

Evaluation of pharmaceutical care in Brazilian primary health services settings: expanding objects and approaches

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*This study was financed in part by the Coordenação de Aperfeiçoamento de
Pessoal de Nível Superior - Brasil (CAPES) - Finance Code 001.*

The objective of this work is to reflect on the objects and approaches usually employed in the evaluation of pharmaceutical care and their potential applicability in primary care settings. We conducted the review of the literature, and, to exemplify the advantages of expanding these objects and approaches, a real-world problem situation was selected: morbidity and mortality related to lack of treatment adherence by hypertensive patients in Brazilian primary health care services. Our reflections highlight the need to evaluate the effects of interventions, understood within Donabedian's normative model as 'outcomes,' which can be clinical, humanistic, or economic. Our findings show that most published studies, even those that set out to report outcomes, actually evaluate processes, such as number of visits, number of problems identified, types of problems, or acts of the practice performed by pharmacists. On the other hand, we also identify a need for study designs and indicators to enable 'finer' normative assessment. We also discuss the importance of shifting research toward an evaluative paradigm to allow strategic, logic, effects, production, efficiency, and implementation analyses. Finally, we suggest some possible indicators to evaluate pharmaceutical care interventions in the selected problem situation, through an extension of the objects and approaches proposed.

Keywords: Pharmaceutical care. Health evaluation. Primary care. Medication adherence. Hypertension.

INTRODUCTION

Health evaluation is a vast field of research. Within it, the complexity of the objects of evaluation coexists with methodological challenges—a combination which influences its objectives and effectiveness. The evaluation process ranges from guiding managers' decision-making to ensuring that desired or expected objectives are

actually reached (Mattos, Baptista, 2015). In this paper, we start from the premise that evaluation can contribute to improving the evaluated program or intervention (Brousselle *et al.*, 2011); in this specific case, we consider the potential of expanding the objects and approaches of evaluation studies to improve pharmaceutical care.

One of the motivators of this work is the authors' professional experience in a clinical pharmacy service that developed several process indicators, e.g., "number of visits," "types of problems identified," and "types of pharmaceutical services provided," and erroneously presented these in reports as result indicators. In this case, we will discuss the need for analyses of intervention

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effects to improve the quality of pharmaceutical care services.

The development of evaluation models, i.e., normative elements that allow interpretation of indicators (Champagne *et al.*, 2011), is an important tool for the actors involved in this process—both the evaluators and the evaluated—to understand the dimensions of what professionals will do. One of the objectives of such models is to allow institutionalization of the evaluation process while simultaneously allowing comparison of different services. For our discussion of evaluation models, we will address an example case: pharmaceutical care in primary care settings.

The Brazilian Federal Board of Pharmacy recently published the following conceptual definition of pharmaceutical care:

[it] is the model of practice that guides the provision of various directly patient-, family-, and community-centered pharmaceutical services, with the goal of preventing and solving problems related to pharmacotherapy; the rational and optimal use of medicines; the promotion, protection, and recovery of health; and the prevention of diseases and other health conditions” (CFF, 2016, p.55).

From an evaluative standpoint, each of the actions involved in pharmaceutical care, be they policies, programs, projects, or activities, can be regarded as interventions designed to correct problem situations of varying magnitude and complexity. An intervention can be conceptualized as an “organized system of action” (Champagne *et al.*, 2011). The relationship between the components of a pharmaceutical care intervention and the problem situation which it seeks to remedy is in Figure 1. This schematic illustrates a proposal of how the components of an intervention—structure, with its physical, resources, organizational, and symbolic dimensions; actors and their practices; the intervention process itself; the desired effect; and, finally, the setting or context within which it takes place—relate to one another (Champagne *et al.*, 2011). The pharmaceutical care interventions discussed herein seek to influence morbidity and mortality related to medication adherence issues in patients with hypertension treated at primary health care facilities in Brazil, with the ultimate objective of generating effects related to clinical, humanistic, and economic aspects.

In this paper, the term *intervention* is used not in the sense of *pharmaceutical intervention*, defined by the Federal Board of Pharmacy as a “professional act

planned, documented, and carried out by a pharmacist with the purpose of optimizing pharmacotherapy, promotion, protection, and recovery of health, prevention of diseases and other health conditions” (CFF, 2016); these individual activities will be referred to throughout as *acts of practice*, so as to prevent confusion with the term *intervention* as used in the context of evaluation research. These *acts of practice* can be part of several types of interventions or programs.

