

# Drug Utilization Evaluation in Upper Respiratory Infection in Pediatric Population in North Indian Tertiary Hospital

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## ABSTRACT

**Background:** According to the WHO, around 5 million childhood deaths occur per year and around 20% of all childhood deaths are due to acute respiratory tract infections. **Materials and Methods:** A cross-sectional study was carried out in a tertiary care hospital for 6 months (December-May) on pediatric patients (age ≤ 12 years) diagnosed with URTI. Data like demographic details, diagnosis, World Health Organization (WHO) prescribing indicators, different classes of drugs prescribed, antibiotic treatment, etc., were gathered from the pediatric Outpatient Department (OPD). **Results:** A total of 153 prescriptions were evaluated; of these, 84 (54.9%) were males and the rest, 69 (45.1%), were females. Mainly, school children 89 (58.17%) of the age group between 6-12 years visited the outpatient pediatric department with commonly recorded clinical symptoms of fever and cough, accounting for 81% and 66.7%, respectively. The average number of drugs prescribed was 2.38 per prescription; commonly prescribed medication for the management of URTI was antipyretics 111 (72.5%), antihistamines 94 (61.3%), followed by antibiotics 55 (35.9%). Amoxiclav (31.66%) and Cefixime (30%) were the common antibacterial prescribed. Moreover, it was observed that the antibiotics were prescribed without investigations for bacterial infections. Most medications (85%) were from the WHO model list of essential medicines; their generic name was prescribed by 36.43%. **Conclusion:** Symptomatic treatment was offered in most audited prescriptions and antibiotics were prescribed with no definite evidence of bacterial infection. Initiation of Antimicrobial Stewardship programs and National Action Plan on Antimicrobial Resistance (NAP-AMR) guidelines in healthcare institutes can help prescribers follow rational drug therapy.

**Keywords:** Drug Utilization Evaluation (DUE), Upper Respiratory Tract Infection (URTI), Pediatric Outpatients (OPD), Rational drug therapy.

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## INTRODUCTION

Drug utilization evaluation (DUE) is defined as "the marketing, distribution, prescription and use of the drug in a society with special emphasis on resulting medical, social and economic consequences" by the World Health Organization (WHO) in 1997.<sup>1,2</sup> The DUE aims to assure the safety and effectiveness of medication utilized appropriately to promote public health.<sup>2</sup> It is intended to investigate drug and prescription trends and develop the criteria and standards for doctors to get proper feedback on

their prescriptions.<sup>3</sup> Every drug used in the hospital cannot be evaluated. Thus, DUE studies focus on the medication whose assessment and use advancement will lead to a more significant clinical impact. Generally, drugs that are most used, higher in cost and have a high rate of adverse effects are enrolled in DUE studies.<sup>4</sup>

Upper Respiratory Tract Infection (URTI) is a broad term for acute infections of the nose, paranasal sinuses, pharynx, larynx and trachea caused by various viruses, the most common of which is rhinovirus.<sup>5</sup> The most prominent URTI signs and symptoms are myalgia, anorexia, low-grade fever, runny nose, congestion and coughing and sneezing. A small percentage of cases (0.5-10%) are accompanied by bacterial complications, most commonly caused by Group A Streptococci (GAS).<sup>6</sup> Virus-induced URTI is treated



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with antihistamines, antipyretics, anti-inflammatory drugs, cough suppressants, decongestants and expectorants.<sup>7</sup> Antibiotics are frequently recommended to address URTIs in primary care settings since it is difficult to identify and distinguish between these individuals because the clinical presentations associated with bacterial or viral-related URTIs frequently overlap.<sup>8</sup> However, with a few notable exceptions like acute otitis media, antibiotics are often not required for treating URTIs. Frequent use of antibiotics places a strain on healthcare systems, which can lead to clinical failure and accelerate the emergence of antibiotic resistance.<sup>9</sup>

