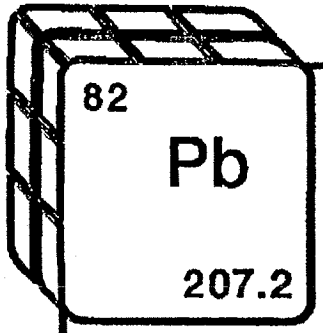


A PROBABILISTIC RISK ASSESSMENT OF THREE HEALTH EFFECTS UNDER ALTERNATIVE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR LEAD

Ronald G. Whitfield
Argonne National Laboratory

Thomas S. Wallsten
University of North Carolina

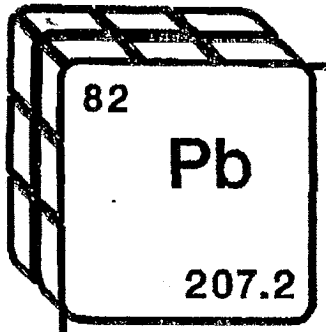
Presented to

Environmental Protection Agency
Clean Air Scientific Advisory Committee
Subcommittee on Health Risk Assessment

March 11-12, 1986

N 31044

TEH 0413071

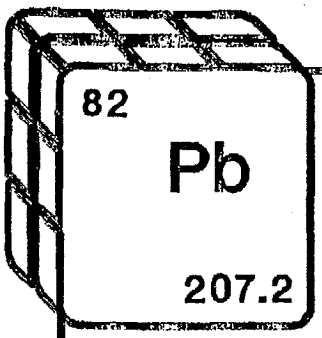


THIS PRESENTATION TO CASAC FOCUSES ON METHODOLOGY AND HIGHLIGHTS THE RESULTS

- Methodology is still new to many people
- Full results and complete documentation are contained in report
- Excerpts of results are in staff paper

DUP050454127

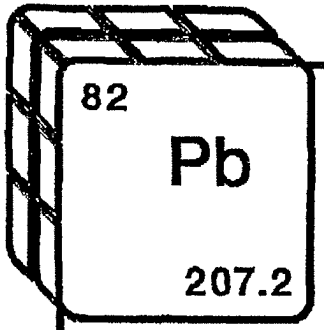
TEH 0413072



PURPOSE OF RISK ASSESSME OF LEAD HEALTH EFFECTS

To develop probability distributions over fractions of the population at that would suffer certain well-defin health effects under alternative NAAQS for lead.

DUP050454128



AN EPA ADMINISTRATOR HAS STATED SIMPLY THE NEED FOR AND REQUIREMENTS OF A PROBABILISTIC RISK ASSESSMENT

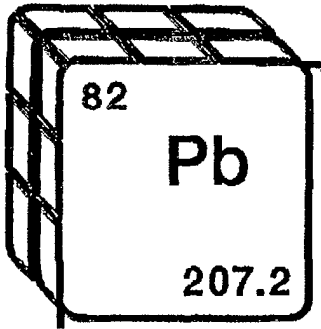
If I am going to propose controls that may have economic and social effects, I need to have some idea of how much confidence should be placed in the estimates of risk that prompted those controls.

...we must insist on risk calculations being expressed as distributions of estimates and not as magic numbers...

...we need to expose to public scrutiny the assumptions that underly our analysis...

William D. Ruckelshaus
Risk in a Free Society,
Risk Analysis, 4(3)1984

DUP050454129

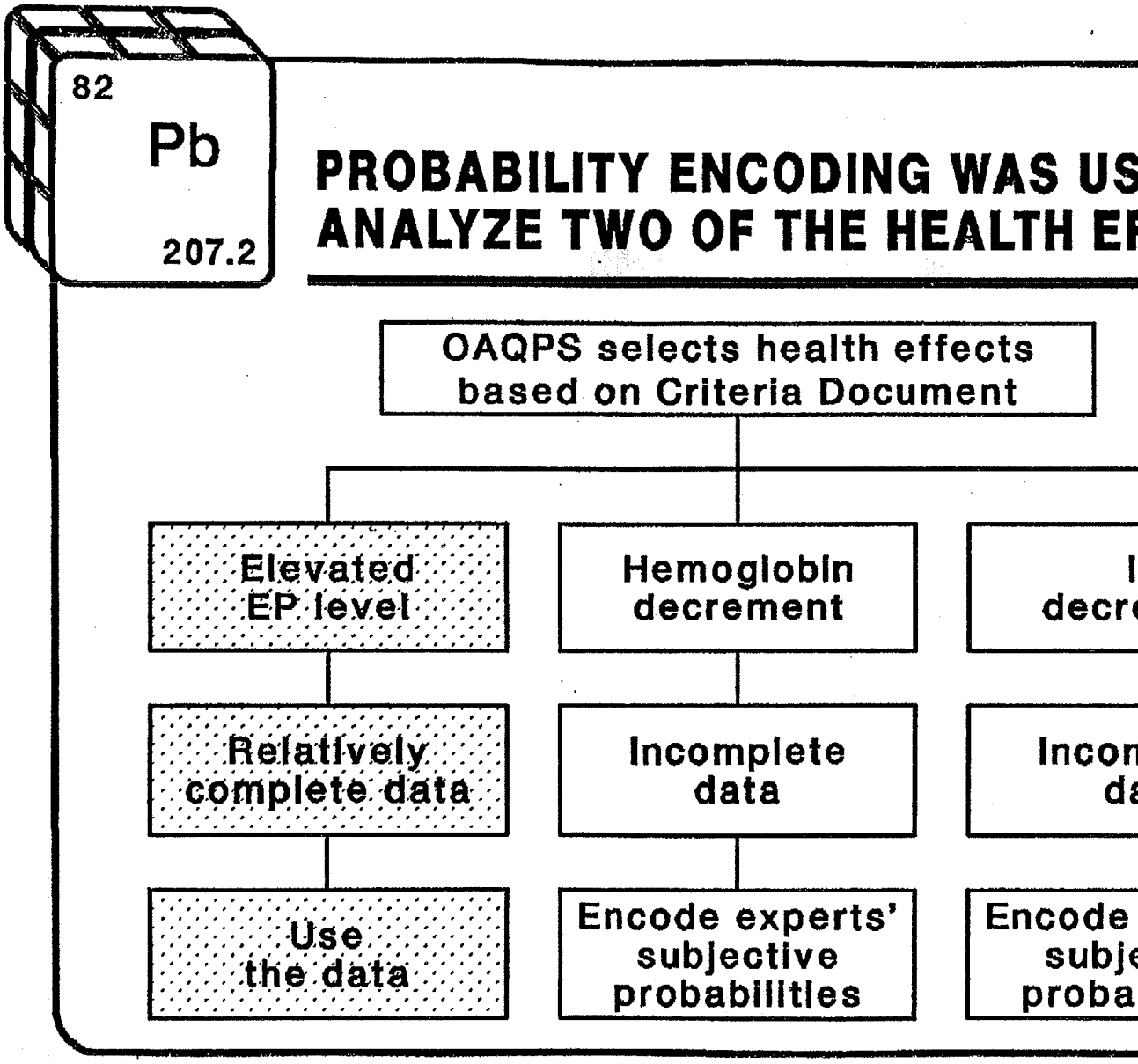


THERE ARE TWO SOURCES OF UNCERTAINTY

- Uncertainty associated with data
  - Sampling error
  - Measurement error
- Uncertainty associated with lack of data
  - Extrapolation from animal models
  - Extrapolation from related data bases
  - Theories involved in the extrapolation
  - Unknown factors

DUP050454130

TEH 0413075



DUP050454131

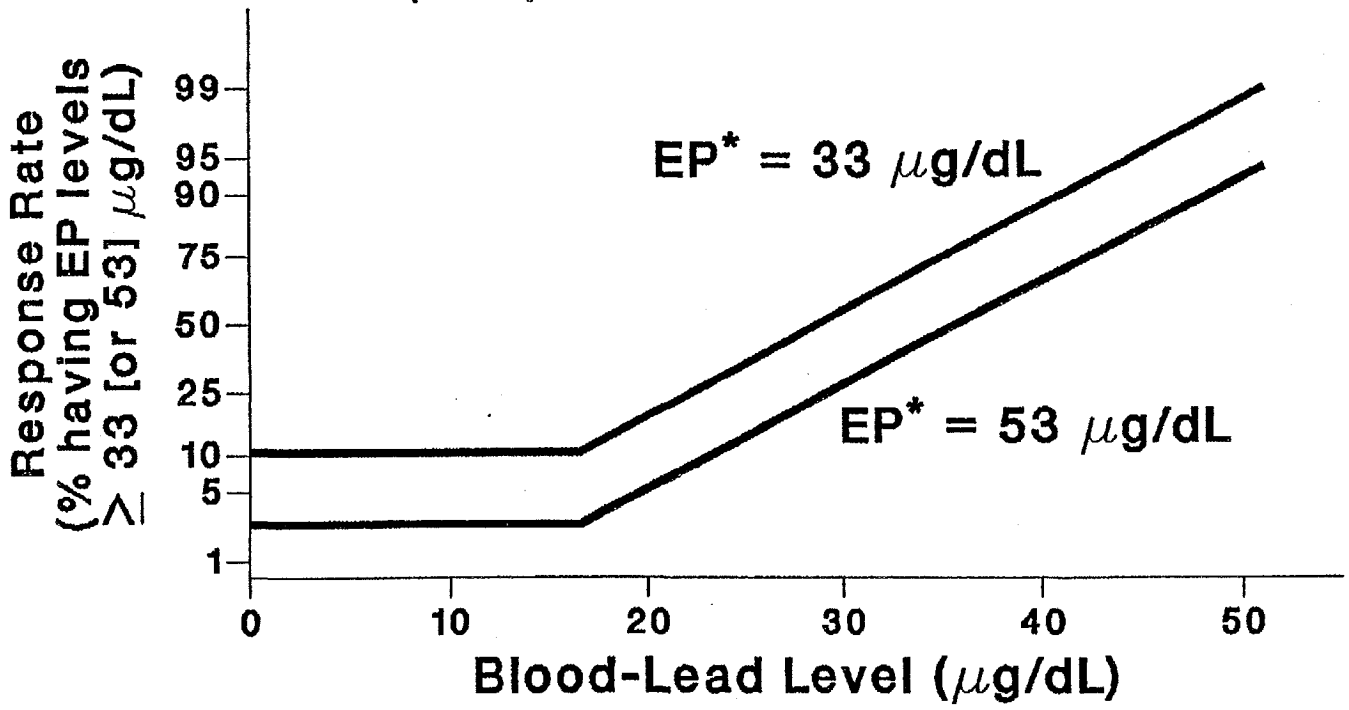
82

Pb

207.2

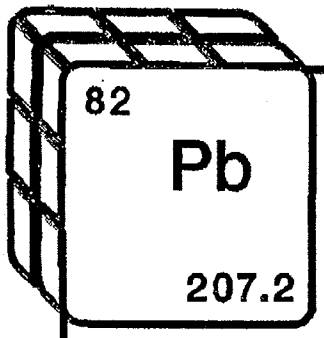
MEAN RESPONSE RATE vs. DOSE RATE FOR EP LEVELS $\geq$ 33 μg/dL AND 53 μg/dL

