



## Personal Formulary for Otitis Media Developed by Residents of Pharmacology

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### ABSTRACT

**Background:** The choice of antibiotics is not always carefully made as it is often based on previous experience or promotional campaigns by pharmaceutical companies. To bring order to the crisis and reduce the availability of hospital-based drugs to those who are most needed and effective in their field, P-Drug development is needed. The purpose of personal design is to promote safe, effective, and economical decision-making.

**Aim:** To develop personal formulary for otitis media.

**Materials and Method:** Residents were taught about how to analyze and give score ( $\alpha$ ) to drugs used for otitis media available in market. Four parameters according to P-drug concept of Joshi and Jayawick Ramarajah, efficacy (0.4), safety (0.3), cost (0.2) and convenience (0.1) was taken into consideration for each group and their drugs. Scores was given to each four parameters from 1 to 10 for each drug. Each parameter was given a fractional numerical rating ( $\beta$ ) according to the importance i.e. 0.4 for efficacy, 0.3 for safety, 0.2 for cost and 0.1 for convenience.

**Results:** Taking all of above factors in consideration, penicillin group has got highest total score and was chosen the most suitable group for making personal formulary of otitis media. Two drugs (ampicillin & amoxicillin) are commonly prescribed for otitis media. Among ampicillin and amoxicillin, amoxicillin has good oral absorption and less G.I side effects, so amoxicillin got higher efficacy and safety points. Adding clavulanate to amoxicillin increases the efficacy of amoxicillin and also augments its action against penicillinase producing bacteria without adding any additional adverse effects. So, amoxicillin + clavulanate has highest efficacy points with same safety point of amoxicillin.

**Conclusion:** We have noticed significant improvement in attitude and skills of residents after this project. The whole exercise will be helpful in promoting rational use of medicines by students in their future career as doctors.

**Keywords:** P-Drug, Efficacy, Safety, Cost, Convenience.

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### INTRODUCTION

Otitis media is one of the most common diseases in children where antimicrobials are prescribed. However, the physician must address many important questions about the proper management of acute otitis media (AOM), and there are differences of opinion among the medical community on a number of important issues. The purpose of this statement is to address the many controversial questions related to AOM's antimicrobial administration and to present a view of each consensus. It should be emphasized that much remains to be learned about the management of this

common childhood disorder and that further research may authorize a review of these ideas in the near future; these recommendations, therefore, should be taken as temporary and based on the current 'state of the art'.

For the purpose of this paper, AOM is defined as a sudden onset of middle ear inflammation associated with effusion and one or more of the following: pain, fever and irritability. Diagnosis should be established by careful examination with pneumatic otoscopy.

Experimental studies to find out if antibiotic treatment affects the effect of AOM have been difficult to interpret due to the high rate of spontaneous recovery in infected children.<sup>1</sup> Antimicrobial therapy is one of the cornerstones in the management of AOM but some studies have suggested that its common use is not indicated.<sup>2-4</sup> However, in the preantibiotic period, AOM complications such as mastoiditis were more common than today;<sup>5,6</sup> this difference may be due to the current general use of antibiotics. A recent meta-analysis of 5400 children with AOM showed that antimicrobial treatment improved



'primary control' by 13.7% even though it was automatically detected in 81% of cases.<sup>1</sup> Because it is probably not possible to determine a priori which AOM cases will lead to retaliatory problems, similarly it is not possible to determine which cases require antimicrobial treatment and will be resolved automatically. Therefore, it would seem prudent to consider all cases of people seeking antimicrobial treatment to reduce the risk of complications.

The three most commonly recovered bacteria associated with otitis media are *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*, which are all commensal within the nasopharynx; most *H. influenzae* isolated is non-typeable.<sup>7-9</sup>

However, the choice of antibiotics is not always carefully made as it is often based on previous experience or promotional campaigns by pharmaceutical companies.<sup>10,11</sup> To bring order to the crisis and reduce the availability of hospital-based drugs to those who are most needed and effective in their field, P-Drug development is needed. The purpose of personal design is to promote safe, effective, and economical decision-making.

A personal formulary is an effective extension of the personal concept of drugs, described in part 2 of the WHO "Guide to Good Prescribing". Essential drug use.<sup>12</sup> In 2001, the 'Teachers' Guide to Good Prescribing' was developed as a companion volume to help medical educators use the 'Guide to Good Prescribing' in teaching. Since Education is the cornerstone. It is a way of guiding students on treatment and exposure to the process of making consecutive decisions to develop descriptive skills.<sup>13</sup>

## MATERIALS AND METHODS

This study was carried out in the Department of Pharmacology, IGIMS, Patna among the residents of department of pharmacology.

