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Drug Use Evaluation of Iron with Folic Acid During Pregnancy at Alem Ketema Enat Hospital, North shoa, Amhara, Ethiopia

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Abstract
Drug Use Evaluation (DUE) is the ongoing, systematic and criteria-based program of medicine evaluations that will ensure appropriate medicines use. Correct dosage of Iron with Folic Acid (IFA) is recommended by WHO to prevent Iron deficiency anemia during pregnancy. Even if it affects populations, pregnant mothers are prone to develop anemia. Iron deficiency anemia contributes for 95% of anemia during pregnancy reflecting the need for iron to pregnant women. Foliate supplementation is encouraged before conception but still has significant protective effect for birth weight. In addition to the mother, anemia has a significant impact to the fetus. Anemia has contributed 20% of maternal deaths in Africa. The national guideline of Ethiopia recommends a minimum of 6 months supply of IFA during pregnancy. A cross-sectional criteria based study design was conducted on 348 Antenatal care (ANC) attendants retrospectively from October to June 2016 to evaluate the extent of correct dosage of IFA at Alem Ketema Enat hospital. This data was analyzed using MS excel 2010 and the result shows only 19 % of ANC attendants took the correct IFA dosage as recommended by WHO and the national protocol. Therefore the hospital should design quality improvement project on the correct supplementation of IFA to pregnant women.
Keywords: Drug use evaluation, Iron with Folic Acid, Pregnancy, WHO Drug Use Evaluation Criteria, North Shoa, Ethiopia

1. INTRODUCTION

The Drug and Therapeutics Committee(DTC) is responsible for numerous important drug management functions. The DTC evaluates new drugs for the formulary, develops policies for drug use, and identifies and corrects drug use problems. Drug use problems in health institution can be identified using drug use evaluation criteria set by WHO [1,2].

Drug Use Evaluation (DUE) is the Ongoing, systematic and criteria-based program of medicine evaluations that will ensure appropriate medicine use. Interventions are necessary when inappropriate therapy is identified. A DUE will Define appropriate medicine use (by establishing criteria) ,Audit criteria against what is being prescribed, Give feedback to prescribers on all identified problems and Monitor to see if criteria are followed and prescribing is improved. DUE can be either disease or therapy based investigation[3,4].

Indicators Suggesting Need for DUE are Overuse or underuse of medications, Problems indicated from WHO/MSH indicator studies , High number of adverse drug reactions, Signs of treatment failures, Excessive number of non-formulary medications used, Use of high-cost medicines where less expensive alternatives exist and Excessive number of medicines within a therapeutic category [5-7].

1.1 Statement of the problem

Anemia is likely cause for women and new born morbidity and mortality and has impact on the growth of children, and on work effectiveness in adults [8]. Even if it affects all populations, mothers are highly affected by anemia [9,10]. Iron deficiency anemia is the leading cause of anemia in pregnancy and is responsible for 95% of anemia during pregnancy reflecting the need for iron in pregnant woman [11]. In pregnancy, anemia has a significant impact on the health of the fetus as well as that of the mother. 20% of maternal deaths in Africa have been attributed to anemia [12].

IFA deficiency anemia contributes adverse effects on the woman and new born health. Daily oral IFA provision is advised during antenatal care to lower the likelihood of low birth weight, maternal anemia [13]. Preterm labour, low weight gain, premature rupture of membrane, placenta previa, cardiac arrest, lowered resistance to infection, hemorrhage, poor cognitive development and reduced work capacity are among the maternal risks. On the same way, low birth weight, prematurity, fetal distress which contribute to prenatal morbidity and mortality are among fetal and neonatal risks [14].

In the United States, about 4000 pregnancies are affected by neural tube defects annually; among 50% of these defects could be prevented with daily intake of 400 micrograms of folic acid throughout the peri conception period [15]. The prevalence of Folic acid supplementation intake in peri connectional period in Qatar,

Canada, USA Korea, and United Arab Emirates is 20.3%, 25%, 32% 10.3%, and 45% respectively [16].

Increased intake of Folate is recommended from 2 mg to 4 mg per day during pregnancy. Studies showed that 500 mg of iron is required to raise maternal red blood cell volume and 300 mg of iron for fetal erythropoiesis [17].