Adapted from Piomelli et al. (1982)

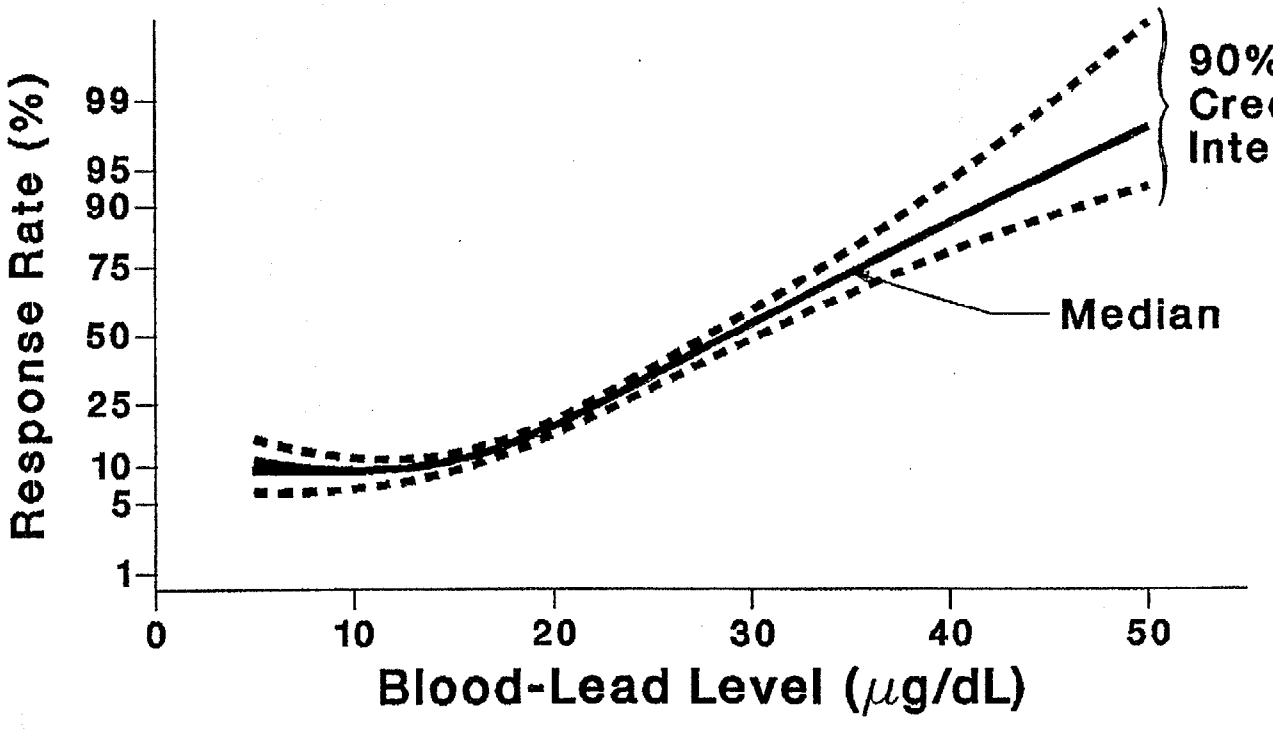


DUP05045413 2

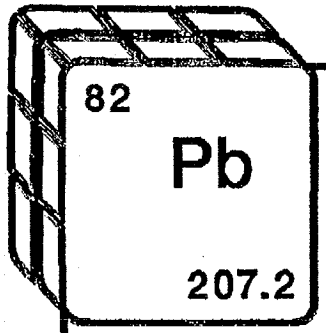
TEH 0413077



MEDIAN RESPONSE RATE AND 90% CRE
INTERVAL vs. DOSE FOR EP ≥ 33 μg/dL



DUP050454133



PROBABILITY ENCODING WAS USED TO ANALYZE HEMOGLOBIN EFFECTS

OAQPS selects health effects based on Criteria Document

Elevated EP level	Hemoglobin decrement	IQ decrement
Relatively complete data	Incomplete data	Incomplete data
Use the data	Encode experts' subjective probabilities	Encode experts' subjective probabilities

