ANALYSIS OF NHANES II

BLOOD LEAD STUDY

PLMR-58-83

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The U.S. Government's second National Health and Nutrition Examination Survey - known as NHANES II - was designed to assess nutritional status of the population based on questionaires and examinations administered in 64 sample areas over a 4 year period. As an added part of the study, venous blood lead measurements were made on 9936 persons (1).

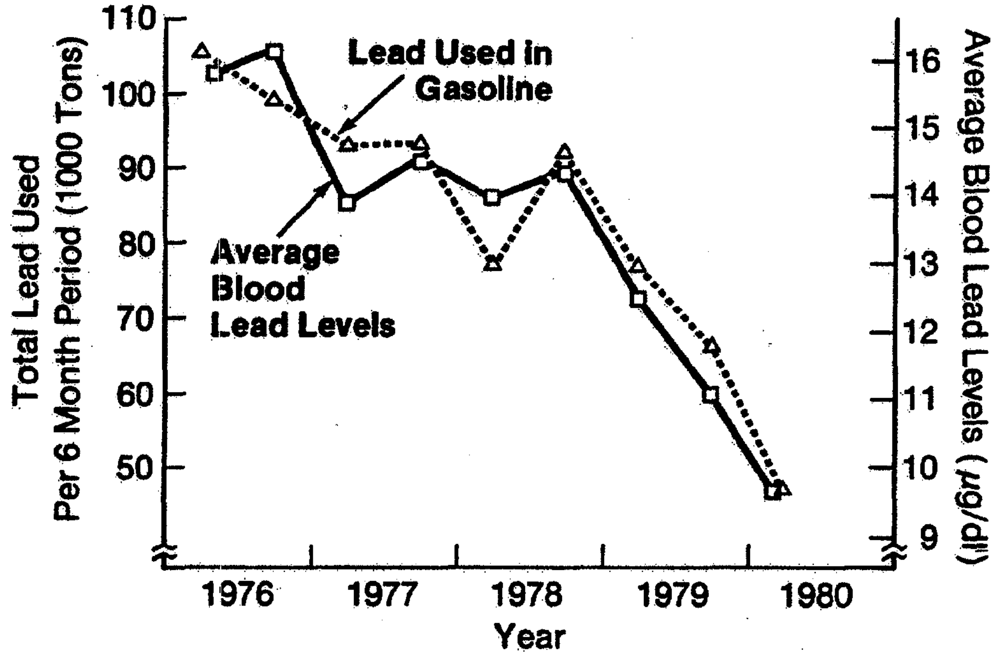
The study was designed for cross-sectional analysis - that is, to obtain a value for each measured variable representative at the study midpoint - and not for chronological analysis. However, an apparent blood lead decrease of 37% over the 4 year study period prompted attempts to analyze the time trend (2).

NHANES II

- Assessment of National Health Status
- February 1976 to February 1980
- 64 Sampling Sites
- 6 Months to 74 Years of Age
- 27,801 Persons Selected — 20,322 Examined
- 9,936 Venous Blood Lead Levels Determined
- Not Designed for Chronological Trend Analysis
- Apparent 37 Percent Reduction in Blood Lead

Attention was drawn to this representation of the parallel declines of six month average blood lead and total U.S. gasoline lead use (3). This figure might well have led some to infer that the blood lead decline was solely due to the decline in total gasoline lead use.

Gasoline Lead and NHANES II Blood Lead Levels (Feb. 1976 — Feb. 1980)



