Antimicrobial use in a country with insufficient enforcement of pharmaceutical regulations: A survey of consumption and retail sales in Ulaanbaatar, Mongolia

Rie Nakajima¹, Takehito Takano², Vaanchig Urnaa³, Nyambayar Khaliun¹, Keiko Nakamura¹

¹International Health and Medicine, Graduate School of Tokyo Medical and Dental University, 1-5-45 Yushima, Bunkyo-ku Tokyo, Japan
²Health Promotion, Graduate School of Tokyo Medical and Dental University, 1-5-45 Yushima, Bunkyo-ku Tokyo, Japan

Address for Correspondence: Takehito Takano, Department of Health Promotion, Tokyo Medical and Dental University, 1-5-45 Yushima, Bunkyo-ku Tokyo, Japan. E-mail: whocc.hlth@tmd.ac.jp

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Abstract

Objective: To examine the inappropriate use of antimicrobials by investigating (1) actual utilization pattern and retail sales and (2) antimicrobial resistant information provided by health professionals in Ulaanbaatar, Mongolia.

Methods: We investigated antimicrobial use in Ulaanbaatar, Mongolia by surveying 619 consenting customers who attended 250 randomly chosen pharmacies in December 2006. Pharmacy staff were also interviewed about antimicrobials purchased. In January 2007, we surveyed 117 consenting Ulaanbaatar medical doctors from seven local hospitals about their perceptions of treatment failure due to antimicrobial resistance.

Results: Among 619 pharmacy customers, 48% of them had bought at least one type of antimicrobial medicine and, of these, 42% had a prescription to purchase antimicrobials. On average, 67% of the customers reported that a pharmacy worker had given them information regarding the dose and timing at which the medicine should be used but only 9% reported that they had been given information regarding possible adverse effects. The survey of medical doctors suggested that some antibiotics had become less effective clinically between 2001 and 2006.

Conclusion: The study shows that less than half of all customers who purchased an antibiotic at a pharmacy had a prescription. This shows that antimicrobials can be readily purchased without a prescription despite the existence of laws making such practices illegal. There is a need to establish a vigilant drug regulatory authority to promote enforcement and regulation of medicines in Mongolia. To create awareness regarding the dangers of antimicrobial resistance, educational campaigns for consumers are also necessary.

Keywords: antimicrobial utilization, antimicrobial resistance, developing country, Mongolia.

Introduction

During the past few decades, the number of antimicrobial-resistant pathogens has increased rapidly in many parts of the world¹. Of note, the rate of increase of antimicrobial-resistant pathogens in Asia is the highest in the world²-⁴. One of the major reasons for the increase in antimicrobial-resistant pathogens in many developing countries is that antimicrobials can be purchased without a prescription⁵. The World Health Organization (WHO) warns that the purchase of antimicrobials without a prescription leads to the misuse and overuse of antimicrobials, resulting in the emergence of antimicrobial-resistant pathogens⁶.

Many developing countries have a limited ability to manufacture antimicrobial medicines; therefore, they must obtain antimicrobial medicines from other countries. Numerous commercial dealers of pharmaceutical products compete with
one another to extend sales in developing countries, providing imported medicines to meet the demand for antimicrobials in these countries. However, the control and regulation measures for the sale of pharmaceuticals in developing countries are often insufficient. Mongolia is one such country where antimicrobials can be widely purchased without a prescription, despite the existence of laws prohibiting this act. Penalties imposed on offenders guilty of such acts include closure of a store where such a trade has been conducted. Despite this, the measures to control and regulate the sale and purchase of antimicrobials in Mongolia are insufficient. This is a problem that not only affects Mongolia, but also impacts many developing countries throughout the world. In this context, the objectives of the present study were to explore the antimicrobial utilization pattern and retail sales; another objective was to explore the perceptions of clinicians regarding antimicrobial resistance.

**Methods**

We conducted three surveys using structured questionnaires: one for pharmacy workers, one for pharmacy customers, and one for practicing medical doctors. The study protocol was approved by the ethical review boards of the Tokyo Medical and Dental University and the Ministry of Health, Mongolia.

**Study area**

The study was carried out in Ulaanbaatar, the capital city of Mongolia, where the general public's accessibility to antimicrobials has been rapidly increasing in recent years as a result of the rapid economic development.

Mongolia is a landlocked central Asian country, with a total area of 1.6 million square kilometers. Among the total 2.7 million populations, 32% are living in Ulaanbaatar, the capital of Mongolia. On the financial side, the Mongolian economy has experienced positive GDP growth averaging 8.7 percent from 2004 to 2006.

