Model for the evaluation of drug-dispensing services in primary health care

ABSTRACT

OBJECTIVE: To develop a model for evaluating the efficacy of drug-dispensing service in primary health care.

METHODS: An efficacy criterion was adopted to determine the level of achievement of the service objectives. The evaluation model was developed on the basis of a literature search and discussions with experts. The applicability test of the model was conducted in 15 primary health care units in the city of Florianópolis, state of Santa Catarina, in 2010, and data were recorded in structured and pretested questionnaires.

RESULTS: The model developed was evaluated using five dimensions of analysis for analysis. The model was suitable for evaluating service efficacy and helped to identify the critical points of each service dimension.

CONCLUSIONS: Adaptations to the data collection technique may be required to adjust for the reality and needs of each situation. The evaluation of the drug-dispensing service should promote adequate access to medications supplied through the public health system.

DESCRIPTORS: Pharmaceutical Preparations, supply & distribution. Good Dispensing Practices. Primary Health Care. Health Services Evaluation.
INTRODUCTION

Drug therapy is the main therapeutic tool used for maintaining health and treating disease processes in modern society. In this context, drug dispensing is an essential primary health care service provided by the Brazilian Unified Health System (SUS), and it comprises a set of services and actions known as pharmaceutical assistance. Pharmaceutical assistance aims to promote access and the rational use of medicines in the health care system. In this perspective, the efficacy of the drug-dispensing service in primary health care units is closely associated with the efforts to implement pharmaceutical assistance. Through this service, beneficiaries will have their needs met with regard to access to medications, information, and guidance on drug therapy.6

However, access to medications in primary health care units remains limited.11 Only 45.0% of the beneficiaries who received a prescription through SUS had access to all the drugs prescribed.16 Since 1996, drug misuse is the leading cause of intoxication6 and the limited access to information and guidance on prescription drugs remains a reality.1

Considering that the quality of drug therapy is directly related to the that of primary health care services3 and is strategic in the health care process involving pharmaco-therapy, it is believed that the goals of the drug-dispensing service in primary health care are not being adequately met.

The aim of the present study was to develop a model for evaluating the efficacy of the drug-dispensing service in primary health care.

METHODS

This methodological14 and qualitative study aimed to develop a model for evaluating the management12 of the drug-dispensing service. We adopted the efficacy criterion, which is defined as the evaluation of the extent to which the service goals and objectives are achieved in a group of beneficiaries in a given period, regardless of the costs involved.6

From this perspective, a literature review and discussions with experts were conducted for the development

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*a* Agência Nacional de Vigilância Sanitária. Resolução da Diretoria Colegiada da ANVISA – RDC nº 44, de 17 de agosto de 2009. Dispõe sobre Boas Práticas Farmacêuticas para o controle sanitário do funcionamento, da dispensação e da comercialização de produtos e da prestação de serviços farmacêuticos em farmácias e drogarias e dá outras providências. Diário Oficial Uniao. 18 ago 2009; Seção 1:76-81.

*b* Fundação Osvaldo Cruz. Sistema Nacional de Informações Tóxico-Farmacológicas. Brasil 2008: tabela 6: casos registrados de intoxicação humana por agente tóxico e circunstância [cited 2014 Apr 12]. Available from: http://www.fiocruz.br/sinitox/cgi/cgilua.exe/sys/start.htm?sid=386 and/or http://www.fiocruz.br/sinitox_novo/media/Tabela%206%20-%202008.pdf
of the evaluation model, which comprised a logical model, evaluation matrix (dimensions, indicators, measures, and parameters) and a classification model. A method known as “ideal type” was used for defining the parameters, and it allowed comparisons between the reality observed and a predetermined imaginary model, which needs to be consistent with this reality. In addition, the developed model was tested. The data were obtained using the technique of direct observation of drug-dispensing services as well as a structured and pretested questionnaire-based interview in two municipal primary health care units. The data were standardized in a spreadsheet, and they were analyzed and classified according to the parameters established in the proposed evaluation model.

For the literature review, the Scientific Electronic Library Online (SciELO) was searched using the terms “drug dispensing” and “pharmaceutical assistance”, without restriction on the publication date, study location, and/or language. For the second term, only assessment studies were considered. The search was performed in June 2009 and updated in March 2014.

