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Patterns of Medication Use during Pregnancy: A Cross-Sectional Study from Iran

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ABSTRACT

Background & Objective: The frequency of medication usage during pregnancy is prevalent. The present study was conducted with aim to investigate the patterns of medication used during pregnancy.

Materials & Methods: This prospective cross-sectional study was conducted on 326 pregnant mothers attending in two Iranian Hospitals (Tehran, Iran) from November 2021 to September 2022. Participants' data, including used medications, indications, and gestational age at usage were collected and recorded. Drugs were categorized into supplements, Over-The-Counter (OTC) medicines, and medicines for acute/short or chronic/long-time diseases. Data were analyzed using SPSS software (version 22). $P<0.05$ was considered statistically significant.

Results: Considering supplements, about 94% of pregnant mothers had taken at least one drug, and excluding supplements, this rate was 61%. The maximum and minimum medications were used in the first trimesters of pregnancy. The highest rate of medications was related to the group of acute/short-term disease (46%). Antiemetics (13.8%) and anti-infective (7.97%) were mostly consumed drugs. Concerning chronic-long term disease (27.3%), hypothyroidism (18.71%) was the most frequent disease needed medication. The most prevalent used OTC was Acetaminophen (6.74%). Maternal factors for using more medications during pregnancy were old age, non-Iranian nationality (afghan), and living in the suburbs.

Conclusion: Anti-hypothyroidism, Anti-infective, Antiemetics, and Acetaminophen were mostly consumed drugs during the first trimester of pregnancy. These findings indicate that mothers should be aware of the safety of medicines and the time of consumption. Maternal risk factors for using medications during pregnancy should be considered in prenatal visits. It is recommended to perform pre-pregnancy consultation emphasizing controlling underlying disease and awareness of drugs' adverse effects.

Keywords: Pregnancy, Medication, Prevalence, Prenatal care, Fetus

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1. Introduction

Adverse effects of medication during pregnancy became of great concern after Thalidomide and Diethylstilbestrol disasters in 1960 and 1971 **(1)**. A French investigation in 2019 indicated that the use of medications during pregnancy is increasing in past decades **(2,3)**. The increase in the mother's age coinciding with more antenatal co-morbidities also results in more medication usage during pregnancy **(4,5)**.

There are different systems to categorize medications according to the potential teratogenicity; FDA pregnancy categories (A, B, C, D, X classifications) is the most popular **(6)**. Accordingly, the first trimester of pregnancy is a critical period for fetal organogenesis,

while mothers who are unaware of their pregnancy may continue prescribed medications (7,8). Many pregnant women also regularly use some medicines or self-administration supplements without declaring to their doctors or health care providers (9-11). Besides the teratogenicity of medications, committing pregnancy termination by mothers due to fear of drugs' teratogenicity adversely affects pregnancy outcomes (12,13).

In recent decades, different types of medications may be consumed by pregnant women. Additionally, the classification systems can not include all new medications according to their potential adverse effects because of the exclusion of pregnant women from clinical trials (14,15). Considering mothers' unawareness regarding the teratogenicity of drugs, interrupting necessary medications during pregnancy, or interrupting breastfeeding during medications usage, the Centers of Disease Control and prevention (CDC), through an urgent call in 2005, outlined the necessity of a medication registration system during pregnancy (16). Providing such information, many health systems in different countries have collaborated (17-20) and generated useful data for health care providers and pregnant women (4,14).

To the best of our knowledge, except some studies about herbal medications (21, 22,23), there is no solid system or well-known research paper from Iran focusing on medications in pregnancy. As further research is still needed, the present study was conducted with aim to uncover the pattern of medications usage during pregnancy among Iranian mothers. The outcome of the present study will show the frequency and pattern of medication usage during pregnancy that would be useful for both healthcare providers and mothers.