DUP050454134

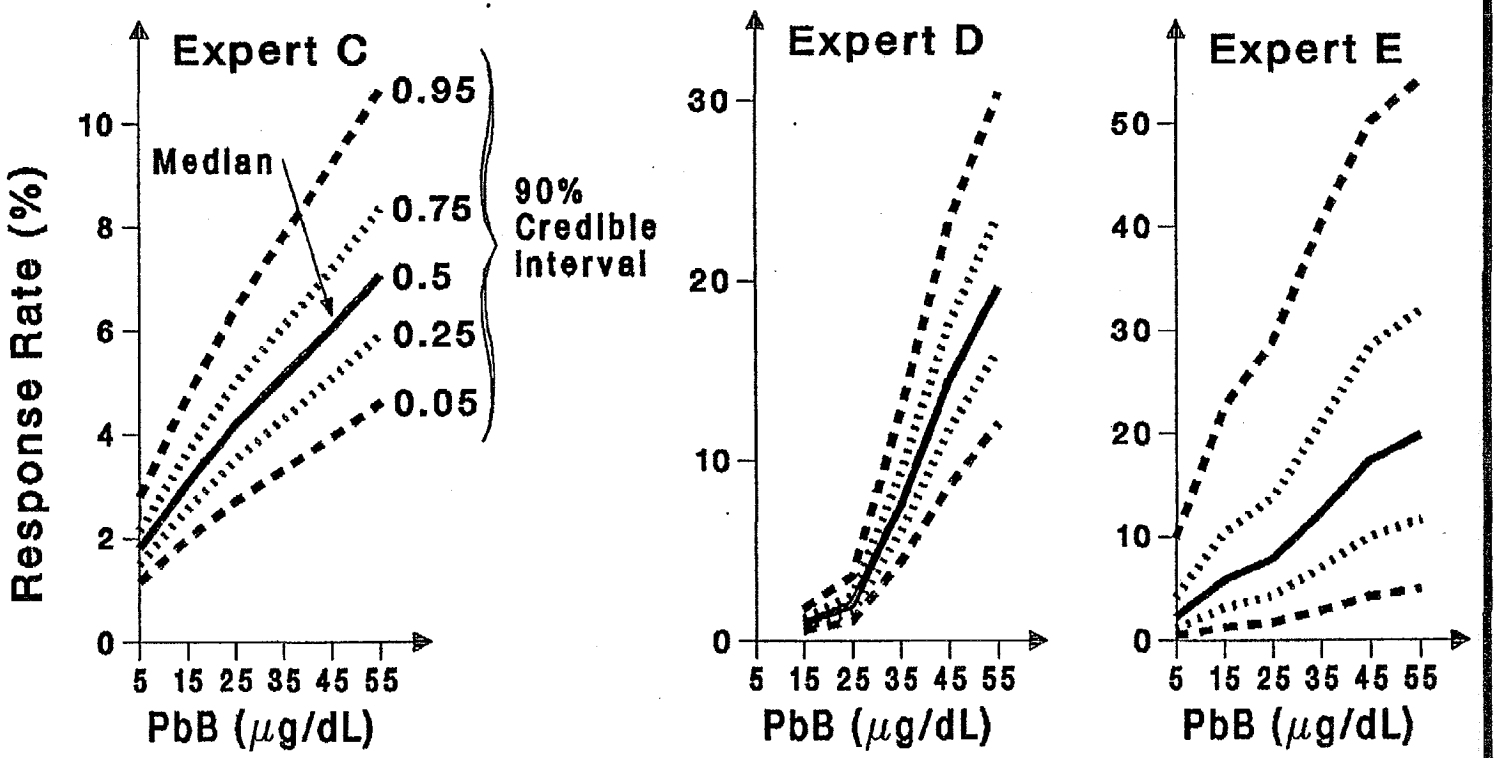
TEH 0413079

82

Pb

207.2

JUDGMENTS ABOUT LEAD-INDUCED RESPONSE RATES FOR Hb $\leq$ 9.5 g/dL AMONG CHILDREN AGES 0-3 YEARS vs. PbB



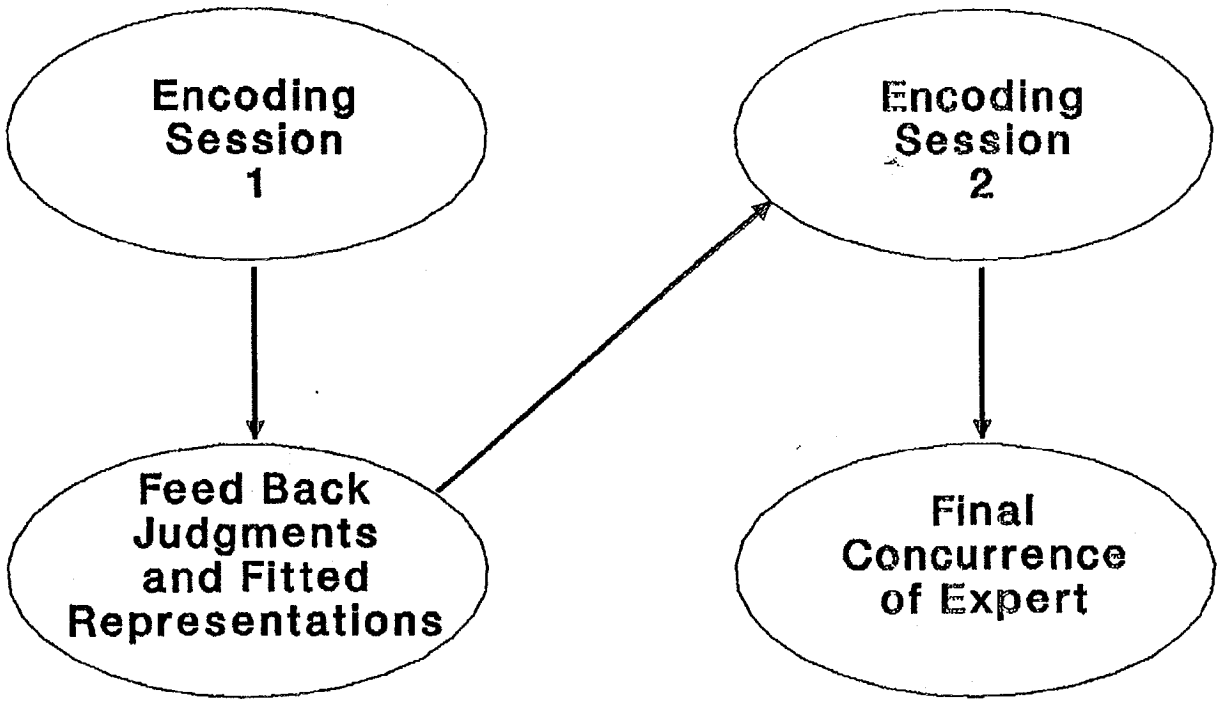
Note: Ranges on Response Rate ~~and PbB~~ Differ Across Experts

DUP05045413S

TEH 0413080

82
Pb
207.2

PROBABILISTIC JUDGMENTS WERE OBTAINED IN A FOUR-STEP PROCESS



DUP050454136

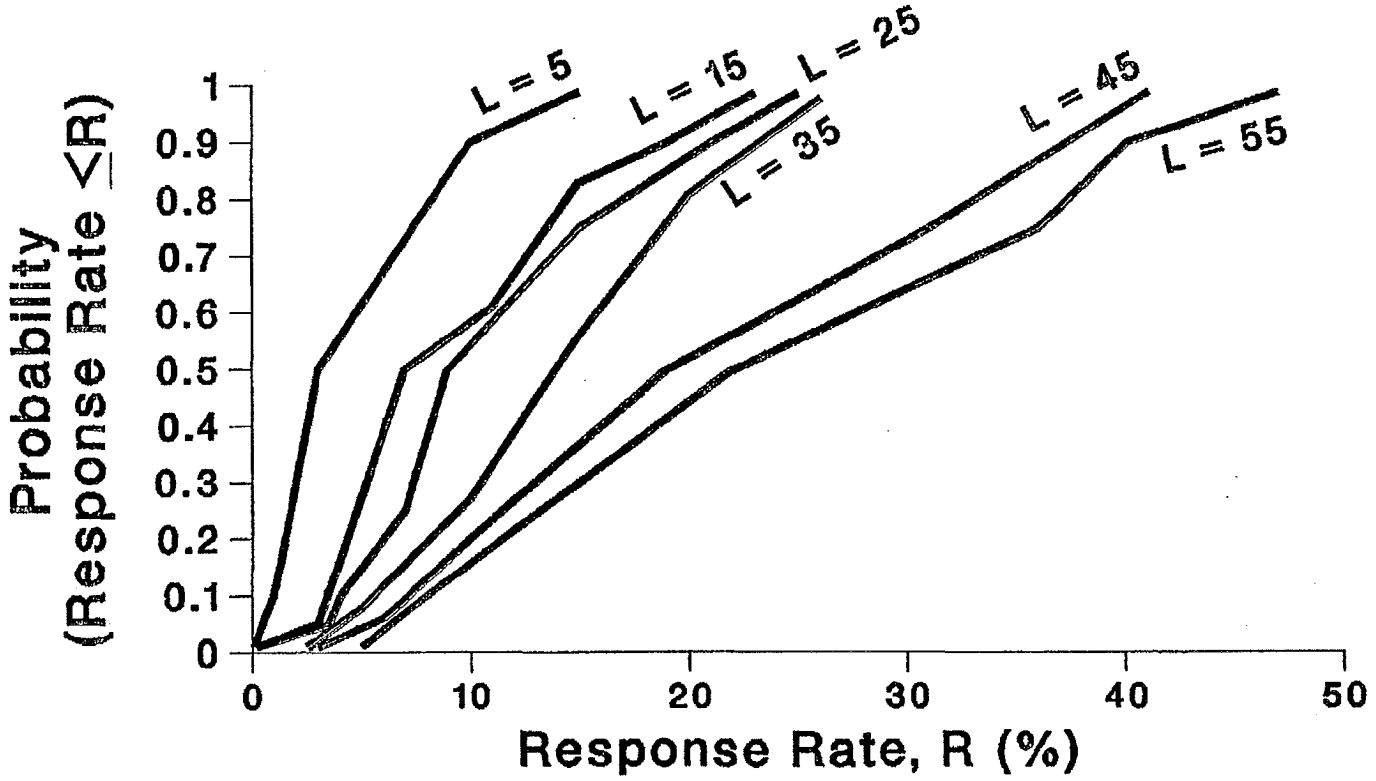
TEH 0413081

82

Pb

207.2

EXPERT E's PROBABILITY JUDGMENTS ABOUT PERCENTAGE OF U.S. CHILDREN AGED 0-3 HAVING LEAD-INDUCED HEMOGLOBIN LEVELS ≤ 9.5g/dL AT EACH INDICATED BLOOD-LEAD LEVEL (μg/dL)



