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The role of socioeconomic status and oxidative balance score in erectile dysfunction: A cross-sectional study

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ABSTRACT

Background: Erectile dysfunction (ED) is a complex disorder of biopsychosocial etiology. Approximately 3%–77 % of adult men worldwide are more or less affected by ED.

Objective: This cross-sectional study investigated the association between ED and socioeconomic status (SES) based on a nationally representative adult male population.

Methods: The poverty income ratio (PIR), which refers to household income ratio to the established poverty line, was used to assess SES. Oxidative stress related to diet and lifestyle was reflected by oxidative balance score (OBS). Erectile function was evaluated using a questionnaire. Based on the results of the questionnaire, participants were divided into two groups of those without ED (always or almost always be able to erect and keep erection, usually be able to erect and keep erection) and with ED (sometimes be able to erect and keep erection, never be able to erect and keep erection). Multivariate logistic regression, multiple models, and restricted cubic spline (RCS) were used to analyze and describe the interaction between ED, OBS, and SES. Results: Compared with men without ED, those with ED were more likely to be older in age (43.98 vs 37.74, P < 0.0001), and less educated (P < 0.001), and with a ratio of family income to poverty less than 3.5 (P = 0.02), higher BMI (30.11 vs 27.84, P < 0.0001), lower OBS (21.71 vs 23.17, P = 0.04), having habit of smoking (P = 0.04), with diabetes (P < 0.0001), and with hypertension (P = 0.003). Participants with higher PIR were more likely to report good erectile function than those with lower PIR through multivariate analysis (OR = 0.49, 95 % CI = 0.31-0.78, P = 0.005). The RCS model revealed a negative non-linear correlation of PIR with ED when PIR \leq 3.89. It is interesting to note that PIR was > 3.89 showed a positive non-linear relationship with ED. Conclusion: The social determinants of health and intake of oxidants and antioxidants were

considered as risk factors for ED and could be studied as a research focus in the future.

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1. Introduction

Erectile dysfunction (ED), which refers to an inability to achieve or maintain erection sufficient for satisfactory sexual intercourse, is often a serious ill health condition that causes great anxiety to patients [1]. Global prevalence of ED is reported to be 3%–77 % [2]. The Massachusetts Male Aging Study predicted that ED may affect as many as 18 million men. Such a public problem could be reflect in the increasing financial expenditures on ED because study has revealed that annual expenditure on ED was \$185 million in 1994 and soared to \$330 million in 2000 [3]. If not addressed, related financial outlay will further increase as the number of ED patients goes up. Moreover, ED would lower life quality of men and reduce economic productivity, posing great economic burden on the society [3,4]. Although phosphodiesterase-5 inhibitors could significantly improve the symptom of ED, the treatment still remains a challenge.

As chronic inflammation with endothelial dysfunction may play an important role in erectile process, ED is therefore often considered a precursor to cardiovascular diseases [5,6]. This is reasonable because penis can be seen as a thicker blood vessel. Given the important role of oxidative stress mechanisms in cardiovascular system, research attention has been increasingly paid to the relationship between ED and oxidative stress. Studies showed that the -e of ROS leads to vascular endothelial dysfunction, which reduces bioavailability of nitric oxide (NO) and impairs relaxation of cavernous smooth muscle [7]. Humans as independent individuals are exposed to oxidants and antioxidants on a daily basis. Whether there is a link between ED and diet-lifestyle-induced redox reactions should be investigated. Currently, we lack sufficient evidence describing the relationship between diet and lifestyle-induced oxidative stress and ED.

It has been shown that drinking 400 ml red wine daily for 2 weeks can significantly improve the antioxidant status and reduce oxidative stress in both young and older subjects, and thereby protecting the cardiovascular system [8]. However, people in a higher financial status tend to consume red wine more readily and also they are generally in better health because of their higher SES than low-income population. This suggests that SES plays an important role in the health management. The correlation between social conditions and ED has been understudied. K. STEVEN et al. showed that in rural central New York, good health and SES of men aged 50–76 years old are important factors in reducing the risk of ED [9]. This is consistent with the results from a number of studies reporting the association between ED and certain clinical or social conditions. In contrast, in a report published in 2006, Joaquim De Almeida Claro et al. indicated that they did not find a solid correlation between ED and income level. Similarly, no quantitative relationship between individual SES and ED has been reported in previous studies. Whether man with a higher income are less likely to experience ED and whether there is a dose-response relationship between SES and ED requires comprehensive analysis. As lower SES may trigger a potential stress response, we hypothesized that the intake of oxidants and antioxidants in daily life could mediate the complex relationship between SES and ED. In order to explore the role of SES and OBS in erectile dysfunction, we conducted this study.

