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From the desk. To the bench. To the bedside.

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Familial factors associated with adolescent pregnancy in San Juan City

Airene J. Perez, RN

Abstract

Introduction One significant challenge facing the Filipino youth today is adolescent pregnancy, as the nation having one of the highest rates of adolescent births rates in the ASEAN region. Various sociocultural, economic, and individual factors have been identified as contributing factors. However, the impact of family, including maternal intergenerational factors, has yet to be substantially explored. This study aimed to investigate the root cause of adolescent pregnancy in San Juan city through the identification and examination of common familial factors.

Methods This was an unmatched case-control study with a 1:2 ratio using a non-probability sampling. It included two groups of adolescent females: pregnant/ever pregnant and non-pregnant) aged 13 to 19. A three-part modified questionnaire was used to collect the data and was administered through a face-to-face interview.

Results This study revealed that adolescent women in grandparent-headed families are 4.47 (CI: 1.33, 15.0) times more likely to be pregnant as adolescents compared to the reference group. Adolescents with low educational attainment among their fathers and mothers are 4.25 (CI: 1.80, 10.10) and 3.30 (CI: 1.58, 6.93) times more likely to get pregnant, respectively. Additionally, if a mother is unemployed, they were 1.89 (CI: 1.09, 3.30) times more likely to get pregnant, and if their mother passed away, they were 4.24 (CI: 1.03, 17.42) times more likely to experience pregnancy. Moreover, they are 7.69 (CI: 4.21, 14.02) and 9.07 (CI: 2.74, 30.03) times more likely to get pregnant if their mother and sister have a history of adolescent pregnancy. There was also a significant association found between severe family dysfunctionality (p=0.0430) and adolescent pregnancy. Cases were 8.33 times less likely to have a severely dysfunctional family than controls.

Conclusion A statistically significant association was found between adolescent pregnancy and several familial factors, including exposure to a grandparent-headed family structure, low parental educational attainment, maternal unemployment, maternal death, and a family history of early pregnancy involving the mother or an older sister. While moderate family dysfunction was also associated, this relationship was not statistically significant.

Key words: Adolescent pregnancy, Familial factors, Intergenerational factors

According to the United Nations Population Fund (2020), adolescent pregnancy continues to be one of the major issues impacting young Filipinos today, as the country continues to have one of the highest rates of adolescent births among ASEAN nations. In the Philippines, there were 47 births per 1,000 women between the ages of 15 and 19 compared to 44 and 33.5 for the world and other ASEAN regions (Denila et al., 2024). Considering the enormity of the adolescent pregnancy situation in the country, preventive policies and programs were developed. In 2012, Republic Act No.10354, recognized as the

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Responsible Parenthood and Reproductive Health Act of 2012, was implemented according to the Philippine Commission on Women (2012). In 2021, Executive Order No. 141, "Adopting as National Priority the Implementation of Measures to Address the Root Causes of the Rising Number of Teenage Pregnancies and Mobilizing Government Agencies for the Purpose," was also adopted (Commission on Population and Development, 2021). Despite existing laws and interventions, adolescent pregnancy remains a challenge. The Commission on Population and Development has raised the alarm over the significant increase in adolescent pregnancies, especially in the number of births among women who are 10 to 14 years old (Moaje, 2025). According to the Philippine Statistics Authority (2023), births among 10-14 years old have increased by 35.13 percent (2,320 in 2021 to 3,135 in 2022), and the registered live births by adolescent women aged 19 and under also altered in 2022 when live births in that category increased by 10.15% (136,302 in 2021 to 150,138 in 2022). It was also noted that in 2020, the youngest mother who gave birth was 10 years old.

Wall-Wieler et al. (2016) mentioned the importance of recognizing risk factors before identifying ways to reduce adolescent pregnancy. Several literature sources have pointed out an interplay of sociocultural, economic, and individual factors as their determinants (Alukagberie et al., 2023; Senkyire et al., 2022; Mpimbi et al., 2022). Still, the impact of family, including maternal intergenerational factors, especially in the Philippines, has yet to be substantially explored. Furthermore, there is a lack of research regarding the roots of adolescent pregnancy instances at both the national and local levels. The researcher acknowledges that at the national level, laws have been crafted to ensure that adolescent pregnancy has been recognized; thus, government agencies have created strategies that will equip adolescents to avert "teen pregnancy." At the local level, data and information are available, health service providers have been trained, and health services/information are prepared to address the sexuality and reproductive health needs of adolescents. However, the researcher observed the need to go beyond health education and looked into factors leading to behavioral change and multifactorial strategies to break the repetitive chain of adolescent pregnancy.

This study aimed to examine the root causes of adolescent pregnancy in San Juan City by identifying and analyzing common familial factors. The city was purposely selected due to its documented incidence of adolescent pregnancy and the availability of relevant demographic and health data, which provide a meaningful context for investigating these factors in an urban setting. Furthermore, the study sought to generate evidence to inform interventions that adopt a whole-of-government approach, with the goal of breaking the cycle of adolescent pregnancy.

Methods

The research was an unmatched case-control study with a 1:2 ratio, aimed at identifying family factors linked to adolescent pregnancy. The study was conducted after receiving ethics committee approval from the Ethics Review Committee of the UERMMCI Research Institute for Health Sciences with RIHC ERC Code 1739/G/2024/106.

The study involved two (2) groups of adolescent females (currently pregnant/ever-pregnant and non-pregnant) aged 13 to 19 years old, residing in San Juan City. The cases were adolescents who were either pregnant or had given birth to at least one (1) child and had undergone prenatal visits to the barangay health centers and stations in the city. The controls were adolescents who were neither pregnant nor had given birth before, lived in the same city, and were enrolled at the city's public high school.

This study used convenience sampling. The 81 cases were taken from the adolescent (13-19 years old) pregnancy watch board list 2022-2023 and were chosen based on their age and current place of residence. The 162 controls were chosen based on the student's class section and availability, current place of residence, and parental consent.

A modified questionnaire was utilized to gather the data, which was administered through a face-to-face interview. The three-part modified questionnaire, which underwent face validation and reliability testing, was used for both the case and control groups. The first two parts of the questionnaire were based on the research by Cleland et al. (2014) regarding the World Health Organization's Topics for In-depth Interview and Focus Group Discussions: Partner Selection, sexual behavior, and Risk-taking, Section One: Socioeconomic and Family Characteristics, which was translated into Tagalog. The third part was adapted from another study (Cabahug et al., 1992). The collected data on family income, family structure,

family size, and the mother's and older sister's adolescent pregnancy were categorized and measured using a grouping method. The Filipino Family Adaptation, Partnership, Growth, Affection, and Resolve (APGAR) score (Cabahug et al. 1992) was measured using a 5-item Likert scale, whose value ranges from 0 (never) to 2 (always), with a maximum possible score of 10 and a minimum possible score of 0.

Face validation was done for the questionnaire to measure if the questionnaire was clear, appropriate, and adequate for the study participants. Before data collection began, the questionnaire was revised with the validator's corrections.

A test-retest reliability was also conducted. Correlation was used to measure the strength and direction between the two responses (Collins 2007). A correlation is considered statistically significant if the p-value is less than 0.05, and is generally regarded as having a strong correlation when the r-value of two variables is more than 0.7 (Mindrila et al.).

Descriptive statistics entailed using the mean with standard deviation for numerical variables and counts with percentages for categorical variables. Frequency distribution tables were generated to show the comparative distribution of pregnant/ever-pregnant and non-pregnant adolescents according to socio-demographic characteristics (father's monthly income, father and mother's educational attainment, employment status, and vital status), family structure, household size, family history of adolescent pregnancy (maternal and older sister), and family functionality. To determine the association between socio-demographic characteristics, family history of adolescent pregnancy, and family functionality, the odds ratio was computed with a 95% confidence interval and using p-value <0.05 as the cut-off for significance. SPSS version 21 was used to analyze the data.

Results

Two hundred forty-three (243) adolescent females participated in the study, 81 pregnant or previously pregnant from the adolescent pregnancy watch board list of the City of San Juan (cases), and 162 non-pregnant from San Juan National High School (controls).

Among the variables studied, including family structure and household size, father's and mother's profiles, history of adolescent pregnancy, and family APGAR, it was observed that the father's monthly income was relatively similar for both cases and controls (less than P10,957). Among the cases, a higher proportion of the father's income ranged between less than Php10,957 (42%) and Php10,957 to Php21,194 (23.5%) while the father's income of controls ranged between Php10,957 to Php21,194 (24.1%) and Php 21,195 to Php 43,828 (10.5%) as compared to cases (Table 1).

For the family structure and household size, it was shown that extended families (44.4%) and blended families (6.2%) made up most of the cases' family structure compared to controls. Regarding the number of members per household, the cases have less than 4 members (21%) compared to controls. On the other hand, there are more nuclear and single-parent families (41.36% and 16.7%, respectively) among controls than cases, and there are 4 or more members per household (84.6%) among controls than cases (Table 2).

The father's profile revealed that among the cases, 58% of the fathers have completed their high school education. A higher percentage of those who have not attended any schooling at all or have just completed their pre- and primary education were also observed (4.9%, 3.7%, and 17.3%, respectively) among the fathers of cases than controls. Furthermore, there was also a higher prevalence of unemployed fathers (12.35%) and deceased fathers (14.8%) as compared to controls. Among the controls, a higher percentage of fathers have attended college (35.8%), and the majority were employed (82.1%) and still living (91.4%) as compared to the cases (Table 3).

Conversely, the majority of the cases' mothers have completed high school (65.4%), and a higher percentage of those who have finished pre- and primary school (3.7% and 16%) are also present compared to controls. There was also a higher rate of unemployment, 53.1%, and deceased (7.4%) mothers among the cases as compared to the mothers of controls. In comparison, a higher percentage of the controls' mothers have attended college (36.4%), and the majority were employed (57.4%) and still living (98.2%) as compared to the cases (Table 4).

Table 5 revealed that among the cases, adolescent pregnancy in the mother and sister occurred more (71.6% and 17.3%) than in controls (24.7% and 2.5%). In contrast, an older age of adolescent pregnancy among mothers was noted for controls (M=23.5, SD = 5.2 years old) than cases (M=19, SD = 3 years old). Similarly, the age of adolescent pregnancy in elder sisters was older for controls (M=17.8, SD = 1.3 years old) than for cases (M=16.6, SD = 1.3 years old).

Table 1. Father's monthly income information.

	Cases n=81	Controls n=162	Total N=243
Father's monthly income (PhP)			
< 10,957	34 (42.0)	67 (41.3)	101 (41.5)
10,957 to 21,194	19 (23.5)	39 (24.1)	58 (23.9)
21,195 to 43,828	7 (8.6)	17 (10.5)	24 (9.9)
43,829 to 76,669	0	6 (3.7)	6 (2.5)
76,670 to 131,484	0	1 (0.6)	1 (0.4)
131,485 to 219,140	0	3 (1.9)	3 (1.2)
> 219, 140	0	1 (0.6)	1 (0.4)
NA	21 (25.9)	28 (17.3)	49 (20.2)

Table 2. Family structure and household size.

	Cases n=81	Controls n=162	Total N=243
Family structure			
Nuclear family	24 (29.6)	67 (41.4)	91 (37.45)
Extended family	36 (44.4)	55 (34)	91 (37.45)
Single-parent family	8 (9.9)	27 (16.7)	35 (14.4)
Grandparent family	8 (9.9)	5 (3.1)	13 (5.35)
Blended family	5 (6.2)	8 (4.94)	13 (5.35)
Household size			
< 4	17 (21.0)	25 (15.4)	42 (17.3)
≥ 4	64 (79.0)	137 (84.6)	201 (82.7)

Table 3. Fathers' profile.

Paternal Characteristics	Cases n=81	Controls n=162	Total N=243
Father's highest educational attainment/ year completed (n, %)			
No Grade Completed	4 (4.9)	3 (1.9)	7 (2.9)
Pre-Primary/ Pre-School	3 (3.7)	4 (2.5)	7 (2.9)
Primary/ Elementary	14 (17.3)	19 (11.7)	33 (13.5)
Secondary/ High School	47 (58.0)	72 (44.4)	119 (49.0)
Tertiary/College	11 (13.6)	58 (35.8)	69 (28.4)
Vocational	0	3 (1.9)	3 (1.2)
NA/Don't know	2 (2.5)	3 (1.9)	5 (2.1)
Father's employment status			
Employed	58 (71.6)	133 (82.1)	191 (78.6)
Unemployed	10 (12.35)	11 (6.8)	21 (8.64)
NA/Don't know	13 (16.05)	18 (11.1)	31 (12.76)
Father's Vital Status (n,%)			
Alive	69 (85.2)	148 (91.4)	217 (89.3)
Dead	12 (14.8)	14 (8.6)	26 (10.7)

Table 4. Mother's profile.

Maternal Characteristics	Cases n=81	Controls n=162	Total N=243
Mother's highest educational attainment/ year completed (n, %)			
No Grade Completed	0	0	0
Pre-Primary/ Pre-School	3 (3.7)	3 (1.9)	6 (2.5)
Primary/ Elementary	13 (16)	14 (8.6)	27 (11.1)
Secondary/ High School	53 (65.4)	82 (50.6)	135 (55.5)
Tertiary/College	10 (12.3)	59 (36.4)	69 (28.4)
Vocational	1 (1.2)	4 (2.5)	5 (2.1)
NA/Don't know	1 (1.2)	0	1 (0.4)
Mother's employment status			
Employed	32 (39.5)	93 (57.4)	125 (51.4)
Unemployed	43 (53.1)	66 (40.7)	109 (44.9)
NA/Don't know	6 (7.4)	3 (1.9)	9 (3.7)
Mother's vital status (n,%)			
Alive	75 (92.6)	159 (98.2)	234 (96.3)
Dead	6 (7.4)	3 (1.8)	9 (3.7)

A greater proportion of moderate dysfunctionality was seen among cases (44.4%) than among controls (29.6%), while severe dysfunctionality was seen more among controls (11.1%) than among cases (1.2%) (Table 6).

Table 7 shows that the family socio-demographic factors statistically associated with adolescent pregnancy were the following: a grandparent-headed family structure (OR=4.47), the father's highest educational attainment being pre-primary to primary/elementary (OR=4.25) and secondary/high school or vocational (3.30), the mother's highest educational attainment being pre-primary to primary/elementary (OR=5.55) and secondary/high school (3.81), the mother's unemployment (OR=1.89), and the mother's vital status as dead (OR=4.24). Cases were 4.47 times more likely to have a grandparent-headed family structure than controls. Cases were 4.25 times more likely to have fathers who had completed pre-primary or primary/elementary education than controls. Cases were 3.30 times more likely to have fathers who had completed secondary/high school or vocational education than controls. Cases were 5.55 times more likely to have mothers who completed pre-primary to primary/elementary education than controls. Cases were 3.81 times more likely to have a mother who had completed secondary/high school education than controls. Cases were 1.89 times more likely to have mothers who were unemployed than controls. Cases were 4.24 times more likely to have mothers who are no longer living than controls.

The history of adolescent pregnancy in the mother and older sister was also found to be statistically associated with adolescent pregnancy. Cases were 7.69 times more likely to have a mother with a history of adolescent pregnancy than controls, and for every year increase in the age of mothers with a history of adolescent pregnancy, the odds of being pregnant with an adolescent decrease by 23.8%. Cases were also 9.07 times more likely to have an older sister with a history of adolescent pregnancy than controls (Table 8).

There was also a significant association found between severe family dysfunctionality (p=0.0430) and adolescent pregnancy. Cases were 0.12 times more likely or 8.33 times less likely to have a severely dysfunctional family than controls (Table 9).

Discussion

Curbing the "alarming trend" of early and unintended pregnancy in the Philippines is of utmost importance, and this national problem cannot be traced to a single cause. In addition to examining the interactions among biological, economic, and sociocultural factors,

Table 5. Family history of adolescent pregnancy and age at adolescent pregnancy.

Family characteristic	Cases n=81	Controls n=162	Total N=243
Family history of adolescent pregnancy (n,%)			
Mother			
Yes	58 (71.6)	40 (24.7)	98 (40.3)
No	23 (28.4)	122 (75.3)	145 (59.7)
Older sister			
Yes	14 (17.3)	4 (2.5)	18 (7.4)
No	27 (33.3)	70 (43.2)	97 (39.9)
NA	40 (49.4)	88 (54.3)	128 (52.7)
Age at adolescent pregnancy (mean, sd)			
Mother	19.0, 3.0	23.5, 5.2	-
Older sister	16.6, 1.3	17.8, 1.3	-

Table 6. Family adaptation, partnership, growth, affection, and resolve (APGAR) information.

Family functionality	Cases n=81	Controls n=162	Total N=243
Family functionality (APGAR)			
Highly functional	44 (54.3)	96 (59.3)	140 (57.6)
Moderately dysfunctional	36 (44.4)	48 (29.6)	84 (34.6)
Severely dysfunctional	1 (1.2)	18 (11.1)	19 (7.8)

Table 7. Family socio-demographic factors associated with adolescent pregnancy.

Factors	Odds ratio (95% CI)	p-value
Father's monthly income		
< 10,957	2.03 (0.80, 5.12)	0.1340
10,957 to 21,194	1.95 (0.72, 5.26)	0.1880
> 21,194	1.0	-
Family structure		
Grandparent family	4.47 (1.33, 15.0)	0.0150
Extended family	1.83 (0.98, 3.42)	0.0600
Blended family	1.74 (0.52, 5.86)	0.3680
Single-parent family	0.83 (0.33, 2.07)	0.6850
Nuclear family	1.0	-
Household size ≥ 4	0.69 (0.35, 1.36)	0.2820
Father's highest educational attainment/ year completed		
Pre-primary to Primary/Elementary	4.25 (1.80, 10.10)	0.0010
Secondary/High school/Vocational	3.30 (1.58, 6.93)	0.0020
Tertiary/College	1.0	-
Mother's highest educational attainment/ year completed		
Pre-primary to Primary/Elementary	5.55 (2.13, 14.45)	0.0001
Vocational	1.48 (0.15, 14.59)	0.7400
Secondary/High school	3.81 (1.79, 8.11)	0.0010
Tertiary/College	1.0	-
Father's employment status		
Unemployed	2.08 (0.84, 5.18)	0.1140
Employed	1.0	-
Mother's employment status		
Unemployed	1.89 (1.09, 3.30)	0.0240
Employed	1.0	-
Father's vital status		
Dead	1.84 (0.81, 4.18)	0.1470
Alive	1.0	
Mother's vital status		
Dead	4.24 (1.03, 17.42)	0.0450
Alive	1.0	-

Table 8. Family history of adolescent pregnancy factors associated with adolescent pregnancy.

Factors	Odds ratio (95% CI)	p-value
Adolescent pregnancy in the mother	7.69 (4.21, 14.02)	0.0001
Adolescent pregnancy in the older sister	9.07 (2.74, 30.03)	0.0001
Mother's mean age at adolescent pregnancy	0.76 (0.70, 0.83)	0.0001
Older sister's mean age at adolescent pregnancy	0.52 (0.21, 1.31)	0.1660

Table 9. Family adaptation, partnership, growth, affection, and resolve (APGAR) associated with adolescent pregnancy.

