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Critical Issues in Biomonitoring:
A Community Forum

Sponsored by:
Marin Breast Cancer Watch: A non-profit organization dedicated to finding the causes of breast cancer through community participation in the research process.

Co-Sponsored by:
The Marin County Department of Health and Human Services: The mission of the Marin County Department of Health and Human Services is to promote and protect the health, well being, self-sufficiency and safety of all people of Marin. The Department of Health and Human Services provides a full range of public health and human services programs for the citizens of Marin County.

The Bay Area Breast Cancer and Environment Research Center: One of four research centers created by the National Institute of Environmental Health Sciences (NIEHS) and the National Cancer Institute (NCI) to explore the effects of environmental stressors on the development of the mammary gland and the onset of puberty. The work of this landmark center will lead to a better understanding of breast cancer causes and will identify ways to prevent breast cancer in the next generation.

The California Environment Health Tracking Program: The goal of the CEHTP is to develop a comprehensive plan for a standards-based, coordinated, and integrated system, at the state level, that enables public health actions through linkage, monitoring, reporting, and communication of health effects and environmental hazards and exposure data.

Acknowledgements:
We thank the community and scientific members of the Biomonitoring Advisory Board who actively participated in the planning and implementation of this community forum. Without their expertise, time and energy, this forum could not have been possible.

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Peter Flessel, Ph.D.
Diana Lee, MPH, RD
Fern Orenstein, MED

In addition, we would like to thank the following individuals for their contribution to making the community forum a success:
Staff members: Christine Arnesen, RN, MPH (planning and consultation), Betsy Barton, MA and Suzan Dexter
Evaluation Consultant: Dr. Robert Lee, Survey Research Center, UC Berkeley
Brochure Design: Kaya Blake, UCSF Comprehensive Cancer Center
Media Presentation: David Hoffman, Producer and Tom Valens, Tamalpais Productions

Forum Sponsorship
This forum was made possible by funds received from the Marin County DHHS through the CDCP (Grant #H57/CCH 923112-01). Additional funding support was from NIEHS and NCI (grant #UO1-ESO12801) and the National Center for Environmental Health, CDC (grants #U50/CCU 922449-01, #U50/CCU 922449-02).

The contents of the Forum are solely the responsibility of the conveners and do not necessarily represent the official views of the funders.

Executive Summary

"Critical Issues in Biomonitoring", a Bay Area community forum, brought together environmental health and breast cancer advocates, academic and community-based researchers, public health professionals, public policy leaders, health educators, ethicists and community members to facilitate a dialogue on important issues relevant to biomonitoring.

The community forum was held October 9, 2004 at the UCSF Mission Bay Campus in San Francisco. Nearly one hundred speakers and participants representing a wide variety of important perspectives on biomonitoring, breast cancer research, environmental tracking, environmental contaminants and toxics, community-based, participatory research, environmental justice issues and environmental and breast cancer advocacy attended.

This report outlines the collaborative process undertaken by the Advisory Planning Committee. Consistent with the principles of community-based, participatory research, the Advisory Planning Committee reflected the intended audience for the event; researchers, community members, public health professionals, and members of environmental and breast cancer advocacy organizations.

The Advisory Planning Committee assisted with the development of the community forum to ensure that the agenda and the local and national experts invited to speak would appropriately address the challenging and complex issues associated with biomonitoring and the relationships between biomonitoring and scientific research, scientific research and community ethics, the community and the environment and the environment and public policy. A consensus process was used to achieve agreement on the agenda and the presenters and panel discussants.

In addition to planning the agenda, the Advisory Committee identified small group discussion topics, reviewed evaluation methods, provided input on the format and content of the report and assisted in planning for future dissemination of forum materials and results.

The forum consisted of three plenary sessions on *Biomonitoring*, *Scientific and Laboratory Issues* and *Community Research Ethics in Environmental Public Health*, and two panels focused on *Methods, Benefits and Challenges in Public Health and in Research* and *Engaging Communities in Biomonitoring Research and Advocacy Efforts* were held.

Following plenary and panel discussions attendees participated in small group discussions convened by facilitators who recorded all the participant's comments and recommendations. The small group discussions focused on the following questions:

- How can we best incorporate the concept of uncertainty when communicating risk?
- How can we best address the issues associated with the use of breast milk as a biospecimen for biomonitoring studies?
- What are the specific benefits and challenges of incorporating biomonitoring into research settings and/or into public health surveillance programs?
- How can we design community biomonitoring surveillance and research studies that reflect and incorporate the principles of community-based participatory research?

At the end of the day, the recommendations from each small group discussion were presented back to forum speakers and participants.

The community forum provided an opportunity to develop products that will serve as a resource on biomonitoring. As an outcome of the community forum, we developed two forum-related products, a DVD and a written summary of the proceedings that will be made available to interested

organizations, researchers, public health professionals and community members to increase their understanding and knowledge of issues associated with biomonitoring.

This project also sought to evaluate the effectiveness of "community forums" as an early and effective communication model for translating research and technical information, for communicating risk and facilitating an interactive exchange among public health professionals, researchers and community members. The results of the evaluation indicated:

- 90% stated that community forums are a good way to get information to the community on topics such as biomonitoring.
- 88% of respondents agreed that holding a community forum is a good way to involve community members in the research process.
- 95% of respondents agreed that holding a community forum is a good way to involve community members in the research process.
- 46% of respondents plan to hold subsequent community meetings or educational projects focused on biomonitoring.
- 59% of respondents plan to form partnerships to do community-based participatory research using biomonitoring.

This community forum set the stage and brought in the resources for an informative, stimulating dialogue about biomonitoring. It is hoped that both the information and recommendations derived from the forum will prompt future community forums on biomonitoring, encourage funding for community-based participatory environmental research studies, environmental tracking programs and public health surveillance projects and ultimately influence public policy.

Sincerely Yours,

Janice Barlow
Executive Director
Marin Breast Cancer Watch

Introduction

Biomonitoring has the potential to make a significant contribution to the research on the role environmental factors play in the development of disease, including breast cancer. According to the California Biomonitoring Needs Assessment Report, biomonitoring can:

- Assist in linking environmental exposures and pollution-related disease.
- Provide, in combination with environmental monitoring, detailed information about differences in exposures across geography, race, ethnicity and socio-economic status.
- Illuminate the relationships between genetic predispositions or sensitivities and disease outcomes.
- Explain differences in rates of diseases in relation to environmental causation once associations are known.

Although biomonitoring is considered a powerful tool for closing the gaps in current environmental exposure data, it is still an emerging science. The Center for Disease Control's recent effort at biomonitoring has produced reference ranges for a number of chemicals, but there is still little known about how to interpret the meaning of these statistics when applied to research or public health. The uncertainties associated with biomonitoring, combined with a growing public interest in its use, highlight the need to develop *early* and *effective* communication models that facilitate an interactive exchange of information and concerns among community members, breast cancer advocates, laboratory technologists, researchers, medical ethicists, public health professionals and health care providers. Community forums are widely used as models for translating research and technical information, for communicating risk and for eliciting community involvement.

The major goal of this project is to facilitate communication among researchers, health professionals, breast cancer and environmental advocates and members of the community on issues related to biomonitoring that will enhance risk communication, inform decision-making and provide opportunities for future community-based biomonitoring research in the Bay Area.

The specific aims of this project are:

1. To design and implement a forum that will stimulate an exchange of information among researchers and community members of varied perspectives, experiences and expertise on the individual and group risks and benefits of biomonitoring.

2. To educate a diverse audience of interested and concerned researchers, public health professionals, health providers, breast cancer advocates, environmentalists, scientists and community members about the current state of the science of biomonitoring.

3. To solicit the input and viewpoints of the community forum presenters and participants for use in setting priorities for future local biomonitoring studies.

4. To identify partnerships interested in collaborating on community-based, participatory breast cancer research projects using biomonitoring in the Bay Area.

5. To develop a strategy to evaluate to what extent personal goals were met, questions were answered, information was exchanged, mutually respectful relationships were formed and communication channels were created through participation in this type of process.

6. To use the information generated from the evaluation to develop relevant technical information for the community and the press about the newly emerging technology of biomonitoring.

Program Definitions

Community: Common definitions include these elements:

- Sense of belonging-membership
- Common experience and history linked to place and emotional/spiritual connection
- Fulfillment of individual and social needs
- Influence- the individual and community feel that they matter
- Positive valuing of unity, diversity and cultural pluralism
- Commitment to shared values and meaning
- Social ties- interpersonal relationships, family, classmates, co-workers, support groups, friends, neighbors, other local organizations
- CIOM Guidelines: When members of a community are naturally conscience of their activities as a community and feel common interests with other members, the community exists, irrespective of the study proposal.

Dianne Quigley: Community Research Ethics in Environmental Public Health

Biomonitoring:

"Biomonitoring is an assessment of the internal dose by measuring the parent chemical (or it's metabolite or reaction product) in human blood, urine, breast milk, saliva, adipose tissue or other tissues."

Dr. Larry Needham: "Scientific and Laboratory Issues"

Community-Based Participatory Research:

"Community-Based, Participatory Research (CBPR) is a collaborative approach to research that equally involves all partners- community members and scientists- in the research process and recognizes the unique strengths each brings to the process. CBPR begins with a research topic of importance to the community with the aim of combining research knowledge and community action to improve community health and eliminate health disparities"

Fern Orenstein, Marin Breast Cancer Watch:
A Successful Model of Community-Based Participatory Research

Glossary of Terms and Concepts Associated with Biomonitoring

A

absorption (biological): Process of active or passive transport of a substance into an organism: in the case of a mammal, such as a human being, this is usually through the lungs, gastrointestinal tract, or skin.

acute: Short-term, in relation to exposure or effect. In experimental toxicology, "acute" refers to studies of two weeks or less in duration (often less than 24 h).

adverse effect: Change in morphology, physiology, growth, development or lifespan of an organism that results in impairment of functional capacity or impairment of capacity to compensate for additional stress or that results in an increase in susceptibility to the harmful effects of other environmental influences.

B

bioaccumulation: Progressive increase in the amount of a substance in an organism or part of an organism that occurs because the rate of intake exceeds the organism's ability to remove the substance from the body.
PARTIAL SYNONYM bioconcentration.

bioavailability: Extent to which a substance to which the body is exposed (by ingestion, inhalation, injection, or skin contact) reaches the systemic circulation, and the rate at which this occurs. EXACT SYNONYM biological availability, physiological availability.

bioconcentration: Process leading to a higher concentration of a substance in an organism than in environmental media to which the organization is exposed.
PARTIAL SYNONYM bioaccumulation.

biological monitoring: Continuous or repeated measurement of potentially toxic substances, their metabolites or their biochemical effects in tissues, secreta, excreta, expired air or any combination of these. Its purpose is to evaluate occupational or environmental exposure and health risk by comparison with appropriate reference values based on knowledge of the probable relationship between ambient exposure and resultant adverse health effects.
BROADER TERM environmental monitoring, monitoring.

biomarker: 1. Indicator signaling an event or condition in a biological system or sample and giving a measure of exposure, effect, or susceptibility. As related to biomonitoring, a biomarker is the presence of any substance, or a change in any biological structure or process that can be measured as a result of exposure. Many biomonitoring studies focus on chemical substances or their metabolites as biomarkers.

2. Parameter that can be used to identify and effect in an individual organism and can be used in extrapolation between species for risk assessment.

biomonitoring: See EXACT SYNONYM biological monitoring.

body burden: Total amount of a chemical present in an organism at a given time. Note: This can be a misleading term in that it suggests that the detection of a substance always means that it is causing adverse effects.

C
CDC: U.S. Centers for Disease Control and Prevention

chronic exposure: Continuous or repeated exposure to a substance over a long period of time, typically the greater part of the total life-span in animals or plants (usually, several years in man). ANTONYM acute exposure.

D
dose: Total amount of a substance administered to, taken or absorbed by an organism.

dose-effect relationship: Association between dose and the magnitude of a continuously graded effect, either in an individual or in a population or in experimental animals.

dose-response relationship: Association between dose and the incidence of a defined biological effect in an exposed population.

E
emission: Release of a substance from a source, including discharges to the wider environment.

environment: Aggregate, at a given moment, of all external conditions and influences to which a system under study is subjected. Note: Includes natural and man-made influences; for humans, all influences other than hereditary, including diet and lifestyle.

environmental monitoring: Continuous or repeated measurement of agents in the environment to evaluate environmental exposure and possible damage to living organisms. Measurements obtained are compared with appropriate reference values based on knowledge of the probable relationships between ambient exposure and resultant adverse effects.
RELATED TERM biological monitoring.

epidemiology: Study of the distribution and determinants of health-related states or events in populations and the application of this study to control of health problems.

excretion: Discharge or elimination of an absorbed or endogenous substance or of a waste product, and/or their metabolites, through some tissue of the body and its appearance in urine, feces, or other products normally leaving the body. Excretion of most chemical compounds from the body occurs mainly through the kidney and the gut, although volatile compounds may be largely eliminated by exhalation. Excretion by perspiration and through hair and nails may also occur. Excretion by the gastrointestinal tract may take place by various routes such as the bile, the shedding of intestinal cells and transport through the intestinal mucosa.

exposure assessment: Process of measuring or estimating concentration (or intensity), duration and frequency of exposures to an agent present in the environment or, if dealing with hypothetical cases, estimating exposures that might arise from the release of a substance, or radionuclide, into the environment.
RELATED TERM risk assessment.