The discussions with experts, with the aim of strengthening the internal validity of the study, were conducted in four specific periods during model development in the institutions where the research team worked. A total of 16 professionals were consulted and they included pharmacists from the municipal primary health care units where the model was tested, researchers involved in health care evaluation and in pharmaceutical sciences, and SUS managers from the state and municipality.

The tests were conducted in Florianópolis, SC, Southern Brazil, in 2010, using a study sample that was defined on the basis of the following factors: number of health districts present in the municipality, types of primary health care units, and the flow of beneficiaries, with the latter being defined as the mean number of people served daily by the pharmacies of each unit. Overall, 15 primary health care units were selected, three in each of the five health districts in the municipality, so that one primary health care unit had pharmacies that were locations for the dispensing of drugs under special control via Ordinance MS 344/98 in the district and two units had pharmacies that did not have these special drugs. Among the two units not having the special drugs, one had a larger flow and the other had a smaller flow of beneficiaries in their respective pharmacies. In each unit selected, 10 services were recorded for each shift (morning and afternoon).

The main study limitation was considered to be the Hawthorne effect, a phenomenon whereby the subjects under observation may act differently when they are aware of being observed. Therefore, standard clarification procedures were adopted to minimize this effect.

The study was approved by the Human Research Ethics Committee of the Universidade Federal de Santa Catarina (Opinion 541, 2009 December), as established by Resolution 196 of the National Health Council. In addition, research permission was obtained from the Municipal Health Secretariat of Florianópolis.

RESULTS

Evaluation model developed

For model building in 2009, among the studies reviewed, five were considered to be directly related to the goal of this study: two were conceptual studies discussing drug dispensing and three studies proposed drug-dispensing indicators to rate pharmaceutical assistance. Considering the few nationwide studies found, two official publications and two publications recognized in the research field were included.

In 2014, considering the updated bibliography used to support the discussion of the results of the present study, three other studies on drug dispensing and two official publications were reviewed. One of these studies, which was published after completion of the evaluation model presented herein, was the only study that proposed a model for evaluating the drug dispensing.

By consulting other publications and discussing with experts, the topic to be evaluated was defined as follows: drug dispensing is a health service that guides the beneficiary to make adequate use of medications, adhere to treatment, and prevent disease. The service should supply good-quality medicines, in the dose and concentration necessary for the treatment prescribed, and with the required packaging for preserving product quality. Furthermore, the relationship between the pharmacist and beneficiary should allow the identification and resolution of certain problems related to drug therapy and potential negative outcomes of the therapy in progress. For this purpose,
several activities are required, including technical actions, such as separation and preparation of the required medications as well as administrative procedures related to inventory record and control, and clinical actions, including the evaluation of prescription adequacy and guidance provided.

Considering the efficacy criterion, the following goals for drug dispensing were adopted: a) understanding the needs of beneficiaries or their guardians; b) evaluation of prescription adequacy; c) provision of good-quality medicines in the amount needed for effective treatment; d) provision of the necessary information to beneficiaries or their guardians; e) implementation of the systems for inventory control and beneficiary monitoring.

The Figure represents the logical model to evaluate the efficacy of drug-dispensing service; this model served as the reference when defining the indicators and used the following five dimensions of analysis that define the service dynamics: user embracement, evaluation of prescription, separation and preparation of medicines, beneficiary guidance upon medicines delivery, and data recording.

The beneficiary approach served as indicator of the dimension user embracement. Primary health care units which attempt to understand beneficiaries’ needs aim to establish interpersonal relationships on the basis of trust and respect so as to address problems faced by the beneficiaries. Therefore, it was important to verify whether the service provided could identify service beneficiaries and whether professionals were available to give support on relevant issues related to drug therapy or those associated with health care throughout the drug-dispensing process.