Factors	Odds ratio (95% CI)	p-value
Family functionality (APGAR)		
Moderately dysfunctional	1.64 (0.93, 2.87)	0.0850
Severely dysfunctional	0.12 (0.02, 0.94)	0.0430
Highly functional	1.0	-

the Commission on Population and Development has emphasized that interventions to prevent adolescent pregnancy should be initiated at the household level. This study shows the different family factors significantly associated with adolescent pregnancy in San Juan City and focuses on seven main findings. First, in terms of family structure, this study observed that adolescent mothers are 4.47 times more likely to have a grandparent-type family structure. According to Reis et al. (2023), adolescents who do not live

with their biological parents may experience unstable family dynamics, resulting in early sexual initiation. This is consistent with the analysis of the Philippine National Demographic and Health Survey (NDHS) 2017, which indicated that adolescent pregnancy was more prevalent among teens living without either parent (Tabei et al., 2021). Parents significantly influenced their children's sexual behavior (Ashcraft et al., 2017), and a systematic review and meta-analysis by Kassa et al. (2018) revealed that adolescents who lack parental communication regarding their sexual and reproductive well-being were three times more likely to engage in childbearing.

Second, a greater proportion of fathers and mothers in the cases have only completed high school (58% and 65.4%, respectively) compared to the proportion of fathers and mothers of controls who finished college (35.8% and 36.4%, respectively). When it comes to paternal education, it was observed in this study that the father's education, specifically pre-primary to primary and secondary/high school/vocational, was significantly associated with adolescent pregnancy. Cases were 4.25 times more likely to have fathers who had completed pre-primary or primary/elementary education than controls. Cases were 3.30 times more likely to have fathers who had completed secondary/high school or vocational education than controls. Additionally, an association has also been found between maternal education and adolescent pregnancy, specifically preprimary to primary/ elementary and secondary/high school. Cases were 5.55 times more likely to have mothers who completed pre-primary to primary education and 3.81 times more likely to have completed high school education than controls.

According to Price et al. (2008), adolescents whose parents possessed low levels of education were more likely to engage in early sexual activity. On the other hand, educated parents set greater educational and employment ambitions for their children, encouraging them to avoid early pregnancy (Risby et al. 1998). Based on a systematic review of cohort studies conducted by Reis et al. (2023), lower maternal education emerged as a significant risk factor linked to early initiation of sexual activity. Jordahl et al. (2009) discovered in their study, "Bioecological Analysis of Risk and Protective Factors Associated with Early Sexual Intercourse Among Low Income Adolescents," that maternal education is a protective factor against early sexual intercourse among low-income adolescents. This may explain why the control group, despite being categorized as poor, did not experience adolescent pregnancy. This is further supported by East et al. (2007), who noted that a mother's educational level acted as a mediator in the cycle of intergenerational adolescent pregnancies. Mothers with higher levels of education were generally more engaged and supportive, modeling effective parenting practices that foster a nurturing home environment, thereby shielding adolescents from risky behaviors like early sexual initiation (Hendrick et al., 2019).

Third, unemployment among the mothers (OR=1.89) was associated with adolescent pregnancy. Economic stress resulting from joblessness could lead to poor parenting practices, which could cause adverse childhood experiences according to Judd et al. (2023). Extended periods of joblessness among mothers have also been linked to a greater likelihood of severe child abuse (Repetti et al., 2009). These adverse childhood experiences could influence a child's decision to adopt health-harming behaviors as an adult, such as participating in early sexual interaction that may lead to early unintended pregnancy (Bellis et al., 2013).

Fourth, having a deceased mother was significantly associated with a higher likelihood of adolescent pregnancy. Maternal figures have a unique influence in assisting adolescents in developing their sense of empowerment and purpose (Konowitz et al., 2023). Maternal figures have a unique influence in assisting adolescents in developing their sense of empowerment and purpose and they have also been traditionally viewed as the primary parents responsible for giving guided sexual education (Konowitz et al., 2023). According to Quijano-Ruiz et al. (2021), daughters subconsciously learn about sexual behaviors from their mothers, and the lack of a maternal role model can increase the likelihood of early sexual interaction and adolescent pregnancy. Additionally, a longitudinal and intergenerational study conducted in Cebu, Philippines, by Gipson et al. (2017) from 1994 to 2009 also found that when a mother is empowered, her daughter is less likely to engage in sexual activity, suggesting that a lack of maternal guidance may contribute to early sexual experiences and pregnancy. Furthermore, a literature review by Guzzo et al. (2021) indicated that adolescents may exhibit sexual risk behaviors as a coping mechanism for grief, which can lead to unintended pregnancies.

Fifth, when it comes to the mother's history of adolescent pregnancy, it was noted that the cases were 7.69 times more likely to have a mother with a history of adolescent pregnancy than controls. However, it was observed that with each additional year in the age of mothers who had a history of adolescent pregnancy, the likelihood of experiencing an adolescent pregnancy decreased by 23.8% (OR= 0.76). Aside from the sociodemographic factors the mother and daughter share, the family environment was also a factor. Several studies have shown that an adolescent pregnancy between a mother and a daughter may occur across generations because mothers influence their daughter's perception and attitudes toward sexual and reproductive health practices (Meade et al., 2008; Wall-Wieler et al., 2016; Liu, 2018; Black, 2018). A Swedish birth cohort study examining the direct and indirect associations of intergenerational transmission of early childbearing found that daughters gradually began to adopt and replicate their mother's behavior regarding the timing of childbearing. This indicates that if the mother views early childbearing positively, her daughters are more inclined to emulate it (Högnäs et al., 2019).

Sixth, the present research discovered that adolescent mothers were 9.07 times more likely to have an older sister who experienced early pregnancy. This finding was consistent with the birth cohort research in Manitoba conducted by Wall-Wieler et al. (2016), which found that an adolescent girl whose older sister had an adolescent pregnancy was more likely to get pregnant. A qualitative study by East et al. (2013) mentioned that an adolescent who has an older sister who experienced adolescent birth may also view it as an acceptable situation. Through the social modeling theory (Bandura, 1977), adolescents who witnessed their older sister's early pregnancy may consider early sexual interaction as a norm and adolescent pregnancy as a path to adulthood (East et al., 1992). In terms of a mother's behavior, it has been observed that mothers who have an older daughter who became pregnant early will have lower monitoring, lower achievement expectations, increased tolerance, and increased acceptance of early sexual activity and early childbearing toward her other children (East et al., 1999).

Lastly, severe family dysfunctionality was noted to be statistically associated with adolescent pregnancy (OR= 0.12). This finding aligns with the research conducted by Lusica et al. (2018), which examined the connection between family APGAR scores and teenage pregnancy. According to the study, the Family APGAR score of women living in a poor community (Payatas, Quezon City), was notably linked to an increased risk of teen pregnancy. Additionally, research on the factors influencing early sexual activity identified dysfunctional household dynamics and poor parental relationships as risk elements for early sexual initiation (Price et al. 2009). Muyibi et al. (2010) also identified that the family as a whole has a significant impact on addressing adolescent issues. The study suggests that low family cohesion indicates insufficient family support and inadequate parental monitoring and supervision, which can lead an adolescent to develop relationships with deviant peers and participate in high-risk behaviors. Conversely, adolescents who have high-quality parenting and have supportive and functional families delay their sexual debut and are less inclined to engage in high-risk sexual activity (Okigbo et al., 2015; Abiodun et al., 2020).

The study also revealed that there was a higher percentage of severe dysfunctionality seen among controls (11.1%) than cases (1.2%). Most of the controls were noted to have a family structure of nuclear and single-parent families, and according to Abubakar et al. (2020) a dysfunctional family may be characterized by several factors such as financial hardship, conflict between family members, and parental separation, all of which can adversely affect children's psychological well-being. On the other hand, most of the cases were already living with their partner and children (Extended and Blended family), and adolescent pregnancy may already be the result of their previously dysfunctional home environment. Dysfunctional families can pass on a dysfunctional way of life to their children or the next generation, leading to the perpetuation of these social issues. A study by Orluwene et al. (2015) mentioned that adolescents in dysfunctional families are more prone to engaging in reckless sexual behaviors; thus, fostering family connectedness could act as a protective influence against risky sexual practices, even among youth considered at high risk.

Study Limitations

This study has several limitations. For the case group, pregnant adolescents who could not visit the health center/stations for their prenatal check-ups were not included in the study. For the control group,

adolescent women have not undergone pregnancy tests to verify their non-pregnant status. There may have been selection bias since the interviewed students were chosen based on their availability. In addition, respondents generally fell within a limited and low-income range.

Conclusion

Based on this study, a significant statistical association has been found amongst adolescent's exposure to a grandparent family structure, parents' low educational attainment, unemployed mother, deceased mother, exposure of the adolescent to early pregnancy brought about by a member of the family (mother and older sister), and severe family dysfunctionality.

The role of female members in a family plays a factor in the incidence of adolescent pregnancy. Adolescent girls exposed to female family members who had a history of early pregnancy are most likely to participate in early sexual activities, which can result in unplanned pregnancies. Similarly, the death of the mother or parents who are least present in the lives of their daughters, with extended family members given the responsibility to care for the adolescent girl, is most likely to engage in risky behaviors. Overall, the values and factors passed on by the family create an impact on the ability of the adolescent to make sound decisions that can curve her productivity and future. For future studies, a multivariate analysis should be conducted to control for other variables that were found to be associated with adolescent pregnancy. Quantitative research can be conducted to look into the in-depth relationship between adolescent girls modeling the condition of their mother and/or sister who had an adolescent pregnancy. Similarly, an independent study (with a larger sample size and a range of respondents' economic classifications) can also be conducted to associate family and early pregnancy among adolescents. Further research into the protective and risk factors related to family dysfunctionality can also be done to better understand their relationship with early pregnancy.

Recommendation

Lobbying for necessary ordinances must be done regarding the provision of age and development-appropriate reproductive health education in schools on topics such as the physical, social, and emotional transformations in an adolescent, the different skills and self-protection against adolescent pregnancy, and responsible teenage behavior. It is essential to advocate for and support the thorough execution of the Comprehensive Sexuality Education (CSE) program by the Department of Education, which seeks to enhance the overall well-being of Filipino adolescents by effectively incorporating scientifically-based, age- and developmentally suitable, and culturally and gender-sensitive information on the cognitive, emotional, physical, and social dimensions of sexuality into the K-12 curriculum.

Launch educational initiatives that focus on strategies to improve family relationships and emphasize the connection between dysfunctional family environments and irresponsible sexual behavior, as well as adolescent pregnancy, targeting both parents and young people within the community.

Provide necessary information and services on the different modern natural and artificial forms of planning the family among adolescent mothers to prevent repeated pregnancies. Ensure the functionality of community—and school-based teen centers, which provide adolescents with relevant information and services related to health, employment, psychosocial development, and education. This teen facility will serve as a haven for adolescents, where trained peer educators and service providers will be available to deliver immediate assistance and referrals to their established network based on the needs and conditions of the adolescents.

Strengthen the collaborative and partnership mechanism of the City Population Development (POPDEV) Office with relevant regional line agencies such as the Department of Education (DepEd) to include and reach out of school youths (OSYs) through the Alternative Learning System (ALS) and come up with strategies that will encourage adolescent mothers to continue and complete their education. Similarly, the same approach should be done with the Technical Education and Skills Development Authority (TESDA), the Public Employment Service Office (PESO), and the Skills and Livelihood Training Center, which can equip and capacitate adolescents to become productive and employable, thus disrupting the cycle of poverty and intergenerational pregnancy.

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Larvicidal activity of *Annona squamosa* (Atis) leaves extract on *Aedes aegypti*

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Abstract

Introduction Effective mosquito control is pivotal in the epidemiology of vector-borne diseases, but no successful preventive measures have been recorded for dengue vector control. Hence, possible alternatives to chemical larvicides have been explored, including plant alcoholic extracts. This study determined the larvicidal efficacy of *Annona squamosa* ethanolic leaf extracts against third instar larvae of *Aedes aegypti*.
Methods Three replicates of varying concentrations of *Annona squamosa* ethanolic extract (i.e., 10%, 40%, and 70%) versus positive (Novaluron) and negative controls (tap water) were used to determine larval mortality.
Results Greatest larval mortality was noted using the 70% concentration (i.e., 24% versus the observed values of 20% and 8%, respectively for the 40% and 10% ethanolic concentrations). Relative to the controls, the mean differences in the mortality rates of the *Aedes aegypti* larvae across the leaf ethanolic concentrations were statistically significant (i.e., p-value < 0.05). There was increasing trend in larval mortality over time, but 50% lethal dose was not achieved. In conclusion, the different *Annona squamosa* ethanolic leaf extracts could be used as alternative botanical larvicides against *Aedes species*.

Key words: *Annona squamosa*, *Aedes aegypti* mosquito, larvicidal activity

Vector-borne diseases (VBDs), particularly mosquito-borne diseases, pose a substantial threat to the population in the world, including countries in South and Southeast Asia, such as the Philippines. These VBDs infect over a billion people each year, contributing to more than a million deaths globally. The growing public health significance of these VBDs has created difficult challenges in over a hundred tropical and subtropical nations. In the Philippines, dengue remains to be a significant public health concern.[1] The flavivirus propagation has been facilitated by rapid urbanization, environmental degradation, lack of reliable water supply, and improper management and disposal of solid waste. Mosquito vector control measures are crucial for preventing dengue by stopping the spread of mosquito populations and enhancing environmental sanitation to improve public health services.[2-5] Mosquito vector control is believed to be one effective undertaking that can lessen the financial burden associated with dengue infection, including improvement of the dengue disability-adjusted life years (DALY).[3,6]

Although there is no single successful preventive measure recorded for mosquito vector control, addressing various links in the chain of dengue infection and transmission can significantly impact on the public health burden of dengue. Some successful strategies to prevent dengue transmission include environmental sanitation, avoiding mosquito bites, administering the dengue vaccine to the selected members of the high-risk population, and using insecticides and larvicides. The advent of conventional pesticides demonstrates a successful move to control the mosquito population. However, this success has

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been short-lived due to the development of resistance by mosquito strains to the commonly used pesticides, ecological imbalance, and potential harm of certain chemicals in manufactured pesticides to mammalian species, including humans.[7]

Thus, science and health experts have diligently worked to develop safe, biodegradable, and cost-effective larvicidal / adulticidal chemical formulations. Several studies have utilized various plant parts as potential alternatives to control the mosquito population, while maintaining balance in the ecosystem.[8-13] Environmental advocates recommend the use of plant-based preparations for mosquito control, according to the perception that these will be less harmful to the ecosystem, including non-targeted organisms. Thus, exploratory studies have been conducted, evaluating extracts from various genera of plants for their larvicidal and insecticidal properties. More than two thousand species of plants are believed to possess insecticidal and larvicidal activity. One such plant is the *Annona squamosa*, a small tree in the Annonaceae family. The various parts of the atis (sugar apple) plant also have multiple uses.[14-18]

Several previous experiments tested and screened over 3,500 species of plants, and multiple research studies demonstrated *Annona squamosa* plant parts exhibiting mosquito larvicidal activity. Hence, this study aimed to determine the efficacy of the *atis* (sugar apple) ethanolic extract, of varying concentrations, as larvicide for the *Aedes aegypti* third instar larvae. Creating an ethanolic leaf extract which could serve as an add-on or substitute to the chemical larvicides currently being used in public places (e.g., airports), if proven to be effective to it, could prove to be promising. In this way, potential adverse reactions brought by the chemical larvicides currently being used could potentially be hindered or lessened, if plant-based alternatives could be identified and mass-produced.

Methods

A. Identification and Collection of Plant Material

The plant of interest, *Annona squamosa* (i.e., local name *atis* or sugar apple), belonging to the Family Annonaceae, was identified and authenticated by the Bureau of Plant Industry (BPI). After certification was granted for authenticity, mature leaves of *Annona squamosa* were collected. The bulk samples were collected, washed with tap water, and shade-dried at room temperature for 7 to 14 days. The dried leaves were ground into fine powder using an electric blender, from which the extract was prepared. Blended leaves then underwent maceration at the University of the Philippines Pharmacy – National Institutes of Health. Maceration was performed by placing the powdered leaves in a beaker and soaking them in 10%, 40%, and 70% ethanol. The mixtures were then allowed to stand at room temperature for three (3) days with frequent agitation. The resulting extracts were stored in the refrigerator until analysis.

B. Test Organism

The larvae of *Aedes aegypti* were reared by placing an improvised black pail trap containing 1,000 ml of water and a submerged piece of black board in various designated areas across Terminals 1 to 4 of Ninoy Aquino International Airport (NAIA) in Manila, Philippines. The traps were left in place for seven (7) days to facilitate larval development. To synchronize and promote hatching, one (1) tablespoon of yeast was dissolved and added to the 1,000 ml of water after 24 hours. The observation of the mosquito life cycle then followed. On the fifth day, larvae that were noted to be 4-5 mm in length were readied for harvest. Twenty-five (25) pieces of third instar larvae were carefully transferred to the testing cup filled with 200 ml of dechlorinated water using a pipette and covered with mesh. A designated entomologist and a vector control technician of the Department of Health (DOH) supervised the rearing and harvesting of the experimental organisms. Laboratory-reared *Aedes aegypti* larvae, specifically third instar, were then subjected to different concentrations of the *Annona squamosa* ethanolic leaf extracts.

C. Larvicidal Activity

Twenty-five (25) samples of third instar *Aedes aegypti* larvae were placed in a testing cup, which was then covered with a safety net or mesh to prevent any accidental emergence of the larvae as adult mosquitoes. For each concentration, three replicates were established alongside corresponding controls. These included Novaluron as the positive control, tap water as the negative control, and ethanol at concentrations of 10%, 40%, and 70%. Two (2) ml of ethanolic leaf extract was added to the experimental larvae, as well as to the non-experimental arm.

Every two (2) hours, larval mortality was counted for a period of twenty-four (24) hours. The number of dead larvae was recorded, with dead larvae being recognized as non-movement of the larvae despite physical stimulation and probing. The test runs were performed thrice conducted on different days.

Results

Table 1 shows the mortality rate of *Aedes aegypti* larvae, observed after 24 hours of exposure to different concentrations of *Annona squamosa* leaf extract. The higher the extract concentration, the higher the mortality rate of *Aedes aegypti* larvae --- i.e., more larvae died at a 70% ethanolic leaf extract concentration compared to the 40% and 10% concentrations. The positive control, Novaluron, had a 68% mortality rate, while the negative control, tap water, yielded a 0% mortality rate.

Table 2 reveals the mean differences in the mortality rate of *Aedes aegypti* larvae across the various ethanolic leaf extract concentrations, compared to the positive and negative controls. The mean difference was derived using the standard deviation formula. The results indicated a significant difference between the experimental intervention and control arms (i.e., all with p-values < 0.05).

Table 3 demonstrates the proportion of *Aedes aegypti* larvae that died over 24 hours at two-hour intervals. It showed that at a 70% concentration, there was a higher mortality rate, compared to the 40% and 10% concentrations, and the mortality rate of the larvae increased over time. The mortality of the larvae was first observed after four hours of observation and progressed after that. However, from 18 to 24 hours, less mortality was observed at 10% and 40% concentrations.

This study did not achieve the lethal dose 50 (LD50) within 24 hours of exposure and observation. The ethanolic leaf extract of *Annona squamosa* resulted in 24% mortality at a 70% concentration. Nonetheless, the experiment indicated that increasing the ethanol solvent concentration for extracting *Annona squamosa* leaves corresponded with higher mortality rates in *Aedes aegypti* larvae.

Table 1. Mortality rates of *Aedes aegypti* larvae after 24 hour-exposure to different *Annona squamosa* ethanolic leaf extract concentrations.

