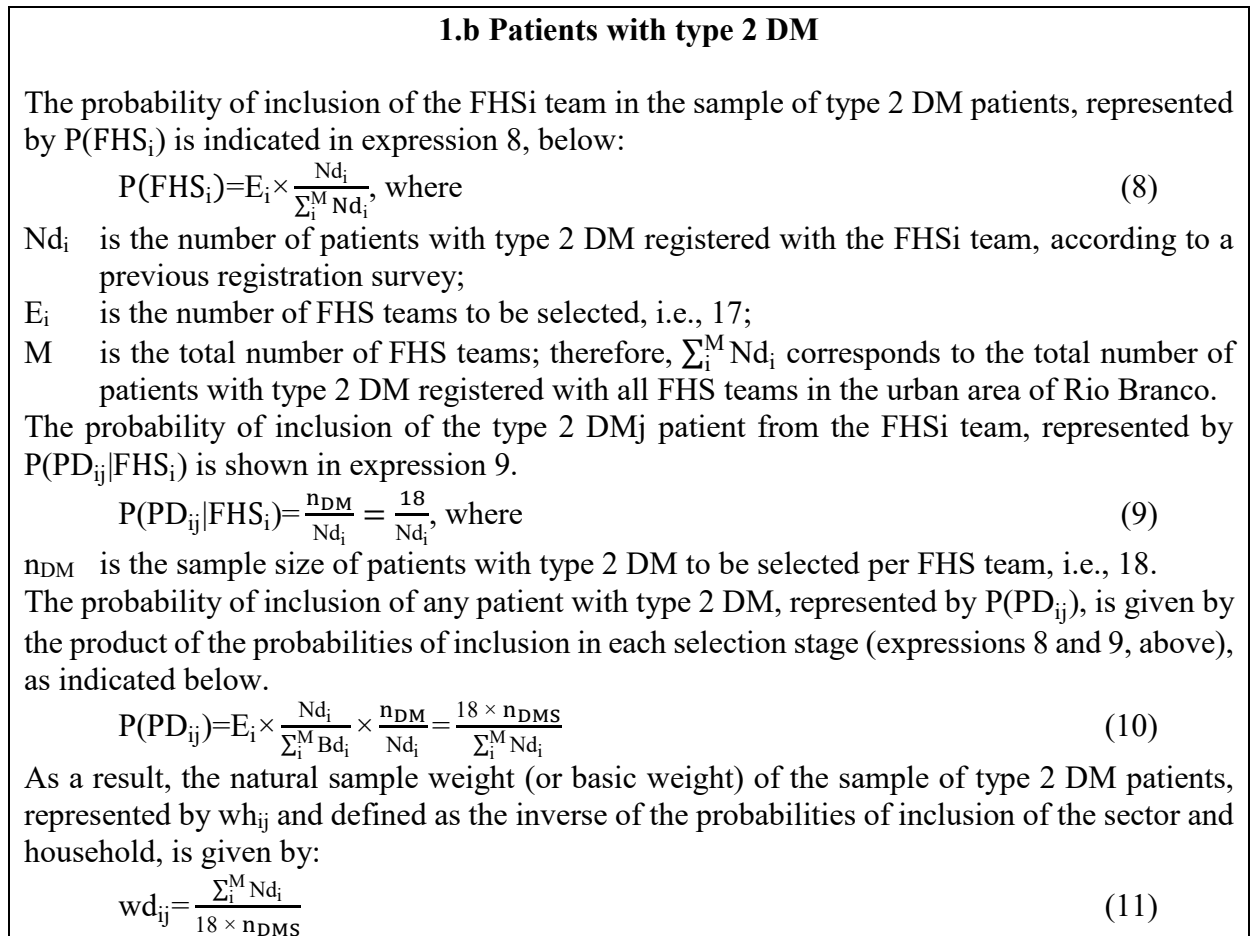


Figure 1. Probabilistic scheme of patient samples.

SAMPLE WEIGHTING

Sample weighting is a fundamental step to calculate the sample weights to produce valid estimates for the research population. This process was carried out independently for each population, as indicated in Figure 1. Thus, the basic sampling weight was calculated for each population and was defined by the inverse of the product of the probabilities of inclusion of the sample of the FHS team and the patient within each team. These probabilities are presented in Figure 1.

