

ANE 06-149 EGYPT S)16 Blood-Pb Survey Post - Remediation Blood Lead Level Survey in Shoubra El Kheima, Qalyoubia, July 13, 2006

Livelihood and Income from the Environment Program
Lead Pollution Clean-up in Qalyoubia

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PROTOCOL ABSTRACT

Lead is a widespread environmental contaminant found in air, drinking water, soil, canned food, beverages, and paint. It can enter the body through inhalation, ingestion, and dermal contact. Lead is considered as a toxin that has no biological function but causes adverse health effects. Children under seven years of age and fetuses are particularly susceptible to lead toxicity because of their developing nervous system, small body mass, and less ability to excrete lead from their bodies.

The private sector secondary lead smelting industry in the Cairo metropolitan area has traditionally been located in the northern suburb of Shoubra El Kheima, Qalyoubia. Shoubra El Kheima is a well known industrial-residential area in Greater Cairo that contains the greatest part of Egypt's lead smelting industry. Secondary lead smelters almost ceased activities in 2001 as the Egyptian government encouraged smelters to move to new industrial zones and install up-to-date technology to reduce harmful emissions from the smelting process. The former contaminated sites of secondary lead smelters were remediated in 2005 – 2006.

This study is intended to estimate the health benefit of closing the secondary lead smelters and remediation activities conducted following closure at the secondary lead smelters in Shoubra El Kheima. The population living in the vicinity of the smelters and those who were enrolled for the 2004 Epidemiologic Study for lead will be asked to participate again and submit a blood sample to compare it with the blood lead level (BLL) estimated in the 2004 Epidemiologic Study. Habits and behaviors of the study population that may influence exposure to lead will be determined again to estimate the effects of such habits and behaviors on BLL over time. The results are expected to guide further cost benefit analyses for the remediation activities and will inform policy makers and stakeholders about the importance of conducting such remediation activities in the future for additional contaminated sites.

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SCIENTIFIC BACKGROUND AND OBJECTIVES

Summary

This protocol is designed to provide a method for evaluation of the health effects of remediation activities conducted for the lead smelters in Shoubra El Kheima by the Livelihood and Income From the Environment Program's Lead Pollution Clean-up in Qalyoubia Project (LIFE-Lead). In this study, people who participated in the 2004 Epidemiologic Study will be identified and asked to participate in this follow-up study by giving a new blood sample.

The Blood Lead Level (BLL) of the new samples will be compared to the BLL of the old samples to estimate any difference in the BLL that may be attributed to the remediation activities including the closure of the sites. This would explain to what extent remediation activities were successful in terms of health gains by reducing the BLL of the population in the smelters area.

As this is the first time in Egypt to conduct remediation activities using standard methods with a very high cost, it is important to explore the health effects of such activities. This may enable cost benefit estimation of the on-site remediation activities. The results are expected to indicate that lead remediation shows a financial cost benefit based on the improved health conditions of local residents even with the high cost of site remediation.

The protocol was based on a sampling framework developed by NAMRU-3. The methodology has been changed to reflect blood lead level sampling versus the NAMRU-3 qualitative study that aimed to understand the behavior, knowledge and perceptions associated with typhoid transmission.

Background

Lead is a widespread environmental contaminant found in air, drinking water, soil, canned food, beverages, and paint. Lead is considered as a toxin that has no biological function but causes adverse health effects (US-EPA, 2003). It can enter the body through inhalation, ingestion and dermal contact. Children below seven years of age and fetuses are particularly susceptible to lead toxicity because of their developing nervous system, small body mass, and they have less ability to excrete lead from their bodies (Amira et al, 2000). In general, if adults and children swallow the same amount of lead, a bigger proportion of the amount swallowed will enter the blood in children than in adults (ATSDR, 1999).

Effects of lead on children include neurobehavioral manifestations such as decreased intelligence, developmental delay, and coma. A fetus could suffer decreased gestational age, weight, and miscarriage. Among adults, manifestations range from hypertension to encephalopathy at high blood lead levels (US-EPA, 2003). The biokinetics and toxic effect of lead differs according to gender. For example, during pregnancy and breast feeding, lead stored in bones of females may re-enter their blood and contribute to adverse health effects on both the mother and her baby (ATSDR, 1999).

In Egypt, some studies were conducted to estimate the BLL among children and some occupational groups in Shoubra El Kheima. The blood level for children living in Shoubra El Kheima was between 7.8 and 39 $\mu\text{g}/\text{dL}$ compared to blood lead levels between 4.5 and 12.1

µg/dL for children living in the Dokki Area used as a control area (Amira et al., 2001 and Salem et. al., 2000).

The private sector lead smelting industry in the Cairo metropolitan area has traditionally been located in the northern Cairo suburb of Shoubra El Kheima, Qalyoubia. Shoubra El-Kheima is a well known industrial-residential area in Greater Cairo that contains the majority of Egypt's lead smelting industry. Most of the environmental lead contamination coming from stationary sources (71.4%) in 2001 was attributed to the secondary lead smelting industry in this area (EEPP, 2003).