Personal formulary for antibiotic therapy of otitis media was developed by using various standard text books, journals available in the library and on internet. Current Index of Medical Specialties (CIMS) was used to determine cost of drugs.<sup>14</sup> Residents were taught about how to analyze and give score ( $\alpha$ ) to drugs used for otitis media available in market. Four parameters according to P-drug concept of Joshi and Jayawick Ramarajah,<sup>15</sup> efficacy (0.4), safety (0.3), cost (0.2) and convenience (0.1) was taken into consideration for each group and their drugs.

1. **Efficacy** was derived according to the efficacy profile written in standard text books. Drug with more efficacy were given higher score.
2. **Safety** of a drug were described according to the side effect profile written in standard text books. Drug with more side effects were given lower score.
3. **Cost** was compared by taking average of costs of different brands written in Current Index of Medical Specialties (CIMS).
4. **Convenience** was compared according to the availability of drug, dosage form, dosage schedule, route of administration.<sup>16,17</sup>

Scores was given to each four parameters from 1 to 10 for each drug. Each parameter was given a fractional numerical rating ( $\beta$ ) according to the importance i.e. 0.4 for efficacy, 0.3 for safety, 0.2 for cost and 0.1 for convenience. Score ( $\alpha$ ) was multiplied by fractional numerical rating ( $\beta$ ) to get total score ( $\gamma = \alpha \times \beta$ ). Higher total score indicates a better value. The drug with the highest score became the personal drug choice. Then the senior residents and postgraduate kept a copy of personal drug description as a personal formulary.<sup>15-19</sup>

## RESULTS

**Table 1:** Selection of Personal Formulary from Drug Groups for Otitis Media

Drug/Drug Group	Efficacy (0.4)	Safety (0.3)	Cost (0.2)	Convenience (0.1)	Total
1. Penicillin	8 (3.2)	9 (2.7)	8 (1.6)	9 (0.9)	8.4
2. Macrolides	8 (3.2)	7 (2.1)	7 (1.4)	9 (0.9)	7.6
3. Cephalosporins	9 (3.6)	8 (2.4)	6 (1.2)	7 (0.9)	8.1
4. Cotrimoxazole	7 (2.8)	6 (1.8)	10 (2.0)	8 (0.8)	7.4

**Table 2:** Selection of Personal Drug among Penicillin

Drug/Drug Group	Efficacy (0.4)	Safety (0.3)	Cost (0.2)	Convenience (0.1)	Total
Ampicillin	7 (2.8)	8 (2.4)	9 (1.8)	8 (0.8)	7.8
Amoxicillin	8 (3.2)	9 (2.7)	8 (1.6)	9 (0.9)	8.4
Amoxicillin + Clavulanate	9 (3.6)	9 (2.7)	7 (1.4)	9 (0.9)	8.6



**Table 3:** Cost of drug/drug group available in India used in Treatment of Otitis Media

Drug/Drug Group	Dose	No of Brands	Average Cost for lowest dose for course of treatment
<b>1. Penicillin</b>			
a. Ampicillin	500 mg BD	9	71.41
b. Amoxicillin	500 mg TDS	36	141.74
c. Amoxicillin +Clavulanate	500 mg + 125mg TDS	97	350.07
Total Average			187.74
<b>2. Cephalosporins</b>			
a. Cefaclor	250 mg TDS	3	590.81
b. Cefdinir	300 mg BD	9	414.09
c. Cefixime	200 mg BD	74	118.97
d. Cefpodoxime	100 mg BD	61	154.89
e. Cefprozil	250 mg BD	3	574.86
f. Ceftriaxone	1 g BD	56	1017.10
g. Cefuroxime	250 mg BD	48	320.18
Total Average			455.84
<b>3. Macrolide</b>			
a. Clarithromycin	250 mg BD	18	297.78
b. Erythromycin	500 mg QID	4	142.83
c. Azithromycin	500 mg OD	84	163.59
Total Average			201.4
4. Cotrimoxazole	800 mg + 160 mg BD	5	33.88

**Table 4:** Description of Amoxycillin + Clavulanate as Personal Formulary Otitis Media

Tablet 625 mg	Otitis Media	Amoxycillin + Clavulanate
<b>DOSAGE</b>		
<b>Otitis Media:</b> In adults 625 mg TDS for 7 Days.		
<b>WHAT TO TELL THE PATIENT</b>		
<b>Information:</b> Amoxycillin + Clavulanate is effective against causative organism.		
<b>Side effect:</b> Rash, Exfoliative Dermatitis, Allergic Reaction.		
<b>Contraindication:</b> Hypersensitivity to penicillin, With Allopurinol.		
<b>Instruction:</b>		
Take Tab. Amoxycillin + Clavulanate 625 mg TDS per day for 7 days.		
<b>Next appointment:</b> Review after 7 days.		
<b>Follow up:</b> Review after 7 days.		