Percentage (%) of Extract	Dead Larvae Mean After 24 Hours (N=25)	± Standard Deviation	Mean Mortality Rate	± Standard Deviation
10%	2	0.25	8%	0.02
40%	5	1.92	20%	0.38
70%	6	1.96	24%	0.47
Novaluron	17	0.41	68%	1.90
Water	0	0	0%	0

Table 2. Mean difference in mortality rates of the *Aedes aegypti* larvae across several *Annona squamosa* ethanolic leaf extract concentrations versus the positive (Novaluron) and negative (tap water) controls.

	Annona Ethanolic Extract	Positive Control (Novaluron)	Negative Control (Water)
***Annona* Ethanolic Extract**		20.556* Sig < 0.001	-4.111* Sig 0.007
Positive Control (Novaluron)	-20.556* Sig < 0.001		-24.667* Sig < 0.001
Negative Control (Tap Water)	4.111* Sig 0.007	24.667* Sig < 0.001	

Table 3. The proportion of dead *Aedes aegypti* larvae at two-hour intervals over a 24-hour observation period and exposure to varying concentrations of *Annona squamosa* leaf ethanolic extract.

Percentage of Extract	Number of Replicates	Proportion of Dead Larvae at 2-Hour Intervals											
		2 hours	4 hours	6 hours	8 hours	10 hours	12 hours	14 hours	16 hours	18 hours	20 hours	22 hours	24 hours
0.1 (10%)	1st	0%	0%	4%	0%	0%	4%	0%	0%	0%	0%	0%	0%
	2nd	0%	0%	0%	4%	0%	0%	0%	4%	0%	0%	0%	0%
	3rd	0%	0%	4%	0%	0%	4%	0%	0%	0%	0%	0%	0%
0.4 (40%)	1st	0%	0%	4%	0%	4%	0%	8%	0%	0%	8%	0%	0%
	2nd	0%	0%	4%	0%	4%	0%	8%	0%	8%	0%	8%	0%
	3rd	0%	0%	4%	0%	4%	0%	8%	0%	8%	0%	8%	0%
0.7 (70%)	1st	0%	0%	4%	0%	4%	0%	0%	0%	0%	0%	0%	0%
	2nd	0%	0%	4%	0%	0%	4%	0%	0%	8%	0%	8%	8%
	3rd	0%	4%	0%	9%	0%	8%	11%	0%	12%	0%	13%	0%

Discussion

This study investigated the efficacy of *Annona squamosa* ethanolic leaf extract in eliminating third-instar *Aedes aegypti* larvae. The findings indicated that while the ethanolic leaf extract of *atis* was able to kill mosquito larvae, it did so at a slower rate compared to the positive control (Novaluron), which led to a quicker larval mortality rate.

A similar outcome was observed in another experimental study wherein thirteen different plant species were tested with different concentrations of a positive control (temephos) and a negative control (water), resulting in mortality rates of 100% and 0%, respectively. The investigation of the Ipomoea cairica plant extract indicated larval mortality rates of 40% for the leaves and 100% for the stem.[19]

Another epidemiologic experiment evaluated the larvicidal activity of fifty plant species from the Columbian Caribbean Region using 95% ethanol with maceration technique, employing temephos as positive control and dimethyl sulfoxide (DMSO) 1% as negative control. Seeds of the following plants stood out for their larvicidal activity, namely *Annona squamosa*, *Annona cherimolia*, *Annona muricata*, *Tabernaemontana cymose* Jacq, and *Mammae americana* L. which determined lethal dose fifty (LD50) values of 58.44ppm, 65.10ppm, 84.82 ppm, 25.02 ppm, and 38.58 ppm, respectively.[20]

Another study investigated the larvicidal activity of the ethanolic extract of *Inula racemosa* Hook (Family Compositae) roots against *Aedes alpobictus* using 95% ethanol. This experimental investigation showed the ethanol extract's lesser toxicity (i.e., 14 times less toxic), compared to the positive control chlorpyrifos.[21]

The lethal activity of *Annona squamosa* leaf extract may be due to various phytochemical compounds it contains such as alkaloids, flavonoids saponins, tannins, glycosides and triterpenoids. These work in different ways to cause mortality in the *Aedes aegypti* larvae. In the phytochemical analysis of *Annona squamosa* Linn, alkaloids, tannins, flavonoids, phenols, and saponins were detected in the leaves.[22]

This is further supported by findings in another epidemiologic investigation which evaluated the in vitro larvicidal activity of *Annona squamosa* leaves extract against *Culex* mosquito. This study revealed that *Annona squamosa* had phytochemical components, such as tannins, glycosides, alkaloids, and terpenoids, which were all theorized to contribute to the plant's larvicidal activity.[23]

Another review on the different larvicidal compounds isolated from plant extracts against *Aedes aegypti* demonstrated that acetogenins had the highest larvicidal potential, killing 50% of *Aedes aegypti* larvae at a concentration of 0.01 ug/ml.[24]

While all *Annona squamosa* leaf extract concentrations have a mortality impact on *Aedes* species, their effects are slower than those of Novaluron, which has a faster effect on the death of *Aedes* larvae. The lower efficacy of *Annona squamosa* leaf extract could be attributed to plant-based factors. These include the plant's geographical origin, plant age, time of harvest or collection, part of the plant to be used, the storage condition of the plant material, type and quantity of active chemicals the plant contains, extraction technique, plant species selected, and the solvent used for isolation and its potentials.[25-27] Furthermore, other factors, including temperature, air humidity, and water pH, may affect the body resistance of each larva.[9]

The use of suitable solvents affects the efficacy of larvicides in *Annona squamosa*. Ethanol is a universal solvent that can bind all chemical components in natural plants. It has been stated that the metabolites found in the cytoplasm of plants may be dissolved in the solvent and eventually extracted.[28]

Another plausible explanation for the lower mortality of using plant extracts to kill *Aedes aegypti* is brought about by the extraction procedure done, which is the maceration process. Maceration is one of the bioactive natural product extraction methods that use water, aqueous, and non-aqueous solvents that have been conducted at room temperature. Maceration is the simplest, most practical method with the lowest energy consumption or expenditure. It is compatible with ionic liquid at room temperature, which is extremely important for obtaining secondary metabolites since ionic liquid has been shown to have a high extraction capacity, not requiring the external supply of energy.[29]

Conclusion

In conclusion, the different *Annona squamosa* ethanolic leaf extracts could be used as alternative botanical larvicides against *Aedes species*. This epidemiologic experiment documented varying mortality rates of *Aedes aegypti* larvae, exposed to 70%, 40%, and 10% ethanolic leaf extract concentration. It also showed a significant difference using the experimental intervention and controls, as it displayed the mean difference in mortality across the various ethanolic leaf extract concentrations, compared to positive and negative controls. The proportion of *Aedes aegypti* larval death at two-hour intervals over 24 hours showed that mortality rate of larvae generally increased over time. Although the study did not reach the lethal dose at 50 (LD50) due to the short period of observation (i.e., 24 hours only), *Annona squamosa* leaf extract still had 24% larval death in the study.

Recommendations

However, additional research with various mosquito genera and extraction techniques is necessary to firmly establish the use of plant extracts as viable alternatives for controlling mosquito populations and reducing the incidence of dengue and other vector-borne diseases (VBDs). Moreover, conducting detailed phytochemical analyses of these plant species and determining their lethal dose 50 could effectively clarify the larvicidal properties of these plant-based solutions.

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Relationship of work stress and dysglycemia among healthcare workers doing shift work in a level 1 government hospital in Antipolo City

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Abstract

Introduction This cross-sectional study investigated the relationship between work stress and dysglycemia among healthcare workers engaged in shift work at a level 1 government hospital in Antipolo City, Philippines.

Methods Work stress was assessed using the Effort-Reward Imbalance (ERI) Questionnaire, and dysglycemia was measured through a 75g oral glucose tolerance test (OGTT).

Results A total of 126 healthcare workers aged 20–55 years participated Results showed that 65.1% of participants experienced work stress, with nurses reporting the highest prevalence (43.9%). Dysglycemia was present in 33.3% of participants, predominantly in the form of impaired glucose tolerance. Despite the high prevalence of both work stress and obesity (61.9%), no statistically significant associations were found between work stress and dysglycemia ($p = .51$), gender and work stress ($p = .59$), occupation and work stress ($p = .059$), or obesity and dysglycemia ($p = .70$).

Conclusion The findings suggest that while work stress is common among healthcare workers, especially nurses, it may not directly predict dysglycemia in relatively young and active populations. However, the long-term metabolic risks associated with chronic occupational stress should not be overlooked. Future longitudinal studies with larger samples are recommended to better assess causality and guide workplace wellness programs.

Key words: Dysglycemia, work stress, shift work, effort-reward imbalance, healthcare workers, occupational health

Dysglycemia, which includes impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), is a critical early marker in the progression toward type 2 diabetes mellitus (T2DM). Globally, the burden of diabetes is increasing, with the International Diabetes Federation (2019) estimating that 463 million adults were living with diabetes in 2019, with projections indicating a 51% rise by 2045. In the Philippines, data from the 8th National Nutrition Survey reveal that 4.2% of adults aged 20 and above have IFG (Jimeno, 2025). Despite this, local data on dysglycemia prevalence among healthcare workers remains limited, even though this population faces unique occupational risks.

Healthcare workers engaged in shift work are particularly vulnerable to metabolic disorders due to circadian disruption. Shift work has been shown to disturb normal biological rhythms, leading to hormonal imbalances and impaired glucose metabolism. Pan et al. (2011), in a large prospective

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study, found that female nurses working rotating night shifts had an increased risk of developing T2DM. Similarly, Sharma et al. (2017) noted that night-shift healthcare workers had higher postprandial glycemic excursions and delayed insulin responses. These findings highlight the physiologic impact of disrupted sleep-wake cycles on glucose regulation among shift workers.

Work stress further compounds this risk. The Effort-Reward Imbalance (ERI) model by Siegrist (1996) conceptualizes work stress as the result of an imbalance between the effort expended at work and the rewards received. Chronic exposure to such imbalance has been linked to adverse metabolic outcomes. Garbarino et al. (2019) demonstrated that occupational stress is associated with increased risk of metabolic syndrome, including hyperglycemia, and emphasized the role of sleep problems as a mediating factor. Tzeng et al. (2012) also reported that high ERI scores were associated with poor physical and psychological well-being among healthcare professionals. In the Philippine context, Jabonete et al. (2018) found that hospital nurses reported moderate levels of work stress, though their study did not include other healthcare roles such as physicians or ancillary staff.

Given these considerations, this study aims to determine the relationship between work stress and dysglycemia among healthcare workers engaged in shift work in a level 1 government hospital in Antipolo City. Specifically, it seeks to: (1) assess the prevalence of work stress, dysglycemia, and obesity; (2) explore the relationships of gender and occupation with work stress; and (3) examine the association between obesity and dysglycemia.

Methods

Ethics clearance was obtained from the University of the East Ramon Magsaysay Memorial Medical Center Ethics Review Committee. This study used a cross-sectional analytic design to investigate the relationship between work stress and dysglycemia among healthcare workers engaged in shift work at a level 1 government hospital in Antipolo City, Philippines. The study population included hospital personnel aged 20 to 55 years who worked outside the traditional 8:00 AM to 5:00 PM schedule. Individuals previously diagnosed with pre-diabetes or diabetes, pregnant women, and those taking glucose-lowering medications were excluded.

A total of 126 participants were selected from a pool of 187 eligible employees using simple random sampling using a master list of employees, and randomization was performed using the RANDBETWEEN function in Microsoft Excel. The sample included physicians, nurses, and ancillary staff such as midwives, laboratory technicians, and administrative personnel.

Data collection involved face-to-face interviews, during which participants completed the Effort-Reward Imbalance (ERI) Questionnaire to assess work stress. An ERI score of >1 means that work stress is present. Anthropometric measurements, including height and weight, were taken to compute body mass index (BMI), with obesity defined as BMI >25 based on Asia-Pacific guidelines. Dysglycemia was assessed through a 75g oral glucose tolerance test (OGTT), with fasting plasma glucose >100 mg/dL and/or 2-hour plasma glucose >140 mg/dL classified as dysglycemia.

Data were analyzed using OpenEpi. Descriptive statistics were used for demographic profiling. Chi-square tests and prevalence ratios were applied to examine associations between variables, including work stress, dysglycemia, obesity, gender, and occupation. A p-value <0.05 was considered statistically significant.

Results

Table 1 shows the demographic profile of the participants. The participants were relatively young with a mean age of 36. There is a slight predominance of female participants (55.6%). Nurses comprised the largest proportion of the respondents (36.5%). A significant number of the participants were obese (61.9%).

Table 1. Demographic profile of the participants (N=126).

	Number of Participants (n, %)
Mean Age	36, SD = 7.5
Gender	
Male	56, 44.4%
Female	70, 55.6%
Number of obese participants	78, 61.9%
Job Distribution	
Doctors	37, 29.4%
Nurses	46, 36.5%
Ancillary staff	43, 34.1%

Data in Table 2 indicate that more participants reported work stress (65.1%). Across the three job categories, nurses represented the highest group (43.9%) experiencing work stress compared to ancillary staff and doctors.

Table 2. Distribution of work stress among healthcare workers doing shift work (n = 126).

Parameter	n	%
With work stress	82	65.1
Physicians	22	26.8
Nurses	36	43.9
Ancillary	24	29.3
Without work stress	44	34.9
Physicians	15	34.1
Nurses	10	22.7
Ancillary	19	43.2

Table 3 shows the prevalence of dysglycemia among the participants. Although most of the participants still have normal blood glucose, it is noted that 33.3% of the participants already have dysglycemia. Among these participants with dysglycemia, 88.1% of them have impaired glucose tolerance indicating an impaired compensatory response of their bodies to increases in blood sugar during meals.

Table 3. Distribution of dysglycemia among healthcare workers doing shift work (n = 126).

Parameter	n	%
With dysglycemia	42	33.3
FPG >=100 mg/dl	27	64.29
2h PPG >=140 mg/dl	37	88.10
FPG>=100 mg/dl, AND 2h PPG >=140 mg/dl	22	52.38
Without dysglycemia	84	66.7

Only 35.37% of the participants with work stress have dysglycemia and only 29.55% of the participants without work stress have dysglycemia (Table 4). Although participants with work stress had a higher proportion of dysglycemia compared to those without work stress (Prevalence Ratio = 1.197), the association was not statistically significant (p = .51).

Work stress was prevalent among both genders, reported by 62.5% of male participants and 67.14% of female participants (Table 5). A slightly higher proportion of female participants reported work stress compared to males (Prevalence Ratio = 0.93, p = .59), but this difference was not statistically significant.

Across all three job categories, a significant number of participants have reported work stress than those without work stress (doctors: 59.46%, nurses: 78.26%, ancillary: 55.81%) Although work stress is most prevalent among nurses, it was not statistically significant (p = .059) (Table 6).

Table 7 shows that among the obese participants, the prevalence of dysglycemia was 34.62% and among the non-obese participants, the prevalence was 31.25%. Although obesity was slightly prevalent among obese participants than non-obese participants with a prevalence ratio of 1.12, statistical analysis did not provide sufficient evidence to establish a relationship between obesity and dysglycemia (p = .70)

Table 4. Relationship of work stress and dysglycemia among healthcare workers doing shift work (N= 126)

	With Dysglycemia		Without dysglycemia		Total
	Observed	%	Observed	%	
With work stress	29	35.37	53	64.63%	82
Without work stress	13	29.55	31	70.45%	44
Total	42		84		126

x^2 (1, N = 126) = 0.43, p = .51
Prevalence ratio (PR): 1.197, 95% CI [0.6961, 2.058]

Table 5. Relationship of gender and work stress among healthcare workers doing shift work (n = 126)

	With Work Stress		Without Work Stress		Total
	Observed	%	Observed	%	
Male	35	62.50	21	37.50	56
Female	47	67.14	23	32.9	70
Total	82		44		126
x^2 (1, N = 126) = 0.29, p = .59 Prevalence Ratio (PR): 0.9309, 95% CI [0.7172,					

Table 6. Relationship of occupation and work stress among healthcare workers doing shift work (n=126).

	With Work Stress		Without Work Stress		Total
	Observed	%	Observed	%	
Doctor	22	59.46	15	40.54	37
Nurses	36	78.26	10	36.96	46
Ancillary	24	55.81	19	44.19	43
Total	84		44		126
x^2 (2, N = 126) = 5.66, p = .059					

Table 7. Relationship of obesity and dysglycemia among healthcare workers doing shift work (n=126).

	With Dysglycemia		Without dysglycemia		Total
	Observed	%	Observed	%	
Obese	27	34.62	51	65.38	78
Non-obese	15	31.25	33	68.75	48
Total	42		84		126
x^2 (1, N = 126) = 0.15, p = .70 Prevalence Ratio (PR): 1.12, 95% CI [0.6594, 1.861]					

Discussion

This study investigated the relationship between work stress and dysglycemia among shift-working healthcare workers in a level 1 government hospital in Antipolo City. The primary hypothesis posited that high work stress, as measured by the Effort-Reward Imbalance (ERI) model, would be associated with dysglycemia. However, the findings did not support this hypothesis. Although work stress was prevalent among participants (65.1%), only 33.3% exhibited dysglycemia, and the association between the two was not statistically significant ($p = .51$). Similar findings were observed: there was no significant association between gender and work stress ($p = .59$), occupation and work stress ($p = .059$), or obesity and dysglycemia ($p = .70$).

The lack of a significant relationship between work stress and dysglycemia contrasts with prior studies. Garbarino et al. (2019) reported that chronic occupational stress was linked to metabolic syndrome, and Li et al. (2012) identified associations between job strain and diabetes, especially among obese individuals. Heraclides et al. (2011) further suggested that obesity modifies the relationship between job stress and diabetes risk. However, these studies were often conducted in older populations or used longitudinal designs, which may account for the discrepancy. The relatively young mean age of participants in this study (36 years) could have conferred a degree of metabolic resilience. Alhumaid et al. (2022) supported this, citing that younger individuals possess greater hormonal and metabolic flexibility, allowing better regulation of blood glucose under stress.

The high prevalence of work stress, particularly among nurses, aligns with existing literature. Tzeng et al. (2012) found that nurses often report higher ERI ratios compared to other healthcare professionals. In this study, several hospital-related factors may have contributed to elevated stress levels: staffing shortages, high nurse-to-patient ratios (often 1:7 to 1:10 in the medical ward), long working hours, and physically demanding tasks such as repeated stair use. These findings are consistent with McHugh et al. (2023) and Kim et al. (2023), who reported that heavy workloads and overtime are linked to nurse burnout and intent to leave the profession. Additionally, this study was conducted during the tail end of the COVID-19 pandemic, a period still marked by infection control protocols (e.g., PPE use, triage measures, isolation policies), which have been shown to heighten perceived work stress (Hoedl et al., 2020).

Despite the high prevalence of obesity (61.9%) among participants, dysglycemia remained relatively low. This may be attributed to several protective factors. The physically active nature of hospital work may have improved insulin sensitivity, as suggested by Ahmed et al. (2020). Moreover, health literacy and access to healthcare services likely enabled early self-monitoring and preventive behaviors, as discussed by Bailey et al. (2014). Majority of the participants with dysglycemia (88.1%) exhibited impaired glucose tolerance (IGT), a postprandial phenomenon that may reflect early stages of beta-cell dysfunction. Nonetheless, the young age of the population and the absence of long-term stress exposure might explain the lack of overt metabolic disturbances despite the presence of risk factors.

