

Mapping community pharmacy services in Brazil: a scoping review

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The delivery of clinical pharmacy services has been growing in Brazilian community pharmacies, and it is necessary to have a comprehensive understanding of the topic. This scoping review aimed to provide an overview of Brazilian studies about clinical pharmacy services in community pharmacies. Original research articles, with no restriction of time, study design, or patient's health condition, were included. Searches were conducted in PubMed, Scopus, Web of Science, Scielo, and Lilacs. Two reviewers conducted the screening, full-text reading, and data extraction independently. ROB and ROBINS-I were used for the assessment of quality. Charts and tables were built to summarise the data. Seventy-two articles were included. A diversity of study designs, number of participants, terms used, and outcomes was found. São Paulo and Sergipe States had the highest number of studies (n=10). Pharmacists' interventions were not fully reported in 65% of studies, and most studies presented an unclear risk of bias. Studies were very diverse, impairing the comparisons between the results and hindering their reproducibility. This review suggests using guidelines and checklists for better structuration of pharmacists' interventions as well as reporting results and measuring fidelity in future research.

Keywords: Community pharmacy services. Pharmacists. Pharmacy research. Terminology. Public Reporting of Healthcare Data.

INTRODUCTION

The Brazilian health system comprises a complex network of healthcare providers that deliver free-of-charge services to the population through the Unified Health System (*Sistema Único de Saúde* – SUS) and can be complemented by private paid services from the Supplementary Health (Paim *et al.*, 2011; Silva, Fegadolli, 2020). SUS is a universal healthcare system organised according to levels of care (primary, secondary, and tertiary) depending on how specialised a service is (Paim *et al.*, 2011). Primary healthcare is designed to cover the

whole country for the provision of ease-of-access general health practice. However, similarly to other countries, the system is fragmented, hindering the continuity of effective and qualified services to the population (Mendes, 2010; Silva, Fegadolli, 2020). In attempt to overcome the Brazilian health system's fragmentation, the organisation of healthcare networks was established in 2010, which is a set of actions to integrate logistical, technical, and management aspects to provide integral healthcare (Brasil, 2010). In this context, Brazilian pharmaceutical assistance has been developed for both logistical activities of access to medicines and the promotion of rational use of medicines through clinical pharmacy services (CFF, 2016a).

Clinical pharmacy services are healthcare activities developed by the pharmacist directly to the patient to optimise the medication use process and to help in

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the management of acute and chronic diseases (CFF, 2016a; Rotta *et al.*, 2015b). These services are considered 'complex interventions' because they comprise several intertwined elements, dynamically interacting with one another, to achieve the desirable health results (Clay *et al.*, 2019; Craig *et al.*, 2008). All the components of structure and process of each clinical service must be clearly defined to guarantee their quality and reproducibility (Clay *et al.*, 2019; Rotta *et al.*, 2015a).

The population can receive clinical pharmacy services in Brazilian community pharmacies, which are non-hospital, non-outpatient, patient care facilities, public or private, designed to assist the population in the provision and use of medications (Correr, Otuki, 2013). As community pharmacies are spread throughout the Brazilian territory, most patients have easy access to them, and they can be a strategic place for the development of healthcare (CFF, 2016a; Correr, Otuki, 2013; Leite *et al.*, 2017).

Clinical pharmacy services have expanded recently in Brazil (CFF, 2016a) due to a combination of factors. First, there were relevant policy and legislation improvements related to pharmacists' professional activities enacted by the Brazilian Pharmacy Federal Board (CFF, 2013a, 2013b) and the National Health Agency (Brasil, 2009, 2014). Second, there were governmental programmes providing upskill training for pharmacists and implementation of clinical pharmacy services in public community pharmacies (Brasil, 2012). Last, there has been a tendency of some private community pharmacy chains to increase the provision of clinical pharmacy services delivered (ABRAFARMA, 2017).

Along with this expanding scenario of clinical pharmacy services provision, important research has been conducted. It has been shown by some primary studies that medication dispensing is the most common clinical service delivered in Brazilian community pharmacies, while other clinical services, such as pharmacotherapy monitoring and follow-up of patients on medication, seem not to be fully consolidated yet (CFF, 2015; Leite *et al.*, 2017; Oliveira *et al.*, 2017). However, unlike countries in Europe and North America, which concentrate most studies about clinical pharmacy services, including several literature reviews (Alhusein, Watson, 2019;

Costa *et al.*, 2019; Rotta *et al.*, 2017), to the authors' best knowledge, there are no secondary studies (i.e., literature review) in Brazil to date assessing Brazilian research on the topic. Therefore, it is timely and of great importance to have a comprehensive record of the state of the knowledge to both facilitate future research and support policy makers and pharmacy practice innovation in Brazil.

Based on the above-mentioned information, this scoping review aimed to provide an overview of Brazilian studies about clinical pharmacy services in community pharmacies. Furthermore, it also aimed to investigate how these services were structured and delivered, whether the evaluation of the intervention fidelity was measured, the terminology employed, the risk of bias (ROB), and the quality of the report of the pharmaceutical interventions performed.

METHODS

This scoping review was conducted according to the recommendations of The Joanna Briggs Institute (2015) for scoping reviews, and a protocol was developed (available at: https://osf.io/c49nj/). The PRISMA-ScR Checklist – Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews (Tricco *et al.*, 2018) was used for reporting results, and it is available in Supplementary Material 1.

Eligibility criteria

Original research articles, with no restrictions of publication date or study design, that evaluated the effect of clinical pharmacy services provided in Brazil to individual patients and reporting health outcomes or process indicators were included. All types of clinical pharmacy services delivered directly by the pharmacist or under his direct supervision were included, in public or private community pharmacies, and without restriction of participants' socio-demographic characteristics or health conditions. Reviews, guidelines, protocols, unpublished studies, conference proceedings, and articles written in non-Roman characters were excluded. Studies with interventions addressed to a group of patients with no

report of individual outcomes, interventions performed along with a multi-disciplinary healthcare team or where the role of the pharmacist was not specifically described, and non-Brazilian studies were also excluded. As recommended for scoping reviews, no study was excluded based on methodological quality.

