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ORIGINAL ARTICLE

Prospective Drug Utilization Evaluation Analysis in Outpatient Departments with Ear, Nose, and Throat Outpatients: Incorporating Benchmarks and World Health Organization Indicators

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ABSTRACT

Objectives: Drug utilization studies are tools for determining the effectiveness of drug use. The aim of the study was to evaluate drug usage patterns in ear, nose, and throat (ENT) outpatient settings by incorporating established benchmarks and World Health Organization (WHO) indicators.

Materials and Methods: A cross-sectional study on drug utilization evaluation (DUE) was conducted on 800 patients from the ENT outpatient department. We gathered data on currently prescribed medications and identified any discrepancies with a thorough analysis. Continuing educational activities such as "dear doctor" letters and personal consultations were used to rectify any irrational prescribing patterns among physicians. The WHO/International Network for Rational Use of Drugs core drug use indicators, specifically prescribing and patient care indicators, and established benchmarks were applied to encourage rational prescribing.

Results: The three most common diagnoses were pharyngitis (51.49%), allergic rhinitis (25.11%), and acute suppurative otitis media (21.17%). Montelukast, in combination with levocetirizine (13.77%) and amoxicillin in combination with clavulanic acid (8.81%), was the most frequently prescribed medication. The average number of drugs per prescription was 4.2% (±1.1), with low usage of generic names (33.0%) and suboptimal reliance on the essential drugs list (76.7%). Furthermore, patient care indicators demonstrated room for improvement, particularly concerning consultation times (6 minutes), dispensing times (30 seconds), and drug labeling practices (0% labeled). The DUE improved the prescribing rate of first-line drugs for five diseases and few aspects of prescribing and patient care indicators.

Conclusion: There is an overuse of prescribed drugs, a need for more utilization of generic names, and less than optimal use of the essential drugs list. Additionally, shortcomings in patient care were observed, including issues in consultation, drug dispensing times, and labeling. However, DUE effectively improved WHO patient care metrics and the prescription of first-line drugs warranting its implementation.

Keywords: Drug utilization evaluation, World Health Organization, amoxicillin, suppurative otitis media, benchmarking, montelukast

INTRODUCTION

Drug utilization evaluation (DUE) aims to promote appropriate drug utilization through continuous, authorized, and systematic quality improvement processes, including reviewing prescriptions, providing clinicians feedback, developing optimal drug use standards, and educating patients to optimize therapeutic benefits and reduce adverse effects.[1] The doctor of Pharmacy (PharmD) students' experiences offer the invaluable opportunity to observe and understand the complex aspects of healthcare in real-world settings. A noticeable lack of first-line drug prescriptions was observed during a visit to the ear, nose, and throat (ENT) outpatient department (OPD).

A literature review on DUE within ENT OPDs revealed a significant research gap. Previous studies[1-12] have not included post-DUE analysis, an essential part of the DUE process. These studies did not employ the World Health Organization (WHO)/

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International Network for Rational Use of Drugs (INRUD) patient care indicators.[13] These indicators provide a comprehensive framework for assessing rational drug use and monitoring the performance of health systems.[13] Therefore, our study aimed to evaluate drug usage patterns in ENT outpatient settings by incorporating established benchmarks and WHO/INRUD core drug use indicators.

MATERIALS AND METHODS

Study design and setting

A cross-sectional study with intervention to improve drug prescribing using established benchmarks was conducted in the ENT OPD. The study duration was six months (November 2022 to April 2023).

Study participants and sampling technique

We included outpatients visiting the ENT department aged <65, whereas patients with comorbidities, severe ailments, and elderly were excluded. A combination of convenience and purposive sampling methods was used to select participants.

Sample size

The sample size was calculated using the Roasoft sample size calculator with a 5% margin of error and 95% confidence level. The recommended sample size is 377 for a population size of 20,000 members.

Data collection

Demographic data, including age, sex, weight, area of residence, occupation, and marital status, were collected from the patients. Patients' past medication history, current medication, history of the present illness, and diagnosis were collected.

Prescription analysis

We used WHO/INRUD core drug use indicators, namely prescribing and patient care indicators. Prescribing indicators will assess medication prescribing patterns, whereas patient care indicators evaluate the quality of care delivered to patients.[13] These indicators will help to evaluate the hospital's support in promoting rational drug use.

Benchmark set-up

We established a benchmark of 90% for increasing the prescription rate of first-line drugs. We conducted a one-month follow-up to monitor the progress.

