Blood Lead Slope Factor Models for Adults: Comparisons of Observations and Predictions

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Here we explore the appropriateness of various parameter values for the Bowers et al. model [Risk Anal 14:183-189, 1994] in the context of predicting the influence of site-related exposure to lead in soil on the blood lead (PbB) levels of women of childbearing age. We outline the parameters prescribed by Bowers et al. as well as those prescribed by the U.S. Environmental Protection Agency (U.S. EPA). Comparison of the PbB levels predicted by the Bowers et al. model to those predicted by the validated O’Flaherty pharmacokinetic model indicates that the Bowers et al. model performs favorably when parameter values prescribed here are used. Use of the U.S. EPA-prescribed parameters yields predicted PbB levels that substantially exceed the validated O’Flaherty model predictions. Finally, both the U.S. EPA-prescribed parameter values and the parameter values recommended herein are used to predict PbB levels among adults living in four Superfund communities. Comparison of predicted PbB levels for these communities indicates that the U.S. EPA parameters overstate the incremental influence of lead in soil on PbB levels. Differences between the parameter values prescribed here and the U.S. EPA-prescribed parameters yield substantially different cleanup criteria for lead in soil, although conservative parameter values may still be appropriate for screening purposes — Environ Health Perspect 106(Suppl 6):1569-1576 (1998). http://ehpnet1.niehs.nih.gov/docs/1998/Suppl-6/1569-1576bowers/abstract.html

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The potential health effects of environmental lead on children are often the focus of risk assessment and site remediation proposals, and adults are assumed to be protected by the standards developed for children because of their lower susceptibility to health effects associated with lead. However, adults may be exposed to lead in industrial settings where children are not a population of concern. Recent work (1,2) has resulted in the development of models designed to predict blood lead (PbB) levels in adults arising from environmental and other exposures to lead. Such models can be used to assess the impact of soil lead concentrations on adult PbB levels, and in turn, can be used to calculate acceptable soil lead concentrations for industrial sites.

The U.S. Environmental Protection Agency (U.S. EPA) has recently focused on the adult lead model developed by Bowers et al. (2) and is recommending its use for the calculation of industrial site soil lead cleanup levels based on assumptions concerning adult exposure to lead (3). Acceptable soil lead concentrations are based on a requirement that a percentage of adults have PbB levels below a specified target PbB level. The U.S. EPA has chosen to focus on protection of pregnant women in the workplace and their unborn children and has therefore specified that exposure must be limited to ensure that the fetus has a 95% probability of having a PbB level below 10 µg/dl.

When any model is used in a regulatory context such as the U.S. EPA proposal just described, it is important that the model be validated; that is, model predictions must be compared to empirical observations, and this comparison must demonstrate that the model’s predictions in some sense compare favorably to these observations. The purpose of this paper is to present comparisons of PbB levels predicted by the Bowers et al. model with adult blood lead information from Superfund sites and to assess whether such comparisons can be used to constrain values assigned to the model’s input exposure parameters. We also compare predictions calculated by the Bowers et al. model to predictions calculated by the O’Flaherty model (1).

Description of the Bowers et al. Adult Blood Lead Model

The Bowers et al. model predicts a median PbB level estimate for an adult (PbB

\[ Pb_{\text{adult}} = Pb_{\text{baseline}} + \left( \frac{BSF \times C}{I \times A \times FS \times EF \times K} \right) \]  

where

- \( Pb_{\text{baseline}} \) = baseline blood lead level attributable to non-site exposures (µg/dl);
- \( BSF \) = biokinetic slope factor (µg/dl lead blood per mg/day lead uptake);
- \( C \) = concentration of lead in soil (µg/g);
- \( I \) = soil ingestion rate (g/day);
- \( A \) = fraction of lead in soil that is absorbed (dimensionless);
- \( FS \) = fraction of ingested soil that is from the contaminated site;
- \( EF \) = exposure frequency, equal to the number of days per year during which an individual is exposed to site soil (days/year);
- \( K \) = conversion constant (years/day) or 1/365.

The term in the parentheses on the right side of Equation 1 is the increment to PbB levels that is attributable to exposure to site soil.

The U.S. EPA has selected a target to protect the fetus such that no more than 5% of fetuses have PbB levels exceeding 10 µg/dl (PbB

\[ Pb_{\text{target}} = Pb_{\text{adult}} \times R_{fetal/adult} \times GM^{0.45} \]

where

- \( R_{fetal/adult} \) = ratio of fetal PbB levels to maternal PbB levels (dimensionless).
GSD = geometric standard deviation of PbB levels among women of childbearing age (dimensionless). The geometric standard deviation (the antilog of the arithmetic standard deviation of the log-transformed data) is a measure of the range, or spread, in PbB levels for a group of people.

Equation 2 assumes that the distribution of PbB levels is log-normal. Under these conditions, the 95th percentile PbB level in the population is GSD1.645 times higher than the geometric mean PbB level in that population, which in this case is equal to the product of PbBadult and Rfetal/adult.

