Exmo. Presidente da Assembleia Legislativa da Região Autónoma dos Açores,

A resistência aos antibióticos é um dos maiores riscos à saúde humana no mundo. Em Portugal e no ano de 2016, o consumo de antibióticos atingiu 21,6 doses diárias definidas por 1000 habitantes por dia. Entre outubro de 2015 e setembro de 2016, as farmácias comunitárias portuguesas dispensaram 8,5 milhões de caixas de antibióticos (61 milhões de euros), representando um decréscimo de 4% ao período homologo de análise.

No sistema de saúde português, os antibióticos orais são dispensados nas farmácias comunitárias em caixas com quantidades pré-definidas. No entanto, a prescrição médica apresenta-se como flexível ao nível de unidades farmacêuticas, existindo diferentes posologias, pelo que pode originar ineficiências no sistema de dispensa tradicional de medicamentos nas farmácias comunitárias. Verificou-se num estudo que 50% da população portuguesa entrevistada admitiu que acumulou medicamentos em casa devido ao "número excessivo de comprimidos nas caixas". De acordo com Ramalhinho et al., 18,9% dos 1192 participantes portugueses em estudo em Portugal (Algarve) declararam que usam antibióticos para automedicação, enquanto 23% informaram que acumulavam sobras de antibióticos. Também, 14% do total de participantes afirmaram que poderiam utilizar as sobras de antibióticos quando ficassem doentes, enquanto 25% as iriam eliminar através do lixo comum ou rede de esgotos. Apenas 16 participantes (1,3%) declararam que poderiam dar sobras de antibióticos a outras pessoas.

Como verificado anteriormente, o problema das sobras de medicamentos que são originadas em sistemas rígidos de dispensa (atualidade nas farmácias comunitárias) pode ser minimizado através de um sistema que permita a dispensa de unidades farmacêuticas de acordo com a posologia prescrita pelo médico. Assim os utentes teriam à disposição um novo sistema de dispensa de medicamentos de antibióticos orais que proporciona a dispensa de um número exato de unidades farmacêuticas prescritas pelo médico, originando poupanças socioeconómicas para os utentes e sistema de saúde.

Relativamente ao estudo que se encontra em anexo (elaborado no HDES, Açores e do qual sou autor), e no qual se baseia-se esta petição, verifica-se que existe um potencial de poupança nos Açores de 45.858 unidades farmacêuticas de antibióticos orais, correspondendo a um valor total 12.921,04 € (sendo que no total do país este potencial atinge 1.544.317 unidades farmacêuticas de antibióticos orais, correspondendo a um valor total 434.08,85 €), caso exista um circuito especial de dispensa de antibióticos orais em unidose nas farmácias comunitárias. Ressalva-se também a necessidade de os antibióticos orais serem fornecidos gratuitamente pelas unidades hospitalares aos pacientes que têm alta e têm que completar o esquema terapêutico em ambulatório (uma vez que neste momento não existe unidose nas farmácias comunitárias).

Assim e de forma resumida, esta petição pretende:

1 - A criação de um circuito especial de dispensa de antibióticos em unidose nas farmácias comunitárias, com controlo das dispensas semelhante ao circuito de medicamentos estupefacientes em Portugal e nos Açores

2 - A dispensa gratuita em unidose de antibióticos orais pelas unidades hospitalares a utentes que têm alta e que têm que completar o esquema terapêutico em ambulatório (já prescrito e iniciado na unidade hospitalar).

As sobras de antibióticos são um problema de saúde pública uma vez que afetam a saúde humana e promovem a resistência aos antibióticos. Um sistema de dispensa em unidose de medicamentos aplicado à dispensa de antibióticos orais permite obter benefícios socioeconómicos para os sistemas de saúde. Assim, o tamanho das caixas de antibióticos orais deve ser reanalisado pela indústria farmacêutica, de forma a corresponder com as práticas de prescrição habituais dos médicos e os governos devem implementar regras e legislação especifica direcionada ao circuito de dispensa de antibióticos nas farmácias comunitárias e hospitais.

Com os melhores cumprimentos,

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ORIGINAL RESEARCH ARTICLE

The benefits of a unit dose system in oral antibiotics dispensing: Azorean hospital pharmacists tackling the socioeconomic problem of leftovers in Portugal

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Abstract

Background In Portugal, oral antibiotics are usually dispensed in a predefined package size at the local community pharmacy. This rigid system can create inefficiencies (e.g. leftovers), since prescription regimens are flexible and sometimes the package does not correspond exactly to the prescribed treatment. To provide a solution to this problem, the Hospital do Divino Espírito Santo de Ponta Delgada (HDES) opened a Public Sales Unit (PSU) with a unit dose dispensing system of pharmaceuticals for its patients.

Objectives The aim of this study was to characterize and evaluate the unit dose system for oral antibiotics dispensing at the HDES-PSU, and to extrapolate the results at the Portuguese nationwide level.

Method Oral antibiotics dispensing dynamics at the HDES-PSU were examined over a period of 1 year. Dispensed prescriptions were analyzed, and relevant information was collected and entered into a digital database for analysis. To extrapolate results at a nationwide level, a database from Statistics Portugal was used.

Results The results revealed that the 663 registered interventions provided overall savings of 3939 pharmaceutical units, corresponding to €1032.99. The Portuguese nationwide extrapolation indicated that a total of 276,833 pharmaceutical interventions could be registered, corresponding to 1,544,317 pharmaceutical units saved and to €434,085.85 in monetary savings.

Conclusion The present study provides insights into how a unit dose dispensing system can contribute to solving the socioeconomic problems raised by leftovers of oral antibiotics dispensing practices occurring in healthcare systems such as the Portuguese one.

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Key Points

Leftover antibiotics are a public health problem as they affect human health and promote antibiotic resistance.

A unit dose dispensing system of pharmaceuticals applied to oral antibiotics provides significant socioeconomic benefits for healthcare systems.

Oral antibiotics package sizes must be reanalyzed by the pharmaceutical industry in order to comply with common prescription habits of physicians.

Governments should implement specific rules and legislation for the antibiotic dispensing circuit in pharmacies and hospitals.

Introduction

According to the World Health Organization (WHO) [1, 2], antibiotic resistance is a major risk to the health of societies around the globe. In Europe, data from 2016 suggest that this menace is currently present in the old continent and could threaten its public health [3]. Moreover, the consumption of antibiotics and their misuse are serious contributors to antibacterial resistance [4–6].