Commencing supplementation post conception had a lesser but still significant protective effect according to odds ratios (OR 0.82, 95% CI 0.77–0.87) for birth weight<10th centile, and (OR 0.78, 95% CI 0.72–0.84) for birth weight<5th centile[18]. A study showed a high prevalence of folate deficiency anemia among Senegalese women (15-49 years), particularly those living in rural settings and breastfeeding women.[19]

To alleviate this pandemic problem, there is a great effort in providing IFA for pregnant mothers. According to International Nutritional Anaemia Consultancy Group (INACG) recommendation, 400 µg folic acid and 60 mg/iron per day for 6 months is needed where as anaemia prevalence is 40% or more, 3 months after delivery should be given [20]. World Health Organization recommends provision of 60 mg Iron+400 µg folic acid daily for 6 months for all pregnant women [9].

The Ethiopian national guideline for control and prevention of micronutrient deficiencies highlights the need of daily IFA supplementation for at least 6 months during pregnancy and 3 months postpartum period [21]. This applies for all pregnant mothers without considering their hemoglobin level. But health institutions like hospitals and health centers that provide IFA per protocols are very low in different parts of Ethiopia. Therefore, effectiveness and quality of this service depends on the adherence of health care providers to IFA supplementation protocols [22]. Nationally survey showed that only <1% of the pregnant women takes IFA supplements for more than 90 days out of the recommended 180 days. 83% of women did not take IFA And; and 15% of them took for less than 60 days during their pregnancy. Astudy in Addis Ababa showed that 2.4% of the pregnant women took IFA supplements for more than 90 days of the recommended 180 days. 60.8% of women did not take iron, 7.6% pregnant women took between 60-80 days and 29.2% of them took for less than 60 days during their pregnancy [23].

Alem Ketema Enat hospital DTC has endorsed the need to assess the appropriate adherence of the IFA supplementation protocols for pregnant mothers served in the hospital using WHO drug use evaluation criteria format.

2. METHODS AND MATERIALS

2.1 Study design

Cross sectional criteria based retrospective study was done using pregnant women's medical records from June to Oct, 2016 at Alem Ketema Enat Hospital.

2.2 Study area and period

Alem Ketema Enat Hospital is found in Amhara Regional State in North Shoa, MerhabeteWoreda. It is 185 km away from Addis Ababa and 584 kms far from the regional state, Bahirdar. The hospital has 54 beds and serves for more than 1,137,473 catchment population. Data were collected from 1-30 Nov,2016.

2.3 Source population

All cards of pregnant mothers that have visited Alem ketema Enat hospital for ANC purpose in the MCH clinic from June to Oct, 2016.

2.4 Study population

Medical records of pregnant women systematically selected for review and health care providers working from ANC.

2.5 Sample size and sampling technique

2.5.1 Sampling and sample size

Systematic random sampling technique was used to select 348 ANC cards from 1095 pregnant mothers documented on ANC register from June to Oct, 2016.

2.6 Sampling procedure

There were 1095 Antenatal care (ANC) clients from June to October 2016. The 348 study medical records were selected by systematic random sampling method every 3 serial numbers from ANC registered book.

2.7 Variables of the study

2.7.1 Dependent variables

Correct Iron with folic acid (IFA) Dosage (dose, frequency and duration)

2.7.2 Independent variables

- Patient characteristics: age, weight,
- Diagnosis(anemia)
- Indications(treatment or prophylaxis)
- Contraindications to IFA
- Drug interactions with IFA
- prescribers qualification

2.8 Data collection

DTC subcommittee members (Physicians and pharmacists) collected data by setting criteria using WHO DUE format.

2.9 Data processing and analysis

The collected data was manually entered and checked by using MS excel. It was edited, cleaned and descriptive statistics was used.

2.10 LIMITATIONS OF STUDY

Across sectional descriptive study but limited to a primary hospital may compromise to generalize the national IFA supplementation status.

3. RESULT

Demographic and clinical characteristics

Out of 348 medical records reviewed more than half (204 (58.60%)) of pregnant women were 26-35 years of age and almost all (320(92%)) of them weighed 43-60kg (**Table 1**).

