INTRODUCTION

The introduction of antibiotics into medical practice has significantly reduced mortality due to infections and has improved safety in terms of surgical and transplantation results. However, the antibiotic resistance of various bacterial pathogens has reached a pandemic level over the last two decades. Studies predict global costs of billions of dollars and tens of millions of deaths by 2050 due to microbial resistance to antibiotics [1-3].

Antimicrobial resistance is largely attributed to inappropriate and excessive use of antibiotics. The failure of the initial treatment may mean that the infection spreads, worsens and is more difficult to treat. In some countries, antibiotics can be purchased without prescription or even from the Internet, which has led to increased antibiotic use across the European Union (EU) [4, 5].

The European Antibiotic Awareness Day coordinated in 2008 by the European Center for Disease Prevention and Control (ECDC) aims to increase caution in the use of antibiotics. “Antibiotic administration: always preceded by a medical recommendation”, “Use antibiotics cautiously in your interests and public health!” were topics and slogans meant to draw attention to the only way antibiotics should be administered in order to maintain their effectiveness, or the only way to reduce the consumption of these drugs, which is currently excessively high in Europe and especially in Romania [6].

In May 2015, The World Health Assembly adopted the Global Action Plan on Antimicrobial Resistance with five strategic objectives: raising awareness and understanding of antimicrobial resistance; monitoring and research into antimicrobial resistance; reducing the incidence of infections; optimizing the use of antimicrobial drugs, and ensuring sustained investment in combating antimicrobial resistance [6].

All 28 EU Member States and Iceland and Norway participate in EARS-Net (European Antimicrobial Resistance Surveillance Network) by regularly reporting data on antimicrobial resistance for bacteria and antibiotic groups under supervision [7].

According to the CARMEN study (Consumption of antibiotics, microbial resistance and nosocomial infections) [8], the total consumption of antibiotics in Romania in 2015 remained very high by accentuating the preferential use of antibiotics at risk of selecting bacterial resistance and inducing severe infections such as those determined by Clostridium difficile. Compared to the European Economic Area (EEA), the 2011-2015 dynamics for AB - J01 in Romania showed a growing trend towards relative stationarity in the EEA. In 2015, the consumption of antibiotics in the J01 category in Romania exceeded 48.7% of the European average. The value of consumption per capita significantly exceeded the European average, with Romania ranking second in 2015 after France.

Despite recent warnings regarding the alarming rise of multi-resistant germline infections, the preferential use of broad spectrum antibiotics and strong dysmicrobism-inducing categories continues, to the detriment of those with narrow spectrum, and as a consequence available evidence indicates a very high level of antibiotic resistance — one of the highest in Europe. In Romania, the use of antibiotics continues to be excessive. Romania is still among the first countries to use antibiotics for systemic use, and in 2016 it ranked fourth in the European Union. This critical situation is due to insufficient information in the general population regarding the role, benefits, and risks of antibiotics, their excessive prescription in both hospital and outpatient settings, and still relatively easy access to antibiotics, disobeying the rules of prescription release only.

Antibiotics are substances that destroy or prevent the development of microorganisms such as bacteria, fungi, or protozoa, and are a valuable resource for infections, the efficacy of which must be maintained by administering them only when recommended by the physician. Microbial resistance to antibiotics has risen to alarming levels in all parts of the world and is today one of the most serious threats to public health and global development. Microbial resistance to antibiotics also implies an economic burden, as these infections induce an increase in the average duration of hospitalization, and thus, additional health costs and losses in labor productivity. The total consumption of antibiotics in Romania in 2015 was extremely high and it was characterized by the increased use of antibiotics at risk of selecting bacterial resistance and inducing severe infections and thus, Romania was on the second place in Europe. Romania is still among the first countries in the use of antibiotics for systemic use, in 2016 it ranked fourth in the European Union. This critical situation is due to insufficient information in the general population regarding the role, benefits, and risks of antibiotics, their excessive prescription in both hospital and outpatient settings, and still relatively easy access to antibiotics, disobeying the rules of prescription release only.

