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Critical analysis of the compounded medication formulary dispensed at the outpatient pharmacy of a tertiary public hospital in São Paulo

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Abstract

Objectives: To realize a critical analysis of the list of medicines compounded for the care of outpatients, identifying which medicines are registered, the quantity served and a bibliographical survey to support the therapeutic indication, concentration and pharmaceutical form, making a proposal for the exclusion, maintenance or replacement of the pertinent items. **Methods:** A cross-sectional, qualitative, and semi-quantitative study on medications compounded by the pharmacotechnical unit and supplied to the outpatient pharmacy of the Central Institute of the Hospital das Clínicas of the Faculty of Medicine of the University of São Paulo, regarding the quantity served between September 2023 and September 2024, therapeutic indication, concentration and pharmaceutical form. The quantity served and the medicines registered were obtained from two administrative reports (without patient identification) from the outpatient prescription and fulfillment system. A descriptive statistical analysis of the frequency of the collected data was performed. **Results:** A total of 172 medicines were identified for supply, in which oral solutions with 3,022,955 mL (44.96% of the quantity), had the highest consumption. Among the 172 medicines, 23 of them represent 80% of the quantity served, being vitamin B12 (11.06%), omeprazole (7.51%), hydroxyzine (5.56%), artificial saliva (5.42%), baclofen (5.09%), amitriptyline + lidocaine (4.86%), semi-solid petroleum jelly (4.03%), four presentations of magnesium sulfate (10.62%), massage ointment (3.74%), Eisenberg solution (3.38%), urea in *cold cream* (2.26%), carboxymethyl cellulose (CMC) gel (2.25%), polyethylene glycol (PEG) (1.78%), clonazepam (1.77%), propantheline (1.77%), codeine (1.59%), prednisone (1.58%), gentamicin + betamethasone (1.56%), urea in lanette cream (1.33%) and liquor carbonis detergens – LCD in lanette lotion (1.25%). With the bibliographic research, 133 medications (77.32%) were maintained, 28 (16.28%) were excluded and 11 medications (6.40%) were replaced. **Conclusions:** This study contributes to a better understanding of the productive capacity of the pharmaceutical technology sector, serving as a starting point for new studies, assisting in the redesign of compounding processes, improvements in infrastructure, and the alignment of the range of compounded medications with the needs of patients and the institution.

Keywords: pharmacy service, hospital; drug compounding; health services research; pharmacy administration.

Análise crítica do elenco de medicamentos manipulados atendidos na farmácia ambulatorial de um hospital público terciário em São Paulo

Resumo

Objetivos: Para realizar análise crítica do elenco de medicamentos manipulados para atendimento dos pacientes ambulatoriais, identificando quais os medicamentos cadastrados, a quantidade atendida e levantamento bibliográfico para embasamento de indicação terapêutica, concentração e forma farmacêutica, realizando uma proposta de exclusão, manutenção ou substituição dos itens pertinentes. **Métodos:** Estudo transversal, qualitativo e semiquantitativo, sobre os medicamentos manipulados pela unidade de farmacotécnica e atendidos à farmácia ambulatorial do Instituto Central do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, quanto a quantidade atendida entre setembro de 2023 e setembro de 2024, indicação terapêutica, concentração e forma farmacêutica. A quantidade atendida e os medicamentos cadastrados foram obtidos de dois relatórios administrativos (sem identificação de pacientes) do sistema de prescrição e atendimento das receitas ambulatoriais. Foi realizada a análise estatística descritiva de frequência dos dados coletados. **Resultados:** Foram identificados ao todo 172 medicamentos manipulados e atendidos, em que as soluções orais com 3.022.955 mL (44,96% da quantidade) tiveram o maior consumo. Dentre os 172 medicamentos, 23 deles representam 80% da quantidade atendida, sendo eles vitamina B12 (11,06%), omeprazol (7,51%), hidroxizina (5,56%), saliva artificial (5,42%), baclofeno (5,09%), amitriptilina + lidocaína (4,86%), vaselina semissólida (4,03%), quatro apresentações de sulfato de magnésio (10,62%),

