ORAU
OAK RIDGE ASSOCIATED UNIVERSITIES

Kingston Project Surveillance Program

Baseline Medical Screening Results

August 17, 2010

Oak Ridge Associated Universities (ORAU) is a university consortium leveraging the scientific strength of major research institutions to advance science and education by partnering with national laboratories, government agencies, and private industry. ORAU manages the Oak Ridge Institute for Science and Education for the U.S. Department of Energy.

ORAU 10-OEWH-1174

Executive Summary

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On December 22, 2008, a dike failed at the Tennessee Valley Authority's (TVA) Kingston Fossil Plant. About 5.4 million cubic yards of fly ash was released and subsequently covered about 300 acres nearby. TVA funded an effort by Oak Ridge Associated Universities (ORAU) and physician medical toxicologists from Vanderbilt University Medical Center (VUMC) so that an independent health screening of people who resided near the ash spill could be conducted.

A screening evaluation protocol was designed to provide a baseline medical evaluation of participants as well as test for biological evidence of exposure to the constituents of fly ash. The medical evaluation included the following components: health history, physical examination, spirometry (breathing test), chest x-ray, routine urinalysis, complete blood count, blood chemistries, and biological monitoring tests. The biological monitoring tests were chosen to examine for evidence of effects on the body related to exposure to fly ash and included testing for aluminum, arsenic, barium, beryllium, chromium, cobalt, copper, nickel, selenium, thallium, and vanadium. These components of fly ash (with the exception of selenium and thallium) were chosen for testing because they were found to be in higher concentrations in fly ash-contaminated soil than in non-fly-ash-contaminated soil in Roane County. Selenium and thallium did not exceed regional background soil measurements but were included in the screening due to their potential health risks.

A total of 214 individuals (representing 112 households) self-identified to participate in the screening evaluation between September 2009 and April 2010. It is estimated that there were nearly 100 households within one mile of the spill and residents from 12 of those households were represented in the surveillance program. Within one to two miles of the spill, there were approximately 650 households, and residents from 37 participated in the program. Approximately half of the participants lived within two miles of the spill. The ages of the participants ranged from less than one year old to 89 years of age, with 18.7% of those examined being under age 18 and 25.2% of those examined being older than age 65. Fifty-three percent of the participants were female and 98% were white.

The most common symptoms reported by participants were those related to upper airway irritation, including runny nose, cough, and congestion. The physical examination for most participants was essentially normal, with many abnormalities or variations due to preexisting medical conditions. There were no findings that would indicate local or systemic toxicity related to constituents identified in the ash.

Pulmonary (lung) function tests were done for all participants older than six years of age (N=194). The majority of the participants (N=146, 75.2%) had normal lung function tests. Mild abnormalities were found in 21 (11%), moderate abnormalities in 12 (6%), and moderately severe to very severe abnormalities in 13 (7%), and undetermined abnormalities in 2 (1%). The majority of the individuals with abnormal tests (30 out of 48) were smokers. Abnormal tests were observed among 18 nonsmokers, with 12 (67%) of the abnormal tests being categorized as mild abnormalities. When those with any abnormal findings were categorized by distance from the spill, there was a similar distribution of abnormalities for those living within two miles of the spill compared to those living greater than two miles away. Therefore, it is not likely that exposure to fly ash is responsible for the abnormal test results. These abnormalities may be due to multiple factors, such as emphysema, smoking, asthma, and respiratory infections, at the time of the testing.

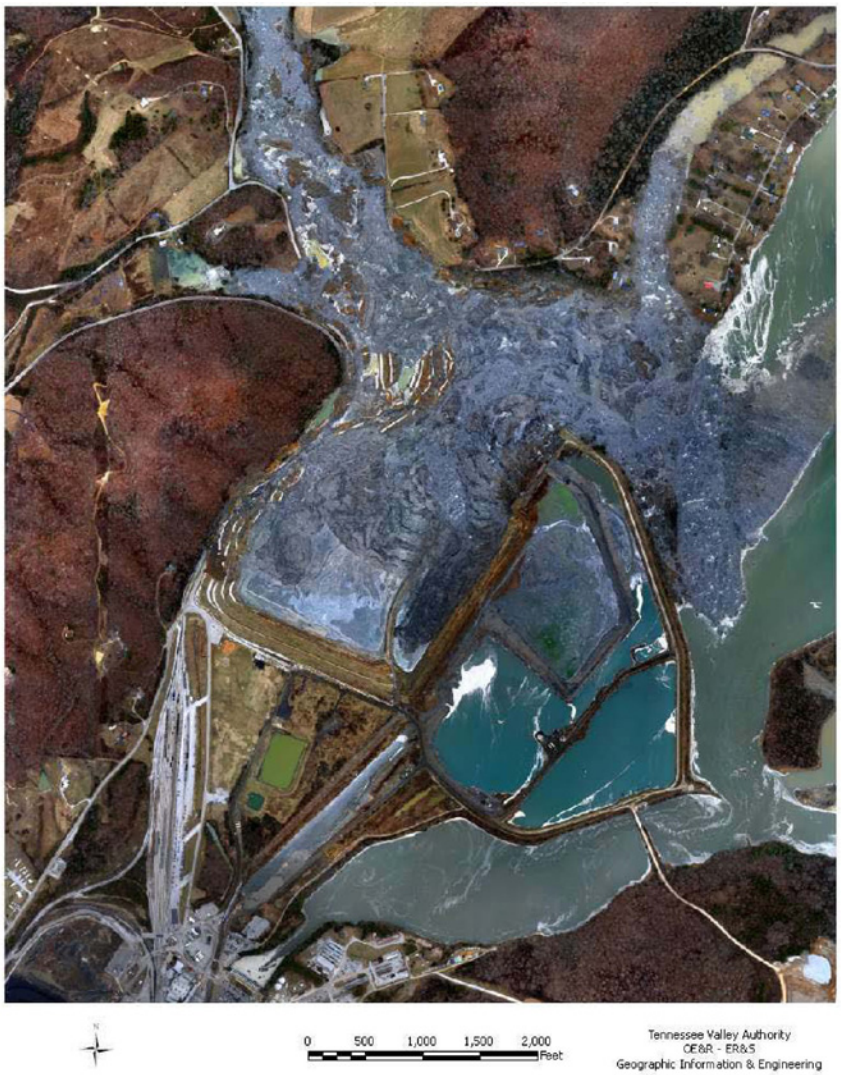
Chest x-rays did not reveal any conditions expected to be caused by exposure to fly ash. Two individuals were found to have a mass in their lungs that needed further follow-up with their primary care doctor.

No elevations were found in the blood tests for arsenic, cobalt, and nickel. A few individuals demonstrated slightly elevated blood values for copper (N=17; 8.3% of those tested), aluminum (N=6; 3.0% of those tested), and chromium (N=1; 0.5% of those tested). While the levels measured were higher than the normal values, none showed levels approaching a toxic range. For selenium, which is a trace micronutrient, elevated blood values were found for 55 participants (27% of those tested). Selenium is a part of normal diet and can be included in vitamins and other supplements. Because 27% of the participants had elevated values, it was important to determine whether the increase was coming from diet and supplements or from fly ash. Forty of the participants with elevated values returned for a repeat measurement of selenium after reduction in dietary and supplement sources and all had subsequent values within the normal range. These participants did not have abnormalities on physical examination or laboratory findings consistent with selenium toxicity.

The urine tests for beryllium, thallium, arsenic, and vanadium did not reveal any elevations.
A review of all the medical findings suggests no baseline effects on physical health; however, it is recommended that repeat evaluations of this group of individuals be performed periodically over several years to assess whether there have been any changes in health that may be related to the fly ash spill.

INTRODUCTION

On December 22, 2008, a fly ash retaining pond wall failed at the Tennessee Valley Authority (TVA) Kingston Fossil Plant (KIF) in Harriman, Tennessee, releasing approximately 5.4 million cubic yards of fly ash that covered 300 acres of land and water. Several embayments of the Emory River were filled with ash, and the main channel of the Emory was obstructed, interrupting the normal flow of the river. No injuries or deaths were reported; however, 26 homes were either damaged or destroyed and many people were forced to leave their property. The landslide caused by the ash derailed a train and disrupted local utilities. Initial response was provided by the Roane County Office of Emergency Management and Homeland Security. A unified command center was established following the disaster in order to coordinate the efforts of all contributing agencies: the Tennessee Emergency Management Agency, TVA, United States Environmental Protection Agency (EPA), Tennessee Department of Health (TDH) and the Tennessee Department of Environment and Conservation (TDEC). The disaster significantly impacted the natural environment as well as the general well-being of the community.



