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GLP-1 Receptor Agonists and Substance Use Disorders: A Public Health Opportunity with Emerging Safety Concerns

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Keywords: GLP-1 receptor agonists; Substance use disorders; Pharmacovigilance; Psychiatric safety; Public health; Behavioral pharmacotherapy

According to the Global Burden of Disease Study (GBD), mental and substance use disorders accounted for approximately 183.9 million disability-adjusted life years (DALYs) worldwide in 2010, representing 7.4% of all global DALYs. Within this group, illicit drug use disorders alone were responsible for an estimated 20 million DALYs [1]. SUDs are also strongly associated with years lived with disability (YLDs): together with mental disorders, they account for approximately 22.9% of all global YLDs [2]. This highlights the chronic and debilitating nature of these conditions, and the considerable strain they place on healthcare systems and social structures. Glucagon-like peptide-1 receptor agonists (GLP-1RAs) have significantly improved metabolic outcomes in patients with obesity and type 2 diabetes [3]. Beyond their established role, emerging evidence suggests potential efficacy in addressing substance use disorders (SUDs) and behavioral addictions [4,5]. This intersects critically with public health priorities, given the high global burden of both obesity and SUDs, often co-occurring in vulnerable populations.

Preclinical studies indicate that GLP-1RAs modulate dopaminergic reward pathways, attenuating craving, compulsive use, and withdrawal-related behaviors [6,7]. Observational data further suggest reduced rates of alcohol intoxication and opioid overdose in patients treated with GLP-1RAs [8,9]. These findings offer promising avenues for integrated care strategies targeting metabolic and addictive comorbidities. However, recent population-based studies raise concerns regarding psychiatric safety. GLP-1RA use has been associated with increased risks of depression, anxiety, and suicidal behavior, particularly in patients with rapid weight loss or pre-existing psychological vulnerabilities [10]. While causality remains to be confirmed, such findings necessitate caution in off-label or experimental use. From a public health perspective, the potential expansion of GLP-1RAs to populations with SUDs underscores the need for: (i) targeted pharmacovigilance, (ii) risk-benefit assessments in diverse demographic groups, and (iii) [11] integration of mental health screening into treatment protocols. Furthermore, anecdotal reports and pharmacosurveillance data have noted rising instances of misuse and non-medical use, particularly of semaglutide [12].

In conclusion, while GLP-1RAs represent a novel and potentially transformative tool in managing SUDs and associated comorbidities, robust epidemiological evidence and continuous safety monitoring must guide their implementation. Public health systems should prioritize real-world data collection and long-term outcome evaluation before widespread adoption in this context.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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Prevalence of Anemia Among Pregnant Women Attending Antenatal Care in Dhamar Governorate, Yemen: A Cross-Sectional Study

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SUMMARY

Background: Anemia, a chronic condition affecting millions globally, poses greater risks to pregnant mothers, particularly in regions like Yemen. However, data on pregnancy-related anemia in Yemen is scarce. This study aimed to gauge anemia prevalence in Yemen's Dhamar governorate, identifying associated pregnancy-related risk factors.
Methods: Through a questionnaire-based cross-sectional study involving a total of 157 pregnant participants, data on sociodemographics (age, education, income) and health history (gestational age, parity, hemorrhage) were collected. Utilizing SPSS v25, frequencies, percentages, and binary logistic regression (OR, AOR) with 95% confidence intervals ($p<0.05$) were calculated.
Discussions: Results highlighted 17% of pregnant women in medical centers had anemia (43% of which are mild, 23% moderate, 33% severe). Significantly, rural residence and lower socioeconomic status were linked ($p=0.021$, 0.015) with AORs of 0.305 (CI: 0.111-0.835) and 3.86 (CI: 1.294-11.542).
Conclusion: In conclusion, anemia affects pregnant women, particularly those in rural areas with lower incomes. Addressing this requires targeted medical interventions to mitigate anemia's prevalence and impact during pregnancy.

Keywords: anemia, pregnant mothers, Hb, cross-sectional study

INTRODUCTION

Anemia can be defined as the reduction of hemoglobin (Hb) or red blood cells count (RBC) below normal range. Patients with anemia usually have undistinguishable symptoms like pallor, lethargy and tiredness, but others exhibit acute signs such as shortness of breath. The potential consequence is the gradual hypoxia status of many tissues in the body. The pattern of clinical signs depends on the underlying cause as well as the severity of anemia together with available comorbidities. Notably, clinical manifestations begin to develop whenever Hb drops below 7 g/dl [1]. However, WHO has detailed classification of the severity of anemia during pregnancy with 10.9-10 g/dl range is mild, 9.9-7 g/dl moderate and < 7 g/dl severe based on Hb concentration [2,3]. Globally, approximately 36.8% of pregnant women are anemic, and based on the severity of anemia, mild anemia was the highest (70.8%). Around half of the anemia in pregnancy was found in the third trimester (48.8%) [4]. In the developing world, many countries suffer from poor nutrition, recurrent infections together with multiple pregnancy cases which render women prone to anemia [5,6]. These factors are attributed to the low socio-economic status of those countries. Nevertheless, the most common type of anemia is iron deficiency anemia (75% of all cases) [7] followed by

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macronutrient (iron, folate and cyanocobalamin) [8] or micronutrient (vitamins A, B6, C, and E) deficiency [9]. The consequences of a mother having anemia during pregnancy include premature labor, abortions and low-weight birth baby, among others [10]. The risk goes also toward pregnant mother where preeclampsia was demonstrated in few cases and even morbidity in rare cases [11].

Numerous studies have consistently identified socioeconomic factors as significant risk factors for pregnancy anemia. Pregnant women from lower socioeconomic backgrounds, including those with lower education levels, lower income, and residing in rural areas, are at a higher risk of developing anemia during pregnancy due to limited access to nutritious food, healthcare facilities, and antenatal care [12,13].

Maternal nutritional status is another significant risk factor for pregnancy anemia. Pregnant women with inadequate intake of iron, folic acid, and essential nutrients are at an increased risk of developing anemia during pregnancy [14]. Additionally, women with pre-existing medical conditions such as sickle cell anemia or thalassemia are also at a higher risk of developing anemia during pregnancy. Furthermore, studies have shown that parity, gestational age, and maternal age are additional risk factors for pregnancy anemia. Women with higher parity, advanced maternal age, and later gestational age have been found to be at a higher risk of developing anemia during pregnancy [15].

The previous literature concerning prevalence of pregnancy anemia in Yemen is limited. Therefore, the goal of this study was to screen the prevalence of anemia in pregnant women attending antenatal care in Dhamar governorate, Yemen. The investigation of the attributing factors was also discussed.

METHODS

Study area and population study

This was a cross-sectional study designed to evaluate prevalence and risk factors associated with anemia among pregnant women in clinics and antenatal centers and medical hospitals of Dhamar city, Yemen. The study was carried out during the period between September and December 2021 in Dhamar city, one of the 12 directorates of Dhamar Governorate, Yemen. Dhamar city is located 100 km south of the capital, Sana'a. Altitude is about 2,400 meters above sea level. Population was 173,000 according to 2004 national statistics.

Sample size and inclusion/exclusion criteria

All pregnant mothers in any age, socioeconomic level or pregnancy trimester admitting to antenatal care or medical hospitals and accepted to participate were recruited to the current study. A total of 157 (response rate of 98%) pregnant women agreed to participate in the present study. Individuals with missing information or those who refused to measure Hb were excluded from this study to avoid inconsistency. Main methodology figure of the present study is provided in Fig 1.

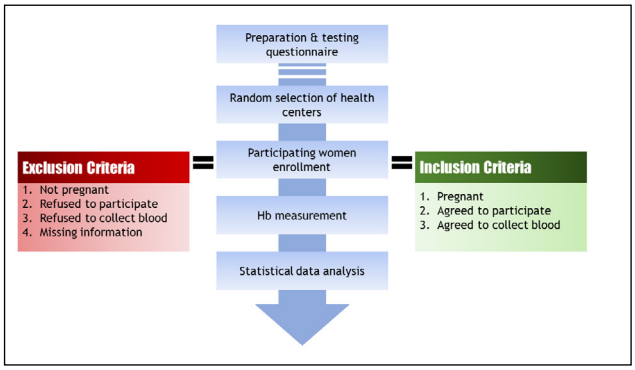

Figure 1. Flowchart showcasing the main steps in conducting this study along with inclusion and exclusion criteria

Recruitment and Data collection

The data of the present study was gathered through interviewing the pregnant women face to face after getting informed consent using structured and pre-tested questionnaire. The questionnaire was originally developed in English and then translated into Arabic (mother language). The tested and validated questionnaire contained a series of questions regarding sociodemographic characteristics (age, residence, education, family income) and health history (gestational age, number of springs, hemorrhage incidence) (detailed in Table 1). The Hb is the most prominent and the most important among the questionnaire questions. The questionnaire information were developed based on standard previous reports [16,17].

Descriptor	Definition
Urban	Within the borders of the city (otherwise rural)
Literate	secondary school or higher (otherwise illiterate)
Poor	Mean monthly income < $100 (otherwise good)
Malnourished	BMI < 18 (25 < BMI > 18 well-nourished)

Table 1. Definition of demographic descriptors and other risk factors

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Sample collection and processing

All participants enrolled in this study was asked for permission to withdraw a 5-ml blood sample. A qualified lab technician was responsible for blood collection. If not was directly used to measure Hb using a ready-to-use colorimetric kit (SPINREACT, Spain), the blood sample was stored in the refrigerator at 4°C.

Ethical approval

Prior to conducting this study, ethical clearance was obtained from the Biochemical Technology Program at Dhamar University (approval number FAS2021-18). In addition, a consent permission letter was submitted to the Ethical Review Committee of the university to obtain approval for the study protocol. This letter was then presented to the antenatal care centers and medical hospitals that participated in the study, in order to ensure that all participants provided informed consent before any data was collected. These measures were taken to ensure that the study followed ethical guidelines and protected the rights and welfare of the participants.

Statistical analysis

The dataset underwent a thorough cleaning and coding process before being inputted into statistical package for social sciences (SPSS® package, version 25) software for comprehensive analysis. The outcome variables were categorized into binary groups, with '1' indicating anemia and '0' representing the control group. Age, number of offspring and Hb variables were dichotomized also. To explore the relationships between the predictor variables and the outcomes, "Exploratory" binary logistic regression models were employed. Each independent variable was subjected to bivariate analysis to detect any associations with the dependent variable, using a significance threshold of $P < 0.05$. To adjust for potential confounders, multivariate logistic regression analysis was conducted, also at a significance level of $P < 0.05$. The strength of the associations was quantified using adjusted odds ratios (AOR) with 95% confidence intervals (95% CI), ensuring the interpretation of the findings was robust. All statistical procedures adhered to established analytical standards.

RESULTS

Socio-demographic information

Based on the surveyed sample, a total of 157 pregnant mothers were enrolled in the current study. Of whom, about two-thirds (64.3%) was less than 30 years old while 35.7% was more than 30 years. About 53.5% of the participants reside in rural regions of Dhamar governorate. Approximately two-thirds (68.8%) of the pregnant women were literate. Demographic characteristics are summarized in Table 2.

Character	Frequency	Percent
Age		
< 30	101	64.3%
> 30	56	35.7%
Residence		
Rural	84	53.5%
Urban	73	46.5%
Educational level		
Illiterate	49	31.2%
Literate	108	68.8%
Offspring		
< 4	93	59.2%
> 4	64	40.8%
Gestational age		
< 18 weeks	72	45.9%
> 18 weeks	85	54.1%
Socioeconomic level		
Poor	101	64.3%
Good	56	35.7%

Table 2. Percentage of socio-demographic characteristics of the enrolled participants

Prevalence of anemia

Our results, as shown in Fig 2, indicated that the severity of anemia was distributed to the three main categories in the anemic pregnant mothers. The majority of anemic mothers had mild anemia (43.33%) while 23.33% had moderate anemia. Moreover, 33.33% of the anemic pregnant women had severe anemia. Collectively, the anemia in pregnancy as a whole constituted nearly 17% from all pregnant mothers.

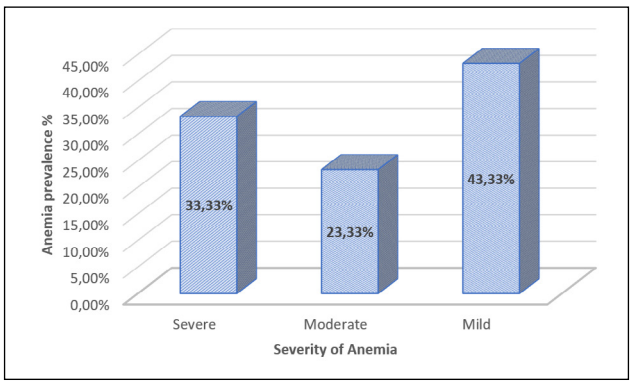

Figure 2. Distribution of anemia according to severity

Risk factors

AOR of 2.418 (95% CI = 0.699-8.365) between age and pregnancy anemia means that older women (above 30 years) have 2.418 times higher odds of developing anemia during pregnancy compared to younger women (below 30 years). However, the p-value of 0.163 suggests that this result could be due to chance and is not statistically significant. This means that more evidence is needed to confirm whether age is a significant risk factor for anemia during pregnancy. Women living in rural areas are much more likely to develop anemia during pregnancy than women living in urban areas, according to the odds ratio of 0.305 (95% CI = 0.111-0.835) with statistically significant outcome (p value = 0.021). We also obtained an AOR of 0.583 between education (illiterate and literate) and pregnancy anemia indicating a negative association between education and anemia in pregnancy, signifying that literate women may have a lower risk of developing anemia during pregnancy. However, the AOR of 0.583 is relatively small, indicating that the effect of education on the risk of anemia may not be substantial. Additionally, it is important to note that this association does not necessarily imply causation, and other factors such as access to healthcare and nutrition may also contribute to the risk of anemia in pregnancy. The present study also found an AOR of 0.613 (95% CI = 0.187-2.011) for the relationship between the number of offspring (less than 4 and 4 or more) and anemia during pregnancy. This denotes that there could be a negative association between the two variables, implying that women with four or more children may have lower odds of developing anemia during pregnancy than those with fewer than four children. Nonetheless, the p-value of 0.42 indicates that this association is not statistically significant. Upon investigating the association between gestational age and the risk of anemia during pregnancy, an AOR of 0.4 was obtained. This mirrors a negative association between gestational age and anemia in pregnancy, i.e. women who are further along in their pregnancy may be at a lower risk of developing anemia albeit this difference was not statistically significant. Nonetheless, the direction of the association indicates that gestational age may be an important factor to consider when assessing the risk of anemia in pregnancy. Based on the significant AOR of 3.865 (95% CI = 1.294-11.542) with a p-value of 0.015, it can be concluded that there is a strong positive association between socioeconomic level and pregnancy anemia. The finding indicates that pregnant women with a poor socioeconomic status are at a significantly higher risk of developing anemia compared to those with a good socioeconomic status. Therefore, efforts to improve socioeconomic conditions for pregnant women may be an effective preventative measure against pregnancy-related anemia. Similarly, the present study found that women who had less than three antenatal care visits might have a lower chance of developing anemia during pregnancy than those who had more than three visits, but this finding is not strong enough to say for sure (p value of 0.085). The odds of having anemia in pregnancy among those who are malnourished are 0.93 times the odds of having anemia in pregnancy among those who are not malnourished, after controlling for the effects of other variables in the statistical model. In other words, malnutrition appears to be negatively associated with anemia in pregnancy, but the effect is very small. The p-value of 0.894 indicates that the observed association between malnutrition and anemia in pregnancy is not statistically significant. Likewise, the same findings were obtained concerning twins, multigravida, smoking, hemorrhage and chronic diseases in which the causality was failed to be established nor statistical significance. The risk as well as logistic regression analysis are described in Table 3.

DISCUSSION

In the present study, we found that the prevalence of anemia among the pregnant women to represent 17% while the remaining 83% were at normal Hb range. Of the 17%, the severity was distributed to 43.33%, 23.33%, and 33.33% among mild, moderate and severe anemia. This reflects the wide distribution of anemia among pregnancy in Dhamar city which requires health measures to limit the incidence and, at the same time, provide medical interventions to "normalize" the anemic pregnant mothers. This necessitate the interplay among many health sectors to leading to a comprehensive solution.

In Sana'a (the capital city), the prevalence of anemia among was 25%; of which 70.83% had mild anemia, 28.13% had moderate anemia, and only 1.04% had severe anemia [18]. Another study in the capital city found higher prevalence rate (40%) [19]. These data confirm health burden of anemia in pregnancy in Yemen albeit it is decreasing, 40% in 2017, 25% in 2020 and 17 in 2021. This may lead us to the generalizability of anemia nationwide in Yemen according to the present literature.

We also analyzed the potential risk factors leading to anemia among pregnant women. These involved demographic factors such as age, residence, educational level, number of offspring, socioeconomic level and gestational age. Among all these demographic factors, only two factors, namely, residence and socioeconomic level were statistically significant (p value 0.021, 0.015) with AOR and CI of 0.305 (0.111-0.835), 3.86 (1.294-11.542). There is evidence to suggest that limited access to nutrition and healthcare services in rural areas may contribute to a higher prevalence of anemia among pregnant women. Pregnant women in rural areas may have limited access to nutritious foods, healthcare facilities, and prenatal care, which can increase their risk of developing anemia. Additionally,

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Factor	Normal	Anemic	Odds ratio (95% CI)	Adjusted odds ratio (95% CI)	P-value
Age < 30 > 30	 80 48	 21 9	1.400 (.593-3.305)	 2.418 (0.699-8.365)	 0.163
Residence Rural Urban	 74 54	 11 19	.422 (.186-.960)	 0.305 (0.111-0.835)	 0.021
Education Illiterate Literate	 43 85	 7 23	.602 (.239-1.513)	 0.583 (0.187-1.814)	 0.351
Offspring < 4 > 4	 76 52	 18 12	1.026 (.456-2.310)	 0.613 (0.187-2.011)	 0.42
Gestational age < 18 weeks > 18 weeks	 62 65	 10 20	.524 (.227-1.208)	 0.4 (0.146-1.097)	 0.075
Socioeconomic level Poor Good	 78 49	 23 7	2.064 (.824-5.171)	 3.865 (1.294-11.542)	 0.015
Antenatal care visits < 3 times > 3 times	 97 30	 18 12	.464 (.201-1.072)	 0.423 (0.159-1.124)	 0.085
Malnutrition Yes No	 53 74	 10 20	.698 (.302-1.612)	 0.93 (0.32-2.705)	 0.894
Twins Yes No	 8 119	 1 29	.513 (.062-4.265)	 0.524 (0.053-5.197)	 0.581
Multigravida Yes No	 61 66	 14 16	.947 (.427-2.101)	 0.942 (0.33-2.689)	 0.911
Smoking Yes No	 13 114	 4 26	1.349 (.407-4.474)	 1.056 (0.249-4.474)	 0.941
Haemorrhage Yes No	 19 108	 2 28	.406 (.089-1.847)	 0.415 (0.077-2.235)	 0.306
Chronic diseases Yes No	 9 118	 3 27	1.457 (.369-5.744)	 1.98 (0.34-11.539)	 0.447

Table 3. Multivariate binary logistic regression analysis of determinants of anemia among pregnant women

rural populations may have limited access to education about healthy behaviors during pregnancy, such as the importance of consuming a balanced diet and taking iron and folic acid supplements. These factors may contribute to a higher prevalence of anemia in rural regions compared to urban areas. Therefore, interventions to improve access to healthcare, nutrition, and education in rural areas may help to reduce the prevalence of anemia among pregnant women [20]. A low socioeconomic level is associated with an increased risk of anemia during pregnancy due to various factors. Women from lower socioeconomic backgrounds may have limited access to nutritious food, healthcare facilities, and antenatal care, which are crucial for maintaining maternal health and reducing the risk of anemia during pregnancy. Poor maternal nutrition is a significant risk factor for anemia during pregnancy, and women from lower socioeconomic backgrounds may not have access to the resources needed to maintain a balanced diet. Moreover, women from lower socioeconomic backgrounds may not be able to afford transportation to antenatal care visits or may have work obligations that prevent them from attending. Limited access to education about healthy

behaviors during pregnancy may also contribute to a higher prevalence of anemia in this population [21]. On the other hand, the clinical factors examined were antenatal care visits, malnutrition, twins, multigravida, smoking and chronic diseases. However, none of these factors was a significantly associated with the incidence of pregnancy anemia.

Globally, anemia is a prevalent health concern among pregnant women, with varying prevalence rates across different regions and countries. A systematic review and meta-analysis of 39 studies from low- and middle-income countries reported an overall prevalence rate of 38.2% among pregnant women, with the highest prevalence in South Asia (49.2%) and the lowest in Latin America and the Caribbean (18.7%). A separate study in Ethiopia found an overall prevalence rate of 58.9%. Anemia during pregnancy can result in adverse outcomes for both the mother and the fetus, such as preterm birth, low birth weight, and maternal mortality. Therefore, it is crucial to address this issue through interventions such as iron and folic acid supplementation, improving maternal nutrition, and managing underlying medical conditions [22,23]. Since WHO has accepted the lower normal limit of Hb in pregnancy to 11 g/dl, all values below this range is considered to be anemic [24].

Indeed, many reports assessed the prevalence of anemia during pregnancy in different geographic areas correlating wide factors with fluctuating outcomes. For example, an Ethiopian study found that 16.88% of pregnant women in the community were anemic (hemoglobin level < 11 g/dl). Multivariable analysis revealed that several factors were significantly associated with anemia. These included a history of malaria attack within the year prior to the study, a history of excessive menstrual bleeding, unplanned pregnancy, and a meal frequency of three times or less. These findings highlight the importance of addressing modifiable risk factors such as malaria prevention, menstrual health, family planning, and adequate nutrition to reduce the burden of anemia during pregnancy [25]. Our findings were in good agreement with this study with respect to anemia prevalence (16.88% versus 17% in our study).

Similarly, unmatched case-control study conducted in Jigjiga Somali region and East Ethiopia in 2019. This study has identified three significant predictors of anemia in pregnant women. The first predictor is an inadequate intake of red meat, with those who consume red meat 1-2 times a month or not at all being at a higher risk of anemia. The second predictor is insufficient consumption of green vegetables, with those who consume green vegetables 1-2 times a week or 1-2 times a month being at a higher risk of anemia. Finally, a mid-upper arm circumference (MUAC) of less than 23 cm was found to be strongly associated with anemia. These findings are statistically significant with p values < 0.05 and highlight the importance of consuming a balanced diet during pregnancy to prevent anemia and ensure a healthy pregnancy [26].

Other researchers conducted a prospective study of 300 pregnant women in India and found that 67% of them were anemic. The study found that maternal age, education, socioeconomic status, and hemoglobin level were significantly associated with anemia during pregnancy. The p-values for these associations were less than 0.05. Parity, occupation, and gestational age were not found to be significant risk factors for anemia during pregnancy [10].

Moreover, another study performed in Bangladesh found that the overall prevalence of anemia among pregnant women was 58.9%, with 36.3% being mildly anemic, 62.4% being moderately anemic, and 1.3% being severely anemic. Binary logistic regression analysis revealed that several factors were significantly associated with anemia among pregnant women. These factors include monthly family income between 11,000-20,000 Taka, joint family size, gestational age in the third trimester, birth spacing less than 2 years, excessive blood loss during previous surgery, consumption of 1-4 food groups in the past 24 hours, and not regularly having breakfast. These findings highlight the importance of addressing these factors in order to prevent anemia among pregnant women [27]. It seems that the data of anemia prevalence in East Asia (India and Bangladesh) regions correlate well with each other. Furthermore, East African regions (primarily Ethiopia) outputted similar findings, i.e. the major determinant was the geographic area, climate and their consequences on lifestyle and other environmental factors [28].

Limitation

The low sample size which is attributed to the war-torn mode of the general population. Moreover, the present study suffer from selection bias since Khat-chewing habit is greatly widespread even in women which could be a confounding factor since Khat's polyphenols chelate iron and prevent its intestinal absorption [7]. Also, Strong seasonal variation exists in the prevalence of moderate to severe anemia among pregnant women. During the dry season, the prevalence is lower (around 8.7%), while it increases significantly during the rainy season (reaching 41.2%) [29]. This could be another influencing factor that we did not examine.

CONCLUSION

This study found that anemia is prevalent among pregnant women in Dhamar governorate, Yemen, with 17% of pregnant women admitted to medical centers and health care centers having anemia. The severity of anemia varied, with 43% being mild, 23% moderate, and 33% severe cases. Residence in a rural area and having a lower socioeconomic level were identified as

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significant risk factors for anemia during pregnancy. These findings underscore the need for appropriate medical interventions to reduce the prevalence and incidence of anemia during pregnancy, particularly among pregnant women living in rural areas and those with low income.

Facing pregnancy anemia is multifaceted and require different interventions, nutritional, healthcare and socioeconomic support. Nutritional interventions include encouraging iron, multivitamins (vitamin B9 and vitamin B12 for erythropoiesis and vitamin C for increase iron absorption) continuous intake and conducting awareness campaigns to educate pregnant women about the importance of proper nutrition during pregnancy. Healthcare intervention involve strengthening antenatal care services by ensuring regular check-ups for pregnant women. ANC visits provide opportunities for early detection and management of anemia, training healthcare providers, and improve data collection and reporting systems to monitor anemia prevalence and track progress. Lastly, addressing socioeconomic factors that contribute to anemia, such as poverty, low education levels, and inadequate food security besides the bad habits such as Khat-chewing (Tea consumption is linked to iron-deficiency anemia through inhibiting iron absorption [30,31]) are deeply necessary.

CONFLICT OF INTEREST

None declared.

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ABBREVIATIONS

AOR	adjusted odds ratio
CI	confidence intervals
Hb	hemoglobin
OR	odds ratio
RBCs	red blood cells
WHO	World Health Organization

AUTHOR CONTRIBUTIONS

All authors participated in study conception and design, data acquisition, analysis and interpretation, drafting or revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

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APPENDIX

Questionnaire:

Degree and Prevalence of Anemia among Pregnant Women in Dhamar City hospitals

1-Age, year(العمر)	<20	20-29	30-39	≥40
2-Residence (الإقامة)	(ريف)Rural		(مدينة)Urban	
3- Level of education (مستوى التعليم)	a. No educated غير متعلمة	b. Primary School اساسية	c. Secondary School ثانوية	d. University جامعه

4-Number off springs عدد الاولاد	0-1	2-3	4-5	More than five

5-Gestational age عمر الحمل	a-First trimester الأشهر الثلثة الاولي	b-Second trimester الأشهر الثلثة الثانية	d-Third trimester الأشهر الثلثة الاخيرة

6-Socioeconomic level المستوى المعيشي	a-Good level مستوى جيد	b-Medium level مستوى متوسط	c-Bad level مستوى سيء

7-Antenatal care visits زيارات رعاية ما قبل الولادة	a-0-1visit	b-2-3Visits	C.4-5Visits	d. More than 5 Visits

8-Risk factors عوامل الخطر	Yes	No
a- Twins توأمان		
b. Multigravida		
C .Bad habits عادات سيئة		
d Smoking التدخين		
e. Hemorrhage النزيف		
f. Chronic diseases امراض مزمنة		

9-Level of hemoglobin (Hb):.....

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Simulative and empirical comparison of health scales' scores derived by confirmatory factor analysis and sum of items

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SUMMARY

We focus on how combining questionnaire's items to derive a score. Data simulation and real data were used to compare questionnaires' scores derived by sum of items and scores derived from a confirmatory factor analysis. We investigated the equivalence of the sum of items and the latent factor scores from confirmatory factor analysis in simulative and empirical studies. We investigated to what extent the derivation of the score may have influenced the assumptions of linear model analysis. Deriving the questionnaire's scores using the sum of items or the application of the confirmatory factor analysis is equivalent. This evidence is confirmed in the simulation settings and by empirical data.

Keywords: Health scales; psychometric scores; sum of items; confirmatory factor analysis; simulation study

INTRODUCTION

The use of scales, questionnaires and tests is common in many fields of health research, social sciences, and behavioural research [1]. The spread of these tools' use in health research is justified for these measures are an apparently simple instrument and their use seems as limitless [1–3]. Moreover, numerous valid and reliable scales, are available nowadays. These scales can be administered in electronic form making the collection of large amounts data easier than ever [4]. However, using scales in health research is not a simple task; especially challenging is the proper application of statistical analysis tools [3,5–7]. Scales are composed of items investigating specific aspects and are generally coded as multiple-choice questions. How combining such items to derive a suitable score is the matter of our discussion. There are two ways to merge results from different items performing an overall score. On the one hand, the simpler and most common approach is to sum the scores (SS) from the single items. On the other, the overall score could be computed via a confirmatory factor analysis or by similar approaches aimed to derive a latent factor score of the items (LFS).

The two methods are not theoretically interchangeable [8,9]. On the one hand, Mc Neish and Wolf [8] stated that sum scoring has a negative effect on the validity, reliability and qualitative classification from sum-score cut-off. On the other hand, Widaman and Revelle [9] reciprocated that sum scores are valid and reliable, especially when the dimensional structure of a set of items is well established. Furthermore, Widaman and Revelle highlight that the sum score is a more general solution since it does not depend on the analytical sample, while the factor score does.

While evidence from both viewpoints supports choosing one method over the other, some practical aspects still require further investigation. Firstly, it is of interest to understand in which condition the two approaches are equivalent and how this situation can be identified. Afterwards, we used real data from a rehabilitation registry, the "Smart&Touch-ID registry" [10], in which vertain tools were used to evaluate

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the usability of digital rehabilitation solutions (System Usability Scale) and the efficacy on clinical outcome (the Yoni task). Moreover, we showed regression efficiency and showed how to improve the validity of linear model assumptions.

METHODS

Theoretical background

It is convenient to highlight that sum of items' scores (SS) and the latent factor score (LFS) are analytically similar for they are both a linear combination of the items. The following equation represents a linear combination of X_p elements with w_p being weights.

$$Y = w_1X_1 + w_2X_2 + \ldots + w_pX_p \qquad (1)$$

In other words, the element Y is a score computed by p elements X, not all the p elements equally contribute to Y so the w_i (with $0 \leq i \leq 1$) element represent the contribution (generally referred as weight) of X_i on Y. Here the first difference between the SS and the LFS. In the SS, the weights are equal and assume the value of 1. In the LFS these weights differ, depending on the item and by its correlation with the latent factor.

The variance of Y can be represented by the following equation.

$$\sigma_Y^2 = w_1^2\sigma_1^2 + w_2^2\sigma_2^2 + \ldots + w_p^2\sigma_p^2 + 2 w_1w_2r_{1,2}\sigma_1\sigma_2 + 2\, w_1w_3r_{1,3}\sigma_1\sigma_3 + \ldots + 2\, w_{p-1}w_pr_{p-1,p}\sigma_{p-1}\sigma_p \qquad (2)$$

Where σ^2_j represents the variance of a given item j and $r_{jk}\sigma_j\sigma_k$ represents the covariance between the items j and k. This formulation is common to overall scores computed as the sum of items (here referred as the X) and to overall scores computed using latent factor analysis. Specifically, in the SS the weight element corresponds to 1 for all the items. For SS the variance is given by the sum of the items' variance plus items' covariance.

For the LFS, the expected value and its variance are thus similar to the one of SS. In summary, even if performed by different procedures, the SS and the LFS are similarly interpreted for they are both linear combination of the items. The difference between the two is the weight for a single item. The LFS is computed considering different weights for different items. These weights, often referred as factor loadings, are proportional to the correlation between the variables and the latent factor. There is also a difference between the expected value and the variance performed by these two methods. This numerical difference between the sum score and the factor score is again due to the numerical value of the weight.

Simulation studies

The simulation studies were conducted using the R software vers. 4.0.2. Briefly, we firstly simulated one latent factor (SLF) following the Z~N (0;1) distribution using the MVRnorm function from the MASS package [11]. Afterwards, five, nine and 17 items following the Z~N(0;1) distribution were generated having a given correlation pattern with the above mentioned latent factor using the rnorm_pre function of the faux package [12]. We simulated items having a medium to strong correlation to the latent factor, namely a correlation coefficient of 0.45, 0.6 and 0.75. We then simulated different scenarios to investigate to what extent the correlation between the items and the latent factors may have influenced the analyses. Firstly, we simulated iso-correlated variables. In a second set of simulations, we used variables with a range of correlations but still with a central or median correlation value of 0.45, 0.6 and 0.75. Specifically, in the five-variable setting the correlations between the items and the latent factor ranged between 0.35 to 0.55, by steps of 0.05 for the setting with a median correlation of 0.45. Similarly, for the settings with a median correlation of 0.6 (r = 0.5 to 0.7 by 0.05) and for the setting with a median correlation of 0.75 (r = 0.65 to 0.85 by 0.05). In the simulations with nine and 17 variables we adopted the same ranges with steps of 0.025 and 0.0125, respectively. A second set of simulation was conducted to investigate the effects of having skewed variables defined as ordinal categories, according to most common operative situations occurring when analysing data from questionnaires. To this aim, we firstly simulated a continuous rightly skewed latent factor using the rs_norm function from the fGarch package [13]. Afterwards, a series of five level Likert variables were simulated using the formula $V[i] = LAF \cdot r[i] + LAF \cdot \sqrt{(1-r[i]^2)}$, where r[i] represents the correlation coefficient between the variable and the latent factor. The function parameters were set to obtain items with a skewness greater than 1, defining highly skewed items. Finally, each simulation described above was performed with a sample size of 100, 250, 500 and 1000 observations to investigate to what extent the sample size may have influenced the relation between the SS and the LFS. The simulated scenarios are reported on Table 1, the simulation programs for normally distributed and skewed data were reported on Supplementary Files.

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Table 1. Representation of the not iso-correlated simulation scenarios

	$M_{correlation}$ = 0.45	$M_{correlation}$ = 0.60	$M_{correlation}$ = 0.75
Item number	Correlation between the items and the latent factor		
1	0.3500	0.5000	0.6500
2	0.4000	0.5500	0.7000
3	0.4500	0.6000	0.7500
4	0.5000	0.6500	0.8000
5	0.5500	0.7000	0.8500
Item number			
1	0.3500	0.5000	0.6500
2	0.3750	0.5250	0.6750
3	0.4000	0.5500	0.7000
4	0.4250	0.5750	0.7250
5	0.4500	0.6000	0.7500
6	0.4750	0.6250	0.7750
7	0.5000	0.6500	0.8000
8	0.5250	0.6750	0.8250
9	0.5500	0.7000	0.8500
Item number			
1	0.3500	0.5000	0.6500
2	0.3625	0.5125	0.6625
3	0.3750	0.5250	0.6750
4	0.3875	0.5375	0.6875
5	0.4000	0.5500	0.7000
6	0.4125	0.5625	0.7125
7	0.4250	0.5750	0.7250
8	0.4375	0.5875	0.7375
9	0.4500	0.6000	0.7500
10	0.4625	0.6125	0.7625
11	0.4750	0.6250	0.7750
12	0.4875	0.6375	0.7875
13	0.5000	0.6500	0.8000
14	0.5125	0.6625	0.8125
15	0.5250	0.6750	0.8250
16	0.5375	0.6875	0.8375
17	0.5500	0.7000	0.8500

$M_{correlation}$: represents the median or central value of the correlation series

A supplementary set of simulation has been performed where 10% of times where randomly assigned to a null correlation (Results reported on Supplementary Tables 1-4).

Empirical studies

Firstly, we investigated data obtained by the administration of the System Usability Scale (SUS), an instrument made by ten multiple choice items with response coded by a five points Likert scale (1=strongly disagree, 5=strongly agree). The SUS is a valid tool for the measure of usability of a wide range of technological systems or devices. The score of the SUS ranges from 0 to 100 and indicates the overall perceived usability of a technological system. In this study, the SUS overall scores were scored according to Brooke [14]. Notably, the SUS score computed according to Brooke is a SS-like score.

The SUS also considers two subscales or main aspects that affect the user's experience toward a technological system: the usability and the learnability subscales. The first indicates the ease of use perceived by the user during the interaction with the technology. Instead, the learnability subscale refers to the perceived ease of learning of using the technological system. Learnability and usability subscales were obtained in accordance to Lewis and Sauro's indications[15,16].

Secondly, the Yoni tasktool was investigated, we used the Yoni-48 which is the short version of the Italian Yoni task for the assessment of social cognition ability, and especially Theory of Mind (ToM)[17–19]. The Yoni-48 task includes 48 items in total, of those items 42 assesses ToM (mental items) and six are control items (physical items). The mental stimuli comprise 21 affective and 21 cognitive ToM items.

The task is digital and includes static visual cartoon-like stimuli, in which a face named "Yoni" appeared at the centre of the screen, surrounded by four coloured elements (for example fruit, animals, means of transport, or faces). Subjects are instructed to click as fast as they can on the elements Yoni refers to, based on the sentence reported at the top of the screen (e.g., "Yoni is thinking of …", "Yoni likes …"). For each item, only one answer is correct (score 0–1). Yoni total raw score, and sub-scores (such as affective and cognitive raw score), are computed by summing items.

Statistical analysis

The LFS and the SS were performed for all simulated scenarios and for the empirical sets of data. The comparison between the simulated latent factor, the LFS and SS was qualitatively evaluated by visual inspection of the scatterplots and quantitatively reported by the calculation of the correlation coefficients. In the simulation study, the bootstrap Pearson correlation coefficients with 95% confidence limits between the simulated latent factor, the latent factor from the confirmatory factor analysis and the score performed by the sum of items were reported using the ci_cor function for normally distributed and continuous data. The Spearman correlation coefficient was adopted when the items were simulated as skewed and ordinal categorical. The LAVAAN package [20] of the R software was used to perform the LFS according to the codes reported on Supplementary files. Briefly, the items were considered as continuous variables when analysing the data from the simulation study with items simulated as continuous variables and for the empirical study conducted using the SUS for it is a CTT instrument. In contrast, for the simulated settings with skewed and categorical variables and for the Yoni-48, the LFS was computed using a code considering the true/false dichotomous nature of the Yoni items using the ordered="TRUE" option of the CFA function of LAVAAN.

RESULTS

Simulation study. Comparison between the latent factor scores and the scores performed by items' sum.

In the first simulation setting we set the items' weight as constant being associated to the SLF factor with a fixed correlation coefficient between the items and the latent factor. In this first simulation setting we confirmed that the SS and the LFS are asymptotically equal in the iso-correlated scenarios when the items are continuous and normally distributed. The correlations between the SS and the LFS have very high values being above 0.95 also for small sample sizes and number of items (Table 2).

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Table 2. Pearson correlation coefficients and 95% confidence limits obtained by bias corrected bootstrap with continuous iso-correlated items distributed as a standardized normal distribution

	Bootstrap Pearson correlation coefficients with 95% confidence limits		
Simulation Scenarios	LAF with LFS	LAF with SS	LFS with SS
V = 5, N = 100, r = 0.45	0.6877 (0.5931; 0.7625)	0.7390 (0.6540; 0.8018)	0.9588 (0.9410; 0.9699)
V = 9, N = 100, r = 0.45	0.8071 (0.7403; 0.8584)	0.8267 (0.7640; 0.8745)	0.9912 (0.9874; 0.9936)
V = 17, N = 100, r = 0.45	0.8560 (0.8087; 0.8901)	0.8721 (0.8282; 0.9043)	0.9971 (0.9961; 0.9978)
V = 5, N = 250, r = 0.45	0.7114 (0.6623; 0.7537)	0.7158 (0.6668; 0.7579)	0.9973 (0.9966; 0.9978)
V = 9, N = 250, r = 0.45	0.8299 (0.7970; 0.8570)	0.8387 (0.8064; 0.8645)	0.9970 (0.9965; 0.9975)
V = 17, N = 250, r = 0.45	0.8829 (0.8607; 0.9015)	0.8877 (0.8659; 0.9059)	0.9992 (0.9990; 0.9993)
V = 5, N = 500, r = 0.45	0.7563 (0.7216; 0.7879)	0.7595 (0.7248; 0.7914)	0.9979 (0.9976; 0.9982)
V = 9, N = 500, r = 0.45	0.8264 (0.7997; 0.8496)	0.8291 (0.8022; 0.8523)	0.9990 (0.9988; 0.9991)
V = 17, N = 500, r = 0.45	0.8931 (0.8774; 0.9081)	0.8973 (0.8820; 0.9111)	0.9992 (0.9991; 0.9993)
V = 5, N = 1000, r = 0.45	0.7431 (0.7191; 0.7663)	0.7433 (0.7190; 0.7660)	0.9998 (0.9998; 0.9998)
V = 9, N = 1000, r = 0.45	0.8304 (0.8134; 0.8460)	0.8324 (0.8157; 0.8481)	0.9992 (0.9992; 0.9993)
V = 17, N = 1000, r = 0.45	0.8961 (0.8853; 0.9058)	0.8968 (0.8860; 0.9066)	0.9999 (0.9999; 0.9999)
V = 5, N = 100, r = 0.60	0.8350 (0.7846; 0.8726)	0.8528 (0.8064; 0.8877)	0.9904 (0.9864; 0.9928)
V = 9, N = 100, r = 0.60	0.9032 (0.8665; 0.9300)	0.9094 (0.8740; 0.9351)	0.9982 (0.9974; 0.9987)
V = 17, N = 100, r = 0.60	0.9299 (0.9052; 0.9471)	0.9357 (0.9122; 0.9522)	0.9993 (0.9991; 0.9995)
V = 5, N = 250, r = 0.60	0.8344 (0.8050; 0.8594)	0.8364 (0.8068; 0.8612)	0.9992 (0.9990; 0.9993)
V = 9, N = 250, r = 0.60	0.9136 (0.8958; 0.9276)	0.9165 (0.8994; 0.9302)	0.9993 (0.9992; 0.9994)
V = 17, N = 250, r = 0.60	0.9427 (0.9315; 0.9519)	0.9443 (0.9335; 0.9535)	0.9998 (0.9998; 0.9998)
V = 5, N = 500, r = 0.60	0.8656 (0.8453; 0.8840)	0.8667 (0.8464; 0.8848)	0.9995 (0.9994; 0.9996)
V = 9, N = 500, r = 0.60	0.9100 (0.8955; 0.9223)	0.9109 (0.8962; 0.9233)	0.9998 (0.9997; 0.9998)
V = 17, N = 500, r = 0.60	0.9481 (0.9404; 0.9554)	0.9495 (0.9418; 0.9563)	0.9998 (0.9998; 0.9999)
V = 5, N = 1000, r = 0.60	0.8557 (0.8412; 0.8696)	0.8558 (0.8411; 0.8693)	0.9998 (0.9998; 0.9999)
V = 9, N = 1000, r = 0.60	0.9122 (0.9029; 0.9204)	0.9129 (0.9039; 0.9212)	1 (1; 1)
V = 17, N = 1000, r = 0.60	0.9490 (0.9436; 0.9540)	0.9492 (0.9437; 0.9541)	1 (1; 1)
V = 5, N = 100, r = 0.75	0.9205 (0.8964; 0.9376)	0.9268 (0.9037; 0.9436)	0.9974 (0.9965; 0.9980)
V = 9, N = 100, r = 0.75	0.9550 (0.9374; 0.9677)	0.9572 (0.9398; 0.9694)	0.9996 (0.9994; 0.9997)
V = 17, N = 100, r = 0.75	0.9682 (0.9568; 0.9762)	0.9703 (0.9592; 0.9780)	0.9998 (0.9997; 0.9999)
V = 5, N = 250, r = 0.75	0.9167 (0.9016; 0.9297)	0.9175 (0.9020; 0.9303)	0.9997 (0.9997; 0.9998)
V = 9, N = 250, r = 0.75	0.9597 (0.9512; 0.9663)	0.9608 (0.9526; 0.9673)	0.9998 (0.9998; 0.9999)
V = 17, N = 250, r = 0.75	0.9739 (0.9687; 0.9781)	0.9744 (0.9694; 0.9787)	1 (0.9999; 1)
V = 5, N = 500, r = 0.75	0.9342 (0.9237; 0.9434)	0.9346 (0.9244; 0.9438)	0.9999 (0.9999; 0.9999)
V = 9, N = 500, r = 0.75	0.9576 (0.9507; 0.9634)	0.9579 (0.9509; 0.9638)	0.9999 (0.9999; 0.9999)
V = 17, N = 500, r = 0.75	0.9765 (0.9730; 0.9797)	0.9769 (0.9734; 0.9800)	1 (1; 1)
V = 5, N = 1000, r = 0.75	0.9285 (0.9210; 0.9355)	0.9285 (0.9209; 0.9354)	1 (1; 1)
V = 9, N = 1000, r = 0.75	0.9587 (0.9542; 0.9626)	0.9589 (0.9547; 0.9629)	1 (1; 1)
V = 17, N = 1000, r = 0.75	0.9767 (0.9742; 0.9790)	0.9768 (0.9742; 0.9791)	1 (1; 1)

LAF = Simulated latent factor; LFS = Latent factor score performed via confirmative factor analysis; SS: Score performed by the sum of items; V = Number of items; N = Sample size; r = Pearson correlation coefficient between the items

The correlations between the simulated latent factor with the SS and the LFS are not particularly high with correlations in the range of 0.7-0.8 for scenarios with small sample sizes and number of variables. We observed the same pattern when the items had different correlations with the simulated latent factors (Table 3).