The European consumption of antibiotics in the community has been stable over the past few years, with a slight increase in 2015 and 2016 [3]. Following Europe's trend, Portugal registers the same consumption behavior, reaching 2.16 packages per 1000 inhabitants per day (21.6 defined daily doses per 1000 inhabitants per day) in 2016 [3]. According to QuintilesIMS [7], Portuguese community pharmacies dispensed 8.5 million packages of antibiotics (61 million euros) between October 2015 and September 2016, a 4% decrease when compared with the homologous period of analysis.

In the Portuguese healthcare system, physicians prescribe the active pharmaceutical ingredient and its dose and dosage form associated with a specific dosage regimen. Afterwards, the prescribed pharmaceuticals (e.g. oral antibiotics) are dispensed at a local community pharmacy in a predefined package size in terms of pharmaceutical units. When community pharmacists analyze the physician prescription and the type of dispensing in the local community pharmacy, a dilemma arises as the prescription regimen is flexible while the predefined package size is a rigid system, which could lead to inefficiencies in the dispensing system. This rigid system is a result of regulation imposed by Portuguese legislation and, according to Mukherjee and Saha [8], size of packages is determined by pharmaceutical companies mostly by economic cost and convenience rather than by scientific knowledge. To corroborate the existence of this inefficiency, Sabry et al. [9] found that only 60% of the prescribed antibiotics, which were analyzed at 36 Egyptian community pharmacies, were in the right quantity for obtaining efficient treatment. Also, a report from Health Care Without Harm Europe [10] showed that approximately 50% of the surveyed Portuguese population accumulate pharmaceuticals at home due to "excessive number of pills in the package".

Antibiotic leftovers from past treatments are the typical source for antibacterial self-medication [11–15]. It also appears that there is an association between prescribed use of antibiotics and self-medication from leftovers [16]. Developed and developing countries seem to be at a higher risk, with leftovers of penicillins being one of the most used medicines in self-medication [11]. The antibiotic leftover problem can be exacerbated by a rigid dispensing system at the community pharmacy [12, 14]. In fact, in accordance with some authors, antibiotic self-medication can be tackled by adopting a unit dose system that allows the exact number of pharmaceutical units required for treatment to be dispensed [12, 15–18]. According to Ramalhinho et al. [15], 18.9% of the 1192 Portuguese participants in their study, which took place in Portugal (Algarve region), declared that they use antibiotics for self-medication and 23% of them accumulate antibiotic leftovers. Moreover, 14% of the study sample acknowledged that they could use them when they get sick again, whereas 22.5% will dispose of them in the garbage or sewer system. Only 16 participants (1.3%) stated that they will give leftover antibiotics to someone else. However, the authors further state that the leftover antibiotics problem in Portugal is more associated with non-adherence to prescriptions and side effects, rather than packaging size [15]. In a Greek study [19], the authors declared that 15.3% of the 1139 participants used antibiotic leftovers for self-medication, with amoxicillin (18.3%) and amoxicillin/clavulanic acid (15.4%) being the most commonly used antibacterials, followed by second-generation cephalosporins and ciprofloxacin (2.3%). Likewise, Raz et al. [20] found that 114 (24.4%) of the 467 adults living in Northern Israel who took their study questionnaire accumulated leftover antibiotics, with amoxicillin (31.6%) and amoxicillin/clavulanic acid (9.8%) being the most commonly used antibacterials. Of the 114 previous respondents, 26.3% acknowledged they would take antibiotics without prescription [20]. Antibiotic leftovers raise some concerns as they can promote subtherapeutic self-medication initiatives that can contribute even further to worsening the antibiotic resistance problem [21].

Antibiotic leftovers can also pose a threat to public health as they are linked to the promotion of antimicrobial resistance in the environment. As Ramalhinho et al. [15] found, leftovers can be discarded through the garbage or sewer system. In a study focused on medication wastage, Law et al. [22] found that the total cost of unused household medication reached about 60,000 US dollars (US$) in their sample (US$117 billion when making a national projection), with 18% being antibiotics. They further stated that the most common ways to dispose of these medications was through the garbage or the toilet sink, which could harm the environment, promote antibacterial resistance and cause genetic modifications in humans and animals [22]. In Austria, a study targeting household garbage found that 8% of the waste analyzed was related to antibiotics. The authors' extrapolation for Austria projected that the costs of pharmaceutical waste for the national healthcare system could reach €179,000,000 [23].

As seen before, the problem of pharmaceutical leftovers created by rigid dispensing systems can be tackled using a system that allows the dispensing of pharmaceutical units corresponding to the dose regimen prescribed by the physician. As this more efficient system is not implemented in Portuguese community pharmacies and to provide a local solution to this leftover problem, the Hospital do Divino Espírito Santo de Ponta Delgada (HDES), located in the Azorean island of São Miguel, opened a Public Sales Unit (PSU), a unit dose dispensing system, which is only accessible to in-house hospitalized patients who have been discharged or received treatment at the emergency unit. With it, patients gained access to a new dispensing system that provided the exact number of pharmaceutical units necessary to complete the treatment prescribed by the physician, as pharmacists and pharmacy technicians evaluate prescriptions that are based on predefined package size of pharmaceuticals and retain or provide extra pharmaceutical units according to the dose regimen prescribed. Patients then buy the optimal number of pharmaceutical units needed and obtain socioeconomic savings for them and the healthcare system. The present study aims to characterize and evaluate the unit dose system for oral antibiotics dispensing at the HDES-PSU, and to extrapolate the results at a nationwide level. This study is the first, to our knowledge, to analyze and predict the economic impact of having a unit dose system for antibiotics in countries where antibacterials are only dispensed in predefined package sizes at a community pharmacy.

Materials and methods

Design and setting

The present retrospective and hospital-based study was developed during a period of one year (July 1, 2016 to June 30, 2017) in HDES, which is the only hospital providing services to the 137,856 inhabitants of São Miguel Island, representing 55% of the population of the nine islands of the archipelago of the Azores, an autonomous region of Portugal (Portugal Census, 2011). In HDES-PSU, prescriptions were received, analyzed and validated by a pharmacist or a pharmacy technician. Using a computer, these healthcare professionals verified if a prescription came from in-house hospitalized patients who have been discharged (hospitalizations) or who received treatment at the emergency unit (emergencies). If this prerequisite was fulfilled, then the professionals proceeded to dispense the pharmaceuticals, according to Fig. 1.