DUP050454137

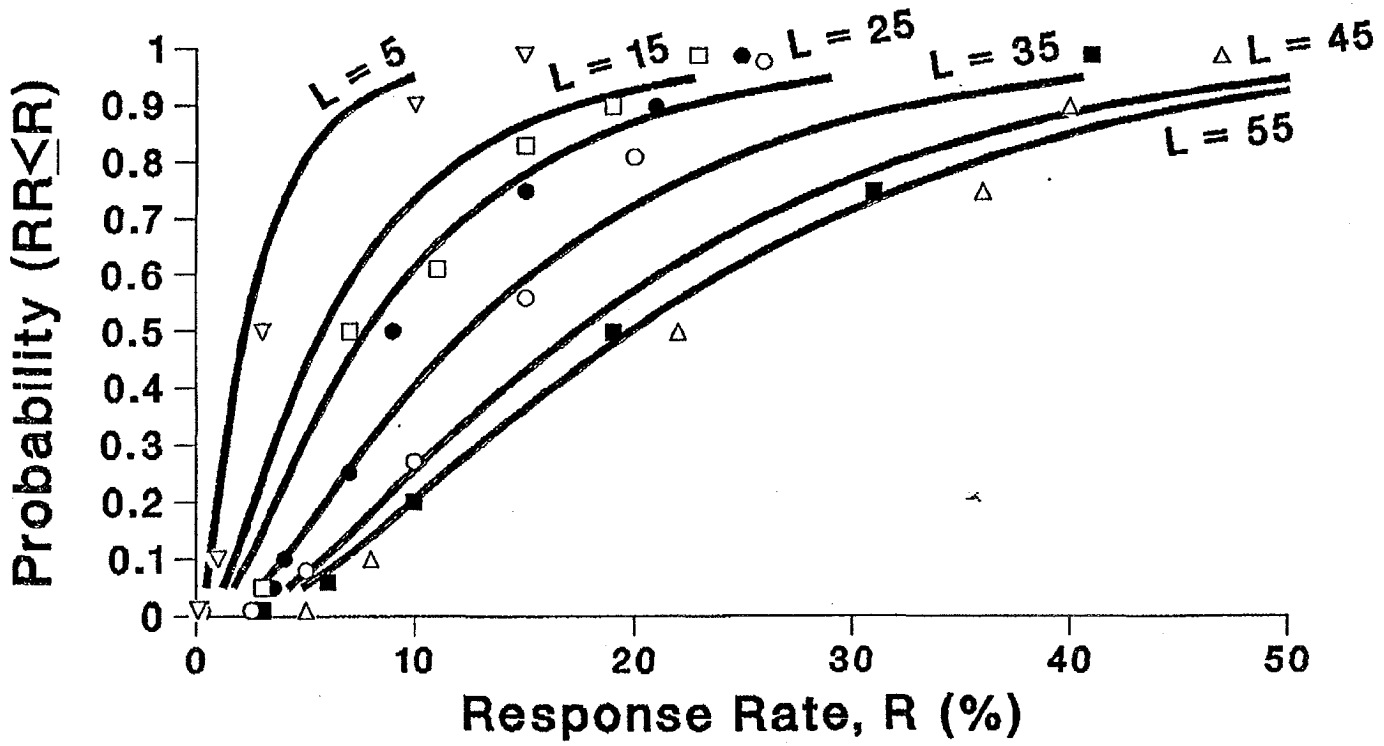
TEH 0413082

82

Pb

207.2

FUNCTIONAL REPRESENTATIONS OF EXPERT E's PROBABILITY JUDGMENTS



DUP050454138

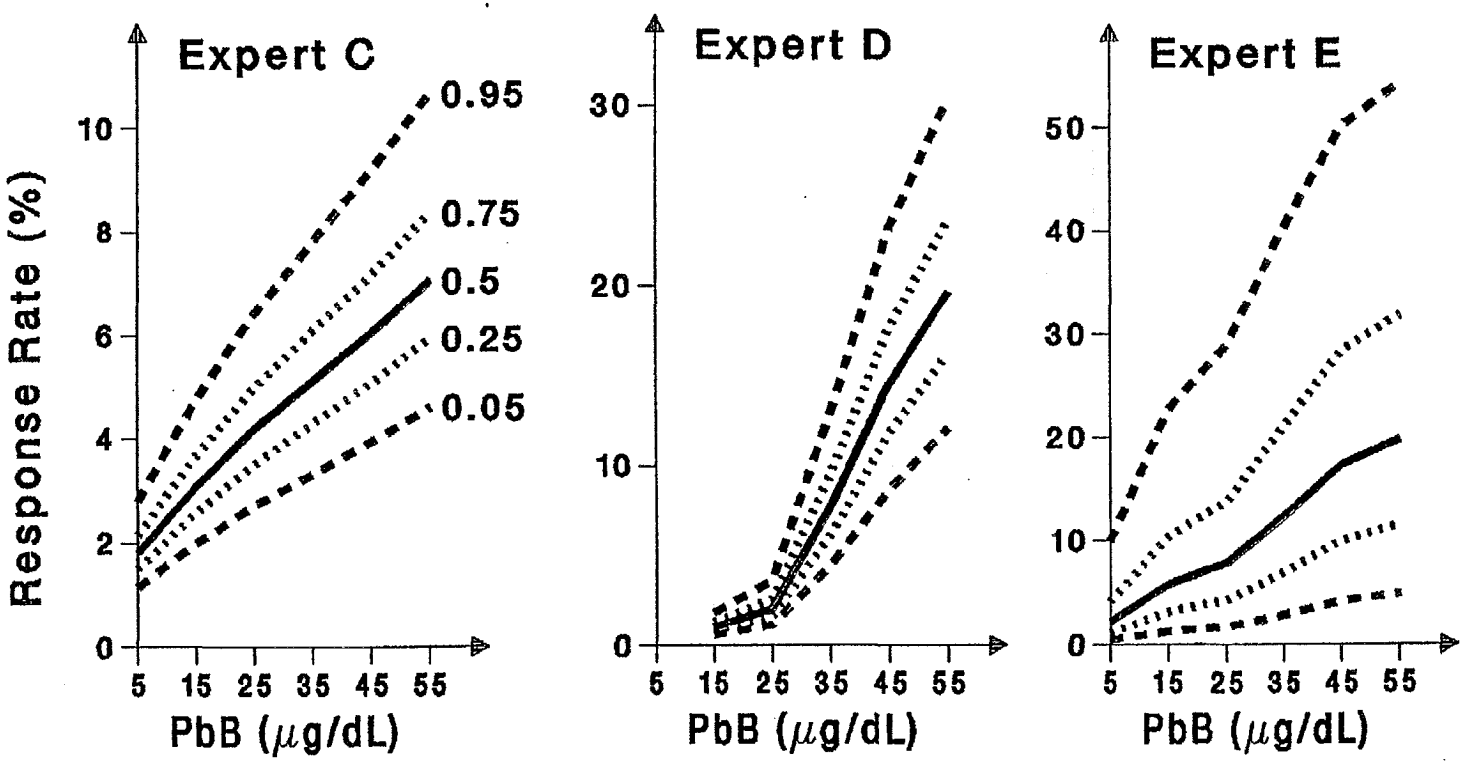
TEH 0413083

82

Pb

207.2

JUDGMENTS ABOUT LEAD-INDUCED RESPONSE RATES FOR Hb $\leq$ 9.5 g/dL AMONG CHILDREN AGES 0-3 YEARS vs. PbB



Note: Ranges on Response Rate ~~and PbB~~ Differ Across Experts

DUP05045413 9

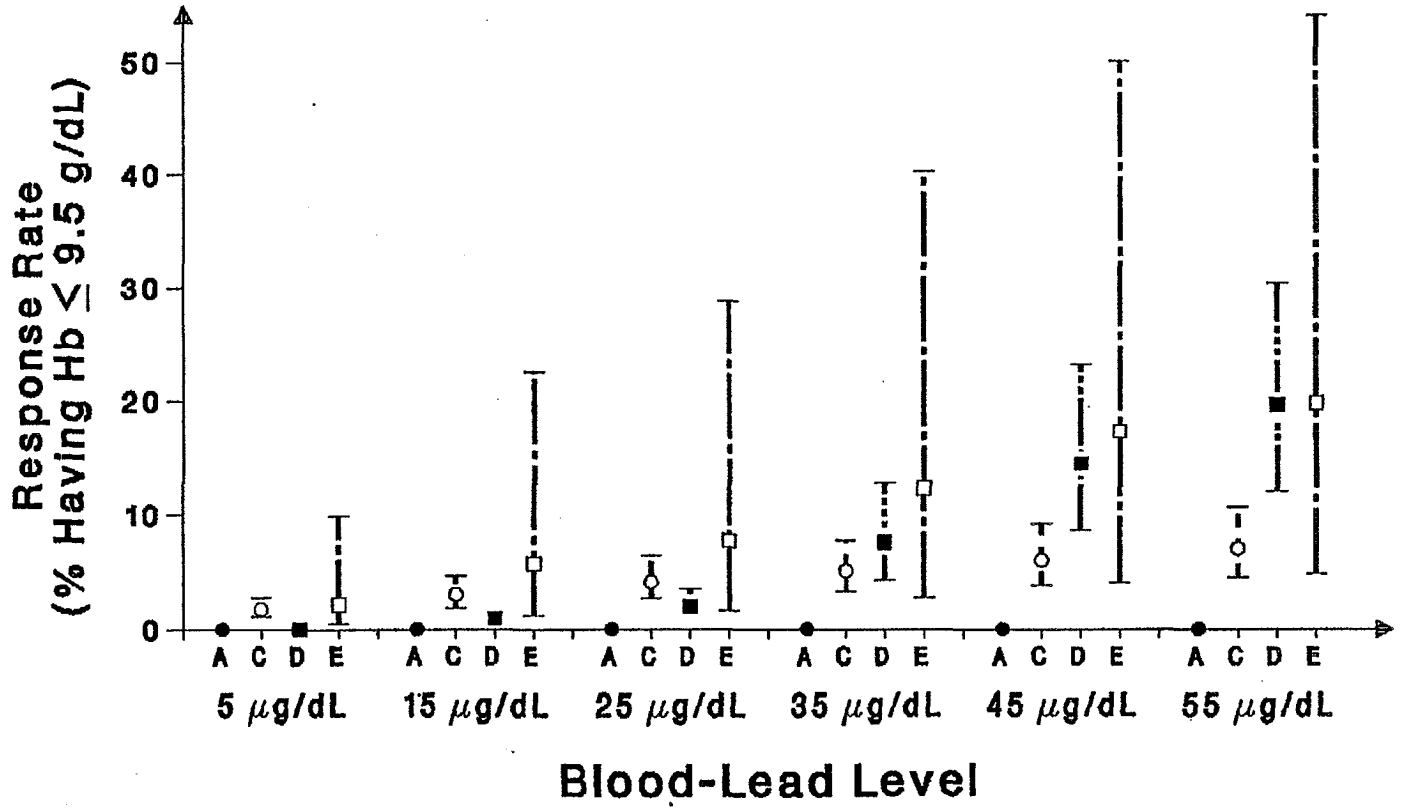
TEH 0413084

82

Pb

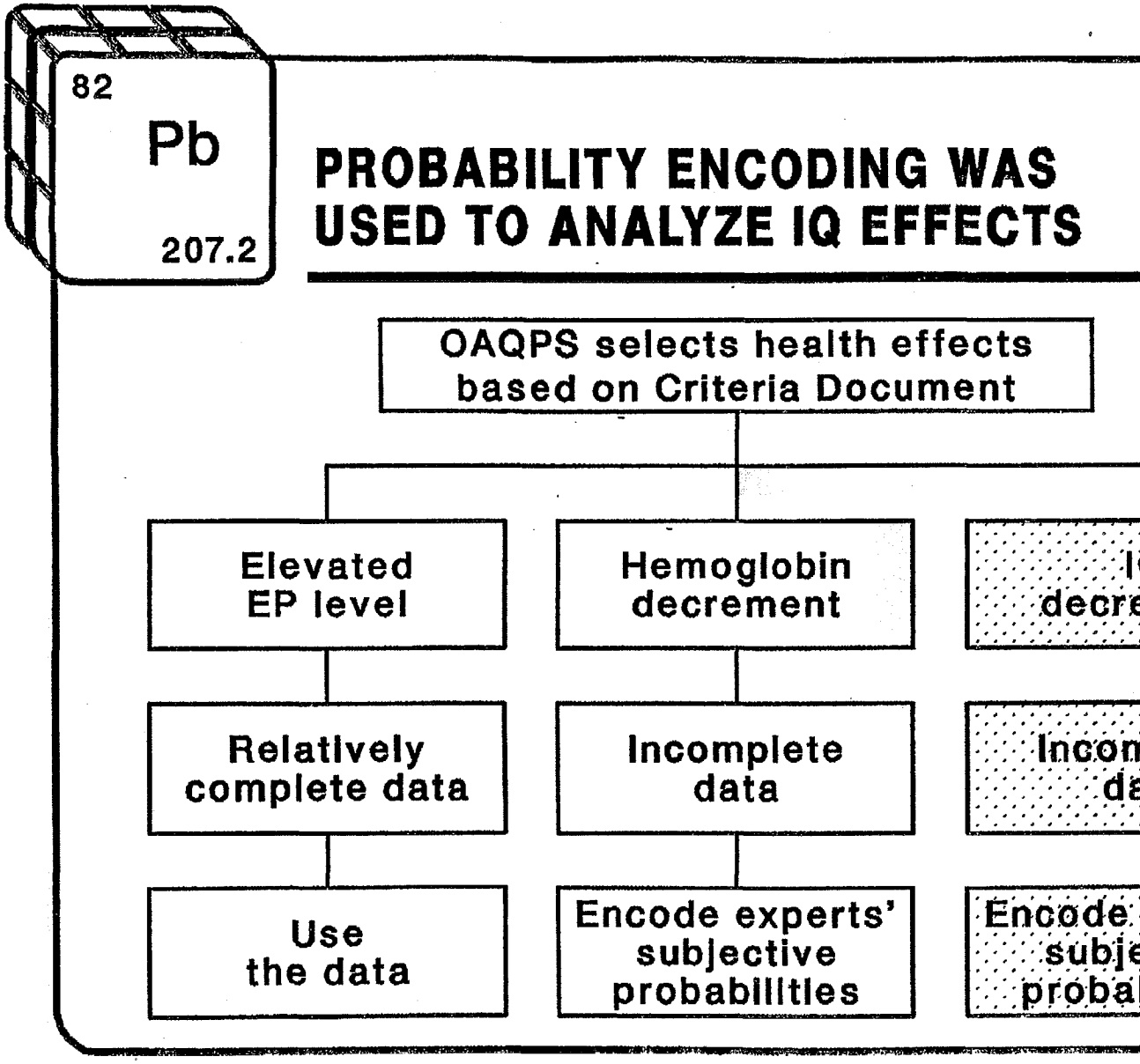
207.2

COMPARISON OF MEDIAN AND 90% CREDIBLE INTERVAL JUDGMENTS ABOUT LEAD-INDUCED HEMOGLOBIN EFFECTS FOR CHILDREN AGES 0-3 YEARS

