

HEALTH CONSULTATION

**Evaluation of Health Studies Possibilities and Limitations at
the Abex/Remco Hydraulics Facility**

Willits, Mendocino County, California

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Executive Summary

Evaluation of Potential Epidemiological Health and Other Health and Exposure Research Studies at the Abex/Remco Hydraulics Facility (Chromium-Plating Facility), City of Willits, Mendocino County, California

This health consultation evaluates epidemiological health studies and other health and exposure research activities that could be conducted to understand the potential impact on the community of Willits, California, of chemical contaminants released from a former chromium-plating facility, Abex/Remco Hydraulics (hereafter “Remco”) from 1963-1995, in order to assess the potential scientific value and utility of such research. This health consultation is written to fulfill an activity proposed in a previously released Public Health Assessment (PHA) about Remco to determine what health study options, if any, would be suitable.

In the PHA, the California Department of Health Services (CDHS) concluded that chromium emissions from Remco increased the chance that exposed residents could get cancer or other health problems. Hexavalent chromium can cause lung or other cancers and illnesses, including asthma, decreased lung function, gastric irritation, and changes in kidney function. Some community members have expressed interest in health studies. This Health Consultation is a technical assist provided to the community as a follow-up activity cited under “Ongoing Actions” in the PHA.

This document covers:

1. “Type-1” exploratory or descriptive epidemiological studies that describe patterns of disease, or generate hypotheses about the effects of exposure to hazardous substances. Type-1 studies typically can only suggest the possibility of an association, and often the results are as likely due to chance as a true exposure-outcome association.
2. “Type-2” analytical studies that are specifically designed to test scientific hypotheses about the association between adverse health outcomes and hazardous exposures. Type-2 studies are more rigorous than Type-1 studies.
3. Clinical health- and exposure-related research activities that may be possible to conduct in Willits.

The scientific validity of an environmental epidemiological study depends on the extent to which the study method, as applied for the particular study, has the capability of showing the presence of an exposure-outcome association, if one exists. This requires evaluating how likely it is that alternative explanations may have accounted for the results, rather than the exposure being studied. Alternative explanations include chance, misclassification (incorrectly categorizing persons, such as considering someone exposed when that person is really not exposed), bias (error in the study design that may skew results), and confounding (the possibility that there is another factor, not the one studied, that is causing the disease, but is not accounted for).

1. Chance is a likely explanation of findings (low statistical power).

A study in Willits would not be likely to detect an increase in disease that could be reliably distinguished from chance, because the appropriate study population—those who would be most likely to have some illness from the exposure—was relatively small. Adequate statistical power requires a population sample size large enough to address the specific question being studied.

2. Possible misclassification (categorizing persons into the wrong groups).
In epidemiology, if persons who have little exposure are grouped with those who have high exposures, it will be difficult to accurately assess whether the exposure causes a disease. In Willits, accurate classification of exposure would be difficult. Accurate classification of illness (outcome) would vary depending on the outcome and the source of data.
3. Bias (systematic error in the study design that may skew the findings).
Many years have elapsed since the greatest exposures in Willits have occurred. The study may be biased if, for example, residents who moved away cannot be located, and those who still live in the area participate. If, for example, those who had moved away were sicker than those who stayed, then the study could incorrectly suggest that the study group (those assumed to be exposed) was healthier than they really were.
4. Confounding.
Confounding exists when a third factor exists that is associated with the exposure, and when this factor by itself can make people more likely to get the disease (even without the exposure). Confounding could occur if the Willits population was compared to another community, and (for example) persons in Willits had less access to health care, which contributed to their poor health relative to the other community, unrelated to their Remco exposure.

We applied these criteria in assessing the possibility for developing a scientifically valid epidemiological study in the Willits community. This evaluation focuses primarily on scientific validity and utility of the study concept, rather than practical or logistical issues.

Aspects of the population and exposures in Willits limited the range of possible health study options. Although many persons would be expected to have had relatively low exposures, based on exposure modeling, searching for increases in disease patterns in a group of persons with low exposure is likely to be difficult, as changes in disease patterns are likely to be subtle. Attempting to address this problem by selecting a smaller group of people known to be more highly exposed (such as only those living very near Remco during the earliest years of operation when exposures were highest) would result in the problem of low statistical power.

Type-2 studies that were considered included cohort studies of residents, school children, and former workers. However, the factors discussed above translated to a situation in which the criteria required for Type-2 studies could not be met.

In evaluating Type-1 studies, we considered whether the study had the potential to generate new hypotheses or additional information regarding potential exposure-disease relationships. Type-1 studies already conducted or not recommended include health statistics reviews of existing data

and a survey of residents' illnesses. Type-1 studies that could be considered include a case report or case reviews of illnesses (detailed write-up of a person(s) with a particular illness that may be associated with the exposure), and an exposure registry, although its significant limitations must be kept in mind (a registry is a listing of those who are exposed who would be followed over time to ascertain what illnesses may develop).

Clinical health- and exposure-related research activities were also reviewed as to scientific and public health value. Those not recommended included tests for chromium levels in blood and urine (unlikely to yield useful scientific findings due to the long time since exposure, although this could be valuable as a medical screening for individual patients). Activities that could be considered include exposure investigations of chromium levels in lung and other organs to better understand the burden of chromium in exposed persons (because chromium may be retained for years in tissue), and biological screening tests for early cancer detection, which may benefit residents at increased risk for cancer.

The choice to pursue the funding necessary to conduct a study is a significant one and the affected community's interest and full understanding of the goals and limitations of the proposed research should be critical to the decision.

Note: The Environmental Health Investigations Branch of CDHS prepared this health consultation under a cooperative agreement with the federal Agency for Toxic Substances and Disease Registry (ATSDR), as part of its public health assessment of potential community health risk posed by chemical emissions (e.g., hexavalent chromium, volatile organic compounds, cadmium, and lead) from Remco. ATSDR is mandated to help prevent or reduce the harmful effects of exposure to hazardous substances. However, the scope of the cooperative agreement that funded the PHA and this document no longer includes conducting actual research, such as the health studies that are reviewed in this document. If the affected community is interested in pursuing any of the research ideas that are described in this health consultation, funding sources would need to be identified outside of the ATSDR-funded cooperative agreement.