Key limitations of the study should be acknowledged. The cross-sectional design precludes causal inferences. Additionally, reliance on a single-site hospital sample may reduce the generalizability of findings to other institutions or geographic regions.

Conclusion

This study demonstrated that while work stress is highly prevalent among healthcare workers, especially nurses, it is not significantly associated with dysglycemia in a relatively young and active hospital population. The absence of significant associations may be due to protective factors such as youth, occupational physical activity, and health literacy. Nonetheless, the high burden of work stress warrants institutional attention, as its long-term consequences may manifest beyond the study's timeframe. Regular monitoring of staff well-being, workplace stress interventions, and metabolic health screening are recommended. Future research should adopt a longitudinal design to explore the cumulative effects of chronic stress on metabolic outcomes, and consider stratification by age, role, and stress adaptation mechanisms to better understand subgroup vulnerabilities.

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Cardiovascular risk in medical students: Is living alone a factor?

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Abstract

Introduction Cardiovascular diseases (CVD) are a leading global health concern. Modifiable behavioral risk factors are increasingly recognized in young adults, especially among medical students who often live independently. This study investigated the association between living alone and modifiable cardiovascular risk factors—sleep quality, sodium intake, physical activity, and body mass index (BMI)—among medical students at UERMMMCI during the 2022-2023 academic year.

Methods Researchers conducted an analytical cross-sectional study among 220 medical students. Validated tools were used: Pittsburgh Sleep Quality Index (PSQI), Scored Sodium Questionnaire, International Physical Activity Questionnaire (IPAQ), and BMI classification. Researchers performed statistical analyses using Chi-square tests and calculated relative risks (RR) with 95% confidence intervals.

Results A significant positive association was found between living alone and poor sleep quality (RR 2.132 p = 0.047). No significant associations were observed between living alone and sodium intake (RR 0.96 p = 0.6868), physical activity (RR 1.18 p = 0.2239), or BMI (RR 1.03 p = 0.7367).

Conclusion Among the studied cardiovascular risk factors, only poor sleep quality was significantly more prevalent among students living alone. These findings highlight the importance of interventions targeting sleep hygiene in this demographic.

Key words: Cardiovascular diseases, risk factors, medical students, sleep quality, dietary, living alone

Cardiovascular diseases (CVDs) encompass disorders of the heart and blood vessels, including hypertension, coronary heart disease, and cerebrovascular disease.[1] These conditions remain the leading cause of premature mortality both globally and in the Philippines.[2-4] Although symptoms often emerge in adulthood, the underlying risk factors typically begin in adolescence. Addressing these risk factors early is crucial.

Many young adults live independently while attending college or working, introducing new lifestyle challenges.[5] Research links social isolation to poorer cardiovascular health outcomes.[6] High-risk behaviors—smoking, excessive sodium consumption, and physical inactivity—are also more common among individuals who live alone.[7]

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Modifiable cardiovascular risk factors such as poor diet, inadequate sleep, physical inactivity, and elevated BMI contribute to CVD development.[8] Preventing CVD by determining the prevalence of these modifiable risk factors among individuals who live alone is of importance, as it poses social, economic, and health burden, along with a reduction in their quality of life.[5]

The study sought to determine the association between living alone and the presence of modifiable cardiovascular risk factors among medical students enrolled in UERMMMCI in the school year 2022-2023.

Methods

The UERM Research Institute for Health Sciences Ethics Review Committee approved this analytical cross-sectional study (RIHS ERC Code: 1449/C/2023/021).

Participants

The study included regular first- to third-year medical students at UERMMMCI in 2022-2023. Eligible participants either lived alone or with family. Students who lived with non-family members or shared a space only on weekends were excluded. Researchers used non-probability, convenience sampling by distributing physical questionnaires during class visits.

Sample Size

A preliminary study of 30 participants informed the sample size calculation for comparing two proportions. At 95% confidence, 80% power, and assumed proportions of 0.60 and 0.366, a minimum of 218 participants was required.

Data Collection Tools

Researchers used four standardized tools:

1. Pittsburgh Sleep Quality Index (PSQI): This 19-item tool (plus 5 optional items) assesses sleep quality across 7 components. Its initial evaluation had α=.83 of internal reliability, test-retest reliability for the global scale of 0.85, 89.6% sensitivity, and 86.5% specificity. A global PSQI score >5 indicates poor sleep.[9]
2. Scored Sodium Questionnaire (SSQ): This 34-item tool evaluates sodium intake over the past 6 months. It has an AUC of 0.79, 61.5% sensitivity, and 90.0% specificity. Scores >65 denote high sodium consumption[10,11].
3. International Physical Activity Questionnaire (IPAQ): This self-report tool assesses moderate-to-vigorous physical activity. It has a test-retest reliability of 0.74, criterion validity of 0.41, and concurrent validity of 0.72. Category 1 reflects low activity; Categories 2-3 reflect moderate-to-high activity[12].
4. Body Mass Index (BMI): BMI was computed using self-reported height and weight, classified using Asia-Pacific cut-offs. BMI >23 kg/m^2 was considered above normal[13-15].

Researchers verified the completeness and validity of responses, tallied scores, and used SPSS for statistical analysis.; relative risk (RR) with 95% CI was calculated for association. Chi-square tests assessed for statistical significance.

Results

The demographic characteristics are summarized in Table 1. The final sample included 220 students: 112 lived alone and 108 with family. Among the 220 participants, 63.2% were female, and 84.6% were aged 23-26. First-year students made up the largest proportion (36.8%).

Sleep Quality

Living alone significantly increased the likelihood of poor sleep quality (RR = 2.132, 95% CI: 0.97–4.55, p = 0.0476) (Table 2).

Sodium Intake

Sodium intake did not differ significantly between those living alone and those living with family (RR = 0.9643, p = 0.6868) (Table 3).

Physical Activity

No significant association emerged between living arrangement and physical activity level (RR = 1.181, p = 0.2239) (Table 4).

Body Mass Index

BMI was not significantly associated with living alone (RR = 1.033, p = 0.7367) (Table 5).

Table 1. Demographic characteristics of the participants.

Demographic Factors		UERM Medical Students	
		Frequency	Proportion
Sex	Male	81	36.8
	Female	139	63.2
Age in years	19 – 22	21	9.5
	23 – 26	187	84.6
	27 – 30	10	4.6
	31 – 43	2	1
Year Level	Year 1	133	36.8
	Year 2	50	22.7
	Year 3	37	16.8

Table 2. Analysis on the effect of living alone on sleep quality.

Participants	Poor Sleep Quality	Good Sleep Quality	Relative Risk (95% Confidence Interval)	p-value
Living alone	100	12	2.132	0.0476
Living with family	86	22	0.9733 to 4.558	

Table 3. Analysis on the effect of living alone on sodium intake.

Participants	High Sodium Intake	Low Sodium Intake	Relative Risk (95% Confidence Interval)	p-value
Living alone	76	36	0.9643	0.6868
Living with family	76	32	0.8054 to 1.154	

Table 4. Analysis on the effect of living alone on physical activity.

	Low Physical Activity	Moderate to High Physical Activity	RR (95% Confidence Interval)	p value
Living alone	60	52	1.181	0.2239
Living with family	49	59	0.9038 to 1.553	

Table 5. Analysis on the effect living alone on body mass index (BMI).

	Above normal BMI	Normal BMI	RR (95% Confidence Interval)	p value
Living alone	75	37	1.033	0.7367
Living with family	70	38	0.8529 to 1.255	

Discussion

Sleep Quality and Living Alone

Among the cardiovascular risk factors, only sleep quality showed a significant association with living alone. Those living independently were over twice as likely to report poor sleep. Disrupted sleep may result from environmental factors—noisy dorms, irregular routines, or lack of emotional support.[16] An outcome-based recommendation by the National Sleep Foundation, a nonprofit organization based in the United States dedicated to improving health and well-being through sleep education and advocacy states that the appropriate amount of sleep duration for an adult is 7-9 hours.[17] Filipinos had one of the highest rates of sleep deprivation in Asia: national data show 46% of Filipinos report insufficient sleep, and 32% sleep less than six hours per night.[18] International and local studies among medical students also highlight prevalent poor sleep, but they seldom consider living arrangements.[19-21] Inadequate sleep duration—typically defined as fewer than 6 hours or more than 9 hours per night—has been consistently associated with an elevated risk of adverse cardiovascular outcomes, including hypertension and coronary heart disease. This association follows a U-shaped pattern, wherein both short and long sleep durations are linked to increased cardiovascular morbidity and mortality.[22-24] Among university students, particularly those living alone, irregular sleep patterns and poor sleep hygiene may be compounded by academic stress, social isolation, and lack of structured routines, further increasing their vulnerability to cardiovascular risk. Therefore, targeted interventions that promote healthy sleep behaviors, stress reduction techniques, and awareness of the health consequences of sleep deprivation may serve as important strategies in mitigating cardiovascular disease (CVD) risk in this population.

Sodium Intake and Living Arrangement

No statistically significant difference in sodium intake was observed between students based on their living arrangements. This finding suggests that individual dietary choices may play a more influential role in sodium consumption than residential status alone. Factors such as personal food preferences, cooking habits, cultural influences, and exposure to processed foods likely contribute to this variability. Additionally, disparities in affordability and access to healthy, low-sodium food options—particularly among students with limited financial resources—further complicate the ability to draw direct associations between living arrangement and sodium intake.[25-26] These results highlight the need for broader nutritional interventions that account for individual behavior and structural barriers to healthy eating.

Physical Activity and Living Alone

Contrary to previous studies, living alone was not associated with lower levels of physical activity among students.[27] Factors such as access to exercise facilities, digital fitness platforms, and peer influence may play a more significant role than living arrangement in shaping physical activity habits.[28]

Body Mass Index and Living Alone

Living alone did not significantly affect BMI. Although some literature links independent living to higher obesity risk; it has been suggested that poor lifestyle behaviors such as eating salty or sugary food and low physical activity have been associated with increasing BMI particularly among university students who are living alone.[25,29] In contrast, another study revealed that, although the BMI of university students increased from the start to the end of the same school year, the students living with their parents/relatives reported a greater increase in BMI.[30] The present findings align with literature suggesting other factors—diet, activity, stress—play larger roles.

Limitations

This study has several limitations. The use of self-reported data introduces the potential for recall and response bias. Additionally, non-modifiable cardiovascular risk factors such as family history and pre-existing medical conditions were not assessed. The use of convenience sampling further limits the generalizability of the findings to the broader student population.

Conclusion

Among the assessed modifiable cardiovascular risk factors, only poor sleep quality was significantly more

common in students living alone. No differences were found in sodium intake, physical activity, or BMI.

Recommendations

Institutions should promote proper sleep hygiene and stress management strategies, particularly for students living independently. Future research should include longitudinal data and account for non-modifiable risk factors.

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Factors influencing the delivery of basic pre-hospital trauma care during disaster by the Emergency Medical Services of the Bureau of Fire Protection

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Abstract

Introduction The Philippines is considered a disaster-prone country, making basic pre-hospital trauma care essential in the disaster response. The Bureau of Fire Protection (BFP) is mandated by law as the lead agency in providing emergency medical services (EMS) in the country, which plays a critical role in disaster response. This study aimed to investigate the influence of the different factors (knowledge, training, experience, and logistics) on the disaster preparedness of the BFP EMS personnel and to identify the strongest predictor among the factors.

Methods A correlational study was done among 125 EMS personnel in the Bureau of Fire Protection-National Capital Region (BFP-NCR) using stratified random sampling. A four-part questionnaire, which included a demographic form, a 20-item knowledge test, a logistics compliance checklist from the Department of Health licensing tool, and the Emergency Preparedness Information Questionnaire (EPIQ) was used. Statistical analysis done were Pearson correlation and logistic regression.

Results The findings showed that knowledge (OR = 0.299, 95% CI: 0.128–0.689), training (OR = 3.2, 95% CI: 1.8–5.6), and experience (OR = 1.9, 95% CI: 1.1–3.4) affected the level of disaster preparedness. Furthermore, logistics did not show a significant effect ($p > 0.05$).

Conclusion The strongest predictor of disaster preparedness among the factors is knowledge. Even though logistics is an essential factor, its effectiveness still depends on the proper utilization by trained personnel. Recommendations include continuous training and retention of experienced personnel, which are essential to enhance BFP EMS readiness during disasters.

Key words: emergency medical services, disaster preparedness, trauma care, EMS training, Bureau of Fire Protection

The Philippines is one of the most disaster-prone countries in the world. In the World Economic Forum (2018) report, the Philippines ranked 3rd among 173 countries vulnerable to disaster risk and natural hazards. It frequently experiences typhoons, earthquakes, floods, and volcanic eruptions, with an average of 20 tropical storms annually (GFDRR, 2017). In this situation, it is critical that Emergency Medical Services (EMS) work well, especially when it comes to providing life-saving pre-hospital trauma care. The World Health Organization considers EMS an essential component of a robust healthcare system (Beyramijam et al., 2021; Ho, 2020; Mehmood, 2018). The EMS delivers care during a disaster and helps mitigate the impact (Catlett et al., 2011) because

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they are the first to recognize the nature of a disaster and evaluate the situation immediately to determine the resources needed (Committee on Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations, 2012). The primary goal of EMS in disaster response is to maintain continuity of medical services through triage, life-saving support, rapid diagnosis and treatment, or transfer of casualties to emergency departments (Tourani et al., 2018).

Under Republic Act No. 11589, the Bureau of Fire Protection (BFP) is mandated to suppress fires, respond to disasters, and provide emergency medical services (EMS). Executive Order No. 56 designates the BFP as the lead agency for public EMS. Despite ongoing modernization efforts, EMS capacity remains inconsistent across regions.

Previous studies have demonstrated that factors such as training, experience, and logistics affect how well EMS personnel provide pre-hospital trauma care. The study by Haghparast-Bidgoli (2010) identified several factors that hinder effective pre-hospital care, including the availability and distribution of resources, administration and organization, staff qualifications and competencies, communication and transportation, involvement of organizations and lay people, and infrastructure. Research on the key predictors of disaster preparedness among EMS personnel remains limited. In the Philippines, the absence of advanced EMT or paramedic training and the lack of a national regulatory framework further hinder efforts to strengthen the EMS system (Padlan & Gaerlan, 2018).

This study would fill that gap by examining the relationship between knowledge, training, experience, and logistics of BFP-NCR EMS personnel to their level of disaster preparedness. It also aimed to determine the most important predictor among all factors in the delivery of basic pre-hospital trauma care.

Method

Study Design

This study used a correlational design to examine the relationship between preparedness and different factors affecting the delivery of basic pre-hospital trauma care. The study protocol was reviewed and approved by the UERMMMCI Ethics Review Committee.

Study Population and Setting

Eligible participants were Bureau of Fire Protection (BFP) emergency medical services (EMS) personnel with a minimum of three months of service. Ambulance drivers were excluded. A stratified random sampling technique was employed to ensure representative sampling across key subgroups.

Sample Size

Using finite population correction from a target population of 185 EMS personnel, the required sample size was calculated to be 125, based on a 95% confidence level and a 5% margin of error.

Data Collection Tools

Four tools were used: a demographic profile sheet, a 20-item knowledge test from the BFP Emergency Medical Responder Manual, the DOH logistics compliance checklist, and the Emergency Preparedness Information Questionnaire (EPIQ) by Garbutt et al (2008). Approval was secured from the BFP-NCR Regional Director. Informed consent was obtained, and participants completed the questionnaire in 30–45 minutes.

Data Analysis

Data were encoded using Microsoft Excel and analyzed using SPSS 29 for Windows. Pearson correlation tested associations, and binary logistic regression identified predictors. A significance level of 0.05 was used. Odds ratios and 95% confidence intervals were reported.

Study Variables

The dependent variable was disaster preparedness, measured using the Emergency Preparedness Information Questionnaire (EPIQ) and categorized as high or low based on the median score. Independent variables included: (1) knowledge, assessed through a 20-item multiple choice test and categorized as good or poor based on the median score; (2) training, categorized based on completion of Basic Life Support (BLS), First Aid, and Emergency Medical Technician (EMT) training; (3) years of EMS experience with a

cut off of 3 years; and (4) logistics capability, measured by compliance with the DOH licensing tool checklist, categorized into compliant, partially compliant, or not compliant.

Results

A total of 125 Emergency Medical Services personnel participated in the study, of which majority were male (67.2%) and between the ages of 30–39 years (76%) as seen in Table 1. Most of the personnel were nurses by profession.

In terms of knowledge, 55.2% (n=69) of respondents scored at or above the median score of 10 and were classified as having good knowledge in basic pre-hospital trauma care. The remaining 44.8% (n=56) had poor knowledge.

The Emergency Preparedness Information Questionnaire (EPIQ) revealed that 60.8% (n=76) had high levels of disaster preparedness, while 39.2% (n=49) were categorized as having low preparedness based on a median cutoff score of 110.

Capability as seen in Table 2 was assessed through three indicators: training, experience, and logistics. In training, 44% (n=55) were fully capable, 24% (n=30) were capable, and 32% (n=40) were not capable. In terms of experience, 59.2% (n=74) had three or more years in EMS, while 40.8% (n=51) had less than three years. Regarding logistics, 21.6% (n=27) were compliant with the DOH checklist, 52.8% (n=66) were partially compliant, and 25.6% (n=32) were not compliant.

Pearson correlation showed that knowledge ($r=0.95$, $p<0.01$), training ($r=0.92$, $p<0.01$), and experience ($r=0.75$, $p<0.05$) were significantly associated with disaster preparedness (Table 3). Logistics also had a positive correlation ($r=0.72$, $p<0.01$), but its significance was not supported in the logistic regression model (Table 4).

Logistic regression analysis (Table 5) identified knowledge (OR=0.299, 95% CI: 0.128–0.689), training (OR=3.2, 95% CI: 1.8–5.6), and experience (OR=1.9, 95% CI: 1.1–3.4) as significant predictors of disaster preparedness. Logistics compliance did not reach statistical significance (p=0.209).

Table 1. Demographic profile of emergency medical service personnel of the Bureau of Fire Protection-National Capital Region

Variables	Frequency (n=198)	Percentage (%)
Age ($\bar{x}$ = 35)		
20-24	5	4
25-29	17	13.6
30-34	47	37.6
35-39	48	38.4
40-44	3	2.4
45-50	3	2.4
>50	2	1.6
Gender		
Female	41	32.8
Male	84	67.2

Discussion

This study looked into the factors that influence the delivery of basic pre-hospital trauma care during disasters by the emergency medical services personnel within the Bureau of Fire Protection. The results indicated that knowledge, training, and experience were strongly associated with a higher level of disaster preparedness. Knowledge resulted as the most significant predictor among the different factors. The

Table 2. Capability status of the emergency medical service of the Bureau of Fire Protection (Logistics, Training, and Experience).

Capability Factor	Category	Frequency (n=125)	Percentage (%)
Logistics	Compliant	27	21.6
	Partially Compliant	66	52.8
	Not Compliant	32	25.6
Training	Fully Capable	55	44.0
	Capable	30	24.0
	Not Capable	40	32.0
Experience	≥3 years	74	59.2
	<3 years	51	40.8

Table 3. Relationship between knowledge of basic pre-hospital trauma care and the disaster preparedness level of the Bureau of Fire Protection EMS Team.

Variable	Mean	p value	r-value
Knowledge of Basic Pre-Hospital Trauma Care	10.304	6.30E-63	0.95
Disaster Preparedness	124.92		

* The reference (comparator) category used was *Poor Knowledge* (<10).
**R-value: Pearson Correlation Coefficient

Table 4. Relationship between variables of the capability status of emergency medical services and the disaster preparedness level of the Bureau of Fire Protection.

