



Care plan for HIV+ patients in specialized Aids centers in Brazil: Pharmacotherapeutic form and pilot study

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ABSTRACT. The objective of this study is to describe a pharmacotherapy form model to monitor patients' pharmacotherapeutic follow-up (PF) on antiretroviral therapy in a specialized center of Ceará, Brazil. Description comprises its structure up to application. The preparation and application of the PF registration model were carried out by means of a focal group. The following steps were used for the draft: 1. Review of the literature; 2. Diagnosis of place where pharmaceutical care was undertaken; 3. Choice of the PF method; 4. Selection of clinical indicators; 5. Evaluation by a committee of experts; 6. Development of a standard functional procedure with timetable and evaluation frequency of the tool's different sections or blocks. 7. Pilot study for evaluation of the form with 25 patients. PF form featured six sections comprising patient's personal data, pharmaceutical anamnesis and records of adherence evaluation, etc. The description and format of the sections are presented in current essay. Further, 322 issues related to antiretroviral drugs were reported during form filling. The multi-section PF form seemed appropriate and applicable for the report of issues related to antiretroviral drugs in HIV positive patients. It was also a helpful guide for pharmaceutical interventions by a multiprofessional team in specialized healthcare settings.

Keywords: documentation, HIV, pharmaceutical care.

Plano de cuidado para pacientes HIV+ em centro especializado em AIDS do Brasil: descrição da ficha farmacoterapêutica e estudo piloto

RESUMO. O objetivo deste estudo é descrever o modelo de ficha farmacoterapêutica utilizada no acompanhamento farmacoterapêutico (AFT) de pacientes em terapia antirretroviral em centro especializado do Ceará, Brasil, da sua estruturação à aplicação. Por meio de um grupo focal, o processo de elaboração e aplicação da ferramenta de registro foi realizado e envolveu as seguintes etapas: 1. revisão bibliográfica; 2. diagnóstico situacional do local de prestação do serviço farmacêutico; 3. escolha do método de AFT; 4. seleção de indicadores clínicos; 5. avaliação por comitê de especialistas; 6. elaboração de procedimento operacional padrão com roteiro e frequência de aferição dos diferentes blocos do instrumento; 7. estudo piloto para aplicação e avaliação inicial da ficha em 25 pacientes/usuários. A ficha de AFT envolveu seis blocos com dados pessoais, anamnese farmacêutica e registros de avaliação da adesão, etc. A descrição e formatação dos blocos são apresentadas no trabalho. Durante o uso da ficha no estudo piloto, foram identificados 322 problemas relacionados com medicamentos antirretrovirais. A ficha de AFT, estruturada com seus diferentes blocos, pareceu ser adequada e aplicável para o registro de problemas com antirretrovirais em pacientes HIV+, sendo útil para nortear intervenções farmacêuticas juntamente com a equipe multiprofissional em serviço de atendimento especializado.

Palavras-chave: documentação, HIV, atenção farmacêutica.

Introduction

The consequences of infection by human immunodeficiency virus (HIV) may be decreased or controlled by currently well-established antiretroviral therapy (ART). ART reduces plasmatic viremia and increases survival chances and life quality in HIV-AIDS patients (VENTURA, 2006). However, lack of posology facility, the great number of medicines for each therapy, memory-related factors, distraction,

routine interruptions and negative physiological state associated with adverse conditions caused by drugs are risk factors for the non-compliance to treatment (CHESNEY et al., 2000).

When the epidemiological aspects, social obstacles and adhesion difficulties to antiretroviral treatment are taken into account, the patients' follow-up facilities by a multidisciplinary team are structured by the aggregation of specialized health

professionals. Medicine-related issues (MRIs) are highlighted within the antiretroviral treatment, especially patients' adherence to treatment and thus the decrease of morbidity-mortality rates directly associated with HIV infection. Pharmacotherapeutic care services or Pharmaceutical Care programs require more actions by the pharmacist in individualized pharmacotherapeutic needs and associated factors. Since the service structure within the Brazilian health system is still a challenge, the strategies that facilitate their materialization with regard to structure, processes and report of results cannot be postponed.

Pharmaceutical Care (PHC) is a pharmaceutical practice developed within Pharmaceutical Assistance for the direct interaction between the pharmacist and the patients aiming at a rational pharmacotherapy and the obtaining of definite and tangible results for an improvement in life quality (IVAMA et al., 2002). Documentation and reports make up the macro-components of Pharmaceutical Care and during pharmacotherapeutic follow up (PF). One of the important obstacles is the structuring and application of instruments that would make easier documentation and data report processes of patients during follow-up. Current essay, therefore, deals with the description, from its structuring to its initial application, of a pharmacotherapeutic form used in the antiretroviral therapy-assisted patients' follow-up at a specialized care center in the state of Ceará, Brazil.