Data acquisition

In accordance with Fig. 1, during this period, the accepted and validated prescriptions were analyzed and the relevant information (global transactions [dispensing of pharmaceuticals], active pharmaceutical ingredients, number of pharmaceutical units prescribed by the physicians, number of pharmaceutical units dispensed to the patient, unitary cost per pharmaceutical unit and source of prescriptions [hospitalizations and emergencies]) was collected and entered into a Microsoft Excel® 2013 database (see Spreadsheet 1 in the electronic supplementary material [ESM] for a detailed description of antibiotic transactions in the HDES-PSU). The calculated total number of pharmaceutical units retrieved resulted from the sum of the prescribed pharmaceutical units in predefined market packages. The number of pharmaceutical units dispensed to the patient resulted from the analysis of the pharmacist or pharmacy technician, according to the prescribed dosage regimen. The unitary cost per pharmaceutical unit was provided by the HDES-PSU software, namely Glintt-HS®. To ensure compliance with the European General Data Protection Regulation (GDPR), demographic data and personal identifiers were not collected during the process.

Data analysis

The active pharmaceutical ingredients data collected from the dispensed antibiotics were grouped into 13 pharmacotherapeutic categories, accordingly to the Portuguese National Authority of Medicines and Health Products pharmacotherapeutic classification [24]. Using Microsoft Excel® 2013, pharmaceutical interventions were calculated (corresponding to each antibacterial that experienced adjustments in the number of dispensed pharmaceutical units, when compared with the prescribed ones) along with the corresponding pharmaceutical savings in units and euros. Afterwards, the data was divided through each pharmacotherapeutic category and, subsequently, analyzed by the source of prescriptions. As a complement, a ranking was created to analyze the savings potential of each pharmacotherapeutic category. To extrapolate results to a national level, a database (NUTS 2013: NUTS I and municipality), from Statistics Portugal [25, 26] was used. The extrapolation was then replicated by geographic location for savings in pharmaceutical units, monetary savings and pharmaceutical interventions. The extrapolation process was performed taking into account the fact that the HDES-PSU is only accessible to in-house hospitalized patients who have been discharged or received treatment at the HDES emergency unit.

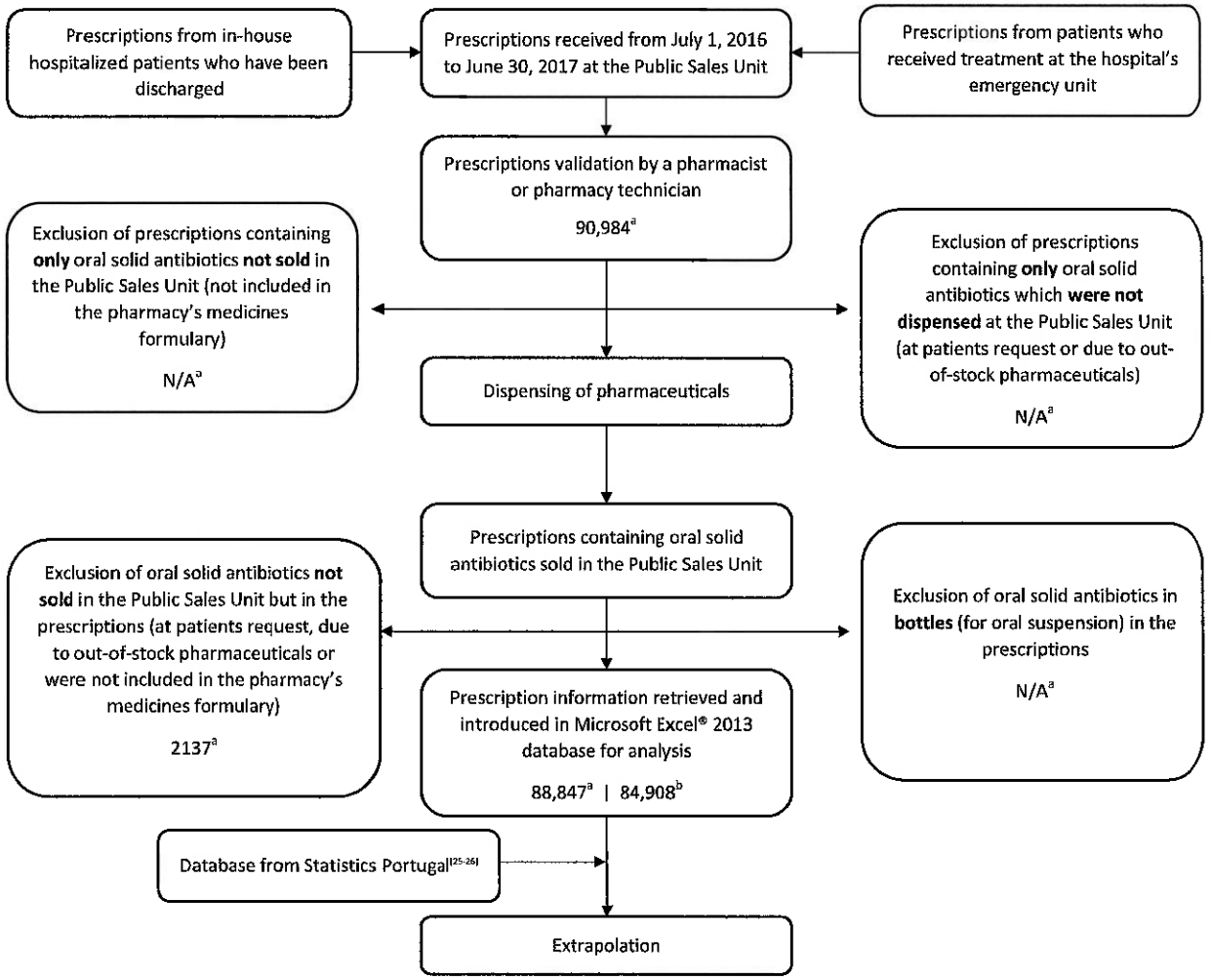

Fig. 1 Flowchart of the data collection and analysis process. [a]Number of prescribed oral solid antibiotic pharmaceutical units. [b]Number of dispensed oral solid antibiotic pharmaceutical units

Results

Overview of the HDES-PSU dynamics

During the period of analysis (1 year: July 1, 2016–June 30, 2017), the PSU was open 294 days and registered 16,791 global transactions of all sorts of pharmaceuticals sold in the PSU. The prescriptions validated by the pharmacist or pharmacy technician contained a total of 90,984 pharmaceutical units of oral solid antibiotics. However, 2137 of these 90,984 pharmaceutical units were excluded as they were not dispensed at the Public Sales Unit because they were patients' requests, out-of-stock pharmaceuticals or were not included in the pharmacy's medicines formulary (see Spreadsheet 2, in the ESM, for a list of antibiotics prescribed but not dispensed at the HDES-PSU). The number of specific transactions associated with the dispensing of oral antibiotics was