2. Materials and methods

2.1. Data sources

National Health and Nutrition Examination Survey (NHANES) is one of a number of nationally representative surveys conducted by the National Center for Health Statistics of the Centers for Disease Control and Prevention using a stratified, multi-stage probability cluster sampling design. It can be used to evaluate the health or nutritional status of the non-institutionalized population in the United States. Data on ED are available in the NHANES 2001–2004, and all the relevant data were collected according to the standardized protocols of the National Centre for Health Statistics (NCHS) [10]. The study protocols were granted by the Ethics Review board of the National Center for Health Statistics (NCHS), and informed consent was signed by each participant.



Fig. 1. Flow diagram of the screening and enrollment of study participants.

2.2. Study population

In the present study, the data were obtained from NHANES from 2001 to 2004 because questionnaire data on ED are available from 2001 to 2002 and 2003–2004. In this study, age, race, education, PIR, OBS, smoking status, hypertension, diabetes were included. People with incomplete information on erectile function or missing data and those aged >55 years old were excluded from our study. A total of 1739 participants were included in the final analysis. A flow chart of subject selection is shown in Fig. 1.

2.3. Definition of ED and OBS

In our study, ED is defined as a dichotomous variable that men who reported "sometimes be able" or "never be able" to maintain

Table 1

The baseline characteristics of the study participants. Data were expressed as the means \pm standard error (SE), or counts (percentages). ED: erectile dysfunction; OBS: oxidative balance score; DM: diabetes mellitus.

Variable	Without ED	With ED	P value
Age (year),	37.74 (0.30)	43.98 (0.97)	< 0.0001
Mean (SE)			
Body mass index (kg/m2), Mean (SE)	27.84 (0.14)	30.11 (0.44)	< 0.0001
Dietary fiber (g/d), Mean (SE)	27.43 (0.56)	26.34 (2.02)	0.62
Total fat (g/d),	155.44 (3.55)	152.51 (10.03)	0.76
Mean (SE)			
Riboflavin (mg/d), Mean (SE)	4.08 (0.10)	3.80 (0.27)	0.26
Niacin (mg/d),	45.78 (0.82)	40.14 (2.41)	0.03
Mean (SE)			
Vitamin B6 (mg/d), Mean (SE)	3.52 (0.06)	3.13 (0.19)	0.05
Total folate (mcg/d), Mean (SE)	739.70 (12.17)	668.64 (41.88)	0.12
Vitamin B12 (mcg/d), Mean (SE)	10.29 (0.49)	8.68 (0.64)	0.02
Vitamin C (mg/d), Mean (SE)	149.02 (5.10)	121.98 (9.54)	0.03
Vitamin E (mg/d),	12.65 (0.26)	11.21 (0.76)	0.1
Mean (SE)			
Calcium (mg/d), Mean (SE)	1597.70 (42.11)	1457.25 (153.69)	0.37
Magnesium (mg/d), Mean (SE)	508.39 (8.81)	475.56 (34.57)	0.34
Iron (mg/d),	29.22 (0.56)	26.31 (1.50)	0.05
Mean (SE)			
Zinc (mg/d),	22.91 (0.56)	21.00 (1.57)	0.22
Mean (SE)			
Copper (mg/d),	2.37 (0.05)	2.15 (0.14)	0.14
Mean (SE)			
Selenium (mcg/d), Mean (SE)	207.06 (3.81)	192.01 (9.43)	0.15
Alcohol (g/d),	26.53 (1.95)	28.86 (8.22)	0.79
Mean (SE)			
Physical activity (MET-minute/week), Mean (SE)	826.98 (56.20)	861.16 (141.78)	0.82
Cotinine (ng/mL), Mean (SE)	77.87 (7.05)	99.70 (17.60)	0.21
Carotene (RE/d), Mean (SE)	286.07 (14.60)	184.11 (18.00)	< 0.0001
OBS,	23.17 (0.27)	21.71 (0.64)	0.04
Mean (SE)			
Poverty to income ratio, n (%)			0.02
<1.5	377 (16.30)	55 (26.24)	
1.5–3.5	507 (30.09)	50 (32.76)	
> 3.5	702 (53.61)	48 (41.01)	0.000
Race, n (%)		07 (0.50)	0.003
DIACK	305 (8.68)	27 (8.52)	
inexican	285 (0.97)	40 (11.38)	
others	119 (8.01)	20 (17.22)	
White Education = (0()	8// (/3./5)	00 (02.88)	< 0.001
Education, n (%)	POF (62.22)	4E (E2 72)	< 0.001
high school	693 (02.23) 429 (07.89)	03 (32.73) 29 (34.9E)	
lingi School	438 (27.88)	50 (24.85)	
Smoking status	233 (9.89)	50 (22.42)	0.04
Never	785 (49 61)	59 (38 95)	0.04
Former	323 (21 32)	36 (25.81)	
Now	478 (29.07)	58 (35 24)	
Hypertention	470 (29.07)	30 (33.24)	0.003
No	1195 (74 77)	96 (61 97)	0.000
Yes	391 (25 23)	57 (38 03)	
Diabetes	0,1 (20,20)	0, (00,00)	< 0.0001
DM	75 (3.69)	33 (24,50)	
No	1511 (96.31)	120 (75.50)	
-	,		

