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A PROSPECTIVE OBSERVATIONAL STUDY TO ASSESS AND EVALUATE EFFECTS OF POLYPHARMACY IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Background: Polypharmacy is the use of an excessive number of medications in the same time period or the simultaneous administration of several medications. Using several drugs can lead to potential issues such drug interactions, unpleasant drug responses, decline in medication adherence, unnecessary prescription costs, and an increase in inappropriate medication use. **Aim:** This study aims to assess polypharmacy within a tertiary care teaching hospital using the MAI and Beer's criteria 2019. **Methodology:** A prospective observational study was conducted at multispecialty tertiary care teaching hospital for a period of six months, involving 100 patients. Clinical notes and medication charts were well documented and analyzed using MS Excel. **Results:** The mean age of the participants is 53.01, with male predominance (65%). A total of 1052 drugs were prescribed. In accordance with MAI criteria, 298 drugs were deemed inappropriate with the highest inappropriateness ranking in the indication. Based on Beer's criteria 2019, 58 (14.01) % of the 413 drugs prescribed to 41 older adults were PIMs. With the highest number of PIMs being 24 where caution is advised in older adults. The participants were greatly impacted by the patient counseling, which promoted the safe and efficient use of medication, which directly affects the participants' health. **Conclusion:** Upon analysis, MAI (28.3 %) was found to be more inappropriate than the Beer's Criteria 2019 (14.01%). A physician and a clinical pharmacist can reduce polypharmacy through interventions such as deprescribing, reducing dosages, increasing patient adherence, preventing adverse effects and interactions, and thus improving patient health.

KEYWORDS: Polypharmacy, MAI, Beers Criteria, Drug- drug interaction, Adverse drug reactions.

INTRODUCTION

Polypharmacy is defined by WHO as the administration of many drugs in the same time period, or the administration of an excessive number of drugs at one time. Older people who suffer from multiple conditions are more likely to have polypharmacy.[1] The BMC Geriatric article has provided a numerical definition of polypharmacy as the use of five or more medications daily.[2]

In elderly patients, it was reported that one half of them use at least five prescription and non-prescription medications, as well as nutritional supplements. As a result of using multiple medications, potential problems arise, such as drug interactions, adverse drug reactions, and a decrease in medication adherence, as well as unnecessary drug expenses, which result in poor prognosis and an increase in inappropriate medication use.[3]

In elderly, there is a complex interaction between physiologic reserves and functional status; as a result, the elderly are prone to having multiple chronic conditions; while treating multiple conditions, the clinician faces the challenge of polypharmacy since the patient may experience new symptoms through adverse drug effects or interactions from multiple medications.[1]

Pros and Cons of Polypharmacy

Pros: Higher response rates caused by synergistic interactions between several pathophysiologic mechanisms. It Could allow for a reduced dose without an increased intolerability risk. It is an optimal treatment option for a chronic disease.

Cons: ADR as well as drug-drug interactions may potentially escalate with polypharmacy. The complicated regimen's increased risk of self-withdrawal has a poor prognosis. An increase in expenses. Possibility for medication duplication.

Polypharmacy categories include

a) **Excessive polypharmacy:** Administering ten or more medications simultaneously.

b) **Polypharmacy:** Administering five to nine medications simultaneously**.**

c) **No Polypharmacy**: - Administration of less than four or no medication simultaneously.

Medication Appropriateness Index (MAI)

Medication Appropriateness Index was developed in 1992 by Hanlon J.T. Schmader K.E, et al based on ten criteria for assessing the appropriateness of prescribing medicine for elderly patients.[4] Nonetheless, the MAI was used in inpatient, long-term care settings since it was deemed to be reliable tool even in other age groups since the reliability studies do not show any statistically significant differences.[5]

According to the MAI, an evaluator must answer 10 questions about the drug which are not specific to the sign, symptom, drug or disease in order to determine whether or not the drug is appropriate.[6]According to MAI, there are three possible rating options: Appropriate, Marginally Appropriate, and Inappropriate.[7] An appropriate drug or one that is marginally inappropriate is given a score of 0.[5]An inappropriate drug is given a score of 1, 2 or 3 based on the MAI Criteria which it meets. A weight of 3 refers to the indication and effectiveness of the drug, while a weight of 2 refers to the dosage, direction, drug-drug interaction, and drug-disease interaction weights. A weight of 1 refers to apparent directionality and duplication of the drug, duration of therapy, and the cost of the drug.[7] Summative scores range from 0 to 18 with 0 representing appropriate and 18 representing maximally inappropriate.[5] If a patient is on multiple drugs, this test can be repeated for each drug in order to determine a total MAI score.