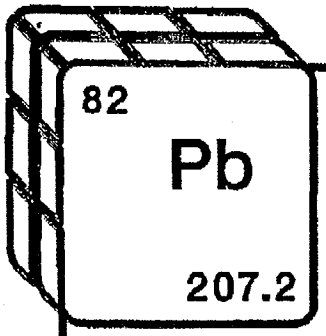


DUP05045414O

TEH 0413085



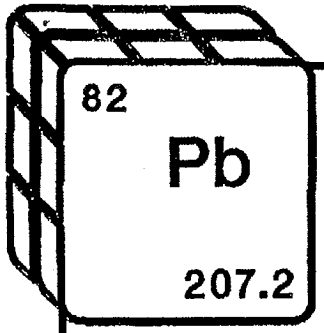
DUP050454141



IQ EFFECTS ARE MORE COMPLICATED THAN HEMOGLOBIN EFFECTS

- Influenced by long-term lead exposure during the course of behavioral and CNS development
- Long-term lead exposure is confounded with other variables that affect IQ
- Thus, it is impossible to observe IQ decrements in individuals and attribute them to a single cause

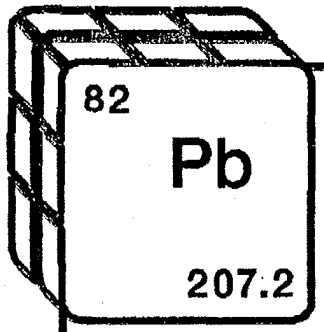
DUP05045414 2



DEVELOPMENT OF IQ PROTOCOL REQUIRED MORE WORK THAN DID HEMOGLOBIN PROTOCOL

- 14 people consulted
- Many drafts circulated
- Focus shifted to consideration of a hypothetical experiment
- Several pilot encoding sessions conducted

DUP0504543



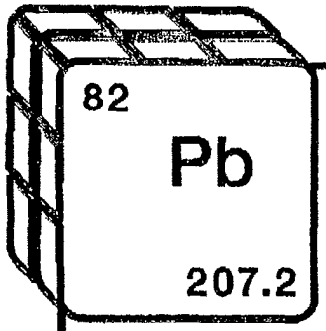
HYPOTHETICAL IQ EXPERIMENTS WERE CONSIDERED FOR LOWER AND HIGHER SES POPULATIONS

1. Large numbers of children randomly assigned at conception to exposure groups

2. Exposure groups defined by blood-level on third birthday
   - Control group (sheltered from lead)
   - Experimental groups (5,15,...,55 μg/dL)

3. WISC-R IQ measured on seventh birthday

DUP05045144

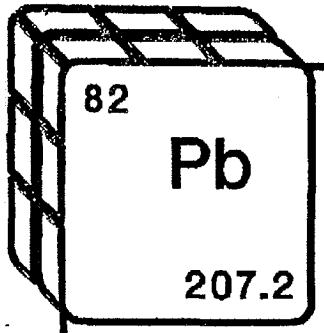


HYPOTHETICAL EXPERIMENT HAD SEVERAL ADVANTAGES

1. Questions were natural to think about
   - Hypothetical data are similar in form to actual data
   - Random assignment minimized need to consider covariates

2. Enabled calculation of important indicators
   - Probability distributions over dose-effect functions (mean IQ decrement vs. PbB)
   - Probability distributions over dose-response functions (percent having $IQ \leq IQ^*$ vs. PbB)

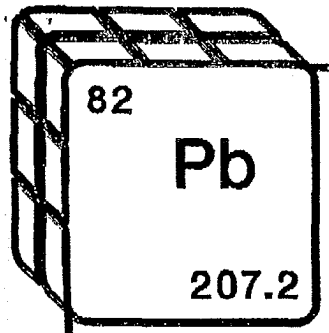
DUP05045145



THREE IQ PARAMETERS ABOUT WHICH JUDGMENTS WERE ENCODED

1. Mean IQ of control group
2. Within-group IQ standard deviation
3. Mean IQ decrements for each experimental group relative to control group

DUP05045146



SIX INDIVIDUALS PARTICIPATED IN THE IQ ENCODINGS

Dr. Kim Dietrich - *University of Cincinnati*

Dr. Claire Ernhart - *Cleveland Metropolitan Hospital*

Dr. Herb Needleman - *Pittsburgh Childrens Hospital*

Dr. Michael Rutter - *Institute of Psychiatry, London*

Dr. Gerhard Winneke - *University of Düsseldorf*

Dr. William Yule - *Institute of Psychiatry, London*

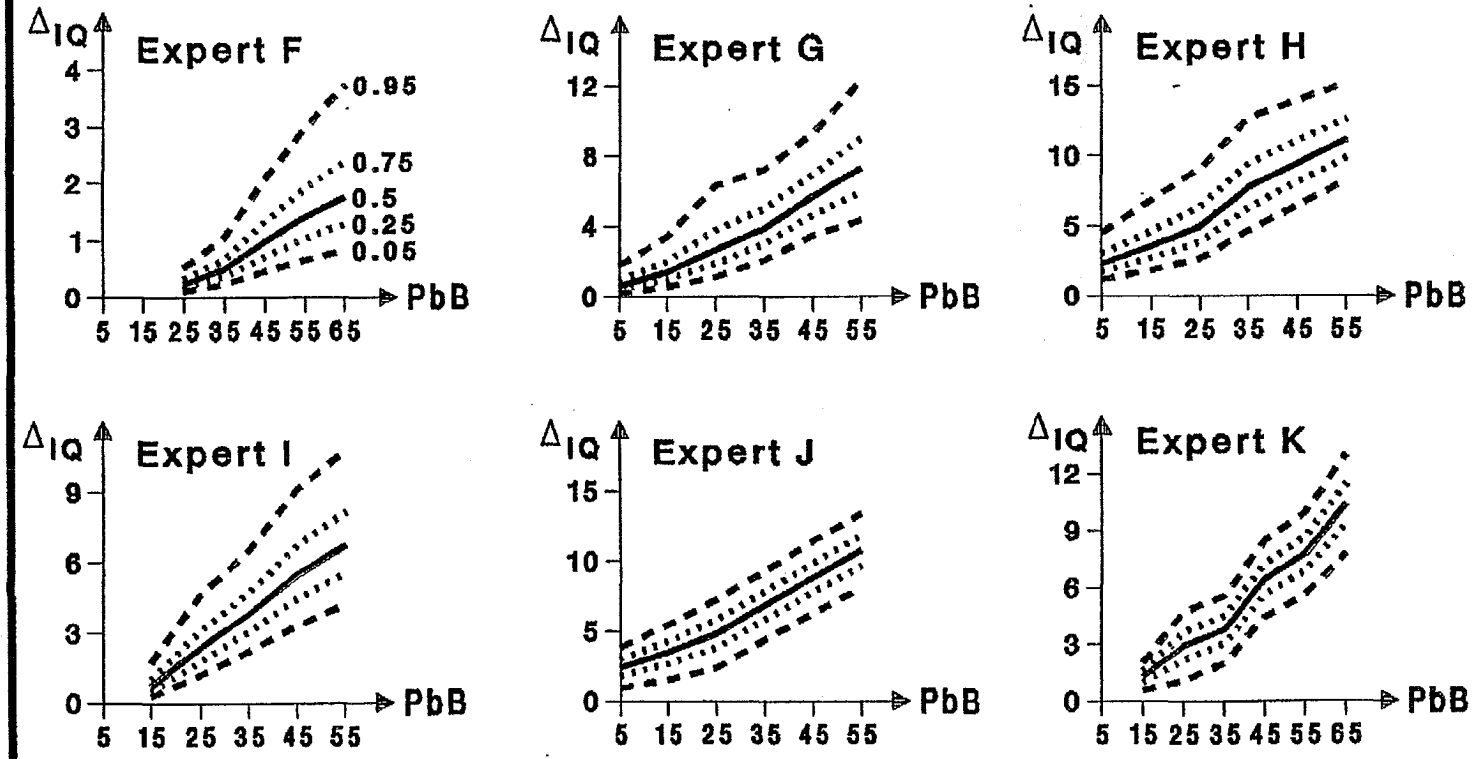
DUP05045414

82

Pb

207.2

LEAD-INDUCED IQ DECREMENTS (Δ_{IQ}) vs. PbB (μg/dL)



