

## Audit of Antibiotic Dispensing in Community Pharmacy (Happy Patient Project)

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### KEYWORDS

Antibacterial Agents; Antimicrobial Stewardship; Community Pharmacy Services; Drug Resistance; Medical Audit; Pharmacies

### ABBREVIATIONS

AMR: Antimicrobial Resistance  
APO: Audit Project Odense  
CP: Community Pharmacy  
CPS: Community Pharmacy Services  
DPR: Drug-Related Problems  
IDIAPJGol: Foundation University Institute for Primary Health Care Research Jordi Gol i Gurina  
NOM: Negative Outcomes Related to Medicines  
PhCF-CP: Pharmaceutical Care Forum in Community Pharmacy  
RECM: Drug Research Ethics Committee  
SEFAC: Spanish Society of Clinical, Family and Community Pharmacy  
semFYC: Spanish Society of Family and Community Medicine  
WHO: World Health Organization

### ABSTRACT

**Background:** Dispensing and prescribing antibiotics is inappropriate in many of the countries in the European Union, including Spain, and a threat to the population's health. To tackle the growth of antimicrobial resistance, the Happy Patient project was set up under the sponsorship of the European Commission.

**Aim:** To ascertain the characteristics of dispensing antibiotic therapy in Spanish community pharmacies.

To compare the variability between different Spanish community pharmacies.

**Methods:** The Audit Project Odense® methodology was used to find out how antibiotics were dispensed in community pharmacies. Pharmacists taking part were asked to record for five consecutive days between the months of February and April 2022 the actions performed during the dispensing of oral antibiotics for human use and for the treatment of acute infections.

**Results:** A total population of 573 patients (59.9% female) of all age groups were interviewed. The patients were 83.6% aware of the purpose for which the antibiotic was prescribed and the most requested antibiotic was amoxicillin followed by amoxicillin with clavulanic acid.

In 15% of dispensations, a triple safety check was completed: interactions, contraindications and allergies. The pharmacist rarely contacted the prescriber but when she did, the prescriber altered the prescription.

In 62.3% of cases, information about the duration of treatment was provided and amoxicillin with and without clavulanic acid was the antibiotic dispensed for which most warnings about side effects were issued. In 24.6% of dispensations there was no advice given at all. In 81.7% the pharmacist agreed with the prescribed treatment.

**Conclusions:** This audit can be a starting point to improve clinical practice and reduce antibiotic resistance. It highlights the need for safety checks in regard to the use of antimicrobials and suggests verifying dispensing to correct errors that may jeopardize the safety and effectiveness of antimicrobial therapy.

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## INTRODUCTION

The discovery of penicillin by Alexander Fleming at the start of the 20th century (1) led to the development of antibiotics. This transformed pharmacotherapy and saves many lives. However, the use of antibiotics has entailed the phenomenon of antibiotic microbial resistance (2).

The World Health Organization (WHO) as part of the antibiotics resistance containment strategy spurs on community pharmacists to notify patients of the correct way to use antibiotherapy and the importance of completing the treatments prescribed (3). When patients visit the CP to pick up medication prescribed by the doctor, the community pharmacist, by means of community pharmacy services (CPS) for dispensing, should perform the process according to a protocol.

The Pharmaceutical Care Forum in Community Pharmacy defines the dispensing of medicines and medical devices as "the CPS aimed to guarantee that the recipients of medicines and medical devices, after an initial evaluation, receive and use the medicines in accordance with their medical needs, at the doses prescribed according to their individual requirements, for the right amount of time, with the information to correctly process their use and in accordance with prevailing legislation" (4).

The dispensing and prescription of antibiotics may not be the most suitable in many European Union countries including Spain (5). This threatens the health of the population. So much so that incorrect use of antibiotics leads to death associated with more than 30,000 people a year in Europe, a figure that rises associated with the number of antibiotic-resistant infections from 2016 to 2020.

The Happy Patient project ([www.happypatient.eu](http://www.happypatient.eu)) (7) aims to reduce antibiotic resistance especially for the pathologies most commonly acquired in the community: infections of the respiratory, urinary and dental tract.

