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Research Article

Pregnancy Related Medication Prescription Patterns

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Abstract

Introduction: Drug use during pregnancy presents significant challenges due to altered pharmacokinetics and pharmacodynamics, with potential adverse effects on the fetus. The USFDA (United States Food and Drug Administration) categorizes drugs from A to X based on their safety in pregnancy, guiding appropriate drug use. Hence, this research aimed to assess rationality in prescription pattern and to identify commonly prescribed medications in pregnant women.

Methodology: A pilot prospective observational study was conducted for three months at Gandhi Hospital, Secunderabad. Women of any gestational age willing to participate voluntarily were included in study while non-pregnancy cases and cases with incomplete data were excluded. Data collection focused on demographics, medical history, and prescribed medications. Prescription pattern was analyzed using WHO (World Health Organization) core prescribing indicators and USFDA pregnancy drug-risk categories.

Results: Study highlighted the prevalence of anemia in 50% of pregnant women making it a possible factor for complications like premature birth and low birth weight if untreated. Majority of prescribed medications belong to Category B. Among 70 prescriptions, average number of drugs per prescription was 5.857 which was excess. Supplemental drug use accounted for 40.97% of the 410 prescription drugs, 168 drugs, and 242 drugs (59.024%) of the non-supplemental drugs prescribed.

Conclusion: Study emphasizes importance of supplemental drug use which was found to be deficient in the prescriptions. It is necessary for the well-being of mother and growth of fetus. Findings provide healthcare professionals with insights into current prescribing practices, aiming to enhance rational drug use in pregnancy.

Keywords: Pregnancy; USFDA drug risk category; prescription pattern.

INTRODUCTION

Drug use in pregnancy is a challenge due to alterations in pharmacokinetic and pharmacodynamic parameters in a pregnant women as some drugs may cross the placenta and show adverse effects on the fetus¹. So, to know appropriate drug use in pregnancy, US Food and Drug Administration (FDA) has given five categories A, B, C, D, and X based on animal and human data trials which shows the effect of drug on the fetus and suggests the level of caution that needs to be used ¹.

High-risk pregnancy relates to a pregnancy complicated by factors that could have a negative impact on the mother's and/or the fetus's health. However, it is both risky and unrealistic to advise against drug use during pregnancy. Doctors shouldn't permit their pregnant patients to avoid getting the treatment they need for their illnesses. Medications are necessary to preserve and restore health which should be done by assessing the risk to benefit ratio ². It is researched that anemia is a major health problem which affects 25% to 50% of the population in world and approximately 50% of pregnant women. Premature birth, low birth weight, high risks of maternal and perinatal death, and other unfavorable outcomes are linked to anemia during pregnancy. This condition maybe due to increase of plasma volume which decreases blood viscosity and leads to better blood circulation

in placenta. However, occurrence of anemia has resulted in more complications associated with infection, folate and vitamin B12 deficiencies if left untreated in a timely manner ³. Thus, responsible drug use, sufficient information, a positive outlook, and awareness of drug use are essential preconditions for optimal mother and child health ⁴. The International Network for Rational Use of Drugs (INRUD) and the World Health Organization (WHO) worked together to create a collection of "core drug use indicators." The three linked areas of "prescribing practices, patient care, and facility-specific factors" are gauged by the indicators. It is now accepted that the primary drug use indicators are "objective measures that can describe the drug use situation in a country, region, or individual health facility ⁵. It also includes the Essential Drug List (EDL) which consists of list of medicines that satisfy priority healthcare needs of population of target country/ state ⁶. Therefore, this study was done to assess the pattern of prescription drugs and associated factors among pregnant women at a tertiary care centre. We desire to use this information to offer the healthcare providers input and recommendations on the rationale behind drug use in pregnancy.

MATERIAL AND METHODS

Aim: To know the rationality of prescribing pattern of drugs in pregnant women.

Objectives: Examine prevalence of poly-pharmacy among the study population. Identify or assess commonly prescribed medications during pregnancy.

Study Design: It is a pilot study done for duration of 3 months. It is a single center Prospective Observational Study done in the In-patient Department of Gynecology and Obstetrics of Gandhi Hospital, Secunderabad. A total of 70 cases were collected of pregnant women admitted in the hospital.