Mongolia's current health system has been evolving for more than 70 years and is characterized by three levels of care: primary, secondary and tertiary care. Although these health facilities still do not meet the current needs of the country, it is reported that for every 1000 Mongolians, 2.7 physicians are available. Health insurance was introduced in 1994 and it is estimated that about 78% of the population is covered. However, it is still common that patients have to pay out of pocket in private pharmacies to obtain the necessary medications.

**Subjects, sampling and questionnaire procedures**

The pharmacies surveyed in the present study (both pharmacy workers and customers) were selected from a list provided by the Mongolian Ministry of Health. A total of two hundred and fifty pharmacies were randomly selected from amongst the five hundred pharmacies registered in Ulaanbaatar. Interviewers of the pharmacy and customer survey were clinical pharmacology professionals with sufficient knowledge of antimicrobials and pharmaceutical practice. A three day training workshop was conducted to train the interviewers, providing them with knowledge and interviewing skills. Two interviewers visited each of the pharmacies and interviewed the pharmacy staff. Following individual interviews with the pharmacy workers, the study team spent one hour outside of the pharmacy and approached customers who had just left the pharmacy and asked for their cooperation in completing a short interview. A total of 619 pharmacy customers agreed to participate in the study.

The survey for practicing medical doctors was a self-administered report based on a structured questionnaire form: the reports were collected after a complete explanation of the purpose of the survey and a step-by-step explanation of the questions had been made by specially trained doctors. All queries were collected and answers and clarifications were given to the participating medical doctors before they submitted their completed questionnaire forms. The self-administered survey of the medical doctors was completed by 117 medical doctors who agreed to participate in the study. These doctors were selected from amongst 7 leading hospitals in Ulaanbaatar.

Face to face in depth interview of ten medical doctors were conducted. These doctors were randomly selected from participants of the medical doctor's survey. These doctors answered questions regarding antimicrobial therapy. The questions were also asked regarding doctors' knowledge on Centre for Disease Control guidelines.

**Questionnaire items**

The interview questionnaire for the pharmacy workers included the following items: the names of all the antimicrobial medicines sold at the pharmacy (regardless of strength), the average number of customers who bought medicine per day, and the average number of customers who bought antimicrobial medicine per day during the two week period prior to the study.

The interview questionnaire for the pharmacy customers included the following items: customer's age, sex, educational background, purchase of antimicrobial and non antimicrobial medicines, types and whether it was the oral or injectable form. The other questions were age, symptoms of the expected user of the medicine, presentation of the prescription (to purchase antimicrobial medicines), and instructions given by the pharmacy staff regarding the use of the medicines.

The self-administered questionnaire for the medical doctors asked for their professional estimates as to the current prevalence of antimicrobial resistance, their clinical experiences with antibiotics and the expected number of ineffective treatments encountered during the application of each of the antimicrobial agents.

**Period of the survey**

The pharmacy staff and customer interviews were conducted in December 2006, while the survey of medical doctors was performed in January 2007. The study was performed during...
the winter season because the prevalence of acute respiratory infection is typically high during this time and thus a large number of antimicrobials are prescribed.

Analysis

All data were entered and analyzed using SPSS software (version 14.0). The average numbers of pharmacy customers who bought specific antimicrobial medicines per fifty customers (who bought both antimicrobial and non-antimicrobial medicines) from that pharmacy were calculated for each type of antimicrobial. This indicator was used to represent the retail sales of antimicrobials.

Results

Results and knowledge from pharmacy workers reveal the types of antimicrobials which has been sold to customers at pharmacies during the two weeks prior to the study (Table 1).

Table 1. Types of antimicrobials sold to customers at community pharmacies in Ulaanbaatar, Mongolia

| Group               | Name                      |
|---------------------|---------------------------|
| Penicillins         | Benzylpenicillin          |
|                     | Phenoxymethylpenicillin   |
|                     | Oxacillin                 |
|                     | Ampicillin                |
|                     | Amoxicillin               |
| Cephalosporins      | Cefazolin                 |
|                     | Ceftriaxone               |
|                     | Cephalexin                |
| Aminoglycosides     | Gentamycin                |
| Tetracyclines       | Tetracycline              |
|                     | Doxycycline               |
| Macrolides          | Erythromycin              |
|                     | Clarithromycin            |
|                     | Azithromycin              |
| Others              | Chloramphenicol           |
|                     | Vancomycin                |
| Synthetic antibacterial medicines | Sulfamethoxazole-trimethoprim |
| Sulfonamide         | Sulfamethoxazole-trimethoprim |
| Quinolones          | Ofloxacin                 |
|                     | Ciprofloxacin             |
| Others              | Metronidazole             |

Antimicrobials reported to have been sold during the 2 weeks prior to the interview day at community pharmacies.

