

RESEARCH ARTICLE

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A comparative assessment of knowledge, attitude, and practice of pharmacovigilance among medical, pharmacy, and nursing students in South-West Nigeria

Comparative Assessment of Pharmacovigilance among Nigerian Students

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Abstract

Objective: To assess the knowledge and attitude of undergraduates in the discipline of medicine, pharmacy and nursing about adverse drug reactions and their reporting.

Methodology: This study was conducted among undergraduate students of medicine, pharmacy and nursing from five tertiary institutions located in South-West Nigeria. The questionnaire consisted of sections on the demographics of respondents, their knowledge, attitude and practice of ADR reporting.

Results: A total of 711 undergraduates (345 medical, 262 pharmacy and 104 nursing students) completed the survey. A larger proportion of medical students knew the correct definition of pharmacovigilance compared to nursing and pharmacy students. The regulatory body for collating and monitoring ADRs in Nigeria was correctly identified by 64.3% of the study participants. The mean pharmacovigilance knowledge score for all respondents was 2.6/10 (SD – 1.3; Range: 0-6). Medical students (3.1/10) had the highest knowledge score, followed by nursing students (2.4/10) and pharmacy students (2.0/10) -P <.000. Nursing students (63.5%) had observed ADRs during their training more than the others. Pharmacy students (30.2%) in comparison to nursing (19.2%) and medical students (15.2%) knew the ADR reporting form (yellow form).

Conclusion: Though the knowledge of Nigerian undergraduate medical, pharmacy and nursing students about adverse drug reactions and their reporting was generally poor, this study identified gaps peculiar to each of the three programmes. There is a need therefore for curriculum review of these programmes to include both theoretical and practical aspects of adverse drug reactions and their reporting.

Keywords: Adverse drug reporting; Perception; Practice; Understanding; Medical Students; Nursing; Pharmacy; Undergraduates

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Plain English Summary

The study evaluated how well undergraduate medical, pharmacy, and nursing students in South-West Nigeria understood and felt about adverse drug reactions (ADRs) and their reporting. A survey method was employed with questions about the student's knowledge, attitudes, and practices regarding ADR reporting.

A total of 711 students participated (345 Medical, 262 Pharmacy, and 104 Nursing). Medical students had better knowledge of pharmacovigilance (drug safety monitoring) than other categories of students. The overall knowledge scores were low, with medical students scoring the highest (3.1 out of 10), followed by nursing (2.4) and pharmacy students (2.0). It was interesting to note that nursing students had observed ADRs more often than the others during their training. Pharmacy students were most familiar with the ADR reporting form, otherwise known as the "yellow form." The conclusion highlighted poor knowledge of pharmacovigilance among respondents and their reporting was generally poor, with specific gaps in each discipline. The study recommended revision of the academic curriculum to include both theoretical and practical training on adverse drug reactions and their reporting.

Background

Adverse drug reactions (ADRs) are common problems associated with medication use and are associated with increased morbidity and mortality (1, 2, 3, 4). A recent systematic review and meta-analysis of thirty-three studies estimated a pooled prevalence of 8.32% of ADRs in primary care settings (5). Adverse drug reactions as a major reason for hospitalization is highlighted in a review by Angamo *et al* with ADR-related hospitalization prevalence of 6.1% and 5.5% in developed and developing countries respectively (6). The economic impact of managing adverse drug reactions is enormous and this has been highlighted in many studies (7, 8). Spontaneous reporting of ADR by healthcare workers is one prominent way of monitoring and preventing further occurrence of ADR. However, there is strong evidence of inadequate reporting of ADRs by healthcare workers worldwide (9, 10, 11). In Nigeria, studies conducted among healthcare workers have shown gross under-reporting of adverse drug reactions (12). Among the reasons for under-reporting, the lack of adequate exposure to pharmacovigilance education during undergraduate education stands out. (9, 13, 14). One of the ways of addressing this problem is to ensure that undergraduate education in medicine, pharmacy and nursing is updated especially regarding modules in pharmacovigilance. This is understandable as these students are future healthcare practitioners and improved training in adverse drug reaction reporting and pharmacovigilance for them will lead to better patient outcomes and reduce healthcare costs. The knowledge, attitude and practice of undergraduate students of medicine, pharmacy and nursing have been reported in several studies conducted in Nigeria (15, 16). However, information about the comparative assessment of the knowledge of undergraduate students of medicine, pharmacy, and nursing in Nigerian universities is lacking. Harmonization of pharmacovigilance activities

