CLIAC Meeting Public Comment Registration Form

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Issue Blood Lead Proficiency Testing Limits in CLIA

PUBLIC COMMENT FORM

Jeff Jarrett

My name is Jeff Jarrett. I am a research chemist working in the lab of the National Center for Environmental Health on biomonitoring of metals. I am also the coordinator for the lab work group of the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP).

I wanted to take this opportunity to make your committee aware of the activity of the ACCLPP advisory committee on the topic of blood lead proficiency testing limits defined in CLIA '88 in the hopes we could look to your committee for guidance about the appropriate way to propose a change to the CLIA regulations.

Who is ACCLPP?
ACCLPP is a Federal Advisory Committee which advises and guides the Secretary and Assistant Secretary of HHS and the Director of CDC regarding new scientific knowledge and technical developments and their practical implications for childhood lead poisoning prevention efforts.

The overall goal of the ACCLPP is to provide advice that will assist the nation in reducing the incidence and prevalence of childhood lead poisoning.

Why is CDC/ACCLPP so concerned about lead exposure?
Lead is a common environmental contaminant, and exposure to lead is a preventable risk that exists in all areas of the United States. Lead is associated with negative outcomes in children, including impaired cognitive, motor, behavioral, and physical abilities, and at very high levels, seizures, coma, and even death. Because lead poisoning often occurs with no obvious symptoms, it frequently goes unrecognized. Blood lead testing is the predominant way of determining an individual's exposure to lead.

Over the years, CDC has responded to the accumulated evidence of adverse effects associated with lead exposures by setting ever lower blood lead levels of concern. Between 1960 and 1990 the blood lead level for individual intervention in children was lowered from 60 µg/dL to 25 µg/dL. In 1991 the CDC recommended lowering the level for individual intervention to 15 µg/dL and implementing communitywide primary lead poisoning prevention activities in areas where many children have BLLs >10 µg/dL. Some activities, such as taking an environmental history, educating parents about lead, and conducting follow-up blood lead monitoring were suggested for children with BLLs of >10 µg/dL. However, this level, which was originally intended to trigger communitywide prevention activities, has been misinterpreted frequently as a definitive toxicologic threshold. Research conducted since 1991 has strengthened the evidence that children's physical and mental development can be affected at BLLs <10 µg/dL and that there is no "safe" threshold for blood lead levels (BLLs) in young children. This highlights the importance of a systematic and society wide effort to control or eliminate lead hazards in children's environments before they are exposed. Currently, approximately 250,000 U.S. children aged 1-5 years have blood lead levels >10 ug/dL.

As case management policies are developed for ever smaller blood lead concentrations, the allowable error in blood lead laboratory results is of greater concern. At <10 ug/dL, the allowable error for blood lead results based on the current CLIA regulations of +/- 4 or +/- 10% (whichever is greater) creates problems with interpreting the data.

Who is the LWG?
The Laboratory Work Group of the Advisory Committee on Childhood Lead Poisoning Prevention was established by ACCLPP to investigate and report on five issues related to laboratory analysis of lead.

The first charge of the Laboratory Work Group states:
"The Laboratory Work Group (WG) will address whether Blood Lead proficiency testing (PT) acceptability limits should be more stringent than the current Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) standard of ±4 µg/dL or ±10% (whichever is greater) and if so, what they should be.

The WG should draft a letter from the ACCLPP to the appropriate federal agency recommending that a change in CLIA '88 regulations be implemented that would tighten the minimum acceptable PT limits for blood lead."

So again, I present this information to you in the hopes that our workgroup could look to your committee for guidance about the appropriate way to propose a change of the CLIA regulations to more stringent criteria for blood lead testing.