Once cleanup had begun at the site, Oak Ridge Associated Universities (ORAU) was approached by TVA to set up a medical screening program in order to assess the health of individuals in Roane County, Tennessee, who felt that their health had been affected by the fly ash spill. ORAU was chosen primarily for its experience in facilitating nation-wide medical surveillance programs for the United States Department of Energy. ORAU contracted with the Tennessee Poison Center

Figure 1: **Aerial Image of Kingston Ash Slide 12/23/2008**

at Vanderbilt University Medical Center (VUMC) in Nashville, Tennessee, for its expertise in medical toxicology and with a local health care organization (Covenant Health). After meeting with physicians, epidemiologists, public health officials, community members, and local government representatives as well as receiving approval from the Oak Ridge Site-wide Institutional Review Board (ORSIRB), the Kingston Project Surveillance Program (KPSP) was established in August 2009 in order to assess the health of persons potentially affected by fly ash from the KIF.

Background

The KIF is situated on a flood plain in Roane County, Tennessee, near the confluence of the Clinch and Emory Rivers between the cities of Harriman and Kingston. Construction began in 1951 and was completed in 1955. At the time, it was the largest coal-fired plant in the world. The KIF has nine coal-fired generating units that produce nearly 10 billion kilowatt-hours of electricity per year and at full generating capacity consumes 14,000 tons of coal per day(1). When coal is burned, different types of waste or coal combustion residuals (CCRs) are produced(2). Most of the waste produced at Kingston is fly ash; when operating at capacity, KIF produces 1,000 tons per day. Fly ash is formed when smoke that contains particulates rises out of the boiler into the stack and the ash/particulates are captured by electrostatic precipitators. The small particles are then mixed with water and piped out of the plant into storage areas. Typically, these ponds are contained by earthen dikes. It was one of these dikes that failed on December 22, 2008, causing the fly ash release.

Fly ash is composed of inorganic matter as well as some organic matter. The source and type of coal used will determine the specific content of material in the fly ash. Material could include metals and metalloids, nonmetals, radioactive solids (inorganic), and polyaromatic hydrocarbons (PAHs) (organic). Metals can include elements such as aluminum, barium, beryllium, chromium, copper, lead, etc. Metalloids share properties of metals but also of other inorganic chemicals and include elements such as boron, silicon, arsenic, and antimony. Sometimes, in the press, terms such as “heavy metals” or “toxic metals” are used in general without naming which substances are being discussed. The term heavy metals is usually intended for a particular subset of metals, such as mercury, chromium, and lead. These metals have a high risk of toxicity at a relatively low dose. The term toxic metals refers to metals that have a potential for toxicity depending on the dose. Examples include the ones listed under heavy metals but also include lithium, lead, mercury, and arsenic. Some fly ash components, such as selenium, are not metals; however, we chose to include this with the general descriptor of metals. For simplicity sake, we will use the term “metals” in this report when referring to metals, metalloids, and selenium.

The key to toxicity is related to the amount that someone gets into his/her body and the effects that occur in the body as a result of this exposure. Some metals such as iron, copper, selenium, and zinc, are important micronutrients and are a part of a healthy, well-balanced diet.

Fly Ash Concerns

Concerns about the risks to public health were based on several factors, with water and air quality being primary. The community and the press raised questions about the potential health effects. Initial investigations by TDH and the Agency for Toxic Substances and Disease Registry (ATSDR) concluded that no health risk was to be expected from exposure to fly ash(3) based on evaluations of the municipal drinking water and well and spring water, sampling of the particulate matter in the air, and analysis of the levels of metals found in the ash. TVA believed that a uniform health assessment should be developed to address community members' health concerns. No landmark studies had previously been published. Therefore, ORAU and the medical toxicologists at the Tennessee Poison Center assessed the risk of exposure to components of fly ash based on expected doses of the fly ash provided by agencies such as TDEC, TVA, and EPA and assumptions based on similar events.

Breathing in fly ash may cause respiratory effects. Fly ash is composed of very small, fine particles. As long as this material remains wet and does not get airborne, breathing it in is unlikely. As the fly ash dries out, it can become airborne and potentially enter the respiratory tract of people in close proximity to the spill. The types of particles that pose the greatest concern are those that measure 10 µ or less (PM10) and particulate matter that measures 2.5 µ or less (PM2.5)(4)because these particles could be deposited deep into the lungs. However, any dust, including large particle size, can be irritating to the eyes, nose, and throat when airborne.

In addition to the fly ash spread out over more than 300 acres, thousands of trucks have entered and left the cleanup site during the recovery effort, and unusually high amounts of gravel dust, road dust, and diesel exhaust have been produced as a result of this high volume traffic. Regular rain in the area throughout 2009 helped the situation, and air monitors have not detected any increase in PM2.5 or PM10(5).

The purpose of this medical screening was to address health concerns of the Roane County community. The medical screening program was available to any resident of Roane County, Tennessee, who felt that his or her health had been affected by the fly ash spill. The screening provided a baseline medical assessment of the community.

At the beginning of this medical surveillance program, there was agreement that the results and findings would be communicated to the participants, Roane County citizens, general public, TVA, and other agencies involved. The data and interpretation of such information are presented here in an initial report discussing the scope of the study, the results, general findings, and recommendations. Factors such as future exposure, environmental changes, and individual health status must be assessed in order to fully establish whether there is a chronic risk to the community.

Expectations

Based on the size of the community living near the Kingston spill, the number of people who had filed law suits against TVA, community interest in a screening program, and feedback from TVA and the general public, it was originally estimated that approximately 70 people would be interested in participation in KPSP, and it was anticipated that two weeks would be sufficient to examine all 70 participants. The whole medical screening program was predicted to last approximately two months. By August 2009, 89 people had already signed up for screenings. It was quickly realized that the program would far surpass the original expectation of 70 participants. The program was extended, and by December 2009, more than 300 people had signed up.

Agencies such as the TDH Environmental Epidemiology Program and ATSDR were consulted to gather information on potential effects of fly ash on human health. Due to the lack of scientific research in this matter, the protocol for the medical screening was largely developed from the principles of medical toxicology practice and risk assessment mentioned earlier and not from established guidelines. Measurable health effects were anticipated to be minimal based on assumptions from general knowledge of the fly ash found at KIF, general chemistry and toxicology, and the draft Public Health Assessment published by TDH. For measurable health effects to occur, fly ash must get into the food chain, water supply, and respirable air over time in significant concentrations, be absorbed by the body, and then accumulate in significant amounts in the body to cause disease.

METHODS

Protocol for Medical Examination

The analysis of the KIF fly ash done by the EPA was the basis for the metals selected in the protocol development. No radioactive solids, PAHs, or volatile organic compounds (VOCs) were detected. Metals that may pose a risk to human health were assessed. Any metal found to be significantly higher in concentration in ash versus regional soil was considered to be a possible hazard. Soil samples from properties near the spill site but not affected by the spill were taken by the EPA on January 2, 2009(7), and were compared with soil samples from affected properties measured by TDEC January 6-7, 2009(6) (Table 1). Those metals that were identified with higher levels in the ash compared to normal soil included arsenic, aluminum, barium, beryllium, chromium, cobalt, copper, nickel, and vanadium. Selenium and thallium did not exceed regional background soil measurements but were included in the screening due to their potential health risks. The risk for exposure to the metals deemed to be potentially hazardous to human health was determined by calculating the amount needed to be ingested by a child before exhibiting adverse health effects. Biological tests are available for each metal of concern; therefore, whole blood, serum or urine (as appropriate for a given metal) was used to measure levels of each metal listed in the KPSP(8).