2. Materials and Methods

This prospective, cross-sectional study was conducted in two academic hospitals affiliated with Shahid Beheshti University of Medical Sciences (Imam Hossein and Taleghani Hospitals, Tehran, Iran, from November 2021 to September 2022). All pregnant women who attended the prenatal-care clinics were invited to participate in the study. The exclusion criteria were difficult verbal communication due to diverse language or accent, women's reluctance to participate, forgetting the name of consumed medications, or which trimester at consumption. All subjects of different gestational ages entered the study after obtaining written informed consent.

A checklist was designed according to a study by luppatielli et al., in 2014 (24) and the views of expert obstetricians. All participants' socio-demographic characteristics (educational, occupational, and residential statuses), clinical and obstetrical information (numbers of gravid, parity, and prenatal visits, types of pregnancy including planned, unwanted and unplanned) were gathered and recorded by medical residents who were trained for the study purpose.

Data about consumed medications during the recent pregnancy, such as the name of medicine, reasons for consumption, and gestational age at taking the drug, were recorded. The reasons for medication usage were categorized into two groups acute/short-term diseases (vomiting, heartburn, constipation, common cold, headache, back pain, neck pain, sleep disorders, urinary tract infection, and other infections) and chronic/long-term diseases (asthma, allergy, thyroid disorders, rheumatologic disease, diabetes, epilepsy, and cardiovascular disease). The consumption of Over-The-Counter (OTC) medicines or prenatal supplements (Folic acid, Iron, Vitamin D, Calcium, and Omega-3) were added to the checklist. The time of initiation of Folic acid utilization (pre or during pregnancy) was also identified. To avoid recall bias, their consumed medications were illustrated to confirm.

Finally, all recorded medications were categorized based on Anatomical Therapeutic Chemical (ATC) Classification System (1st level) to identify which body organs or systems were being affected by chemical substances.

The primary outcome was determining the frequency of medication used during pregnancy. The reasons for taking drug and the trimesters of pregnancy at drug usage were also assessed as the secondary outcome.

The sample size was determined using the community ratio formula and according to a former study by Alemaet al., in 2020 (25), which showed that the prevalence of drug usage (P) during pregnancy was 41%. With a confidence interval (1-α) of 95% and the estimation error (d) of 10% for this sample volume ratio, the total number of pregnant women was estimated at 326.

$$sample\ size = \frac{Z_{1-\alpha/2}{}^2 P(1-P)}{d^2}$$

Analyses of data were performed using SPSS software (version 22). Data were displayed as Mean±Standard deviation for quantitative variables and frequency (percentage) for qualitative variables. Bar graphs were used to display the results graphically. Two-Sample Independent t-test and Chi-square test were used to compare quantitative and qualitative variables, respectively. The Logistic Regression Model was used to indicate the relationships between the variables affecting the pattern of drug usage. Findings were also represented by adjusted OR and at a 95% Confidence Interval (CI). $P<0.05$ were considered statistically significant.

3. Results

Of 358 eligible participants, 12 mothers refused to participate. Twenty mothers were also excluded

because of forgetting the name of consumed drugs. Totally 326 mothers entered to the analysis. The mean age of subjects was 28±6.31 (15-42) years, and the majority of mothers were Iranian (82.6%). Related to educational, occupational, and residential statuses, most of the mothers had university degrees (49.4%), were unemployed (91.7%), and lived in urban areas (72.3%). Of all included population, 44.7% had a planned pregnancy, while the others had unwanted (29.5%) or unplanned pregnancies (25.8%).

More than half of the participants were from a large-sized family. Fifty-five subjects could not remember the time of the first prenatal visit, and 245 (90.4%) pregnant mothers had received their first prenatal care during the first trimester. About 60% of cases received more than five antenatal visits during recent pregnancy (Table 1).

Most of participants (94.2%) consumed at least one medicine. After excluding supplements, this number decreased to 61.3%, with 55% using medication during first trimester, 30% during second trimester, and 15% during the third trimester according to mothers' reports. OTC medications, medication for acute/short-term disease and chronic/long-term disease were consumed by 44 (13.5%), 150 (46%), and 89 (27.3%) women, respectively. The frequency of supplement usage was also 88.3%. Folic acid (79%) and vitamin D (68%) were the most consumed supplements (Figure 1).

