The Sale of Antibiotics without Prescription in Pharmacies in Catalonia, Spain

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(See the editorial commentary by Powers on pages 1350–3)

Background. Current regulations in Spain state that antibiotics cannot be sold without a medical prescription. The objective of this study was to quantify the percentage of pharmacies selling antibiotics without an official medical prescription in Catalonia, Spain, by the simulation of 3 different clinical cases presented by actors.

Methods. A prospective study was performed from January through May 2008. Three different cases were presented at pharmacies: sore throat, acute bronchitis, and a urinary tract infection. Three levels of demand were used to convince the pharmacists to sell an antibiotic.

Results. A total of 197 pharmacies were visited. Antibiotics were obtained from 55 (79.7%) of 69 pharmacies when a urinary tract infection was simulated, 24 (34.8%) of 69 pharmacies when a sore throat was simulated, and 10 (16.9%) of 59 pharmacies when acute bronchitis was simulated (P<.001). Among the pharmacies that sold antibiotics, the pharmacists provided an explanation as to the number of times per day the drug should be taken in 84.3%, explained the duration of treatment in 68.7%, and inquired about allergies prior to the sale of the antibiotic in only 16.9%. Of the 108 pharmacies that did not sell the antibiotics, only 57 (52.8%) explained that they could not be given over the counter for health care reasons or to avoid antibiotic resistance.

Conclusions. These results demonstrate that, although illegal, the sale of antibiotics without a prescription continues in Spain. This should be taken into account by countries that are currently considering the possibility of making some antibiotics available over the counter.

The inappropriate use of antibiotics for the treatment of patients with common infections is a worldwide problem, with implications for increasing treatment costs, adverse events, and selection of antibiotic-resistant germs [1]. Outpatient use of antibiotics accounts for more than two-thirds of antibiotic sales in the world. Self-medication with antibiotics is a common practice in most countries and is one of the reasons for the increase in the antibiotic resistance of the microorganisms in these areas. Moreover, in some countries, it is possible to buy antibiotics in community pharmacies without a prescription signed by a physician. This has been a very common practice in Spain, and it is believed that, at present, 30% of the antibiotics consumed by the population have not been prescribed by a physician [2].

At the end of 2006, the Ministry of Health in Spain launched 2 campaigns to make the general population and health care professionals generally aware of the rational use of antibiotics. One campaign was entitled “Responsible use of antibiotics. Use them well today and they will protect us tomorrow” and continued until 2007 [3]; the other campaign used messages such as “Only take drugs prescribed by the physician and at the doses indicated until finalizing the treatment” or “Do not ask for antibiotics in the pharmacy except if indicated by your physician” [4]. In addition, current regulations state that antibiotics cannot be sold without a medical prescription and should not, in any case, be considered to be over-the-counter medications. Thus, we designed this study to quantify sales of antibiotics without an official prescription in pharmacies in Catalonia, to learn which antibiotics are sold without prescription, and to describe the degree of difficulty for obtaining antibiotics without a prescription.
Table 1. Sale of antibiotics according to the clinical case and statement made to obtain the drug.

<table>
<thead>
<tr>
<th>Result and level of demand (statement)</th>
<th>Urinary tract infection (n = 69)</th>
<th>Sore throat (n = 69)</th>
<th>Acute bronchitis (n = 59)</th>
<th>Total (n = 197)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotic obtained</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (Can you give me something to alleviate the symptoms of the infection?)</td>
<td>52 (75.4)</td>
<td>12 (17.4)</td>
<td>1 (1.7)</td>
<td>65 (33.0)</td>
</tr>
<tr>
<td>2 (Can’t you give me something stronger?)</td>
<td>2 (2.9)</td>
<td>10 (14.5)</td>
<td>5 (8.5)</td>
<td>17 (8.6)</td>
</tr>
<tr>
<td>3 (I would like an antibiotic.)</td>
<td>1 (1.4)</td>
<td>2 (2.9)</td>
<td>4 (6.8)</td>
<td>7 (3.6)</td>
</tr>
<tr>
<td>All</td>
<td>55 (79.7)</td>
<td>24 (34.8)</td>
<td>10 (16.9)</td>
<td>89 (45.2)</td>
</tr>
<tr>
<td>Antibiotic not obtained</td>
<td>14 (20.3)</td>
<td>45 (65.2)</td>
<td>49 (83.1)</td>
<td>108 (54.8)</td>
</tr>
</tbody>
</table>