Table 1: **Basis of the Medical Screening**

Coal Ash Constituent	Residential Property Ash Concentration (mean, range, mg/kg) [TDEC, Jan 6—7, 2009]	Regional Soil Background Concentration (mean, range, mg/kg) [EPA Jan 2, 2009]
Aluminum	14,109 (1,000—22,000)	4,308 (2,170—6,190)
Arsenic	75 (26—100)	8 (1—16)
Barium	357 (180—1,100)	47 (25—95)
Beryllium	3 (1.5—7.9)	0.8 (0.2—2.5)
Cadmium	0 (0—0.2)	0.17 (0.04—0.36)
Chromium	25 (16—43)	16 (4—31)
Cobalt	13 (6.7—29)	5.5 (3.2—8.0)
Copper	46 (25—76)	9.9 (4.3—23)
Iron	13,000 (10,000—21,000)	12,875 (4,880—23,100)
Lead	19 (9.8—29)	16.7 (6.6—27.2)
Manganese	102 (56—260)	389 (61—1,230)
Mercury	0 (0—0)	0.13 (0.12—0.14)
Nickel	23 (13—37)	6.1 (<4.9—8.5)
Selenium	0.2 (0—2.2)	1.9 (1.0—2.0)
Thallium	0.16 (0—1.8)	<5.5
Uranium	2.89 (93—1,000)	<9
Vanadium	77 (42—150)	17 (5—36)
Zinc	40 (25—67)	33 (18—69)

In addition to levels of metals measured, general metabolic markers were collected. A complete blood count (CBC), comprehensive metabolic panel (CMP), and routine urinalysis (UA) were offered to all participants. Measuring these markers provides two benefits. First, detrimental health effects can be detected though general laboratory tests as well as by measuring the level of the metals. Second, any medical screening program has a duty to provide basic information about the general health and well-being of a population. Any abnormal results were reported to the participant, and copies of the medical record were made available so that this information could be shared with their primary care providers or appropriate specialists.

Fly ash is composed of tiny, spherical particles that have the consistency of talcum powder. These particles measure less than 10 microns in diameter and have the ability to enter the lower airway and cause inflammation and irritation. Some individuals who have preexisting medical conditions, especially cardiopulmonary related, may be at increased risk of developing acute respiratory illness. The protocol was designed to test for pulmonary function and measure impairment in individuals due to any disease that affects lung function and results in obstruction or restriction of normal respiration. A pulmonary function test was performed on all individuals over the age of six years. Children less than six years old were not able to perform spirometry because the equipment available locally was not appropriate. If respiratory disease was noticed in children, it was agreed that other means to assess pulmonary function would be sought.

Also, a chest x-ray with two views (posterior-anterior and lateral) was performed on all participants who consented. The purpose was to assess a baseline measurement and to document any physical or structural anomalies in existence at the time of measurement. This program was set up as a medical screening initiative and not a formal study of the effects of fly ash on a population; still, it is anticipated that much of the data collected will contribute to the scientific community's understanding of how CCRs affect human health.

Recruitment and Sample Selection

Participation in KPSP was completely voluntary. The target group was all residents living within a two-mile radius from the spill site on December 22, 2008. However, any resident of Roane County, Tennessee, who felt his/her health may have been affected by the ash spill was allowed to participate. The public was notified through a variety of methods. ORAU set up a Web site, www.orau.org/kingstonproject, where resources could be sought by community residents and participants.

Printed information pertaining to the medical screening was placed in the TVA/EPA Outreach Center, the Roane County Health Department, courthouse, and libraries. Additionally, a 30-day ad ran on Channel 12, a local community outreach information board.

A representative from ORAU attended all public meetings in Roane County or elsewhere concerning the fly ash spill. Anyone interested in the screening could approach the representative to receive more information about registration. Registration could be completed by phone, online, or by sending in a registration card. Near the end of 2009, letters were sent to residents living within two miles from the spill who had expressed concern to TVA about their health but had not signed up yet. This was an attempt to ensure that all residents living within two miles had been contacted.

Questionnaire Development

In preparation for the clinical evaluation of individuals who may have been exposed to the fly ash, a medical history questionnaire was created. The purpose of the questionnaire was to obtain a medical history from each participant in a consistent fashion prior to the evaluation. The medical toxicology physician reviewed the completed questionnaire with the participant to clarify and confirm answers. This allowed for both written and verbal transmission of information for the medical toxicologist.

Each medical history questionnaire was checked and signed by the medical toxicologist. Additional points of clarification could be added to the form by the physician at the time of the medical examination.

Ethical Considerations

Although KPSP is a screening program and is not a research project, all precautions were taken to ensure that every participant fully understood the nature and intentions of the medical testing and evaluation.

Before any person was evaluated, the protocol, medical questionnaire, consent form, and other documents used in the program were submitted for approval to ORSIRB. ORSIRB holds a Federal-wide Assurance (FWA) from the Department of Health and Human Services Office of Human Research Protections and is registered as FWA00005031. An Institutional Review Board (IRB) is a committee made up of members from various scientific backgrounds who review all protocols and methods used for any kind of research or scientific investigation. An IRB must review and approve all projects before they start to assure that risks are minimized, that risks are reasonable in relation to expected benefits, that there is informed consent and that the rights and privacy of persons are maintained. The KPSP was reviewed by the IRB and approved on August 20, 2009, for a period of up to 12 months. Reapproval by ORSIRB is required annually as long as the program remains active.

It was expected that several vulnerable groups would be included as participants in KPSP, among these being children, the elderly, and women of childbearing age. Precautions were taken to ensure that all participants were informed of their legal rights and responsibilities. Informed consent was obtained from all participants, and when applicable, special consideration was used for children. Participants received the consent form in the mail prior to their first appointment for testing scheduled at a local hospital. The purpose of this was to allow participants the necessary time to thoroughly read and evaluate the consent form. It also allowed potential participants to consult with people they trust, such as family members, legal counsel, physicians, members of the clergy, and professional consultants. Participants were asked to bring the form with them to their appointment. At that time a representative from ORAU met privately with each individual or family group, if preferred, and answered any questions they may have had about the nature of the medical screening program, next steps, and consent form.

All personally identifiable information, including biological samples and medical record information, was kept confidential and will remain private unless requested to be released by a participant. A permanent electronic file for each participant will be kept at VUMC, while paper copies of each patient's records will be kept at ORAU's Oak Ridge, Tennessee, office in the Occupational Exposure and Worker Health (OEWH) Program until the completion of the project. The Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) governs how health information can be stored and shared and how it is to be kept confidential. More detail on the measures ORAU has taken to protect personal information can be found in the KPSP consent form.

The Screening Process

Once a person signed up for the screening, a representative from ORAU called to set up an appointment for initial laboratory testing at Roane Medical Center (RMC) in Harriman, Tennessee. Participants were mailed the consent form, the questionnaire, and a special urine collection cup prior to going to the RMC for their appointment. They were also asked to complete the questionnaire.

Testing included laboratory screening for the toxic metals and basic metabolic markers (CBC, CMP, and UA), chest x-ray with two views, and spirometry to measure pulmonary (lung) function.

After results from the laboratory testing were complete, participants were scheduled to meet with and have a history and physical performed by a medical toxicologist from VUMC at a clinic in Kingston, Tennessee. The physician answered questions about exposure to coal ash and potential health effects, explained results from the medical testing, reviewed answers to the medical history questionnaire, and performed a physical examination, looking specifically for signs and symptoms of toxic effects from the fly ash. A few weeks after this evaluation, participants received copies of all their results from the medical testing, a copy of the physical examination findings, and a letter from the physician summarizing everything that was discussed during the appointment. Participants were also asked to provide feedback from their experience in the KPSP so that ORAU could evaluate the program.

Data Analysis

Data from the questionnaire, medical tests, and physical examination were entered into an Access® database and were verified for accuracy by a second reviewer after entry. Distributions of the data were generated and reviewed for this report. Most values were examined for the entire group of individuals. Additional analyses were performed to look at the distribution of values by distance from the spill for some variables.