Several USAID-funded analyses have helped understand lead pollution in Egypt and the potential for reducing it. The threat of multimedia lead exposure was first estimated through a comparative risk analysis effort in 1994. This study ranked lead contamination as one of the country's most serious environmental problems. The Lead Exposure Abatement Plan (LEAP) further documented sources of human exposure to lead in Egypt and potential mitigation measures. A separate Lead Smelter Action Plan (LSAP) defined activities to reduce the threat of secondary smelters.

Beginning in 1997, the Cairo Air Improvement Program (CAIP) implemented the LSAP, relocating and upgrading smelters, supporting policy dialogue to reduce demand for lead-based products, and beginning to investigate contamination at smelter sites following relocation and closure.

An early CAIP study of secondary lead smelters in the governorates of Cairo, Giza, and Qalyoubia indicated that there were 22 lead smelters in the three targeted governorates. These 22 facilities represent the majority of secondary lead smelting operations in Egypt due to the area being a major source of the type of batteries used in secondary smelting and most battery manufacturing operations being located within the three governorates.

CAIP focused efforts in the area of Shoubra El Kheima, which has a population of approximately three million, and five lead smelters as well as approximately 150 other ferrous and non-ferrous foundries. The Awadallah family owns several facilities in Shoubra El Kheima and is responsible for an estimated 75 percent of the national lead smelting production (EEPP, 2003).

Lead smelter properties in Shoubra El Kheima are heavily contaminated with lead and other metals. Lead concentrations of more than 60 percent by weight were found in some of the soil samples during CAIP investigations at an Awadallah site.

Activities supporting the air objective of the Egyptian Environmental Policy Program (EEPP) further addressed contaminated smelter sites, as well as prohibited smelting activities and forced proper smelter site clean-ups in Shoubra El Kheima. Analyses under EEPP followed from and deepened the knowledge from work previously completed by the CAIP.

Secondary lead smelters almost ceased activities in 2001 as the Government of Egypt (GOE) encouraged smelters to move to new industrial zones and install up-to-date technology to reduce harmful emissions from the smelting process. Since 2001, most of the smelter facilities in the area have only been used to refine and manufacture lead products which still were a source of lead contamination to the environment.

In 2002, the CAIP prepared a Preliminary Assessment of the Awadallah Smelter No. 1 (CAIP, 2002). In 2003, the CAIP completed a more detailed soil and dust investigation of the Awadallah Smelter No. 1 and provided the results in a Contaminant Assessment Report (CAIP, 2003). In 2003, a systematic soil and dust sampling program was designed and

completed within a 1-kilometer radius of the Awadallah Smelter No. 1 by EPPP. The results of this sampling event are presented in a Site Investigation Report (EPPP, 2003a).

The results from the Preliminary Assessment and Site Investigation were used by EPPP to prepare a baseline human health risk assessment for receptors within the 1-kilometer radius of the Awadallah Smelter No. 1 (EPPP, 2003b). The results of the EPPP baseline human health risk assessment indicated that the Awadallah Smelter No. 1 presented a multitude of health hazards to workers, nearby residents, and the environment. Human health risks were presented for receptors within a 1-kilometer radius of the Awadallah Smelter No. 1 without differentiating between the various land uses. The risk assessment concluded that a large number of children are at risk of lead exposures that approximate poisoning and on that basis alone risk management actions should be undertaken including medical intervention.

Following the baseline human health risk assessment an epidemiological study was completed in collaboration with the Ministry of Health that documented the blood lead levels of residents living within a 1-kilometer radius of the Awadallah Smelter No. 1 (EPPP, 2004). Blood samples were collected from 299 subjects in 82 homes within the study area. The results of the study showed that 100 percent of men and women, and 84 percent of children less than 7 years of age who live near the smelters have blood lead levels higher than 10 $\mu\text{g}/\text{dL}$. The maximum measured blood lead level was 41 $\mu\text{g}/\text{dL}$ and the mean was 23 $\mu\text{g}/\text{dL}$ in the study area.

The study indicated that the elevated BLLs were associated with lead contamination in soil and dust in the study area (EPPP, 2004). The Epidemiological Study concluded that there is substantial risk to those living near lead smelters in Shoubra El Kheima and that remediation activities should commence immediately to protect residents from the hazards of lead in the environment.

In January 2004, the Governor of Qalyoubia issued a decree that prohibited lead smelting in Shoubra El Kheima, followed by another decree that prohibited the use of the closed lead smelter sites in Shoubra El Kheima unless they were remediated.

The overall goal of LIFE-Lead is to empower local residents in the polluted communities to improve their living conditions. The focus of the project is remediation at seven secondary lead smelter sites two public school, and a medical center. In addition to site remediation, the project includes activities in community involvement and public participation, communications, capacity building, and policy/legal support. The remediation activities conducted by the project do not include off-site activities although the main source for the off-site lead contamination, which are the smelters, are properly controlled with no more dispersion. The remediation activities are expected to conclude by the end of 2006.