METHODS

A prospective study was carried out from January through May 2008 throughout Catalonia. Two actors visited a sample of pharmacies among the 2959 community pharmacies existing in Catalonia in 2007 [5]. A randomized sample of 197 pharmacies from 4 provinces was stratified by urban and rural areas and by richer or poorer socioeconomic zones. Three different clinical cases were presented; each case type was always presented by the same actor. The actors rehearsed with the aid of physicians to obtain standardization of the simulation of the diseases. In all cases, the actors who were simulating patients were very polite and entered the pharmacies stating that they were not from the neighborhood or city, that they were commercial representatives, and that they were passing through. Three cases were presented: (1) sore throat, simulated by an actor during the first months of the study; (2) acute bronchitis, simulated by the same actor who presented with the sore throat, after the previous case was finalized to avoid overlap; and (3) an uncomplicated urinary tract infection, simulated by an actress. In the first case, the patient had had a sore throat for 24 h, with difficulty in swallowing and the sensation of a slight fever. In addition, the patient later added that he was congested and had a cough. In the case of acute bronchitis, the patient presented with a sore throat, a bad cough, the sensation of a slight fever, and yellowish mucus. In the case of an uncomplicated urinary tract infection, the patient explained to the pharmacist that she had discomfort on urination with a burning sensation and the need to urinate more frequently, similar to what she had experienced on other occasions.

Three levels of demand used to obtain the antibiotic were presented in each of the 3 cases. Initially, the pharmacist was asked if something could be given to alleviate the symptoms of the infection (first level of demand). If the antibiotic was not given, the actor used the second level of demand: “This medication is not very strong, can’t you give me something stronger?” If the pharmacist still did not provide the antibiotic, the actor openly stated, “I would like an antibiotic,” which was considered the third grade of demand.

If the pharmacist refused to sell the antibiotic, the reasons for the refusal were asked. A response was considered to be administrative if the reason given only referred to the regulations or law (i.e., the antibiotic cannot be sold without a prescription). A response was considered to be health related if the pharmacist expressed concern that it was not good for the patient’s health to sell them this medication, that antibiotics cannot be given for viral infections, or that selling an antibiotic in this case could lead to the spread of resistance.

We performed descriptive statistical analyses of the results; we used χ² tests to compare qualitative variables and the Student-Fisher’s t test to compare 2 mean values. Differences were considered significant if P < .05.

RESULTS

Urinary tract infection. Antibiotics were sold without a prescription in 55 (79.7%) of 69 different pharmacies in which a urinary tract infection was presented; this was the highest percentage of sales among the 3 scenarios analyzed in this study (P < .001). In 52 instances, the antibiotic was sold under the first level of demand (table 1). In addition, in 2 pharmacies that did not sell the antibiotic, the actress was told that if she had known the name of the antibiotic that she had taken on previous occasions to cure the urine infection, they would have sold it to her. Among the 55 pharmacies that sold an antibiotic, the antibiotics most frequently sold were norfloxacin (22 pharmacies; 40.0%), fosfomycin trometamol (20 pharmacies; 36.4%), and pipemidic acid (8 pharmacies; 14.5%). In 5 pharmacies that did not sell an antibiotic, a preparation with cranberries was recommended for treatment. In another pharmacy, the pharmacist sold an antibiotic and a preparation including vaginal clotrimazole (an antifungal medication) tablets.

Sore throat. Pharmacists were reluctant to sell antibiotics when presented with the case of a sore throat, and antibiotics were obtained in only 24 (34.8%) of 69 instances. The level of demand needed to obtain an antibiotic was also higher in this case, because antibiotics were only obtained in 12 pharmacies with use of the first level of demand (table 1). Among the 24
pharmacies that sold an antibiotic for the treatment of sore throat, the antibiotic most frequently sold was amoxicillin (21 pharmacies; 87.5%), followed by amoxicillin and clavulanic acid (2 pharmacies; 8.3%) and azithromycin in 1 other. Of the 45 pharmacies that refused to sell an antibiotic, the most frequently sold drug was ibuprofen (26 pharmacies; 57.8%), followed by antiseptics with or without anesthetic lozenges (16 pharmacies; 35.6%).

**Acute bronchitis.** Antibiotics were obtained in 10 (16.9%) of 59 pharmacies approached regarding a case of acute bronchitis; amoxicillin was sold in all 10 instances. The antibiotic was sold in response to the first level of demand in only 1 pharmacy (table 1). Of the 49 pharmacies that did not sell an antibiotic, anticold drugs alone or in combination with cough remedies were sold in 21 (42.9%), ibuprofen was sold in 12 (24.5%), and preparations including acetaminophen were sold in 10 (20.4%).