Table 1 Demographic and clinical characteristics of Pregnant women attending antenatal care at Alem Ketema Enat Hospital, 2016(N=348)

Variable	Frequency
Age(Years)	
15-25	126(36.30%)
26-35	204(58.60%)
36-45	12(3.40%)
46-50	6(1.70%)
Weight(Kg)	
43-60	320 (92%)
61-75	28 (8%)
Record of gestational age present	
Yes	253(72.6%)
No	11 (3.2%)
Unknown	84(24.2%)
Gestational age during visit	
1-12wks	63(18%)
13-24wks	118(34%)
25-42wks	167(48%)
Number of Previous pregnancy	
1-3	217(62.5%)
4-6	112(32.0%)
7-9	12(3.5%)
10-12	7(2.0%)
History of illness present	
Yes	139(40%)
No	209(60%)

Out of 348 medical records reviewed the following relevant data were assessed. Weight of 29% of ANC visitors was taken once and 69% of ANC visitors was taken more than once but 2% of the visitors weight was not taken. The availably of record of gestational age at first ANC visit was 79% and 21% had unknown/unrecorded gestational age at 1st ANC visit. The earliest visit is 5 weeks and latest is 36weeks.

This chart review revealed that Iron with folic acid (IFA) was not supplied for mothers at each ANC visit. Only for 50% (**Table 2)** of mothers were supplied with IFA during each ANC visit. For ANC visits of more than

once, only 6% of mothers got supplementation at each ANC visit where as 2 and 3 ANC visits corresponded with iron supplementation.

Table 2Total number of ANC visits and the status of IFA at each ANC Visit at Alem Ketema Enat Hospital ,2016 (N=348).

# of ANC visits	# of times IFA was supplied	% of ANC clients	Interpretation
Once	Once	44	Correct
Twice	Twice	4	Correct
three times	three times	2	Correct
Sub total		50	
Twice	Once	20	Not correct
3 times	Once	15	Not correct
3 times	Twice	2	Not correct
4 times	Twice	2	Not correct
4 times	Once	2	Not correct
4 times	three times	2	Not correct
4 times	Twice	2	Not correct
4 times	Once	3	Not correct
5 times	Once	1	Not correct
6 times	Once	1	Not correct
Sub total		50	

ANC= Antenatal Care, IFA =Iron with Folic Acid

Anemia and others maternal health problems are affected by number of pregnancies. This DUE has assessed the number of mothers with previous pregnancies and the result shows the following. From all the charts seen, 29 % had 1 previous pregnancy, 22% had 2 previous pregnancies , 20% had 3 previous pregnancies and the rest 29 % had >4 previous pregnancies.

This DUE (chart review) has tried to assess if prescribers consider mothers' tolerance and adherence to prescribed iron . Unfortunately, no chart contained information that prescribers tried to assess ADR to iron and adherence to its use.

Concerning concomitant illness , 40% of them had 18 different medical conditions-the commonest being UTI (**Table 3**). For the same reason of safety of drugs in pregnancy, prescribers should have assessed self medication history but no one did this. Encouragingly enough, vaccination (TT) coverage is excellent (98%).

Table 3 History of illness and drugs given during ANC visit at Alem Ketema Enat Hospital, 2016(N=348)

	History of illness present	Drug given	(%)
1	AMEBIASIS	Metronidazole	2
2	AGE	AUGMENTIN	1
3	dispepsia	Antacid tab	5
4	Epilepsy	Phenobarbitone	1
5	HBV CARRIER	no treatment	1
6	HIV	option B+	1
7	hyper emisis gravida	metochlopramide	3
8	Pneumonia	c.peniciline	1
9	preclampsia	Diazepam	2
10	renosinsitus+asthma	amoxicillin,citrizine,salbutamol,prednisolone	1
11	syphilis+ UTI	AUGMENTIN	1
12	T.vaginalis	Metronidazole	1
13	URTI	Amoxicillin etc	1
14	UTI	CEFRIAXONE etc	15
15	UTI + T .vaginalis	Augmentin + metronidazole	1
16	UTI +HBV	no treatment	1
17	UTI,ANEMIA	AUGMENTIN	1
18	UTI+GARDIASIS	AUGMENTIN + TINDAZOLE	1
		Total	40

Regarding access to IFA, 99% (Table 4) of the clients were getting iron prophylaxis but not the whole

course of pregnancy. From the anemic cases(7%) ,only 1% of them were treated with IFA full dose for treatment & switched to the ANC standard prophylaxis dose of iron .