According to the WHO data, 5 million childhood deaths occur per year of age less than five years and around 20% of all childhood deaths are due to acute respiratory tract infections.<sup>10</sup> India accounts for 45-86% of antibiotic prescriptions for treating URTIs, representing 20-65% of Outpatient (OP) visits and 12-35% of Inpatient (IP) visits in general hospitals.<sup>11</sup> Even though much data supports the self-limiting nature of acute URTIs.<sup>12</sup> The abuse of antibiotics is an issue since it leads to bacterial resistance development, an increase in complications of severe infection/disease, a rise in the health care cost and the onset of adverse effects. Currently, antibiotics are the type of medication that is frequently overused.<sup>13</sup> Inappropriate antibiotic use may result from a patient's assumption that antibiotics benefit URTIs or difficulty differentiating between viral and bacterial infections during diagnosis.<sup>12</sup>

The percentage of URTI cases prescribed antibiotics has become a critical metric for detecting antibiotic misuse.<sup>14</sup> The WHO has used this indicator to evaluate antibiotic use in URTI cases comprehensively.<sup>15</sup> The WHO estimated in a report titled Medicines Use in Primary Care in Developing and Transitional Countries that the percentage of URTI cases prescribed antibiotics increased over time from 43% to 71% between 1990 and 2006,<sup>16</sup> despite systematic reviews showing that antibiotics are of limited effectiveness in URTI.

Although URTIs are well-known to affect pediatric patients often, there are only a few studies from north India to show the prescribing pattern in URTI patients.<sup>12</sup> This study in Haryana state of north India is the first to detail the prescribing of drugs in children with URTI. Hence, the present study aimed to evaluate the drug utilization pattern of antibiotics and other drugs used in URTI in patients attending pediatric OPD. Analysis of prescribing patterns can also help with cost-effective medical care and the reduction of adverse drug response or antibiotic resistance.

## MATERIALS AND METHODS

### Study methods and design

The research used a cross-sectional study design to analyze prescription trends in pediatric patients with URTI. Throughout six months (December-May), the study was supervised at a

tertiary care hospital in North India. The sample size met the inclusion criteria, such as being diagnosed with URTI, being less than or equal to 12 years and being willing to participate. Exclusion criteria included patients above 12 years old, those with co-morbidities and incomplete or missing prescriptions (incomplete diagnosis, drugs, patient details, etc.).

Different parameters were used while collecting data during the study period after the patient's guardian/attendant signed the informed consent form for participation in this research project.

### Parameters used during the collection of data

Demographic Characters (age, gender, clinical symptoms and diagnosis).

WHO rational use of drugs indicators/prescribing indicators.<sup>17</sup>

Total number of prescriptions.

Total number of drugs prescribed.

Average number of drugs/prescriptions.

Total number of prescriptions with antibiotics.

Total number of antibiotics administered.

Percentage of encounter with injection prescribed.

Percentage of drugs prescribed by generic name.

Percentage of drugs from WHO model list of essential medicines.

Different classes of drugs: Names of the drugs prescribed on the prescriptions were recorded, including branded and generic drugs (Whichever is written). Branded drugs were evaluated for generic salt or active ingredients from the literature, followed by their therapeutic class. Then, different drugs were divided into different therapeutic classes.

### Statistical Analysis

In the current study, a descriptive statistical analysis was performed, where numbers and percentages were determined.

## RESULTS

### Gender and age distribution

A total of 153 prescriptions were enrolled from the pediatrics outpatient department, in which the number of male populations was 84(54.9%) and that of female populations was 69 (45.1%). This shows that URTI is more prevalent in the male than the female population. Most of the patients diagnosed with URTI were found to be in the age group of school children (6-12 years), i.e., 89 (58.17%) (Figure 1 and Table 1).

### Distribution of URTI patients based on the visit of months

The study data was collected for five months (Dec-Apr) from a tertiary care hospital in North India. More than half of the URTI patients who visited the outpatient department were found in March 55 (35.95%), followed by February 39 (25.5%). During these months, there has been a change of season in North India. (Figure 2).

### Distribution of sample based on clinical symptoms

The table elaborates on the distribution of data based on the clinical symptoms. Most complaints were a fever of 124 (81%), a cough of 102 (66.7%), a running nose, sore throat, vomiting, nasal congestion, etc., (Table 2).

### WHO prescribing indicators

WHO prescribing indicator was used to analyze prescribing patterns in this study.<sup>17</sup> Based on these indicators, the total number of prescriptions was 153 and the number of drugs prescribed was 365. Average number of drugs was 2.38 per prescription. The number of prescriptions with antibiotics was 55 and the number of antibiotics audited was 60. Injectables were encountered for 6.3% and 36.43% of drugs were audited with generic names. About 85% of the medications were from the WHO model list of essential medicines for children (Table 3).