Description of the Remediated Sites --

Awadallah Secondary Lead Smelters Nos. 1, 2, and 3--

As part of Awadallah's commitment to the Governorate of Qalyoubia (GOQ), Awadallah ceased operation at his three smelters in Shoubra El Kheima in 2004. Awadallah completed preliminary remediation activities at his three secondary lead smelters in the study area. These remediation activities consisted of painting the walls, excavation and removal of soil from the floors, backfilling with sand, and pouring a concrete cap on the floor over the remaining contaminated soil. These preliminary remediation activities limited the amount of contaminated soil carried from the site by workers and operations into the residential areas surrounding the sites.

Although Awadallah can be complimented for his efforts, significant lead contamination was still present at the site in quantities that were dangerous to the workers. LIFE-Lead completed the remediation in late May 2006 and clearance samples indicated that lead levels were below the allowable level as defined by the Risk Based Remediation Goals developed by the project in conjunction with the EEAA for industrial facilities.

Seoudi Secondary Lead Smelter--

The Seoudi Secondary Lead Smelter is located among an industrial area in close proximity to the Ismailia Canal Road. The Seoudi Smelter, which started operations as a leased facility in the late 1980's, was one of the main sources of lead pollution in the area. The 325 m² smelter included one rotary furnace and a filter that was not properly designed to regulate emissions from the smelter according to the Egyptian Environmental Law (Law 4/1994) requirements. The smelting process adopted in this smelter was lacking all measures of environmental controls; the rotary furnace was not designed according to standards, batteries were charged to the furnace without breaking, and proper pollution controls were not installed. Therefore, the Seoudi Smelter was closed by the GOQ in 2001.

LIFE-Lead remediated the smelter in the spring of 2006. Clearance samples indicated that lead levels were below the allowable level as defined by the Risk Based Remediation Goals developed by the project in conjunction with the EEAA for industrial facilities.

EI Mahy Secondary Lead Smelter--

The EI Mahy Smelter is one of the oldest smelting facilities in Shoubra El Kheima. It is located in a mixed residential/industrial area in Shoubra El Kheima on the Ismailia Canal Road. The plant footprint includes an area of approximately 2,000 m².

Operations started more than 25 years ago using two smelting furnaces and two kettles for lead refining as well as a pipe extrusion facility. The two smelting furnaces were fired by heavy fuel (Mazot). The smelting process adopted in the smelter was lacking all measures of environmental standards; batteries were charged to the furnace without breaking, and proper pollution control systems were not installed. In 1999, the owner removed the furnaces and confined site activities to refining and pipe extrusion, and subsequently natural gas was used for firing kettles.

LIFE-Lead remediated the smelter in the spring and early summer of 2006. Clearance samples indicated that lead levels were below the allowable level as defined by the Risk Based Remediation Goals developed by the project in conjunction with the EEAA for industrial facilities.

Hypothesis

Remediation activities that took place in the secondary lead smelters during the period 2005 through 2006 have dramatically improved the environment conditions in terms of lower lead concentrations in soil and on facility surfaces. After elimination of such sources of continuous lead dispersion to the surrounding environment, the off-site soil contents of lead are expected to decrease over time. Consequently, it is anticipated that high BLLs of the population living in this vicinity of the smelters, as estimated in the 2004 Epidemiologic Study, have been reduced.

The remediation activities for the secondary lead smelters listed above started in 2005 and is expected to conclude by the end of summer 2006. By the beginning of November 2006, this BLL study is expected to commence considering that the half life of the lead in blood is approximately 28 ± 4 days. It is anticipated that the BLLs in the original sample population will show decreases by November 2006 due to the remediation and community awareness and participation activities conducted by LIFE-Lead.

Determining the BLL of the population living in the vicinity of the remediated sites will enable the estimation of the direct health effect of the remediation and community awareness and participation activities on the population of the study area.

Goals and Objectives

There are two primary goals and objectives for this BLL Study. The goals and objective include the following:

- An estimate of the BLL in children below 7 years of age, females of reproductive age, and adult males living in the vicinity of the lead smelters following the completion of remediation and community awareness and participation activities.
- A comparison of the BLL of the population subgroups with that obtained in the 2004 Epidemiologic Study to estimate possible reduction in blood lead of the study population that may be attributed to remediation and community awareness and participation activities conducted by LIFE-Lead.

METHODOLOGY

Rationale for the Study

The previous uncontrolled operation of the secondary lead smelters in Shoubra El Kheima has contaminated soil, dust, and air in the area. Activities supporting the air objective of the EEPP further addressed contaminated smelter sites, as well as prohibited smelting activities and forced proper smelter site clean-ups in Shoubra El Kheima. Analyses under EEPP followed from and deepened the knowledge of the CAIP activities. Lead smelter sites in this neighborhood are heavily contaminated with lead and other metals. Lead concentrations of more than 60 percent by weight were found in some of the soil samples taken during the CAIP investigations at the Awadallah Secondary Lead Smelters (EEPP, 2003a).