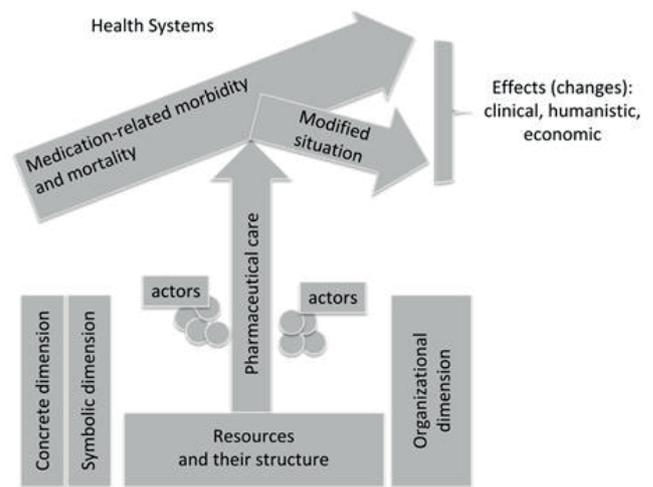


FIGURE 1 - Pharmaceutical care as an intervention (organized system of action).

Source: adapted from Champagne *et al.*, 2011

Brouselle *et al.* (2011) suggest that care, in general, can be understood as an intervention that changes the initial path of a problem situation (produces an effect)—in this case, morbidity and mortality related to poor medication adherence, a phenomenon which has a direct relationship with access to medicines and their use.

The understanding that pharmaceutical care may influence morbidity and mortality rates has been advocated at least since the 1990s, by Hepler and Strand (1990), although the concept that the outcomes, or effects, of such care should be evaluated from clinical, humanistic, and economic standpoints is more recent (Mendes, 2011; Cipolle, Strand, Morley, 2004). According to Souza, Moreira and Borges (2016), some of the general effects of improved adherence on clinical outcomes in hypertension, for example, include positive impacts on the mental and physical domains, as well as improvement in overall quality of life.

The structure that supports and enables an intervention—in the case at hand, pharmaceutical care—

covers several interdependent dimensions. The most discussed is the physical dimension, described in Figure 1 as ‘resources and their structure’, which is related to financial, human, physical, technical, and information resources (Champagne *et al.*, 2011); these can encompass health facilities, physical spaces, technologies/devices, and public or private funds (Mattos, Baptista, 2015). The other dimensions are at least equally important, despite being the object of less research.

The symbolic dimension is related to attitudinal issues, which correspond to the set of beliefs, representations, and values (Champagne *et al.*, 2011) that may influence the pharmacist or other actors involved (patients, other providers, managers, the community, funders/payers, and political actors) to communicate with one other and give meaning to their actions (Champagne *et al.*, 2011; Mattos, Baptista, 2015). For instance, the actors may have the financial, physical, or other resources necessary to carry out an intervention, but if they lack confidence to do so in their specific context or situation, the intervention can fail. Besides, there is the concrete dimension, which concerns the lived experiences of these actors (Barsaglini, 2011) and can have a positive or negative influence on the setting. Mattos and Baptista (2015) adopt the term “symbolic representations” instead (representations of health and illness, of life itself, shared values, collective norms), which, in this case, would involve both the symbolic and concrete dimensions; this broader conceptualization explains why some authors include only one dimension in this part of the model (Champagne *et al.*, 2011; Mattos, Baptista, 2015).

The organizational dimension corresponds to a set of laws, regulations, conventions, political norms (governmental or otherwise), the organization of social groups (Champagne *et al.*, 2011; Mattos, Baptista, 2015), and rules that define the distribution and exchange of resources—the ‘rules of the game’ of the intervention (Champagne *et al.*, 2011), which can be influenced by or influence the actors involved.

These dimensions are mobilized by the actors, who use them to produce the goods and services needed to carry out the intervention (Champagne *et al.*, 2011). The actors can be health providers, managers, or members of the target audience of the intervention and can help or hinder the process, depending on how they interact with the intervention components. According to Champagne *et al.* (2011), the actors are engaged in a permanent ‘game’ of cooperation and

competition and are those who, as a result of their characteristics, intentions, interests, and convictions, shape the intervention at a given point in time and in a given context.