The actions performed in the Community Pharmacy are based on current scientific evidence and centred on the patient. This kind of strategy entails all the usual health professionals within the community setting. "Happy Patient" includes healthcare professionals accessible to patients in accident and emergency, health centres, socio-health centres, dental clinics and community pharmacies. The project is carried out in four countries with a high prescription of broad spectrum antibiotics (France, Poland, Greece and Spain) and a low prescription country (Lithuania) (8).

"Happy Patient" (9) is the acronym for "Health Alliance for Prudent Prescription and Yield of Antibiotics in a Patient-centred Perspective". This is a consortium of research bodies, universities, scientific societies, foundations and a governmental entity (see Appendix 1). The Spanish Society for Clinical, Family and Community Pharmacy (SEFAC)

takes part in this project as a scientific society representing Spanish community pharmacists.

The community pharmacy project (CP) consists of an initial audit in which it is sought to tackle the intervention in regard to antibiotics from the point of view of the pharmacist. The aim is to analyze the characteristics and possible areas of improvement. Subsequently, training and specific materials are received targeted both at community pharmacists and patients to encourage a rational use of antibiotics. Consequently, the quality of the pharmaceutical intervention during community pharmacy services (CPS) for dispensing this group of medicines.

A second audit will be performed to ascertain the impact of the training received (see Appendix 2) and to evaluate whether the intervention performed by community pharmacists taking part in the project has progressed.

This paper briefly reports the global results of the initial audit of the project "Happy Patient" in CP in Spain. Its aims were:

- To ascertain the antibiotherapy dispensing characteristics in Spanish community pharmacies.
- To compare the variability among the different Spanish community pharmacies whilst antibiotics are dispensed.

## MATERIAL AND METHODS

To see the situation of different Spanish community pharmacies for dispensing antibiotics the "Audit Project Odense" (APO) method was used (10). Pharmacies taking part were asked to fill in a registration form for each orally administered antibiotic prescription received for at least five days. All pharmacies taking part had to record at least 25 antibiotic dispensing records (Figure 1). All pharmacists taking part, in addition to other health professionals (pharmacy technicians, assistants) who might take part in the dispensing procedure, also had an instructions sheet available to correctly fill out these registration forms (Figure 2).


The study was performed in Spain in 20 CP between February and April 2022. Only oral antibiotics for human use and treatment of acute infections were included. No antibiotics for veterinary or prophylactic use were recorded.

The registration sheets filled in were scanned and sent to the principal investigators of the "Happy Patient" project who statistically processed the data. Computerized data processing was performed with the programme Microsoft Excel® version 2021.

The study was approved by IDIAPJGol Research Ethics Committee for Medicines (RECM) with code 21/120-P.

### HAPPY PATIENT-1: Acute infections in community pharmacies

Dispensing of any antibiotic prescribed orally by any doctor picked up in the pharmacy



Age (years)		Sex		Training	Antibiotics (only oral)	Location of the infection	Duration of treatment	Safety	Recommendation	Opinion	Contact with the prescriber
		F	M								
				At least 1X	Only 1X	Only 1X		At least 1X	At least 1X	Only 1X	Only 1X
				Pharmaceutical							
				Non-pharmaceutical							
				Penicillin V or pivmecillinam							
				Amoxicillin							
				Amoxicillin + clavulanic acid							
				Phosphomycin							
				Nitrofurantoin							
				Trimethoprim ± sulfondamide							
				Macrolides or clindamycin							
				Tetracyclins							
				Cephalosporins							
				Quinolones							
				Metronidazol							
				Other antibiotics							
				Known							
				Unknown							
						Number of days 999=unknown					
								Drug interactions verified			
								Contraindications verified			
								Allergies verified			
								None of the above verified			
								Discuss treatment duration			
								Discuss treatment dose			
								Notify the risk of antimicrobial resistance			
								Take just before going to bed			
								Do not take with alcohol			
								Do not take with dairy products			
								Take whilst standing/seated			
								Be careful with sun or ultraviolet light			
								Information on adverse effects			
								Request medical assistance if symptoms worsen			
								Return the excess medication			
								No recommendation issued			
								I agree with the treatment			
								I don't agree with the treatment			
								Insufficient information to say			
								Yes, switch in prescription			
								Yes, no switch in prescription			
								No contact with the prescriber			

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Figure 1 Antibiotic prescriptions record sheet



## 1. 2022 record

### Instructions for pharmacists to use the HAPPY PATIENT record.

Please record at least 5 days but continue up to 25 records if necessary for any oral antibiotic dispensed to treat acute infections

Antibiotics used as prophylaxis and for veterinary use are excluded from this study.