F
FDA: U.S. Food and Drug Administration

G No entries

H

hazard: Set of inherent properties of a substance, mixture of substances or a process involving substances that, under production, usage or disposal conditions, make it capable of causing adverse effects to organisms or to the environment, depending on the degree of exposure; in other words, a source of danger. RELATED TERM risk

hazard assessment: Determination of factors controlling the likely effects of a hazard such as the dose-effect and dose-response relationships, variations in target susceptibility, and mechanisms of toxicity.
RELATED TERM exposure assessment, risk assessment

I
intake: Amount of a substance that is taken into the body, regardless of whether or not it is absorbed; the total daily intake is the sum of the daily intake by an individual from food, drinking-water, and inhaled air.

J, K No entries

L
long-term exposure: Continuous or repeated exposure to a substance over a long period of time, typically the greater part of the total life-span in animals or plants (usually several years in man).
EXACT SYNONYM chronic exposure.

M
metabolism: Sum total of all physical and chemical processes that take place within an organism; in a narrower sense, the physical and chemical changes that take place in a given substance within an organism. Metabolism includes the uptake and distribution within the body of chemical compounds, the changes (biotransformation) undergone by such substances, and the elimination of the compounds and of their metabolites from the organism.

metabolite: Any intermediate or product resulting from metabolism.

monitoring: Continuous or repeated observation, measurement, and evaluation of health and/or environmental or technical data for defined purposes, according to prearranged schedules in space and time, using comparable methods for sensing and data collection. Evaluation requires comparison with appropriate reference values based on knowledge of the probable relationship between ambient exposures and adverse effects.
NARROWER TERM biological monitoring, environmental monitoring

N

NTP: U.S. National Toxicology Program

natural occurrence: Presence of a substance in nature, as distinct from presence resulting from inputs from human activities.

NIEHS: U.S. National Institute of Environmental Health Sciences

O

occupational exposure: Exposure to substances, intensities of radiation etc. or other conditions while at work.

P

persistence: Attribute of a substance that describes the length of time that the substance remains in a particular environment before it is physically removed or chemically or biologically transformed. Note: Sometimes misused without reference to length of time.

pollutant: Any undesirable solid, liquid or gaseous matter in an environmental medium: "undesirability" is often concentration-dependent, low concentrations of most substances being tolerable or even essential in many cases. (In the context of air pollution, an undesirable modification is one that has injurious or deleterious effects.) A primary pollutant is one emitted into the atmosphere, water, sediments or soil from an identifiable source. A secondary pollutant is a pollutant formed by chemical reaction in the atmosphere, water, sediments, or soil.

Q No entries

R

risk:

1. Possibility that a harmful event (death, injury or loss) arising from exposure to a chemical or physical agent may occur under specific conditions.
2. Expected frequency of occurrence of a harmful event (death, injury or loss) arising from exposure to a chemical or physical agent under specific conditions.

risk assessment: Identification and quantification of the hazard resulting from a specific use or occurrence of a chemical or physical agent. Risk assessment considers any possible harmful effects on individual people or on society of using the chemical or physical agent in the amount and manner proposed and via all possible routes of exposure. Quantification ideally requires the establishment of dose-effect and dose-response relationships in likely target individuals and populations. RELATED TERM exposure assessment

route of exposure: Means by which an agent gains access to an organism. Access can be via the gastrointestinal tract (ingestion), lungs (inhalation), skin (topical), or by other routes, such as intravenous, subcutaneous, intramuscular or intraperitoneal.

S

safety: Reciprocal of risk: practical certainty that injury will not result from a hazard under defined conditions.

1. Safety of a drug or other substance in the context of human health: the extent to which a substance may be used in the amount necessary for the intended purpose with a minimum risk of adverse health effects.
2. Safety (toxicological): The high probability that injury will not result from exposure to a substance under defined conditions of quantity and manner of use, ideally controlled to minimize exposure. RELATED TERM risk.

T

toxic: Able to cause injury to living organisms as a result of physicochemical interaction.

toxicity: Adverse effects of a substance on a living organism, defined with reference to the quantity of substance administered or absorbed, the way in which the substance is administered (inhalation, ingestion, topical application, injection) and distributed in time (single or repeated doses), the type and severity of injury, the time needed to produce the injury, the nature of the organism(s) affected, and other relevant conditions.

toxicity test: Experimental study of the adverse effects of exposure of a living organism to a substance for a defined duration under defined conditions.

toxicokinetics: Process of the uptake of potentially toxic substances by the body, the biotransformation they undergo, the distribution of the substances and their metabolites in the tissues, and the elimination of the substances and their metabolites from the body. Both the amounts and the concentrations of the substances and their metabolites are studied. The term has essentially the same meaning as pharmacokinetics, but the latter term should be restricted to the study of pharmaceutical substances.

toxicology: Scientific discipline involving the study of the actual or potential danger presented by the harmful effects of substances (poisons) on living organisms and ecosystems, of the relationship of such harmful effects to exposure, and of the mechanisms of action, diagnosis, prevention and treatment of intoxications.

U

uptake: Entry of a substance into the body, into an organ, into a tissue, into a cell, or into the body fluids by passage through a membrane or by other means. PARTIAL SYNONYM absorption.

V No entries

W

weight-of-evidence for toxicity: Extent to which the available biomedical data support the hypothesis that a substance can cause a defined toxic effect such as cancer in humans.

X

xenobiotic:

1. Strictly, any substance interacting with an organism that is not a natural component of that organism.

2. Any man-made compound with a chemical structure foreign to a given organism. SN anthropogenic substance.

Y, Z No entries

Forum Program

8:00 **Registration & Continental Breakfast**

8:15 **Welcome:** *Janice Barlow*, *MS, CNP,* Executive Director, Marin Breast Cancer Watch

8:30 **Opening Plenary: "Overview of Biomonitoring"** *Richard Jackson, MD, MPH*

9:10 **"Scientific and Laboratory Issues"** *Larry Needham, Ph.D.*

Questions & Answers

9:45 **"Methods, Benefits and Challenges of Biomonitoring in Public Health & Research"**
Panel will provide an overview of the complexities of using biomonitoring in public health surveillance and in research studies.
Moderator: *Anh Thu Quach, MPH*
Panelists: *Peggy Reynolds, Ph.D.; Paul English, Ph.D., MPH; Barbara Materna; Mary Wolff, Ph.D.*

Questions & Answers

11:10 **Break**

11:30 **"Engaging Communities in Biomonitoring Research & Advocacy Efforts"**
Panel will highlight specific approaches aimed at incorporating community participation into biomonitoring research and public policy advocacy.
Moderator: *Christine Arnesen, RN, MPH*
Panelists: *Sharyle Patton, BA; Cliff Johnson, MSPH; Fern Orenstein, M.ED; Romel Pascual, MA; Alicia Salvatore, MPH*

1:00 **Lunch/Keynote Presentation "Environmental Policy in the California Legislature"**
Bruce Jennings, Ph.D.

2:00 "**Community Research Ethics in Environmental Public Health"**
Panelists: *Dianne Quigley, MA; Lori Copan, R.Ph., MPH*

Questions & Answers

3:00 **Break**

3:20 **Small Group Discussions**

4:20 **Small Group Presentations**
Coordinator: *Christine Arnesen, RN, MPH*

4:50 **Evaluation & Closing**
Janice Barlow, MS, CNP

5:00 **Reception**

Summary of Presentations

While it is not possible to include the content of all of the presentations made at the conference, the following paragraphs summarize many of the key points made by the scientific and community speakers.

Richard Jackson MD, MPH

Dr. Richard Jackson received his MD from the University of California at San Francisco. During his residency as a Pediatrician, he took time off for a 2-year stint with Centers for Disease Control and Prevention (CDC) as an Officer in the Epidemic Intelligence Service. He obtained his MPH from the University of California at Berkeley and began work as a Public Health Medical Officer with the California Department of Health Services.

Dr. Jackson helped set up California's Birth Defects Monitoring Program, successfully pushed for passage of California's Birth Defects Prevention Act, assisted in the establishment of California's tough guidelines for reporting pesticide use, and provided major contributions to a National Academy of Sciences report on pesticides in infants' and children's diets that eventually helped lead to passage of the Food Quality Protection Act by the U.S. Congress in 1996.

Dr. Jackson was selected to be Director of CDC's National Center for Environmental Health (NCEH). One of NCEH's most important initiatives under Dr. Jackson's leadership has been measuring and reporting the levels of an unprecedented 116 environmental chemicals in people's bodies in the *National Report on Human Exposure to Environmental Chemicals*.

Dr. Jackson co-authored the book: Urban Sprawl and Public Health: Designing, Planning and Building for Healthy Communities (2004). He has also served as Senior Advisor to the Director of CDC and was Co-lead on CDC's Strategic Planning process areas related to Health Systems. In April of 2004, California Governor Arnold Schwarzenegger announced Jackson's appointment as the State Public Health Officer. His earliest goals in this role are to help the state confront budget and staffing challenges, as well as terrorism and the obesity epidemic.

Excerpts from Richard Jackson: "Overview of Biomonitoring"
In thinking about the environment and health, we often presume that more research is the answer. In the 1970's, the banning of DDT was a *policy* decision because DDT was a known cancer threat. The problem with the recently proposed Senate Bill 1168 (Ortiz) was that it was too complex. The governor *did* recently sign three essential bills which also encountered resistance:

- Asthma equipment in the schools
- Epinephrine availability in the schools
- The clean needle exchange program to prevent HIV

The California Department of Health Services has been downsized from a core of 1600 public health professionals in recent years. The majority of employees are over 50 years old; there is a critical need for younger, talented staff.

With *biomonitoring*, like any bill, the proponents need to be able to describe the bill in 30 seconds. The bill has to be simple and based on *good science*, not a survey of 300 chemicals. *Simplicity is the key*. Proponents should review the Federal Funds Participation Register, which provides matching funds for state programs to advance a successful bill. A proposed bill needs to be based on good science and valid data.

I think we should all be guided by the Institute of Medicine's *definition of public health*:

> *"The purpose of public health is to fulfill society's interests in assuring the conditions in which people can be healthy."*

Therefore, we need to focus not only on the research and information, but also on actually creating the conditions that promote health. You can tell people what to do or not do, but you must also address the living environment and resources they need.

(Public Health) Risk Assessment is only part of the picture. I call it RAOD – Risk Assessment Obfuscation and Delay. Risk Assessment is an engineering tool; a mathematical model applied to biology. RA often complicates issues, nobody truly understands what it means, and it can lead to delays. An example is methyl bromide fumigant in the strawberry fields of Ceres, in the Central Valley area. Since methyl bromide is a known carcinogen that destroys ozone, establishing hazardous exposure levels are delaying public health action.

An environmental health success story concerning biomonitoring is the removal of lead from gasoline, paint and industrial processes. The NHANES (National Health and Nutrition Examination Survey) data proved a 34% reduction in blood levels of lead. There are 4 million children born in the U.S. each year; calculate the economic benefits of preventing lead poisoning for future generations. Biomonitoring data was used in developing political policies to ban lead – the power of real data prevailed opposing arguments. It (lead banning) was a public health teachable moment. Another example, cotinine (the exposure of non-smokers from environmental tobacco smoke) resulted in the banning and control of second hand smoke. The data was irrefutable. Emerging examples are the association of phthalates and dieldrin and higher breast cancer levels.

Biomonitoring today is like the state of virology in the 1930's. It has to be based on good science to establish valid benchmarks which can lead to sound policy. In some instances, biomonitoring alone can provide policy direction without risk analysis. For example, organic diets are shown to lower organophosphate levels. To me, this just makes good sense.

Larry Needham, Ph.D.

Dr. Larry Needham is Chief of the Organic Analytical Toxicology Branch, Division of Laboratory Sciences, National Center for Environmental Health, Centers for Disease Control and Prevention.

He received his BS in Chemistry with minors in Mathematics and History from Middle Tennessee State University. Dr. Needham also holds a Ph.D. in Organic Chemistry with a minor in Inorganic Chemistry from the University of Georgia.