Status of Capability	p value	r-value
Logistics	6.30E-63	0.72
Training	1.08E-53	0.92
Experience	3.67E-24	0.75

* In each factor, the lowest performing group served as the comparator ("Not Compliant", "Not Capable", "< 3 years")
** R-value: Pearson Correlation Coefficient

Table 5. Best predictor of good basic pre-hospital trauma care in a disaster situation.

Variable	Odds Ratio	95% Lower Limit	95% Upper Limit	p value
Knowledge				
Good (≥10) knowledge vs Poor knowledge	.299	.128	.689	<0.01
Poor (<10) knowledge				
Logistical Capability				
Compliant vs Not Compliant	2.021	0.39	6.049	.209
Partially Compliant vs Not Compliant	1.08	0.39	3.000	0.887
Not Compliant				
Training Capability				
Fully Capable vs Not Capable	3.2	1.8	5.6	<0.01
Capable vs Not Capable	1.8	1.15	2.82	<0.01
Not Capable				
Experience Capability				
≥3 years vs <3 years	1.9	1.1	3.4	<0.05
<3 years				

findings are congruent with the study of Abebe et al. (2023). They noted that the factors that increased the odds of good practice in pre-hospital care included providing advanced life support, adequate monitoring, and access to defibrillators, having 4-5 years of work experience, and having the opportunity to continue education.

The findings of this study are also consistent with previous research by Nandasena (2018) and Sener (2006). They indicated that inadequate knowledge among EMTs affects emergency response efficacy. Furthermore, James (2015) also emphasized that education and training significantly reduce casualties and mitigate disaster impacts. The findings of this

study support the need for regular refresher courses, knowledge evaluations, and training simulations to enhance EMS performance. In the Philippines, where EMS personnel are primarily trained only as EMT-Basic (DOH, 2018), knowledge gaps may hinder effective trauma care in disaster settings.

Training was also identified as a major factor. EMS professionals who have comprehensive training of EMT, Basic Life Support, and Standard First Aid were three times more likely to be adequately prepared during a disaster. This confirms the findings of Beyramijam et al. (2021) and Abebe et al. (2023), who emphasized the significance of continuous training in disaster response. As suggested by James (2015) and Ciottone (2015), comprehensive EMS training improves triage accuracy, critical decision-making, and casualty outcomes during disasters. Therefore, scaling up BLS, Advanced Cardiovascular Life Support (ACLS), and EMT training programs, along with potential introduction of Advanced EMT or Paramedic programs, may significantly elevate the overall quality of EMS in the country.

This study also shows that experience enhances disaster preparedness. This aligns with the study of Abebe et al. (2023) and Ciottone (2015), which emphasized the significance of experience in decision-making and field competence. Experience also influences self-efficacy in high-pressure scenarios, which are crucial in mass casualty incidents (Uhm et al., 2019). However, it is important to note that the duration of service in this study does not correspond to the consistent exposure to actual disasters. This shows a possible limitation of this factor.

The Department of Health (2018) issued the *Revised Rules and Regulations Governing the Licensing of Land Ambulances*, outlining the required equipment for Type 1 and Type 2 ambulances—essential logistics for EMS teams. While logistics showed a strong correlation with disaster preparedness, logistic regression analysis revealed it was not a significant predictor. This suggests that equipment alone is insufficient to enhance preparedness without qualified and experienced personnel to utilize it effectively, a conclusion supported by Lyng et al. (2021). Similarly, Padlan and Gaerlan (2018) highlighted long-standing issues in the Philippine EMS, including logistical inconsistencies and a lack of standardization.

Alotaibi and Khan (2019) emphasized the interrelationship between knowledge, training, and experience, noting that improvements in one area often enhance overall disaster preparedness. Their findings support the need for a multifaceted approach to strengthening EMS personnel readiness, aligning with the *Action Framework for Pre-Hospital Emergency Medical Services* issued by the Department of Health (2014). This approach includes targeted training, retention of experienced personnel, and ongoing education. Additionally, the present study underscores existing gaps in recognizing EMS as a professional discipline in the Philippines, which may hinder institutional support for a comprehensive and sustainable training system.

A key limitation of this study is its focus on a single region, which limits the generalizability of the findings. Future research should explore disaster preparedness among EMS personnel in other regions, particularly those frequently exposed to diverse disaster types such as volcanic eruptions and earthquakes.

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Mental health awareness and stigmatization: a cross-sectional study of knowledge, attitudes, and perceptions among medical students at a Philippine medical school

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Abstract

Introduction Mental health plays a crucial role in overall well-being, yet stigma and misconceptions persist, even among future healthcare professionals. This study assessed medical students' knowledge, attitudes, and perceptions (KAP) regarding mental health and explored their association with sociodemographic characteristics.

Methods We conducted an analytical cross-sectional study among 270 medical students at a private Philippine university from September to October 2023. Participants completed a validated questionnaire. Descriptive statistics, Spearman's correlation, and odds ratios were calculated.

Results Most respondents exhibited high knowledge (80.7%), positive attitudes (90.4%), and favorable perceptions (95.6%) toward mental health. Students who had not interacted with individuals with mental illness were 2.87 times more likely to display negative attitudes (OR = 2.87, 95% CI: 1.19–6.90, p = 0.015). Attitude and perception showed a moderate positive correlation (r = 0.409, p < 0.001), while knowledge and perception demonstrated a weak negative correlation (r = -0.129, p = 0.034).

Conclusion These medical students generally possessed good knowledge, positive attitudes, and perceptions regarding mental health. Academic progression and real-life exposure positively influence attitudes, highlighting the need for experiential learning to reduce stigma and promote empathy in medical training.

Key words: Mental health, medicals, knowledge, attitudes, perception, Philippines

Mental health remains a critical public health issue worldwide. According to the World Health Organization (WHO), over 1.1 billion people suffer from mental disorders, yet only 30% to 40% receive treatment. This treatment gap widens in low- and middle-income countries, where up to 85% of individuals with mental illness lack access to care[1-2]. Stigmatization and misinformation exacerbate this disparity, with mental health often perceived as less legitimate than physical health. Many individuals—including healthcare workers and medical students—harbor misconceptions, viewing individuals with mental illness as dangerous or incapable of recovery. These biases may negatively influence patient care and hinder help-seeking behavior[3].

Medical students represent the future of healthcare delivery. Their knowledge, attitudes, and perceptions

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(KAP) toward mental health can shape clinical practice and influence public health discourse. Previous research has shown varying levels of mental health literacy and stigma among medical students worldwide, highlighting the need for continuous assessment and targeted education.[4-5]

This study aimed to evaluate medical students' KAP regarding mental health in a private Philippine university and to explore the associations between these variables and sociodemographic characteristics. Findings from this research may inform interventions designed to reduce stigma, promote empathy, and improve mental healthcare delivery in future medical practice.

Methods

Study Design

Ethics approval was obtained from the Ethics Review Committee of the UERMMMCI Research Institute for Health Sciences, ERC Code: 1589/C/2023/161. An analytical cross-sectional study among medical students enrolled at a private university in the Philippines was done. Data collection occurred from September to October 2023.

Participants and Sampling

Eligible participants included currently enrolled medical students aged 18 years or older during the academic year 2023–2024 using a convenience sampling method. The computed minimum sample size was 384.

Research Instrument

The authors used a structured questionnaire adapted from a previous study. to assess students' knowledge, attitudes, and perceptions (KAP) regarding mental health.[6] The instrument included:

- Knowledge: 20 yes/no/not sure items adapted from a study and modified with four additional questions on mental health treatment.[7]
- Attitude: 17 items based on a 5-point Likert scale (strongly disagree to strongly agree) adapted from a study.[8]
- Perception: 7 items using a 5-point Likert scale, originally adapted from 2 studies.[9-10]

Data Collection Procedure

The survey was disseminated through the university-issued email accounts. An informed consent section was included at the beginning of the questionnaire. Participation was voluntary, and all responses were collected anonymously.

Data Processing and Analysis

Data analysis was done using R software. Descriptive statistics summarized demographic characteristics and KAP levels. The following were the cutoffs for classification:

- High Knowledge: score ≥14 out of 20
- Positive Attitude: score ≥62 out of 85
- Positive Perception: score ≥26 out of 35:

Spearman's rank correlation was applied to assess relationships among KAP variables. Odds ratio was used to evaluate associations between KAP outcomes and demographic characteristics.

Results

Demographic Profile

A total of 270 medical students participated in the survey, yielding a response rate of 70%. The majority were female (68.9%) and between 23 to 26 years of age (81.5%). Most respondents were in their first (35.2%), second (29.3%), or third (31.5%) year of medical school, with only 4.1% in their fourth year (Table 1). A large proportion (82.6%) reported having prior experience speaking with someone diagnosed with a mental disorder (Table 2).

KAP Scores

Students scored an average of 15.07 (SD = 2.01) on the 20-item knowledge test. Mean attitude and perception scores were 67.93 (SD = 4.68) and 30.37 (SD = 2.77), respectively. (Table 3). Most respondents had high knowledge (80.7%), positive attitudes (90.4%), and positive perception (95.6%). (Table 4)

Table 1. Respondent's demographics (N = 270).

Category	Level	%
Year Level	1st year	35.19
	2nd year	29.26
	3rd year	31.48
	4th year	4.07
Age	18 to 22 years	11.85
	23 to 26 years	81.48
	28 years or older	6.67
Sex	Female	68.89
	Male	30.74
	Prefer not to say	0.37
Information Source	Social Media	93.70
	Formal Education	89.63
	Environment	64.07
	Books	65.19
	Seminar	60.74

Table 2. Mental health related experience.

Experience	Yes	No
Have experience of talking with a person with a mental disorder	82.59	17.41
Have been diagnosed with a mental disorder	15.93	84.07
Have visited a psychologist or psychiatrist	24.44	75.56

Table 3. Descriptive statistics for KAP variables.

	Mean (SD)	Median (IQR)
Knowledge	15.07 (2.01)	15 (3.00)
Attitude	67.93 (4.68)	69 (6.00)
Perception	30.37 (2.77)	31 (3.00)

Table 4. Distribution of KAP classifications

	Frequency	Relative Frequency %
Adequate knowledge	218	80.7
Inadequate knowledge	52	19.3
Positive attitude	244	90.4
Negative attitude	26	9.6
Positive perception	258	95.6
Negative perception	12	4.4

Correlation Between KAP Variables

Attitude and perception scores showed a moderate positive correlation ($r = 0.409$, $p < 0.001$), while knowledge and perception demonstrated a weak negative correlation ($r = –0.129$, $p = 0.034$). No significant correlation was found between knowledge and attitude ($r = 0.066$, $p = 0.279$) (Table 5).

Table 5. Correlation matrix of KAP scores.

Variable Pair	Spearman's ρ	P-Value
Knowledge and Attitude	0.066	0.279
Knowledge and Perception	-0.129	0.034
Attitude and Perception	0.409	<0.001

Associations with Sociodemographic Factors

Knowledge

Third-year students were more likely to have adequate knowledge compared to first-year students (OR = 6.03, 95% CI: 2.33–14.97, $p = 0.0001$). Fourth-year students also had a higher likelihood of adequate knowledge (OR = 8.77, 95% CI: 0.50–154.1, $p = 0.0458$)—though the wide CI indicates some imprecision due to smaller sample size. Second-year students, age group, gender, and experience-related variables (e.g., prior diagnosis or speaking to someone with mental illness) were not significantly associated with knowledge. Advancing year level is strongly associated with better knowledge of mental health, particularly in third-year students. (Table 6)

Attitude

Students who had not spoken to someone with a mental disorder were significantly more likely to have a negative attitude (OR = 2.87, 95% CI: 1.20–6.72, $p = 0.015$). Year level, age, gender, prior diagnosis, and psychiatric consultation were not significantly associated with negative attitudes. Direct social interaction with individuals with mental disorders significantly reduced the likelihood of having a negative attitude, confirming the value of real-life exposure in lowering stigma (Table 7).

Perception

Students with no previous diagnosis (OR = 2.81, p = 0.0918), no experience talking to someone with mental illness (OR = 2.50, p = 0.1366), and those who had not seen a mental health professional (OR = 2.31, p = 0.1556) all trended toward having more negative perceptions, but results did not reach significance. While no associations reached statistical significance, the ORs suggest a consistent trend—lack of personal experience with mental health issues (whether through diagnosis or interaction) may contribute to negative perceptions (Table 8).

Table 6. Association between adequate knowledge and demographic indicators.

Variable		OR	95% CI	p value
Year Level	First year	reference		
	Second year	1.041	0.5466 to 2.031	0.9074
	Third year	6.029	2.325 to 14.97	0.0001
	Fourth year	8.770	0.4989 to 154.1	0.0458
Age	18 – 22	1.402	0.5465 to 3.500	0.5088
Gender	Female	1.005	0.5349 to 1.957	0.9881
Have experienced talking with a person with mental disorder		1.356	0.6131 to 2.839	0.4278
Have been diagnosed with a mental disorder		2.615	0.9681 to 7.097	0.0710
Have visited a psychiatrist or psychologist		1.258	0.8973 to 1.171	0.5389

Table 7. Association between negative attitude and demographic indicators

Variable		OR	95% CI	p value
Year Level	First year	reference		
	Second year	0.8140	0.3268 to 2.030	0.6790
	Third year	0.5907	0.1978 to 1.691	0.3361
	Fourth year	1.728	0.3301 to 7.781	0.5195
Age	18 – 22	1.682	0.4063 to 7.515	0.4900
Gender	Male	1.209	0.4888 to 2.686	0.6623
Have not experienced talking with a person with mental disorder		2.870	1.195 to 6.722	0.0149
Have not been diagnosed with a mental disorder		2.150	0.8704 to 5.040	0.0714
Have visited a psychiatrist or psychologist		1.139	0.4451 to 2.742	0.7570

Table 8. Association between negative perception and demographic indicators.

Variable		OR	95% CI	p value
Year Level	First year	reference		
	Second year	3.142	0.6429 to 16.06	0.1580
	Third year	2.906	0.5964 to 14.85	0.1907
	Fourth year	1.626	0.07344 to 36.01	0.6271
Age	18 – 22	1.520	0.3198 to 6.028	0.5976
Gender	Female	2.301	0.5145 to 10.68	0.2763
Have not experienced talking with a person with mental disorder		2.500	0.8037 to 7.776	0.1366
Have not been diagnosed with a mental disorder		2.808	0.8995 to 8.707	0.0918
Have visited a psychiatrist or psychologist		2.307	0.8021 to 6.893	0.1556

Discussion

This study examined the knowledge, attitudes, and perceptions (KAP) of medical students in a Philippine university toward mental health and analyzed their association with various sociodemographic factors. The results revealed that most students had high levels of knowledge (80.7%), positive attitudes (90.4%), and favorable perception (95.6%) toward mental health—findings consistent with those from studies in Indonesia and Uganda.[5-6]

Knowledge and Its Sociodemographic Correlates

Year level emerged as a strong and statistically significant factor associated with higher mental health knowledge. Specifically, third-year students had over six times the odds of having adequate knowledge compared to first-year students (OR = 6.03, p = 0.0001). Fourth-year students showed a similar trend (OR = 8.77, p = 0.0458), although the wide confidence interval suggests imprecision, likely due to the smaller sample size. This supports previous findings that mental health literacy improves as students advance in their academic and clinical training.[6]

Other demographic factors such as age, gender, prior diagnosis, and interaction with people with mental illness did not show significant associations with knowledge levels. Nonetheless, students who had been diagnosed with a mental disorder had a higher level of knowledge (OR = 2.62, p = 0.071), consistent with the notion that personal experience contributes to deeper understanding.[6] Similar studies pointed out that students who had seen a psychologist or psychiatrist exhibited improved knowledge, attitude, and views regarding mental health issues.[6] Having a close relationship with someone who has a mental illness demonstrates less stigma, better knowledge, and a positive attitude.[11]

Attitude Toward Mental Illness and Predictive Factors

The study confirmed that lack of exposure to individuals with mental disorders significantly increased the likelihood of harboring negative attitudes (OR = 2.87, p = 0.015). This supports findings from earlier studies indicating that interaction with individuals with mental illness reduces stigma and fosters empathy.[6,11] Conversely, year level, age, and gender were not significantly associated with negative attitudes, although previous literature suggests that women are typically more accepting of individuals with mental disorders than men.[12]

Interestingly, the data showed that students who had not been diagnosed with a mental disorder showed a tendency toward more negative attitudes (OR = 2.15, p = 0.0714), again suggesting the potential destigmatizing effect of personal experience.[13]

Perception and Its Influencing Variables

Although no variables showed a statistically significant association with negative perception, the trends were notable. Students who had no previous diagnosis (OR = 2.81), had not interacted with someone with a mental disorder (OR = 2.50), or had not visited a psychiatrist or psychologist (OR = 2.31) tended to have more negative perceptions. These findings echo earlier studies suggesting that first-hand exposure—through personal experience or interaction—can positively shape perceptions toward mental illness.[6] One possible explanation for this could be that students who visit a professional (a psychiatrist or psychologist) gain more understanding about mental health from the explanations provided by the professional.[6] Those with low perceptions are those who are less educated, have limited access to mental health resources, and do not have a family history of mental illness[14]. Improvements were observed from the experience of interacting with people who had mental illnesses, including improved perspectives and a development of empathy.[15]

Interestingly, while female students were more likely to have a negative perception (OR = 2.30), this contradicted earlier literature and may reflect sample variability.[11]

Another finding is that the higher the year level, the lower the proportion of people who have a negative perception of people with mental health disorders. However, the results are not statistically significant. Positive changes were observed from the experience of interacting with people who had mental illnesses, including changes in perspectives and the development of empathy[15].

Correlation Between Knowledge, Attitude, and Perception

The correlation analysis revealed a moderate positive relationship between attitude and perception ($r = 0.409$, $p < 0.001$), suggesting that students with more positive attitudes also viewed mental illness in a more accepting light. This aligns with previous studies that emphasized the interplay between belief systems and perceptions shaped by media, experience, and training.[6,16]

Unexpectedly, the study found a weak but statistically significant negative correlation between knowledge and perception ($r = -0.129$, $p = 0.034$). This may suggest that increased theoretical knowledge does not always translate into empathetic perceptions, particularly in the absence of personal interaction. Some literature suggests that higher levels of education and clinical exposure may desensitize individuals, increasing stigmatization in the absence of emotionally meaningful encounters.[10]

Conclusion

This study revealed that medical students generally possess high levels of knowledge and demonstrate positive attitudes and perceptions toward mental health. The findings highlighted the influence of clinical exposure and academic progression on mental health literacy. Moreover, direct interaction with individuals experiencing mental illness significantly reduced the likelihood of harboring negative attitudes. These outcomes emphasize the necessity of integrating mental health more deeply into medical training, not just through didactic instruction but through meaningful, human-centered experiences. Addressing stigma early in medical education can better equip future physicians to deliver compassionate and informed mental health care.

Limitations

This study had several limitations. First, the authors employed a convenience sampling method, which may introduce selection bias and limit the generalizability of the findings beyond the participating institution. Second, the response rate did not reach the calculated minimum sample size, potentially affecting the power of statistical tests. Lastly, the study relied on self-reported data, which may be subject to social desirability bias, especially when assessing attitudes and perceptions toward mental illness.