Interventions to promote the prescribing rate of first-line drugs

Dear Doctor letter

A "Dear Doctor" letter, or a "Dear Healthcare Professional" letter, is a written communication typically sent by a researcher, pharmaceutical company, medical device manufacturer or regulatory authority to healthcare professionals, including doctors, nurses and pharmacists. The purpose of a Dear Doctor letter is to provide important information about a product or medication, such as new safety concerns, updated prescribing guidelines and recalls. These letters are typically used to inform healthcare professionals about significant changes or new findings related to a particular drug or medical device. The letter aims to ensure that healthcare professionals are aware of important updates and can take appropriate action to ensure patient safety.[14]

Personal consultation with the treating physicians

Personal consultations are essential to effective healthcare communication, offering clarity and depth to treatment guidelines. Facilitate information exchange, resolve doubts, and provide context-specific advice that may not be fully conveyed through written communication. Such consultations address individual queries, present real-life cases, discuss potential obstacles, and provide specific guidance. They supplement written communication by reinforcing its content and offering continual support. Personal consultations are integral to a comprehensive and personalized educational experience in healthcare, promoting understanding and support.

Statistical analysis

We calculated the mean and standard deviation or median and interquartile range (whichever is appropriate) for quantitative data. We calculated frequencies and percentages for qualitative data.

Ethical approval

The study was approved by the Institutional Human Ethics Committee (approval number: VIPT/IEC/159/2022, date: 20.10.2022). We obtained written informed consent from the participants who were willing to participate.

RESULTS

Table 1 represents the most common diagnoses of ENT OPD. Ear-related conditions primarily comprised acute suppurative otitis media (ASOM) (21.17%), impacted ear wax (20.39%), and chronic suppurative otitis media (CSOM) (17.25%). Nose-related diagnoses were allergic rhinitis (25.11%), upper respiratory tract infections (17.94%), sinusitis (17.48%), and rhinosinusitis (16.14%). Throat conditions were predominantly pharyngitis (51.49%), with tonsillitis (19.15%) and adenotonsillitis (18.30%).

Table 2 shows the most commonly prescribed drugs for ENT patients in our study. Montelukast combined with levocetirizine appears to be the most commonly prescribed drug, accounting for 13.77% of all prescriptions, followed by amoxicillin and clavulanic acid (8.81%). There is a high level of levocetirizine, both in combination with other drugs and as a standalone treatment.

Table 3 outlines the WHO/INRUD prescribing indicators. The average number of drugs prescribed per prescription was 4.2%, in contrast to the WHO reference value of less than 2%. Similarly, the percentage of drugs prescribed by generic names was 33.0%, notably lower than the WHO's ideal standard of 100%. Regarding encounters with an antibiotic prescribed, the percentage was 17.5%, which remained within the acceptable range set by the WHO of 30%. The percentage of encounters with an injection prescribed was 0%, significantly lower than the WHO benchmark of 20%. Moreover, the percentage of drugs prescribed by the Essential Drug List (EDL) was 76.7%, less than the WHO reference value of 100%.

Table 1. Distribution of diagnoses in the OPD

ENT	Diagnoses	n (%)
Ear-related disease	ASOM[a]	54 (21.17)
	Impacted ear wax	52 (20.39)
	CSOM[b]	44 (17.25)
	Otomycosis	29 (11.37)
	Otitis externa	20 (7.84)
	Others	56 (21.9)
Nose-related disease	Allergic rhinitis	56 (25.11)
	URTI[c]	40 (17.94)
	Sinusitis	39 (17.48)
	Rhinosinusitis	36 (16.14)
	Post-op FESS[d]	26 (11.66)
	Epistaxis	9 (4.04)
	Others	17 (7.62)
Throat-related disease	Pharyngitis	121 (51.49)
	Tonsillitis	45 (19.15)
	Adenotonsillitis	43 (18.30)
	Tonsillopharyngitis	10 (4.26)
	Others	16 (6.80)

[a]ASOM: Acute suppurative otitis media, [b]CSOM: Chronic Suppurative Otitis Media, [c]URTI: Upper respiratory tract infection, [d]FESS: Functional endoscopic sinus surgery, OPD: Outpatient department, ENT: Ear, nose, and throat