among healthcare workers is important and will likely lead to better outcomes, hence the need to assess the knowledge and practice of future prescribers and carers of patients. Observations from this study would provide a template for future interventions in the curricula and training activities of these students in the field of pharmacovigilance. This study assessed the knowledge, attitude and practice of ADR reporting among medical, pharmacy, and nursing students in selected tertiary institutions in South-West Nigeria.

Materials and Methods

A descriptive cross-sectional study was conducted among undergraduate students of Nursing, Pharmacy, and Medicine from five Nigerian universities between October and December 2021.

Study setting

The study was conducted among undergraduates of five universities located in South-West Nigeria. Students of undergraduate programs in Medicine and Nursing from two different universities and those in Pharmacy from another university. The participating universities are Ekiti State University and Afe Babalola University (Medicine); University of Ibadan and Ogun State University (Pharmacy); Obafemi Awolowo University (Nursing).

Selection of study participants

Students in the final two years of their undergraduate programmes (Pharmacy and Nursing) and those in the final three years in Medicine were invited to participate in the study. These were students who had completed modules in Pharmacology in the different programmes. This was done after the Co-PI in each of the study sites had informed the students about the rationale, aims and objectives of the study.

Study instrument

The questionnaire was developed by the authors based on an extensive literature search for similar

studies with necessary modifications done to cater to the study setting and population. Pre-testing of the instrument was done, and it was also reviewed for content validity by specialists in Clinical Pharmacology and Pharmacy. The calculated Cronbach's alpha for the instrument was 0.82 confirming good internal consistency for the instrument. The 28-item questionnaire had sections on the demographic characteristics of respondents, students' knowledge of ADR and its reporting, and their attitudes and practices regarding pharmacovigilance. The section on knowledge comprised 10 questions/statements with a weight of one (1) for each correct answer and zero (0) for a wrong answer. Questions in this section include the definition and types of ADRs, types of ADRs to be reported, and who is to report among others (Appendix A). Hence, the minimum and maximum obtainable scores for this segment are 0 and 10 respectively. Respondents were classified based on their scores into good (>6), average (4-5) and poor (<4). The sections on attitude and practice had 8 and 6 questions/statements respectively. These sections were not allotted any score because they were descriptively assessed. The last item was an open question for respondents to suggest ways of improving their knowledge and practice of pharmacovigilance.

Study Procedure

The questionnaires were administered in each of the participating institutions by co-authors who worked there. The questionnaires were distributed during academic activities by the focal persons after the respondents had been informed about the study's aims and objectives. The time lag between informing respondents and administration of

questionnaires was less than 10 minutes. A time frame of 30 minutes was allowed for the completion of the study. Completion of the questionnaire by respondents was taken as implicit consent.

Data analysis

Collected data was screened for accuracy, completeness, and consistency and those found incomplete or missing in addressing important variables were discarded. Data analysis was performed with IBM SPSS version 25 (Armonk, NY: IBM Corp). Categorical variables (sex, academic programmes, year of study/level of students and knowledge level) were summarized using frequencies and percentages while the normally distributed continuous variables (pharmacovigilance knowledge score) were summarized using mean and standard deviation. The normality of data was determined using the Kolmogorov-Smirnov test. Comparison of means (pharmacovigilance knowledge score) of the variables (academic programmes, year of study, sex) was done using ANOVA and Student t-test as appropriate. Association between categorical variables (academic programmes, year of study, sex and score category) was assessed using the Chi-square test. A P-value less than 0.05 was accepted as a statistically significant association.

Results

A total of 711 undergraduates comprising 345 medical, 262 pharmacy and 104 nursing students completed the survey with a mean age of 24.6 (SD 6.4) years. Female students (436; 61.3%), those within the age range 21-30 years (449; 67.6%) and those in the 4th year of study (477; 67.1%) were in the majority (Table 1).