Recommendations

The authors recommend that medical schools integrate structured experiential components—such as patient interactions, mental health simulations, and reflective practice—into their curricula. These elements may foster empathy, reduce stigma, and translate cognitive knowledge into more favorable attitudes and perceptions. Lastly, targeted educational interventions should prioritize students with minimal personal exposure to mental illness, as they may be at greater risk for stigma.

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Multivariable risk prediction model for early onset neonatal sepsis among preterm infants

Navid P. Roodaki, MD

Abstract

Introduction Neonatal sepsis is a significant cause of morbidity and mortality, particularly among preterm infants, and remains a pressing global health concern. Early-onset neonatal sepsis is particularly challenging to diagnose due to its nonspecific clinical presentation, necessitating effective and timely diagnostic tools to reduce adverse outcomes. Traditional methods, such as microbial cultures, are slow and often unavailable in resource-limited settings. This study aimed to develop a robust multivariable risk prediction model tailored to improve early detection of Early Onset Sepsis (EOS) among preterm infants in the Philippines.

Methods We conducted a retrospective analysis at a tertiary hospital in the Philippines using data from 1,354 preterm infants admitted between January 2019 and June 2024. Logistic regression models were employed, and predictors were selected through reverse stepwise elimination. Two scoring methods were developed: one based on beta coefficients divided by standard errors and another standardized to a total score of 100. The models were validated using Receiver Operator Characteristic curve analysis.

Results Version 1 of the scoring model demonstrated an Area Under the Curve (AUC) of 0.991, with a sensitivity of 90.91% and a specificity of 98.10%. Version 2 achieved an AUC of 0.999, with a sensitivity of 96.4% and a specificity of 92.44%.

Conclusions The developed models provide a reliable, region-specific tool for early detection of neonatal sepsis. Further validation across diverse populations and the integration of emerging diagnostic technologies, such as biomarkers and artificial intelligence, are warranted to enhance their applicability and accuracy.

Key words: Neonatal sepsis, Risk prediction, Logistic models, Predictive model, Philippines

Neonatal sepsis remains a major global health concern, affecting approximately 3 million newborns annually, with mortality rates reaching up to 33% in low- and middle-income countries.[1] In the Philippines, bacterial sepsis is a leading cause of neonatal death, with an incidence of 4–9 per 1,000 live births and a case fatality rate of about 7% within the first 28 days of life.[2,3]

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Early-onset sepsis (EOS) is difficult to diagnose due to nonspecific clinical signs such as lethargy, poor feeding, and respiratory distress, which often overlap with other neonatal conditions.[4,5] Diagnostic confirmation via blood culture is delayed by 24–72 hours, and advanced laboratory markers remain inaccessible in many low-resource settings.[1,6,7] These limitations contribute to delayed interventions and increased risk of poor outcomes, particularly in lower-level hospitals lacking neonatal intensive care units (NICU).[7-9]

At Ilocos Training and Regional Medical Center (ITRMC), data from 2019–2023 showed a case fatality rate of 60% in culture-proven and 11% in clinically

diagnosed EOS, with an overall fatality rate nearing 20%. These findings underscore the urgent need for early, reliable, and accessible risk stratification tools. This study aimed to develop a predictive model for EOS using clinical and laboratory variables obtainable at the bedside or through basic diagnostic testing, tailored to the needs of primary and secondary healthcare settings in resource-limited environments. This study developed a multivariable prediction model using identified maternal and neonatal predictors for early onset neonatal sepsis among preterm infants at a tertiary hospital in Region 1.

Methods

Research Design

This is a cross-sectional study wherein the researcher reviewed charts from the past five years (January 1, 2019 to June 30, 2024) done at ITRMC.

Participants/Subjects

For this research, preterm neonates (less than 37 weeks age of gestation) by pediatric age admitted within the first 72 hours of life from January 1 2019 to June 30, 2024 both well and sick preterm neonates were included. Excluded were those with incomplete data and who were moribund (those receiving only palliative care) or born with conditions incompatible with life such as, but not limited to, anencephaly, hydrops fetalis, trisomy 18.

Sample Size

The "one-in-ten rule," which states that one predictive variable can be studied for every ten events, was used to determine the sample size.[10] To reflect the locale of the study, the prevalence of mortality among preterm neonates with sepsis cases was used, which is 26.8%. The minimum sample size was calculated considering assumptions of 10 events per parameter (EPP), the proportion of mortality among preterm infants (p=0.268) and 22 predictors (p). To develop the risk prediction model, 821 preterm infants were needed to achieve a 95% confidence interval. To account for chart availability from 2019 to 2024, as well as potential losses and missing data, all available charts were initially reviewed, and those meeting the inclusion criteria were included in the study.

Data Source and Measurements

Candidate variables for the EOS prediction model were selected through literature review and expert consensus involving a pediatric infectious disease fellow, a neonatologist, and the lead researcher. Existing scoring systems for neonatal mortality such as CRIB II – Clinical Risk Index for Babies II , SNAP II – Score for Neonatal Acute Physiology II, TRIPS II – Transport Risk Index of Physiologic Stability II and STABLE – Sugar and Safe care, Temperature, Airway, Blood pressure, Lab work, Emotional support were reviewed to guide variable selection, although these tools were not designed specifically for EOS risk assessment.[11] Variables were excluded based on unavailability at the institution, poor documentation (>60% missing), or inconsistent recording practices.

Following ethical clearance from the University of the East Ramon Magsaysay Memorial Medical Center-Research Institute for Health Sciences and Ilocos Training and Regional Medical Center (ITRMC), data collection commenced. Medical records from January 1, 2019 to December 31, 2023, were reviewed. Identifying details were excluded to maintain confidentiality. For 2022–2023, cases were identified through the electronic medical record system using diagnostic filters. For earlier years (2019–2021), manual NICU charts were retrieved and screened by pediatric age and diagnosis. All charts labeled as EOS were validated by two neonatologists; both clinically and culture-proven EOS cases were included if diagnosed within 72 hours of life.

Data were extracted using a standardized form capturing maternal, perinatal, and neonatal variables relevant to EOS. Manual and electronic sources were used, with data entered into a digital logbook. A biostatistician performed routine data quality checks, and discrepancies were resolved by reviewing original records. Missing data were documented after efforts to retrieve supplementary information.

Model Development

Data were independently encoded by two individuals using Microsoft Excel to ensure accuracy and completeness, and discrepancies were resolved

through dataset comparison. All analyses were conducted using SPSS version 27. To minimize bias and maintain objectivity, a biostatistician oversaw the entire analysis process. Candidate variables identified during data collection were included in multivariable logistic regression models. A reverse stepwise selection approach was applied to iteratively remove non-significant predictors, yielding a parsimonious model based on statistical relevance.

Predictor scores were assigned using three methods:

1. β/SE method – Scores were derived from the t-statistic, calculated by dividing each beta coefficient by its standard error, to reflect the strength and precision of each predictor.
2. Regression coefficient-based method – For models with categorical predictors, coefficients were rounded and summed as described in a study improving interpretability while maintaining diagnostic utility.[10]

Cut-off thresholds were determined using receiver operating characteristic (ROC) curve analysis to optimize sensitivity and specificity. The final model's performance was validated using an independent dataset of preterm neonates admitted between January 1 and June 30, 2024. External validation was conducted to minimize bias. Only predictors with p-values < 0.05 were retained in the final model. Model development followed the Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD) guidelines to ensure methodological transparency and reproducibility.[12]

Results

A total of 1,354 preterm neonate charts were reviewed. Variables with >30% missing data, including gestational age based on last menstrual period/ ultrasound and assisted delivery, were excluded from analysis. Most mothers were aged 30–39 years (45.35%), with geographic representation primarily from La Union (56.28%). Marital status was nearly evenly distributed between single (46.82%) and married (45.27%) women. The majority of deliveries were via normal spontaneous delivery (73.93%).

Among neonates, gestational age was evenly distributed across prematurity categories, with 35.60% born <28 weeks. Over half (54.65%) had birth weights between 1500–2400 grams, while 22.01% weighed <1000 grams. Males comprised a slight majority (55.83%) of the cohort (Table 1).

Table 2 compares 394 preterm neonates with early-onset sepsis (EOS) to 960 controls. Significant differences were identified in several maternal and neonatal factors. Multiparity (p=0.016) and history of preterm birth (p<0.001) were more common in the non-EOS group, suggesting a potential protective effect. Lack of prenatal care was strongly associated with EOS; 35.79% of mothers in the EOS group had no prenatal visits versus 8.85% in controls (p<0.001).

Preeclampsia (p=0.017), single marital status (p<0.001), and vaginal delivery (p<0.001) were significantly associated with increased EOS risk. Neonates born at <28 weeks' gestation (p=0.002) and with birth weight <1000g (p<0.001) were significantly overrepresented in the EOS group. Need for resuscitation at birth was also higher in this group (p=0.004). No significant associations were found with gravidity, umbilical cord complications, bag of water (BOW) status, neonatal sex, or respiratory interventions (Continuous Positive Airway Pressure, oxygen therapy). Respiratory Distress Syndrome also did not differ significantly (p=0.463), highlighting the complex interplay of EOS risk factors.

The logistic regression analysis identified several significant factors associated with neonatal sepsis, providing valuable insights into its predictors (Table 3). Vaginal delivery was strongly associated with neonatal sepsis, with an odds ratio (OR) of 2.33 (95% CI: 1.67–3.26, p<0.001), suggesting that neonates delivered via this route are over twice as likely to develop sepsis compared to those delivered by other methods. Extremely preterm birth, defined as gestational age less than or equal to 28 weeks, exhibited the highest risk, with an OR of 7.34 (95% CI: 4.46–12.09, p<0.001), underscoring the vulnerability of this population. Similarly, neonates with a birth weight below or equal to 1000 grams demonstrated a substantially elevated likelihood of sepsis (OR: 6.63, 95% CI: 3.94–11.16, p<0.001).

Inadequate prenatal care, indicated by fewer than one prenatal consultation, was also a significant risk factor, with an OR of 3.26 (95% CI: 1.99–5.35, p=0.037). A maternal history of urinary tract infection within 28 days prior to delivery was associated with a moderate increase in risk (OR: 1.45, 95% CI:

Table 1. Demographic profile of maternal and neonatal patients.

Clinical Predictors	**Sepsis** (n=1,354)	
	f	%
Maternal		
Maternal Age		
• <18 years old	199	14.70
• 19 to 29 years old	429	31.68
• 30 to 39 years old	614	45.35
• 40-49 years old	112	8.27
Address		
• La Union	762	56.28
• Pangasinan	279	20.61
• Ilocos Sur	203	14.99
• Ilocos Norte	58	4.28
• Outside Region 1	52	3.84
Marital Status		
• Single	634	46.82
• Married	613	45.27
• Partnered	107	7.90
Type of Deliver		
• NSD	1001	73.93
• CS	353	26.07
Neonatal		
Ballard Score/Pediatric Age		
• <28 weeks	482	35.60
• 28 to 31 weeks	435	32.13
• 32 – 36 weeks	437	32.27
Birth weight		
• <1000 grams	298	22.01
• 1000 – 1499 grams	316	23.34
• 1500-2400 grams	740	54.65
Neonatal Sex		
• Male	756	55.83
• Female	598	44.17

1.10–1.91, p=0.008). Additionally, maternal fever significantly increased the likelihood of neonatal sepsis, with an OR of 1.61 (95% CI: 1.22–2.13, p<0.001).

The EOS risk prediction model was developed using logistic regression coefficients to assign weighted scores to each significant predictor. The strongest predictors—gestational age ≤28 weeks (B = 1.994; OR = 7.34) and birth weight ≤1000 g (B = 1.892; OR = 6.63)—received the highest scores, reflecting their strong association with EOS. Other predictors, including vaginal delivery, ≤1 prenatal consultation, maternal fever, and recent maternal UTI, were assigned proportionally lower scores based on their coefficients.

Table 4 shows two scoring versions constructed for clinical application:

- Version 1: B/SE method, total score = 31
- Version 2: B×10 scaling, total score = 68

Both systems emphasized key predictors while maintaining usability. The model enables flexible risk stratification based on accessible maternal and neonatal data, supporting early identification and timely management of high-risk preterm neonates.

Table 2. Clinical and epidemiologic predictors of EOS
Table 2.1. Prepartum predictors of EOS

Clinical Predictors	**Sepsis** (n=394)		**Non-Sepsis** (n=960)		**p value**
	f	%	*f*	%	
Prepartum					
Gravidity					
· 1	140	35.53	276	28.75	
· 2	104	26.40	250	26.04	0.31
· 3	87	22.08	227	23.65	
· 4	63	15.99	207	21.56	
Parity					
· None	96	24.37	274	28.54	
· 1	173	43.91	380	39.58	0.016
· 2	111	28.17	293	30.52	
· 3	14	3.55	13	1.35	
History of Preterm birth					
· None	267	67.77	544	56.67	<0.001
· Yes	127	32.23	416	43.33	
History of abortion		0.00			
· None	262	66.50	535	55.73	<0.001
· Yes	132	33.50	425	44.27	
Number of Prenatal Consult		0.00			
· None	141	35.79	85	8.85	
· 1	72	18.27	79	8.23	
· 2	69	17.51	151	15.73	<0.001
· 3	45	11.42	203	21.15	
· ≥ 4	67	17.01	442	46.04	
Presence of Pregnancy related complication					
· None	314	79.70	736	76.67	
· Preeclampsia	73	18.53	212	22.08	
· Gestational Diabetes Mellitus	1		9	0.94	0.017
· Abruptio Placenta	4	1.02	1	0.10	
· Placenta Previa	2	0.51	1	0.10	
Marital Status		0.00			
· Single	162	41.12	472	49.17	
· Married	174	44.16	439	45.73	<0.001
· Partnered	58	14.72	49	5.10	
Maternal Fever					
· Present	148	37.56	294	30.63	0.15
· Not Present	246	62.44	148	15.42	
Maternal Infection in the past 28 days					
· None	80	20.30	461	48.02	
· UTI	126	31.98	278	28.96	0.408
· Pneumonia	188	47.72	221	23.02	
Use of Antibiotics 28 days prior to delivery					
· Yes	77	19.54	216	22.50	0.347
· No	317	80.46	744	77.50	
Gestational Age based on LMP		0.00		0.00	
History of delivering a newborn previously admitted at NICU					
· Yes	137	34.77	370	38.54	0.195
· No	257	65.23	590	61.46	
Number of Internal Examinations					
Bag of Water (BOW)					
· Intact	132	33.50	320	33.33	
· Leaking	146	37.06	357	37.19	0.209
· Ruptured	116	29.44	283	29.48	

Characteristic of BOW					
· Meconium stained	161	40.86	400	41.67	
· Foul smelling	115	29.19	303	31.56	0.455
· Clear	118	29.95	257	26.77	
APGAR 1st minute					
· Less than or equal to 6	242	61.42	575	59.90	0.498
· Greater than or equal to 7	152	38.58	385	40.10	
APGAR 5th minute					
· Greater than or equal to 7	394	100.00	960	100.00	0.216

Table 2.2. Intrapartum predictors of EOS.

Clinical Predictors	**Sepsis** (n=394)		**Non-Sepsis** (n=960)		**p value**
	f	%	*f*	%	
Intrapartum					
Type of Delivery					
· NSD	337	85.53	664	69.17	<0.001
· CS	57	14.47	296	30.83	
Ballard Score/Pediatric Age					
· <28 weeks	162	41.12	320	33.33	
· 28 to 31 weeks	131	33.25	304	31.67	0.002
· 32 – 36 weeks	101	25.63	336	35.00	
Umbilical Cord Winding					
· None	342	86.80	861	89.69	0.125
· Yes	52	13.20	99	10.31	

Table 2.3. Immediately postpartum predictors of EOS.

Clinical Predictors	**Sepsis** (n=394)		**Non-Sepsis** (n=960)		**p value**
	f	%	*f*	%	
Immediately Post-Partum					
Birth weight					
· <1000 grams	104	26.40	194	20.21	
· 1000 – 1499 grams	120	30.46	196	20.42	<0.001
· 1500-2400 grams	170	43.15	570	59.38	
Resuscitation				0.00	
· None	219	55.58	614	63.96	0.004
· Yes	175	44.42	346	36.04	
Respiratory support				0.00	
· IPPV/NIPPV	199	50.51	520	54.17	
· CPAP	95	24.11	220	22.92	0.164
· 02 cannula	100	25.38	220	22.92	
Neonatal Sex				0.00	
· Male	229	58.12	527	54.90	
· Female	165	41.88	433	45.10	0.153
Presence of Respiratory Distress Syndrome				0.00	
· Yes	207	52.54	534	55.63	
· No	187	47.46	426	44.38	0.463

As shown in Figure 1 and Table 5, both Version 1 and Version 2 of the EOS risk prediction model demonstrated excellent discriminatory power, with identical AUC values of 0.803 (95% CI: Version 1: 0.728–0.879; Version 2: 0.727–0.878; SE = 0.038; p < 0.001). The optimal cut-off scores—9 for Version 1 and 19 for Version 2—achieved balanced sensitivity and specificity. These findings confirm the models' robustness and clinical utility, with consistent performance across two scoring approaches. The inclusion of clinically relevant predictors and strong model calibration support their use in guiding early detection and management of EOS among preterm infants.

Table 3. Logistic regression analysis identifying factors associated with neonatal sepsis.

Factor	Coefficient (B)	SE	Odds Ratio	95% CI	p-value
Delivered Vaginally	0.846	0.170	2.33	1.67-3.26	<0.001
≤ 28 weeks AOG	1.994	0.254	7.34	4.46-12.09	<0.001
Birth weight ≤ 1000 grams	1.892	0.266	6.63	3.94-11.16	<0.001
≤ 1 prenatal consult	1.182	0.253	3.26	1.99-5.35	<0.037
History of UTI 28 days prior to delivery	0.373	0.141	1.45	1.10-1.91	0.008
Maternal Fever	0.478	0.142	1.61	1.22-2.13	<0.001

Table 4. Developed early onset sepsis calculator version 1 and 2.

Factor	**Version 1**		**Version 2**	
	Coefficient (B)/SE	**Assigned Score**	**Coefficient (B)10**	**Assigned Score**
Delivered Vaginally	4.98	5	8.46	8
Less than or equal 28 weeks AOG	7.85	8	19.94	20
Birth weight less than 1000 grams	7.10	7	18.92	19
Less than or equal 1 prenatal consult	4.67	5	11.82	12
History of UTI 28 days prior to delivery	2.64	3	3.73	4
Maternal Fever	3.36	3	4.78	5
Total		31		68

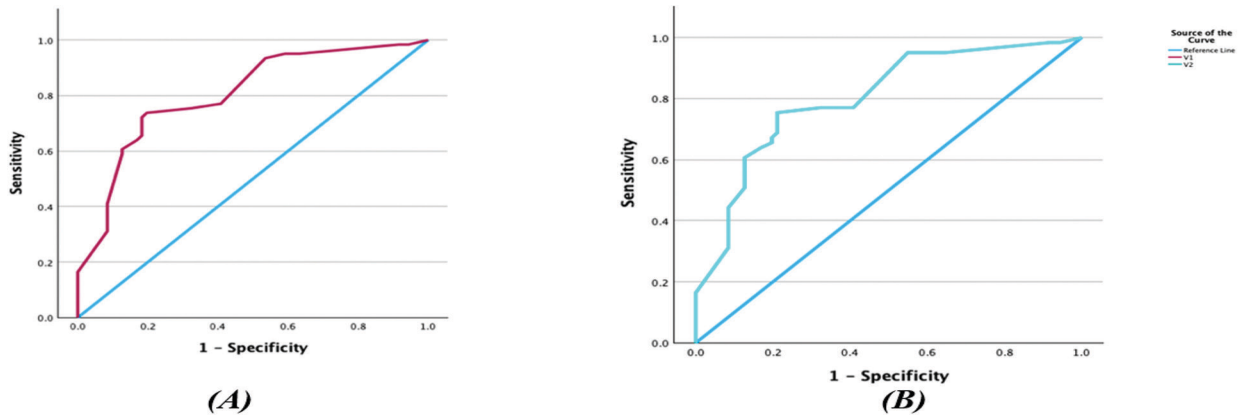

Figure 1. ROC curve analysis comparing the predictive performance of version 1 and 2 EOS calculator.