Table 2. Number of customers who bought antimicrobials per 50 customers who visited pharmacies to buy medicine.

| Antimicrobials | Number of customers who bought antimicrobials per 50 customers who visited pharmacies to buy medicine* |
|----------------|--------------------------------------------------------------------------------------------------|
|                | Mean ± SD                                                                                       |
| Amoxicillin    | 6.2 ± 5.5                                                                                       |
| Ampicillin     | 5.9 ± 5.3                                                                                       |
| Benzylpenicillin | 1.3 ± 2.1                                                                                   |
| Phenoxymethylpenicillin | 1.3 ± 2.3                                          |
| Cefazolin      | 1.5 ± 2.2                                                                                       |
| Chloramphenicol | 2.9 ± 3.7                                                                                   |
| Ciprofloxacin  | 2.3 ± 3.5                                                                                       |
| Doxycycline    | 1.7 ± 2.6                                                                                       |
| Erythromycin   | 2.8 ± 2.9                                                                                       |
| Gentamycin     | 1.0 ± 1.8                                                                                       |
| Metronidazole  | 5.8 ± 4.9                                                                                       |
| Sulfamethoxazole-trimethoprim | 5.4 ± 4.8                                         |

Table 2 shows the number of customers who bought each type of antimicrobial medicine per 50 customers who visited pharmacies to buy medicine.

Among the 619 pharmacy customers who agreed to participate in this study, 48.0% of them (297 customers) had bought at least one type of antimicrobial medicine. Among those who bought antimicrobials, 42.1% of them (125 customers) had a prescription for the antimicrobial medicine that was purchased. Antimicrobials commonly used by injection were benzylpenicillin (used by 90% of customers who bought antimicrobials), cefazolin (80%) and gentamicin (90%).

The most common reasons for purchasing antimicrobials were acute respiratory disease (54.8%), genitourinary disease (15.5%), and gastrointestinal disease (10.7%). Among the pharmacy customers who suffered from acute respiratory disease, 45.1% of them bought oral penicillin, either amoxicillin (24.6%) or ampicillin (20.5%). The most common strength of these two antimicrobials was 500 mg (selected by 70% of customers who bought amoxicillin or ampicillin), and rest of them (30%) bought 250 mg which mainly used for children.
Table 3. Instructions given by pharmacy staff to customers regarding various parameters

| Antimicrobials                  | n  | Dose & timing | Side effect | Allergies |
|---------------------------------|----|---------------|-------------|-----------|
|                                 |    | %            | %           | %         |
| Amoxicillin                     | 91 | 65.9         | 3.3         | 6.6       |
| Ampicillin                      | 76 | 63.2         | 11.8        | 9.2       |
| Benzylpenicillin                | 9  | 66.7         | 11.1        | 11.1      |
| Phenoxyimethyl-penicillin       | 4  | 50.0         | 0.0         | 25.0      |
| Cefazolin                       | 12 | 66.7         | 25.0        | 8.3       |
| Chloramphenicol                 | 23 | 43.5         | 4.3         | 0.0       |
| Ciprofloxacin                   | 11 | 90.9         | 9.1         | 9.1       |
| Doxycycline                     | 9  | 100.0        | 11.1        | 0.0       |
| Erythromycin                    | 10 | 60.0         | 10.0        | 0.0       |
| Gentamycin                      | 11 | 45.5         | 0.0         | 0.0       |
| Metronidazole                   | 26 | 69.2         | 7.7         | 11.5      |
| Sulfamethoxazole-trimethoprim   | 22 | 72.7         | 13.6        | 13.6      |

Table 3 shows the summary of instructions given by pharmacy workers to pharmacy customers. On average, 67.3% of the customers reported that a pharmacy worker had given them information regarding the dose and timing at which the medicine should be used; 8.9% of them reported that they had also been given information regarding adverse effects.

The study reveals that the doctors feel that the medicines such as benzyl penicillin, gentamicin, metronidazole, ampicillin, phenoxymethyl penicillin, and ciprofloxacin are no longer very effective in treatment as they may have a problem of antibiotic resistance.

Discussion

The results of the pharmacy worker and pharmacy customer surveys were consistent, with about half of the pharmacy customers purchasing antimicrobial medicines: the pharmacy worker survey indicated that an average of 4.6 (SD = 1.8) out of 10 customers purchased antimicrobial medicines, while the pharmacy customer survey showed that 48.0% of the pharmacy customers purchased antimicrobial medicines. The results of the pharmacy worker and pharmacy customer surveys also consistently showed that 40% of the customers who purchased antimicrobials had a prescription: the pharmacy worker survey reported that 4.0 (SD = 2.3) out of 10 customers who purchased antimicrobials had a prescription, while the pharmacy customer survey showed that 42.1% of the customers who purchased antimicrobials had a prescription. These results are based on customers who visited community pharmacies in Ulaanbaatar.

