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Assessment of Kenyan pregnant women's tolerance to adverse effects of iron and folic acid supplementation: A retrospective study

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Abstract

Iron and folic acid supplementation is a maternal and fetal health imperative. This study introduced an examination of antenatal tolerance to the adverse effects of the supplements, defined as persisting with supplementation for a longer duration than the group mean. Multiple logistic regression modeled tolerance against maternal and supplement-related factors. The number of adverse effects experienced was not associated with tolerance [p=0.14, adjusted odds ratio (aOR): 0.8 (0.6–3.4)], but counseling on adverse effects was associated with it [p=0.01, aOR: 3.0 (1.3–7.1)]. Nausea (an important side effect as identified by previous compliance analyses), constipation, and black stool (newly identified) were the only distresses significantly associated with the tolerance ([p=0.02, aOR: 4.4 (1.3–14.9)]; [p=0.03, aOR: 2.1 (1.1–4.3)]; and [p=0.047, OR: 4.2 (0.9–19.2)], respectively). Tolerance analysis presented can identify additional pertinent context-specific adverse effects. Intensified counseling on the effects to improve the tolerance and compliance to antenatal iron and folic acid supplementation should be encouraged and supported. *(Afr J Reprod Health 2026; 30 [13]: 55-62).*

Keywords: Iron and folic acid supplementation; pregnant women; adverse effects; tolerance; predictors of tolerance

Résumé

La supplémentation en fer et en acide folique constitue une priorité en matière de santé maternelle. Cette étude a introduit une analyse de la tolérance prénatale aux effets indésirables des suppléments, définie comme la poursuite de la supplémentation pendant une durée supérieure à la moyenne du groupe. Une régression logistique multiple a modélisé la tolérance en fonction de facteurs maternels et liés aux suppléments. Le nombre d'effets indésirables ressentis n'était pas associé à la tolérance [p = 0,14, odds ratio ajusté (ORa) : 0,8 (0,6–3,4)], mais le conseil sur les effets indésirables y était associé [p = 0,01, ORa : 3,0 (1,3–7,1)]. Les nausées (un effet secondaire important identifié par des analyses antérieures de l'observance), la constipation et les selles noires (nouvellement identifiées) étaient les seules manifestations significativement associées à la tolérance ([p = 0,02, ORa : 4,4 (1,3–14,9)] ; [p = 0,03, ORa : 2,1 (1,1–4,3)] ; et [p = 0,047, OR : 4,2 (0,9–19,2)], respectivement). L'analyse de la tolérance présentée peut permettre d'identifier d'autres effets indésirables pertinents et spécifiques au contexte. Un renforcement du conseil sur ces effets afin d'améliorer la tolérance et l'observance de la supplémentation prénatale en fer et en acide folique devrait être encouragé et soutenu. *(Afr J Reprod Health 2026; 30 [13]:55-62).*

Mots-clés: Supplémentation en fer et en acide folique ; femmes enceintes ; effets indésirables ; tolérance ; facteurs prédictifs de la tolérance

Introduction

Efforts in ameliorating intolerance to the adverse effects of oral iron and folic acid supplementation (IFAS) may contribute to better obstetric outcomes and maternal and infant health. The concept of 'tolerability' to these effects necessitated distinct analysis, and there was a need to generate a fresh discourse that we had avoided in order not to confound the key messages in our earlier publications.[1,2] In these previous publications, we conducted an analysis of various maternal, institutional, and supplement-specific determinants influencing compliance, as determined by the standard duration (at least 90 days) of intake for prenatal iron and folic acid supplementation (IFAS)1. From the same data set, we subsequently excluded women who did not ingest the supplements to analyze the influence of the individual IFAS side effects experienced during the duration of intake on compliance.[2] In this present paper, we excluded women who did not experience

distress from IFAS to remain with a group from which we examined tolerance to the side effects and associated factors. The analysis of tolerance can provide population-level dynamics and insights on IFAS, as well as for the new initiative that may replace IFAS, the Multiple Micronutrient Supplements (MMS).[3]