### Distribution of data based on number of medications recommended per prescription

The number of prescriptions containing one drug was 9, followed by two drugs was found to be 89 and for three drugs, the number of prescriptions was 42 and for four drugs was 13. More than half of prescriptions contain 2 or 3 drugs in them (Table 4).

### Different routes used for administration

Different routes of administration of drugs were prescribed during the analysis of prescription. The most prescribed drug for the route of administration was oral route 315 (86.3%), followed by parenteral 23 (6.3%), nasal 19 (5.2%) and inhaler 8 (2.2%).

### Different class of drugs prescribed in URTI

Different classes of drugs were prescribed during the prescription writing for URTI. Among 153 prescriptions, the most commonly prescribed classes of drugs were Antipyretics and antihistamines, accounting for more than 60% of prescriptions. Around one-third of the patients were prescribed antibiotics. Other classes were expectorants, mucolytics and bronchodilators, prescribed in about 20% of the prescriptions. However, some miscellaneous classes of drugs, like multivitamins and proton pump inhibitors, were also prescribed. A detail of the classes of the drugs is given in Figure 3.

### Different types of antibiotics used in URTI

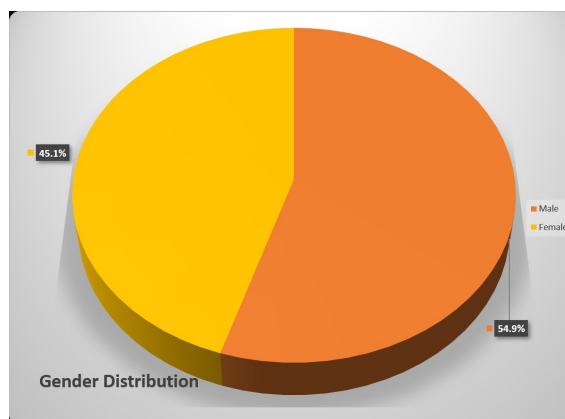
Among the prescriptions with antibiotics, 60 antibiotics were prescribed, with an average of 1.09 per prescription (5 prescriptions were with two antibiotics). It has been observed that

**Table 1: Distribution of Patients Based on Age Groups.**

Age Groups (years)	Male	Female	Total	Percentage (%)
Infants (0-1)	13	09	22	14.38
Pre-School (2-5)	21	21	42	27.45
School Children (6-12)	50	39	89	58.17
Total	84	69	153	100

**Table 2: Distribution of Data Based on the Clinical Symptoms (n=153).**

Symptoms	Number of prescriptions	Percentage (%)
Fever	124	81
Cough	102	66.7
Running Nose	35	22.9
Cold	21	13.7
Sore Throat	17	11.1
Vomiting	14	9.2
Nasal Congestion	5	3.3
Headache	3	2



**Figure 1: Distribution of Patients Based on Gender.**

**Table 3: WHO Prescribing Indicator Tool.**

Indicators	Number [n (%)]
Total number of prescriptions	153
Total number of drugs prescribed	365
Average number of drugs/prescriptions	2.38
Total number of prescriptions with antibiotics	55
Total number of antibiotics administered	60
Percentage of encounter with injection prescribed	6.3%
Percentage of drugs prescribed by generic name	36.43%
Percentage of drugs from WHO model list of essential medicines	85%

**Table 4: Distribution of data based on number of drugs prescribed per prescription (n=153).**

Number of drugs per prescription	Number of prescriptions	Percentage (%)
1 drug	9	5.88
2 drugs	89	58.17
3 drugs	42	27.45
4 drugs	13	8.5

