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ORIGINAL ARTICLE

Design for Pharmacotherapeutic Follow-Up of Psychiatric Patients Served in a Public Outpatient Outpatient: Implementation Study

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Highlights:
1. The implementation of pharmaceutical care helps promote mental health.
2. Pharmaceutical support can expand access to healthcare.
3. The service increased patient therapeutic adherence, improving symptoms.

ABSTRACT

Objective: Report the experience of implementing a pharmacotherapeutic monitoring service in a public outpatient psychiatric clinic. *Methods:* This is an implementation study using the design thinking model, developed in the mapping, creation and implementation stages, adapted from Stickdorn and Schneider. *Results:* Patient needs were mapped and implementation limitations were assessed. Needs for review of drug therapy, more frequent consultations, symptom monitoring and control were identified. In the creation phase, the practice model was conceptualized and structured, including anthropometric assessment, screening for symptoms of anxiety and depression, and the integration of telemonitoring services. During implementation, the model was tested with 20 patients, resulting in 114 consultations, 67.5% of which were carried out remotely and 32.5% in person. Patients were screened for hypertension (25%), diabetes (10%), depression (70%), and anxiety (60%). A total of 176 problems related to pharmacotherapy (PRF) and 612 pharmaceutical interventions (PI) were identified, with health advice (43.5%) and monitoring recommendations (19.1%) being the most frequent. Medical acceptance for therapy adjustments occurred in 41% of cases, and the absenteeism rate was 38.4%. *Conclusion:* Despite implementation challenges, service *design* proved to be relevant for configuring and standardizing the structuring process, and pharmacotherapeutic monitoring proved to be important for integrating patient care in public health environments.

Keywords: Pharmaceutical Care; Mental health; User-Centered Design; Unified Health System.

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INTRODUCTION

It is estimated that 71% of people with psychosis around the world do not receive effective mental health services, statistics on depression and anxiety indicate an increase of more than 25% in the first year of the Covid-19 pandemic alone[1] . In Brazil, data showed that the pandemic affected people's mental health, revealing symptoms of anxiety and depression associated with sleep disorders[2].

With growing demand, one of the main concerns is the number of sufficient health professionals to provide assistance. The World Health Organization (WHO) has set a target of one psychiatrist per 10,000 inhabitants worldwide[3]. Data up to 2022, in Brazil, showed that there are 6.51 psychiatrists per 100,000 inhabitants, proportionally lower[than] WHO recommendations[3,4]. In this way, the increase in demand in an already overloaded system directly influences the increase in the global burden of diseases and contributes to the emergence of comorbidities.

From this perspective, the creation of actions and services aimed at the area of mental health, still considered neglected, is emerging[1]. Considering the importance of managing psychotropic therapy, the pharmacotherapeutic monitoring (FA) service becomes very useful. This service aims to prevent and solve pharmacotherapy problems, in order to achieve good clinical results for patients, reduce risks, and contribute to improving the efficiency and quality of healthcare[5].

Therefore, organizing and implementing pharmaceutical services can be an alternative to alleviate therapy problems and promote the expansion of care for psychiatric patients, especially those treated in the public network. An agile method for implementing AF with quality and in a standardized way is through Design Thinking[6].

This method is defined as an interdisciplinary practice that combines *design*, management and process engineering skills, with the aim of improving existing services and innovating to meet users' expectations and needs[1]. In order to make health services effective and safe for patients and effective for the Unified Health System – SUS[6].

Therefore, the objective of this study was to apply the service *design methodology* to develop a Pharmacotherapeutic Monitoring model in a public outpatient psychiatry center.

METHOD

Study location

This study was conducted at the Aristides Novis Mental Health Center (CeSMAN), located in the city of Salvador, Bahia, Brazil, which provides care to patients with mental suffering in the context of the SUS. This center offers multidisciplinary community care covering the Psychosocial Care Network, working with chronic, serious and persistent illnesses.

Study design and design steps

This is a study with qualitative and quantitative approaches using design thinking concepts, principles and tools, established by Stickdorn and Schneider[6], being adapted and developed in three stages: mapping, creation and implementation.

For each stage, the respective objectives were to discover unmet user needs; define, conceptualize and design services that create understanding and solve identified needs; develop and test a pharmaceutical service model employable in an outpatient psychiatric center.