Non-compliance to prenatal oral iron and folic acid taken daily has been attributed to many factors, including the attendant adverse effects.[2,4-7] The most common of these effects are gastrointestinal discomforts, which are not dose-dependent and are limited to metallic iron taste, constipation, nausea, vomiting, epigastric pain, heartburn, and diarrhea, mainly due to unabsorbed iron toxicity to the intestinal mucosa.[8] The influence of adverse effects associated with IFAS is imperative and has in part previously informed the policy change from a sole recommendation of the daily regimen of 60 mg of elemental iron plus 0.4 mg of folic acid to an option of weekly intermittent supplementation, the latter exhibiting fewer adverse effects.[9,10]

Kenyan prenatal women are orally administered with tablet or syrup forms of 60-65 mg elemental ferrous salt + 0.4 mg folic acid taken daily for a minimum of 90 days during pregnancy. This drug combination is classified as an essential drug in the country under 'drugs that affect the blood'.[11-12] The adverse effects of IFAS are inadvertent to preventive and therapeutic intentions. It is a reality that prenatal women have to tolerate the effects to accrue maternal and fetal benefits of the combined supplement. In our study setting, pregnant women experienced an average of two IFAS adverse effects during the prenatal period.[2]

The commonness and potential effects of these distresses cannot be unheeded. It is therefore vital to understand population-level context-specific factors associated with the effects. Compliance with the IFAS regimen (minimum of 90 days of supplementation during pregnancy) and the tolerance analysis (based on the collective mean days of supplementation) are two distinct potential approaches for the distribution and effects of attendant supplementation side effects. These analyses and further elucidation of the predictors can allow the identification of possible considerations to minimize the impact of the adverse effects. We were thus motivated to analyze context-specific iron and folic acid supplement (IFAS) tolerance and the associated modifiable factors that may appreciably influence the daily regimen of oral antenatal IFAS.

Methods

Study design and participants

Data were collected retrospectively through maternal recall in a descriptive, cross-sectional study involving postnatal women with children aged 0 to 60 months. A modified World Health Organization Safe Motherhood Assessment standard questionnaire was used. The study was conducted in Kalama Ward, formerly a division, within Machakos County in the lower eastern region of Kenya.

Sampling and data collection

As previously reported, an overall primary sample size of 346 mothers (of children in the age groups 0–11, 12–23, 24–35, 36–47, and 48–60 months) was determined, where a 5% contingency was applied to a sample size of 66 per age group.[1] The average daily numbers of mother-child pairs attending all the mother-child welfare clinics in Kalama Ward were obtained from existing records. The numbers sampled from each facility were proportionate to size based on these records. Study subjects were selected randomly. Mothers of children in the same age groups (0–11, 12–23, 24–35, 36–47, and 48–60 months) were separately assigned numbers in order of their arrival time at the facility and selected using random tables, while excluding underage mothers (<18 years of age) and guardians. Roughly equal representations of children's age groups were ensured to moderate the effects of recall bias, which may be more prevalent among mothers of older children. The specific sample size derivation for this paper is shown in the study profile (Figure 1). Those who ingested the supplements (n=277) and experienced IFAS-associated adverse effects (n=138).

Mothers were asked to recall the cumulative number of days (continuously or intermittently) they took the supplements in their previous immediate pregnancies. They were shown tablet and syrup forms of the supplement to ease recollection. One at a time, possible adverse effects were read to the study participants, and they were

asked if their experiences during the antenatal period were attributed to IFAS. Other data sets collected included maternal socioeconomic and demographic characteristics, antenatal clinic (ANC) attendance, counseling on IFAS, and forms of supplements taken.