1 A medication's **indication** refers to the sign, symptom, disease, or condition for which it is prescribed.

2 Its **effectiveness** refers to whether the medication will produce the intended result.

3 A **dosage** is the total amount of medication consumed per day.

4 **Direction**s are instructions to the patient for how to take the medication; **Practicability** means that something can be put into practice.

5 **Drug-drug interaction** refers to the effects that the administration of one medicine has on another; clinical significance means that the interaction is harmful.

6 **Drug-disease interaction** refers to an effect of a drug on a pre-existing disease or condition; a drug-disease interaction that is clinically significant is harmful.

7 The **unnecessary** prescription of two or more drugs from the same chemical or pharmacological family which is neither beneficial nor safe.

8 **Duration**: the length of a treatment.

9 **Pricing**: cost of a drug in comparison with similar products that are equally effective and safe.[8]

This tool has been demonstrated to be feasible, content valid, predictive valid, and reliable in ambulatory settings, and its efficacy has been recommended in clinical settings.

Table No 1: MAI Criteria.

MAI Criteria	Value
Is there an indication for the drug?	3
Is the medication effective for the condition?	3
Is the dosage correct?	2
Is the direction correct?	2
Are there clinically significant drug-drug interactions?	2
Are there clinically significant drug-disease/condition interactions?	2
Are the directions practical?	1
Is there unnecessary duplication with other drug(s)?	1
Is the duration of therapy acceptable?	1
Is this drug the least expensive alternative compared to others of equal utility?	1

BEER'S Criteria 2019

Americans Geriatrics Society described Beer's Criteria as "A compendium of medications potentially to avoid or consider with caution because they present an unfavorable balance of benefits and harm for older adults."[9] Beer's Criteria is a crucial tool for giving quality of life treatment and clinical care that is effective. Dr. Mark Beer proposed a tool in 1991 that provides a list of drugs that are assessed to be inappropriate for long-term care facilities. It was intended to decrease improper prescribing, identify drugs or medication classes that should be avoided in older adults, and prevent adverse drug reactions (ADR). Since 2011, AGS has been in charge of updating the criteria every three years. The Beer's Criteria for PIM usage in older adults was revised by AGS in 2019. This update includes specific recommendations for a drug or class of drugs that older adults should avoid or use cautiously.

- 30 drugs or classes of drugs that most people should avoid.
- 40 drugs or classes of drugs that should be taken cautiously or avoided by those who have specific illnesses or conditions.

In order to monitor and enhance the care of older individuals, Beer's Criteria are largely utilized by healthcare professionals, researchers, and educators. The 2019 update includes medications that may be harmful for older adults, medications that could aggravate a condition or syndrome, medications that should be used cautiously, medications with clinically significant interactions, and medications whose doses should be avoided or lowered due to renal function.

The goal of the AGS Beer's Criteria is to examine the quality of treatment, costs, and patterns of drug use in older adults while also enhancing prescription selection, educating clinicians, and reduction of ADRs. These principles, together with clinical judgment, should only be used as a guide, not as a punishment. In some cases, it is impossible to avoid taking a certain medication indicated in the criteria, or the recommendation does not apply to a particular demographic. Therefore, when a drug is to be ceased, modified, or added, a physician should take into account variables specific to the patient.

OBJECTIVES

The purpose of the study is to screen polypharmacy based on MAI and Beer's Criteria 2019, to examine ADR, DDI and to counsel patients for safe and effective use of polypharmacy prescription.

MATERIALS AND METHOD

A Prospective observational study was conducted for a period of 6 months in the 1000 bedded multi speciality tertiary care teaching hospital. The study was approved by the Institutional Ethics Committee (R.No. MCP/IEC/PD/PR/65). After receiving written or verbal consent, the study comprised 100 patients of either gender who were above 18 years old and routinely taking at least five medications.