## DISCUSSION

Rational drug use (RUD) involves that patients should receive the medication that suits their clinical needs, the right dose and duration, at the lowest possible cost to them and their community.<sup>20, 21</sup> The above requirements will be met by the WHO to Good Prescribing Guide which provides medical students with a standard model of medical consultation and placement and provides a six-step guide to the rational decision-making process: (1) describe the patient's problem, select (medicine), (4) write a prescription and start treatment, (5) provide details with the patient's patients, and (6) monitor treatment. One of the key

principles of the WHO approach is the division of step 3 into two steps; that is, Step 3a, consider the suitability of a standard p-drug for the treatment of the disease in general, and step 3b, verify its suitability for a particular patient and change the medication if necessary.

As a result, PG students, who as educators teach undergraduate students to practice standardized treatment for common disorders and develop a set of personalized methods using National and international treatment guidelines, formulas, textbooks and other drug information sources. The emphasis is on future physicians should understand both the steps of the drug selection process,



which is to ensure the suitability and modification of the drug for individual treatment.<sup>22</sup>

PG students taught about the concept of P drugs. Students did this work in their groups using diagnostic, therapeutic costs using Current index of medical specialties (CIMS) and textbooks available from the college and the department's library. The students worked on the project and presented their findings. The presentation was followed by a discussion. For anxiety disorders, each of these four methods was rated between 0 and 1 and was divided by looking at performance as the most important parameter given 0.4 points, safety 0.3, cost 0.2, and ease of use of 0.1. They then determined the drug / drug group using a standard textbook.<sup>23</sup>

Four groups of drugs (penicillin, cephalosporins, macrolide & cotrimoxazole) are routinely prescribed for anti-microbial therapy of otitis media. Most of the causative organisms have acquired resistance against sulfonamides<sup>24</sup>, so cotrimoxazole was given least score in efficacy (7). Macrolides and penicillin are active against most of the bacteria causing otitis media<sup>25</sup> but are not so effective in severe infection, so they are given score of 8 in efficacy. Higher generation cephalosporins have broader spectrum of activity<sup>26</sup>, so they are given highest score (9) regarding efficacy.

All adverse effects seen with sulfonamides can be produced by cotrimoxazole. Nausea, vomiting, stomatitis, headache and rashes are the usual manifestations. Folate deficiency (megaloblastic anemia) is infrequent, occurs only in patients with marginal folate levels. Blood dyscrasias occur rarely<sup>27</sup>. So, cotrimoxazole was given least safety points (6). Macrolide also cause some gastrointestinal disturbance<sup>28</sup>, so 7 safety points are given to this group. Beta-Lactams are generally safe in patients who doesn't show allergic reaction to these drugs, so they are given highest safety points (9).

Cotrimoxazole was found to be cheapest option for treatment of otitis media. So, it was given highest point in cost (10). Higher generation cephalosporins tends to be costlier, so this group has got least score (7).

Some drugs in cephalosporins groups are injectables, so they are given least score in convenience (7). Macrolides and amino-penicillin are generally given orally, so they got highest score in convenience (9).

Taking all of above factors in consideration, penicillin group has got highest total score and was chosen the most suitable group for making personal formulary of otitis media. Two drugs (ampicillin & amoxicillin) are commonly prescribed for otitis media.

Among ampicillin and amoxicillin, amoxicillin has good oral absorption and less G.I side effects<sup>29</sup>, so amoxicillin got higher efficacy and safety points. Adding clavulanate to amoxicillin increases the efficacy of amoxicillin and also augments its action against penicillinase producing bacteria without adding any additional adverse effects. So,

amoxicillin + clavulanate has highest efficacy points with same safety point of amoxicillin.

Amoxicillin + clavulanate covers all the three major causing micro-organisms viz. streptococcus pneumoniae, haemophilus influenzae and moraxella catarrhalis.<sup>7, 8, 9</sup>

Although amoxicillin + clavulanate was bit costlier. But, it has got highest total score and it was selected as our P-drug.

## CONCLUSION

Taking efficacy, safety, cost & convenience for selecting p-drug for otitis media and giving more weightage to efficacy followed by safety, cost & convenience, amoxicillin + clavulanate was chosen as p-drug for empirical antibiotic therapy of acute otitis media. We have noticed significant improvement in attitude and skills of residents after this project. Students can develop personal formulary after proper discussion and have know-how to prescribe rather than what to prescribe which is the goal of WHO. The whole exercise will be helpful in promoting rational use of medicines by students in their future career as doctors.

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