Keywords: antibiotics, bacterial resistance, antibiotic costs

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information and/ or erroneous mentality in the general population regarding the role, benefits, and risks of administering antibiotics; excessive prescriptions in both hospital and outpatient settings; relatively easy access to antibiotics, disobeying the regulations regarding their release solely on prescription.

The aim of our study was to analyze and compare the consumption of antibiotics and their distribution on different antibiotic groups in several hospitals in Romania. The main objectives pursued were: the ratio of the consumption of antibiotics in the total consumption of drugs; expenditure on antibiotics on a case-by-case basis for acute cases treated in continuous hospitalization; the distribution of antibiotics used into different antibiotic groups, primarily alternative antibiotics which represent a very high ratio of total antibiotic consumption.

MATERIAL AND METHOD
For our study, the data were collected from 16 hospitals in Romania (marked as “Hospital 1”, …., “Hospital 16” in order to preserve confidentiality). The data provided by each hospital were annual exports for drug use. The hospitals are located in different geographical areas of the country. Of the 16 hospitals, 3 are large clinical or county hospitals (numbered S1.1-S3.1), 5 hospitals are large town or county hospitals (numbered S4.2-S8.2), and 8 are small town hospitals (numbered S9.3-S16.3). In the 16 hospitals of the received exports we identified the drugs used, total drug consumption was calculated and the antibiotics used were identified. We calculated the ratio of antibiotic consumption in total drug expenditure and the ratio of each antibiotic group in total antibiotic use.

In order to obtain more easily comparable results, the complexity of the treated cases was equated. We analyzed drug consumption in acute cases treated in Continuous Hospitalization (DRG - Diagnosis Related Groups), the value of drugs/ antibiotics being reported in weighted cases.

Acute cases were categorized into DRG. DRG is a patient classification system based on diagnosis, surgical procedures, and other clinical information such as patient age, complications, and comorbidities. DRG offers the opportunity to make a correlation between the type of cases that the hospital treats (i.e. the case complexity index - CCI or the case-mix index, which expresses the necessary resources for the hospital in accordance with the patients treated) and the costs associated with them. One case can be characterized by the relative value (RV) or CCI, based on the consumption of resources needed to treat the case. The relative value expresses the ratio between the resources needed to treat a DRG group and the average resource consumption for all DRG groups. The total of treated cases (sum of case-mix indexes) in a hospital is characterized by the weighted case which represents the complexity of the cases treated and adjusts the cases discharged according to the resources associated with each type of case [9].

RESULTS
The weighted value of the consumption of antibiotics in total drug expenditure is shown in Figure 1. The percentage of antibiotics in the total expenditure on medicines was between 12.3% and 33.43%. In the case of large hospitals in category 1, the mean of the values was 29.58%. The mean for large hospitals was the highest, with a decrease depending on the category of the hospitals. In the case of medium-sized hospitals in category 2, the mean was 26.13%, and in the case of small hospitals in category 3 the mean was 21.43%.

Figure 1. The weighted value of antibiotic consumption of the value of total drug consumption

![Figure 1](image)

Antibiotics (% of the total costs for medicines)

Note: Hospitals

Figure 2. Costs on antibiotics per weighted cases in patients who received antibiotics

![Figure 2](image)

Costs ATB/WC (RON) in patients who received ATB

Note: ATB-antibiotics, WC-weighted case

The weighted value of consumption of different types of antibiotics of the value of total antibiotic consumption in the hospitals studied is shown in Table 1.

Within the analyzed hospitals, no combinations of antibiotics in the J01R group were used, their ratio being 0 in all the analyzed hospitals. These antibiotics are not listed in Romania in the Nomenclature of Medicines on the NAM website (National Agency for Medicines).