The distribution of medication usage is shown in Figure 2, in which drug for thyroid diseases, particularly hypothyroidism, was the most used drug. Of used OTCs (13.5%), Acetaminophen by 6.74%, was the most consumed medication.

Of medications consumed for acute/short-term disease (46%), Antiemetics (13.8%) and anti-infective (7.97%) were the most consumed medications. Regarding medicines used for chronic/long-term disease (27.3%), medicines for hypothyroidism (18.71%) and diabetes (5.21%) were the most reported drugs. According to ACT classification, medications related to the alimentary tract and metabolisms were the most used drugs during pregnancy (Table 2). Medication usage according to FDA classification is also presented in (Figure 3). No medication in the X teratogen classification was consumed by the participants.

The time of first prenatal care and number of prenatal visits were different among the two groups of using and non-used medications. Most cases using medications, had their first prenatal care during the first trimester. Medication usage in mothers who lived in urban areas was lower than in those who lived in the suburbs. Detailed data are shown in Table 1.

A significant relationship was observed between acute/short medication and mother's residency (P=0.04); mothers from cities used less medicines for acute diseases than mothers from suburbs. The time of first prenatal care was also significantly correlated with medication usage for acute/short-term disease; using medications for acute/short-term disease decreased when the first antenatal care was postponed (OR=0.27; P=0.004). There were statically significant relationships between maternal age (P=0.001) and nationality (P=0.03), with using medications for chronic-long term diseases. Medication usage was more frequent among older mothers.

Moreover, Iranian mothers used more medications for chronic long-term disease than non-Iranian counterparts. Regarding OTC medications, no significant relationships were observed between OTC consumption and several variables including, participants' education, occupation, age, family size, nationality, parity, and time of first antenatal visit (P>0.05).

Further analysis showed that attending the private (P=0.001) and academic prenatal clinics (P=0.004) were the significant factors for using more and fewer medications for acute/short-term diseases, respectively. Of mothers who planned for their pregnancy, 37.9% took drugs for acute-short term illness. This percentage among mothers with unwanted or unplanned pregnancies was 53% and 51%, respectively. Planning for pregnancy was a significant factor in using fewer medications (P=0.03). The majority of participants attending private clinics did not consume OTC medications (71.4% vs. 28% of cases with OTCs consumption; P=0.04). With respects to centers giving prenatal care, attending academic clinics was a significant factor in consuming fewer medications for chronic/long-term diseases (22% vs. 78%; P=0.014).

History of abortion was also a significant factor in using fewer medications for chronic/long-term disease (P=0.03).

Table1. Socio-demographic and obstetrical characteristics of all participants (used and non-used medications) attending at antenatal clinics

Variables	Total N=326	Using medications (N=200)	Not Using medications (N=126)
Age (year; Mean±Std)	28.48±6.31	29.88±6.19	27.82±6.48
Educational status			
Illiterate	30(9.2%)	18(60%)	12(40%)
Lower Diploma	135(41.4%)	80(59.3%)	55(40.7%)
University degree	161(49.4)	102(63.4%)	59(36.6%)
Occupation			
Unemployed Employed	299(91.7%) 27(8.3%)	183(61.2%) 17(63.0%)	116(38.8%) 10(37.0%)
Residency			
Urban area	230(72.3%)	133(57.8)	97(42.2%)
Suburb	88(27.7%)	62(70.05%)	26(29.0%)
Nationality			
Iranian	252(82.6%)	162(64.2%)	90(35.7%)
Non-Iranian (Afghan)	57(18.4%)	33(57.9%)	24(42.1%)
Mother's sibling			
1	22(6.7%)	12(54.5%)	10(45.5%)
2	35(10.7%)	24(68.6%)	11(31.4%)
3	50(15.3%)	33(66%)	17(34%)
≥4	219(67.2%)	131(59.8%)	88(40.2%)
Time of first prenatal care			
First trimester	245(90.4%)	157(64.1%)	88(35.9%)
Second trimester	18(6.6%)	10(55.6%)	8(44.4%)
Third trimester	8(3%)	1(12.5%)	7(87.5%)
Numbers of prenatal care			
1-2 times	65(22.2%)	27(41.5%)	38(58.5%)
3-4 times	56(19.1%)	32(57.1%)	24(42.9%)
≥5	172(58.7%)	125(72.7%)	47(27.3%)