The dimension “evaluation of prescription” used two indicators: analysis of prescription and evaluation of drug therapy. The drug prescription to a beneficiary, either to initiate or continue treatment, should be analyzed and interpreted according to its legal and technical aspects (drug name, dosage, dosage form, and frequency and duration of treatment) before preparing the medications or authorizing their distribution, ensuring that they are free from problems that may bring losses. To this end, it was observed that the service could identify any legal or technical nonconformity in the prescriptions. Moreover, the therapeutic aspect should be analyzed by investigating whether the therapies prescribed complied with basic parameters related to drug indication, dosage, contraindications, and interactions, and whether positive or negative outcomes occur during drug therapy, assuming the professionals’ responsibility for the therapies indicated. Although drug dispensing has important limitations in the identification and solution of problems related to drug therapy and the negative outcomes of drug therapy, this service can help solve some problems in this scope and/or guide beneficiaries towards a reassessment of drug therapy integrated with the reference health team. Therefore, it was noted if there was identification of therapeutic inconsistencies and checking the health status of beneficiaries with the use of medicines.

The dimension “separation and preparation of medicines” included two indicators: assessment of the quantitative and qualitative aspects of medicines, and compliance with the preparation techniques. The verification of product quantity and expiration date before its distribution avoids qualitative and quantitative errors, which can compromise the effectiveness and safety

Figure. Logical model for evaluating the efficacy of the drug-dispensing service in primary health care.
of treatment.\textsuperscript{9,10,4,7} Therefore, was observed if there was any inconsistency identification of the validity or quantity before delivering the medicine. After separating the medications, the service should be provided in such a way that beneficiaries could maintain drugs in proper storage conditions and adequately identify them. Considering that some drugs purchased via municipal health system were those in the hospital stocks, their supply in the original packaging was often unfeasible; therefore, their fractionation was necessary. Thus, it was necessary to verify whether repackaging preserved product labeling, identification, and expiration date.

The dimension “beneficiary guidance upon medicines delivery” employed two indicators: guidance on medicines use and guidance on the outcomes of drug therapy. Some data should not be omitted in this step, such as how much, when, and how to take these medications as well as treatment duration. At the initiation of treatment and during its duration, it is important to prioritize these aspects.\textsuperscript{9,10,4,7} Therefore, it was necessary to assess the provision of guidance on product use and on access to medications that were unavailable. Furthermore, it was necessary to verify whether beneficiaries acknowledged the goal of treatment because those aware of the therapeutic effect to be achieved can better evaluate drug effectiveness and safety by diagnosing signs and symptoms that may indicate the need to return to primary health care services.\textsuperscript{9} Therefore, proper guidance on the purpose, safety, and effectiveness of treatment was also investigated.

The dimension “data recording” used the indicators record of medicines outflow/supply and record of care rendered to the beneficiary. To meet the technical and administrative needs of inventory control, it is necessary to record the outflow of dispensed medications. This helps to maintain the drug stocks needed to meet the demand, thereby avoiding inventory overlaps or product shortages.\textsuperscript{10} Accordingly, we assessed whether all drug outflow had been recorded in the inventory control system. In addition to this record, it is essential to register the service provided to the user for keeping the medical history of the beneficiary. The drugs provided, the amount dispensed, and any nonconformities and interventions during the drug-dispensing service must be recorded in the medical history of each beneficiary. The data recorded in the medical history helps to avoid prescription reuse and serves as a data source for other health care services and for the beneficiaries themselves. The interventions recorded in the medical history are primarily those related to prescription changes or interventions performed after beneficiary’s complaints on therapy effectiveness or safety.\textsuperscript{9,10} Accordingly, we verified whether inconsistencies, interventions, and drug therapy data had been recorded in the medical history of beneficiaries.

Table 1 summarizes the information in the questionnaire of an evaluation matrix, which consisted of dimensions, indicators, measures, and the parameters adopted in the model.

After data collection and analysis according to the parameters shown in Table 1, service efficacy in each primary health care unit was rated using the combination of attributes assigned to the five drug-dispensing dimensions according to the following guidelines:

- an acceptable drug-dispensing service cannot have unacceptable ratings in any of the dimensions of analysis and should necessarily have acceptable ratings in the dimensions “evaluation of prescription” and “beneficiary guidance upon medicines delivery”;
- a regular service cannot have unacceptable ratings in the dimension “evaluation of prescription” and “beneficiary guidance upon medicines delivery”.