erection, while those who reported "always or almost always be able" or "usually be able" were considered as without ED [11].

OBS is a combined indicator to the overall balance between pro-oxidant and antioxidant exposure in diet and lifestyle. Generally, a higher OBS indicates a predominance of antioxidants over pro-oxidants. Many studies have found a negative association between OBS and ageing-related diseases, including type-2 diabetes, osteoarthritis, cardiovascular disease and cancer. Both diet and lifestyle contribute to OBS. The assignment scheme of the OBS components is showed in table s1(refer enced Zhang et al. [10]). Each component was divided into three intervals respectively, with a score of 0–2 based on the intake level. Overall OBS was calculated by adding the point assigned to each component.

In NHANES, dietary intake data were obtained from the 24-h dietary recall interview (24HR), which was conducted at a mobile screening center. The types and amount of food and beverages consumed during the 24 h before the interview are collected and recorded in the NHANES computer-assisted dietary interview system. Lifestyle factors associated with OBS in this study were smoking, alcohol consumption, body mass index (BMI) and physical activity. Information on alcohol consumption is obtained from 24-h reports. To assess active and passive smoking, serum cotinine is used to reflect smoking status. Weekly metabolic equivalents (MET) were calculated from individual-specific leisure activity data over the past 30 days obtained from household interviews [10,12]. Race was defined as non-Hispanic white, non-Hispanic black, Mexican American and others. Educational background was categorized as less than high school (less than 9th grade and 9-11th grade), high school (high school grade/ged or equivalent) and above high school (some colleges or AA degree and college graduate or above) [13].

PIR, an index of poverty status, refers to the total household income divided by the poverty threshold. PIR was divided into three categories of <1.5, 1.5–3.5 and > 3.5 [14]. According to smoking status, we classified smoke as never, former and now. The participants underwent several measurements of blood pressure. Hypertension was defined as having a mean blood pressure reading \geq 140/90 mmHg from multiple measurements, a prior diagnosis of hypertension, or the use of medication to lower high blood pressure. The diagnostic criteria for diabetes are: 1. doctor told you have diabetes; 2. glycohemoglobin HbA1c (%) \geq 6.5; 3. fasting glucose (mmol/l) \geq 7.0; 4. random blood glucose (mmol/l) \geq 11.1; 5. two-hour oral glucose tolerance test (OGTT) blood glucose (mmol/l) \geq 11.1; 6. use of diabetes medication or insulin.

2.4. Statistical analysis

Appropriate 4-year sample weights were applied in performing the analyses. The sampling weights were applied following the NHANES analytic guidelines [15]. Weighted prevalence comparisons were conducted using x^2 test for categorical variables and Student's *t*-test for continuous, variables, and the Mann-Whitney *U* test for continuous non-normally distributed variables. Logistic regression was employed to measure associations between PIR, redox catalyst and ED. Variables with P < 0.1 in univariate analysis were included in the multivariate analysis. Four logistic regression models were utilized in our study: (I) Only adjustment for poverty to income (crude model); (II) Crude model + age + race + education (model I); (III) Model I + diabets (model II); (IV) Model II + OBS (model III). The results were demonstrated as adjusted OR with 95 % CI. In addition, the RCS was further used in our analysis to explore the possible curve shape between PIR and ED. All statistical tests were 2-sided with a significance threshold of $P \le 0.05$.