In his current position, Dr. Needham identifies and conducts studies involving human exposure to environmental organic toxicants. These exposure assessments are important for evaluating human exposure for purposes of risk assessment and risk management, and for relating human exposure to adverse health outcomes; thus they often serve as the scientific basis for policy decisions in environmental public health.

Upon completion of these studies, Dr. Needham works closely with officials and senior management within CDC to ensure that the data are used for addressing public health issues and for shaping National environmental health policy. Dr. Needham serves as a team member or as the spokesperson for these studies before White House Committees, staffs of Congress, scientific delegations, peer review panels, and international officials, and as a consultant to domestic and international delegations on environmental health concerns. He is affiliated with The American Chemical Society,

Division of Environmental Chemistry and Division of Chemical Toxicology; International Society for Exposure Assessment (immediate Past-President); and International Society for Environmental Medicine.

Dr. Needham has co-authored three books, contributed 15 chapters to a variety of publications and has been published in over 300 journal articles. Dr. Needham is the recipient of numerous CDC and HHS awards.

Excerpts from Larry Needham: "Scientific and Laboratory Issues"

I will be talking about the laboratory issues and data from NHANES 1999-2000. I will start with a definition:

- Biomonitoring: Assessment of internal dose (what gets in the body) by measuring the parent chemical (or its metabolite or reaction product) in human blood, urine, milk, saliva, adipose or other tissue.

We assess human exposure to environmental chemicals. Perhaps you have all seen this paradigm, showing the pathway from a chemical originating from a source. The chemical can undergo transformation and can be transported long distances. Eventually that chemical ends up in an environmental media, such as air, water, food, soil, dust and sediment. People may come into contact with that medium and thus have contact with the chemical of interest- that is exposure. The exposure mass is classified as the amount of chemical that is in contact with the human surfaces such as the skin. The chemical can be absorbed into the body following inhalation, ingestion or dermal contact. The amount of chemical absorbed into the body is the internal-dose. The chemical can be eliminated directly into the feces or urine, or it can be metabolized and distributed to the target organ. At the target organ, a certain amount of that chemical dose may be biologically effective and can lead to an effect. But, as a note of caution, just because we can measure a chemical in the body does not mean it will continue down this pathway to cause an effect. Because our measurement methods are very sensitive, we are capable of measuring very, very low concentrations of environmental chemicals in the body.

There are various ways to assess human exposure to environmental chemicals:

- The traditional ways- using questionnaires, videotaping, time/activity information, geographic information systems.
- Environmental assessment- measuring the amount of chemical in food, soil, air, dust sediment and earmarking the contact time we have with that media to estimate how much of that chemical gets into the body.

What our laboratory does, and other laboratories do, is assess exposure via biomonitoring. We measure what is actually in the body, and personally believe that is the best way in the public health paradigm to associate exposure to health effects. Two questions that are often asked in public health:

1. Why do people who have had the same exposure get different doses?
2. Why do people respond differently to similar doses?

The answer to the first question is found in pharmacokinetics, which is defined as absorption of the chemical into the body, distribution of the chemical within the body, metabolism of the chemical, and elimination of the chemical or its metabolite(s). Different people depending upon such factors as genetics, demographics, and nutritional status "handle" similar chemicals differently. The answer to the second question is found in pharmcodynamics. Again, people respond differently to the same doses. Therefore two people with the same exposure can get different doses, and likewise two people with the same exposure can get different effects.

There are three main routes of entry of chemicals into the body- ingestion, inhalation and dermal contact. Once in the body, there are some chemicals that are persistent (long lived) and some that are not persistent. Chemicals get into the body and hence into the blood supply and they go in different directions. In general, the non-persistent chemicals (like commonly used pesticides, phthalates and so forth) go through the kidney and are all eliminated in the urine. The persistent chemicals including the persistent organic pollutants (POPs) go into deposition sites in the body. For example, the organic POPs like dioxin, PCBs, and DDTs store in the adipose tissue (fat) while the inorganic chemical, lead, stores in the bone. The persistent organic chemicals are of concern to lactating women, in that a portion of the internal dose of these chemicals can end up in the breast milk.

In our laboratory we generally measure the internal dose of a persistent chemical in blood, specifically in the lipid portion of blood; we have also measured them in adipose tissue and breast milk. As mentioned, persistent chemicals have a very long half life (often several years) in the body so measuring that chemical in blood after exposure, even if the measurement is done quite some time after exposure, is an accurate means for classifying the exposure status of that individual. Again, examples of such chemicals are dioxins and PCBs. However, for non-persistent chemicals the situation is much different. Non-persistent chemicals have a very short half-life; the half life can be a day or less. Also, these chemicals are generally metabolized. Following their metabolism, we see a build up of the metabolite in the urine (elimination route). There is a very short time window that we have to assess exposure by measuring these metabolites in urine. Obviously, we would like to broaden this time window. One approach is to measure adducts, such as DNA, hemoglobin, and albumin of these chemicals. These adducts have in general much longer half-lives in the body than the parent chemical or its metabolite(s). However, this does not mean the approach of measuring the parent chemical or its metabolite(s) is not worthy of study. Certainly, it would be if we had one time exposures to these chemicals and could not collect urinary samples until days afterwards. But generally, we are not exposed only one time to a non-persistent chemical. Most often, the exposure is a continuous or at least a continual exposure.

Surveys like the National Health and Nutrition Examination Survey (NHANES), when we are looking at 5000 people for instance, are catching some people soon after their exposure, and others at different time intervals following exposures. Therefore, if we measure urinary concentrations on a large number of people, we get a good estimate of the exposure status of that population. The NHANES mechanism is used to provide us biological samples for our (CDC's) *National Report on Human Exposure to Environmental Chemicals (National Report).*

What is the *National Report on Human Exposure to Environmental Chemicals*?

- An ongoing (every two years) biomonitoring assessment of the exposure of the US population to selected environmental chemicals.
- Matrices monitored are urine, blood and its components (serum).
- The data are broken down by geometric means and percentiles.
- The population is stratified along age, sex, and race/ethnicity.
- As mentioned, the *National Report* data are based on biological samples provided by NHANES (National Health and Nutritional Examination Survey) conducted by the CDC's National Center for Health Statistics.
- Population is a stratified, complex, multistage probability sample of civilian, non-institutionalized US population.
- Includes detailed history, physical and lab exams.
- Primary focus is generation of clinical data, but exposure data can be linked to clinical data and nutritional status.
- We get only a small portion of the biological sampling; the rest goes to other studies.

NHANES 1999-2000:

- About 5000 participants annually from 15 locations.
- Continuous annual sample.
- Includes home interview.
- Over-sampled for African American population, Mexican Americans, adolescents (12-17 years), older Americans (60+ years), pregnant women, and in year 2000 also low-income women.

The 2000-2001 data is currently being worked out. Results should be available March or early spring of 2005.

In terms of interpreting data in the *National Report*, we caution that the presence of a chemical in the body does not mean that the chemical or that amount of the chemical causes disease. For many chemicals in the *National Report*, more research is needed to interpret these levels. The *National Report* provides new exposure data, but does not identify levels that cause disease, and additional studies are also needed.

Here are a few of the blood level success stories:

- Lead used in gasoline declined from 1976-1980; what the affect of this decrease would have on the average blood lead levels of the US population was debated. Many of the mathematical models indicated that it would make little difference. However, the NHANES measurements found:
    1. A substantial decline in blood lead levels (BLLs), 10 times more than predicted from environmental modeling.
    2. Decline in lead levels in blood of children aged 1-5 years.
    3. A continuing decline of blood lead levels as evidenced by NHANES III (1988-1994) and NHANES 1999-2000 data.
    4. However, higher prevalence of BLLs occur in children living in urban settings, such as lower SES, immigrants, and refugees. CDC, HUD, and EPA are working together on this issue.

Switching from lead to organic chemicals: The Organohalogen Compounds in Breast Milk in Sweden study shows that there has been a large decrease in exposure to dioxins and dioxin-like PCBs in people during the time period of 1970-2000. At the same time, a new group of chemicals, the brominated flame retardants, were increasing rapidly, up until legislation was introduced, and now we are seeing their levels decrease. However, the human levels in the US of these brominated flame retardants are much, much higher than the levels in Sweden. Here in the US, we are seeing samples instead of being 100 nanograms per gram, we are seeing 400 per gram in the US serum or milk samples.

Other Second *National Report* results:

- DDT banned in US in 1973.
- DDE, metabolite of DDT, is 3 times higher in Mexican Americans than in Non-Hispanic blacks or Non-Hispanic whites.
- Also measurable in 12-19 years old (who of course were born after the ban on DDT).
- Exposure may be coming from DDE persisting in environment or by ingestion of imported foods.

DDT and other POPs are the subject of the Treaty originating from the Stockholm Convention of 2001- A treaty signed by more than 50 countries for the stopping of these chemicals or the use of these chemicals, except in certain areas such as malaria control.

Food Quality Act of 1996:

- EPA mandate to implement exposure risk component with a focus on children.
- Aggregate and cumulative exposures. Aggregate is multiple route exposures for one chemical whereas cumulative is 2 or more chemicals that have the same mechanism of action.
- Organophosphate Insecticides.
- Safety factor for children most re-evaluated.
- Evaluate efficacy of implementation of NHANES.

I am not able to show the data, but in fact the levels of organophosphates in the US populations are decreasing. Chronic low level exposures to organophosphate insecticides has not been a public health concern in the way that lead has, but important nonetheless. The way we follow the exposure trend to these pesticides is by measuring their metabolites in urine in everyone 6+ years of age in the NHANES survey.

Environmental Tobacco Smoke: There has also been a decline in exposure of non-smokers in the US population to tobacco smoke. There was a drop in mean levels from NHANES III to 1999. The drop was nearly three fold, from .2 to .06. Certainly, more good public health news.

There are additional chemicals to be included in future *National Reports*:

- Brominated flame retardants
- Bisphenol A
- Perfluorinated chemicals
- Pyrethroids
- Additional phthalate metabolites
- Arsenic
- Acrylamide
- 30+ volatile organic chemicals

Thus the NHANES data are very important in several public health decisions involving human exposure to environmental chemicals; however, there are many issues that these data do not adequately address. These include: exposures to young children; exposures to point sources of certain chemicals; and occupational exposures. Therefore, our laboratory at NCEH collaborates with investigators in academia and government (both foreign and domestic) to address many of the important issues in environmental public health.

Peggy Reynolds, Ph.D.

Dr. Peggy Reynolds is a Cancer Epidemiologist in the California Department of Health Services' Environmental Health Investigations Branch, and currently serves as the Chief of the Environmental Epidemiology Section.

She received her Ph.D. in Epidemiology from the University of California at Berkeley and spent several years as an Epidemiologist for the California Tumor Registry and San Francisco Bay Area SEER (Surveillance, Epidemiology and End Results) program. She has conducted a number of cancer epidemiology studies, with a particular focus on environmental risk factors. Her research is currently focused on female breast cancer and on cancers in children.

Dr. Reynolds has served as the Principal Investigator for a study of regional variations in breast cancer in California, a study of body burden levels of endocrine disruptors in breast cancer patients, a study of breast cancer incidence in flight attendants, and a statewide study of patterns of childhood cancer.

Excerpts from Peggy Reynolds: “Biomonitoring: An Epidemiologic Perspective”

There are questions about the places we live and work. There are questions about what types of places may have differences in disease rates. Are disease rates higher in some groups than others? Are disease rates higher in some areas than others? Are there aspects about the places we live that may influence our risk for various disease outcomes? Are risks higher in urban areas or in rural areas? Are risks higher in people who live in intensely agricultural areas, who live in high traffic areas or near industrial plants? To quote our current president, "This is our job (to find the answers) but it's really hard work".

There are many challenges. First there are the challenges associated with the nature of epidemiologic research, such as:

- Epidemiology is observational, not experimental- People cannot be assigned to risk or exposure condition.
- Study population does not represent the population at large- When we do epidemiology studies, we do not involve everyone in the study, so typically the study population is more or less representative of the population at large, making the weight of the evidence across studies a very important consideration.
- Risk factors are difficult to measure- Not only in environmental studies but in epidemiology studies in general.
- Disease latency- As a cancer epidemiologist, I am particularly aware of the disease latency problem. Probably for breast cancer, the window of risk is not the period of time being studied, but is much, much earlier in development, maybe puberty or even before that. We are not entirely sure.
- Need to account for other risk factors- In these studies, we can't look at just one factor because our lives are complicated. We need to take into account other risk factors.
- Statistical uncertainty- In addition, there is statistical uncertainty in research.

Despite these challenges, it is important to keep in mind that it is the epidemiological studies that provide us with the human health evidence. When we start to look at what the risks are to human health, you can do a risk assessment which is theoretical and involves modeling, but it is very useful to have human health evidence from actual studies in people to contribute to our knowledge.