Note: Ranges on IQ Decrements and PbB Differ Across Experts

DUP050454148

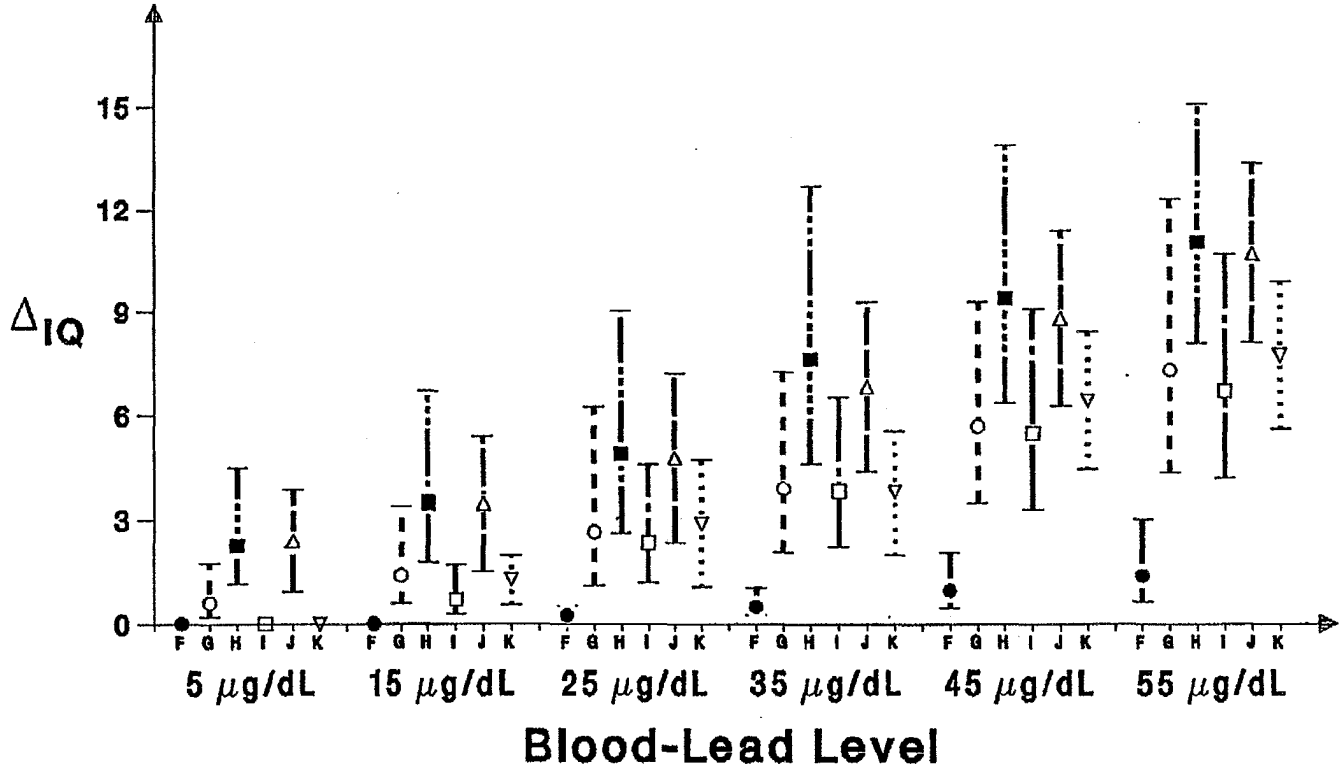
TEH 0413093

82

Pb

207.2

COMPARISON OF MEDIAN AND 90% CREDIBLE INTERVAL JUDGMENTS ABOUT LEAD-INDUCED IQ DECREMENTS FOR A LOWER SES POPULATION



DUP0504149

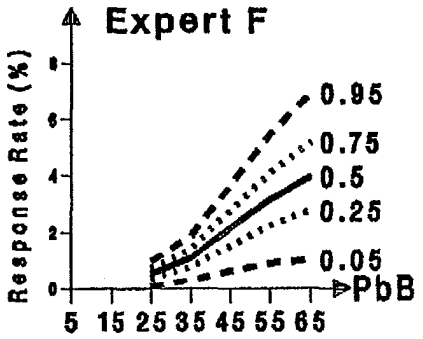
TEH 0413094

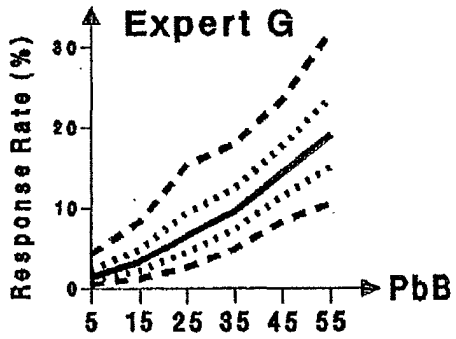
82

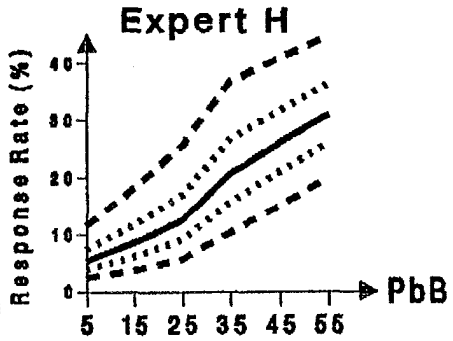
Pb

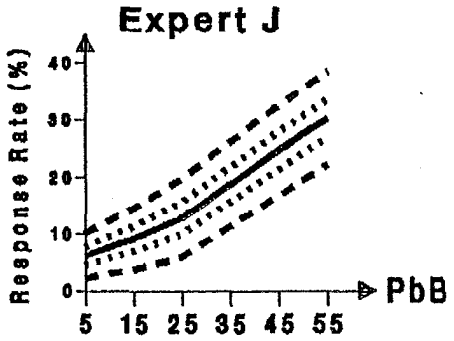
207.2

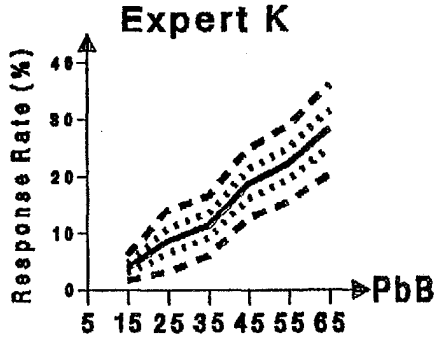
LEAD-INDUCED RESPONSE RATE FOR IQ $\leq$ 85 IN A LOWER SES POPULATION vs. PbB (μg/dL)











Note: Ranges on Response Rate and PbB Differ Across Experts

DUP05045150

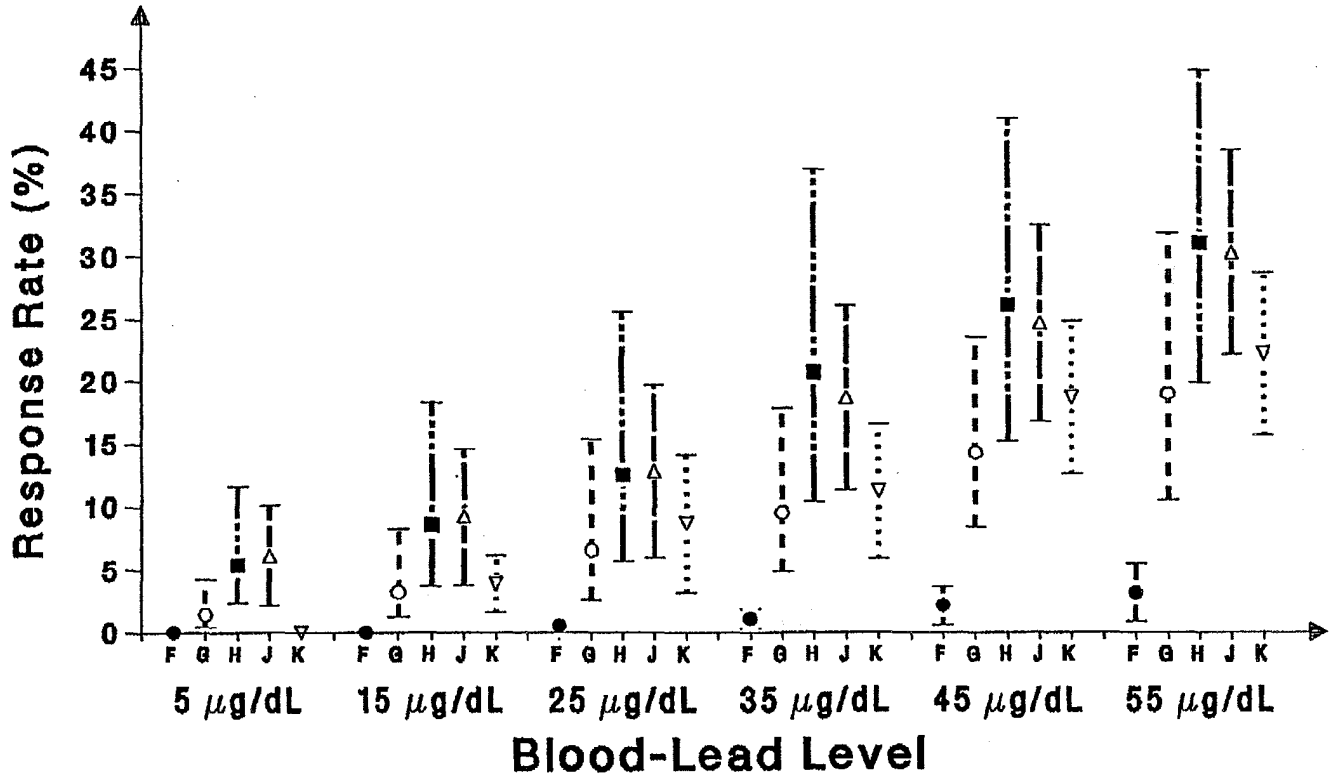
TEH 0413095

82

Pb

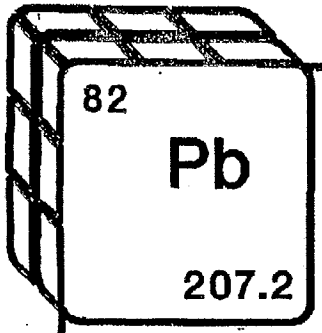
207.2

COMPARISON OF MEDIANS AND 90% CREDIBLE INTERVALS OF RESPONSE RATES FOR IQ ≤ 85 IN A LOWER SES POPULATION vs. PbB



DUP05045415 1

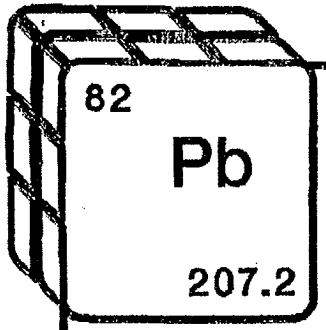
TEH 0413096



OBSERVATIONS ABOUT THE PROBABILISTIC RISK ASSESSMENT

1. Uses statistical and judgmental uncertainty, as appropriate
2. Participating experts were generally comfortable with the process
3. Focused on well-defined scientific issues
4. Judgmental disagreements attributable to interpretations of evidence, not definitions or policy implications
5. There is substantial overlap in the pattern of judgments
6. Resulting probability estimates were obtained in a systematic, open, and defensible manner

