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Editorial/Editoriale

The Lead Industry and Public Health: The Association of Occupational and Environmental Clinics (AOEC) Panel on the Management of Lead-exposed Adults (2001-2005)

L'Industria del Piombo e la Sanità Pubblica: La Commissione dell'Associazione delle Cliniche Ambientali e del Lavoro (AOEC) sul Trattamento degli Adulti esposti a Piombo (2001-2005)

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Summary

In 1991 the United States Center for Disease Control and Prevention (CDC) reduced the level of concern for lead poisoning in children to a blood lead concentration of 10 μg/dL. The blood lead standard for adult workers set by the Occupation Safety and Health Agency (OSHA), however, remained at 50 μg/dL, unchanged over thirty years. In order to address this discrepancy, in 2001, the Association of Occupational and Environmental Clinics (AOEC) convened a panel to prepare guidelines for medical management of lead-exposed adults. The panel of 13 lead-poisoning experts was charged with preparing guidelines for adults by consensus. However, two of its members were nominated by the lead industry trade organization, the Battery Council International (BCI). At the outset, the panel agreed that their recommendations should be consistent with modern epidemiologic findings and the CDC guidelines for children and not attempt to judge the "feasibility" issues raised by the industry repre-

Riassunto

Nel 1991 il Centro americano per il Controllo e la Prevenzione delle Malattie (CDC) ridusse il livello di soglia per l'intossicazione da piombo nei bambini ad una concentrazione nel sangue pari a 10 μg/dL. Il livello di piombo nel sangue per i lavoratori adulti fissato dall'Agenzia per la Salute e la Sicurezza nell'ambiente di lavoro (OSHA) era rimasto comunque a 50 μg/dL, immodificato da trent'anni. Al fine di affrontare questa incongruenza, nel 2001 l'Associazione delle Cliniche Ambientali e del Lavoro (AOEC) riunì una commissione per preparare le linee guida per il monitoraggio clinico di adulti esposti al piombo. La commissione, composta da 13 esperti nel settore della tossicologia da piombo, fu incaricata di concordare le linee guida per gli adulti. Inoltre due membri della commissione erano stati nominati dall'organizzazione delle industrie per il commercio del piombo, il Battery Council International (BCI). In via preliminare, la commissione convenne che le loro raccomandazioni dovessero

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sentatives. After two years of almost monthly teleconferences the industry representatives rejected the blood lead levels arrived at by compromise and again insisted on including the cost to industry in the medical guidelines. In their efforts to intimidate the medical scientists on the panel, the BCI enlisted lead industry attorneys whose threatening letters to the AOEC and major government environmental and occupational health agencies led the AOEC to terminate the panel's activities. While the lead industry representatives succeeded in delaying the release of the recommendations, the major conclusions of the panel were published and widely disseminated by 2010. Eur. J. Oncol., 16 (2), 69-73, 2011

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essere coerenti con i più recenti dati epidemiologici e con le linee guida del CDC per i bambini e di non tenere in considerazione i problemi di "fattibilità" sollevati dai rappresentanti dell'industria. Dopo due anni di teleconferenze quasi mensili, i rappresentanti dell'industria respinsero i livelli di piombo nel sangue su cui era stato trovato un compromesso e insistettero ancora affinché, nelle linee guida cliniche, venisse incluso il costo per l'industria. Nel loro tentativo di intimidire gli scienziati della commissione, la BCI si rivolse agli avvocati dell'industria del piombo che, con le loro lettere minatorie all'AOEC e alle più importanti agenzie governative di sanità pubblica e ambientale, riuscirono nell'intento di bloccare le attività della commissione. Mentre i rappresentanti dell'industria del piombo riuscivano a far ritardare la divulgazione delle raccomandazioni, le conclusioni più rilevanti a cui era pervenuta la commissione furono pubblicate e largamente diffuse nel 2010. Eur. J. Oncol., 16 (2), 69-73, 2011

Parole chiave: **avvelenamento da piombo, industria, adulti, trattamento, salute nell'ambiente di lavoro**

In 1975, the Occupational Safety and Health Agency (OSHA) set a blood lead level of 50 μg/dL as the upper acceptable occupational blood lead. The "medical removal protection program" (MRP) in the OSHA Standard required that the worker be transferred to lower exposure jobs with retention of salary for up to 18 months when the blood lead exceeded 50 μg/dL. The worker was not to be returned to the heavy exposure job unless the blood lead remained below 40 μg/dL. But in 1991, the CDC designated 10 μg/dL as the level of concern for children. No adjustment had been made in the federal standards for the acceptable blood lead in adults in over 30 years.