In 2004, LIFE-Lead started remediation designs for the five secondary lead smelters. Due to remediation of the contamination sources (i.e., the secondary lead smelters), it is anticipated that the lead levels in soil outside the smelters will decrease overtime. The health effects of such remediation activities are undetermined and hence, the cost benefits of the remediation activities.

In this study, we will attempt to determine the health effect of the remediation activities of LIFE-Lead by estimating the reduction of BLLs of the population living in the vicinity of the smelters by comparing it to the previous BLLs estimated in the 2004 Epidemiologic Study.

It was estimated that the economic benefits of universal screening exceeds the cost when more than 14% of children had elevated blood levels above 10 $\mu\text{g}/\text{dL}$ blood (AAP, 1998). As long as 100% of adults and 84% of children had BLLs above the same limits as estimated in the 2004 Epidemiologic Study, there would appear to be an economic benefit to the general population. This benefit can only be confirmed through the conduct of a second BLL study and a comparison to the Study conducted in 2004.

Type of the Study

This study relies on applied standard epidemiologic methods using a quantitative approach to estimate the potential positive effect of remediation activities that took place in the smelters sites on the health status of the population living in the vicinity of lead smelters. It is crucial to reach a conclusion regarding the health effects of these remediation activities based on complete data and proper design as this is the first time in Egypt to conduct remediation activities for industrial sites using an approved remediation methodology.

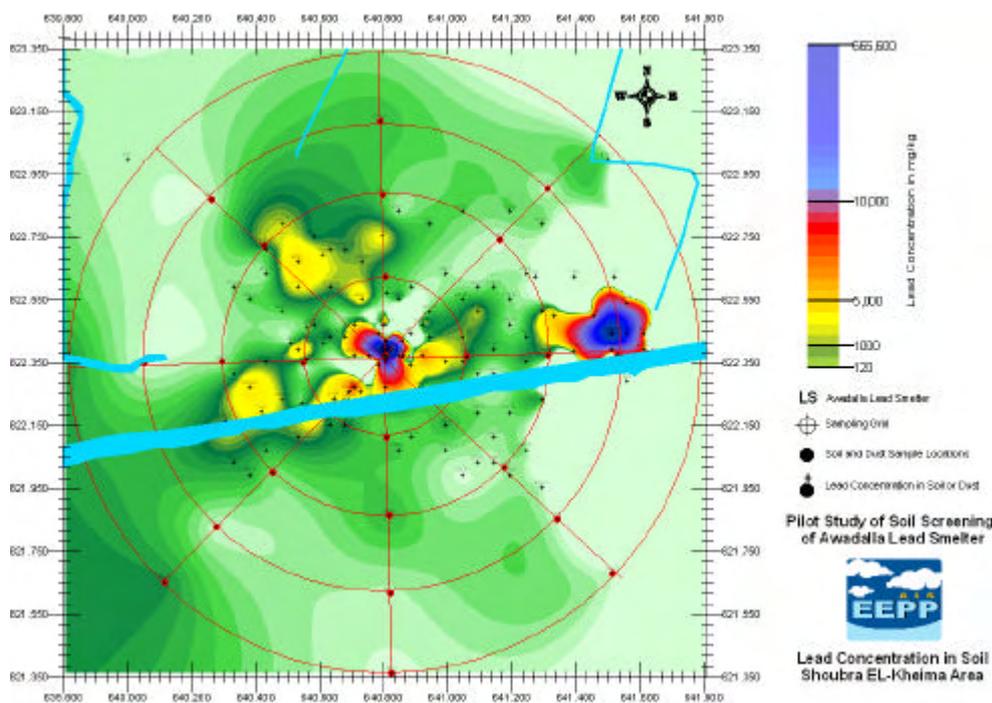
A prospective cohort study in which the BLL of the population living in the vicinity of the smelters estimated before the remediation activities in 2004 Epidemiologic Study will be estimated again and compared for the same individuals after the remediation has taken place in 2005 and 2006. The BLL of the study population will be compared to their previous BLL estimated in the 2004 Study to detect any positive health effect for the remediation activities.

Study Site

The study will be conducted in Shoubra El Kheima. The study area is defined as the area within a one-kilometer radius circle centered on the former Awadallah Secondary Lead Smelter No. 1 stack. This circle contains the five remediated secondary lead smelter sites and the El Shahid Ahmed Shaalan School. According to the extensive soil study (160 soil samples) done by CAIP in 2003 and 2004, this circle was considered to contain the contaminated area by air dispersed lead from the smelters. Accordingly, it was considered and examined thoroughly prior to the conduct of the 2004 Epidemiologic Study.

Figure 1 shows lead contamination levels from the soil screening conducted within the 1-kilometer radius of the Awadallah Secondary Lead Smelter No. 1 stack in 2003.

Figure 1: Lead Contamination Levels in 2003



Source: EEPP, 2003

From this area, participants in the 2004 Study will be contacted and they will be asked to participate in this study by giving another blood sample to determine their current BLL content. The study site includes areas from four administrative districts in East Shoubra El Kheima including Mostorod, Bahteem, Masaken El-Amiria, and El-Zawya El-Hamra. Table 1 provides the estimated population by age and sex within the study area according to the administrative district.