Table 1 Overall dispensing dynamics of oral antibiotics unit doses

Variable description	Adjustments		
	Positive[a]	Negative[b]	Total
Monetary savings (€)	1153.28	− 120.29	1032.99
Pharmaceutical interventions (n)[c]	610	53	663
Savings in pharmaceutical units (n)	4418	− 479	3939

[a]Positive adjustments occurred when pharmaceutical interventions led to fewer pharmaceutical units dispensed than those prescribed

[b]Negative adjustments occurred when pharmaceutical interventions led to more pharmaceutical units dispensed than those prescribed

[c]Corresponds to each antibiotic that experienced adjustments in the number of dispensed pharmaceutical units

5389, corresponding to 84,908 pharmaceutical units and €28,717.01. According to Table 1, in this sample, a total of 663 pharmaceutical interventions were registered, which led to positive and negative adjustments between the number of pharmaceutical units dispensed and the prescribed ones. These interventions allowed global savings of 3939 pharmaceutical units, corresponding to €1032.99.

Savings in pharmaceutical units by pharmacotherapeutic category

The analysis of the dynamics of savings in pharmaceutical units within each antibiotic pharmacotherapeutic category demonstrated that, except for the aminoglycosides, all categories recorded positive and overall savings (Table 2). Only four pharmacotherapeutic categories did not have negative adjustments: (1) aminoglycosides; (2) antitubercular; (3) cephalosporins, first generation; and (4) chloramphenicol and tetracyclines. The negative adjustments occurred when the prescribed pharmaceutical units were insufficient to complete the dosage regimen prescribed by the physician, which led to the dispensing of more pharmaceutical units than prescribed.

According to Table 2, the penicillins and beta-lactamase inhibitor combinations comprised the pharmacotherapeutic category that recorded more overall adjustments in pharmaceutical units, reaching 1013 pharmaceutical units saved. Analyzing each individual category, we found that the urinary anti-infectives and antiseptics (which only incorporate the active pharmaceutical ingredient nitrofurantoin) provided the higher percentage of savings in pharmaceutical units (31.32%) when dividing the overall savings in pharmaceutical units (830) by the number of prescribed ones (2650). Applying the same calculation method to the total numbers in Table 2, the percentage of overall savings in pharmaceutical units was 4.43%.

Monetary savings by pharmacotherapeutic category

The monetary savings analysis in Table 3 allowed us to view the economic impact of the adjustments made in the dispensing of antibiotics and their pharmaceutical units. The penicillins and beta-lactamase inhibitor combinations comprised the pharmacotherapeutic category that registered the highest amount of monetary savings (€279.98).

When analyzing each pharmacotherapeutic category separately, the urinary anti-infectives and antiseptics provided the highest amount of economic savings (€161.99) versus its prescribed value (€517.28). The only pharmacotherapeutic category that did not produce any economic savings impact was the aminoglycosides.

Table 2 Savings in pharmaceutical units by pharmacotherapeutic category

Pharmacotherapeutic category	Savings in pharmaceutical units (*n*)			Type of pharmaceutical units (*n*)	
	Positive[a]	Negative[b]	Overall[c]	Dispensed	Prescribed
Aminoglycosides	0	0	0	100	100
Aminopenicillins	647	− 22	625	4191	4816
Antitubercular	8	0	8	328	336
Cephalosporins, first generation	16	0	16	1840	1856
Cephalosporins, second generation	339	− 4	335	5841	6176
Chloramphenicol and tetracyclines	44	0	44	804	848
Isoxazolyl penicillins	203	− 202	1	6983	6984
Macrolides	92	− 22	70	4127	4197
Other antibacterials	512	− 116	396	5607	6003
Penicillins and beta-lactamase inhibitor combinations	1028	− 15	1013	34,491	35,504
Quinolones	457	− 30	427	15,734	16,161
Sulfonamides and associations	183	− 9	174	3042	3216
Urinary anti-infectives and antiseptics	889	− 59	830	1820	2650
Total	4418	− 479	3939	84,908	88,847

[a]Positive savings are when pharmaceutical interventions led to fewer pharmaceutical units dispensed than those prescribed

[b]Negative savings are when pharmaceutical interventions led to more pharmaceutical units dispensed than those prescribed

[c]Overall savings is equal to the sum of positive and negative savings

Table 3 Monetary savings by pharmacotherapeutic category

Pharmacotherapeutic category	Overall monetary savings (€)[a]	Type of pharmaceutical units (€)	
		Dispensed	Prescribed
Aminoglycosides	0.00	19.35	19.35
Aminopenicillins	110.21	854.61	964.82
Antitubercular	2.86	117.37	120.23
Cephalosporins, first generation	11.52	1296.90	1308.42
Cephalosporins, second generation	129.17	2041.34	2170.49
Chloramphenicol and tetracyclines	13.28	243.53	256.81
Isoxazolyl penicillins	0.25	1534.06	1534.31
Macrolides	54.37	3664.05	3718.39
Other antibacterials	74.58	1083.86	1158.44
Penicillins and beta-lactamase inhibitor combinations	279.98	10,245.21	10,525.19
Quinolones	161.34	6677.09	6838.40
Sulfonamides and associations	33.44	584.35	617.79
Urinary anti-infectives and antiseptics	161.99	355.29	517.28
Total	1032.99	28,717.01	29,749.92

[a]Overall monetary savings is the sum of positive and negative savings (associated with the adjustments in Table 2)

Savings by pharmacotherapeutic category: hospitalizations versus emergencies

As previously reported, prescriptions came from patients discharged from the HDES (hospitalizations) and from the emergency room (emergencies). Prescriptions from emergencies provided higher savings in pharmaceutical units (2386) than from hospitalizations (1553) (Table S1 in the ESM). However, the overall savings divided by pharmaceutical units prescribed showed that hospitalizations provided 8.69% of savings while emergencies recorded only 3.36%. In terms of hospitalizations, the pharmacotherapeutic categories that provided more absolute savings were (1) penicillins and beta-lactamase inhibitor combinations (525); (2) other antibacterials (340); and (3) cephalosporins, second generation (234). If we analyze each individual category (fraction between savings and pharmaceutical units prescribed in a category), a different result becomes evident as new antibacterials emerge as providing higher levels of savings: (1) chloramphenicol and tetracyclines (20.19%); (2) cephalosporins, second generation (18.99%); and (3) urinary anti-infectives and antiseptics (18.87%). The isoxazolyl penicillins category presented negative results (− 91; − 3.03%), while aminoglycosides remained neutral as there were no prescriptions from this category. Regarding emergencies, the pharmacotherapeutic categories that provided more absolute savings were (1) urinary anti-infectives and antiseptics (662); (2) aminopenicillins (602); and (3) penicillins and beta-lactamase inhibitors combinations (488). The individual analysis of each category reported a similar outcome: (1) urinary anti-infectives and antiseptics (37.83%); (2) aminopenicillins (13.11%); and (3) sulfonamides and associations (4.23%). The aminoglycosides, antitubercular and cephalosporins (first generation) categories did not achieve savings.