The study was carried out between September 2021 and December 2022 and was approved by the Ethics Committee of the Federal University of Bahia under opinion number 3,978,405/2020. And it followed the guidelines of the Standards for Reporting implementation Studies Statement (STaRI)[7].

Mapping Step

In the mapping stage, semi-structured interviews were carried out with users, conducted by a pharmacist. The interview followed the pharmaceutical consultation model, with the aim of obtaining (a) demographic data, (b) patient knowledge about their disease, (c) use of medications and (d) clinical condition status[8].

At this stage, an evaluation of the patients' clinical records was also carried out, through observations in medical records[9], research in the scientific literature of cases using design thinking , mainly related to the development of pharmaceutical services, and studies regarding the incorporation of pharmacotherapeutic monitoring in the SUS, in addition to meetings between project members and outpatient pharmacists.

These approaches, in addition to contributing to the discovery of users' profiles, aimed to verify the organization and quality of recorded data, evaluate the use of data for the implementation of the service, identify the target audience and the direction of the service, with based on the experiences of professionals and the search for assistance by users, as well as identifying possible limitations to the implementation process.

Creation Stage

At this stage, the documentary research and field observations were interpreted, based on the proposal for thematic analysis of qualitative data[10] verified in the mapping stage. From then on, this information was discussed in meetings with health professionals, to develop and prioritize ideas and define practice concepts, including defining the pharmaceutical consultation method and care flows.

Implementation Stage

In the implementation stage, the practice model was tested with users for a period of up to 11 months. Twenty-seven patients were recruited and completed the initial mapping interview. Due to mobility, communication and economic issues, seven patients were unable to continue with the research.

The pilot stages consisted of (1) monthly follow-up care, (2) final care, and (3) analysis of indicators. Corroborating the results with data from the first interview.

These results were expressed based on the indicators proposed by the WHO [11] and based on previous results[12], with the aim of monitoring the performance of the service. The attendances, the average time of pharmaceutical consultations, the interventions carried out, the non-attendance rate, medical acceptance of pharmaceutical interventions and the health condition of the patients were quantified, as shown in table 1.

RESULTS

The results were expressed according to the findings of each stage. However, as the design thinking is considered a non-linear methodology, some steps occurred simultaneously, making the process dynamic, adaptable and flexible [6] (Figure 1).

Indicator	Objective	Calculation
Absenteeism rate	Assess patients' non-attendance for scheduled services	Total number of missed appointments (in-person or remote) scheduled, divided by the total number of appointments scheduled in the same period.
Average pharmaceutical consultation and telemonitoring time	Determine the pharmacist's dedicated time to patients during consultation and telemonitoring	Average obtained by dividing the total time for consultations/telemonitoring by the number of consultations/telemonitoring in a given period.
FI medical acceptance rate	Evaluate prescribers' acceptance of pharmaceutical intervention in relation to therapy adjustment requests.	Total number of FIs accepted by prescribers, divided by the total number of FIs addressed to prescribers.
Medication adherence	Assess the number of patients with low adherence to pharmacological therapy	Total number of forms with a MAT score < 5 (non-adherence), divided by the total number of forms answered in the same period.
PRF number identified by patient	Evaluate the percentage of PRF identified by the pharmacotherapeutic monitoring service	Total number of PRF identified, divided by the total number of patients treated in the same period.
FI number identified by query	Evaluate the percentage of FI performed by the pharmacotherapeutic monitoring service	Total number of FI performed, divided by the total number of consultations in the same period.
Health condition control	Evaluate the percentage of patients who achieved improvement in clinical parameters, in relation to previous care.	Total number of patients who had clinical parameters considered within normal limits (which were altered in previous visits), divided by the total number of parameters recorded as non-compliant, in a given period. E.g.: total number of patients with PHQ-9 < 10, (who in previous consultations had PHQ-9 > 10), divided by total number of PHQ-9 >10.

Table 1 – Indicators for evaluating the pharmacotherapeutic monitoring service implemented in a psychiatric outpatient clinic.

Source: Adapted from WHO (1993); Tewksbury *et al*. (2018).

Mapping

By observing the medical records, it was possible to identify the lack of standardization and organization of interprofessional patient records. Suggestions for improvements are timely, including updating information such as accurate histories on the use of medications, records of adherence problems and reports of adverse reactions, also highlighting the need for medical records to be available electronically.