pomada para massagem (3,74%), solução de Eisemberg (3,38%), ureia em *cold cream* (2,26%), gel de carboximetilcelulose (CMC) (2,25%), polietilenoglicol (PEG) (1,78%), clonazepam (1,77%), propantelina (1,77%), codeína (1,59%), prednisona (1,58%), gentamicina + betametasona (1,56%), ureia em creme lanete (1,33%) e *líquor carbonis detergens* – LCD em loção lanete (1,25%). Com a pesquisa bibliográfica, foram mantidos 133 medicamentos (77,32%), 28 (16,28%) foram excluídos e 11 medicamentos (6,40%) substituídos. **Conclusões:** O estudo corrobora para melhor elucidação da capacidade produtiva do setor de farmacotécnica, sendo um ponto de partida para novos estudos, auxiliando na remodelação dos processos de manipulação, melhorias na infraestrutura e no alinhamento do elenco de medicamentos manipulados às necessidades dos pacientes e da instituição.

Palavras-chave: serviço de farmácia hospitalar, composição de medicamentos, pesquisa sobre serviços de saúde, administração farmacêutica.

Introduction

Pharmaceutical technology is the pharmaceutical area related to the preparation of medicines, an activity anchored in pharmaceutical practice since the profession's inception. Preparation consists of transforming active pharmaceutical ingredients into medicines, encompassing the stages of pharmaceutical evaluation of the prescription, manipulation (compounding), fractionation, conservation, transportation, and dispensing.[1-3]

In hospital pharmacies, medications of strategic and economic interest are prepared, meeting the needs of healthcare institutions and patients both individually and collectively, particularly when treatment with industrially manufactured products is unavailable. Thus, compounded medications fill this care gap.[1-6]

Compounding can be performed based on magistral or official (pharmacopeial) formulas and can be carried out for minimum stock or in a personalized and individual manner. It is also possible to adapt dosage forms available on the market, ensuring safety, quality, and efficacy of use.[1-6]

To ensure compliance with Good Compounding Practices in pharmacies, the Brazilian Health Regulatory Agency (ANVISA), through Collegiate Board Resolution (RDC) No. 67 of October 8, 2007, provides technical regulations and eight annexes for classifying medications and describing the requirements for compounding.[1,2,4]

Among these requirements, the legislation addresses physical infrastructure, human resources, compounding, transportation, storage, quality control, and labeling. The technical regulations highlight the role of the pharmacist's technical responsibility in the prescription evaluation process, a fundamental and initial step in medication preparation. This involves verifying the feasibility of compounding, dose, route of administration, physicochemical and pharmacological compatibility of the request; and, if necessary, carrying out pharmaceutical intervention with the prescribing professional; in addition to developing, establishing criteria, and updating the guidelines and operations of the pharmaceutical technology sector.

The technical regulations also stipulate that the physical infrastructure must segregate the compounding of solid dosage forms from others. Additionally, the area must be compatible with the facility's capacity, considering the compounding demand to better meet patient needs. Therefore, a critical analysis of the medication portfolio is necessary.

The hospital pharmacy of the Central Institute of the Hospital das Clínicas, University of São Paulo Medical School (HCFMUSP), houses the Hospital Pharmaceutical Technology Unit (UFAR), where medications standardized by the Pharmacology Commission are produced in various dosage forms (tablets, capsules, syrups, solutions, emulsions, creams, ointments, among others) and special formulations for clinical research protocols are developed. Magistral and pharmacopeial formulations are also compounded to meet prescriptions for inpatients and outpatients, in addition to requests for specialty outpatient clinics.[8]

The objective of this study was to critically analyze the portfolio of compounded medications for outpatient care; furthermore, to conduct a qualitative and quantitative analysis of these medications to propose adjustments and rationalization of the portfolio.

Methods

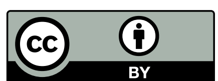
This was a cross-sectional, qualitative, and semi-quantitative study aimed at critically analyzing the portfolio of medications compounded by the Hospital Pharmaceutical Technology Unit and dispensed at the outpatient pharmacy of the Pharmacy Division of the Central Institute of the Hospital das Clínicas, University of São Paulo Medical School (ICHC-FMUSP).

Data collection was performed using two administrative reports (devoid of patient identification) extracted from the Hospital Information and Management System (SIGH), the system used for prescribing and dispensing outpatient prescriptions: a) a registry report of compounded medications and b) a report on the dispensed quantities of these medications. The variables contained in the reports were: code, medication name, annual consumption, and unit. The reports were generated and stored in Microsoft Excel® spreadsheet format.