Data analysis

One of the primary obstacles to prolonged supplementation is the experience of adverse effects. Consequently, we assessed tolerance to these effects in relation to the duration of supplementation, quantified in days. We defined tolerance as the propensity to continue IFAS supplementation despite experiencing associated side effects, as reflected by a reduced impact of these adverse effects on the duration of supplementation. Individuals tolerant were operationally defined as those reporting a mean or greater number of days of supplementation. For this novel analysis, tolerance refers to the length of time supplement users are able to persist with supplementation despite encountering adverse effects. Accordingly, supplementation for more than the mean cumulative duration, specifically beyond the lower bound of the 95% confidence interval (38.3 days), was classified as indicative of tolerance, whereas supplementation for fewer days (≤ 38.3 days) was classified as intolerance. The lower, rather than the upper, confidence interval was selected as the cutoff to maximize the sensitivity of the tolerance indicator to the greatest extent numerically possible.

This operational definition represents a modified adaptation of the pharmaceutical concept of tolerance, which is defined as a decrease in response over time with continued use of the same drug dose.[14] In the context of the present study, the "response" was operationalized as the duration of supplementation in days, given a consistent exposure to IFAS side effects (dose). Higher durations of supplementation were therefore interpreted as greater tolerance.

In a multiple logistic regression analysis among those who experienced adverse effects, we modeled tolerance as a dependent variable and associated factors as independent variables, adjusting for maternal knowledge of the minimum duration of prenatal supplementation. In separate logistic regression analysis, tolerance and the specific adverse effects were dependent and independent variables, respectively, and here we also included all cases that took the supplements, whether they experienced any adverse effects or not. In this analytical approach, we adjusted for modifiable, tolerance-associated factors found in the first logistic regression analysis: number of ANC visits, duration of supplementation, and counseling on IFAS adverse effects.

Ethical consideration

The study was approved by the Great Lakes University of Kisumu ethical research committee. Additional approval was obtained from the National Commission for Science, Technology and Innovation (NACOSTI), Kenya. The anonymity of the study participants was ensured throughout the data collection period, and privacy was ensured by conducting the interviews in secluded rooms. Only mothers who consented to the study were interviewed, and consent was obtained verbally and through signed consent forms.

Results

Study profile and characteristics of the study participants

The study profile (Figure 1) shows that, out of the original sample size of 346 used in the compliance analysis in the previous publication, excluding participants who did not ingest the supplements left 277 cases.[1,2] These 277 cases were used in the present tolerance-by-adverse-effects analysis, as they included a comparison group of cases that did not experience side effects. Further exclusion of those who did not experience any adverse effects left 138 cases for the analysis of general factors predicting tolerance.

The general characteristics of the study participants have already been presented elsewhere.[2] In summary, most mothers who reported at least one adverse effect were multigravidae and in marital arrangements. Less than half had attained a secondary school education, and only close to one-tenth of them were in salaried employment at the time of the study. As profiled in Table 1, slightly more than half of the mothers had been counseled on IFAS adverse effects at least once antepartum. On average, participating mothers