Background

Purpose of this Health Consultation

This health consultation evaluates epidemiological health studies and other health and exposure research activities that could be conducted to understand the potential impact on the community of Willits, California, of chemical contaminants released from a former chromium-plating facility, Abex/Remco Hydraulics (hereafter “Remco”) from 1963-1995, in order to assess the potential scientific value and utility of such research.

This health consultation is written to fulfill an activity proposed in a previously released Public Health Assessment (PHA) written by the Environmental Health Investigations Branch (EHIB), within the California Department of Health Services (CDHS), about Remco to determine what health study options, if any, would be suitable. CDHS has been conducting a public health assessment of the potential health risk to the community posed by chemical emissions from Remco. The Consultation is a technical assist provided to the community as a follow-up activity cited under “Ongoing Actions” in the PHA.

EHIB has prepared this health consultation under a cooperative agreement with the federal Agency for Toxic Substances and Disease Registry (ATSDR). ATSDR is federally mandated to conduct activities to help prevent or reduce the harmful effects of exposure to hazardous substances, including determining the level of public health hazard posed by a site, recommending actions that need to be taken to safeguard people’s health, and at times, conducting health studies in some communities that are located near hazardous sites or in locations where people have been exposed to toxic materials.

However, the scope of the cooperative agreement that funded the PHA and this document no longer includes conducting actual research, such as the health studies that are reviewed in this document. If the affected community is interested in pursuing any of the research ideas that are described in this health consultation, funding sources would need to be identified outside of the ATSDR-funded cooperative agreement.

Site Background

The Remco site is located at 934 South Main Street, in the City of Willits in northern California. Remco’s operations included chrome plating in 1963-1995 (1). Hexavalent chromium is the primary chemical of concern, although to a lesser extent, other chemicals such as volatile organic compounds, cadmium, nickel, zinc, and lead were released (2).

In 1997, as a result of a lawsuit filed by the City of Willits against the former owners of the facility (the Whitman Corporation), the Federal District Court for northern California ordered a Consent Decree¹ establishing the Willits Remediation Trust (hereafter “the Willits Trust” or “the

¹ A Consent Decree is a legal document, approved and issued by a judge, that formalizes an agreement reached between the City of Willits and the former owners (potentially responsible parties [PRPs]), where PRPs will conduct the clean-up action at the Remco site; cease or correct actions or processes that are polluting the environment; or

Trust”) (2). The Willits Trust is responsible for and funded to conduct site investigation, cleanup, and medical monitoring (although this is not defined in the Trust), as set forth in the Consent Decree. In 2000, the site itself was acquired by the Trust.

EHIB Activities at the Remco Site

In June 2000, the U.S. Environmental Protection Agency (EPA) requested assistance from CDHS to evaluate the potential health impact posed by the facility. In July 2004, the final PHA that evaluated health impacts from chromium emissions into the air was released. The report concluded that chrome-plating operations at Remco were a source of exposure that created an increased chance for exposed Willits residents to get cancer, and that some residents could have experienced health problems other than cancer. The report concluded that releases of airborne hexavalent chromium posed a past public health hazard (1963-1995), and that currently and in the future, there is an indeterminate health hazard from exposure to hexavalent chromium and lead in dust that may be generated during site remediation or demolition (2).

Because of our findings of potential increased risk of different health problems among community members, we decided to consider what health study options may be suitable for this site¹.

Potential Health Effects of Hexavalent Chromium

Hexavalent chromium is currently known to cause both noncancer and cancer health effects. Noncancer health effects include asthma, bloody nose, nasal septum scarring and perforation, runny nose, mild decreased lung function, bronchitis, gastric irritation, and subtle changes in kidney function. Lung cancer is the primary cancer associated with hexavalent chromium exposure; other cancers (nasal, stomach) have been suggested, but are not well studied. Hexavalent chromium is not the only type of exposure or risk factor that may cause these noncancer and cancer health effects.

Demographics

Based on 2000 census data, approximately 15,000 people live in the Willits area, with 5,073 people living within the city limits or the incorporated area. The ethnic make-up is roughly 3% Native American Indian, 14% Hispanic or Latino, and 83% White (3). In 1995, 33% of the total population was under age 19 and 13% was over age 65. In the past, the population of the City of

otherwise comply with initiated regulatory enforcement actions to resolve site contamination. The Consent Decree describes actions that PRPs are required to perform and may be subject to a public comment period.

¹The “Ongoing Actions” section of the PHA states: “CDHS/ATSDR will continue to consult with in-house experts (physicians, epidemiologists, etc.) to determine what, if any, study options are suitable for the site. If a scientifically grounded, feasible health study can be conducted at the site, CDHS/ATSDR recommend, and will solicit, community input in the development of any health study activities at the site. These activities could fall under the medical monitoring provision of the Consent Decree. It is unclear whether the Consent Decree will need to be amended for the medical monitoring provision to move forward.”

Willits was estimated to be 3,410 in the 1960s; 3,091 in the 1970s; 4,008 in the 1980s; and 5,006 in the 1990s.

Baechtel Grove Middle School opened in 1954, and during the years of Remco operations, the school population ranged from 520 to 580 students (2).

Discussion

Epidemiology—Studying Diseases in Groups of People

Epidemiology is a science that helps us understand what causes disease by studying how frequently diseases occur and how they are distributed in different populations.

In any community, it is expected that some people will have illnesses. If a certain exposure caused additional illness in the community, this may be reflected in an increased number of persons with a certain illness (e.g., did more people get lung cancer than what we would expect for this population?).