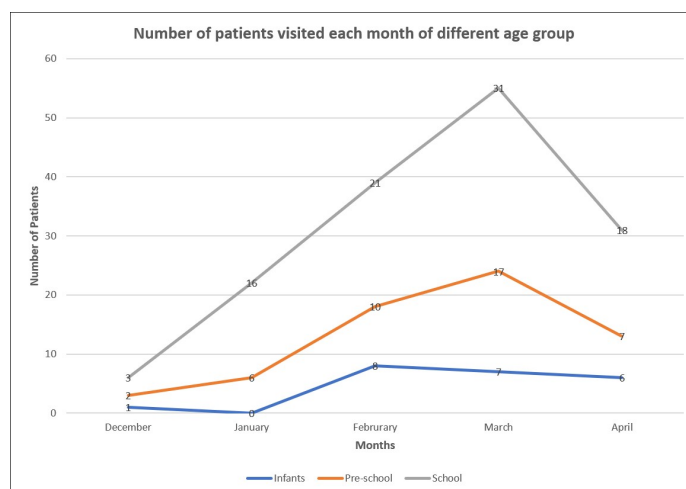
almost all the patients were prescribed a single antibiotic except 5 prescriptions in which Cefixime, augmenting and azithromycin were prescribed concomitantly. Amoxiclav and Cefixime were the most prescribed, followed by ceftriaxone and azithromycin. Other antibiotics like amikacin, ofloxacin, gentamycin, ampicillin and ampicillin were also prescribed (Figure 4).

## DISCUSSION

A doctor's prescription could be seen as an indication of the patient's condition and the drug's therapeutic value. Additionally, it presents an overview of the fundamentals of the healthcare delivery system. The medical community faces a severe threat from the growing issue of antibiotic resistance. The overuse and improper usage of antibiotics have greatly exacerbated this rapidly developing issue. Antibiotics are unnecessary for most URTIs, as most are caused by viruses.<sup>8</sup>

All the prescriptions were analyzed over a period of 6 months, based on drug utilization evaluation in URTI outpatients among the pediatric population. We observed that 84 male patients (54.9%) were as compared to female 69(45.1%), with a higher incidence in male subjects. Studies also reported that URTI is observed more in males as compared to females, as reported by Baby *et al.*, (2019) (males 55.4% and females 44.5%) and Palikhe *et al.*, (2008) (males 61.9% and females 38.1%).<sup>18,19</sup>

Based on age groups, the number of patients frequently visiting the outpatient department were School Children (6-12 years) 58.17% as compared to other age groups, Pre-School (2-5 years)

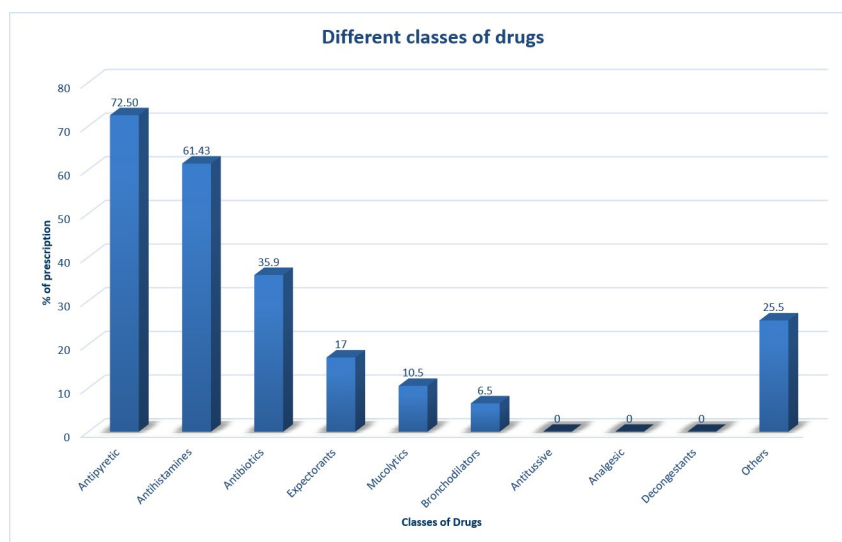
**Figure 2: Distribution of Patients Based on Month Visited.**

and Infants (0-1 years) shown in Table 2. However, this contrasted with research by Das *et al.*, (2006), where the age group of 2-5 years (44.8%) frequently visited the pediatric outpatient department.<sup>20</sup>