Model Parameters

The predictions generated by the Bowers et al. model depend on the values selected for each of the parameters in Equation 1. Equation 2 must then be satisfied to ensure that 95% of the unborn children have PbB levels below PbBtarget or 10 μg/dl. This section describes recommended parameter values for these equations based on Bowers et al. (2) and current work described here, as well as on values the U.S. EPA recommends for these parameters. Values for each of these parameters can be based on site-specific information. The following discussion focuses on default values that can be used in lieu of such information.

Geometric Standard Deviation

To protect unborn children, the assumed value of the geometric standard deviation should reflect the range of PbB levels that would arise in a local population of women of childbearing age. The Third National Health and Nutrition Examination Survey (NHANES III) database, which provides the best and most recent nationally representative survey of PbB levels, identifies each subject’s location in terms of four broad regions in the United States (Midwest, Northeast, South, West). For women of childbearing age between the years of 20 and 40, geometric standard deviation in these four geographic areas ranged from approximately 1.8 to 1.95 during Phase 1 (1988–1991), and from approximately 1.75 to 1.9 during Phase 2 (1991–1994), as indicated in Table 1. Note that Brody et al. (4) define the population of childbearing women as ranging between 12 and 49 years of age. Because relatively few women over 40 years of age bear children and very few women below the age of 20 are expected to work at sites with highly contaminated soil (because of school age requirements and child labor laws), we have restricted our definition of this group to include women between 20 and 40 years of age.

The U.S. EPA has recommended a geometric standard deviation of PbB levels between 1.8 and 2.1 (3), with the low end of the range recommended for a homogeneous population and the high end of the range recommended for a heterogeneous population. However, the NHANES III data indicate that this range may place too much emphasis on high values. Moreover, at individual sites, heterogeneity in PbB levels can be expected to be substantially less, as the geographic regions referred to in Table 1 are very large. Because these regions are so large, the geometric standard deviation values are inflated by the wide range of lead exposure conditions (e.g., soil and dust lead concentrations) across these regions. In contrast, when identifying a target soil lead concentration for an individual site, the population is exposed to that particular concentration of lead. To account for the tendency for site-specific geometric standard deviations to be smaller than geometric standard deviations for populations living over a broad geographic area, we assume that values from 1.7 to 1.9 are a reasonable range for the GSD for women of childbearing age.

Fetal/Adult Ratios

For the purpose of this investigation we assume the value of the fetal-adult ratio parameter is 0.9, meaning that the PbB level of the fetus is approximately 90% of the PbB level of the mother. This is the same value that the U.S. EPA prescribes for this parameter.

Baseline Blood Lead Levels

Based on data collected as part of the NHANES III study (4,5), the U.S. EPA recommends that baseline PbB levels range from 1.7 to 2.2 μg/dl among women of childbearing age who are not exposed to substantial sources of lead beyond background. For our comparison of the Bowers et al. model to the O’Flaherty model, we set PbBbaseline equal to the baseline PbB level predicted by the O’Flaherty model for a 20-year-old woman born in 1970 who is not exposed to any substantial sources of lead above background exposures (next section). For other analyses, we use a baseline PbB level of 2.0 μg/dl, which is approximately the midpoint of the U.S. EPA recommended range of 1.7 to 2.2 μg/dl.

Biokinetic Slope Factor

A study of the relationship between PbB levels and tap water lead concentrations for 941 middle-aged men living in Britain (6) can be used to estimate the biokinetic slope factor for adults. The study concluded that each increase in the concentration of lead in drinking water of 1 μg/l is associated with an increase in PbB levels of 0.06 μg/dl. Assuming that the change in PbB levels (ΔPbB) attributable to changes in the concentration of lead in water (ΔCw) is equal to

\[ \Delta \text{PbB} = \text{BSF} \times A_w \times I_w \times \Delta C_w \]  

where \( A_w \) and \( I_w \) are the absolute absorption rate for lead in water and intake rate for water, respectively, then the BSF is equal to \( \Delta \text{PbB} \) divided by the product of \( A_w \) \( I_w \) and \( \Delta C_w \).

A value of BSF was calculated by Bowers et al. (2) by assuming that all lead in drinking water is soluble and that 8% of soluble lead is absorbed into the circulatory system (see below). Assuming that men in this study ingested 2 liters/day of tap water suggests that the BSF is equal to 0.375. The U.S. EPA presents an alternative analysis in which a BSF value of 0.4 is derived (3).