In situations in which people have been exposed to a potentially hazardous chemical, sometimes there is the chance to learn more about this chemical's effects on humans. However, not all situations are necessarily suitable for studying a given research question, and criteria are useful to understand what studies would be effective.

Scientific Criteria for Evaluation of Potential Research Studies

The scientific validity of an environmental epidemiological study depends on the extent to which the study method, as applied for the particular study, has the capability of showing the presence of an exposure-outcome association, if one exists. This requires evaluating how likely it is that alternative explanations may have accounted for the results, rather than the exposure being studied. Alternative explanations include: chance or coincidence (a problem occurring because of low statistical power), misclassification (categorizing persons into the wrong groups, such as considering someone exposed when that person is really not exposed), bias (error in the study design that may skew the findings), and confounding (the possibility that there is another factor, not the one studied, that is causing the disease but is not accounted for).

We applied these criteria in assessing the possibility for developing a scientifically valid epidemiological study in the Willits community, to investigate if health problems have been associated with past exposures. This evaluation will focus on the scientific validity and utility of the study concept more than the practical and logistical issues involved.

Other Considerations in Evaluating Potential Research Studies

The potential value of a study also depends on a number of issues including public health significance, community perspective, involvement and support for the study, scientific importance, and, as discussed above, scientific validity, or the ability to provide definitive results (4). However, without scientific validity, other criteria become moot.

Other considerations include: money/resources (typically, costs are between \$50,000 for a small study and \$200,000-\$500,000 per year for a large study); time required (many studies take 4-5 years); and whether the project contributes to the goals of the ATSDR program mandates, if ATSDR is to fund the study. These goals include identifying people at health risk, evaluating the relationships between exposure and adverse health effects, and intervening to eliminate exposures or mitigate adverse health outcomes. Other institutes within the National Institutes of Health also fund health studies.

Conducting a study typically involves several phases: working with the community to decide on the study; planning the study; seeking funding; collecting data; analyzing data; sharing results to the community; and writing and publishing findings. Costs depend on the number of people involved, whether they need to be tracked and contacted, the length of time of the study, and the need for any laboratory tests or exams. The likelihood of obtaining funding depends on the strength of the proposal.

Types of Epidemiological Studies and Other Health and Exposure Research Activities Covered

This document covers:

1. “Type-1” exploratory or descriptive epidemiological studies that describe patterns of disease, or generate hypotheses about the effects of exposure to hazardous substances.
2. “Type-2” analytical studies that are specifically designed to test scientific hypotheses about the association between adverse health outcomes and hazardous exposures. Compared to Type-2 studies, Type-1 studies yield more limited results, in that they can only suggest the possibility of an association, and typically the results are as likely due to chance as a true exposure-outcome association.
3. Clinical health- and exposure-related research activities that may be possible to conduct in Willits.

This report will first discuss the most rigorous studies, Type 2, then Type 1, followed by clinical health and exposure research activities.

Type-2 Health Studies (Analytical Studies That Test Hypotheses)

The Type 2 studies possible in Willits are cohort studies.¹ A cohort study is one in which a

¹ Case-control studies are another Type 2 study, but cannot be applied in Willits. Case-control studies start with a group of people with a certain illness and a comparison group of people without the illness, and then systematically

specified group of people is identified based on their exposure, and then they are studied as to whether or not they developed certain illnesses. If a cohort is constructed based on records of who lived, worked, or attended school in a specific area in the past and compared to another group without the exposure being studied, this is called a “retrospective cohort study.” In this study design, after the cohorts are constructed, the investigators then review data to ascertain how many subjects in the exposed and unexposed groups became ill.

Retrospective Cohort Study in Willits: Community members

1. Description

A group of persons (“retrospective cohort”) would be selected based on, for example, their residence in Willits at any time during 1963-1995. To find such a list, investigators could use old phone books, property tax records, voting registration, and word-of-mouth. Once names are found, if the person no longer lives in Willits, investigators would try to search different databases and other sources to find out where the person now lives and get an address and phone number if necessary. Then the person would be contacted by phone or sent a questionnaire and asked about specific illnesses he or she might have. A comparison group of persons, such as a neighboring community, selected using the same techniques for the same time period, who are as similar as possible other than for the exposure, would be used to compare the rates of diseases between the two groups.

This study could compare incidence or prevalence of specific health problems of persons between those who lived in Willits during the exposure period and those of a comparison population. The incidence is the number of new cases of a disease that develop among a group of persons during a specific time period. The prevalence of disease is the proportion of persons in a population with an illness that exist at a certain point in time.

Or, the list of names could be sought in cancer records to determine if the person had developed cancer, or sought in mortality records, to see if the person was deceased, and what was the cause of death. In this case, the comparison rates would be based on the region or state rates.

2. Evaluation According to Epidemiological Criteria

- a. Statistical power—The power that the study has to distinguish if the results are due to chance depends on several factors: how large the study population is; how rare or common the disease is; and how much of a change from the expected the difference is. The population of the city of Willits was about 3,000 in 1960, and about 5,000 in the 1990s. The unincorporated areas of Willits were estimated to be about 10,000 in the 1980s. If all members of an exposed population with a size of about 10,000 could be identified and tracked, that would be a population large enough to have fairly good statistical power to detect elevations for many diseases, as long as the elevation in illness is fairly substantial and the disease is fairly

assess if the persons who had the illness also had a factor or exposure in common more frequently than those without the illness. If we looked for cases of a particular illness in Willits, that would mix up the exposure and the illness, because Willits is also the exposure area.

common. For example, it would be easier to detect an increase if twice the number of people had a certain illness, than to detect a situation in which an additional 5% of the population had developed the illness. Also, an increase would be easier to detect if the disease affected 10 out of 100 persons, but much harder to detect if the disease was so rare that it typically occurred only in 1 in 100,000 persons. However, for reasons explained in the following section, this larger population size would not be appropriate for a study group.