Material and methods

The care center for the development of current PHC service was selected by a working team of professors in Hospital Pharmacy, Pharmaco-economy, Applied Pharmacology, Pharmaceutical Care, pharmacists specialized in AIDS service in the state and members of the Study Center in Pharmaceutical Care (Ceatenf) of the Federal University of Ceará. After much discussion, the Center for Medical Specialties José de Alencar (Cemja) in Fortaleza, Ceará State, Brazil, was chosen owing to the great number of HIV patients and to its features as an institute at the secondary health level.

Systematic meetings by the above specialists were carried out for the structuring of documentation and report of procedures on patients' follow-up. A bibliographical review was undertaken in specific information sources that mentioned PHC in HIV patients, aspects on treatment adherence, pharmacoepidemiological profile, lifestyle of HIV patients and types of instruments for documents and reports used in pharmacist-engaging service and clinics.

A situation diagnosis (pilot study) was undertaken between October and November 2008 at Cemja. Indexes on the structure, process and clinical results to be used during the proposed service were agreed upon. This was especially true with regard to the stage for the documentation and information report of patients during follow-up. The Dáder follow-up method as process indicator was specifically selected in the case of the structuring of the pharmacotherapy form (MACHUCA et al., 2003), with PRM classification according to the Second Consensus of Granada (SANTOS et al., 2004). The process of form elaboration was undertaken according to the particular characteristics of the population under analysis and the feasibility of the service.

The pharmacotherapeutic form was formatted and evaluated after four meetings of the group and then submitted to the Committee of Specialists comprising three specialized professionals from Ceatenf-service for its immediate agreement. It was determined that pharmacotherapeutic follow-up would be carried out in monthly meetings with patients, within nine encounters. A form following the Standard Operational Procedure (SOP) was prepared to standardize filling up and the insertion of sections or blocks in the pharmacotherapeutic form. The Ethics Committee of the Federal University of Ceará, Ceará State, Brazil, gave its approval (Protocol 191/08) and the form was used as a pilot model for an analysis of its applicability.

Results and discussion

The pharmacotherapeutic follow-up form of the HIV patient had a six-structure/block structure, each of which aimed at specific information to be registered during the PF individual interview.

Section A refers to a single section with 25 questions on the patient's personal data and lifestyle. It is filled with the information furnished at the first interview and with that on the patient's clinical sheet. The Section is divided into two sub-items: Patient's Data define the social profile of the patient (sex, age, civil status, race, schooling etc), coupled to his/her economic and labor situation; Lifestyle comprises information on habits (uses of licit or illicit drugs), physical, religious and recreational activities.

Section B was applied during the first interview and filled according to the information given by the patient and to the analysis of his/her clinical sheet. It actually contains pharmacotherapeutic data and Pharmaceutical Care. Section B block was subdivided into seven sub-sections (II to VIII) with the following items: II – remote pharmaceutical clinical sheet (Figure 1); III – pharmacological sheet on self-medication and on routinely taken medicines during the last 30 days,

except antiretroviral ones; IV – general problems that may interfere with the treatment; V – evaluation of the patients' knowledge on the disease, modes of virus infection, transmission, treatment, forms of prevention and other disease complications; VI – Data on antiretroviral therapy and other treatments, time and place of diagnosis, symptoms at the start of ART, initial and secondary antiretroviral treatment timetables and other information; VII – problems related to antiretroviral medicine (Figure 2), coupled to pharmaceutical interventions undertaken; VIII – laboratory exams undertaken, retrieved from information from the initial visit to the doctor's up to the clinical sheet.

SECTION B – Pharmacotherapeutic data and data on Pharmaceutical Care

Starting date: _____ End: _____

II) REMOTE PHARMACEUTICAL CLINICAL SHEET

- Means of contamination

1. ☐ Sexual relations 4. ☐ Use of injected drugs
2. ☐ Blood transfusion 5. ☐ Others: _____
3. ☐ Labor accident 6. ☐ Unknown

- How did you become aware of the infection?