The attributes of the dimensions “evaluation of prescription” and “beneficiary guidance upon medicines delivery” were considered to be more suitable in the final rating of the service because these dimensions required specific cognitive conditions – clinical expertise – for service provision. The dimension “separation and preparation of medicines”, despite being a specific activity of the drug-dispensing service, required less complex cognitive conditions compared with those of the previous two dimensions. The dimensions “user embrace” and “data recording”, although important, were not exclusive of the drug-dispensing service and were part of all primary health care practices.

Therefore, the efficacy of the drug-dispensing service in the primary health care units could be classified as follows:

- acceptable service: most of its dimensions are classified as good. Dimensions “evaluation of prescription” and “beneficiary guidance upon medicines delivery” should necessarily be considered acceptable, and no dimensions should be considered unacceptable;
- regular service: up to two dimensions are classified as unacceptable, except for the dimensions “evaluation of prescription” and “beneficiary guidance upon medicines delivery”;
- unacceptable service: most of its dimensions are rated as unacceptable, or the dimensions “evaluation of prescription” and “beneficiary guidance upon medicines delivery” are rated as unacceptable.

The following rating was defined for the municipality:

- acceptable: most of its services are acceptable and up to 20.0% services are classified as unacceptable;
| Dimension                        | Indicator                                         | Measurement                                                                 | Parameter                                                                                                                                                                                                 |
|---------------------------------|---------------------------------------------------|-----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| User embracement               | Beneficiary approach                               | Was a friendly approach adopted?                                            | Yes = when beneficiaries were identified in ≥ 50.0% of the services provided and were welcomed, or when professionals were at the disposal of beneficiaries in ≥ 50.0% of the services. No = when beneficiaries were identified in < 50.0% of the services. |
|                                 |                                                   | (a) Were the beneficiaries welcomed? (b) Were attempts made to identify the beneficiaries? (c) Were professionals at the disposal of the beneficiaries? |                                                                                                                                                                                                           |
| Evaluation of prescription      | Analysis of prescription                           | Were prescriptions analyzed? (a) Were legal nonconformities identified? (b) Were technical nonconformities identified? | Yes = nonconformities were identified in some prescriptions among the health services provided (a perceived event). No = no nonconformities were identified (no perceived event). |
|                                 |                                                   |                                                                            |                                                                                                                                                                                                           |
|                                 | Evaluation of drug therapy                         | Was drug therapy evaluated? (a) Were therapy nonconformities identified? (b) Was the health status assessed during drug therapy? | Yes = when the health status of beneficiaries was identified in ≥ 50.0% of the services provided or when nonconformities were identified in any of the therapies among the health care services provided (a perceived event). No = when the health status of beneficiaries was identified in < 50.0% of the services provided and no nonconformities of therapy were observed. |
| Separation and preparation of mediciness | Assessment of the quantity and quality of mediciness | Was drug quantity and expiration date assessed? (a) Were nonconformities in quantity and expiration date identified? Were these aspects verified? | Yes = when nonconformities in quantity or quality were identified or when the verifications were confirmed (a perceived event). No = when nonconformities in quantity or quality of the medicines supplied were not observed and when the verifications were not confirmed. |
|                                 |                                                   |                                                                            |                                                                                                                                                                                                           |
|                                 | Compliance with the preparation techniques          | Were the medications prepared? (a) Were the medications accompanied by drug description leaflets with data on the active ingredient, batch number, expiration date, and drug concentration (criteria for product fractionation)? | Yes = it meets the fractionation criteria in ≥ 50.0% of the services provided. No = it meets the fractionation criteria in < 50.0% of the services provided.                                                                 |
|                                 |                                                   |                                                                            |                                                                                                                                                                                                           |
|                                 | Beneficiary guidance upon medicines delivery       | Was any guidance on medicines use provided? (a) Was any guidance on the method of use (amount, when, how, and for how long) provided? (b) Was any guidance on drug access during periods of unavailability provided? | Yes = the method of use was informed in ≥ 50.0% of the services provided and guidance on drug access during periods of unavailability was provided. No = the method of use was informed in < 50.0% of the services provided. |
|                                 | Guidance on medicines use                          |                                                                            |                                                                                                                                                                                                           |
|                                 | Guidance on the outcomes of drug therapy           | Was any guidance on the outcomes of drug therapy provided? (a) Was the purpose of the medication informed? (b) Was product safety informed? (c) Was product efficacy informed? | Yes = the medication purpose, efficacy, or safety were informed in ≥ 50.0% of the services provided. No = the purpose, efficacy, or safety were informed in < 50.0% of the services provided. |
| Data recording                  | Record of medicines outflow/supply                 | Was medicines outflow/supply recorded? (a) Was the outflow of all products recorded? | Yes = product outflow/supply was recorded in the inventory control system in ≥ 50.0% of the services provided. No = product outflow/supply was recorded in the inventory control system in < 50.0% of the services provided. |
|                                 | Record of care rendered to the beneficiary         | Was the care provided to the beneficiary recorded? (a) Were interventions or nonconformities recorded? (b) Were prescription drugs recorded? | Yes = when prescription drugs were recorded in ≥ 50.0% of the services provided or the medical interventions or nonconformities observed were recorded (a perceived event). No = when prescription drugs were recorded in < 50.0% of the services provided or when no medical interventions or nonconformities were recorded. |
• unacceptable: > 40.0% municipal services are unacceptable;
• regular: includes other cases.