Table 2. The most commonly prescribed ENT-related drugs during the study

Commonly prescribed drugs	Frequency	%
Montelukast + Levocetirizine	469	13.77
Amoxicillin + Clavulanic acid	300	8.81
Levocetirizine	117	3.44
Sodium chloride nasal drops	96	2.82
Azelastine + fluticasone nasal spray	91	2.67
Ambroxol + Levocetirizine + Montelukast	72	2.12
Xylometazoline nasal drops	70	2.06
Ciprofloxacin	61	1.79
Paradichlorobenzene + Chlorbutol + Turpentine oil + Lidocaine ear drops	53	1.56
Levodropropizine + Chlorpheniramine maleate	53	1.56
Others Pantoprazole	500	14.68
Acetaminophen	350	10.28
Thiamine, riboflavin, niacin, pyridoxine, pyridoxal, biotin, pantothenic acid, folic acid, and vitamin B12	219	6.43

Investigating WHO patient care indicators (Table 4) yielded some significant findings. The average consultation time was six minutes, considerably shorter than the WHO reference value of 30 minutes or more. The average dispensing time was 30 seconds, significantly below the WHO-recommended minimum of 60 seconds. Regarding medication-related indicators, the percentage of drugs dispensed was 95.6%, slightly below the WHO standard of 100%. The study found that none of the drugs were adequately labeled, in stark contrast to the WHO reference value of 100%.

Table 5 illustrates the influence of DUE on first-line drug prescriptions for various ENT diseases assessed one month after DUE. The percentage of first-line drug prescriptions for sinusitis increased from 53.4% to 81.9%. Similarly, the rate of first-line drugs used for pharyngitis increased from 43.8% to 82.7%. For patients diagnosed with ASOM, the percentage of first-line drug prescriptions increased from 55.6% to 80.6%, whereas the percentage of first-line drugs prescribed for CSOM increased from 47.8% to 87.4%. For otitis externa, an increase from 45.0% to 84.2% was noted. Table 6 shows an improvement in a few aspects of WHO/INRUD prescribing and patient-care indicators. There was an increase in the percentage of drugs prescribed generically (33.0% to 45.3%) and those from the EDL (76.6% to 82.1%). The average consultation time improved slightly from 6 to 7 minutes.

Table 3. WHO/INRUD prescribing indicators

Indicator	Percentage prescription	WHO reference values
Average number of drugs prescribed per prescription	4.2%	< 2%
Percentage of drugs prescribed according to generic names	33.0%	100%
Percentage of encounters with antibiotic-prescribed drugs	17.5%	< 30%
Percentage of encounters with prescribed injections	0%	< 20%
Percentage of drugs prescribed by EDL*	76.7%	100%

*EDL: Essential drugs list, WHO: World Health Organization

Table 4. WHO/INRUD patient care indicators

Indicator	Frequency/ percentage	WHO reference value
Average consultation time (in minutes)	6 minutes	≥ 30 minutes
Average dispensing time (in seconds)	30 seconds	≥ 60 seconds
Percentage of drugs dispensed	95.6%	100%
Percentage of adequately labeled drugs	0%	100%

Table 5. Improvement in prescribing rate of first-line drugs post-DUE analysis

Disease	Baseline percentage of prescribed drugs	DUE impact on prescribed drugs after 1 month
	Percentage of first-line drugs	Percentage of first-line drugs
Sinusitis	53.4	81.9
Pharyngitis	43.8	82.7
ASOM[b]	55.6	80.6
Otitis externa	45.0	84.2
CSOM[c]	47.8	87.4

[a]DUE: Drug utilization evaluation, [b]ASOM: Acute suppurative otitis media, [c]CSOM: Chronic suppurative otitis media

Table 6. Impact of DUE on WHO core prescribing and patient care indicators

WHO core indicators	Baseline	Post DUE
Prescribing indicators		
Percentage of drugs prescribed by generic name	33.0%	45.3%
Percentage of drugs prescribed by EDL	76.6%	82.1%
Patient care indicator		
Average consultation time (in minutes)	6 minutes	7 minutes

DISCUSSION

Key results

Our study evaluated the prevalence of ENT diseases, identifying ASOM, allergic rhinitis, and pharyngitis as the most common, whereas Otitis externa, epistaxis, and tonsillopharyngitis were the least frequent. A combination of montelukast and levocetirizine was prescribed, with amoxicillin clavulanic acid as the most commonly used antimicrobial agent. However, the study identified concerns regarding prescription practices, including a high mean number of medicines prescribed, limited use of generic names and subpar reliance on the EDL. Additionally, the findings indicated potential areas for improvement in patient care, particularly consultation and dispensing times and drug labeling practices. This study underscores the need to enhance these practices to optimize patient care and safety in treating ENT diseases.