Inclusion Criteria: Pregnant women at any gestational week getting admitted in the hospital. Age above 15 years. Women willing to voluntarily participate in the study.

Exclusion Criteria: Any non-pregnancy cases excluded. Patients who left abruptly. Cases with incomplete data and without proper discharge summary not considered.

Study Procedure

The study data was gathered by utilizing a data collection form that included patient demographics (age, sex, height, weight, history in family, risk factors, past medication history, past medical illnesses- HTN (hypertension), dyslipidemia. The safety of drugs prescribed in pregnant women was assessed by following USFDA pregnancy drug - risk category. From the cases collected the commonly prescribed medications (supplemental and non-supplemental) were identified. The WHO core prescribing indicators were used in this study to assess the prescription pattern of drugs. Patient consent was taken prior to participating in the study by explaining them about research work. All cases followed up on daily basis until discharge.

Data Analysis

All the gathered data was entered in excel sheet and analyzed for study report. Means and standard deviations were used for normally distributed numerical variables. Descriptive data analyzed and presented as percentages. Study was initiated after getting the ethical approval.

RESULTS AND DISCUSSION

A total of 70 cases were collected and analyzed for rational drug use in pregnancy from the in-patient department of gynecology. In this study there were equal number of cases in the age group between 15-24 years (32, 45.714%), and 25-34 years (32, 45.714%) followed by only 6 patients (8.571%) of age 35-44 which was almost similar to study done by **Abhinaya Birudula et al** ⁷, that showed maximum cases collected in age group of 21-25 years age of 56%. The age group in women who conceived was observed to be young population, which could be due to illiteracy or girls getting married at a young age and becoming pregnant. The gestational age of majority of study population were admitted in the third trimester 56 cases (80.00%) followed by second trimester 12 cases (17.142%) and only 2 cases from first trimester (2.857%) in the hospital, whereas another study done by **Gudeta Duga Geresu et al** ⁸, showed more cases admitted during 2nd trimester (65%) followed by 3rd trimester (24.6%) and 1st trimester (9.8%). Also it was observed that most of the cases were admitted in the third trimester which was possibly due to more health complications developed in women during the course of pregnancy. From our study it is observed that larger population of pregnant women were of multi-gravida cases 45, 64.285% followed by primi-gravida cases 25, 35.714%, which was similar to a study done in eastern Ethiopia by **Neim Bedewi et al** ⁹, showing 59.62% cases as multi-gravida. Majorly anemia was seen in the study population during pregnancy and detection of this in early stages could avoid risk associated with morbidity in later stages of pregnancy. 46 cases (38.655%) in pregnant women presented with anemia, followed by gestational diabetes mellitus 12 (10.084%) and thrombocytopenia 09 (7.563%), epilepsy 8 (6.72%), hypothyroidism 07 (5.882%), gestational hypertension and gestational hypothyroidism each of 07 (5.882%), acute gastritis 04 (3.361%), vaginal candidiasis 4 (3.361%), jaundice 3 (2.52%) and only 01 (0.840%) of typhoid and sickle cell anemia as shown in **Figure 1**. This was similar to a study done by **Shivani Patel et al** ¹⁰, which showed more cases of anemia (42.3%) in pregnancy as well.