Lead Concentration

The concentration of lead in soil is site specific, or in the case of a cleanup level, calculated. Note that this parameter must reflect the fact that soil ingestion may consist of both exterior soil ingestion and

Table 1. Summary blood lead data for women of childbearing age (20 to 40 years) based on NHANES III, Phase 1 (1988–1991) and Phase 2 (1991–1994).

| Region        | Geometric mean (μg/dl) | GSD | Phase 1 | Geometric mean (μg/dl) | GSD | Phase 2 |
|---------------|------------------------|-----|---------|------------------------|-----|---------|
| Midwest       | 1.84                   | 1.94|         | 1.48                   | 1.89|         |
| Northeast     | 2.39                   | 1.82|         | 1.74                   | 1.76|         |
| South         | 1.54                   | 1.88|         | 1.42                   | 1.77|         |
| West          | 1.77                   | 1.83|         | 1.36                   | 1.81|         |
interior dust ingestion, depending on the pattern of worker exposure. Dust lead concentrations are typically less than soil lead concentrations in the absence of additional interior sources of lead such as paint. As a result, the adjusted soil concentration parameter value, which is a time-weighted average of the soil and dust lead concentrations, may be less than the soil lead concentration per se at the site.

**Soil Ingestion Rate**

Although several investigators have empirically measured the amount of soil children ingest daily (7), little information is available concerning the amount of soil adults ingest. However, it seems likely that the soil ingestion rate among adults is less than is among children, as the hand-to-mouth behavior that is prevalent during childhood is virtually absent among adults (8, 9). Recent analyses indicate that the median ingestion rate among children is 0.04 g/day (7). We assume that the adult ingestion rate is 50% of the childhood rate, or 0.02 g/day. (Here, soil ingestion rates are time-averaged values for each child studied.) The U.S. EPA recommends a value of 0.05 g/day for this parameter (3).

**Absorbed Soil Lead**

The fraction of ingested soil lead that is absorbed into the body’s circulatory system is equal to the product of the fraction of lead in soil that is soluble in the gastrointestinal tract and the fraction of soluble lead that is absorbed. In the context of childhood risk assessments, the U.S. EPA guidance for the integrated exposure uptake biokinetic (IEUBK) model recommends assuming that 60% of lead in soil is soluble (10). The U.S. EPA also uses this value in the context of adult risk assessments (3), in part based on preliminary work examining adult absorption of lead from soil (11). It should be noted that the fraction of lead in soil that is soluble can be highly site specific. The O’Flaherty model predicts no assumption about the amount of soil lead that is soluble; however, the O’Flaherty model’s default parameter values assume that in adults 8% of this soluble lead is absorbed. Therefore, based on the O’Flaherty model assumptions about absorption of soluble lead, the absolute absorption rate, or the product of these two factors for the absorption rate of lead in soil, is 4.8% (60% × 8%).

It should be noted that the fraction of soluble lead absorbed into the body’s circulatory system among women of childbearing age, and especially among pregnant women, is somewhat controversial. The U.S. EPA recommends using a value of 20% (and hence an absolute absorption fraction of 20% × 60%, or 12%) (3) rather than the aforementioned soluble lead absorption rate of 8% assumed in the O’Flaherty model. Two possible reasons given by the U.S. EPA work group (3) for suspecting that absorption of soluble lead may exceed the 8% value are a) altered calcium metabolism during pregnancy, and b) fasting, which affects all adults.

Although calcium metabolism changes during pregnancy (and hence lead metabolism, as the body treats these two substances similarly), other physiologic factors also change during pregnancy. For example, blood and other tissue volume increase during pregnancy, so that even if the absolute quantity of lead in a woman’s body increases during that period, the concentration of lead in various tissues like blood may not increase. Moreover, lead excretion may increase during pregnancy, offsetting a potential increase in lead absorption.

The largest study of its kind to date (12) found that PbB levels did not increase among lead-exposed women during pregnancy. This empirical finding indicates that no special adjustment to the absorption parameter is necessary to account for pregnancy-related phenomena. We will therefore assume that among pregnant women, 8% of soluble lead is absorbed.

Fasting has an effect on lead absorption, with absorption increasing as a function of hours between meal times (13). However, a time-averaged absorption value of 8% is not implausible. James et al. (13) note in the introduction to their paper that although absorption of soluble lead after a prolonged period of fasting is approximately 60%, absorption of soluble lead at mealtime is about 4%. Moreover, validations of the O’Flaherty model indicate that the 8% absorption rate value is valid for chronic long-term exposures to lead (1).

**Ingestion from Site-Affected Soils**

We assume that 50% of ingested soil is from site-affected soils. This value reflects the assumption of an 8-hr workday. During the remaining waking hours, adults may ingest soil and dust at other locations (e.g., at home or while recreating). As the U.S. EPA omits this parameter from its version of the Bowers et al. model, the agency effectively assumes that its value is 100% (3).

**Exposure Frequency**

We assume that individuals are exposed to site soil 250 days per year. This frequency reflects the assumption that exposure occurs during weekdays 50 weeks per year (i.e., an individual works 5 days per week and spends 2 weeks away from the site each year). The U.S. EPA currently recommends a central tendency exposure frequency of 219 days per year (3).