In terms of the monetary savings analysis, prescriptions from emergencies provided higher monetary savings (€554.52) than from hospitalizations (€478.47) (Table S2 in the ESM). In concordance with the results obtained in the previous pharmaceutical units analysis, overall monetary savings divided by the total monetary value prescribed showed that hospitalizations provided higher monetary savings (8.89%) than emergencies (2.28%). In terms of hospitalizations, the pharmacotherapeutic categories that provided more absolute monetary savings were (1) penicillins and beta-lactamase inhibitor combinations (€169.01); (2) cephalosporins, second generation (€93.77) and (3) quinolones (€87.88). If we analyze each individual category, a different result will emerge: (1) cephalosporins, second generation (20.49%); (2) chloramphenicol and tetracyclines (19.71%); and (3) urinary anti-infectives and antiseptics (18.66%). The isoxazolyl penicillins category presented similar results to the pharmaceutical units analysis (− €19.89; − 3.03%).

Regarding emergencies, the pharmacotherapeutic categories that provided more absolute monetary savings were (1) urinary anti-infectives and antiseptics (€129.21); (2) penicillins and beta-lactamase inhibitor combinations (€110.96); and (3) aminopenicillins (€105.42). As for the individual analysis, results were identical to the pharmaceutical units analysis: (1) urinary anti-infectives and antiseptics (37.82%); (2) aminopenicillins (11.49%) and (3) sulfonamides and associations (4.62%). As expected, and like the pharmaceutical units analysis, the categories of aminoglycosides,

Table 4 Savings potential by pharmacotherapeutic category

Pharmacotherapeutic category	Intra-category analysis		Inter-category analysis		Overall savings potential
	Monetary savings potential	Savings in pharmaceutical units potential	Monetary savings potential	Savings in pharmaceutical units potential	
Aminoglycosides	13	13	13	13	13
Aminopenicillins	2	2	5	3	2
Antitubercular	8	9	11	11	10
Cephalosporins, first generation	11	11	10	10	11
Cephalosporins, second generation	4	4	4	6	5
Chloramphenicol and tetracyclines	6	6	9	9	8
Isoxazolyl penicillins	12	12	12	12	12
Macrolides	10	10	7	8	9
Other antibacterials	3	3	6	5	4
Penicillins and beta-lactamase inhibitor combinations	7	7	1	1	3
Quinolones	9	8	3	4	6
Sulfonamides and associations	5	5	8	7	7
Urinary anti-infectives and antiseptics	1	1	2	2	1

The savings potential scale goes from 1 to 13 (1 = best savings potential; 13 = worst savings potential)

antitubercular and cephalosporins (first generation) did not achieve monetary savings.

Savings potential by pharmacotherapeutic category

In order to have an integrated analysis between monetary savings and savings in pharmaceutical units, a saving potential ranking was created. According to the intra-category analysis performed in Table 4, the urinary anti-infectives and antiseptics category seemed to have a greater potential for savings (1st). The inter-category analysis, also in Table 4, showed that the penicillins and beta-lactamase inhibitor combinations was the category that achieved a higher savings potential (1st), both in pharmaceutical units and euros. The aminoglycosides category appears to be in the opposite situation in both the intra-category and inter-category analysis (13th). The overall savings potential, which results from the average of the four savings potentials, shows that the following three pharmacotherapeutic categories, namely the urinary anti-infectives and antiseptics (1st), the aminopenicillins (2nd) and the penicillins and beta-lactamase inhibitor combinations (3rd) can provide high levels of savings, while the cephalosporins (first generation) (11th), the isoxazolyl penicillins (12th) and the aminoglycosides (13th) categories provide low levels of savings.

Extrapolation of results

To calculate the possible effects of the unit dose dispensing system of HDES on oral antibiotic dispensing in the Portuguese healthcare system, we extrapolated the results using the Statistics Portugal database [25, 26]. Firstly, we calculated the averages of the number of hospitalizations and emergencies that occurred between 2016 and 2017 per geographic location. According to the averages calculated in Table S3 (see the ESM), which resulted from the average of the 2016 and 2017 values, the municipality of Ponta Delgada registered 17,774 hospitalizations and 111,900 emergencies. Regarding the autonomous regions of Portugal, the Azores recorded more hospitalizations (26,788) and emergencies (192,080) than Madeira (19,875 and 121,311, respectively). Mainland Portugal documented 855,464 hospitalizations and 6,127,770 emergencies. For all of Portugal's territory, the figures were 902,126 and 6,441,161, respectively. Afterwards, and using the average data of Ponta Delgada (which possesses the same characteristics as the HDES-PSU sample), we obtained the values of our study sample for hospitalizations (2301) and emergencies (14,490).

With the data from Table S3 (see the ESM), it was possible to initiate the extrapolation process. According to Table 5, Ponta Delgada, which represents São Miguel island and the HDES, obtained, in the extrapolation, a total of €7978.25 in monetary savings and 29,586 savings in pharmaceutical units, as a result of 4889 pharmaceutical interventions.

If our extrapolation to all of Portugal's territory reflected the characteristics of the HDES-PSU sample, we will have achieved about 276,833 pharmaceutical interventions, corresponding to 1,544,317 pharmaceutical units saved and ultimately resulting in a monetary saving of €434,085.85.