Table 3. Pearson correlation coefficients and 95% confidence limits obtained by bias corrected bootstrap with continuous not iso-correlated items distributed as a standardized normal distribution

	Bootstrap Pearson correlation coefficients with 95% confidence limits		
Simulation Scenarios	LAF with LFS	LAF with SS	LFS with SS
V = 5, N = 100, r = 0.45	0.7025 (0.6088; 0.7741)	0.7395 (0.6552; 0.8024)	0.9495 (0.9291; 0.9638)
V = 9, N = 100, r = 0.45	0.8188 (0.7551; 0.8679)	0.8274 (0.7651; 0.8748)	0.9902 (0.9866; 0.9927)
V = 17, N = 100, r = 0.45	0.8631 (0.8175; 0.8954)	0.8720 (0.8283; 0.9043)	0.9948 (0.9928; 0.9962)
V = 5, N = 250, r = 0.45	0.7233 (0.6753; 0.7649)	0.7176 (0.6693; 0.7594)	0.9873 (0.9845; 0.9896)
V = 9, N = 250, r = 0.45	0.8361 (0.8045; 0.8618)	0.8390 (0.8069; 0.8650)	0.9901 (0.9879; 0.9918)
V = 17, N = 250, r = 0.45	0.8886 (0.8679; 0.9067)	0.8880 (0.8662; 0.9060)	0.9956 (0.9946; 0.9964)
V = 5, N = 500, r = 0.45	0.7692 (0.7359; 0.7996)	0.7600 (0.7257; 0.7919)	0.9920 (0.9907; 0.9932)
V = 9, N = 500, r = 0.45	0.8321 (0.8057; 0.8546)	0.8300 (0.8033; 0.8531)	0.9905 (0.9890; 0.9919)
V = 17, N = 500, r = 0.45	0.8948 (0.8793; 0.9095)	0.8982 (0.8832; 0.9120)	0.9941 (0.9931; 0.9950)
V = 5, N = 1000, r = 0.45	0.7536 (0.7304; 0.7759)	0.7445 (0.7202; 0.7670)	0.9903 (0.9892; 0.9913)
V = 9, N = 1000, r = 0.45	0.8354 (0.8188; 0.8502)	0.8336 (0.8168; 0.8491)	0.9907 (0.9897; 0.9916)
V = 17, N = 1000, r = 0.45	0.9010 (0.8907; 0.9103)	0.8970 (0.8862; 0.9070)	0.9964 (0.9960; 0.9968)
V = 5, N = 100, r = 0.60	0.8451 (0.7966; 0.8808)	0.8531 (0.8073; 0.8878)	0.9821 (0.9754; 0.9870)
V = 9, N = 100, r = 0.60	0.9099 (0.8758; 0.9351)	0.9100 (0.8745; 0.9352)	0.9959 (0.9945; 0.9969)
V = 17, N = 100, r = 0.60	0.9344 (0.9112; 0.9507)	0.9355 (0.9121; 0.9520)	0.9976 (0.9967; 0.9982)
V = 5, N = 250, r = 0.60	0.8435 (0.8156; 0.8678)	0.8382 (0.8094; 0.8629)	0.9917 (0.9899; 0.9931)
V = 9, N = 250, r = 0.60	0.9179 (0.9010; 0.9311)	0.9167 (0.8995; 0.9304)	0.9951 (0.9940; 0.9960)
V = 17, N = 250, r = 0.60	0.9459 (0.9356; 0.9547)	0.9445 (0.9336; 0.9536)	0.9975 (0.9969; 0.9980)
V = 5, N = 500, r = 0.60	0.8748 (0.8553; 0.8920)	0.8670 (0.8469; 0.8851)	0.9937 (0.9927; 0.9946)
V = 9, N = 500, r = 0.60	0.9140 (0.8999; 0.9258)	0.9116 (0.8970; 0.9238)	0.9949 (0.9940; 0.9956)
V = 17, N = 500, r = 0.60	0.9494 (0.9417; 0.9564)	0.9502 (0.9427; 0.9570)	0.9972 (0.9967; 0.9976)
V = 5, N = 1000, r = 0.60	0.8638 (0.8501; 0.8768)	0.8568 (0.8424; 0.8703)	0.9930 (0.9922; 0.9937)
V = 9, N = 1000, r = 0.60	0.9157 (0.9069; 0.9234)	0.9138 (0.9048; 0.9221)	0.9950 (0.9944; 0.9955)
V = 17, N = 1000, r = 0.60	0.9519 (0.9468; 0.9566)	0.9493 (0.9438; 0.9543)	0.9979 (0.9976; 0.9981)
V = 5, N = 100, r = 0.75	0.9306 (0.9087; 0.9460)	0.9271 (0.9049; 0.9435)	0.9891 (0.9854; 0.9919)
V = 9, N = 100, r = 0.75	0.9604 (0.9450; 0.9716)	0.9576 (0.9402; 0.9696)	0.9967 (0.9956; 0.9976)
V = 17, N = 100, r = 0.75	0.9719 (0.9617; 0.9790)	0.9701 (0.9591; 0.9778)	0.9982 (0.9975; 0.9986)
V = 5, N = 250, r = 0.75	0.9261 (0.9127; 0.9378)	0.9193 (0.9040; 0.9319)	0.9927 (0.9911; 0.9939)
V = 9, N = 250, r = 0.75	0.9638 (0.9560; 0.9697)	0.9608 (0.9527; 0.9673)	0.9960 (0.9951; 0.9967)
V = 17, N = 250, r = 0.75	0.9765 (0.9719; 0.9803)	0.9745 (0.9694; 0.9788)	0.9978 (0.9973; 0.9982)
V = 5, N = 500, r = 0.75	0.9426 (0.9334; 0.9506)	0.9346 (0.9245; 0.9438)	0.9931 (0.9920; 0.9941)
V = 9, N = 500, r = 0.75	0.9615 (0.9552; 0.9668)	0.9585 (0.9516; 0.9642)	0.9957 (0.9950; 0.9963)
V = 17, N = 500, r = 0.75	0.9779 (0.9746; 0.9810)	0.9775 (0.9742; 0.9805)	0.9978 (0.9975; 0.9981)
V = 5, N = 1000, r = 0.75	0.9368 (0.9301; 0.9431)	0.9294 (0.9220; 0.9363)	0.9931 (0.9922; 0.9938)
V = 9, N = 1000, r = 0.75	0.9623 (0.9583; 0.9657)	0.9597 (0.9555; 0.9636)	0.9959 (0.9954; 0.9963)
V = 17, N = 1000, r = 0.75	0.9791 (0.9768; 0.9811)	0.9769 (0.9744; 0.9792)	0.9981 (0.9979; 0.9983)

LAF = Simulated latent factor; LFS = Latent factor score performed via confirmative factor analysis; SS: Score performed by the sum of items; V = Number of items; N = Sample size; r = Pearson correlation coefficient between the items

Most notably, having skewed ordinal categorical data does not substantially change the results reported above (Tables 4 and 5).

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Table 4. Spearman correlation coefficients and 95% confidence limits obtained by bias corrected bootstrap with five level Likert iso-correlated items with positive skewness

	Bootstrap Pearson correlation coefficients with 95% confidence limits		
Simulation Scenarios	LAF with LFS	LAF with SS	LFS with SS
V = 5, N = 100, r = 0.45	0.5714 (0.4399; 0.6812)	0.6259 (0.5072; 0.7202)	0.9617 (0.9358; 0.9762)
V = 9, N = 100, r = 0.45	0.7340 (0.6461; 0.8064)	0.7460 (0.6550; 0.8174)	0.9630 (0.9508; 0.9753)
V = 17, N = 100, r = 0.45	0.7392 (0.6445; 0.8118)	0.7402 (0.6457; 0.8128)	0.9725 (0.9592; 0.9827)
V = 5, N = 250, r = 0.45	0.5683 (0.4882; 0.6397)	0.5879 (0.5116; 0.6548)	0.9420 (0.9243; 0.9553)
V = 9, N = 250, r = 0.45	0.7025 (0.6401; 0.7565)	0.6985 (0.6377; 0.7504)	0.9759 (0.9689; 0.9818)
V = 17, N = 250, r = 0.45	0.7893 (0.7369; 0.8327)	0.8005 (0.7507; 0.8406)	0.9836 (0.9783; 0.9881)
V = 5, N = 500, r = 0.45	0.6737 (0.6242; 0.7165)	0.6655 (0.6158; 0.7093)	0.9847 (0.9815; 0.9874)
V = 9, N = 500, r = 0.45	0.7027 (0.6588; 0.7414)	0.6948 (0.6504; 0.7337)	0.9901 (0.9877; 0.9921)
V = 17, N = 500, r = 0.45	0.8294 (0.8014; 0.8535)	0.8218 (0.7935; 0.8472)	0.9919 (0.9905; 0.9934)
V = 5, N = 1000, r = 0.45	0.6026 (0.5638; 0.6394)	0.5955 (0.5570; 0.6314)	0.9896 (0.9885; 0.9908)
V = 9, N = 1000, r = 0.45	0.7436 (0.7175; 0.7683)	0.7358 (0.7080; 0.7606)	0.9922 (0.9910; 0.9932)
V = 17, N = 1000, r = 0.45	0.7993 (0.7756; 0.8206)	0.7934 (0.7702; 0.8146)	0.9927 (0.9915; 0.9938)
V = 5, N = 100, r = 0.60	0.7262 (0.6375; 0.7988)	0.7470 (0.6611; 0.8146)	0.9767 (0.9659; 0.9849)
V = 9, N = 100, r = 0.60	0.8321 (0.7669; 0.8833)	0.8371 (0.7695; 0.8873)	0.9737 (0.9541; 0.9845)
V = 17, N = 100, r = 0.60	0.8562 (0.7927; 0.9017)	0.8507 (0.7840; 0.8959)	0.9908 (0.9855; 0.9947)
V = 5, N = 250, r = 0.60	0.7317 (0.6694; 0.7841)	0.7354 (0.6748; 0.7865)	0.9763 (0.9688; 0.9822)
V = 9, N = 250, r = 0.60	0.8127 (0.7648; 0.8517)	0.8082 (0.7618; 0.8470)	0.9922 (0.9903; 0.9941)
V = 17, N = 250, r = 0.60	0.8769 (0.8424; 0.9037)	0.8776 (0.8437; 0.9040)	0.9960 (0.9949; 0.9973)
V = 5, N = 500, r = 0.60	0.7907 (0.7540; 0.8227)	0.7820 (0.7439; 0.8139)	0.9926 (0.9912; 0.994)
V = 9, N = 500, r = 0.60	0.8188 (0.7900; 0.8447)	0.8128 (0.7835; 0.8387)	0.9945 (0.9934; 0.9955)
V = 17, N = 500, r = 0.60	0.9001 (0.8802; 0.9164)	0.8938 (0.8741; 0.9115)	0.9963 (0.9957; 0.9971)
V = 5, N = 1000, r = 0.60	0.7308 (0.7013; 0.7591)	0.7333 (0.7040; 0.7598)	0.9908 (0.9897; 0.9921)
V = 9, N = 1000, r = 0.60	0.8393 (0.8207; 0.8572)	0.8358 (0.8157; 0.8531)	0.9961 (0.9956; 0.9967)
V = 17, N = 1000, r = 0.60	0.8806 (0.8652; 0.8946)	0.8795 (0.8640; 0.8933)	0.9973 (0.9969; 0.9977)
V = 5, N = 100, r = 0.75	0.8092 (0.7312; 0.8683)	0.8269 (0.7548; 0.8798)	0.9779 (0.9658; 0.9866)
V = 9, N = 100, r = 0.75	0.9144 (0.8739; 0.9427)	0.9114 (0.8672; 0.9406)	0.9939 (0.9906; 0.9966)
V = 17, N = 100, r = 0.75	0.8989 (0.8538; 0.9329)	0.9022 (0.8545; 0.9344)	0.9935 (0.9883; 0.9965)
V = 5, N = 250, r = 0.75	0.8230 (0.7765; 0.8611)	0.8338 (0.7892; 0.8688)	0.9920 (0.9894; 0.9944)
V = 9, N = 250, r = 0.75	0.8762 (0.8393; 0.9059)	0.8794 (0.8439; 0.9072)	0.9958 (0.9943; 0.9971)
V = 17, N = 250, r = 0.75	0.9323 (0.9118; 0.9484)	0.9324 (0.9117; 0.9485)	0.9972 (0.9963; 0.9981)
V = 5, N = 500, r = 0.75	0.8689 (0.8445; 0.8898)	0.8701 (0.8462; 0.8905)	0.9933 (0.9915; 0.9949)
V = 9, N = 500, r = 0.75	0.8856 (0.8650; 0.9039)	0.8855 (0.8645; 0.9033)	0.9962 (0.9953; 0.997)
V = 17, N = 500, r = 0.75	0.9415 (0.9288; 0.9521)	0.9407 (0.9282; 0.9514)	0.9980 (0.9975; 0.9985)
V = 5, N = 1000, r = 0.75	0.8235 (0.8012; 0.8436)	0.8262 (0.8049; 0.8452)	0.9930 (0.9917; 0.9942)
V = 9, N = 1000, r = 0.75	0.9042 (0.8916; 0.9162)	0.9032 (0.8899; 0.9148)	0.9971 (0.9967; 0.9976)
V = 17, N = 1000, r = 0.75	0.9270 (0.9170; 0.9366)	0.9274 (0.9172; 0.9368)	0.9983 (0.9981; 0.9986)

LAF = Simulated latent factor; LFS = Latent factor score performed via confirmative factor analysis; SS: Score performed by the sum of items; V = Number of items; N = Sample size; r = Pearson correlation coefficient between the items

Table 5. Spearman correlation coefficients and 95% confidence limits obtained by bias corrected bootstrap with five level Likert not iso-correlated items with positive skewness

	Bootstrap Pearson correlation coefficients with 95% confidence limits		
Simulation Scenarios	LAF with LFS	LAF with SS	LFS with SS
V = 5, N = 100, r = 0.45	0.5423 (0.4058; 0.6575)	0.6021 (0.4765; 0.7039)	0.9057 (0.8589; 0.9385)
V = 9, N = 100, r = 0.45	0.7344 (0.6486; 0.8088)	0.751 (0.6624; 0.8227)	0.9541 (0.9360; 0.9698)
V = 17, N = 100, r = 0.45	0.7505 (0.6583; 0.8215)	0.7401 (0.6470; 0.8127)	0.9632 (0.9409; 0.9772)
V = 5, N = 250, r = 0.45	0.5820 (0.5015; 0.6530)	0.5900 (0.5164; 0.6570)	0.8719 (0.8390; 0.8982)
V = 9, N = 250, r = 0.45	0.7061 (0.6414; 0.7612)	0.6918 (0.6299; 0.7458)	0.9554 (0.9435; 0.9660)
V = 17, N = 250, r = 0.45	0.7945 (0.7448; 0.8366)	0.7974 (0.7463; 0.8376)	0.9783 (0.9716; 0.9839)
V = 5, N = 500, r = 0.45	0.6913 (0.6443; 0.7323)	0.6678 (0.6197; 0.7111)	0.9623 (0.9552; 0.9688)
V = 9, N = 500, r = 0.45	0.7179 (0.6769; 0.7551)	0.7015 (0.6595; 0.7400)	0.9752 (0.9698; 0.9798)
V = 17, N = 500, r = 0.45	0.8269 (0.7973; 0.8524)	0.8205 (0.7914; 0.8464)	0.9826 (0.9793; 0.9858)
V = 5, N = 1000, r = 0.45	0.6098 (0.5725; 0.6452)	0.5954 (0.5579; 0.6309)	0.9660 (0.9602; 0.9708)
V = 9, N = 1000, r = 0.45	0.7514 (0.7260; 0.7756)	0.7378 (0.7101; 0.7622)	0.9876 (0.9859; 0.9891)
V = 17, N = 1000, r = 0.45	0.8063 (0.7829; 0.8265)	0.7989 (0.7763; 0.8196)	0.9828 (0.9803; 0.9852)
V = 5, N = 100, r = 0.60	0.7456 (0.6585; 0.8153)	0.7450 (0.6540; 0.8144)	0.9568 (0.9368; 0.9724)
V = 9, N = 100, r = 0.60	0.8306 (0.7666; 0.8824)	0.8521 (0.7899; 0.8981)	0.9763 (0.9649; 0.9847)
V = 17, N = 100, r = 0.60	0.8634 (0.8053; 0.9059)	0.8521 (0.7871; 0.8977)	0.9837 (0.9737; 0.9907)
V = 5, N = 250, r = 0.60	0.7424 (0.6815; 0.7924)	0.7317 (0.6715; 0.7817)	0.9583 (0.9443; 0.9687)
V = 9, N = 250, r = 0.60	0.8237 (0.7792; 0.8609)	0.8082 (0.7628; 0.8466)	0.9848 (0.9794; 0.9888)
V = 17, N = 250, r = 0.60	0.8873 (0.8552; 0.9123)	0.8828 (0.8506; 0.9082)	0.9895 (0.9863; 0.9923)
V = 5, N = 500, r = 0.60	0.7983 (0.7635; 0.8289)	0.7745 (0.7367; 0.8066)	0.9779 (0.9730; 0.9824)
V = 9, N = 500, r = 0.60	0.8209 (0.7915; 0.8475)	0.8118 (0.7822; 0.8392)	0.9814 (0.9776; 0.9849)
V = 17, N = 500, r = 0.60	0.8971 (0.8774; 0.9135)	0.8897 (0.8694; 0.9076)	0.9906 (0.9887; 0.9925)
V = 5, N = 1000, r = 0.60	0.7496 (0.7217; 0.7760)	0.7435 (0.7157; 0.7691)	0.9757 (0.9718; 0.9791)
V = 9, N = 1000, r = 0.60	0.8452 (0.8271; 0.8627)	0.8353 (0.8152; 0.8527)	0.9935 (0.9927; 0.9944)
V = 17, N = 1000, r = 0.60	0.8816 (0.8656; 0.8954)	0.8780 (0.8623; 0.8921)	0.9916 (0.9903; 0.9928)
V = 5, N = 100, r = 0.75	0.8401 (0.7696; 0.8922)	0.8115 (0.7290; 0.8701)	0.9778 (0.9638; 0.9869)
V = 9, N = 100, r = 0.75	0.9126 (0.8688; 0.9422)	0.9139 (0.8695; 0.9437)	0.9849 (0.9788; 0.9909)
V = 17, N = 100, r = 0.75	0.9126 (0.8701; 0.9425)	0.9036 (0.8563; 0.9361)	0.9870 (0.9806; 0.9926)
V = 5, N = 250, r = 0.75	0.8295 (0.7830; 0.8666)	0.8210 (0.7722; 0.8596)	0.9747 (0.9616; 0.9828)
V = 9, N = 250, r = 0.75	0.8814 (0.8463; 0.9100)	0.8736 (0.8371; 0.9029)	0.9880 (0.9841; 0.9914)
V = 17, N = 250, r = 0.75	0.9364 (0.9159; 0.9518)	0.9302 (0.9079; 0.9471)	0.9926 (0.9904; 0.9948)
V = 5, N = 500, r = 0.75	0.8780 (0.8530; 0.8987)	0.8670 (0.8417; 0.8881)	0.9855 (0.9820; 0.9886)
V = 9, N = 500, r = 0.75	0.8914 (0.8712; 0.9089)	0.8834 (0.8625; 0.9019)	0.9898 (0.9879; 0.9917)
V = 17, N = 500, r = 0.75	0.9429 (0.9308; 0.9532)	0.9409 (0.9288; 0.9516)	0.9932 (0.9918; 0.9946)
V = 5, N = 1000, r = 0.75	0.8375 (0.8164; 0.8564)	0.8283 (0.8068; 0.8479)	0.9879 (0.9857; 0.9898)
V = 9, N = 1000, r = 0.75	0.9114 (0.8993; 0.9226)	0.9052 (0.8919; 0.9167)	0.9949 (0.9943; 0.9957)
V = 17, N = 1000, r = 0.75	0.9308 (0.9207; 0.9399)	0.9290 (0.9189; 0.9381)	0.9940 (0.9930; 0.9949)

LAF = Simulated latent factor; LFS = Latent factor score performed via confirmative factor analysis; SS: Score performed by the sum of items; V = Number of items; N = Sample size; r = Pearson correlation coefficient between the items

We observed that both LFSs and SSs are normally distributed and centred on 0, for normally distributed items while they are skewed when the scores are derived from skewed items.

The results above reported were confirmed by simulation conducted having 10% of items randomly assigned to a null correlation with the simulated latent factor. More specifically, in these simulation settings we only observed an overall reduction of the correlation between the simulated latent factor and the score computed from the variables.

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Empirical studies

Analysis of the SUS

The analytical dataset derived from the application of the SUS in a clinical setting was composed by 208 participants of which 112 (53.8%) were women. The median age was 68 years (5th to 95th range = 45.4 to 81) with a median year of education of 13 years (5th to 95th range = 5 to 17). We observed a strong correlation between the LFSs and the SSs, for the overall total score and for both the subscales of learnability and usability. Specifically, we observed a Spearman correlation coefficient of 0.928 between the total LFS and the SS. The Spearman correlation coefficients between the subscales of learnability and usability were in the same range (R=0.964 and R=0.957 for the learnability and usability subscales, respectively). Notably, we observed a strong left skewness of both the LFS and the SS for the total and the subscales of the SUS. The LFS and SS distributions and correlations for the total SUS and the subscales were reported on Figure 1.

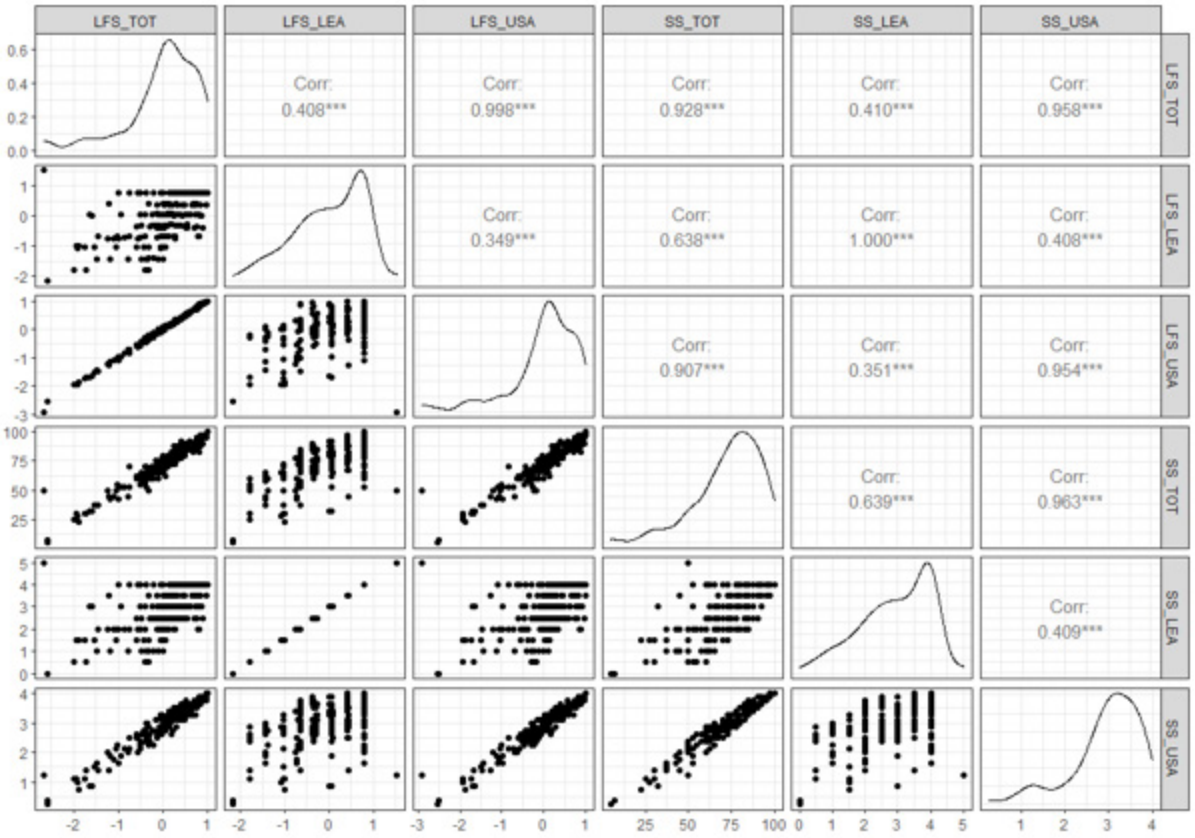
Analysis of the Yoni task

The Yoni task was administered to 235 participants (men=127 (54%)). The median age was 35 years (5th to 95th range = 19 to 54), the median education was 16 years (5th to 95th range =9 to 21). We reported a moderate to high Spearman correlation coefficient between the LFS and the SS for the total YONI scores (R=0.931) and for the subscales (R=0.942 and R=0.624, for the affective and cognitive subscales, respectively). Both of the LFS and the SS were positively skewed.

DISCUSSION

In the present work we showed some interesting aspects of the application of the SS and LFS approaches to derive scales' scores. Firstly, using numerical simulation we showed that the SS and the LFS are interchangeable when the items are iso-correlated to the latent factor. Basically, the fact that all the items have the same correlation with the latent factor corresponds with having the same weights in equation (1). Notably, those weights are not necessarily equal

Figure 1. Spearman correlations of latent factor scores and sum of items scores in the SUS



LFS_ = Latent factor score, SS_ = Sum of item's score, TOT = total score, LEA = Learnability score, USA = Usability score

to one when the LFS is performed via a confirmatory factor analysis but have the same value when the SS is performed. This is the reason why the correlation between the LFS and the SS tends towards one when the correlation between the items and the latent factors are all equals. Therefore, the LFS and the SS are asymptotically equivalent when the items are equally correlated. Here a sample size above 500 and even a minimal number of items seems to be sufficient to guarantee the equivalence between the SS and the LFS. Moreover, according to our numerical simulation, it seems that the correlations between the LFSs and the SS are extremely high also in the presence of different strength of correlation between the items defying the latent factor and for ordinal categorical skewed items as well. This result points out the hypothesis that the use of LFS and SS are interchangeable in most common situations met when analysing scales. In fact, we may assume the syllogism that if the LFS is the best way to represent a latent factor (as we report by our simulation) and the LFS is equivalent to the SS then the SS also can be used to portray that given latent factor. The quantitative nature of the interchangeability between the LFS and the SS could be a matter of discussion. Here it could be suggested that the two are interchangeable given a certain level of correlation, for example above 0.9.

The interchangeability of the LFS and the SS is in agreement with the work from Widaman and Revelle [9] but not with the work of McNeish and Wolf [8]. The congeneric measurement model is a general approach where it is assumed that every item is differently related to a given construct [6,21]. It is intuitively correct as we can imagine that not all of the items in a scale share the same ability to represent a given construct. However, the different correlations between an item and its latent factor does not seem to influence the correlation between a score computed by the sum of items or the one derived by the application of a confirmatory factor analysis.

This result is truly conditioned to our simulation settings. However, our simulations may not represent the reality of scales of common use where the items are generally well intercorrelated. Notably, our results seems as quite robust being confirmed for sets of low and high correlations between the items and the latent factors. On the other hand, we cannot exclude that this evidence would not be confirmed in more extreme settings. Specifically, when both high and low correlated items are present.

In conclusion to our simulation studies aimed to investigate the relation between the LFS and the SS, we can state that the correlation structure between the items determine the similarity between the LFS and the SS. The similarity between the LFS and the SS is remarkable in the situations likely faced during analysis of scales. Here the use of a SS or a LFS to portray the latent factors are quite interchangeable. Moreover, there is a specific reason that justify the use of SS over the LFS, the so-called "indeterminacy of the factor scores" [22–24]. Briefly, the indeterminacy arises from the fact that, when the latent factor is not unique there is not a unique solution for the factor analysis. As a consequence, a virtually infinite number of solutions could be derived to define the relationship between the items and the latent factor [23,24].

It seems that the SS and the LFS are quite similar in most of the cases. However, there could be a number of situation when this is not the case. We can imagine that extreme correlation structures between the items may results in large differences between the SS and the LFS. For example, when there are relatively few items that are strongly correlated to the latent factor and a plethora of items with small or null correlation with the latent factor, acting as disturbance or white noise variable. Intuitively, here the LFS will be more accurate to represent the latent factor than the SS. Our work provides some suggestions to identify some of these situations as we showed the importance of the correlation structure between the items. In this perspective, it could be recommendable to perform an exploratory factor analysis before deciding which approach use to derive a score [25–27]. According to the results of an exploratory analysis, the researcher could even decide to exclude some items if they are not sufficiently correlated to the latent factors to define the confirmatory factor model [28].

We showed that the SSs and the LFs are strongly correlated when the correlation between the items and the latent factors are similar. This same approach could be used reversely, deriving a LFS and the SS and look at their correlation before to conduct the further analyses or to decide which approach to use. Here we showed that in case of a strong correlation between the LFS and the SS it seems reasonable to adopt any of the two approaches, even according to personal preferences, practical aspects or believe. On the contrary, the existence of a moderate or weak correlation between the LFS and the SS could represent a question mark that deserves a further investigation.

Some interesting evidence emerged by the analysis of real data here provided. Firstly, it seems that it is not uncommon that the LFS and the SS are strongly correlated in real settings; this is more evident for the SUS then for the Yoni task instrument. Notably, the difference between LFS and SS we observed in the SUS compared to the Yoni task seems to be more related to specific features of the tools and possibly by the study sample than to the CTT or IRT type tools. Specifically, on the Yoni task instrument we observed differences between the SS and the LFS for the cognitive score only while the correlations between the SS and the LFS appeared as satisfactory for other scores. However, we cannot fully exclude that the type of tool may have played a role. Theoretically, the IRT items are not parallel instruments for each of them have its own IRF, this should determine inaccuracy of the SS even if the ranking of subjects should not be affected by its use [29]. However, we observed a high correlation between the SS and the LFS of the Yoni

total and affective scores. Both the LFS and the SS computed from the SUS and the Yoni task are skewed as the single items' score. This result is obvious when considering the loading of the single item should not improve the LFS and so the use of confirmatory factor analysis does not enhance the LFS distribution.

The present work has many strength points. Firstly, we showed when the two approaching of deriving scores from scales are equivalent. Here, we showed that in the most commonly situations the agreement between the two procedures is satisfactory, despite the presence of items with different correlations to the latent factors or even the presence of uncorrelated items that should determine a relevant difference between the two types of scores, at least theoretically. This is a relevant achievement because allows to use a simpler method to derive score's scales or even justify the use of sum of items scores, or relatively similar approaches, which is also intended to be used according to many scales' instruction manuals. Notably, our results are confirmed in different scenarios considering different sample sizes, correlation structures and items distributions.

Some limitations may have affected the present work. Firstly, the number of simulative scenarios may be limited by the number of items considered and the correlation range between the variables and the latent factors. Moreover, we simulated a very simple structure having only two latent factors while some scales may have a more complex structure. We did not observe any relevant differences when using different settings in some preliminary evaluation. However, many of the scales in use do not have such a complex structure and are composed with a limited number of items, for practical reasons of reducing the time to fill in the scale and because it seems that increasing the number of items does not necessarily improve the performances of the scale [30].

Finally, we explored strong and weak correlations between the items and the scale even if a moderate to strong correlation between the item and the scale should be assumed. Another possible limitation is the extensive use of simulations which have a limited capacity to represent the empirical complexity. However, we showed how simulative results are confirmed by real data.

ETHICAL STATEMENT

The project was approved by the ethic committee of the Don Gnocchi Foundation on 17.2.2021

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An Examination of Public Concerns Relating to Combined Text and Graphic Alcohol Warning Labels: An all-Ireland Cross-Sectional Study

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SUMMARY

Alcohol remains a serious threat to the health and wellbeing of people across the island of Ireland. Ireland introduced legislation to introduce mandatory alcohol warning labels (AWLs) in 2026, although implementation is deferred until 2028. The cross-sectional survey research sought to explore support for AWLs across the island. The remainder of the survey then explored concerns people had with more graphic AWLs, as well as exploring what additional warnings or information people would like to see displayed in AWLs. Responses were gathered from 475 staff members and students at two universities, one located in Ireland and the other in Northern Ireland. A high level of support for the proposed Irish AWLs was noted (77.9%), with support for more graphic cigarette-style AWLs lower at 60.2%. The potential development of graphic AWLs evoked a considerable range of concerns thematically arranged as 1) Children; 2) Desensitisation; 3) Risks Over-played; 4) No Impact; 5) Unpleasant Viewing; 6) Addiction; 7) Trauma Trigger; 8) Stigmatisation; 9) Diverse Warnings. Although overall there is support for AWLs amongst the convenience sample, there remains confusion about the need and intent of AWLs. Further research is therefore recommended.

Keywords: Alcohol; Alcohol Control; Alcohol Warning Labels; Health Promotion; Public Health; Ireland

INTRODUCTION

Alcohol consumption is a commercial determinant of health (CDoH) that has a significant negative impact on individuals, families, communities, and the environment [1-4]. The impact of alcohol on global mortality and morbidity is significant. In terms of mortality, alcohol consumption is responsible for more than 3 million deaths per annum globally. Looking at morbidity, in excess of 5% of the total global burden of disease and injury is attributable to alcohol [5-6]. In their recent analysis for the European Commission, Chua et al. identified 16 diseases directly attributable to alcohol [7]. However, the wider negative impacts of alcohol on the self, partners, families, children and communities must also be acknowledged [8-13]. Ireland and Northern Ireland are no exception, and the negative impacts of alcohol and the need for alcohol controls are very evident in both jurisdictions [14-18].

Considering the threat posed by alcohol the Irish Government passed the Public Health (Alcohol) Act, 2018 [19], in recognition of the central role of policy in protecting the health of nations [20]. Although this Act, and related legislation, has come under criticism for its slow roll-out, identified deficits, and poor enforcement [21-29], it still represents an important achievement for alcohol control in Ireland, and many of the general public endorse the principles of the Act [30-31]. The

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Public Health (Alcohol) Act included a wide suite of measures [19], some of the most notable being the introduction of minimum unit pricing [32], and strict restrictions on advertising. Although Ireland faced intense legal opposition from regional and global forums [33], the Act also mandated that starting in May 2026 a prescribed alcohol warning label (AWL) would be required on all containers of alcohol sold in Ireland [34]. The introduction of the AWLs has been postponed by the Irish Government until 2028 [35].

As is evident in Figure 1, this alcohol warning label includes a focus on the dangers of developing both liver disease and cancer associated with alcohol consumption (Figure 1). The AWL also includes a pictogram warning pregnant women not to drink, as well as nutritional information, and a website address for additional information supplied by a governmental body in Ireland [36].

Figure 1. Ireland's Proposed Alcohol Warning Label [36]

Although the causal link between alcohol consumption and liver disease is well known [37-38], the inclusion of a cancer health warning on alcoholic beverages as part of Europe's Beating Cancer Plan has focused significant attention on the issue of AWLs over the last 5 years [39]. The U.S. Surgeon General's 2025 Advisory on Alcohol and Cancer Risk has contributed to a consensus on this issue, at least among the Public Health community [40]. The US has had a mandatory text warning on distilled spirits labels since 1988 [41]. However, as Figure 2 shows, this refers mainly to pregnancy, cognitive performance, and general health risk. Unlike the US warning (Figure 2), the mandated Irish alcohol warning label does not feature signal words such as 'warning' or 'danger' (see Figure 1). However, the 2025 European Commission study on effective alcohol warning labels specifically notes the importance of the use of these words [7].

GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

Figure 2. The health warning statement required on distilled spirit labels under the Alcoholic Beverage Labelling Act (ABLA) of 1988 [41]

A recent European Commission report has noted the lack of awareness of the health risks of alcohol consumption [42]. This report also rejected self-regulation and co-regulation with industry and supported the use of alcohol warning labels [42]. Although there are some contrary findings [43-46], there is increasing evidence to support the use of alcohol health warning labels [47-53]. The findings of the European Commission's AlHaMBRA Project investigating alcohol warning messaging suggest a combination of images and text should be used in AWLs and should focus on cancer and the harm to the unborn [52]. This report also highlighted the importance of a prescribed size, position, border and colouring of such warnings. Although Ireland's proposed warning includes a pictogram warning against drinking alcohol while pregnant, it does not feature similar images for the cancer and liver disease messaging, which may reduce their impact [54].

Further research on AWLs has been called for [55]. In an investigation of AWLs in France, Dossou et al. noted that respondents found the warnings to be vague, lacking credibility, and ineffective [56]. Graphic warnings can also result in greater reactance and therefore resistance to such warnings [57 58 59]. May et al. have noted that the 'alcohol causes cancer' message may be a difficult message to accept amongst some populations [59]; people's individual perception of risk around alcohol is an important part of the message getting through [60]. Care is also needed to avoid health warnings contributing to stigma. This is particularly relevant to warning labels that use pictorial images of women who are pregnant and who may feel stigma or shame when viewing these images. However, Wolfson and Poole emphasise that a supportive alcohol policy must be at the centre of raising awareness of Foetal Alcohol Syndrome, at individual and societal levels [61]. Examples of supportive alcohol policies include alcohol warning labels, routine screening and brief interventions.

In summary, alcohol warning labels, can differ in message and delivery. Evidence is emerging about which elements of the nature of alcohol warning labels might reach populations we hope will benefit. This study aimed to investigate the level of support for AWLs among an all-Ireland sample, as well as to explore the types of information people wanted to see on AWLs. This study also sought to understand any concerns respondents might have about AWLs.

METHOD

Data was collected via a cross-sectional convenience sample of students and staff at two universities on the island of Ireland. One university is a traditional red-brick high status university, the other is newer and more vocationally oriented technological university that caters to a more diverse student population within

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a more regionally focused context [62]. Potential respondents were invited to participate in an online (MS Forms) survey. Data were downloaded via Excel and examined in SPSS (closed questions) or NVivo (open-ended questions). The survey consisted of three elements: demographic questions, closed questions, and open-ended questions. The closed questions included two questions asking about AWLs, alongside an image of both the proposed Irish AWL (see Figure 1) and a current combined text and graphic lung cancer warning, as required under EU regulations [63]. Two open-ended questions followed this section. The two questions asked were 'Are there any concerns you would have about alcohol warning labels that contained graphic images?' and 'Is there any other information you would like to see/ would not like to see on alcohol warning labels?'.

Following recommendations concerning data immersion, all open-ended data were read three times prior to analysis [64]. Open-ended questions were examined using reflexive thematic analysis [65-66]. All data were analysed independently by FH and JMS and agreed upon. The first author is a heterosexual married man and father in his mid-50s, with a background in public health geography. His research experience and interests include tobacco, gambling and alcohol control. He is a non-drinker. The second author is a heterosexual married woman and mother in her mid-50s. Her professional background is as a social worker and thanatologist. She has professional experience working with homeless populations who have substance use problems, and is a minimal social drinker. Reflective logs were kept, facilitating the reflexivity required in the research process [67-68]. All authors reviewed and refined the final themes.

RESULTS

Responses were collected from 475 participants. Males constituted 27.4% (130) of the sample and females 70.5% (335). Ten respondents (2.1%) described themselves as Non-binary/Gender fluid. The participants ranged in age from 18 to 73, with a mean age of 37.0 (SD = 14.3 years). As shown in Table 1, the results demonstrate a high degree of support for the proposed Irish AWLs. 77.9% (370) of respondents strongly supported or tended to support their introduction, with only 9.9% (47) opposing. Support for graphic cigarette-style AWLs was somewhat lower at 60.2% (291), with 26.3% (125) opposing.

Level of support & opposition	Support for the proposed Irish AWL	Support for Graphic 'Cigarette Style' AWLs
Strongly support	48.4% (230)	38.5% (183)
Tend to support	29.5% (140)	22.7% (108)
Neither support nor oppose	12.2% (58)	12.4% (59)
Tend to oppose	6.5% (31)	16.0% (76)
Strongly oppose	3.4% (16)	10.3% (49)

Table 1. Levels of Support & Disagreement for the Introduction of Alcohol Warning Labels

Using reflective thematic analysis, a total of nine themes were identified. These were Children; Desensitisation; Risks Over-played; No Impact; Unpleasant Viewing; Addiction; Trauma Trigger; Stigmatisation; Diverse Warnings. Blaming women was identified as a sub-theme of Stigmatisation.

A notable theme identified was 'Children'. This theme encapsulated a concern of how warning images might adversely affect them. This can be seen in the following extracts where some spoke of concerns for their own children, and some children in general:

"That they would be visible to children in shops which could be traumatic for them."

"If a child saw them, depending on how graphic it would traumatise the child"

"Whilst cigarette packets are hidden in shops, if alcohol had the same labels it would need to be hidden also. I do not like the idea of my children seeing such graphic images."

"Perhaps just making sure they are not too graphic to scare children but at the same time it would be good to warn children of alcohol's effects."

As can be seen from these responses, some respondents felt that graphic AWLs could potentially traumatise a child. Concern of the exposure of young people to inappropriate content is not new, dating back decades [69]; however, in more recent times, online exposure has been a concern. However, physical images remain a concern [70].

The second theme identified was Desensitisation. This theme related to the perceived erosion of the impact of graphic AWLs over time, where they would cease to have an effect. Evidence of this theme can be seen in the following quotations:

"People would be desensitised to the images over time."

"I'll become desensitised to it just like I did with cigarettes."

"People become immune to graphic images."

Desensitisation to warning labels has been noted in the cognate field of tobacco control research [71-73]. However, combined text and graphic tobacco warning labels remain a powerful tool in tobacco control [74-75].

The third theme identified was termed Risks

Overplayed. As some drinkers did not consider the risks applied to them, they appeared to reject the 'need' for alcohol warning labels. For some, they considered tobacco to be more dangerous than alcohol, and that the risks were not comparable. This can be seen in the following extracts:

"I think the risks are overplayed and graphic images will not assist."

"It tends to demonise alcohol but moderate/low levels of alcohol are safe and ok."

"I don't think tobacco/nicotine consumption and moderate alcohol consumption carry the same risks. To me, it makes sense to have those images on cigarette packets, as smoking even occasionally can be harmful, but I think having graphic images on alcohol would be excessive [I am open to correction!]"

It is interesting to note that this denial of the need for action is similar to one of the standard strategies of the alcohol industry to avoid government regulation. As part of this suite of strategies, they routinely deny that action is required, divert attention away from the issue, and delay any form of regulation [76-78].

The fourth theme identified was the concept of No Impact, which was identified in the responses. This theme was based on the idea that AWLs are essentially redundant as they will have no impact on consumer drinking habits. This can be seen in the following quotes:

"I don't think having warnings or images on alcohol is going to make a massive difference in the overall purchasing or intent on consuming alcohol"

"I don't think warning labels will deter people from becoming addicted."

"They will most likely be ignored."

"It tends to not deter anyone from smoking, so chances are it wouldn't deter people from drinking either. It's simply unpleasant to look at."

All of these responses perceive that AWLs may have minimal impact. AWLs do have an evidence base, working alongside a suite of alcohol control initiatives [47-52], but it might be argued that individuals surveyed here are unaware of or unconvinced of the evidence.

Another theme to emerge was that of 'Unpleasant viewing'. Respondents reported that they found warning imagery to be unpleasant. This theme can be seen in the extracts below:

"For someone trying to enjoy themselves or celebrate occasionally, seeing graphic images like those on cigarette packaging is not very pleasant."

"For me personally, I don't want to see these images."

"It's just off putting."

This finding is notable as the proposed Irish AWL does not feature any of the stark imagery used for some other addictive products. Presumably, this response relates to some of the EU-mandated tobacco warning labels which can be quite graphic [63]. Such warnings do routinely include images designed to evoke fear and disgust to deter smokers and would-be smokers [79-81]. The concern that it is "off putting" perhaps speaks to concerns of whether their enjoyment may be influenced by AWLs in contrary to pleasure in alcohol consumption [82].

The sixth theme identified was that of Alcohol Dependence. Some respondents felt that the current warnings do not adequately convey the risk of alcohol dependence, or the addictive potential of alcohol. This can be seen in the following quotations:

"I would like acknowledgements that drinking alcohol can lead to dependency on it or addiction in some situations."

"alcoholism warning signs"

"The risk of addiction"

"More information on the definition of alcoholism/addiction and dependence particularly in Ireland. I believe that many people have no idea that the quantity of alcohol they consume per week could be categorised as dependent."

The addictive nature of alcohol is well-known and widely acknowledged [83-85]. In contrary to other perceived risks (e.g. risk of cancer or liver problems), this appears to be an important risk to the public, and one that is missing. This could be, because as the first one indicates, they only see the risk applying in some circumstances [60].

Another important theme identified within the data was termed Trauma Trigger. This theme was concerned that graphic images could potentially serve as a trigger to some people that would link to past negative experiences. This can be seen in the following quotations:

"If in a bar/restaurant and all individual bottles have graphic images they may be triggers from previous trauma for people."

"Could be a trigger for people's mental health depending on their own personal experiences."

"Graphic images relating to pregnancy or development of the child could upset or trigger people who are experiencing child loss or have FAS themselves."

"Depending on the topic, it might be triggering to people to see these pictures and cause them to drink more, or it could become a deterrent"

There has been a significant increase in the focus on trauma in recent years [86-89]. There are calls to explore the interplay between trauma and alcohol [90], however, it is unclear how these warning labels might contribute (or not) to short- or long-term trauma for individuals at risk.

The eighth theme identified related to Stigma. Some respondents felt that the warnings could further stigmatise people who are alcohol dependent or who are experiencing alcohol problems. This can be seen in the quotations below:

"Could potentially lead to stigmatising people who are alcohol dependent further."

"One concern I would have is a lack of sensitivity towards those who suffer/have suffered from similar issues to those graphically displayed on packaging, particularly in consideration of the high prevalence

and visibility of alcohol products across Irish society. A fear-led approach to harm reduction could also lead to unfair judgment against individuals with addiction or other ill-health"

"The potential for increasing stigma towards problematic alcohol users"

Stigma is a powerful force within society [91], and most people strive to present themselves favourably to those around them most of the time [92]. Excess alcohol use can be both highly celebrated, but also highly stigmatised [93-98].

A sub-theme relating to stigma identified through this research was that of blaming women. Several participants felt that AWLs could become yet another tool to criticise women. This feeling was evident in the following quotes:

"Leave out the pregnancy warnings, there's enough judgment and far too much advice given to pregnant women, the last thing they need is to be judged if they're having a small glass of wine now and again. I would strongly object to singling out pregnant people."

"I would be concerned that issues relating to women are not construed as shaming."

"In terms of alcohol and pregnancy and FASD risk, I think this information is vital and necessary but am concerned that some people think women are being blamed."

"That women will be vilified more in relation to pregnancy and alcohol consumption."

The strength of feeling related to this theme is very evident in the use of terms such as 'judged', 'shaming', 'blamed', and 'vilified'. Respondents raised concerns over the warnings leading to increased blame and stigma targeted at pregnant women who do consume alcohol [99-100].

The final theme identified in this research was the breadth of information that people thought should be included in alcohol warning labels. This theme was termed Diverse Warnings. These included, for example, a range of what might be termed environmental concerns. Some respondents expressed a desire for information on: water quality in the region of origin, pesticides and organic status, soil heavy metals, and the carbon footprint. Example quotes include:

"info about pesticides or organic status of grains/ fruit used to make alcohol water quality in region used to make alcohol info on whether heavy metals tested and results"

"Environmental… e.g. how much carbon is used to produce and distribute"

Other respondents sought a significant expansion of the financial information available on the warning to include issues such as Eurozone price comparisons, the allocation of the minimum unit price requirement increase to retailers, VAT and excise information, and information on the manufacturer's ownership. Exemplars of such quotes include:

"I would like to see a Eurozone comparison of the price of a particular drink in comparison to its Irish price in order to allow drinkers to see how much they are being additionally charged for it. Also, for consumer transparency, any alcohol sold under minimum unit pricing needs to expressly state how none of the additional money collected goes to the exchequer and that it only goes to the retailers."

"Vat and excise portion of cost"

Several respondents requested that the alcohol warnings covered a wider range of health issues associated with alcohol, including: the number of deaths from alcohol; alcohol-related brain injury; FASD; alcohol-related suicide; breast cancer; the dangers of young people drinking alcohol; the dangers of the elderly drinking alcohol; vomiting; drink-driving; and risk-taking, including unprotected sex. Examples of such statements include the following:

"Effects on mental health also number of young people that have alcohol related deaths"

"Need to see: Impact of alcohol on brain health across lifespan - FASD, Teenage Brain, Wernickes Korsakoffs and Dementia."

"Risky behaviour including Sex without protection."

Some respondents also voiced a desire to see warnings that addressed such issues as alcohol's link with violence, public order, rape, domestic violence, child neglect, and social, emotional and financial impacts.

"The link between domestic violence & child neglect and alcohol"

"Perhaps a greater emphasis on the social, emotional and financial impact of alcohol abuse/ misuse"

"rape and death driving rates under the influence of alcohol"

Several respondents voiced support for information on allergens, calorific content, caffeine content, and the danger of combining alcohol and cocaine. This can be seen in the following quotes:

"I strongly think the issue of the combined effects of Alcohol & Cocaine use SHOULD be highlighted as part of any campaign."

"Would like to see allergens and alcohol by volume."

Finally, other respondents suggested that the warnings should feature well-known celebrities discussing the dangers of drinking. Others argued that alcohol warning labels should also be in braille. Evidence for this can be seen in the following statements:

"I would like to see images and text in braile"

"About 10 years ago there was a campaign against smoking featuring the actor Yul Brynner, warning against the dangers of smoking. It was only released after he died of lung cancer. Perhaps warnings from public figures about how there is basically nothing beneficial to your health about the use of alcohol, and there is no safe amount to take in pregnancy etc. would be effective."

