DOI: 10.1590/1413-812320222712.13092022EN

Medicine dispensation in the prison system: Is pharmaceutical care assured?

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Abstract *This paper aims to analyze the process of medicine dispensation in prisons. A qualitative study was conducted in seven penitentiaries in Paraíba with 13 health professionals and 43 people deprived of liberty using essential/strategic medicines from February to August 2016. The results were categorized from the perspective of Bardin's content analysis. Three categories emerged: medicine storage location in the prison system, delivery process in the prison system, and health-related responsibilities with pharmaceutical care. We can conclude that the lack of pharmacies, the legal non-compliance regarding the availability of skilled professionals with technical competencies to perform the dispensation, focusing on the quality/safety standards and relevance of the use and storage guidelines associated with the lack of clarity in the definition of health responsibilities of managers from a government authority, are factors that compromise the policy since they increase the investment, but do not ensure pharmaceutical care in the prison system.*
Key words *Pharmaceutical Services, Prisons, Good Dispensation Practices*

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Introduction

To ensure therapeutic care, incorporation of health technology within the SUS[1] and people's access to medicines, with the necessary safety, efficacy, and quality, and promote rational use, the Ministry of Health (MoH) approved the National Medicines Policy (PNM) (Ordinance No. 3,916/1998)[2] and the National Pharmaceutical Care Policy (PNAF) (Resolution No. 338/2004)[3]. The documents consider that Pharmaceutical Care (PC) involves a set of actions and services that aim to ensure comprehensive therapeutic care and the promotion, protection, and recovery of health in public and private establishments that perform pharmaceutical activities, where drugs are an essential supply[4].

However, PC is not limited to the methods of supplying medicines. It has a systemic and multidisciplinary professional nature, which implies promoting the necessary articulation of the several procedures to ensure the supply of medicines per the criteria of need, quality, quantity, risk, and cost-benefit, respecting the stages of conservation, control of quality, safety and therapeutic efficacy of medicines, monitoring, and evaluation of use, obtaining and disseminating information on medicines and continuing education of health professionals, patients, and the community toward the rational use of medicines in health care[2,5]. Therefore, the selection, programming, acquisition, storage/distribution, quality control/use, prescription, and dispensing activities are part of an effective PC[3].

Since 1973, the term dispensing has been legally defined in Brazil as the supply of medicines to consumers in compliance with a medical prescription or not. It has often been understood simply as the delivery of medicines, compliance with legal norms, or mere bureaucracy. However, the PNM, the PNAF, and the recent enactment of Law No. 13,021[6] approach the goal of a simple supply of medicines to promote the rational use of medicines[7].

Thus, dispensing medicines is one of the steps for rational consumption, and it must be accompanied by relevant information for proper use[8]. Adopting the National List of Essential Medicines is recommended as a strategy (RENAME) to streamline this step[9]. It should be noted that the national legal apparatus has guaranteed health care for all Brazilians since the 1980s, including people deprived of liberty (PDL), textually assuring them of medical, pharmaceutical, and dental care[10].

For this reason, the Brazilian government implemented the National Health Plan for the Penitentiary System (PNSSP)[11]. With the successful experience of implementing teams, the National Comprehensive Health Care Policy for People Deprived of Liberty in the Prison System (PNAISP) was established in 2014. It aimed to promote access to the health care network, providing humane and qualified comprehensive care[12].

Moreover, it is essential to note that some international standards provide principles for treating PDLs. The Nelson Mandela Rules make it clear that "all prisoners must be treated with respect, because of their inherent human worth and dignity"[13]. The Bangkok Rules emphasize that prisons require qualified health professionals to care for inmates[14].

Access to and availability of medicines for the population are essential indicators of the effectiveness and equity of health systems. The availability of medicines must meet epidemiological needs in an integrated and guided way to ensure the correct and adequate use of pharmaceutical products[15]. In this sense, this research aimed to analyze the dispensing essential and strategic medicines of continuous use in prison units from the perspective of health professionals and PDLs.