When doing environmental epidemiological studies, there are additional challenges. The challenges associated with environmental epidemiologic research include:

- Environmental exposures are ubiquitous- We need to develop studies where there is variability, i.e., by studying populations that have had variations in environmental exposures. Without variability, we will not be able to find differences.
- Risk information is limited- i.e., limited toxicology, little chemical data, limited measurement tools for exposure and limited human health information.
- Formulations change- Once we design a study, the formulations may change so we may not be studying what is currently relevant to human health.
- Respondents cannot self-report ambient exposures from their environment.

Biomonitoring is a tool and within that context, has its own set of challenges. The challenges of biomonitoring in epidemiological research include:

- Logistics of collecting samples.
- Cost is an issue. Many of the assays that are potentially interesting are expensive. In addition, it is expensive to collect biospecimens from study participants.
- Expectations represent one of the biggest problems we face in the public health community. What are reasonable expectations in terms of what we can learn from biomonitoring in an

individual or a community? What can we know from the kinds of samples we can collect from people?

- Informed consent- Obtaining informed consent from individuals and from communities is particularly challenging when we are collecting human samples as part of the study.
- Risk Communication- The challenges associated with communication are huge, given all the limitations and challenges, given what we know and do not know. How do we really communicate in a way that is meaningful to others in a public forum?

There are several ways biomonitoring specimens can be used in environmental epidemiology, examples include:

- As indicators of risk- Biospecimens can be used in an effort to classify people according to risk in looking at health outcomes.
- Validating indirect measures- Biomarkers can be used to validate the degree to which people are classified as more or less exposed, or have a higher or lower risk from environmental exposures based on:
    1. Self report.
    2. Residential/neighborhood attributes, i.e., what we might be able to infer from GIS studies or from other environmental data that has been collected.
    3. Other data sources.

A brief example of a small biomarker study we are doing, which is nested within a larger study, is The California Teachers Study (CTS). The CTS is a cohort study of 133,479 women that was started in 1995. The sample is derived from members of the State Teachers Retirement System and includes both active and retired teachers throughout the state of California. It is a longitudinal, prospective study designed initially to study breast cancer, but is going to be valuable in the future to look at a whole variety of human health outcomes. One of the things we have been doing with this large cohort study, since it is not practical or economically feasible for us to collect biospecimens (blood and urine samples) on such a large sample, is to design a number of "nested studies" within the larger study to help us see if other measures we have collected on these women will assist us in classifying them in terms of being at risk.

The CTS Biomarker Study is an extension of a validation/calibration study that is already funded. This small validation study was designed to validate both environmental indicator data and dietary indicator data. It was designed to evaluate factors that might help to explain the observed urban/rural difference in breast cancer rates in California. The CTS Biomarker Study population is a small sub-sample of the CTS cohort. It is a convenience sample of 134 urban and 194 rural women living in the southern San Francisco Bay Area. Urban was defined as being a metropolitan area according to the census. Rural was defined as areas of less than 50,000 people outside a metropolitan area. The urban women were drawn from southern Alameda County and the more urban areas of San Jose. Rural women were from those areas classified as being the most rural parts of San Benito, Santa Cruz and Monterey Counties.

Biospecimen collection consisted of a 24-hour urine collection, accompanied by a questionnaire regarding specific exposures during the 24-hour urine collection period and a buccal swab for DNA analysis. Collecting a 24-hour urine sample is not an easy task, but there was a dedicated group willing to participate. The same may not be found in other population groups or samples. For some of the metabolites of interest, a 24-hour sample was needed in order to have representation over a period of time as opposed to a single void.

The Biomarker Study's objectives were to validate exposure measures for:

- Traffic, using urinary markers for polycyclic aromatic hydrocargons (PAH’s).

- Pesticides, using urinary markers of organphosphate pesticides (OP's), which are quite transitory.
- Other compounds of interest.

What is biomonitoring measuring? What we are measuring in terms of biospecimens is a function not only of exposure, but also host factors and genotypes, in terms of people who are better able or less able to metabolize specific types of exposures. It is a fairly complex Issue in terms of thinking through what we are actually measuring when we get a biospecimen. "Mis-measures" poses an additional biomonitoring challenge. When doing biomonitoring, we want to be careful. Potential mis-measures include:

- Monitoring the wrong thing, at the wrong time, among the wrong people.
- Measuring too few samples, the wrong samples for chemicals of interest or things that are too hard to detect.

Avoiding "mis-measures" requires:

- A clear and precise statement and common understanding of the purpose of monitoring before sampling. We want to be able to clearly say "These samples will tell us *this* and these samples will not tell us *that*."
- Good study design.
- Good protocols.

Also, we need to understand the context of the exposures in order to assess them well. We should strive to ensure meaningful involvement of the person who contributed the specimen, lives in the community or who is otherwise at the receiving end of the exposure in the assessment.

Paul English, Ph.D., MPH

Dr. Paul English is Chief of the Epidemiologic Investigations Unit, Environmental Health Investigations Branch at the California Department of Health Services. He has a Ph.D. in Epidemiology and an MPH in Epidemiology/Biostatistics, both from the University of California at Berkeley. He is Principal Investigator of a cooperative agreement with Centers for Disease Control and Prevention to begin to lay the framework for establishing an Environmental Health Tracking Network for the state of California. He also has a grant funded by the National Cancer Institute to investigate exposure assessment methods for cancer research. His primary interests include health effects of traffic-related pollutants, environmental health surveillance, spatial patterns of disease and environmental correlates of male reproductive health.

<u>Excerpts from Paul English: "Benefits of Biomonitoring for Environmental Health Tracking"</u>

I would like to acknowledge the CDC for providing the co-operative agreement to the State Health Department. We also received funding from the California Wellness Foundation and I would also like to acknowledge our excellent staff. We have a staff of 10-11 individuals working on this project. A couple of the staff members are here today- Geoff Lomex and Eddie Oh. Without them, we would not have much success with this project.

The Environmental Tracking Initiative is defined as the ongoing collection, integration, analysis and interpretation of data about environmental hazards, exposures to environmental hazards, and human health effects potentially related to environmental hazards. It is not only trying to look at some of the associations between chronic disease and environmental exposures, but also trying to build the infrastructure to do surveillance on chronic disease and exposure just for their own sake.

What are some of the questions we might want to be interested in beyond the breast cancer issue? There are a number of other issues we might want to be interested in. These are questions raised by the PEW Environmental Health Commission that issued an influential report in 2000. For example:

- Issues about cancer clusters, childhood cancer clusters and autism in relation to environmental exposures.
- Impact of pesticide exposure.
- Proportion of birth defects related to environmental exposures.
- Increased incidence/epidemic of asthma related to changing environment or related to that.
- Adult onset of diseases such as Parkinson's & Alzheimer's. Are they related to cumulative environmental exposures?
- Lupus and Multiple Sclerosis in communities with hazardous waste sites. Is there a relationship there?
- Autism and learning disabilities that have been increasing over the past several years. Are they related to environmental exposures?

Our group put together (after legislation SB 702) an expert panel chaired by the former Dean of the School of Public Health at Berkeley. A couple of the members of the panel are here today- Dr. Needham and Dr. Solomon. The purpose of the expert panel was to provide recommendations to legislature for the ongoing surveillance of environmental exposure and disease affecting Californians.

Aims of the Working Group Mandate: Biological Monitoring for Exposure Tracking:

- Provide recommendations to the legislature for the ongoing surveillance of environmental exposure and disease affecting California.
- Focus of the prevalence and determinants of chronic disease.
- Obtain an ongoing picture of health of Californians.
- Establish a database that may facilitate the examination of the relationship between chronic disease and the environment.

Here are some of the main recommendations the SB 702 Panel developed:

- There is an urgent need for a coordinating office of all CA databases that track environmental health.
- Environmental health data needs to be shared and integrated in a standardized manner and communicated to the public in a timely manner.
- Public health and environmental agencies lack adequate staff and resources to respond to environmental health threats.
- Industries that produce, import or store chemical, biological or physical agents in CA should be required to report:
    1. Full chemical/toxic properties.
    2. Location and quantity of manufacturer.
    3. Lab methods for environmental and biological sampling.
- State laboratory biomonitoring capabilities need to be enhanced.
- California needs NHANES and CAL-HEXAS surveys. HEXAS couples environmental samples such as dust and air monitoring to nutritional exam and health exam from NHANES.
- Surveillance systems for asthma, childhood neuro-developmental and neurological diseases need to be developed and enhanced.
- Need to develop standardized protocols for investigating disease clusters/build health education capability.
- Hazard exposure and health data to be reported by race and income.

The report also concluded that the total cost for nine environmentally laden diseases in California was 10 billion dollars a year or $288 per person. If we could put together an effective surveillance system

that would only reduce 1% of environmental diseases, we would save the state 100 million dollars annually.

I want to briefly talk about data linked demonstration projects including the Central Valley South Coast Children Environmental Tracking Project. Looking at exposures around conception and birth is becoming a much more important time period of interest for exposure and following up through infancy and childhood. This includes looking at risk of Sudden Infant Death Syndrome, term low birth weight, and pre-term birth weight, as well as autism spectrum disorders and mental retardation.

As far as tracking exposures, a couple of points I would like to make are:

- Effective hazard/exposures tracking requires a mix of methods.
- Biological monitoring is one of many methods.
- Biological monitoring appears to be the best method for tracking some exposures but not for others.
- Biological monitoring combined with other methods can inform pathway analysis.

Conclusions about biomonitoring point out some of the limitations we need to keep in mind:

- Biological monitoring provides a direct measure of body burden at a given point in time, depending upon pharmacokinetics. However, due to:
    1. Variable excretion rates among populations
    2. The short retention period of certain chemicals
    3. The lack of relevant and reliable biomarkers for many types of pollutants
    4. The inability to trace how a person actually got the chemical into their body

Biological monitoring does not necessarily capture all of the relevant information about human exposure.

In the cortex of the expert working groups' report on tracking, we were attempting to make recommendations that would provide source-to-dose perspectives in order to guide exposure prevention efforts. Therefore, we are talking about starting at the source of an exposure and looking at emissions in products and actual exposure or internal dose. In addition, we are looking at multiple sources and are concerned about both acute exposures and lifetime average exposure. What determines an acute exposure event vs. a lifetime average - the source may differ, for example, in an acute exposure event – indoor exposures may be most important but for chronic exposures, we need to take into account sources from food, lawns, homes and agriculture.

To stress the point that Peggy has been making, another role for biomonitoring is to validate some of these models that are coming up. So when you see these models of predicting, these are the individuals who are getting high exposures to outdoor exposures. Can we do a sub-sample using biomonitoring to do validation work for these models? The same goes same with water and with occupational exposures.

Biomonitoring is important for capturing unique (individual) exposures:

- Exposures in food (e.g., Hg, POPS)
- Exposures from products (BFRs, phthalates)
- Occupational Exposures

One example is information from the hazardous air pollutant database looking at modeled benzene exposures in the San Francisco Bay Area. We can use biomonitoring as an important tool to validate these types of models of predicting higher levels of benzene in these areas of the SF Bay Area.

Evaluation Function: Biomonitoring is an important tool for evaluating interventions:

- Lead phase out.

- Impact of Polybrominated Diphenyl Ethers (PBDE) phase out.
- Occupational interventions (lead hazard reduction).

To summarize:
From the perspective of a state deploying multiple methods to track exposures to environmental hazards (source-to-dose), biological monitoring is a vital tool for:

- Evaluating exposures to hazards not easily measured through direct media/environmental sampling or modeling.
- Identifying unrecognized routes of exposure.
- Identifying unrecognized exposures.
- Validating exposure models.
- Informing interventions.
- Evaluating intervention strategies.

Interactions between methods: Biological monitoring is an important tool for validating exposure models:

- Modeled exposure to hazardous air pollutants (e.g. benzene).
- Modeled exposure to pesticides.

Barbara Materna, Ph.D., CIH (presenting for Patrice Sutton)
Chief, Occupational Health Branch, California Department of Health Services

Excerpts from Barbara Materna: "Assessing Exposure to Chemicals in the Environment: Methods, Benefits and Challenges of Biomonitoring in Research Studies"

I wanted to start out with a story, not about biomonitoring, but about investigating the link between environment and illness. So, all the epidemiologists in the room--please bear with me. Dr. Snow was a physician and a pioneer in the science of epidemiology. He had developed a theory based on his own research during the cholera epidemic that took place in the 1800's. His theory was: the disease was being spread by a poison contained in sewage that was in the water supply. During the 1854 cholera epidemic in his London neighborhood, he interviewed families of the victims and determined that the drinking water from the Broad Street pump was linked to an increase in deaths from cholera. He did this by mapping--a technique that we are really looking at lately.