- b. Exposure or outcome misclassification (categorizing persons into the wrong groups)—If all persons who ever lived in the greater Willits area from 1963-1995 are eligible for the study, then some persons will have received much higher exposures than others, depending on how long they lived in Willits, where they lived, and where they spent their time. Accurately knowing those differences is difficult. If persons who have low exposures are grouped with those who have high exposures, it may make it difficult to accurately assess whether the exposure causes a disease. While persons receiving low exposures may still be at risk, the proportion of exposed who develop a specific illness is likely to vary according to the degree of exposure. The population receiving low exposures may, for example, only experience a very slight increase in the proportion of the population that develops a particular illness. This would not likely to be distinguishable statistically (see “statistical power”, above).

On the other hand, if the study were limited to those with presumed greater exposure, such as only those who lived within the yellow contour outlined in the public health assessment (2) for example (average 1 microgram per meter cubed), during the high exposure period (1963-1975), then the population size would be too small to have adequate statistical power.

How accurately the illness (outcome) would be classified would vary depending on the outcome and the source of data.

- c. Bias (systematic error in the study design that may skew the findings)—Identifying and then including the correct group of persons would be one of the most challenging aspects of constructing a study in Willits. Many years have elapsed since the greatest exposure occurred. Even if phone books are searched, such a method would typically only identify one person, the head of household. Many people will have moved away, gotten married, and changed names. The phone book will have names only, not other helpful identifiers such as social security number or date of birth. The study might be biased if, for example, residents who moved away cannot be located, and those who still live in the area participate. If, for example, those who had moved away were sicker than those who stayed, then the study could incorrectly suggest that study group (assumed to be exposed) was healthier than they really were.

Bias can also occur if only a subset of those identified as eligible actually choose to participate in a study, if that group does not accurately represent the whole group. For example, if only those who have health problems in Willits choose to participate, then the results would be biased because it would appear that the exposed group had more health problems than a comparison group. Or, if people in Willits who were quite sick decided not to participate, then the study results could underestimate the amount of illness in the exposed community.

To determine whether the amount of illness in a community is unusually high or not, it is also necessary to determine what the amount of illness would be typically—that is, how much illness would there have been if the exposure had never occurred? This is generally difficult to assess. It is hard to find another community or comparison group that is exactly the same except for the exposure in question, and other differences between the communities will affect the results of the comparison.

- d. Confounding (the possibility that there is another factor, not the one studied, that is causing the disease but is not accounted for)—Confounding could occur if the Willits population (exposed population) was compared to another community, for example, and persons in Willits had worse health care which contributed to their poor health compared to another community, unrelated to their Remco exposure.

Recommendation: do not pursue.

Retrospective Cohort Study in Willits: Baechtel Grove Middle School Students

1. Description

A group of former students would be selected based on the criteria that they attended Baechtel Grove School at any time during 1963-1995. To find such a list, investigators could use high school year books and records. Persons would be searched as in the Willits community study. The comparison group would be one or two other comparable schools during the same time periods. Again, questionnaires, phone interviews, cancer data, or mortality records would be searched.

2. Evaluation According to Epidemiological Criteria

- a. Statistical power—This population size is not large enough to determine an elevation in most disease rates, unless the elevation, compared to what is expected, is quite large. For example, most cancers do not become very common until later in life, and most of the Baechtel Grove cohort would not be old enough yet to expect much cancer. In order for an increase to be large enough to be distinguished from chance variation, the number of lung cancers would have to be 4 times higher than would be typically expected for a population of this size and age. Although this magnitude of increase has been noted among workers who were exposed to very high levels over many years, it is not likely to be seen among persons with exposures estimated. For asthma, most cases have already developed by the age of 6, so there would be few students still likely to develop the disease by the time they reached middle school.
- b. Exposure misclassification (categorizing persons into the wrong groups)—Although Baechtel Grove School is located very near the Remco facility, school attendees were only present for a portion of the day and for 3 years at the most. While we do not know exactly what levels of exposure were received, we can assume that some level of exposure occurred and was reasonably similar across all students. However, we do not know if the amount of exposure they had for the period of time they had it was enough to prompt a significant increase in

illness.

- c. Bias (systematic error in the study design that may skew the findings)—Similar to the cohort of Willits residents, identifying and including the correct group of persons is a challenging aspect of designing a study in Baechtel Grove School. However, more information exists than for the general population of Willits, as yearbooks will help establish a cohort, even if girls get married and other names change. On the other hand, children may be more likely to move away from Willits than adults who have settled and may have jobs in the area, thus there may be more persons who require tracking. Adults often do not accurately recall symptoms from childhood that no longer exist.
- d. Confounding—Confounding could occur similar to the first study.

Recommendation: do not pursue.

Retrospective Cohort Study in Willits: Former Remco Workers

Issues of statistical power and selection bias are probably the greatest concerns in considering a study of former Remco workers. Although the group would be assumed to have had fairly significant exposures, the size of the population overall is too small to have good statistical power, and identifying and following up a group complete enough to avoid selection bias would be challenging.

Recommendation: do not pursue.

Type-1 Health Studies—Exploration and Hypothesis-Generating Investigations

Cross-Sectional Survey

1. Description

A cross-sectional survey is one in which the disease of the individual and the exposure is assessed at the same time. In the case of Willits, this would mean that a health survey of illnesses would be conducted among current residents. Respondents would indicate whether or not they had certain illnesses, and whether or not they lived in Willits (or certain parts of Willits) during Remco operations.

2. Evaluation According to Epidemiological Criteria

Selection bias is likely to be a significant problem in this type of design. The comparison group of unexposed persons will not have lived as long in Willits. This group of persons who more recently moved to Willits may be different demographically than those who have lived in Willits for a long time, in ways that may have influenced their health status. Also, in cross-sectional surveys, it is difficult to relate the occurrence of the illness in time with the exposure, which makes it hard to conclude if exposures were likely to be related to disease.

Recommendation: do not pursue.