Antibiotic costs on weighted cases in patients treated with antibiotics

According to Figure 2, although the complexity of the cases was equalized by the value of the average...
Table 1. The weighted value (mean as percentage) of consumption of different types of antibiotics of the total antibiotic consumption

<table>
<thead>
<tr>
<th>Type of antibiotic</th>
<th>Group of antibiotic</th>
<th>Large hospitals %</th>
<th>Medium-sized hospitals %</th>
<th>Small hospitals %</th>
<th>Variation in hospital consumption, minimum-maximum, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intestinal anti-infectives</td>
<td>A07AA</td>
<td>1.89</td>
<td>1.56</td>
<td>2.72</td>
<td>0.04 (S5.2)-9.5 (S12.3)</td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>J01A</td>
<td>13.5</td>
<td>0.71</td>
<td>0.31</td>
<td>33.21 (S1.1)-0.01 (S11.3)</td>
</tr>
<tr>
<td>Beta-lactamic antibiotics</td>
<td>J01C</td>
<td>15.79</td>
<td>36.44</td>
<td>37.87</td>
<td>9.5 (S1.1)-64.27 (S5.2)</td>
</tr>
<tr>
<td>Beta-lactamic antibiotics (cephalosporins, monobactams, carbapenems)</td>
<td>J01D</td>
<td>22.41</td>
<td>17.41</td>
<td>38.15</td>
<td>3.59 (S5.2)-57.06 (S10.3)</td>
</tr>
<tr>
<td>Sulfonamides and trimethoprim</td>
<td>J01E</td>
<td>0.10</td>
<td>0.15</td>
<td>0.07</td>
<td>0.01 (S16.3)-0.6 (S6.2)</td>
</tr>
<tr>
<td>Macrolides, lincosamides, and streptogramins</td>
<td>J01F</td>
<td>1.67</td>
<td>1.52</td>
<td>3.12</td>
<td>0.01 (S15.3)-10.17 (S16.3)</td>
</tr>
<tr>
<td>Aminoglycosides</td>
<td>J01G</td>
<td>1.69</td>
<td>1.83</td>
<td>3.53</td>
<td>0.82 (S3.1)-7.73 (S15.3)</td>
</tr>
<tr>
<td>Quinolones</td>
<td>J01M</td>
<td>5.93</td>
<td>7.02</td>
<td>3.68</td>
<td>1.48 (S16.3)-10.78 (S8.2)</td>
</tr>
<tr>
<td>Steroidal antibacterials, imidazole derivatives and nitrofuran derivatives</td>
<td>J01XC/J01XD/J01XE</td>
<td>2</td>
<td>4.2</td>
<td>5.6</td>
<td>0.99 (S15.3)-9.05 (S16.3)</td>
</tr>
<tr>
<td>Alternative antibiotics</td>
<td>-</td>
<td>35.02</td>
<td>29.18</td>
<td>4.97</td>
<td>0.01 (S15.3)-55.02 (S4.2)</td>
</tr>
</tbody>
</table>

Table 2. Weighted value (mean) of the cost of different types of antibiotics on weighted cases in patients who received these antibiotics

<table>
<thead>
<tr>
<th>Type of antibiotic</th>
<th>Group of antibiotic</th>
<th>Large hospitals (lei)</th>
<th>Medium-sized hospitals (lei)</th>
<th>Small hospitals (lei)</th>
<th>Variation in hospital costs, minimum-maximum (lei)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intestinal anti-infectives</td>
<td>A07A</td>
<td>6.72</td>
<td>9.62</td>
<td>3.84</td>
<td>0.01 (S5.2)-27.42 (S4.2)</td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>J01A</td>
<td>309.89</td>
<td>45.26</td>
<td>11.27</td>
<td>0.01 (S16.3)-408.66 (S2.1)</td>
</tr>
<tr>
<td>Beta-lactamic antibiotics</td>
<td>J01C</td>
<td>12.78</td>
<td>17.37</td>
<td>14.23</td>
<td>8.55 (S14.3)-26.62 (S5.2)</td>
</tr>
<tr>
<td>Beta-lactamic antibiotics (cephalosporins, monobactams, carbapenems)</td>
<td>J01D</td>
<td>11.28</td>
<td>6.57</td>
<td>9.6</td>
<td>5.20 (S1.1)-16.52 (S3.1)</td>
</tr>
<tr>
<td>Sulfonamides and trimethoprim</td>
<td>J01E</td>
<td>1.11</td>
<td>1.02</td>
<td>1.26</td>
<td>0.79 (S4.2)-3.43 (S9.3)</td>
</tr>
<tr>
<td>Macrolides, lincosamides, and streptogramins</td>
<td>J01F</td>
<td>18.92</td>
<td>10.56</td>
<td>13.69</td>
<td>0.01 (S15.3)-31.06 (S11.3)</td>
</tr>
<tr>
<td>Aminoglycosides</td>
<td>J01G</td>
<td>2.2</td>
<td>2.95</td>
<td>2.64</td>
<td>1.36 (S13.3)-4.82 (S4.2)</td>
</tr>
<tr>
<td>Quinolones</td>
<td>J01M</td>
<td>11.01</td>
<td>8.34</td>
<td>4.23</td>
<td>2.14 (S9.3)-17.13 (S2.1)</td>
</tr>
<tr>
<td>Steroidal antibacterials, imidazole derivatives and nitrofuran derivatives</td>
<td>J01XC/J01XD/J01XE</td>
<td>9.28</td>
<td>6.38</td>
<td>11.75</td>
<td>3.44 (S15.3)-21.24 (S16.3)</td>
</tr>
<tr>
<td>Alternative antibiotics</td>
<td>-</td>
<td>65.77</td>
<td>32.92</td>
<td>39.11</td>
<td>19.88 (S5.2)-98.46 (S2.1)</td>
</tr>
</tbody>
</table>