Removing the handle of the Broad Street pump stopped the cholera epidemic. It was later determined that the laundry water from diapers of an infected infant was dumped in a cesspool located just three feet away from the Broad Street pump.

This story demonstrates the public health value of connecting information about the environment with information about illness. In investigating these factors, there is an analogy to appropriate uses of biomonitoring.

Acknowledging that infectious disease is still an important issue worldwide, I am now going to continue to talk about the connection between chemicals, the environment and illness.

The Environment, Health and Illness Prevention (2004):

- 70,000 – 100,000 chemicals put into commerce.
- More on the way: 80% increase in global chemical production is projected for 1995-2020.

What do we know about the safety of these chemicals?

- A full set of health information is lacking for 93% of chemicals versus 7% that have the information. Basic health information is defined as having information about acute toxicity, chronic toxicity, developmental or reproductive toxicity, as well as human toxicity and environmental fate.

I am now turning to the workplace, which is where I am going to place the focus of my talk. To protect workers from the health impacts of chemicals, OSHA has set standards that limit exposures--these are called permissible exposure limits (PELs).

How do we assess exposure to chemicals in the environment?
- No single exposure assessment is the "gold standard".
- Biomonitoring is one type of exposure measurement that has a lot of value.

What is biomonitoring measuring?
We are measuring the interaction of factors leading from chemical exposure to disease, including the effects of susceptibility. We need to assess the information in the context of the whole picture, the human factors that affect susceptibility, the environmental impact and the genetic factors all interact to affect this pathway leading eventually to chemical disease.

Benefits of biomonitoring in exposure assessment:
- Measures how much chemical goes into the body.
- Measures all routes of exposure.
- Accounts for "impact of individual on agent" meaning the interaction between the individual with the chemical that is being brought into the body. The individual has its own particular ability to update the chemical, excrete the chemical, metabolize the chemical and there are things about the individual that will affect all of that.

What does the workplace have to do with biomonitoring?
- Workers are very often exposed to much higher levels of a chemical they work with than community members.
- There are certain areas in the product life stream where workers are particularly involved, such as in manufacturing and in waste disposal.
- Occupational studies are the primary means in which we have identified many of the links between chemicals and human health outcomes, including cancer (e.g., benzene, asbestos).
- Often most of the highly characterized exposures are found in workplace situations, as the employer may be required to conduct exposure monitoring.

Finally, I want to point out that if you are doing community studies, and if you do not ask about exposures received at work, you can draw erroneous conclusions because most of the exposures may occur there.

So what do we know about biomonitoring and its use in the workplace?
- It is required routinely for only two chemicals: lead and cadmium.
- Guidelines also exist for Biological Exposure Indices which were established at the American Conference of Governmental Industrial Hygienists.

What are some of the possible benefits of biomonitoring in the workplace?
- Finding out their individual internal dose may be of use to workers.
- Can give the worker information about their health status.
- May be able to pinpoint an increased risk of illness from a specified chemical exposure.
- Can detect failures in control measures so improvements can be made.

- Can identify harmful exposures through skin or ingestion even if levels are low.

Challenges to implementing biomonitoring in the workplace:
- Mistrust by employers in regard to regulatory mandates and liability issues.
- Mistrust by workers in regard to drug testing, lack of results, privacy and discrimination issues.
- Not much incentive for employers or employees.

Other challenges:
- The ability to classify workers based on their genotypes into susceptible subgroups is nearly at hand and could have important applications in preventing workplace disease.
- How do you protect "hypersusceptibles" from workplace hazards?
- How do you prevent discrimination in employment?

I want to emphasize that:
- Biomonitoring is not a substitute for workplace air monitoring.
- OSHA's authority to require workplace participation is unclear.
- If used exclusively, it may:
    1. Reinforce "blame the worker" attitude rather than focus on workplace changes needed.
    2. Provide incentive to "change the worker".
    3. Health damage could be occurring between dangerous exposure and biomonitoring testing.
    4. Does not provide information on source or mechanism of exposure.

Recommended criteria for using biomonitoring in the workplace:
- Serves as an appropriate tool for prevention.
- Not to be used to direct resources from reducing the use of toxic substances in the workplace or from redesigning technology so it is safer and healthier.
- Should be used in conjunction with environmental testing.
- Utilize tests that are accurate, reliable and measure the right thing at the right time.
- Provide for medical removal protection for earnings and job security in the event that this information finds that workers are at higher risk or need to be out of their job temporarily.

Summary:
Biomonitoring is a powerful tool to understand impacts of chemical exposure on health. The goal is to prevent illness and stop chemical exposure "upstream from the pump". The implementation needs to focus on the balancing of issues including transparency for all and individual privacy, and using the knowledge for reducing exposures to individuals and populations as a whole, especially those at greater risk.

Mary Wolff, Ph.D.

Dr. Mary Wolff is Professor in the Department of Community and Preventive Medicine as well as the Derald H. Ruttenberg Cancer Center and Director of the Division of Environmental Health Science at the Mount Sinai School of Medicine in New York, NY.

She holds the Ph.D. in Chemistry, and her research interests center around application of biological markers to determine exposures of humans to chemicals that occur in the environment. She has published widely on exposure assessment topics including air pollutants, lead, polycyclic aromatic hydrocarbons, solvents, pesticides and halogenated hydrocarbons. Her research has attempted to incorporate available knowledge of pharmacokinetic variability into exposure assessment.

Since 1987, she has investigated breast cancer risk associated with environmental exposures and the genetic determinants of these risks in a number of studies. More recently, the emphasis of her research has shifted to childhood exposures and health risks.

Dr. Wolff is Director of the Center for Children's Environmental Health and Disease Prevention Research, a NIH/EPA-funded multidisciplinary research program to study urban exposures and infant development. She and her colleagues in the Division of Epidemiology recently received a 7-year grant from NIEHS to investigate environmental and genetic risks for early puberty, research that is intended to elucidate breast cancer risk. Other current interests include physical and dietary modulation of environmental etiologies of disease. Dr. Wolff hopes in these studies to address the importance of environment and individual susceptibility, from both genetics and the built environment, in racial/ethnic disparities in health.

Excerpts from Mary Wolff: "Growing up Healthy: Environmental and Genetic Determinants of Puberty"
I came here today because I am involved in a series of national studies to look at environmental influences on the onset of pubertal development in girls. We believe that this is where biologically significant exposures may take place in relation to breast cancer. One reason I became involved in this area is because I believe that studying exposures at or around the time of breast cancer diagnosis is less likely to yield data relevant to cancer prevention.

Why are we interested in biomarkers? One reason is that they offer a more accurate indication of individual dose. In epidemiology, what we seek is an association between an outcome and an exposure. The more accurately the exposures are measured- the better the estimation of effect. That is the idea behind using biomarkers in cancer etiology. Unfortunately, too often we do not take into account the limitations in using biomonitoring and technological advances have made it possible to measure more chemicals at lower levels increasing our ability to incorporate biomarkers into our research. However, just because you can measure it, doesn't mean it is useful in cancer etiology or in elucidating other adverse outcomes, such as childhood development and reproductive development.

I'm going to speak briefly about two aspects of biomonitoring that are relevant to the work that we are doing. Biomarkers indicate body levels of non-persistent chemicals, and both types have been studied with regard to breast cancer. Two problems to think about are:

- Timing: When you measure these biomarkers in relation to exposure and to cancer development.
- Reliability or Validity of these biomarkers in terms of how they reflect a person's exposure.

The operable time to look at exposures may be in the time of puberty rather than late in life when most cancer occurs. We know that for radiation, early childhood is a very important window. Also, if we are looking as often and in breast cancer and reproductive studies at hormonal effects, we absolutely have to take into account the levels of endogenous hormones that are present through all stages of life.

Questions regarding reliability and validity of exposure biomarker measurement and risk assessment:

- Are persistent biomarkers really good indicators for chronic disease risk assessment?
- Are non-persistent biomarkers relevant for risk assessment?

Post-exposure fate of a persistent chemical in blood and urine:
The storage depot is adipose tissue and chemicals that are persistent traditionally in relation to breast cancer:

- DDE, PCB and Chlordane are considered robust biomarkers because there is an association with age, they don't metabolize very much and they are stored in adipose.

Post-exposure fate of non-persistent chemicals in blood and urine:
Blood levels generally go down but urinary levels last a bit longer. The window for the persistent chemicals is a matter of years, while in the non-persistent chemicals; it is a matter of hours.

There are a few exceptions:
- If you are constantly exposed to a non-persistent chemical, even though the levels are rapidly eliminated, you get a sustained dose.

Here are some examples of biomarkers and their use in risk assessment:
Long term:
- Organochlorines (90 days)
- Blood lead, bone lead (10-20 years)

Intermediate:
- Phthalate acids
- Phytoestrogens
- PAH-DNA adducts

Acute:
- Pesticides

Unclear:
- PAH-OH
- Alkyl phenols

Challenges:
- Organophosphates are not good biomarkers unless you are working in fields where they are applied continuously as the results are not consistent.
- There is also a problem with variability among populations. There can be excretion patterns that have no relation to the chemicals you are studying within a heterogeneous group.
- Need to understand dilution factors in doing urinary biomarkers.

Levels of pesticides:
Levels of various pesticides have gone down since legislation has been introduced and as the use of the specified pesticides has been lowered for public use.

Breast feeding:
Serum levels of children and months of breast feeding (1978) in Michigan:
- Looked at DDE, PCB, PBB
- The longer a woman breast feeds, the higher the levels of chemicals in the infant.
- Breast feeding is an important variable. On the other hand, levels in the mother decline because she is dumping them into the infant.

In a Long Island Study, it was found that women who did not lactate have higher levels of OC.

Timing of exposure and risk:
- Windows of exposure is directly related to risk (measured at diagnosis, risk in early life or risk of recurrence)
- Sustained exposures (peak versus average)
- Susceptibility (gene-environment effect)
- Multiple exposures

Sharyle Patton, BA

Sharyle Patton is Director of the Commonweal Health and Environment Program, a project of Commonweal, a non-profit organization based in Bolinas, California. Commonweal has programmatic interest in three areas: cancer, children at risk and environmental health. Ms. Patton was a participant in a pilot biomonitoring study conducted by the Mt. Sinai School of Medicine, Environmental Working Group and Commonweal which measured human biospecimens of 9 individuals for the presence and level of 210 chemicals.

Ms. Patton served as the Northern Co-Chair of the International Persistent Organic Pollutants (POPs) Network, a network of over 300 public-interests groups around the globe who are active in UN negotiations dealing with chemical contamination. This network helped create (with governments) the Stockholm Convention, a UN treaty that will ban certain POP's chemicals and severely restrict others. In her role as Northern Co-chair for the Community Monitoring Working Group, Ms. Patton helped organize a regional grass-roots campaign within the United States which sought to influence the United States position at the treaty negotiations and worked internationally to support NGO education of governments regarding the importance of a POP's treaty protective of human health.

Previously Ms. Patton served as Director of the Citizens Network for Sustainable Development. Ms. Patton also served as the Public Sector Representative on the United States Delegation to the UN Commission on Sustainable Development. She was a Public Sector Representative on the United States Delegation to the UN Summit, Habitat II and its follow-up conference in Nairobi as well as on the US Delegation to Rio Plus Five. Ms. Patton was active as an NGO representative at the UN summits on women's issues in Cairo and Beijing and participated as a representative of Commonweal with the International Women's Health Network and WEDO. Ms. Patton is the co-editor of the book "The People's Treaties from the Earth Summit " (Commonweal, 1993). She is also a videographer who over the past twenty years has produced a large body of work, including the PBS NOVA documentary, *The Man Behind the Bomb*, the story of peace activist and nuclear physicist Leo Szilard.

Excerpts from Sharyle Patton

I have no slides. You will have to look at me. I am your case study. I am the person who was part of a cohort for a pilot study conducted by the Mt. Zion School of Medicine, Environmental Working Group and Commonweal, to test nine participants for a total of 210 chemicals. In my own body, I have 108 chemicals. I basically won the PCB contest and the dioxin contest. My dioxin levels are similar to the lower levels found in "Cancer Alley" in Louisiana. What is interesting about this is that I grew up in a fairly pristine area of Colorado, high in the Rockies, where we raised our own beef and grew our own vegetables. And now I live in Bolinas, crossroads of the world, where it is very easy to eat organic vegetables.

So I'm not living next door to a factory or an incinerator that would indicate I would be highly exposed to toxins. I know my exposure, the highest among women in this cohort because I have never breast fed, so that's interesting. I have a copy of the study results; I would like to pass it around so you all can see what it looks like. I am subject #6 and Davis Baltz who is here in the audience is subject #3. To let you know how obsessive I am about all of this, since I have gotten my results I have started a small musical group, called the "Long Term Effects". If we ever record a CD we're going to call it "And More Research is Needed".