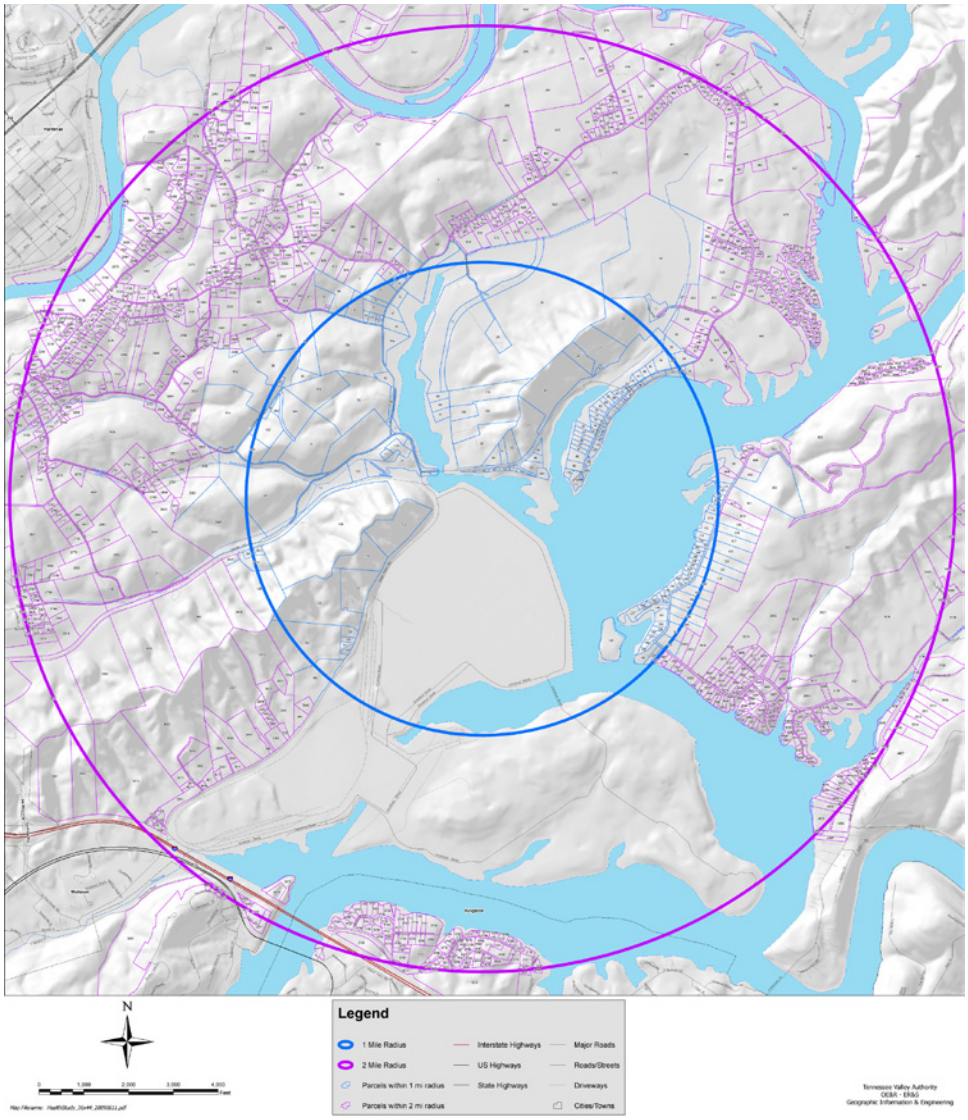
RESULTS AND ANALYSIS

Participants

Initially, 320 people signed up for the screening, but 106 withdrew of their own choosing, leaving 214 in the final group to be tested. Of these, 107 (50%) signed up by phone, 85 (40%) online, and 19 (9%) by mail; 3 (1%) were not specified. August 2009 and December 2009 had the most participants sign up due to a press release and the last official day for registration, respectively.

Using GIS (geographic information system), TVA located the center of the spill and calculated areas of one mile and two miles from that point (Figure 2). The distribution of participants in Figure 3 shows the location of households by distance from the spill. People living down river from the spill site as well as those living along the shoreline in other areas made up the largest number of participants.

Figure 2: **Health Study Target Area**



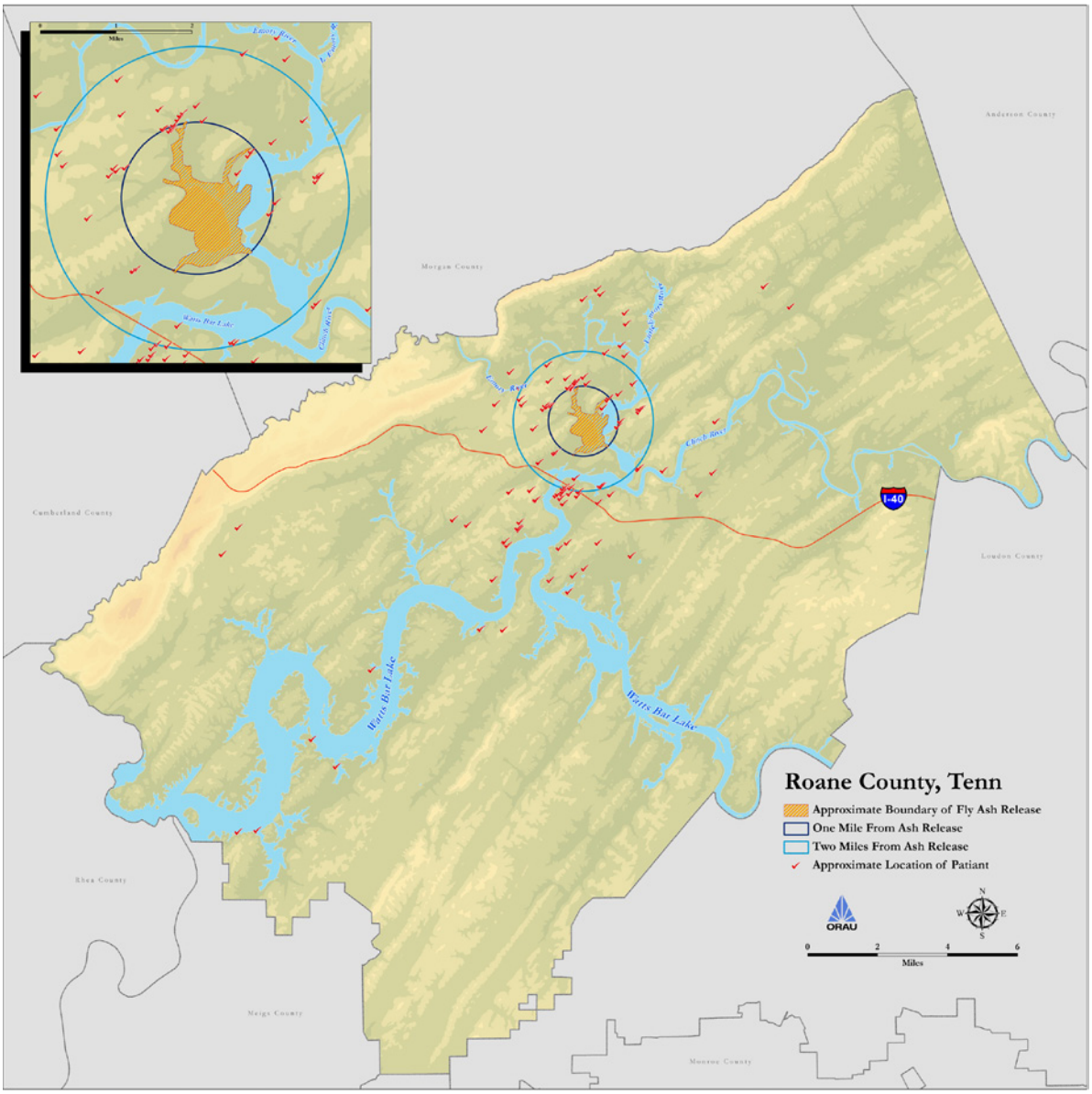
Demographics

Two hundred fourteen (214) people participated in the KPSP process, representing 112 households. Approximately half lived within two miles from the spill prior to the event, and half lived outside the two-mile radius.

It is estimated that there were nearly 100 households within one mile of the spill, and members from 12 of those households were represented in the program. Between one and two miles from the spill, there were approximately 650 households, and members from 37 of these households participated in the program. Thirty lived within one mile of the spill, 83 within one to two miles, and 101 more than two miles away. All participants were Roane County residents.