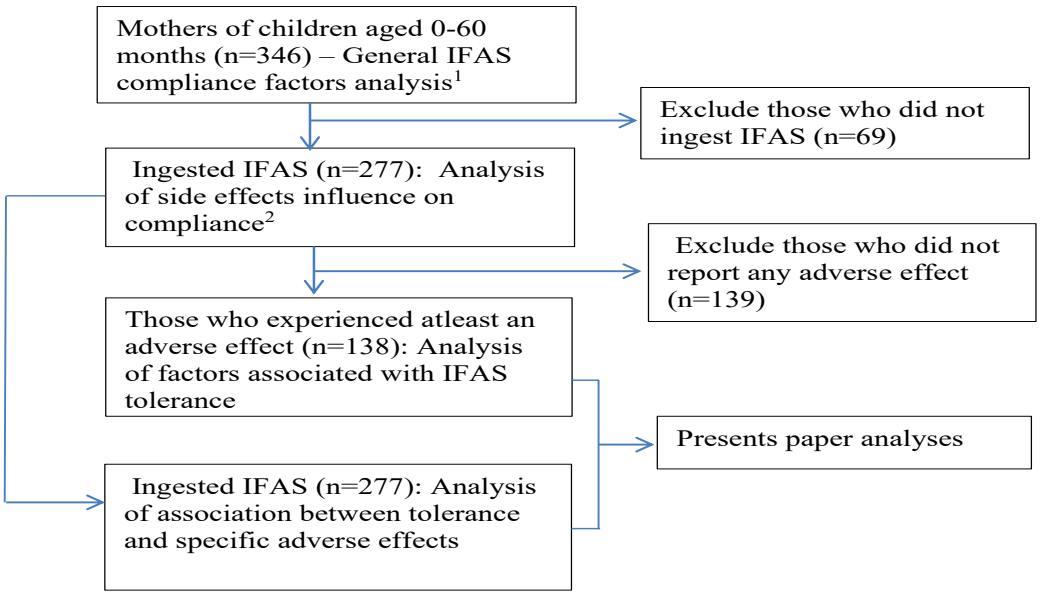

Figure 1: Study profile

Table 1: Supplementation profile of mothers who experienced adverse effects (n=138)

Factors	Proportions/values
Counselled on IFAS adverse effects, % (n)	52.2 (68)
Mean days of supplementation, ±SD	43.3±30.7
Mean number of adverse effects experienced, ±SD	2.4±1.5
Proportion of mothers tolerant to adverse effects, % (n) [a]	39.1 (84)
Tablets (not syrup) form of iron-folate ingested, % (n) [∞]	94.2 (130)
Combined formulation, % (n) [b]	58.6 (74)

[a]Tolerant participants were defined as those who took iron supplements for more than the lower limit (CI, 95%) of group mean ->38.3 days
[b]Those who did not take combined forms, did take iron and folic acid tablets separately
Abbreviations: SD=Standard deviation (α= 0.05)

had ingested the supplements for 43.3 days, and about 39% of them were tolerant of the supplements' adverse effects, meaning the side effects did not cause substantial hindrances to their supplement intake. The majority of the participants took tablets rather than syrup formulations, as a fixed-dose combination rather than as separate regimens of iron and folic acid.

Determinants of tolerance to IFAS adverse effects

Table 2 depicts the distribution of IFAS adverse effects tolerance by maternal and supplement characteristics among study participants who only experienced adverse effects (n=138), and the uni- and multivariate analyses adjusted for maternal knowledge on the standard duration of supplementation (90+ days). Several factors were associated with IFAS adverse effects tolerance. In univariate analysis, these were number of ANC visits [p=0.006, OR, 3.5 (1.4–8.8)], with attendance ≥4 times more likely to be tolerant; in multivariate analysis, gestational age at first ANC visit [p=0.04, aOR, 2.4 (1.0–5.5)] with earlier ANC starters more likely to be tolerant; and in both uni- and multivariate analyses, counseling on adverse effects with those exposed to counseling more likely to be tolerant.

Those who used a combined form of the supplement were also more likely to be tolerant as shown by both uni- and multivariate analysis.

Table 2: Maternal and supplement factors associated with tolerance to IFAS among only those who experienced the side effects (n=138)