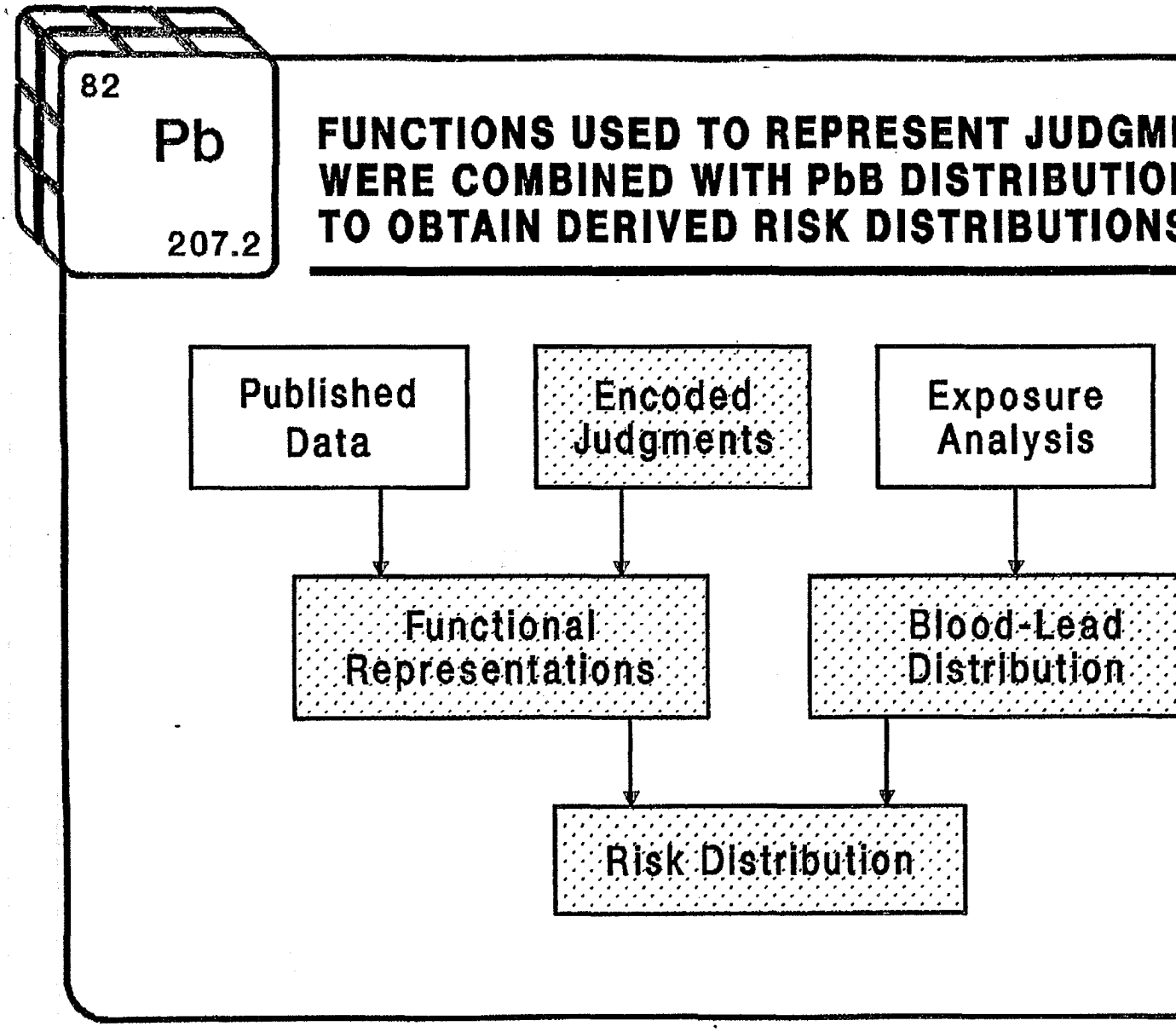
DUP0504152



POTENTIAL USEFULNESS OF PROBABILISTIC RISK ASSESSMENT

1. Each expert's uncertainty is represented probabilistically
2. Range of uncertainty across experts is represented probabilistically
3. Implications of these uncertainties can be explicitly derived
4. These representations and implications should be useful to analysts and decision makers in considering maximum allowable PbB levels

DUP0504153



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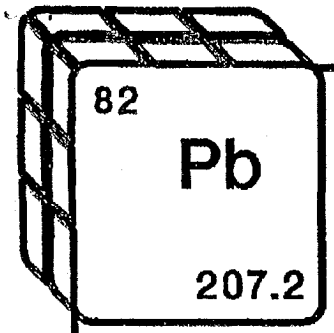
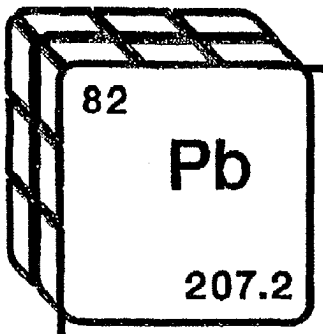


EXPOSURE ESTIMATES FOR RISK CALCULATIONS

1. Estimated mean PbB levels are averages over wide areas around a point source
2. Mean PbB levels are based on air-quality estimates at geographic centroids
3. Mean PbB levels are for 84-month cohorts
4. PbB distributions are assumed to be lognormal with GSD = 1.42 μg/dL

DUP05045415 5



UPPER AND LOWER BOUND GM PbB LEVELS (μg/dL) FOR CHILDREN AGES 0-6 YEARS

	Baseline (1974-1980)	Post Control (1990-1996)
Source 5:		
Lower Bound	7.7	1.3
Upper Bound	13.4	3.7
Source 2:		
Lower Bound	17.2	1.3
Upper Bound	24.5	3.7

DUP0504156

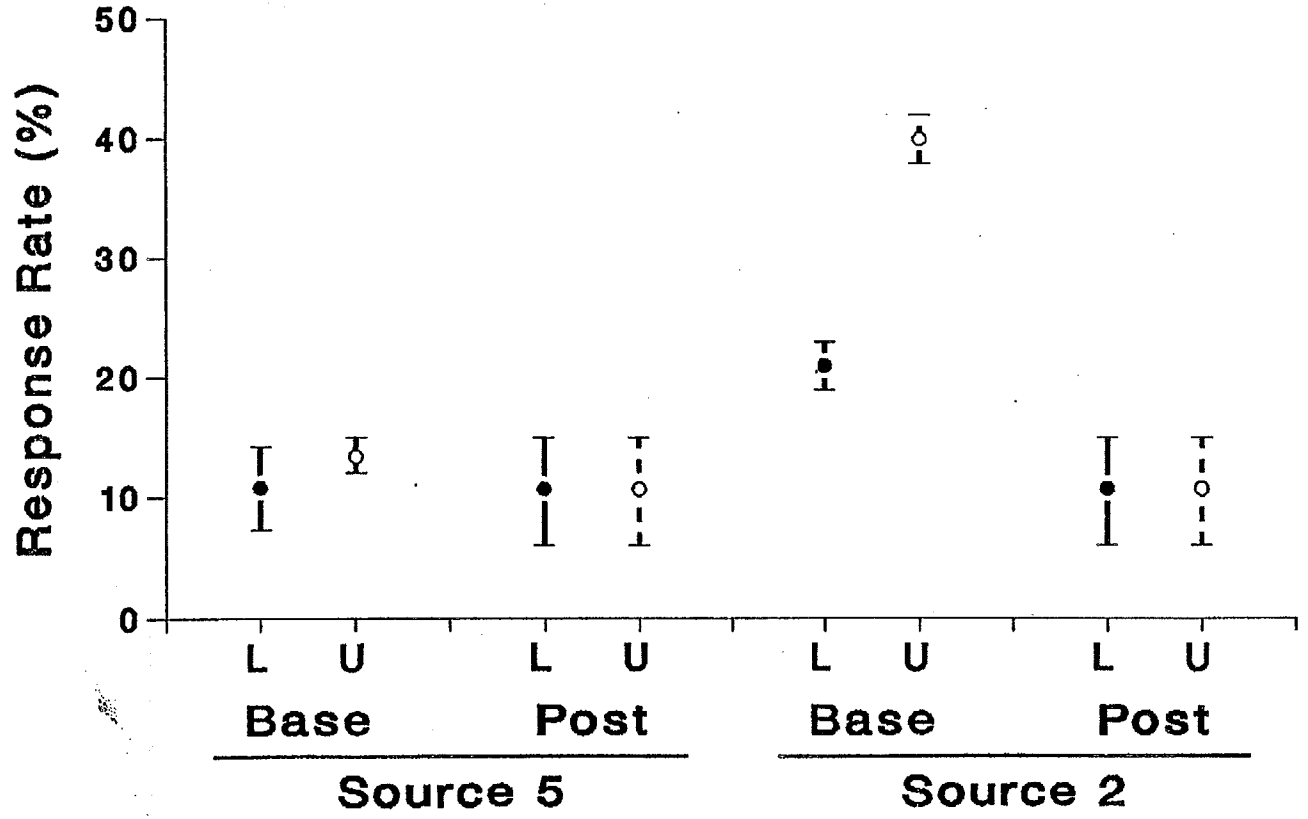
TEH 0413101

82

Pb

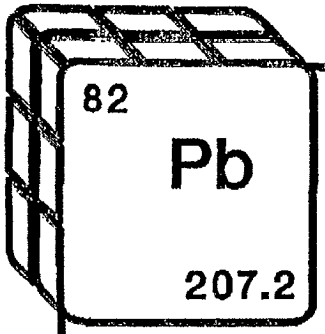
207.2

MEDIANS AND 90% CREDIBLE INTERVALS FOR RESPONSE RATES FOR LEAD-INDUCED LEVELS $\geq$ 33 μg/dL



DUP0504541 57

TEH 0413102



UPPER AND LOWER BOUND GM PbB LEVELS (μg/dL) FOR CHILDREN AGES 0-3 YEARS

	Baseline (1974-1980)	Post Control (1990-1996)
Source 5:		
Lower Bound	8.6	1.4
Upper Bound	13.9	3.7
Source 2:		
Lower Bound	19.4	1.4
Upper Bound	27.0	3.6