The Patient Documentation Form accurately recorded the demographic information about the patients, along with the reasons for admission, prior medical histories, laboratory results, diagnoses, and treatments. Before the counselling session began, a questionnaire was asked to the patient in the language in which they felt most comfortable, and the patient was then counseled and a second time following counselling to ensure they understood.

The data was thoroughly documented, entered into Microsoft Excel spreadsheets, and then further examined. Adverse drug reactions were assessed using the ADR Causality Assessment Scale: Naranjo Causality Assessment Scale. Using the Medscape drug interaction checker, drug-drug interactions were observed.

RESULTS

Gender distribution

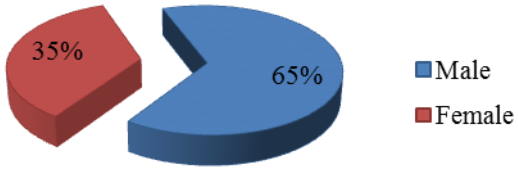

Fig No.1: Graphical distribution of Study participants in line with Gender.

Age distribution

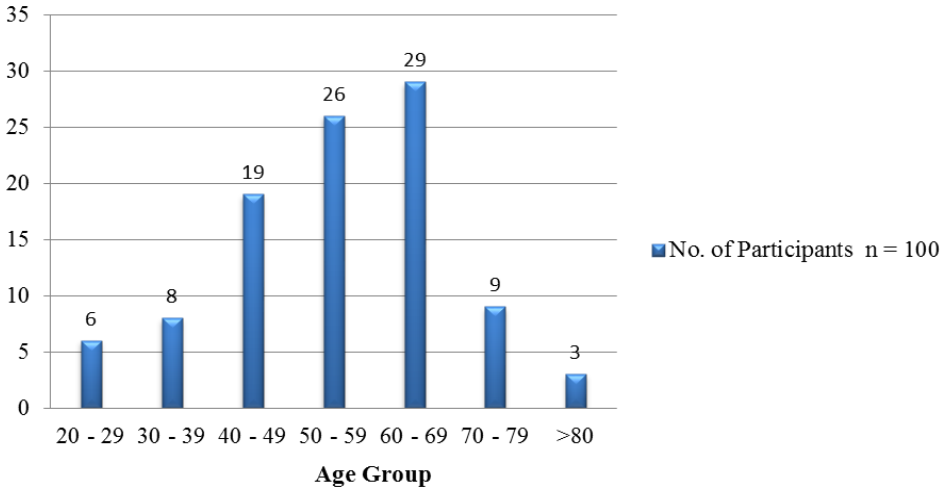

Fig No.2: Graphical Distribution of Study Participants in line with Age.

Social habits distribution

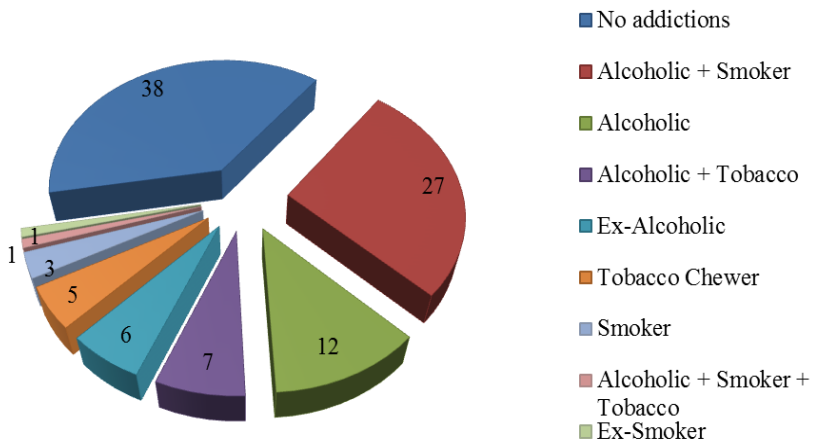

Fig No.3: Graphical Distribution of Study Participants according to Social History.