Fill in one line each time an antibiotic is dispensed. If a patient received multiple antibiotics fill in each antibiotic on one line. We recommend using one registration sheet a day to record immediately after each consultation.

<b>Age</b>	Specify age in years. In case of a child under one year specify 0
<b>Sex</b>	Specify woman (W) or man (M)
<b>Training</b>	<b>At least 1 tick</b> Specify whether the person dispensing the antibiotic is a pharmacist or another staff member (e.g. pharmacist technician). If both are involved please mark both.
<b>Antibiotics (only oral)</b>	<b>Only 1 tick</b> Specify the group of antibiotics dispensed. If necessary please use the list provided to determine the group to which the prescribed antibiotic belongs. If an antibiotic is not on the list, please mark "others". Do not use this option for other drugs that are not antibiotics. If a patient receives multiple antibiotics please use one line for each antibiotic.
<b>Location of the infection</b>	<b>Only 1 tick</b> Please specify whether the location of the infection is known during dispensing.
<b>Duration of the treatment</b>	Specify the duration of the treatment prescribed in numbers (e.g. how many days the patient should take the antibiotic if the whole course is taken as prescribed). Specify 999 if the treatment duration is not specified in the prescription. Please remember not to record the use of prophylactic antibiotics.
<b>Safety</b>	<b>At least 1 tick</b> Specify which verifications were performed during the dispensing. Pharmacological interactions include all interactions with the rest of the medicines used by the patient. Contraindications include all patient situations, characteristics or diseases. Allergies include all allergies to the antibiotic prescribed and related crossed allergies. If multiple verifications are made, please specify all those applicable.
<b>Recommendation</b>	<b>At least 1 tick</b> Tick the boxes that specify recommendations given to the patient during the dispensing. This does not include the recommendations given to the patient by the prescriber. You may tick different answers. Discussion of the duration of the treatment might include encouraging the patient to take the entire prescription and/or explaining the dose regimens.
<b>Opinion</b>	<b>Only 1 tick</b> Specify whether you agree with the antibiotic prescribed in each specific situation. Only include disagreements with a clinical rationale (e.g. unnecessary antibiotic, incorrect choice of antibiotic, incorrect dose/duration). You should not include disagreements for administrative reasons (e.g. lack of patient/prescriber information).
<b>Contact with the prescriber</b>	<b>Only 1 tick</b> Please specify whether there has been contact between the pharmacy and prescriber e.g. specify "no contact with prescriber" if there not been no contact between pharmacy and prescriber. If there has been contact with the prescriber please specify whether or not this entailed any clinical modification (e.g. switch in dose/antibiotic) to the prescription.

**Figure 2** Instructions to correctly fill in the antibiotic prescriptions record sheet

## RESULTS

A total of 573 antibiotic prescription users were interviewed. The estimated time to fill in the information for each patient was under one minute.

Filling in the registration sheets among Spanish CP taking part was highly variable (14 to 53 records, with a median of 28 records). A total of 59.9% of users (n=343) were women mainly belonging to the age group 40 to 49; 12.6% (n=72) of total users in the age group 0 to 19. The predominant user in this group was a man. A total of 78.4% (n=449) of records were filled in by pharmacists. **Figure 3** reports the kinds of antibiotics prescribed. A total of 83.6% (n=479) of users knew about the kind of infection for which they had been prescribed an antibiotic. The most commonly prescribed antibiotic was amoxicillin (n=148), followed by amoxicillin with clavulanic acid (n=129) and macrolides or clindamycin (n=86).

To avoid possible negative outcomes associated with medicines (NOM), safety verifications on using prescribed medicines prior to dispensing, were 30.2% (n=173), 23.7% (n=136) and 48.5% (n=278) drug interactions, contraindications and allergies, respectively. No verification was made in 39.1% (n=224) of cases of dispensing.