Table 1: Study Area Population by Age and Sex

	Mostorod	Bahteem	Masaken El-Amiria	El-Zawya El-Hamra	Total
Children from 0 - 7 yrs	4,128	16,754	9,222	11,778	41,882
Adult males	7,186	29,167	1,055	20,504	72,911
Adult females	6,633	26,924	14,820	18,926	67,303
Total	17,946	72,845	40,097	51,208	182,096

Source: EEPP, 2004

Target Population

The following population subgroups live within a one-kilometer radius circle centered on the former Awadallah Secondary Lead Smelter No. 1 stack.

- Children from 0 to 84 months of age.
- Females in the reproductive age group of between 15 and 49 years of age.
- Adult Males (above 18 years of age).

Selection of Study Population--

Using the database for the 2004 Epidemiological Study, all individuals who participated in the 2004 Study (299 participants) will be contacted and asked to participate in this study by giving a new blood sample to the Ministry of Health representatives. All data necessary to contact those individuals who participated in the 2004 Study including their full names, home addresses including GPS information to spot their residence are available from the 2004 database at the ministry. These participants include residents of 82 households of the following categories:

- 134 with children below 7 years of age.
- 88 females in the childbearing age of between 15 and 49 years of age.
- 77 adult males (above 18 years of age).

The BLL of these participants will be compared with their previous BLLs from the 2004 Study and the change in BLL will be calculated. The difference in BLL between the two sampling events will be used to determine the effect of LIFE-Lead remediation activities on the health of the population living in the vicinity of the smelters.

For each recruited family, an informed consent will be signed by the head of the family for him/herself and the children) and a simple questionnaire will be completed by interviewing the head of the family. A sample of venous blood will be collected by trained personnel from the family members to include 1 to 2 children below 7 years of age, the father, and the mother. Blood will be analyzed to determine its lead level.

Recruitment of Data Collectors

The Ministry of Health and the LIFE/Lead technical team will form three teams to work simultaneously to collect blood for analysis of the BLL. The teams will be comprised of one Ministry of Health lab worker, a LIFE/Lead social worker, one female nurse from the local health office, and a LIFE/Lead GIS expert.

Lab workers will have experience in the withdrawal of blood from children and will be responsible for collecting the necessary blood samples from the study participants. Social workers will have experience in community work and household surveys and will be responsible for interviewing the family and completing the questionnaire. Nurses will serve as facilitators with the community members as they know and trust her. The use of the nurse will also facilitate the participation of the people being sampled.

The Ministry of Health and the LIFE/Lead team will train the team responsible for data collection before field activities commence. Piloting of the data collection tools and team work will be done for one day in an area away from the study area and the results will be discarded. The principal investigator will be responsible for training data collection teams and conducting the pilot study.

Sampling Methods and Sample Size

Participants in the study will be identified by their previous participation in the 2004 Study and all of them will be asked to participate in this follow up study. All needed personal information like names, home addresses, and GPS readings of their house location is available from the 2004 Study. Each family will be contacted and asked to participate again in the follow up study.

The intention is to include all participants from the 2004 Study to obtain a new post-remediation sample of blood for comparison. Once a family is approached and agrees to participate, a blood sample will be collected from the same individuals who gave blood for the 2004 Study. If someone in the family is not available at the time of interview, a subsequent visit will be made at a convenient time as confirmed by the other family members. Table 2 shows the number of residents to be sampled and their anticipated gender and age.

Table 2: Gender and Age of Residents to be Sampled

Group	Blood samples
Children below 7 years	134
Females aged 15-49 yrs	88
Adult males	77
Total	299

Source: EPPP, 2004

Missing Data

A family or a person within the family who is not available at time of interview will be paid a subsequent visit at a convenient time indicated by the family. If possible this subsequent visit will occur on the same day or the next day.

It is anticipated that some residents that were previously sampled will not be available or will be unwilling to participate in the study. Therefore, missing data is anticipated due to the following:

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in Shoubra El Kheima, Qalyoubia

- An unwillingness by the family to participate in the follow up study.
- The entire family has moved permanently.
- A family member has moved from the family house due to various reasons like getting married, traveling for work, etc.
- Other unforeseen reasons in which a family or a person cannot be reached for the entire field work period.

In cases of inability to find participants at their home addresses from the 2004 Study, all available methods will be done to reach them by inquiries to their neighbors or paying them a second visit at a different time.

Once it has been determined that a previous study participant is considered missing, a matched neighbor by age and sex from the nearest door in the same building will be asked to replace the missing candidate. Sensitivity analysis will be conducted to estimate the weight of missing data. Also, statistical analyses will be conducted twice. The first analysis will be conducted where the matched participants will not be included. The second analysis will be done including the matched participants as replacements for the missing participants to evaluate the difference in the results.

Data Collection

Venous blood samples will be collected using a heparinized test tube. Determination of the BLL will be done using standard analytic methods in a qualified laboratory. Blood will be analyzed to determine its lead level for each sample using Atomic Absorption Spectrophotometer using the standardized method approved and recommended by the US Environmental Protection Agency (USEPA).