Information sources and study selection

Searches were done without time limit in the following databases: PubMed, Scopus, Web of Science, Scielo, and Lilacs (last update: November 2020). Additionally, manual searches were performed in Google Scholar and in the Brazilian bibliography database Portal de Periódicos CAPES/MEC. Search strategies used a combination of the following keywords: 'community pharmacy services', 'pharmaceutical services', 'clinical pharmacy', 'pharmacist intervention', 'pharmacist', and 'Brazil'. Complete search strategies are available in Supplementary Material 2. All articles retrieved were imported to a reference manager, duplicates were removed, and then two researchers (AAG and IM) independently screened titles and abstracts based on the inclusion criteria. In a second stage, full-text articles were independently evaluated by these two researchers. Discrepancies were conciliated in a discussion meeting using a third researcher as referee (AB).

Data extraction and charting process

Data of the finally included articles were extracted independently in duplicate (AAG and IM) using a form developed according to the objectives of this scoping review. The extracted data were authors, year of publication, city/state where the study was conducted, study design, number of participants, nature of community pharmacy (i.e., private or public), type of clinical pharmacy service and its characteristics, terms used to describe the service, outcomes or processes evaluated, and conceptual framework used. Grouping of the services with similar characteristics was done based on the descriptions extracted from the studies in comparison with the Brazilian Pharmacy Federal Board (Conselho Federal de Farmácia - CFF) recommendations

(CFF, 2016a). A narrative synthesis of the extracted information was performed. When possible, data were summarised using descriptive statistics, including percentages as appropriate, and tables were built.

Quality of the studies

As part of the mapping of this scoping review, a quality analysis of the included studies was done to critically evaluate their limitations but not to produce evidence or conclusions. Cochrane Collaboration tools were used: ROB (The Cochrane Collaboration, 2008) was used for the randomised controlled trials (RCT), and the Risk of Bias in Non-randomised Studies of Interventions (ROBINS-I) (Sterne et al., 2016) was used for other study designs. We decided to use ROB and ROBINS-I to keep a minimum number of tools in order to avoid heterogeneity of data with comparisons between the results of different tools that could hinder reliable conclusions. Because of the wide variability of study designs, both tools were adapted according to the nature of intervention of the clinical pharmacy services and outcomes according to Tonin et al. (2019). RCT studies were classified as of low ROB in the blinding domain when authors reported efforts to guarantee blinding of all information as possible. A narrative analysis of the report of interventions was done considering the essential concepts and components of the DEPICT checklist (Rotta et al., 2015a), but an in-depth analysis with a systematic application of the instrument for each study was not done because it was out of the scope of this review.

RESULTS

After the removal of duplicates, 1,225 entries were found from the database search; 1,096 articles remained, and their titles and abstracts were screened. Finally, 129 full-text articles were evaluated for eligibility, and 72 were finally included for analysis. A manual search was also conducted, retrieving 115 articles, but after screening, no study was included. Figure 1 provides a flowchart of this scoping review. The data extracted are summarised in Table I, and the references of the included studies are available in Supplementary Material 3.

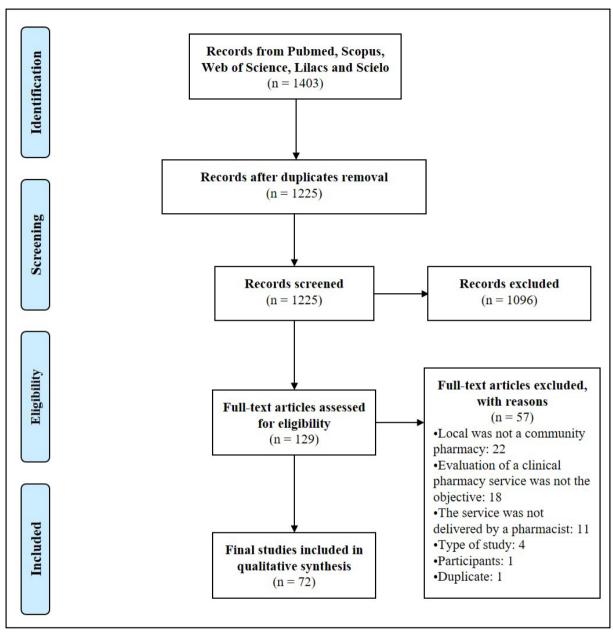


FIGURE 1 - Flowchart of the literature selection for this scoping review.

TABLE I - Summary of the data from studies included in the scoping review

Authors/year of publication	City/state	Nature of CP ^a	Study design	PS ^b evaluated	Participants (n intervention group / n control group)	Health condition	Outcomes (ECHO model)	Other elements evaluated
Firmino et al., 2015	Fortaleza, CE	Public	RCT ^c	Medication therapy management	Patients (26/30)	Hyp ^d /CAD ^c	Clinical	DRP^{f}
Mourão et al., 2013	Ouro Preto, MG	Public	RCT	Medication therapy management	Patients (50/50)	DM2 ^g	Clinical	Medication used profile
Obreli-Neto <i>et al.</i> , 2011a, 2011b, 2015	Salto Grande, SP	Public	RCT	Medication therapy management	Patients (97/97)	Elderly - DM2, hyp	Clinical, economic	Adherence