Health Statistics Reviews

1. Description

a. Cancer Registry Review

This is a review of the numbers of cancer cases that have occurred in the city of Willits, compared to the number that would be expected. This review has been conducted, and the results are reported in the public health assessment (2). The review did not find a statistically significantly elevated number of cancer or lung cancer. The number of lung cancers and respiratory cancers was greater than the number expected, but the difference was not large enough to be distinguished from a difference that could occur by chance.

b. Mortality Data Review

This has been conducted by a consulting firm, Exponent, on behalf of the owners of the current Remco property, PepsiAmerica. The review did not find a statistically significant increase in mortality.

c. Studies of specific health problems have been suggested by community residents such as developmental disabilities or miscarriage (spontaneous abortion). As no registry exists for these health outcomes, these studies would use data collected for administrative, not research purposes, and may not be accurate enough to use in a study.

2. Evaluation according to epidemiological criteria

As noted, cancer and mortality data reviews have been conducted; they used existing, reliable data and did not require extensive resources. Their lack of finding an association between chromium and health conditions must be interpreted in light of study limitations. The results may reflect the absence of a true relationship, but could also be a result of methodology shortcomings, particularly low statistical power (not enough people in the study sample to detect statistically significant elevation in rates) and exposure misclassification (the area studied may include those who were not exposed, or not exposed to high enough levels of chromium to cause an effect).

Trends based on reviews of data sources other than cancer registry or mortality data are similarly or more likely to be primarily influenced by aspects of how the data are collected or who is represented in the database, rather than truly indicative of who has disease or not, thus would be unlikely to yield useful information. For example, selection bias is likely to be a significant limitation, as only a fraction of miscarriages, which is unlikely to be representative, would be included in hospital discharge data.

Recommendation: do not pursue additional reviews.

Case Report or Case Series

A case report or case series reports on the experience of a single patient or group of patients with a similar diagnosis. In this type of study, a clinician may identify an unusual aspect of a patient's disease or a patient's history, which may suggest a new hypothesis. Case reports can represent the first clues to identifying a disease's link to an exposure. A case series is a collection of individual case reports that typically occur within a specific time or in a particular place. For example, a report of three persons with a rare liver cancer who worked in a vinyl chloride plant led to the hypothesis of a link between this exposure and outcome.

Case reports can suggest hypotheses, but cannot be used to test a hypothesized association between an exposure and an outcome, as the event may have occurred by coincidence.

Recommendation: consider as appropriate cases arise.

Exposure Registry

1. Description

An exposure registry is a listing of persons exposed to a specific hazardous substance. The National Exposure Registry was started by ATSDR to help scientists understand how long-term exposure to hazardous substances may affect human health. This is done by identifying and following the health of individuals who have come into contact with specific substances at selected locations. Another purpose of the Registry is to have a mechanism through which participants may be notified of the results of research related to their exposure. Currently, ATSDR does not have the funding to establish any additional registries, although it maintains several sub-registries of persons exposed to certain chemicals and for persons exposed at the World Trade Center attack on September 11, 2001.

In Willits, an exposure registry could consist of persons who were exposed to chromium, for example, either defined by residential proximity to the Remco facility during the exposure period, or employment at Remco. Registry participants would be followed up periodically with surveys to assess their health. The registry could be used to generate hypotheses, but would be less useful in testing hypotheses, as participants would not have been selected according to standards applied to Type-2 studies, and as the relevant population which may have received significant exposure is likely to be relatively small, which greatly limits statistical power. A chromium registry could include not only persons with Remco exposures, but be expanded to other sites with known chromium exposure. The rates of illness in the registry could be compared with information about health collected by the federal government in the National Health Interview Survey. Although these comparisons would be limited by sample size, still, if several cases of an unusual illness were noted to occur in the registry, this could suggest directions for future exploration.

2. Evaluation According to Epidemiologic Criteria

Statistical power would not meet standards desirable for Type-2 studies, but a registry could allow the possibility of identification of patterns of illness within the most highly exposed population of former workers and residents, provided the occurrence was extremely unusual in some way. However, the chances of this are unknown.

Recommendation: can be considered, although no funding exists currently for this resource-intensive activity. The small sample size poses an inherent limitation; a chromium registry would be more likely to be fruitful if could be combined with other similarly exposed populations.

Clinical Health and Exposure Research Activities

These are evaluated as to general scientific and public health value they may provide.

Biomonitoring Studies for Chromium in Body Fluids

These studies would involve collecting and analyzing biological specimens (e.g., blood serum or urine) for chromium.

Although learning about the exposure of persons who lived or worked in Willits during Remco operations may be desirable, this is not likely to be feasible in this population. Chromium is quickly excreted from the body after exposure. It can only be measured in blood for the life of the blood cell (about 120 days), and in urine within a few days (5). However, because chromium can be retained in body tissues for many years (6), elevated chromium levels can occasionally still be detected in urine after the typical excretion period. However, past studies of chromium suggest that it would be unlikely to detect an increase in chromium levels in urine or blood samples this long after exposure had ended. Also, chromium is an essential nutrient, so everyone will have some background levels of it, which will make it difficult to distinguish from Remco-related exposures. Although not scientifically valuable as an exposure study, screening individuals with concerns about past exposure could have value by ruling out current or significant past exposure.

Recommendation: do not pursue.

Biomonitoring for Chromium in Body Tissues/Organs

This would provide information on the levels of chromium retained in the lung or other body tissues from environmental and/or occupational exposures years after exposure ceased.

1. Biopsy tissue—Establish a system whereby formerly exposed residents can give permission to allow analysis for chromium concentrations of removed body tissue. Examples would include biopsies and other tissue removal (e.g., liposuction or removal of lipomas). Also, existing lung tissue stored under requirements for preservation of such specimens (for example, taken during biopsy or lung resection) could be evaluated. Permission would be sought from the patient prior to evaluation of stored tissue.
2. Autopsy tissue—Similar to planned organ donation, establish a system whereby formerly exposed residents can give permission in advance to allow chromium tissue analysis of their lungs and potentially other organs after they are deceased.