Several authors have proposed different models that have been used in the evaluation of health services in general and pharmaceutical services as well (Marin *et al.*, 2003; Correr, Otuki, Soler, 2011; Sartor, Freitas, 2014). According to Champagne (1991), these different models may include complementary dimensions; however, all usually include evaluation of performance (outcomes/effects) as one of their goals.

Within this context, this paper aims to reflect on the objects and approaches usually employed in the evaluation and their potential applicability to pharmaceutical care in primary care settings.

METHODS

In this narrative review, we explore the proposal of normative assessment and evaluative research and present reflections on an example application of these theories to pharmaceutical care in primary care settings. We collected data through a review of books that covered the topic of interest.

Our representation of the processes of care and evaluation followed the reference framework of the Donabedian model (Donabedian, 1980) and the Champagne *et al.* (2011) model; i.e., we adopted normative assessment and evaluative research to construct our research question: “*Which objects and approaches can be proposed to broaden evaluation of pharmaceutical care interventions?*”.

To assist in our reflections on the evaluation of pharmaceutical care in primary care settings, we defined a problem situation: morbidity and mortality due to lack of medication adherence in patients with hypertension. In this problem situation, uncontrolled hypertension due to lack of treatment adherence (pharmacological or otherwise) is the health need. We adopted the World Health Organization definition of “adherence”, which conceptualizes it as a multidimensional factor (WHO, 2003) related not only to the act of taking medication as prescribed, but also to the way in which patients lead their own treatment (Bezerra, Lopes, Barros, 2014), and, consequently, related to individual patient behavior. Also, this case was selected because, at the very least, multidisciplinary work is required to ensure adherence.

RESULTS AND DISCUSSION

Donabedian described the hegemonic model of health services evaluation (Mattos, Baptista, 2015). This model, first proposed in 1980, is based on what is known as the structure–process–outcome triad. Within the context of clinical services, it can be applied as shown in Figure 2.

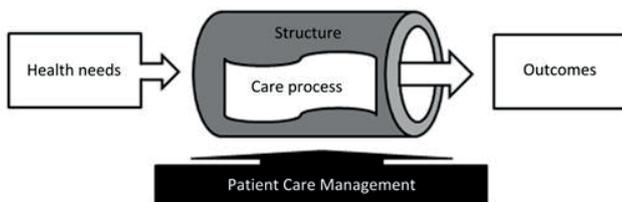


FIGURE 2 - Representation of the Donabedian structure–process–outcome model as it applies to the provision of clinical services.

Source: adapted from Donabedian (1980).

For providing clinical services, structural conditions are necessary. The structure is a dynamic entity, which is not restricted to buildings and furniture, but also includes human resources and access to evidence-based information (Mattos, Baptista, 2015; Storpirtis *et al.*, 2008), as previously discussed.

Processes, in turn, cover the activities which involve health providers and patients, based on accepted standards. In the specific case of health services or facilities, in addition to how each patient or patient population receives the services, support activities and existing definitions of processes—understood as the constituent elements of practices that involve the provider-user relationship—should also be covered (Costa, 2009). In most cases, indicators such as *number of visits*, *number of patients seen*, *number of referrals*, or *number of patients discharged* could be considered aspects of the processes of an intervention. However, they present these indicators to managers as the outcomes of the service provided. It should be noted, however, that these indicators can represent productivity outcomes when service implementation is under evaluation (Brasil, 2014).

Outcomes should not be described only as those that “affect the patient’s health,” because the “expected results” of what is under evaluation depend on the intervention of interest and the object of evaluation.

For instance, the organization or implementation of a clinical pharmacy service may be an intervention that seeks organizational rather than clinical results; thus, its evaluation should analyze this type of outcome (*Were the expected instances created? Were the chains of command clear? Have the designed processes implemented?*). It is also useful for evaluation to focus on “clinical, humanistic, and economic” aspects, to ensure that it achieves an even more robust assessment.

Notice that the Donabedian model is part of a so-called normative assessment. Normative assessments require the adoption of criteria, which may be related to: the implementation fidelity of each intervention in relation to the initial plan or design; the coverage of the intervention in relation to the initially planned target audience or population; the quality of the intervention, i.e., whether the process of care corresponds to the original design; cost, i.e., whether the intervention can be carried out within the expected budget; and, finally, the effect of the intervention, i.e., whether the intervention achieved the expected initially outcome. These criteria may be directly or indirectly related to one or more focuses of evaluation—i.e., structure, process, or outcome (Champagne *et al.*, 2011).