**Pharmacies that sold antibiotics.** No differences were observed in the sales of antibiotics between rural and urban pharmacies, or between pharmacies in richer and poorer socioeconomic zones. An antibiotic was more frequently obtained from pharmacies in urban areas than in rural areas (46.5% vs. 40.9%), although the difference was not statistically significant. Male pharmacists were more prone to sell antibiotics (52.6%) than were female pharmacists (41.6%), although the difference was not statistically significant; this finding was also observed in the case of urinary tract infection. Although the difference was not statistically significant, younger pharmacists were more reluctant to sell antibiotics than were older pharmacists. Pharmacists aged >50 years sold antibiotics in 50% of the time, whereas antibiotics were only provided by 45.5% of pharmacists who were aged 30–50 years. Pharmacists who were aged <30 years were more reluctant to sell antibiotics without a prescription and only sold antibiotics in 37.8% of instances.

Of the 89 pharmacies that did sell an antibiotic overall, 74 (83.1%) explained how to take the drug; this explanation was offered most often for the case of urinary tract infection (52 [94.5%] of 55 pharmacies; \( P < 0.001 \)). The duration of treatment was only commented on by 62 (69.7%) of 89 pharmacists who sold antibiotics. It should be noted that 61 (68.5%) of the 89 pharmacists who sold an antibiotic asked about other symptoms, 15 (16.9%) asked the patient about possible drug allergies prior to the sale of the antibiotic, and only 4 (4.5%) recommended that the patient see a physician if their condition did not improve with the antibiotic provided (table 2). In the case of urinary tract infection, which was portrayed by a 33-year-old actress, the possibility of pregnancy was only asked about by 2 (3.6%) of 55 pharmacists who sold her an antibiotic.

**Pharmacies that did not sell antibiotics.** Of the 108 pharmacies that did not sell antibiotics, the pharmacist cited purely administrative reasons for not selling the drug in 51 (47.2%), referring to the prohibition of selling an antibiotic without an official prescription signed by a physician. In 26 (24.1%) of these pharmacies, only a reasoned response related to health or antibiotic resistance was provided. In the remaining 31 pharmacies (28.7%), both types of response were given. Some of the pharmacists’ comments complemented these data. In 3 pharmacies, the pharmacists openly criticized the prohibition of selling an antibiotic without a prescription. Another pharmacist commented that the ibuprofen (for acute bronchitis) sold would not be effective but that nothing else could be sold. In other pharmacies, the patient was instructed to try other pharmacies if they wanted antibiotics. In 63 (58.3%) of the 108 pharmacies that did not sell an antibiotic, the pharmacist recommended that the patient visit a physician.

**DISCUSSION**

The results of this study demonstrate that antibiotics continue to be sold without a prescription in Spain, primarily for the treatment of supposed bacterial infections. There are some limitations to our study. We did not wish to distinguish whether the person who attended to the patient was a pharmacist. Both pharmacists and other employees work in pharmacies. Our
objective was to not know possible differences between the two, because we did not wish to raise suspicion; the actors attempted to approach as normal customers who may be attended to by either a pharmacist or an employee. In addition, all the reports for this study were provided by actors who are not physicians. Nonetheless, because each case was represented by an actor, no significant differences were expected in the performance in the different pharmacies visited. The actors prepared their presentations of the cases with physicians to achieve the maximum standardization for each case, and they carried out a pilot study (10 pharmacies) in which the authors of the study accompanied the actors. The representation was always the same for each case; the actors memorized prepared responses for if the pharmacist asked about aspects related to the infection that was being simulated. The actors who participated in the study have many years of experience acting as patients in tests for medical students and residents in the specialty of family medicine.

Spain is one of the European countries in which the consumption of antibiotics has been high in the past, although in recent years, a reduction has been observed in the rate of prescription of these drugs by primary care physicians [6, 7]. On the other hand, the total consumption of antibiotics has not decreased, and the sale of antibiotics without a prescription in community pharmacies is the main reason for this difference [2]. At the end of 2006 and during almost all of 2007, a massive institutional campaign was launched by the Ministry of Health to publicize the need for individuals to visit a physician in cases of infectious illness and to encourage individuals to not request antibiotics in pharmacies. This campaign was distributed through television, the radio, the press, and posters distributed in health care centers, hospitals, and pharmacies. Therefore, we performed this study at the beginning of 2008 to determine the impact of this campaign and to discern the difficulty involved in obtaining an antibiotic by going directly to the pharmacy without having previously seen a physician. We believe that the methodology of this study, using the simulation of clinical cases, is closer to the real-life scenario than are methods used in other studies, such as questionnaires, which are subject to deceptive responses. This is not the first time that actors have been used to determine the attitude of pharmacists. In 2 studies that used actors to simulate cases of rhinosinusitis, antibiotics were sold in 70% of pharmacies approached in Greece and in 58% of pharmacies approached in Brazil [8, 9]. In Brazil, antibiotics were obtained in 74% of the pharmacies after insistence. In our study, we examined possible differences in antibiotic sales among 3 common clinical cases: sore throat, acute bronchitis, and repeated urinary tract infection. The way in which the clinical cases were presented suggested the possibility of viral infection in the 2 respiratory infections (sore throat and acute bronchitis) and a probable bacterial etiology in the uncomplicated urinary tract infection. The results obtained in this study demonstrated the ease of obtaining an antibiotic for treatment of urinary tract infection but the difficulty in obtaining antibiotic for treatment of respiratory infections. This is good news, because we subjectively believed that the sale of antibiotics in the pharmacies would be quite frequent despite the government campaign.