**Description of the O’Flaherty Model**

The O’Flaherty model has been described elsewhere in detail (1) but is briefly summarized here. The model is a complex multicompartment pharmacokinetic model that calculates PbB levels for an individual as a function of time from birth until any selected adult age, thus reflecting an integrated lifetime exposure to lead. The model accommodates multiple pathway exposure scenarios, including lead intake through diet, water ingestion, inhalation, and soil and dust ingestion for children. We have modified a version of the model to include a soil and dust ingestion pathway for adults in order to perform the comparisons described below.

Several standard assumptions concerning typical lead exposures for the U.S. population over the past few decades are built into the model. Alternative exposure scenarios, including short-term exposures and non-steady-state exposures, can also be modeled. The model has been extensively validated by comparing predicted PbB levels with data from several adult exposure studies, with excellent results (1).

**Comparison of Blood Lead Levels Predicted by the Bowers et al. Model and the O’Flaherty Model**

This section compares PbB level predictions calculated by the Bowers et al. model to PbB level predictions calculated by the O’Flaherty model. The population of interest is women of childbearing age exposed to soil with elevated lead concentrations.

There are differences between the O’Flaherty model and the Bowers et al. model that complicate comparison of their predictions. Unlike the Bowers et al. model, which provides a single PbB level estimate as a function of static exposure assumptions, the O’Flaherty model characterizes the pharmacokinetics of lead over time. Specifically, the O’Flaherty model simulates the intake, uptake,
distribution, and excretion of lead over time as an individual ages. Because the PbB levels predicted by the O’Flaherty model depend on both current exposure and the body’s accumulated lead burden (which in turn reflects past exposures), all exposures to lead since birth must be specified to use the O’Flaherty model. In contrast, the Bowers et al. model requires detailed specification of only current lead exposure. Past exposure is reflected in the value of PbBbaseline. In addition, the O’Flaherty model predicts PbB levels over time, whereas the Bowers et al. model provides only one estimate of PbB levels that represents body lead burden at any adult age. It is therefore not clear which PbB levels calculated by the O’Flaherty model should be compared to the PbB levels predicted by the Bowers et al. model.

With these differences in mind, we used the following parameter values in the Bowers et al. model to predict PbBadul, and where possible, the assumptions for the corresponding parameters in the O’Flaherty model.

PbBbaseline: this value was set equal to the blood level lead predicted by the O’Flaherty model for a 20-year-old woman not exposed to any site-affected soil containing lead.

BSF: as noted in the preceding section, this parameter is assumed to equal 0.375 ng/dl per µg/day lead uptake. There is no explicit corresponding value in the O’Flaherty model, as the BSF reflects the model’s pharmacokinetic simulation.

C: as described below, we compare predictions calculated by the Bowers et al. model to comparisons calculated by the O’Flaherty model under four different site soil lead concentration scenarios: C = 0 µg/g, C = 500 µg/g, C = 2500 µg/g, and C = 10,000 µg/g.

T: both models assume the daily soil ingestion rate is 0.02 g/day.

A: both models assume that for adults, 8% of ingested soluble lead is absorbed into the body’s circulatory system. Both models assume that 60% of lead in soil is soluble. Hence, absolute absorption of lead in soil is 4.8% (60×8%).

FS: both models assume that 50% of ingested soil is from the contaminated site.

EF: both models assume that subjects are exposed to site-affected soil 250 days per year.

For the O’Flaherty model, we assume that exposure of individuals to site-affected soils begins at 19 years of age and continues for the duration of the simulation, i.e., through age 40. We used default parameters to quantify exposure to lead via other pathways (e.g., dietary lead and lead in tap water). The O’Flaherty model predicts that a female born in 1970 who is not exposed to site-affected soil containing lead will have a PbB level of 3.73 µg/dl at age 20. For the Bowers et al. model, we assume that this level represents the value of PbBbaseline.

Table 2 compares the PbB levels predicted by the Bowers et al. model to the PbB levels predicted by the O’Flaherty model for ages 20, 25, and 40. Comparisons are made for site soil lead concentrations of 0, 500, 2500, and 10,000 µg/g.

The results in Table 2 indicate that the two models produce similar PbB level predictions when the specified parameter values are used. The Bowers et al. model is more conservative (i.e., predicts higher PbB levels) when compared to the predictions calculated by the O’Flaherty model after 1 year of exposure to site-contaminated soils. When the Bowers et al. model predictions are compared to the O’Flaherty predictions after 6 years of exposure, the Bowers et al. predictions appear to be even more conservative for small to moderate exposures (up to 2500 µg/g). However, the gap between the predictions of the two models narrows in the case of an assumed concentration of 10,000 µg/g. Finally, compared to the O’Flaherty predictions for PbB levels after 20 years of exposure, the Bowers et al. model is still more conservative, with the exception of the scenario in which site soil lead concentrations are assumed to be 10,000 µg/g. In this last case, the Bowers et al. model-predicted PbB level is somewhat lower than the O’Flaherty model prediction (4.96 vs 5.42 µg/dl).

