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Childhood Lead Poisoning: Definitions and Priorities

ABBREVIATIONS. Pb, lead; CDC, Centers for Disease Control.

By using motor developmental status as the outcome measurement, Dietrich et al,[1] in the current issue, have tried to lend objectivity to the controversial question of whether neurologic damage in childhood can be attributed to low lead (Pb) levels. Previous prospective studies have shown a lack of consistency between Pb exposure and many measurements of cognitive development and language skills. Children who have elevated blood Pb levels are frequently subject to other neurologic risk conditions, including poverty, disorganized family situations, low maternal intelligence (IQ) and education, and poor nutrition, particularly anemia. The problem is to separate the effect of Pb from the confounding variables. This is particularly difficult when the effect of Pb is small (eg, 3 to 5 IQ points) and the effect of the other confounding variables (eg, maternal IQ) is greater. Under these circumstances, the adequacy of controlling for confounding variables is critical. Although numerous studies of low Pb effect have been published, their perspectives have ranged widely between considering multiple variables and considering none at all, while including all confounding variables is almost impossible. Possible omissions include prenatal factors, such as quality of prenatal care and maternal nutrition, paternal IQ, and educational interventions, such as enrollment in Head Start.

Before 1970, concern about childhood Pb poisoning centered on symptomatic disease, generally requiring blood Pb levels >70 μg/dL (3.38 μmol/L), with Pb encephalopathy rarely occurring at <100 μg/dL (4.83 μmol/L). Clinical findings such as lead lines in the gums and bones, basophilic stippling in red blood cells, and lead chips in the intestines have essentially disappeared from pediatric practice as Pb values dropped to <50 μg/dL (2.41 μmol/L), the level considered necessary for symptomatic disease. With the onset of environmental regulations in the early 1970s, particularly elimination of Pb from gasoline and paint, blood Pb levels in US children have dramatically and steadily fallen from an earlier mean of 17 μg/dL (0.82 μmol/L) in the early 1970s to a current mean of 6 μg/dL (0.29 μmol/L). For example, a 1970 study of San Francisco inner-city children showed that more than half had blood Pb levels >20 μg/dL (0.97 μmol/L), whereas a second study in 1991–1992[2] found only 1.7% with comparable levels, a 30-fold decrease.

With steady disappearance of symptomatic lead poisoning and falling mean blood Pb levels in US children, interest has centered on whether low blood levels, previously thought safe, could cause neurologic changes in small children, affecting such functions as intelligence, behavior, and speech. Studies beginning in the late 1970s, which are still controversial, have suggested that such low blood Pb levels could. Although too small to be clinically significant in individual children (eg, an IQ change of 3 to 5 points), this Pb effect is claimed to be important when applied to large populations. Responding to these studies, the Centers for Disease Control (CDC) has steadily decreased the blood Pb level indicative of lead poisoning from 40 μg/dL (1.93 μmol/L) in 1970, to 30 μg/dL (1.45 μmol/L) in 1975, to 25 μg/dL (1.21 μmol/L) in 1985, and finally to 10 μg/dL (0.48 μmol/L) in October 1991.[3] Furthermore, in the latest CDC report universal blood Pb screening was recommended for all children between 9 months and 6 years old and a costly strategic plan was developed encompassing testing, monitoring, treatment, and Pb abatement. Critics have claimed that the evidence for low Pb level effect does not warrant such action because of the problems of small effect, confounding variables, and questionable outcome measures. Complicating the problems of small effect and confounding variables are charges of investigator bias, faulty methodology, flawed statistics, and overstated conclusions.

Accusations of poor investigative technique and misconduct have been leveled against Dr Herbert Needleman, the leading proponent of low Pb damage in children, and he is currently being investigated by the University of Pittsburgh and the National Institutes of Health.[4,5] The charge of misconduct referred to falsification, fabrication, and plagiarism, and his attorney has indicated that Needleman has been cleared of misconduct as defined. Questions concerning methodology, documentation, scientific validity, and unwarranted conclusions await the release of the full report. These criticisms are important because Needleman has been a principal advisor to the federal government on lead issues, he played a pivotal role in the CDC decision to lower the definition of lead poisoning, and his work has great influence on other investigators in the field.

The costs of a total Pb screening, treatment, and abatement program are also a source of controversy. The 1991 CDC Strategic Plan to Eliminate Childhood Lead Poisoning[6] estimated the total program cost nationwide at $974 million over a 5-year period, an apparent gross underestimate. For example, the California Department of Health Services[7] estimated that the first year of a state screening program would

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cost $50 million, which included only the price of the laboratory test for children receiving public assistance in the state and did not include abatement or other aspects of a total program. The low predicted cost of the CDC program appears to be based on faulty assumptions. For example, Pb abatement for a typical dwelling was assumed to cost $2 000; Needleman[8] had earlier estimated $5 000, and the actual amount required to delead the average inner-city home in a Baltimore program is $20 000.[9] In contrast to the CDC estimate of $974 million for a total Pb testing, treatment, and abatement program, Needleman estimated the cost of Pb abatement alone to be $10 billion,[8] and a trade paper recently estimated the potential Pb abatement market to be $600 billion.[10]

Dietrich et al[1] squarely faced the problems of confounding variables and small effect in studying low lead levels. They had hoped to have a method that would clearly evaluate the effects of lead. Unfortunately, they found small and inconsistent effect sizes with motor developmental outcomes influenced by confounding variables which had plagued studies using other outcomes.

In summary, we still face a dilemma and a paradox with low Pb exposure. Although Pb levels in children have markedly decreased in the past 20 years, the number of asymptomatic children defined as having Pb poisoning has increased: less lead has become more disease. Investigations show that the slight effect of low Pb levels on the nervous system, if any, are confused by multiple confounding variables, and management is complicated and expensive. The problem of falsely labeling children as brain-damaged on the basis of low blood Pb levels is real. Chelation testing and treatment are risky and of unproven long-term benefit. Pb testing, treatment, and abatement would carry a multibillion dollar price tag. In the meantime, serious and proven health-care problems of US children are inadequately funded. These include lack of immunization, prematurity, high infant mortality, pediatric acquired immunodeficiency syndrome, child abuse, violence, drugs, and the diseases of homelessness and malnutrition. Our sense of priority demands that funds are not diverted from these critical childhood needs into a questionable lead testing and management program.

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AMERICANS WANT CHOICE TO USE UNAPPROVED DRUGS

Almost 80% of Americans believe that a patient with a fatal, incurable disease, has the right, in consultation with his or her physician, to choose a promising drug treatment, even if not approved by the FDA, according to a recent survey.

The survey of 1,009 adults, conducted by The Wirthlin Group, a national public opinion firm based in McLean, VA, also found that of the 80%, 88% would still want the freedom of choice even if the drug had serious but reversible side effects. . .

In a prior survey conducted by the research firm, 88% of respondents believed that life-sustaining medical treatment should be withheld or withdrawn from terminally-ill patients if the patient or family desires such action.

"These findings suggest a general trend that people want a greater voice when it comes to dealing with terminal illness," says Richard B. Wirthlin, chairman of The Wirthlin Group.

Americans want choice to use unapproved drugs. *The Hospital Formulary*. 1991:26;922–923.

Noted by J.F.L., MD