Table 2 summarizes the logic of classification of the proposed model.

Testing the evaluation model

In the 15 primary health care units evaluated, 288 services were provided; 12 services from two primary health care units were not included because of the decreased flow of beneficiaries. There was a limitation to measure the indicators analysis of prescription and assessment of the quantitative and qualitative aspects of medicines because these indicators can only be observed if happen verbal manifestation between health worker and beneficiary during drug-dispensing service. However, all the services provided identified cases of legal or technical nonconformities on prescriptions. Most of these cases were related to the expiration date of prescription, which is regulated by the municipality, and product usage, which led professionals to discuss this issue with the beneficiary. Thus, relevant data for the indicator analysis of prescriptions were easily obtained. The indicator assessment of the quantitative and qualitative aspects of medicines could not be fully rated because only the quantitative aspects were witnessed. According to the reports of those who participated in the study, to make drug dispensing more agile, the quality and validity of medicines are assessed in other sectors of the pharmaceutical services, such as product storage and inventory control.

Table 2. Classification model of the degree of efficacy of drug dispensing in municipal primary health care units.

| Dimension                          | Indicator and measure                                                                 | Rating of variable efficacy | Rating of service efficacy | Rating of municipality efficacy |
|------------------------------------|---------------------------------------------------------------------------------------|-----------------------------|---------------------------|-------------------------------|
| User embracement                  | Beneficiary approach Was a friendly approach adopted?                                  | Yes = Acceptable No = Unacceptable | ACCEPTABLE Predominance of acceptable ratings, presence of acceptable rating in the dimensions “evaluation of prescription”, and “beneficiary guidance upon medicines delivery”, and absence of unacceptable ratings | ACCEPTABLE Predominance of acceptable ratings; ≤ 20.0% of unacceptable ratings |
| Evaluation of prescription        | Analysis of prescription Was the analysis of prescription performed?                  | Yes + Yes = Acceptable Yes + No = Regular No + No = Unacceptable | REGULAR Maximum of two unacceptable ratings and absence of unacceptable ratings in the dimensions “evaluation of prescription” and “beneficiary guidance upon medicines delivery” | REGULAR ≤ 40.0% of unacceptable ratings |
| Separation and preparation of medicines | Assessment of the quantity and quality of medicines Was the verification of drug quantity and expiration date performed? | Yes + Yes = Acceptable Yes + No = Regular No + No = Unacceptable | UNACCEPTABLE Predominance of unacceptable ratings or presence of unacceptable ratings in the dimensions “evaluation of prescription” and “beneficiary guidance upon medicines delivery” | UNACCEPTABLE > 40.0% of unacceptable ratings |
| Beneficiary guidance upon medicines delivery | Guidance on medicines use Was any guidance of medication use provided? | Yes + Yes = Acceptable Yes + No = Regular No + No = Unacceptable | | |
| Data recording                    | Record of medicines outflow/supply Was product outflow/supply recorded?               | Yes + Yes = Acceptable Yes + No = Regular No + No = Unacceptable | | |
DISCUSSION

The proposed evaluation model expanded the understanding of drug dispensing compared with the model used by Escher et al because it incorporated elements of pharmaceutical care adopted by Angonesi and Galato et al, among other authors. This may explain the small but significant difference between Escher et al’s model and our model.