1. ☐ Prenatal test 5. ☐ Routine exams
2. ☐ Pre-operative tests 6. ☐ Sought help due to suspicions
3. ☐ Symptoms 7. ☐ Others: _____
4. ☐ Blood donation

- Associated diseases

1. ☐ Hypertension 7. ☐ Heart condition
2. ☐ Diabetes 8. ☐ Asthma/ Chronic obstructive pulmonary disease (COPD)
3. ☐ Dyslipidemia 9. ☐ Kidney condition
4. ☐ Neuropathia 10. ☐ Liver condition
5. ☐ Arthropathia 11. ☐ Gastritis or ulcers
6. ☐ Dermatopathia 12. ☐ Others: _____

- Already diagnosed and treated opportunist diseases: 1. ☐ Yes Specify which: _____
2. ☐ No

1. ☐ Neurotoxoplasmosis 6. ☐ Recurring infections by fungus on the skin, mouth and throat
2. ☐ Neurocryptococcosis 7. ☐ Hansen's disease
3. ☐ Cytomegalovirus 8. ☐ Tuberculosis
4. ☐ Candidiasis 9. ☐ Others: _____
5. ☐ Pneumocystosis

- Allergies: 1. ☐ Yes: Which? _____ 2. ☐ No 3. ☐ Unknown
4. ☐ Medicines: Which? _____
1. ☐ Food 2. ☐ Dust/Smoke 3. ☐ Others: _____
3. ☐ Animals

- Eating habits: 1. ☐ Specific food diet: Which? _____
2. ☐ Coffee
3. ☐ Tea
4. ☐ Others: _____

IMPORTANT OBSERVATIONS:

Figure 1. Remote pharmaceutical clinical sheet (Block B).

VIII) Problems related to medicines (PRM) – Antiretroviral Treatment (ART)

PRM	Medicine	Description of probable PRM	Cause*	Type	Date
1)					
2)					
3)					
4)					
5)					
6)					
7)					
8)					
9)					
10)					
11)					
12)					
13)					
14)					
15)					
16)					
17)					
18)					
19)					
20)					

* A) Category: Necessity (PRM1, PRM2); Efficaciousness (PRM3, PRM4); Safety (PRM5, PRM6); B) Cause: 1 – Facility to receive medicines; 2 – interaction; 3 – non-adhesion; 4 – prescription mistake; 5 – dispensation mistake; 6 – administration mistake; 7 – self-medication; 8 – negative reactions; 9 – others (which ?). C) Type: 1 – Potential; 2 – Real.

Figure 2. Problems related to medicines (PRM) – Section B.

Section C comprises 14 questions and describes the patient's adhesion profile to antiretroviral therapy and similar issues (Figure 3). The questionnaire developed by Delgado and Lima (2001) has been inserted.

"Degree of Adhesion to Treatments" (DAT) is composed of 7 closed questions and four open ones, structured according to the adhesion test by Morisky (MORISKY et al., 1986). The questions retrieve more information provided in the questionnaire and should be applied on the second meeting with the patient and in all following months.

SECTION C – ADHESION TO ANTIRETROVIRAL THERAPY AND SIMILAR ISSUES

Starting date: _____ End: _____
Date: ____/____/____ Number: ____

IX) GENERAL EVALUATION OF ADHESION

9.1.1) Does the patient need any help to take medicines? 1. ☐ Yes 2. ☐ No

9.1.2) Is there any strategy used by the patient to facilitate adhesion?
1. ☐ Yes Which? _____
2. ☐ No

9.1.3) Is the patient aware of risks in the non-compliance to therapy? 1. ☐ Yes 2. ☐ No

9.2) ADHESION TO THERAPY (Initial approach) (Delgado & Lima (2001))
Degree of Adhesion to Treatment (DAT)

1. Have you ever forgotten to take medicines prescribed for your disease?
Always 1 Almost always 2 Frequently 3 Sometimes 4 Rarely 5 Never 6

2. Have you ever been careless with regard to timetable for taking medicines?
Always 1 Almost always 2 Frequently 3 Sometimes 4 Rarely 5 Never 6

3. Have you ever skipped taking medicines because you felt somewhat better?
Always 1 Almost always 2 Frequently 3 Sometimes 4 Rarely 5 Never 6

4. Have you even skipped taking medicines on your own accord after feeling worse?
Always 1 Almost always 2 Frequently 3 Sometimes 4 Rarely 5 Never 6

5. Have you ever taken more than one or more pills on your own accord after feeling worse?
Always 1 Almost always 2 Frequently 3 Sometimes 4 Rarely 5 Never 6