Table 2

Univariate and multivariate regression analysis. Ref: reference. OBS: oxidative balance score; DM: diabetes mellitus.

	Univariate regression analysis		Multivariate regression analysis				
Character	Estimate	Pr (> t)	OR (95 % CI)	Estimate	Pr (> t)	OR (95 % CI)	
Poverty to income							
< 1.5	Ref	Ref	Ref	Ref	Ref	Ref	
1.5–3.5	-0.39	0.18	0.68 (0.38,1.21)	-0.26	0.41	0.77 (0.40,1.48)	
> 3.5	-0.74	< 0.001	0.48 (0.34,0.67)	-0.71	0.005	0.49 (0.31,0.78)	
Age	0.07	< 0.0001	1.07 (1.04,1.10)	0.07	<0.001	1.08 (1.04,1.11)	
Race							
black	Ref	Ref	Ref	Ref	Ref	Ref	
mexican	0.51	0.09	1.66 (0.91,3.04)	0.57	0.08	1.77 (0.92,3.39)	
other	0.71	0.08	2.04 (0.91,4.54)	0.68	0.15	1.97 (0.76,5.08)	
white	-0.17	0.57	0.85 (0.46,1.55)	0.18	0.58	1.19 (0.61,2.33)	
Education							
above high school	Ref	Ref	Ref	Ref	Ref	Ref	
high school	0.05	0.81	1.05 (0.68,1.63)	0.09	0.72	1.09 (0.65,1.85)	
less than high school	0.98	< 0.001	2.68 (1.65,4.35)	0.80	0.01	2.22 (1.20,4.12)	
OBS	-0.04	0.003	0.96 (0.93,0.98)	-0.03	0.04 0.97 (0.94,1.0		
Smoking status							
Never	Ref	Ref	Ref	Ref	Ref	Ref	
Former	0.43	0.03	1.54 (1.05,2.27)	-0.01	0.96	0.99 (0.60,1.62)	
Now	0.43	0.03	1.54 (1.06,2.25)	0.09	0.71	1.10 (0.66,1.83)	
Hypertention							
No	Ref	Ref	Ref	Ref	Ref	Ref	
Yes	0.6	0.004	1.82 (1.23,2.68)	0.13	0.56	1.14 (0.72,1.81)	
Diabetes							
DM	Ref	Ref	Ref	Ref	Ref	Ref	
No	-2.14	< 0.0001	0.12 (0.07,0.21)	-1.56	<0.001	0.21 (0.11,0.41)	

3. Results

A total of 1739 participants were included in the present analysis, and 153 participants were defined as having ED (Fig. 1). The 1739 participants recorded in NHANES may represent 48.9 million non-institutionalized residents in the United State. Approximately, among the 1739 participants with complete data, 54 % of them were white, 19 % were black, 19 % were Mexican American and 8 % were from other races. Baseline characteristics of the participants by with/without ED are displayed in Table 1. Compared with men without ED, those with ED were more likely to be older in age (43.98 vs 37.74, P < 0.0001), and less educated (P < 0.001), and with a ratio of family income to poverty less than 3.5 (P = 0.02), higher BMI (30.11 vs 27.84, P < 0.0001), lower OBS (21.71 vs 23.17, P = 0.04), having habit of smoking (P = 0.04), with diabetes (P < 0.0001), and with hypertension (P = 0.003) (Table 1). Compared to non-ED participants, ED participants always had lower levels of niacin (40.14 vs 45.78, P = 0.03), vitamin B₆ (3.13 vs 3.52, P = 0.05), vitamin B₁₂ (8.68 vs 10.29, P = 0.02), vitamin C (121.98 vs 149.02, P = 0.03), Iron (26.31 vs 29.22, P = 0.05). table s2 sh owed that the levels of riboflavin, magnesium and OBS were increased with elevated PIR.