Participants lived in four cities: Harriman–157 (73%), Kingston–46 (22%), Ten Mile–6 (3%), and Rockwood–5 (2%). When asked their locations at the time of the spill, 175 (82%) said they were home, 18 (8%) did not specify, 13 (6%) were out of state, and 8 (4%) were in state but not home.

Figure 3: **Residential Locations of Kingston Project Participants**



The majority of participants (98%) identified white as their race, and 2% answered black. No other ethnic or racial categories were represented among the participants. The gender distribution consisted of 53% females and 47% males. See Table 2 for a comparison of demographic distribution of the KPSP participants compared to TDH survey participants from January 2009 and county statistics as reported by the U.S. Census Bureau.

Table 2: **Comparison of Participants with TDHC Survey and Roane County Population**

	Kingston Project Surveillance Program	Tennessee Department of Health (January 2009)	Roane County, Tennessee(9)
Persons under 5 years old	5.1 %	-----	5.0 %
Persons under 18 years old	18.7 %	24.1 %	20.4 %
Persons 65 years and older	25.2 %	16.7 %	17.5 %
Black	2.0 %	0.5 %	2.8 %
White	98.0 %	98.1 %	95.9 %
Female	53.0 %	53.4 %	51.4 %
Male	47.0 %	46.6 %	48.6 %

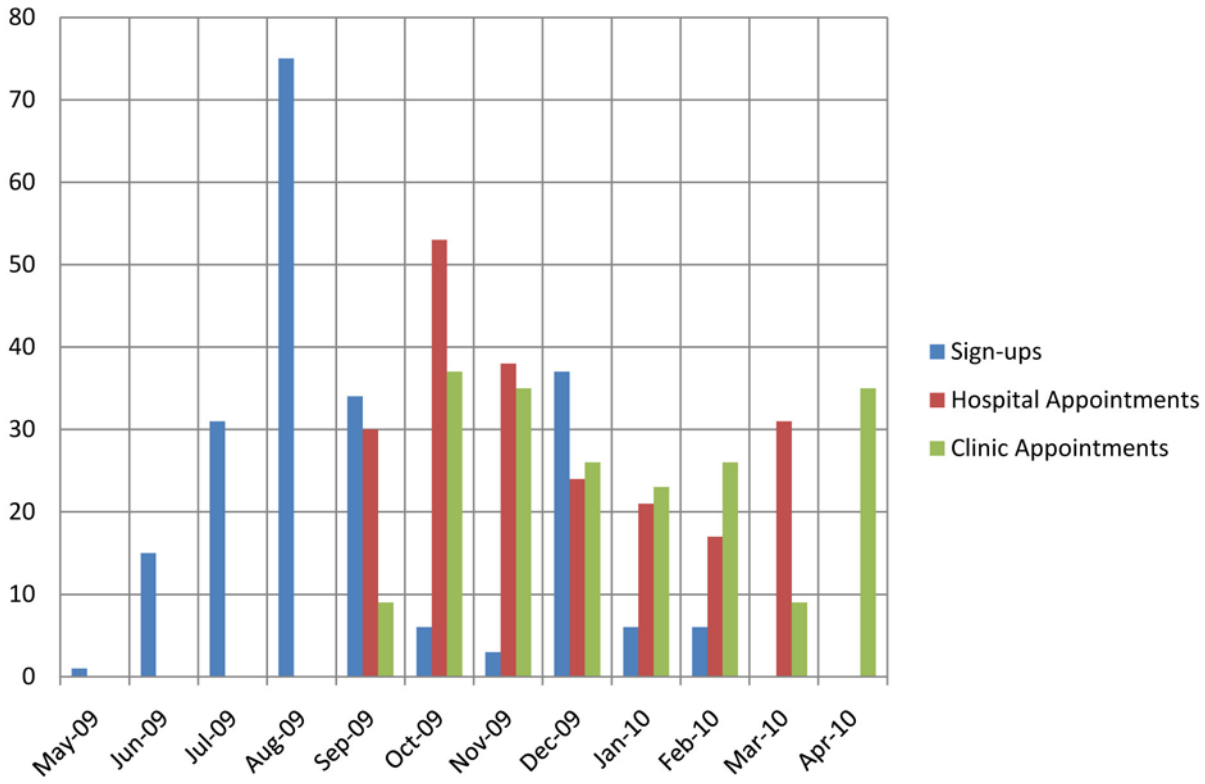
Table 3: **Age Distribution of Participants**

Age Group	Participants	Percent
<18 years	40	18.69%
18—44 years	43	20.09%
45—64 years	77	35.98%
65+ years	54	25.23%

The age distribution (Table 3) was also representative of Roane County's population. The largest age group was 45 to 64 years old, followed by those who were older than 65. The percentage of participants older than age 65 was higher in the participant group than in the rest of Roane County (25.2% vs. 17.5%). One explanation for this larger percentage is that the primary area affected by the ash spill contains a large number of retirees.

Figure 4 shows the flow of activity from initial sign-up through final clinic appointment with the medical toxicologist. Sign-ups began in May 2009, with a peak in August 2009 and another in December 2009. A total of 320 individuals initially signed up to participate in the surveillance program. Hospital appointments for blood, urine, x-ray, and spirometry testing began in September 2009 and were completed in March 2010. Clinic appointments with the medical toxicologist began in September 2009, and the last appointments were in April 2010.

Figure 4: **KPSP Participant Flow**



After signing up for the surveillance program, 106 individuals decided not to participate before the hospital testing phase of the program, leaving 214 participants.

Signed up	**320**
Dropped out	106
Had at least one test performed but declined clinic visit with the medical toxicologist	14
Total number with complete evaluation by MD	**200**

Fourteen of these participants wanted to have some or all of the hospital testing performed but did not want to be evaluated by the medical toxicologist. Two hundred individuals had both hospital and clinic appointments and therefore fully participated in the program.

Lab testing	Total =212
Both urine and blood	198
Only urine	6
Only blood	8

Two hundred twelve of the 214 participants had some or all of the blood and urine testing for metals, with 204 out of 212 having complete testing. Therefore, some people did not have a complete metal exposure evaluation.

Chest radiograph	208
Pulmonary function tests	194

Two hundred eight participants had a chest radiograph, and 194 underwent pulmonary function testing. Chest radiographs were declined because of recent radiographs or age of a child. Pulmonary function tests were not performed for the 20 children under the age of 6.

Medical Examination Findings

The most common symptoms reported by participants were those related to upper airway irritation, including runny nose, cough, and congestion. The abnormalities and variations that were found in the physical examinations were related to underlying medical conditions. There were no findings that would indicate local or systemic toxicity related to contaminants identified in the fly ash.

Pre- and post-spill medical problems were reported by participants. Of significance was the number of patients with increased HEENT (head, eye, ear, nose, and throat) and pulmonary complaints after the spill. This does not necessarily imply that fly ash caused this, because very little fly ash was reported airborne at the time. However, activities related to the cleanup effort, pollen, general dusts, etc., may have played a role in this. Most of these complaints related to irritated eyes, runny nose, cough, and congestion.

Medical problems related to:	Pre-spill	Post-spill
Head, eye, ear, nose, and throat (HEENT)	48 (23%)	133 (65%)
Pulmonary (Lung)	77 (38%)	106 (52%)

Chest radiography examination was performed on 208 patients. Two cases of lung mass (unrelated to fly ash spill) were found. Both were referred to their physicians for follow-up.