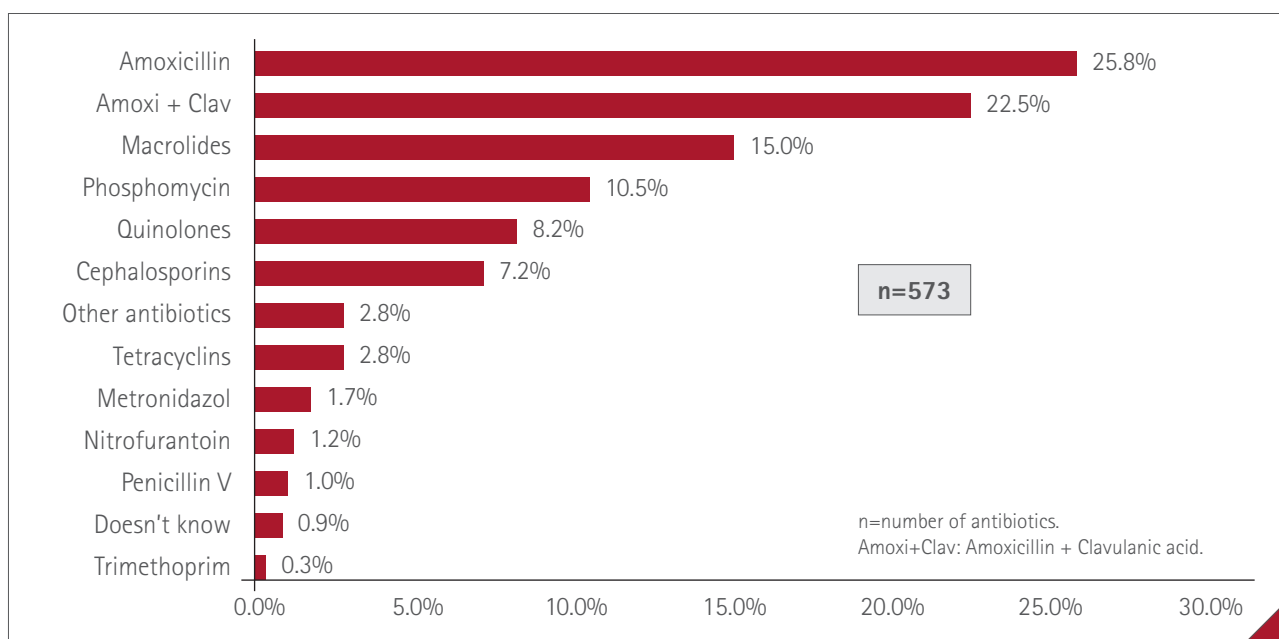
**Table 1** reports the personalized information for the medicine provided to users in regard to the use of prescribed antibiotics.

The pharmacist and technician agreed in 80.1% (n=459) of cases with the treatment prescribed by the doctor. However, not having sufficient information to decide was manifested in 17.6% of total cases and the prescriber was only contacted to request clarifications in four cases of dispensing (0.7%).

In regard to the personalized information for the medicine supplied to patients by pharmacies, 30% (n=6) of the 20 pharmacies taking part offered personalized information for the medicine about how long treatment lasts in at least nine out of every ten cases of dispensing. A total of 25% (n=5) of CP notified at least one in two times about the risk of antimicrobial resistance, whilst in 30% of CP (n=6) this warning did not occur under any circumstances.

**Table 1** Personalized medicine information given to users

Personalized information for the medicine	Percentage % (number of prescriptions n)
Duration of the treatment	62.3% (357)
Treatment dose	47.8% (274)
Information on adverse effects	39.4% (226)
Notify the risk of antimicrobial resistance	25.8% (148)
Not consume alcohol	10.6% (61)
Request medical assistance if symptoms worsen	9.8% (56)
Return excess medication	5.4% (31)
Take medicine just before going to bed	4.9% (28)
Do not take with dairy products	2.1% (12)
Beware of the sun or ultraviolet light	1.6% (9)
Take whilst standing/seated	1.6% (9)
No recommendation issued	14.0% (80)



**Figure 3** Types of antibiotics recorded

A total of 20% (n=4) of CP notified adverse effects in over 70% of the dispensing performed and in 95% (n=19) of pharmacies at least one safety verification was made.