Table 2. Distribution of participants' medication usage by Anatomical Therapeutic Chemicalat Classification System in

Group	Frequency	Percent
Alimentary tract and metabolism	119	35.85
Anti-infective for systemic use	62	18.67
Systemic hormonal preparations, excluding sex hormones and insulin	58	17.47
Genito-urinary system and sex hormones	35	10.54
Nervous system	33	9.95
Blood and blood-forming organs	10	3.01
Respiratory system	6	1.81
Cardiovascular system	3	0.90
Sensory organs	3	0.90
Musculoskeletal system	2	0.60
Dermatological	1	0.30

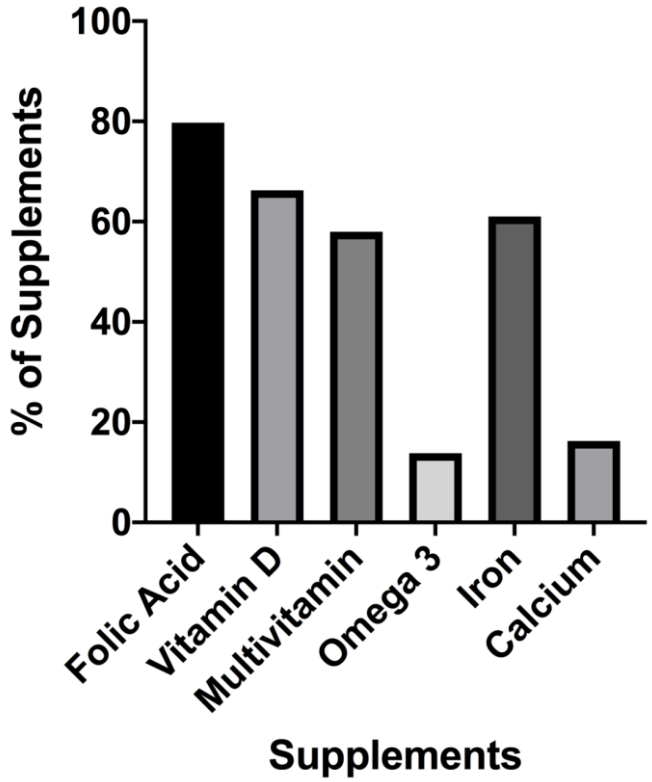


Figure 1. Estimated percentages of consumed supplements during pregnancy

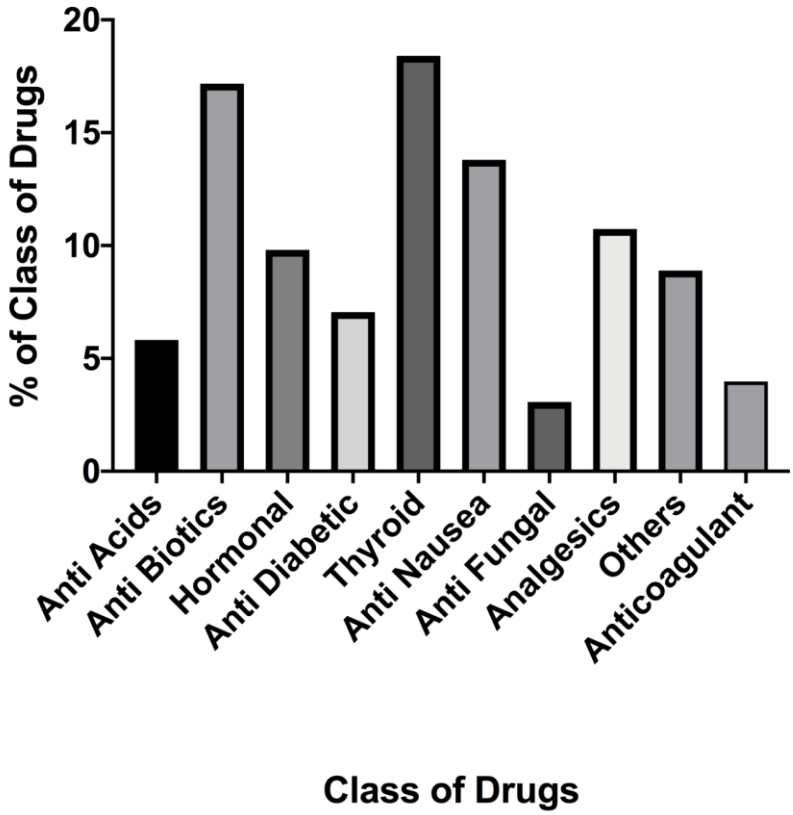


Figure 2. The distribution of different classes of medications during pregnancy

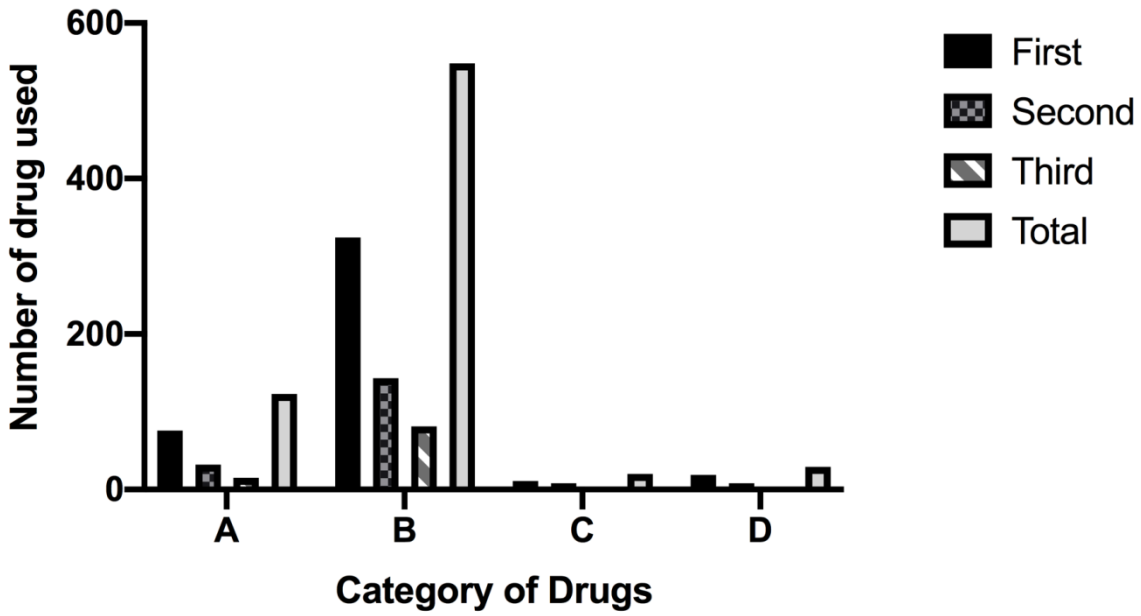


Figure 3. **The times (trimesters) of medication usage during pregnancy according to FDA classification**

4. Discussion

The present research is among very few studies from Iran that have evaluated the frequency of medication usage and types of consumed medicine during pregnancy. The results of the current study showed that 61.3% of pregnant women used at least one medication except for supplements. This rate is notably higher than the reported rate by Mashayekhi et al. from Iran. They showed 19% medication usage during pregnancy among the subjects **(26)**. This remarkable difference may be due to considering OTC medications in our study. Moreover, the studies from other countries also showed different rates; the medication usage rates (excluding supplements) in northern European countries, Germany, and France were reported 44-47%, 85%, and 93%, respectively **(27)**. Two other studies from the United States of America and Sweden showed that about 50% of mothers used at least one drug during pregnancy **(27,28)**.