A literature review was conducted regarding the dosage form, concentration, and therapeutic indication of the compounded medications, consulting pharmaceutical technology textbooks, scientific articles, and the UpToDate® database.[9-22]

The research database was constructed from the SIGH reports, incorporating the following study variables:

- Medication: Description of the medication as recorded in SIGH.
- Dosage Form: According to ANVISA's controlled vocabulary – capsule, mouthwash, cream, dermatological emulsion, gel, paste, powder, ointment, oral solution, topical solution, suppository, and oral suspension.[8]
- Compounding Room: According to RDC No. 67/2007 – liquids, semi-solids, and solids.
- Compounding Room: According to the local physical structure – for internal use, external use, and capsules.
- Route of Administration: According to ANVISA's controlled vocabulary – buccal, hair, dermatological, oral, and rectal.[8]



- Annex: Classification of medications according to the annexes specified in RDC No. 67/2007 – Annex I: Good Compounding Practices in Pharmacies or Annex III: Good Compounding Practices for Hormones, Antibiotics, Cytostatics, and Substances Subject to Special Control.
- Annex III: Sub-classification of medications falling under Annex III, according to the active ingredient: hormones, antibiotics, and substances subject to special control.
- Therapeutic Indication: According to the literature research.
- Concentration of the Compounded Medication: According to the literature.
- Dispensed Quantity: Units of compounded medications dispensed at the outpatient pharmacy from September 2023 to September 2024.
- Bibliographic References.
- Proposal: Maintenance, exclusion, or substitution of the medication.
- Substitute Medication: In case of item substitution, the alternative item to be dispensed for the same therapeutic indication.

With the collected data, a descriptive statistical analysis of absolute and relative frequencies of the variables in the data collection spreadsheet was performed. Furthermore, based on the literature review, a qualitative analysis of the registered medications was conducted, considering whether the concentration and dosage form were appropriate for the therapeutic indication. Concurrently, data validation and cleaning were performed, addressing issues such as duplicates.

Additionally, the quantity of each item dispensed over the last year was evaluated. For compounded medications with the same therapeutic indication but multiple concentrations, in the event of a substitution, the projected consumption was calculated by summing the annual consumption of the medication to be substituted with that of the new medication to be offered. The medication with the higher annual consumption was considered the basis for this calculation, aiming to adequately adjust care for patients who would be transitioned from using one concentration to another. Finally, a proposal was made for the exclusion, maintenance, or alteration of the item.

Results

A total of 172 medicines were identified for outpatient care. Considering the various routes of administration according to ANVISA's controlled vocabulary, the following distribution was obtained: 92 medications (53.0%) for the dermatological route, 59 (34.0%) for the oral route, 14 (8.0%) for the hair route, 5 (3.0%) for the rectal route, and 2 medications (1.0%) for the buccal route. Table 1 presents the distribution of dosage forms according to their respective routes of administration.[8]

As shown in Table 2, the dosage forms were allocated to their corresponding compounding rooms, along with the quantity of medications compounded and dispensed between September 2023 and September 2024. In the room dedicated to medications for external use, 106 different medications (61.63%) were compounded, totaling 2,149,066 units (31.96%). The dosage forms compounded in this room included creams, ointments, dermatological emulsions, gels, topical solutions, and pastes.

In the internal use room, 49 different medicines (28.49%) were compounded, totaling 3,838,408 units (57.08%). The dosage forms compounded in this room included oral solutions, oral suspensions, suppositories, and mouthwashes. A separate room exclusively for solid oral medications, capsules, and powders was also identified, with 17 different medications (9.88%) compounded, totaling 736,786 units (10.96%) during the study period.

Regarding the classification of the compounded medications according to the relevant annexes of RDC No. 67/2007, 147 (85.47%) of the formulations fell under Annex I, while 25 (14.53%) followed Annex III. Of the medications classified under Annex III, 14 (8.14%) were substances subject to special control, 10 (5.81%) were antibiotics, and 1 (0.58%) was a hormone.