Methods

This exploratory, qualitative, and descriptive study was conducted in seven prisons in the state of Paraíba from February to August 2016. The following inclusion criteria were adopted to select the prison units: having a health unit in its physical structure, with a team of professionals per the PNAISP and a prison population of fewer than 800 inmates, for safety and feasibility reasons.

During the initial visits to the prison units, we observed and recorded in the field diary[16] the routine of the services and the physical structure of the pharmacy/medicine storage and dispensing place.

Health professionals and people deprived of liberty (PDL) were interviewed in subsequent visits. We adopted purposeful sampling, and our sample included professionals from the health teams and PDLs, using the following inclusion criteria: for doctors and nurses, we adopted the criterion of working for at least six months in the unit, and for PDLs, being men or women sentenced to a closed regime who had been using essential and strategic medicines for at least

Ciência & Saúde Coletiva, 27(12):4589-4598, 2022

three months. Thus, 13 health professionals and 43 PDLs were interviewed.

We conducted individual, semi-structured, audio-recorded interviews scheduled per the participants' convenience and the service's routine to collect data, which had a mean duration of 21 minutes. The sample closure[17] for health professionals occurred by exhaustion (in which all available individuals are included) and for the other research participants by theoretical saturation (interrupted capture of the collected data because the information no longer contributes to improving the intended theoretical reflection).

The results were categorized from the perspective of content analysis[18]. The analysis units were identified after a free-floating reading of the interviews. They were grouped per content similarity. Subsequently, the statements were broken down and grouped into three categories: medicine storage in the penitentiary system, medicine dispensing in the penitentiary system, and health responsibilities to ensure pharmaceutical care.

The State University of Paraíba Research Ethics Committee approved the research under CAAE nº 20476213.4.0000.5187. Study participants signed the Informed Consent order to protect the confidentiality of the research participants and the prison institutions, the interviews were identified sequentially per the cities (α, β, γ, δ, ε, ζ, η), with inmates (1, 2, ...) and professionals (A, B, ...), and the domain was exclusive to the researchers.

Results

Characterization of the participants

Fourteen professionals were interviewed: six doctors, seven nurses, and a representative of the Penitentiary Health Coordination of Paraíba. We also interviewed 43 participants deprived of liberty using essential or strategic medicines, of which 35 (81.4%) were men and 8 (18.6%) were women. Regarding age group, prisoners were classified as follows: 1 (2.3%) under 19, 4 (9.3%) 20-29 years, 19 (44.2%) 30-39 years, 9 (20.9%) 40-49 years, 8 (18.6%) 50-59 years, and 2 (4.6%) aged 60 or over.

When investigated the pathologies, 21 (48.8%) had hypertension, 3 (7%) had diabetes, 8 (18.6%) were hypertensive and diabetic, 5 (11.6%) had a TB diagnosis, 1 (2.3%) had leprosy, 1 (2.3%) had leprosy and diabetes, and 4 (9.3%) were HIV-positive.

Regarding the professionals responsible for prescribing drugs, 39 medical records (90.7%) showed they were doctors, 03 (7%) nurses, and 01 (2.3%) medical record did not mention who made the initial prescription.

Three categories emerged after analyzing the results: medication storage location in the penitentiary system, medication dispensing process in the penitentiary system, and healthcare responsibilities to ensure PC.

Discussion

Storage of medicines in the penitentiary system

The 1988 Federal Constitution provides in its art. 5, XLIX that "prisoners are assured respect for physical and moral integrity", showing the need to respect human rights within penitentiaries, such as the number of prisoners inside cells, as the conglomerate in a small space will generate severe health and behavioral issues, removing fundamental rights[19].

The Inter-American Commission on Human Rights (IACHR) highlights the poor situation of health services in Brazilian prisons, underscoring the lack of necessary medicines and equipment and warning that overcrowding, lack of hygiene, and inadequate ventilation are severe threats to the health of inmates[20].

After on-site observation, we found that in penitentiaries α, γ, δ, ε, and ζ had no physical structure housing the pharmacy. This unavailability was attested in the service professionals' statements, as seen below:

Medicines are kept in the drawers of the cabinets in the offices because there is no pharmacy here. (ε-H).