Table 4: **Abnormal Findings on Chest X-Ray**

	Number of Participants	Percent of Positive Findings	Percent of Total
Calcified Granulomas	2	8.70%	0.97%
Emphysematous Change	1	4.35%	0.48%
Enlarged Left Ventricle	1	4.35%	0.48%
Infiltrate	1	4.35%	0.48%
Large Hiatal Hernia	1	4.35%	0.48%
Mass/Nodule/Unidentified Density	4	17.39%	1.93%
Mild Aortic Atherosclerosis	1	4.35%	0.48%
Pulmonary Hyperinflation	8	34.78%	3.86%
Scarring	5	21.74%	2.42%
Splenic Artery Aneurysm	1	4.35%	0.48%
Thoracic Compression Fracture	1	4.35%	0.48%

Pulmonary (lung) function tests were done for all participants older than six years of age (N=194). The majority of the participants (N=146, 75.2%) had normal lung function tests. Mild abnormalities were found in 21 (11%), moderate abnormalities in 12 (6%), moderately severe to very severe abnormalities in 13 (7%), and undetermined abnormalities in 2 (1%). The majority of the individuals with abnormal tests (30 out of 48) were smokers. Abnormal tests were observed among 18 nonsmokers, with 12 (67%) of the abnormal tests being categorized as mild abnormalities. When participants with any abnormal findings were categorized by distance from the spill, there was a similar distribution of abnormalities for those living within two miles of the spill compared to those living greater than two miles away. Therefore, it is not likely that exposure to coal ash is responsible for the abnormal test results. These abnormalities may be due to multiple factors, such as emphysema, smoking, asthma, and respiratory infections, at the time of the testing.

Table 5: **Spirometry Results by Distance from Spill**

		<1 mile	1—2 miles	>2 miles	Total
Obstruction or Restriction	**Normal**	24 (82.76%)	52 (73.24%)	70 (74.47%)	146 (75.26%)
	Undetermined	0 (0.00%)	2 (2.82%)	0 (0.00%)	2 (1.03%)
	Mild	2 (6.90%)	6 (8.45%)	13 (13.83%)	21 (10.82%)
	Moderate	2 (6.90%)	5 (7.04%)	5 (5.32%)	12 (6.19%)
	Moderately Severe	1 (3.45%)	5 (7.04%)	4 (4.26%)	10 (5.15%)
	Severe	0 (0.00%)	0 (0.00%)	2 (2.13%)	2 (1.03%)
	Very Severe	0 (0.00%)	1 (1.41%)	0 (0.00%)	1 (0.52%)
	Total per Group	29 (100%)	71 (100%)	94 (100%)	194 (100%)

Table 6: **Metals: Blood Results**

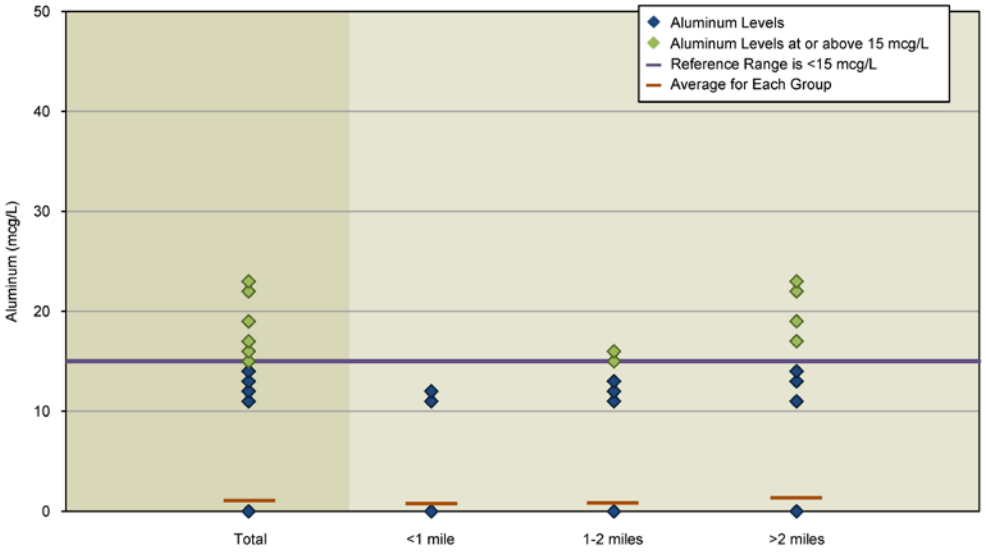
	Number of Participants Tested	Minimum Values	Maximum Values	Average Values	Number of High Values	Percent of High Values
Aluminum (mcg/L)	206	0.0	23.0	1.1	6	3.0%
Arsenic (mcg/L)	200	0.0	0.0	0.0	0	0.0%
Chromium (mcg/L)	206	0.0	2.0	0.1	1	0.5%
Cobalt (mcg/L)	204	0.0	0.0	0.0	0	0.0%
Copper (mcg/L)	204	55.0	250.0	116.5	17	8.3%
Nickel (mcg/L)	202	1.0	7.2	2.0	0	0.0%
Selenium (mcg/L)	203	110.0	470.0	212.0	55	27.1%

Table 7: **Metals: Urine Results**

	Number of Participants Tested	Minimum Values	Maximum Values	Average Values	Number of High Values	Percent of High Values
Arsenic (mcg/g creat)	204	0.00	540.0	10.5	7	3.4%
Barium (mcg/L)	204	0.00	20.0	0.4	1	0.5%
Beryllium (mcg/g creat)	203	0.00	0.0	0.0	0	0.0%
Thallium (mcg/g creat)	204	0.00	0.0	0.0	0	0.0%
Vanadium (mcg/g	204	0.00	0.0	0.0	0	0.0%

Aluminum was tested in serum for 206 individuals (Figure 5). Values in the people tested ranged from 0 to 23.0 micrograms/liter (mcg/L), with the average being 1.07 mcg/L. Six individuals had a value greater than or equal to 15.0 mcg/L, which is the reference value for aluminum in serum. Two of the people lived between one and two miles from the spill and had values of 15.0 and 16.0 mcg/L, respectively, the other four had values ranging from 17.0 to 23.0 mcg/L and lived more than two miles from the spill. None of the six individuals had a value high enough to cause medical problems or require additional treatment.

Figure 5: **Serum Aluminum in KPSP Participants by Distance from Spill**



Arsenic was tested in whole blood for 200 individuals and in a first morning urine sample for 204 individuals. No individual had any arsenic detected in his/her blood, which would indicate recent exposure. Seven individuals had arsenic detected in their first urine (Figure 6). Since a single random urine sample is not considered to be conclusive for evaluation of arsenic levels, each of the seven individuals completed a 24-hour urine collection to characterize whether there was an elevation in organic or inorganic arsenic. In each instance, the 24-hour urine calculations showed normal values.

Figure 6: **Urine Arsenic (First Morning Sample) in KPSP Participants by Distance from Spill**