Note that one factor complicating comparison of these models is that the O’Flaherty model predicts that because of lead excretion the baseline PbB level will decrease with age for an adult not exposed to lead in soil. That is, excretion of lead outweighs the effect of ongoing background level exposures. The O’Flaherty model also predicts that the effect of excretion outweighs the effect of exposure to the sum of background lead concentrations and exposure to soil containing low concentrations of lead. As the results in Table 2 indicate, for the specified exposure conditions, it is not until the concentration of lead in soil reaches 10,000 µg/g that lead uptake outweighs excretion; as a result, PbB levels increase with age. Actually, for the parameters specified, PbB levels increase with age for some level of lead in soil between 2500 and 10,000 µg/g. The exact break-even point could be identified by conducting additional simulations.

Table 3 offers an alternative way to view these predictions. Here, each cell is the difference between the predicted value in the corresponding cell in Table 2 and the baseline PbB level concentration of 3.73 µg/dl at age 20.

The results in Table 3 show that the incremental PbB levels predicted by the Bowers et al. model are similar to, although somewhat greater than, the incremental values predicted by the O’Flaherty model after 1 year of exposure. After 6 years of exposure, the O’Flaherty model predicts a higher increment in PbB levels because of exposure to higher lead concentrations in soil. However, because the “no soil lead exposure” PbB level predicted by the O’Flaherty model drops between the ages of 20 and 25, a decrease that the Bowers et al. model cannot consider because the model is a static equation, the Bowers et al. model predicts higher PbB levels for each soil lead concentration at ages beyond 20 years. PbB levels at age 40 reflecting exposure to soil containing 10,000 µg/g lead is the one exception to this pattern. For example, the incremental effect of a soil lead concentration of 10,000 µg/g (compared to no exposure) on PbB

### Table 2. Comparison of the Bowers et al. and O’Flaherty models: predicted blood lead levels.

| Soil lead, µg/g | Bowers et al. model | O’Flaherty model at age 20, 1-year exposure | O’Flaherty model at age 25, 6-year exposure | O’Flaherty model at age 40, 21-year exposure |
|----------------|---------------------|-------------------------------------------|-------------------------------------------|-------------------------------------------|
| 0              | 3.75*               | 3.73                                      | 3.03                                      | 2.34                                      |
| 500            | 3.79                | 3.78                                      | 3.13                                      | 2.50                                      |
| 2,500          | 4.04                | 3.98                                      | 3.48                                      | 3.13                                      |
| 10,000         | 4.96                | 4.74                                      | 4.82                                      | 5.42                                      |

*Set equal to O’Flaherty model prediction for a 20-year-old woman not exposed to site-affected soils containing lead.
levels predicted by the Bowers et al. model (1.23 μg/dl) is less than the incremental effect predicted by the O'Flaherty model at age 25 (1.09 – 0.70, or 1.79 μg/dl). Nevertheless, the Bowers et al. model predicts a higher PbB level of 4.96 μg/dl among individuals exposed to soil containing 10,000 μg/g lead, compared to the O'Flaherty model prediction of 4.82 μg/dl at age 25. At age 40, the incremental effect of a soil lead concentration of 10,000 μg/g on PbB levels predicted by the O'Flaherty model (1.69 to –1.39, or 3.08 μg/dl) exceeds the incremental increase predicted by the Bowers et al. model (1.23 μg/dl). However, the O'Flaherty model continues to predict lower PbB levels when soil lead concentrations are assumed to be 2500 μg/g or less. The differences between the two models described in the preceding paragraph reflect two factors: a) the O'Flaherty model's predictions reflect the general decline in PbB levels with age when exposure to lead is low to moderate (hence the negative values in the first three rows of the age 25 and age 40 columns in Table 3); and b) the O'Flaherty model predicts a stronger association between soil lead concentrations and PbB levels after several years of exposure. The Bowers et al. model, which does not provide temporal detail for predicted PbB levels, collapses these two phenomena, resulting in higher predicted PbB levels associated with low to moderate soil lead exposure but a smaller incremental increase in PbB levels associated with changes in soil lead concentrations for exposure periods beyond approximately 2 years.

A comparison of PbB levels predicted by the Bowers et al. model and the O'Flaherty model at specified soil lead concentrations depends on the value of several exposure parameters. We present a further comparison of the two models using the U.S. EPA recommended values (3) for two of the exposure parameters:

1: Daily soil ingestion is 0.05 g/day. 
FS: The fraction of soil ingested that is from the affected site is 100%.

Table 4 details the predictions made by the Bowers et al. model and the O'Flaherty model when these assumptions are employed. Comparing the values in Table 4 to the values in Table 2 indicates that in all cases both models now predict substantially higher PbB levels. The results in Table 4 also indicate that the Bowers et al. model results are uniformly conservative when compared to the O'Flaherty model predictions at all ages for soil lead concentrations of 0 and 500 μg/g. At a soil concentration of 2500 μg/g, the Bowers et al. model's predictions are similar to the O'Flaherty model predictions. Finally, at a soil concentration of 10,000 μg/g, the O'Flaherty model predictions exceed the Bowers et al. model predictions for exposure periods exceeding 3 years (detailed simulation results by year not shown).