Drug distribution of drugs per patient

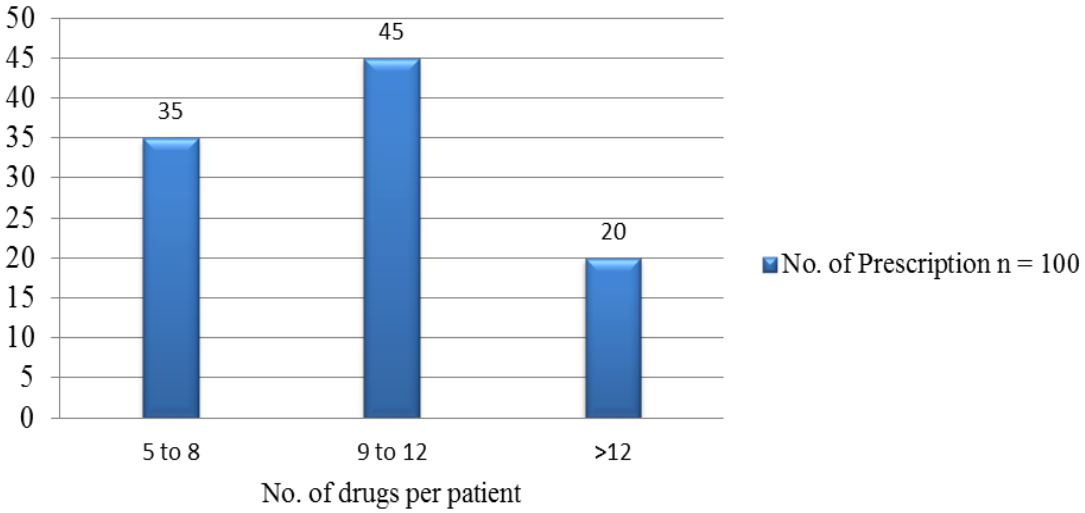

Fig No.4: Graphical Distribution of drugs per Patient.

Appropriate and inappropriate drugs distribution according to MAI Criteria

Table No.2: Distribution of Appropriate and Inappropriate Drugs according to MAI Criteria.

Total No. drugs Prescribed	No. of Appropriate Drugs Prescribed	No. of Inappropriate Drugs Prescribed
1052	754	298 (28.3%)

Total MAI criteria drugs

Table No.3: The summation of each criteria of all the patients inappropriately prescribed drugs.

MAI Criteria	MAI Scores	No. of Drugs with inappropriate MAI Score
Drug Indication	**3**	**168**
Effectiveness	3	163
Duration of therapy	1	87
Drug – Drug interaction	2	52
Drug – Disease/ Condition Interaction	2	36
Duplication	1	32
Correct dosage	2	14
Direction Practical	1	4
Correct direction	2	3

MAI scores: 0 – Appropriate, 1-3 - Inappropriate

In Table No.3, 1052 drugs were analyzed using MAI, and scores were assign.

Potentially Inappropriate Medication Accordance with Beer's Criteria 2019:

Table No.4: List of Potentially Inappropriate Medication.

PIM	No. of Prescriptions	Recommendations
Beer's Category 1 PIM use in Older Adults		
Regular Insulin	14	Avoid using without concurrent use of basal or long acting insulin
Proton pump inhibitors	2	Avoid schedule use for >8 weeks
Nitrofurantoin	1	Avoid in individuals with CrCl <30ml/min
Digoxin	1	Avoid as first line therapy in heart failure
Beer's Category 2 PIM use in older adults that may exacerbate the condition		
NSAIDs in CKD	4	Avoid
Diltiazem in Heart Failure	1	Avoid or Use with Caution
Acetaminophen in Heart Failure	1	Avoid or Use with Caution
Antiepileptics in history of fall	1	Avoid
Beer's Category 3 PIMs to be used with caution in Older Adults		
Diuretics	19	Caution use
Tramadol	3	Caution use
Aspirin	2	Caution use in > 70ys Older Adults
Beer's Category 5 PIMs to be avoided or dosage reduction with the varying kidney function in Older Adults		
Spironolactone	4	Dose reduction when CrCl<30ml/min
Tramadol	2	Dose reduction when CrCl<30ml/min
Ciprofloxacin	2	Dose reduction when CrCl<30ml/min
Enoxaparin	1	Dose reduction when CrCl<30ml/min

Beer's Criteria Analysis

Table No.5: Analysis of BEERs Criteria 2019.

Total No. of Older Adults	41
Total No. of drugs prescribed in Older Adults	413
Total number of PIMs prescribed in Older Adults	58
% of PIMs prescribes in Older Adults	14.01

As per Table No.5, 41 participants in the 60 - 80 year old group met the Beer's Criteria, and they were evaluated for Potentially Inappropriate Medications. It is observed that 58 (14.01%) of the 413 prescribed drugs to Older Adults were PIMs, which should be avoided or used carefully.