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Plaster et al., 2012	Vila Velha, ES	Public	RCT	Medication therapy management	Patients (38/36)	Metabolic syndrome	Clinical	Adherence
Aguiar et al., 2012	Aracaju, SE	Public	Quasi- experimental	Medication therapy management	Patients (35) (pilot study)	Elderly, hyp	Clinical	DRP, adherence
Aguiar, Balisa- Rocha, Lyra Junior, 2013	Aracaju, SE	Public	Descriptive- evaluative	Medication therapy management	Pharmacists (2) and patients (69) (pilot study)	No restriction	Humanistic (satisfaction, patients)	Infra-structure, follow-up process, counselling, use of EBP ^h , communication skills (<i>pharmacists</i>)
Andrade et al., 2009	Vitória, ES	Private	Cross- sectional	Medication therapy management	Patients (50/41)	No restriction	Humanistic (satisfaction)	NA*
Balisa-Rocha et al., 2012	Aracaju, SE	Public	Quasi- experimental	Medication therapy management	Patients (34) (pilot study)	Elderly, DM2	Clinical, humanistic (QoL')	Medication use profile, DRP
Brito et al., 2009	Aracaju, SE	Public	Quasi- experimental	Medication therapy management	Patients (30)	Elderly	NA	Medication use profile
Brune, Ferreira, Ferrari, 2014	Pontal do Araguaia, MT	Public	Quasi- experimental	Medication therapy management	Patients (25)	Нур	Clinical	DRP
Cazarim <i>et al.</i> , 2016, 2017, 2018	Ribeirão Preto, SP	Public	Quasi- experimental	Medication therapy management	Patients (104)	Hyp/CAD	Clinical, humanistic (QoL), economic	Adherence
Correr et al., 2009a, 2009b, 2011	Curitiba, Paranaguá, Colombo, Campo Largo, PR	Private	Quasi- experimental	Medication therapy management	Patients (50/46)	DM2	Clinical, economic, humanistic (satisfaction, QoL)	Medication use profile
Foppa et al., 2016	Florianópolis, SC	Public	Quasi- experimental	Medication therapy management	Patients (51)	Parkinson's	Clinical, humanistic (QoL)	Adherence, DRP
Garabeli et al., 2016	Ponta Grossa, PR	Public	Cross- sectional	Medication therapy management	Patients (110)	DM1	Clinical, humanistic (QoL)	NA
Loureiro et al., 2012	Fortaleza, CE	Public	Quasi- experimental	Medication therapy management	Patients (45)	HIV/AIDS	Clinical, humanistic (QoL)	DRP, medication use profile
Lyra Junior et al., 2007	Ribeirão Preto, SP	Public	Quasi- experimental	Medication therapy management	Patients (30)	Elderly	Humanistic (QoL)	DRP
Marques et al., 2009	Alfenas, MG	Public	Quasi- experimental	Medication therapy management	Patients (74)	No restriction	NA	Medication use profile, DRP
Melo <i>et al.</i> , 2017; Melo, Castro, 2017	São Paulo, SP	Public	Cross- sectional	Medication therapy management, dispensing	Pharmacist (1) and assistants (4)	No restriction	NA	Counselling, follow-up process, components of dispensing
Mendonça et al., 2016	Divinópolis, MG	Public	Descriptive (retrospective)	Medication therapy management	Patients (92)	No restriction	Clinical	DRP, medication use profile
Silva, Bazotte, 2011	Maringá, PR	Private	Quasi- experimental	Medication therapy management	Patients (51)	DM2	Clinical	NA
Silva et al., 2013	Recife, PE	Public	Quasi- experimental	Medication therapy management	Patients (14) (pilot study)	Elderly - dys ^j	Clinical	Medication use profile, DRP, adherence

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Souza et al., 2009	Recife, PE	Public	Quasi- experimental	Medication therapy management	Patients (10) (pilot study)	Нур	Clinical	Medication use profile; DRP
Detoni et al., 2017	1 city, MG	Public	Cohort	Medication therapy management	Patients (83)	$COPD^k$	Clinical	NA
Santos et al., 2019	Lagoa Santa, MG	Public	Cross- sectional (phase I), quasi- experimental (phase II)	Medication therapy management	Patients (1,057)	No restriction	Clinical	DRP, medication use profile
Scarabelin et al., 2019	São Paulo, SP	Public	Qualitative	Medication therapy management	Patients (10)	Prostate cancer	NA	Communication with the pharmacist, medication use profile
Gomes et al., 2020	Florianópolis, SC	Public	Cohort	Medication therapy management	Patients (240)	Chronic hepatitis C (treatment with sofosbuvir)	Clinical, humanistic (satisfaction)	Medication use profile (with identification of adverse reactions and cure rate)
Afonso et al., 2017	Igaratinga, MG	Public	Descriptive	Dispensing	Patients (198)	No restriction	Humanistic (satisfaction)	NA
Baldon <i>et al.</i> , 2006	Curitiba, PR	Private	Cross- sectional	Dispensing	Pharmacists (101)	Pregnancy	NA	Knowledge, therapeutic choice, use of EBP
Bastos, Caetano, 2010	4 cities, RJ	Private	Qualitative	Dispensing	Pharmacists (15)	No restriction	Humanistic (perception, satisfaction)	NA
Bonadiman et al., 2018	8 cities, ES	Public	Descriptive (quantitative)	Dispensing	Pharmacists (11) and patients (294)	No restriction	Humanistic (satisfaction, patients)	Knowledge (pharmacists)
Cassaro et al., 2016	9 cities, ES	Public	Cross- sectional	Dispensing	Patients (408)	No restriction	Humanistic (satisfaction)	NA
Ferreira <i>et al.</i> , 2016, 2018	Goiânia, GO	Public	Quasi- experimental	Dispensing	Patients (104) and pharmacists (2)	No restriction	Humanistic (satisfaction)	Knowledge about treatment and adherence (patients), use of EPB, dispensing process, human resources (pharmacists)
Lima <i>et al.</i> , 2017; Soeiro <i>et al.</i> , 2017; Araújo <i>et al.</i> , 2017	PNAUM¹ (all Brazilian regions)	Public	Cross- sectional	Clinical pharmacy services (dispensing, health education, drug therapy follow-up)	Pharmacists (285) and patients (8,803)	No restriction	Humanistic (satisfaction)	Infrastructure, human resources, counselling, knowledge
Luz et al., 2017	Divinópolis, MG	Public	Mixed (qualitative/ quantitative)	Dispensing	Pharmacists (4) and patients (69)	No restriction	Humanistic (satisfaction)	Dispensing process, counselling, knowledge
Obreli-Neto et al., 2013	Ourinhos, Assis, SP	Private	Cross- sectional	Dispensing	Pharmacists (41)	OC ^m	NA	Counselling, communication skills, dispensing process
Oliveira et al., 2016	São Paulo, SP	Public	Cross- sectional	Dispensing	Pharmacists (4)	No restriction	NA	Dispensing process, counselling