Table 1: Socio-demographics of respondents

Variable	Frequency (%)
Sex	
Male	275 (38.7)
Female	436 (61.3)
Age group	
Less than 20 years	136 (20.5)
21 – 30 years	449 (67.6)
31 – 40 years	48 (7.2)
Above 40 years	31 (4.4)
Academic programme	
Medicine and Surgery	345 (48.5)
Pharmacy	262 (36.8)
Nursing	104 (14.6)
Year of Study	
4th	477 (67.1)
5th	211 (29.7)
6th	23 (3.2)

Table 2 shows the breakdown of responses to knowledge-related questions according to the course of study. The definition of pharmacovigilance was known by 61.3% of respondents while types of ADRs were correctly identified by 50.4% of respondents. The regulatory body for collating and monitoring ADRs in Nigeria

was correctly identified by 64.3% of the study participants with a greater proportion of medical students than pharmacy and nursing students. Eighty-three per cent (83%) of respondents knew the cadre of healthcare workers responsible for reporting ADRs. Other details are as stated in Table 2.

Table 2: Breakdown of responses to knowledge-related questions according to the course of study

Statements/Questions	Correct responses (All respondents)	Correct responses (Medicine)	Correct responses (Pharmacy)	Correct responses (Nursing)
Definition of ADRs	430 (61.3)	269 (78.7)	109 (42.7)	52 (50.0)
Identify types of ADRs	351 (50.4)	252 (75.4)	82 (31.7)	17 (16.3)
What is the international online database for reporting ADRs called?	101 (14.6)	43 (13.1)	30 (11.6)	20 (19.2)
Which of the following cadre of healthcare workers is responsible for ADR reporting?	575 (83.0)	316 (92.7)	159 (64.1)	100 (96.2)
Awareness of the National Pharmacovigilance Programme in Nigeria	271 (38.9)	104 (30.9)	93 (36.3)	74 (71.2)
Rare adverse effects can be identified in which phase of clinical trial?	230 (35.9)	126 (43.9)	103 (41.4)	1 (0.01)
What is the regulatory body for collating and monitoring ADR in Nigeria	436 (64.3)	228 (70.4)	146 (58.4)	62 (59.6)
Where is the International ADR monitoring centre located?	109 (18.5)	79 (30.0)	22 (10.0)	8 (7.7)
The most important purpose of Pharmacovigilance is ...	387 (56.3)	223 (68.0)	107 (41.8)	8 (7.7)
What method is used to monitor ADRs of new drugs once they are introduced into the market?	271 (42.9)	91 (31.5)	101 (42.1)	79 (76.7)

The mean pharmacovigilance knowledge score for all respondents was 2.6/10 (SD – 1.3; Range: 0-6). According to the earlier stated classification, the majority (546; 76.8%) of respondents had poor

knowledge while only a few fell within the good knowledge bracket (9; 1.3%). Figures 1 and 2 show the breakdown of the knowledge scores and classification.