Table 5 Extrapolation of results: monetary savings, savings in pharmaceutical units and pharmaceutical interventions

Sample description (geographic location)	Monetary savings (€)[a]		Savings in pharmaceutical units[a] (n)		Pharmaceutical interventions[a] (n)
	Hospitalizations	Emergencies	Hospitalizations	Emergencies	
HDES-PSU[b]	478.47	554.52	1553	2386	663
Ponta Delgada[d]	3695.93	4282.32	11,996	18,431	4889
Azores region	5570.30	7350.74	18,080	27,778	8251
Madeira region	4132.81	4642.47	13,414	20,609	5323
Mainland Portugal	177,885.21	234,504.54	577,373	887,065	263,259
All of Portugal's territory	187,588.10	246,497.74	608,866	935,451	276,883
All of Portugal's territory (Global)[c]	434,085.85		1,544,317		276,883

HDES Hospital do Divino Espírito Santo de Ponta Delgada, *PSU* Public Sales Unit

[a]Results from a cross-multiplication between the calculated average for hospitalizations and emergencies of each geographic location (Table S3 in the ESM) and HDES-PSU results

[b]Data retrieved from Table 1, Table S1 and Table S2 (see ESM)

[c]Results from the sum of the hospitalizations and emergencies variables

[d]Represents São Miguel island and the HDES

Discussion

Impact of the HDES-PSU unit dose system

The unit dose dispensing system discussed in the present case study created a new scenario for oral antibiotic dispensing in the Azores archipelago. The results obtained demonstrated that there are positive socioeconomic outcomes for patients and healthcare systems. Firstly, this unit dose concept allowed the reduction of antibacterial leftover accumulation as it provided patients the exact number of pharmaceutical units necessary to complete the dose regimen prescribed. A total of 3939 antibiotic pharmaceutical units (4.43% of the oral antibacterial pharmaceutical units prescribed) did not reach patients' households due to the unit dose dispensing system, providing monetary savings of €1032.99 for both patients and the healthcare system. These findings are in accordance with Kardas et al. [12], Ramalhinho et al. [15] and Grigoryan et al. [16–18]. Secondly, with the reduction of antibiotic leftovers, the probability of initiating self-medication can be reduced, as demonstrated by data provided by Skliros et al. [19], Raz et al. [20] and Ramalhinho et al. [15]. Finally, this unitary distribution process meant a reduction in the probability of patients incorrectly disposing of leftover antibiotics or providing them to someone else, as was demonstrated by Ramalhinho et al. [15]. Stopping these activities diminishes the possibility of the rise of multi-resistant organisms, releasing the growing pressure on our small available antibacterial portfolio.

Evaluation of savings potential

The evaluation of the savings potential of the following three pharmacotherapeutic categories: (1) urinary anti-infectives and antiseptics, (2) aminopenicillins and (3) penicillins and beta-lactamase inhibitor combinations demonstrated that they possess the highest potential of the pharmacotherapeutic categories analyzed in the current study. To understand why they provide more savings, it is important to analyze the dosage regimens and the number of pharmaceutical units in the packages prescribed by the physicians. The aminopenicillins and penicillins and beta-lactamase inhibitor combinations were prescribed in pill boxes with 16 pharmaceutical units, while the urinary anti-infectives and antiseptics were mostly prescribed in pill boxes with 50 pharmaceutical units. The most common dosage regimens for the first two pharmacotherapeutic categories was one pharmaceutical unit every 12 h or 8 h, for 7 or 8 days (14, 16, 21 and 24 pharmaceutical units dispensed), while for the urinary anti-infectives and antiseptics it was one pharmaceutical unit every 8 hours for 5–10 days (15–30 pharmaceutical units dispensed). In some scenarios, such as at hospital discharge, a reduced number of pharmaceutical units can be dispensed to complete the dosage regimen already started by the patient at the hospital. As found in the present study, 8.69% of the pharmaceutical units prescribed by hospitalization services did not reach the patient, whereas in prescriptions from emergencies, only 3.36% were not dispensed. These data suggest that, in previous cases, the pill boxes were not suited for the dosage regimens prescribed by the physician. Consequently, hospital pharmacists should consider the possibility of providing

the entire course of the necessary antibiotic to the patient at hospital discharge.

Extrapolation analysis

According to our research, the most prescribed pharmacotherapeutic category was the penicillins and beta-lactamase inhibitor combinations. Similarly, Ramalhinho et al., found that this category was also the most prescribed in the Portuguese Algarve region [27] and throughout Portugal's mainland [28]. However, the 9-year analysis of the consumption of antibiotics by each of the Portuguese geographic regions revealed that the consumption patterns can differ between regions [28]. When compared with the findings of Skliros et al. [19] and Raz et al. [20] in Greek and Israelite populations, respectively, the category most found was aminopenicillins (this category was the fourth most prescribed in the present study). However, Raz et al. [20] found that the second most used antibiotic by rural Greek individuals came from penicillins and beta-lactamase inhibitor combinations. Ramalhinho et al. [27] also reported that 4.2% of the analyzed prescriptions corresponded to the active pharmaceutical ingredient nitrofurantoin, as opposed to Skliros et al. [19] and Raz et al. [20], who did not report any antibacterial from the urinary anti-infectives and antiseptics category, which is the one with a higher savings potential in our study. These data suggest that antibiotic prescribing similarities could exist even between different countries and regions, which could reinforce the nationwide extrapolated data.

The extrapolated data tries to provide a nationwide scenario of what the role and contribution of this unit dose dispensing system could be. This extrapolation demonstrated that it is possible to provide direct economic savings (€434,085.85) to the Portuguese healthcare environment, which could be used for reinvestment purposes in the healthcare system. There are also indirect socioeconomic savings, mostly due to the prevention of 1,544,317 pharmaceutical units being dispensed, therefore eliminating the possibility of them being used and discarded incorrectly and consequently lessening the antibiotic resistance problem. As we saw before, the dimensions of predefined antibiotic pill boxes are not in concordance with the antibiotic regimens prescribed by physicians. Moreover, if we applied a unit dose dispensing system in community pharmacies, we would probably see a major increase in the numbers obtained in the extrapolation process.

Limitations and advantages

The current work has some limitations. Firstly, our sample prices and prescribed package sizes do not reflect entirely the real market (market prices can be higher and there are prescribing software limitations in the information about package sizes on the market). Secondly, the data collected may not reflect the exact specificities of nationwide antibiotic prescribing habits, which is a factor of influence to be considered in the extrapolation process. Thirdly, the HDES-PSU operation costs were not taken into consideration, which is essential to analyze the cost–benefit relationship for the functioning of the unit dose dispensing system. However, the present study has at least three advantages. Firstly, it provides information about the possible adjustments that can be made to the oral antibiotic packages in the Portuguese pharmaceutical market to make them more socioeconomically effective for the healthcare system. Secondly, it points out possible strategies to be adopted by hospitals to reduce the socioeconomic burden of antibiotic leftovers. Finally, the extrapolation process provides a measurement of the socioeconomic impact of a unit dose system for oral antibiotic dispensing, where data can be used to raise awareness within government entities and force them to take action.