Another approach developed by Donabedian evaluates the quality of health services and proposes the “seven pillars of quality”: efficacy, effectiveness, efficiency, optimality, acceptability, legitimacy, and equity (Donabedian, 1990). As his original model is normative, it fails to cover all of these aspects of the evaluation process (Mattos, Baptista, 2015).

Figure 3 illustrates, to a certain extent, the limitations of normative evaluation as described above, whereby only the components of the intervention are evaluated, ignoring their interrelationships. The latter are objects of evaluative research.

There are six types of analyses in evaluative research. Each seeks to analyze the adequacy of a different component of the intervention and how pertinent they are within the intervention context or setting. The strategic analysis determines the relevance and feasibility of interventions; logic analysis evaluates the suitability of whether objectives with the means used to achieve them and; analysis of production focuses on the relationship between these means and the quantity and quality of the services provided. Analysis of effects measures the effectiveness of the interventions, i.e., the extent to which the provided services influenced the health

status of their users. Analysis of efficiency correlates resources and effects, but from an economic standpoint, while implementation analysis studies the relationship between the intervention and its context and compares it to the effects achieved (Champagne *et al.*, 2011).

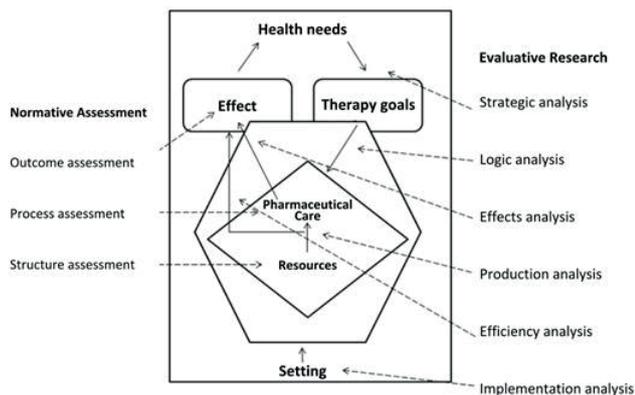


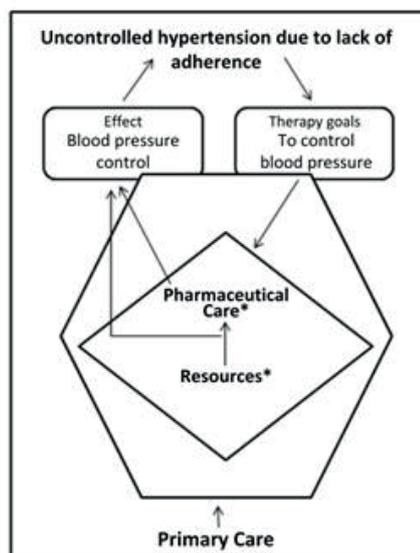
FIGURE 3 - Components of a health intervention. Source: adapted from Champagne *et al.*, 2011

Fitting this model of the components of evaluation of a health care intervention to our problem situation of pharmaceutical care—case management of patients with uncontrolled hypertension due to lack of medication adherence—generates the scenario illustrated in Figure 4. In this scenario, only one clinical outcome—namely, blood pressure control, considered a short-term outcome or result—was defined as an effect; however, other long-term outcomes could have been defined, such as the rate of hospitalization or death by cardiovascular disease. Humanistic outcomes, such as life quality or satisfaction degree, could also have been included, as well as organizational outcomes or even economic outcomes, such as costs (cost-utility and cost-effectiveness).

In order to change the problem situation, i.e., address the health needs of the target population due to low adherence, pharmaceutical care actions, including referrals involving other actors, to enhance patient empowerment, achieves the goal or effect of therapy. Effective implementation of these, in turn, requires resources to enable achievement of the desired effect (blood pressure control). Within this context, we propose indicators that cover the different components of normative assessment and evaluative research (Table I).