A brief questionnaire will be completed by a trained social worker with each family. This questionnaire will be asking participants about their risks of exposure to lead from the environment. It will include the same questions included in the questionnaire used in the 2004 Epidemiologic Study excluding questions that are expected to remain unchanged.

For analysis of the blood samples to estimate lead level, the Environmental Monitoring and Occupational Health Studies Center (EMOHSC) in the Egyptian Ministry of Health has been chosen as a sole source for this analysis. The EMOHSC is well equipped and the staff is trained on blood withdrawal and performing the chemical analysis for lead in blood using the Atomic Absorption Spectrophotometer according to the standard technique. Moreover, the EMOHSC has agreed to submit 10% of the samples for Quality Control checks to an outsider laboratory chosen by the study team.

Quality Control

The blood sample withdrawn is anticipated to be between 8 and 10 cc. Every tenth sample will be divided between 2 test tubes and given different code numbers to be treated at the lab as different samples. The estimated lead contents in every pair will be compared and no more than a 10% variation in the BLL between the two samples will be accepted.

Study Period

It is expected that 15 to 20 blood samples can be collected per day. Therefore it is anticipated that 20 to 25 working days will be required for collection of the 299 samples. Three teams will be working simultaneously so, the field work is expected to be completed in 7 to 10 working days starting early in November 2006.

Study Activities

Preliminary activities should include a familiarization meeting in which researchers meet central level officials at the Ministry of Health and Population, the GOQ, and the local level health office to discuss the objectives of the study and obtain their support. In addition, the Ministry of Health focal point will arrange for a meeting with the lab directors at the EMOHSC where blood analysis for lead is going to take place to develop an agreement and necessary arrangements. Preliminary activities will include the following:

- Secure the final approval of the methodology to be used by the Ministry of Health.
- Team to identify nurses working at the local health office and known by people living at the study area.
- Request official approval to recruit these nurses to work for the study.
- Identify lab workers from Ministry of Health with pediatric experience to be assigned to blood collection from children participating in the study.
- Develop a contractual agreement between LIFE-Lead and the laboratory.
- Team to train the team of nurses and/or technicians who will be responsible for sample taking on the proper approach to residents, common questions, responses to questions that they might face, and proper sampling procedures.

Recruiting data collectors will be prior to the commencement of field work. The same data collection team who worked for the 2004 Epidemiologic Study will be contacted to complete the work, if they are available. If a previous member of the collection team is unavailable, that person will be replaced by someone with similar capabilities. The training of the data collection team and pilot testing will be done one week before starting the field work.

Data Analysis

Data will be entered on Microsoft Access 2003 software using the same database that was used for the 2004 Epidemiologic Study as it is available and complete. Data checks and cleaning will be done by the principal investigator. The database will be transformed into an SPSS 13.0 software package for statistical analysis.

To manage possible missing values, a sensitivity analysis will be conducted to estimate the weight of missing values. Also, statistical analyses will be conducted twice where in the first time, the matched participants will not be included in the analysis. The second analysis will include the matched participants as replacements for missing persons to evaluate a difference in results, if any.

The mean BLL \pm standard deviation will be reported for the study group and subgroups (i.e., children, women of child bearing age, and adult males). The 2004 and 2006 BLL results of the population living in the vicinity of the smelters will be compared. The possible difference will be estimated using Paired t-test and the percent change in the BLL will be calculated. Then, the BLL will be converted into a binary variable and the frequency and percentages of the departure from the standard level for blood Pb at 10 $\mu\text{g}/\text{dL}$ of blood will be presented by group. A comparison between the baseline data (2004 data) and the new data for each group will be done using a Chi square test to estimate the health effect of the remediation activities conducted by LIFE-Lead on the health of the population living in the vicinity of the lead smelters.

INSTITUTIONAL RESPONSIBILITIES AND AGREEMENTS

All publications will be submitted to the Ministry of Health and Population and USAID for review and clearance before submission to any outside agency or scientific journal. All publications, in either scientific journals or reports will be done with the participation and/or agreement of all study collaborators. The order of authorship will reflect the degree of contribution/ involvement of each of the authors. The participation and contribution of all participating centers and staff will be acknowledged in all publications.

SIGNIFICANT RISKS

Risks

This is a minimal risk study. There is minimal risk encountered in the study originating from withdrawing 2 to 5 cc of blood from each participant. This risk includes pain during needle insertion, possibility of inflammation at site of insertion, and the possibility of bleeding for those who have bleeding disorders. There is no risk encountered with data collection as confidentiality will be maintained and consent will be obtained in writing from each adult participants and the guardian of participating children.

Qualifications of Medical Personnel

Lab technicians will be monitored by the principal investigator and unqualified personnel will be excluded from the team immediately.

INFORMED CONSENT PROCESS

Consent

The Ethical Approval of the Research Ethics Committee at Ministry of Health and Population will be contacted prior to the commencement of work by the collaborating partner at the Ministry of Health and Population. This focal person will be responsible to request ethical clearance and other administrative clearances. A copy of the ethical clearance will be provided to every participant and an Arabic version of the consent will be explained to them.