In 2003, the Association of Occupational and Environmental Clinics (AOEC) attempted to address this question. The Association convened a panel of thirteen experts to develop guidelines for the management of lead exposure in adults. As a non-profit, non-governmental association of 60 occupational health clinics, the AOEC is supported in part by the U.S. Agency for Toxic Substances and Disease Registry (ATSDR), and the National Institute of Occupational Safety and Health (NIOSH) as well as by member clinics. The panel was charged with developing guidelines to serve as medical advice for health care practitioners (physicians, nurses, industrial hygienists, social workers, etc.) confronted with individuals exposed to lead. The AOEC also hoped to provide an authoritative base for updating the OSHA lead standard. In contrast to the guidelines for children produced by the CDC, OSHA faced pressure from industry. Although the AOEC received financial support from ATSDR and NIOSH, the federal agencies had no input into the panel's deliberations.

The panel worked from a preliminary document prepared by an *ad hoc* committee formed in 2000 by the Adult Blood Lead Epidemiology and Surveillance Program (ABLES), representing 37 state occupational health programs. In addition to eleven envi-

ronmental scientists including distinguished occupational health physicians, the AOEC panel included two representatives of the lead industry. The hope was to achieve consensus.

At the first and only face-to-face meeting of the AOEC expert panel in 2003, it became evident that two very different camps were represented. One was committed to protecting the lead industry, and downplayed the epidemiologic evidence of health effects. The other was committed to protecting health, and believed that cost analysis was not appropriate for medical experts; economic issues should be considered separately from medical science issues. After two and a half years of almost monthly telephone conference calls, not surprisingly, no consensus was reached. No guidelines were released by the panel. The story of how lead industry interests delayed the development of guidance for the management of lead-exposed adults follows.

One of the most enduring arguments against industry's responsibility to correct the conditions that cause lead poisoning is that industry did not know how toxic lead was. Yet use of lead by humans precedes written records, and knowledge of its hazards can be traced back two millennia. While early descriptions of lead poisoning provided a basis for clinical diagnosis when the lead source was evident, the cause remained debatable when the source was not obvious and the symptoms non-specific. Towards the end of the twentieth century, large epidemiologic studies in the general population documented adverse lead effects in adults as well as in children even at very low levels of exposure.

The conflict between industry and public health was clearly drawn. The medical community found it difficult to justify subjecting workers to a completely preventable disease. On the other hand, industry has an obligation to protect the interests of its stockholders. The Lead Industry Association (LIA) had a fiduciary responsibility to defend lead industry interests. The LIA exercised that responsibility by protesting published diagnoses of lead poisoning as incorrect in the first quarter of the twentieth century. When denial and blaming the victim would no longer satisfy an increasingly concerned public, the LIA attacked the science and the scientists. They dubbed the scientists, "environmentalists," with all the pejorative connotations of a four letter word.

Healthy skepticism was transformed into cynical denial. The lead industry attempted to undermine any conclusions that might lead to preventive action. The LIA had reason to believe that the interpretation of data was subject to bias since it could easily purchase the services of scientists willing to spotlight the uncertainty inherent in epidemiologic studies. The industry also found that there was a soft underbelly to environmental science. Statistics do not command the compelling causal logic of the germ theory.

With the "level of concern" for blood lead in children set at 10 μg/dL by the CDC, and the OSHA standard for occupational exposure remaining at 50 μg/dL, the AOEC panel met in Washington, D.C. in 2003. A physician nominated to the panel by the Battery Council International (BCI), stated the industry's position in an email to fellow panelists. The industry would oppose any recommendations that would set the level of concern for workers at that set for children. With the exception of the two industry representatives, the panelists had agreed that lowering the acceptable blood lead level from 50 μg/dL to 10 μg/dL was justified by the epidemiologic data which indicated no threshold. How the recommendation should be phrased was discussed in conference calls over a period of two years. The concept of cumulative exposure over time was stressed and the limit for long-term exposure was set at 10 μg/dL.

A compromise seemed to be reached on the most crucial issue, setting the acceptable upper limit for short term exposure in the workplace at 20 μg/dL, half the OSHA standard, but twice the CDC level for children. This high blood levels were hard to defend on scientific grounds in view of the evidence that there was no threshold; harm had been detected at the lowest blood lead levels examined. The compromise took into account the practical desire for slow change but was, nevertheless, to no avail. After the compromise seemed acceptable to all the panelists, industry demanded that the panel reconsider "feasibility."