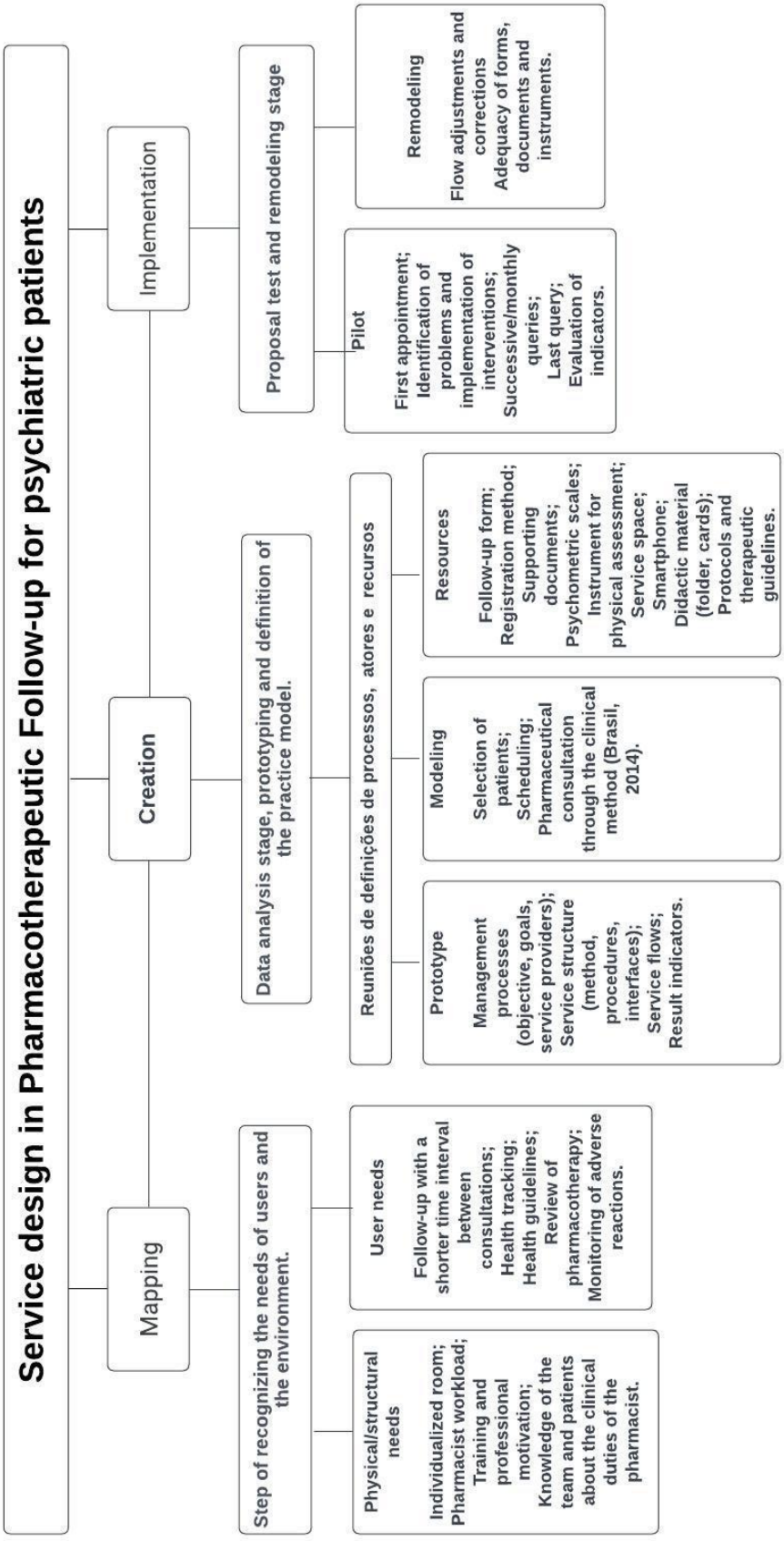

Figure 1 – Design thinking structure for the development of a Pharmacotherapeutic Monitoring service model for psychiatric patients.

Source: Research data, (2023)

In the initial interviews, patients (N=27) reported discomfort and inconvenience due to the use of medications, (Table 1) and many stated that they had not been advised about this possibility, which consequently led to abandonment of treatment. On this occasion, it was also identified that the majority of patients self-managed therapy and showed signs of anxiety and depression.