Conclusion

The present case study provides insights into how the unit dose dispensing system can help to eradicate the antibiotic leftover problem. Pharmacists are essential gatekeepers in this process, ensuring that the prescribed dose regimen is dispensed and therefore reducing the socioeconomic impact for patients and healthcare systems such as the Portuguese one. The antibiotic leftover issue is a serious threat to healthcare ecosystems. With the rise of antibiotic resistance phenomena, strategies must be put in place in order to diminish its occurrence.

It is critical to think about a new and specific antibiotic circuit in the Portuguese healthcare system and other similar healthcare systems. Currently, the available antibiotic portfolio is under pressure and, if no action is taken, effective antimicrobials could be near extinction. Moreover, innovation in the research and development of new antibacterials is slow, and new formulations may take a long time to enter the market.

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Declarations

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Os benefícios de um sistema de dispensa em unidose e o contributo dos farmacêuticos açorianos no combate aos problemas socioeconómicos gerados pelas sobras de antibióticos orais em Portugal

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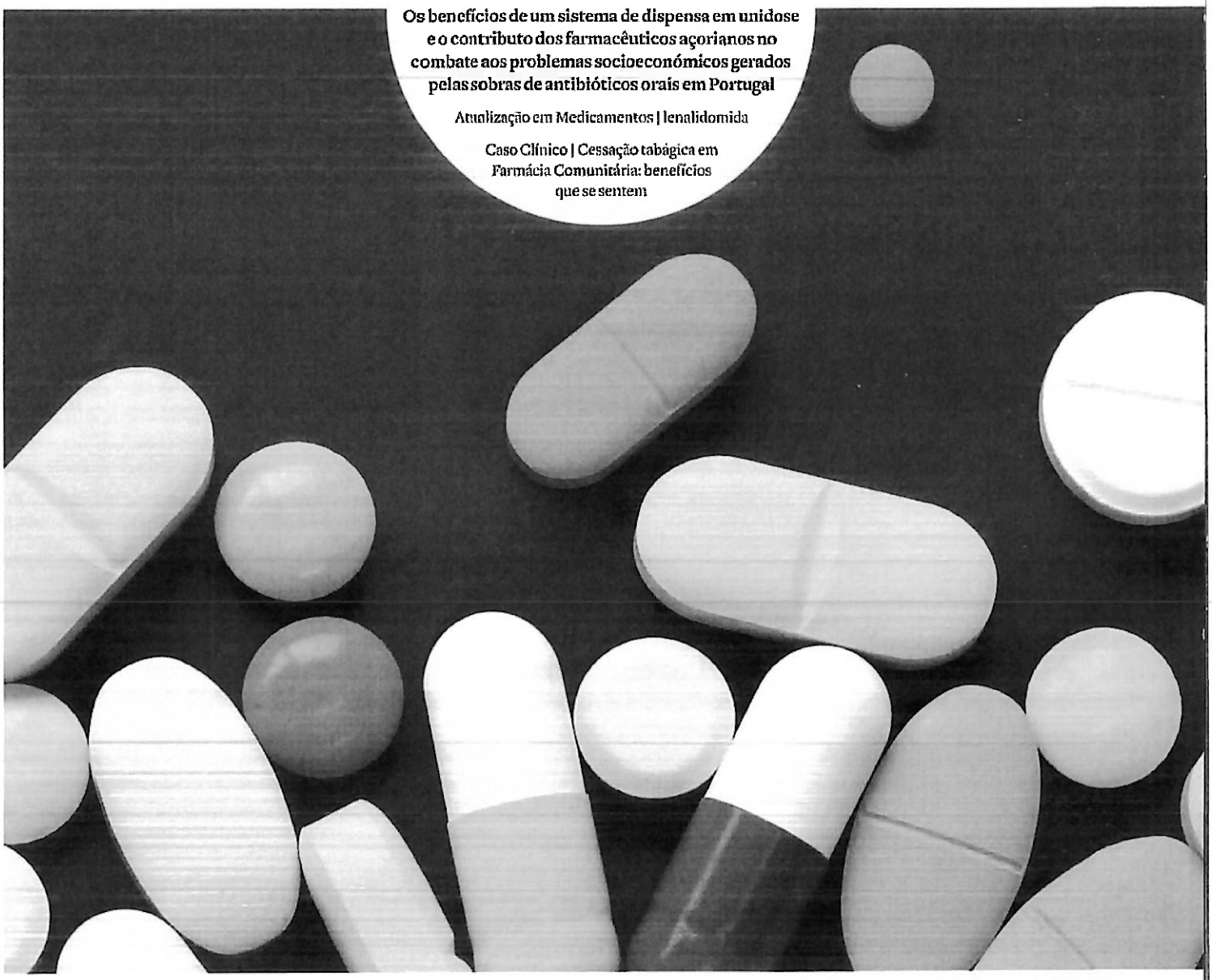

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Os benefícios de um sistema de dispensa em unidose e o contributo dos farmacêuticos açorianos no combate aos problemas socioeconómicos gerados pelas sobras de antibióticos orais em Portugal

Introdução

A resistência aos antibióticos é um dos maiores riscos à saúde humana no mundo. Em Portugal e no ano de 2016, o consumo de antibióticos atingiu 21,6 doses diárias definidas por 1000 habitantes por dia. Entre outubro de 2015 e setembro de 2016, as farmácias comunitárias portuguesas dispensaram 8,5 milhões de caixas de antibióticos (61 milhões de euros), representando um decréscimo de 4% ao período homologo de análise.

No sistema de saúde português, os antibióticos orais são dispensados nas farmácias comunitárias em caixas com quantidades pré-definidas. No entanto, a prescrição médica apresenta-se como flexível ao nível de unidades farmacêuticas (UF), existindo diferentes posologias, pelo que pode originar ineficiências no sistema de dispensa tradicional de medicamentos nas farmácias comunitárias. Verificou-se num estudo que 50% da população portuguesa entrevistada admitiu que acumulou medicamentos em casa devido ao "número excessivo de comprimidos nas caixas". De acordo com Ramalhinho et al., 18,9% dos 1192 participantes portugueses em estudo em Portugal (Algarve) declararam que usam antibióticos para automedicação, enquanto que 23% informaram que acumulavam sobras de antibióticos. Também, 14% do total de participantes afirmaram que poderiam utilizar as sobras de antibióticos quando ficassem doentes, enquanto que 25% as iriam eliminar através do lixo comum ou rede de esgotos. Apenas 16 participantes (1,3%) declararam que poderiam dar sobras de antibióticos a outras pessoas.