In this way, medicines are not organized by alphabetical order and class, nor is their validity verified. Medicines arriving at the units are only placed at the intended location and distributed on-demand.

Units β and η are equipped with a place for storing medications. However, they are not authorized by the Regional Pharmacy Council or the Health Permit issued by the Municipal Health Surveillance to ensure compliance with the technical and health requirements that cover the operation of the medicine dispensing establishment[21].

In penitentiary β, the place for the pharmacy has a window without a grid or screen, allowing

the direct incidence of sunlight and the entry of birds and other animals that can contaminate the place and invalidate the use of medicines. On the other hand, even with a specific place to store medications and with a physical structure very close to the recommended standards, penitentiary η did not have the proper organization, as highlighted in the following statements:

The pharmacy is very dirty. It has bird droppings. [...] not infrequently, we attend, and we cannot deliver medication or attend an emergency simply because of the lack of access, or the medicine validity has expired or in visible disuse condition when we pick it up. (β-C).

The pharmacy is in a room behind that door. I've never seen it, but we need it often, and they say it's closed. (β-40).

The pharmacy operates in a proper location, albeit in substandard conditions, with storage that only the employee in the sector understands. (η-A).

Inadequacies in terms of physical space are found not only in penitentiary units. A study conducted in the state of Espírito Santo observed that there are also difficulties and non-compliance in the services of the SUS network[17,22]. This disorganization can compromise the quality of medicines, causing services to spend resources to provide them. Prisoners receive medicines with compromised pharmacological properties[21]; consequently, health needs are not met, with unresolved issues.

The Bangkok Rules state that penitentiary establishments must "have facilities, material and pharmaceutical products that enable sick prisoners to be provided with adequate care and treatment" and that professionals must have sufficient professional training to meet the needs of this population[14,23].

The environment intended for the storage of medicines must meet the technical standards of current legislation and the manufacturer's specifications, preserving their identity, integrity, quality, safety, efficacy, and traceability, with the necessary conservation to keep the quality of medicines[21]. Also, Law No. 13,021 of August 8, 2014, conditions the operation of pharmacies to competent authority's authorization/licensing, the presence of a pharmacist, and the observance of a convenient location, considering the health aspect[4].

We could not ascertain a routine of cleaning the environment in penitentiaries with pharmacies. Furthermore, the internal and external areas of pharmacies are not in good physical and structural conditions to allow hygiene, thus posing risks to users and employees, as can be seen in the following statements:

In this place, medicines get moldy due to the lack of hygiene. We lose many, not because they don't need it. It is because the medication is not recognized as a component as important as a doctor and nurse in health care. (η -I).

They can verify that ventilation, lighting, and hygiene are compromised. The entry of insects, rodents, or other animals should be considered. (β-B).

The structures of existing pharmacies do not promote adequate pharmaceutical care and compromise efforts to implement policies. Thus, guaranteeing adequate structure and consequent expansion of the population's access to medicines, fundamental for the organization of services by state and municipal managers to secure an efficient operation, should be highlighted as challenges for proper PC[5].

Drug dispensing process in the penitentiary system

Among the technical-assistance steps to ensure pharmaceutical care, dispensing consists of the pharmacist's service, in compliance with a prescription by a qualified professional, which involves the analysis of the legal/technical aspects of the prescription, the implementation of interventions, the delivery of medicines to the patient or guardian, with guidelines on the proper and safe use and conservation/disposal, to ensure patient safety, access, and adequate use[8], besides providing adequate guidance and education regarding medication use and care and the promotion of adherence toward the best therapeutic results and risk reduction[7].

The World Health Organization emphasizes that the needs of each prisoner must be considered to carry out an effective drug treatment, providing continuous and individualized medication for the appropriate period and dose, which reduces the risk of complications and hospitalizations and improves well-being[24].

In the setting of the researched penitentiaries, the delivery of medication varies with the professionals of each penitentiary and the convict's disease and behavior. However, we failed to classify the delivery as a dispensation in each since it did not fulfill the minimum necessary aspects.