Table 1 – Sociodemographic and clinical information identified during the initial interview, (N=27)

Questions asked during the initial interview	**Results n (%)**
Sex *	Female 17 (62.9) Male 10 (37.1)
Psychiatric diagnosis**	Disorders and schizophrenics 9 (33.3) Bipolar affective disorder 4 (14.8) Recurrent depressive disorder 3 (11.1) Schizoaffective disorder 2 (7.41) Severe mental retardation 2 (7.41) No registration 3 (11.1) Other disorders 4 (14.8)
Autonomy in medication management	Takes medication without assistance 19 (70.4) Needs reminders or assistance 5 (18.5) Unable to take alone 3 (11.1)
Do any of the medications bother you?	Yes 17 (63) No 10 (37)
Are you experiencing or have you experienced any symptoms in the last few months?	Yes 18 (66.6) No 9 (33.4)
What symptoms are you feeling or have you felt?	Fatigue/tiredness 10 (16) Headache 10 (16) Sleep Problems 9 (14.2) Involuntary movements 8 (12.6) Mood change 9 (14.3) Gastrointestinal problem 4 (6.3) Sexual problem 6 (9.5) Dizziness/imbalance 7 (11.1)
Little interest or little pleasure in doing things? [the]	Not once 6 (22.2) Several days 7 (25.9) More than half of days 6 (22.2) Almost every day 8 (29.6)
Feeling "down", depressed or without perspective? [the]	Not once 4 (14.8) Several days 5 (18.5) More than half of days 11 (40.7) Almost every day 7 (25.9)
Thinking about hurting yourself in some way or that it would be better to be dead? [the]	Not once 14 (51.8) Several days 4 (14.8) More than half of days 6 (22.2) Almost every day 3 (11.1)
Do you feel nervous , anxious or very tense? [b]	Not once 5 (18.5) Several days 10 (37.0) More than half of days 3 (11.1) Almost every day 9 (33.3)

Difficulty relaxing? [b]	Not once 6 (22.2) Several days 7 (25.9) More than half of days 8 (29.6) Almost every day 6 (22.2)

[*] Mean age, (±SD) 44.3, (±10.4); [**] average of 10.4 years of psychotropic treatment

[the] Questions from the PHQ-9 form, answered by patients' self-report, using the last 15 days as a parameter; [b] Questions from the GAD-7 form, answered by patients' self-report, using the last 15 days as a parameter.

Source: Research data, (2023).

According to the thematic analysis of qualitative data, during meetings with the multidisciplinary team, analysis of medical records, scientific research and interviews with patients, the most commonly appeared terms were observed such as: "low adherence", "complex therapy regimes", " prolonged psychotropic treatment", "adverse drug reactions", "therapeutic ineffectiveness", "patients using many medications", "psychotropic polypharmacy", "patients with psychoses", "long interval between medical appointments", "lack of knowledge about the disease and treatment" and "lack of diagnosis", as shown in figure 2.

In this way, it was understood as needs to be met by users, care directed to patients with severe mental disorders, care with a shorter time interval between consultations, review and optimization of pharmacotherapy, health guidance and advice, monitoring of adverse reactions and flows integrated into multidisciplinary services.

In addition to the users' perception, limitations for implementation were observed at this stage, such as issues regarding the pharmacist's time availability, due to the overload of administrative duties, training of the unit's pharmacists and structural adequacy of a physical space to provide care. Points of attention for implementation were also related to the lack of knowledge of patients and the multidisciplinary team about the pharmacist's clinical activities.