Como verificado anteriormente, o problema das sobras de medicamentos que são originadas em sistemas rígidos de dispensa pode ser minimizado através de um sistema que permita a dispensa de UF de acordo com a posologia prescrita pelo médico. Dado que este sistema mais eficiente não se encontra implementado nas farmácias

comunitárias e de forma a se encontrar uma solução para o problema das sobras, o Hospital do Divino Espírito Santo de Ponta Delgada (HDES) é único hospital da ilha de São Miguel (Açores), abriu uma Unidade de Venda ao Pública (UVP) que permite a venda de medicamentos através de um sistema de dispensa de medicamentos em unidose, sendo apenas acessível a utentes do provenientes do HDES com alta hospitalar ou que foram atendidos nas urgências deste mesmo hospital. Assim os utentes têm à disposição um novo sistema de dispensa de medicamentos que proporciona a dispensa de um número exato de UF prescritas pelo médico, originando poupanças socioeconómicas para os utentes e sistema de saúde.

Metodologia

Este estudo retrospetivo e hospitalar foi desenvolvido entre 1 de julho de 2016 e 30 de junho de 2017 no HDES. Na HDES-UVP, as prescrições foram analisadas e validadas por um farmacêutico ou técnico de farmácia. Recolhida e analisada toda a informação necessária, foi efetuada uma extrapolação a nível nacional, utilizando como referência dados do INE, I.P.

Resultados

Durante o período em análise, a UVP esteve aberta durante 294 dias e registou um total de 16.791 transações de todo o tipo de medicamentos vendidos na UVP. As prescrições validadas revelaram conter 90.984 UF de antibióticos orais sólidos. Relativamente às transações específicas associadas à dispensa de antibióticos orais, foram efetuadas cerca de 5.389 transações que correspondem a 84.908 UF e a 28.717,01€. Através da análise da dispensa destes antibióticos orais, foi possível criar um *ranking* de potencial de poupança monetária e de UF por categoria farmacoterapêutica. Assim, e recorrendo à Tabela A, verifica-se que através da análise do *ranking* de potencial de poupança global (que resulta da média entre os *rankings* referentes à análise dentro de cada categoria e entre categorias farmacoterapêuticas) que a categoria dos (1ª) anti-infeciosos e antissépticos urinários, das (2ª) aminopenicilinas e das (3ª) associações de penicilinas com inibidores das lactamases beta são as que conseguem atingir altos níveis de poupança, enquanto que a categoria das (11ª) cefalosporinas de 1ª geração, das (12ª) isoxazolilpenicilinas e dos aminoglicosídeos apresentam-se com um menor potencial de poupança.

Tabela A. Potencial de poupança por categoria farmacoterapêutica (adaptado de Costa et al. 2021).

Categoria farmacoterapêutica	Análise intra-categoria		Análise inter-categorias		Potencial de poupança global
	Potencial de poupança monetária	Potencial de poupança em UF	Potencial de poupança monetária	Potencial de poupança em UF	
Aminoglicosídeos	13	13	13	13	13
Aminopenicilinas	2	2	5	3	2
Anti-infeciosos e antissépticos urinários	1	1	2	2	1
Antituberculosos	8	9	11	11	10
Associações de penicilinas com inibidores das lactamases beta	7	7	1	1	3
Cefalosporinas de 1ª geração	11	11	10	10	11
Cefalosporinas de 2ª geração	4	4	4	6	5
Cloranfenicol e tetraciclinas	6	6	9	9	8
Isoxazolilpenicilinas	12	12	12	12	12
Macrólidos	10	10	7	8	9
Outros antibacterianos	3	3	6	5	4
Quinolonas	9	8	3	4	6
Sulfonamidas e suas associações	5	5	8	7	7

A escala de potencial de poupança varia entre 1 e 13 (1= maior potencial de poupança; 13= menor potencial de poupança)

De forma a estimar os possíveis efeitos do sistema de dispensa em unidose do HDES na dispensa de antibióticos orais ao nível do sistema de saúde português, foi efetuada uma extrapolação recorrendo à informação disponibilizada pelo INE I.P.

Recorrendo à Tabela B verificou-se que Ponta Delgada, que representa a ilha São Miguel e o HDES, obteve na extrapolação uma poupança de 7.978,25€ e de 30.427 UF, que resultaram de 4.889 intervenções farmacêuticas.

Tabela B. Extrapolação de resultados: poupança monetária, poupança em UF e intervenções farmacêuticas (adaptado de Costa et al. 2021).

Descrição da amostra	Poupança monetária (€)		Poupança em UF (n)		Intervenções farmacêuticas (n)
(Localização Geográfica)	Internamentos	Urgências	Internamentos	Urgências	
HDES-UVP	478,47	554,52	1.553	2.386	663
Ponta Delgada	3.595,93	4.282,32	11.996	18.431	4.889
Açores	5.570,30	7.350,74	18.080	27.778	8.251
Madeira	4.132,81	4.642,47	13.414	20.609	5.323
Portugal continental	177.885,21	234.504,54	577.373	887.065	263.259
Todo o território português	187.588,30	246.477,74	608.866	935.451	276.883
Todo o território português (Global)	434.085,85		1.544.317		276.883

Um sistema de dispensa em unidose de medicamentos aplicado à dispensa de antibióticos orais permite obter benefícios socioeconómicos para os sistemas de saúde

Se a extrapolação para todo o território português refletisse as características da amostra da HDES-UVP, obteríamos cerca de 276.833 intervenções farmacêuticas que resultaram numa poupança de 1.544.317 UF, correspondendo a 434.085,85€.

Considerações finais

As sobras de antibióticos são um problema de saúde pública uma vez que afetam a saúde humana e promovem a resistência aos antibióticos. Um sistema de dispensa em unidose de medicamentos aplicado à dispensa de antibióticos orais permite obter benefícios socioeconómicos para os sistemas de saúde. Assim, o tamanho das caixas de antibióticos orais deve ser reanalisado pela indústria farmacêutica, de forma a corresponder com as práticas de prescrição habituais dos médicos e os governos devem implementar regras e legislação específica direcionada ao circuito de dispensa de antibióticos nas farmácias comunitárias e hospitais. ❚

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