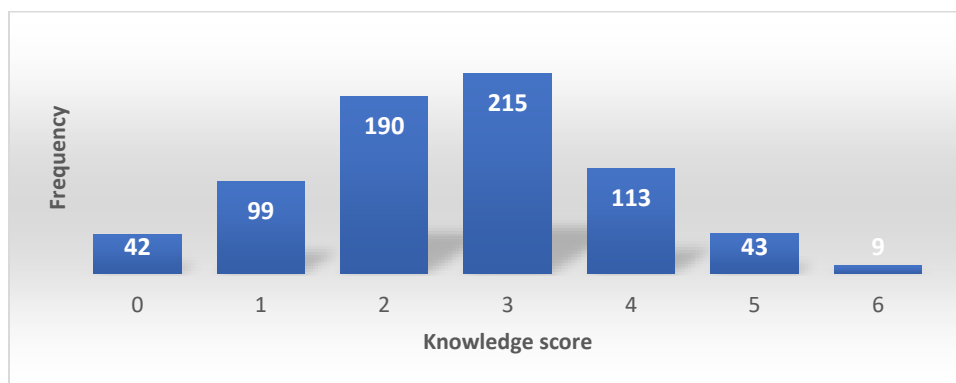


Figure 1: Pharmacovigilance Knowledge Score of Respondents

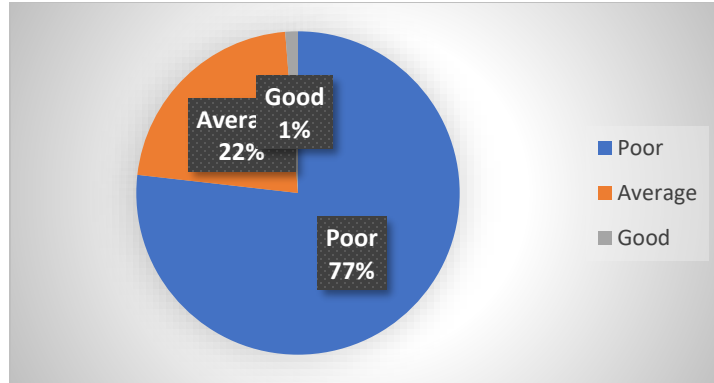


Figure 2: Level of knowledge of respondents

Female respondents (2.72 ± 1.25) had a higher knowledge score than males (2.40 ± 1.36), a statistically significant difference ($P = .002$). A comparison of the knowledge scores between respondents from different academic programmes showed that medical students ($3.1/10$) had the highest knowledge scores, followed by nursing students ($2.4/10$) and pharmacy students ($2.0/10$). The difference between the mean of the different groups was statistically significant – $P < .000$. Using

the Tukey HSD Post Hoc test, statistically significant differences in the mean were found between the three groups ([Supplementary Table 1](#)). In addition, students in their 6th year had the highest mean score ($3.7/10$) followed by those in their 4th and 5th year ($2.7/10$ and $2.3/10$ respectively). The difference in the means here was also statistically significant ($P = .018$). Figures 3 and 4 show these comparisons.

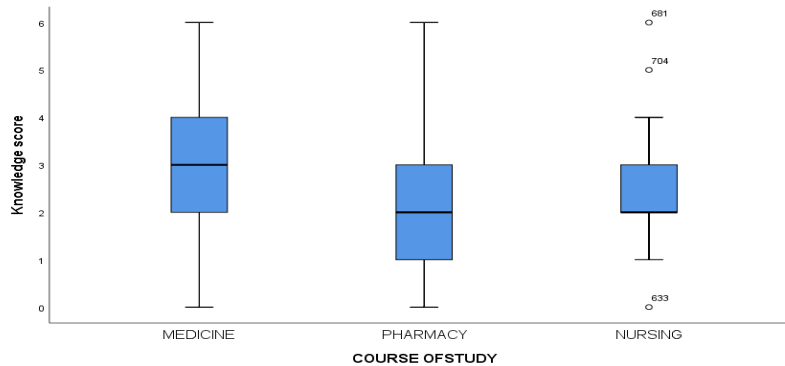


Figure 3: Comparison of knowledge score among the three categories of students

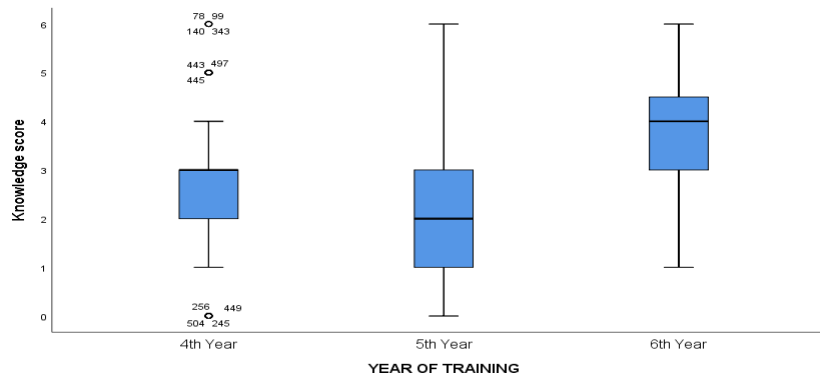


Figure 4: Comparison of knowledge score and year of study

Regarding the attitude and perception of the respondents, only 29.4% felt well-equipped to report ADRs in the future. The majority (73.1%) of respondents opined that ADR reporting should be made compulsory in practice while 487 (68.5%) of

respondents want pharmacovigilance centres established in every healthcare facility. The comparative analysis of the attitudes of students from various programmes is shown in Table 3.