The costs on weighted case antibiotics in patients who received antibiotics were the highest in large hospitals and in small hospitals 9.82 lei.

The weighted value of the costs for different types of antibiotics in weighted cases in patients who received antibiotics in the hospitals included in the study is shown in Table 2.

The costs on weighted case antibiotics in patients who received antibiotics were the highest in large hospitals in the tetracycline group (130.66 lei), which was well above the mean (22.47 lei). The tetracycline group is followed by the alternative antibiotics (65.77 lei), which were also well above the mean.

The costs on weighted cases of antibiotics in patients receiving antibiotics were the highest in medium-sized hospitals in alternative antibiotics (32.92 lei), which were well above the mean of weighted costs (9.59 leis). The alternative antibiotics were followed by the tetracycline group (18.30 leis) and the beta-lactamic antibiotic group (17.37 leis). These two groups are approximately twice as large as the mean cost per weighted case.

The costs on weighted cases of antibiotics in patients receiving antibiotics were the highest in small hospitals in the group of alternative antibiotics (39.11 lei). These were well above the mean of costs per weighted case (9.15 lei). Alternative antibiotics were followed by the group of beta-lactamic antibiotics (14.23 lei) and the macrolide, lincosamide, and streptogramin group (13.69 lei).

The costs on weighted cases of antibiotics in patients receiving antibiotics were the highest in the hospitals analyzed in the group of alternative antibiotics (42.18 leis). These were well above the mean of costs per weighted case (11.78 lei). The group of alternative antibiotics was followed by the group of tetracyclines (34.92 lei), which was about 3 times higher than the mean of costs per weighted case and the beta-lactamic antibiotic group (13.69 lei).

DISCUSSIONS
The motivation of this study was the tendency towards inadequate use of antibiotics in some hospitals in Romania and the users’ mentality about antibiotic therapy. This excessive use of antibiotics has led to antibiotic resistance and it causes additional health expenditure and loss in labor productivity.
Consumption of antibiotics is expressed as “defined daily doses DDD/ 1000 inhabitants/ day” based on Anatomic Chemical Therapeutic (ATC) indexing. It is used to report the usual consumption of antibiotics in outpatient services (outside the hospital, sometimes called community) and consumption in the hospital sector. DDD is an internationally accepted unit of measurement of antibiotic use in order to make comparisons between countries. The indicator takes into account the amount of antibiotics consumed (dose) and the potential ecological effect - meaning the development of resistance to antimicrobials [3, 7].

A group of resistant multidrug bacteria has been described which predominantly causes most infections in health care. Thus, the term ESCAPE encompasses the following bacterial species: *Enterococcus faecium*, *Staphylococcus aureus*, *Clostridium difficile*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Enterobacteriaceae*.

**Figure 3. Costs on antibiotics per weighted case in patients who received antibiotics in the three categories of hospitals**

*Note: ATB-antibiotics, WC-weighted case*

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which cover all Gram-negative enteric bacteria including Escherichia coli, Klebsiella pneumoniae, Proteus spp., and Enterobacter spp. [10].