Following a search of the scientific literature, the therapeutic indications for the compounded medications were obtained. By applying a Pareto diagram based on the compounded quantity, 24 medications were identified. These are presented in Table 3, along with their therapeutic indications, dispensed quantity, and cumulative frequency of the items.[9-22]

As shown in Table 3, 12 medicines (6.98%) accounted for 51% of the total dispensed quantity. These were: Vitamin B12 (743,711 mL - 11.06%), Omeprazole (504,777 mL - 7.51%), Hydroxyzine (374,110 mL - 5.56%), Artificial Saliva (364,514 mL - 5.42%), Baclofen (342,514 mL - 5.09%), Magnesium Sulfate 20% (261,704 mL - 3.89%) and 25% (125,272 mL - 1.86%), Eisenberg Solution (227,422 mL - 3.38%), Quetiapine (150,742 mL - 2.24%), Clonazepam (119,104 mL - 1.77%), Codeine (106,580 mL - 1.59%), and Prednisone (106,116 mL - 1.58%). These medications are all liquid dosage forms, reflecting the volume of patient care, and have various therapeutic indications, primarily used for personalized dose adjustment.[2,4]

Additionally, 9 (5.23%) medicines were semi-solid dosage forms, representing 23% of the dispensed quantity. These were: Amitriptyline + Lidocaine (326,924 g - 4.86%), Semi-solid Vaseline (270,721 g - 4.03%), Massage Ointment (251,705 g - 3.74%), Urea in Cold Cream (151,785 g - 2.26%), Carboxymethylcellulose (CMC) Gel (151,256 g - 2.25%), Propantheline (118,997 g - 1.77%), Gentamicin + Betamethasone (104,761 g - 1.56%), Urea in Lanette Cream (89,261 g - 1.33%), and Liquor Carbonis Detergens (LCD) (84,361 mL - 1.25%). As shown in Table 2, these are the dosage forms with the highest number of available formulations for dispensing. The medications listed above may have diverse indications, ranging from skin infections, dermatological conditions such as psoriasis and general dermatitis, hyperkeratosis, to other conditions like excessive salivation, analgesia, hydration, or providing a topical cooling sensation. Similarly, their main characteristic is the availability of a single active ingredient in varying concentrations to meet different therapeutic indications.[7-14,16,17]

Table 3 also reveals the presence of four presentations of Magnesium Sulfate (accounting for 11% of the dispensed quantity): 250 mg and 500 mg capsules, and 20% and 25% oral solutions. This is due to magnesium being used in varying amounts according to patient needs.

Based on the preceding analyses, proposals were made regarding the maintenance, substitution, or exclusion of items. The results were as follows: 133 medicines (77.33%) were proposed for maintenance, 28 medications (16.28%) for exclusion, and 11 medications (6.40%) for substitution. The medications proposed for exclusion and the corresponding reasons are listed in Table 4.

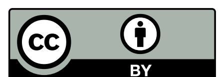


Table 1. Medicines dispensed to outpatient patients, distributed by pharmaceutical dosage forms and routes of administration at ICHC-FMUSP, from September 2023 to September 2024.

Dosage Form	Dermatological n (%)	Oral n (%)	Capillary n (%)	Rectal n (%)	Buccal n (%)
Cream	43 (25.00)	-	-	-	-
Oral solution	-	28 (16.28)	-	-	-
Ointment	25 (14.53)	-	-	-	-
Capsule	-	16 (9.16)	-	-	-
Dermatological emulsion	-	-	14 (8.14)	-	-
Gel	14 (8.14)	-	-	-	-
Oral suspension	-	12 (6.98)	-	-	-
Topical solution	9 (5.23)	-	-	-	-
Suppository	-	-	-	5 (2.91)	-
Mouthwash	-	2 (1.16)	-	-	2 (1.16)
Paste	1 (0.58)	-		-	-
Powder	-	1 (0.58)	-	-	-
Total	92 (53.48)	59 (34.16)	14 (8.14)	5 (2.91)	2 (1.16)

Table 2. Medicines dispensed to outpatient patients, distributed by compounding area, dosage forms, and quantity compounded and dispensed at ICHC-FMUSP, from September 2023 to September 2024.

Dosage Form	External Medications n (%)	Quantity Dispensed	Internal Medications n (%)	Quantity Dispensed	Capsule Area Medications n (%)	Quantity Dispensed
Cream	43 (25.00)	698,016 g (10.38)	-	-	-	-
Oral solution	-	-	28 (16.28)	3,022,955 mL (44.96)	-	-
Ointment	25 (14.53)	583,279 g (8.67)	-	-	-	-
Capsule	-	-	-	-	16 (9.30)	617,153 capsules (9.18)
Dermatological emulsion	14 (8.14)	208,767 mL (3.10)	-	-	-	-
Gel	14 (8.14)	644,219 g (9.58)	-	-	-	-
Oral suspension	-	-	12 (6.98)	381,577 mL (5.67)	-	-
Topical solution	9 (5.23)	6,930 mL (0.10)	-	-	-	-
Suppository	-	-	5 (2.91)	997 units (0.01)	-	-
Mouthwash	-	-	4 (2.33)	432,879 mL (6.44)	-	-
Paste	1 (0.58)	7,855 g (0.12)	-	-	-	-
Powder	-	-	-	-	1 (0.58)	119,633 g (1.78)
Total	106 (61.63)	2,149,066 (31.96)	49 (28.49)	3,838,408 (57.08)	17 (9.88)	736,786 (10.96)