PbB levels predicted by the O'Flaherty model have been compared to the results reported by a number of controlled exposure studies and to the results from several epidemiologic studies (1). None of these studies included exposure to adults through the ingestion of soil. However, accurate prediction of PbB levels reflecting exposure to lead in water and food depends on the assumed fraction of soluble lead absorbed into the body's circulatory system. O'Flaherty assumed that 8% of soluble lead is absorbed, and the excellent comparisons reported in her paper between predicted and observed PbB levels strongly support the assumption that 8% is a reasonable average absorption value for adults over a chronic time period. The favorable comparisons shown here between the PbB levels predicted by the Bowers et al. model and the O'Flaherty model suggest that 8% is also a good choice for soluble lead absorption in the Bowers et al. model.

### Comparison of Blood Lead Levels Predicted by the Bowers et al. Model with Observed Levels at Superfund Sites

An alternative approach to evaluating the parameter value assumptions for the Bowers et al. model directly compares the model's predictions to empirical PbB level data. We compiled average PbB levels among pregnant women, nursing women, and other adults, as well as average soil and dust lead concentrations in their communities for a number of Superfund sites: Midvale, Utah; Butte, Montana; Leadville, Colorado; and Granite City, Illinois (14-17). Table 5 lists average PbB levels for pregnant women, nursing women, and other adults in the four Superfund communities.

Table 6 details soil lead concentrations, dust lead concentrations, and bioaccessibility values. Column 5 of Table 6 is the average bioaccessible soil and dust lead concentration for each community. This parameter is the average of the lead concentration in dust and the lead concentration in soil multiplied by a bioaccessibility factor for that community that represents the fraction of lead in those media that are soluble and hence bioaccessible in the human gastrointestinal tract. Default bioaccessibility values are assumed for Leadville and Granite City; bioavailability for Butte and Midvale are based on information available in the risk assessments performed for children at these sites (18,19).

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**Table 3.** Comparison of the Bowers et al. and O'Flaherty models: predicted incremental blood lead levels relative to the baseline value of 3.73 μg/dl.

| Soil lead, μg/g | Predicted PbB level increment relative to the baseline value of 3.73 μg/dl |
|----------------|--------------------------------------------------------------------------------|
|                | Bowers et al. model | O'Flaherty model at age 20, 1-year exposure | O'Flaherty model at age 25, 6-year exposure | O'Flaherty model at age 40, 21-year exposure |
| 0              | 0                   | 0                                             | –0.70                                      | –1.39                                      |
| 500            | 0.06                | 0.05                                          | –0.60                                      | –1.23                                      |
| 2,500          | 0.31                | 0.25                                          | –0.25                                      | –0.60                                      |
| 10,000         | 1.23                | 1.01                                          | 1.09                                       | 1.69                                       |

**Table 4.** Comparison of the Bowers et al. and O'Flaherty models using revised assumptions: predicted blood lead levels.

| Soil lead, μg/g | Predicted PbB levels, μg/dl |
|----------------|------------------------------|
|                | Bowers et al. model | O'Flaherty model at age 20, 1-year exposure | O'Flaherty model at age 25, 6-year exposure | O'Flaherty model at age 40, 21-year exposure |
| 0              | 3.73*               | 3.73                                          | 3.03                                       | 2.34                                       |
| 500            | 4.04                | 4.0                                           | 3.6                                        | 3.1                                        |
| 2,500          | 5.27                | 5.0                                           | 5.2                                        | 6.2                                        |
| 10,000         | 9.88                | 8.6                                           | 11.4                                       | 16.2                                       |

*Set equal to O'Flaherty model prediction for a 20-year-old woman not exposed to site-affected soils containing lead.
Table 5. Average blood lead levels (µg/dl) and sample size in parentheses.

| Community       | Pregnant women | Nursing women | Other adults |
|-----------------|----------------|---------------|--------------|
| Midvale, UT (14) | 1.71 (18)      | 2.62 (16)     | 2.68 (43)    |
| Butte, MT (15)  | 2.27 (24)      | 2.59 (11)     | 3.78 (48)    |
| Leadville, CO (16) | 2.23 (29)   | 2.07 (23)     | 3.52 (121)   |
| Granite City, IL (17) | 1.6 (14)    | Not available | 3.8 (123)    |

Table 6. Average environmental lead levels and sample sizes in parentheses.

| Community       | Soil lead, µg/g | Dust lead, µg/g | Bioaccessibility | Average bioaccessible soil and dust lead concentration* |
|-----------------|-----------------|-----------------|------------------|--------------------------------------------------------|
| Midvale, UT (14) | 511 (112)       | 540 (112)       | 0.48             | 252                                                    |
| Butte, MT (15)  | 905 (215)       | 625 (224)       | 0.24             | 184                                                    |
| Leadville, CO (16) | 1528 (203)     | 851 (245)       | 0.60             | 714                                                    |
| Granite City, IL (17) | 450 (375)     | 1283 (371)      | 0.60             | 520                                                    |

*The last column to the right is equal to the average of the soil and dust lead concentrations (columns 2 and 3) multiplied by the bioaccessibility value (column 4).