Multivariate analysis on the association between ED and PIR showed that participants with higher PIR were more likely to report a good erectile function than those of lower PIR (Table 2). In particular, such a relationship was most pronounced in those with PIR >3.5 (OR = 0.49, 95 % CI = 0.31-0.78, P = 0.005). Participants with lower education (less than high school) also appeared to be more closely associated with ED than those with higher education (OR = 2.22, 95 % CI = 1.20-4.12, P = 0.01). Our results showed a significant association between OBS and ED, and suggested that higher OBS was a protective factor for ED (OR = 0.97, 95 % CI = 0.94-1.00, P = 0.04).

When examining the relationship between ED and PIR, we found that participants with a PIR <1.5 showed 51 % greater chance of reporting ED than those with a PIR >3.5 (model 3). Moreover, Table 3 demonstrated that the association between ED and PIR remained significant in each model (Crude Model, Models 1, 2 and 3) (Table 3).

A dose-response relationship between PIR and ED is shown in Fig. 2. The restricted cubic spine model revealed a negative non-linear correlation of PIR with ED when PIR \leq 3.89. Interestingly, a positive non-linear correlation of PIR with ED was observed when PIR>3.89.

4. Discussion

In the present study, we aimed to assess the correlation between SES, the level of oxidants/antioxidants intake and ED. Currently, most of the studies on ED focused on hormone levels [16], vascular endothelial function [17], and adverse psychological status [18], few studies were interested in the association between ED and social environmental factors. The latest study on this was published by Eric J et al. [19]. In their final cohort, PIR <2 was considered as low SES and PIR \geq 2 served as the comparison group. They indicated that participants with lower SES were significantly more likely to report ED. Among other factors included in our study, age, PIR >3.5, OBS, less than high-school education, and without diabetes were the main influence factors for ED. These results suggested that socio-economic factors are equally significant contributors in the occurrence and development of ED in addition to biological and emotional toll from chronic stress is related to poor physical function and could result in ED [20]. Our dose-response relationship analysis between PIR and ED showed that the probability of reporting erectile dysfunction decreased gradually with the increase of income level, but the probability of ED increased when the income reached a certain level. The probability of ED decreased with income when PIR \leq 3.89 and increased when PIR>3.89. This is an interesting finding and our study was the first to reveal such a relationship.

Oxidative stress has been shown to play an important role in the development of ED. Tang et al. reported that miRNA-92a inhibitor can effectively improve diabetic ED through inhibiting oxidative stress and endothelial dysfunction [21]. To describe the risk of ED based on the exposure to oxidants and antioxidants in real world, our study used OBS to measure the level of oxidative stress in the participants, with a greater exposure to antioxidants correlating with a higher OBS. In order to report the results in more details, we also analyzed the relationship between the intake of each oxidant and antioxidant and PIR. We found that the levels of riboflavin, magnesium and OBS were increased with elevated PIR, suggesting that PIR affected the levels of oxidant and antioxidant intake. Our finding indicated that intake of oxidants and antioxidants can affect erectile function, and we speculated that intake levels of oxidant and antioxidant may affect erectile function in men of lower SES. The causal relationships behind these findings are complex and

 Table 3

 Association between erectile dysfunction and poverty to income. Ref: reference.

	Crude model ^a		Model 1 ^b		Model 2 ^c		Model 3 ^d	
Character < 1.5	95%CI Ref	Р	95%CI Ref	Р	95%CI Ref	Р	95%CI Ref	Р
1.5–3.5 > 3.5	0.68 (0.38,1.21) 0.48 (0.34,0.67)	0.18 <0.001	0.71 (0.37,1.36) 0.43 (0.28,0.66)	0.28 <0.001	0.73 (0.38,1.40) 0.45 (0.29,0.70)	0.283 <0.001	0.77 (0.39,1.52) 0.49 (0.31,0.77)	0.43 0.004

^a Crude model: poverty to income ratio.

^b Model 1: poverty to income ratio + age + race + education.

^c Model 2: poverty to income ratio + age + race + education + diabetes.

 d Model 3: poverty to income ratio + age + race + education + diabetes + OBS.



Fig. 2. Dose-response relationship between erectile dysfunction and poverty to income. The red solid line indicates the estimated risk of erectile dysfunction. The horizontal dashed line indicates odds ratio is 1. The longitudinal dashed line indicates PIR is 3.89. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

largely unknown.