Based on the results of the present study, pregnant women with earlier and higher numbers of prenatal visits consumed more medications. Moreover, mothers living in the suburbs report more medication usage. These results indicated that mothers who suffered from different complications needed earlier medical consultations and more follow-up visits **(29)**.

By considering supplements, our results indicated that 88.3% of pregnant women consumed supplements during pregnancy. Our results are confirmed by previous findings showing widespread supplement usage during pregnancy. This rate is close to the rates reported from Pakistan (100%) (29), Ethiopia (87.7%), India (79%), and Malaysia (81%) **(20-32)**.

Among consumed supplements, Folic acid (79%) and Vitamin D (68%) were the most used supplements in the current research. This finding shows that about 20% of our participants did not benefit from Folic acid, which needs consideration. Also, only 19.23% of our subjects took Folic acid before pregnancy. Although all participants had not planned pregnancies, these findings show that there was not enough awareness regarding the benefits of taking Folic acid pre-pregnancy. Accordingly, pre-pregnancy initiation and continuing of Folic acid through the first trimester of pregnancy should be emphasized for women who attend prenatal clinics for pregnancy consultations. Moreover, the high prevalence of taking Vitamin D supplements in our study may relate to a high prevalence of Vitamin D deficiency among pregnant Iranian population **(33,34)**.

The results of the present study also demonstrated that most medications were used during the first trimester of pregnancy and medications for hypothyroidism followed by Antibiotics and Antiemetics were the most used drugs for chronic and acute diseases. The high prevalence of medication usage during the first trimester might correlate to the results of routine laboratory tests (including blood, urine, and screening of thyroid disorders) that were administered through the first prenatal visits. In addition to the reasonable implementation of prenatal hypothyroidism screening in Iran, previous studies in our country demonstrated a high prevalence of hypothyroidism **(35,36)**. It also seems that the notable rate of medication consumption during the first trimester correlates to common symptoms in early pregnancy, like morning sickness, reflux, bloating, hyperemesis gravidarum, bacteriuria, and urinary tract

infection. Other studies **(36-38)** have also shown the highest medication consumption during the first trimester; however, using medication in this critical period needs more caution. In contrast with these findings, an investigation from Pakistan demonstrated the highest medication consumption in the third trimester of pregnancy **(30)**. In line with our results, several studies have also shown that drugs for hypothyroidism were the commonly used drugs **(31,32,37)**. In contrast, studies from Pakistan and USA did not confirm our findings and reported that Levothyroxine was not a frequently used medication in pregnant population **(27,30)**.

Unlike previous studies **(25,32)**, antihypertensive drugs were not the frequently used medications in our study. This diversity in the results may be due to the low incidence of this complication among Iranian population **(39,40)**. Other factors like participants' recall bias in reporting medications, and differences in the risk factors of hypertensive disorders like participants' age, BMI, and gravidity may also be involved.

According to our results, the rate of used drugs for acute/short-term diseases (46%) was notably lower than the reported rates by other studies from developed countries (66.2% and 61.4%) **(35,37)**. Comparing the rate of medication consumption for chronic/long-term disease, our obtained rate (27.3%) was higher than reported rates from industrialized countries (17.4% and 12.4%) **(37,41)**. This different result may be related to the age of the participants. The mean age of our population study was as the same as recent studies studies **(21,22)**. Regarding the usage of OTC medications, our results demonstrated a rate of 13.5% that was close to the reported rate by Cleary et al. (19.5%) **(42)** and much lower than the reported rates by Lupattieli et al., (63%) and Baghianimoghadam et al. (35%) **(41,43)**. Following other studies, our findings demonstrated that of OTCs, Acetaminophen as an analgesic agent was the most common used drug during pregnancy **(35,37)**.