As can be seen from the extracts above the Diverse Warnings theme clearly demonstrates the wide breadth of information that respondents would like to see featured on AWLs.

DISCUSSION

This all-Ireland mixed methods study identified considerable support for the proposed Irish AWLs at 77.9%. High levels of support for such warning labels have been noted elsewhere [101]. Support for graphic cigarette-style AWLs was lower at 60.2%. The potential development of AWLs evoked a considerable range of concerns. These concerns focused on nine themes, including a simple distaste for such images (Unpleasant Viewing), as well as concerns over their potential adverse impact on young people (Children). It was also felt that such images could harm those with prior alcohol related trauma (Trauma Trigger), and those using alcohol or alcohol dependent (Stigmatisation; Blaming Women). Respondents also denied the utility of AWLs, stating that they were unnecessary (Risks Over-Played), would have minimal impact (No Impact), or would only have short-term effects (Desensitisation). The final themes identified are related. Respondents argued in favour of an extensive range of warnings and information on AWLS (Diverse Warnings), and felt a key risk, addiction was missed. This concern about policy change and what it might mean amongst the public is an important consideration in effectiveness [102,30].

AWLs are relatively new, certainly as a legal requirement within Ireland or the rest of Europe. The AWLs introduced voluntarily to date have tended to be small, inoffensive, and rather bland. Any significant change is likely to invoke concerns, as it was when graphic warning images were first introduced on tobacco packaging to help combat the scourge of smoking. However, the damage wrought by alcohol is such that decisive action is required [1,5-6]. AWLs have significant potential as a means of alcohol control [42-55,103], and as such should be mandated both within the EU and globally as soon as possible. Alcohol consumption must also become denormalised. Therefore, ethically sensitive further research needs to be conducted with specific groups to identify how to address potential concerns they may have regarding graphic AWLs. Such groups should include children, pregnant women, and those with past or current alcohol addiction issues.

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Risk factors of multidrug-resistant gonococcal infections: an analysis of data from the sentinel surveillance network- Québec, Canada, 2017–2019

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SUMMARY

The emergence of antimicrobial resistance (AMR) in *Neisseria gonorrhoeae* is a worrying global phenomenon, with major implications for public health. This study, a cross-sectional analysis of an open cohort, explored the risk factors associated with multidrug-resistant (MDR) gonococcal infections in the province of Québec, Canada, using data from the sentinel surveillance network from 2017 to 2019. The data comprised sociodemographic, epidemiological, and clinical information, collected through self-administered questionnaires, direct case interviews and chart reviews coupled with laboratory AMR data for five antibiotics: azithromycin, tetracycline, ciprofloxacin, cefixime, and ceftriaxone. Missing data were handled using multiple imputation with chain equations (MICE); generalized estimating equations (GEE) were used to assess correlates of MDR. The analysis included 714 participants with a total of 775 cases. We observed very frequent resistance to ciprofloxacin (74.3%), while resistance to tetracycline and azithromycin was 19.9% and 21.3%, respectively. MDR was found in 12.5% of cases. Multivariate analysis indicated that having five or more sexual partners in the past two months (aPR=1.61, 95%CI: 1.07-2.41) was associated with MDR. In conclusion, our results show an association between the number of sexual partners and MDR, supporting the hypothesis that resistance can develop more rapidly in dense sexual networks. It is crucial to address the issue of circulating resistant strains through ongoing surveillance, research, and targeted interventions to manage and contain them before they become widespread.

Keywords: Gonococcal infections, Multidrug resistance, Québec, Surveillance

INTRODUCTION

Antimicrobial resistance (AMR) among *Neisseria gonorrheae* represents a major threat to effective therapies, complicating both clinical management and public health control. In 2020, estimates showed that 82.4 million people were newly infected with gonorrhea; showing the seriousness of the situation [1]. This observed persistent high incidence could be due to several factors and among others, we can mention: urban residence, sexual orientation, sexual intercourse without condom use, alcohol and illicit substance abuse, socioeconomic factors, low screening rate, cultural and practice-related factors (beliefs surrounding antibiotic use, availability of over-the-counter antibiotics, doctor-patient relationships) and last but not least, AMR of circulating strains [2]. Given this background, the WHO has warned of the emergence of non-treatable cases of gonorrhea in the near future [3]. Canada has seen an increase in gonococcal cases in most provinces. There has been an increase of 65.4% between 2010 (33.5 cases

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per 100,000 population) and 2015 (55.4 cases per 100,000 population) [4]. In 2021, there was a further major increase in gonococcal infection rates to 84.2 cases per 100,000 population [5]. In the province of Québec in particular, this problem requires closer attention as the incidence rate has increased from 11.7 per 100,000 population to 84.8 per 100,000 population between 2002 and 2022 [6]. A laboratory-based surveillance program has been in place in the province of Québec to monitor *N. gonorrhoeae* AMR. Isolates received as part of that surveillance represent approximately 20% of cases reported, and strains resistant to various antibiotics have been documented [7–10]. In addition, epidemiological and clinical data were available for a subset of isolates as part of a sentinel surveillance network. A common limitation in surveillance systems is the presence of incomplete data on key clinical, behavioural, and sociodemographic variables. The "missingness" in data can lead to biased estimates and possibly affect the study conclusions; yet deep methodological considerations around data completeness are rarely emphasized in applied surveillance studies.

Leveraging data from the sentinel network, an open cohort for gonococcal infection surveillance in Québec, we pursued two objectives in the present study: (1) to determine correlates of MDR *N. gonorrhoeae* infections, and (2) to compare analyses performed with and without multiple imputation of missing data in order to assess the robustness of findings.

METHODOLOGY

Study setting, design and participants

This study used data from the sentinel surveillance network, which was an open cohort for gonococcal infections, implemented in three regions of the province of Québec (Montréal, Montérégie and Nunavik), from September 2015 to March 2020. As previously described, individuals who tested positive for *N. gonorrhoeae* at one of the 26 sites of the sentinel surveillance network and were at least 14 years old at the time of the consultations were enrolled in the study after consent. The collection of sociodemographic, epidemiological, and clinical information was made possible by a combination of auto-administered questionnaires, direct case interviews, as well as chart reviews. More information on the design of the sentinel network and the laboratory procedures at the Laboratoire de santé publique du Québec (LSPQ), where all samples were sent, can be found in previous publications [7,10,11].

Data extraction and study variables

The laboratory findings obtained from the LSPQ were integrated with sociodemographic, epidemiological, and clinical information gathered through the sentinel surveillance network. Subsequently, the database underwent a denominalization process to safeguard the anonymity of patient data. For the purpose of this study, we extracted data collected from 2017 to 2019. In this study, we covered the resistance profile of five antibiotics: azithromycin, tetracycline and ciprofloxacin; and increased minimum inhibitory concentration (MIC) of 3rd generation cephalosporins (3GC), namely cefixime and ceftriaxone. Due to the very low prevalence of isolates showing decreased susceptibility to 3GC, the cut-off point was based on literature reviews, with the aim of examining the emergence of an increased MIC to the 3GC. The cut-offs used to define the resistance or increased MIC level to different antibiotics can be found in Table 1.

The main outcome was the MDR status of *N. gonorrhoeae isolates*. MDR was defined as 1) resistance to ciprofloxacin AND 2) resistance to tetracycline AND 3) either resistance to azithromycin OR increased MIC to 3GC (cefixime or ceftriaxone) [12].

Independent variables included basic sociodemographic characteristics (age, residency area, gender, etc.) as well as epidemiological information (number of sex partners in last 2 months, sex outside of the province, previous STBBIs, etc.)

Statistical analyses

Descriptive statistics of baseline characteristics as well as specific resistance levels were presented in frequency tables or figures with counts and percentages.

Using generalized estitmating equations (GEEs), regressions analyses (univariate and multivariable) were carried for assessing correlates of MDR. Results were presented in terms of prevalence ratios (PRs) and their 95% confidence intervals (CI) [13,14]. The final multivariate analysis included all collected variables identified *a priori* in the literature review. A p-value<0.05 was considered statistically significant. GEEs were used to account for correlation between multiple visits by same individuals and the resulting dependence on variance estimates. Multivariate adjusted prevalence ratio (aPR) were computed with log link, poisson distribution and robust "sandwich" variance estimator, which corrects for potential problems caused by overdispersion.

Another aspect of this study was that we compared two procedures for handling missing data. The first one, used in a previous study [7], involved adding a "missing indicator" for variables with more than 20% missing data, a simple but less ideal approach. The second procedure, which we employed here, was

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Table 1. Cut-offs of resistance or increased MIC to tested antibiotics

ANTIBIOTICS	Resistance	Increased MIC	REFERENCE
azithromycin	MIC ≥2 mg/L	-	[7,31,32]
cefixime	-	MIC ≥ 0.06 mg/L	[8,33]
ceftriaxone	-	MIC ≥ 0.03 mg/L	[8,34]
tetracycline	MIC ≥ 2 mg/L	-	[8,35]
ciprofloxacin	MIC ≥ 1 mg/L	-	[8,34]

MIC: minimal inhibitory concentration

multiple imputation using chained equations (MICE), a more robust but complex technique. By analyzing correlations before and after data imputation with MICE, we assessed the robustness of findings and the impact of missing data on our results. MICE is flexible and can accommodate various types of missingness and variable distributions, making it widely used in practice [15–17]. We performed multiple imputations using n=90 iterations, with a seed value of 12345, and employing the Fully Conditional Specification (FCS) method to ensure robust and reproducible results.

Analyses were performed using R version 4.3.2 and the SAS statistical suite software version 9.4 (SAS Institute Inc., Cary, NC, U.S.).

Ethical considerations

Because these analyses were for population health surveillance purposes, this study was considered non research in accordance with the Québec Public Health Act (2001, c. 60, a. 36; 2009, c. 45, a. 13). The project was reviewed by the Québec Public Health Ethics Committee and individuals were notified of the data collection and given the opportunity to opt out.

RESULTS

Baseline characteristics of participants

The study covered 714 participants with a total of 775 cases of gonococcal infection during the period between January 1, 2017, and December 31, 2019. Two cases were excluded because MIC values were missing.

The most prevalent age group was individuals over 35 years old (43.1%) and the most frequent anatomical site of infection was the urogenital site (69.1%). The majority of participants (85.0%) were men who have sex with men (MSM). Most resided in the region of Montréal (71.1%), and 33.8% of participants had five or more sexual partners in the last 2 months. Table 2 presents the baseline characteristics of participants.

Resistance / increased MIC levels

Ciprofloxacin was the antibiotic against which the highest frequency of resistance was observed (74.3%). The frequencies of resistance against tetracycline and azithromycin were respectively 19.9% and 21.3%. The proportions of increased MIC of 3GC were 9.4% for cefixime and 13.3% for ceftriaxone. Figure 1 displays the percentage of specific resistance/increased MIC levels for each antibiotic among *N. gonorrhoeae* cases in Québec, Canada, between September 1, 2017, and December 31, 2019.

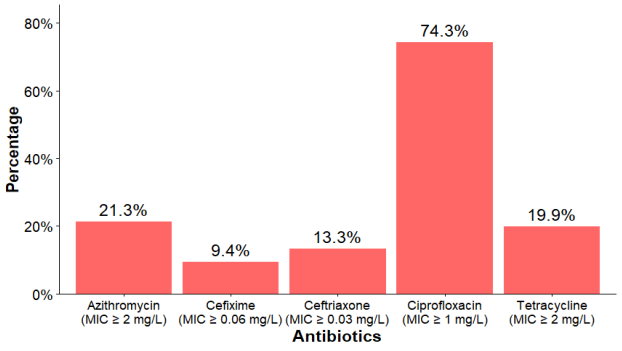

Figure 1. Specific Resistance/Increased MIC levels against each antibiotic

Table 2. Baseline characteristics of study participants between 2017 and 2019 (N=714)*

Characteristics	n	Percentage
Anatomical site of infection		
Urogenital	493	69.1%
Rectal	136	19.1%
Pharyngal	85	11.9%
Sex of sexual partners (past year)		
MSM	607	85.0%
HSM/W	107	15.0%
Age group		
Less than 25 years	131	18.4%
25 to 35 years	275	38.5%
More than 35 years	308	43.1%
Residency area		
Montréal	508	71.2%
Outside Montréal	206	28.9%
Number of sex partners (past 2 months)		
0 to 4	473	66.2%
≥ 5	241	33.8%
Material Deprivation Index		
Q1 (most privileged)	143	20.0%
Q2 to Q4	441	61.8%
Q5 (most deprived)	130	18.2%
Sex outside of Québec (past 2 months)		
Yes	137	19.2%
No	577	80.8%
Money, drugs, or other given or received in exchange for sexual relations (past year)		
Yes	114	16.0%
No	600	84.0%
Previous STBBIs		
None	231	32.4%
HIV	138	19.3%
Other than HIV	345	48.3%

MSM - men who have sex with men; HSM/W- heterosexual men and women; STBBIs-sexually transmitted and bloodborne infections; Q - quintile.
** After multiple imputation for sex of sexual partners (1.26% missing), number of sexual partners (13.3% missing), previous STBBIs (8.1% missing), sex outside of Québec (34.5% missing), material deprivation index (6.3% missing), and money, drugs, or other given or received in exchange for sexual relations (27.9% missing). There were no missing values for age, region of residence, and anatomical site of infection.*

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As summarized in Table 3, 12.5% (97/775) of *N. gonorrhoeae* isolates were classified as MDR. The most common MDR pattern, present in 4.9% of the isolates, included resistance to azithromycin, tetracycline, and ciprofloxacin, with varying susceptibility to ceftriaxone and cefixime. In contrast, 87.5% (678 isolates) were not classified as MDR, with the largest group (44.1%) showing susceptibility to azithromycin and ceftriaxone but resistance to ciprofloxacin.

Correlates of MDR gonococcal infections

The multivariate analysis using GEEs aimed to identify correlates of MDR among gonococcal infections, as detailed in Table 4. Data on all cases of gonococcal infections (n = 775) were included in the analyses.

Across analyses using both imputed and non-imputed datasets, certain factors showed consistent associations with MDR, though none of the variables demonstrated statistical significance. Examining age groups revealed interesting findings. Before imputation, the aPR was 1.65 (95% CI: 0.87-3.11, p-value: 0.118) among individuals aged 25 to 34 years and 1.28 (95% CI: 0.67-2.45, p-value: 0.453) among those aged 35 years or more. After imputation, the aPRs were 1.64 (95% CI: 0.85-3.17, p-value: 0.135) and 1.27 (95% CI: 0.65-2.49, p-value: 0.471), respectively. The number of sex partners in the past two months displayed notable associations. Before imputation, the aPR was 1.61 (95% CI: 1.07-2.41, p-value: 0.020 among individuals with five or more partners) compared to those with fewer partners. After imputation, the aPR slightly decreased to 1.52 (95% CI: 0.99-2.36, p-value: 0.054). Furthermore, other factors such as sexual orientation, having given or received money or drugs in exchange of sex exhibited aPR >1 but also did not demonstrate statistically significant associations with MDR.

Table 3. Resistance/Increased MIC to multiple antibiotics

Antibiograms						
azithromycin	**ceftriaxone (≥ 0.03 mg/L)**	**cefixime (≥ 0.06 mg/L)**	**tetracycline R**	**ciprofloxacin R[a, b]**	**n**	**Percentage**
Isolates classified as MDR					**97**	**12.5**
S	X	X	R	R	38	4.9
R			R	R	33	4.3
R	X		R	R	10	1.3
S	X		R	R	9	1.2
S		X	R	R	4	0.5
R	X	X	R	R	3	0.4
Isolates not classified as MDR					**678**	**87.5**
S			S/I	R	342	44.1
S			S/I	S/I	131	16.9
R			S/I	R	77	9.9
S			R	S/I	38	4.9
R			S/I	S/I	20	2.6
Other susceptibility profiles[c,d]					70	9.0
Total number of isolates					**775**	**100.0**

R: resistant; S: susceptible; S/I : susceptible or with intermediate susceptibility
[a] Including one isolate not susceptible to cefixime (MIC = 0.5 mg/L) and with decreased susceptibility to ceftriaxone (MIC = 0.12 mg/L);
[b] Including one isolate with decreased susceptibility to cefixime (MIC = 0.25 mg/L)
[c] Including two isolates with decreased susceptibility to cefixime (MIC = 0.25 mg/L), azithromycin S, ceftriaxone (MIC = 0.03 mg/L), tetracycline R and ciprofloxacin S/I;
[d] Isolates not classified as multidrug-resistant and n < 20.

Table 4. Multivariate analysis of correlates of multidrug resistance among gonococcal infection cases, sentinel surveillance network, Québec, Canada, 2017–2019

a-Before MICE imputation[a]						b-After MICE Imputation*					
	Characteristics	**aPR**	**95% CI**		**P-value**		**Characteristics**	**aPR**	**95% CI**		**P-value**
Age group	< 25 ans	1	-	-	-	**Age group**	< 25 ans	1	-	-	-
	25 to 34	1.65	0.87	3.11	0.118		25 to 34	1.64	0.85	3.17	0.135
	≥35	1.28	0.67	2.45	0.453		≥35	1.27	0.65	2.49	0.471
Residency area	Outside Montréal	1	-	-	-	**Residency area**	Outside Montréal	1	-	-	-
	Montréal	1.02	0.64	1.63	0.914		Montréal	0.99	0.61	1.60	0.968
Sexual orientation	HSM/F	1	-	-	-	**Sexual orientation**	HSM/F	1	-	-	-
	MSM	1.14	0.58	2.26	0.687		MSM	1.12	0.55	2.25	0.744
Number of sex partners in the past 2 months	0 - 4	1	-	-	-	**Number of sex partners in the past 2 months**	0 - 4	1	-	-	-
	≥5	1.61	1.07	2.41	0.020		≥5	1.52	0.99	2.36	0.054
	Missing	0.78	0.376	1.68	0.538						
Anatomical site of infection	Urogenital site	1	-	-	-	**Anatomical site of infection**	Urogenital site	1	-	-	-
	Pharynx	0.91	0.47	1.73	0.776		Pharynx	0.84	0.44	1.61	0.617
	Anus-rectum	0.96	0.60	1.53	0.870		Anus-rectum	0.93	0.58	1.49	0.775
Material Deprivation Index (quintiles)	Quintiles 2–4	1	-	-	-	**Material Deprivation Index (quintiles)**	Quintiles 2–4	1	-	-	-
	Q1 (most privileged)	0.92	0.56	1.51	0.749		Q1 (most privileged)	0.93	0.57	1.53	0.805
	Q5 (most deprived)	0.94	0.54	1.65	0.840		Q5 (most deprived)	0.98	0.58	1.65	0.968
	Missing	1.27	0.65	2.47	0.473						
Previous STBBIs	None	1	-	-	-	**Previous STBBIs**	None	1	-	-	-
	Other than HIV	0.97	0.55	1.71	0.930		Other than HIV	1.23	0.73	2.05	0.424
	HIV	0.98	0.46	2.16	0.950		HIV	1.02	0.50	2.09	0.938
	Missing	1.00	0.40	2.46	0.994						
Sexual relations occurred during travel outside Québec	No	1	-	-	-	**Sexual relations occurred during travel outside Québec**	No	1	-	-	-
	Yes	1.21	0.68	2.15	0.514		Yes	1.10	0.63	1.91	0.721
	Missing	1.30	0.74	2.28	0.345						
Money, drugs, or other given or received in exchange for sexual relations	No	1	-	-		**Money, drugs, or other given or received in exchange for sexual relations**	No	1	-	-	-
	Yes	1.31	0.65	2.65	0.437		Yes	1.14	0.58	2.23	0.689
	Missing	1.02	0.56	1.85	0.939						

aPR adjusted Prevalence Ratio

STBBIs sexually transmitted and bloodborne infections

[a] A specific category for missing values "missing indicator" was used when the proportion was ≥ 20%.

‡Lifetime reported STBBIs other than HIV including chlamydia, gonorrhea, syphilis, lymphogranuloma venereum, hepatitis C, hepatitis B, herpes, Trichomonas vaginalis, Mycoplasma genitalium, hepatitis A, vaginitis, scabies and crabs.

MSM - men who have sex with men; HSM/W- heterosexual men and women.

** After multiple imputation for sex of sexual partners (1.26% missing), number of sexual partners (13.3% missing), previous STBBIs (8.1% missing), sex outside of Québec (34.5% missing), material deprivation index (6.3% missing), and money,* drugs, or other given or *received in exchange for sexual relations (27.9% missing). There were no missing values for age, region of residence, and anatomical site of infection*.

DISCUSSION

In this open cohort for the surveillance of gonococcal infections in Québec, we observed a high resistance rate to ciprofloxacin (74.3%), but still low proportions of increased MIC for the 3GCs (9.4% and 13.3% respectively for cefixime and ceftriaxone). During the same study period, resistance against 3GCs was generally low across the globe: across all the 194 member states of the WHO regions, only 35% (n=69) and 26% (n=51) reported *N. gonorrhoeae* isolates with decreased susceptibility or resistance to respectively ceftriaxone and cefixime in 2017–18 [18].

The high proportion of ciprofloxacin resistance observed in our study, is consistent with global trends reflecting the increasingly challenging nature of antibiotic resistance in *N. gonorrhoeae* isolates. In fact, in Central Asia, reports showed resistance against ciprofloxacin (88.5%), ceftriaxone (12.8%) and cefixime (11.5%) [19]. A retrospective observational study of the AMR data of gonococcal isolates reported to WHO by 73 countries across the globe in 2017–18 also showed a resistance level of 77% against ciprofloxacin [18]. The antimicrobial activity of ciprofloxacin is mediated by inhibition of bacterial topoisomerases II and IV [20]. Resistance in *N. gonorrhoeae* is mainly due to mutations in the *gyrA* and/or *parC* genes, which code for these enzymes and these mutations interfere with the binding of ciprofloxacin to its target site, reducing its efficacy against bacteria [21]. The high prevalence of resistance observed against ciprofloxacin could be attributed to the emergence and rapid spread of mutant clones with mutations in these genes [21].

Our study conducted in the province of Québec shed light on the prevalence of MDR gonococcal infections, revealing a prevalence of 12.5%. This finding is consistent with national trends observed across Canada, where reports indicated fluctuating rates of MDR *N. gonorrhoeae* ranging from 12.2% in 2017 to 12.4% in 2019 [8]. Different proportions were reported in other international contexts. In Melbourne (Australia) the proportion of MDR was around 2% [22], and in Spain, the proportions ranged from 0.25% in 2016 to 0.42% in 2019 [23]. Similarly, based on their definition, England and Wales reported MDR rates at 3.5% [24]. The observed disparities in MDR prevalence highlight the complex interplay of regional factors, including healthcare practices, antimicrobial stewardship efforts, and possibly varying rates of antibiotic use and resistance patterns. Factors such as population demographics, sexual health education, accessibility to healthcare services, and surveillance systems could also contribute to the observed differences. Our findings highlighted the need for continued vigilance and collaborative efforts at local, national, and international levels to address the rising threat of MDR gonococcal infections effectively. Implementing comprehensive strategies, including enhanced surveillance, antimicrobial stewardship programs, and targeted interventions, will be crucial in curtailing the spread of MDR and safeguarding public health.

In our study, the assessment of the determinants of MDR gonococcal infections was conducted with the dataset before and after MICE imputation. The results from both sets of analyses demonstrated consistency, affirming the robustness of our findings. Even though none of them showed statistical significance, factors such as sexual exposure during travels outside of Québec as well as sexual relations given or received in exchange of money, drugs or others were found to be associated with MDR gonococcal infections in the multivariable analyses. These findings are consistent with previous research undertaken in England, Wales, and the Nordic countries of the European Union, which found similar risk factors for STIs, including gonorrhea [24–26].

Although not found significant in our analysis, it is known that transmission during travel is an important factor in the dissemination of resistant strains from one country to another. In a study published in 2017, a ceftriaxone-resistant *N. gonorrhoeae* isolate was identified in a patient in Canada, with epidemiologic and genomic data suggesting its spread from Asia [9]. Travels have been shown to be, in several studies, a risk factor of STIs in general. During travels especially for tourism purposes, people tend to have riskier sexual behaviours such as inconsistent condom use, having unprotected sex with casual partners or

engaging in sexual relations with multiple partners [27–29]. In this perspective, pre-travel consultations should be strengthened to reduce the spread of STIs, including MDR gonococcal infections. During these consultations, healthcare experts should educate tourists about sexual risks, emphasizing the importance of continuous condom use and transactional sex. Personalized advices considering the destination, activities, and health status are vital and tailored therapies are especially crucial for travelers visiting regions with high MDR gonococcal infections rates [30]. Our study also found having 5 or more sex partners in past 2 months to be associated with MDR gonorrhea. This observation could be explained by the fact that individuals having higher number of sex partners might be at higher risks of STIs leading to a more frequent use of antibiotics for treatment purposes and thereby contributing to the development and spread of MDR gonorrhea. Attempts to combat the emergence of antibiotic resistance should include not just cautious antibiotic usage, but also comprehensive initiatives that address the underlying behavioural factors of STI transmission.

While our study provided a comprehensive analysis, it is essential to acknowledge certain limitations that may affect the generalizability of our findings. The majority of participants enrolled in the sentinel network cohort were men who have sex with men (MSMs), comprising 85.0% of participants. Consequently, the applicability of our results may be restricted to populations with similar gender or sexual orientation distributions. Additionally, it is important to exercise caution in interpreting our findings as the study clinics were situated in only three 3 out of the 18 regions of the province of Québec, potentially limiting the representativeness of diverse geographical areas. Furthermore, our study relied on self-reported data, which could introduce recall and desirability biases.

CONCLUSION

Our results demonstrated an association between the number of sexual partners and MDR, reinforcing the hypothesis that MDR can develop more rapidly within dense sexual networks. The rapid development and transmission of resistant strains within these networks poses a serious threat to public health, as it facilitates the spread of dangerous and very difficult-to-treat isolates. It is also important to critically address the question of circulating resistant isolates, highlighting the need for ongoing surveillance, research and appropriate interventions to manage and contain these highly resistant strains before they become widespread.

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ETHICAL STATEMENT

Because the analyses were for population health surveillance purposes, this study was considered nonresearch in accordance with the Québec Public Health Act (2001, c. 60, a. 36; 2009, c. 45, a. 13). The Québec Public Health Ethics Committee reviewed the project, and individuals were notified of the data collection and given the opportunity to opt out.

CONFLICT OF INTEREST

None declared.

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USE OF ARTIFICIAL INTELLIGENCE TOOLS

None declared.

DATA AVAILABILITY

No additional data are available.

DISCLAIMER

The findings and conclusions in this publication are those of the authors and do not necessarily represent the official position of the authors' affiliated institutions.

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Global, regional, and national burden of gout, 1990-2021: an analysis of the global burden of disease study 2021

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SUMMARY

Aim: The global incidence rate of gout has shown a consistent increase, requiring an in-depth study of potential risk factors at the national and regional levels. This study uses data from the 2021 Global Burden of Disease, Injury, and Risk Factors Study to analyze the incidence trend of gout, in order to reveal the global disease burden of gout and provide a basis for optimizing prevention and control strategies for healthcare systems.

Subject and Methods: This study collected data on gout from 1990 to 2021. Conduct decomposition analysis and frontier analysis to determine the changing trends of various indicators and their influencing factors.

Results: According to global data in 2021, the number of incidence cases of gout reached 9,402,000 (95% uncertainty interval [UI]: 7,439,000-11,732,000 cases), and the number of prevalence cases was 56,475,000 (95% UI: 45,162,000-70,288,000 cases). The number of cases of DALYs was 1,748,000 (95% UI: 1,186,000-2,485,000 cases), an increase by 17.15-21.86% since 1990. Further analysis of the data from 1990 to 2021 showed that the estimated annual percentage changes (EAPCs) of the age-standardized incidence rate (ASIR), age-standardized prevalence rate (ASPR), and age-standardized disability-adjusted life-year rate (ASDR) were 0.67 (95% UI: 0.61-0.73), 0.87 (95% UI: 0.8-0.95), and 0.86 (95% UI: 0.78-0.93), respectively. There were more male cases than female cases, and the growth rate was higher in males than in females. However, the rising trend of the global incidence and disability burden of gout in women needs attention.

Conclusion: With social progress, the burden of gout increases, mainly due to population growth and aging. Gout is associated with a high body mass index. Weight loss diets and lifestyle adjustments need to be promoted to reduce health burdens and prevent recurrences.

Keywords: decomposition analysis, frontier analysis, global disease burden, gout

INTRODUCTION

Primarily, gout is caused by elevated uric acid levels and consecutive MSU deposition provoking inflammatory gout flares. If untreated gout might cause irreversible joint damage. When involving the bone cortex, it can lead to gouty fractures and deformities. An early symptom of gout usually manifests as monoarthritis of the lower extremities, which, if recurrent attacks occur, may evolve into chronic arthritis and joint damage [1, 2]. The global prevalence of gout is 0.1%-10%, and it is generally higher in developed countries than in developing countries [3-5].

Due to a wide range of severe complications including hypertension, cardiovascular disease, renal impairment, diabetes, obesity, hyperlipidemia, and metabolic syndrome, gout constitutes a great threat to individual health and imposes a huge socioeconomic burden on global healthcare systems [6-8]. The risk of gout can be increased by drinking, and excessive intake of meat, seafood, and sugared beverages. Moreover, chronic diseases such as hypertension,

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diabetes, hypercholesterolemia, and renal insufficiency have been recognized as high-risk factors for gout attacks [9]. As the global economy rapidly develops and urbanization accelerates, the incidence of gout has been rising in several regions worldwide, making it a public health issue to be addressed [10].

An in-depth and comprehensive assessment of the epidemiological status of gout is of great significance. To ensure the high accuracy and good timeliness of assessment results, the most up-to-date and comprehensive database resources are required. It should be noted that the Global Burden of Disease Study (GBD) 2021 offers the most detailed and comprehensive data on the burden of gout to date, which is an invaluable reference for related research on gout.

Currently, the study data available on the global burden of gout are mostly limited to the year 2019 and earlier [11]. To fully reflect the current situation of gout in real time, an in-depth and detailed analysis of the current epidemiological status of gout worldwide was conducted using the data from the GBD 2021 in this study. In addition, the trend of change in the gout burden over the past three decades under the joint influence of population aging, growth trend of population, and epidemiological drivers was further explored, and the specific position of countries or territories during the development of the gout burden was analyzed to reveal potential and achievable benefits and possible room for improvement in the future. This paper intends to provide more rigorous, scientific, and robust data and theoretical basis for the development of prevention and control strategies for gout worldwide.

METHODS

Overview

The study data were derived from the GBD 2021, an updated version of GBD 2019, guaranteeing the timeliness and accuracy of the data [12] (http://ghdx.healthdata.org/gbd-results-tool). The GBD 2021 extensively collects information from 100,983 independent sources and undergoes a rigorous quality assessment process, fully revealing the global burden of 371 diseases and injuries. This database provides detailed estimates of population size, fertility, incidence, prevalence, death rate, and disability-adjusted life years (DALYs) using a unified and comparable methodological framework in the world's five sociodemographic index (SDI) regions and 204 countries and territories.

Since gout does not directly cause death events (the nonfatal property), this study focused on the assessment of prevalence, incidence, and DALYs. We exhaustively reported the specific values of prevalence, incidence, DALYs, age-standardized incidence rate (ASIR), age-standardized prevalence rate (ASPR), and age-standardized death rate (ASDR) per 100,000 population, as well as 95% uncertainty intervals (UIs). These data were examined separately based on sex, age, location, SDI, and sociodemographic factors, ensuring the comprehensiveness and accuracy of the results.

To obtain consistent and comparable data, ASIR, ASPR, and ASDR were described per 100,000 population as the base unit in this study. The preparation of the study report strictly adhered to the extensive principles and requirements of the EQUATOR Network [13] to ensure its quality and standardization. In addition, the University of Washington Institutional Review Board waived the informed consent requirement for access to the GBD data because the de-identified and aggregated data were used and did not directly disclose private information.

Definition

The GBD 2021 explicitly categorizes gout in the etiology classification system, and cases of gout are identified by the M10 code from the International Classification of Diseases Version 10 (ICD-10). For the gout diagnosis, the GBD strictly follows the criteria for primary gout established by the American College of Rheumatology (ACR). Specifically, the GBD adopts the diagnostic criteria issued by the ACR in 1977, which defined in detail the necessary conditions for the gout diagnosis: the presence of MSU crystals in the joint fluid or an abscess containing MSU crystals, and at least six of the twelve preset gout-related signs or symptoms are strictly verified [14].

SDI

The quintile of the SDI provided in the GBD 2021 was used as the benchmark for analysis in this study. As defined by the GBD, the SDI is a composite indicator for fully assessing the level of socioeconomic development of a specific country or territory. It takes into account several key dimensions, including the educational level of the population under the age of 25, per capita income, and total fertility rate, thereby creating a comprehensive analytical framework for fully examining and evaluating the socioeconomic development status of a country or territory [12]. Based on their SDI, countries and territories are assigned into low, low-middle, middle, high-middle, and high SDI groups.

Statistical analysis

Crude incidence rates (including the prevalence, incidence, and DALYs), as one of the basic indicators for assessing epidemiological trends, are subject to

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differences in the age structure of the population, which may produce heterogeneity in the gout burden. To obtain comparable statistical indicators, ASIR, ASPR, and ASDR were used for estimates of the gout burden.

To accurately track the annual change trend of the gout burden, this study presented a detailed profile of gout globally in 1990-2021. The estimated annual percentage changes (EAPCs) for ASIR, ASPR, and age-standardized DALYs were further calculated [EAPC=100 × (exp(β) - 1)] to fully characterize the temporal evolution of the gout-induced disease burden over this period. EAPC, as a widely recognized and commonly used assessment tool, can quantitatively demonstrate the change trends of age-standardized indicators over a specific period, which relies on the model constructed from a regression analysis of the natural logarithm of the incidence rate: ln (rate) = α + β × (calendar year) + ε.

Meanwhile, a linear regression model was utilized to strictly define the 95% confidence interval (CI) of EAPC, thereby ensuring the rigor of the EAPC estimates. As described by the principle of statistics, the age-standardized rate is considered to display an increasing/decreasing trend when both the EAPC value and the lower limit of its 95% CI are higher/lower than 0 [15, 16].

In addition, this study assessed the association of global gout burden (ASIR, ASPR, and ASDR) in 2021 with human development-related indicators using a linear regression model. To further quantify the specific impact of age structure, population growth, and epidemiological changes on the global gout burden, decomposition analyses were conducted [17].

To deeply explore the potential relation of gout burden with sociodemographic development, a frontier analysis model centered on ASIR, ASPR, ASDR, and SDI was established based on the data in 1990-2021. This model intends to provide an in-depth understanding of the potential room for improvement in gout DALY rates in specific countries or territories [18].

By comparative analysis of the data between 1990 and 2021, the changes in each indicator were calculated. The epidemiological data related to gout in 1990-2021 underwent a comprehensive descriptive analysis and visualization by sex, age, location, and year. All graphs were plotted using R4.0.5.

RESULTS

Incidence, prevalence, and DALYs for gout in 1990-2021

Globally, the number of incidence cases of gout had more than doubled from 3,983,000 (95% UI: 3,179,000-4,912,000) in 1990 to 9,402,000 (95% UI: 7,439,000-11,732,000) in 2021. During this period, the ASIR of gout continued to rise from 93.1 cases per 100,000 people (95% UI: 74.4-115.48) in 1990 to 109.07 cases per 100,000 people (95% UI: 86.38-135.76) in 2021, with a rate of increase of 17.15% (Supplementary Table 1, Fig. 1-A).

The number of prevalence cases of gout rose from 22,265,000 (95% UI: 17,793,000-27,966,000) in 1990 to 56,475,000 (95% UI: 45,162,000-70,288,000) in 2021. The ASPR of gout displayed an increasing rate of 21.86% from 536.54 cases per 100,000 people (95% UI: 430.28-665.72) in 1990 to 653.82 cases per 100,000 people (95% UI: 526.13-810.46) in 2021 (Supplementary Table 2, Fig. 1-B).

The estimated number of DALYs cases of gout increased from 698,000 (95% UI: 470,000-1,000,000) in 1990 to 1,748,000 (95% UI: 1,186,000-2,485,000) in 2021. The ASDR of gout displayed an increasing rate of 21.3% from 16.67 cases per 100,000 people (95% UI: 11.25-23.95) in 1990 to 20.22 cases per 100,000 people (95% UI: 13.77-28.77) in 2021 (Supplementary Table 3, Fig. 1-C).

The EAPCs for the prevalence, incidence, and DALYs in 1990-2021 were 0.67 (95% UI: 0.61-0.73), 0.87 (95% UI: 0.8-0.95), and 0.86 (95% UI: 0.78-0.93), respectively (Supplementary Tables 1-3), suggesting that the gout-related GBD continues to increase.

The incidence, prevalence, and DALYs for gout in 1990-2021 increased in both males and females, with increases in ASIR, ASPR, and ASDR in males three times those in females (Fig. 2). In 2021, the number of prevalence cases was 42,130,000 (95% UI: 33,505,000-52,849,000) in males and 14,345,000 (95% UI: 11,462,000-17,901,000) in females, with males far outperforming females in both the number of cases and growth rate (Supplementary Table 2, Fig. S1).

From 1990 to 2021, the 60-94 years old groups had the fastest growth in the incidence, prevalence, and DALYs, and the incidence continued to rise with age (Fig. 3). By 2021, the fastest increases in ASIR and ASPR were seen in the 95+ years old group, and the most significant increase in ASDR was seen in the 85-89 years old group. The number of incidence cases, prevalence cases, and DALYs cases was the largest in the 55-59, 65-69, and 55-59 & 65-69 years old groups (Supplementary Tables 1-3, Figure S2).

Figure 1. Change trends of incidence cases, ASIR (A), prevalence cases, ASPR (B), DALYs cases, and ASDR (C) of gout in 1990-2021

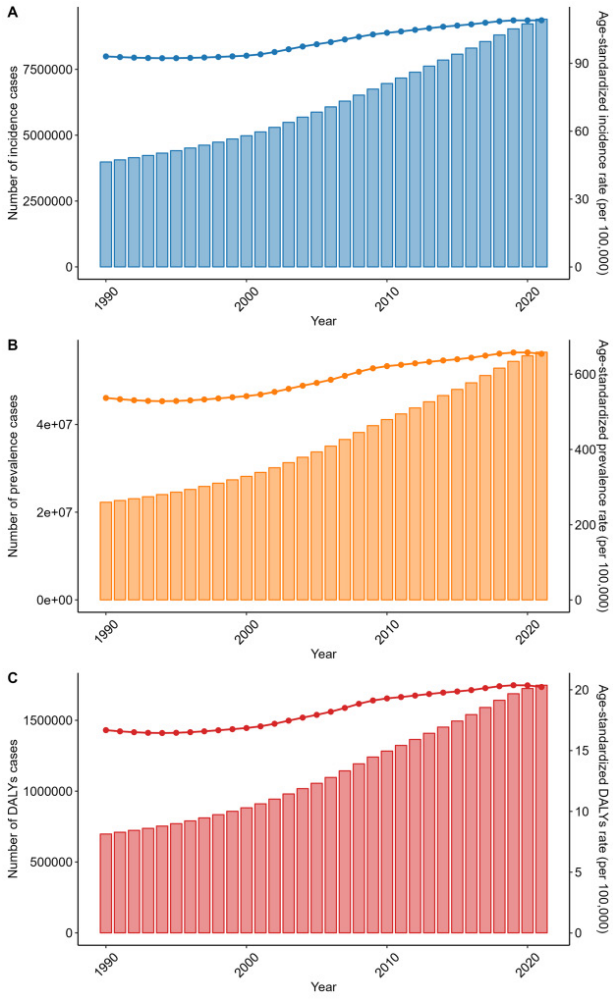

Figure 2. Global ASIR, ASPR, ASDR (A), incidence cases, prevalence cases, and DALYs cases (B) of gout by sex in 1990-2021

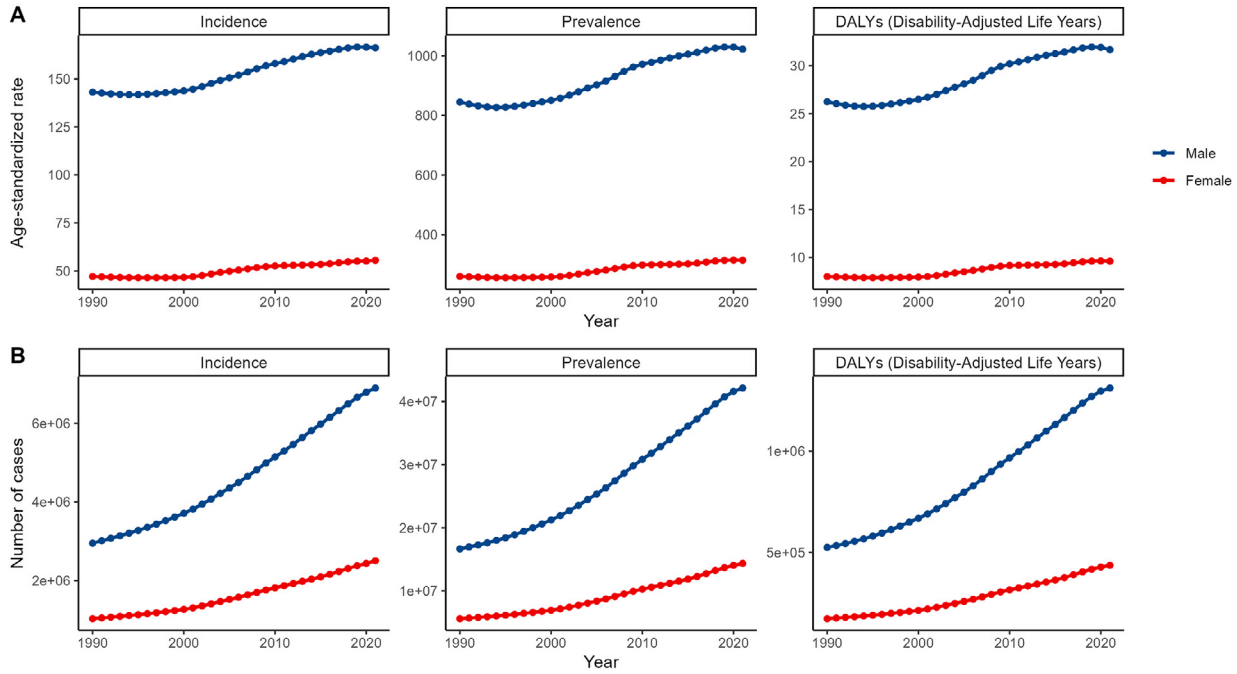

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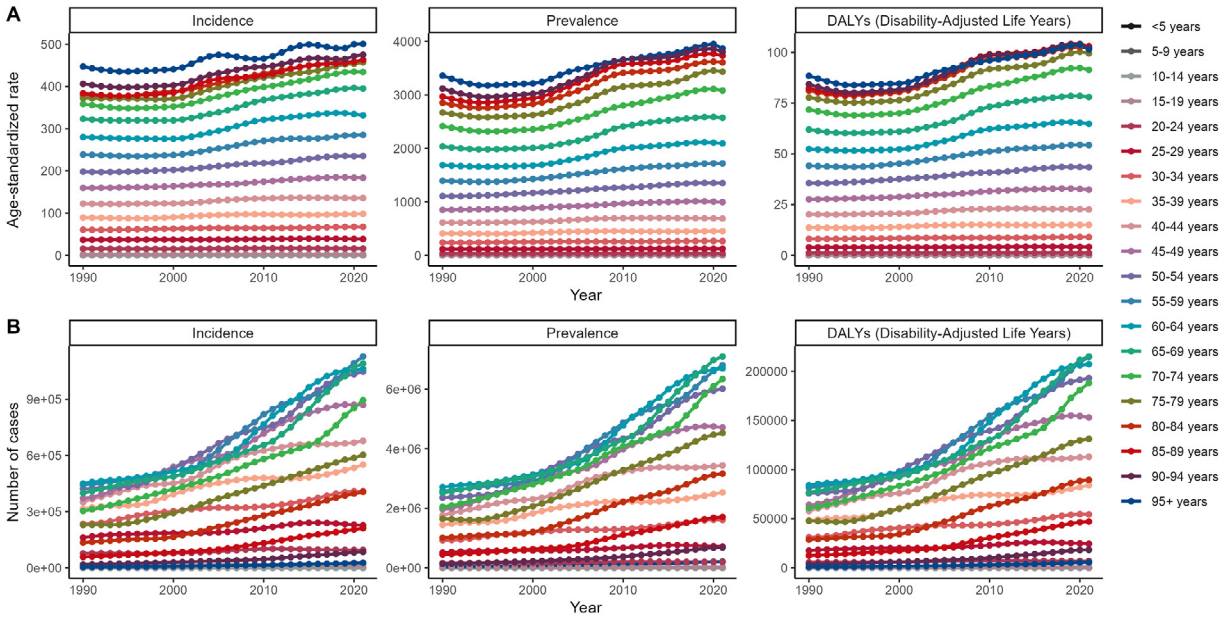
Figure 3. Associations of global gout incidence rate, death rate, and DALY rate with age in 1990 and 2021. ASIR, ASPR, ASDR (A), incidence cases, prevalence cases, and DALYs cases (B)



Gout burden across GBD regions

We thoroughly analyzed and categorized the number of incidence cases, prevalence cases, and DALYs cases of gout globally and across GBD regions, and observed clear data and trends (Fig. 4). We also visualized the EAPCs for the prevalence, incidence, and DALYs for gout (Fig. S3).

The increase or decrease in the number of incidence cases of gout in 1990-2021 significantly varied across territories, including a minor increase in 11 territories, a stable or minor decrease in four territories, a significant decrease in 37 territories, and a significant increase in two territories (Fig. 5).

Particular attention was given to the more economically developed North America, in which the ASIR, ASPR, and DALYs for gout had the most significant increases (Fig. 4). Specifically, the number of prevalence cases and the prevalence rate of gout increased from 3,230,000(95% UI: 2,600,000-4,050,000) and 971.4 cases per 100,000 people (95% UI: 771.5-1216.38) in 1990 to 9,500,000 (95% UI: 7,724,000-11,695,000) and 1658.09 cases per 100,000 people (95% UI: 1349.93-2024.88) in 2021, respectively. It can be seen that the number of gout cases in North America increased by up to 70.7% over the last three decades (Supplementary Table 2).

The increase rate was the lowest in West Africa, from 425.51 cases per 100,000 people (95% UI: 340.81-533.67) in 1990 only to 430.34 cases per 100,000 people (95% UI: 344.91-535.63) in 2021, and the EAPC for the prevalence was even 0 (-0.04 to 0.05) (Supplementary Table 2).

Furthermore, Central Latin America showed the lowest ASIR, ASPR, and DALYs for gout by 2021 (Fig. 6A), and the number of incidence cases, prevalence cases, and DALYs cases was the smallest in Oceania (Fig. 6B). These data present a detailed distribution of the global gout burden, and help further develop targeted public health strategies and interventions.