Consent Form

The guardian of the child will be interviewed and the objectives of the study will be explained to him/her. An Arabic copy of the informed consent will be signed before each blood withdrawal. An informed consent will be signed by each adult individual before giving data or samples. A witness will sign on behalf of the person if he/she cannot read and write.

MAINTENANCE OF RECORDS

Archiving of Study Data

Copies of all notes, codes, and data will be maintained in a locked filing cabinet and a password protected computer belonging to the office of LIFE-Lead. Access to the hard copies or the database will be restricted to the primary investigator.

Research Protocol

A copy of the protocol will be maintained in the LIFE-Lead office. The original consent form and questionnaire will be kept by the project. Upon completion of the study, all documentation will be turned over to LIFE-Lead where it will be kept in a secure place for archival purposes. All information that could be used to identify the study subjects will be removed.

Individual Medical Records

A copy of the results of the BLL will be provided to each individual once the results are received from the laboratory. The participants will be advised to keep it in their health record and show it to their family doctor, if they have one. Those participants with a BLL exceeding the safe limit will be referred for medical assistance at the EMOHSC and the National Toxicology Center, Cairo University.

REFERENCES

Amira M. Koura, Sohair I Salem, El-Sayed M. ElMahdy, Hisham A. Orban 2001 : Biochemical indicators of lead exposure in blood and urine of children. Kasr El-Aini Medical Journal; vol 7; no 2; May 2001; 55:69.

AAP: American Academy of Pediatrics, 1998: Screening for Elevated Blood Lead Levels. PEDIATRICS Vol. 101 No. 6 June 1998, pp. 1072-1078.

ATSDR: Agency for Toxic Substances and disease Registry, 1999: Toxicological Profile for Lead. US Department of Health and Human Services, Public Health Service. Cited on the web at URL: <http://www.atsdr.cdc.gov/toxprofiles/tp13.pdf>

CAIP, 2002. Cairo Air Improvement Project (CAIP). Preliminary Assessment: Awadallah Secondary Lead Smelter in Shoubra El Kheima. Chemonics International, Inc. USAID/Egypt, Office of Environment. USAID Contract No. 263-C-00-97-00090-00. February 2002. Improvement

CAIP, 2003. Cairo Air Improvement Project (CAIP). Contamination Assessment of the Awadallah Secondary Lead Smelter at Shoubra El Kheima. Chemonics International, Inc. USAID/Egypt, Office of Environment. USAID Contract No. 263-C-00-97-00090-00. May 2003.

EEAA, 2002. Ministry State of Environmental Affairs and United Nations Development Program; 2002. The National Environmental Action Plan 2002/2017.

EEAA, 1997. Egyptian Environmental Affair Agency (EEAA). Lead Smelter Action Plan. Technical Cooperation Office for the Environment, EEAA, Cairo. February 1997.

EEPP, 2003a. Egyptian Environmental Policy Project (EEPP). Site Investigation Report: Awadallah Lead Smelter. Chemonics International, Inc. USAID/Egypt, Office of Environment. USAID Contract No. 263-C-00-97-00090-00. December 2003.

EEPP, 2003b. Egyptian Environmental Policy Project (EEPP). Baseline Human Health Risk Assessment: Awadallah Secondary Lead Smelter. Chemonics International, Inc. USAID/Egypt, Office of Environment. USAID Contract No. 263-C-00-97-00090-00. December 2003.

EEPP, 2004. Egyptian Environmental Policy Project (EEPP). Screening Epidemiological Study: Blood Lead Levels in the Vicinity of the Awadallah Smelter. Chemonics International, Inc. USAID/Egypt, Office of Environment. USAID Contract No. 263-C-00-97-00090-00. June 2004.

Salem S., Mosseilhy S., KhalifaAG., Al-Ashmawy E., Karam El Din M., Salah I. 2000 : Blood lead delta aminolevulinic acid dehydratase and neurobehavioral abilities among children exposed to environmental lead pollution. Journal of Arab child; Volume 11, Number 4, December 2000, 531:550.

United States Agency for International Development and Egyptian environmental Affairs Agency; 2003: 2000/2001 Lead Emissions Inventory for the Greater Cairo Area Trend Report; page 1-3:2-4.

Zaki A, El-Shazly M, Abdel-Fattah M, El-Said K, Curtale F 1998: Lead toxicity among working children and adolescents in Alexandria, Egypt. Eastern Mediterranean Health Journal vol. 4 Issue 3, pages 520-529

APPENDICES**Appendix I****Post-Remediation Blood Lead Level Survey in
Shoubra El Kheima, Qalyoubia**QUESTIONNAIRE

1. Code #:
2. Address:
3. GPS: N _____ E _____
4. Date:
5. Name of interviewer:
6. Area:

A. Home Characteristics

7. How long has the family lived in this residence?
8. Which floor is the flat?
9. When was the last time the home renovated/re-painted?
10. How does the family attempt to control dust/dirt interiorly? Electric sweeper others
11. Where do the family take-off and keep their shoes? inside outside
12. What is the status of the windows looking at the street? opened closed

B. Child Data

13. Age:
14. Gender:
15. Does the child go to play on the street?
16. Where does the child spend most of his time? in-house outside
17. Does the child have the habit of putting his hand into his mouth?
18. Does the child wash his hands before meals?
19. Does the child eat strange items like mud or paint?
20. Does the child put pencil, colored pens into his mouth?
21. Does the child eat vegetables/fruits without washing?
22. Does the mother put Kohl (traditional coloring material) into his eyes?