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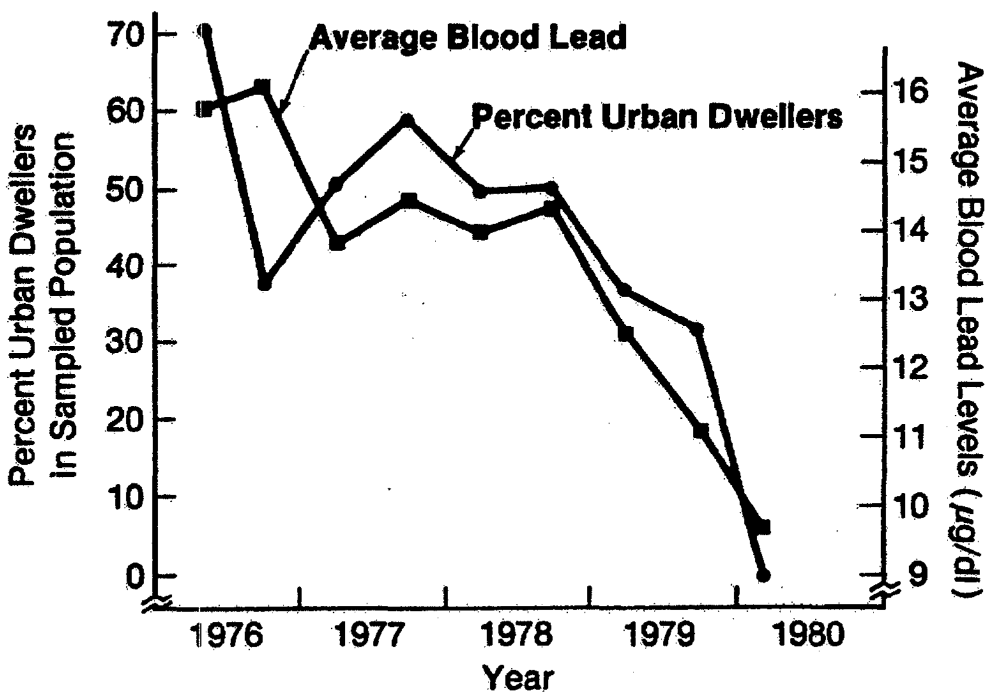
Once the basic data became available, further examination showed that there is substantial confounding because of nonuniformity of subject characteristics over the 4 year course of the NHANES II study.

This figure shows one example of such confounding (4).

These considerations resulted in a number of more detailed analyses, including our own. To contrast the features of the various analyses, it is helpful to consider the identifiable factors which might affect apparent blood lead.

Urban Dwellers Sampled and NHANES II Blood Lead Levels (Feb. 1976 — Feb. 1980)



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It is generally agreed that exposure to lead may occur via a number of routes. In several analyses of the NHANES II data conducted or sponsored by government groups, it was assumed that only exposure to lead from gasoline decreased during the study period (5,6,7). Their assumption that food lead was unchanged was justified on the basis of calculated lead content for a constant market basket of foods (8). However, 64% of the U.S. households surveyed in 1979 by the Economics and Statistics service of the U.S. Department of Agriculture reported diet changes during the period 1977 to 1979 (9). Furthermore, aluminum cans were displacing soldered cans during this period (10). Therefore, we made provision in our analysis for possible changes due to these or other unquantifiable factors.

Returning to gasoline lead, it should be noted that the other analyses referred to used total national gasoline lead use as the index of exposure. Yet, the 64 sites visited during NHANES II had a wide range of lead exposures as shown by air lead data. To account for this variability, we calculated the site-specific gasoline lead density for each location visited. Each site consisted of one or more counties. The gasoline lead consumed in the site county at the time of the visit was calculated from state gasoline consumption and lead dosage, and county and state populations, using the fact that gasoline consumption is highly correlated with population in most of the U.S. (11). The site-specific lead <u>density</u> then was calculated by dividing county lead use by county area. This approach allows for exposure to gasoline lead by ingestion as well as inhation.

The study design factors listed in the chart were treated as classification variables. Caravan itinerary covers region of the country and season. Personal variables are sex, age, and race, and residence variables are size of city or town and in or outside of the core city of a Standard Metropolitan Statistical Area.

Quality control data on the laboratory analysis of blood leads for the last 3 years of NHANES II do not indicate any significant problem. However, there were no check samples carried through the sequence of field collection, storage, shipment and final analysis at the home laboratory, so we allowed for a possible trend contribution from this source.

Identifiable Factors Potentially Influencing Blood Lead Trend

Exposure
- Air Lead from Gasoline
- Food and Beverages
- Water
- Paint
- Dust

Study Design
- Caravan Itinerary
- Personal Variables
- Residence Characteristics

Study Execution
- Laboratory Analysis
- Sample Handling

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We investigated the time trend contribution attributable to the demographic factors alone, for demographics and gasoline lead, and for demographics, gasoline lead and time, which was used as a surrogate for unquantifiable time-related blood lead effects. Details are given in our paper (12) which is appended to this report.

Of particular interest is this comparison of national gasoline lead use and site-specific lead density. National gasoline use is not statistically significant as a blood lead predictor in the presence of the time surrogate for other time-related blood lead effects. On the other hand, site-specific lead density and its logarithm retain their significance.