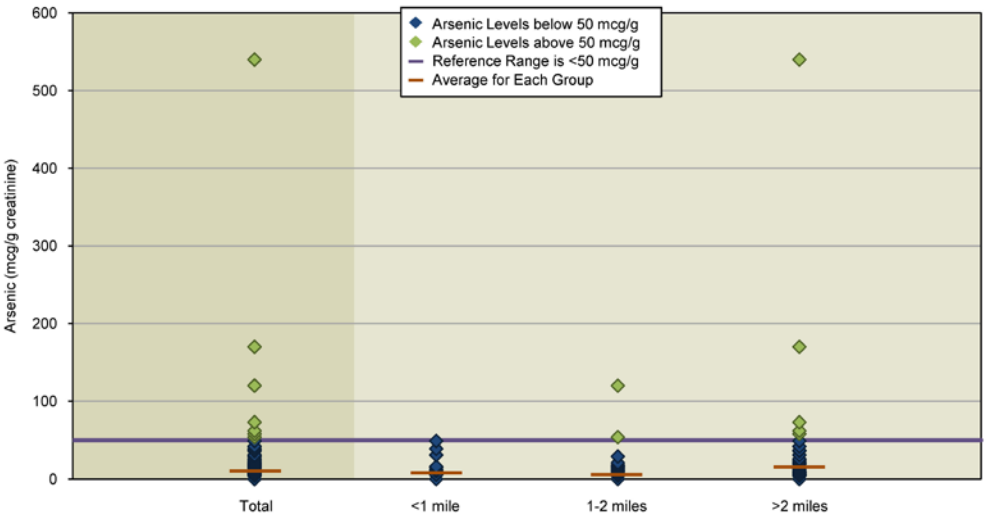


Figure 7: **Serum Nickel in KPSP Participants by Distance from Spill**

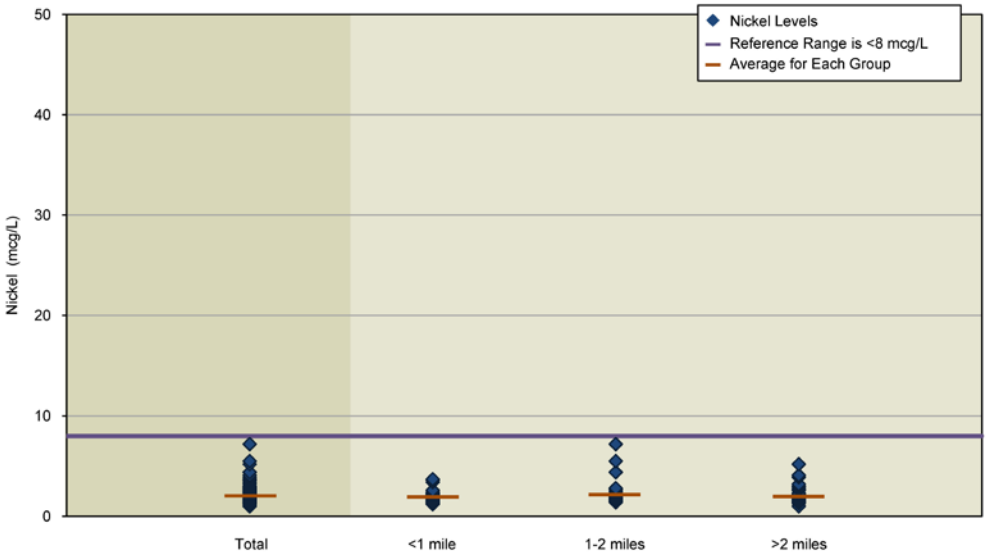
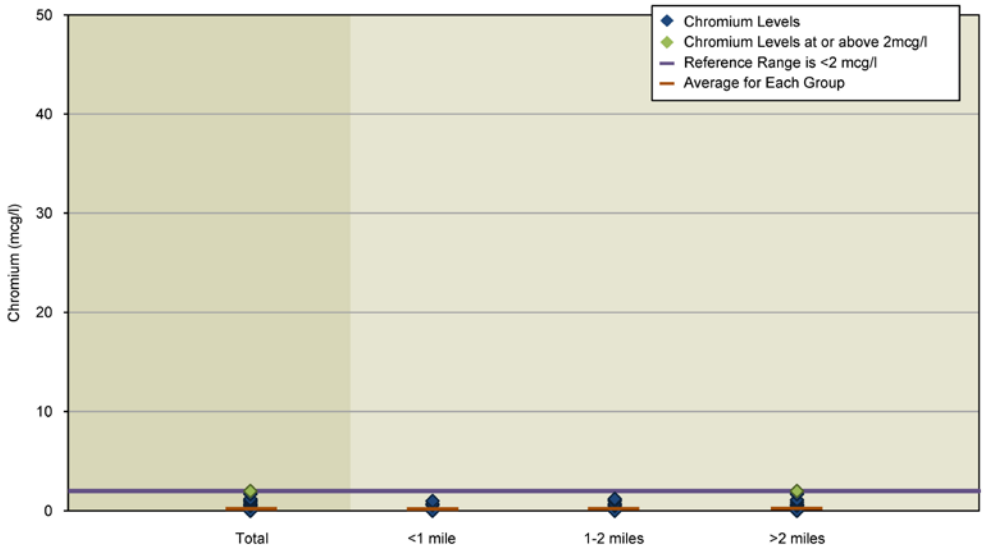


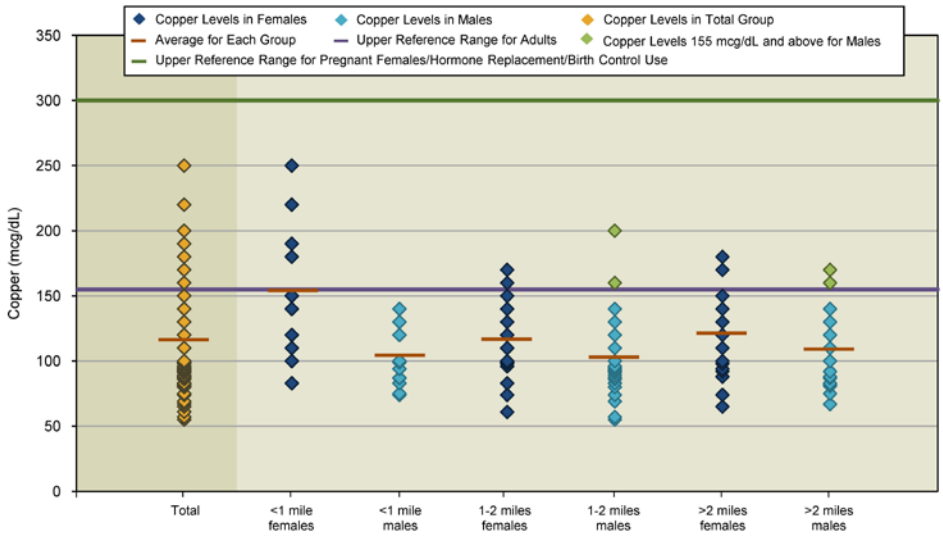
Figure 8: **Serum Chromium in KPSP Participants by Distance from Spill**



Cobalt was tested in whole blood for 204 individuals. **Chromium** and **nickel** were tested in serum for 206 and 202 individuals, respectively. No individual had any cobalt detected in his/her sample. No individual exceeded the reference value (the reference value for each metal is the level under which 95% of the people tested should fall) of <8.0 mcg/L for nickel (Figure 7). The reference range for chromium in serum is <2.0 mcg/L and there was one individual that had a value of 2.0 mcg/L (Figure 8). All other chromium values were below the reference range.

Copper was tested in serum for 204 individuals (Figure 9). Values in the people tested ranged from 55.0 to 250.0 mcg/L, with the average being 116.5 mcg/L. Seventeen individuals had a value greater than 155.0 mcg/L, which is the reference value for copper in serum. Copper is an element that is available naturally and is a micronutrient in human diet, thus it is considered an essential metal. While daily intake varies according to diet, absorption of copper can vary among individuals. Serum levels of copper can be elevated beyond standard ranges because of underlying liver disease, anemias, inflammatory diseases, pregnancy, and use of oral contraceptives or estrogen hormones(10). An upper reference range of 300.0 mcg/L is used for women who are pregnant, using hormone replacement (estrogen), or who are taking birth control pills. Acute poisoning from exposure to copper occurs after ingestion of large amounts of certain copper salts like copper sulfate. Clinical manifestations from acute copper poisoning were not evident in any patients with elevated serum copper levels. Six of the 17 with elevated copper lived within one mile of the spill, five lived within one to two miles, and six lived more than two miles away. Exposure to copper in the environment rarely causes disease in adults.

Figure 9: **Serum Copper Levels in KPSP Participants by Distance from Spill**



Selenium was tested in whole blood for 203 individuals (Figure 10). Values in the people tested ranged from 110.0 to 470.0 mcg/L, with the average being 212.0 mcg/L. Fifty-five individuals had a value greater than 230.0 mcg/L, which is the reference value for selenium in whole blood. Some participants were taking health supplements that may have contained selenium. Also, diet can increase selenium concentrations. Forty of the participants with elevated values returned for a repeat measurement of selenium after reduction in dietary and supplement sources, and all had subsequent values below or near the normal range (Figure 11). These participants did not have abnormalities on physical examination (11-13).