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Authors/year of publication	City/state	Nature of CP ^a	Study design	PS ^b evaluated	Participants (n intervention group / n control group)	Health condition	Outcomes (ECHO model)	Other elements evaluated
Piccoli, Brito, Castilho, 2017	Niterói, RJ	Public	Cross- sectional	Dispensing	Pharmacists (6) and patients (154)	HIV/AIDS	NA	Knowledge, dispensing process, counselling
Volpato et al., 2005	Joinville, SC	Private	Cross- sectional	Dispensing	Pharmacists (70) and assistants (37)	Sinusitis	NA	Counselling, dispensing process, therapeutic choice
Zanella, Aguiar, Storpirtis, 2015	São Paulo, SP	Public	Cross- sectional	Dispensing	Pharmacists (7) and assistant (1)	Mental disorders	NA	Dispensing process, counselling
Ajalla, Castro, 2003	Campo Grande, MS	Private	Quasi- experimental	Minor ailment management	Pharmacists and assistants (185)	STD^n	NA	Counselling, therapeutic choice
Cadore <i>et al.</i> , 1999	Porto Alegre, RS	Private	Cross- sectional	Minor ailment management	Pharmacists (20) and assistants (94)	Cough	NA	Counselling, therapeutic choice
Coulibaly et al., 2017	Alto Solimões, AM	Private	Qualitative	Minor ailment management	Pharmacists and assistants (11)	Urethritis	NA	Counselling, therapeutic choice
Galato <i>et al.</i> , 2011	SC	Private	Cross- sectional	Minor ailment management	Pharmacists (291)	No restriction	NA	Counselling, therapeutic choice, knowledge
Halila <i>et al.</i> , 2015; Hipólito Júnior et al., 2017	PR	Private	Cross- sectional	Minor ailment management, pharmacy procedures#	Pharmacists (533)	No restriction	NA	Counselling, knowledge, infrastructure, use of EBP, identification of pharmacy procedures#, payment for PS
Lima <i>et al</i> ., 1989	Porto Alegre, RS	Private	Cross- sectional	Minor ailment management	Pharmacists (20) and assistants (20)	Diarrhoea	NA	Knowledge, counselling, therapeutic choice
Mesquita et al., 2013	Aracaju, SE	Private	Cross- sectional	Minor ailment management	Pharmacists (25)	Headache; diarrhoea	NA	Counselling, therapeutic choice, use of EBP, communication skills
Naves et al., 2008	Brasília-DF, Taguatinga, GO	Private	Quasi- experimental	Minor ailment management	Pharmacists and assistants (78)	STD	NA	Counselling, therapeutic choice, knowledge
Neto, Galato, 2011	Tubarão, SC	Private	Qualitative	Minor ailment management	Pharmacists and assistants (20)	STD	NA	Knowledge, counselling, therapeutic choice
Rocha <i>et al.</i> , 2014	Aracaju, SE	Private	Mixed (qualitative/ quantitative)	Minor ailment management	Pharmacists (35) (pilot study)	No restriction	NA	Knowledge, use of EBP, counselling
Rocha et al., 2015	Aracaju, SE	Private	Cross- sectional	Minor ailment management	Pharmacists (40)	Sinusitis; pregnancy	NA	Counselling, therapeutic choice, use of EPB, communication skills
Santos et al., 2013	Aracaju, SE	Private	Cross- sectional	Minor ailment management	Pharmacists (24)	Headache	NA	Counselling, therapeutic choice
Gerenutti, Martinez, Bergamaschi, 2017	Socoraba, SP	Public	Cohort	Medication review	Patients (130/229)	HIV/AIDS	Clinical	Adherence
Rigoni et al., 2015	Tubarão, SC	Public	Quasi- experimental	Medication review	Patients (40)	Нур	Clinical, humanistic (satisfaction)	Adherence, medication use profile
Zatta, Perassolo, 2017	Novo Hamburgo, RS	Private	Quasi- experimental	Medication review	Patients (18)	DM2	Clinical	Adherence