Table 5. Comparative performance metrics of version 1 and version 2 scoring models.

Model	AUC	SE	95 CI	Cut-off Value	p value
Version 1	0.803	0.038	0.728-0.879	9	<0.001
Version 2	0.803	0.038	0.727-878	19	<0.001

Discussion

This study developed and validated a multivariable risk prediction model for early-onset neonatal sepsis (EOS) among preterm infants, addressing the need for timely, accurate, and context-appropriate tools for early identification of high-risk neonates. The model integrates clinically relevant maternal and neonatal variables—many of which are accessible at the point of care—and was operationalized into two scoring systems suited for various clinical settings, particularly in resource-limited environments.

The predictors included in the model—gestational age ≤28 weeks, birth weight ≤1000 grams, vaginal delivery, fewer than one prenatal consultation, maternal fever, and recent maternal UTI—are consistent with previously established risk factors in the literature.[3,11-13] Gestational age and birth weight emerged as the strongest predictors, reflecting the well-documented vulnerability of extremely preterm and very low birth weight infants to infection. Vaginal delivery and inadequate prenatal care were also significantly associated with increased EOS risk, likely reflecting increased pathogen exposure and missed opportunities for maternal infection screening, respectively.

The scoring system was translated from regression coefficients and developed into two versions: one using the B/SE method (Version 1), and the other using a scaled B×10 approach (Version 2). Both demonstrated excellent predictive performance (AUC = 0.803) and were calibrated to balance clinical practicality with statistical accuracy. While Version 1 offers a simpler format suitable for low-resource settings, Version 2 provides greater risk granularity, making it more appropriate for tertiary care centers where more detailed decision-making is feasible. ROC analysis confirmed strong discriminative ability for both models, with comparable AUC values and high sensitivity and specificity. The models performed similarly to established tools such as the Kaiser Permanente (KP) calculator and more complex systems like NeoSeD and ANN-based modelshile maintaining simplicity and ease of use.[14-17] Importantly, this model does not require laboratory markers or advanced maternal screening data such as Group B Streptococcus (GBS) status, making it more applicable to settings with limited diagnostic infrastructure. The high sensitivity of Version 2 (100%) makes it ideal for settings where missing a case of EOS could have severe consequences. Conversely, Version 1's greater specificity (98.10%) may be preferable in environments where minimizing overtreatment and conserving antibiotic use is essential—especially in the context of rising antimicrobial resistance. These findings support the flexible implementation of the model depending on clinical priorities and resource availability.

A major strength of this study lies in its use of routinely collected maternal and neonatal variables to develop an accessible, interpretable risk model. Unlike more complex machine-learning-based tools, the scoring system is intuitive, easily integrated into clinical workflows, and requires no additional technology—features critical for low- and middle-income countries.

Although the model demonstrated strong internal validity, external validation across diverse populations and healthcare settings is necessary to establish generalizability. Prospective studies comparing this tool with existing calculators, such as the KP model, would provide further insights into clinical performance and potential for integration into neonatal sepsis management protocols.

The EOS risk prediction model presented here offers a pragmatic, evidence-based tool for stratifying sepsis risk in preterm neonates using readily available clinical information. By facilitating early detection and timely referral, particularly in resource-constrained settings, the model holds promise for improving neonatal outcomes and optimizing care delivery.

Conclusion

This study successfully developed a multivariable risk prediction model for early-onset neonatal sepsis (EOS) among preterm infants, addressing the study objectives comprehensively. Significant predictors identified

include gestational age less than 28 weeks, birth weight below 1000 grams, vaginal delivery, no prenatal consultation, maternal fever, and maternal history of urinary tract infections. The scoring systems developed from these predictors demonstrated excellent predictive performance, with an Area Under the Curve (AUC) of 0.803, indicating strong discriminatory power. By integrating maternal and neonatal clinical variables, the model provides a practical tool for EOS risk stratification in resource-limited settings. This study highlights the multifactorial nature of EOS and underscores the importance of maternal and neonatal health factors in early identification and management of at-risk neonates.

Limitation

The research was conducted in a single tertiary hospital, potentially limiting the generalizability of the findings to other healthcare settings, particularly those with differing patient populations, resources, and pathogen profiles. The retrospective nature of data collection may have introduced biases, such as incomplete or inaccurate medical records, which could affect the reliability of the identified predictors. Additionally, the study relied on maternal and neonatal clinical variables, which may not fully capture other significant factors, such as genetic predisposition or unmeasured environmental influences, that could contribute to EOS. The absence of external validation of the developed risk prediction model further limits its applicability across diverse populations.

Recommendations

To address these limitations, recommendations include external validation, may or may not integrate laboratory markers such as procalcitonin, CRP, Interleukin, prospective study designs, and embedding the model into clinical workflows to improve neonatal outcomes. The findings provide a practical and evidence-based tool for EOS risk stratification, particularly in resource-limited settings.

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Enhancing awareness of research participants' bill of rights: a study in a rural municipality in the Philippines

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Abstract

Introduction Documenting a research participant's awareness of the bill of rights is achieved with an informed consent. In recent years, the informed consent document has increasingly become confounding to research participants in its complexity. As such, the awareness of research participants' bill of rights has emerged as a lingering issue since studies that test awareness of research participants' bill of rights are limited. Hence, this study aimed to determine the participants' awareness of the bill of rights after an educational intervention.

Methods A quasi-experimental study was done where participants' awareness of clinical trial participants' bill of rights was determined after an educational intervention.

Results There was a significant difference ($p < 0.001$) in awareness of the elements of the bill of rights (including voluntary participation, being told about the benefits and risks of participating in the study and right to withdraw from the study) after the intervention except for the element which asked about the details describing clinical trial objectives and activities. A significant difference was observed before and after intervention among females, middle aged participants and older, among those who did not complete high school and among those unemployed. Their awareness of the elements of the bill of rights was lesser than their counterparts.

Conclusions Significant difference in the awareness of bill of rights was observed after the educational intervention. Additional intervention could be given to participants who are females, of older age group (middle age and older), did not complete high school, and the unemployed when they participate in clinical trials to ensure their awareness of the bill of rights of clinical trial participants. Varied learning materials must be given to participants to emphasize the clinical research objectives and activities as well.

Key words: Bill of rights, research participants, clinical trials, informed consent

Documenting a study participant's awareness of the bill of rights as applied to clinical research is commonly believed to be achieved with an informed consent. It is a widely accepted fact that the ethical principles of research which serve as the foundational basis of the research participants' bill of rights are clearly outlined in the informed consent form.

It is therefore not unexpected that a study involving adults with psychiatric conditions, cognitive impairment, and other factors that may affect informed consent reported a substantial increase in published literature on informed consent over the preceding three decades.[1] In a separate study involving researchers working with human participants, findings indicated that most participants understood key components

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of informed consent, including study confidentiality, the nature of the study, compensation, voluntariness, and the right to withdraw.[2] These elements are also articulated in established guidance documents, such as the *Bill of Rights of Research Participants* issued by the University of Iowa Human Subjects Office / Institutional Review Board.[3]

Indeed, a meta-analysis study found that participants demonstrated the highest level of understanding (over 50%) regarding voluntary participation, blinding (excluding knowledge about investigators' blinding), and freedom to withdraw at any time, and that only a small minority of patients demonstrated comprehension of placebo concepts, randomisation, safety issues, risks, and side effects.[4]

While the informed consent document is increasingly confounding to research participants in its complexity, the essential elements that uphold the research participants' bill of rights must always be upheld by researchers while study or research participants' awareness must be assured. However, studies that actually test awareness of research participants' bill of rights is limited.

In this study, the authors utilized the *Research Participants' Bill of Rights* developed by the Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard University. This document, designed to promote ethical standards and participant protection in clinical research, outlines essential rights that should be communicated to individuals involved in research.[5] The authors included only the elements relevant to the diagnostic trial ongoing at the time of the study. These elements were: (1) right to be treated in a polite and caring manner. (2) right to be told what the study is trying to find out and why it might - or might not- be a good option for you. (3) right to understand every form you are asked to sign or fill out. (4) right to be told about possible side effects or discomforts that might happen during the study, (5) right to be told about any benefits from being in the study, (6) right to ask any questions about the study, (7) right to take your time when you're deciding if you want to be in the study, (8) right to refuse to be in the study, or to change your mind about being in the study after it has started, and (9) right to receive a copy of the consent form you sign if you decide to join the study. Some elements of the original document were excluded from the analysis as they were not relevant to the objectives of the current study.

In this study, the authors focused on determining whether awareness of research study participants' bill of rights could be improved with educational intervention. To our knowledge, this is among the first of studies on awareness of research participants' bill of rights in clinical trials a rural context in the Philippines.

Methods

This was a quasi-experimental study which included all study participants of an ongoing clinical study who were of legal age with no cognitive impairment and consented to participate in the study.

Ethics approval was obtained from the University of the East Ramon Magsaysay Memorial Medical Center Research Institute for the Health Sciences Ethics Research Committee.

This flowchart illustrates the sequence of activities undertaken by study participants, from enrollment to post-intervention assessment and feedback (Figure 1).

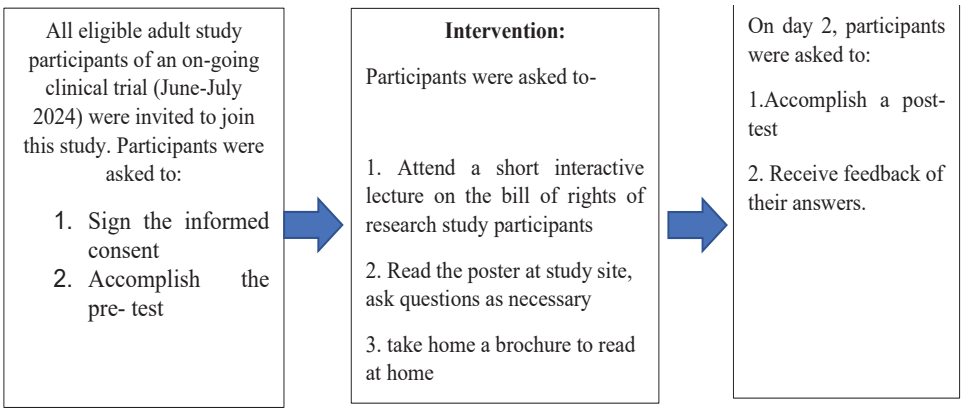

Figure 1. Schema of the study.

The informed consent form, educational materials (contents of poster/ tarpaulin and brochure) were translated from English to the native language of the region (Waray) by 2 native speakers who have been living in the study site for at least 10 years. The pre and post-test was adapted from Bill of rights for research participants and translated also to Waray by the 2 native speakers previously described.

The difference in number of participants who answered yes in the pre and post-test was determined by Chi square test and Fisher's test at $p<0.05$

Results

There were a total of 263 participants. Table 1 shows the age distribution of the participants with 125 (48%) females and 138 (52%) males. After the educational intervention, there was a significant difference in the awareness of the elements of the bill of rights, except for element which describes the clinical trial's objectives and activities. There was also a significant difference between the 2 groups, with significantly less females answering yes indicating lesser awareness of the elements of the bill of rights.

Table 2 presents the age distribution based on WHO classification: 43 participants (16%) were categorized as youth (18–24 years), 113 (43%) as young adults (25–44 years), 73 (28%) as middle-aged (45–60 years), 33 (12.5%) as elderly (61–75 years), and 1 participant (0.4%) as senile (76–90 years).

Following the intervention, a significant improvement in awareness of the elements of the Research Participants' Bill of Rights was observed, with the exception of Element 2, which pertains to understanding the objectives and activities of the clinical trial. A statistically significant difference in awareness was also noted across age groups, with older participants (middle-aged, elderly, and senile) demonstrating lower awareness, as reflected by fewer affirmative ("yes") responses.

Table 3 presents the educational attainment of the participants. Two participants (0.8%) did not complete primary school, 63 (24%) completed only elementary or primary education, and 198 (75%) were high school graduates.

Following the educational intervention, there was a significant increase in participants' awareness of the elements of the Research Participants' Bill of Rights, with the exception of the element describing the clinical trial's objectives and activities. A significant difference in awareness was also observed across educational attainment groups, with high school graduates demonstrating greater awareness compared to those with lower levels of education.

Table 1. Comparison of distribution of participants before and after intervention according to sex (Total n= 263).

BOR	No to Yes		Yes to Yes		No to No		No to unrecalled		Yes to unrecalled	
Element	Female N=125, n (%)	Male N=138, n (%)	Female N=125, n (%)	Male N=138, n (%)	Female N=125, n (%)	Male N=138, n (%)	Female N=125, n (%)	Male N=138, n (%)	Female N=125, n (%)	Male N=138, n (%)
1- right to be treated in a polite and caring manner.	56 (44.8%)	58 (42%)	26 (20.8%)	69 (50%)	N/A	N/A	43 (34.4%)	10 (7.2%)	0 (0%)	1 (0.7%)
2- right to be told what the study is trying to find out and why it might - or might not- be a good option for you.	71 (56.8%)	93 (67.4%)	9 (7.2%)	9 (6.5%)	N/A	N/A	45 (36%)	36 (26.1%)	N/A	N/A
3- right to understand every form you are asked to sign or fill out.	61 (48.8%)	50 (36.2%)	30 (24%)	74 (53.6%)	N/A	N/A	33 (26.4%)	13 (9.4%)	1 (0.8%)	1 (0.7%)
4- right to be told about possible side effects or discomfort that might happen during the study.	49 (39.2%)	118 (85.5%)	0 (0%)	2 (1.4%)	1 (0.8%)	0 (0%)	75 (60%)	18 (13%)	N/A	N/A
5- right to be told about any benefits from being in the study.	59 (47.2%)	124 (89.9%)	N/A	N/A	1 (0.8%)	0 (0%)	65 (52%)	14 (10.1%)	N/A	N/A
6-right to ask any questions about the study.	67 (53.6%)	126 (91.3%)	N/A	N/A	1 (0.8%)	0 (0%)	57 (45.6%)	12 (8.7%)	N/A	N/A
7- right to take your time when you're deciding if you want to be in the study.	91 (72.8%)	97 (70.3%)	10 (8%)	35 (25.4%)	1 (0.8%)	0 (0%)	23 (18.4%)	6 (4.3%)	N/A	N/A
8- right to refuse to be in the study, or to change your mind about being in the study after it has started.	65 (52%)	125 (90.6%)	N/A	N/A	1 (0.8%)	0 (0%)	59 (47.2%)	13 (9.4%)	N/A	N/A
9-right to receive a copy of the consent form you sign if you decide to join the study.	18 (14.4%)	53 (38.4%)	N/A	N/A	40 (32%)	14 (10.1%)	67 (53.6%)	71 (51.4%)	N/A	N/A

Table 2. Comparison of distribution of participants before and after intervention according to age classification (N= 263).

BOR	No to Yes					Yes to Yes				
Element	Youth N=43, n (%)	Young Adult N=113, n (%)	Middle Age N=73, n (%)	Elderly N=33, n (%)	Senile Age N=1, n (%)	Youth N=43, n (%)	Young Adult N=113, n (%)	Middle Age N=73, n (%)	Elderly N=33, n (%)	Senile Age N=1, n (%)
1- right to be treated in a polite and caring manner.	22 (51.2%)	57 (50.4%)	27 (37%)	29 (46%)	0 (0%)	17 (39.5%)	50 (44.2%)	22 (30.1%)	7 (11.1%)	0 (0%)
2- right to be told what the study is trying to find out and why it might - or might not- be a good option for you.	28 (65.1%)	70 (61.9%)	48 (65.8%)	18 (54.5%)	0 (0%)	2 (4.7%)	6 (5.3%)	6 (8.2%)	4 (12.1%)	0 (0%)
3- right to understand every form you are asked to sign or fill out.	22 (51%)	41 (36.3%)	34 (46.6%)	13 (39.4%)	1 (100%)	13 (30%)	67 (59.3%)	18 (24.7%)	6 (18.2%)	0 (0%)
4- right to be told about possible side effects or discomfort that might happen during the study.	49 (39.2%)	101 (89.4%)	31 (42.5%)	5 (15.2%)	0 (0%)	0 (0%)	1 (0.9%)	1 (1.4%)	0 (0%)	0 (0%)
5- right to be told about any benefits from being in the study.	31 (72.1%)	104 (92%)	38 (52.1%)	10 (30.3%)	0 (0%)	N/A	N/A	N/A	N/A	N/A
6-right to ask any questions about the study.	30 (69.8%)	103 (91.2%)	43 (58.9%)	17 (51.5%)	0 (0%)	N/A	N/A	N/A	N/A	N/A
7- right to take your time when you're deciding if you want to be in the study.	31 (72.1%)	80 (70.8%)	47 (64.4%)	29 (87.9%)	1 (100%)	6 (14%)	28 (24.8%)	9 (12.3%)	2 (6.1%)	0 (0%)
8- right to refuse to be in the study, or to change your mind about being in the study after it has started.	31 (72.1%)	106 (93.8%)	41 (56.2%)	12 (36.4%)	0 (0%)	N/A	N/A	N/A	N/A	N/A
9-right to receive a copy of the consent form you sign if you decide to join the study.	27 (62.8%)	64 (56.6%)	39 (53.4%)	8 (24.2%)	1 (100%)	10 (23.3%)	43 (38.1%)	14 (19.2%)	4 (12.1%)	0 (0%)

BOR	No to No					No to unrecalled					Yes to unrecalled				
Element	Youth N=43, n (%)	Young Adult N=113, n (%)	Middle Age N=73, n (%)	Elderly N=33, n (%)	Senile Age N=1, n (%)	Youth N=43, n (%)	Young Adult N=113, n (%)	Middle Age N=73, n (%)	Elderly N=33, n (%)	Senile Age N=1, n (%)	Youth N=43, n (%)	Young Adult N=113, n (%)	Middle Age N=73, n (%)	Elderly N=33, n (%)	Senile Age N=1, n (%)
1- right to be treated in a polite and caring manner.	N/A	N/A	N/A	N/A	N/A	4 (9.3%)	6 (5.3%)	23 (31.5%)	19 (57.6%)	1 (100%)	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)
2- right to be told what the study is trying to find out and why it might - or might not- be a good option for you.	N/A	N/A	N/A	N/A	N/A	13 (30.2%)	37 32.7%)	19 (26%)	11 (33.3%)	1 (100%)	N/A	N/A	N/A	N/A	N/A
3- right to understand every form you are asked to sign or fill out.	N/A	N/A	N/A	N/A	N/A	8 (22%)	5 (4.4%)	21 (28.8%)	12 (36.4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (6.1%)	0 (0%)
4- right to be told about possible side effects or discomfort that might happen during the study.	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	13 (30.2%)	11 (9.7%)	40 (54.8%)	28 (84.8%)	1 (100%)	N/A	N/A	N/A	N/A	N/A
5- right to be told about any benefits from being in the study.	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	12 (27.9%)	9 (8%)	34 (46.6%)	23 (69.7%)	1 (100%)	N/A	N/A	N/A	N/A	N/A
6-right to ask any questions about the study.	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	13 (30.2%)	10 8.8%)	29 (39.7%)	16 (48.5%)	1 (100%)	N/A	N/A	N/A	N/A	N/A
7- right to take your time when you're deciding if you want to be in the study.	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	6 (14%)	5 (4.4%)	16 (21.9%)	2 (6.1%)	0 (0%)	N/A	N/A	N/A	N/A	N/A
8- right to refuse to be in the study, or to change your mind about being in the study after it has started.	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	12 (27.9%)	7 (6.2%)	31 (42.5%)	21 (63.6%)	1 (100%)	N/A	N/A	N/A	N/A	N/A
9-right to receive a copy of the consent form you sign if you decide to join the study.	6 (14%)	6 (5.3%)	20 (27.4%)	21 (63.6%)	0 (0%)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table 3. Comparison of distribution of participants before and after intervention according to their educational attainment (N= 263).