Among the exclusions, 20 (11.62%) were due to having no dispensed quantity during the study period, 5 (2.90%) due to duplicate registry entries, 2 (1.16%) due to containing corrosive active ingredients indicated for in-office use and application by a medical professional, and 1 (0.58%) due to being produced on a semi-industrial scale.

The proposed substitute medications and the corresponding projected consumption calculations are presented in Table 5.

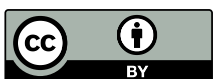


Table 3. Therapeutic indications of compounded medicines representing 80% of the quantity dispensed at the outpatient pharmacy of ICHC-FMUSP from September 2023 to September 2024.

Medicine	Therapeutic Indication	Quantity Dispensed n (%)	Cumulative Frequency n (%)
Vitamin B12 1,000 mcg/mL oral solution	Replacement therapy for vitamin B12 deficiency. Prevention of megaloblastic anemia and neurological damage. Antineuritic. Appetite stimulant.	743,711 mL (11.06)	743,711 (11.06)
Omeprazole 2 mg/mL oral solution	Antiulcer agent, proton pump inhibitor, reflux esophagitis.	504,777 mL (7.51)	1,248,488 (18.57)
Hydroxyzine 2 mg/mL oral solution	Antihistamine, sedative, anxiolytic, and antiemetic.	374,110 mL (5.56)	1,622,598 (24.13)
Artificial saliva solution	Hyposalivation and xerostomia.	364,514 mL (5.42)	1,987,112 (29.55)
Baclofen 1 mg/mL oral solution	Skeletal muscle relaxant.	342,514 mL (5.09)	2,329,626 (34.65)
Amitriptyline + lidocaine gel (4% + 2%)	Neuropathic pain.	326,924 g (4.86)	2,656,550 (39.51)
Petrolatum semisolid 100% ointment	Emollient.	270,721 g (4.03)	2,927,271 (43.53)
Magnesium sulfate 25% oral solution	Choleretic. Laxative. Hypomagnesemia.	261,704 mL (3.89)	3,188,975 (47.42)
Comfort massage ointment	Analgesic, vasodilator, antipruritic. Rubefacient for musculoskeletal trauma. Analgesic and anti-inflammatory.	251,705 g (3.74)	3,440,680 (51.17)
Magnesium sulfate 500 mg capsule	Choleretic. Laxative. Hypomagnesemia.	249,682 capsules (3.71)	3,690,362 (54.88)
Eisenberg solution 1 mEq Na and K/mL oral solution	Urinary alkalinizer. Fanconi syndrome.	227,422 mL (3.38)	3,917,784 (58.26)
Urea 10% in cold cream	Keratolytic in psoriasis, ichthyosis, atopic dermatitis and hyperkeratosis. Moisturizer for xeroderma.	151,785 g (2.26)	4,069,569 (60.52)
Carboxymethylcellulose (CMC) 3% gel	Topical soothing agent.	151,256 g (2.25)	4,220,825 (62.77)
Quetiapine 5 mg/mL oral solution	Antipsychotic, antimanic, anticholinergic. Autism and alcoholism.	150,742 mL (2.24)	4,371,567 (65.01)
Magnesium sulfate 20% oral solution	Choleretic. Laxative. Hypomagnesemia.	125,272 mL (1.86)	4,496,839 (66.87)
Polyethylene glycol (PEG) 54.8 g sachet for oral solution	Bowel preparation for colonoscopy and radiological or surgical procedures.	119,633 g (1.78)	4,616,472 (68.65)
Clonazepam 0.4 mg/mL oral suspension	Anxiety, agitation, myoclonus, sleep disorders, seizure disorders, tardive dyskinesia, acute vertigo episodes, panic disorder, neuroirritability, burning mouth syndrome.	119,104 mL (1.77)	4,735,576 (70.43)
Propantheline 10 mg/g gel	Reduction of salivary secretion.	118,997 g (1.77)	4,854,573 (72.19)
Codeine 3 mg/mL oral solution	Analgesic and antitussive.	106,580 mL (1.59)	4,961,153 (73.78)
Prednisone 2 mg/mL oral suspension	Adrenal insufficiency. Rheumatologic, dermatologic, allergic, ophthalmic, respiratory, hematologic, gastrointestinal diseases. Immunosuppressant.	106,116 mL (1.58)	5,067,269 (75.36)
Gentamicin + betamethasone in lanette cream (0.1% + 0.1%)	Primary and secondary skin infections. Medium-potency corticosteroid for atopic dermatitis, severe dermatitis, vulvar lichen sclerosus, scabies (post-scabicide), seborrheic dermatitis and stasis dermatitis.	104,761 g (1.56)	5,172,030 (76.92)
Urea 20% in lanette cream	Keratolytic in hyperkeratosis. Nail thickening and foot xerosis. Enhances antifungal efficacy.	89,261 g (1.33)	5,261,291 (78.24)
Liquor carbonis detergens (LCD) 15% in lanette lotion	Psoriasis.	84,361 mL (1.25)	5,345,652 (79.50)
Magnesium sulfate 250 mg capsule	Choleretic. Laxative. Hypomagnesemia.	78,026 capsules (1.16)	5,423,678 (80.66)