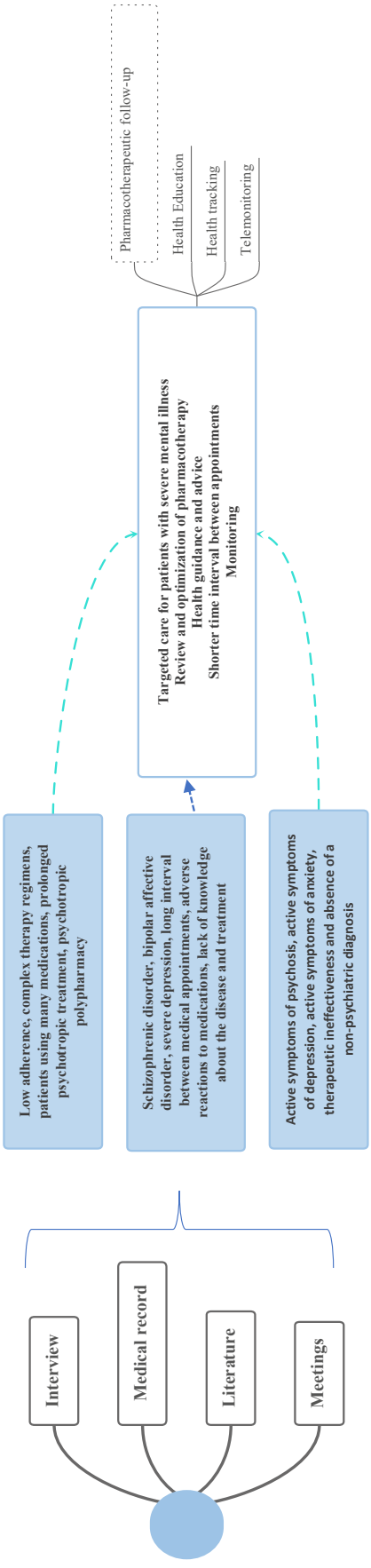

Figure 2 – Data analysis to identify user needs during the mapping stage.

Through interviews, medical record analysis, literature review and meetings, frequent situations faced by users were identified. This data provided a better understanding of the needs to be met, thus allowing the definition of strategies to resolve or mitigate such demands.

Source: Research data, (2023).

Creation

The structuring of this service consisted of an attempt to meet the needs of patients, identified in the mapping phase. Therefore, it was designed to develop a prototype that consisted of a written representation regarding the management of the service to be implemented. It included detailing the structure necessary for the operation of the services, defining the practice model and management processes, identifying the resources available and necessary for implementation and the procedures for operating the service. This prototype was presented to a team composed of representatives from the municipality's mental health technical area and professionals from the outpatient unit. On this occasion, timely *feedback* was obtained to refine the proposal and adapt it according to users' needs.

In this way, the service flow was designed according to the sequence of actions: (1) patient selection, (2) appointments, (3) pharmaceutical consultation and (4) monitoring.

The target audience consisted, preferably, of patients with severe mental disorders, problems with medication adherence, polypharmacy, presence of adverse reactions or patients with misunderstanding about the use of medications. The selection was planned to be carried out by active search, referrals by the multidisciplinary team or by spontaneous demand. Appointments could be made remotely or in person. For return consultations, the flow followed the initial service and could also be scheduled at the end of each service.

The PA was modeled according to the clinical method of the Ministry of Health[8] following the steps of: pharmaceutical anamnesis, identification and evaluation of problems related to pharmacotherapy, preparation of a care plan, records of assistance in medical records, successive consultations for continuity of care and evaluation criteria through process and clinical indicators (Figure 3).