Significance of National Gasoline Lead and Site Specific Lead Density

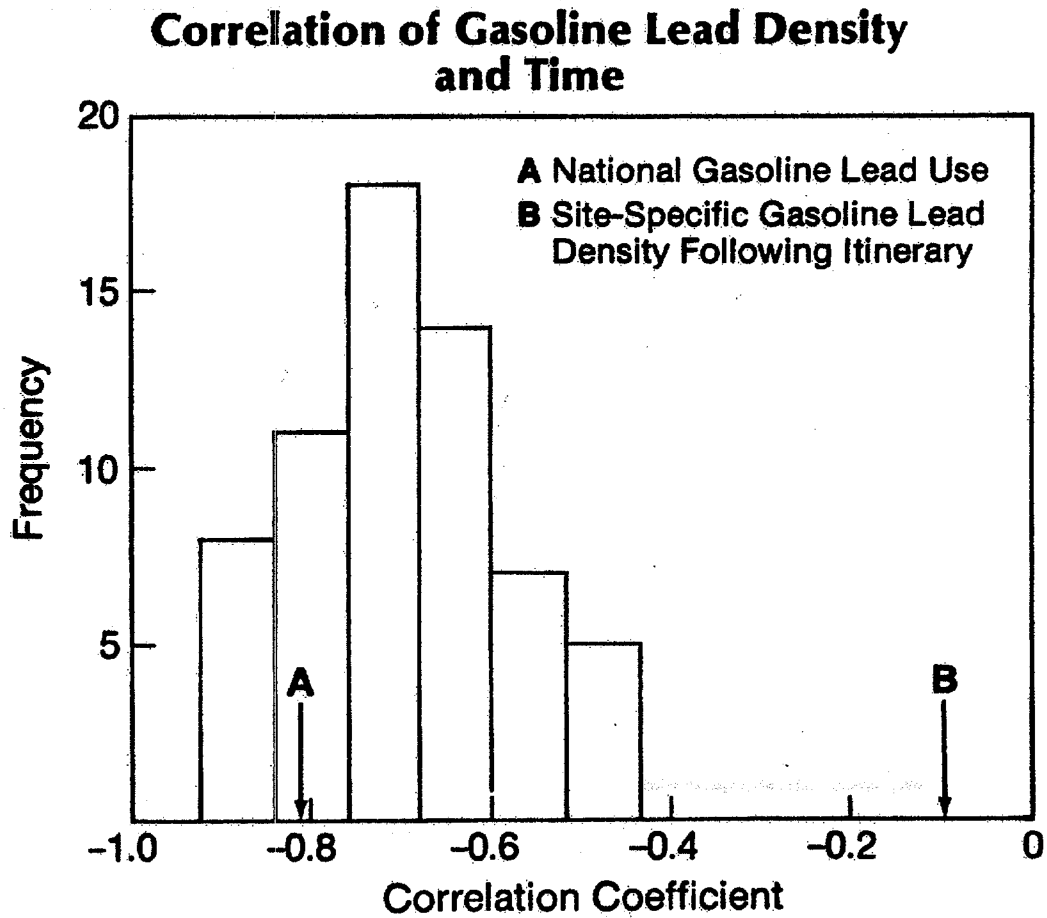
Gasoline Lead Exposure Variable	Significance Level*	
	Lead Exposure Variable	Time
National	0.8850	≤ 0.0001
Site Density	0.0022	≤ 0.0001
Log (Site Density)	0.0019	≤ 0.0001

*All models included the full set of 30 demographic terms.

The histogram shows the frequency distribution of the correlations with time of the site-specific lead densities at each of the NHANES II sites over the 4 years of the study.

The arrow at A shows that total national gasoline lead use is highly correlated with time. But, as indicated by the arrow at B, the site-specific lead densities at the sites when they were actually visited is poorly correlated with time.

Thus, national gasoline lead use not only fails to reproduce the time history of lead exposure as the caravans moved from site to site, but it also obscures the influence of other potential time-related effects because it is highly correlated with time.