Table 4. Compounded medicines excluded from dispensing at the outpatient pharmacy of ICHC-FMUSP and reasons for exclusion.

Medicine	Reason for Exclusion
Acetic acid 2% topical solution	Not dispensed
Acetic acid 3% topical solution	Not dispensed
Citric acid 200 mg/mL oral solution	Not dispensed
Salicylic acid 3% in cold cream	Not dispensed
Aluminum chloride 10% topical solution	Not dispensed
Potassium chloride 6% oral solution	Semi-industrial scale
Sodium fluoride 4% mouthwash	Not dispensed
Furosemide 8 mg/mL oral suspension	Not dispensed
Potassium hydroxide 5% topical solution	Corrosive
Potassium hydroxide 10% topical solution	Corrosive
L-carnitine 600 mg/mL oral solution	Not dispensed
Magnesium sulfate 20% oral solution	Duplication
Urea and salicylic acid (40% + 10%) in semisolid petrolatum	Duplication
Urea and salicylic acid (10% + 5%) in lanette cream	Not dispensed
Urea and salicylic acid (20% + 6%) in lanette cream	Duplication
Urea and salicylic acid (20% + 15%) in lanette cream	Not dispensed
Urea and salicylic acid (40% + 10%) in lanette cream	Duplication
Urea and salicylic acid (20% + 10%) in semisolid petrolatum	Not dispensed
Urea and salicylic acid (40% + 2%) in semisolid petrolatum	Not dispensed
Urea and salicylic acid (40% + 12.5%) in semisolid petrolatum	Not dispensed
Urea and salicylic acid (40% + 7.5%) in semisolid petrolatum	Not dispensed
Urea 4% in lanette cream	Not dispensed
Urea 5% in carboxymethylcellulose (CMC) 3% gel	Not dispensed
Urea 10% in carboxymethylcellulose (CMC) 3% gel	Duplication
Urea 10% in carboxymethylcellulose (CMC) 3% gel	Not dispensed
Urea 5% in glycerin dermatological emulsion	Not dispensed
Urea 5 g in propylene glycol dermatological emulsion	Not dispensed
Vitamin B12 500 mcg/mL oral solution	Not dispensed

Table 5. Substituted medicines, replacement medicine, and projected consumption of medications dispensed at the outpatient pharmacy of ICHC-FMUSP, from September 2023 to September 2024.