The study's findings align with and differ from previous research, demonstrating the impact of regional environmental factors. ASOM was identified as the most common ear condition, while otitis externa was the least common, a trend similar to one study.[5] Regarding nasal disorders, allergic rhinitis was the most prevalent, and epistaxis was the least frequent, consistent with findings in other research[15] and reflective of region-specific allergens. Among throat conditions, pharyngitis was the most frequent, while tonsillopharyngitis had the lowest prevalence, showing some variation from other studies.[5,16] These variations underscore the importance of considering local factors in evaluating ENT conditions.

Our study revealed a high prevalence of the combination of montelukast and levocetirizine, contrasting with findings from other studies. One study demonstrated that antimicrobials were the most frequently prescribed drugs, a notable difference from the current findings.[17] Another study reported levocetirizine as the most commonly prescribed single drug, and this study similarly observed a high prescription rate for it, often combined with montelukast.[6] This suggests a regional preference for combination therapy. Additionally, some research found non-steroidal anti-inflammatory drugs to be the most frequently prescribed drugs, highlighting possible variations due to differences in prevalent conditions or prescribing habits among the study populations.[1]

The study identified amoxicillin-clavulanic acid as the most frequently prescribed antimicrobial agent, accounting for 8.81% of all drug prescriptions. This finding aligns with previous research,[7,18] reinforcing the reliability of the results. However, a contrasting outcome was observed in another study,[19] where cefpodoxime and clavulanic acid were the most commonly prescribed antibiotics. This variation may reflect differences in prescription patterns influenced by several factors, including patient needs, physician preferences, antibiotic availability, and local microbial resistance patterns.

Research has highlighted the prevalence of specific pathogens in ENT infections. Analysis of bacterial samples from patients with these infections shows that the predominant organisms are *Streptococcus* spp., including *Streptococcus pneumoniae*, *Staphylococcus* spp., and *Haemophilus influenzae*.[20] These microorganisms are generally susceptible to amoxicillin, supporting its use in current prescribing practices.[21] Consequently, amoxicillin is widely recognized as the primary treatment for most ENT infections requiring antibiotic therapy, consistent with findings from other studies.[22] This study thus provides valuable insights into effective management strategies for ENT infections, adding to existing literature on the topic.

Using WHO/INRUD core drug use indicators, this study assessed rational drug use, finding that a total of 3,405 drugs were prescribed, with an average of 4.2 (±1.1) drugs per prescription. This average was lower than other studies, such as those reporting higher values,[23,24] but it still exceeded the benchmark recommendation of fewer than two drugs per prescription. The observed average reflects a balanced approach to drug therapy, aiming to minimize polypharmacy, defined as using more than five drugs[25] to help reduce healthcare costs, improve patient adherence, and lower the risk of adverse drug events. The association between the number of prescribed drugs and an increased risk of drug interactions highlights the importance of reducing prescription quantities to improve patient outcomes and healthcare efficiency.[17,26]

Only 33% of medications were prescribed using generic names, while most were issued as brand names, a trend higher than observed in other studies.[2] Prescribing generic drugs could significantly reduce therapy costs and minimize the risk of medication errors. Healthcare providers need to focus on prescribing generics. Additionally, they should prioritize

clear and legible handwriting or adopt electronic prescribing systems to ensure the highest safety and quality standards in medication administration.[27] Similar findings were observed in studies showing a strong preference for brand names over generics in prescriptions.[7]

The study reported a lower rate of antibiotic usage (17.5%) compared to prior research.[5,6] This could be due to the high prevalence of self-limiting viral infections, with antibiotics prescribed only for severe cases.[22] Notably, the study did not use injections, significantly below the WHO reference of less than 20%. This finding is consistent with previous studies[3,6] and may be attributed to the focus on OPD patients or increased physician awareness about the potential adverse effects of overusing injections. Additionally, 76.7% of prescriptions in the study included drugs from the EDL, which is higher than in previous studies.[17,23,28] This reflects a growing acceptance of essential medicines, which promote health equity and cost-effectiveness.[29] However, there is still room for improvement in optimizing EDL utilization.