Medication delivery occurred in the medical/nursing office without safeguarding the inmate's privacy in all the penitentiaries studied. More-

over, the medical prescription is not retained in the medical records, or it is not recorded correctly:

Here we only deliver the medicines. It is only sometimes possible to provide guidance. However, as they often already took it before being arrested, we felt calmer. They already know how to take it and, thus, we advanced our work. (α-A).

The medication is delivered, and the prescription is retained, sometimes in fractions or the whole box. It depends on the stock, the period of the month, the patient's condition, and the security agent in charge. (ε-G).

The dispensing process should generally involve evaluating the prescription, correlating the prescribed drugs with the patient's health conditions and characteristics, and considering factors that would interfere with the treatment outcome and patient safety[25].

The international literature has pointed out the central role of health technology assessment (HTA) in the access to medicines and its potential beyond the delivery of the medicine and the purpose of allocating resources in situations of scarcity[26].

In this sense, when asked about the regularity of this delivery, inmates of some penitentiaries stated that they receive the medicines monthly, depending on the stock, regardless of the clinical condition or routine evaluation:

We pick up all once a month. (β-38).

They deliver one blister weekly. (γ-15).

Having only one monthly meeting with the convict compromises the communication and dialogue. It prevents the professional from identifying the patient's level of knowledge and experience with the treatment.

The lack of structure of pharmacies identified in the study also prevents the realization of fractionation in the delivery of medicines. The delta penitentiary is the only one that delivers the medicines more fractionally, as can be seen in the statements:

The doctor or nurse gives it to me for three days. (δ-23).

The nurse gives me the pills for four days. (δ-24).

This fractionated delivery is essential for the success of the dispensing process. The pharmacist must ask the user questions about the drug use process and correct any irregularities, such as those related to the indication, dosage, treatment time, and expected results, besides possible adverse reactions, drug, and food interactions, drug storage, and monitoring when necessary[21].

We should mention that the number of people deprived of liberty in some units can be a factor that hinders daily and individualized follow-up, depending on the number of health professionals and prison officers to meet the demand. However, the occupation of cells above the established number of spaces violates human rights, which is cruel, inhuman, or degrading treatment and infringes the constitutional guarantee of human dignity, endangering the physical, moral, and psychological integrity of individuals and hampering access to elementary material resources for life[27,28].

Moreover, individual pharmaceutical care ensures treatment adherence and positively impacts clinical outcomes. In practice, the medication can be delivered without a health professional, but it will only be delivered with the effective collaboration of prison security officers:

Every month the hypertensive and diabetic patients come up, I check their blood pressure and deliver the medication for 15 days. Then, if there are few officers to bring the inmates for the next 15 days, I ask an officer to deliver it. I send it with the name, and they already know precisely how to take it. (ζ-I).

Another relevant characteristic of medication delivery is related to the person responsible for distributing the medication and the place where it is carried out, done several times in several places by different professionals:

The nurse is the one who delivers. Also, the head of the pharmacy delivers, depending on the time. I come to the grid, and they notify the unit. I come and receive. (β-12).

The agents. Usually, they deliver at the gate of the pavilion or in the cells. There's no need to talk to a doctor or nurse. Everyone is already using the drug. (ζ-37).

The nursing technician delivers; the nurse also delivers; the psychologist delivers; the social worker delivers; even the convict who helps in the services delivers. That is the reality: if necessary, anyone can deliver. (γ-E).

Only two of the seven prisons in this study had a professional responsible for the health unit's pharmacy, and they were not pharmacists. In the other units, as highlighted in the statements, the medicines are delivered by several people without a pre-established protocol. Furthermore, we also observed that this delivery is often carried out at the entrance grid of the pavilions without any specific and individualized guidance. Also, identifying whether inmates know how to read to understand the recommendation for use has yet

to be observed, although leaflets or prescriptions do not accompany the drugs.

Several authors report that approximately 50% of prescription drugs are prescribed, dispensed, or applied inappropriately without a pharmacist[29-32] in Brazil. Medicine dispensing is a private attribution of the pharmacist[25,33]. It cannot be delegated to others, as pharmacists can provide adequate guidance on the correct and safe use, evaluate and interpret the prescription, and guide users on the correct preservation and disposal, considering therapeutic aspects, contraindications and interactions, and technical and legal aspects[25].