ADR Assessment Based On Naranjo Scale

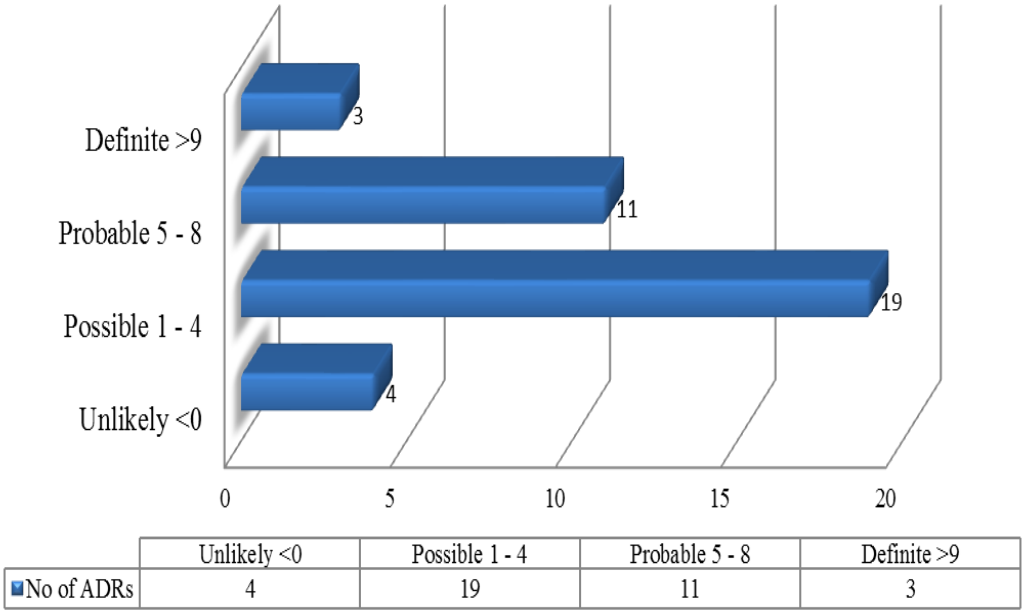

Fig No.5: Graphical Representation of ADR Assessment based on Naranjo Scale.

Evaluation of Patient Counselling

Table No.6: Percentage of Correctness of Questionnaire.

Questions	% of Correct Answers Before Counseling	% of Correct Answers After Counseling
Does the patient know about the time, frequency of medication?	28.0	86.0
Does the patient know which medication is to be taken before food and after food?	26.0	90.0
Does the patient know what to do if dose is missed?	6.0	59.0
Does the patient is adherent to medication?	20.0	80.0
Does the patient know about the medical condition, symptoms of the disease suffering?	18.0	70.0
Does the patient know about the medication indication?	25.0	79.0
Is the patient physically active?	5.0	30.0
Does the patient taking any alternate therapy?	10.0	15.0

DISCUSSION

In this study, the MAI and Beer's Criteria tools were used to evaluate polypharmacy. Additionally, this study monitors adverse effects and drug interactions in study participants with more than five drugs in prescriptions.

During the six-month study period, research was conducted at multispecialty tertiary care teaching hospital. The study involved 100 patients of either gender above 18 years of age, with the majority of them between the ages of 60-70. Men comprised 65% of the participants while women made up 35%, as with **Mohan PBN et al 2021**[10] with a dominant male population (73%). It was observed that 1052 drugs were prescribed among 100 patients, spread across 35 prescriptions with 5 - 8 drugs, 45 prescriptions with 8 - 12 drugs, and more than 20 prescriptions with more than 12 drugs this is very similar to the findings by **Iffath F et al. 2019**[11] which had 56 prescriptions with 5 to 10 drugs per prescription. When compared to this study's 35 prescriptions with 5-8 medicines, the study by **Mohan PBN et al. 2021**[10] had 68 prescriptions with 6–8 drugs per prescription. The minimum and maximum number of drugs prescribed in our study was 5 and 20, respectively. Minimum and maximum medication concentrations in the study by **Somers A. et al. 2012**[4] are 2 and 20, respectively.