Figure 1 shows the PbB level averages in Table 5 plotted against the average bioaccessible soil and dust lead concentration in the far right column of Table 6 for each demographic group (pregnant women, nursing women, and other adults). Figure 1 also shows the best fit (ordinary least squares) regression line for each of these data sets. The slope of the regression line corresponding to each demographic group can be interpreted as the incremental impact of bioaccessible lead in dust and soil on PbB levels. Table 7 details the slope and intercept of the regression line corresponding to each data set.

These slopes can be compared to the slopes predicted by the Bowers et al. model using various assumptions for the BSF, the soil and dust ingestion rate, and the fraction of soluble lead that is absorbed into the body’s circulatory system. Note that the slope value need not be altered to reflect the relative bioavailability of lead in soil versus the bioavailability of soluble lead, as this factor has already been accounted for as a component of the values on the horizontal axis. Using the default parameter values recommended by Bowers et al. (*BSF*=0.375, soil ingestion = 0.02 g/day, soluble lead absorption = 8%), the predicted slope is $6 \times 10^{-4}$, a value similar to the observed slope values of $0$, $6 \times 10^{-4}$, and $9 \times 10^{-4}$. Use of the U.S. EPA recommended parameter values (*BSF*= 0.4, soil ingestion = 0.05 g/day, soluble lead absorption = 20%) in the Bowers et al. model yields a slope of $4 \times 10^{-3}$, which exceeds the observed slope values by a factor of 5 to 10. These results indicate that use of the Bowers et al. model with parameter values recommended here better predicts the observed slope describing the relationship between PbB levels and the average bioaccessible soil and dust lead concentration. Additionally, note that the intercepts reported in the far right column of Table 7 are somewhat less than the PbBbaseline value we calculated using the O’Flaherty model in the preceding section (3.73 µg/dl), and are within or exceed the range of baseline PbB levels recommended by the U.S. EPA (1.7–2.2 µg/dl). Alternative regression lines fit to these data would have either larger intercepts and smaller slopes (implying a smaller BSF value or absorption factor) or they would have smaller intercepts (implying a lower baseline PbB level) and larger slopes.

Figure 1 shows the observed relationship between PbB levels and environmental lead concentrations for Butte, Montana; Midvale, Utah; Granite City, Illinois; and Leadville, Colorado. The average bioaccessible soil and dust lead concentration values correspond to those given in Table 6, which are the average of the measured soil and dust lead concentrations multiplied by a site-specific bioaccessibility factor. • and ○ correspond to pregnant women; ♂ and ♂—represent to nursing women, and ▲ and ▲—represent other adults.

In light of the favorable comparisons between observed PbB levels for these communities and PbB levels predicted using the exposure parameter values recommended here, the Bowers et al. parameter value assumptions should be viewed as more plausible than the U.S. EPA parameter value assumptions. We conclude the following:

- The effect of lead in soil and dust on PbB levels at the four locations studied here is small for pregnant women, women who are nursing and for other adults.
- The product of the ingestion rate and the fraction of soluble lead absorbed into the circulatory system is better approximated by 0.02 g/day×8% than by the U.S. EPA recommended assumption of 0.05 g/day×20%.
- The product of our recommended values for the ingestion rate, absorption rate, and BSF is approximately equal to the observed slope values reported in Table 7 (6×10^{-4} and 9×10^{-4}). Because validation of the O’Flaherty model indicates that 8% is a reasonable value for the absorption parameter, the product of the ingestion rate and the BSF should be between 7.5×10^{-3} (6×10^{-4}+0.08) and 1.12×10^{-2} (9×10^{-4}+0.08). The product of the

Table 7. Predicted observed blood lead levels in adults at Superfund sites: the slope of the relationship between blood lead levels and the average bioaccessible soil and dust lead concentration.

| Group         | Slope, µg/dl per µg/g average bioaccessible soil and dust lead | Intercept, µg/dl |
|---------------|---------------------------------------------------------------|-----------------|
| Other adults  | $6 \times 10^{-4}$                                            | 3.14            |
| Pregnant      | 0                                                             | 1.93            |
| Nursing       | $9 \times 10^{-4}$                                            | 2.40            |
Table 8. Parameter values used for calculation of soil cleanup levels.

| Parameter                                | Value                        |
|------------------------------------------|-----------------------------|
| BSF (biokinetic slope factor)            | 0.375 or 0.4 µg/d PbB level per µg/day lead uptake |
| J (soil ingestion rate)                  | 0.02 or 0.05 g/day          |
| A (fraction of soil lead that is absorbed) | 60% (soil vs soluble) times 8, 12, or 20% (soluble lead) |
| FS (fraction of ingested soil from site) | 50 or 100%                  |
| K (conversion factor)                    | 1/365 years/day             |
| PbBbaseline (baseline PbB level)         | 2 µg/dl                     |
| R (ratio of fetal to maternal blood lead)| 0.9                         |