Figure 10: **Blood Selenium in KPSP Participants by Distance from Spill**

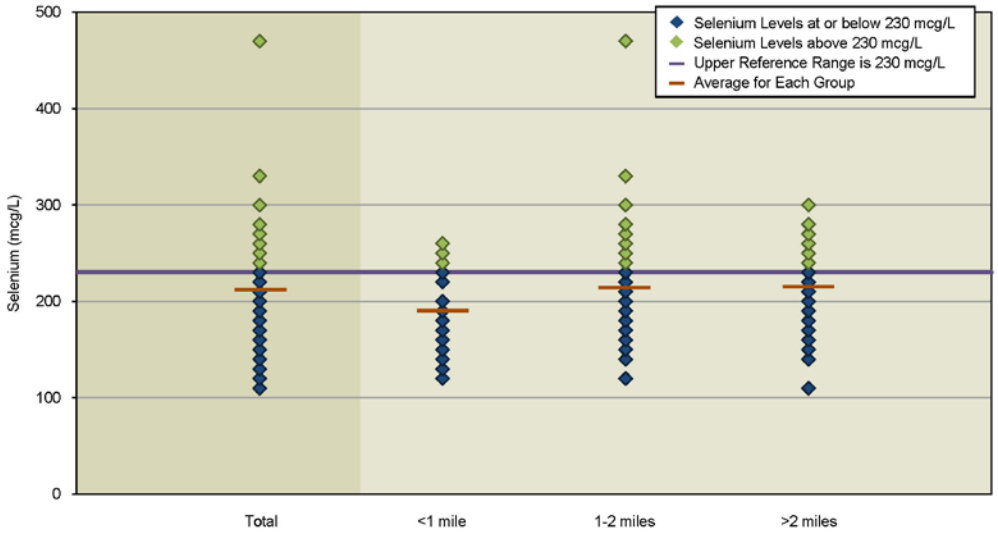
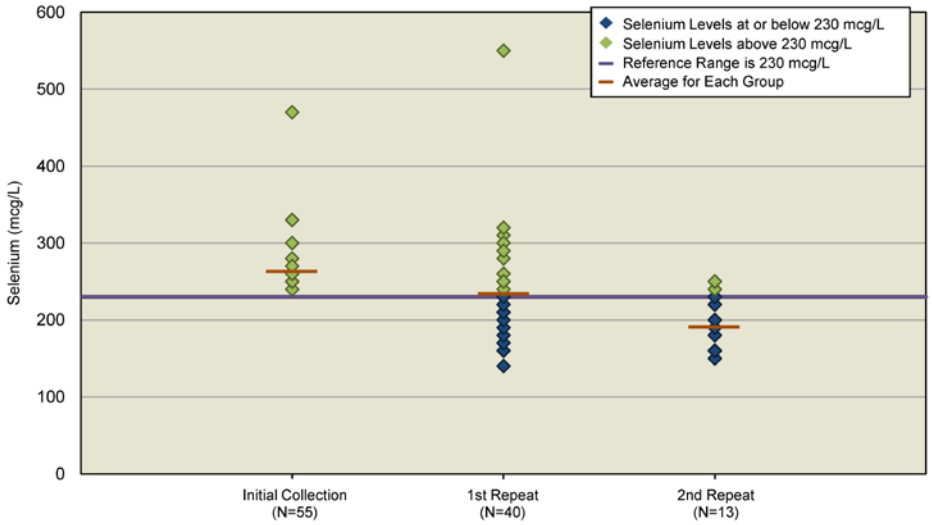
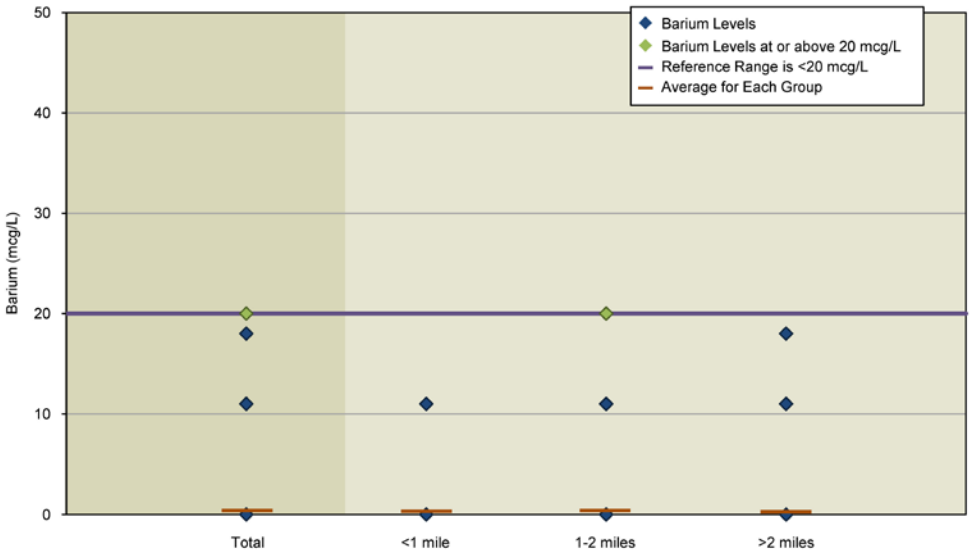


Figure 11: **Repeat Selenium Testing in KPSP Participants**



In addition to being tested for arsenic (discussed above), urine also was tested for **barium** (N=204), **beryllium** (N=203), **thallium** (N=204), and **vanadium** (N=204). The reference range for barium in the urine is <20.0 mcg/L and there was one individual that had a value of 20.0 mcg/L (Figure 12). All other barium values were below the reference range.

Figure 12: **Urine Barium (First Morning Sample) in KPSP participants by Distance from Spill**



No individual had any evidence of beryllium, thallium, or vanadium in their urine.

Participant Satisfaction

A satisfaction survey was included in the results packet mailed to participants in the medical screening. Surveys were received from 36 of the 200 individuals who completed the entire screening process. Surveys were assigned a score of satisfied or not satisfied based on responses to each question. A satisfied response equated to 75% or more satisfaction on scorable items, and a not satisfied response equated to less than a 75% level on scorable items. Overall, 94% of participants completing surveys answered that they were satisfied with the screening program.

Conclusions

In summary, it appeared that, in the baseline health evaluation, there have been a significant number of HEENT and breathing complaints since the spill. In addition, several unrelated medical conditions were diagnosed by chest radiography, pulmonary function testing and routine blood work. Patients with these conditions have been referred to their primary care physicians. Laboratory evaluations for metals revealed a small number of individuals with increases in values above the standard reference range. The increases do not appear to be related to exposure to fly ash because increases do not appear to be related to distance from the spill. In addition, several different elevated values for metals would be expected from fly ash exposure, not just one metal elevation.

Many of the tests for metals showed zero values in all individuals tested (blood arsenic, cobalt and nickel, and urine beryllium, thallium, and vanadium). This indicates that actual exposure to fly ash was minimal in all participants. Most elevated blood values were observed for copper and selenium, which are both micronutrients and influenced by diet, dietary supplements, and medications.

The findings of this surveillance program, based on a single screening exam for the 214 participants, are compatible with the conclusions discussed in the Public Health Assessment for the Coal Ash Release(3) prepared by the TDH in 2009. After careful consideration of all available data, the report concluded that they did "not expect harm to health from touching, eating, drinking, or breathing the metals in coal fly ash. No harm is expected from breathing the air as long as adequate dust suppression measures are in place."

Analysis of the available data from this baseline medical examination suggests no expected long-term effects on physical health from current levels of exposure. It is recommended that a repeat evaluation of this group of individuals be performed after a period of time to assess whether there have been any changes in health that may be related to the fly ash spill.

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ACRONYMS

ATSDR ..... Agency for Toxic Substances and Disease Registry

CBC ..... Complete blood count

CMP ..... Comprehensive metabolic panel

CCRs..... Coal combustion residuals

EPA..... Environmental Protection Agency

FWA ..... Federal-wide Assurance

GIS ..... Geographic information system

HEENT..... Head, eye, ears, nose, and throat

HIPAA..... Health Insurance Portability and Accountability Act

IRB ..... Institutional Review Board

KIF..... Kingston Fossil Plant

KPSP..... Kingston Project Surveillance Program

OEWH ..... Occupational Exposure and Worker Health

ORAU ..... Oak Ridge Associated Universities

ORSIRB..... Oak Ridge Site-wide Institutional Review Board

PAHs ..... Polyaromatic hydrocarbons

RMC..... Roane Medical Center

TDEC ..... Tennessee Department of Environment and Conservation

TDH..... Tennessee Department of Health

TVA ..... Tennessee Valley Authority

UA..... Urinalysis

VOCs ..... Volatile organic compounds

VUMC ..... Vanderbilt University Medical Center