A total 1052 medications were subjected to the MAI Criteria; scores were assigned based on how appropriate they were. The MAI identified 298 (28.3%) medications as having been prescribed inappropriately based on one or more of the criteria, that is less than the research conducted by **Lorna M. Rt al. in 2012**[5], which identified 384 (55.1%) unsuitable pharmaceuticals out of 697 total drugs. The studies by **Adem L et al in 2022**[12] and **Dhyani V et al in 2015**[7] both reported the highest MAI scores for the criteria of indication, effectiveness, correct dosage, unnecessary duplication and indication, expense, drug disease interaction respectively. Our study ranks highest for the number of inappropriately prescribed drugs with the highest indication and effectiveness scores.

In accordance with Beer's Criteria, 41 participants met the age requirements. A total of 58 (14.01%) PIMs that need to be avoided or used cautiously were prescribed to older adults. This study by **Brahma DK, et al 2021**[13], which found that 14.01% of PIMs were administered inappropriately based on Beer's Criteria, is remarkably similar to our research. Out of 58 drugs, 18 were of PIMs used in older adults, 7 PIMs older adults that exacerbate conditions, 24 PIMs use with caution and 9 PIMs to be avoided or reduced with varying kidney function in older adults, In contrast to the study by **Brahma DK, et al. in 2021**[13], which found that 30 medications were PIMs in the majority of older adults, 25 medications were typically to be avoided in older adults with certain conditions, 16 medications were to be used with caution in older adults, and 16 medications were to be avoided or reduced with varying kidney function in older adults.

Patient counseling involves patient answering questionnaires about the drugs, disease, and management, where yes or no is an answer. Before counselling, patients have scarce knowledge about the drugs and disease, which increases after counselling. On the health and wellbeing of the patient, patient counselling had a favorable effect.

The overall number of severe drug-drug interactions identified was 28, matching the findings of a study by **Karthik J. S. et al 2016**[14] that also found 28 such interactions. In contrast to **Ahmad A. et al 2015.'S**[15] study, which revealed that Ondansetron and ofloxacinwere the next-most common DDI, the typical DDI found in our research is to be Azithromycin and Ondansetron.

The ADR were assessed using the Naranjo ADR Probability Scale, which yielded 3 definite, 19 possible, 11 probable, and 4 unlikely ADRs, as opposed to 27 probable, 2 definite, and 1 potential ADRs and no unlikely ADRs in the study by **Ramnath KV et al. 2016.**[16]

CONCLUSION

This study provides insights on the evaluation of polypharmacy based on MAI and Beer's Criteria 2019. In this study, 45% of prescriptions contained 8 -12 drugs, which was indicative of excessive polypharmacy.The study found that a substantial number of patients receive inappropriately prescribed medications. The MAI (28.3 %) was found to be more inappropriate than the Beer's Criteria 2019 (14.01%). As the number of medications is increased, the risk of adverse effects and drug-drug interactions increases, which in turn leads to a Prescribing Cascade.

Informed and judicious use of medications will reduce the inappropriate use of drugs and increase their effectiveness, which in turn will reduce the risks associated with polypharmacy. Patients' adherence is directly impacted by the minimum number of drugs consumed during treatment improving patient health, patient counselling enhances patient quality of life. In order to minimize the adverse effects, drug - drug interactions, and other risks associated with polypharmacy, it is necessary to identify the prevalence of any potential problems.

A physician and a clinical pharmacist can reduce polypharmacy through interventions such as deprescribing, reducing dosages, increasing patient adherence, preventing adverse effects and interactions, and thus improving patient health.A Clinical Pharmacist taking on the role of Patient Counsellor increases patient awareness about medication, frequency of medication,

disease conditions, and treatment plans, which ultimately result in safe and effective use of medicines.

Abbreviations

- ADR - Adverse Drug Reaction
- AGS - American Geriatric Society
- BMC - BioMed Central
- CrCl - Creatinine Clearance
- DDI - Drug – Drug Interaction
- IEC - Institutional Ethics Committee
- MAI - Medication Appropriate Index
- NSAIDs - Non Steroidal Anti Inflammatory Drugs
- PIM - Potentially Inappropriate Medication
- WHO - World Health Organization

Conflict of Interest

The authors declare no potential conflict of interest.

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