Medicine	Replacement Medicine	Projected Consumption
Betamethasone 0.5% in cold cream	Betamethasone 0.1% in cold cream	74,900 g
Diltiazem 2% in lanette cream	Diltiazem 2% in semisolid petrolatum	29,834 g
Liquor carbonis detergens (LCD) and salicylic acid (20% + 3%) in lanette lotion	Liquor carbonis detergens (LCD) and salicylic acid (20% + 5%) in lanette lotion	21,712 mL
Quetiapine 12.5 mg capsule	Quetiapine 5 mg/mL oral solution	151,050 mL
Urea and salicylic acid (15% + 5%) in lanette cream	Urea and salicylic acid (20% + 5%) in lanette cream	3,678 g
Urea and salicylic acid (20% + 10%) in lanette cream	Urea and salicylic acid (20% + 7%) in lanette cream	32,400 g
Urea and salicylic acid (30% + 7%) in lanette cream	Urea and salicylic acid (30% + 5%) in lanette cream	11,819 g
Urea and salicylic acid (40% + 12%) in lanette cream	Urea and salicylic acid (40% + 20%) in lanette cream	1,152 g
Urea and salicylic acid (40% + 15%) in lanette cream		
Urea and salicylic acid (20% + 3%) in semisolid petrolatum	Urea and salicylic acid (15% + 2%) in semisolid petrolatum	1,124 g
Urea 30% in lanette cream	Urea 20% in lanette cream	103,598 g

Discussion

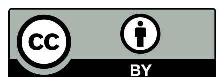
Hospital pharmaceutical technology, grounded in its core essence and objective, meets the various individual and collective demands of patients. Therefore, when defining the medication portfolio, it must be aligned with the institution's pharmacotherapeutic profile. In the present study, 172 different medications were identified for outpatient care, which aligns with the objective of pharmaceutical technology applied to the reality of ICHC-FMUSP. This institution is a tertiary care referral center, conducting approximately 950,000 outpatient visits per year, distributed across 40 medical and multi-professional specialties, according to institutional video data. Thus, it is evident that the medication portfolio must include formulations in various dosage forms and with different routes of administration.[1,2,4,5]

The choice of administration route is made according to the therapeutic indication, ensuring the pharmacokinetic characteristics of the medication. In this survey, five routes of administration were identified, with the dermatological route prevailing (53%), followed by the oral route (34%) among the 172 medications studied.

Among the characteristics of a good dosage form, we can list ease of administration, thereby achieving the desired therapeutic effect and treatment adherence. Therefore, the availability of medications in diverse dosage forms for use via different routes of administration aims to ensure therapeutic success and the desired action of the active ingredient.[23]

According to RDC No. 67/2007, the compounding of solid dosage forms must be carried out in a segregated manner. Based on this principle, as shown in Table 2, the pharmaceutical technology unit designated a separate room exclusively for capsule compounding, while other dosage forms are segregated according to their intended use: internal use (oral solutions, oral suspensions, suppositories, and mouthwashes) or external use (creams, ointments, dermatological emulsions, gels, topical solutions, and pastes).

Among the requirements established by Annex III, there is a need for dedicated rooms and utensils for medications containing hormones, antibiotics, and cytostatics, to prevent environmental cross-contamination and ensure the safety of compounding assistants.



In this regard, the pharmaceutical technology sector does not have a segregated room. Consequently, compounding of these substances is performed using the campaign method, at the end of the day, followed by terminal cleaning, as a contingency measure. A restricted number of formulations (1- 0.58%) requiring this approach was observed, allowing the campaign method to be used as a palliative measure to ensure minimum safety conditions.

Furthermore, Annex III of RDC No. 67/2007 addresses the compounding of substances subject to special control, of which 14 medications were identified in this study. The process involves adapting solid (tablets and capsules) and liquid (ampoules) dosage forms, with due care taken regarding the pharmacist's requisition of these medications, appropriate storage in a locked cabinet, and attention during the crushing and partitioning of dosage forms to ensure the pharmacological effect.[1]

Among the challenges faced by services within the Brazilian Unified Health System (SUS) is the management of available resources (financial, supplies, and human), while patient demand continues to grow. Therefore, approaches addressing this aspect are necessary to achieve good resource management, ensuring patient care and access to medications.

As shown in Table 2, this study enabled the quantification of units compounded in each compounding room, according to the dosage form. This quantity serves as a starting point, and further studies are needed, considering that the pharmaceutical technology sector at ICHC-FMUSP prepares medications for outpatients, inpatients, and medical and multi-professional outpatient clinics for procedures. These data will be used to assess the need for resizing the rooms and to support financial investments for infrastructure readjustment.

Regarding the compounding rooms in the pharmaceutical technology sector, the fact that formulations such as dermatological emulsions and topical solutions—both liquid dosage forms—are compounded alongside semi-solid dosage forms is justified because their active ingredients are identical, thereby avoiding cross-contamination.