6. Have you ever interrupted therapy after perceiving you hadn't any more pills?
Always 1 Almost always 2 Frequently 3 Sometimes 4 Rarely 5 Never 6

7. Have you ever taken the medicines prescribed by your doctor for any other reason than that of the doctor's?
Always 1 Almost always 2 Frequently 3 Sometimes 4 Rarely 5 Never 6

8. If the answer to question 1 was Yes, why did you forget to take the prescribed medicine?

9. If the answer to question 2 was Yes, why were you careless with regard to the timetable in taking medicines?

10. If the answer to question 3 was Yes, why did you refrain from taking the medicine in such situation?

11. If the answer to question 4 was Yes, why did you refrain from taking the medicine in such situation?

Figure 3. Adhesion to antiretroviral treatment and similar issues (Section C).

Section D is composed of six questions and collects further information so that the pharmacist would have more data for a broader knowledge of the interviewee's conditions. These themes comprise changes in routine strictly due to antiretroviral medicines, knowledge on medicine interaction, difficulties in obtaining the required medicine, care with regard to storing of medicines and their administration, family support with regard to treatment. Section D should be filled on the second meeting.

Section E comprises eight questions on attendance and on the relationship between the patient and Pharmacy Service, with special emphasis on the assistance given by other professionals from the multidisciplinary team targeting the HIV patient. The interviewer should fill Section E on the fifth meeting. Information in Section E includes questions on the patient's satisfaction with antiretroviral therapy and attendance at the

pharmacy, trust in the medical team and information provided by the multidiscipline team on the aim of treatment, side effects of antiretroviral therapy, medicine interactions and the storing of medicines.

Section F comprises "Questionnaire on the patients' satisfaction vis-à-vis the Pharmacist and the Pharmaceutical Care program", adapted by Lyra Júnior et al. (2005), with 14 objective questions on pharmacist-researcher attendance and on the information provided by the professional. Two other questions deal with the patient's awareness with regard to the importance of the pharmacist for the patient's health and the importance in his/her participating in the Pharmaceutical Care program. Section F should be applied at the end of the pharmacotherapy follow-up.

Since documentation/report is a macro-component of pharmaceutical care and since the harmonization of procedures and behavior is highly required, the form was structured for the Brazilian pharmaceutical care milieu. An instrument for pharmacotherapeutic report was thus established for HIV patients within a clinical environment.

A pilot study with 28 patients attended at the HIV-AIDS center was carried out in November 2008 to evaluate the feasibility and possible adjustments of the above-mentioned instrument. Patients comprised 14 males (56%) and their mean age was 37. Most were diagnosed for infection since one year, at the most. Most of the interviewed patients were single.

Problems on antiretroviral medicines were reported in the clinical sheet. Three hundred and twenty-two PRMs were identified totaling 12.9 PRMs per patient. When true PRMs ($n = 217$; 67.4%) were taken into account, or rather, PRMs that actually occurred, PRM-5 (safety of medicine which is not dose-dependent, $n = 153$; 70.5%) was the most relevant. PRM-4 (efficaciousness of medicine and dependent on dose/adhesion, $n = 33$; 15.2%) and PRM-1 (need of medicine/non-adhesion, $n = 29$; 13.4%) came next. Further, 295 pharmaceutical interventions were performed throughout PF, duly registered in the clinical sheets, whether accepted or not, by the agents involved (pharmacist-patient; pharmacist-patient-doctor; pharmacist-doctor).

Average time spent for the application of the PF clinical sheet sections was 40 min during the first meeting and 15 min for the next ones.

According to Pereira and Freitas (2008), Pharmaceutical Care in Brazil is still a fledgling activity and is slowly being introduced and implemented. Actually, pharmaceutical care

coincides with the redefinition of pharmaceutical activity nationwide. One of the factors that make difficult its consolidation is the unsatisfactory access of medicines by users of the Brazilian National Health System (SUS) and the near lack of scientific documents that would convince government and private health managers that such a practice is an asset and not a liability.

The authors researched articles under the keyword 'Pharmaceutical Care' in Medline/Pubmed databases within a country under analysis. They found that there were 46 articles on Pharmaceutical Care published and indexed in Brazil, ranking first in Latin America. However, this ranking showed a low publication scores when compared to the scientific production in developed countries.

Within the context of documentation and report in pharmaceutical practice, the systematic report on activities, measurements and evaluation of results has been defined by the Brazilian Agreement in Pharmaceutical Care as one of the macro-components in professional practice (IVAMA et al., 2002), reported in the technological models in Spain, US, UK, Canada and France (ANGONESI, 2010); PEREIRA; FREITAS, 2008).