The CARMIN study [8] was followed by the release of data on bacterial resistance to antibiotics in Romania: MRSA (methicillin-resistant Staphylococcus aureus) was at the highest level among European countries participating in EARS Net, at 50.6% of all the reported strains of Staphylococcus aureus, a situation explained by high beta-lactam antibiotic consumption and insufficient infection control measures in medical units; another emerging issue of antibiotic resistance of Gram-positive cocci was glycopeptide resistance of Enterococcus faecium, reaching 40% in 2016; in the case of Pseudomonas aeruginosa 58.8% resistance to carbapenem, and 53.4% bacterial multiresistance (the highest levels reported by EARS Net countries); for Acinetobacter baumannii 85.3% carbapenem resistance, and 84.5% bacterial multiresistance; antibiotic multiresistance of the major Enterobacteriaceae (Escherichia coli and Klebsiella pneumoniae) remained high: 11.7%, and 55.2%, respectively.

These high levels of bacterial resistance to antibiotics place Romania among the first places in the EARS Net countries. [7, 11].

Alternative antibiotics for infections by Gram positive cocci (MRSA - methicillin-resistant Staphylococcus aureus, multidrug-resistant Streptococcus pneumoniae) are glycopeptides, linezolid, daptomycin, dalbavancin, and ceftaroline. Their total consumption in 2016 amounted to 0.037 DDD/1000 inhabitants/day, continuing an obvious growth trend for 2011-2016 [8].

Alternative antibiotics for infections caused by Gram negative bacteria are carbapenems and colistin. In terms of colistin consumption, it recorded a significant increase in 2011-2016, from 0.020 DDD/1000 inhabitants/day (2011) to 0.035 DDD/1000 inhabitants/day, an additional 70%, with a consumption 2.2 times higher than the European average. The explanation for this consumption is related to the increase of gram-negative bacteria resistant to carbapenems (Acinetobacter baumannii, Pseudomonas aeruginosa, Klebsiella pneumoniae), but also to the excessive use of colonization with such germs [8].

The ECDC website does not provide separate data on outpatient and hospital categories in Romania. The main antibiotic groups used in 2016 were penicillins - 54.3%, cephalosporins - 16.8%, and quinolones - 11.6%. In absolute terms, the highest consumption in Romania was represented by penicillins (J01C) - 16 DDD/1000 inhabitants/day, other beta-lactam antibiotics (cephalosporins, carbapenems) (J01D) - 5 DDD/1000 inhabitants/day and quinolones J01M) - 3.4 DDD/1000 inhabitants/day [8].

According to the analysis of our study in the 16 hospitals, the highest antibiotic value distribution was in the case of alternative antibiotics (such as colistin, daptomycin, fosfomycin, linezolid, nitrooxine, tetrozolid, teicoplanin, and vancomycin on the NAM list in Romania), and the value of 32.42%, respectively. This value is an alarm signal because almost one-third of the antibiotic value consumption is represented by the consumption of alternative antibiotics. Alternative antibiotics were followed by beta-lactam antibiotic group (27.35%) and other beta-lactam antibiotics (18.96%), whereas tetracyclines had a ratio of 6.42%.

The average expenditure on alternative antibiotics on a weighted case in patients who received alternative antibiotics was highest in large hospitals (65.77 lei). Within medium-sized and small hospitals there were similar values, in medium-sized hospitals the average was 32.92 lei, while in the small ones it was 39.11 lei.

Resistance to antibiotics can be controlled by the proper use of antibiotics and by prevention of the cross-fertilization of antibiotic-resistant microorganisms. According to the World Health Organization (WHO), proper use of antibiotics means the cost-effective use of antibiotics that maximize the therapeutic effect while minimizing the toxic side effects of antibiotic administration and the development of antibiotic resistance [12].