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Authors/year of publication	City/state	Nature of CP ^a	Study design	PS ^b evaluated	Participants (n intervention group / n control group)	Health condition	Outcomes (ECHO model)	Other elements evaluated
Dosea <i>et al.</i> , 2017	3 cities, SE	Public	Qualitative	Clinical pharmacy services (medication dispensing, medication review, medication therapy management, pharmacy procedures#)	Pharmacists (11)	No restriction	NA	Barriers and facilitators for implementation of the services
Franceschet, Farias, 2005	Florianópolis, SC	Private	Cross- sectional	Clinical pharmacy services (dispensing, counselling)	Pharmacists (90)	No restriction	NA	Infra-structure, human resources use of EBP, counselling, dispensing process
França Filho et al., 2008	SC	Private	Cross- sectional	Clinical pharmacy services, pharmacy procedures#	Pharmacists (228)	No restriction	Humanistic (satisfaction)	Infrastructure, human resources, knowledge of EBP
Reis et al., 2015	Aracaju, SE	Private	Cross- sectional	Clinical pharmacy services (counselling, dispensing, medication therapy management)	Pharmacists (39)	No restriction	NA	Use of EBP, counselling, therapeutic choice, knowledge
Santos Júnior et al., 2020	Recife, PE	Public	Quasi- experimental	Clinical pharmacy services (health education, dispensing, medication review, medication therapy management)	Pharmacists (23) and patients (842 - medication therapy management)	No restriction	Clinical (patients)	Physical structure and resources, knowledge (pharmacists), work process (i.e., systematisation, counselling, number and type of interventions, collaboration with healthcare team), DRP, medication use profile
Aquino et al., 2019	Divinópolis, MG	Public	Quasi- experimental	Clinical pharmacy services (intervention to pharmacotherapeutic empowerment)	Patients (47)	DM2	Clinical	Adherence, self-care, self-efficacy, DRP
Santos, Silva, Tavares, 2018	Itaim Paulista, SP	Public	Descriptive (retrospective)	Clinical pharmacy services (consultation, health education)	Patients (1,080)	No restriction	Clinical	DRP, number of interventions

^{*}NA = not applicable; "Community pharmacy; bPharmaceutical service; 'Randomised clinical trial; dHypertension; "Coronary arterial disease; fDrug-related problems; Diabetes mellitus type 2; bEvidence-based practice; Quality of life; Dyslipidaemia; Chronic obstructive pulmonary disease; National research about access, use and promotion of medication rational use; "Oral contraceptives; "Sexually transmitted disease. #Pharmacy procedures: monitoring of parameters (i.e., blood pressure, capillary blood glycaemia), injectable drug administration.

Note: The complete list of references of the included studies are available in Supplementary Material 3.

The 72 articles reported results from 61 different studies. These studies employed a wider variety of research designs. Most were observational studies (29/61; 47.5%: 21 cross-sectional, 3 cohort, 5 descriptive), followed by interventional studies (24/61; 39.3%: 4 RCT, 20 quasi-

experimental), qualitative research (5/61; 8.2%), mixed-methods studies (2/61; 3.3%), and a two-phase study (cross-sectional and quasi-experimental) (1/61; 1.6%).

The number of participants in the studies had a wide variation from 10 to 8,803. Out of the 61 studies, 9.84%

(6/61) were self-reported as pilot studies and included from 10 to 69 participants. The majority of interventional studies (n=19/24; 79%) included fewer than 100 participants in the intervention groups, ranging from 10 to 842; cross-sectional design studies included 4 to 8,803; descriptive studies had a variation from 69 to 1080; cohort studies from 83 to 240; mixed and qualitative studies included from 10 to 69; and the two-phase study included 1,057 participants.

The setting of these studies varied. Most were conducted in public community pharmacies in 38/61 studies (62.3%), and the others were performed in private community pharmacies. A great part of the studies (51/61; 83.6%) were conducted regionally, in a single community pharmacy, or in pharmacies from the same city. Only one large national study named *PNAUM* (National Research about Access, Use and Promotion of Medication Rational Use) was performed in 2015 in 120 major cities at public

community pharmacies (Araújo et al., 2017; Lima et al., 2017; Soeiro et al., 2017). In this cross-sectional study, pharmacists and patients were interviewed to rise up the clinical activities developed by pharmacists to evaluate the satisfaction concerning dispensing and counselling, the access of the patients to the health system, and other pharmacy administrative issues.

Geographically, the studies were distributed unevenly across Brazil, with higher prevalence of the southeast with 39.3% (n=24/61) of the studies, followed by the south with 26.2% (n=16/61) and the northeast with 24.6% (n=15/61). Only one study involved more than one state. The most productive states were Sergipe and São Paulo, both with 10 studies, followed by Minas Gerais and Santa Catarina, both with 8 studies. Figure 2 shows the distribution of studies across Brazil and the number of universities with pharmacy courses in each state.

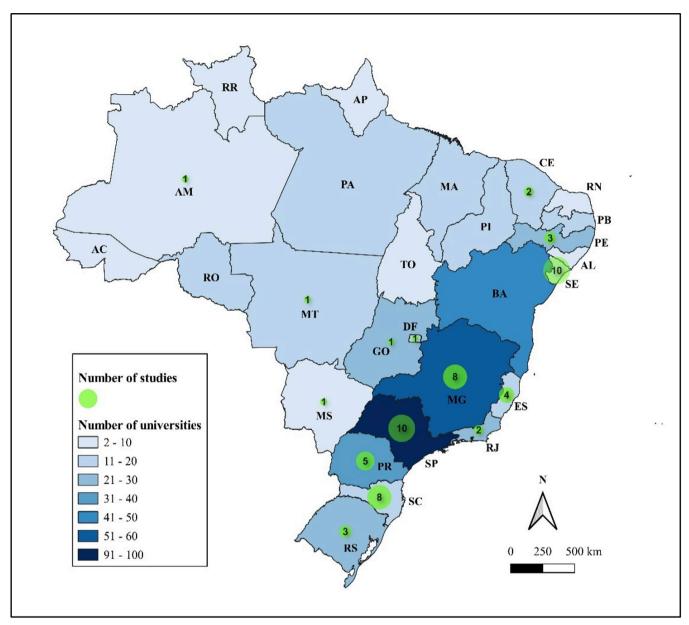


FIGURE 2 - Geographic distribution of the studies and number of universities with pharmacy courses by state.