Maternal or supplement factors	% tolerant[a]	P-value, OR (CI, 95%)	P-value, aOR (CI, 95%)[b]
Age of the mother			
<30 years	40.9	0.55, 0.8 (0.4-1.7)	0.36, 1.5 (0.6-3.6)
>30 years	35.6		
Gravida			
Primigravidae	41.8	0.64, 0.9 (0.4-1.7)	0.82, 1.1 (0.5-2.5)
Multigravidae	37.8		
Number of ANC visits			
≥4,≥4	45.1	0.006, 3.5 (1.4-8.8)	0.05, 0.22 (0.1-0.6)
<4,<4	18.9		
Gestational age at first ANC visit			
1st trimester	46.5	0.07, 0.5 (0.3-1.1)	0.04, 2.4 (1.0-5.5)
Other trimesters or never attended	31.3		
Received counseling on adverse effects			
Yes	52.8	0.001, 0.2 (0.1-0.6)	0.01, 3.0 (1.3-7.1)
No	27.2		
Combined form			
Yes	58.1	0.00, 6.68 (3.0-	0.00, 0.1(0.1-0.5)
No	17.2	14.8)	
Number of adverse effects			
≤2	42.2	0.4, 0.90 (0.7-1.12)	0.14, 0.8 (0.6-1.1)
>2	34.5		

[a]Pregnant women supplemented with IFAS for more than the mean number of cumulative days (lower CI, 95% – >38.3).
[b]Adjusted for maternal knowledge on the duration of supplementation (90+ days)
Abbreviations: OR= Odds Ratio; aOR= Adjusted Odds Ratio; ANC= Antenatal Clinic (prenatal clinic); IFAS=Iron and folic acid supplementation.

Table 3: IFAS tolerance by adverse effects experiences among those who ingested the supplements

Adverse effects	% tolerant[∞] (n=277)	P-values and Odds Ratios (OR)*	
		P-value, OR (CI, 95%)	**P-value, aOR (CI, 95%)**
Nausea	23.8	0.08, 2.5 (0.9-7.0)	0.02, 4.4 (1.3-14.9)
Vomiting	28.6	0.30, 1.9 (0.6-6.0)	0.06, 3.8 (3.8-15.1)
Constipation	34.2	0.10, 1.6 (0.9-2.7)	0.03, 2.1 (1.1-4.3)
Diarrhea	31.2	0.20, 1.7 (0.8-3.7)	0.30, 3.0 (1.1-7.8)
Black stool	15.4	0.05, 4.2 (0.9-19.2)	0.04, 0.1 (0.03-0.9)
Stomach cramps	28.6	0.47, 1.8 (0.4-9.6)	0.20, 2.7 (0.4-16.8)
Severe stomach pains	53.1	0.17, 0.6 (0.3-1.3)	0.70, 1.2 (0.5-3.3)
Heartburn	25.0	0.10, 2.3 (0.8-6.5)	0.20, 2.2 (0.7-7.7)
Chest pains	46.6	0.28, 0.8 (0.5-1.3)	0.40, 1.3 (0.7-2.6)
Blue colour lips and fingernails	33.3	0.49, 1.5 (0.5-4.4)	0.20, 2.6 (0.7-9.7)
Clumsy Skin	42.9	0.96, 1.0 (0.21-4.3)	0.80, 1.4 (0.2-8.9)

[∞]Pregnant women supplemented with IFAS for more than the mean number of cumulative days (lower CI, 95% – >38.3).
*****Cases analyzed all those who ingested the supplements and reported side effects or not. aOR based on adjustment for number of ANC visits, length of supplementation, and counseling on side effects

Tolerance by experienced adverse effects

Distributions of tolerance by adverse effects among those who ingested the supplements, irrespective of whether they experienced or reported side effects or not (n=277), are shown in Table 3. Relatively, the most tolerable adverse effects were severe stomach pains (59.1%) and chest pain (54.6%), while the

least tolerated were black stool, nausea, and heartburn. Out of all 11 adverse effects reported, only nausea [p=0.03, aOR: 0.2 (0.07-8.5)], constipation [p=0.03, aOR: 0.5 (0.2-0.9)], diarrhea [p=0.03, aOR: 2.5 (1.1-7.8)], and black stool [p=0.04, aOR: 6.1 (1.0-36.8)] were significantly associated with tolerance in a multivariate analysis adjusted for modifiable factors of the number of ANC visits, trimester of starting ANC visits, and counseling for IFAS.