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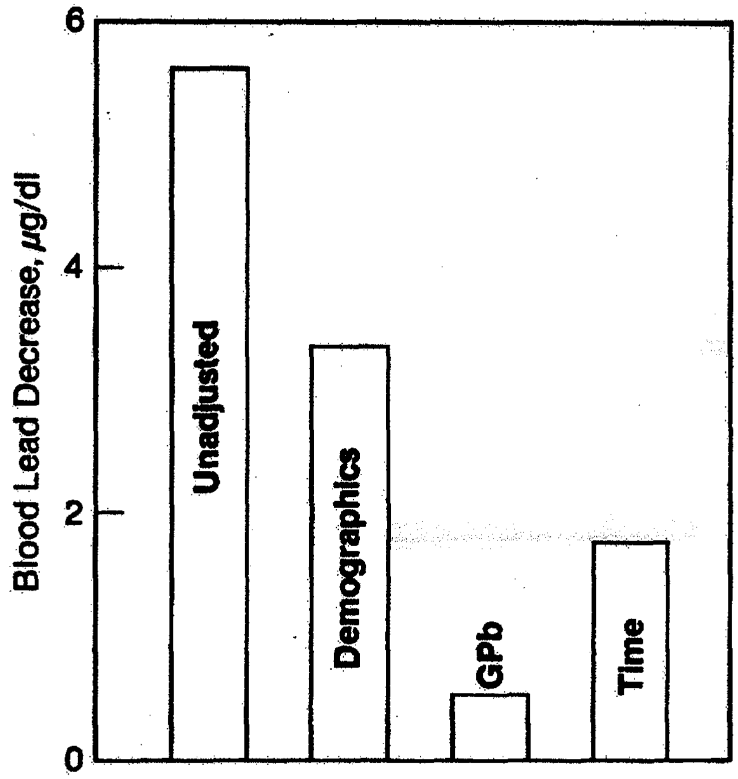
Using site-specific lead density as the measure of exposure to gasoline lead, stepwise regression analysis showed that

- Over half the apparent blood lead decrease can be accounted for by changing demographics.
- About one-tenth of the apparent blood lead decrease can be accounted for by gasoline lead exposure.
- A significant time trend still remains after accounting for demographics and gasoline lead exposure.

Contributions to Blood Lead Decrease 1976-80



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To complement the stepwise regression analysis reported in (12), we analyzed the NHANES II blood lead data by the method of split-plot covariance analysis (13). This method takes its name from agricultural applications, where a field or "plot" is "split" and planted with two varieties of plant. To validly compare performance of the two varieties grown under the same conditions "within-plot" corrections - such as for different numbers of the plant varieties - must be made. To compare performance of the varieties in different fields, or plots - say under different climatic conditions - "between-plot" corrections are required.

The situation is analogous for the NHANES II blood lead data set. Here, corrections are required for within-site differences in the characteristics of the subjects. The within-site analysis adjusts the raw observed blood lead value of each individual at a site to the value he would have if his personal and residence characteristics were the average values for the site.

The between-site analysis amounts to an adjustment of the site-adjusted blood leads to the value each would have if every site had the same value of each of the personal, residence and itinerary variables. After these adjustments all observations are on a common basis relative to demographics, and the remaining time trend is attributable to lead exposure factors and/or other trend influences.

By omitting or including site-specific lead density in the adjustment process, we were able to estimate the contribution of gasoline lead to the blood lead decrease.

Steps in Blood Lead Trend Analysis

Within-Site Analysis	Adjust for Differing Characteristics of Individual Subjects
↓ Between-Site Analysis	Further Adjust for Differing Site Characteristics — With and Without Gasoline Lead
↓ Residual Time Analysis	Quantify Unexplained Time Trend
↓ Gasoline Lead Contribution Analysis	Compare Unexplained Time Trend With and Without Gasoline Lead Exposure

The split-plot analytical approach was applied to 216 models for blood lead as listed.

An important result is that use of the NHANES II blood lead weighting factors, or the basis of residual weighting, or the transformation of the dependent variable blood lead did not affect the overall results, which were consistent throughout.

Analyses for Residual Time Trend

Factor	Options
BPb and ln BPb	2
P, R, I and 26 combinations of current and lagged site specific gasoline lead density and their logarithms	27
With and without BPb weighting factors	2
Residuals weighted according to $1/S^2$ and N	2

Number of models = 2 x 27 x 2 x 2 = 216

Consistent results regardless of BPb weights, residual weighting, and BPb or ln BPb

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Because the results were consistent, the overall picture can be grasped by examining a few cases.