Our results showed that several factors, including the mother's residency, the time of first prenatal care, type of medical centers, and planning for pregnancy, could statistically impact medication usage for acute/short complications. Mothers from suburbs with unplanned pregnancies or those who received earlier prenatal care in private clinics used more medications for acute/short-term diseases. In our country, the health services for maternal care in suburb areas are free of charge. This less expensive access to health system in suburbs compared to services by private health care providers (medical doctors or midwives) may be the reason for more medication usage for acute/short complications in the suburbs. We also suppose that less expensive services in academic health centers and more supervision on prescribing drugs are the reasons of less drug usage for acute/short-term symptoms among patients. It also seems that unplanned pregnancy may be along with less concern about drug consumption. We could not find other studies assessing the roles of the mother's residency, type of medical centers, or planning for pregnancy; an investigation from Brazil indicated that the time of first prenatal care was not a significant factor affecting medication usage **(37)**.

The results of the present study also showed that medication usage for chronic/long-term disease was not a prevalent pattern among young non-Iranian mothers or who attended academic prenatal clinics. Mothers with a history of abortion (miscarriage or spontaneous) were also concerned about adverse drug effects and used fewer medications for chronic/long-term disease. Consistent with our findings, previous studies have confirmed the relationship between the increase in maternal age with the prevalence of chronic complications and more medication usage **(5,26,37)**. Lupattelli et al., also reported that pregnant women with a history of abortion (miscarriage or spontaneous) used more medication for their chronic complications than mothers without such a history **(24)**.

Our results also showed that attending private clinics could significantly decrease consumption of OTC medications. It may result in more prescribed medications rather than self-prescription of OTCs. To our knowledge, the present study was the only investigation that has evaluated such a factor; therefore, we could not compare our findings with the results of other literature. We also suggest more focusing on health care providers in private sections to evaluate the patterns and indications of drug prescribing as well as more educating mothers for rational drug prescription during pregnancy.

Based on the results of the current research, we recommend that health system and maternal care providers should be aware regarding maternal medication usage and their reasons. Moreover, providing the data base specifically related to pregnant mothers' medications and probable adverse effects on pregnancy outcomes and childhood period would be beneficial. Another issue concerns appropriate medications among pregnant mothers who should not discontinue their prescribed medications. Discontinuing such medications could not be done without informing health care providers.

Although the present study was the first investigation from Iran that included all medications, it had several limitations. Small sample size and place of the study which were just from one region could not reflect the whole pattern of medication usage among pregnant mothers of Iran. The other main limitation was the recall bias. Few participants could not remember their consumed medicines and the estimated time of consumption. We do not include breast-feeding period which is important considering medication usage. Another limitation was selection bias; also sampling was not randomly performed. In our study, herbal medications were not considered, and we did not

evaluate the effects of used medication on pregnancy outcomes. Future cohort studies during the whole pregnancy and postpartum can provide more informative and complementary data.

5. Conclusion

Our findings showed that not all but a reasonable percentage of the participants received necessary supplements during pregnancy. Anti hypothyroidism, anti-infective, Antiemetics, and Acetaminophen were the most used drugs consumed during the first trimesters of pregnancy. These findings indicate that mothers should be aware of the safety of medicines and the time of consumption. Pre-pregnancy consultation emphasizing controlling underlying disease, initiation of acid folic, and awareness of drugs' adverse effects should be recommended. This study may also highlight the need for specific solid registration system for pregnant mothers with a focus on their medications.

6. Declarations

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Ethical Considerations

The ethics approval was obtained from the institutional review board of Shahid Beheshti University of Medical Sciences according to the Helsinki declaration (ethical code: IR.SBMU.MSP.REC.1398.904).

Authors' Contributions

A.Sh, H.N.F., and M.Y. carried out the design and coordinated the study. H.N.F., R.S.F., Z.F, and H.N participated in most of the experiments and prepared the manuscript. The authors read and approved the content of the manuscript.

Conflict of Interest

The authors declare that there is no conflict of interest.

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