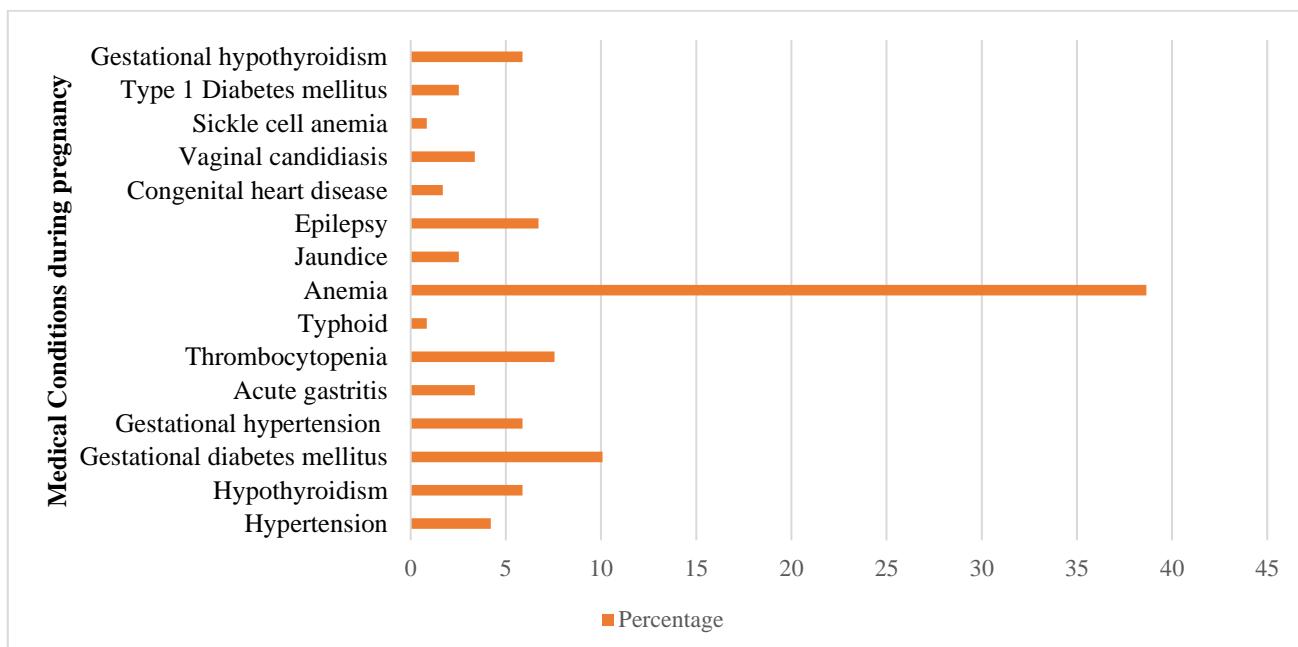


Figure 1: Medical Co-morbidities present during pregnancy in study population

The total number of drugs prescribed in 70 cases were observed to be 410. Rational use of drugs in pregnancy requires balancing of risk to benefit ratio related with use of drugs. From **figure 2** the following observations were made such as highest amount of drug prescribing was seen in 3rd trimester 318 (77.5%) followed by 2nd trimester 75 (19.02%) and 1st trimester 14 (3%). A study by **Gudeta Duga Geresu et al**⁸, showed maximum drugs were prescribed in 2nd trimester (68.2%). This maybe due to the presence of health complication in 3rd trimester which require immediate treatment to prevent harm to the fetus. Also in our study it was observed that majority of prescribed drugs belonged to the category B 199 (48.5%) of the USFDA pregnancy drug risk

category followed by category C 117 (28.5%), category A 84 (20.4%), Category N (not classified) 7 (1.7%), Category D 3(0.73%) and none from category X drugs, whereas a study by **Gudeta Duga Geresu et al**⁸, reported major drug prescription from Category C (54.2%) cases. However, in our study some cases were prescribed with category D drugs such as midazolam for sedation as an anesthesia during c-section and carbamazepine to treat pregnancy seizures. Nonetheless, these drugs must be best avoided in pregnancy. But due to some potential benefits of use of these drugs in pregnancy they are prescribed despite the risks involved. No drugs were prescribed from category X.