Previous research has shown that chromium can remain in the lung for years after exposure ceases, and that chromium concentrations vary greatly within different parts of one individual's lungs (7). Chromium can be found in many organs in addition to lungs (6). Some researchers have found chromium content of lungs of persons with lung cancer to be higher than that of persons without lung cancer (probably due to chromium exposure from cigarettes) (8). Some have studied chromium workers, finding that the amount of chromium that accumulated in their bronchi and lungs significantly increased according to the progression of malignant changes in the lining of the bronchus (9).

The logistical and practical limitations of this type of study include the difficulty in obtaining specimens, and the fact that accumulation of specimens would take quite some time.

Recommendation: scientifically valid, although logistically complex; can be considered.

Biomarkers for Early Cancer Detection Studies

Researchers are now developing new tests to detect cancer earlier by looking for cancerous cells in body fluids, such as sputum (fluid coughed up from the lungs), saliva, urine, or blood and evaluating a variety of molecular changes in cell deoxyribonucleic acid (DNA) (10). These techniques are new and it is not known at this time which technique might be most effective, or how effective they might be in populations with differing risks for cancer. However, many studies are now assessing the usefulness of these methods. This raises the possibility that exposed Willits residents who are at greater risk for cancer than general populations may consider participation in research studies in this area. The fact that lung cancer in particular is a highly fatal disease that can best be treated when detected in early stages suggests that applying methods of early detection for this population may be beneficial, although tests exist for other cancers as well. This type of effort would require coordination with researchers in this field, and its specific benefits to the Willits population would be unknown, given that no biomarkers have been validated as to their efficacy at this time.

Recommendation: this would further scientific knowledge although benefits to the community are unknown; can be considered if there is strong interest on the part of the community.

Biomarkers for Detecting Chromium-Related Changes in Protein Expression

Although we can test for the presence of chromium metal directly in biological specimens, new research techniques have been developed to test whether persons exposed to chromium express molecular biomarkers (e.g., proteins) in a different pattern than those who have not been exposed. This general area of research on genes and proteins is called toxicogenomics,¹ and proteomics² is an area within this field. In this type of study, a group of persons with known high

¹ Toxicogenomics: the collection, interpretation, and storage of information about gene and protein activity in order to identify toxic substances in the environment, and to help treat people at the greatest risk of diseases caused by environmental pollutants or toxicants.

² Proteomics: the study of the set of proteins produced (expressed) by an organism, tissue, or cell, and the changes in protein expression patterns in different environments and conditions. Proteomics has been explored as a method of identifying metal-specific genetic markers of exposure and response.

chromium exposure (ideally workers with high and recent exposures) would be identified, and serum would be obtained and analyzed using proteomic techniques to assess patterns of protein expressions. This would be an initial, hypothesis-generating effort, which could be followed by more rigorous laboratory studies. However, because this would be the first application of this method to chromium, this method would best be tested among a group of persons with known, high, and recent chromium exposure.

Recommendation: do not pursue in this population without a test that has been shown to be effective in a population with known current exposures to chromium.

Children's Health Considerations

ATSDR recognizes that infants and children may be more sensitive than adults to environmental exposures. This sensitivity is a result of several factors: 1) children may have greater exposures to environmental toxicants than adults because, pound for pound of body weight, children drink more water, eat more food, and breathe more air than adults; 2) children play outdoors close to the ground, increasing their exposure to toxicants in dust, soil, surface water, and ambient air; 3) children have a tendency to put their hands in their mouths while playing, thereby exposing them to potentially contaminated soil particles at higher rates than adults (also, some children ingest non-food items, such as soil, a behavior known as "pica"); 4) children are shorter than adults, meaning that they can breathe dust, soil, and any vapors close to the ground; 5) children grow and develop rapidly; they can sustain permanent damage if toxic exposures occur during critical growth stages; and 6) children and teenagers may disregard "No Trespassing" signs and wander onto restricted locations. This report presents a number of potential studies that investigate possible health effects of chromium among exposed children, an area which has virtually no scientific information at this time. Risks to children in the Willits area are characterized in our earlier report (2).

This document addresses considerations about children's health in several ways. As much of what is known scientifically about chromium is based on adult males, information is needed on persons who were children at the time of exposure. Children may be more susceptible to the effects of chromium because their lungs are still developing, so a lung toxicant should be carefully evaluated as to effects.

Conclusions

As concluded by CDHS in its previously released public health assessment on Remco, past releases of airborne hexavalent chromium posed a public health hazard in the past (1963-1995). Currently and in the future, there is an indeterminate health hazard from exposures that may be generated during cleanup. Despite this exposure hazard, method limitations in satisfying the criteria for scientific validity limits the potential for research studies, including the relatively small size of the most highly exposed population, the difficulty in accurately defining a study population, and the fact that exposure ceased so long ago.

Type-2, or analytical epidemiological studies, are not recommended in Willits because of the limitations of the situation in constructing studies adhering to rigorous scientific methods.

Type-1 studies in Willits offer a narrower scope of potential results (hypothesis generation), and

are limited in that the likelihood they would provide new or valuable information is restricted. Type-1 studies are similarly not recommended, with the qualified exception of possible case reports/ series or an exposure registry.

However, other scientific studies may be of value in Willits. Specifically, although chromium is unlikely to be detectable in body fluids at levels that would be distinguishable from background, it would be useful to assess the presence and levels of chromium in body tissues in environmentally- and occupationally-exposed persons. Participating in research using biomarkers for early cancer detection may further scientific knowledge, although the specific health benefit to Willits residents is not known.

The choice to pursue the funding necessary to conduct a study is a significant one and the affected community's (or workers') interest and full understanding of the goals and limitations of the proposed research should be critical to the decision.

It should be noted that the scope of the cooperative agreement that funded the PHA and this document no longer includes conducting actual research; thus if the affected community is interested in pursuing any of the research ideas that are described in this health consultation, funding sources would need to be identified outside of the ATSDR-funded cooperative agreement.