Furthermore, the proposed model allowed the measurement of service efficacy. Given that an efficacy service, when achieving its goals and objectives, is more likely to produce the expected results compared with an inefficacy service, the selection of this criterion allowed us to focus on the work process. Its mode of classification, in which the sum of the scores and combination of the results could assess the efficacy of each dimension, for each service and municipality or a set of studied services, allowed the identification of critical points that deserve intervention, both at the primary health care unit and municipal levels. The model proved to be feasible for different types of primary health care units/pharmacies in each municipality.

Our collected data provided the necessary information to measure the indicators, and the collection method adopted can be adapted to the reality and needs of each municipality, minimizing the limitations inherent to the technique of direct observation. A previous study examined different data collection methods for the evaluation of drug dispensing in pharmacies and indicated that the best option is the one adopted by external observers and simulated clients aimed to enhance the internal and external validity of the study.

With regard to the limitation inherent to the direct observation technique, we tried to minimize the Hawthorne effect on the health worker by explaining to each participant, upon signing the consent form, that the aim was to evaluate the service, primary health care units, and municipal system, and not themselves, and that their confidentiality would be maintained, including the confidentiality of the primary health care units studied. It is likely that this effect may have influenced the degree of efficacy, which was perceived in the indicator record of medicines outflow/supply, for which it was observed that all drug-dispensing services provided maintained an outflow record of all drug prescriptions provided, which is not common in these services. Concerning the Hawthorne effect on the beneficiaries, this technique served for the researcher to act as an aide of the health worker.

For a better understanding of the parameters evaluated, fourth-generation evaluation studies are recommended, in which the subjects involved in the service should be considered during the entire evaluation process.

Despite its poor scientific evaluation in Brazil, drug dispensing has been available to the public for years as the main source of access to prescription drugs. In addition to the few studies on drug dispensing, their publishing and indexing in national databases are scarce. However, the studies available have raised concerns about the quality of drug-dispensing services in Brazil. This scenario, coupled with the conceptual diversity and broad understanding of the dimensions involved in drug dispensing and the untapped potential of this service in support of outpatient follow-up, raises concerns regarding the concept of drug dispensing and the pharmaceutical assistance services that SUS has been implementing.

A constant service evaluation model is necessary so that SUS can implement its principles and guidelines. To further the importance of this issue, we hope that this study will contribute to the evaluation of drug-dispensing services under SUS and the institutionalization of evaluations to improve the decision-making process in which the democratic principle is respected and the political directionality for transformation of reality is achieved.
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This study was based on the dissertation of Sartor VB, titled: “Avaliação do serviço de dispensação de medicamentos na rede de atenção básica do SUS”, presented to the Programa de Pós-Graduação em Saúde Coletiva at the Universidade Federal de Santa Catarina, in 2010.

The authors declare no conflict of interest.
Limitations to the access to medication in basic health care services still exist and they need to be addressed. These include the inability of many users to obtain all prescription medications, the inadequate use of medications (a public health problem), and the limited access to information and guidance regarding the use of these medications.

The aim of this study was to present an evaluation model to assess the effectiveness and management of drug distribution service in primary health care. Its results are expected to provide information that helps promote decision making with the view to ensure the quality of this service through Brazilian Unified Health System (SUS).

The proposed evaluation model is based on the adoption of an efficacy criterion and allows the assessment of the level of achievement of the service objectives. An effective drug distribution service is more likely to produce the expected results. The efficacy criterion allowed us to focus on the operational processes. This evaluation model allowed the evaluation of the efficacy of each distribution variable (acceptance, evaluation of prescription; medication sorting and preparation, guidance, and recording of the data generated) for each service and city evaluated, with the goal to identify the critical points that need intervention, both at the level of the health care units/pharmacies and at the municipal level.

With the implementation of proposed evaluation model, the results are expected to help SUS managers to take concrete political decisions that could improve the drug distribution system within the primary health care network.

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