For untransformed blood lead as the dependent variable, before adjustment to remove any effects, the 4-year decrease is 5.8 ug/dl. After within-site and between-site adjustment for itinerary, personal, and residence (DEM) variations, this is reduced to about 1.6 μg/dl, with R_A^2=0.53.

Including current site-specific lead density (G Pb) or its lagged values (G Pb_{30} - 30 days lag, G Pb_{45} - 45 days lag) in the model accounts for up to 0.5 $\mu g/m^3$ of the 4-year decrease.

Note that the addition of lagged lead density terms after the first one has little effect on either the blood lead decrease attributable to gasoline lead or on R_A^2. Also note in the last two lines that making the adjustment for gasoline lead before any adjustment for demographics reduces the 4-year decrease by less than 1 μg/dl, but with R_A^2 of only 0.20 to 0.21.

Typical Model Results*

Effects Removed	Blood Lead, μg/dl		
	Remaining Four Year Decrease	Attributable to Gasoline Lead	R^2_A
None	5.80		
DEM	1.62		0.53
DEM, GPb	1.27	0.35	0.59
DEM, GPb, GPb_{30}	1.21	0.41	0.59
DEM, GPb, GPb_{30}, GPb_{45}	1.19	0.43	0.58
DEM, log GPb	1.48	0.14	0.57
DEM, log GPb, log GPb_{30}	1.10	0.52	0.60
DEM, log GPb, log GPb_{30}, log GPb_{45}	1.09	0.53	0.59
GPb	5.17		0.20
log GPb	4.93		0.21

*Dependent variable BPb, residuals weighted by $1/S^2$ no BPb weights

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DEM, GPb, GPb_{30}, GPb_{45}	1.19	0.43	0.58
DEM, log GPb	1.48	0.14	0.57
DEM, log GPb, log GPb_{30}	1.10	0.52	0.60
DEM, log GPb, log GPb_{30}, log GPb_{45}	1.09	0.53	0.59
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log GPb	4.93		0.21

*Dependent variable BPb, residuals weighted by $1/S^2$, no BPb weights

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From the site-by-site analysis (12) and from the additional split-plot analysis of covariance on the individual observations just discussed, we conclude that national gasoline lead use is not a valid index because it does not reflect the exposures due to lead use at the NHANES II sites at the times they were sampled. Further, confounding of total national gasoline lead use with time precludes estimation of other unquantifiable, time-related effects.

We found that over half of the apparent blood lead decrease is traceable to changes in site subject demographics.

From a large number of models we estimate that 5 to 10% (or 0.3 to 0.6 $\mu g/dl$) of the blood lead decrease is attributable to gasoline lead exposure.

This estimate is consistent with the existing literature. It agrees with the estimate based on an air lead decrease of about 0.3 $\mu g/m^3$, an α value in the range 1 to 2 (14,15). It is also consistent with the Frankfurt study (16).

Finally, after adjustment for both demographics and gasoline lead exposure, a significant blood lead time trend remains.

Conclusions

- National gasoline lead use is not a valid index of exposure at NHANES II sites
- Over 50% of the apparent blood lead decrease is attributable to demographics
- 5 to 10% of the apparent blood lead decrease is attributable to gasoline lead exposure
- The blood lead decrease of 0.3 to 0.6 μg/dl attributable to gasoline lead is consistent with the observed air lead decrease
- A significant blood lead time trend remains after accounting for demographics and gasoline lead exposure

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ASSESSMENT OF BLOOD LEAD LEVELS IN THE U.S.A. FROM NHANESII DATA

John M Pierrard*, Charles G Pfeifer+ and Ronald D Snee+

ABSTRACT

Changing demographics of the subject groups at the 64 sites sampled during NHANESII accounts for over half the apparent 5.61 ug/dl blood lead decrease from 1976 to 1980. Site-specific gasoline lead exposure accounts for 0.51 ug/dl of the blood lead decrease, in agreement with the change expected due to the decrease of 0.32 ug/m^3 in average air lead and the accepted range $1 \leq \alpha \leq 2$ for blood lead response to air lead change.

INTRODUCTION

The U.S. Government's second National Health and Nutritional Examination Survey (NHANESII) was a cross-sectional study designed to assess national health status. Venous blood lead levels (BPb) were measured for 9,936 of the 20,333 examinees. Mobile caravan teams visited 64 sites in the contiguous U.S.A. and Hawaii between 1976 and 1980. A preliminary analysis reported a 36.7% reduction in BPb over the four-year study period and noted that the decrease in BPb reflects the decrease in national use of lead in gasoline production (ref 1).