Public Health Action Plan

The Public Health Action Plan contains a description of actions regarding this site taken, to be taken, or under consideration by ATSDR and CDHS. The purpose of the Action Plan is to ensure that this health consultation not only identifies public health hazards, but also provides a plan of action designed to mitigate and prevent adverse human health effects resulting from exposures to hazardous substances in the environment. CDHS and ATSDR will follow up on this plan to ensure that actions are carried out.

Completed Actions

1. CDHS wrote a public health assessment (PHA) assessing community health risk from airborne exposure to hexavalent chromium from Remco (final PHA released in 2004).
2. CDHS wrote and distributed a fact sheet for the community presenting the PHA findings.
3. CDHS conducted trainings for physicians in the Willits area on environmental health issues, specifically focusing on the Remco facility exposures.
4. CDHS with ATSDR trained mental health professionals in the Willits area on environmental health exposures and the psycho/social effects on individuals and communities.
5. CDHS held community meetings with outside experts addressing questions the community has expressed, such as about chromium monitoring and health effects of volatile organic compounds.

Ongoing Actions

1. CDHS convened and works with a group of community and other stakeholders, conducting approximately quarterly publicly attended site team meetings to ensure communication about the site evaluation.
2. CDHS has written a comprehensive PHA reviewing other exposure pathways and contaminants from Remco (public comment version released in February 2006).

Planned Actions

1. CDHS will provide this information to the community after the health consultation is finalized (2006).

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Certification

The health consultation “Evaluation of Health Studies Possibilities and Limitations at the Abex/Remco Hydraulics Facility” was prepared by the Department of Health Services under a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR). It is in accordance with approved methodology and procedures existing at the time the health consultation was prepared.

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The Division of Public Health Assessment and Consultation, ATSDR, has reviewed this health consultation and concurs with the findings.

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Appendix A—Glossary

Adverse Health Effect

A change in body function of the structure of the cells that can lead to disease or health problems.

ATSDR

The Agency for Toxic Substances and Disease Registry (ATSDR) is a federal public health agency with headquarters in Atlanta, Georgia, and ten regional offices in the United States. ATSDR's mission is to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and diseases related to toxic substances. ATSDR is not a regulatory agency, unlike the U.S. Environmental Protection Agency (EPA), which is the federal agency that develops and enforces environmental laws to protect the environment and human health.

Bias

Bias can occur in an epidemiological study when a systematic error is introduced into a study, such as when comparison groups are selected differently or information is collected differently in ways that skew the results.

Biomarker

A cellular or molecular indicator of exposure, disease, or susceptibility to disease.

Biomonitoring

Analysis of blood, urine, tissues, etc., to measure chemical exposure in humans or animals.

Cohort Study

An epidemiological study in which the subjects (participants in the study) are selected according to whether or not they are exposed to the factor under investigation, and their disease status is then ascertained.

Confounding

Confounding exists when a third factor exists that is associated with the exposure, and when this factor by itself can make people more likely to get the disease (even without the exposure).

Consent Decree

A legal document, approved and issued by a judge, that formalizes an agreement reached between the City of Willits and the former owners (PRPs), where PRPs will conduct the cleanup action at the Remco site; cease or correct actions or processes that are polluting the environment; or otherwise comply with initiated regulatory enforcement actions to resolve site contamination. The Consent Decree describes actions that PRPs are required to perform, and it may be subject to a public comment period.

Cross-Sectional Study

An epidemiological study that examines the relationship between exposure and health outcome in a population at a certain point in time. It can be used for assessing prevalence of a condition in the population.

Epidemiology

A branch of medical science that deals with how frequently diseases occur, how they are distributed, and how to use this information to control disease in a population.

Exposure

Coming into contact with a chemical substance.

Exposure Registry

An exposure registry is a listing of persons exposed to hazardous substances. ATSDR currently has four active subregistries: trichloroethylene (TCE), trichloroethane (TCA), benzene, and dioxin. An important purpose of the registry is to help scientists understand how long-term exposure to hazardous substances may affect human health. This is done by identifying and following the health of individuals who have come into contact with specific substances at selected locations. Another purpose of the registry is to have a mechanism through which participants can be notified of the results of research related to their exposure. The registry is used to facilitate epidemiologic research in ascertaining any adverse health effects of persons exposed to low levels of chemicals over a long period of time.

Health Effect

ATSDR deals only with adverse health effects (see “Adverse Health Effect”).

Indeterminate Public Health Hazard

The category is used in public health assessment documents for sites where important information is lacking (missing or has not yet been gathered) about site-related chemical exposures.

Inhalation

Also called breathing. It is a way a chemical can enter your body (see “Route of Exposure”).

Misclassification

Misclassification occurs when a study subject is inaccurately assigned the wrong exposure or outcome. This is a potential source of error in an epidemiological study.

PHA

Public Health Assessment. A report or document that looks at chemicals at a hazardous waste site and determines if people could be harmed from coming into contact with those chemicals. The PHA also recommends possible further public health actions if needed.

Population

A group of people living in a certain area or the number of people in a certain area.

Prevalence

The total number of cases of a disease in a population at a given time.

Public Health Assessment

See PHA.

Retrospective Cohort Study

An epidemiological study in which the subjects (participants in the study) are selected according to whether or not they are exposed to the factor under investigation, and their disease status is then ascertained. It differs from prospective cohort in that the outcome (disease or condition) of interest has already occurred at the start of the study.

Route of Exposure

The way a chemical can get into the body. There are three exposure routes:

1. Breathing (also called inhalation)
2. Eating or drinking (also called ingestion)
3. Getting something on the skin (also called dermal contact)

Screening

Applying a test to a population that is not yet symptomatic, for the purpose of classifying them with respect to their likelihood of having a disease. The screening test itself does not diagnose illness. Those with a positive test are sent on for further evaluation by a subsequent diagnostic test or procedure to determine whether they do in fact have the disease.