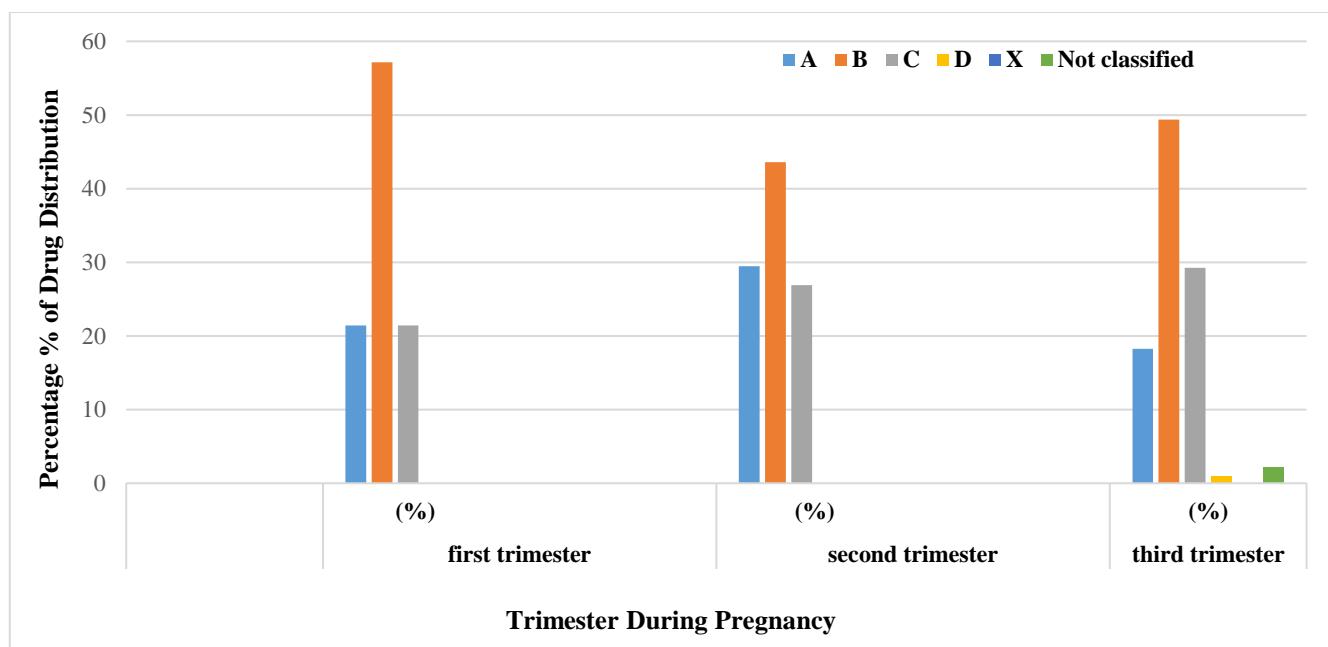


Figure 2: Drug Prescription as per USFDA drug risk category in various Trimesters.

In majority of cases oral dosage forms of drugs were prescribed 45, 72.580% followed by parenteral preparations 16, 25.806% and only 1 drug was prescribed in vaginal route of administration 1.612%. This was similar to a study done by **Shivani Patel et al**¹⁰, which also showed oral dosage forms being prescribed maximum of 81.53%. In this study it was observed that **supplemental drugs** were prescribed the more starting with calcium carbonate 57 (13.9%), Iron 50 (12.19%), Vitamin C 39 (9.51%), and **non-supplemental drugs** as ranitidine 21 (5.12%), cefotaxime 19 (4.6%), metronidazole 18 (4.3%), insulin and isophane 15 (3.6%), paracetamol 14 (3.4%), disodium hydrogen citrate 13 (3.6%), Thyroxine sodium 12 (2.9%), labetolol 12 (2.9%), pantoprazole 10 (2.4%), ondansetron 9 (2.19%), metformin 9 (2.19%), levetiracetam 8 (1.9%), tranexamic acid 7 (1.7%), progesterone 7 (1.7%), iron folic acid 6 (1.46%), L-arginine 5 (1.2%), folic acid 5 (1.2%), neutral protamine 5 (1.2%), folic acid + pyridoxine+mecobalamin 5 (1.2%), eicosapentanoic acid 5 (1.2%), levocetirizine 4 (0.97%), vitamin A and B 4 (0.97%), Azithromycin, nitrofurantoin, aspirin, sodium valproate, ceftriaxone, betamethasone, lactulose, buscopan, amoxiclav 3 (.73%) each, and midazolam, ambroxol, nifedipine, amoxicillin, chlorpheniramine, vitamin D3, fluconazole 2 (0.48%) each and 1 case (0.24%) each of propranolol, carbamazepine, arginine, furosemide, nicardipine, heparin, racecadotril, metoclopramide, ursodeoxycholic acid. This was comparable to study done by **Mevhibe Tamirici et al**¹¹, that showed prescription of supplemental drugs as vitamins and minerals to be more.