The research aim of these studies was also diverse. Fifteen out of 24 (62.5%) interventional studies evaluated patient outcomes from medication therapy management services, with a follow-up period from 6 to 36 months. Cross-sectional studies were addressed in most cases (18/21; 85.7%) to evaluate elements of the work processes of the pharmacist (i.e., communication skills, knowledge, information provided to patients in counselling, and therapeutic decisions) of dispensing and minor ailment management services. Qualitative (n=5) and mixed-

methodology studies (n=2) were restricted to evaluate the perceptions of the pharmacists about their satisfaction, knowledge, and behaviour in providing clinical pharmacy services (dispensing and minor ailment management) and the barriers faced to the service implementation.

Out of the 61 studies, 36 (59%) reported outcomes — isolated or along with other elements of the medication use process. From the 36 reporting outcomes, 25 reported clinical, 19 humanistic, and 3 economic outcomes. Two studies reported all three outcomes, and seven studies

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reported two of them. Six studies (Dosea *et al.*, 2017; França Filho *et al.*, 2008; Franceschet, Farias, 2005; Halila *et al.*, 2015; Hipólito Júnior *et al.*, 2017; Reis *et al.*, 2015) investigated what services pharmacists delivered to patients, but without in-depth assessment of their implementation or procedures.

Although some studies used performance indicators to evaluate the pharmacist behaviour in delivering clinical pharmacy services (Aguiar *et al.*, 2013; Galato *et al.*, 2011; Melo, Castro, 2017; Melo *et al.*, 2017; Santos Júnior *et al.*, 2020), no study had systematically measured the fidelity of the interventions.

Studies reported the clinical pharmacy services with a heterogeneity in the terms used and showed a diverse comprehension about their definition. Several terms to designate minor ailment management services were used. 'Indication of drugs' (Ajalla, Castro, 2003), 'self-medication' or 'responsible self-medication' (Cadore *et al.*, 1999; Rocha *et al.*, 2014, 2015), 'OTC counseling' (Halila *et al.*, 2015), 'recommendation of non-prescription medicines' (Mesquita *et al.*, 2013), and 'recommendation of OTC drugs' (Santos *et al.*, 2013) were some terms of the diverse terminology found.

Medication therapy management services were described in some studies (Aguiar et al., 2012; Aguiar, Balisa-Rocha, Lyra Junior, 2013; Cazarim et al., 2016, 2017, 2018; Lyra Junior et al., 2007) as 'pharmaceutical care', which is a generic term. Others used the term 'pharmaceutical care program' (Andrade et al., 2009; Mourão et al., 2013; Obreli-Neto et al., 2011a, 2001b, 2015; Silva, Bazotte, 2011) to describe a set of services offered to patients along with medication therapy management, such as educative group activities or additional consultation about health issues. In addition, 'pharmaceutical care model' was used in a study to describe a service comprised by one consultation with the pharmacist for the evaluation of the drug prescription, identification of possible drug-related problems (i.e., adverse reactions and interactions), and guidance about treatment, with no follow-up (Gerenutti, Martinez,

Bergamaschi, 2017). Some of the most recent publications used the term 'comprehensive medication management' (Detoni *et al.*, 2017; Santos *et al.*, 2019; Santos Júnior *et al.*, 2020) or 'comprehensive medication review' (Scarabelin *et al.*, 2019) to describe medication therapy management services.

Quality of the studies

Results of the ROB assessment for RCT and non-RCT studies are summarised in Figures 3 and 4. RCT (n=4) presented low ROB in generation of random sequences and selective report domains. Allocation concealment was unclear in 50% of the RCT studies. One study (Mourão *et al.*, 2013) presented a high ROB in blinding of participants because the control group had access to all basal laboratory tests during the study, which could have interfered in the results of the intervention. Three studies (Firmino *et al.*, 2015; Mourão *et al.*, 2013; Plaster *et al.*, 2012) did not report blinding of outcome assessment (unclear ROB). Incomplete data were due to incomplete reporting of participant dropouts in two studies (Firmino *et al.*, 2015; Plaster *et al.*, 2012).

High heterogeneity in the studies' execution and reporting were observed in non-RCT designs (n=57). Interventions were not fully described in most non-RCT studies (n=37; 65%). Incomplete or unclear reporting of sources of clinical data (e.g., consultation interviews, prescription, electronic databases, or other), frequency and duration of the intervention, and details on the structured processes of the service was found (Rotta et al., 2015a). Consequently, most quasi-experimental, observational, and other studies presented great possibility of ROB in the intervention grouping domain from ROBINS-I when the process of the service interventions was not clearly reported (Sterne et al., 2016). Further, 29 studies (58.8%) showed unclear or high ROB due to not controlling confounders. Participant dropout was not sufficiently reported in 10 studies, resulting in an unclear ROB in the loss of data domain.

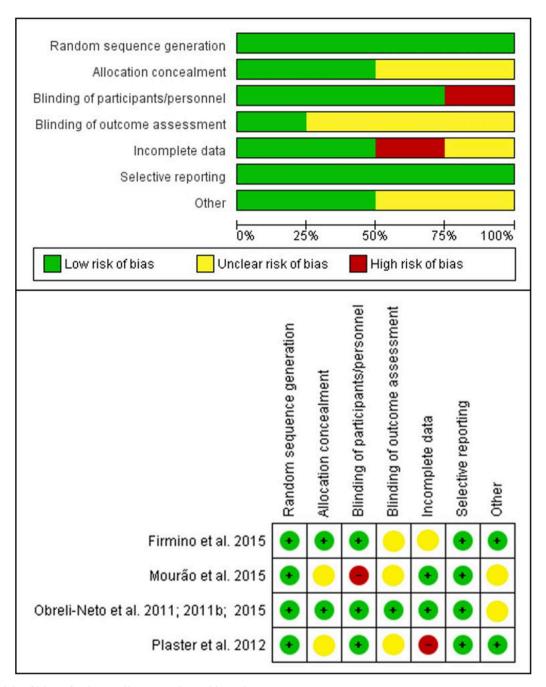


FIGURE 3 - Risk of bias of RCT studies as evaluated by ROB.