## DISCUSSION

To reduce antibiotic resistance, it may be suitable to ascertain the quality of dispensing in the CP. The purpose is to guarantee the efficacy and safety of the antimicrobial treatments prescribed. Obtaining a starting point such as the "Happy Patient" Audit is essential to help optimize the use of antibiotics, because analysis of the data obtained would enable making improvements and ensuring correct clinical practice, as has been carried out in other countries (11,12).

Although many pharmacists are aware of antibiotic resistance and agree that incorrect use is one of the main reasons for resistance, antibiotics are not correctly dispensed in all cases (13). They are sometimes dispensed without a medical prescription both in Spain (14) and in our close setting (15,16) or in the rest of Europe (17).

Antibiotic dispensing during the "Happy Patient" audit in Spanish CP was mainly to women (59.9%). This data is in accordance with the results of the systematic review by Schröder et al. in 2016. This concludes that more antibiotics were dispensed to women (18), which could be accounted for by more visits by women to health centres. We must also highlight that, during the "Happy Patient" audit and at earlier ages (0–10 years), males are prescribed more antibiotics than women; and that similar values are revealed in the studies published using meta-analysis techniques.

In the study by Bianco et al in 2021 (16) performed on 415 community pharmacists in Italy, 95.5%, 66.2% and 55.0% of pharmacists ask about allergies to antibiotics, notify patients about adverse effects and inform about the duration of the treatment, respectively. If we compare this to our study in regard to safety warnings we see that recommendations on allergies to antibiotics are almost half in our study (95.5% vs 48.5%), approximately 20% less in terms of warning about adverse effects (66.2% vs 39.4%); whilst there is slightly more information in our study (62.3% vs 55%) about the duration of treatment.

One of the possible roles of the community pharmacist in managing antibiotherapy, according to Liaskou et al. in 2018 (19), may be health education in patients. Despite this our results in the medicine's personalized information to patients reveal low percentages of information on bacterial resistance (25.8%); return of excess medicine (5.4%); what to do if symptoms worsen (9.8%) and even in 14% of dispensing no personalized information on the medicine was issued. The latest Eurobarometer results (17) published by the European Commission, suggest that 85% of Spaniards surveyed believe that unnecessary use of antibiotics renders

them ineffective, which could account for this little information on bacterial resistance. It is also true that those who believe that antibiotics are effective to cure colds (36%) and those who do not know whether or not they are effective for this pathology (9%) include almost half of those surveyed; whereby patient health education over a rational use of antibiotics is necessary, especially for common pathologies such as the common cold or symptoms such as a cough, which do not usually require antibiotics to be cured.

One of the measures generally recommended to prevent resistance is reducing the prescription of broad spectrum antibiotics (20). However, we observe that in our study only 16.1% of dispensing is broad spectrum antibiotics (penicillin V and macrolides). These data may help, together with those obtained by prescribers, to improve the quality of prescription of antimicrobials, as recommended by the European Union (20).

After the analysis of the audit, a subsequent educational intervention with the pharmacist might improve clinical practice and rational use of antibiotics, as has occurred in successful interventions focused on the community pharmacist in arterial hypertension, diabetes or dyslipidaemia (21). Furthermore, when a multidisciplinary approach is applied to management of antibiotics a significant reduction in unnecessary consumption is revealed (22). If the community pharmacist performs tests such as streptococcal A in upper respiratory tract (23) or lower respiratory tract infections such as C reactive protein (24), may also mean a fall in unnecessary prescription of antibiotics.

However, an intervention by the pharmacist on the rational use of the medicine may lead to dissatisfaction in patients; in thinking that if their pathology actually requires an antibiotic (positive test) it is a waste of time having to go to the doctor to get a prescription from her (25).

The interventions a posteriori, have revealed, in different studies, the increased quality of dispensing, which improves patient safety and information on necessary aspects of pharmacotherapy (26–28). Moreover, it is related to a better adherence to antibiotics (29,30), improved perception of the information received by the patient and an increased knowledge on antibiotic resistance (29,31,32). These educational interventions may be: follow up and adherence to pharmacotherapeutic guidelines, tackling infections, training on requests for antibiotics in the CP without a prescription and good dispensing practices, and healthcare education for patients (33).