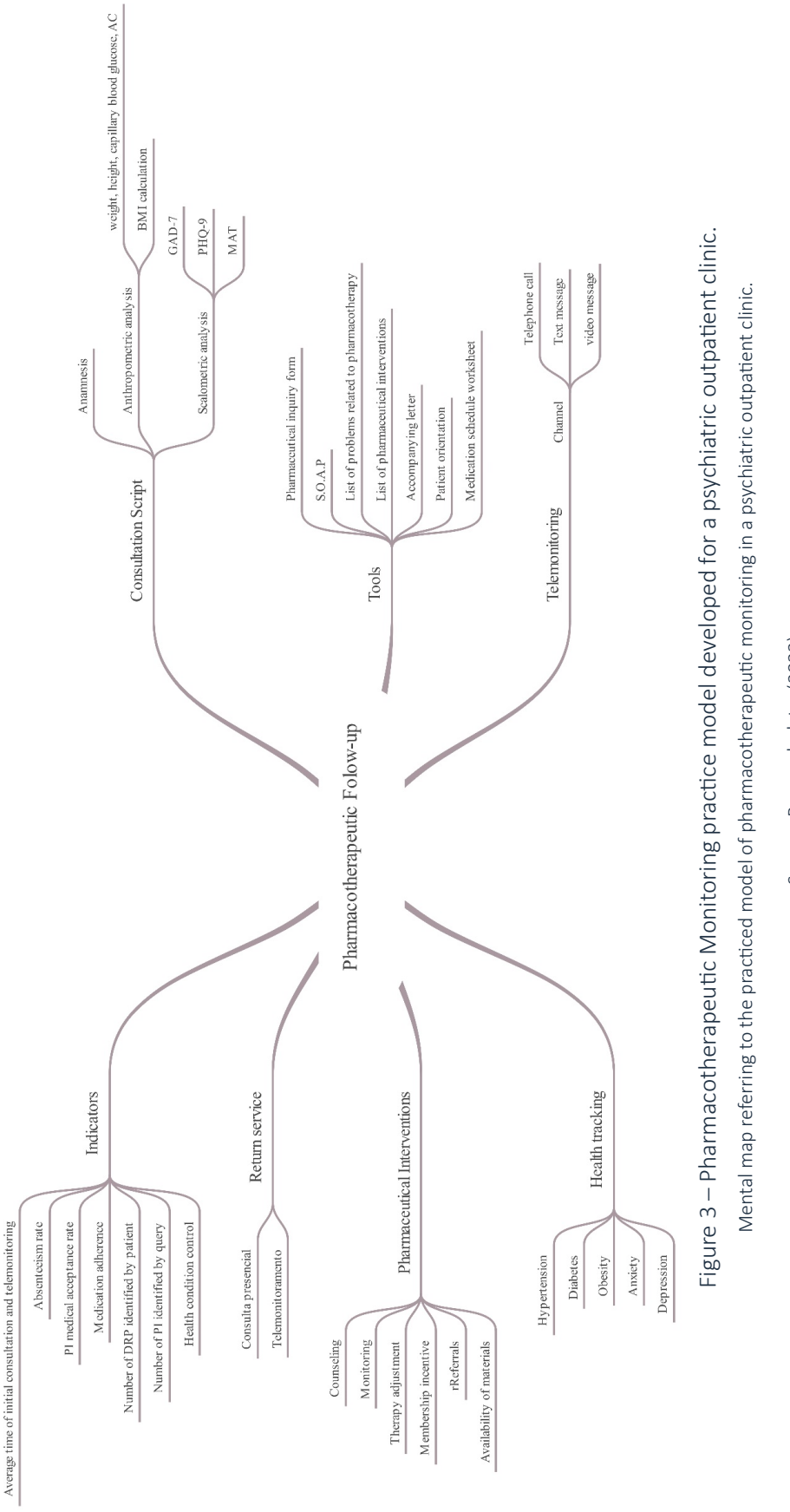

Figure 3 – Pharmacotherapeutic Monitoring practice model developed for a psychiatric outpatient clinic.

Mental map referring to the practiced model of pharmacotherapeutic monitoring in a psychiatric outpatient clinic.

Source: Research data, (2023).

In the anamnesis, in addition to sociodemographic data, past and current history of health conditions and the relationship with the use of medications, other sources of information were used, such as reports from family members/caregivers, health professionals and data from medical records. Potential PRFs or those being experienced by the patient, as well as pharmaceutical interventions, were classified, according to a list, contained in the standardized form for pharmaceutical consultation[8].

Pharmaceutical care was documented and made available in the patients' records using the SOAP method, (subjective, objective, assessment and plan)[13]. Furthermore, it was necessary to standardize other tools for the practice model, such as referral letters, a list of patient instructions, medication dosage calendars and teaching materials such as folders and cards.

The health screening service was introduced to screen for some clinical conditions. Therefore, blood pressure measurement, anthropometric assessment (measurements of weight, height, abdominal circumference and calculation of body mass index – BMI), capillary blood glucose and scalometric assessment of symptoms of anxiety and depression were included in the face-to-face consultation script. , as well as medication adherence.

To screen for anxiety, the scalometric measurement instrument Generalized Anxiety Disorder (GAD-7) was inserted, which, in addition to screening, classifies the severity of anxiety[14]. And the Patient Health Questionnaire (PHQ-9) was used to assess depression[15]. The Medication Adherence Measurement instrument was also used to assess adherence to psychotropic therapy[16].

To resolve the demand for the time interval between return appointments, the integration of the telemonitoring service was structured, which was designed to be offered on a monthly basis. Telemonitoring took place via telephone call, video call and text message via the messaging application " *WhatsApp* ".

In addition to helping to reduce the wait for clinical care, telemonitoring had the purpose of monitoring patients' complaints, in order to guarantee the safety and effectiveness of pharmacological therapy. At this time, new PRFs could be identified and new interventions were necessary, representing a cyclical and continuous process for some patients.