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FIGURE 4 - Risk of bias of non-RCT studies as evaluated by ROBINS-I.

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DISCUSSION

This scoping review provided for the first time an overview of studies about clinical pharmacy services in Brazilian community pharmacies. It found a great diversity of research approaches, outcomes evaluated, and methodological quality. The research on this topic has been concentrated in a couple of research universities, unevenly distributed across the country. Additionally, the service characteristics frequently were not comprehensively described, impairing the understanding of the association between the interventions performed and the results obtained.

Since a wide range of methodologies and study designs was employed in the assessment of clinical pharmacy services, it was not possible to closely compare the studies. This variability found among the Brazilian studies may hamper the production of evidence on the effectiveness of the services through secondary studies (i.e., systematic reviews), as the soundness of the conclusions of those studies relies on the methodological quality of the primary studies and their homogeneity (Bonetti *et al.*, 2020).

It is important to note that the majority of the studies (59%, n=36) had a non-interventional design, were conducted at one or few regional community pharmacies, and had a convenience, non-representative sample. These characteristics may hinder the development of robust conclusions (Clancy, 2002). RCTs are considered the gold standard for the evaluation of health interventions (Clancy, 2002), yet only four Brazilian RCTs on clinical pharmacy services were found in this review. This highlights the need of further well-designed interventional studies to fill some gaps in the regional literature. Nonetheless, observational studies, when well performed, can provide real-world evidence on the effects of interventions and are especially meaningful to assess daily clinical pharmacy services in specific settings and contexts (Elm et al., 2007). Additionally, non-interventional research designs are simpler, less expensive, and faster than interventional studies (Clancy, 2002; Nedel, Silveira, 2016). These may lead researchers to choose these designs, considering that most of the research in Brazil is produced by public universities (ABC, 2019; Web of Science Group, 2019), where time and resources are often scarce (ABC, 2019).

The concentration of the Brazilian research production in public universities (ABC, 2019; Web of Science Group, 2019) influenced the geographic distribution of the studies included in this scoping review. States from southeastern and southern regions presented a higher concentration of studies on pharmacy services, which is coincident with the higher number of universities and pharmacy courses (INEP, 2018). Besides, those states show better physical infrastructure of community pharmacies and human resources in comparison to other Brazilian regions (IBGE, 2010; Leite et al., 2017; Souza et al., 2017). However, an exception was noticed in Sergipe (northeastern region), which presented one of the higher number of studies per state but not a higher number of universities (INEP, 2018). In Sergipe State, there is a research group in a federal university focused on the study of clinical pharmacy services, which may explain the considerable number of publications in this region.

Another factor that prevents further comparison was the use of distinct terminologies related to the clinical pharmacy services studied. Similarly to other countries (Imfeld-Isenegger et al., 2019), the terminology of services can be confusing and frequently misunderstood. Some studies indicate that this variation of terminologies may be related to the conceptual and professional practice transitions that have happened in recent years in Brazil (Costa et al., 2017; Fegadolli, Cavaco, Fonseca, 2018). With the curricular changes in the pharmacy courses (Brasil, 2017) and the governmental incentives for training pharmacists on clinical pharmacy services (Brasil, 2012), a model centred on the patient (CFF, 2016a) has gradually replaced the traditional biomedical model of care focused on medicines (Fegadolli, Cavaco, Fonseca, 2018). Further, most of the included studies in this scoping review (n=44; 72.1%) were published before 2016, when the conceptual framework of the Brazilian Pharmacy Federal Board (CFF, 2016a) had not yet been published. This material comprises the terms and concepts on each clinical service; thus, the great variability found among the included studies could also be due to the absence of a nation-wide reference at that time to support terminology standardisation for clinical pharmacy services.

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Guidelines of different pharmacy practices are available in some countries to help pharmacists to perform clinical pharmacy services, such as the guidelines for dispensing medicines of the Pharmacy Board of Australia (2015), the recommendations for medication therapy management services of the American Pharmacists Association of the United States (2008), the model standards for clinical practice for pharmacists from Canada (NAPRA, 2009), and the regulatory framework for community pharmacy services and guidelines of European countries (Abrahamsen, Burghle, Rossing, 2020; WHO, 2019). In Brazil there are no national guidelines for the performance of all clinical pharmacy services in the conceptual framework (CFF, 2016a), but recently the Brazilian Pharmacy Federal Board published guidelines with recommendations for clinical practice on minor ailment management (CFF, 2016b, 2017, 2018, 2020). Development of guidelines for the other clinical pharmacy services is still needed to support pharmacists in their professional activities and standardisation of practice.

Many studies have not given a complete report of the processes and actions of pharmacists, which prevents them from being reproduced by another practitioner (Clay et al., 2019; Craig et al., 2008). As clinical pharmacy services are considered complex interventions, all the processes must be well defined and standardised for their provision to patients, to evaluate outcomes, and to ensure reproducibility (Clay et al., 2019; Craig et al., 2008; De Barra et al., 2019; Rotta et al., 2015b). Therefore, multiple components must be considered in the delivery and reporting of clinical pharmacy services, such as access of the patient to health services (e.g., educational level, ability to buy medication or to make an appointment), adherence, relationship with the physician, complexity of the pharmacotherapy, and the actions that pharmacists must plan for patients to achieve treatment goals (Clay et al., 2019; Craig et al., 2008).