Table 4 Results of Drug Use Evaluation process indicators at Alem Ketema Enat Hospital, 2016(N=348)

S.No.	Indicator	Threshold (%)	Finding (%)	Interpretation
1	Indication	100	99	excellent though less than the threshold by 1
2	Dose	100	97	Excellent though less than the threshold by 3
3	Duration	90	19	Bad practice
4	Contra indications	95	0	Excellent but questionable as history taking did take into account ADR, etc
5	Medicine interaction	90	96%	Excellent

4. DISCUSSION

The aim of this study was to determine the rate of correct dosage of Iron with folic acid during pregnancy and designing improvement plan accordingly at Alem ketema Enat Hospital. This study has revealed that Only for 50% of ANC clients were supplied with IFA during each ANC visit and all of them have gotten IFA once in their visits but only 19% of them have gotten the correct dosage as recommended by WHO [20]. This study revealed somewhat different result when compared with a study done in Mizan-Aman Town that showed the dosage(correct dose, frequency and duration) was found to be 70.6%[24]. The probable reason may be the difference in geographic locations, healthcare providers skill mix variation and health institutions variation in providing protocols and timely monitoring and evaluation.

In another study done in Goba woreda had shown that 46.8% of ANC clients had received IFA once in their visit where as our study shows 100% coverage of IFA supplementation once in their visit. The likely difference may be variations in study time, organizational concern for IFA coverage, health care providers knowledge of IFA role for anemia prevention and treatment and availability of IFA guideline and protocol[26].

In contrast to WHO and the national recommendation [9,21], fewer than one-in-twenty women (3.5%) took the supplements for more than 90 days. The problem of duration of therapy was similar with another the study done in Ethiopia [25] where the median total duration of the supplementation was only 30 days. In general 19.6%, 5.5% and 6.2% of ANC clients took the supplements for 1–30, 31–60 and 61–90 days respectively.

5. Conclusion

DUE of IFA showed that utilization was not in compliance with the threshold, especially for duration of therapy. The study also revealed that there is no gap in chart completeness and Pregnant mothers come to the hospital for ANC visit late which compromises the benefits of getting iron in the early stage in pregnancy. Prescribers do not assess history of ADR and adherence to iron and the prescribing habit is not in accordance with the WHO recommendation of correct dosage (correct dose, frequency and duration).There is no frequent health education on safe use and benefits of IFA supplementation and vaccination during pregnancy in the hospital as well as on the need to consume food rich with iron and vitamin C .

6. Recommendation

6.1 Recommendation for Alem Ketema Enat Hospital

The hospital better conduct continuous monitoring and evaluation to provide correct dosage of IFA for pregnant mothers.

The hospital should ensure that those working in ANC unit are well aware of IFA provision and supplementation protocols

The hospital better mobilize the community to start early ANC follow up and for full course of IFA supplementation.

6.2 Recommendation for Health care providers

All health care providers working in the ANC should be aware of the latest recommendations on IFA supplementation.

They should prescribe IFA at each ANC visits with full course of treatment.

Declarations

Ethics approval and consent to participate

Ethical clearance was obtained from Drug and Therapeutic Committee (DTC) of Alem Ketema Enat Hospital. Following the endorsement by the DTC, the hospital Senior Management was informed about the objectives of

the study and permission the hospital Senior Management was obtained and accordingly it was presented to ANC unit. Informed verbal consent was obtained from health care providers in the ANC to confirm willingness.

Consent for publication

Not applicable.

Availability of data and material

The data collected for this study can be obtained from the authors upon a reasonable request

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

The authors generate the original idea, involved in proposal writing, designed the study and participated in all implementation stages of the project. They analyzed the data and finalized the write up of the manuscript. They were responsible for critically revising the proposal and the manuscript, and participated in its design and interpretation. They were responsible for data collection, initial analysis and drafting of manuscript. Both authors reviewed and approved the final manuscript.

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