Implementation

Through the pilot, with the follow-up of 20 patients, the majority female (60%), an average of 43.8 (±11.4) years. The most frequent diagnoses were classified as Schizophrenia, schizotypal and delusional disorders (ICD: F20 to F29) with 50.0%, followed by [affective] mood disorders (ICD: F30 to F39) with 35%. A total of 114 consultations were carried out, 67.5% (n=77) remotely and 32.5% (n=37) in person . With an absenteeism rate of around 38.2%. The average time per consultation was 53 minutes for initial and in-person consultations (ranging from 30 to 85 minutes) and 11 minutes for voice calls (ranging from 6 to 20 minutes).

In the screening of clinical conditions, it was observed that 25% of patients in follow-up had blood pressure above 140-90 mmHg, 10% capillary blood glucose above 140 mg/dL, 70% with BMI above 25.0 kg/m^2, showing overweight or obesity, 70% with symptoms of depression and 60% symptoms of anxiety. These patients did not report or were unaware of a previous diagnosis of hypertension and diabetes.

During the study period, a total of 176 PRFs were identified, an average of 8.8 (±2.23) per patient, the most frequent being related to selection and prescription problems (43.2 %; n =76), followed by patient administration and adherence (17.6%;n=31) and monitoring (15.3%;n=27). The total IF was 612, with an average of 5.4 (±2.85) per service, among these, health counseling (43.5%) was the most frequent, followed by monitoring recommendations (19.1%) and encouraging adherence (15.4%). The suggestion to adjust therapy corresponded to 9.8% of FIs and was accepted by 41% by prescribers.

Medication non-adherence was present in 75% of patients seen at the initial consultation and 30% at the last consultation. Control of anxious and depressive symptoms was present in 57% and 28% of patients, respectively, comparing the values of the GAD-7 and PHQ-9 scales between the first and last pharmaceutical consultation.

DISCUSSION

The health situation of the Brazilian population and the current scenario of the SUS impose challenges on health managers and professionals to guarantee comprehensive care. Taking into account that pharmaceutical assistance aims to ensure the population's access to medicines by promoting their correct use[17], it is essential to discuss the role of the clinical pharmacist in an organized and integrated way, with the health demands of the Brazilian population. Therefore, this article reports the process of implementing a PA service in a psychiatric outpatient clinic , using the design thinking methodology , where it was possible to plan and develop a practice model centered on patients with serious mental disorders.

Based on the stages of this study, the need for an individualized service was identified to track certain clinical conditions, provide health information and guidance, as well as assist patients with the shortest possible time interval and on a regular basis. In this sense, it is important to highlight both the potentially favorable activities and the weaknesses in implementing the aforementioned service.

Regarding potentially favorable activities, the possibility of offering personalized support targeted at the specific clinical conditions of patients with severe mental disorders stands out. In this sense, telemonitoring was relevant for expanding care, making it possible to monitor the manifestation of patients' symptoms and adverse reactions. A study showed that remote service represents a crucial tool for achieving positive health results, such as improvements in the quality of care, increased patient satisfaction and increased efficiency and productivity in the work environment[18].

Through this study, changes in clinical parameters were observed in blood pressure, blood glucose, weight and psychiatric symptoms of the patients treated, highlighting the lack of diagnosis, lack of follow-up, therapeutic failure and/or low adherence to therapies. Users who participated in the interview, when the diagnosis was absent, would report that they were unaware of the previous condition. Tracking for conditions related to mental health, by pharmacists, is still incipient, there are few investigations into the impact on clinical outcomes and economic evaluation, and it is important to expand studies in this area[19]. In this sense, the pilot results, associated with literature findings, contribute to reinforcing this practice in structuring pharmaceutical care at CeSMAN.

One of the main actions carried out during the AF was counseling and guidance on information related to illness, rational use of medications and healthier habits. Despite evidence linking patients' little knowledge about their diagnosis and treatment with low medication adherence[20], we observed that users did not have specific knowledge, which directly influenced the negative evolution of the disease. Therefore, professionals in the field have the responsibility to identify this need and provide adequate and safe information, considering that health education is a basic right of patients[21].

Positive results in identifying and resolving problems involving therapeutic approaches, as well as positive impacts on clinical management were also considered potential. From the pilot monitoring, it was possible to identify an average PRF of around 8.8 per patient. It is close to that found in studies involving elderly people[22] and higher than the study carried out with cardiovascular patients[23]. Differences in study methodology, clinical profile of patients and ways of classifying PRF may justify these disagreements.