An important component in preventing and controlling infections is the existence of a guide to antibiotics which could provide support for proper antibiotic choice, correct dosing, route of administration, and duration of antibiotic therapy, thus promoting appropriate antibiotic prescribing. There is a regulation in Romania, the Order of the Ministry of Health no. 1101/2016, regarding the approval of the Norms for the surveillance, prevention, and limitation of healthcare associated infections. This involves the existence of a Committee for the prevention of infection related to healthcare which describes the existence of a doctor responsible for the policy of using antibiotics within the unit. The unit manager is responsible for publishing the statistical information on healthcare associated infections on the website of the unit, as well as the results of tests for the efficiency of cleanliness and disinfection, the use of antibiotics, and the breakdown of alternative antibiotic use [13].

Prior to the issuance of this order, an extremely low number of healthcare associated infections was officially reported, which represented an important barrier in knowing the real dimensions and characteristics of this phenomenon in Romania. A first step in correcting the situation was the introduction of the national surveillance system for Clostridium difficile infections.

The long-term solution is to develop and implement a comprehensive strategy, such as the multidisciplinary team approach, the implementation of a strict policy of judicious use of antibiotics and disinfectants, the increase of specific budgets and dedicated staff (epidemiologists), and professional training.

**Study limitations.** One of the limitations of our study was the impossibility of collecting data for total antibiotic use in Romania, as there are no internet-accessible databases for drug use. Thus, it was not possible to estimate the consumption of antibiotics in outpatient facilities purchased from pharmacies, with or without prescription, and it was not possible to obtain exports for medications from all the hospitals in the country. Data from the literature refer to the total consumption of antibiotics in Romania, and to the CARMIN study [8] in Romania, not separate reports for the outpatient and hospital sectors, according to the ECDC. This consumption is strictly related to group J01, but our group...
also included A07A, i.e. intestinal anti-infectives. Consumption does not even differentiate alternative antibiotics, they are calculated in their anatomical group, namely in groups J01D and J01X. Another important limitation of the analysis is the fact that in the case of antibiotic resistance alternative antibiotics are not always used, but there are other antibiotics that are used in such infections but which have other indications as well. Thus, we cannot accurately identify the number of infections with resistant microorganisms, and the fact that these antibiotics have other (multiple) uses would falsify the current analysis with the over-assessment of the alternative antibiotics. Even so, there is an over-assessment of their use as alternative antibiotics because vancomycin is increasingly used as a treatment for Clostridium infection, a fact this is correlated with the increase in the use of alternative antibiotics as this increase was due to vancomycin.

**Conclusion**

Our analyses confirm the inadequate antibiotic trend which results in high antibiotic consumption in Romania according to literature. In the 16 analyzed hospitals, it appears that the distribution of alternative antibiotics is very high. An alarming ratio, however, is found primarily in medium-sized and small hospitals, where the costs for alternative antibiotics per weighted case outweigh the expenses of other weighted cases of first choice antibiotic groups. The greatest share of alternative antibiotics is in large hospitals, followed by medium-sized and small hospitals. As compared to 2015, when Romania ranked second in antibiotic use, in 2016 Romania ranked only fourth, but its consumption was still well above the average in Europe. In order to reduce the consumption of antibiotics it is necessary to promote the proper use of antibiotics by informing the population about the risk of their excessive and erroneous use. This responsibility belongs to the Ministry of Health, the family physician, and the pharmacist.

The purchase of antibiotics should be restricted in all countries in Europe and released solely based on a prescription. Moreover, it should be followed and monitored regularly. In some cases, where possible, primarily in outpatient settings, antibiotics should be replaced by alternative products, i.e. natural products with beneficial effects in the case of less serious infections, but with antibiotic-like effects. There should be a microbiologist and an epidemiologist in each county who would supervise the use of antibiotics and resistance occurring in that particular county. The use of antibiotics should be regulated by published guides dedicated to each type of health facility (hospitals or family physician units, etc.), which should be drafted and renewed annually by country-wide specialists. Hand hygiene, infection, patient isolation, and screening on hospital admission are of great importance in the prevention of healthcare associated infections. In Romania, but also across Europe, we must strive to reduce the use of antibiotics using narrow spectrum antibiotics, avoiding the use of broad spectrum antibiotics and alternative ones. Thus, we can maintain the effectiveness of antibiotics so that the healing cure does not turn into a weapon against us.

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