Table 3: Comparative analysis of attitudes of students from various programmes

Statements/Questions	Course of Study	Yes (N%)	No (N%)
With your present knowledge, do you think you are well-equipped to report ADRs in your future practice?	Medicine	59 (17.1)	286 (82.9)
	Pharmacy	74 (28.8)	183 (71.2)
	Nursing	79 (76.0)	28 (24.0)
Do you think reporting of known ADRs will make no significant contribution to the reporting system?	Medicine	74 (21.8)	265 (78.2)
	Pharmacy	71 (28.3)	180 (71.7)
	Nursing	73 (70.9)	30 (29.1)
Are you aware of the existence of a national pharmacovigilance programme in Nigeria?	Medicine	104 (30.9)	233 (69.1)
	Pharmacy	93 (36.3)	163 (63.7)
	Nursing	74 (71.2)	30 (28.8)
Should the teaching of pharmacovigilance be included in the undergraduate curriculum of health sciences	Medicine	319 (93.0)	24 (7.0)
	Pharmacy	198 (76.4)	61 (23.6)
	Nursing	92 (88.5)	12 (11.5)

While 198 (28.5%) respondents have observed ADRs during their training, only 79(11.4%) have ever reported any form of ADR. More nursing students (76.0%) had observed ADRs during their training than their colleagues in other programmes. Among respondents, 149 (21.3%) had seen the "Yellow" reporting form while 132 (19%) have had some form of training on ADR reporting during their education so far. The ADR reporting form (yellow form) is known to more pharmacy students in comparison to nursing and medical students.

Pharmacy students (25.5%) had more training in reporting ADRs than nursing students (18.4%) and medical students (14.5%). Nursing students (73.1%) felt more prepared to report ADRs than pharmacy (28.8%) and medical students (17.1%) respectively. Only 91 (13.1%) knew about the availability of a pharmacovigilance committee in their associated healthcare facility. The comparative analysis of the above-mentioned ADR practice issues is shown in Table 4.

Table 4: The comparative analysis of the ADR reporting practice among students of the three programmes

Statements/Questions	Course of Study	Yes (N%)	No (N%)
Have you ever observed an ADR during your training?	Medicine	58 (17.1)	281 (82.9)
	Pharmacy	74 (28.8)	183 (71.2)
	Nursing	79 (76.0)	28 (24.0)
Have you ever reported an ADR during your training	Medicine	18 (5.3)	324 (94.7)
	Pharmacy	37 (15.0)	210 (85.0)
	Nursing	24 (23.1)	80 (76.9)
Have you ever seen the "Yellow" reporting form	Medicine	52 (15.2)	290 (84.8)
	Pharmacy	77 (30.2)	178 (69.8)
	Nursing	20 (19.2)	84 (80.8)
Have you ever received any training on ADR reporting	Medicine	49 (14.5)	288 (85.5)
	Pharmacy	64 (25.2)	190 (74.8)
	Nursing	19 (18.4)	84 (81.6)

The most common themes identified from the comments of respondents on how to improve awareness and practice of ADRs generally are: the inclusion of pharmacovigilance modules in the undergraduate curriculum of the academic programmes (medicine, pharmacy, nursing),

establishment of pharmacovigilance committees and centres in affiliated healthcare facilities.

Discussion

This study assessed the knowledge, attitude and practice of pharmacovigilance and adverse drug

reaction reporting among undergraduate students of medicine, pharmacy and nursing at some Nigerian universities located in the South-Western region of Nigeria. Results of this study show that the knowledge of the respondents about pharmacovigilance and adverse drug reporting was generally very poor. While their attitude was positive, the level of practice or acquisition of skills required for good pharmacovigilance varied across the programmes.

The poor knowledge of ADRs and pharmacovigilance by students of medicine, pharmacy and nursing has been reported by several workers: Tekel *et al* found that 69.9% of respondents in their study had poor knowledge while Bepari and co-workers in their study among Saudi students of healthcare courses reported grossly inadequate knowledge (17, 18). Results of studies conducted among individual groups of students from medicine, pharmacy and nursing in different countries are also in keeping with this trend. Findings from this study showed that medical undergraduates had the highest knowledge score followed by nursing and pharmacy students respectively. This is contrary to reports from similar studies comparing the knowledge, attitude and practice of pharmacovigilance among these categories of students. Studies conducted among healthcare students in Croatia and Saudi Arabia showed that pharmacy students were more knowledgeable about adverse drug reactions and their reporting (19, 20). In a similar study conducted in Saudi Arabia by Bepari *et al*, knowledge about adverse drug reactions and pharmacovigilance was higher among pharmacy students followed by medical and nursing students (18). This finding may have been influenced by the fact that students in their 6th year scored highest thereby influencing the overall score for medical students; it is a known fact that only medical students spend six years in training.