Regarding FIs, counseling was the most frequent and corresponded to 43.5%. This same classification was also the most frequent (33.5%), found in the study that evaluated patients with tuberculosi [24]. A possible hypothesis for these findings is due to patients' lack of knowledge regarding diagnosis, treatment and health issues, as previously discussed.

Regarding clinical findings, an increase in medication adherence was noticed during follow-up. The increase in adherence of 82.9% was evidenced in a study involving psychiatric patients[25]. Regarding psychiatric conditions , 57% and 28% of patients showed attenuation of anxiety and depression symptoms, respectively. Similar indicators were verified in previous studies and showed a reduction in the severity of anxiety and depression symptoms, reinforcing the potential of the pharmacist's clinical activities[26].

With regard to weaknesses, low medical acceptance (41%) was observed in accepting suggestions for changing therapy. Previous studies found acceptance of 98.2%[27] and 90.3%[28], reflecting greater awareness among prescribers about pharmaceutical practice. This low result may be related to the service being new, and the team's lack of knowledge about the clinical activities of pharmacists. It is important to highlight that during the study period, the outpatient clinic participated in strikes, doctor replacements and absences during the Covid-19 pandemic, which made it difficult to discuss clinical cases, limiting interaction with prescribers.

Another indicator that proved to be fragile and deserves attention is the high rate of absenteeism. Previous discussions highlighted issues involving the structure of the service, patients' physical and financial conditions, forgetfulness, as well as a feeling of apparent improvement in the symptoms experienced by users[29].

Weaknesses in implementation were also verified by the absence of an adequate pharmaceutical room/office to provide care, availability of pharmacists' time due to administrative duties, absence of electronic medical records and mainly the lack of training of professionals, including pharmacists and professionals of technical support.

In Brazil, similar factors were found, in addition to the structural difficulties and administrative duties of pharmacists, reiterating a lack of management support in the health unit, lack of knowledge of other professionals, lack of interest on the part of the pharmacist himself, and work overload[30].

Another difficulty encountered was the lack of electronic medical records. Studies report the positive impact of electronic availability on patient safety, such as sharing multidisciplinary procedures, disease management and preventive care, and improving the quality of care[31]. In this sense, it is strategic for managers to prioritize this demand and promote the replacement of manual medical records for electronic ones, ensuring greater security and agility in the handling of patient information.

Due to the initial implementation process, it was not possible, at the time of writing this article, to integrate pharmaceutical services with other services offered by the outpatient clinic. This strategy is beneficial for patients, as it allows for greater resolution of health situations, covering the medical, pharmaceutical and social areas. As the process progresses, progress is expected towards more effectively integrated assistance flows.

Despite the challenges, the implementation of pharmaceutical care has been a strategy that contributes to stimulating health education and a more accessible care practice for the population, strengthening the SUS, stimulating the qualification of services, promoting greater integration between the multidisciplinary team and increasing the population's access to quality healthcare. However, there are still challenges to be resolved, therefore, studies involving economic analysis, impacts on patients' health and quality of life, are necessary to reinforce the importance of this service.

CONCLUSION

The implementation of the pharmacotherapeutic monitoring service in a public psychiatric outpatient clinic, using the design thinking methodology , represents a significant step in the search for comprehensive, quality care for patients with serious mental disorders. Throughout this study, we identified the pressing need for individualized and regular care, aiming to effectively monitor the specific clinical conditions of these patients.

The results obtained reveal both the potential and weaknesses of this model. We highlight the importance of telemonitoring in expanding access to healthcare, as well as the benefit of pharmaceutical interventions in improving medication adherence and alleviating psychiatric symptoms.

On the other hand, we face challenges such as low medical acceptance of suggestions for therapeutic changes, the high rate of patient absenteeism and the lack of adequate structure for the provision of pharmaceutical care. It is essential to overcome these barriers through investments in professional training, improving infrastructure and integrating pharmaceutical services with others offered by the outpatient clinic.

Despite the difficulties encountered, the implementation of pharmaceutical care represents an advance in the promotion of mental health and the qualification of public health services. Furthermore, the need for additional studies to evaluate the economic, clinical impact and quality of life of patients is highlighted, in order to strengthen the importance of this service in the context of the SUS.

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