Figure 4. Changes in global gout burden in 204 countries and territories in 1990-2021. Incidence cases (A), prevalence cases (B), DALYs cases (C)

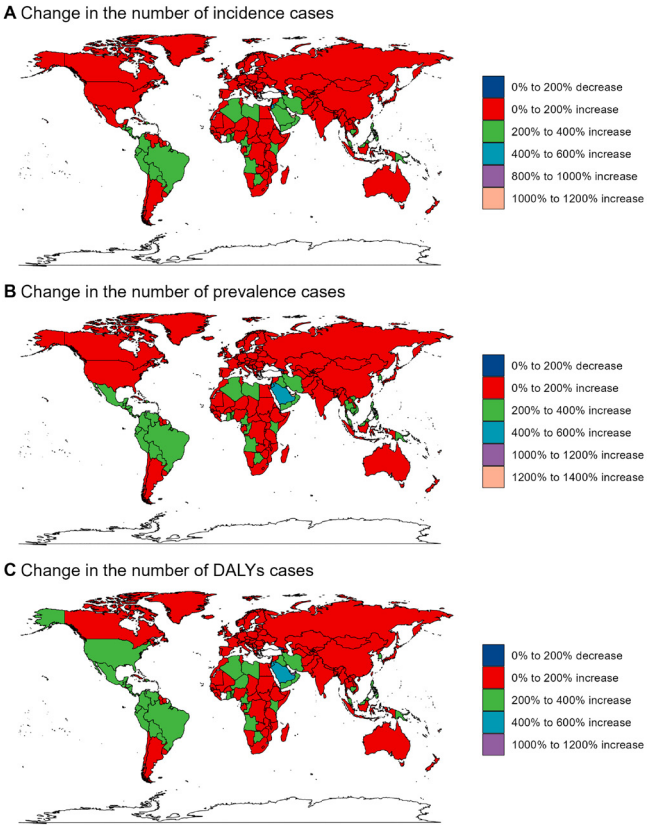


Figure 5. Increase or decrease in the number of incidence cases of gout in 1990-2021 across territories

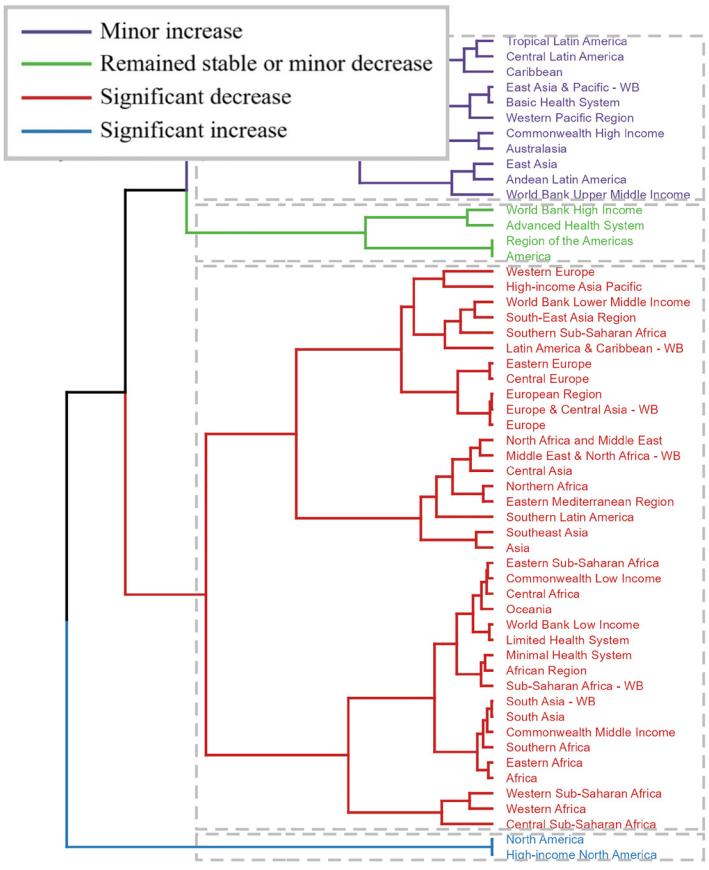


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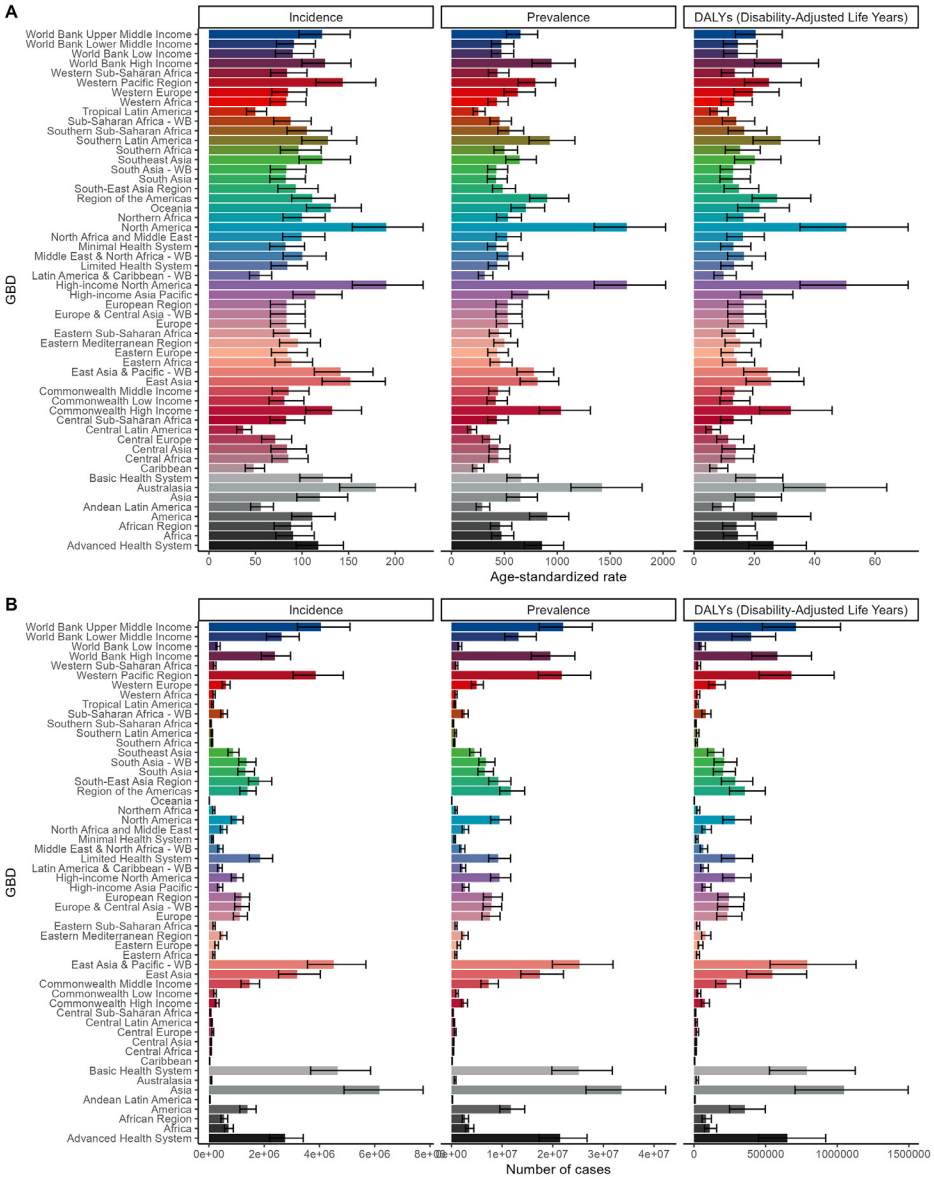
Figure 6. Increase or decrease in ASIR, ASPR, ASDR (A), incidence cases, prevalence cases, and DALYs cases (B) in 2021 across territories



Gout burden across Countries or territories

In 2021, ASIR, ASPR, and ASDR were 191.95 per 100,000 people (95% UI: 155.54-231.03), 1677.1 per 100,000 people (95% UI: 1369.5-2044.08), and 50.95 per 100,000 people (95% UI: 35.36-71.75), respectively, in the United States, achieving the highest increasing rates of 31.33%, 76.28%, and 73.77% in the last three decades (Supplementary Tables 1-3, Fig. S4 A-C). In China, the number of incidence cases, prevalence cases, and DALYs cases was 3,080,000 (95% UI: 2,425,000-3,891,000), 16,788,000 (95% UI: 13,144,000-21,278,000), and 526,000 (95% UI: 353,000-758,000) (Supplementary Tables 1-3, Fig. S4 D-F). The EAPCs for the incidence, prevalence, and DALYs in Nigeria were -0.26 (95% UI: -0.35 to -0.18), -0.25 (95% UI: -0.34 to -0.15), and -0.21 (95% UI: -0.3 to -0.12), respectively, suggesting that the most significant negative growth over time occurs in Nigeria. In addition, negative growth was also found in Nauru, Northern Mariana Islands, Somalia, Sweden, and Zimbabwe, while all other countries or territories showed positive growth (Supplementary Tables 1-3).

Gout burden across SDI regions

ASIR, ASPR, and ASDR all exhibited varying degrees of increase in each SDI region in 1990-2021. Specifically, the high SDI region showed the most significant growth in ASIR, ASPR, and ASDR by 27.83%, 43.07%, and 41.9%, respectively, in the last three decades (Supplementary Tables 1-3 and Fig. S5). By 2021, the three indicators all reached the peak in the high SDI region (Fig. S6A). In 2021, the number of incidence cases was the largest in the middle SDI

region, and the number of prevalence cases and DALYs cases was the largest in the high SDI region (Fig. S6B). In contrast, both the number of cases and the growth rate reached the bottom in the low SDI region compared with the other SDI groups in terms of disease prevalence and negative impacts on quality of life (Fig. 6). To sum up, the population health status is undergoing changes in different SDI regions in the context of global economic and social development, with the high SDI region facing serious health challenges.

Decomposition analysis of gout burden

This study conducted an in-depth analysis of the change trends of the incidence, prevalence, and DALYs for gout globally and in five SDI regions between 1990 and 2021, followed by a detailed decomposition analysis. This study intends to assess the specific impact of aging, epidemiological changes, and population growth on the gout burden. The results revealed that the overall global gout burden displayed a significant increasing trend in 1990-2021.

Specifically, population growth was the key driver of the increasing gout burden globally. Population growth was responsible for 52.31%, 47.72%, and 48.5% of the annual increase of incidence, prevalence, and DALYs, respectively, in 1990-2021, as verified by the graphs and decomposition tables. Besides, the impact of population growth on the gout burden was particularly significant in the low SDI region, responsible for 92.53%, 93.06%, and 92.22% of the increase in incidence, prevalence, and DALYs, respectively.

Furthermore, the impact of population aging on the gout burden was most significant in the middle SDI region and less significant in the low SDI region. Based on the data in 2021, nonetheless, its impact on the incidence, prevalence, and DALYs in the low SDI region showed no increasing trends.

Finally, the impact of epidemiological change on the three indicators was most significant in the high SDI region, suggesting their non-negligible impact on the overall gout burden in the high SDI region. In the low SDI region, the epidemiological change had some influence on the gout prevalence (Supplementary Tables 4-6, Fig. S7).

Frontier analysis of gout burden

The effective difference (EF) is explicitly defined as a measure of the gap of a country or territory from the level of health at the global frontier. Based on the SDI, this indicator assesses the difference between the actual health burden observed and the lowest theoretically achievable burden of disease. With the help of EF, we can not only reveal the specific position of countries or territories during the development of the gout burden but highlight the possible benefits achievable and room for improvement.

Our in-depth analysis revealed a remarkable trend: The EF value tended to decline as the SDI gradually increased, signifying that the gap in the health burden and the disease burden of a country or territory is gradually narrowing, and the variability of this trend is also decreasing (Fig. S8). Most importantly, the frontier trends of ASIR, ASPR, and ASDR all became more stable when the SDI crossed the threshold (0.4).

To further present a clear picture of the gap of a country and territory from the global frontier, we estimated the EF and plotted graphs based on the 2021 data on ASIR, ASPR, ASDR, and SDI (Supplementary Table 7, Fig. S8. The black solid line outlines the global frontier, while the dots represent different countries and territories). As marked by blue dots, the gap in the health burden and the disease burden was narrowing in some countries or territories such as Somalia, Chad, Central African Republic, and Mali, reflecting a favorable development trend. In contrast, such a gap was widening in the United States, Canada, New Zealand, and Australia, as marked by red dots. These findings greatly contributed to our in-depth understanding of the health development status of countries and territories, and their relative position to the global frontier.

DISCUSSION

Through a comprehensive analysis of the global gout burden in 1990-2021, this study revealed complex differences and trends in the gout burden across countries and territories and SDI regions. The results showed that ASIR, ASPR, and age-standardized DALY rates of gout were all on the rise globally. The total number of gout patients more than doubled from 1990 to 2021, and the prevalence increased in most GBD regions, consistent with previous GBD studies that the ASPR of gout increases over time [19, 20]. ASPR, ASIR, and age-standardized DALY rates were all at their highest levels in the high SDI region and lower in the low SDI region. This finding highlights the persistent socioeconomic disparities in the global gout burden, suggesting that gout is not only a widespread medical and rheumatologic problem but an increasingly prominent socioeconomic issue [21]. In the high and high-middle SDI regions, the great gout burden may be associated with the potential of gout in chronic continuous joint destruction and with cardiometabolic and renal diseases (hypertension, myocardial infarction, stroke, obesity, type 2 diabetes mellitus, hyperlipidemia, hyperuricemia, and chronic kidney disease) [22, 23]. The prevalence of these diseases is also higher in highly developed areas. Therefore, despite a perfect healthcare system and effective public health interventions in high SDI regions, optimization of nutrition and lifestyle and medications for adequate prevention and treatment

and lowering serum uric acid (SUA) are an integral part of comprehensive gout management [24].

The sex and age distribution of gout patients exhibits statistically significant differences. It was found in this study that males had significantly higher prevalence, incidence, and DALY rates than females, consistent with previous studies [19, 21]. Notably, the global prevalence and burden of disability increased disproportionately in females with gout compared with males. Female gout patients are characterized by higher rates of obesity and associated cardiometabolic sequelae [25, 26]. Obesity is recognized as a major risk factor for gout and hyperuricemia [27-29], which elevates SUA levels and raises the gout risk by decreasing uric acid excretion and promoting uric acid production [30-35]. According to a supplementary analysis of randomized dietary intervention trials, a healthy slimming diet can help reduce SUA levels, particularly in patients with baseline hyperuricemia [36]. Furthermore, bariatric surgery is linked to decreases in SUA levels and incidence of gout and hyperuricemia [37, 38]. Recently, a sex-specific cohort study further pointed out that excess fat is associated with the risk of gout in both males and females, in line with our finding of a more obvious out-of-standard BMI in females[38]. Therefore, social strategies to assist females in achieving and maintaining a healthy weight may have positive implications for reducing the incidence of gout in females.

The gout burden showed an increasing trend from 1990 to 2020 in most regions, and the incidence, prevalence, and DALYs for gout greatly varied across regions due to environmental factors [39-41]. In high-income regions, the rise in age-standardized DALY rate may be partly attributed to high exposure to gout risk factors, such as renal dysfunction and high BMI. The average annual incidence of gout resulting from renal dysfunction remains high in high-income countries in the Asia-Pacific region, and it is reported that these countries have a higher incidence of renal dysfunction. Moreover, it further increases with age, worsening the gout burden [42]. Obese patients (BMI >30 kg/m^2) have more than twice the risk of developing gout compared with people with BMI <30 kg/m^2 [43]. Purine-rich foods, such as fish (anchovies, sardines, scallops, and mussels) and meat (bacon, beef, liver, turkey, veal, and venison), are one of the risk factors for gout. Beer is more significantly associated with an increased risk of gout than wine or spirits. The risk of gout in males will rise in case of daily consumption of two or more sugary soft drinks, high-fructose fruits, or any fruit juices [9]. However, the impact of potential racial differences on gout incidence also varies in high-income regions, as previous studies argued that African Americans possess a higher risk of gout [44-46] and lower health-related quality of life compared with white Americans [47]. The potential reasons may be attributed primarily to differences in non-genetic social determinants [48], such as poverty and poor dietary habits, which may influence the BMI. Research suggests that all risk factors for gout and hyperuricemia are more prevalent in black adults than in white adults, and that the former is younger and less educated and has higher rates of poverty. This indicates that racial differences in sociodemography, lifestyle, and clinical factors are more important [49], and blacks have less access to health care [50]. Traditionally, gout has been recognized as a disease of affluent men ("disease of kings") [51], but given the associations of socioeconomic status, food insecurity, diet quality, and obesity, the burden of gout-related cardiometabolic and renal sequelae now becomes extremely high in low-income people. To reduce racial differences in the prevalence of gout and hyperuricemia, we can popularize a healthy dietary pattern such as that described in the *Dietary Guidelines for Americans* [52], and reduce barriers to adherence [53], including interventions for people receiving Supplemental Nutrition Assistance Program benefits (who typically have poorer diet quality than others) [54].

The decomposition and frontier analyses revealed that population growth was the key driver of the increasing gout burden globally, and the burden was borne primarily by developed countries with stronger coping capacities. However, measures can be taken to reduce the gout burden across countries and territories with different levels of development and within the same country and territory at different stages of development. Economically developed countries such as the United States and Canada bore more gout burden, highlighting a major challenge for healthcare systems. Significant EF was present between gout-related DALYs and the global frontier in some countries, suggesting room for improvement. Although health losses due to gout are associated with socioeconomic and demographic indicators, some developing countries performed well in gout-related DALYs in the frontier analysis, which could provide a useful reference for developed countries. The increasing gout burden should be incorporated into global and national health agendas to help reduce the number of patients in more regions and the risk of gout and other complications.

Limitations

Several limitations are worth noting. First, the gout burden estimates of GBD deviated from the actual data due to the diversity of data sources and heterogeneity of quality. Specifically, the gout burden in low- and middle-income regions may be underestimated due to the uneven distribution of healthcare resources. Second, based on the requirement of GBD, only high BMI and renal dysfunction were included as risk factors for gout because only their causality with gout has been proved by sufficient population-based evidence. However, there are also other risk factors such as hyperuricemia, fasting plasma glucose, genetic factors, cardiovascular disease, diabetes, drinking, and diet involving the

intake of purine-rich foods (red meat and seafood) and high-fructose beverages. It is worth noting that GBD currently includes consumption of red and processed meats and drinking as risk factors for other diseases such as cardiovascular disease [55]. However, the evidence for causality between these factors and gout remains to be evaluated. Third, although the relation between DALYs and SDI can be explained, it cannot be considered causality.

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CONFLICTS OF INTEREST

The authors declare no competing interests.

ETHICS APPROVAL

Not applicable-The GBD 2021 study is an open database, and all data is anonymous.

CONSENT TO PARTICIPATE

Not applicable

CONSENT FOR PUBLICATION

Not applicable

AVAILABILITY OF DATA AND MATERIAL

The data for this study were obtained from the GBD database (http://ghdx.healthdata.org/gbd-results-tool).

CODE AVAILABILITY

Not applicable.

AUTHORS' CONTRIBUTIONS

Fangfang Deng and Bo Chen conceived and designed the study; Fangfang Deng, Fan Hu, and Huali Guo analyzed and visualized the data. Fangfang Deng wrote the draft of the manuscript. All authors read and approved the final manuscript.

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Examining Youth Protections against Gambling in Ireland: A Tiger Team (Red Team) Examination of the National Lottery

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SUMMARY

Background: Youth gambling in Ireland is of growing concern.
Objectives: Thus, this study evaluated youth gambling protections in the Irish National Lottery's online age verification system.
Methods: A Tiger Team (Red Team) methodology was used. This involved using falsified National Lottery accounts (n = 56).
Results: Over half (55.4%) of attempts were successfully verified, with successful verification significantly varying by gender.
Conclusions: These findings highlight vulnerabilities in the National Lottery's online age-verification system and underscore the urgent need for more robust safeguards to prevent underage access.

Keywords: National Lottery; Youth gambling; Youth protections; Age verification; Ireland; Public health

INTRODUCTION

The gambling industry is currently undergoing rapid transformation. Due to increasing digitisation and technological advancements, gambling has become widely accessible 24 hours a day [1]. This ease of access has increased the industry's revenue exponentially, with consumer net losses predicted to reach almost US$700 billion by 2028 [2]. Ireland poses as a major contributor to this expansion, with €9.8 billion staked by the population in 2019 [3], making the Irish the fourth-biggest gamblers in the European Union [4-5]. Ireland's National Drugs and Alcohol survey (NDAS) revealed that 49% of the adult population engaged in gambling activity in the year 2019-20, with this figure dropping to just 20% upon exclusion of the lottery [6]. The National Lottery has also expanded its digital reach within recent years – with online platforms amassing €132.2 million in game sales in 2023 [7].

This extended outreach of The National Lottery may seem benign, given that lottery purchases are often not considered gambling [8]. However, online gambling can pose additional negative consequences in comparison to offline counterparts; such as poorer physical and mental health, lower overall quality of life and greater financial insecurity [9]. Furthermore, possessing online gambling accounts and/or mobile gambling apps has been linked with higher reports of problematic gambling behaviours [10]. Recent estimates from the Economic and Social Research Institute (ESRI) suggest that 1 in 30 (or 130,000) adults in Ireland suffer from problem gambling [11], with a further 7.1% (or 279,000 adults) demonstrating 'moderate evidence' of problem gambling.

In addition to the elevated risks of addiction, online gambling also raises issues of underage access and harm [12]. Youth gambling is a major concern, with the European School Survey Project on Alcohol and Other Drugs (ESPAD) for Ireland 2024 reporting that

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32.2% of 15-16 year-olds had gambled for money in the year 2024 [13] (up from 24% in 2019 [14]). Furthermore, 26.1% of adolescents reported utilising online gambling platforms [13], associated with a 4.2-fold higher odds of excessive gambling [14]. Lotteries remain among the most common gambling activities for adolescents, with 15.6% engaging in lotteries on-site, and a further 7.2% online [13].

Despite National Lottery gambling often being normalised among Irish households [8, 15], recent evidence has demonstrated that gambling before the age of 18 almost doubles the probability of developing problem gambling in adulthood [16]. Similarly, an examination of 3,000 individuals treated for problem gambling in Ireland, between 2008-2019, discovered that half of these adults had begun to gamble before age 17 [17]. Moreover, online gambling at age 17 was found to be a significant independent predictor of engagement in online gambling at age 20, alongside team sport participation [18]. Recent research has demonstrated that Irish online gambling sites perform poorly in terms of responsible gambling compared to other jurisdictions [12].

In response to the illegality of underage gambling, the Irish Office of the Regulator of the National Lottery (ORNL) commissioned two 'test purchasing' exercises on the under-age purchase of National Lottery products in retail premises by Ipsos MRBI, in 2018 and 2024 respectively. A test purchase exercise involves an agency hiring children to try and purchase items with a minimum age requirement. Such tests are used in many countries to assess compliance with legislation restricting the purchase of cigarettes, alcohol, or in this lottery tickets/ scratch cards.

In 2024, 562 retail premises were tested. The research found that 71% of test purchases by 15-17 year olds were challenged, an 8% increase on 2018 [19]. Nevertheless, despite 92% of outlets displaying the mandatory '18+' signage, almost 3 in 10 test purchases were not refused [20]. As can be seen in the extract of Ireland's National Lottery Act, 2013, detailed in Table 1, it is illegal to sell National Lottery tickets to children.

Table 1. Ireland's National Lottery Act, 2013 [21]

Sale of National Lottery tickets
42… (6) A person, including the operator, shall not sell or offer for sale by any means a National Lottery ticket to a person under the age of 18 years or invite from such a person an offer to buy a National Lottery ticket.

Ireland has a poor record of enforcement of Public Health related legislation. This can be seen in relation to tobacco [22-23], alcohol [24-26], and gambling control [27], as well as in relation to road safety enforcement [28-33], and environmental protections [34].

As established, the gambling industry is becoming increasingly digital in nature. Despite this shift, experimental research surrounding the underage accessibility of online gambling platforms remains limited. Recent evidence on responsible gambling practices across 39 Irish websites found that 94.9% of operators did not require registrants to provide identity documents [13]. This raises concerns regarding the adequacy of age-verification measures in protecting young people. Accordingly, the present study sought to test whether underage individuals could successfully register for online gambling accounts in the Irish context. Given its ubiquity and cultural normalisation, the National Lottery was selected as the case platform.

METHOD

This research aimed to explore the effectiveness of underage youth player protections on Ireland's National Lottery. To do so this study adopted a Tiger Team approach to exploring underage player protections in the National Lottery [35]. A Tiger Team approach, sometimes referred to as a Red Team or Red Teaming, involves covert attempts to gain entry to specific sites [36]. Although the term was originally employed to describe elite special forces testing physical security systems it evolved to cover the testing of cyber-security systems [37-38]. As such this study employed deception, a strategy that can be employed deliberately and thoughtfully in psychological and social science research to good effect [39-41]. Although care is always needed when using deceptive methods in research this research was conducted on the basis of its aim to deliver a public good [42], it was reasonable in this specific context [40]. We conducted an experimental assessment of age-verification procedures on the official Irish National Lottery online platform (lottery.ie). 60 test accounts were created, evenly distributed by gender and assigned stereotypical Irish names (e.g., *Róisín Murphy*, *Tadhg Daly*).

Unique email accounts were generated for each fictitious identity using ten different providers (e.g., Outlook, Gmail &Yahoo). The emails were then employed to register for online lottery accounts. Creating lottery accounts further consisted of providing a fabricated home address, date of birth, phone number and answers to two security questions ('*Your mother's maiden name*' and '*Your place of birth*').

In order to assess the age-verification processes of the National Lottery, counterfeit blank identity documents (IDs) were initially created within Adobe Photoshop to simulate required government-issued photographic ID. This blank was then imported into Microsoft PowerPoint and copied 60 times.

This research also sought to explore the potential impact of gender (male vs female) different forms of identity verification (passport vs driving licences) on the outcomes of attempts to establish fraudulent National Lottery accounts. Therefore, 30 Irish passport images

and 30 Irish driver licence images were generated, distributed evenly by gender. Publicly available headshots were used as photographs. These ID images were then printed and re-photographed to mimic a typical upload. Finally, each account submitted images of the assigned falsified IDs through the lottery.ie online verification system.

Four accounts were excluded due to technical issues with email providers, leaving 56 test accounts (male = 28, female = 28). Verification outcomes were collected using MS Excel. Lottery accounts were created between December 2023 and March 2024; counterfeit IDs were submitted between September and December 2024. No gambling activity or financial transactions were undertaken as part of this research project. It is worth noting that gambling activity is not permitted by the National Lottery prior to successful ID verification.

This research was approved by the Research Ethics Committee at the Technological University of the Shannon (TUS) Midwest.

RESULTS

All 56 test accounts (100%) successfully registered for lottery.ie. Upon submitting counterfeit IDs, 31 accounts received verification (55.4%). The remaining 25 accounts (44.6%) were blocked by the National Lottery. Blocking occurred at different stages; 9 accounts (16.1%) were blocked after submitting IDs for verification, 4 accounts (7.1%) during ID submission, and 12 accounts (21.4%) before ID submission.

Therefore, a total of 44 IDs were submitted to the National Lottery (25 passports and 19 driver's licences). Of these, 20 passports (45.5%) and 11 driver's licences (25%) were verified. Chi-square analysis did not identify this difference as significant.

Verification outcomes differed significantly by gender. 25 female IDs (89.3%) were verified, compared to 6 male IDs (21.4%). Chi-square analysis identified this difference as statistically significant ($\chi^2(1) = 26.09$, $p < .001$).

DISCUSSION

The results indicate that the Irish National Lottery's online age-verification system is vulnerable, with over half of the falsified accounts (55.4%) being successfully verified. Female accounts were verified significantly more often than male accounts; potentially reflecting order effects as female IDs were submitted first. This result could also imply that males are subject to more stringent verification, consistent with evidence that males are more likely to gamble underage [13] and develop problem gambling [11].

Furthermore, all accounts were created from the same IP address, which may have influenced verification outcomes and does not fully reflect real-world conditions. These findings highlight a public health concern, as early exposure to gambling increases the risk of problem gambling later in life [16,17].

CONCLUSION

Problem gambling is a significant problem for a small but substantial group within society [1,2,43]. The long-term impact of youth initiation into gambling is a particular concern for their future trajectories into problematic gambling [16]. Evidence to date has demonstrated that test-purchasing of National Lottery products has identified significant weaknesses in face-to-face purchasing [19-20]. This research extends this finding into the online arena. The National Lottery's online age-verification system inadequately prevents underage access, with over half of test accounts approved (55.4%). As such it fails to protect young people. Verification success varied significantly by gender in this analysis, with 'male' accounts being more likely to be rejected. Our findings underscore the need to implement reliable, robust verification measures to reduce youth exposure to gambling and associated harms. The National Lottery Act should be amended to include a system of routine underage test-purchasing checks, with associated penalties and enforcement for breaches. This evaluation should be completed by the State's Environmental Health Service, who should receive appropriate extra funding, personnel and training to take on this additional role.

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DATA AVAILABILITY STATEMENT

Data available on request from the authors.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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The MIGHTY project (P2022ASXKR): demographic and health status profiles among migrants and non-migrants in a region of central Italy between 2011-2023 using Healthcare Utilization Databases

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SUMMARY

Background: Accurate identification of migrants using Healthcare Utilization Databases (HUDs) remains challenging, as citizenship and place of birth may classify residents differently. This study compared two migrant identification criteria and assessed their impact on demographic and health status estimates in an Italian region.
Methods: A population-based observational study was conducted in the Marche Region (Central Italy), including all residents between 2011 and 2023. The HUDs used were the Regional Beneficiaries Database (RBD), the Hospital Discharge Records, and the Drug Prescriptions Database. Migrants were classified using RBD's country of birth (RBD birth criterion) and citizenship (RBD citizenship criterion), distinguishing Italians (Ita-Marche), migrants from High Migratory Pressure Countries (HMPC), and from Highly Developed Countries. Agreement between criteria was assessed using Cohen's k. Health status was evaluated in residents aged ≥50 years using the Multisource Comorbidity Score (MCS).
Results: Using RBD birth criterion, 88.6% of residents were classified as Ita-Marche, 10.0% as HMPC, and 1.4% as HDC; using RBD citizenship criterion, these proportions shifted to 92.1%, 7.6%, and 0.3%, respectively. Agreement was moderate (k between 0.67-0.70). HMPC residents were notably younger and showed a more favourable health profile: 67% had MCS equal to 0 vs 45% among Ita-Marche, while multimorbidity (MCS ≥5) was lower (9% vs 21.5%). Similar patterns emerged using both criteria.
Conclusion: HUDs are a reliable source of secondary data that has long been used in the healthcare sector. Their use in epidemiological studies allows for up-to-date and detailed overview of the demographic structure and comorbidity profiles of healthcare beneficiaries according to their country of origin. The study showed that the two criteria for identifying migrants lead to variations in demographic estimates and health indicators, which should be carefully considered by decision-makers when planning targeted health services and allocating resources according to population needs.

Keywords: Migrants; Demography; Health Status; Administrative Databases; Italy

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INTRODUCTION

One of the key goals of the 2030 Agenda for Sustainable Development is to ensure good health and well-being for all individuals, promoting equitable access to healthcare services. In Italy, this principle is embodied by the National Health Service (*Servizio Sanitario Nazionale*, SSN), which guarantees access to Essential Levels of Assistance (*Livelli Essenziali di Assistenza*, LEA). These LEA include a range of healthcare services and benefits provided universally, either free of charge or upon payment of a small participation fee (ticket), aiming to reduce disparities and uphold the right to health for all residents [1].

In 2023, more than five million foreign residents live in Italy, with the majority (85%) concentrated in the central and northern regions. These individuals primarily originate from countries with high migratory pressure, such as Morocco, Albania, China, Ukraine, India, Bangladesh, and Egypt[2]. The scientific literature highlights significant challenges faced by the foreign population in accessing healthcare services, often linked to language barriers, limited health literacy, and insufficient knowledge of the healthcare system's organization[3]. Within this context, understanding the demographic, health and healthcare access profiles of migrants is the first step for planning targeted organizational and policy responses.

Electronic health databases provide valuable resources for this purpose, as they systematically collect comprehensive data on healthcare services, including hospitalizations, drug prescriptions, and outpatient care. These databases are a useful source of data for epidemiological studies and can be used for a variety of population-based study objectives[4].

Nevertheless, the identification of migrants within electronic health databases remains a methodological challenge in Italy. The most readily available criterion, citizenship, represents the closest approximation to the concept of foreigner or immigrant, but it is not consistently available across administrative databases, and when present, its quality varies across data sources and regions, leading to inconsistencies in classification [5]. An alternative criterion is the country of birth, which remains constant over time and is uniquely defined. However, this approach has limitations: on one hand, it may be too broad, as it includes Italian citizens born abroad; on the other hand, it may be too narrow, as it excludes the descendants of immigrants, the so-called "second generation" foreigners, who do not have Italian citizenship even though they were born in Italy and may still face barriers in accessing healthcare [5]. These two criteria produce a different quantification and demographic distribution of the migrant population. Understanding the methodological implications of selecting one criterion over the other, e.g. in terms of misclassification bias, is essential for epidemiological analyses and for informing health promotion strategies and healthcare planning aimed at reducing potential inequalities.

To address these questions, this study was conducted within the framework of the PRIN PNRR 2022 project MIGrants' HealTh and healthcare access in ItalY (MIGHTY, Prot. P2022ASXKR) and provides a systematic comparison between these two migrant identification criteria in a large, unselected population using regional longitudinal datasets. The MIGHTY project aims to quantify and assess healthcare utilization among the migrant populations using healthcare administrative databases, as well as to evaluate their health conditions in real-world settings and compare them with those of the Italian population. Specifically, this paper focuses on comparing two criteria for identifying migrants and their effect on the evaluation of demographic and health status profiles among migrants and Italians resident in Marche Region, between 2011 and 2023 using Healthcare Utilization Databases.

METHODS

Study design and data sources

A population-based observational study was conducted, including all individuals with healthcare coverage in Marche Region, a central Italian region with approximately 1.5 million inhabitants.

The study was based on healthcare utilization databases of the Marche Region, specifically: Regional Beneficiaries Database (RBD) for information on residents, including a unique anonymous identification code, date and place of birth, sex, nationality, date of death, and healthcare coverage start and end dates; Hospital Discharge Records (HDR) containing demographics recorded at the time of hospitalization, and details on hospital admissions and discharges, primary and up to five secondary diagnoses, as well as up to six procedures coded according to the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM); Drug Prescriptions Database, which contains drug prescriptions coded according to the Anatomical Therapeutic Chemical (ATC) classification system reimbursed by the Nation Health Service, the date of dispensation, the Italian unique identifier of the pharmaceutical package, and the quantity dispensed.

All databases were linked using a deterministic record linkage procedure based on the beneficiary's unique anonymous identification code.

Reference population

The reference population was identified annually from 01/01/2011 to 31/12/2023 based on the subject's presence in the RBD and was defined using two criteria (Figure 1):

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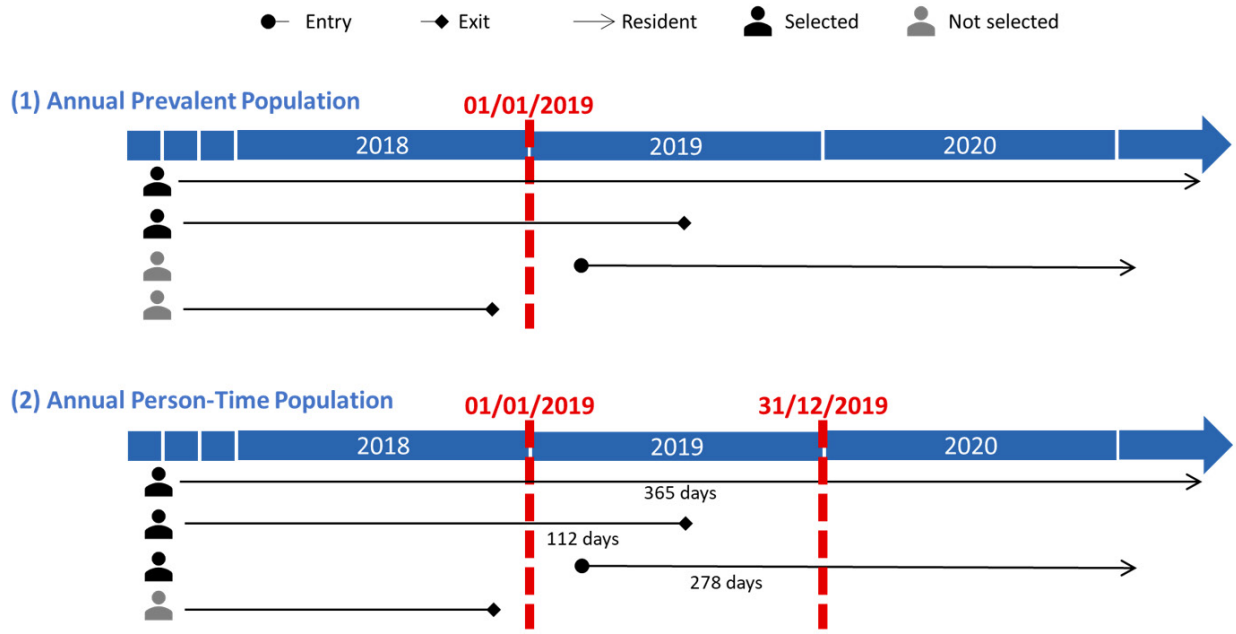
Figure 1. Annual reference population from 2011 to 2023 based on the (1) Annual Prevalent Population and (2) Annual Person-Time Population criteria. Entry may occur by birth or moving to Marche Region; Exit may occur by death or moving to another region/country



1) **Annual Prevalent Population**: Subjects who, as of January 1st of the year of analysis (1/1/20XX, from 2011 to 2023), had a recorded start date of healthcare coverage before January 1st of the reference year (1/1/20XX) and an end date of healthcare coverage (due to moving to another region/country) occurring after January 1st of the reference year and no recorded date of death before January 1st of the reference year (i.e., either missing or occurring after this date).
2) **Annual Person-Time Population**: Subjects who, at any time between January 1st and December 31st of the year of analysis (1/1/20XX – 31/12/20XX, from 2011 to 2023), had a recorded start date of healthcare coverage before December 31st of the reference year and an end date of healthcare coverage (due to moving to another region/country) occurring after January 1st of the reference year and no recorded date of death before January 1st of the reference year (i.e., either missing or occurring after this date). For this second group, the observation time was computed in terms of person-years (py) for each calendar year.

Definition of population groups

Two criteria were used to classify residents as Italians or Migrants.

The first was based on the place of birth recorded in the RBD (**RBD birth criterion**). The quality of this field, along with other demographic variables, is periodically controlled and monitored by the Region through consistency checks with the Italian tax code in RBD, a sixteen-character alphanumeric expression. The first six characters encode the surname and first name, the next five encode date of birth and sex, the sixteenth is a control letter, and positions 12 to 15 indicate the place of birth, corresponding to the Italian municipality or foreign country. For individuals born abroad, position twelve contains the letter 'Z' followed by a three-digit country code.

On the bases of RBD birth criterion, three population groups were defined:

- Ita-Marche: Individuals born in an Italian municipality.
- HMPC: Individuals born in a High Migratory Pressure Countries.
- HDC: Individuals born in a Highly Developed Countries.

The second criterion was based on the nationality field in RBD (**RBD citizenship criterion**) by which the name of the country of citizenship was used to classify residents in the same three population groups.

The classification of countries and the assignment of subjects to one of the three population groups followed the definition suggested by Trappolini and colleagues [6] and is detailed in Supplementary Table S1.

Statistical analysis

To describe the demographic profile of the three populations, age-sex pyramids from 2011 to 2023 were performed using the Annual Person-Time Population according to the RBD birth and citizenship criteria.

The Cohen's Kappa with confidence interval at 95% (CI 95%) was used to measure agreement between the RBD birth and citizenship criteria, applied to the Annual Person-Time Population.

To evaluate the health status profile, the Multisource Comorbidity Score (MCS) [7] was calculated for individuals aged 50 years or older within the Annual Prevalent Population from 2013 to 2023. Briefly, the MCS evaluates an individual's overall health status by identifying comorbid conditions based on data from the Hospital Discharge Records and the Drug Prescription Databases in the two years preceding January 1st of each reference year (1/1/20XX). A weight is assigned to each condition according to its association with one-year mortality, and the total MCS is obtained by summing these weights. The final score was categorized as 0, 1-4, 5-9, 10-14, 15-19, and 20 or more, with higher classes indicating poorer health conditions. The MCS has been validated at the national level as a predictor of mortality and healthcare utilization; however, because it is based on hospital discharge diagnoses and reimbursed drug prescriptions, it may not capture conditions managed exclusively in outpatient settings or not requiring pharmacological treatment.

Variables were summarised as absolute and percentage values. All statistical analyses were conducted using R.

RESULTS

During the period 2011-2023, based on the Annual Prevalent Population, the three population groups were distributed as follows: an average 88.60% of individuals were classified as Ita-Marche, 9.95% as HMPC, and 1.45% as HDC, according to RBD birth criterion (Table 1). When applying the RBD citizenship criterion, the distribution shifted to 92.11% Ita-Marche, 7.57% HMPC, and 0.32% HDC. A similar distribution was observed when considering the Annual Person-Time Population, with minor variations across population groups.

The concordance between RBD birth and citizenship criteria, when applied to the Annual Person-Time Population, ranging from a minimum Cohen's Kappa of 66.77% (95% CI: 66.54%-66.99%) in 2011 to a maximum of 70.23% (95% CI: 70.05%-70.41%) in 2023. Table 2 reports an example of this concordance for the year 2019, for which Cohen's Kappa was 69.03% (95% CI: 68.84%-69.23%). Overall, most of individuals classified as Ita-Marche based on RBD birth criterion (87.10%) were also categorized as Ita-Marche according to RBD citizenship criterion. Discrepancies emerged, with 3.42% of individuals categorized as HMPC by RBD birth criterion being classified as Ita-Marche by RBD citizenship criterion, and 1.14% of those identified as HDC by RBD birth criterion being classified as Ita-Marche under RBD citizenship criterion. Notably, the highest frequency of Italian citizenship was observed among individuals born in Argentina, Northern Macedonia, Albania, and Morocco (83.09%, 40.43%, 38.92%, and 37.39%, respectively, data not shown).

Table 1. Average annual population between 2011-2023 according to population groups (Birth vs RBD citizenship criteria) and to reference population (Annual Prevalent Population vs Annual Person-Time Population)

	Annual Prevalent Population (n, %)	Annual Person-Time Population (py, %)
RBD birth criterion		
Ita-Marche	1,345,300 (88.60%)	1,346,919 (88.52%)
HMPC	151,120 (9.95%)	152,628 (10.03%)
HDC	21,932 (1.45%)	22,103 (1.45%)
RBD citizenship criterion		
Ita-Marche	1,398,604 (92.11%)	1,400,267 (92.02%)
HMPC	114,891 (7.57%)	116,408 (7.65%)
HDC	4,857 (0.32%)	4,974 (0.33%)

py: person-year; Ita-Marche: Italian residents in Marche Region; HMPC: migrants from High Migratory Pressure Countries residents in Marche Region; HDC: migrants from Highly Developed Countries residents in Marche Region; RBD: Regional Beneficiaries Database.

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Table 2. Frequency distribution of Annual Person-Time Population in 2019 according to birth and RBD citizenship criteria

RBD birth criterion	RBD citizenship criterion			Total
	Ita-Marche	*HMPC*	*HDC*	
Ita-Marche	**1,331,313 (87.10%)**	16,461 (1.08%)	173 (0.01%)	1,347,947 (88.19%)
HMPC	52,202 (3.42%)	**105,658 (6.91%)**	291 (0.02%)	158,151 (10.35%)
HDC	17,396 (1.14%)	280 (0.02%)	**4,718 (0.31%)**	22,394 (1.47%)
Total	1,400,911 (91.65%)	122,399 (8.01%)	5,181 (0.34%)	1,528,491 (100%)

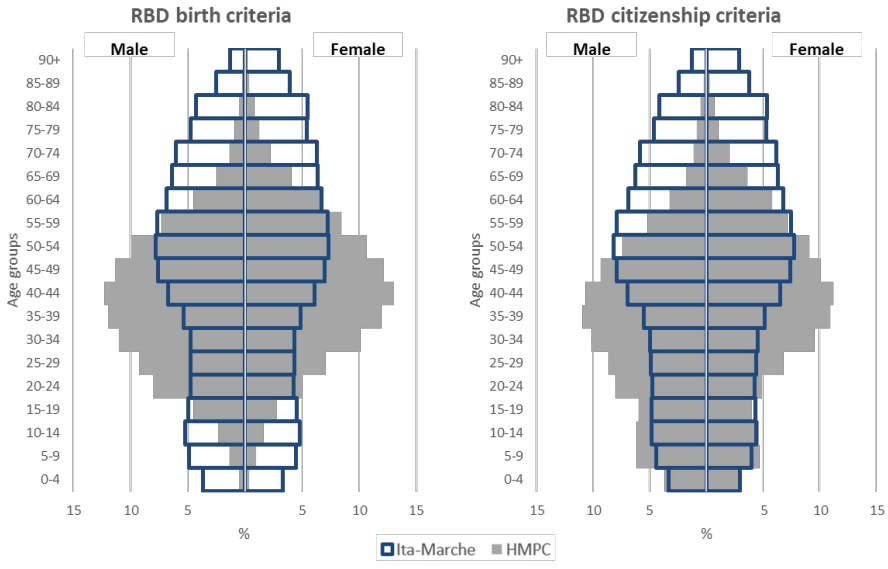
Ita-Marche: Italian residents in Marche Region; HMPC: migrants from High Migratory Pressure Countries residents in Marche Region; HDC: migrants from Highly Developed Countries residents in Marche Region; RBD: Regional Beneficiaries Database.

Demographic profile

The RBD birth and citizenship criteria yielded distinct demographic profiles when analysing age-sex pyramids from 2011 to 2023. All annual age-sex pyramids of the Ita-Marche, HMPC and HDC population groups are shown in the Supplementary Material Figure S1 and S2, to show changes over time. Figure 2 shows, as an example, the age-sex pyramids for the Ita-Marche and HMPC population groups, based on RBD birth and citizenship criteria, in 2019. The Ita-Marche group exhibited a classic stationary population pyramid, characterized by a wider middle section, indicative of an aging population with a relatively balanced distribution across age groups. In contrast, the HMPC group displayed a distinctly younger demographic profile, with a marked concentration of individuals in the working-age brackets (20-54 years), particularly among males, and a sharp narrowing at older ages. When comparing the two classification criteria, the RBD birth criterion identified a smaller proportion of individuals aged 0-14 years, while the RBD citizenship criterion produced a broader pyramid base and a less pronounced working-age predominance.

The HDC group consisted of a few thousand individuals, mainly concentrated in the 35-39 and 50-54 age groups, but according to the RBD citizenship criterion, the dispersion of the age distribution was greater (Supplementary Material Figure S1-S2).

Figure 2. Age-sex pyramids for the Ita-Marche (Italian residents) and HMPC (residents from High Migratory Pressure Countries) population groups based on RBD birth and citizenship criteria in 2019



Ita-Marche: Italian residents in Marche Region; HMPC: migrants from High Migratory Pressure Countries residents in Marche Region; HDC: migrants from Highly Developed Countries residents in Marche Region; RBD: Regional Beneficiaries Database.