The systemization of work and documentation of pharmacotherapeutic history integrates the evaluation of the patient's status with pharmaceutical care and results obtained (CERDÁ; ALMIÑANA, 2004). Lyra Júnior (2007) has shown that PHC practices have a positive clinical, humanistic and economic impact on the health services of several countries. However, a reformulation in research design is required. In other words, the pharmaceutical interventions and their structures should be more adequately described to evaluate the structures of pharmaceutical services at the national, state and municipal levels, within the government and private domain.

According to Cerdá and Almiñana (2004), activities should be reported according to norms, preferentially in the patient's clinical history by means of an independent chart which should at least inform the patient's pharmacotherapeutic profile, with previous and current treatments; non-documented prescriptions and self-medication; posology adjustments; modifications with regard to intake manner, posology intervals, pharmaceutical form or chemical agents (therapeutic exchange); PRMs and potential mistakes of medication and real ones detected; possible therapeutic dual medicines; compliance to therapy; interactions; side effects and reactions to medicine; symptoms and clues that characterize concomitant processes that may affect

pharmacotherapy; all educational activities provided to the patients and his/her family or relatives.

The structure of the 'Pharmacotherapeutic Follow-up Chart of the HIV Patient' was organized by thematic sections or blocks for the easy management of the pharmacist and to facilitate the tabulation and analysis of the data collected. In fact, Section A (social and demographic data and lifestyle) provided the social environment of the patient. It is a basic stage in the situation analysis and investigation phases of the Dáder method for pharmacotherapeutic follow-up. The section focuses on important information for the negotiation process with the patient on pharmacotherapeutic issues and the planning of interventions, based on the specific features of each patient during follow-up. The above aspects, also dealt with in Section B, furnish pharmacotherapeutic data, information on health-disease complex and PHC indexes involved in the pharmaceutical and pharmacological clinical sheet. These data coupled to results from laboratory tests, especially virus load and T CD4+ lymphocytes, signalize priority in future strategies.

The broadening of the discussion on the questionnaire developed by Delgado and Lima (2001) called "Degree of Adhesion to Treatments" (DAT), with four open questions from the Morisky Test (MORISKY et al., 1986), is dealt with in Section C. The latter informs on adhesion to antiretroviral therapy. In fact, the interdisciplinary team felt the need to include open questions so that the patients may have the opportunity to manifest their own awareness to factors related to the compliance of their antiretroviral medicine management. Moreover, the patient's self-report is an excellent tool to evaluate adhesion (GIR et al., 2005).

A fundamental issue for greater accuracy in the verification of variables in Sections E and F comprises the activities of the social assistant in the process, who is one of the multidisciplinary team members in HIV patient care. Social assistants were chosen since they, as interviewers, are not be directly involved in the pharmacotherapeutic process of the patient's follow-up. Physicians, nurses and pharmacists were excluded from the process due to the possibility of inhibiting the interviewed patient, with subsequent doubtful results. The satisfaction focus evaluated in Sections E and F should be distinguished. Section E comprises 8 questions and evaluated the patient's satisfaction as a whole with regard to Pharmacy Service. It analyzes more specifically the activities of the multidisciplinary care team vis-à-vis the HIV patients within the context of their awareness of care

in the use of medicines. On the other hand, Section F evaluates the patients' satisfaction degree, specifically the servicing pharmacist, and assesses the logistic stage in the distribution of prescribed antiretroviral medicines. In fact, it is a highly useful tool for the identification of possible opportunities in the improvement of the professional and of the Pharmaceutical Care program through decision-taking for service increase.

Conclusion

The pharmacotherapeutic form was planned and structured so that complete and specific information on interviewed and followed-up HIV patients would be available. Problems on medicines, mainly antiretroviral ones, were identified. In fact, problems with antiretroviral medicines are mainly due to contrary reactions (PRM-5). Form filling time was adequate and data reported were useful for pharmaceutical intervention together with the multiprofessional team.

Besides the information above, the document also included the adhesion profile and the satisfaction level of the interviewed patients with regard to the health team, the pharmacist and especially Pharmaceutical Care proper.

Since documentation and report are basic for specific strategies that would warrant the proposed pharmacotherapeutic success, it seems that, at a first instance, the form is adequate and feasible in Pharmaceutical Care service for HIV patients attended at specialized units or in secondary health care level.

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