Discussion

We tested a simple method to estimate the level of tolerance to IFAS adverse effects and analyze the associated factors among resource-poor rural Kenyan pre-natal women. It was found that 39.1% of the women who experienced the effects during the antenatal period were tolerant. Earlier ANC starters, those with more antenatal visits, and those who received counseling on the IFAS side effects were more likely to be tolerant than their respective counterparts. Out of the 11 reported adverse effects, only three were negatively associated with tolerance. These were nausea, constipation, and stool discoloration, and the last two were identified as important by the present tolerance analysis and not by our previous compliance analyses.[12] Tolerance was expressed based on a cut-off mean (lower CI) days of antepartum supplementation, as opposed to compliance, which is based on the minimum cut-off of 90 days of pre-natal supplementation – a global proxy indicator of optimum intake used in Demographic Health Surveys (DHS). Tolerance, the presently novel and tested analysis, on the other hand, indicates relative comparison within the study cohort from a localized area and, therefore, is more context-specific. It potentially offers a complementing approach to the understanding of the area-specific dynamics in IFAS highlighted by compliance analysis.

The number of ANC visits antepartum is critical in increasing opportunities for prenatal women and health worker interactions. We had previously proven in the same study location that the frequency of ANC attendance was positively associated with IFAS compliance, and this had also been shown in other locations.[1,15,16]

In our previous analysis, initiating ANC earlier was not associated with compliance. However, in this present analysis, this sound practice is associated with tolerance, a demonstration of the variations in the sensitivities of tolerance and compliance – an indication of tolerance being more context specific. In a compliance analysis for the same study group, only nausea was associated with compliance.[2] In tolerance analysis, two more side effects have come up, which is critical. These are constipation and stool discoloration, and it has been identified that counseling is critical in reducing the effects of the experienced adverse effects. Amidst many adverse effects, it may be overwhelming to counsel on all of them at the same time, and thus the tolerance analysis is critical in prioritizing those to focus on. Part of counseling may include informing pregnant women that they should expect the adverse effects, that they are temporary and will disappear as the body adjusts to the supplements, and that they should contact their health workers if the effects last long.[17]

Implications for policy and practice

The present analysis supports the recent WHO policy recommendation of doubling the number of pre-natal contact points from four to provide more opportunities for counselling[10]. Counselling on side effects is key, and programs should complement compliance and tolerance analysis in identifying the side effects to prioritize counselling.

Study limitations

Several limitations warrant consideration when interpreting the findings of this study. Establishing a definitive causal relationship between iron-folate supplementation and reported side effects was challenging, potentially due to confounding factors such as concurrent medication use, dietary habits, and pregnancy-related hormonal fluctuations. Furthermore, the study's cross-sectional design relied on participant recall in ascertaining the duration of supplementation, a known limitation of the Demographic and Health Survey (DHS) methodology, introducing the possibility of recall bias – and measures to minimize such biases are discussed elsewhere.[2]

Conclusion

Tolerance analysis demonstrated its utility in identifying stool discoloration and constipation as

salient adverse effects associated with concurrent iron and folic acid supplementation among Kenyan antenatal women. These findings underscore the need to strengthen clinical contact between pregnant women and healthcare providers, as well as to promote and support targeted counseling on the management of supplement-related gastrointestinal discomfort. Given its capacity to generate context-specific insights, tolerance analysis is recommended for presentation alongside compliance outcomes in cross-sectional studies.

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Conflicts of interest

The authors declare that they had no competing interests before and during the research.

Contributions of authors

SOO and MJ conceptualized the study and the design. SOO and GOD further refined the study design and the tools. MJ collected the data. SOO analyzed the data. SOO wrote the first draft of the manuscript. MJ and GOD provided further technical and editorial inputs to the draft. The manuscript was reviewed and approved by all the authors before submission.

Availability of data and materials

The datasets and/or analyses during this study are available from the corresponding author on reasonable request.

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