Table 9. Soil cleanup levels assuming alternate geometric standard deviation values.

| GSD | EF, days/year | Soil ingestion mediated by dust ingestion? | PbBabs, µg/dl | Soil lead cleanup level, µg/g |
|-----|---------------|-------------------------------------------|---------------|-------------------------------|
| Bowers et al. recommended parameter values: BSF=0.375, J=0.02 g/day, fraction of soluble lead absorbed = 8%, FS=50% |
| 1.7 | 250           | No                                        | 4.64          | 21,400                        |
| 1.9 | 250           | No                                        | 3.87          | 15,100                        |
| 1.7 | 250           | Yes                                       | 4.64          | 28,500                        |
| 1.9 | 250           | Yes                                       | 3.87          | 20,200                        |
| U.S. EPA recommended parameter values: BSF=0.4, J=0.05 g/day, fraction of soluble lead absorbed = 20%, FS=100% |
| 1.8 | 250           | No                                        | 4.23          | 1,350                         |
| 2.1 | 250           | No                                        | 3.28          | 770                           |
| 1.8 | 250           | Yes                                       | 4.23          | 1,800                         |
| 2.1 | 250           | Yes                                       | 3.28          | 1,020                         |

ingestion rate value and the BSF value we recommend is $7.5 \times 10^{-3}$ $(0.02 \text{ g/day} \times 0.375)$, a result that falls within the aforementioned range of $7.5 \times 10^{-3}$ and $1.12 \times 10^{-2}$. In contrast, the product of the U.S. EPA recommended values for these parameters $(0.05 \text{ g/day} \text{ and } 0.4)$ is $2.0 \times 10^{-2}$, which falls outside the observed range.

Use of the Bowers et al. Model to Set Soil Lead Cleanup Levels

In this section, we calculate soil cleanup levels using the Bowers et al. model (Equation 1), Equation 2, and the parameter values in Table 8. Table 9 considers alternative assumptions for several parameters, including: the geometric standard deviation, exposure frequency, the possibility that some fraction of soil ingested is comprised of dust, the soil ingestion rate, and the fraction of soluble lead that is absorbed. Note that mediation of soil ingestion by dust assumes that 50% of soil ingestion reflects dust ingestion, and that dust has a lead concentration equal to one-half the lead concentration in soil.

There is a wide disparity in the calculated cleanup levels shown in Table 9, reflecting the differences in exposure parameters. This observation underscores the necessity of choosing parameter values that reflect the exposure scenarios and populations representative of site usage. We believe that the U.S. EPA’s choice of exposure parameters, which result in cleanup levels between 770 and 1800 µg/g, are too conservative, for the reasons described in this communication. However, although we believe the cleanup levels derived here using our recommended parameters are health protective, we also understand that public policy considerations may mean that such soil lead concentrations are not suitable for generic screening purposes. In deriving technically defensible soil lead screening levels for use as a starting point to identify sites requiring further study and collection of site-specific information, we make the following recommendation. For those exposure parameters that are more uncertain such as adult soil and dust ingestion rates, we suggest choice of a conservative value. However, for those parameters such as absorption or the geometric standard deviation for which substantial information is available, we believe use of the values recommended here is most justified. In any event, soil lead concentrations in excess of screening levels are an indication that site-specific information should be collected; substantial parameter value uncertainty indicates a need for further research.

Conclusions

Predictions generated by the Bowers et al. model compare favorably to predictions generated by the validated O’Flaherty model when the parameter values prescribed herein are used. Although these two models are difficult to compare because of the complexity of the O’Flaherty model the results presented here strengthen the arguments for the use of 8% for soluble lead absorption. Using a soluble lead absorption much higher than 8% in the O’Flaherty model would result in that model overpredicting PbB levels compared to those seen in the studies used to validate the model.

Additionally, blood lead predictions generated using the Bowers et al. model prescribed exposure parameters as well as the U.S. EPA (3) recommended exposure parameters have been compared to observed average PbB data from a number of Superfund sites. Although blood lead–environmental lead slopes calculated using the parameters recommended herein compare favorably to the site data, slopes calculated with the U.S. EPA parameters substantially exceed observed slopes for these sites. This empirical evidence, when combined with the conclusions concerning the absorption of soluble lead based on a comparison of the Bowers et al. and O’Flaherty models, suggests that adult soil and dust ingestion rates for normal activities average about 20 m/g/day. Use of values much higher than those recommended herein for soluble lead absorption and soil and dust ingestion rates will result in a substantial overprediction of observed PbB levels at these sites.

Accurate prediction of PbB levels, together with the identification of scientifically justified soil lead levels, depends on the use of valid values for all parameters used in the model, including those not discussed in depth in this paper, such as the blood lead geometric standard deviation. Moreover, models such as those described here often help identify areas where research is most required to further reduce uncertainty.
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