The literature discusses several definitions of evaluation indicators (Jannuzzi, 2012; Jannuzzi, 2005; Worthen, Sanders, Fitzpatrick, 2004; Brasil, 2007; Alves,

2010). For this review, we can define the indicators by the criteria, aspects, or dimensions of an intervention that are of interest to the evaluators—e.g., in normative assessment, these can be the structures, processes, or outcomes of the program (Alves, 2010). We can define an indicator as “a quantitative or qualitative factor or variable, empirically connected to the criterion variable, that provides a simple and reliable means to measure the occurrence of a phenomenon” (Patton, 1997, in Alves, 2010). Jannuzzi, in a discussion of social programs derived from public policies, notes further aspects that we can apply to the indicators of other interventions; in this context, these would be “measures used to enable operationalization of an abstract concept or demand of programmatic interest. Indicators point out, suggest, approximate, translate into operational terms” those aspects of interest defined from theoretical or programmatic choices defined a priori (Jannuzzi, 2005).



*Health education, medication review, follow-up
 **E.g., financial resources, pharmacist, office/clinic, protocols, patient information, evidence-based information sources and databases

FIGURE 4 - Schematic illustration of intervention on the problem situation in the primary care setting.

It should be borne in mind that the indicators chosen for an evaluation depend entirely on the design of the study—which may be qualitative and quantitative—and that the examples presented herein are intended only to illustrate the nature of indicators, i.e., serving as a concrete synthesis of an aspect of evaluative interest:

The choice of the type of indicator, i.e., of what is to be measured depends on what we are evaluating, whether it is the supply, utilization, coverage, or impact of the

program/intervention (...) The type of indicator used and the complexity of the evaluation depends on the intended use of the result of the evaluation (Brasil, 2007).

TABLE I - Possible indicators for normative assessment and evaluative research of pharmaceutical care interventions in the selected problem situation

Normative Assessment: Potential interventions and indicators

STRUCTURE ASSESSMENT

Analyzes the expected necessary elements for carrying out the activities as compared to the resources actually mobilized/implemented during the intervention

Examples of potential indicators for a program to “Foster pharmaceutical care activities in a Municipal Regional Health Trust”

- Proportion of basic health units with an embedded pharmacist’s office within the regional network as compared to the proportion planned for full program operation.
- Proportion of pharmacist’s offices in basic health units participating in the program which have received Internet connectivity equipment as compared to the original goal of 75%.
- Number of working hours of pharmacy providers working on program activities as compared to the planned minimum.

PROCESS ASSESSMENT

Analyzes the planned care process as compared to that actually implemented, and planned actions as compared to those actually carried out

Examples of potential indicators for a project to “Improve the quality of pharmacist consultations for hypertensive patients at a Basic Health Unit”

- Proportion of patients with care plans entered in their medical records at first consultation by the end of the project, as compared to the planned goal of recording care plans in 80% of patients.
- Proportions of the number and type of pharmaceutical interventions provided for in the program which were actually carried out.
- Proportion of pharmacist consultations for elderly hypertensive patients with polypharmacy during which the Medication Organization pharmaceutical procedure (CFC, 2016), provided for in the program, was actually carried out.

OUTCOME ASSESSMENT

Measurement of the observed clinical, humanistic, and/or economic effects of the intervention and comparison with the expected outcomes (whether the intervention actually caused the effects is not assessed)

Examples of potential indicators for an intervention to “Improve medication adherence in hypertensive patients”

- Proportion of elderly patients participating in the program who, according to caregivers, took their antihypertensive drugs “as prescribed” in at least 80% of doses.
- Percent variation in responses to the 1986 Morisky–Green–Levine Medication Adherence Scale (MGLS) in patients who took part in the project for 6 months.
- Reduction in hospitalizations for primary care-sensitive conditions related to high blood pressure in patients who took part in the project for 12 months and who exhibited improved adherence to therapy.
- Reduction in emergency department visits for hypertensive crisis in patients who took part in the program.
 - Change in degree of satisfaction with level of treatment adherence in patients who took part in the program and who reported dissatisfaction at the start of the project.

continuing

TABLE I - Possible indicators for normative assessment and evaluative research of pharmaceutical care interventions in the selected problem situation

Evaluative Research: Potential interventions and indicators

STRATEGIC ANALYSIS

Relationship between the problems to be addressed and the objectives of the intervention

Example of a potential indicator for an intervention to “Improve adherence through behavioral changes in hypertensive patients”

- Extent to which the goals of therapy adequately address the causes of low adherence (which could be attributable mainly to deficiencies in the distribution or access to medicines rather than to patient behaviors).