International researchers have developed checklists to help pharmacists and authors to plan, evaluate, and report interventions, and some of these instruments are available in the literature (Clay *et al.*, 2019; De Barra *et al.*, 2019; Rotta *et al.*, 2015a). The DEPICT checklist (Rotta *et al.*, 2015a), for example, gathers the essential elements into an adequate report of pharmacist interventions. According to this checklist, information about the qualification of the pharmacist (e.g., training),

contact and communication with the recipient (e.g., face-to-face or telephone, one-on-one contact, or contact with a group), focus of intervention (e.g., on a specific medical condition or without restriction), frequency and duration of consultations, sources of data (e.g., interviews, patient diary, medical records), description of the content of the educational material provided or the protocol or guide used to make therapeutic decisions, detailed pharmacist actions (interventions, referral, counselling), and other processes are some elements to be considered in a clinical pharmacy services report (Craig *et al.*, 2008; De Barra *et al.*, 2019; Rotta *et al.*, 2015a).

Clinical pharmacy service implementation is a challenge in many countries, as reported by Imfeld-Isenegger et al. (2019), who evaluated the characteristics and implementation of medication review services in Europe. This scoping review demonstrated that Brazil suffers a similar situation. An indication of this difficulty is the low number of studies. Only ten studies on medication therapy management (Andrade et al., 2009; Garabeli et al., 2016; Gomes et al., 2020; Melo, Castro, 2017; Mendonça et al., 2016; Obreli-Neto et al., 2011a, 2011b, 2015; Santos Júnior et al., 2020; Scarabelin et al., 2019) included in this review were related to service implementation. Other publications refer to services offered for scientific purposes, including pilot studies developed during the research period only and not as continued services offered by a community pharmacy.

The implementation of innovative services is a complex and long-term process that requires a comprehensive approach in several domains (Varas-Dorval et al., 2020). A successful implementation depends on a sound theoretical background that might be supported by use of models and frameworks (Moullin et al., 2015; Varas-Dorval et al., 2020). In recent years, some theoretical frameworks for the implementation of innovative services into practice have been developed for guiding healthcare professionals (Moullin et al., 2015). The Framework for the Implementation of Services in Pharmacy (FISpH), for instance, is a model created to be used in clinical pharmacy services. It includes some core concepts, such as the process to implement an innovative service, the contextual domains that could influence patients' behaviour, the barriers and facilitators,

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and the strategies and evaluation of the implementation programme (Moullin *et al.*, 2016a).

A core element of the implementation frameworks that appears to be frequently neglected by researchers is evaluation (Moullin et al., 2016b; Patwardhan, Amin, Chewning, 2014). Service evaluation often seems to be focused only on patients' outcomes and cost-effectiveness, without an in-depth assessment or report of implementation indicators, such as fidelity measures (Moullin et al., 2016a). The fidelity of an intervention is the extension that an intervention is implemented as originally intended and planned by the developers (Carroll et al., 2007; Craig et al., 2008). The evaluation of the pharmacist behaviour through systematic fidelity measures in the delivering of the service allows to determine clearer relationships of the outcomes achieved and identify the issues that could hinder or facilitate the achievement of positive outcomes (Carroll et al., 2007; Patwardhan, Amin, Chewning, 2014; van der Laan et al., 2019). Considering the complexity of clinical pharmacy services, the role of each intervention's components and its effect on the outcomes need to be clarified (van der Laan et al., 2019).

The literature strongly recommends measuring the fidelity of interventions delivered in studies of clinical pharmacy services to support authors and practitioners in establishing the relationships between the proposed interventions and the expected outcomes (Carroll et al., 2007; De Barra et al., 2019; Moullin et al., 2016a). Studies have demonstrated that high-fidelity interventions present better clinical, humanistic, and economic outcomes in comparison to those with low fidelity (Durlak, DuPre, 2008; von Thiele Schwarz Hasson, Lindfors, 2015). Besides, measuring fidelity can help identify the elements associated with an ineffective clinical pharmacy service, such as poor implementation processes (Moullin et al., 2016a; Patwardhan, Amin, Chewning, 2014; van der Laan et al., 2019). Finally, consistently reporting the fidelity in studies can better clarify the real effect of the clinical pharmacy services on patients' outcomes.

Limitations

This scoping review may have some limitations. The search strategy was developed to be as inclusive as possible, but it may not have included all studies on clinical pharmacy services due to the heterogeneity of terms used by authors to describe similar services. Comparisons between the study's results were not possible due to the great variability of research designs, outcomes, and other elements assessed. Although a scoping review does not formally require a methodological quality assessment of the included studies, we performed this step to provide a qualitative overview of the available evidence in Brazil. The domains of tools were adapted and interpreted according to the nature of the interventions to avoid bias.

Strengths

To the best of our knowledge, this is the first scoping review that evaluated studies on clinical pharmacy services delivered in community pharmacies in Brazil. To date, no comprehensive literature review has assessed these Brazilian publications and their methodological quality. Considering the recent expansion of the services in Brazil, this mapping shows the research scenario in the country and may be useful in the development of future studies on the topic.

CONCLUSION

This scoping review on clinical pharmacy services delivered in Brazilian community pharmacies has shown the studies were diverse and heterogeneous in several aspects. First, services were evaluated through a great number of methodological designs, and the studies presented the results of the analysis from different outcomes or other elements of the service's process. Second, they were unevenly distributed across the Brazilian territory. Third, studies showed a nonstandardisation of the terminology used to describe the services, along with an unclear or incomplete report of the interventions performed in several cases. Lastly, the studies' quality assessment has shown an unclear or high ROB in several domains of the instruments used, which may hinder their reproducibility. Through these findings, this scoping review suggests that well-designed Brazilian studies, with more robust methodologies and well-structured and reported interventions, are required

to reach more reliable results. Additionally, fidelity measures are needed for evaluation of the implementation of clinical pharmacy services. We recommend the use of frameworks, guidelines, and checklists in the development of the interventions and to conduct future studies on clinical pharmacy services in Brazilian community pharmacies.

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