Sensitive Populations

People who may be more sensitive to chemical exposures because of certain factors such as age, sex, occupation, a disease they already have, or certain behaviors (cigarette smoking). Children, pregnant women, and older people are often considered special populations.

Statistics

A branch of applied mathematics concerned with the collection and interpretation of numerical data and the use of probability theory to estimate information about populations. Statistics can be used to calculate numeric summaries that condense information, numbers that are used to make comparisons, or numbers that portray relationships or associations.

Statistical Power

A test's statistical power in a given study is the probability or chance of detecting a difference (an effect) between two populations, if one really exists.

Toxic

Harmful. Any substance or chemical can be toxic at a certain dose (amount). The dose determines the potential harm of a chemical and whether it would cause someone to get sick.

Toxicology

The study of harmful effects of chemicals on humans or animals.

Type-1 Study

Exploratory or descriptive epidemiological studies that describe patterns of disease, or generate hypotheses about the effects of exposure to hazardous substances. Compared to Type-2 studies, Type-1 studies yield more limited results, in that they can only suggest the possibility of an association, and typically the results are as likely due to chance as a true exposure-outcome association.

Type-2 Study

Analytical epidemiological studies that are specifically designed to test scientific hypotheses about the association between adverse health outcomes and hazardous exposures.

Appendix B—Statistical Power

Statistical power provides a key piece of information that helps show how the results would be interpreted. The power of a statistical test measures the test's ability to lead to a correct decision. It represents the ability of the study to detect a difference in the occurrence of a disease between two study populations (in this case, between an exposed population and an unexposed population) (11).

Imagine, for example, that a chemical exposure really did cause increased illness in a community. However, if the test does not have enough statistical power for the situation, then the test result will probably not be interpreted as an increase in illness. The result could appear (falsely) that there is no difference between the exposed and unexposed group in the amount of illness. How much statistical power a study design has depends on how many people are in it, how frequently the illness you are studying occurs, and whether you are trying to determine if there is a big difference in the amount of illness in two populations, or whether you are trying to detect a small difference. The bigger the effect you are looking for, the easier it is to recognize (so less statistical power is needed). For example, it is easier to determine if the rate of cancer is 5 times what it is typically (which is a 400% increase), than trying to determine if the rate of cancer increased by 5%. However, rarely are there situations in which cancer rates (or other disease rates) are 5 times what they are typically.

The drawbacks to conducting a study even if it has inadequate statistical power may not be immediately apparent. However, an analogy on a more personal level may help exemplify the downside of this type of choice. Suppose you went into a clinic and asked for a test for the AIDS virus. The nurse tells you "We can give you a test, but it is only 50% accurate (it has a 50-50 chance of detecting the AIDS virus, if the AIDS virus is there)." What would you do? Is it still helpful to get the test? On the other hand, if the nurse tells you the test is 99% accurate, you would probably feel more confident about taking the test.

In an epidemiological study, 50% power would mean that a study has a 50% chance of detecting an increase in the disease (of the magnitude selected, such as a fivefold increase, or a 5% increase), if an increase of that level truly exists. In a particular study population, one might have very high power to detect a fivefold increase, but very low power to detect a 5% increase, even if it is real. (For example, a study might have a 90% power, or 90% a chance of detecting if there is 5 times as much cancer as one would expect (400% increase), but only a 10% chance of detecting a small increase like a 5% increase.) Although there is no hard-and-fast rule, at least 80%-90% power is typically considered desirable.

Appendix C—Lung Cancer Screening

Lung cancer is a highly fatal cancer; fewer than 15% of patients will survive (12). Chances of survival are greater if the cancer is detected in the earliest stages; the percentage of patients who are diagnosed at the earliest stage have a 5-year survival rate of 90%. Unfortunately, most lung cancers are now diagnosed at an advanced stage.

Currently in this country, routine screening (using a chest X ray) is not recommended for lung cancer (13). This policy is based on several large randomized controlled trials conducted mainly in the 1970s that studied mortality from lung cancer among male cigarette smokers. Those studies did not find that fewer patients died of lung cancer when they received additional screening. However, these studies have been re-evaluated since that time, causing this “no-screen” recommendation to be questioned. One problem with the studies was that the comparison groups also received screening, although not as much or as frequently. Also, advances in treatment techniques for early stage lung cancer have also been made, which could help improve outcomes for patients with lung cancer detected today.

More screening is not always helpful to the patient, and could have negative effects. One potential harm from screening using X rays is the possibility of false positive findings. That is, the X rays would show some seeming abnormal finding that was not really cancer (14). The problem with false positives is that confirming whether a finding is a cancer often requires an invasive procedure such as a biopsy of lung tissue. Another potential harm is over-diagnosis, that is the diagnosis of a small or slowly growing tumor that would not have caused any clinical problem for the person. Another consideration is the risk of radiation from X ray or other screening using radiation, such as computed tomography (CT) scans. Before broad recommendations are made to physicians on how to treat patients, scientific studies are conducted to determine if the value of the screening outweighs the risks. Currently, the potential value of lung cancer screening using traditional methods (X ray or CT scan) is being studied in a large screening trial being conducted by the National Cancer Institute.

At the same time as advances are being made in determining the value of lung cancer screening using X-ray techniques, researchers are also studying a wide range of new techniques using biomarkers that could be used to detect cancer earlier by looking for cancerous cells in body fluids, such as sputum (fluid coughed up from the lungs), saliva, urine, or blood and evaluating a variety of molecular changes in cell deoxyribonucleic acid (DNA) (10).

These techniques are new and it is not known at this time which technique might be most effective, or how effective they might be in populations with differing risks for cancer. However, the fact that different techniques exist, and the need for additional information about how effective they might be, raises the possibility that research could be conducted among exposed Willits residents, as they would be presumed to be at greater risk for cancer than general populations. The fact that lung cancer is a highly fatal disease that can best be treated when detected in early stages builds a strong argument for applying methods of early detection for this population.