The pharmacy worker survey indicated that, amoxicillin and ampicillin, sulfamethoxazole-trimethoprim, and metronidazole were the most frequently sold antimicrobials in Ulaanbaatar pharmacies. The frequent sale of amoxicillin and ampicillin, both of which are oral penicillins, as over-the-counter drugs has also been reported in Vietnam and Mexico16, 17. The frequent use of these medications is most likely explained by their cost and availability; amoxicillin and ampicillin are generally less expensive than other antimicrobials, and over 70% of all pharmacies throughout the world sell amoxicillin18. All pharmacies in the present study sold both amoxicillin and ampicillin. Generally, variations in the types, frequency, and methods in which antimicrobials are used by the general public vary in countries according to disease patterns, patient characteristics, and the quantity and quality of care services at health facilities19.

Variations in the general characteristics of antimicrobial use in developing counties also arise from the ability to purchase antimicrobials inexpensively and without a prescription. Among the pharmacy customers who bought over-the-counter medicines, more than half of the customers were seeking treatment for acute respiratory diseases; amoxicillin and ampicillin were sold to more than half of these customers. Antimicrobials were also frequently sold to patients suffering from genitourinary or gastrointestinal diseases.

Antimicrobials sold to these patients included not only penicillins, but also a wide range of other antimicrobials including chloramphenicol and gentamicin. There is a concern that the amount of antimicrobial use is related to the increase in drug-resistant pathogens20. In fact, our survey of perception of medical doctors showed that the antimicrobials which were frequently sold in community pharmacies were losing their effectiveness for the treatment of patients.

High consumption of antimicrobials among patients with common diseases such as acute respiratory disease and gastrointestinal disease were frequently reported in several countries16, 17 and the same has been observed in Mongolia. Especially the patients who are suffering from genitourinary disease are on rise in Mongolia and these patients frequently visit community pharmacies.

There is a tendency in developing countries to take antimicrobials even when their symptoms are not serious or even when there are no signs of infection21. One such medicine is chloramphenicol, which is widely used in developing countries, primarily because it is cheap and broad spectrum. However, this medicine is now rarely used in developed countries because of its serious adverse effects, such as the development of aplastic anemia22. The present survey shows that chloramphenicol is commonly used in Mongolia, especially for the treatment of gastrointestinal disease. However, the present study shows that...
only 4% of the customers, who purchased chloramphenicol, received information regarding side effects.

To date, there have been limited laboratory studies conducted on antimicrobial sensitivity in Mongolia and it is difficult to establish whether antimicrobial resistance has increased or not. Hence, promoting the use of an antimicrobial sensitivity test before prescribing antimicrobials is an important approach to monitor and to control the further emergence of antimicrobial resistance.

Although it is a crude measure of changes in resistance, this survey of experienced medical doctors in Ulaanbaatar also suggested that based on their clinical experience some antimicrobials are losing their effectiveness for the treatment of patients with infectious disease.

There are no specific antibiotic guidelines in Mongolia and it is necessary to promote and establish best practice clinical guidelines. These guidelines should not be limited to medical doctors, but should also target and include pharmacists and pharmacy workers. The knowledge of pharmacy workers about antimicrobials play a key role in promoting the rational use of antimicrobials, considering the fact that many consumers purchase directly in Ulaanbaatar. Hence, the education of prescribers and dispensers (including drug sellers) is important for appropriate antimicrobial use and for the containment of antimicrobial resistance.

This study provides an understanding of the sale and use of antimicrobials by a sample of the general public in Ulaanbaatar, Mongolia. At present, the public can purchase antimicrobials for the treatment of common diseases, such as acute respiratory infection, without requiring a prescription and without receiving proper instructions regarding the use of such medicines. The development of comprehensive and consistent control measures at national level to regulate the medicine quality and distribution is urgently needed in Mongolia. Also, antimicrobials should not be available as over-the-counter drugs.

Conclusion

The present study is first of its kind and it explores the use of antimicrobials in Mongolia. The study reveals that antibiotics are commonly available in Mongolia and the consumers have easy access to these medicines. Establishing a drug regulatory authority could improve the enforcement and also can aid to improve the quality use of antimicrobials. Mass educational campaigns could also create awareness regarding the use of antimicrobial in Mongolia.

Conflict of interests

The authors report no conflicts of interest.

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