So what is my reaction to having all those chemicals in my body? I always thought I would age gracefully, that I would have my skin covered with age spots as testimony to spending far too many years looking for fossils in Montana and that I would never do Botox, because who wants to look placid in times like these? Not me! But I never understood that my body in fact constitutes a diary of my daily life in ways that I don't particularly appreciate. Have I polished my shoes black sitting on an

old foam mattress? If I live by an incinerator? If I walk down a golf course drinking a bottle of beer, my body will keep a record of that too. And at no point in my life have I given permission for my body to be used as a toxic waste storage site. If one of you in the audience gave me a hug without my permission, I would have legal recourse and I could sue you for assault and battery. If you threw paint on my car, I wouldn't even have to say I disliked the color.

There are no return addresses on the chemicals in my body. I don't know where to send the rental bill for using my body for possible storage site. As you can see this is really compelling information, it is not like having your teeth cleaned, it is not like having your temperature taken, it has deep significance and therefore can be used as an organizing tool.

St. Lawrence is an island off the coast of Alaska about 40 miles from Russia, so as you can guess it was a site of a lot of activity during the Cold War. People there had a sense that they might have been exposed to a great deal of chemical contamination because they were seeing lesions in the fish they were eating. They were also seeing lesions in the internal organs of the seals they were eating. In addition, Annie Aloha was a health care worker in the community and she thought she was seeing a lot more diseases than she wanted to see. They partnered with Alaska Communities Against Toxics and SUNY in collaboration with David Carpenter to apply for a grant to NIEHS to have them monitored. The community was very much involved in the design of the project, as well as the implementation, and what to do with the data once the results came back. They monitored for a small panel of chemicals, including PCBE- flame retardant.

When the data came back, their exposures to PCBE (by looking at blood) was 10 times higher than it was in the lower 48 states. When first presented to the community, the reaction of the elders, the community and the two tribes of the Yup'iks was to cry. The reason they cried was because what they felt was true had been validated and they could now use that information to ask for toxic cleanup around the military sites. They knew that part of their contamination has to do with global contamination, the global soup in which we are continually bathed. They looked at the PCBs and decided some of them were more volatile than others. Although part of the global soup that moves around a lot, some were part of our body that does not move around that much. So you might be contaminated from the local sources. They had some less volatile PCB's and monitored the soil where they had been living, and sure enough those PCBs were there. This meant that the community members were being contaminated by a local source so therefore they could go after that local source by talking to the US Government, and by talking to Alaska, and by talking to the US Military to instigate some kind of clean up and possibly of some kind of compensation. Annie died two years ago from cancer. She was the 12th person in the village to die from cancer.

The group brought their concerns to the United Nations, to the POPs Treaty, and we did the same thing as well with our body burden study. The POPs treaty was a UN treaty (now called the Stockholm Treaty) that banned 12 of the most persistent organic pollutants used on the face of the earth. It has a mechanism for adding further chemicals under the mandate of that treaty. In order to talk to delegates about chemical contamination, a group of us joined together to form the international elimination of POPs network in which a group of 300 to 450 NGOs around the world meets regularly at the negotiations with the delegates to talk about what it means to have toxic chemicals in your body. For developing countries, they have many other issues to be concerned about, like poverty, water, gender issues and refugees. So toxic chemicals may not seem to have a high priority for developing countries, but in fact they do understand that chemicals do move around the world, and that they can be contaminated by the industrial countries. They also understand that if you are a developing country and you have concerns about infectious diseases, especially HIV/AIDS, and if you know that toxic chemicals are known to undermine the immune system, then of course you are deeply concerned about toxic contamination.

We collected biomonitoring studies around the world that have been completed in the past two to three decades and have put together a brochure that says, “He’s got his mother’s hair, his father’s eyes and the chemical company’s dioxins, PCBs”, etc. which we passed around to delegates. We also did panels for the delegates of scientists who spoke about the signal disruption capabilities of POP chemicals (i.e., Pete Meyers, Sandra Steingraber). The panels were sponsored by WHO and the Environmental Ministries of the Netherlands and Iceland. Sandra also passes a vial of recently expressed breast milk around to the delegates. She is a biologist so she knew all the possible ways chemicals could pass through to the fetus during pregnancy and the effect on the developing fetus. When she passed abound the breast milk, she was breast milk feeding at the time, Sandra said “Yes, this is the very best food for infants, no doubt about it, but this is also the most contaminated food on the face of the earth.” This had an effect on the delegates and changed the way they negotiated. The French Delegation says they will never look at pesticide policies the same way again.

We had a lot to do with getting a strong treaty, which was enforced, with record speed. Now there are 60 countries around the world that are busy implementing this treaty. This is an example of using biomonitoring data to create policy change.

Another study that was done has to do with the Environmental Working Group, who biomonitored the breast milk of 21 women in 14 states. The effect was to help legislation in a number of states including Washington, Maine, California, and Hawaii to pass legislation to ban some forms of a flame retardant called PCBE. An additional study is being conducted by a group of NGOs gathered together including the Breast Cancer Fund, The National Environmental Trust and others, which developed after looking at CDC studies and realizing that women of childbearing age were particularly exposed to phthalates. If you are pregnant, phthalates can damage the developing fetus. They started a campaign that would help women choose which kinds of personal care products they wanted to buy, those that contained toxic chemical and those that don’t. You can go on the website www.safecosmetics.org to find out more information on personal care products. So this is another way biomonitoring data can be used for a marketing campaign.

To summarize what NGOs can do in communities and what community-based groups can achieve, with communities defined not in terms of geographical area, but communities or persons concerned around a particular occupation, a particular health outcome or a particular chemical. What we have done in these successful campaigns is that we have not talked about how these chemicals can be linked conclusively to a particular outcome.

What we are saying is that these chemicals are there, we know there is cause for concern, so let’s think about getting rid of them. We have also been able to control the media about these chemicals in regards to how the data is released. It is important to have messages that are understandable to the general populace, that are palatable, doesn’t bring people to their knees in fear, and makes them feel that there is nothing they can do about it. It resonates, it makes sense in what they know about how the world works and is actionable. If you are concerned about these chemicals, there is something you can do. All the way from working at the international level on a UN treaty, to changing the kind of nail polish you use. So let’s not wait until the studies, as valuable as they are, are completed- lets move now. As many of us have learned, to speak truth to power, we are learning to speak complexity to simple-mindedness; we are learning to speak precaution to risk assessment.

Clifford L. Johnson, MSPH

Cliff Johnson is the Director of the Division of Health and Nutrition Examination Surveys (DHANES), National Center for Health Statistics (NCHS) for Centers for Disease Control and Prevention.

DHANES is responsible for conducting the National Health and Nutrition Examination Survey (NHANES). Mr. Johnson has been with the NHANES program for more than 25 years.

As Director of DHANES, he is responsible for managing the planning and implementation of methodologic and analytic research for the National Health and Nutrition Examination Survey (NHANES) as well as the ongoing/continuous NHANES survey. NHANES data have been instrumental in establishing public health programs and monitoring nutrition and health policy on many public health issues including folic acid fortification, obesity, hypertension and environmental health.

Mr. Johnson holds a BS in Mathematics and Statistics from Colorado State University and an MSPH in Biostatistics from the University of North Carolina. He has authored or co-authored over 100 articles and given more than 150 oral presentations. In addition, he has been a member of many national and international committees and workshops on nutrition and health and has served as an expert consultant to New Zealand and Canada on the content and conduct of examination surveys. He has also served on numerous federal committees and working groups in the area of nutrition and health policy including the National Cholesterol Education Program Coordinating Committee, the Interagency Board for Nutrition Monitoring and Related Research, the National Institutes of Health Nutrition Coordinating Committee, and the CDC Folic Acid Working Group.

<u>Excerpts from Cliff Johnson: "NHANES, CHANES and NYC HANES"</u>
Earlier in the conference today, we heard from Dr. Jackson and Dr. Needham who provided some information about the NHANES survey, especially the biomonitoring aspect of the study.

My focus today is on CHANES (Community Health and Nutrition Examination Survey) and NYC HANES (New York City Health and Nutrition Examination Survey). The goal is to mention some of the lessons we have learned including some of the outreach and community involvement aspects that we have from the national survey that we are proposing for community based studies. Particularly, the first example that we have been involved with, the NYC HANES.

When we do NHANES at the national level, it is a national survey to assess health and nutritional status of the population, so the environmental assessment is one piece of a very broad and complicated survey that looks at:

- Nutritional status
- General risk factors
- Infectious disease
- Numerous chronic diseases
- Environmental health

So in that sense, one of the frustrations people have about NHANES is:

- It does not work at other levels, county levels, other than at the national level because of the way the survey is designed.
- Also, our level of community involvement is different than what we have heard from presenters early on in this session, in that our community is the whole US population. The people that we seek information from includes a scientific advisory board and the federal organizations that support and make NHANES go.

It is a complicated survey to run and does require funding and resources from several federal agencies to make it work. In a sense, our community involvement at the national level is at that board level. Each and every year, we go to 15 counties that make up the national survey so in that sense, we do have an active community involvement. The survey is not representative of the county we go

to, but is representative of a group of counties throughout the United States with similar characteristics that then make up the national survey.

We came up with the concept that we need to move from this national survey, which is unique in that it does:

- Home interview
- Broad spectrum of health examinations
- Has specially equipped mobile examination centers, both one trailer versions and four trailer versions

NHANES was conducted sporadically in the past, but since 1999 have been conducted continuously. The environmental component has really expanded greatly from what it was in the past. This is primarily based on the fact there is a lot more information that can be gathered secondary to gains in the laboratory methods.

The idea of the community-based HANES or CHANES is to assess the health and nutrition status of a defined population or community. We have heard from others that this defined community could be both geographic or a population-based group, or a group of people who are being studied. The idea would be to look at or explore these groups with the same methodology and protocols used in the national survey, which then allows the direct comparison to know how the community population, county, and state compares with the national data we collect on an ongoing basis.

The potential study populations could be:

- A geographically defined area: a state, a county, a city, and a broad set of US territory or counties.
- Population subgroups: defined ethnic or minority groups.

One of the other criticisms of the national survey was that we were only able to look at the non-Hispanic black population and the Mexican American population at the national level with enough sample size to be able to do analytic results. This is all tied into sampling and how easy or costly it is to do other population groups. This would also be an approach to look at other ethnic groups we do not typically look at in the national survey.

This is a little closer to what is being done in the NYC Hanes:

- New York City Department of Health and Mental Hygiene
- Probability sampling of NYC adults (n=2000)
- Interviews and examinations conducted at fixed sites in four boroughs
- June to December 2004

This is the first time NCHS has partnered with another organization- in this case a city health department, to actually conduct an NHANES-like study in a specific community. It was at the interest and request of the NYC Commissioner of Health, Dr. Friedman. He and his staff recognized a window of opportunity and a set of financial resources to conduct one of these studies. NCHS has worked closely with them for the last year and three-quarters to put together the NYC HANES.

The level of community involvement, in terms of what NYC has done, how they went about deciding the content, the operational aspect, the sample design, human subject issues, reporting the results, data collection and ownership and the analysis related aspects were discussed. Originally, they wanted to do a study of all five boughs. By the time they got though with the complications and all the issues discussed above, they ended up doing 2000 people, selecting a few hundred from the five

boughs and this is NY City as a whole. They couldn't go deeper, otherwise the sample size might go much higher. The survey is now ½ to ¾ of the way done.

NYC HANES content:

- Health interview including mental health
- Blood Pressure
- Height, weight, waist circumference
- Blood and urine collection
- Lab: lipids, glucose, HgA1c, Hip C, Herpes type 2, Corinne, metals, pesticides and stored (repository)

They did not just go with an environmental/biomonitoring approach as you can see, but they did select a few environmental variables. Again, the content of the survey is a key issue. I often say the same thing Dr. Jackson said this morning, "Keep it simple. Walk, don't run to start with".

NYC HANES Responsibilities:
NCHS:

- Sample design
- NHANES protocols
- IT architecture
- Component applications
- Training
- Consulting

NYC:

- Overall study design
- IRB and clearances
- Project management
- Data Collection
- Labor management
- QA/QC
- Data analysis

NYC HANES Lessons learned:

- Strong vision and support needed at top of organization.
- Starting small-operational aspects of the survey are very difficult.
- Adding human sampling expands the complexity involved. Makes questionnaires a piece of cake.
- Outreach is crucial and must be continuous. This is the one critical piece to success.
- Study manager essential and on site.
- More extensive training and pilot testing needed.
- Constant oversight of staff need due to short study duration.
- Staff should possess basic computer skills.
- Helpful to have cross-functional staff with clinical skills.