When asked about the professional responsible for delivering the medication and guiding its use, inmates and professionals reported:

The health worker provided guidance, or people in the cells. Here many take these medications. (α-4).

The nurse gives guidance to everyone. (β-7).

The doctor explains how to use it when they serve people. (δ-F).

The pharmacy head also guides the use of medications. (η-K).

We identified a few cases in which the professional responsible for the pharmacy is the one guiding the treatment. The recommendations indicate that the pharmacist, when available, should take special care in providing information and ensure that the user understands the entire process of using the medication[17].

Health responsibilities to ensure pharmaceutical care

Recognizing the legal and ethical duty and recommendations described in international human rights documents, the new Sustainable Development Goals (SDGs) to be achieved by 2030 aim to provide access to medicines, ensuring that all human beings can reach their potential in dignity and equality in a healthy environment[34]. This access is an indispensable part of the right to health under the resolution of the United Nations Commission on Human Rights[35]. Therefore, presumably, the reflections raised here are grounded on the theoretical recognition of the principle of human dignity as a primary value of the Brazilian State[28].

Pharmaceutical services in the SUS network are intended to provide users with qualified access to medicines. Thus, the MoH makes available to the municipalities the National Pharmaceutical Care Management System (HÓRUS), which is a tool for the qualification of the PC management since it allows the definition of flows and responsibilities in the work process, the systematic registration of actions, and the possibility of monitoring in real-time the service by issuing and evaluating reports that allow greater agility, security, and control of the activities described here[18].

When we interviewed the professionals, we asked them who would be responsible for acquiring and distributing medicines to guarantee PC in prison units. The pharmaceutical management professional reported how medicines are distributed to prisons:

As we don't have a pharmacist, I [nurse] ask the units and the medicines for hypertension and diabetes to be sent monthly by the state coordination. We depend on municipalities for tuberculosis, leprosy, and HIV. (ζ-I).

In the absence of the pharmacist in the health teams in the penitentiaries, the responsibility for requesting, receiving, and storing the medicines is most commonly attributed to nursing.

We need help accessing the Integrated Agreed Programming (PPI) of the state and municipalities and verifying whether this agreement is known to all and portrays the responsibilities. The MoH must ensure the regular supply of primary medication kits to all teams composed of the professionals mentioned above. In this sense, each sphere of government has responsibilities regarding the acquisition, distribution, and access of inmates to prescribed treatments[11].

Notably, some medicines financed by the SUS are the Federal Government's responsibility and others the State Health Secretariat's. However, users seek access to medicines in the municipalities, and the municipal management only sometimes has the necessary information to guide the correct organization and distribution[36].

The PNSSP institutionalized the Penitentiary Pharmacy program in 2003 to provide comprehensive health care for the prison population, contributing to greater control or reducing the most prevalent health problems and incidents. As a result, the kits consist of essential medicines (AH/DIA), with the amount established proportionally to the number of prisoners linked to the health teams registered in the National Registry of Health Facilities (CNES)[37].

When asked if they recognize who is responsible for the supply, some prison health professionals confirmed that partnerships are taking place with the municipalities but face difficulties:

Everyone should be responsible: the city, state, and federal government. Here we have good polit-

ical relationships. When the state doesn't send, the municipality gets by to ensure them and prevent these subjects from seeking other bodies or network services. So, we've managed never to get stuck with TB and HIV medications. (α-A).

We need to have a friendly relationship with the municipality. The state does not seem to recognize the existence of prisoners and prisons. It's because we are too far away. However, when things get tough, the municipality appeals, and the prisoners leave the penitentiary and wander into the health services of the network. It is scary. (ε-G).

However, health teams report difficulty accessing the service network and guaranteeing the necessary medicines. According to professionals, the prison seems to be a geographical excerpt on the municipality's margins. If it were not for isolated actions by professionals and family members, PC would be relegated to convenience, failing to comply with health responsibilities:

We have difficulties because we only sometimes receive all the essential medicines. However, sometimes the professionals replace the medication with one they have at the popular pharmacy and the family members who take it. (δ-F).