The organization responsible for monitoring and collation of ADR reports in Nigeria is the National Agency for Food and Drug Administration Control (NAFDAC). In this study, 64.3% of respondents were aware of this fact with a larger proportion of medical students compared to pharmacy and nursing students. This is in contrast to reports from similar studies from Pakistan and Malaysia where pharmacists had more knowledge in this aspect (21, 22).

The attitude of study respondents towards pharmacovigilance was mainly positive with the majority advocating for it to be made compulsory and the establishment of a pharmacovigilance committee in every healthcare facility. Positive

attitudes towards adverse drug reaction reporting have been shown in studies conducted among healthcare students in Pakistan, Saudi Arabia and Ethiopia (17, 19, 21).

Adverse drug reactions were observed by a larger proportion of nursing students when compared to pharmacy and medical students. Nursing students are exposed to bedside patient monitoring during their training significantly more than pharmacy and medical students, hence, the higher rate of observation. This finding also highlights the need for all medical, nursing and pharmacy undergraduates to have adequate exposure to patient monitoring during their training. In this study, pharmacy students had experience with the "yellow form" and had received more training than their counterparts. Training in ADR reporting was received by 19% of our respondents, lower than 49% and 39% reported in a study among healthcare students in Ethiopia and Saudi Arabia respectively (17, 19).

There was a consensus by respondents on the need to improve training on pharmacovigilance and ADR reporting for undergraduates in medicine, pharmacy and nursing through the inclusion of relevant topics in the curriculum. Several studies have also identified this need for increased exposure of students to theoretical and practical aspects of pharmacovigilance and adverse drug reaction reporting. In a review by Reumerman *et al*, the need to improve the curricula and training of healthcare students in pharmacovigilance was highlighted (23). In addition, the World Health Organisation (WHO), recognizing the importance of pharmacovigilance education to healthcare students has put in place a WHO Pharmacovigilance Core Curriculum (24). This study has shown while students may have some theoretical knowledge of pharmacovigilance and ADR reporting, their practical exposure was grossly inadequate.

Conclusion

Though the knowledge of Nigerian undergraduate medical, pharmacy and nursing students about adverse drug reactions and their reporting was generally poor, this study identified gaps peculiar to each of the three programmes. The relatively better theoretical knowledge of medical students of pharmacovigilance did not translate into good practical experience. Nursing students had more experience observing ADRs but showed poor knowledge and exposure to tools for reporting ADRs. Pharmacy students had more practical exposure to tools for reporting ADRs. There is a need therefore for curriculum review of these

programmes to include both theoretical and practical aspects of adverse drug reactions and their reporting.

List of Abbreviations

ADR: Adverse drug reactions
NAFDAC: National Agency for Food and Drug Administration and Control
SD: Standard deviation
PI: Principal Investigator
WHO: World Health Organization
ANOVA: Analysis of Variance

Declarations

Ethical approval and consent to participate

Ethical approval for the study was obtained from the Research and Ethics Committee of Ekiti State University Teaching Hospital (EKSUTH), Ado-Ekiti, Nigeria (EKSUTH/A67/2019/05/007) before the commencement of the study.

Consent for publication

All the authors gave consent for the publication of the work under the Creative Commons Attribution-Non-Commercial 4.0 license.

Availability of data and materials

The data and materials associated with this research will be made available by the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

Nil.

Author contributions

Conceptualization: FJO, ATA; Data curation: FJO, BI, ATA, OA; Methodology/formal analysis/validation: FJO, OJ, OG; Project administration: JOF; Writing – original draft: JOF, TAA, AJO; Writing, review and editing: FJO, ATA, OG, OAJ, AEJ, BI, OJ, OA (all authors).

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