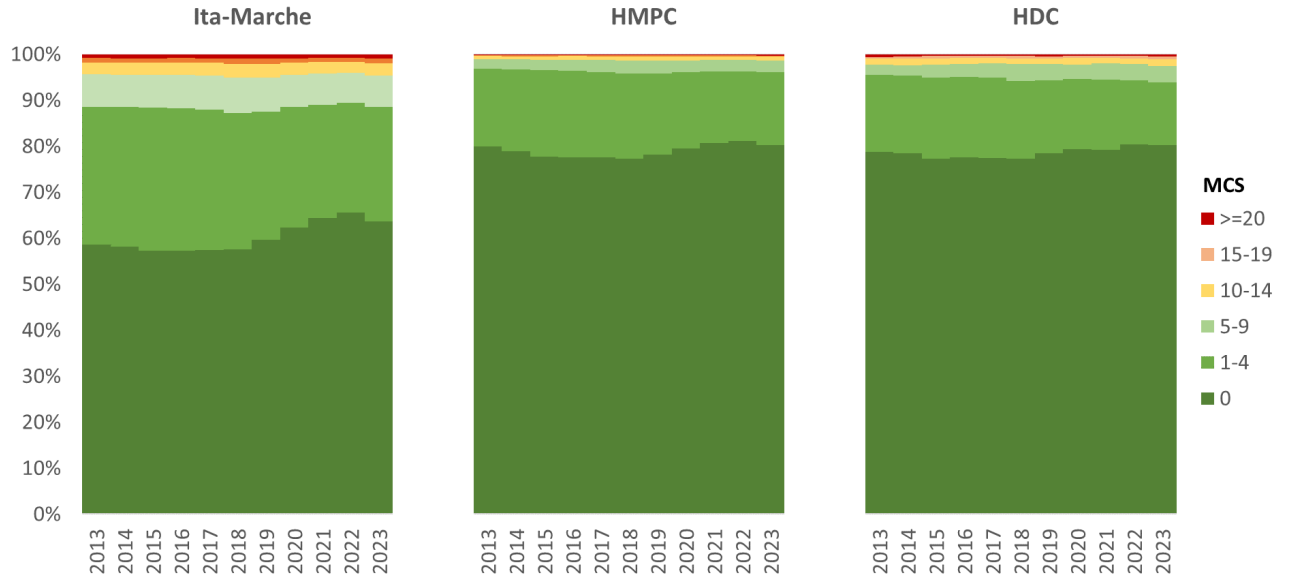
Health status profile

RBD birth and citizenship criteria highlighted comparable health status profiles for each population group. Overall, the health status in subjects aged 50 years or older, as measured by the Multisource Comorbidity Score (MCS), was better among individuals in the HMPC group than among those in the Ita-Marche group throughout the study period (Supplementary Materials Table S2). HDC had a health status profile more similar to the HMPC group than to the Ita-Marche group. However, the HDC group showed substantial differences in the distribution of MCS classes, in particular among 0 and 1-4 classes, when comparing RBD birth and citizenship criteria.

According to RBD citizenship criterion, individuals with an MCS of 0, indicating no condition traced in HDR or drug prescription databases, were on average 78,97% in the HMPC group and 60.13% in the Ita-Marche group, between 2013 and 2023 (Figure 3). The percentage of individuals with an MCS of 1-4 was consistently higher in the Ita-Marche group (ranging from 24.72% to 31.17%) compared to the HMPC group (15.12% to 18.88%); the proportion of individuals with an MCS of 5 or higher (5-9, 10-14, 15-19, and ≥20) was markedly greater in Ita-Marche (11.65%) than those observed in the HMPC group (3.76%).

The most frequent conditions, identified by MCS, varied across the populations (Supplementary Table S3): "Pain and inflammation" was the first most common condition in HMPC (36.99%) and the second most common in Ita-Marche (43.11%), while "Hypertension" was the second most common condition in HMPC (27.37%) and the first most common in Ita-Marche (44.88%); in both groups, the third most common condition was "Hyperlipidaemia" (16.28% HMPC vs. 29.28% Ita-Marche). Moreover, Ita-Marche group showed higher proportion in Coronary and peripheral vascular disease (18.18% vs 7.48%), Heart failure (14.72% vs 6.90%), Chronic pulmonary diseases (15.05% vs 6.57%), Gout (11.87% vs 3.72%) than HMPC group. It is worth noting the lower prevalence of these conditions among HMPC compared to Ita-Marche. Among the four age classes (50-59, 60-69, 70-79, and 80+) the HMPC health profile was consistently better than the one of the Ita-Marche. In 2023, proportion of individuals with no recorded comorbidities (MCS = 0) was constantly higher in HMPC compared to Ita-Marche, especially among older age groups (80+: 51.91% vs. 22.72%; 70–79: 57.33% vs. 36.85%, respectively). Conversely, Ita-Marche had a higher prevalence of multimorbidity, with more individuals classified in the 5–9 and 10–14 MCS categories (Supplementary Figure S3).

Figure 3. Health status profile calculated with Multisource Comorbidity Score (MCS) between Ita-Marche, HMDC and HDC population group, considering the RBD citizenship criterion



Ita-Marche: Italian residents in Marche Region; HMPC: migrants from High Migratory Pressure Countries residents in Marche Region; HDC: migrants from Highly Developed Countries residents in Marche Region; RBD: Regional Beneficiaries Database; MCS: Multisource Comorbidity Score.

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DISCUSSION

This is the first population-based study aimed at comparing different criteria for identifying residents based on their migrant status and assessing the effects of these criteria on demographic and health profiles, using healthcare utilization databases. Two approaches were proposed for the identification of migrants within the Healthcare Utilisation Databases: one based on place of birth and one from the citizenship fields in the RBD.

The criteria used in this study highlight crucial differences in the identification of migrants, as demonstrated by the moderate concordance observed by Cohen's Kappa values. The criterion based on citizenship shows a broader base of the sex-age pyramid in HMPC population and, therefore, has a greater capacity to identify second-generation migrants compared to the criterion of place of birth [8]. In working age groups, the differences between the two criteria can be considered negligible, although after 35 years the shape of the pyramid diverges slightly, likely reflecting longer residence in Italy and citizenship acquisition among migrants. Indeed, more than 40% of citizenship acquisitions in Italy occur among individuals aged ≥35 years [9,10].

On the other hand, people who obtain Italian citizenship as adults often maintain the cultural background and lifestyle of their country of origin [11,12]. Consequently, the choice of one criterion over another is linked to the objective of the study and the definition of the target population.

The three population groups showed distinct demographic structures, regardless of the identification criteria, as evidenced by the age-sex pyramids overtime. As expected, the Ita-Marche group exhibited an aging population with a balanced distribution across age groups, whereas the HMPC group showed a younger demography, characterized by a predominance of working-age individuals (20-54 years) and a narrower representation of the older age groups [13,14].

The low percentage of older age groups among HMPCs is partly due to the fact that migration is typical of young people seeking work [15] and partly to the well-known demographic phenomenon known as the "salmon effect," whereby older migrants return to their country of origin [16].

The different age distribution between HMPC and Ita-Marche groups persists even among individuals aged 50 years and older and may partially explain the different health profiles observed in the two populations. Indeed, the analysis of health status using the Multisource Comorbidity Score revealed a better health profile among the HMPC and HDC groups compared to the Ita-Marche group, particularly in older age classes. This "healthy migrant effect", widely documented in the scientific literature, reflects the selective migration processes, where younger and healthier individuals are more likely to migrate [17–19]. Furthermore, according to Campostrini et al [20], migrants in Italy generally exhibit better health behaviours and attitudes compared to the native population, including lower rates of smoking, alcohol consumption, and obesity; in a comparative study of European surveys, it was also observed that, after controlling for socioeconomic status, migrants self-reported better health than natives in Italy [18]. However, in our study we observed a high proportion of pain and inflammation conditions in the HMPC group, pointing out potential unmet healthcare needs, especially in the management of acute conditions and pain.

In the Marche region, the percentage of foreign residents in 2024 was 8.90%, lower than in most regions of northern and central Italy, but perfectly in line with the Italian average (8.91%) [13]. The proportion of migrants has risen steadily from 3% in 2002 to 10% in 2015, remaining at around 9% to date. This trend shows that migrants are not anymore, a marginal quota of regional population, therefore demographic, social, economic as well as health status profiles should be taken into account health policy considerations and health service planning.

This study has several strengths, foremost among them is its population-based design. The use of healthcare utilisation databases allowed to cover the entire population of an Italian region over a long observation period. The completeness and reliability of these secondary data sources has been amply demonstrated by their use in epidemiological studies for more than a decade. Consequently, the results obtained in comparing the two criteria for identifying the populations of interest can be considered valid and reproducible at national level. Moreover, the results of this study provided up-to-date and detailed information on the demographics and health status of resident migrants from countries with high migration pressure or highly developed countries, information not available through official national statistics alone. Since health data is routinely recorded in healthcare utilization databases throughout Italy, the same methodological approach can be repeated over time for regular monitoring and applied to other Italian regions. Certain limitations must also be acknowledged. Health status was assessed using the MCS, which relies on information from hospital admissions and reimbursed pharmaceutical prescriptions only. As a result, conditions that do not require hospitalisation or pharmacological treatment provided by the Regional Health Service are not traceable. Nevertheless, it should be considered that this comorbidity index is validated at national level. Finally, migrants from high migratory pressure countries may underutilize healthcare services, due to cultural and linguistic barriers, and limited health literacy, which could lead to under-ascertainment of some health conditions in this population.

In conclusion, this study showed a detailed overview of the demographic profiles and health

status of residents in the Marche region based on their country of origin. Furthermore, this population-based study provides useful information on the criteria for identifying migrants based on their country of origin and their impact on demographic and epidemiological assessments in real-world. Accurate identification method of migrant populations, when using HUDs, is essential not only for valid research but also for assessing and monitoring access to care in order to reduce and prevent possible disparities of this segment of the resident population.

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University of Milano-Bicocca: Elisa Barbiano di Belgiojoso, Stefania M.L. Rimoldi, Dario Pescini, Paolo Berta, Nadia Solaro, Paola Chiodini, Alessandro Avellone, Antonella Zambon.

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AUTHORS' CONTRIBUTIONS

RG and MI conceptualized the study, developed the methodology for data analysis and drafted the manuscript. MI managed the data and performed the formal statistical analyses. MP and FC were in charge for data extraction and authorized their utilization. RG, MI, AF, ES assisted in the results interpretation. All authors assisted in manuscript revision, read and approved the final manuscript. RG is the guarantor of the overall content of the work.

CONFLICT OF INTEREST

The authors have declared no conflict of interest.

DATA AVAILABILITY STATEMENT

Restrictions apply to the availability of these data. The datasets generated and/or analysed during the current study are property of a third party that is the Regional Health Agency of Marche (ARSMarche) and, although they are anonymized, datasets are not publicly available due to the current regulation on privacy. The description of the administrative databases is available from the website ARSMarche/Flussi.

Other researchers can obtain access to the data through a formal request based on a research project to the Regional Health Agency of Marche.

ETHICS STATEMENT

This observational study fulfils the Italian regulations of ethics committees, which require only standard written informed consent at the time of hospital admission.

Ethical review and approval were waived for this study. We did not mention ethical safeguards simply because not pertinent in our study. All data were anonymized and managed in a manner that protected the privacy and confidentiality of individuals represented in the datasets.

According to Article 9 of the General Data Protection Regulation (European Union Regulation 2016/679), pseudonymized administrative data can be used without specific written informed consent when patient information is collected for healthcare management, quality evaluation, and improvement. All procedures adhered to the 1964 Helsinki Declaration and its subsequent amendments.

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The Italian Ministry of University and Research had no role in the design of the study, the collection, the analysis, the interpretation of the data, or the decision to approve publication of the finished manuscript.

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From Screens to Stress: Public Health Implications of Cancer Worry in a Digitally Connected World

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SUMMARY

Aims: This study examines how digital information environments, genetic testing experiences, health behaviors, and psychological distress influence cancer-related worry among adults in the United States. It further considers the public health implications of elevated or reduced cancer worry for prevention and risk communication.
Methods: Data were drawn from a nationally representative survey of 6,252 U.S. adults. Measures included reliance on social media for health decision-making, smoking status, history of genetic testing, and psychological distress. Multivariable analyses assessed associations between these factors and levels of cancer worry.
Results/Findings: Reliance on social media for health decisions was associated with greater cancer worry, indicating that exposure to misinformation or amplified risk cues may heighten anxiety. Smoking was also linked to increased worry, consistent with higher perceived vulnerability. In contrast, individuals who had undergone genetic testing reported lower cancer worry, suggesting that structured risk information can reduce uncertainty. Psychological distress emerged as the strongest predictor of extreme cancer worry, highlighting the central role of mental health in shaping risk perceptions.
Conclusions: Cancer worry is influenced by the interaction of digital information sources, behavioral risk factors, and psychological distress. Public health efforts should focus on strengthening digital health literacy, countering online misinformation, and incorporating mental health assessment into cancer prevention and communication strategies. These approaches may help support balanced risk appraisal and reduce unnecessary distress in the population.

Keywords: Cancer, Social Media, Genetic Testing, Smoking, Education, Prevention

INTRODUCTION

Cancer is a leading cause of mortality for both men and women in the United States [1, 2]. In 2025, the American Cancer Society projects that approximately 2 million new cancer cases will be diagnosed in the United States, with around 600,000 people expected to die from the disease [3-5]. The emotional and psychological toll of cancer is profound, affecting not only those diagnosed but also their families and caregivers [6-8]. A cancer diagnosis often brings fear, anxiety, and uncertainty as patients navigate treatment decisions, potential side effects, and financial burdens [9-11].

Social media plays a crucial role in the creation, exchange, and dissemination of user-generated

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content, transforming the way people access and share information [12, 13]. With approximately 5.24 billion users worldwide, social media platforms have become an integral part of daily life, influencing communication, business, healthcare, and education [14, 15]. In the healthcare domain, social media has become an essential resource for information seekers, patients, caregivers, and healthcare professionals [16, 17]. Many individuals turn to these platforms to find and share knowledge about chronic diseases, including their causes, symptoms, diagnosis, treatment options, and preventive measures. Despite many benefits, the widespread use of social media in healthcare also presents challenges, particularly in the spread of misinformation. False or misleading health claims can easily go viral, influencing public perceptions and potentially leading to harmful consequences [18, 19]. Some users may rely on unverified sources instead of consulting medical professionals, making it essential for regulatory bodies, healthcare experts, and technology companies to implement measures that promote accurate and science-based health information [20].

Genetic testing plays a vital role in cancer prevention by identifying individuals who have inherited genetic mutations that increase their risk of developing certain types of cancer [21, 22]. Many cancers, such as breast, ovarian, colorectal, and prostate cancer, have been linked to specific genetic mutations, including BRCA1, BRCA2, and Lynch syndrome-associated genes [23, 24]. This proactive approach allows for earlier screenings and interventions that could significantly improve long-term health outcomes.

Anxiety and depression play an important role in understanding the psychological factors that may influence cancer risk and progression [25, 26]. While they are direct biomarkers for cancer, research suggests that chronic stress, depression, and anxiety, conditions identified through the Patient Health Questionnaire-4 (PHQ-4), a brief screening tool, can contribute to cancer risk through behavioral, hormonal, and immune-related mechanisms [27, 28]. The fear of developing cancer, often referred to as cancer worry or cancer anxiety, can significantly impact an individual's overall health and well-being [10, 29]. Persistent anxiety about getting cancer can lead to chronic stress, heightened cortisol levels, and immune system dysregulation, which may inadvertently increase susceptibility to various health issues, including cancer itself [30]. Consistent with prior work, chronic psychological distress has been associated with immune dysregulation, prolonged inflammatory responses, and hypothalamic–pituitary–adrenal axis disruption—mechanisms described as indirect pathways linking psychosocial factors to disease progression and overall health rather than direct causal risk factors for cancer [31].

Additionally, individuals who excessively worry about cancer may experience health-related anxiety, leading to frequent medical visits, unnecessary tests, and a diminished quality of life due to constant fear [32]. On the other hand, in some cases, extreme worry may result in avoidance behavior, where individuals delay screenings or medical check-ups due to fear of receiving bad news [33]. This can be particularly dangerous, as delayed diagnoses often lead to worse outcomes if cancer is present.

In Section 2, we describe the material and methods to investigate various factors that might affect cancer-related worries. In Section 3, we present results, and in Section 4, we provide discussions and future directions.

MATERIALS AND METHODS

Sample

The Health Information National Trends Survey (HINTS) 2022, Cycle 6, conducted by the National Cancer Institute (NCI) [34], is about collecting information about cancer without looking at previous medical history. HINTS is a cross-sectional study of health communication among the US adult population. The description of the methodology of the survey and sampling procedure can be obtained from NCI (USDHHS 2022) [34]. A total of 6,252 surveys were included in the final dataset.

In this study, we consider "Worry about getting cancer" as the outcome variable. Cancer worry was measured using a single self-reported survey item asking respondents how worried they were about getting cancer, with response options ranging from "not at all worried" to "extremely worried". Also, race/ethnicity, age, education level, and use of information from social media to make decisions about health, genetic testing, and PHQ4 scores are considered independent variables.

Statistical Analysis

Data was analyzed by using IBM SPSS version 28. The preliminary selection of questions was based on the bivariate association between respondents' various characteristics such as age, sex, education, worrying about getting cancer, health status, PHQ-4 scores, etc. Based on this analysis, we studied the effect of race, education, age, genetic testing, social media use, and PHQ-4 scores on their worry about getting cancer using a multinomial regression model. We eliminated responses "Refused" and "Don't know" to survey items under study.

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Table 1. Characteristics of the Population

		Number of People	Marginal Percentage
Worried About Getting Cancer	**Extremely**	401	9.2%
	Moderatly	706	16.3%
	Somewhat	1273	29.4%
	Slightly	1218	28.1%
	Not at all	739	17.0%
Race/Ethnicity	**Non-Hispanic White**	2469	56.9%
	Non-Hispanic Black or African American	679	15.7%
	Hispanic	792	18.3%
	Non-Hispanic Asian	242	5.6%
	Non-Hispanic Other	155	3.6%
Education	**Less than High School**	207	4.8%
	High School Graduate	662	15.3%
	Some College	1264	29.1%
	Bachelor's Degree	1303	30.0%
	Post-Baccalaureate Degree	901	20.8%
Gender	**Male**	1665	38.4%
	Female	2672	61.6%
Smoking Status	**Current**	466	10.7%
	Former	1032	23.8%
	Never	2839	65.5%
Age Group (Years)	**18-34**	791	18.2%
	35-49	1036	23.9%
	50-64	1291	29.8%
	65-74	841	19.4%
	75+	378	8.7%
Use Social Media Information to Make Health Decisions	**Strongly Agree**	49	1.1%
	Somewhat Agree	653	15.1%
	Somewhat disagree	918	21.2%
	Strongly Disagree	2717	62.6%
Genetic Testing for Specific Disease	**No**	4158	95.9%
	Yes	179	4.1%
flipped PHQ4 Scores Categories	**Severe**	191	4.4%
	Moderate	401	9.2%
	Mild	995	22.9%
	Normal	2750	63.4%
Valid		4337	
Missing		1915	
Total		6252	

Table 2. Correlation

		Worried About Getting Cancer
Smoking Status	**Pearson Correlation**	0.058**
	Sig. (2-tailed)	<.001
	N	5782
Ever Had Cancer	**Pearson Correlation**	0.151**
	Sig. (2-tailed)	<.001
	N	5822
Use Social Media Information to Make Health Decisions	**Pearson Correlation**	0.075**
	Sig. (2-tailed)	<.001
	N	4653
Overall, how confident are you that your genetic testing results are correct and accurate?	**Pearson Correlation**	-0.011
	Sig. (2-tailed)	0.665
	N	1567
Genetic Testing for Specific Disease	**Pearson Correlation**	-0.063**
	Sig. (2-tailed)	<.001
	N	5856
Age Group	**Pearson Correlation**	0.042**
	Sig. (2-tailed)	0.001
	N	5784
Race/Ethnicity	**Pearson Correlation**	-0.021
	Sig. (2-tailed)	0.113
	N	5521
Gender	**Pearson Correlation**	-0.046**
	Sig. (2-tailed)	<.001
	N	5782
Education	**Pearson Correlation**	-0.005
	Sig. (2-tailed)	0.681
	N	5787
PHQ-4 Categories	**Pearson Correlation**	-0.183**
	Sig. (2-tailed)	<.001
	N	5740

*** Significant at the 0.01 level (two-tailed)*
**Significant at the 0.05 level (two-tailed)*

RESULTS

The population characteristics reveal important demographic, behavioral, and psychological patterns related to cancer worry (Table 1). In terms of cancer concern, nearly 54% of individuals report being "Somewhat" or "Slightly" worried about getting cancer, while only 9.2% are "Extremely" worried. The majority of the sample consists of non-Hispanic Whites (56.9%), followed by Hispanics (18.3%), and non-Hispanic Black or African Americans (15.7%). Educational attainment is relatively high, with 50.8% holding a bachelor's or post-baccalaureate degree and only 4.8% having less than a high school education. Women (61.6%) outnumber men (38.4%) in the sample.

The correlation analysis, presented in Table 2, examines the relationships between worry about getting cancer and various demographic, behavioral, and psychological factors. Several variables show statistically significant associations at the 0.01 level ($p < .001$), though most correlations are weak. Smoking status is positively correlated with worry about cancer ($r = 0.058$, $p < .001$), suggesting that smokers tend

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to report higher levels of cancer worry compared to non-smokers. Similarly, individuals who have ever had cancer show a stronger positive correlation with worry ($r = 0.151$, $p < .001$), indicating that those with a cancer history experience greater anxiety about the disease. Social media use for health decisions also has a weak but significant positive correlation ($r = 0.075$, $p < .001$), implying that those who rely more on social media for health-related information tend to worry more about cancer. Reliance on social media for health decision-making was associated with a modest but statistically significant increase in cancer-related worry, indicating a consistent relationship of small magnitude within the population. Interestingly, genetic testing for specific diseases is negatively correlated with cancer worry ($r = -0.063$, $p < .001$), meaning that individuals who have undergone genetic testing tend to worry less about cancer. However, confidence in genetic testing accuracy does not show a significant relationship with cancer worry ($r = -0.011$, $p = .665$). Age is weakly but significantly correlated with cancer worry ($r = 0.042$, $p = .001$), suggesting that older individuals may experience slightly greater concern.

Gender was negatively correlated with cancer worry ($r = -0.046$, $p < .001$), indicating that males reported lower worry than females, while race/ethnicity and education showed no significant associations. Psychological distress exhibited the strongest correlation ($r = -0.183$, $p < .001$), with higher distress linked to extreme cancer worry. Overall, behavioral, psychological, and demographic factors influenced worry, though effect sizes were modest. Table 3 showed a significant association between social media use for health decisions and cancer worry ($\chi^2 = 55.790$, $p < .001$). Individuals who relied on social media reported higher worry, suggesting possible effects of risk amplification or misinformation exposure.

The results in Table 4 indicate a statistically significant association between genetic testing for a specific disease and worry about getting cancer ($\chi^2 = 55.292$, $p < .001$). The majority of individuals in the sample (95.3%) have not undergone genetic testing, and among them, cancer worry is fairly evenly distributed across levels of concern. However, among the small proportion who have undergone genetic testing (4.7%), a distinct pattern emerges, this group has a higher proportion of individuals reporting "Extremely" worried about cancer (59 out of 277; 21.3%) compared to the non-tested group (511 out of 5,579; 9.2%). This suggests that those who undergo genetic testing may experience heightened cancer-related worry, potentially due to an increased awareness of their health risks. Although genetic testing was associated with lower cancer worry overall, the

Table 3. Association between the Use of Social Media Information to Make Health Decisions and Worrying about Getting Cancer

		How worried are you about getting cancer?					Total
		Not at all	Slightly	Somewhat	Moderately	Extremely	
Use Social Media Information to Make Health Decisions	**Strongly Agree**	12	16	10	7	9	54
	Somewhat Agree	113	175	189	121	97	695
	Somewhat disagree	130	252	322	178	91	973
	Strongly Disagree	565	848	824	447	247	2931
Total		820	1291	1345	753	444	4653

Chi-Square Tests

	Value	Degrees of Freedom	Asymptotic Significance (2-sided)
Pearson Chi-Square	55.790[a]	12	<.001
Likelihood Ratio	54.428	12	<.001
Linear-by-Linear Association	26.355	1	<.001
N of Valid Cases	4653		

[a]. 0 cells (0.0%) have an expected count of less than 5. The minimum expected count is 5.15

Table 4. Genetic Testing for Specific Diseases and Worrying about Getting Cancer

		How worried are you about getting cancer?					Total
		Not at all	Slightly	Somewhat	Moderately	Extremely	
Genetic Testing for Specific Disease	**No**	1083	1557	1577	851	511	5579
	Yes	53	43	83	39	59	277
Total		1136	1600	1660	890	570	5856

Chi-Square Tests

	Value	Degrees of Freedom	Asymptotic Significance (2-sided)
Pearson Chi-Square	55.292[a]	4	<.001
Likelihood Ratio	48.220	4	<.001
Linear-by-Linear Association	22.987	1	<.001
N of Valid Cases	5856		

[a]. 0 cells (0.0%) have an expected count of less than 5. The minimum expected count is 26.96

Table 5. Association between PHQ-4 Score and Worrying about Getting Cancer

		How worried are you about getting cancer?					Total
		Not at all	Slightly	Somewhat	Moderately	Extremely	
PHQ-4 Categories	**Normal (0-2)**	863	1074	1052	514	249	3752
	Mild (3-5)	155	342	376	206	161	1240
	Moderate (6-8)	67	108	136	102	81	494
	Severe (9-12)	28	48	71	47	60	254
Total		1113	1572	1635	869	551	5740

Chi-Square Tests

	Value	Degrees of Freedom	Asymptotic Significance (2-sided)
Pearson Chi-Square	233.267[a]	12	<.001
Likelihood Ratio	222.434	12	<.001
Linear-by-Linear Association	192.228	1	<.001
N of Valid Cases	5740		

[a]. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 24.38

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presence of a smaller subgroup reporting extreme worry likely reflects heterogeneity in testing indications and results, such as positive findings, uncertain variants, or strong family history, which could not be examined due to limitations in the available data.

Table 5 shows a strong association between psychological distress (PHQ-4) and cancer worry. Individuals with normal PHQ-4 scores were least worried, whereas increasing distress corresponded to progressively higher levels of moderate and extreme cancer worry. Among those with severe distress, only 11% reported no worry, while 24% reported extreme worry, the highest of any group. Although an association between anxiety and cancer worry may appear intuitive, this finding is notable because the PHQ-4 measures general psychological distress rather than cancer-specific anxiety. The strength of this association exceeded that of sociodemographic factors, health behaviors, and information sources, suggesting that extreme cancer worry reflects broader emotional vulnerability rather than informed risk appraisal alone.

The Chi-Square test results confirm a highly significant relationship ($\chi^2 = 233.267$, $p < .001$) between psychological distress and cancer worry, indicating that this association is unlikely to be due to chance.

The Relationship Maps show how social media use, genetic testing, and psychological distress relate to cancer worry.

Figure 1 indicates that individuals who rely on social media for health decisions tend to report higher cancer worry, likely reflecting exposure to alarming content or misinformation. Figure 2 shows that those who have undergone genetic testing are more likely to report moderate or extreme worry, whereas individuals without testing tend to report lower worry. Figure 3 demonstrates a strong link between severe psychological distress (PHQ-4 scores) and extreme cancer worry, highlighting mental health as a key factor shaping heightened cancer-related concern.

Figure 1. Relationship map between Cancer Perception and the use of social media for making health decisions.

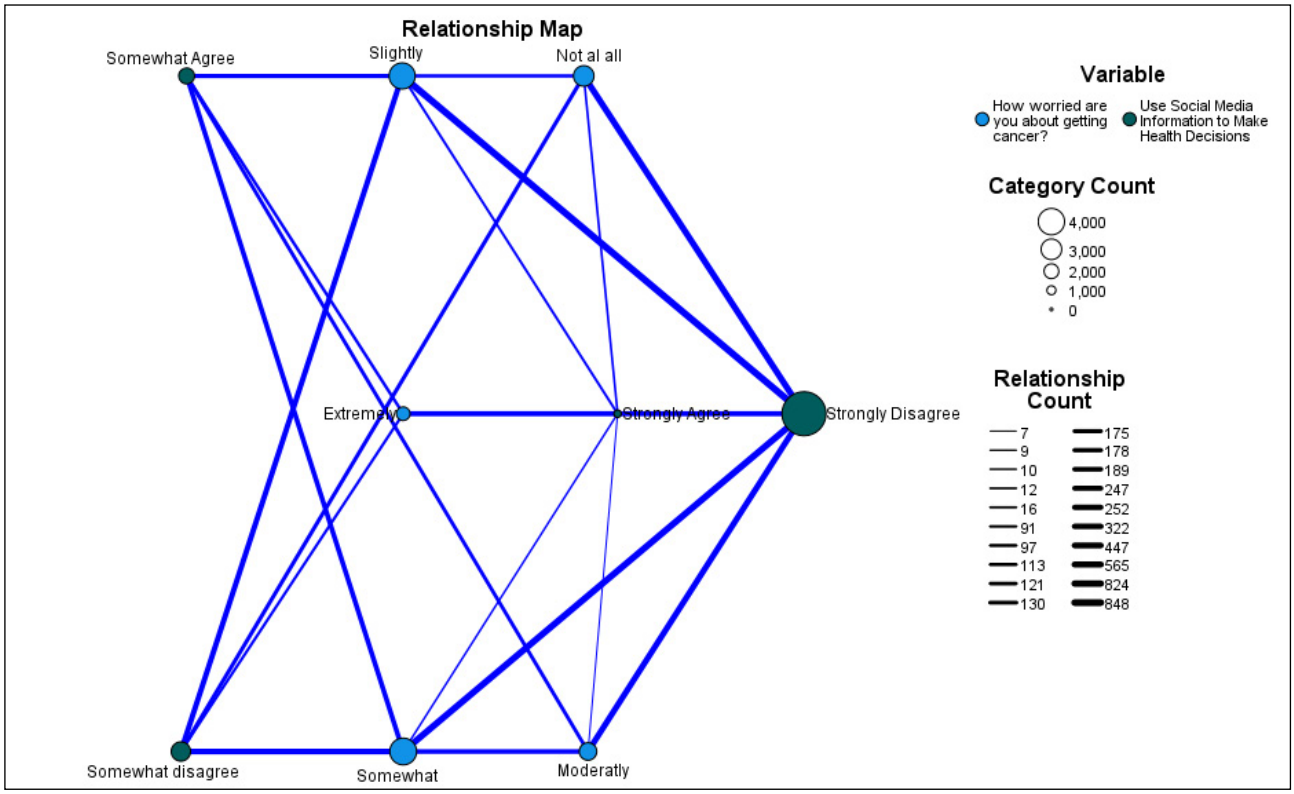


Figure 2. Cancer Perception and Genetic Testing

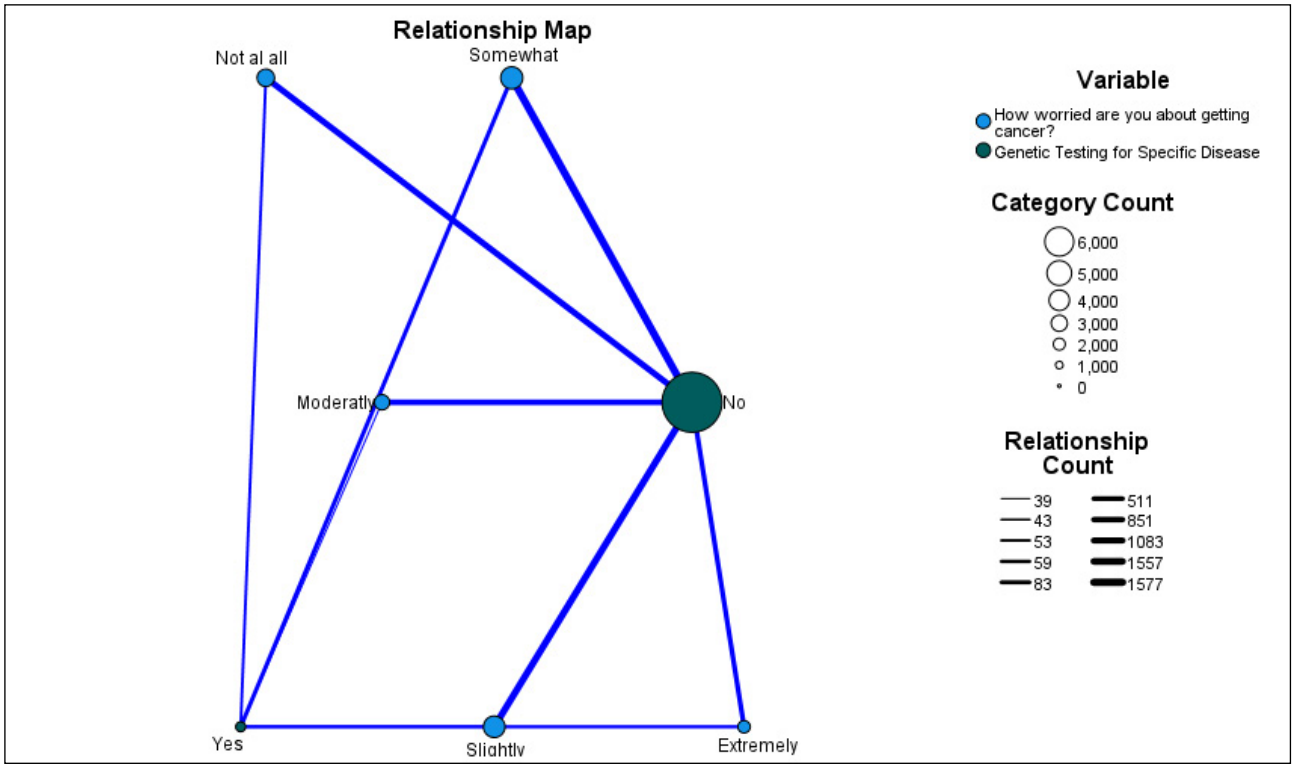
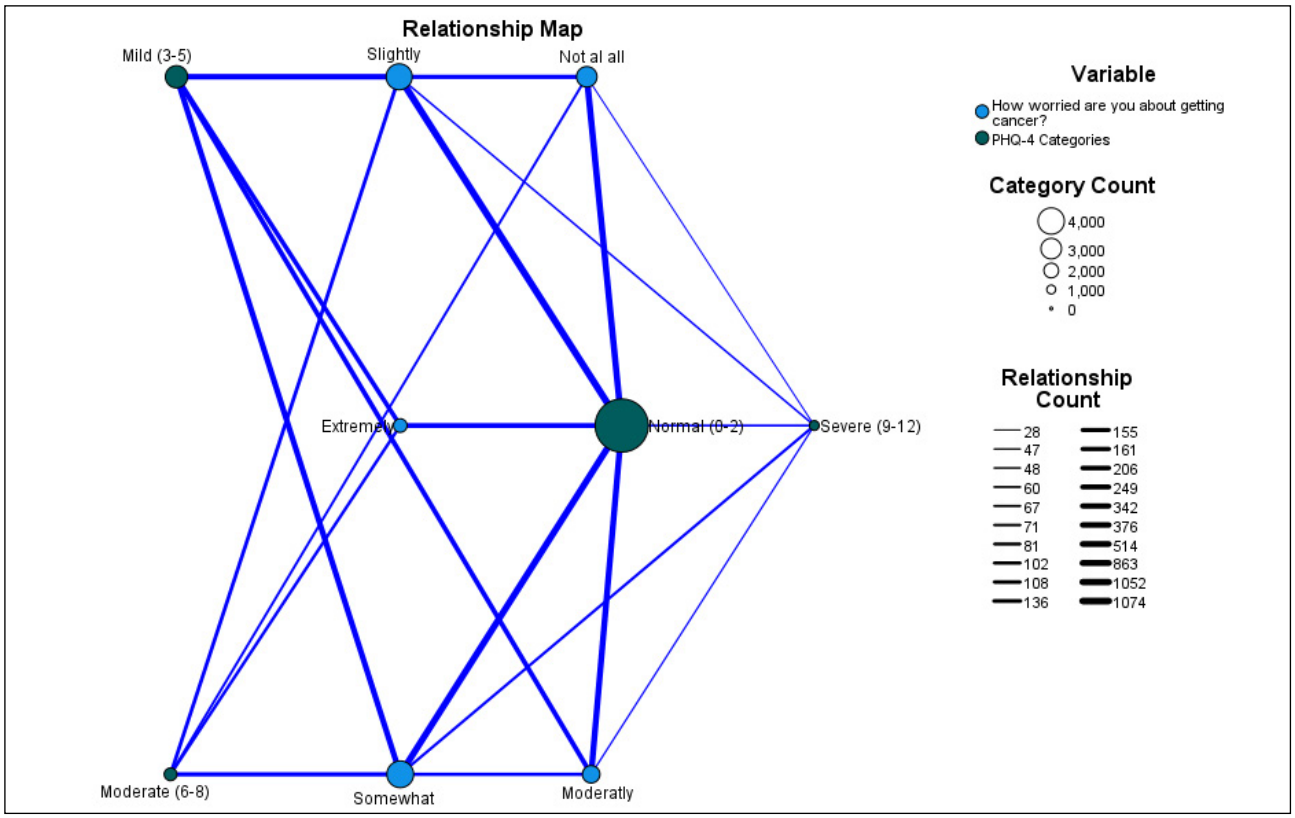


Figure 3: Cancer Perception and Psychological Distress



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The logistic regression analysis (Table 6) investigates factors influencing individuals' likelihood of being "Extremely" worried about getting cancer, using "Not at all worried" as the reference category. The results (Table 7) reveal several significant predictors, with race/ethnicity, education, gender, smoking status, attitudes toward health information, genetic testing, and psychological distress playing key roles in determining extreme worry levels.

Table 6. Logistic Regression - Model Fitting Information

Model	Model Fitting Criteria	Likelihood Ratio Tests		
	-2 Log Likelihood	Chi-Square	df	Significance
Intercept Only	8730.827			
Final	8305.805	425.023	88	<.001

Pseudo R-Square

Cox and Snell	0.093
Nagelkerke	0.098
McFadden	0.032

Likelihood Ratio Tests

Effect	Model Fitting Criteria	Likelihood Ratio Tests		
	-2 Log Likelihood of Reduced Model	Chi-Square	Degrees of Freedom	Significance
Intercept	8305.805[a]	0.000	0	.
Race/Ethnicity	8401.129	95.324	16	<.001
Education	8375.916	70.111	16	<.001
Gender	8315.405	9.600	4	0.048
Smoking Status	8319.101	13.296	8	0.102
Age Group	8329.058	23.253	16	0.107
Use Social Media Information to Make Health Decisions	8337.372	31.567	12	0.002
Genetic Testing for Specific Disease	8326.559	20.755	4	<.001
PHQ-4 Scores	8421.731	115.926	12	<.001

Table 7. Parameter Estimates

		Parameter Estimate	Std. Error	Wald	Degrees of Freedom	Sig.	Odds Ratio	95% Confidence Interval for Odds Ratio	
								Lower Bound	Upper Bound
Variable	**Intercept**	-1.021	0.530	3.716	1	0.054			
Race/ Ethnicity	**non-Hispanic White**	0.800	0.373	4.588	1	0.032	2.225	1.070	4.625
	non-Hispanic Black or African American	0.261	0.394	0.437	1	0.509	1.298	0.599	2.809
	Hispanic	1.431	0.384	13.886	1	<.001	4.182	1.970	8.877
	non-Hispanic Asian	1.341	0.456	8.667	1	0.003	3.823	1.566	9.337
	non-Hispanic Others (Comparison Category)								
Education	**Less than High School**	-0.071	0.292	0.060	1	0.807	0.931	0.526	1.649
	High School Graduate	-0.415	0.225	3.420	1	0.064	0.660	0.425	1.025
	Some College	-0.533	0.203	6.883	1	0.009	0.587	0.394	0.874
	Bachelor's Degree	-0.257	0.204	1.578	1	0.209	0.774	0.518	1.155
	Post-Baccalaureate Degree (Reference Category)								
Gender	**Male**	-0.368	0.136	7.332	1	0.007	0.692	0.530	0.903
	Female (Reference Category)								
Smoking Status	**Current**	0.581	0.215	7.313	1	0.007	1.788	1.173	2.724
	Former	0.279	0.162	2.970	1	0.085	1.321	0.962	1.814
	Never (Reference Category)								
Age	**18-34**	-0.210	0.295	0.506	1	0.477	0.810	0.454	1.446
	35-49	0.350	0.275	1.612	1	0.204	1.419	0.827	2.434
	50-64	0.192	0.266	0.524	1	0.469	1.212	0.720	2.041
	65-74	0.277	0.276	1.008	1	0.315	1.320	0.768	2.268
	75+ (Reference Category)								

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		Parameter Estimate	Std. Error	Wald	Degrees of Freedom	Sig.	Odds Ratio	95% Confidence Interval for Odds Ratio	
								Lower Bound	Upper Bound
Use Social Media Information to Make Health	**Strongly Agree**	0.173	0.497	0.121	1	0.728	1.189	0.449	3.149
	Somewhat Agree	0.413	0.174	5.640	1	0.018	1.511	1.075	2.125
	Somewhat disagree	0.390	0.169	5.343	1	0.021	1.478	1.061	2.058
	Strongly Disagree (Reference Category)								
Took Genetic Testing for Specific Disease Ever had cancer	**No**	-1.014	0.270	14.137	1	<.001	0.363	0.214	0.616
	Yes (Reference Category)								
PHQ-4	**Severe**	1.865	0.310	36.282	1	<.001	6.455	3.518	11.841
	Moderate	1.320	0.216	37.219	1	<.001	3.745	2.450	5.724
	Mild	1.176	0.160	53.748	1	<.001	3.241	2.367	4.438
	Normal (Reference Category)								

Race/ethnicity emerges as a strong predictor of extreme worry about cancer. Hispanic individuals exhibit the greatest concern, being over four times more likely to be extremely worried compared to the reference group (non-Hispanic others) (Odds Ratio = 4.182, p < .001). Similarly, non-Hispanic Asians display significantly increased worry (Odds Ratio = 3.823, p = .003), suggesting heightened cancer-related anxiety within these populations. Non-Hispanic Whites also have higher odds of extreme worry (Odds Ratio = 2.225, p = .032), though to a lesser extent than Hispanics and Asians.

Education appears to serve as a protective factor against extreme worry. Individuals with "Some College" education are significantly less likely to be extremely worried (Odds Ratio = 0.587, p = .009), and "High School Graduates" also exhibit reduced odds of worry (Odds Ratio = 0.660, p = .064), though this finding is only marginally significant. However, individuals with less than a high school education or a bachelor's degree do not show significant differences in extreme worry levels. These results suggest that while some higher education is beneficial in lowering anxiety about cancer, the effects may not be uniform across all educational levels.

Gender also plays a notable role in predicting extreme worry. Males are significantly less likely to be extremely worried compared to females (Odds Ratio = 0.692, p = .007), indicating that women tend to experience greater cancer-related anxiety. This aligns with prior research showing that women, in general, report higher levels of health-related concerns than men.

Smoking behavior is another significant factor influencing extreme worry about cancer. Current smokers have 1.79 times higher odds of extreme worry (Odds Ratio = 1.788, p = .007), suggesting that individuals who actively smoke may perceive themselves at a heightened cancer risk.

Interestingly, age does not emerge as a significant predictor of extreme worry. None of the age groups (18-34, 35-49, 50-64, 65-74) show a significant difference compared to the 75+ reference group. This finding suggests that age alone does not substantially impact cancer-related anxiety, counter to the expectation that older individuals might be more worried due to increased health risks. Although age was not a consistent predictor of extreme cancer worry, older adults were less likely to rely on social media for health decisions, suggesting that age-related

differences in worry may be mediated by variation in digital information exposure rather than age itself."

Attitudes toward using social media for health-related decisions are linked to extreme worry about cancer. Those who "Somewhat Agree" that they rely on social media for health decisions are significantly more likely to be extremely worried (Odds Ratio = 1.511, p = .018). Similarly, those who "Somewhat Disagree" with using social media for health decisions also show elevated worry levels (Odds Ratio = 1.478, p = .021). However, those who "Strongly Agree" or "Strongly Disagree" do not show statistically significant differences, indicating that moderate reliance on social media for health information may be associated with heightened cancer concerns.

Genetic testing status is also a significant factor. Individuals who have not undergone genetic testing for cancer-related diseases are significantly less likely to be extremely worried (Odds Ratio = 0.363, p < .001). This suggests that those who undergo genetic testing may become more aware of their cancer risk, leading to heightened anxiety, while those who remain untested may experience lower levels of concern.

Among all predictors, psychological distress (PHQ-4 scores) emerges as the strongest determinant of extreme worry about cancer. Individuals experiencing severe psychological distress are 6.45 times more likely to be extremely worried (Odds Ratio = 6.455, p < .001), making this the most pronounced effect in the model. This finding highlights the critical role of mental health in shaping cancer-related concerns. The strongest predictors of extreme worry about cancer include psychological distress, race/ethnicity, smoking behavior, social media reliance for health decisions, and genetic testing status (Figure 4).

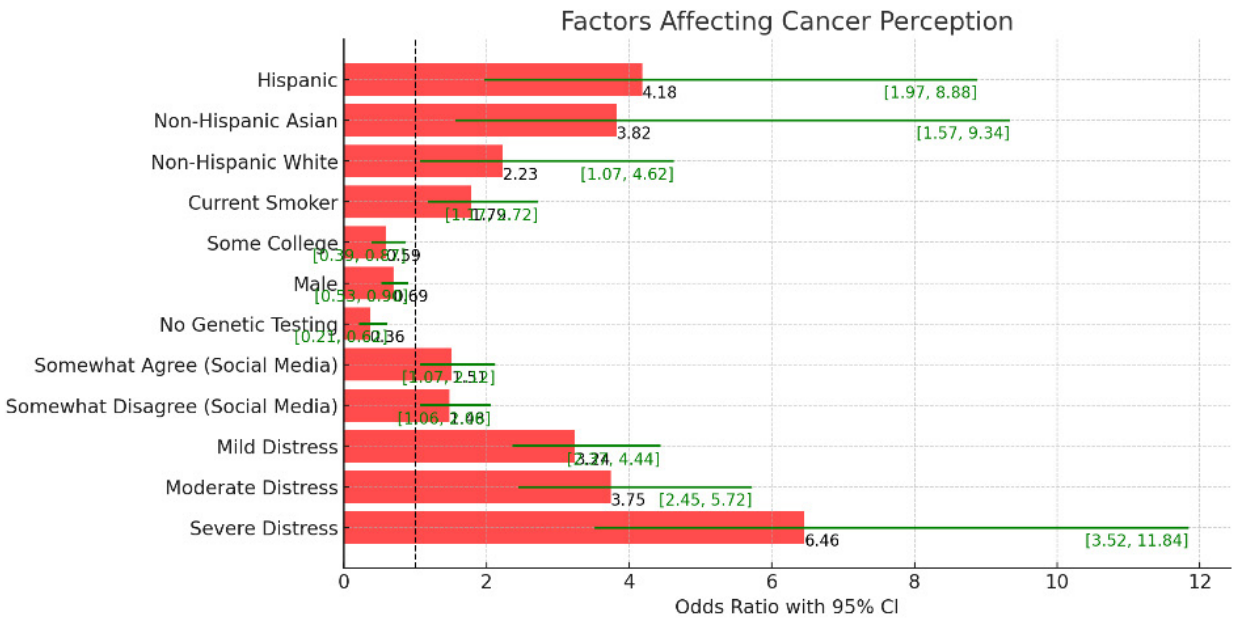
DISCUSSION

The findings from this study reveal critical insights into the psychological and behavioral factors

influencing extreme worry about cancer, with significant public health implications. High levels of worry, particularly among certain racial/ethnic groups, smokers, and individuals experiencing psychological distress, may contribute to heightened health anxieties, increased healthcare utilization, and potential mental health burdens. The strong association between psychological distress and extreme worry suggests that cancer-related anxiety is not merely a response to medical risk but is also deeply intertwined with broader mental health concerns. This heightened worry may lead to increased demand for cancer screenings and medical consultations, potentially overwhelming healthcare resources, particularly in communities where health literacy is lower. On the other hand, excessive worry could also have a paralyzing effect, where individuals avoid seeking medical care due to fear of a cancer diagnosis, delaying early detection and worsening health outcomes. Addressing these disparities and anxiety levels is crucial to improving public health messaging, early detection, and mental health support systems.