LOGIC ANALYSIS

Relationship between the objectives of the intervention and its theoretical framework or the means made available to achieve them

Examples of potential indicators for a project of “Implementation of a pharmaceutical referral service for hypertensive patients within a municipal primary care network”

- Degree of scientific evidence about the effectiveness of this type of service (are there published experiences demonstrating positive effects of such referral services for this patient population?).
- Relationship between the objectives of the pharmaceutical care program and the resources earmarked for its implementation (e.g., Is the number of providers to be hired consistent with the planned number of consultations?).

EFFECTS ANALYSIS

Tests for a causal relationship between the intervention and the set of effects it can produce (predicted and unpredicted; positive, negative, or neutral). Evaluates the generalizability of the effects of a given program.

Example of potential indicators for a project to “Improve adherence through behavioral changes in hypertensive patients”

- Comparison of responses to the 1986 MGLS between patients who took part in the program and patients from a control group which did not take part.
- Variability in improvement in treatment adherence when the same program is implemented by teams with different degrees of motivation.

PRODUCTION ANALYSIS

Assesses the relationship between the resources used and the quantity and/or quality of the services produced by the intervention

Examples of possible indicators for a program to “Improve the quality of pharmacist consultations for hypertensive patients at a Basic Health Unit”

- Number of pharmaceutical care encounters needed to obtain one patient whose blood pressure is “controlled” according to international parameters.
- Quality of the accessibility of pharmaceutical consultations (measured after 12 months of project implementation) for those hypertensive patients considered to be at greatest risk.

continuing

TABLE I - Possible indicators for normative assessment and evaluative research of pharmaceutical care interventions in the selected problem situation

EFFICIENCY ANALYSIS

Includes different types of economic evaluations (e.g., cost-benefit, cost-effectiveness, or cost-utility analyzes) used to judge the relationship between the results obtained and the resources employed in the intervention, considering the latter as costs.

Example of a potential indicator for a program to “Foster pharmaceutical care activities in a Municipal Regional Health Trust”

- Comparison of out-of-pocket costs to patients and their families for hospitalization due to complications of uncontrolled hypertension in patients who take part in the program vs. a control group not taking part in the program.

IMPLEMENTATION ANALYSIS

Studies the relationship between the intervention and its context (organizational, social, political); can also analyze the influence of this relationship on the effects achieved by the program. Can be used to study an intervention in a given context or to compare the same intervention in different contexts.

Examples of a potential indicator for an intervention to “Improve medication adherence in hypertensive patients”

- Differences in the implementation of technical aspects of the program (implementation of pharmaceutical procedures, defined according to CFF (2016), expected to improve adherence) between municipalities with and without outsourced health facility management models (effect of different organizational contexts on the program).
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These examples, far from being a “showcase” or “dashboard” for selection of indicators, are intended to encourage those interested in pharmaceutical care to start designing evaluations that incorporate a broader range of objects and to use approaches that go beyond merely describing or tallying the activities carried out in a given program or facility. Regarding the types of evaluation, we sought to discuss the need for a vision that extends beyond the Donabedian model to introduce evaluative research components as well. It bears stressing that “*different types of indicators are not mutually exclusive*” (Brasil, 2007). It is essential that this reflection be extended to the providers who carry out pharmaceutical services as well as also to the managers who promote these services, at all levels of health care, to encourage their participation throughout the evaluation process, from designing assessments to defining indicators (Onocko, Furtado *et al.*, 2013). Notice that the case or problem situation, created for this paper and the proposed indicators for its evaluation represent a micro-scale vision of the pharmaceutical care process that focuses on each patient as an individual, i.e., it would fall under the scope of “case management.” If we assess the case at the macro scale, which often represents the manager’s view, the indicators might

have been broader, representing the process as a whole and focused on addressing coverage-related indicators; analyses of production, efficiency, and implementation might have been included as well. Finally, it is worth noting that our reflection does not intend to exhaust the topic of evaluation in pharmaceutical care, nor the use of models (and the objects and approaches that compose them) for this purpose. Our intended purpose, instead, was to generate discussion about these topics. We can develop many indicators from this proposal. Furthermore, evaluations can be carried out, focusing on only one of the presented dimensions.

Pharmaceutical care can be understood as a type of health intervention that seeks to improve medication-related morbidity and mortality outcomes. In this sense, it is necessary to rethink the process of evaluating pharmaceutical care and its focus, seeking to identify the relationships between the components of a health intervention and address issues beyond those covered by the classic Donabedian model.

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Received for publication on 25th September 2018
Accepted for publication on 29th September 2019