Theoretically, participants with higher SES were more likely to focus on physical health and receive better treatment [22], which may explain why participants of higher SES were less likely to report ED. In recent study, Sanne Rasmussen et al. demonstrated that nearly two-thirds of the participants with ED did not contact their general practitioners because of economic reasons and more than half were too embarrassed to contact their general practitioners [23]. Reasonably, participants with higher SES are more likely to have health insurance. In addition, their findings also showed that ED participants with higher levels of education were more likely to seek formal treatment, which suggested that this group of ED patients were more likely to receive help from their doctor to improve their erectile function. Our research also found that participants with lower education (less than high school) were more strongly associated with ED than those with higher education.

Previous studies considered lower SES as a risk factor for many diseases, including cardiovascular outcomes [24,25], and short-term SES improvement can improve long-term cardiovascular disease outcomes in China [26]. Based on the close relationship between ED and cardiovascular disease, we believed that our findings were reliable. The results of our study suggested that SES, intake of oxidants and antioxidants should be taken into account in the overall assessment and clinical treatment planning for patients with ED.

5. Conclusions

Our study indicated that lower SES and OBS were directly related to ED. The social determinants of health and intake of oxidants and antioxidants as risk factors for ED could be considered as the focus in future studies. There is also a need for a more comprehensive analysis on the assessment and treatment of ED. The relationship between the level of reductant oxide intake and ED require further exploration with longer follow-up.

6. Limitations

Although our study used a well-established database and several recently published studies using the same data, there may be some bias in the findings. The limitations of this study included the fact that the sample source was limited to NHANES, and there may be geographic and demographic biases. Erectile dysfunction is a complex problem, which is affected by many factors, such as psychological, physiological, and environmental factors. However, this study did not involve all risk factors. At the same time, as the limited sample size, the absence of data regarding full comorbidities and drugs and similar issues is undeniable. These limitations need to be improved and refined in subsequent studies.

Ethics approval

The study protocols were granted by the Ethics Review board of the National Centre for Health Statistics (NCHS), and informed consent was signed by each participant. This study received IRB exemption from our institution as we used publicly available deidentified data.

Data availability statement

Data associated with our study has been deposited into "figshare" online website (https://doi.org/10.6084/m9.figshare. 21993272). The data used to support the findings of this study are also available from the corresponding author upon request.

CRediT authorship contribution statement

Yanfei Fang: Writing – review & editing, Visualization, Formal analysis, Data curation. Zhong Dong: Writing – review & editing, Visualization, Methodology, Formal analysis. Ting Huang: Writing – review & editing, Resources, Data curation. Lei Wang: Formal analysis, Data curation. Wentao Fan: Formal analysis, Data curation. Bin Wang: Software, Resources. Qing Yang: Software, Resources. Min Xu: Writing – review & editing. Dong Li: Writing – review & editing. Yongjin Fang: Writing – review & editing, Visualization, Software. Zekun Xu: Writing – review & editing, Supervision, Software, Resources, Methodology, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2023.e22233.

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National Health and Nutrition Examination Survey

NCHS Ethics Review Board (ERB) Approval*

Survey Name/Date	NCHS IRB/ERB Protocol Number or Description
NHANES 2021-2022	Protocol #2021-05
NHANES 2019-2020	Protocol #2018-01
NHANES 2017-2018	Protocol #2018-01 (Effective beginning October 26, 2017)
	Continuation of Protocol #2011-17 (Effective through October 26, 2017)
NHANES 2015-2016	Continuation of Protocol #2011-17
NHANES 2013-2014	Continuation of Protocol #2011-17
NHANES 2011-2012	Protocol #2011-17
NHANES 2009-2010	Continuation of Protocol #2005-06
NHANES 2007-2008	Continuation of Protocol #2005-06
NHANES 2005-2006	Protocol #2005-06
NHANES 1999-2004	Protocol #98-12
NHANESJI	Institutional Review Board (IRB) approval and documented consent was obtained from participants
NHANES II	Underwent internal human subjects review, but IRB approval using current standards was not obtained.
NHANESI	Underwent internal human subjects review, but IRB approval using current standards was not obtained.
NHES	Underwent internal human subjects review, but IRB approval using current standards was not obtained.

* In 2003, the NHANES Institutional Review Board (IRB) changed its name to the NCHS Research Ethics Review Board (ERB). In 2018, the name was changed from NCHS Research Ethics Review Board to NCHS Ethics Review Board. Page last reviewed: August 24, 2022

hllps://www.cdc.gov/nchs/nhanes/irba98.htm

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