In the present study, through the critical analysis of the compounded medication portfolio, it was possible to establish criteria for proposals regarding the maintenance of 133 medications (77.33%), exclusion of 28 medicines (16.28%) (Table 4), and substitution of 11 medicines (6.40%) (Table 5) from the list.

It is noteworthy that this critical analysis will impact the restructuring of care processes involving the pharmaceutical technology sector, the outpatient pharmacy, and the patients. Regarding the compounding process, as shown in Table 4, this study contributed to reducing the number of formulations to be compounded, thereby increasing the sector's operational efficiency and optimizing the service flow for the aforementioned clients.

Addressing the impact on processes inherent to the pharmaceutical technology sector, the pharmaceutical evaluation of outpatient prescriptions and medication compounding orders is highlighted. Through the pharmaceutical evaluation of outpatient prescriptions, it is possible to carry out pharmaceutical interventions related to substituted and excluded medications.

Among the substituted and excluded medications, we can highlight Betamethasone 0.5% cream, which will now be dispensed as Betamethasone 0.1% cream, due to the lack of theoretical basis for using that specific concentration, as it can be indicated for the same clinical conditions. Furthermore, the 0.5% cream had a lower dispensing volume, reflecting its restricted use.

When considering the exclusion of an item from the portfolio, technical and operational criteria were used, such as the absence of dispensing records for the item and technical implications related to compounding and use. Notably, potassium hydroxide, a corrosive active ingredient used in quick in-office medical procedures, is not indicated for home use due to the risk of injury, thereby enhancing safety of use.

By defining a portfolio of compounded medications aligned with patient needs, the outpatient pharmacy increases the confidence and safety of healthcare professionals and patients, impacting treatment adherence.

Additionally, by establishing criteria for compounded medications, the outpatient pharmacy and the pharmaceutical technology sector facilitate collaboration and communication among healthcare professionals, improving patient care.

This study aligns with the objective of pharmaceutical technology and impacts the routine care of patients by providing compounded medications with a personalized approach, tailored to their needs and grounded in technical-scientific evidence, while also identifying and minimizing risks associated with medication use, prioritizing safety. Furthermore, this work can serve as a model for the critical analysis of medications dispensed to other patient populations.

In a previous study conducted at UFAR in 2001, it was discussed that areas of equipment and personnel overutilization and underutilization are economically disadvantageous and should be identified to adjust production lines to quantitative demand. In the first case, excessive consumption of certain medications can lead to production delays, poor quality control, and increased stress for technicians and pharmacists. The opposite situation (underutilization) represents a waste of time and money, or worse, may deprive patients of necessary services due to poor allocation of available resources. The authors further commented that, in the specific context of the Central Pharmacy of HCFMUSP, ideal conditions for resource utilization and improvement of methods and procedures are not always present, due to technical and administrative limitations inherent to public institutions. Nevertheless, there is a continuous effort to update systems, consider new production routines, and overcome barriers that could hinder medication production or compromise the quality of final products.[24]

Regarding limitations encountered during the study, the use of specialized pharmaceutical technology textbooks as references is noted, as this is a limited source regarding the therapeutic indications of the compounded medications.

Conclusion

The present study enabled a 22.6% reduction in the total portfolio (exclusions and substitutions), promoting administrative rationalization and increased clinical safety. This study demonstrates that management of the compounded medication portfolio is essential to align the productive capacity of the pharmaceutical technology sector with the institution's demands.

It can also be concluded that the pharmaceutical technology sector of ICHC-FMUSP fulfills its mission of providing care with different compounded medications, in various dosage forms, for diverse therapeutic indications, according to the needs of the healthcare institution and patients.

Furthermore, the study can be used to support physical infrastructure improvements, mitigating risks of cross-contamination and optimizing the use of scarce financial resources in public institutions.

Collaborators

JGS responsible for project conception, study design, literature review, data collection, descriptive analysis, data interpretation, and article preparation; CEC and PFF responsible for project conception, study design, assistance with descriptive analysis and data interpretation, and article preparation; and VBP responsible for project conception and critical revision of the text and data.

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Conflict of Interest Declaration

The authors declare no conflicts of interest regarding this article.

Artificial Intelligence (AI) Systems

The ChatGPT tool was used to verify spelling and grammatical agreement, as well as to confirm the implementation of requested corrections.

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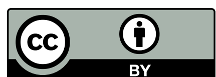

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