Because the NHANESII sample was not selected to insure valid within-study time analyses, several categories of demographic variables were evaluated in the present study to examine their effect on the reported BPb decline. Three alternative measures of exposure to lead from gasoline were tested for their utility as indicators of BPb response. Finally, time was introduced to represent all other time-related BPb effects that may be present.

ADJUSTMENT FOR DEMOGRAPHICS

The effect of changing site demographics on the BPb time trend was investigated by classifying each examinee in terms of 6 personal variables (P) describing race, sex, age and family income, 3 residence variables (R) describing degree of urbanization, and 6 caravan itinerary variables (I) describing season of the year and region of the U.S.A. These classification variables assume a value of 1 if the descriptor applies to the examinee, 0 otherwise. Means were computed for each site based on examinee records with a venous BPb, and the 64 site means further analyzed.

Three BPb adjustments were evaluated corresponding to different selection sets of candidate explanatory terms for variation among site mean BPb's. The first set included the 6 P variables and their 15 two-way interactions; the second set added the 3 R variables to the first set; and, the third set added the 6 I variables to the second set. A weighted least squares stepwise regression procedure was applied to each full set of selection candidates. Weighting was by number of BPb values at each site.

*E. I. du Pont de Nemours & Co., Inc., Wilmington, DE, USA, Petroleum Laboratory, + Engineering Department

Terms were retained if their significance with BPb satisfied the $p < 0.15$ criterion.

Adjusted site mean BPb's were obtained by adding the weighted site mean BPb to the residuals from the final regression model. Each adjusted set of values, along with the unadjusted BPb's, then was regressed on site mean examination date. Values of BPb were predicted at the first and last site mean examination date in NHANESII to evaluate the influence of differential site demographics.

The results of the time analyses on the unadjusted and adjusted site mean BPb's are given in Table 1. They illustrate the confounding inherent among BPb, site demographics and time during the study period. Each group of demographic variables was able to explain some of the time trend with terms from the third selection set reducing the unadjusted decrease by more than half.

Table 1

Time Trend and Four Year Change of Blood Lead
Unadjusted and Adjusted for Demographics

	Time Trend		Remaining Four Year Decrease	
	ug/dl/yr	Std. Error	BPb, ug/dl	%
Unadjusted	-1.43	0.18	5.61	32.7
Adjusted for P	-1.09	0.18	4.29	26.0
for P and R	-0.74	0.17	2.92	18.4
for P, R and I	-0.57	0.14	2.26	14.5

ADJUSTMENT FOR GASOLINE LEAD AND DEMOGRAPHICS

Gasoline lead (GPb) is the best documented of the identified sources of lead which include food, water, paint and dust. National GPb use has been claimed to explain the decrease in unadjusted BPb (ref 2), and so was evaluated as one GPb exposure variable. National GPb use (tonnes) was computed from data by state on lead content and consumption of gasoline. To reflect site to site variation, a GPb density (tonnes/mi^2) for each site was computed by multiplying the relevant state GP use by the ratio of population in the site counties to state population, and dividing by land area of the site counties. The basis for this definition is the correlation between population and gasoline use (ref 3). Subsite GPb density was calculated similarly but based on each BPb examinee's residence characteristics. Applicable data permitted calculation of all 3 GPb exposures for 55 of the original 64 sites.

Mean BPb's from the 55 sites were adjusted as before for 5 selection sets, each containing all of the P,R and I demographic terms and one of the GPb exposure variables or its logarithm. The adjusted BPb's then were regressed on site mean examination date. These results, along with the significance levels of the GPb exposure terms, are given in Table 2. In all cases inclusion of a GPb term further reduced the BPb decrease from the 2.26 ug/dl unaccounted for by demographics. The remaining trend was consistent for all but national GPb use.