The study also incorporated patient care indicators as defined by the WHO/INRUD, offering valuable insights into various aspects of healthcare services. Previous studies on drug utilization in the OPD for ENT have not used these indicators, and by applying them in this context, the study provided new insights into drug use in this specialized area of healthcare. Our investigation reported a brief six-minute average consultation time, significantly lower than the WHO/INRUD recommended 30 minutes, likely due to high patient-to-doctor ratios and multiple responsibilities in OPD settings, especially in teaching hospitals. Although a half-hour consultation might be impractical, there is scope for a moderate increase in the duration.

Our study recorded an average dispensing time of merely 30 seconds, significantly less than the WHO/INRUD recommended minimum duration of 60 seconds. This marked deviation might indicate the existence of time constraints in the medication dispensing process, potentially increasing the risk of errors or contributing to inadequate patient understanding of their medication regimen and management. Our study revealed 95.6% of prescribed medications were successfully dispensed to patients. Although this percentage is slightly less than the WHO/INRUD perfect benchmark of 100%, it nevertheless signifies a remarkable achievement in efficiently dispensing medication. Such an accomplishment sets a robust platform for future endeavors to align fully with the WHO's ideal standards, promoting enhanced patient satisfaction and enriched health outcomes in the healthcare system.

Our research identified a stark deficiency in drug labeling, with an alarming 0% compliance with WHO guidelines, which mandate the inclusion of dosage regimens, patient names, and drug dosage.[30] The absence of critical information poses substantial risks to patients, possibly causing usage or dosage mistakes, thereby affecting safety and treatment outcomes. These findings highlight the need for substantial improvements in consultation, dispensing, and labeling processes.

Amoxicillin is the primary medication for sinusitis, pharyngitis, and ASOM. The American Academy of Otolaryngology's updated 2015 guidelines for adult sinusitis also recommend amoxicillin, with or without clavulanate, as the first-line therapy for most adults for 5-10 days.[31] Similarly, penicillin or amoxicillin is the treatment of choice for pharyngitis, particularly in cases caused by group A *streptococcus*.[35] For acute otitis media, a typical middle ear infection, amoxicillin is the drug of choice.[34] These recommendations highlight the efficacy of amoxicillin for managing a range of ENT conditions.

Current treatment guidelines emphasize topical antibiotics as the preferred choice for otitis externa.[36] These guidelines also recommend a combination of topical antibiotics with steroids and pain medications as the first-line treatment. Oral antibiotics have been found to lack substantial evidence of benefits. Undoubtedly, their misuse may increase resistance among common otitis externa pathogens, leading to more complicated treatment in the future.[32] Topical quinolones are the preferred treatment for persistent ear conditions such as CSOM.[33] Post-implementation of continuing education programs improved the prescribing of first-line drugs for five different diseases. Furthermore, a few aspects of prescribing and patient care indicators increased slightly. Continuing education is pivotal in improving medical practices, promoting more informed, rational decision-making, and optimizing patient treatment strategies.

Study limitations

The strength of our study was implementing a one-month post-DUE analysis and including interventions that improve the prescribing patterns of first-line drugs. Another strength of the study is evaluating WHO/INRUD patient-care indicators to evaluate the quality of care delivered to the patients. Despite providing valuable insights, our study has a few limitations, such as chances of selection bias due to convenience and purposive sampling, a single-centre design restricts the generalizability of the findings to other settings, and a short one-month follow-up may not capture the long-term effects.

Recommendations and scope of further research

Healthcare professionals should update the information on prescribing practices for ENT diseases and should use generic drug names while prescribing. A need for an increase in consultation and dispensing times should be addressed. Future studies should include post-DUE analysis over longer intervals. This approach will help identify discrepancies in prescribing practices and enable timely corrections.

CONCLUSION

The study identified a few discrepancies through post-DUE analysis. The study interventions: "dear doctor" letters and "personal consultations" improved the prescribing rate of first-line drugs. There is a need to conduct post-DUE analysis in DUE studies by establishing benchmarks and including appropriate interventions to improve prescribing rates of first-line drugs.

Ethics

Ethics Committee Approval: The study was approved by the Institutional Human Ethics Committee (approval number: VIPT/IEC/159/2022, date: 20.10.2022).

Informed Consent: A written informed consent was obtained.

Authorship Contributions:

Concept: V.M., Design: V.M., Data Collection and Processing: B.J., B.K.K., B.S.P., A.P., Analysis or Interpretation: V.M., B.J., B.K.K., B.S.P., A.P., Literature Search: V.M., B.J., B.K.K., B.S.P., A.P., Writing: V.M., B.J., B.K.K., B.S.P., A.P.

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