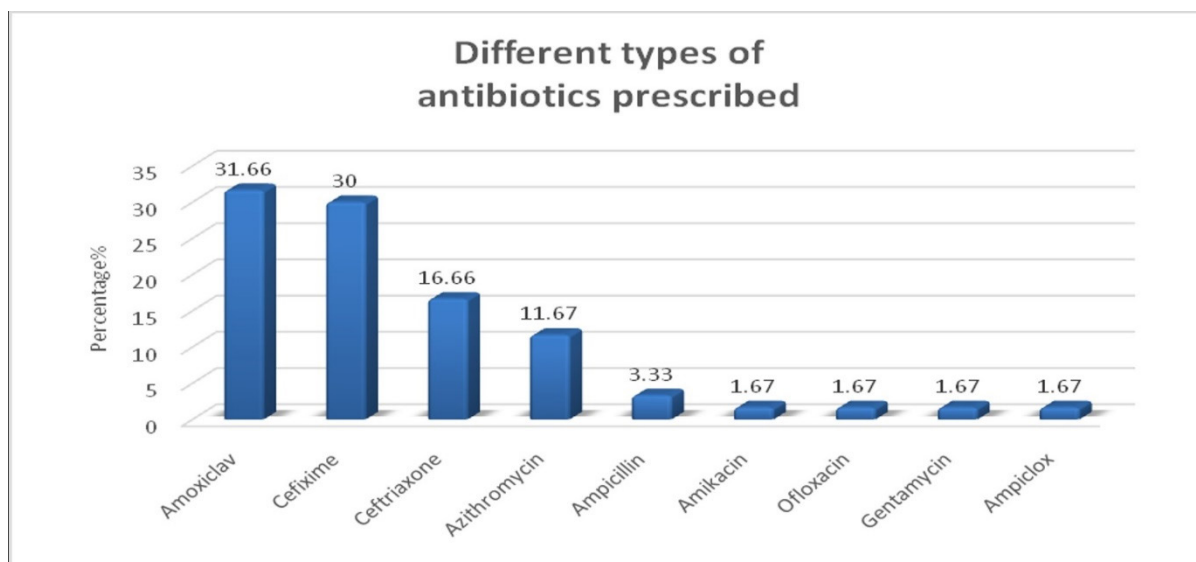
In the present study, conducted over five months (December-April), the number of infections reported in the outpatient department varies from month to month according to the seasonal changes, with the maximum number of cases being in March (35.9%) followed by February (25.5%), April (20.26%). The change in the percentage of patients who visited the OP department from February to March may be due to the change in season or the rollout of viral infections during these months. This is comparable with the results of Findlay *et al.*, (2010), which reported that respiratory infection consultation rates showed a yearly pattern, with the main peak in March during the hot-dry season and the second peak in September during the cold-dry season.<sup>21</sup>

The clinical symptoms or the chief complaints included in the prescription are shown in Table 3. The patients were having one or more clinical symptoms during the outpatient visit. The most common symptom was fever, followed by cough. Similarly, research conducted by Omkar *et al.*, (2022) and Hossain *et al.*, (2011) also reported that fever and cough were the typical clinical symptoms in URTI.<sup>22,23</sup>

For the treatment of URTI, anti-pyretics (72.5%) and anti-histamines (61.43%) were the often-prescribed medications, accompanied by antibiotics (35.9%) and expectorants (16.3%), and followed by the other classes of drugs like mucolytics and bronchodilators given (Table 4). Antibiotics were the third highest prescribed at 35.9%, which was comparable to the use of antibiotics in 33% of the subjects in a study by Sharma *et al.*, (2016); this may be irrational considering that the majority of URTI cases are caused by viruses based on the symptoms.<sup>24</sup> In total, 55 prescriptions with antibiotics audited had 60 antibiotics prescribed; amoxiclav (31.66%) and Cefixime (30%) were often prescribed, accompanied by ceftriaxone and azithromycin.