However, the probabilities of inclusion of patients and the basic weights, whose expressions are in Figure 1, assume that the effective sample maintained exactly the expected sample size, which rarely occurs. Therefore, the basic weights must be corrected for the actual effective sample size.

Thus, the basic sampling weights corrected for variations in sample size are presented as follows:

$$wh_{ij}^* = \frac{\sum_i^M Nh_i}{25 \times n_{AHT}^*} \quad \text{and} \quad wd_{ij}^* = \frac{\sum_i^M Nd_i}{18 \times n_{DM}^*}, \quad \text{where}$$

wh_{ij}^* is the corrected weight of patients in the sample of patients with AHT;

n_{HAS}^* is the effective sample size of AHT patients;

wd_{ij}^* is the corrected weight of patients in the sample of patients with type 2 DM;

n_{DM}^* is the effective sample size of type 2 DM patients.

In general, this type of correction is applied to compensate for non-responses (refusals, patient not found, etc.), but for Edoc-Quali samples, it compensates for the increase in sample size. Fearing that the selected patients would not go to the PHC unit to be interviewed, more patients were selected than expected (20% more), and all those who attended were interviewed. As a result, the effective sample of patients with AHT was 672 patients, and the sample of patients with type 2 DM was 324.

TEAM, TRAINING, FIELD LOGISTICS AND DATA COLLECTION

The Edoc-Quali data collection team was formed by 01 physician, 03 nurses, 01 nutritionist, 01 physical educator, 02 laboratory technicians, 01 nursing technician, and 07 interviewers, totaling 16 professionals. Supervision was carried out by the project coordination.

A pilot test was carried out with patients with AHT and type 2 DM from unselected FHS teams to evaluate the instruments, establish the collection protocol, in addition to identify the duration of the interviews. To standardize the interviews, a manual was created to study and support the activities.

After selecting a patient, their address was registered, and the CHA took an invitation to their home, which contained all the information about the research and its objectives. It also included procedures necessary for physical, clinical, and laboratory assessments, as well as the day and time to attend the unit to be interviewed. The data collection period was from April to July 2019.

On the scheduled day and time, the eligibility criteria were checked at the Basic Health Unit (BHU) and, if so, the project was presented by the interviewers with the necessary guidelines, as part of the process of obtaining consent from the patient. Only then was the IC signed. Then, all the planned procedures took place, namely: interview, physical assessment with anthropometric measurements, vital signs, recording of medical prescription data, pill

counting, collection of biological material (blood and urine) for laboratory analysis, and electrocardiogram.

DATA COLLECTION INSTRUMENTS AND MEASUREMENT PROTOCOLS

For data collection, an individual electronic questionnaire was structured into the following thematic modules:

- 1) patient identification: name, place of birth, date of birth, mother's full name, SUS card number, full address, telephone numbers, email and social network;
- 2) sociodemographic data: sex, self-declared skin color, marital status, and education;
- 3) Primary Care Assessment Tool (*PCATool – Adult Primary Care Assessment Tool*) in the adult version (accessibility, longitudinality, Comprehensiveness, coordination, family and community orientation, cultural competence, and degree of affiliation with the health service). The validated version of the *PCATool* for adults contains 87 items divided into 10 components related to PHC attributes¹⁴;
- 4) health condition: information on stress, sleep, self-rated health, and self-reported morbidities;
- 5) assessment of hypertension (only for hypertensive patients) and diabetes (only for diabetics) – individuals with both morbidities answered both questionnaires: time since diagnosis, treatment time, number of consultations in the last 12 months, time in weeks from the last consultation, Batalla test to measure adherence to treatment²⁰, complications and hospitalizations;
- 6) medications in use: list, dose and frequency, place of obtaining, time without medication, reasons for missing medication, and use of other non-conventional treatment methods;
- 7) medication adherence: instrument that assesses attitudes of medicine intake (IAAFTR) (IAAFTR)²¹;
- 8) lifestyle habits: smoking, alcohol consumption, physical activity using the International Physical Activity Questionnaire (IPAQ) Short Form²² and the Food Frequency Questionnaire (FFQ);
- 9) evaluation of health services: supplementary health, use of the service in the last three months, visit by CHAs, vaccination, and evaluation of the service used;

- 10) quality of life questionnaire: SF-36 questionnaire (*Short-Form Health Survey*), validated in Brazil by Ciconelli²³;
- 11) anthropometry, vital signs, pill counting, electrocardiographic examination, capillary blood glucose, and collection of blood and urine samples.