From the medication prescription pattern it can be deciphered that:

Supplemental drugs were prescribed overall such as vitamins, minerals, Iron, folic acid and calcium are essential in preventing undernourishment of fetus and mother. In this study anemia cases were more so more amount of iron and supplementary medications were prescribed to the patient. Calcium supplements were prescribed for fetal bone development. Folic acid prescriptions were seen less which maybe due to more cases being admitted in third trimester and folic acid is commonly prescribed in the first trimester, to prevent neural tube defects known as anencephaly in fetus seen in early stages of pregnancy. Also vitamin B12 prescriptions seen were less, which should be prescribed more as it is important to prevent B12 deficiency in pregnant women and also to prevent spina bifida in the fetus. The non-supplemental drugs prescribed were ranitidine and pantoprazole in most cases for gastrointestinal irritation. The next commonly prescribed antibiotic was ceftriaxone given as prophylaxis for the treatment of various infections. It belongs to category B which is considered safe in pregnancy as per the USFDA pregnancy guidelines. Metformin and insulin were prescribed for gestational diabetes which were category B. Pregnant women with epilepsy were considered as high risk group population and required continuous monitoring. Levetiracetam, a category- C drug was prescribed commonly based on the risk to benefit ratio. Next commonly prescribed medications observed were levothyroxine for gestational

hypothyroidism. As per the therapeutic drug classification maximum class of medications prescribed in pregnancy were iron supplements 61,14.878 % followed by next class of medications prescribed was calcium supplements 57,13.972% and antibiotics 51,12.439% , multivitamins 45,10.975%, antacids 31,7.560%, anti-diabetic drugs 29,7.073% and anti-hypertensives 17,4.146%, followed by urinary alkalizers 13,3.170%, anti-epileptics and anti-thyroid drugs 12,2.926%, anti-emetics 09,2.195%, hormonal supplements 8,1.951%,

anti-fibrinolitics 7,1.707%, amino acids and anti-histamines 6,1.463% , nutrients and anti-oxidants 5,1.219%, anti-fungal and mucolytics 2,0.487% followed by prokinetic agents and low molecular weight heparin 1, 0.243% as shown in **Figure 3**. This was similar to a study done by **Neim Bedewi et al** ¹¹, which showed similarity in prescription pattern of higher vitamins and supplemental medications followed by antibiotics.

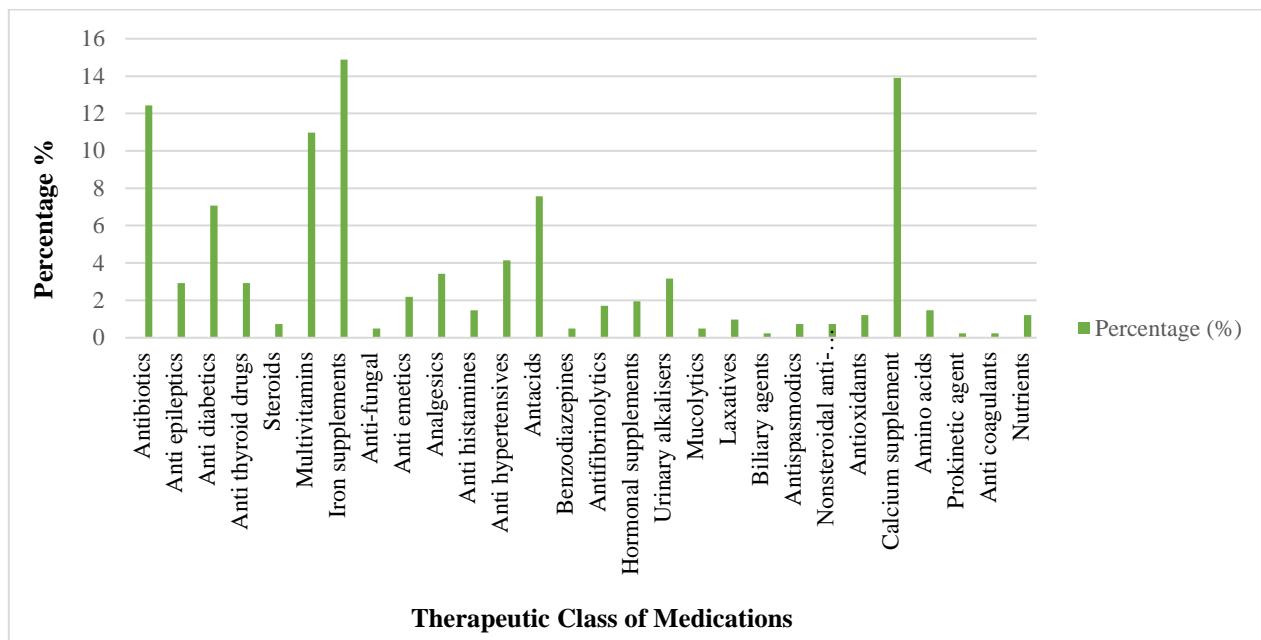


Figure 3: Drug distribution based on therapeutic classes.