This was just a brief summary of some of the things we learned and did not learn. We have received numerous calls from organizations, states, and communities wanting to see how to implement a community HANES. We know how to cost these out and plan them. It all comes down to resources. We do not have resources currently. We have just enough resources to run the NHANES. We don't have enough to do individual community HANES, which gets back to the partnership and community

involvement. It does take creative collaborations whether it is a community HANES project or another kind of study; it still takes all of the above to make things a success.

Fern Orenstein, MED

Fern Orenstein became a member of the Board of Directors of Marin Breast Cancer Watch in 1996 after her own diagnosis of breast cancer. With a focus on research, education and advocacy issues, she serves as a spokesperson for the organization and is actively involved with several community based participatory research projects. Over the past 20 years, she has worked as a trainer, health educator and disease intervention specialist within a variety of communicable disease prevention programs. Ms. Orenstein is currently the Program Director for the California HIV Partner Counseling and Referral Services (PCRS) Program at the CA STD Control Branch in Oakland, CA. The PCRS program provides capacity building for local HIV programs, agencies, and providers working directly with HIV positive clients in a variety of settings.

Excerpts from Fern Orenstein: "Community Based Participatory Research: A Model for Success"
As the first speaker on the panel entitled "Engaging Communities in Biomonitoring Research and Efforts", my role is to provide an overview of community-based, participatory research as background for looking at community involvement in biomonitoring, and for providing a frame of reference. In addition, I will be speaking from the perspective of a community co-investigator on several research studies and as a breast cancer survivor.

My comments will focus on:

- Defining Community-Based Participatory Research taken from a variety of resources
- A historical context of Marin Breast Cancer Watch's participation in CBPR
- Challenges associated with CBPR
- Benefits of CBPR for communities and researchers
- Biomonitoring within the context of CBPR.

While there are many definitions of Community-Based, Participatory Research, this is one I prefer:

> Community-Based, Participatory Research (CBPR) is a collaborative approach to research that equally involves all partners- community members and scientists- in the research process and recognizes the unique strengths each brings to the process. CBPR begins with a research topic of importance to the community with the aim of combining research knowledge and community action to improve community health and eliminate health disparities.

There is a continuum of how communities are involved in CBPR. CBPR begins with a community or a community member identifying a concern or problem, i.e. the community participates in assessing and defining the problem of concern. The community is involved in:

- Developing research methodology
- Data collection and analysis
- Identifying action and policy implications
- Disseminating results to subjects or the community at large
- Taking action/changing behavior
- Identifying sustainable mechanisms (i.e., ways to sustain changes as a result of the research findings)

Some of the other parameters individuals use to define CBPR include:

- A partnership approach to research, i.e. equal contributions of expertise from community members, CBO's, academic-scientific researchers, public health professionals, government representatives.
- A co-learning, empowering process with shared responsibilities and ownership. All of us could spend hours debating what is a fair share of responsibility and ownership. There are two concepts where there needs to be more discussion, clarity and focus, but I think we are making good progress.
- Knowledge gained should be used for change and improved health and well-being.
- Research outcomes should benefit communities.

I would like to acknowledge some of the pioneers in CBPR, folks like Barbara Israel, Meredith Minkler and Nina Wallerstein at UC Berkeley. They are some of the folks that have inspired me to learn more about CBPR and the impact I can have being part of that process.

Next, I would like to share a little historical context. I started my involvement with Marin Breast Cancer Watch with my diagnosis of breast cancer, which prompted me to become involved in the breast cancer and environment movement.

Historical Context:

- Back in 1997, Marin Breast Cancer Watch created its mission to find the causes of breast cancer through community participation in the research process, in which we thought that we could reach our goals through CBPR.
- We identified the community's concerns though a variety of ways:
    - "Town hall" style meetings.
    - "Mapping" workshops in which folks came together in different community centers in Marin and drew representative maps of things they were concerned about in their environments. This approach came out of a mapping project in England done by Laura Potts. The maps were used to get people to share their concerns about breast cancer and the environment. The approach was a kinesthetic, visual, artistic, auditory, multi-sensory way for community members to contribute their expertise and ideas that proved to be very successful.
    - Advisory boards. We have relied on advisory boards for certain projects in order to obtain a wide variety of perspectives and expertise.
    - Web-based input. We have collected community input via telephone, mail and web-based techniques in some of our projects in a way that protected confidentiality.
    - Biomonitoring components: Buccal cells and Nipple Aspirate Fluid (NAF). In the Adolescent Risk Factor Study and the Development of Breast Cancer and in the Personal Environmental Risk Factor Study, we collected buccal cells as described by Dr. Reynolds, as well as NAF. As a community co-investigator and in with other folks from MBCW, we played an integral role in helping the subjects and participants to understand what was being collected, what the limitations were and whether or not the findings would be reported back to them.
    - On the positive side, we increased awareness of biomonitoring issues within the community.
    - On the negative side, we became aware of the human subject limitations in responding to requests for sharing results/findings, i.e. what information we can give back to the community. We held mapping workshops and later on participants would call us and ask what the results were. Even though we told folks there were limitations regarding what we could give back, they didn't process that information. All they know is that you have the information or their tissue and they want answers. There is an insatiable

quest for finding an environmental cause for breast cancer, especially in Marin County and the Bay Area.

Some of the other challenges we have faced in our work at MBCW, and I would love to hear from other community projects if they are finding the same challenges, are:

- Establishing trust between partners, which is a process that takes time.
- Reaching agreement
    1. Balance of power and shared responsibility
    2. Data ownership/future research
    3. Fair authorship

It is about reaching agreements and about building consensus. Again in Meredith Minkler's work, and the early work done in Canada, there have been attempts to identify criteria as to what exactly is a successful CBPR project. What is a balance of power? What is a shared responsibility between community members and scientists? You bring your Ph.D. and I bring my one breast. Unless you are a one-breasted Ph.D., you don't trump me. So we have to think about what is shared responsibility and a balance of power. I don't think there is a clear understanding about what is equal ownership of the data when community members are participants in the design, the implementation and the analysis of a study or about what is fair. I don't have the answers. I'm not sure we know the answers.

Again, it's part of the process of working toward a mutual understanding and I'm pleased we have gotten where we have in discussing this issue. Another issue is: who can use the data for future research when a community group is involved and they want to take the study to another level, but the scientific or principal investigator is not interested or has other ideas. How do you come to some compromise? How do you reach agreement? There is also the issue of fair authorship. Again, these are the issues we need to continue to work on.

- Creating and sustaining infrastructure in a community-based organization is a challenge. We do all these wonderful projects at MBCW and we end up doing bake sales, literally, to stay afloat and cover operating expenses. It's challenging for CBO's to have that level of involvement and expertise and cover operating expenses. This is an issue I hope you are sensitive to.
- Developing relevant research partnerships. This community forum is a perfect example of what can be achieved. We have in attendance a credible balance of community members and scientists, which I think is wonderful.
- Identifying funding resources. I think we are getting there. Kudos to folks at the California Breast Cancer Research Program, the National Institute of Environmental Health Sciences and the Department of Defense-institutions and programs that appreciate the role of the community in the research process.
- Research takes time. As a layperson and a public health professional, I am starting to understand the frustration of some of the folks who don't come to the table as much as I do. Why is it taking you so long to find the answers? Why is it five years later and you still can't tell us anything?

The community benefits of participating in CBPR include:

- Strengthening the community's capacity to address future health concerns. We are bridging cultural, economic, social class, geographical differences, particularly in the NIEHS funded Bay Area Breast Cancer and Environment Center projects. We are bringing together different communities. There are ways to make it work. I am learning new skills every day. We are empowering marginalized communities.

- There is a transfer of knowledge and expertise both ways, from the community person, from the breast cancer survivor who has lived through it to the researcher and visa versa. We all have a lot to learn from each other.

The benefits to the researchers include:

- Researchers learn about how to build trust in a community and in partnerships.
- Local knowledge is shared which often improves the direction of the research.
- A common language is developed.
- Thinking “outside of the box” happens which is really important.

The bottom line is that CBPR gives value to the voices that come from the community.

In addition to giving an overview of CBPR, I wanted to think about how CBPR is linked to biomonitoring:

- Extremely "personal and physical nature of research”. Research in breast cancer in general is extremely "personal and physical" when you are comparing women with breast cancer and women without breast cancer. With biomonitoring, we are getting into my body making it even more personal and physical which is something we need to think about. I hope this topic will be flushed out further in this afternoon's small group sessions.
- Individual versus Community exposures. What is my personal exposure verses the exposures of those who live in my neighborhood?
- "Blaming the Victim" syndrome. We all know about blaming the victim syndrome. It's been going on for a long time and we want to be careful. We do enough self-blame as it is regardless of our religion. We blame ourselves tremendously. I have spent the last eight years since my diagnosis still pondering what I did when my daughter was in my womb, what I was exposed to in the womb, what I did regarding breast feeding and I can go on and on but I think we need to be mindful of blaming.
- Risk communication strategy. The whole issue around do I want to know verses I demand to know. We need real clear messages around how to communicate what biomonitoring means to those who participated in biomonitoring studies. The message needs to be simple and clear. Clearly communicating the limitations are important but it is equally important to link the information to action. Do we have to wait while the jury is out? Are there things we can tell people now? Even if the "cut point" isn't clear, if I know a little bit of something, I can figure out some kind of intervention that I can choose as a consumer to take advantage of the information, whether it's holistic or alternative medicine or whether it's something in mainstream western understanding.
- Precautionary Principle. Finally, the precautionary principle. I think it is very important that it be incorporated into the messages we use when doing biomonitoring in CBPR. As scientists and community members, we should not say we have to wait until we find the perfect way to go about doing this because there may never be a perfect way.
- ?. I end with a ? (question mark) because there is a lot more to discuss.

Romel Pascual, MA

Romel Pascual is the Program Manager of the Environmental Justice Program at USEPA Region 9, which serves California, Arizona, Hawaii, Nevada and the Pacific Territories. His work focuses on environmental policy and program development and implementation as it relates to environmental justice.

Mr. Pascual has a BA in Political Science from UCLA, and received his MA in City and Regional Planning from the University of California, Berkeley. He has served as the Assistant Secretary for

Environmental Justice for the California Environmental Protection Agency (Cal/EPA), where he established Cal/EPA's first environmental justice program. He managed both the Cal/EPA Interagency Working Group on Environmental Justice and the Cal/EPA Advisory Committee on Environmental Justice. Mr. Pascual has also worked with numerous organizations including the Asian Pacific Environmental Network (APEN) and the Urban Habitat Program.

Mr. Pascual co-founded the Bay Area Regional Brownfield's Working Group of approximately 70 residents, community groups, and nonprofit organizations in addition to federal, state and local agencies. This Working Group was the first of its kind in the country. Currently, Mr. Pascual sits on the board of the Neighborhood Initiative on Chemicals and Hazards in the Environment (NICHE Project); and served as an advisor to Urban Habitat Program's Leadership Project and on the boards of the East Bay League of Conservation Voters, Students of Color in Planning, City of Oakland Community Committee on Urban Land Reclamation Project.

Mr. Pascual has authored papers and articles on Brownfield's and military base conversion, as well as a chapter on the development of ethnic urban enclaves known as Filipino Towns in the book Filipino American Design, Architecture and Planning Issues (1996).

Excerpts from Romel Pascual

I am a policy wonk. I am learning a great deal about the various terminologies around biomonitoring, around community-based participatory research, and science that are so instructive in the way in which we do our work in the environmental justice movement. Most of my experience has been informed by community-based organizing and advocacy and really trying to translate that information into good policy at a federal level and more importantly, in this day and age, at the state level where we are seeing a lot of the environmental justice issues really manifest themselves, and really begin to mean something at a very local level. I am happy to see that we have some of our community leaders here, Cynthia Babish, from LA and Karen Pierce, from Bay View Hunter's Point because many of these issues come from the community. We're talking about engagement of the community around research. My experience tells me it is very difficult because:

- The technical aspects of trying to communicate something that is a little abstract, let alone in combination with the abstract notion of environmental justice.
- We need to be very mindful that much of our communication at least at a policy level has been defined by a Decide, Announce and Defend Model. We decide what we want to do, we go out and announce it and then defend it. I hope we don't get stuck in that way of doing our engagement with communities.

I am going to speak about my experience of trying to establish an environmental justice program at a state level. Right now at the state, we have ten pieces of environmental justice legislation. This is probably more than that of any other state. It's really difficult to pull back on statutes that are already there. We can take the opportunity that exists with constructing a framework for environmental justice and move forward in trying to get some of our community-based work accomplished. More specifically, I would like to talk about some of the challenges I saw happening and am experiencing first hand. This is in regards to trying to work within the science context and attempting to relate that within the policy arena, where environmental justice essentially lies.