Anthropometric data included the measurement of weight and height and waist, hip, calf, and arm circumferences, following the protocols recommended by the *American College of Sports Medicine* (ACSM)²⁴, all in duplicate, considering the average measurements.

Weight was measured using a *G-Tech*[®] *Bal Gl 200* digital scale accurate to 50 grams on a flat surface. Participants were instructed to wear light clothing and invited to climb barefoot and with empty pockets in the center of the base of the scale, with their bodies upright and weights evenly distributed over both feet, arms at their sides, and looking straight ahead. In turn, the height was determined on a *Sanny*[®] portable stadiometer accurate to millimeters and with the base always placed on a flat surface. The body mass index (BMI) was calculated as the ratio of the weight (kg) to the height in meters squared (m²)²⁵.

Waist circumference was obtained using an inelastic anthropometric tape accurate to millimeters. The region of lowest magnitude was considered to be in the waist region, with participants breathing normally and their abdomen relaxed. The reading was taken at the end of expiration.

Handgrip strength (HGS), in kgf, was measured using a hydraulic hand dynamometer, following the procedures adopted by the American Society of Hand Therapists²⁶. Blood pressure was measured 30 minutes or more after the last caffeine intake or cigarette smoked. Three measurements were taken: one after 5 minutes of initial rest and the other two at 2-minute intervals. The final value was the arithmetic mean of the second and third measurements. A *Beurer*[®] digital device was used.

The portable electrocardiogram device used was from *Alfamed*, *Compassus 3000*, with 12 leads, with interpretive software. The examination was performed with the patient without metal accessories, in the supine position with the headboard straight, limbs extended along the body, and hands in supination. After skin asepsis, electrodes were positioned on the four extremities of the limbs and in the position of the appropriate precordial leads (V1 to V6), after a period of bed rest of at least 10 minutes. The tracings were obtained at a speed of 25mm per second and with the amplitude calibrated in such a way that 10mm was equivalent to 1.0 mV. The reading resolution was 0.25mm.

BIOLOGICAL MATERIAL COLLECTION

Biological material was analyzed in the same laboratory to ensure the standardization of methods, and all participants fasted for 12 hours. Blood samples were drawn with prior antisepsis of the antecubital fossa. Part of them (7mL) was placed in a test tube without anticoagulant and centrifuged at 1,500 rpm for 15 minutes for subsequent determination of creatinine, triglycerides, total cholesterol, and fractions (HDL, LDL); and the other part (3mL) was placed in a test tube with EDTA for analysis of glycosylated hemoglobin.

A urine sample of approximately 50mL was collected from each individual's mid-stream urine. Samples were placed in standard bottles and transported from the collection site to the laboratory for analysis at a controlled temperature. They were centrifuged, and the supernatant was removed for subsequent biochemical analysis of albumin and creatinine.

Blood glucose was determined using a Roche *Accu-Chek Performa*[®] glucometer with its respective reagent strips. The capillary puncture was performed after antisepsis of the fingers, selected randomly, avoiding those with signs of multiple previous punctures.

CONTROL OF INFORMATION QUALITY AND CONSISTENCY

The electronic questionnaire was applied, and all assessments were made at a single moment, conducted by different health professionals, preventing fraud in the interviews, as each person passed through different sectors that regulated themselves so that all patients were completely assessed. At the end of the week, the coordination team checked the questionnaires to identify missing information and made telephone calls to patients to complete the instruments.

Furthermore, home visits to obtain information about medications made it easier to retrieve missing information. Even after this process, at the end of the field research, a final consistency review was carried out to ensure the quality of the data collected.

The evaluation of the quality of care offered through the structure and process according to managers and professionals, as well as the results obtained from service users, is necessary to strengthen PHC, control complications, and prevent health problems in patients with AHT and DM.

The implementation of evaluation processes contributes to improving technical capacity at all levels of care in the SUS. This occurs by supporting planning, management, and decision-

making processes, providing subsidies for the development and improvement of policies, training managers and professionals, and promoting popular participation. Therefore, knowing how research is developed to analyze, evaluate, and interpret their demands and needs is essential to support new studies on the quality of health care offered to people with chronic diseases that have a major impact on quality of life and healthcare costs.

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