C. Wife Data

23. Age:

24. Level of education: illiterate primary preparatory secondary university
25. Occupation: Not working/housewife Industrial/agricultural worker
Skilled worker Semiprofessional Professional
26. History of chronic diseases:
27. Is she pregnant at time of interview?
28. Is she lactating at time of interview?
29. Number of previous pregnancies:
30. Number of previous deliveries:
31. History of giving birth of a malformed baby:

D. Husband Data

32. Age:
33. Level of education: illiterate primary preparatory
Secondary university
34. Occupation: Not working/housewife Industrial/agricultural worker
Skilled worker Semiprofessional Professional
35. How much is the average expenditure of the family per month?
36. History of chronic diseases:
37. How much time does he spend outside home per day?

Appendix II Research Consent Form

Title of Research Project:

Post-Remediation Blood Lead Level Survey in Shoubra El Kheima, Qalyoubia

Principal Investigator: Dr. Alaa Abou-Zeid, MD, PhD

Subject's name:

Purpose/Description: The inhalation and ingestion of lead can cause serious health effects for children and adults. The environment possibly contains lead in soil, air, and water. Over the past period, many efforts have been completed to remediate the former sites of the lead smelters in Shoubra El Kheima that have been working for many years. We want to know whether these remediation activities have reduced the risk of lead exposure in this area.

This study is supervised by the Ministry of Health and Population. You have been chosen to participate because you are living within the area and you have participated in the first phase of the study in 2004 and we want to follow up with your blood lead level since the closure of the lead smelters and remediation of the smelter sites.

Procedures/Tasks: You freely agree to take part in this investigation, understanding that it involves an interview to obtain information about factors in your life which could expose you to lead from different sources (approximately 15 minutes) and providing 2 to 5 cc of blood (see sample tube of fluid containing 5 ml). The blood will be tested to assess its lead contents.

Risks: Drawing blood by a needle can sometimes cause some discomfort and bruising, and rarely infection.

Benefits: Your participation will benefit you directly as we will provide you with the results of the lead level in your blood that could help your doctor to diagnose and manage your health problems. In addition, it is hoped that the information learned may result in a better understanding of the health effects of the remediation activities conducted in the area.

Alternates to Participation: You do not have to participate in this study and not participating will not affect your access to medical care anywhere within the Ministry of Health and Population facilities.

Confidentially: Information collected about you will be treated in a strictly confidential manner and you will not be personally identified in the reporting and results. All samples will be secured in facilities of the study, and only authorized study personnel will have access to the data.

Costs/Compensation: There are no costs for participating in this study; the test will be provided for free.

Right to Withdraw: Your participation is entirely voluntary, and you may withdraw your consent to participate at any time without penalty, without in any way affecting the health care you receive from any facility belonging to the Ministry of Health and Population.

To learn more about this research, contact Dr. Alaa Abou-Zeid, Faculty of Medicine, Cairo University, telephone (02) 5247230.

For questions about research subjects' rights and research-related injury, contact the office of the Chairman of the Institutional Review Board (a group established to protect the rights of research subjects).

For the Ministry of Health and Population, contact Dr. Magda Rakha, telephone (02) 7948544.

If you agree to join this study, please sign or check the appropriate place below.

NOT VALID WITHOUT THE
IRB STAMP OF CERTIFICATION

Valid from October 1, 2006 until March 31, 2007.

Subject's Name: _____

Subject's Signature: _____

_____ I have read and understand the information on this form.

_____ I have had the information on this form explained to me.

Witness to Consent Procedures: _____

Signature of Investigator: _____

Date: _____

NOTE: Copies of this Consent Form with original signatures must be:

- a) retained on file by the Principal Investigator
- b) copy given to the subject.

Appendix III**Budget**

Category	Price/unit (LE)	No of Units	Cost/category (LE)
Blood analysis	50	300	15,000
Quality control samples and analysis	50	30	1,500
Lab technician	50/day	25 days	1,250
Social worker	100/day	25 days	2,500
Nurse	40/day	25 days	1,000
Total			21,250

Appendix IV**Milestones**

Activities (2006)	April	May	June	July	Aug	Sep	Oct	Nov	Dec
Protocol submission	X								
Meetings with MoHP and approvals	X	X	X						
Administrative clearance from USAID			X	X	X				
Contracting the lab						X			
Training of data collectors							X		
Field work								X	
Data entry								X	
Data analysis, report writing								X	X
Submission of the Final Report									X