DUP05045415B

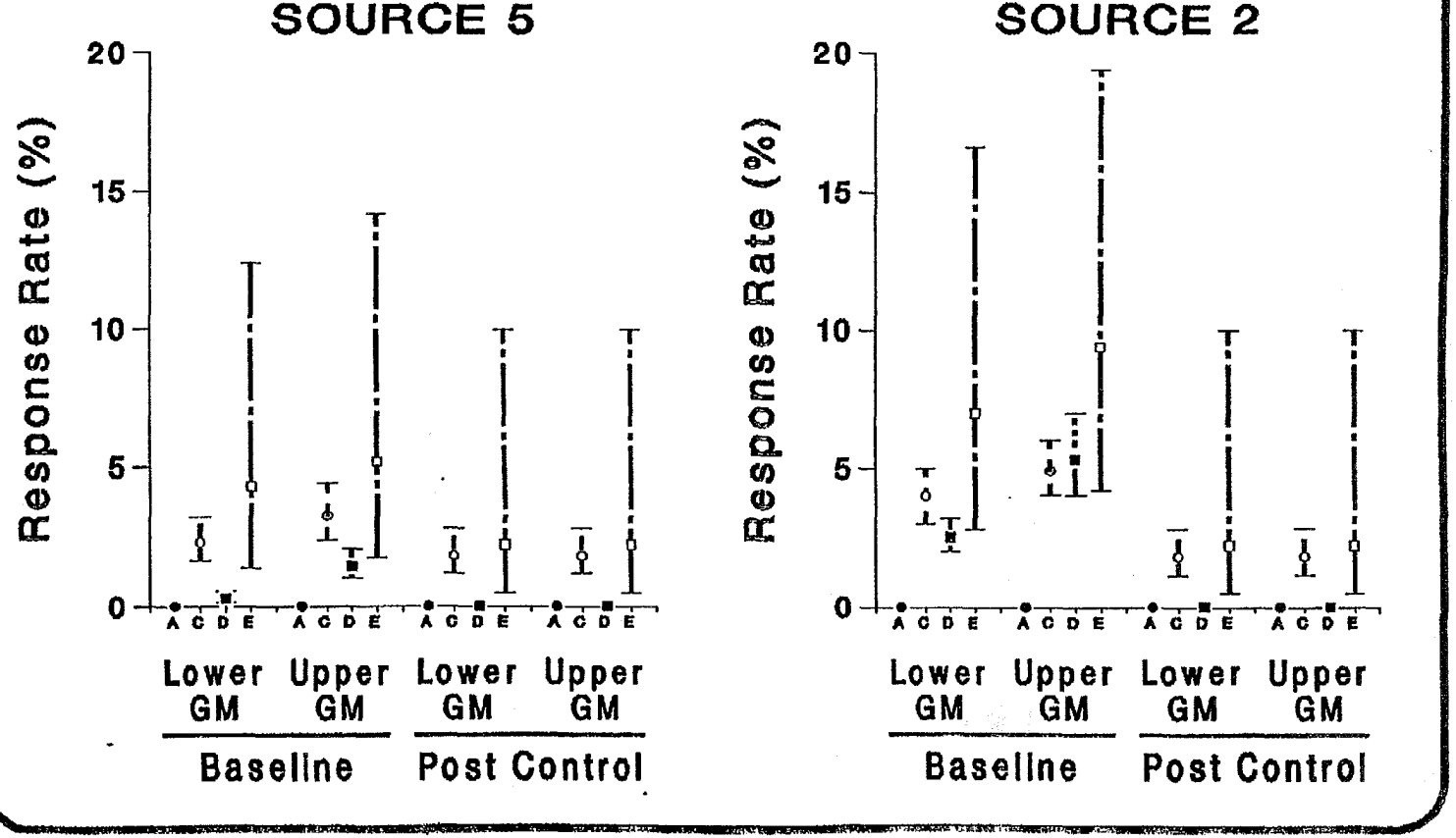
TEH 0413103

82

Pb

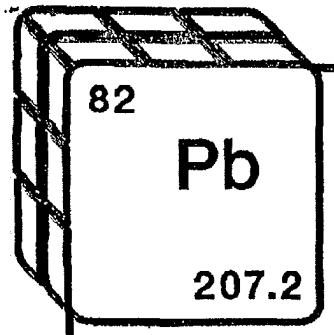
207.2

RESPONSE RATES FOR LEAD-INDUCED HEMOGLOBIN LEVELS ≤ 9.5 g/dL AMONG CHILDREN AGES 0-3 ARE UNCERTAIN AND DEPEND ON EXPOSURE DISTRIBUTIONS



DUP05045159

TEH 0413104



UPPER AND LOWER BOUND GM PbB LEVELS (μg/dL) FOR CHILDREN ON THIRD BIRTHDAY

LOWER SES

	Baseline (1974-1980)	Post Control (1990-1996)
Source 5:		
Lower Bound	7.7	1.3
Upper Bound	12.9	3.7
Source 2:		
Lower Bound	19.2	1.3
Upper Bound	27.1	3.7

DUP05045416O

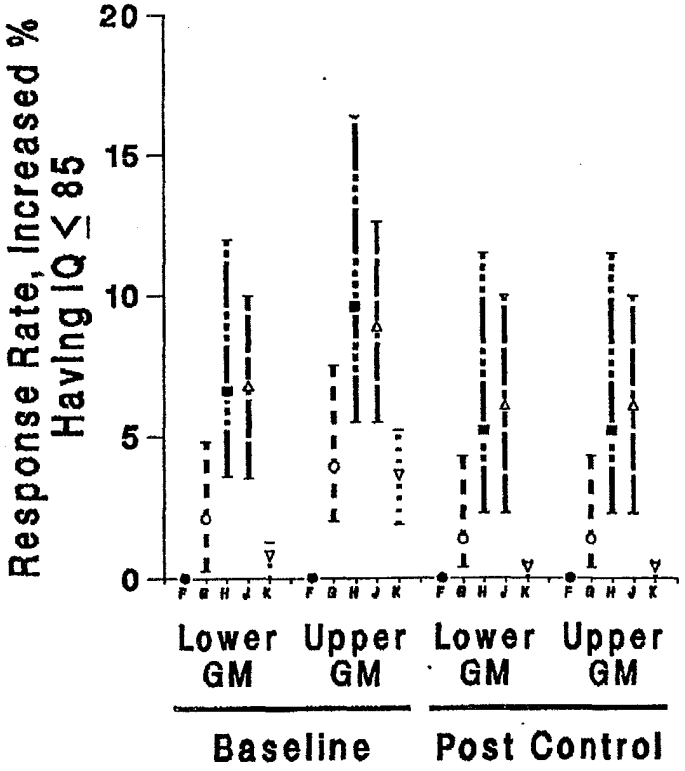
TEH 0413105

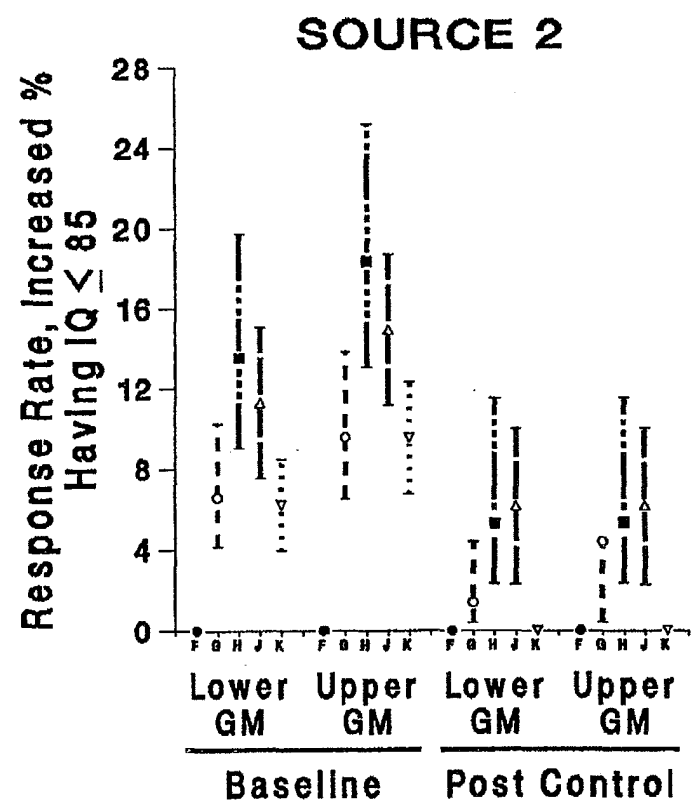
82

Pb

207.2

RESPONSE RATES FOR LEAD-INDUCED IQ LEVELS ≤ 85 AMONG CHILDREN (LOWER SES) AGE 7 ARE ALSO UNCERTAIN AND DEPEND ON EXPOSURE DISTRIBUTIONS





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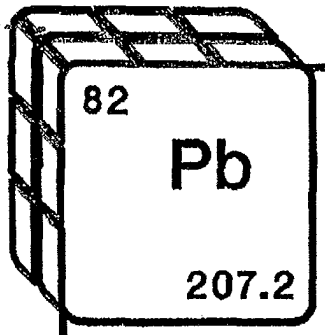

THESE RISK ESTIMATES MAY BE CONSIDERED TO BE ILLUSTRATIVE

1. Demonstrated that dose-reponse and dose-effect relationships can be combined with exposure estimates to calculate risk estimates

2. Specific risk estimates are open to questions due to the preliminary nature of the exposure estimates, which are under further evaluation

3. An improved risk assessment would incorporate a distribution on GM PbB levels rather than lower and upper bounds

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