Given that psychological distress is the strongest predictor of extreme worry about cancer, integrating mental health interventions into cancer prevention programs is essential. From a public health perspective, this emphasizes the need for integrating mental health support into cancer awareness campaigns and screenings. Future interventions should focus on stress reduction techniques, cognitive behavioral therapy (CBT), and accurate cancer risk

Figure 4. Odds Ratio with Confidence Intervals for Factors Affecting Cancer Perception



communication to ensure that psychological distress does not disproportionately heighten cancer-related fear. Routine mental health screenings in primary care settings, stress management programs, and counseling services should be incorporated into cancer awareness and screening campaigns to ensure individuals receive holistic care that addresses both physical and mental health concerns. Additionally, targeted health education programs should be developed for Hispanic and Asian populations, who were found to have the highest levels of cancer-related anxiety.

Another key prevention strategy is addressing misinformation on social media, given that individuals who rely on social media for health decisions were significantly more likely to experience extreme worry. This finding underscores the importance of improving the quality of health information on social media. Public health agencies should strengthen their presence on social media platforms to combat misinformation and ensure that individuals are exposed to accurate and reassuring health messages about cancer risks, prevention, and treatment options.

For smokers, particularly current smokers who showed significantly higher odds of extreme worry, integrating smoking cessation programs with cancer awareness campaigns can serve a dual purpose, reducing both tobacco-related cancer risks and the psychological distress associated with fear of developing cancer. Tailored messages that highlight the benefits of quitting smoking while reducing health anxiety could improve both cessation rates and mental well-being in this group. This study did not include alcohol use in the final models due to limitations in the available measures, including insufficient detail on consumption patterns, which may have constrained our ability to assess combined behavioral risks; future research should examine how alcohol use, alone and in combination with smoking, shapes cancer risk perception and worry.

CONCLUSION

This study underscores the need for multifaceted public health approaches that integrate mental health support, targeted education, smoking cessation interventions, and digital health literacy programs to mitigate excessive worry about cancer. By addressing the psychological and behavioral factors that contribute to extreme worry, public health agencies can create more effective, evidence-based strategies to improve cancer awareness, reduce anxiety, and promote healthier behaviors across diverse populations.

This study reveals that extreme worry about cancer is strongly associated with psychological distress, racial/ethnic background, smoking status, and reliance on social media for health information. Psychological distress emerged as the most significant predictor of cancer-related anxiety, suggesting that extreme worry is not solely based on perceived cancer risk but is closely tied to broader mental health concerns. These findings have important implications for public health, as excessive worry can both increase healthcare utilization and, paradoxically, delay care-seeking due to fear. The study highlights the urgent need to integrate mental health support into cancer prevention strategies.

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Hospital Care Utilization Patterns Among Migrants and Natives in a Central Italian Region between 2011 and 2023: Findings from the MIGHTY Project (P2022ASXKR)

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SUMMARY

Background: Migration has reshaped the demographic profile of Italian regions, yet evidence on differences in hospital care utilisation between migrant and native populations remains limited, particularly over long periods and across full population cohorts. This study evaluates hospital admissions in the Marche Region from 2011 to 2023 according to citizenship.
Methods: A population-based longitudinal study was conducted using Healthcare Utilization Databases on residents of Marche Region, comparing Italian residents with migrants from High Migratory Pressure Countries (HMPC) and Highly Developed Countries (HDC). Age-standardised all-cause, avoidable, and cause-specific hospital admission rates were estimated. Temporal trends were assessed through Poisson regression models. Hospital care utilisation was evaluated using two-step models: logistic regression for the probability of being hospitalized and Poisson regression for the frequency of admissions among hospitalised individuals.
Results: Across 1.52 million person-years and 2.86 million admissions, HMPC and HDC residents consistently showed lower all-cause, avoidable, and cause-specific admission rates than Italians. Hospitalisations declined over time for all groups, with a marked drop in 2020. Avoidable hospitalisations decreased by 42% in the post-pandemic period. Migrants showed a dual pattern: lower probability of being hospitalised (Odds Ratio, 95% CI: HMPC 0.79, 0.75-0.76; HDC 0.53, 0.51-0.56), but higher admission frequency among those hospitalised (Rate Ratio, 95% CI: HMPC 1.10, 1.09-1.10; HDC 1.04, 1.01-1.07) than Italians.
Conclusion: Migrant populations in Marche show lower hospitalisation rates but higher utilisation once admitted, suggesting possible barriers to early or appropriate access. Monitoring hospital use through administrative databases is essential to identify potential inequities and guide targeted interventions.

Keywords: Migrants; Hospitalization rates; Healthcare utilization; Administrative Databases; Italy

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INTRODUCTION

In 2024, Italy counts over five million regular foreigners coming mainly from high migratory pressure countries (HMPCs) reshaping the demographic composition of many Italian regions. Understanding how migrant populations use healthcare services is essential for monitoring equity, evaluating healthcare system performance, and for informing regional and national planning [1, 2].

Scientific literature documents the difficulties faced by the foreign population in accessing health services, partly due to limited language skills and poor knowledge of the organisation of the health system [3]. Italian regional analyses have demonstrated that migrant populations tend to have lower rates of preventive care and higher rates of inappropriate emergency or avoidable hospital admissions compared with native populations [4, 5].

Hospitalisation rates, avoidable hospitalisations, and cause-specific admissions offer valuable information for assessing the performance of local health systems and identifying potential unmet needs. However, national and regional evidence on migrants is still fragmented in Italy, often limited to specific age groups, diagnostic areas, or short observation periods [4-8], leaving gaps in knowledge on the overall population and long-term trends.

In order to monitor the use of healthcare according to citizenship, Healthcare Utilization Databases are a valuable source of data. Their population-based coverage, longitudinal structure, and systematic standardisation enable the monitoring of healthcare use across large, heterogeneous populations and over extended time periods [9].

In Italy, the National Health Service guarantees free basic healthcare to all residents, regardless of nationality or origin. The regions have autonomy in the management of public health, which can lead to significant territorial differences [10, 11]. The territorial, economic and social structure varies considerably between regions and, moreover, migration flows have affected regional territories with different characteristics and at different times [12, 13]. In this context, it is particularly important to analyse specific regional contexts.

The objective of this study is to estimate and compare hospital admissions between migrant and native populations residing in the Marche Region from 2011 to 2023, using routinely collected Healthcare Utilization Databases. The analysis is conducted within the framework of the PRIN PNRR 2022 project "MIGrants' HealTh and healthcare access in ItalY" (MIGHTY, Prot. P2022ASXKR).

METHODS

Study design, data sources and definition of population groups

This investigation is a population-based longitudinal study based on routinely collected administrative healthcare data. The study period covers 1 January 2011 through 31 December 2023. The target population includes all residents of the Marche Region, a Central Italy area with approximately 1.5 million inhabitants.

Data were obtained from two Healthcare Utilization Databases of the Regional Healthcare System: the Regional Beneficiaries Database (RBD) for demographics and healthcare assistance start and end dates for all residents, and the Hospital Discharge Records (HDR), for hospital admissions, including admission/discharge dates, primary and secondary diagnoses and procedures (International Classification of Diseases, 9th Revision, Clinical Modification, ICD-9-CM).

These datasets were deterministically linked at individual level using a unique anonymous identification code assigned to each resident. All data were processed in compliance with the European (GDPR, EU 2016/679) and national privacy laws (D.lgs. 196/2003 and subsequent amendments).

Residents were annually classified in three population groups according to their citizenship recorded in RBD: residents holding Italian citizenship (Ita-Marche), residents from High Migratory Pressure Countries (HMPC), and residents from Highly Developed Countries (HDC) [14].

The Annual Person-Time Population was used as the reference denominator for rates estimations, as described elsewhere (manuscript submitted for publication) [15]. Specifically, individuals were included if, at any time between January 1st and December 31st of a given year (2011-2023), they had a recorded start date of healthcare coverage before December 31st of the reference year, no recorded date of death or end of coverage (due to moving to another Italian region or abroad) before January 1st of the reference year. For all eligible subjects, the observation time was computed in terms of person-years (py) for each calendar year.

Statistical Analysis

All-cause hospital admission rates were calculated as the number of hospital discharges recorded in a given calendar year divided by the corresponding person-years of residents present in the RBD in the same year and expressed per 1,000 py. To allow for comparability between population groups with different age structures, age-standardized hospital

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admission rates were estimated annually based on citizenship (Ita-Marche, HMPC, HDC) and sex, using the direct standardization method. The Italian resident population according to ISTAT data as of January 1st, 2019, was adopted as the reference standard [16]. Temporal trend in hospital admissions for all causes was estimated using a Poisson multiple regression model, adjusted by population groups and sex, using standard population as an offset. The dependent variable was the number of hospitalizations expected in the standard population. In addition, six univariate Poisson regression models were carried out to estimate the trend in hospital admissions stratified by population group and sex.

Analyses were further extended to assess avoidable hospitalizations and cause-specific admissions (Major Diagnostic Categories, MDCs) both based on the primary diagnosis (ICD-9-CM). Avoidable hospitalisations included those due to worsening chronic conditions, acute conditions, and conditions preventable by vaccines [17]. All rates were standardised for age and stratified by population groups, sex, and by dividing the study period into pre- (2011-2019) and post- (2020-2023) COVID-19 pandemic. To evaluate the association of avoidable hospitalisations and admissions for specific causes with population groups, sex and pre/post-pandemic, Poisson multiple regression models were used. Results from Poisson regression analyses were expressed as mean percentage changes (MPC) and 95% Confidence intervals (95%CI).

The hospital utilization was assessed using two-step models [18]. Firstly, a logistic regression analysis was performed to estimate the probability of experiencing at least one hospitalization, considering hospital admission (hospitalized vs. not hospitalized) as the dependent variable. Secondly, to estimate the frequency of hospitalisation among individuals with at least one hospitalisation, a Poisson regression analysis was used, with the number of hospitalisations per individual as the dependent variable. In both models, independent variables included population group, sex, age group (0-18, 19-44, 45-64, ≥65 years), and pre/post-pandemic period; the time during which a subject remained under observation was included in the models as an offset.

All statistical analyses were conducted using R software (version 4.4.2).

RESULTS

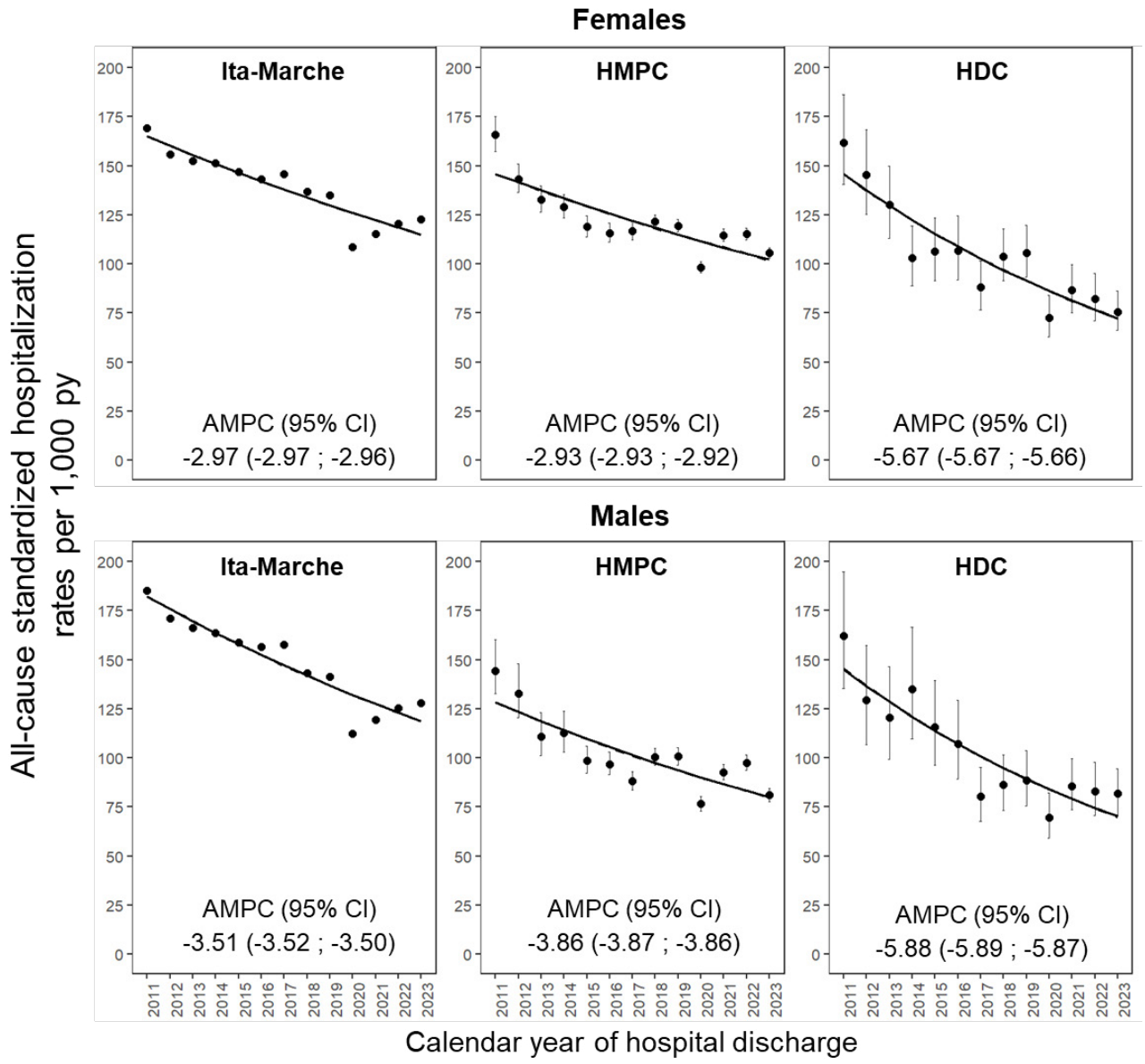
During the study period, a total of 2,856,860 hospital admissions and an average of 1,521,650 person-years were recorded in the Marche Region, resulting in a crude hospitalization rate of 144 admissions per 1000 py. Residents from HMPC and HDC were characterized by crude rates of 97.8 and 95.4 admissions per 1000 py, with 116,409 (7.7%) and 4,974 (0.3%) py, respectively. The HMPC population had a mean age of 36.4 years (SD 18.1) and 55.6% females while the HDC group showed a mean age of 49.0 years (SD 19.1) and 58.9% females. The Italian population was older than HMPC, with a mean age of 47.3 years (SD 24.0) and with a slightly lower proportion of 51.1% females than migrant populations.

All-cause hospital admissions

The standardised hospital admission rates for all causes in the period 2011-2023 were 144, 113 and 105 admissions per 1,000 py for Ita-Marche, HMPC and HDC residents, respectively. The highest rates were observed in 2011 for all population groups, followed by a downward trend in subsequent years and the lowest values in 2020 (Supplementary Table S1). In each stratum considered, rates showed fluctuating courses, with an expected sharp decline in 2020 and a upturn until 2023 for Ita-Marche and until 2022 for the two migrant populations.

Figure 1 shows the estimated annual trends in standardised hospital admission rates for all causes by population groups and sex. Throughout the study period, the Ita-Marche population consistently showed the highest hospitalization rates, although in 2011 the rates for the three female groups were similar. Among women, a clear gradient was observed, with rates highest in Ita-Marche, intermediate in HMPC, and lowest in HDC. Among men, the two migrant groups showed nearly overlapping trends, with a wide gap compared to the Ita-Marche population. The annual mean percentage changes (AMPC) indicated a decrease in hospital admissions across all population groups during the study, with the largest reduction in HDC residents of both sexes, and similar declines among Ita-Marche and HMPC populations (Figure 1).

Figure 1. All-cause age-standardised hospital admission rates and estimated temporal trend by population groups and sex, Marche Region, 2011-2023. Trends were estimated using univariate Poisson regression models with calendar year as the independent variable



***Footnote**: AMPC: Annual mean percentage changes; 95%CI: 95% Confidence Interval; Ita-Marche: Italian citizenship residents in Marche; HMPC: citizens from High Migratory Pressure Countries residents in Marche; HDC: citizens from Highly Developed Countries residents in Marche.*

In the multiple Poisson regression analysis (Table 1), a mean annual decrease of 4% in hospital admissions was estimated for the overall resident population of the Marche Region. Compared with Ita-Marche residents, hospitalization rates were 21.5 and 27.2 admissions per 1,000 py lower among HMPC and HDC residents, respectively. A slight difference of 3 admissions per 1000 py was detected between sexes.

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Table 1. Age-standardized hospital admission rate trends adjusted for citizenship and sex, Marche Region, 2011-2023. Results from the multiple Poisson regression model

	MPC (95% CI)
Calendar year	-4.01 (-4.02; -4.01)
Population groups	
Ita-Marche	1.0
HMPC	-21.53 (-21.55; -21.51)
HDC	-27.18 (-27.20; -27.16)
Sex	
Female	1.0
Male	-3.31 (-3.34; -3.29)

MPC: Mean percentage changes; 95%CI: 95% Confidence Interval; Ita-Marche: Italian citizenship residents in Marche; HMPC: citizens from High Migratory Pressure Countries residents in Marche; HDC: citizens from Highly Developed Countries residents in Marche.

Avoidable hospitalizations

The overall age-standardized rates of avoidable hospitalizations in Marche region were 10.9 and 6.2 per 1000 py in 2011-2019 and 2020-2023 respectively.

The avoidable hospitalizations showed a marked decline from the pre-pandemic (2011-2019) to the post-pandemic (2020-2023) periods across all population groups (Table S2). Among Ita-Marche and HMPC residents, rates decreased in females and in males when comparing the pre-pandemic and post-pandemic periods; HDC residents showed more variable estimates due to smaller population sizes but followed the same overall decreasing trend. Across all population groups, avoidable hospitalizations were consistently higher in males than in females.

The Poisson regression analysis confirmed these findings, indicating a 42.3% reduction in avoidable hospitalization rates during 2020-2023 compared to the pre-pandemic period. Compared to Ita-Marche residents, rates were 11.3% and 6.1% lower among HMPC and HDC residents, respectively. Males exhibited 43.4% higher rates of avoidable hospitalization compared to females (Table 2).

Cause-specific hospital admissions

The cause-specific hospital admission rates declined for nearly all Major Diagnostic Categories and across all population groups (Supplementary Material Table S2). The highest rates in both periods were observed for neoplasms, diseases of the circulatory system, and diseases of the digestive and genitourinary systems. For these causes, rates decreased markedly over time, particularly among Ita-Marche residents (e.g., circulatory diseases from 16.5 to 9.2 per 1,000 py in females and from 29.2 to 18.7 in males).

HMPC residents showed lower cause-specific hospital admission rates than Ita-Marche for most disease categories, with the exception in females for conditions related to pregnancy, childbirth, and the

Table 2. Age-standardized avoidable hospitalization rates and mean percentage changes (MPC) by period, population groups, and sex in Marche Region. Results of the multiple Poisson regression model

	Age-standardised hospital admission rates per 1,000 py	MPC (95% CI)
Period		
2011-19	10.9 (10.4 - 11.5)	1.0
2020-23	6.2 (5.9 - 6.7)	-42.3 (-42.3; -42.3)
Population groups		
Ita-Marche	10.2 (10.1 - 10.2)	1.0
HMPC	9.0 (8.7 - 9.4)	-11.3 (-11.3; -11.2)
HDC	10.1 (8.9 - 11.5)	-6.1 (-6.1; -6.1)
Sex		
Female	7.9 (7.5 - 8.4)	1.0
Male	11.5 (10.9 - 12.2)	43.4 (43.3; 43.4)

MPC: Mean percentage changes; 95%CI: 95% Confidecen Interval; r.c.: reference category; Ita-Marche: Italian citizenship residents in Marche; HMPC: citizens from High Migratory Pressure Countries residents in Marche; HDC: citizens from Highly Developed Countries residents in Marche.

puerperium, where rates were substantially higher (from 41.9 to 52.5 per 1,000 py in HMPC women versus 19.4 to 16.5 in Ita-Marche women). HDC residents presented intermediate or slightly lower rates than Ita-Marche for most conditions but displayed greater variability due to smaller population sizes.

Across all groups, males had higher hospitalization rates than females, especially for circulatory, respiratory, digestive, and injury-related causes. Women had higher rates for hospitalizations linked to genitourinary diseases.

The Poisson regression analyses (Supplementary Material Table S3) showed significant reductions during the post-pandemic period for most of the conditions and in certain cases the reduction was about 30%. An increase of about 29% was observed in "Certain Conditions Originating in the Perinatal Period" and a substantial stability in "Mental Disorders" with a 0.7% annual change.

Compared with Ita-Marche residents, HMPC residents had lower hospitalization rates in most of the considered conditions, in particular for non-communicable and chronic diseases such as neoplasms (-37.9%), circulatory (-26.8%), respiratory (-25.8%), and musculoskeletal conditions (-45.8%). Female HMPC migrants had higher rates for pregnancy-related and perinatal conditions with rates more than doubling than Ita-Marche females. Men had higher rates for circulatory (+77.6%), respiratory (+56.2%), and injury-related admissions (+22.8%), and lower rates for genitourinary diseases (-18.2%) and musculoskeletal conditions (-18.2%).

Use of hospitalization

Table 3 reports the results obtained applying the two-step models. According to the first part of the analysis (logistic regression model), both migrant populations had lower probability of being hospitalized by 21% and 47% for HMPC and HDC respectively. The probability of being hospitalized also declined during the pandemic period by 24% relative to 2011-2019. As expected, the highest probability of hospital admission was observed in the oldest age group.

In the second step (Poisson regression model), which included only individuals with at least one hospitalization, HMPC and HDC groups had higher hospital utilization rates than Ita-Marche (RR = 1.10 and 1.04, respectively). Hospital use was less frequent during the COVID-19 pandemic (RR = 0.96), more frequent among males (RR = 1.04) and older individuals (RR = 1.09 in ≥65 years).

Table 3. Two-step models to assess the use of hospitalization: all-cause hospitalization probability (logistic model) and frequency of hospitalizations (Poisson model)

	Logistic regression			**Poisson regression**		
	OR	95% CI	p	RR	95% CI	p
Period						
2020-23 vs. 2011-2019	0.76	(0.75; 0.76)	<0.001	0.96	(0.96; 0.96)	<0.001
Population groups						
HMPC vs Ita-Marche	0.79	(0.78; 0.79)	<0.001	1.10	(1.09; 1.10)	<0.001
HDC vs Ita-Marche	0.53	(0.51; 0.56)	<0.001	1.04	(1.01; 1.07)	0.002
Sex						
Male vs Female	0.91	(0.91; 0.91)	<0.001	1.04	(1.04; 1.04)	<0.001
Age groups						
19-44 vs 0-18	0.82	(0.81; 0.83)	<0.001	0.80	(0.79; 0.80)	<0.001
45-64 vs 0-18	0.87	(0.86; 0.88)	<0.001	0.90	(0.90; 0.91)	<0.001
≥65 vs 0-18	2.61	(2.59; 2.62)	<0.001	1.09	(1.08; 1.09)	<0.001

OR: Odds Ratio; RR: Rate Ratio; 95%CI: 95% Confidence Interval; Ita-Marche: Italian citizenship residents in Marche; HMPC: citizens from High Migratory Pressure Countries residents in Marche; HDC: citizens from Highly Developed Countries residents in Marche.

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DISCUSSION

This population-based study analysed hospital admissions in the Marche Region over a 13-year period, comparing Migrant and Italian residents using Healthcare Utilisation Databases. The magnitude of hospital admissions was consistent with national estimates reported by the Ministry of Health, as was the pattern in rates over time [19].

During the study period, hospital admissions for all causes were lower in both migrant populations than in the Italian one, and this difference cannot be explained simply by the diverse age structures of the populations. Firstly, because age-standardised hospitalisation rates were used to compare hospital care utilization across the three populations; secondly, because although individuals from HMPCs were younger than Italians, the HDC group had a comparable mean age. This gap in hospital care use has already been reported in other Italian studies [5, 7] and can be attributed to multiple interacting factors, including the well-documented phenomenon of healthy migrants and social, linguistic, and cultural barriers that can limit access to healthcare services, including primary and preventive care.

Our results also showed a downward trend in hospital admissions over time in all three populations, which was more pronounced in the HDC group for both sexes. The mean annual percentage decrease was similar among HMPC and Italian residents, with larger declines observed in males than in females. In fact, this trend reflects the overall Italian and European picture, where reductions in hospital admissions have been reported between 2000 and 2017 [20]. These declines have occurred alongside a reduction in hospital beds per capita and a slight increase in the average length of stay, in line with policies aimed at improving the appropriateness of hospital care and reserving admissions for more serious health conditions [19, 20].

The reduction in hospitalisations saw a sharp decline in 2020, coinciding with the COVID-19 pandemic, reaching the lowest level ever recorded in the study period in all three populations. The pandemic had a uniform impact on hospital use regardless of citizenship, whereas the post-pandemic period appears to be evolving differently among the three populations.

Another important finding emerged from our study. Migrants showed a dual profile: they were less likely to be admitted to hospital, yet those who were hospitalized at least once used hospital services more frequently. Worse health conditions at the time of admission, which may result in repeated hospitalisations, could explain this higher frequency of use. Indeed, our study did not reveal specific conditions for which migrants were admitted more often than Italians, with the exception of conditions related to childbirth. This dual pattern is consistent with findings from an Austrian study [21], according to which migrants reported higher readmission rates despite lower overall hospitalisation rates. The authors suggest that lower hospitalisation rates may reflect barriers to timely and appropriate access to healthcare rather than better underlying health, and that higher readmission rates may indicate more advanced disease severity at first hospital contact or missed opportunities for early intervention. Furthermore, a similar duality has been documented in an Italian study on emergency department utilisation [14], supporting the hypothesis that emergency room contacts may, in some cases, evolve into subsequent hospitalisation.

Further relevant results from our study concerns avoidable hospitalizations and cause-specific admissions, which deepen the understanding of differences in hospital care utilization between migrants and Italian residents in Marche Region.

Rates of avoidable hospitalizations declined markedly during the pandemic period in all citizenship groups and, in addition, both migrant groups had lower avoidable hospital admissions than Italians, whereas males had higher rates than females. These findings should be interpreted with caution, as administrative data do not allow us to distinguish whether the lower avoidable hospitalizations of migrants reflect better health or an unmet need that emerges in later stages of the disease. Other Italian studies reported higher odds [4] and higher rates [22] of avoidable hospitalizations for migrants than Italians, however, these discrepancies depend on population definitions, age restrictions and study design. Our study includes the entire resident population, without age restrictions and excluding undocumented individuals by design.

Strengths and limitations

Our study based on healthcare utilization databases used the citizenship field in the Regional Beneficiaries Database to distinguish between Italian and migrant residents. This proved to be more effective than the one based on country of birth in identifying migrant status [15], but it did not allow for the individual level of social integration in the host country to be taken into account, nor did it detect factors related to the use or misuse of hospital admissions, such as socioeconomic status, linguistic level, or health literacy. Furthermore, it was not possible to consider the impact of the length of stay in Italy, which can only be deduced from administrative databases in a very approximate manner. Moreover, the COVID-19 pandemic introduced sharp changes in hospital utilisation that may have differentially affected the populations groups in ways not fully captured by our models.

One of the strengths of this study is that it is based on a large population-wide cohort that included all residents of the Marche Region over a long period of 13 years. The use of hospital discharge databases allowed for a comprehensive and systematic consideration of hospital admissions over time. In addition, the analysis of avoidable and cause-specific hospitalizations provides a more granular understanding of healthcare utilization patterns beyond overall admission rates.

CONCLUSIONS

In conclusion, this study highlighted differences in hospital admission rates based on nationality and different attitudes towards hospital care. In this regional context, migrants are younger and apparently healthier than their Italian counterparts, but with a higher frequency of readmissions. This study is unable to assess whether these differences are actually disparities, but it does show possible critical issues in public health, suggesting the need for targeted intervention in favour of potentially vulnerable populations.

AUTHORS' CONTRIBUTIONS

RG and MI conceptualized the study, developed the methodology for data analysis and drafted the manuscript. MI managed the data and performed the formal statistical analyses. MP and FC were in charge for data extraction and authorized their utilization. RG, MI, AF, ES assisted in the results interpretation. All authors assisted in manuscript revision, read and approved the final manuscript. RG is the guarantor of the overall content of the work.

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CONFLICT OF INTEREST

The authors have declared no conflict of interest.

ETHICS STATEMENT

This observational study fulfils the Italian regulations of ethics committees, which require only standard written informed consent at the time of hospital admission.

Ethical review and approval were waived for this study. We did not mention ethical safeguards simply because not pertinent in our study. All data were anonymized and managed in a manner that protected the privacy and confidentiality of individuals represented in the datasets.

According to Article 9 of the General Data Protection Regulation (European Union Regulation 2016/679), pseudonymized administrative data can be used without specific written informed consent when patient information is collected for healthcare management, quality evaluation, and improvement. All procedures adhered to the 1964 Helsinki Declaration and its subsequent amendments.

DATA AVAILABILITY STATEMENT

Restrictions apply to the availability of these data. The datasets generated and/or analysed during the current study are property of a third party that is the Regional Health Agency of Marche (ARSMarche) and, although they are anonymized, datasets are not publicly available due to the current regulation on privacy. The description of the administrative databases is available from the website ARSMarche/Flussi.

Other researchers can obtain access to the data through a formal request based on a research project to the Regional Health Agency of Marche.

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Youth Oriented Advertising in Ireland's National Lottery: A Quantitative Content Analysis of Advertisements

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SUMMARY

Background: Gambling on the National Lottery in Ireland peaked recently at an annual gross spend of over €1 billion. There is ample evidence of underage participation in the lotto. Youth participation in gambling is associated with problematic gambling in adulthood. A recent examination of the National Lottery's website identified child-friendly Halloween themed advertising.
Objectives: This research sought to investigate National Lottery advertisements to identify potentially child and youth-oriented marketing.
Methods: Quantitative content analysis of 127 video advertisements hosted on the National Lottery YouTube website were examined, using a pre-constructed six item framework.
Results: There was evidence relating to three of the six categories of content examined. In total 21.3% (n=27) of the videos examined made direct use of signs, symbols, themes, drawings, fictitious characters, or real people of primary or particular appeal to children. A total of 6.3% (n=8) of the videos examined included children, while 0.8% (n=1) featured adolescent, juvenile, or loutish behaviour.
Conclusions: Child-friendly marketing is present in National Lottery advertising. A more robust assessment of all National Lottery marketing materials is required. The Gambling Regulation Act, 2024, should be extended to oversee all gambling in Ireland, including the National Lottery. A public health approach to gambling is required across all state agencies and the Government.

Keywords: Gambling Lottery; children adolescents Ireland advertising

INTRODUCTION

The global gambling industry is rapidly developing. As a result of improvements in digitisation and information and communications technology, access to gambling has now become almost ubiquitous for much of the population [1]. The industry's global revenue has increased significantly, and it has been projected that by 2028, consumer net losses are expected to approach US$700 billion [2]. Ireland is a significant contributor to this growth. In 2019, the Irish population were in the top-quartile of gamblers in the EU [3]; wagering an estimated €9.8 billion [4]. In 2024, Ireland's online gambling market was estimated to be €1.24 billion, with forecasts suggesting that it will increase to €1.40 billion by 2029 [5].

With ticket sales in excess €1 billion in 2021 [6], the National Lottery accounts for a substantial proportion of Irish gambling. According to the National Drugs and Alcohol Survey (NDAS), almost half (49%) of Irish adults gambled in the year 2019-20, with 29% accredited to the lottery alone [7]. The National Lottery has also strategically increased its online offerings in recent years, with their online gambling platforms delivering €155.1 million worth of sales in 2024 [8].

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The National Lottery's broadening online offerings may appear harmless to many, as lottery wagers are often not even considered gambling [9]. However, such an approach is naive. Online gambling can incur equally detrimental effects, including adverse mental and physical health outcomes, lower quality of life, and increasing financial precarity [10]. Mobile gambling applications and online gambling accounts have also been associated with reports of problematic gambling practices [11]. According to recent estimates from the Economic and Social Research Institute (ESRI), 1 in 30 adults in Ireland, or 130,000 people, suffer from 'problem gambling'. In addition, another 7.1% of adults, or 279,000 people, display 'moderate evidence' of problem gambling [12]. This figure is approximately ten times higher than previous estimates. Problematic gambling has been identified as a global issue [13].

The problems associated with gambling on national and state lotteries have been noted internationally [14-15]. An examination of a country's national lottery can be very revealing, as it exemplifies what Markham & Young term '*the global industry-state gambling complex*' [16]. Gambling is increasingly acknowledged as an important commercial determinant of health (CDoH) nationally and internationally [2]. In Ireland the College of Psychiatrists of Ireland have stated that gambling is a 'major Public Health concern' [17].

The damage caused by gambling must not be under-stated [18-21], despite the careful framing by the gambling industry [22-27]. Langham et al. have created a useful taxonomy of gambling harms that focusses on varying dimensions and timespans [28]. When evaluating the harms caused by the global gambling industry it is helpful to consider the impacts on individuals, as well as on partners and families. However, there is also substantial evidence that organised crime routinely utilises the gambling industry to both increase and launder profits from various criminal activities, including illicit drugs revenue, people trafficking and illegal sex work [29-39].

Returning to an individual perspective, online access not only increases the likelihood of addiction to gambling but also poses the additional hazards of underage access and harm [40-41]. The most recent report of the European School Survey Project on Alcohol and Other Drugs (ESPAD) for Ireland in 2024 noted that 32.2% of 15–16-year-olds had wagered in that year [40], which increased 24% in 2019 [42]. Such figures to serve to highlight the serious issue of youth gambling. In addition, 26.1% of adolescent participants reported using online gambling platforms [42]. Young people using online platforms had a 4.2-fold increased risk of problem gambling [43]. Lotteries remain one of the most popular forms of teenage gambling, with a reported 15.6% playing in person and 7.2% playing online [40].

Gambling on the National Lottery is often considered acceptable within Irish households [9, 43]. However, recent research has shown that gambling prior to age 18 nearly doubles the likelihood of problem gambling in adulthood [44]. An examination of 3,000 adults in Ireland who received treatment for problem gambling between the years 2008 and 2019 noted that half of the cohort had started gambling prior to being 17 years of age [45]. Online gambling at 17 years of age has been identified as a significant independent predictor of online gambling activity at age 20 [44].

The National Lottery in Ireland is not unaware of the issue of youth gambling, including underage purchase of their tickets. For example, two underage purchasing exercises on National Lottery items in retail establishments by Ipsos MRBI, were commissioned by the Office of the Regulator of the National Lottery (ORNL), in 2018 and 2024 respectively [46-47]. A total of 562 retail locations were included in the 2024 repeat of the exercise. In this iteration of the study, 29% of test purchases made by 15–17-year-olds were successful [47]. In 2018 the figure for successful purchases was 37% [46].

Gambling in Ireland is notable in that its legislative regulation is divided between National Lottery gambling, and most other forms of gambling. The Irish National Lottery is therefore explicitly exempted from Ireland's Gambling Regulation Act, 2024 [48]. Ireland traditionally has operated a light-touch approach to Government regulation in many commercial spheres [49-50]. Instead, it has supported self-regulation by industry. Therefore, many of the advertising voluntary codes in Ireland explicitly exclude all [51], or the majority, elements of National Lottery advertising [52].

Although officially excluded from such codes, it must be acknowledged that the National Lottery's own codes of marketing and advertising practice are effectively identical to wider industry codes [51-52]. Details of the *National Lottery Advertising and Promotion Code of Practice* from Premier Lotteries Ireland [53], the Operator of the National Lottery in Ireland are detailed in Table 1.

Table 1. National Lottery Advertising and Promotion Code of Practice [53]

Under 18 (Children)
29. Advertising and Promotion activities shall not exploit the susceptibilities, aspirations, credulity, inexperience or lack of knowledge of children; 30. Advertising and Promotion activities shall not be likely to be of particular appeal to children, especially by being associated with youth culture; 31. Advertising and Promotion activities shall not make direct use of: a. signs, symbols, themes, drawings, fictitious characters or real people of primary or particular appeal to children; b. depict adolescent, juvenile or loutish behaviour; c. contain endorsements by recognisable figures who would be regarded as heroes or heroines of children; or d. induce a child to regard National Lottery play as a natural element of his or her leisure time/activities; 32. Advertising and Promotion activities shall not be aimed at persons under 18 years of age; 33. Social media Advertising and Promotion will be designed by PLI to reach only those who are 21+; 34. No suggestion/inference shall be made (in any Advertising and Promotion activities) that anyone under the age of 18 years of age may participate in a National Lottery Game;

The Annual Report of the Regulator of the National Lottery for the year 2017 notes that a breach in advertising standards by the Operator of the National Lottery was observed [54]. Minimal details are given, although no fine appears to have been issued in relation to this breach.

It is clear from the Office of the Regulator of the National Lottery (ORNL) annual reports, that new games and marketing materials proposed by the lottery operator are assessed. The outcomes of such evaluations are annually detailed in the yearly reports of the Regulator. However, a review of these annual reports for the last three years (2022-2024) appears to detail just three instances of game related proposals having been refused approval [55-57]. No details are given in the reports of such rejections, merely the phrase 'Commercially Sensitive' [57].

Youth focussed marketing by the addiction industries has been explored by researchers from a range of countries in recent decades [58-62]. This research has included an examination of the tactics and strategies used by 'Big Gambling' to target young people [24, 63-66].

Similar research has been carried out in Ireland. A recent study by Daly et al. noted child-friendly Halloween themed images for gambling games on Ireland's National Lottery website [67]. Kerr et al. recently explored gambling advertising to young people aged 14-14 in Ireland and stated it had reached saturation level [68]. These authors were so concerned by their findings that they stated that the situation *'warrants calling a 'Code-Red' emergency'* [68]. This is a particular concern in terms of underage gambling, as other research by Daly et al has also noted inadequate age verification checks in Ireland's National Lottery [69]. This finding reinforces earlier research that noted inadequate protections for patrons of Irish online gambling platforms [70].

METHOD

This research sought to investigate other National Lottery advertising materials to determine how child friendly they are. This project utilised quantitative content analysis of visual imagery displayed on Ireland's National Lottery YouTube Channel. This approach is routinely used in media analysis [71]. In Rose's ground-breaking text on visual methodologies she outlines four steps to quantitative content analysis [72]: Finding your images; Devising your categories; Coding the images; Analysing the results. Content analysis of the YouTube videos was based on a priori codes that were developed largely based on child protection marketing guidelines in place in Ireland [51-53]. One additional category examined was that of the inclusion of children in adverts, as this is an acknowledged marketing strategy for appealing to children [73-74]. Table 2 details the categories examined. Content of the videos was screened by one of the authors (FH) and then discussed and agreed with another author (DH).

Table 2. Coding Framework for Content Analysis

Category **Contains advertising and promotion activities that...**
1) ...exploit the susceptibilities, aspirations, credulity, inexperience, or lack of knowledge of children
2) ...make direct use of signs, symbols, themes, drawings, fictitious characters, or real people of primary or particular appeal to children
3) ...depict adolescent, juvenile, or loutish behaviour
4) ...contain endorsements by recognisable figures who would be regarded as heroes or heroines of children
5) ...induce a child to regard National Lottery play as a natural element of his or her leisure time/activities
6) ...include children

This project focussed on the Irish National Lottery YouTube Channel website (http://www.youtube.com/IrishNationalLottery). This site in turn links to the National Lottery website (lottery.ie), as well as to Twitter (twitter.com/NationalLottery), Facebook (facebook.com/nationallotteryireland) and Instagram (Instagram.com/nationallottery). At the time of the analysis (October 2025) the National Lottery YouTube site contained 18 categories of playlist (https://www.youtube.com/@IrishNationalLottery/playlists). Six of these categories were not adverts but video clips showing the weekly results of draws, awards ceremonies, or outlines of how the money raised via the lottery was spent rather than adverts. These were excluded from the analysis, which left 133 videos for analysis. However, 6 videos were unavailable on YouTube, leaving 127 videos for analysis.

As this analysis was based on publicly accessible webpages, this research did not require ethical approval. This analysis was based on video clips contained on the Irish National Lottery YouTube channel.

RESULTS

The results of the quantitative content analysis of the 127 videos are detailed in Table 3 [72]. There were no examples of content relating to three of the six categories of material examined. However, there was evidence relating to categories two, three and six. Of most concern is the finding that 21.3% (n=27) of the videos examined made direct use of signs, symbols, themes, drawings, fictitious characters, or real people of primary or particular appeal to children. In total, 6.3% (n=8) of the videos examined included children, while 0.8% (n=1) featured adolescent, juvenile, or loutish behaviour.

Table 3. Coding Framework for Content Analysis

Category **Contains advertising and promotion activities that...**	**Number of Videos Exhibiting Codes**	**Number of Videos Examined**
1) ...exploit the susceptibilities, aspirations, credulity, inexperience, or lack of knowledge of children	0% (n=0)	127
2) ...make direct use of signs, symbols, themes, drawings, fictitious characters, or real people of primary or particular appeal to children	21.3% (n=27)	127
3) ...depict adolescent, juvenile, or loutish behaviour	0.8% (n=1)	127
4) ...contain endorsements by recognisable figures who would be regarded as heroes or heroines of children	0% (n=0)	127
5) ...induce a child to regard National Lottery play as a natural element of his or her leisure time/activities	0% (n=0)	127
6) ...include children	6.3% (n=8)	127

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Figure 1. Exemplars of Child-Friendly Content from Videos Included on the Official National Lottery YouTube Channel

Anthropomorphic Washing Machine ('Hank') 	Waterslide 
Soft Toy Character 	Another Soft Toy Character 
Soft Toy Characters in Sunglasses 	Tyre Swing 
Tree House 	Wooden Toy Characters 

Child-friendly Image	Game-themed Gambling Advert
	
Riotous Children in Classroom	**Whole Class of Children**
	

Figure 1 details exemplars of some of the imagery used in the advertisements. Please note that these images are stills taken from the videos. To see a selection of the videos themselves, please see Appendix 1. Imagery categorised as Category 2 include anthropomorphic machines (see Figure 2a), a colourful waterslide (see Figure 2b), and speaking soft toy style characters (see Figures 2c, 2d and 2e). Other images include a tyre-swing (see Figure 2f), and a tree house (see Figure 2g).

Further imagery categorised under Category 2 include the wooden toy characters ('Jaspar'; see Figure 2h), as well as the youth-oriented online gambling featured in images 2i (Santa Clause/ Father Christmas & Rudolf) and 2j (the rock, paper, scissors game). In relation to the other categories in the coding framework, figure 2k includes both a depiction of juvenile and loutish behaviour (Category 3) and children (Category 6), while image 2l features an entire class of children (Category 6).

DISCUSSION

It is an issue of concern that evidence relating to three of the six categories examined in the quantitative content analysis was observed. Of particular note was the finding that 21.3% of videos examined featured material that made '*direct use of signs, symbols, themes, drawings, fictitious characters, or real people of primary or particular appeal to children*' [53]. Given the ostensible prohibition on such imagery and themes this would finding appear to indicate a lack of robust appraisal of National Lottery advertising materials.

This finding is important given evidence relating to underage gambling. Evidence suggests that early initiation to gambling is a significant predictor of future gambling issues [65,70-78]. Youth gambling on the National Lottery in Ireland is an acknowledged problem dating back many years [46]. This is notable given both the identified poor performance of the Irish National Lottery age verification process [69], and the child-oriented nature of some National Lottery online game advertising [67]. It is therefore an issue of significant concern that over 20% of elements of National Lottery videos in this sample from the official National Lottery YouTube site featured child friendly imagery. It has been suggested that such marketing is 'priming young minds' for gambling [79].

The values of the Office of the Regulator of the National Lottery are listed as: Independence; Guardianship; Future Focused; Accountability; Professionalism; Valuing Our People; and Transparency [57]. The most important of these in the context of this examination is that of Guardianship. This is described

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Table 4: Functions of the Office of the Regulator of the (Irish) National Lottery [81]

The Functions of the Regulator which support the vision above, are prescribed in the National Lottery Act 2013, and include the following:

1. To procure the holding of the National Lottery.
2. To oversee the operation of the National Lottery and to monitor and enforce compliance by the Operator with the Act and the Licence.
3. To consider for approval certain matters relating to the National Lottery (including schemes for National Lottery games).
4. To manage and control the National Lottery Fund.
5. To exercise the enforcement rights of any trademark of the National Lottery.

The Regulator is required to carry out these functions in a manner most likely to ensure –

a) that the National Lottery is run with all due propriety,
b) that the interests of participants in the National Lottery are protected,
c) that the long-term sustainability of the National Lottery is safeguarded,

and, subject to above points a) to c), to ensure revenues allocated to the Central Fund for disbursement for the purposes permitted by the Act ("Good Causes") are as great as possible, subject to the terms of the Licence

by the Regulator as 'Acting in the public interest with integrity' [57]. The functions of the Regulator of the Irish Lottery are listed in Table 4. However, it is clear that the ORNL has competing and potentially opposing functions that may force it into a compromised position. This is particularly important for an addiction industry, such as gambling, as there is substantial evidence of the pareto (80/20) principal, in which 80% or more of total income is derived from 20% of participants [42, 80].

Thus, the Regulator of the National Lottery is placed in the invidious position of having to both safeguard the long-term viability of the National Lottery, while at the same time seeking to protect gamblers, and safeguard children. This delicate equilibrium is supposed to be achieved, while also maximising revenue. This may force the ORNL into moral jeopardy wherein they compromise on player protections in order to safeguard the money being raised to support 'Good Causes' and the financial viability of the National Lottery itself [82-84].

Examination of the Annual Report of the Office of the Regulator of the National Lottery indicates a penalty was imposed in 2022. The Regulator withheld €150,000 in 2022 for breaches of the licence [55]. It is notable that, as the Regulator stated this '*was the first withholding of monies from payments due to the Operator under the Licence*' [55]. Subsequently in 2024 the Regulator withheld €23,000 for another breach [57].