The Bipartite Interagency Committee (CIB) approves the list of essential medicines for the care of prevalent diseases identified in the primary care of each municipality. Thus, each state and its municipalities will have their list of selected medicines, which must contain the minimum list of medicines for agreement in primary care, whether inside or outside prison units. The financing definitions involve the three spheres of SUS management[36,38].

By guaranteeing access to medication as a human right, the State recognizes it as an obligation to be fulfilled, considering the constant assessment of the population's health needs and, when appropriate and necessary, expanding the list of medications[26].

In the reality studied, the needs are evaluated, and the professionals stated that they send the map with the medication requests for the proper acquisition promptly. However, there is not always a means of transport to get the medication:

I order it every month. It only gets here if I get my car and pick up the medication. There's never a car; state transport is always broken. There's always a problem, or they just don't have the medicine. (ζ-I).

Medicines dispensed within the SUS must be distributed to penitentiary health units under what is established in the CIB. The management is entirely responsible for providing the medication, not professionals, family members, or others[39].

It is also important to highlight that CONASEMS developed a Reference Tool for Pharmaceutical Services in Primary Care (IRSFAB), which aims to have an operative definition of the actions and services offered by the PC in primary care, to support other professionals and improve health outcomes for individuals and the population[15].

Finally, it is worth noting that the responsibilities are joint and several regarding PC for PDLs in the prison environment, as provided for in Ordinance No. 2,765/14, where the MoH is responsible for financing this Component. However, the implementation of health actions and services is decentralized, with solidarity actions between the States and the Federal District[40]. Thus, the imperative need to consider the principle of the dignity of human beings when discussing the right to health as a fundamental right that must be protected and guide the country's legal system and public policies.

Final considerations

Most units visited do not have a pharmacy in their physical structure. When they are in place, these facilities must meet the requirements, compromising the PC, as they do not adequately dispense, store, and preserve medicines. Thus, the conception guiding the dispensing process is restricted to delivering the medication by any professional, not prioritizing individual care and humanized care, nor the importance of the role of pharmacists or prescribers to primarily use medicines included in the RENAME.

However, the prison environment has peculiarities that make dispensing drugs even more complicated, such as the substandard infrastructure, the lack of supplies, and the non-availability of pharmaceutical professionals responsible for the PC. Thus, we should emphasize the inefficient and unsafe medication use in prison units since medications are dispensed without adequate guidance and proper monitoring and evaluation of use.

These factors can compromise the expected clinical results with the use of medicines and increase the risks to the health of the prison population, especially if added to the risks associated with the use of medicines stored improperly, without control of environmental conditions and validity.

Concerning health responsibilities, before dispensing medicines, we should highlight that the inter-federal units must prioritize the organization, structuring, management, logistics, and access to PC medicines, emphasizing that there are political obstacles in the State that exceed administrative and technical levels. This fact ends up installing in practice the non-fulfillment of attributions and competencies of each government authority.

Therefore, we should emphasize the importance of Pharmaceutical Services in Primary Care (SFAB) for PC in municipal management, which must be integrated with other health actions and services to adequately respond to people's health needs, considering from the technical-managing viewpoint, focused on planning, logistics, access to medicines, and from a clinical-assistance perspective to achieve better therapeutic results, arising from the use of drug therapy, seeking to improve people's quality of life.

In this sense, the study's limitation is the impossibility of direct access to the integrated agreement for the actual identification of responsibilities.

The findings contribute to research related explicitly to the penitentiary setting to be undertaken at the federal level to assess the dimension of expenditures and PC's efficiency in prisons, the availability of pharmacies, and the legal compliance of professionals with skill and technical competencies to perform the dispensing and the whole process that this action involves.

Collaborations

KKB Cardins, GMC Costa: study concept; data design, analysis, and interpretation; discussion of the results. KKB Cardins: data collection. KKB Cardins, CHSM Freitas, GMC Costa: writing or critical review of content; review and approval of the final version.

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Article submitted 28/11/2021
Approved 13/08/2022
Final version submitted 15/08/2022

Chief editors: Maria Cecília de Souza Minayo, Romeu Gomes, Antônio Augusto Moura da Silva