After seeming to agree with the compromise, the industry representatives came back with strong objections. On February 10, 2004 the panelists received an email stating: *"Using even crude estimates the vast majority of lead workers worldwide would exceed these estimates and require immediate re-*

moval without any medical evaluations. This would create chaos and widespread workers compensation claims despite most of the workers having no specific findings, symptoms or complaints and no measurable methods of proof or medical evaluations that would disprove any of the subtle effects projected by the calculated 'models'". Rejecting, out of hand, epidemiologic evidence of mental dysfunction, hypertension, and kidney disease in asymptomatic individuals with blood leads below10 μg/dL, the industry representatives continued to define lead poisoning by overt neurological symptoms. They refused to accept the fact that epidemiologic evidence had changed the definition.

Another email from an industry spokesperson echoed British common law: *"There are no risk free jobs and workers are usually made aware of risks and given reasonable protection and accept some risk with almost any job. When the leadership (Wedeen) of the AOEC panel decided to ignore any feasibility issues in the writing of this document for practical use in the workplace, it placed itself above any previous occupational guideline ever developed for this type of document"* (February 11, 2004). *"The reality of the current control of exposure is that it would not be possible to maintain a work force in those industries below 20 μg/dL on an ongoing basis with present day methods"* (May 24, 2004). Industry representatives insisted that the panel include corporate costs, euphemistically labeled "feasibility," in the medical assessment. Feasibility remained the fatal flaw in the attempt to achieve consensus.

Complaints about the guidelines and about the Chair of the Panel (Wedeen) promptly went to the attorneys of the BCI. The BCI attorneys made their displeasure known to the AOEC, and copied their letter of protest to the Director of the Department of Health and Human Services, the Director of ATSDR, and the Director of NIOSH, sponsors of the AOEC. The political clout was not lost on the AOEC. In another email, the industry spokesperson observed that Wedeen was "obviously biased towards the 'radical environmentalists' and were [sic] openly hostile to including my [older] references or balanced information into the document provided by me or others with opposing views. This persistent hostility and bias are the primary reasons that the legal people at BCI became involved." There was no response to a request that the "radical environmentalists" be identified.

The panel attempted to circumvent the "feasibility" controversy by reducing references to the OSHA occupational lead standard in the text, maintaining focus on adults in general, and women of childbearing age, in particular. Pregnant women were advised to avoid blood leads over 10 μg/dL. Some of the panelists agreed that regulations reducing lead in the workplace might be detrimental to workers costing some of them their jobs. These panelists, therefore, favored less restrictive recommendations permitting more exposure despite the potential harm. Confounding the medical recommendations with financial considerations had been rejected by most of the panel from the outset. After 2 years of bickering, and in response to the personal accusations, the Chair made his opinions abundantly clear in an email on August 17, 2005 which contained the following paragraph: "*Lead industry tactics to avoid the engineering requirements to protect workers and the public from the adverse effects of lead are well known. They have been nicely summarized in the June 2005 issue of the Scientific American by David Michaels, PhD, former Assistant Secretary for Environment, Safety and Health for the Department of Energy, in a paper entitled, "Doubt is Their Product." The industry strategy to undermine science, spread disinformation, make personal attacks on scientists, and initiate lawsuits in order to delay meaningful environmental health policies is documented in that paper [later expanded into a book]".*

The dissatisfaction of the BCI attorneys with the draft guidelines and my leadership was brought to the attention of the AOEC Board of Directors. "He has not been even handed. He has been antagonistic to those he views as 'industry representatives' since the first and only meeting of the panel." The panel Chair also received a personal letter from BCI International attorneys with thinly veiled threats.

In the end, the AOEC rejected the final draft prepared by the panel, and distributed a document that compromised further with industry stating that a blood lead up to 30 μg/dL was acceptable in adults. Feasibility trumped health.

As an epilogue to the aborted efforts of the AOEC, David Michaels was appointed Director of

OSHA by President Obama. Eight members of the panel recommended a 20 μg/dL upper limit for adults in a paper unconnected with the besieged AOEC. These guideline concepts were published in the journal *Environmental Health Perspectives* in March 2007. This publication did not have the imprimatur of the AOEC, but the crucial chart of blood lead levels and their effects was copied by the California Department of Public Health in "Medical Guidelines for the Lead-Exposed Worker" published in 2009 and used for "Guidelines for the Identification and Management of Lead Exposure in Pregnant and Lactating Women" to be released by the CDC in 2010.