Table 5: Payments & Fines Levied by the Office of the Regulator of the (Irish) National Lottery (ORNL) to the Operator of the National Lottery [54-57, 85-90]

Year	Payments made to the Lottery Operator	Monies Withheld
2014	€61 million	€0 (0%)
2015	€74 million	€0 (0%)
2016	€69 million	€0 (0%)
2017	€74 million	€0 (0%)
2018	€73 million	€0 (0%)
2019	€83 million	€0 (0%)
2020	€89 million	€0 (0%)
2021	€103 million	€0 (0%)
2022	€90 million	€150,000 (0.0017%)
2023	€84 million	€0 (0%)
2024	€82 million	€23,000 (0.0003%)
TOTAL	€882 million	€173,000 (0.0002%)

The total fines or payments withheld of just 0.0002% of income to the operator (this figure relates purely to their return and excludes prizes, money paid to the Government for re-allocation to 'Good Causes', and a sizeable advertising budget) is miniscule in the context of income (See Table 5). Given inadequate youth protections observed in the operation of the lottery [46,47,69], and child & youth oriented National Lottery marketing observed in this study, and elsewhere [67], it is hard to understand why this figure is so low. In the UK in contrast, gambling operators have been forced to pay multimillion-pound fines for breaching consumer-protection and under-18 gambling regulations [91].

CONCLUSION

A proportion of the population either regularly or periodically engage in problematic gambling [2,7,12,92]. Many adult problem gamblers have a history of underage gambling [42]. Therefore, any child-friendly lotto advertising is a significant issue. It is strongly recommended that child friendly marketing videos on the official National Lottery YouTube website are deleted. Moving forward, it is crucial that a significantly more robust assessment of National Lottery marketing and promotion materials is enforced by the ORNL. As regards policy options, it is suggested that Ireland's new Gambling Regulation Act, 2024, is extended to cover the National Lottery [48]. This would eliminate the problematic and potentially compromised role of the ORNL in having to safeguard gamblers, ensure the viability of the National Lottery, and raise funds for 'Good Causes'. Such legislation would also force the operator of the National Lottery operator to be subject to more restricted marketing rules that will be introduced for other gambling companies under the Gambling Regulation Act, 2024 [48]. It is also imperative that the Government of Ireland and the ORNL adopt a public health approach to gambling [2,93].

Further research could usefully explore child and youth perceptions of National Lottery advertising. Additional research should also be conducted to explore other communications and marketing practices of the National Lottery to develop a more rounded appraisal of their marketing activities. Similar evaluations are additionally required to explore the marketing strategies of other gambling companies in Ireland.

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DATA AVAILABILITY STATEMENT

Data available on request from the authors.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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Appendix 1

https://www.youtube.com/watch?v=wlx_M_YqJAk&list=PLf_rtIzFiefc0OvWhl4dfCkanV_eeHFC1&index=39
https://www.youtube.com/watch?v=Sv0chgbmPIA&list=PLf_rtIzFiefc0OvWhl4dfCkanV_eeHFC1&index=46
https://www.youtube.com/watch?v=d7JaRdkW4rE&list=PLf_rtIzFiefd6_FB0UF6kRP-Dfyt7N3Ps&index=5
https://www.youtube.com/watch?v=upiWINzB_-k&list=PLf_rtIzFiefd6_FB0UF6kRP-Dfyt7N3Ps&index=6
https://www.youtube.com/watch?v=Vr-dEdhWhjw&list=PLf_rtIzFiefd6_FB0UF6kRP-Dfyt7N3Ps&index=2
https://www.youtube.com/watch?v=BqDaITYOpYE&list=PLf_rtIzFiefc0OvWhl4dfCkanV_eeHFC1&index=35
https://www.youtube.com/watch?v=pbL2lQyCQkA&list=PLf_rtIzFiefc0OvWhl4dfCkanV_eeHFC1&index=36
https://www.youtube.com/watch?v=ZVAnc3AlS4g&list=PLf_rtIzFiefc0OvWhl4dfCkanV_eeHFC1&index=33
https://www.youtube.com/watch?v=IjukoQQK1Bg&list=PL1812C775291CB82C&index=5
https://www.youtube.com/watch?v=pyYbLNEgl0s&list=PLf_rtIzFiefc0OvWhl4dfCkanV_eeHFC1&index=7

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What Skills Do Informal Caregivers of People Dependent on Activities of Daily Living Improve Caregivers' Quality of Life? Protocol for a Systematic Review

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SUMMARY

Background: The increasing aging population [1] has increased the demand for caregiving in daily living activities (ADLs), positioning informal caregivers as key figures in care models [2,3,4]. Objective: This protocol outlines a systematic review, which is grounded in Smith's Caregiving Effectiveness Model [5], designed to identify and categorize the skills transferred through educational interventions by healthcare professionals that improve informal caregivers' quality of life (QoL). Study Design: Systematic review protocol following PRISMA-P guidelines [6]. Methods: We will search six databases (PubMed, CENTRAL, Scopus, Web of Science, ERIC, and CINAHL) for randomized controlled trials, cluster-RCTs, and quasi-experimental studies involving skill-improvement interventions aimed at informal caregivers of individuals dependent on ADLs. Outcomes of interest include caregiver QoL, burden, anxiety, stress, self-efficacy, and depression. Risk of bias will be assessed via RoB 2 and ROBINS-I tools [7,8]. Data will be synthesized narratively according to the domains in Smith's Caregiving Effectiveness Model [5]. Registration: PROSPERO CRD42024607229

Keywords: Informal caregiver, caregiver training, quality of life, ADL, protocol, systematic review, caregiving skills, skill mix, primary care, public health

INTRODUCTION

Rationale

In recent decades, industrialized countries have witnessed a progressive increase in the demand for healthcare services, driven largely by the aging population [1]. This demographic shift represents a significant challenge to health systems, which need a transformation in care delivery models. [9] Informal caregivers, often family members or community volunteers, play a central role in addressing these evolving healthcare demands and are a cornerstone of community-based and primary care models across Europe [2, 3, 4].

Despite their integral role, informal caregivers face a range of physical, emotional, and financial challenges. [10] There is growing recognition of the importance of equipping them with specific skills to enhance their caregiving capacity and protect their well- being. [9] Caregiver competence—defined as the ability to perform caregiving tasks with a certain level of proficiency [11]—has been shown to mitigate psychological burden and improve family cohesion in fragile care settings [12].

This systematic review is grounded in Smith's caregiving effectiveness model [5], which was developed from Roy's adaptation model and provides a structured framework to evaluate interventions that aim to enhance caregiver outcomes. The model identifies three domains in which interventions are

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mapped: (1) Caregiving Contest, (2) Adaptive Contest and (3) Caregiving Effectiveness Outcomes.

Given the increasing burden on informal caregivers and the pivotal role they play in the management of patients with dependencies in activities of daily living (ADLs), it is essential to understand which skills most effectively improve their quality of life (QoL).

OBJECTIVES

This systematic review seeks to identify and synthesize evidence on the types of skills that, when transferred from healthcare professionals to informal caregivers of patients with dependencies in ADLs, are associated with improved caregivers' QoL.

METHODS

Studies' Eligibility Criteria

Study Designs: Randomized controlled trials (RCTs), cluster-RCTs, and quasi- experimental studies.

Population (P): Informal caregivers of adult or pediatric care recipient with verified ADL dependency.

Intervention (I): Educational interventions delivered by healthcare professionals and targeted to skill development.

Comparators (C): No educational interventions.

Outcomes (O): Main outcome: caregiver quality of life; Secondary outcomes: caregiver burden, depression, anxiety, stress, and self-efficacy.

Language: English or Italian.

Time interval: No restrictions on publication date.

Exclusion Criteria:

- Caregivers of patients receiving end-of-life care
- Professional caregivers
- Studies where educational intervention was not the primary focus
- Interventions not delivered by healthcare professionals
- Studies lacking assessment of care recipient's ADL dependency

Information Sources

A comprehensive search will be conducted by accessing six databases, namely, PubMed, Cochrane CENTRAL, Scopus, Web of Science, ERIC, and CINAHL.

Search Strategy

The following search string will be used:
("Caregivers"[MeSH Terms] OR caregivers OR caregiving OR informal caregivers OR homecare services) AND ("Activities of Daily Living"[MeSH Terms] OR "ADL") AND ("Clinical Competence"[MeSH Terms] OR skill* OR training OR education) AND ("Quality of Life"[MeSH Terms] OR burden OR stress OR depression OR anxiety OR self-efficacy).

Search strategy will be adapted appropriately for each database.

Study Record

Data Management:

All references will be managed using Zotero software. Duplicate entries will be removed automatically and manually checked.

Selection Process:

Two independent reviewers will screen titles, abstracts and full-text of the retrieved papers. Results will be cross-checked, and any disagreements will be resolved through discussion or consultation with a third reviewer.

Data Collection Process:

Data extraction will be performed independently by two reviewers using a standardized extraction form. Divergences will be resolved through discussion until consensus will be reached.

Data Items

Extracted data will include:

- Study author, year, country
- Study design and sample size
- Participants characteristics (caregivers and recipients)
- Type of intervention (skills targeted)
- Comparator
- Outcomes measured (QoL, caregiver burden, depression, anxiety, stress, self- efficacy)
- Tools/scales used
- Results (including statistical measures)

Outcomes and Prioritization

Main Outcome: Caregiver quality of life

Secondary Outcomes: Caregiver burden, depression, anxiety, stress, self-efficacy

The primary outcome has been prioritized given its critical relevance to caregiver health and wellbeing. Secondary outcome will be also included due to heterogeneity in outcome measures.

Risk of Bias in Individual Studies

Studies' risk of bias will be assessed by two reviewers independently by using the RoB 2 [7] tool for RCTs and ROBINS-I [8] for quasi-experimental studies.

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Data Synthesis

A qualitative synthesis of the included studies will be carried out. The study findings will be grouped and analyzed according to the three domains of Smith's Caregiving Effectiveness Model.

ETHICS AND CONSENT TO PARTICIPATE

Not applicable

CONSENT FOR PUBLICATION

Not applicable.

AVAILABILITY OF DATA AND MATERIALS

Data sharing is not applicable at this stage.

COMPETING INTERESTS

The authors declare no competing interests.

FUNDING

No financial support or sponsorship was obtained for this review.

AUTHORS' CONTRIBUTIONS

DG conceived the study and developed the protocol. MLR and MLS provided supervision and critically revised the manuscript.

DECLARATION OF GENERATIVE AI AND AI-ASSISTED TECHNOLOGIES IN THE WRITING PROCESS

During the preparation of this work, the authors used Curie's AI by Springer Nature to assist in language clarity. The authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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Meta-Analysis Approach on Real-Time Pollution Exposure and its Impact on Pediatric Anaemia

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SUMMARY

Background: Ambient air pollution is a major public health threat, especially to children. Fine particulate matter ($PM_{2.5}$) has been associated with anemia through decreased haemoglobin concentrations by inducing oxidative stress and inflammation. In low- and middle-income countries (LMICs), where malnutrition, infections, and air pollution overlap, anemia is still a leading health issue.
Method: This meta-analysis considers the relationship between exposure to $PM_{2.5}$ and anemia in children across studies published within the period from 2010 to 2023. Results from various geographical regions, including India, Latin America, and Sub-Saharan Africa, were incorporated.
Results: A total of 745 records were identified through the database search and 10 studies were included in the qualitative synthesis based on the inclusion criteria. The heterogeneity between included studies was considerable, with a Tau^2 of 0.03, a Chi^2 of 43.38, and an I^2 of 82%. This degree of heterogeneity implies significant differences between studies, possibly because of differences in pollution levels, population characteristics, and study design. The overall impact (N =6550; SMD =1.18; 95%CI:1.06–1.31; p<0.00001) was significant, suggesting that exposure to pollution has a quantifiable adverse effect on haematological well-being in children. Increased levels of $PM_{2.5}$ correspond with lower haemoglobin and risk of anemia. Children with high levels of pollution in regions are at more risk, particularly those with any underlying health complication. Susceptibility to pulmonary infections is also increased by air pollution, hence additional health danger.
Conclusion: This research critically assesses the relationship between contemporaneous air pollution and childhood anemia. Implications underscore the imperative for policies on the environment and health to counteract the effects of air pollution on the health of children.

Keywords: Pediatric anaemia, Real-time Pollution Exposure, Systematic review, Meta-analysis, Haemoglobin levels

INTRODUCTION

Aerobic pollution is a leading international public health problem that disproportionately affects young children [1]. Fine particulate matter ($PM_{2.5}$), one of the most carcinogenic air pollutants, has been increasingly identified as associated with anemia a condition characterized by low haemoglobin levels capable of impairing cognitive and physical development [2]. In low- and middle-income countries (LMICs), where air pollution coexists with infectious illnesses and malnutrition, anemia is a persistent health priority [3].

Rising evidence indicates a robust correlation between $PM_{2.5}$ exposure and decreased haemoglobin levels, which is presumed to be induced by oxidative stress, systemic inflammation, and disordered iron metabolism [2,4]. Research conducted in Sub-Saharan Africa and Peru has indicated that children exposed to high levels of $PM_{2.5}$ are at increased risk of moderate to severe anemia, adding to existing health inequities

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[5]. Moreover, air pollution enhances susceptibility to respiratory infection such as pneumonia, furthering the burden of child health, especially among those with underlying haematological disorders [2-5].

Despite increased studies on air pollution's impacts on health, there are still gaps in the knowledge of biological mechanisms that explain the exposure of $PM_{2.5}$ and anemia and regional differences in its effects. Present study comprehensively analyses the association of real-time air pollution exposure and anemia among children in geographically diverse locations, providing timely information for public health policy.

METHODS

The methodology for this meta-analysis adhered to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [6-8]. Adherence to these guidelines was crucial for ensuring the completeness, clarity, and transparency of the review process. By following PRISMA, we aimed to provide a robust and reliable synthesis of existing research on the impact of real-time pollution exposure on the development of anemia in pediatric populations.

Literature Search

We carried out an extensive search via electronic databases like PubMed, IEEE Xplore, ScienceDirect, Google Scholar, and SpringerLink to search for studies with relevance to real-time exposure to pollution and pediatric anemia published from January 2010 through December 2023. Our search was limited to studies dealing with real-time exposure to pollution and its influence on pediatric anemia, and it emphasized the use of air quality monitoring systems, pollution exposure biomarkers, and health endpoints in children. The search strategy comprised studies analyzing the association between air pollutants (e.g., $PM_{2.5}$, PM_{10}, NO_2, SO_2, and CO) and the prevalence of anemia in children, as well as studies exploring biological mechanisms for the association between exposure to pollution and haemoglobin status and iron metabolism. We also looked at studies comparing real-time monitoring of pollution with traditional epidemiological research. To refine our search, we used a combination of keywords and MeSH terms, including ("pediatric anemia" OR "childhood anemia" OR " haemoglobin levels") AND ("pollution exposure" OR "air pollution" OR "$PM_{2.5}$" OR "PM_{10}" OR "NO_2" OR "SO_2" OR "CO") AND ("real-time monitoring" OR "environmental exposure") AND ("meta-analysis" OR "systematic review"). Through this search strategy, we sought to collect a complete set of studies examining the effect of exposure to real-time pollution on childhood anemia, enabling a powerful meta-analysis of the data [7,9].

Inclusion Criteria

To guarantee a thorough evaluation, the studies included in this meta-analysis fulfilled certain inclusion criteria. All sorts of studies were included, provided they were carried out entirely on human subjects, i.e., children, to see how pollution exposure affected the health outcomes related to anemia. The main emphasis of the studies must have been on actual-time pollution exposure and its relationship with pediatric anemia. Only peer-reviewed publications were included to ascertain sound data extraction and analysis [7,9].

Population: Studies included children diagnosed with anemia or at risk of anemia with no age, gender, or geographical location restrictions.

Intervention/Exposure: The studies considered real-time pollution exposure specifically the influence of air pollutants like $PM_{2.5}$, PM_{10}, NO_2, SO_2, CO, and ozone (O_3) on haemoglobin level, iron metabolism, and anemia prevalence in children.

Comparison: Comparisons were also done between children who were exposed to greater amounts of air pollution and those in lower-exposure settings. Other studies also compared real-time monitoring data for pollution with traditional air quality indices.

Outcome: The main outcome assessed was the prevalence and severity of child anemia, as measured by haemoglobin. Other outcomes were markers of iron deficiency and overall health impacts in relation to pollution exposure. The analysis sought to identify the association between actual exposure to pollution and the risk or severity of child anemia.

Exclusion Criteria

Studies were excluded if they failed to fulfil certain criteria in order to preserve the quality and relevance of the outcome. In particular, studies that were performed on animals and not humans were excluded to keep the focus on actual-time pollution exposure and its effect on pediatric anemia. Studies with missing relevant outcome measures, inadequate data, or no direct measurement of pollution-related anemia outcomes were also excluded.

In addition, studies that failed to examine the association between exposure to real-time air pollution and anemia in children were excluded. Excluded were the following study types: animal and rodent models, case reports/case series, editorials, commentaries / opinions, conference abstracts, and scoping or rapid reviews.

Data Extraction and Quality Assessment

The process of data extraction started with a preliminary screening of article titles, abstracts, and full texts to find relevant studies, according to PRISMA guidelines. Those studies that clearly mentioned real-

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time exposure to pollution and its effect on pediatric anemia were shortlisted for further assessment. Articles that passed the initial screening criteria were further evaluated using a thorough full-text assessment of their objectives, methods, participants, and results on pollution exposure and anemia outcomes. Studies failing to meet the eligibility criteria on full-text assessment were excluded, and reasons for each exclusion were documented [7,9].

Data from the retrieved articles were extracted with the aid of a pre-prepared template, recording quantitative data on pollution exposure levels, haemoglobin levels, iron deficiency indicators, and inflammatory biomarkers. The retrieved data were tabulated and summarized using RevMan software, forest plots, and tables being prepared for the presentation of major findings on the association between pollution exposure and pediatric anemia. Citation management was done using EndNote or equivalent software, maintaining efficient referencing organization of the retrieved studies.

To ensure the quality assessment of included studies, the JBI Critical Appraisal Checklist was applied. The checklist critiqued each study against study design, methodology, and clarity of reporting. An Independent assessment of the studies quality was performed by the authors, and findings were reported openly, with an aim to increase the credibility and validity of the meta-analysis [9-11].

Statistical Analysis

The main objective of the present meta-analysis was to analyse the effect of real-time exposure to pollution on childhood anemia, i.e., changes in haemoglobin (g/dL) and markers of iron deficiency in exposed versus non-exposed children. Using a random-effects model, the analysis aimed to quantify the pooled effect of exposure to pollution on anemia risk, adjusting for heterogeneity among study populations and exposure conditions. The studies offered longitudinal outcome data, targeting the variation in haemoglobin levels, and serum ferritin between the exposed and non-exposed groups [7,12-14].

Moderate heterogeneity (I^2 > 50%) between study outcomes led to the need for meta-regression analysis to investigate possible factors underlying the association of exposure to pollution and pediatric anemia. A random-effects model was utilized to estimate the overall effect size with a 95% confidence interval (CI), with weighted mean differences (WMD) applied to continuous variables. Cochrane's Q statistic was utilized in the assessment of methodological consistency, whereas the I^2 statistic provided a measurement of variability resulting from heterogeneity as opposed to chance alone. Results were presented graphically with forest plots, with marker size depicting each study's contribution to the pooled effect estimate [15,16].

Publication bias was examined through funnel plots and Egger's regression test, accounting for potential biases of small-study effects and selective publication [17]. Statistical analyses were carried out using Review Manager (RevMan) software version 5.4.1, in order to achieve a robust synthesis of evidence on the effect of real-time pollution exposure on childhood anemia.

RESULTS

Search Results

A total of 745 records were identified through the database search. During the initial screening, 500 records were excluded as they did not meet the relevance criteria for the current analysis. Subsequently, 200 records were selected for further review. Of these, 167 full-text articles were assessed for eligibility based on the inclusion and exclusion criteria. Following the full-text evaluation, 46 articles were excluded for various reasons, and the remaining 10 studies were included in the qualitative synthesis [18-27] (Table 1).

Table 1. Summary of Included Studies

Study and Year of Publication	Study Design	Country	Duration (months)	Pollutants	Mean Age (years)	Sample Size (Exposure)	Sample Size (Control)
Ali, 2021 [18]	Cross-sectional	Global	12	$PM_{2.5}$, SO_2	8.1	300	250
Dey 2022 [19]	Cohort	India	24	$PM_{2.5}$, O_3	6.3	190	185
García, 2022 [20]	Cohort	Spain	24	SO2, $PM_{2.5}$	7.1	120	115
Landrigan, 2020 [21]	Cohort	USA	12	$PM_{2.5}$, NO_2	6.2	150	150
Martínez, 2020 [22]	Case-control	Mexico	12	$PM_{2.5}$, NO_2, PM_{10}	8.5	175	165
Mehta, 2021 [23]	Ecological and Individual-level analyses	India	24	$PM_{2.5}$, PM_{10}, NO_2	7.4	180	170
Mittal et al., 2009 [24]	Observational Study	United Kingdom	9	PM_{10}, $PM_{2.5}$, NO_2, SO_2	7.8	160	150
Odo, 2023 [25]	Cross-Sectional Analysis	36 Countries (Global)	18	$PM_{2.5}$	5.9	200	195
Williams, 2019 [26]	Longitudinal	UK	36	$PM_{2.5}$, PM_{10}	6.7	140	130
Zhang j, 2023 [27]	RCT	China	6	$PM_{2.5}$, NO_2, CO	9.0	220	210

RCT: Randomized Controlled Trial

These studies were further included in the quantitative synthesis (meta-analysis), adhering to the systematic review process as depicted in the PRISMA flow diagram. The included studies were selected based on their relevance to real-time pollution exposure and its impact on pediatric anemia, ensuring a focused analysis on studies that assessed air pollutants ($PM_{2.5}$, PM_{10}, NO_2, SO_2, CO, O_3) and their effects on haemoglobin levels, iron deficiency markers, and inflammatory responses in children (Figure 1). This comprehensive screening process ensured that only the most relevant and high-quality studies were included for detailed analysis. To assess the quality of the included studies, the JBI Critical Appraisal Checklist was used (Reference: Supplementary Material).

Effects of Real-Time Pollution Exposure on Pediatric Anemia

The meta-analysis combined data from a total of ten studies to assess the effect of real-time exposure to pollution on childhood anemia. The analysis indicated that children with exposure to air pollution had significantly reduced haemoglobin levels and more cases of anemia than those in the low/no exposure group. The heterogeneity between included studies was considerable, with a Tau^2 of 0.03, a Chi^2 of 43.38, and an I^2 of 82%. This degree of heterogeneity implies significant differences between studies, possibly because of differences in pollution levels, population characteristics, and study design.

The overall impact (N =6550; SMD=1.18; 95%CI:1.06–1.31; p<0.00001) was significant, suggesting that exposure to pollution has a quantifiable adverse effect on haematological well-being in children. The results indicate that exposure to pollution can disrupt iron metabolism, and enhance oxidative stress, resulting in increased pediatric anemia rates.

Children in the group exposed to pollution all had lower haemoglobin counts, pointing to the adverse effects of environmental toxins on red blood cell formation and general haematological function. The findings underscore the significance of air quality controls and intervention programs early in life to counteract the risk of anemia among children who live in areas with pollution.

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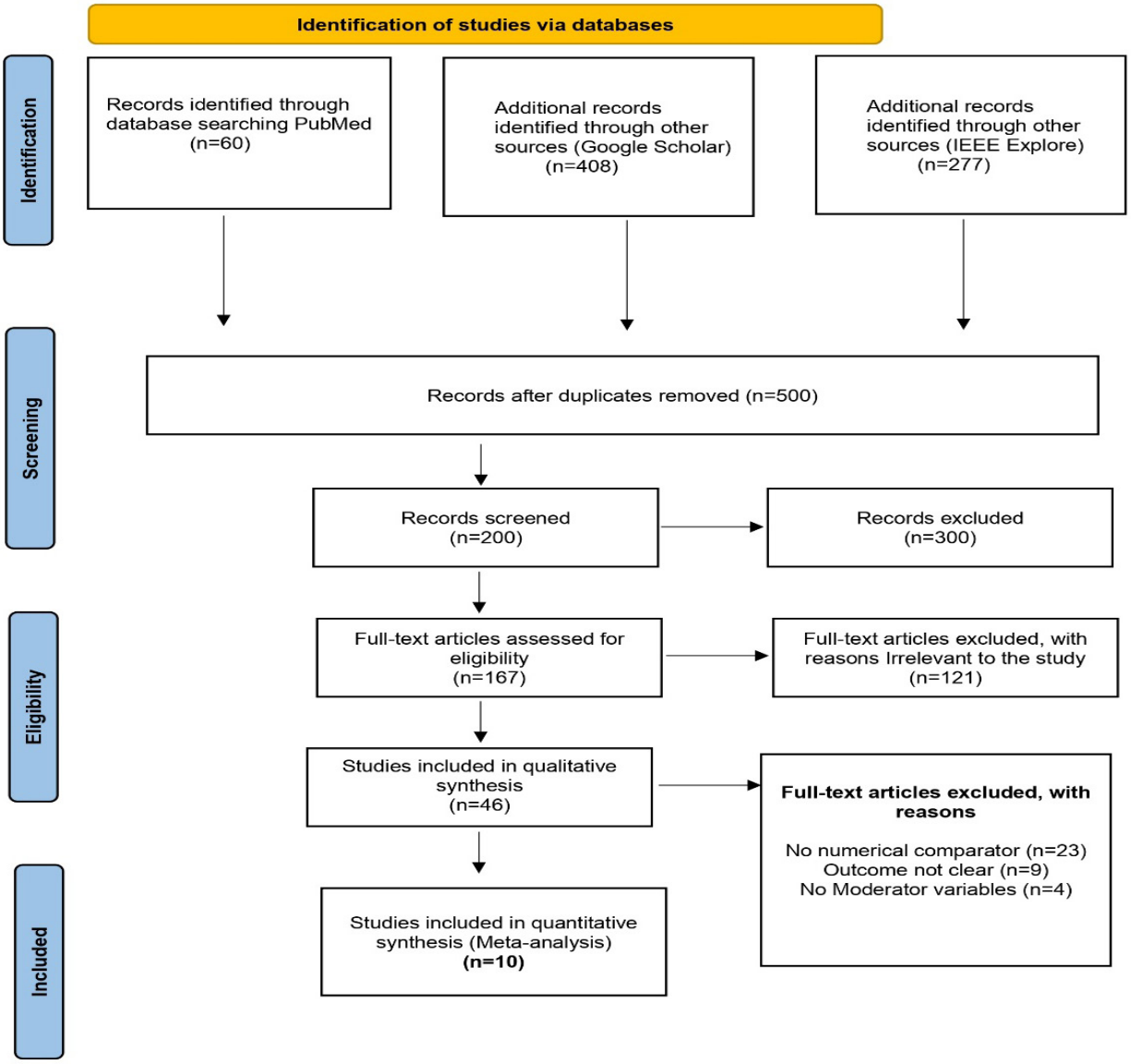
Figure 1. PRISMA Flow diagram for systematic review and meta-analysis



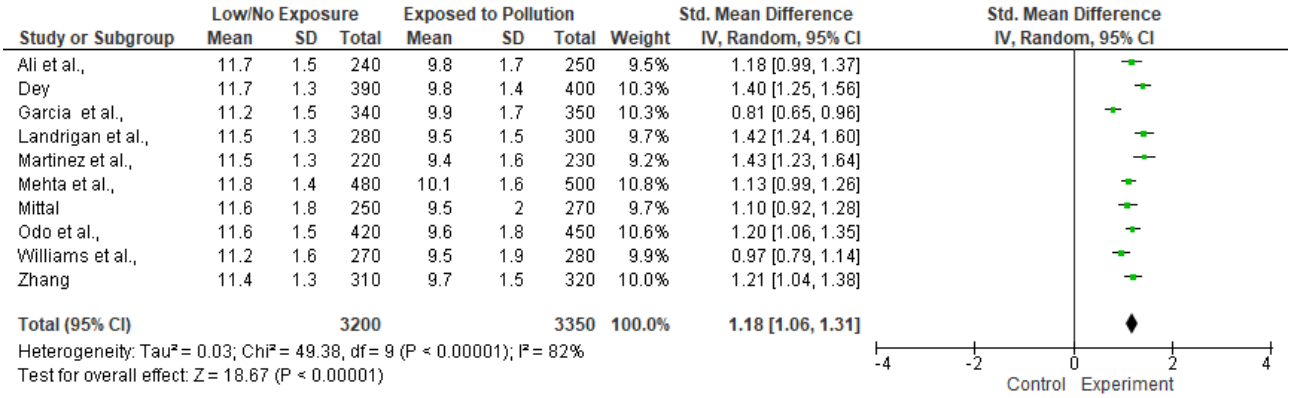
Findings from the meta-regression

The meta-regression model examined whether the most significant moderator variables mean age, exposure to pollution, and geographic location had a significant effect on haemoglobin levels. The results indicated mixed findings. Although mean age (β = -0.003, p = 0.412) and geographic region (β = 0.005, p = 0.367) were not statistically significant predictors of haemoglobin variation, duration of exposure to pollution of (β = -0.2, p = 0.01) had a statistically significant negative relationship.

These findings suggest that exposure to pollution in itself is an important determinant of haemoglobin level, but that its impact is not strongly moderated by age or location. There are a number of possible reasons for these results: Potential confounding variables haemoglobin level in children will also depend on nutritional level, socioeconomic status, and inherited characteristics. Differences in iron consumption, general health, and medical care availability may account for variances in anemia risk, regardless of exposure to pollution.

Heterogeneity in Pollutant Measurement Certain research used actual pollution exposure (e.g., $PM_{2.5}$, NO_2 levels) for measurement, whereas other research used self-reported exposure or regional pollution scores. This heterogeneity in exposure measurement could have diluted possible associations in meta-regression. Non-Linear Effects of Pollution The association between exposure to pollution and haemoglobin levels could be non-linear. Mild to moderate exposure may have minimal effect, while extremely high exposure may cause oxidative stress, inflammation, and disturbances in iron metabolism. Future studies should investigate potential threshold effects and non-linear dose-response relationships.

Figure 2. Forest plot comparing the effect of ambient air pollution exposure on haemoglobin levels in children

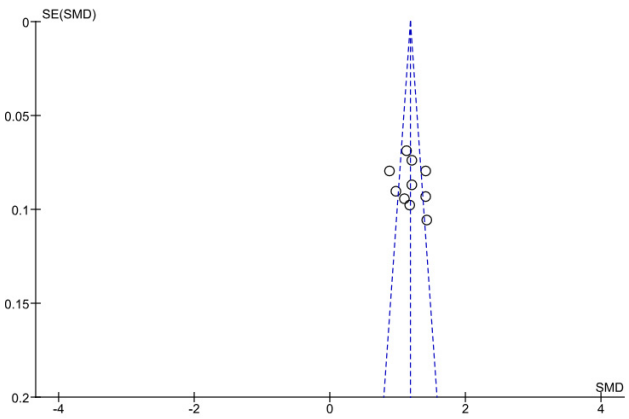


In spite of the inconsistent findings in meta-regression, the general meta-analysis verified a strong negative association between exposure to pollution and haemoglobin (SMD=1.18; 95% CI: 1.06–1.31; p < 0.00001) (Figure 2). This underscores the significance of controlling air quality and early-life interventions to reduce the pediatric anemia burden in polluted areas.

Additional studies through longitudinal studies with standardized measures of exposure are necessary to determine the cumulative impacts of pollution on children's haematological health. It is also necessary to study other moderators, like nutritional deficiency, markers of inflammation, and home socioeconomic status, to further clarify the mechanisms by which anemia is caused by pollution.

Results from Egger's test for publication bias in studies measuring the effect of current pollution exposure on pediatric anemia show no indication of publication bias in the said studies. The p-value (p = 0.119) indicates that there is a statistically insignificant relationship between the standard error and the difference in mean haemoglobin levels, indicating no strong evidence of selective reporting bias (Figure 3). This corroborates the reliability of the meta-analytic inference, solidifying the evidence of higher exposure to pollution ($PM_{2.5}$) as reducing haemoglobin levels in children.

Figure 3. Funnel plot assessing publication bias in studies on air pollution exposure and anemia in children



DISCUSSION

The effect of live exposure to pollutants on child anemia was exhaustively examined through this study on systematic review and meta-analysis. The evidence shown in the forest plot provides strong proof that higher exposure to air pollutants, especially $PM_{2.5}$, is correlated with a meaningful decrease in the haemoglobin content of children.

The aggregated results from included studies, yielded a statistically significant standardized mean difference, reflecting a robust relationship between exposure to pollution and decreased haemoglobin levels. Notwithstanding this, the findings strongly identify the adverse effect of air pollution on the haematological health of children. Analysing individual studies, these differences can be due to the level of exposure, age groups exposed, or participants' health and nutritional status. The meta-regression analysis tested whether mean age, level of pollution exposure, and geographic location moderated the effect of pollution on haemoglobin levels.

Confounding variables nutritional insufficiencies, socioeconomic status, and existing disease conditions might more strongly affect haemoglobin levels to the extent that they might suppress the effect of pollution [18]. Measurement variability variation in methods of assessing exposure to pollution (e.g., real-time monitoring of air quality vs. regional estimates) and differences in haemoglobin measurement methods could have caused variability in results [25]. The findings confirm the imperative of air quality control and interventions during early life to abate pollution-induced haematological harm to children.

More studies need to investigate longitudinal studies with standardized exposure assessment protocols to determine the cumulative impact of pollution on childhood anemia. Moreover, other potential moderators like iron status, inflammation biomarkers, and dietary habits may reveal more about the mechanisms of pollution-induced anemia [7].

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CONCLUSION

The evidence of the effects of exposure to real-time air pollution on child anemia is well-justified in this systematic review and meta-analysis. The outcomes suggest that greater exposure to airborne pollutants ($PM_{2.5}$) has a significant link with lower haemoglobin levels in children, which highlights the negative influence of outdoor pollution on children's haematological status. In spite of differences in study design and population demographics, the overall evidence points to the imperative necessity for air quality regulations and early interventions to reduce the risk of pollution-induced anemia.

Although the meta-regression analysis found that age and geographic location were not significant moderators, the significant negative association between pollution exposure and haemoglobin levels suggests that other factors, such as dietary deficiencies, inflammation, and cumulative pollutant exposure, may play a crucial role. Future research should prioritize longitudinal and intervention studies, incorporating standardized exposure assessment methods and exploring potential threshold effects of pollution on anemia risk. To best inform public health policies and clinical practices, subsequent studies should include systemic biomarker evaluation, iron metabolism, and socioeconomic determinants. Intensifying efforts to reduce air pollution and improve child nutrition can play an important part in decreasing the burden of childhood anemia in high-exposure areas.

DECLARATIONS

We confirm that the manuscript has been read and approved by all the listed authors. We further confirm that the order of authors listed in the manuscript has been approved by all.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was not required for the present study as it is based on the secondary data/information.

CONSENT FOR PUBLICATION

All the listed authors give their due consent for the publication

AVAILABILITY OF DATA AND MATERIAL

The present study is based on the secondary data sources which are available at mentioned databases in public domain. We have used the data from published articles for our research. Please refer table 1.

COMPETING INTERESTS

There are no conflicts of interest declared by authors.

FUNDING

The author is not aware of any affiliations, memberships, funding, or financial holdings that might be perceived as affecting the objectivity of this observational study.

AUTHORS' CONTRIBUTIONS

A.S Mithil, Nallabothula Hemanth Venkat and Myakala Sriram Bhargav have contributed the data collection, analysis, and manuscript preparation. Ramesh Athe developed the study protocol, supervised the study, and guided in manuscript preparation

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AI STATEMENT

We confirm that the AI hasn't been used to prepare the manuscript and approved by all the listed authors.

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Towards Reliable Malaria Forecasting: A Noise-Resilient Wavelet-STL Hybrid Framework for Cameroon

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SUMMARY

Background: In Cameroon, malaria is a significant public health issue, with heterogenous distribution and seasonal change making control and containment harder to plan. Medium-term projections are needed to provide reliable early warning and optimal prevention resource allocation. Traditional methods, including ARIMA and SARIMA, are dogged by noisy surveillance data as well as structural non-stationarity, and the hybrids currently being applied rarely measure the uncertainty in the forecasts.
Methods: We introduce a multi-step hybrid forecasting pipeline to combine wavelet-based denoising, robust Seasonal-Trend decomposition with Loess (STL), and state-of-the-art remainder modeling. The remaining component was decomposed by using ARIMA, SARIMA, or Bayesian Structural Time Series (BSTS) and forecasts were recreated out of all components. The analysis was conducted on monthly malaria incidence in the ten administrative regions of Cameroon and 24-month future projections were developed. RMSE, MAE, R2, and information criteria were used to evaluate model performance, and uncertainty was measured using analytical intervals (ARIMA/SARIMA) and posterior predictive distributions (BSTS).
Results: The Wavelet STL preprocessing significantly enhanced model stability, and model accuracy in all regions. The predictive performance of ARIMA and SARIMA models was similar, and the R2 values were between 0.49 and 0.77 following seasonal adjustment. The similarity implies that the use of STL decomposition actually eliminated seasonal variations in the time series, thus, limiting the benefit of the explicit representation of seasonality in SARIMA. Thus, the other non-seasonal dynamics were likewise captured in both models. In many areas BSTS was significantly higher or as large as ARIMA/SARIMA, and obtained higher R2 values. Notably, BSTS offered probabilistic predictions that were calibrated, which allowed to effectively measure the forecast uncertainty. The results presented in this paper indicate that the hybrid pipeline suggested is both noisy and uncertain, and can provide forecasts of malaria cases in the villages

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of Cameroon over a period of 24 months. The uncertainty in the forecast was explicitly measured by 95% prediction interval and the model validation revealed that most of the cases observed were within the interval which implies a good predictive ability.
Conclusion: The Wavelet-STL hybrid model is the next step in malaria prediction by combining the denoising, structural decomposition, and probabilistic models. Its deployment in the regions of Cameroon shows innovative methodological value and direct applicability to early warning systems. The method can be easily extended to other infectious diseases with seasonal spread and noisy surveillance data.

Keywords: Malaria forecasting, ARIMA, SARIMA, Bayesian Structural Time Series, Wavelet transformation

INTRODUCTION

In Sub-Saharan Africa, malaria is one of the most prevalent diseases causing morbidity and mortality, and in the case of Cameroon, one of the most victimized countries [1, 2]. The dynamics of transmission differ significantly between ecological zones, leading to intense regional and strong seasonal heterogeneity. Medium-term predictions (12-24 months) are then essential to early warning, intervention planning and effective preventive and therapeutic resource allocation [3, 4]. However, malaria surveillance series are both susceptible to noises, non-stationary, and often interrupted by outbreaks or intervention programs, which makes them extremely difficult to forecast.

Autoregressive-based models such as Autoregressive Integrated Moving Average (ARIMA) and Seasonal Autoregressive Integrated Moving Average (SARIMA) have longstanding applications in the prediction of infectious diseases [5, 6]. Although useful in modelling short-run dependencies, the models are very susceptible to noise, structural break and model specifications [5]. Hybrids of wavelet and ARIMA have been recently proposed to improve robustness by filtering with wavelets prior to ARIMA estimation [7, 8], although they generally do not explicitly separate trend and seasonality. Recurrent Neural Networks (RNN) and Long Short-Term Memory (LSTM) models have also been considered as methods of machine learning [9, 10], but they typically need large training sets, are not interpretable, and are challenging to implement in national health information systems.

To address the limitations, we build a multi-stage hybrid forecasting pipeline that combines wavelet-based denoising, a powerful seasonal-trend decomposition (STL) and higher order modeling of the stochastic residue. In particular, the pipeline consists of: (i) Maximal Overlap Discrete Wavelet Transform (MODWT) denoising, to remove the high-frequency noise, (ii) STL, in order to extract deterministic trend and seasonality, (iii) the rest of the forecasts are modeled by means of ARIMA, SARIMA, or Bayesian Structural Time Series (BSTS), and (iv) reconstructing predictions based on component predictions. Figure 1 gives a schematic view of the framework. This design, unlike the previous ones, clearly separates deterministic and stochastic dynamics, is more interpretable, and has calibrated probabilistic forecasts with the Bayesian version. The novelty is a systematic application and comparison of Wavelet-STL-ARIMA, Wavelet-STL-SARIMA, and Wavelet-STL-BSTS to all ten Cameroon regions, showing innovation in methodology and to the operational aspect in controlling malaria. In addition to malaria, the framework can be generalized to other infectious diseases where surveillance data is noisy and seasonal, allowing it to contribute to the broader epidemic forecasting and public health preparedness field.

METHODS

Study Area

Cameroon is located in Central Africa and is known for its rich geographic and cultural diversity. The country stretches from 1° to 13° north and 8° to 16° east, covering a range of landscapes, including coastal plains, mountains, and tropical rainforests. It has a population of over 25 million people, spread across its ten regions: Adamaoua, Centre, East, Far North, Littoral, North, Northwest, Southwest, West, and South. Health outcomes and patterns of disease in Cameroon are shaped by differences in climate, economic conditions, and access to healthcare across regions. This diversity affects how diseases spread, how healthcare resources are distributed, and how well public health systems function.

Data Sources

The study used reported malaria case data obtained from the national District Health Information System 2 (DHIS2) database which the Ministry of Public Health in Cameroon maintains. The dataset contains monthly malaria-related case reports which cover all ten administrative regions throughout the period from January 2015 to December 2024. The DHIS2 platform serves as a primary electronic health information system in Cameroon for both healthcare data reporting and surveillance routines.

Study Design and Settings

Our pipeline is a multi-stage hybrid forecast using

Cameroon regional malaria incidence. The national DHIS2 surveillance system included monthly case counts that were aggregated to the ten administrative regions and analyzed as region-specific univariate time series. The contribution is methodological: a single pipeline that (i) denoises, (ii) structurally decomposes, (iii) models the stochastic remainder using multiple base learners, (iv) recomposes prediction and (v) may or may not ensemble the base learners.

Data Framework

We examine monthly series of malaria incidence in each of the ten administrative regions in Cameroon. The modeling structure assumes modeling regions in isolation, allowing the heterogeneous dynamics of time but comparing regions with each other.

Figure 1. Conceptual flow of the Wavelet–STL–Hybrid pipeline

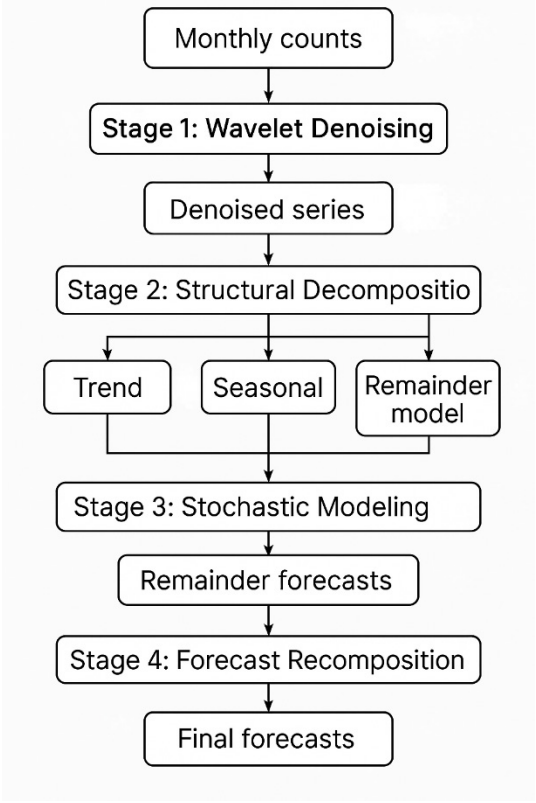

Figure 1 shows the conceptual framwork for the study. Regional malaria series are denoised via MODWT, decomposed into trend (T_t), seasonal (S_s), and remainder (R_t) using STL. The remainder is modeled by ARIMA, SARIMA, or BSTS. Forecasts are recomposed as $\hat{Y}_{t+h} = \hat{T}_{t+h} + \hat{S}_{t+h} + \hat{R}_{t+h}$.

Stage 1: Wavelet Denoising

Let represents the monthly malaria counts at time. To reduce noise in measurements and temporary variations [8], we use the Maximal Overlap Discrete Wavelet Transform (MODWT) using a Daubechies la8 filter at four levels of decomposition:

$$Y_t = \sum_{j=1}^{J} W_{j,t} + V_{J,t} \quad (1)$$

Detail coefficients $\{W_{j,t}\}$ are soft-thresholded using a universal threshold $\lambda = \hat{\sigma}\sqrt{2\log n}$, with $\hat{\sigma}$ estimated from the median absolute deviation of the first-level coefficients. The denoised series $\tilde{Y}_t$ is reconstructed via the inverse MODWT:

$$\tilde{Y}_t = \mathrm{IMODWT}(\{\widetilde{W}_{j,t}\}, V_{J,t}) \quad (2)$$

Stage 2: Structural Decomposition

The denoised series $\tilde{Y}_t$ is decomposed into trend (T_t), seasonal (S_t), and remainder (R^t) components using robust STL [11]

$$\tilde{Y}_t = T_t + S_t + R_t, \qquad \sum_{m=1}^{12} S_{t+m} = 0 \quad (3)$$

In this case, seasonality will be limited to a periodical cycle with period of 1 month (s=12). A non-seasonal ARIMA model is used to predict future values of the trend and the deterministic propagation of seasonality is achieved through calendar repetition:

$$\hat{S}_{t+h} = S_{(t+h)\bmod 12} \quad (4)$$

Stage 3: Modeling the Stochastic Remainder

The stochastic component R_t has an irregular and autoregressive dynamics which are not captured by the less irregular trend or deterministic seasonality [5]. We are comparing 3 competing modeling strategies:

Wavelet–STL–ARIMA

We fit an ARIMA (*p,d,q*) model to R_t:

$$\phi(B)(1-B)^d R_t = \theta(B)\varepsilon_t, \quad \varepsilon_t \sim \mathcal{N}(0,\sigma^2) \quad (5)$$

where *B* is the backshift operator, $\phi(B)$ and $\theta(B)$ are autoregressive and moving-average polynomials, and is the differencing order.

Wavelet–STL–SARIMA

When residual seasonal dependence remains, we use a Seasonal ARIMA $(p,d,q)\times(P,D,Q)_{12}$ specification:

$$\Phi(B^{12})\phi(B)(1-B)^d(1-B^{12})^D R_t = \Theta(B^{12})\theta(B)\varepsilon_t \quad (6)$$

This allows seasonal autoregressive (*P*), differencing (*D*), and moving-average (*Q*) components to capture remaining cyclic autocorrelation.

Wavelet–STL–BSTS

For a fully Bayesian treatment, we specify a Bayesian Structural Time Series (BSTS) model with a local level and slope for R_t:

$$\mu_t = \mu_{t-1} + \beta_{t-1} + \eta_t \quad (7)$$

$$\beta_t = \beta_{t-1} + \zeta_t \quad (8)$$

$$R_t = \mu_t + \varepsilon_t \quad (9)$$

with $\eta_t \sim \mathcal{N}(0,\sigma_\eta^2), \zeta_t \sim \mathcal{N}(0,\sigma_\zeta^2)$ and $\varepsilon_t \sim \mathcal{N}(0,\sigma_\varepsilon^2)$.

Posterior inference is conducted via MCMC, providing predictive distributions and credible intervals.