The policy permitting the over-the-counter sale of antibiotics without a prescription exists not only in Spain but also in many other countries of the world. In Europe, this policy is common in eastern and Mediterranean countries but is rare in northern countries. In some European countries, it has been suggested that some antibiotics currently available as prescription-only medications should be converted to pharmacy medicines, and thus, they could be sold directly in the pharmacy without the need for the prescription from a primary care physician, similar to policies for antmycotic and antiherpetic drugs [10]. This may be the case for azithromycin, which can be acquired in British pharmacies without a prescription for the treatment of chlamydia infections. Similarly, trimethoprim and nitrofurantoin might soon become available over the counter in the United Kingdom. This practice is also common in the United States, mainly among some ethnic minorities [11]. One-third of Latino individuals believe that antimicrobial drugs should be available without a prescription, and many believe that antibiotics are effective against viral infections [12]. Furthermore, 19.2% have acquired antimicrobial agents in the United States without a prescription [12]. A very rapid integration has also been observed in populations that have immigrated to areas where it is easy to obtain over-the-counter antibiotics; 41% of the immigrants from Finland who lived in the south of Spain reported having purchased an antibiotic without an official prescription in a 6-month period [13]. Moreover, in the United States, an appreciable percentage of individuals buy antibiotics in neighboring countries and transport them across the border [11]. The Internet poses another problem. Patients can easily obtain antibiotics, and interestingly, antibiotic capsules and tablets (including ampicillin and tetracyclines) are readily obtainable in the United States from stores. Apart from purchase via the Internet, it is clear that some patients keep part or all of prescribed treatments for future use without a consultation and that actual and intended self-medication occurs everywhere [14–16]. The main sources of medication are pharmacies (with a prescription) and material left over from previous prescriptions [17]. On the other hand, the possibility of acquiring an antibiotic without a prescription should be considered a worldwide problem, and thus, this problem should be approached from a worldwide perspective.

The deregulation of antibacterial medications is a recurrent topic in the debate on pharmaceutical policy. In any case, any over-the-counter medication policy requires that pharmacists have a key role as health care agents. In our study, only 17%
of the pharmacists asked the patient about possible drug allergies and an even smaller percentage asked whether the patient was pregnant. We do not know whether physicians ask these questions more often than pharmacists. Similarly, the selling pharmacist must correctly explain the antibiotic schedule, clearly specifying the dosing and duration of administration, and they should also be concerned about the problem of the spread of antibiotic resistance in the community. In this study, only one-half of the pharmacists who refused to sell an antibiotic provided scientific arguments as to why they could not provide antibiotics. It is interesting that pipemidic acid, an antibiotic very infrequently used in Spain because 33% of the strains of Escherichia coli in Spain are resistant, was sold in >10% of the pharmacies [18]. These levels of resistance undoubtedly contraindicate their current empiric use. It is useless to sell ineffective or poorly effective antibiotics when the main objective of antibiotic treatment is to achieve bacterial eradication. In this respect, the study by Davis et al. [19] on the ineffectiveness of many of the available over-the-counter antibiotic creams to cure infected wounds is interesting.

Accessibility to over-the-counter antibiotics has pros and cons [20]. Patients may benefit specifically from the increase in immediacy and convenience of access to antibacterials and may thereby initiate antibiotic treatment early; there are, however, many drawbacks, with misdiagnosis being perhaps the most important. Diagnosis is often difficult in the primary care clinic, and the distinction between bacterial and viral etiology is even more complicated, especially in respiratory tract infections. Therefore, how can a patient know whether antibiotic treatment is necessary? There are other very important drawbacks, including the increased risk of adverse reactions and drug interactions, particularly in children, elderly patients, and pregnant women, as well as the potential to harm to society in general caused by decreasing susceptibility to antibacterials. Another complication that is frequently ignored in the medical literature is the pressure of the population on both pharmacists and physicians. With regard to pharmacists, this pressure is related to the selling of the antibiotic, and in the case of physicians, there is pressure to provide a prescription for the medicine to be sold, to allow for partial or total reimbursement for the cost of the antibiotic. At present, clinical problems attributable to the spread of resistance and the scarce development of new antibiotics make the rational use of antibiotics necessary in the community setting [1]. Thus, the over-the-counter sale of antibiotics should be restricted worldwide.

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