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Table 2

Time Trend and Four Year Change of Blood Lead
Adjusted for Demographics and Gasoline Lead Exposure

GPb Exposure Variable	Signif. Level p	Time Trend ug/dl/yr	Time Trend Std. Error	Remaining Four Year Decrease BPb, ug/dl	Remaining Four Year Decrease %
National	$\leq$ 0.0001	-0.14	0.12	0.57	3.8
Site Density	$\leq$ 0.0001	-0.44	0.13	1.75	11.3
Subsite Density	0.0311	-0.47	0.12	1.85	11.9
Log (Site Density)	$\leq$ 0.0001	-0.52	0.13	2.05	13.1
Log (Subsite Density)	0.1076	-0.39	0.13	1.55	10.1

TIME-RELATED BLOOD LEAD EFFECTS

In the absence of credible and suitable data on lead sources besides gasoline, a time variable, reflecting site mean examination date, was adopted as a surrogate for other time-related BPb effects. A stepwise regression procedure was used on each of 5 selection sets again containing the full set of demographic terms, one of the GPb exposure variables and the surrogate, time. First, the model was forced to include both time and the GPb variable used; in companion analyses the selection of all terms was allowed to proceed solely on the basis of the inclusion criterion. As shown in Table 3, under both forced and unforced conditions the time variable was significant for all cases, but only Site GPb Density retained significance. When time is taken into account as a surrogate for unquantified time-related BPb effects, national GPb use is no longer significant. These results suggest other time-related BPb effects are present in NHANESII.

Table 3

Significance Levels of Gasoline Lead Exposure
and Time Terms in Models Including Demographics

GPb Exposure Variable	Forced: GPb Signif. Level	Forced: Time Signif. Level	Unforced: GPb Signif. Level	Unforced: Time Signif. Level
National	0.8850	$\leq$ 0.0001	NS	$\leq$ 0.0001
Site Density	0.0022	$\leq$ 0.0001	0.0022	$\leq$ 0.0001
Subsite Density	0.6276	$\leq$ 0.0001	NS	$\leq$ 0.0001
Log (Site Density)	0.0019	$\leq$ 0.0001	0.0019	$\leq$ 0.0001
Log (Subsite Density)	0.7520	$\leq$ 0.0001	NS	$\leq$ 0.0001

NS = Not Selected, $p > 0.15$

CONCLUSIONS

This analysis has shown that many factors related to personal and residence characteristics and sampling itinerary significantly affect NHANESII BPb values, and can account for 3.35 ug/dl of the apparent decrease between 1976 and 1980. Of the GPb exposure variables only Site GPb Density and its logarithm had a significant effect on BPb in the presence of the time surrogate. The portion of the four-year decrease due to Site GPb Density was determined by the analysis to be 0.5 ug/dl. This is consistent with the observed national average air lead decrease of 0.3 ug/m^3 over the same period (ref 4), and the well-documented air lead/blood lead relationship (ref 5,6). Figure 1 shows the relative contributions to the four-year blood lead decrease.

The unexplained portion of the BPb decrease, 1.75 ug/dl, is reflected by the time variable and may be due to improved sample handling over the course of the NHANESII study, effectiveness of numerous government programs to reduce lead intake through food, paint and water (ref 7), or other unquantified causes.

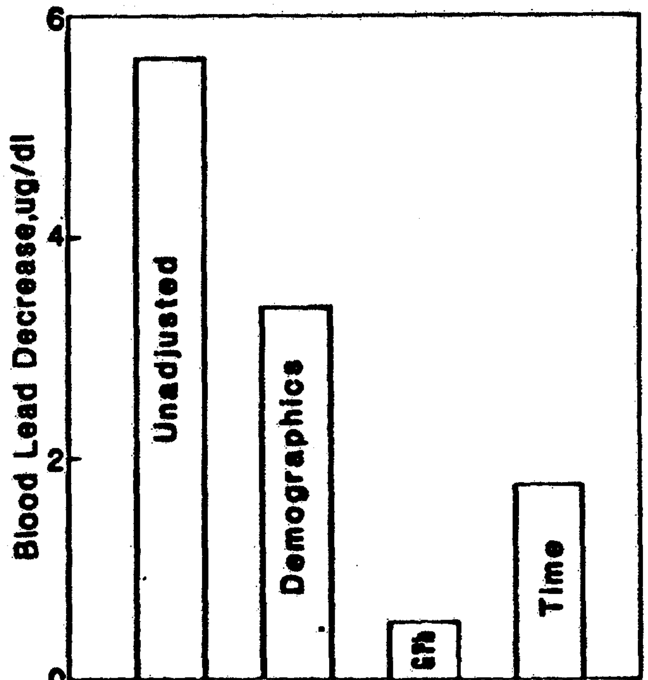

Fig.1 Contributions to Blood Lead Decrease,1976-80

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