**Figure 3:** Analysis of Data Based on Classes of Drugs Prescribed.



**Figure 4:** Different Types of Antibiotics Prescribed.

This is a prescription-based study in which the pattern of the prescribed medication was analyzed, which is the most effective way to evaluate the prescription trends. In addition, we employed WHO prescribing indicators as a tool. We compared our results with the optimal values of this indicator, which helped provide feedback to the prescribers to encourage rational drug therapy. In a present audit, the total quantity of medications prescribed for URTI was 365 from 153 prescriptions and the average number of drugs prescribed per prescription was 2.38 (optimal 3). Studies conducted by Das *et al.*, (2006) and Torvi *et al.*, (2011) from the OP's Department of Pediatric Medicine also documented similar trends of an average number of drugs prescribed, 2.37 and 2.22 per prescription, respectively.<sup>20,25</sup> The number of drugs prescribed by generic name was only 36.43% (optimal 100%), which varies from 13.3%-93% from country to country.<sup>26</sup>

The percentage of drugs from the WHO model list of essential medicines for children in our study was 85% (optimal 100%). This finding was comparable to the study conducted by Omkar *et al.* (2022); drugs audited from the WHO Pediatric Essential List 2012 were 89%.<sup>22</sup> This conception from the WHO is a significant step for rational drug therapy across the globe. It must be noted that the maximum drug prescribed shall be from the essential drug list. However, our study has a good percentage of drugs audited from the WHO model list of essential medicines for children, which shows a better indication for rational drug therapy as drugs are selected on the basis of safety, efficacy and cost-benefit ratio.<sup>27</sup>

We observed that more than 90% of the prescriptions had polytherapy and only a few prescriptions had monotherapy in their prescription for the treatment of URTI. Studies have reported that more numbers of prescriptions contained 2 or 3

drugs in two different hospitals, i.e., teaching and non-teaching hospitals {teaching hospital: (28.6% for two drugs and 48.06% for three drugs), non-teaching hospital: (44.15% for two drugs and 37.01% for three drugs)}, by Malpani *et al.*, (2016).<sup>28</sup>

The prescribed medications were administered orally or parenterally, with 86.3% of prescriptions for oral use. Joshi *et al.*, (2015) documented in their study that the oral route was mostly preferred for administering drugs in the pediatric population. The oral route is the most convenient way of administering medications in children.<sup>29</sup>

## CONCLUSION

Most parameters studied were from the WHO guidelines and WHO rational use of prescribing indicators optimal range. The majority of the patients were offered symptomatic treatment. However, one-third of the prescriptions had one or other antibiotic without documentation of clinical or lab evidence of bacterial infection and five prescriptions also had two antibiotics. To contain the growing menace of AMR, it is recommended to educate beginners regarding Antimicrobial Stewardship programs and National Action Plan on Antimicrobial Resistance (NAP-AMR) guidelines in healthcare institutes to help prescribers to observe rational drug therapy.

## Highlights

The study evaluated drug utilization in pediatric outpatients with Upper Respiratory Tract Infections (URTI), a common cause of childhood morbidity and pediatrician visits.

The study analyzed 153 prescriptions and found that antipyretics and antihistamines were the most commonly prescribed medications for URTI management. Amoxiclav and Cefixime were the most frequently prescribed antibiotics.

Most URTI cases were caused by viruses and required symptomatic treatment. However, many prescriptions included antibiotics, highlighting the need for appropriate antibiotic practices.

The study revealed that many prescriptions included antibiotics without clear evidence of bacterial infection, highlighting the need for rational drug therapy. Implementing Antimicrobial Stewardship programs and following the National Action Plan on Antimicrobial Resistance (NAP-AMR) guidelines can enhance prescribing practices and combat antimicrobial resistance.

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## AUTHOR CONTRIBUTIONS

RR and RKM conceived the study. RR, RKM, R, SB, TS and AKS were involved in protocol writing, database search, article screening and final draft preparation. SB, RR and RKM were responsible for article screening till the writing of the final draft. TS, RJ and SB were consulted for the critical revision of the manuscript to resolve any discrepancies. Finally, all the authors read and approved the final manuscript.

## ETHICS STATEMENT

The Institutional Ethical Committee (IEC) was approved by the Maharishi Markandeshwar Institute of Medical Science and Research Hospital, Mullana, Ambala, Haryana. [Project No.: IEC-2344].

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## ABBREVIATIONS

**AMR:** Antimicrobial Resistance; **DUE:** Drug Utilization Evaluation; **GAS:** Group A Streptococci; **IP:** Inpatient; **NAP-AMR:** National Action Plan on Antimicrobial Resistance; **OP:** Outpatient; **OPD:** Outpatient Department; **SIF:** Soy Isoflavone; **URTI:** Upper Respiratory Tract Infection; **WHO:** World Health Organization; **17BE2:** 17-Beta Estradiol.

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