The prevalence of poly-pharmacy was observed in 92.85%, 65 cases having equal to or greater than 5 medications prescribed as in **Table 1**. This was similar to a study done by **Anuradha Subramanian et al** ¹², which demonstrated poly-pharmacy where minimum 2+ medications to maximum 11+ medications were seen in their study.

Table 1: Poly-pharmacy

No of drugs per prescription	No of cases	Percentage (%)
0-4	05	7.142
5 or more than 5	65	92.857
Total	70	

The study observations of WHO Prescribing indicators were as follows:

- 1) Total number of patients analyzed: 70
- 2) Total number of drugs prescribed: 410
- 3) Average number of drugs per prescription: 5.857
- 4) Percentage of drugs prescribed by generic name: 46.829%
- 5) Percentage of cases collected with antibiotics prescribed: 41.428%
- 6) Percentage of cases collected with injections prescribed: 55.714%
- 7) Percentage drugs prescribed from WHO EDL: 47.05%

As per the WHO (World Health Organization) prescribing indicators the average number of drugs per prescription was 5.857 which was found to be more than the optimal range (< 2). So, we can say that this might have led to poly-pharmacy as seen in this study. Hence it is advisable to reduce the number of drugs prescribed, to prevent any interactions or untoward complications in patient. Percentage of drugs prescribed by generic name was 46.829% which was not 100% as per WHO standards. Too many brand names prescribed might have costed more to the pregnant women. This was similar to a study done by **"Asha B et al** ¹³," which also showed fewer prescriptions with generic name. The reason for this being publicity of brand names by pharmaceutical company representatives, drug bias by physicians which can be attributed to irrational prescription. Percentage of cases collected with antibiotics prescribed was 41.42% which was high and deviating from the optimal range of (20-26.8). This shows over-use of antibiotics which could lead to risk for complications and antibiotic resistance. This was found similar to be in **"Mesfin Fikadu et al** ¹⁴., study. Percentage of cases collected with an injection prescribed was 55.714% which was high and not in WHO optimal range of (13.4% - 24%). This could lead to possibility of high concentration of drug in body causing toxicity. However, this may be due to need for fluid maintenance in pregnant women, which was similar to **"Mesfin Fikady et al** ¹⁴., study. In this research as most of the admits were in 3rd trimester for any minor/major ailments, it would have necessitated the use of parenterals to prevent any untoward health condition. Percentage of drugs prescribed from WHO EDL was 47.05% (24/51) medicines. But as per WHO it should be 100% which was deviating from the standard value. So, prescribing drugs from EDL would promote rational drug prescription and provide better patient

care. Out of the total 410 drugs prescribed the supplemental drug utilization accounted for 40.97 %, in 168 drugs and non-supplemental drug prescribed were 59.024 % in 242 drugs.

CONCLUSION

The study comes to the conclusion that prescription pattern analysis is crucial to understanding the safety of drugs given to expectant mothers. This will also provide feedback to health care professionals on the need to improvise drug treatment regimens. In order to understand the reasoning behind the prescription pattern, this study used WHO prescribing indicators as an evaluation procedure. The results of the study also highlight the importance of clinical pharmacists in helping doctors make clinical decisions that will improve the mother's and the fetus's quality of care. The study then identifies that pregnant women utilize supplemental medications less frequently. This necessitates counselling them on the value and advantages of using vitamin and mineral supplements. This further emphasizes the need for appropriate prenatal care.

Limitations

To maintain the health of the mother and the baby, more extensive measures must be taken to evaluate prescribing practices and monitor drug adherence among the pregnant population, which requires the study to be done on a larger scale. It is observed that over the past 20 years, polypharmacy has become more common, especially in women who have multiple co-morbidities. This requires that effective pharmaco-epidemiological studies are done to comprehend the combined effects of several drugs on the outcomes of the mother and the foetus.

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Conflict of Interest

We declare no conflict of interest

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