However, in the study by Saleh et al. in 2021 (34), after an educational intervention, 19% of community pharmacists still thought they should use broad spectrum antibiotics to try and reduce resistance or 18% thought that the most expensive antibiotic was related to better efficacy and lower resistance.

Beaucage et al. in 2006 (35) compared the effect of a phone call from the community pharmacist three days after routine dispensing with no phone call. In a subsequent

contact after completing the treatment in the control group (without a call) a lower number of NOM were identified, mainly adverse reactions.

A total of 80.1% agreed with the antibiotic prescribed by the doctor and on very few occasions, was it deemed that based on its specifications the treatment was not the most suitable (0.3%). Bearing in mind that an incorrect diagnosis is related to antibiotic resistance (36), there was a critical lack of adapting pharmacotherapy to the patient's health problem and a minimal communication among professionals. However, it must be highlighted that the four times the pharmacist contacted the doctor, the latter was receptive to the switch in prescription. The pharmacist should be more proactive in his actions, because being a specialist in the medicine he could train other health professionals in the pharmacology of antibiotics and collaborate on the correct choice of antibiotherapy (19,37); as the levels of antibiotic prescription vary locally, according to the individual practice of doctors or antibiotic class prescribed (38).

However, in 101 (17.1%) cases of dispensing, the pharmacist stated she did not have sufficient information to deem whether this antibiotherapy prescription was the most suitable. In these cases, without the necessary information, it is impossible for the community pharmacist to use the antibiotic rationally. This therefore facilitates adherence to clinical practice guidelines (37).

Moreover, despite the low frequency of contact with the prescriber (0.7%) in our study, all health professionals, the administration and patients should work together to carry out strategies with the aim of using antibiotics rationally; given that the multidisciplinary work on antibiotic resistance has proven its benefits in different studies (39–41).

### Study weaknesses

The study was performed over a short timeframe, with a limited number of records and in only 20 community pharmacies. Moreover, the interventions were recorded by the members of the community pharmacies themselves. This may lead to bias in the results.

## CONCLUSIONS

This audit enables ascertaining the routine practice of CP during antibiotic dispensing. It may also serve as a starting point to improve clinical practice, which improves the information to users and therapeutic adherence. This in turn would doubtless lead to a reduction in antibiotic resistance.

An intervention in antibiotic dispensing is needed in terms of safety verifications (interactions, allergies and contraindications), personalized information on the medicine (how long treatment lasts, dose, correct administration, adverse effects) and healthcare education (antibiotic resistance, recycling of medicines).

Subsequently, the variation in dispensing in each CP should be verified to correct possible deviations that may endanger the safety and efficacy of antibiotherapy.

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## Appendix 1. Happy Patient Consortium.

The Catalan Institute of Health (ICS), the University of Copenhagen, the Odense General Practice Research Unit, the Norwegian Research Center (NORCE), the University of Groningen, the Capital Region of Denmark, the University of Las Palmas of Gran Canaria, the University Hospital of Nice, "Mano seimos gydytojas" (My family doctor), the Faculty of Medicine of Lodz, the University of Crete, the Spanish Society of Family and Community Medicine (SEMFYC), the European Association of Clinical Pharmacology, the Rennes University Hospital Center, the International University of Catalonia, the Jordi Gol i Gurina University Institute for Research in Primary Health Care Foundation (IDIAPJGol) and the Canarian Scientific and Technological Park Foundation (University of Las Palmas de Gran Canaria).

◀ RETURN

## Appendix 2. Training sessions.

After the audit, a 5-hour multifaceted intervention will be carried out in which there will be individual feedback on the results obtained, feedback on the results at the national level, and a workshop to exchange opinions, establishing objectives and strategies to improve the quality of antibiotic dispensing and infection management.

Additionally, the appropriate use of antibiotics for the management of common community infections, the natural course, and the management of community-acquired infections will be reviewed.

Communication skills will be worked on to use during consultation with patients with infections in the community pharmacy; and communication tools specifically designed to engage with patients regarding community acquired infections and antibiotic use will be provided.

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