BOR	No to Yes			Yes to Yes			No to No		
Element	No schooling N= 2, n (%)	Elementary only N= 63, n (%)	High School N= 198, n (%)	No schooling N= 2, n (%)	Elementary only N= 63, n (%)	High School N= 198, n (%)	No schooling N= 2, n (%)	Elementary only N= 63, n (%)	High School N= 198, n (%)
1- right to be treated in a polite and caring manner.	0 (0%)	29 (46%)	85 (42.9%)	0 (0%)	7 (11.1%)	88 (44.4%)	N/A	N/A	N/A
2- right to be told what the study is trying to find out and why it might - or might not- be a good option for you.	1 (50%)	39 61.9%)	124 (62.6%)	1 (50%)	6 (9.5%)	11 (5.6%)	N/A	N/A	N/A
3- right to understand every form you are asked to sign or fill out.	1 (50%)	34 (54%)	76 (38.4%)	0 (0%)	4 (6.3%)	100 (50.5%)	N/A	N/A	N/A
4- right to be told about possible side effects or discomfort that might happen during the study.	0 (0%)	6 (9.5%)	161 (81.3%)	0 (0%)	0 (0%)	2 (1.4%)	0 (0%)	0 (0%)	1 (0.8%)
5- right to be told about any benefits from being in the study.	0 (0%)	13 20.6%)	170 (85.8%)	N/A	N/A	N/A	0 (0%)	0 (0%)	1 (0.8%)
6-right to ask any questions about the study.	1 (50%)	23 (36.5%)	169 (85.3%)	N/A	N/A	N/A	0 (0%)	0 (0%)	1 (0.8%)
7- right to take your time when you're deciding if you want to be in the study.	2 (100%)	42 (66.7%)	144 (72.7%)	0 (0%)	1 (1.6%)	44 (22.2%)	0 (0%)	0 (0%)	0 (0%)
8- right to refuse to be in the study, or to change your mind about being in the study after it has started.	0 (0%)	17 (26.9%)	173 87.3%)	N/A	N/A	N/A	0 (0%)	0 (0%)	1 (0.8%)
9-right to receive a copy of the consent form you sign if you decide to join the study.	0 (0%)	31 (49.2%)	107 (54%)	0 (0%)	4 (6.3%)	67 (33.8%)	2 (100%)	28 (44.4%)	24 (12.1%)

BOR	No to unrecalled			Yes to unrecalled		
Element	No schooling N= 2, n (%)	Elementary only N= 63, n (%)	High School N= 198, n (%)	No schooling N= 2, n (%)	Elementary only N= 63, n (%)	High School N= 198, n (%)
1- right to be treated in a polite and caring manner.	2 (100%)	27 (42.9%)	24 (12.1%)	0 (0%)	0 (0%)	1 (0.5%)
2- right to be told what the study is trying to find out and why it migaht - or might not- be a good option for you.	0 (0%)	18 (28.6%)	63 (31.8%)	N/A	N/A	N/A
3- right to understand every form you are asked to sign or fill out.	1 (50%)	24 (38.1%)	21 (10.6%)	0 (0%)	1 (1.6%)	1 (0.5%)
4- right to be told about possible side effects or discomfort that might happen during the study.	2 (100%)	57 (90.5%)	34 (0.8%)	N/A	N/A	N/A
5- right to be told about any benefits from being in the study.	2 (100%)	50 (79.3%)	27 (13.6%)	N/A	N/A	N/A
6-right to ask any questions about the study.	1 (50%)	40 (63.4%)	28 (14%)	N/A	N/A	N/A
7- right to take your time when you're deciding if you want to be in the study.	0 (0%)	20 (31.7%)	9 (4.5%)	N/A	N/A	N/A
8- right to refuse to be in the study, or to change your mind about being in the study after it has started.	2 (100%)	46 (73%)	24 (12.1%)	N/A	N/A	N/A
9-right to receive a copy of the consent form you sign if you decide to join the study.	N/A	N/A	N/A	N/A	N/A	N/A

Table 4 presents the employment status distribution of the participants. Of the total, 91 (35%) were unemployed and 172 (65%) were employed. As with the other variables, a significant improvement in awareness of the elements of the Research Participants' Bill of Rights was observed after the intervention. A significant difference in awareness was also noted between the two groups, with unemployed participants showing lower levels of awareness, as indicated by fewer affirmative responses. This difference was observed across all elements except for Element 2, which pertains to the clinical trial's objectives and activities.

Discussion

The four basic ethical principles in research include respect for autonomy, non-maleficence and beneficence and justice. Documentation of these basic tenets in the ethical conduct of research is achieved through an informed consent process. A previous study explored that consenting to participate in a clinical research study after being properly and correctly informed upholds the basic ethical principle of "autonomy" in human research. The authors outlined the key elements of a robust informed consent process, and that one of which is communication by which the physician sensitizes the participants about the nature, procedures, risks benefits, and treatment schedules of the study in a language that is non-technical and understandable by them.[6]

There are at least two emerging issues that add complexity to the informed consent process in clinical trials. The first is the requirement to disclose all details of the clinical trial to prospective participants. A survey done among clinical trial participants in several Southeast Asian countries pointed out that the use of

Table 4. Comparison of distribution of participants before and after intervention according to employment status (N= 263).

BOR	No to Yes		Yes to Yes		No to No		No to unrecalled		Yes to unrecalled	
Element	Not Employed N=91, n (%)	Employed N= 172, n (%)	Not Employed N=91, n (%)	Employed N= 172, n (%)	Not Employed N=91, n (%)	Employed N= 172, n (%)	Not Employed N=91, n (%)	Employed N= 172, n (%)	Not Employed N=91, n (%)	Employed N= 172, n (%)
1- right to be treated in a polite and caring manner.	38 41.8%)	76 (44.2%)	6 (6.6%)	89 (51.7%)	N/A	N/A	47 (51.6%)	6 (3.5%)	0 (0%)	1 (0.6%)
2- right to be told what the study is trying to find out and why it might - or might not- be a good option for you.	56 (61.5%)	108 (62.8%)	10 (11%)	8 (4.7%)	N/A	N/A	25 (27.5%)	56 (32.6%)	N/A	N/A
3- right to understand every form you are asked to sign or fill out.	50 (54.9%)	61 (35.5%)	1 (1.1%)	103 (59.9%)	N/A	N/A	38 (41.8%)	8 (4.7%)	2 (2.2%)	0 (0%)
4- right to be told about possible side effects or discomfort that might happen during the study.	10 (11%)	157 (91.3%)	0 (0%)	2 (1.2%)	1 (1.1%)	0 (0%)	80 (87.9%)	13 (7.6%)	N/A	N/A
5- right to be told about any benefits from being in the study.	19 (20.9%)	164 (95.3%)	N/A	N/A	1 (1.1%)	0 (0%)	71 (78%)	8 (4.7%)	N/A	N/A
6-right to ask any questions about the study.	27 (29.7%)	166 (96.5%)	N/A	N/A	1 (1.1%)	0 (0%)	63 (69.2%)	6 (3.5%)	N/A	N/A
7- right to take your time when you're deciding if you want to be in the study.	65 (71.4%)	97 (70.3%)	0 (0%)	45 (26.2%)	1 (1.1%)	0 (0%)	25 (27.5%)	6 (3.5%)	N/A	N/A
8- right to refuse to be in the study, or to change your mind about being in the study after it has started.	24 (26.4%)	190 (72.2%)	N/A	N/A	1 (0.8%)	0 (0%)	66 (72.5%)	6 (3.5%)	N/A	N/A
9-right to receive a copy of the consent form you sign if you decide to join the study.	2 (2.2%)	69 (40.1%)	N/A	N/A	47 (51.6%)	7 (4.1%)	67 (46.2%)	96 (55.8%)	N/A	N/A

lengthy, detailed, and complex informed consent forms (ICFs) may not truly promote the rights and interests of research participants. The extent of information in ICFs has been the subject of debates for decades; however, no clear guidance is given.[7]

Furthermore, a study observed that advancements in medical research have led to increasingly complex protocols, resulting in the need to convey elaborate and often intricate information during the informed consent process.[8] The complexity of consent documents is further compounded by the perception of both sponsors and investigators, who often regard the informed consent form primarily as a legal and symbolic document representing the participant's agreement to join the study. As a result, the consent process may fulfill legal requirements but frequently falls short in terms of clarity and comprehensibility for participants.

A survey involving both researchers and research participants highlighted that the informed consent process for clinical research enrollment can be complex for both parties.[9] Challenges include balancing respect for participants' autonomy and information needs with the obligation to provide sufficient details to support an informed decision. Research staff expressed concern about participants' level of understanding—concerns that appear to be supported by studies assessing patient comprehension of research information. The survey emphasized the importance of allocating adequate time for informed consent discussions.

A study conducted at a major research center emphasized that although Institutional Review Boards (IRBs) are responsible for reviewing and approving the content of informed consent materials, the actual process of obtaining informed consent from potential participants could vary significantly both within and across studies. As a result, approaches to delivering informed consent may range from allowing participants to review the information independently (e.g., via electronic consent) to actively engaging them in face-to-face discussions—sometimes supported by visual or multimedia aids—to enhance comprehension and support informed decision-making.[10]

Additionally, another study underscored that despite the recognized importance of the informed consent process in clinical research, its effectiveness and validity are frequently questioned. The author noted that in many settings, there is limited emphasis on ensuring participants' true comprehension and voluntary participation, and that the informed consent process often becomes a symbolic act rather than a meaningful ethical safeguard.[11]

A study involving a clinical trial participants suggested that individuals should be actively engaged in discussions about their views on the informed consent document. This approach reinforces the concept of informed consent as an ongoing process, rather than a one-time act focused solely on written information.[12] In the present study, the authors implemented an educational intervention consisting of tarpaulins, a one-page brochure, and a short interactive lecture to enhance awareness of the research participants' bill of rights.

The second issue relates to the need for data collection among participants in rural study sites, such as those included in this study, with the aim of reducing disparities in healthcare. A community-based research study highlighted that one major barrier to addressing health disparities is the inadequate recruitment of underserved populations, which limits the development of culturally-tailored interventions. Additionally, the creation of clear and inclusive research guidelines can help improve recruitment of underserved groups, ultimately contributing to the reduction of health disparities and the achievement of health equity for all.[13]

In fact, a study noted that research on the informed consent process has shown that participants may not fully understand the study they are enrolled in, nor their rights as participants, even after signing a consent form. Misunderstandings may be more common in settings where participants are economically disadvantaged, have limited literacy, are unfamiliar with medical research, or hold different cultural views on health and disease.[8] This was reflected in the results of this study, where unemployed individuals—as well as those with limited employment opportunities, such as women, older adults, and those who did not complete high school—demonstrated lower awareness of the bill of rights, even after the educational intervention.

The study further noted that challenges related to informed consent may be more pronounced in certain settings where participants face difficulties with study compliance, limited ability to assess clinical trial risks, fear of procedures, and concerns about reduced access to medical care.[8] These issues can adversely affect the conduct of clinical research, especially in contexts

burdened by limited resources, weak infrastructure, and low literacy levels. Addressing these challenges may require strategic interventions from researchers, sponsors, and regulatory authorities.

A similar line of reasoning was presented in a study, which emphasized the growing international recognition that populations included in clinical trials should adequately reflect those treated in actual clinical practice.[14] Since the study population resides in a rural community and was recruited to participate in clinical research, it is imperative that they were made aware of the research participants' bill of rights.

Another study agreed that obtaining informed consent from vulnerable populations remains a complex issue. It emphasized that a friendly and approachable process is essential to adequately engage these groups, suggesting that accessible locations such as health centers or community buildings can facilitate participation.[15] In the present study, the village multi-purpose hall served as the venue for research activities. Notably, the full cooperation, support, and presence of local authorities during data collection were also ensured.

A systematic review affirmed that community engagement is essential, particularly when the role of family and community leaders in decision-making is acknowledged and incorporated. Community engagement addresses the importance of perceived personal and/or community benefit in the decision to participate in research and can enhance participants' understanding of the study.[16]

Likewise, a study involving ethnic or minority communities emphasized that certain populations remain underserved by research, leading to lower inclusion rates, under-researched health issues, and insufficient consideration of how different communities respond to health interventions. Minoritized ethnic groups often face health inequalities and significant barriers to accessing health services.[17] In the present study, gathering responses from adults in a rural municipality helped enhance their awareness of the elements of the research participants' bill of rights, thereby empowering them as potential participants in future clinical trials while also safeguarding their personal autonomy.

A study noted that the process of obtaining informed consent can be particularly challenging when working with vulnerable populations or during public health emergencies such as pandemics. Nevertheless, it emphasized that a comprehensive informed consent process remains essential for ensuring credible and ethical research.[18]

A systematic review on issues related to comprehension during the informed consent (IC) process primarily focused on the challenges that potential participants may encounter in understanding IC documents, as well as the strategies employed to improve comprehension. The review aimed to identify and describe the key factors influencing participants' understanding and to evaluate the effectiveness of various approaches designed to enhance the informed consent process.[19]

A study involving participants from two clinical trials found that many studies in low-resource settings face challenges in obtaining valid informed consent due to structural factors such as poverty and unequal access to healthcare.[20] These societal issues continue to pose difficulties for investigators. The study further noted that while all interviewed participants were aware they were involved in research, their understanding of the research's nature and the details of the clinical trials varied widely.[20] In the present study, there was no significant improvement in participants' awareness of the clinical trial activities even after the intervention. This highlights an ongoing challenge for researchers—to strike a balance between providing comprehensive yet easily understandable explanations of the clinical research or trial objectives.

In fact, a study involving participants in a biobanking platform highlighted the importance of engaging communities to develop contextually relevant terminologies that participants can easily understand. The researchers emphasized the need to consider the socio-economic context of communities, cautioning that compensation—while important—may become coercive if not appropriately managed.[21]

Similarly, a community-based study found that the unique ethnic, socioeconomic, and cultural diversities in such settings pose important implications for the informed consent process. These include challenges related to individual decisional autonomy, beneficence, confidentiality, and the act of signing the consent document.[22]

A malaria vaccine trial conducted in Mali, West Africa revealed substantial disparities in comprehension between urban and rural participants: 85% of urban participants understood that participation was voluntary, compared to only 21% of rural

participants.[23] These findings underscore how limited access to education and health information in rural, resource-limited settings can hinder understanding of key elements of informed consent. In contrast, a study in Ontario, Canada, found that 18% of participants admitted to not fully reading the study information document, and 10% reported being afraid to ask questions.[24] These barriers were attributed not to lack of access, but to factors such as overly lengthy and complex consent documents, time pressures during the consent process, and emotional factors such as anxiety. Taken together, these studies highlight that while structural barriers dominate in low-resource settings, psychological and procedural factors may limit informed consent comprehension even in high-resource contexts.

Another vaccine trial conducted in South Africa examined participants' recall and understanding of the components of informed consent. The study found moderate levels of recall and understanding overall, with most participants aware of the risks involved and their voluntary participation. Notably, those with at least a Grade 7 education were significantly more likely to demonstrate higher recall scores compared to those with less education.[25]

As previously noted, a study involving participants in a malaria vaccine trial in Mali, West Africa, revealed that many respondents had difficulty understanding key aspects of the research, such as the right to withdraw, the possibility of side effects, and the distinction between participating in a study versus receiving standard therapy. Comprehension was generally better in the village located nearer to an urban center than in the more remote rural village.[23] Similarly, the village in this study is rural, though not geographically isolated, and participants had relatively better access to information. Following the educational intervention, participants demonstrated improved awareness of key elements of informed consent—paralleling the findings in the less remote village from the Mali study.

The present study identified certain characteristics among potential research participants that may require additional interventions to ensure meaningful informed consent. These include being female, middle-aged or older, having lower educational attainment, and being unemployed. Notably, individuals with these characteristics are often the most accessible participants for community-based clinical trials. This underscores the importance of clearly emphasizing the elements outlined in the participant's bill of rights, in addition to the standard informed consent document. These were also found in a study which found that socio-demographic and economic factors—such as older age, limited education, female gender, and low socioeconomic status—were associated with a diminished quality of the informed consent process.[26]

On one hand, a study involving parents of children enrolled in a prospective cohort study emphasized that, to generate generalizable results and ensure a fair distribution of research risks and benefits, researchers should not exclude underprivileged individuals from participation without valid reason.[27] Therefore, it is essential to thoroughly analyze the characteristics of potential research participants when recruiting for clinical trials, in order to identify factors that may negatively impact the quality of informed consent.[26]

The authors of this paper chose to focus on awareness, as opposed to understanding, due to the extensive body of literature consistently highlighting challenges associated with the understanding component of decision-making in research participation. A 2001 study noted the absence of a standardized approach for measuring understanding, despite various efforts to develop appropriate assessment tools.[1] True understanding of a treatment or research protocol requires that participants receive, encode, retain, and cognitively process the information—tasks that demand a complex interplay of attention, memory, and cognitive function.

Additionally, it has been noted that evaluating a participant's perspective on clinical trials is inherently difficult, as there is no standardized method to accurately measure participant understanding of the information provided.[11]

A study further contends that although participants often do not fully understand the information disclosed during the consent process, there is no established standard for significantly improving this issue. Moreover, attempts to enhance understanding through alternative communication methods and improved consent forms have yielded mixed results. One of the most effective strategies identified is having a study team member or a neutral educator spend more time engaging with participants one-on-one.[27]

In summary, while the informed consent document incorporates all the required principles of research, it can often become overly detailed and lengthy in

its description of the research protocol. In contrast, the research participant's bill of rights presents core elements that are universally applicable, regardless of the type or topic of the clinical research or trial.

The introduction of the research participants' bill of rights at a rural study site made the focus on assessing awareness a logical choice, particularly in light of the challenges surrounding the measurement of understanding as highlighted in the literature.

Conclusion and Recommendation

Following the educational intervention, there was a significant increase in participants' awareness of the elements outlined in the research participants' bill of rights.

Based on these findings, we recommend that a separate document outlining the clinical trial participants' bill of rights be presented, thoroughly explained, and signed by all potential participants prior to their signing of the trial's informed consent form. Additional time for discussion should be allotted for individuals who are older, have not completed high school, are women, or are unemployed. While these groups are often the most accessible in terms of availability and willingness to join clinical trials, the present study found that they continued to demonstrate limited awareness of the bill of rights' elements even after the educational intervention.

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