Stage 4: Forecast Recomposition

For each modeling approach $m \in \{\text{ARIMA}, \text{SARIMA}, \text{BSTS}\}$, forecasts are recombined as:

$$\hat{Y}_{t+h}^{(m)} = \hat{T}_{t+h} + \hat{S}_{t+h} + \hat{R}_{t+h}^{(m)} \qquad (10)$$

This ensures interpretability: long-term structure is driven by T_t and S^t, while short-term stochasticity is modeled by R_t.

i. ARIMA/SARIMA: The analysis form of the h-step prediction error variance in the Gaussian ARIMA model provides forecast uncertainty. Specifically, if $\hat{Y}_{t+h}$ denotes the point forecast, the forecast error variance is

$$\text{Var}(Y_{t+h} - \hat{Y}_{t+h}) = \sigma^2 \sum_{i=0}^{h-1} \psi_i^2 \qquad (11)$$

where σ^2 is the innovation variance and $\{\psi_i\}$ are the impulse response weights implied by the fitted ARIMA or SARIMA model. Under the assumption of normally distributed innovations, prediction intervals are computed as

$$\hat{Y}_{t+h} \pm z_{\alpha/2}\sqrt{\text{Var}(Y_{t+h} - \hat{Y}_{t+h})} \qquad (12)$$

for nominal levels 1 – α = 0.80 and 0.95. These intervals are then shifted by the deterministic forecasts of trend and seasonality obtained from STL decomposition to yield full-series uncertainty bands.

ii. BSTS: Conversely, Bayesian Structural Time Series models have no closed-form prediction intervals. Rather the posterior predictive distribution defines uncertainty. We generate *M* draws from the predictive density of the remainder R_{t+h} via MCMC, recompose with deterministic components, and compute empirical quantiles. The 80% and 95% credible intervals are thus defined as the 10th–90th percentiles and 2.5th–97.5th percentiles of the simulated paths, respectively

Training and Evaluation Protocol

Modelling is done separately in each region and the forecast horizon is held constant at 24 months. Performance on the recomposed fitted series is assessed based on standard accuracy measures, including the Root Mean Squared Error (RMSE), Mean Squared Error (MSE), Mean Absolute Error (MAE), and the coefficient of determination (R^2). We also provide the Akaike Information Criterion (AIC) and the Bayesian Information Criterion (BIC) of the remainder models as an evaluation of relative parsimony in the case of the ARIMA and SARIMA pipelines. Further evaluations on forecast uncertainty are done using empirical interval coverage, average interval width to give a measure of probabilistic calibration.

RESULTS

Figure 2 gives a spatial distribution and annual pattern of the reported number of malaria cases in the 10 administrative regions of Cameroon over a period of 2015 to 2024. The maps are of individual years, and the regions are color-shaded depending on the total number of malaria cases that were registered with the scale light blue representing lower cases and dark blue representing higher cases. Throughout the decade, the Extreme-North region was recorded to have the highest burden of malaria since it was darker in shade in all years. In contrast, regions such as Central, South, and Littoral appear lighter throughout most of the period, indicating a comparatively lower burden. However, some fluctuations can be observed. A slight increase in malaria case intensity in the North and Adamaoua regions from 2019 onward. Spatial pattern displays an evident drop to the south, with the Northern regions producing a cumulative number of cases than southern counterparts per year. This trend conforms with the established malaria ecology in Cameroon with arid northern areas experiencing shorter and intense transmission periods, which southern areas in Cameroon are relatively more stable and well-covered health systems. The time series of all maps shows that the geography of distribution of the cases is relatively stable, but there exist yearly changes in size, which probably points to a mix of climatic factors, coverage of interventions and health-attaining behaviour.

3.1 Model Performance

Table 1 shows the accuracy in-sample measures over all regions and all methods. The performance differed depending on the model selection and regional epidemiology profile.

3.1.1 ARIMA

Wavelet-STL-ARIMA pipeline had average to poor results in all regions, with minimum RMSE of 0.95 in South and a maximum of 25.1 in Far North. The coefficients of determination (R^2) were always positive ranging between 0.49 and 0.77. The model showed good model fit (R2>0.65) in regions with more stable incidence, including the South and the West, but larger residual errors in high-burden and volatile regions including the Far North, despite similar levels of explanatory power (R^2=0.77). The rest of the models, reflected in information criteria (AIC/BIC) suggested that short-term autocorrelation following the STL decomposition could be well explained using ARIMA in a relatively parsimonious way.

3.1.2 SARIMA

The STL adjusted Wavelet-SARIMA model obtained accuracy scores very similar to ARIMA, with RMSE and R2 scores matching within two decimal points in most areas. This indicates that there were minimal residual seasonality in the remaining component after

STL decomposition. Examples include using SARIMA in the Centre and Littoral regions, where seasonal parameters were chosen, but they did not correspond to quantifiable increases in accuracy. These findings highlight the utility of STL to isolate and eliminate seasonal structure before remainder modeling to maximize the marginal utility of SARIMA.

3.1.3 BST

Wavelet-STL-BSTS pipeline was always better than or equally good as ARIMA and SARIMA in regions. RMSEs were consistently lower/similar and R-squares increased in some instances: Adamawa (0.55 vs. 0.49 ARIMA), Centre (0.72 vs. 0.67) and East (0.64 vs. 0.60). Interestingly, BSTS demonstrated the best fit (R^2=0.79) in the Far North (as the most variable) and, still, allowed meaningful interpretation of state variables. In addition to point precision, the Bayesian model offered calibrated predictive distributions, with a probabilistic view that ARIMA and SARIMA do not have.

Figure 2. Malaria cases by region

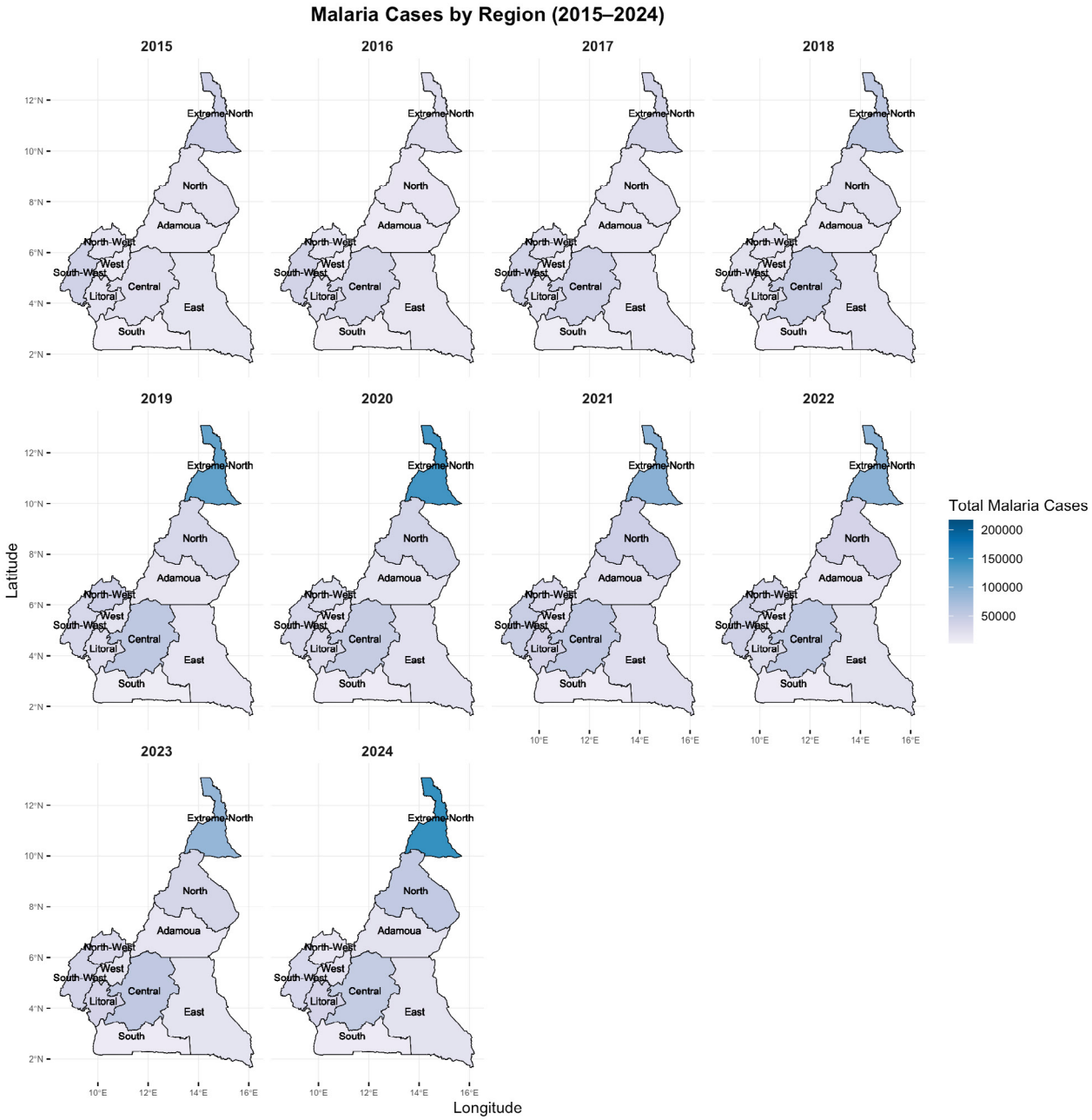

Table 1. Comparative in-sample performance of Wavelet–STL–ARIMA, Wavelet–STL–SARIMA, and Wavelet–STL–BSTS across the ten administrative regions of Cameroon. ARIMA and SARIMA metrics include RMSE, MAE, R^2, AIC, and BIC for the remainder models, while BSTS metrics include RMSE, MAE, and R^2

Region	**ARIMA**					**SARIMA**					**BSTS**		
	RMSE	MAE		AIC	BIC	RMSE	MAE		AIC	BIC	RMSE	MAE	
Adamawa	3.27	2.63	0.494	-7.34	-1.80	3.27	2.63	0.494	-7.34	-1.80	3.09	2.53	0.547
Centre	7.45	5.93	0.671	388.00	399.00	7.47	5.95	0.669	392.00	403.00	6.90	5.64	0.717
East	2.42	1.95	0.603	51.10	62.20	2.37	1.92	0.619	29.90	49.30	2.30	1.88	0.641
Far North	25.10	21.10	0.770	667.00	678.00	24.90	21.10	0.774	635.00	649.00	24.00	20.70	0.789
Littoral	3.80	2.92	0.646	32.90	41.20	3.80	2.92	0.646	32.90	41.20	3.80	2.92	0.646
North	7.56	6.27	0.706	304.00	318.00	7.56	6.27	0.706	304.00	318.00	7.55	6.28	0.706
Northwest	6.54	5.40	0.419	338.00	349.00	6.52	5.38	0.423	336.00	350.00	6.14	5.18	0.489
South	0.95	0.76	0.672	-380.00	-366.00	0.95	0.76	0.673	-381.00	-373.00	0.95	0.76	0.674
Southwest	4.85	3.94	0.621	-83.30	-66.60	4.85	3.94	0.621	-83.30	-66.60	4.81	3.90	0.628
West	2.77	2.25	0.662	68.70	82.60	2.77	2.24	0.661	67.50	81.30	2.70	2.21	0.679

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Figure 3. Regional malaria forecasts using ARIMA models with Wavelet–STL preprocessing

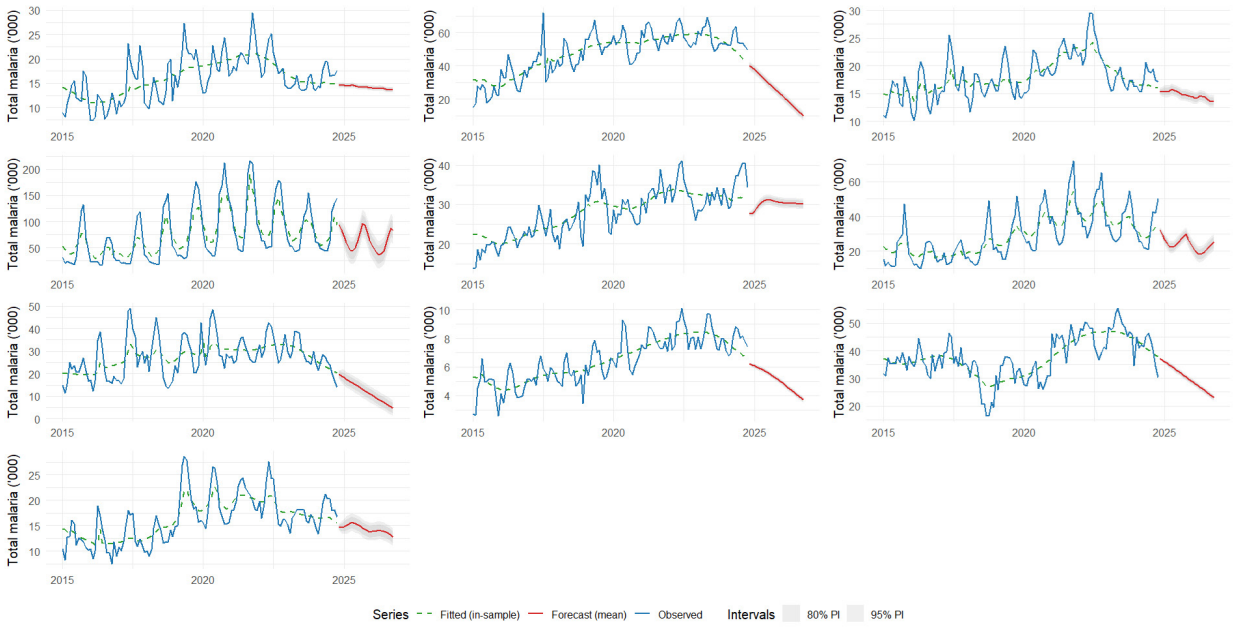


Figure 4. Regional malaria forecasts using SARIMA models with Wavelet–STL preprocessing

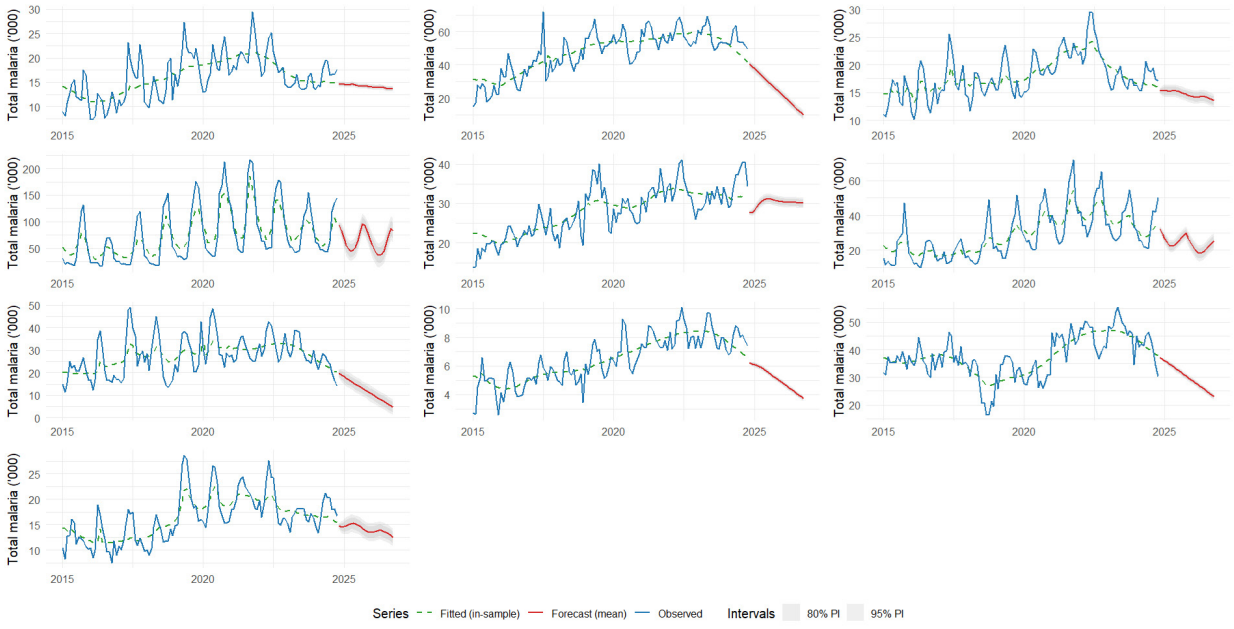
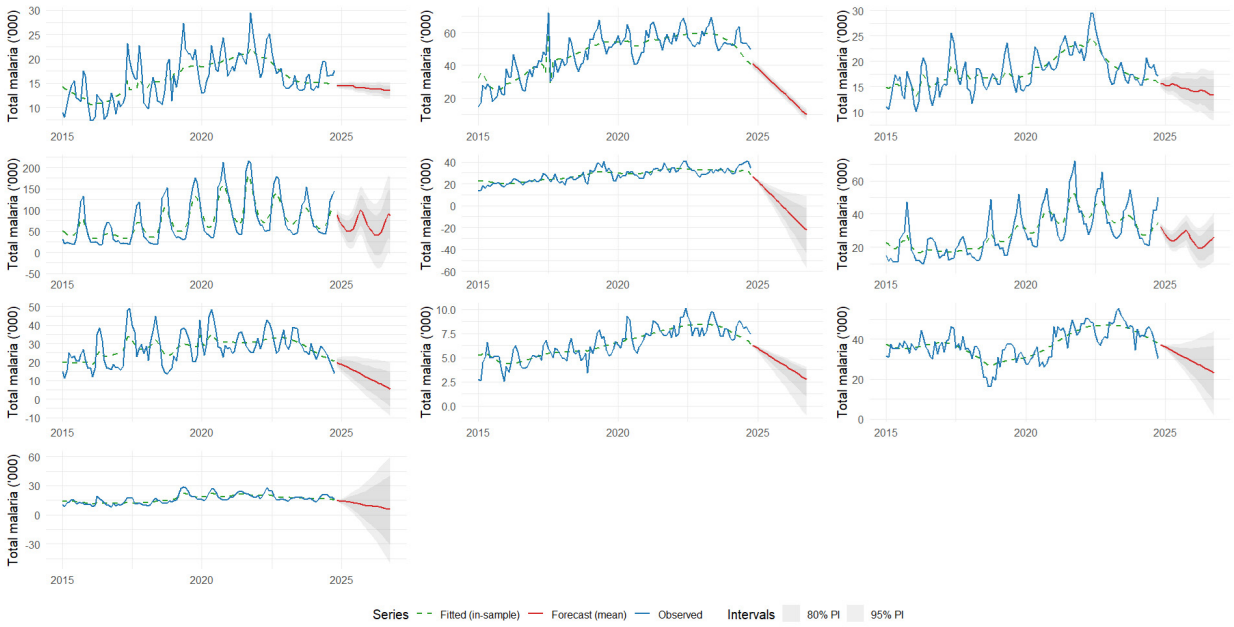


Figure 5. Regional malaria forecasts using the Wavelet–STL–BSTS model



RESULTS

The findings suggest that combining the use of wavelet denoising and STL decomposition in the forecasting system improves stability and accuracy of forecasts, which are better than the traditionally used ARIMA and SARIMA models. Isolating deterministic trend and seasonal signals makes the stochastic rest less complex, enabling more parsimonious models to give robust performance. The similar results between ARIMA and SARIMA indicate that STL is useful in removing seasonal dependencies and thus it requires no explicit seasonal differentiation.

The findings further highlight the advantages of BSTS models, which showed superior performance in settings characterized by high malaria burden and volatile transmission dynamics. This underscores the strength of Bayesian state-space methods in capturing residual uncertainty and generating credible intervals, a feature that is particularly valuable in public health forecasting.

Figures 2-4 illustrate the regional malaria predictions derived via the three Wavelet-STL pipelines. The incidence is observed (black line), 80% and 95% forecasts (red line) fitted in-sample (dashed line) and 24-month forecasts (red line) with 80% and 95% prediction intervals represented (shaded bands). In general, the plots show that Wavelet–STL preprocessing can be used to generate smooth and interpretable series within each of the ten administrative regions. The ARIMA prediction (Figure 2) is consistent with movements of relatively stable areas like the South and West, though forecast errors and broader bands are apparent in the more volatile areas including the Far North. The introduction of seasonal terms using SARIMA (Figure 3) yield almost identical trajectories, as does ARIMA; this is also in line with quantitative measures of residual seasonality of the time series after STL decomposition; there are only slight variations in a few areas, like the Centre and Far North.

Contrastingly, BSTS model was able to outperform the ARIMA and SARIMA model in most regions and had superior explanatory power and reduced forecast errors (Figure 4). In other parts, BSTS recorded higher or equal R^2 values as ARIMA and SARIMA in almost every location, with its maximum being 0.79 in the Far North and Adamawa. The best improvements were in the high-burden and volatile areas where BSTS dropped RMSE of 25.10 (ARIMA) and 24.90 (SARIMA) to 24.00 in the Far North and had a rise in R^2 of 0.77-0.77 to 0.79. On the same note, in the Northwest, BSTS raised R^2 to 0.42-0.42 under ARIMA/SARIMA to 0.49, and reduced RMSE and MAE. Performance improvement, on the contrary, was modest in more stable areas like North and Littoral, and all the models demonstrated similar fits. These findings suggest that BSTS is better able to accommodate regional heterogeneity and temporal volatility and offer a better predictive performance especially in high-burden regions.

Combined, the figures indicate that while the ARIMA and SARIMA pipelines show similar performance following a wavelet and STL preprocessing, the BSTS version has the added benefit of uncertainty-conscious forecasting, which generates plausible and adaptive forecast intervals that enhance the usefulness of the pipeline in malaria early warning and resource planning.

These results are consistent with earlier work

demonstrating the benefits of wavelet-based hybrid approaches in epidemiological time-series analysis [7, 8]. However, the present study extends this evidence base by embedding STL decomposition and systematically contrasting frequentist and Bayesian approaches. Importantly, the probabilistic forecasts produced by BSTS offer practical advantages for malaria early warning systems, where decision-makers rely not only on point forecasts but also on reliable quantification of uncertainty to inform timely interventions [1].

CONCLUSION

This work presents and confirms a multi-stage hybrid pipeline of malaria incidence forecasting in Cameroon by showing that Wavelet-STL preprocessing gave better predictive power by enhancing R^2 between 0.42 -0.77 in baseline models to 0.55 -0.79 after preprocessing, along with uniformly lowering RMSE through regions. Of the rest of the models, ARIMA and SARIMA were found to give stronger baselines, although BSTS invariably gave higher accuracy or equal accuracy and also provided calibrated probabilistic intervals. These findings highlight the significance of noise reduction, structural decomposition, and probabilistic modeling in epidemiological forecasting.

Recommendation

Methodologically, the Wavelet-STL-BSTS pipeline is our recommendation of the most suitable malaria early warning system, especially in areas characterized by unpredictable transmission patterns. In environments where computational resources are limited, the Wavelet-STL-ARIMA variant can also be considered as a viable alternative, since it is also equally accurate in less volatile areas. At the policy level, such a framework could be incorporated into national surveillance systems like DHIS2 so that health authorities can produce rolling 12–24-month projections of resource utilization.

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Health Promoting Lifestyle Profile Among University Students and its Relation with the Study Speciality

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SUMMARY

Introduction: Unhealthy lifestyle behaviours are common modifiable risk factors for NCDs which cause a great decline for age group suffering from chronic diseases. The university years serve as a particularly crucial and formative stage for the overall development of lifelong behaviours that can either promote or seriously impair health outcomes. We aimed to assess health promoting lifestyle profile among university students and detect its determinants.

Methodology: A cross-sectional study was conducted among 397 students (204 medical and 194 non-medical) using health promoting lifestyle profile-II (HPLP-II) questionnaire. Results 75.82% of students were females and 96.22% were non-smokers. Less than half (43.3%) of students achieved total score of HPLP-II higher than 2.5. Medical students reported significant lower median total scores than non-medical ones (median:2.38 vs. 2.5 respectively). They also achieved significant lower median health responsibility (median 2 vs. 2.22) and nutrition (median 2.22 vs. 2.33) subscales compared to non-medical.

Conclusion: the higher burden that medical students face is responsible for the worse lifestyle scores they report. Intervention programs should be carried out to enhance lifestyle behaviours among the whole university students with special attention to medical ones.

Keywords: Keywords: health-promoting lifestyle, HPLP-II, medical, non-medical university students

INTRODUCTION

In the past, infectious diseases represented the main cause of death. Recently, non-communicable chronic diseases (NCDs) surpassed infectious diseases; accounting for more than 70% of worldwide deaths. In addition, two thirds of all years lived with disability in low- and middle-income countries and 85% of deaths in Egypt are caused by NCDs. This shift of disease pattern is attributed to lifestyle change over the years. (1, 2) Unhealthy lifestyle behaviours as poor dietary habits, physical inactivity, smoking and alcohol consumption are major modifiable risk factors for NCDs. Moreover, there is a great decline for the age group suffering from chronic diseases. Early diagnosis of chronic diseases have been observed in younger age groups (3)

A healthy lifestyle is a way of living that helps the individual not only to prevent diseases and reduce their severity, but to promotes the overall well-being of the individual, including his physical, mental, and social health. (4) Health promoting lifestyle behaviours are selfinitiated actions and perceptions which can affect individual wellbeing and quality of life. They encompass six dimensions, health responsibility, physical activity, nutrition, spiritual growth, interpersonal relations and stress management. (5)

University students are experiencing a critical stage of transition from childhood to adulthood. At university life, students are more responsible and have greater autonomy upon their own behaviour. University related events such as academic burden, higher psychological vulnerability can lead to impairment of healthy lifestyle among university students. (6, 7)

The university years represent a particularly crucial stage for the overall development of lifelong behaviours that can either promote or seriously impair individual health outcomes. Lifestyle preferences at university time tend to remain stable. Adopting healthy lifestyle behaviours can improve cognitive function, increase

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self-perception, alleviate stress and improve academic performance. (4)

A study conducted among female university colleges in Saudia Arabia revealed that 96% of the studied students believed that a healthy diet, physical activity, adequate sleep, and stress management were good for their health. Despite that, less than 25% of participants were having the recommended amounts of grains, vegetables, fruits, meats, dairy products, and water. Also, 52% of study participants engaged in daily moderate physical activity and 30% were inactive. Only 25% of participants reported sleeping the recommended daily 7–9 h. (8)

Medical students face stress during their medical education, linked to the numerous academic demands, longer study periods, and preparation time for long-term careers, leading to a risk of neglecting healthy habits. (9)In contrast to non-medical students, medical students receive health education as an ongoing part of the medical curriculum, and so bring different levels of health awareness. (10) Consequently, it is difficult to know whether health-conscious behaviors and lifestyle changes are unique to this sub-population of students. In other words, it is necessary to ascertain whether adopting healthy promoting lifestyle behaviors is a generic problem for students in general, or if medical students are fully aware of and striving for early health at this young age.

Within this context, Sohag University, much like many other educational institutions, has significantly diversified in recent years. It has broadened its enrollment by admitting a larger number of students from a truly vast array of backgrounds, encompassing both medical and non-medical programs.(11) It worth considering that if the future doctors and other health professionals, who are responsible for providing essential guidance and direction toward fostering a healthier and longer-living society, begin their careers with a low starting base or suboptimal health levels, this poses a significant challenge and cause for concern regarding our nation's future health landscape. (12, 13)

Owing to the stressful university life and the long-term effects of lifestyle behaviours on university students, the current study was conducted to determine the status of Sohag university students' healthy lifestyle profile and its determining factors. Also, to detect if the studying field is affecting the students' health-promoting behaviours.

METHOD

Study design

The current study is a cross-sectional study conducted among medical and non-medical students at Sohag University.

Study settings

Sohag University is an independent university located in Sohag Governorate on the Eastern Nile bank. The University includes 19 faculties. The number of registered students at Sohag University was 62,417 students of whom 3979 students were enrolled in the post-graduate programs in the academic year 2021-2022. (14) Sohag Governorate is located in Upper Egypt which is considered one of the regions with the lowest socioeconomic level. (15) Most of the registered undergraduate students belong to Sohag Governorate or the nearby surroundings. This reflects that most of the students may be of low or middle socio-economic level. Faculties of Medicine and Education were chosen to be involved in the current study to study lifestyle health profile of medical and non-medical students.

Study population

The studied population was composed of fourth year students of the selected medical faculty (faculty of Medicine) and non-medical faculty (faculty of Education) in Sohag University. The first three years of medical study at faculty of Medicine at Sohag University includes non-clinical curriculum, the fourth year of medical study is the beginning of engagement in clinical activities with its medical information and accompanying stress. So, students in fourth year medical study and their corresponding fourth year non-medical students were enrolled to participate in the current study.

Sample size and sampling procedure

Cluster sampling method was conducted. Sample size was calculated to be 351 students using Medcalc software version 15.8 (16) based on the following assumptions: mean score of health promoting lifestyle profile-II (HPLP-II) is 2.4 and standard deviation is 0.4 according to the results of a previous study conducted among university students to assess health-promoting lifestyle behavior and its association with student's characteristics (17), power as 80% and confidence level was set at 95%. However, the sample size was increased to 410 students (205 students from each faculty) to compensate for a dropout percent of 16%.

Inclusion criteria were being a student from the selected faculties, at age ranging from 17 to 25. Students who refused to answer or didn't complete the questionnaire were excluded.

Data collection procedure

At the end of lectures time, the study objectives and the questionnaire were explained to the students in the selected faculties, questionnaires were distributed to the students who agree to participate in the study,

and they were asked to fill them. The time required to complete the questionnaire was 15–20 min.

Data collection tool

Data was collected using a predesigned structured questionnaire composed of two parts, the first part includes sociodemographic data (age, gender, residence, number of family members and income), faculty type, smoking, perception of health, chronic illnesses and BMI and the second part includes a validated Arabic version of health promoting lifestyle profile HPLP-II questionnaire (Cronbach's alpha of 0.91). (18) Researchers have got permission to use the HPLP-II scale in the current study.

HPLP-II was developed by Walker et al. (19) to assess lifestyle. It includes 52 behavior statements categorized into six domains (subscales): physical activity, health responsibility, nutrition, spiritual growth, interpersonal relations, and stress management, that uses a 4 points Likert scale (never = 1, sometimes = 2, often = 3, routinely = 4). The mean score is obtained by calculating the total score for the whole HPLP-II and for each subscale and dividing by the number of items in the overall scale and subscales. Higher scores indicate higher adoption of health promoting lifestyle behaviors. To compare those who adopted regular healthy lifestyle behaviors and those who do not, participants were categorized into two groups based on the mean score of HPLP-II; students who achieved overall mean score ≥ 2.5 represented the group with regular healthy lifestyle behaviors, and participants who achieved overall mean scores less than 2.5 constituted the second group who do not adopt healthy behaviors.

Statistical analysis

Data was analyzed using IBM SPSS Statistics for Windows version 20. Quantitative data was expressed as means ± standard deviation, median and inter quartile range. Qualitative data was expressed as number and percentage. Quantitative data was tested for normality by Shapiro–Wilk test. Mann–Whitney U test was used for data which wasn't normally distributed. Chi-square ($\chi 2$) and Fisher exact test were used for comparison of qualitative variables as appropriate. Binary logistic regression analysis was used to determine predictor variables of high scores of HPLP-II (≥ 2.5) of the studied students. A 5% level was chosen as a level of significance in all statistical tests used in the study.

Ethical considerations

Ethical approval was secured from the ethical committee of the Faculty of Medicine in Sohag university, registration number: Soh-Med-24-11-8PD. Informed verbal consent was obtained from the study participants, confidentiality of data was assured, and questionnaires were anonymous.

RESULTS

The current study included 397 students (194 were non-medical students) of whom 301 (75.82%) were females and 235 (59.19%) reported urban residence. The majority of the students (382 (96.22%)) were non-smokers. Most of the studied students (296 (74.56%)) perceived having good health, reported being non-diabetic (389 (97.98%)) and weren't suffering from other chronic diseases (377 (94.96%)). The mean body mass index of the participants was (24.21 ± 5.31). (table 1)

The median total score of HPLP-II among the studied students was 2.44. Regarding scores of HPLP-II subscales, interpersonal relations (IPR) subscales median score was the highest reported one (2.89), followed by spiritual growth subscales (2.75) and stress management subscales (2.5). The lowest reported median score was health responsibility subscales (2.11). (table 2)

Less than half (43.3%) of the studied university students had total score of HPLP-II higher than 2.5 while 56.7% of them had total score of HPLP-II less than 2.5 (Fig.1).

Regarding relation between students' characteristics and their total scores of HPLP-II, residence and faculty type were found to significantly influencing the total scores of the students (P-value = 0.043 and 0.009 respectively), on the other hand there was no statistically significant effect of other students' characteristics on their scores (table 3).

Binary logistic regression applied to determine predictor variables of high total scores of HPLP-II (> 2.5) of the studied students revealed that faculty type and students' perception of health are significant predictors of high total scores of HPLP-II (>2.5). Non-medical students were 1.81 times higher than medical students in achieving higher total HPLP scores (P-value= 0.005) and scores of students perceived their health status excellent was 2.61 times higher than those with poor health perception (P-value=0.025) (table 4,5).

Comparison between total and subscales scores of HPLP-II of medical and non-medical students shows that 56.4% of non-medical students had HPLP-II higher than 2.5 compared to 43.6% of the medical students while 43.1% of non-medical students reported HPLP-II lower than 2.5 compared to 56.89% of medical students. Results also revealed that there is a highly significant difference between total scores of HPLP-II of medical and non-medical students where the median total score of HPLP-II of medical students was 2.38 (IQR=2.17 – 2.62) compared to 2.5 (IQR=2.25 – 2.7) of non-medical students (P-value=0.009).

Table (1): Characteristics of the studied university students (No.=397)

Characteristics	Summary statistics
Age Mean ± SD	21.08 ± 0.97
Gender Male Female	 96 (24.18%) 301 (75.82%)
Smoking Smoker Nonsmoker	 15 (3.78%) 382 (96.22%)
Residence Urban Rural	 235 (59.19%) 162 (40.81%)
Perception of health Excellent Good Poor	 58 (14.61%) 296 (74.56%) 43 (10.83%)
Diabetes Yes No	 8 (2.02%) 389 (97.98%)
Other chronic illnesses Yes No	 20 (5.04%) 377 (94.96%)
Crowdedness index ≤ 1 /room > 1/ room	 172 (43.32%) 225 (56.68%)
BMI Mean ± SD	24.21 ± 5.31
Family members number < 5 ≥ 5	 172 (43.3%) 225 (56.7%)
Family members with income One Two Three or more	 150 (37.78%) 172 (43.32%) 75 (18.89%)
Faculty type Medical Non-medical	 203 (51.13%) 194 (48.87%)

Table (2): Total and subscales scores of HPLP II of the studied university students

Variables	Median (IQ range)
HPLP II Total	2.44 (2.23 – 2.66)
Health Responsibility	2.11 (1.78 – 2.44)
Physical activity	2.25 (1.75 – 2.5)
Nutrition	2.33 (2 – 2.67)
Spiritual growth	2.75 (2.33 – 3.11)
Interpersonal relations (IPR)	2.89 (2.5 – 3.22)
Stress management	2.5 (2.25 – 2.88)

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Figure (1): Total scores of HPLP II among the studied university students

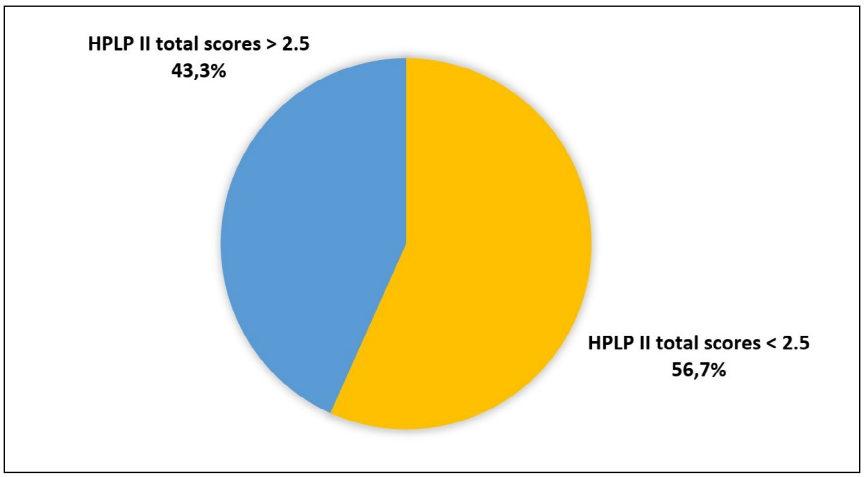

Table (3): Relation between students' characteristics and their total scores of HPLP II.

Characteristics	< 2.5 (N= 225)	> 2.5 (N= 172)	P-value
BMI Median (IQR)	23.15 (21.33- 23.07)	23.73 (22.13-19.23)	0.327*
Gender Male Female	 56 (24.89%) 169 (75.11%)	 40 (23.26%) 132 (76.74%)	0.706
Smoking Smoker Nonsmoker	 9 (4%) 216 (96%)	 6 (3.5%) 166 (96.5%)	0.791
Residence Urban Rural	 143 (63.56%) 82 (36.44%)	 92 (53.49%) 80 (46.51%)	0.043
Perception of health Excellent Good Poor	 28 (12.44%) 167 (74.33%) 30 (13.33%)	 30 (17.44%) 129 (75%) 13 (7.56 %)	0.097
Diabetes Yes No	 4 (1.78 %) 221 (98.22%)	 4 (2.33 %) 168 (97.67%)	0.484**
Other chronic illnesses Yes No	 8 (3.56 %) 217 (96.44%)	 12 (6.98%) 160 (93.02%)	0.123
Crowdedness index ≤ 1 /room > 1/ room	 100 (44.44%) 125 (55.56%)	 72 (41.86%) 100 (58.14%)	0.607
Family members number < 5 ≥ 5	 45 (20%) 180 (80%)	 32 (18.60%) 140 (81.40%)	0.493
Family members with income One Two Three or more	 76 (33.78%) 100 (44.44%) 49 (21.78%)	 74 (43.02%) 72 (41.86%) 26 (15.12%)	0 .098
Faculty type Medical Non-medical	 128 (56.89%) 97 (43.11%)	 75 (43.60%) 97 (56.40%)	0.009

P-value was calculated by Chi-Square Test *P-value was calculated by Mann Whitney U-Test
**P-value was calculated by Fisher's Exact Test P- value <0.05 is statistically significant.

Table (4): Multiple binary logistic regression analysis of predictor variables of high total scores of HPLP II (>2.5) among studied students.

Variables	Adjusted OR (CI $_{95\%}$)	P - value
BMI	1.01 (0.97– 1.05)	0.564
Gender Male Female	 1.03 (0.6– 1.75) 1	 0.921
Smoking Smoker Non smoker	 0.79 (0.24 – 2.7) 1	 0.720
Residence Urban Rural	 0.81 (0.51– 1.29) 1	 0.382
Perception of health Excellent Good Poor	 3.14 (1.29 – 7.6) 2.45 (1.17– 5.14) 1	 0.012* 0.019*
Diabetes Yes No	 1.33 (0.27– 6.56) 1	 0.725
Other chronic illnesses Yes No	 2.41 (0.89– 6.48) 1	 0.082
Crowdedness index ≤ 1 /room > 1/ room	 1.02 (0.66– 1.58) 1	 0.925
Family members with income One Two Three or more	 1.65 (0.89– 3.05) 1.41 (0.79– 2.53) 1	 0.107 0.244
Faculty Medical Non-medical	 1 1.61 (0.98– 2.63)	 0.055

* Statistically significant

Table (5): final model of Multiple binary logistic regression analysis of predictor variables of high total scores of HPLP II (>2.5) among studied students.

Variables	Adjusted OR (CI $_{95\%}$)	P - value
Faculty Medical Non-medical	 1 1.81 (1.19– 2.75)	 0.005*
Perception of health Excellent Good Poor	 2.61 (1.13– 6.03) 2.15 (1.06– 4.37) 1	 0.025* 0.034*

* Statistically significant

Median scores of health responsibility and physical activity subscales of non-medical students were higher than those of medical students and these differences were highly significant (P-value < 0.001) (Fig.2, table 6).

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Figure (2): Comparison between medical and non-medical students regarding total scores of HPLP II

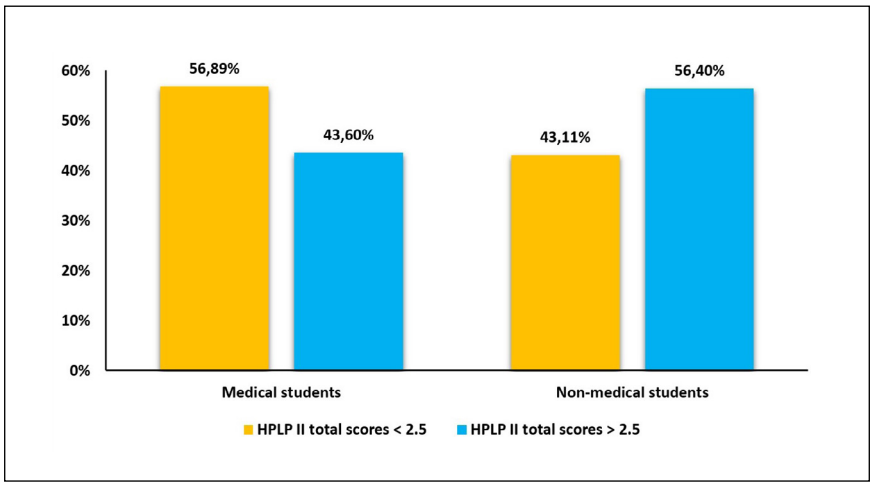

Table (6): Comparison between medical and non-medical students regarding total and subscales scores of HPLP II.

Characteristics	Median (IQR)		P-value
	Medical (N= 203)	Non-medical (N= 194)	
HPLP II Total	2.38 (2.17 – 2.62)	2.5 (2.25 – 2.7)	0.009
Health Responsibility	2 (1.67 – 2.33)	2.22 (1.89 – 2.56)	<0.001
Physical activity	2.13 (1.75 – 2.5)	2.25 (2 – 2.63)	<0.001
Nutrition	2.22 (1.89 – 2.56)	2.33 (2 – 2.67)	0.087
Spiritual	2.78 (2.33 – 3.11)	2.67 (2.33 – 3.11)	0.760
Interpersonal relations	2.89 (2.44 – 3.22)	2.81 (2.56 – 3.11)	0.175
Stress management	2.5 (2.13 – 2.88)	2.5 (2.25 – 2.88)	0.957

P-value was calculated by Mann Whitney U Test
P- value <0.05 is statistically significant.

DISCUSSION

Health was defined by the World Health Organization as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity". (20) One of the primary strategies for promoting and preserving health is adopting a healthy lifestyle and health-promoting activities. University life carries new challenges for the emerging adults due to the unfamiliar life circumstances and the academic burden which can make drastic changes in their lifestyle behaviours. (8, 21)

In this work, we studied university students to detect degree of adoption of health-promoting behaviours among them and its determinants which can guide potential intervention to improve the situation. This research was conducted using HPLP-II score which is a 52-item tool that measures self-initiated health-promoting behaviours as a total as well as clusters. (22)

The present study revealed that the reported median total HPLP-II score was 2.44 (IQR: 2.23:2.66). Interpersonal relations, spiritual growth and stress management subscales were the highest reported median subscale scores, while physical activity and health responsibility were the lowest. Also, 56.7% of the studied students reported a total HPLP-II score less than 2.5. In agreement with our study, a cross-sectional study was conducted among 1112 university students in Saudi Arabia revealed that the studied students displayed a moderate level of health-promoting activities and, the spiritual growth subscale had the greatest mean score, followed by interpersonal relationships, while the physical activity subscale had the lowest mean score. (23) The high score in the interpersonal relationships and spiritual growth subscales reflect the strong family and social ties which maintain positive relationships with family and friends.

Another cross-sectional study conducted among 450 university students in Saudia Arabia concluded that 62.4% of the studied students were physically inactive. Although 78% of the studied students reported having good understanding of principles of eating habits, only 16% of them were satisfied with their eating habits.(24) This may reflect lack of knowledge and poor practice to physical activities among Arab populations. Also, despite having a good nutritious knowledge, small percent can adopt this knowledge to adopt good eating habits which may be due to community habits.

The current study revealed no significant association between gender, smoking, income or chronic diseases and HPLP-II score. Another cross-sectional study conducted in Turkey among 2100 university students revealed presence of no significant association between total HPLP-II score and gender (P value: 0.9) but they revealed significant association between HPLP-II total score and income where participants with the lowest income reported the lowest total score (median 2.38, IQR 0.51), participants with middle income had a middle score (median 2.42, IQR 0.46), and those with good income reported the highest total score (median 2.46 and IQR 0.48), P value 0.02. (25) This may be accused to the wide economic disparity among students in Turkey while those at Sohag University belong to closely related economic levels.

As regard the study speciality, the study between our hands revealed that medical students reported significant lower total HPLP-II scores compared to non-medical counterparts. As regard subscales, medical students reported statistically significant scores for health responsibility and physical activity subscales compared to non-medical ones. In contrast to our results, Chao in his study which included 1062 medical and non-medical university students in Taiwan revealed that medical students reported statistically significant higher total HPLP-II scores, health responsibility subscale and nutrition subscale scores compared to non-medical students. (26) This may be owed to better educational systems in Taiwan emphasizing preventive medicine, provision of health promotive infrastructure (e.g. better access to gym, healthy food or mental health services) in the Taiwanese medical educational institutions. or attributed to economic constraints, poor stress management and lack of support to medical students in Egypt.

In line with our results, Ajrash and Al-Abedi conducted a cross-sectional study among 300 students in Bahrein and showed that medical students achieved significant lower overall score compared to non-medical ones. Moreover, medical students achieved significant lower scores as regard physical activity and nutrition.(27)

The lower lifestyle scores achieved by medical students may be attributed to the high stress and the increased burden accompanying medical study which affects students physical and mental health. Medical students were found to have higher rates of psychosocial morbidities such as anxiety, depression and burnout compared to age-matched university students. The medical program carries a great load of new knowledge, experience, and required practices besides the high stressful impact of exams they try to cope which contribute to the increased stress. Medical students struggle with time management. They try to cope even by following unhealthy behaviours as missing breakfast, consuming more fast foods, having less time for physical activity, having less time for families and friends and may be engaging in non-healthy habits as smoking to alleviate stress.(28)

STUDY LIMITATIONS

The current study has some limitations. First, the cross-sectional design which doesn't provide temporal sequence to ensure causality and couldn't detect changes of lifestyle across time. Second, the self-reported lifestyle practices may be associated with over or under estimation of one's level and biases (e.g., recall or social desirability biases). Also, there is a potential for selection bias.

CONCLUSION

The study sheds light on lifestyle profile of Sohag University Students and its determinants. More than half of the students reported total lower lifestyle scores with the lowest scores achieved in health responsibility and nutrition subscales. Medical students reported significant worse lifestyle scores compared to their non-medical counterparts due to the higher stress and academic burden they face. Intervention programs should be carried out to enhance lifestyle behaviours among the whole university students with special attention to medical ones.

DECLARATIONS

Ethical considerations and Consent for publication:

Ethical approval was secured from the ethical committee of the Faculty of Medicine in Sohag university, registration number: Soh-Med-24-11-8PD. Informed verbal consent was obtained from the study participants, confidentiality of data was assured, and questionnaires were anonymous.

Availability of data and materials:

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests:

The authors declare no conflicts of interest.

Funding:

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