By way of background, environmental justice essentially speaks to two things:

- Communities are the ones who make decisions. These are the people we need to involve in decision-making.
- Adversity and disproportionallly- that individuals are adversely affected and are disproportionally affected which is very difficult to prove. Researchers were very clear on the low hanging fruit: involve communities. The harder piece is to demonstrate adversity, adverse

impact, and then we are into the question of disproportionate impact. That is the 64 thousand dollar question, how do you demonstrate disproportionallity?

In my work for the state of California, I knew that two things drove my work: Community-involvement and good science. Sometimes they don't really speak together, but that's how it really works. Policy develops by individuals who speak the loudest and by individuals who have access to the decision makers. The other piece is good science. Good science informs good policy. There is some disconnect between public health and research and policy.

When we were crafting the first environmental justice program for the state, we knew we needed to start with involvement. What was the multitude of issues in the environmental justice arena including research and data collection? The low hanging fruit, which was the process and involvement, was there. The harder piece was getting the people around the table. A 17 member committee that was appointed represented a fairly good demographic of the state of California and disciplines. It was a good analogy, if you will, of how one could see science playing out. It represented different perspectives from the industry side, the community side and everybody else in the middle and demonstrated how communities had to fight for what they believed.

What we are going to see as we go down this road of CBPR in the context of environmental justice and within the context of community engagement in public policy is that communities will be very hard pressed on whatever issue they had. What struck me as being very enlightening, was when we had a discussion around how do we move beyond public participation and involvement in environmental justice, part of the work of this committee was to craft a direction- a vision for California from where we need to be. It took 2 ½ years of public meetings all over the state and hard discussions among committee members to get us to a certain place. It was within that fighting (good policy comes from very hard fought efforts) that both the communities and the industries realized they wanted the same thing, certainty. They wanted certainty that something isn't going to harm them and certainty regarding regulations, i.e., certain regulations will have certain effects. The definition of certainty and how that evolved was enlightening in that we saw that communities are very sophisticated in recognizing that their community is sick or has public health issues.

Industry members were aware that there was the potential for industry to have an impact on what that condition was in the particular community. The question then became, how do we approach that? We need good science, which is one side of the equation. Then the question became since within this framework, good science doesn't exist so how can we try and try to craft good science? We're not quite sure if it's appropriate science because it doesn't contain the variables that we need. Then it was a question of trying to assess what we currently have, but we can't do that because you don't have anything, so it was a schizoid argument going back and forth between communities and industries.

We did talk about the things we needed to push from an environmental justice advocacy piece, which was the piece of cumulative impact. We need to take the totality of the community and getting to this point is where we struggle and we will continually struggle. One way to get over that struggle, is to continue informing those involved- those that are affected. What I was seeing was that the advocacy efforts at a community level are very powerful. We know from a anecdotal level that access to policy folks are big for some and small for others. What we try to do on the environmental justice side is equal that playing field.
What we need to do is to make sure that access continues to be very wide and open because that is where we are going to get good policy and good science development. You can have communities behind you. You're going to have communities advocate for you. At the same time, we need to work with communities to develop the capacity to understand what it is when we talk about community-based participatory research.

As we move forward in determining how we provide equity across the board, we need to ask how will we achieve this? When communities can come to the table as equals, are part of the decision making process, all of those pieces come together through resources and capacity development. Resources to participate, and capacity to understand. If we focus on that, we can get to a very good place in terms of engagement of communities, doing good science and forming good policy.

Alicia Salvatore, MPH

Alicia Salvatore currently works at the Center for Children's Environmental Health Research at the University of California Berkeley with the CHAMACOS study. CHAMACOS (the Center for the Health Assessment of Mothers and Children of Salinas) is a community-university partnership investigating the environment and children's health in the Salinas Valley, Monterey County, California. Current studies focus on investigating the relationships between pesticide and allergen exposures and health affects in pregnant women and children.

Ms. Salvatore coordinates a federally funded community-based participatory research study to evaluate the efficacy of interventions in reducing pesticide exposures to farm workers and their children. She also coordinates Community Outreach and Translation efforts for the Center and CHAMACOS study.

Prior to this, Ms. Salvatore worked in North Carolina with the North Carolina Farm Worker Health Program and in Burkina Faso West Africa as a Community Health and Development Agent and Health Program Assistant for PLAN International.

She has her MPH from the School of Public Health at the University of North Carolina at Chapel Hill. Ms. Salvatore has an expertise Health Behavior and Health Education and Community-Based Participatory Research. In addition to her work with the Center, she is currently a doctoral student at the University of California Berkeley School of Public Health.

<u>Excerpts from Alicia Salvatore: "Engaging Communities in Biomonitoring Research Efforts: Lessons from the Fields"</u>
I would like to thank Fern for the introduction to CBRP- everything you said and every little point resonates, even though it is a very different population. We work with farm workers and families in Salinas, Monterey County. Not so far away, but a very different world.

I'm going to talk about practical things about our project, i.e. lessons learned from the fields, weaving in some of the CBPR principles related to partnerships.

This was originally one of the first round of centers for children's environmental research-funded by NIEHS and EPA in 1998, and was just refunded for another five years.

There are many different studies and the main objectives are:

- To estimate sources, pathways and levels of in utero for postnatal pesticide exposures of children living in an agricultural community.
- To reduce exposure to children from pesticides with technical and educational interventions.
- To determine the relationships of pesticide exposure and
    - Neuro development
    - Growth
    - Respiratory disease

Now that we are refunded, we are moving forward to developing a clear case for translational research, turning results into action and really involving community members in that process.

Our cohort study population consists of 601 pregnant women who are living in the Salinas Valley (started in 1999-recruited from 2 different organizations)

- Less than 20 weeks gestation
- Medical eligible
- 18 years or older
- Receiving prenatal care at Clinica de Soledad and Nativadad through a comprehensive prenatal program (CPSP)
- Planning to deliver at Nativadad Medical Center

Characteristics of CHAMACOS Mothers:

- Mean Age: 25 years
- 65% Multifarious
- 92% Spanish Speaking
- 85% Born in Mexico; 34% and 5 years in the U.S.
- 96% being within 200% of poverty
- 44% 6th grade education or less
- 44% worked in agriculture during pregnancy
- 84% other agricultural workers in household

The Longitudinal Birth Cohort Study:

	13 weeks	26 weeks	Delivery	6m	12m	24m	42m	60m	84m
Maternal Questionnaire	X	X	X	X	X	X	X	X	X
Paternal Questionnaire			X						
Neuro developmental growth assessment					X	X	X	X	
Home inspections	X				X	X	X	X	
Respiratory Function Tests								X	
School Performance									X

The cohort is the case of use study- the group we do most of the environmental assessments, exposure measurements and development assessments. All are currently in the 42-month assessment.

This type of study is a large, well-funded study. It is the first study of this magnitude to happen in the Salinas Valley, so what I would really like to talk about is some of the lessons we have learned and what challenges we have had and how we have dealt with them.

Results of the Community Assessment:

1. The community has as interest in environmental health research- “There is a need to know how the environment is affecting us.”
2. Children’s health is a primary concern in the community- “I think you will get a very positive response from the questions. They are very interested in their children’s health and how to improve it.”
3. The center must share the results with the community – “I think the reaction of the community is going to be positive, but you need to keep them informed about the study and talk the way you talked to me about the community’s long term benefits from the study and plans to stay in the community for further studies.”
4. Research must be culturally sensitive- “Hire people who can work effectively in our community, people who understand the culture.”

When we were funded, we weaved through the findings of the community assessment and came up with one guiding principal for our center’s work, and these are not exactly the same CBRP principals of Barbara Israel and others have worked on, but there are a lot of the same things weaving throughout. The first thing we realized that we needed to do was create a community infrastructure in Salinas that is both the building and the people. The establishment of our field offices is one of the most amazing parts of our project. We have 20 people working the field office, most of them are former farm workers and only a few of them have gone to college, but they are amazing researchers. They are all teaching us about what it means to do research in the community setting and what is not appropriate. They are at this point in time, research partners. They review everything we do, all protocols, all questionnaires and they have actually brought up a lot of research questions we would not have thought of, i.e. things like homeopathic medicine, that wasn’t on our questionnaire but might be important. The training of these research partners is a real giving back to the community as well because they will possibly continue and do research studies of their own in the future.

Other partnerships (we all know developing partnerships is a very important part of a successful ad meaningful study):

We have two advisory boards based in the community:

1. A community advisory board which represents a broad spectrum of constituents, including both farm worker advocates and farm workers themselves, the health sector and also representatives from the agriculture sector council. This board also reviews publications before they are published and gives feedback.
2. Intervention Farm worker Council- for the intervention, is exclusively all farm workers. They meet every other month and have been very involved in receiving questionnaires, protocols, etc. The council also co-authors publications and in doing presentations.

Community Outreach:

We have made it a priority to become visible and known in the community and explaining, “what is research.” A lot of the things we did in terms of outreach in the initial stages of our project, was just going out in the community, being seen, going to meetings, attending events in the community- getting our name out there and also talking to the people about who we were and what we were about, why we were there, what we were looking for and what was their role in the process as well. So we demonstrated some hands on demonstration materials, such as the urine bags- the sorts of things that participants could come to the table and touch and play with, so at the same time they were going to participate in the study, they wouldn’t be so scared or nervous about what was entailed in the urine sampling of infants etc.

Also, our name CHAMACOS, in Spanish means little children, which was created with our partners. The logo was created by a local artist for the newsletter and for our calendar. These are things we do in the community to get our name out there.

Another important lesson we learned is that not all Spanish is the same. It is important to be culturally appropriate which does not mean just translating materials into Spanish. Spanish in Salinas is very diverse, we have people speaking their regional Spanish from the areas of Mexico in which they came from, and then there is the language spoken in Salinas, which means everything needs to go through people who not only speak Spanish, but also are from the community that understands what we are looking for.

Language Translation and Literacy:

- Greater than 90% speak Spanish
- Not all Spanish is the same
- Translate, back translate, and then check again
- 44% have less than a 6th grade education
- Read all the material, including consent forms

Tracking is essential- we have done many things and it's really hard work to keep people in the studies.

Tracking & Retention: Less to Follow-up:

- 601 pregnant women enrolled
  - 18 miscarriages, 5 stillborns and neonatal deaths
  - Of the 578 women remaining:
    - 8.6 % lost before delivery
    - 9.5% lost between delivery and 6 months
    - 6.5% lost between 6mo and 12mo
    - 2.5% lost between 12 mo and 24 mo
- 25% total lost
- Over ½ because they moved and could not be located

Tracking and Retention Strategies:

- Visits scheduled at participants convenience
- Pay for transportation and childcare
- Regular phone calls
- Contact info more than four family members friends
- Birthday cards for child participants
- Participant incentives
  - Gift certificates, key chains, car seats, strollers, hats, toys
  - Tee shirts and tote bags
  - Raffle

Additional enrollment options:

- Telephone only
- Medical records only
- Go to where the people are using the ultimate research machine fully outfitted for use in rural areas

Of course, consent and ethical issues are huge, although our staff is well trained and we continue to talk about ethical issues all the time to force ourselves the principal investigators to think about the issues.

- Take special care to not effect immigration status, housing employment, child custody, etc.
- Staff training
- Multiple consents
- Allow storage and analysis of banked samples
- Protecting identity of participants given the political nature of our research topic
- Reporting illegal activities
- Reporting results
- Intervening mid-research

We make sure our participants understand what they are being asked to do. We break down our consents into multiple pieces even though we are following the same cohort over time, we build in more consents and everything is read out loud, even if people know how to read.

Because of the cost of the research effort, we also ask in our consents if they will allow us to use the consents for later analysis, which is an ethical issue. If people do not understand what they are being asked to do or can't really project what might be done with the samples, it can become and ethical concern.

When we go into people's homes, we see things we really don't want to see, including some of them living in really, really bad situations. We have been linking people up to community resources but we have decided not to report adverse housing because of peoples immigration concerns. There is an ongoing dialogue we have been having with our community partners.
Reporting results is really a challenge. Up until this point, we have not been giving individual levels results because the state of science is that we can't really properly communicate risk in a way that makes sense to people. When we sit around, even the screen tests can't make sense of what we think. We have changed that and we have actually had to fight the IRB – UC Berkeley to get it switched. Now we are giving people the option of getting their individual level results- so if anyone has any great ideas around risk communication, about pesticides especially, given how challenging they are and because we are talking about people's children, we are trying to figure out the best way to communicate results to still allow people to have hope and also to not overwhelm them.

In terms of intervening mid-research, we really haven't had any "out theres" in terms of- there is not a real good understanding in terms of pesticide- we have not contacted anyone to this point to intervene in cases of outlying pesticide concentration, but we have in regard to neurodevelopmental assessments- we have intervened.
Basically:

- 16% of children live in poverty. We know that children in low-income areas are more at risk for exposure in the Salinas Valley and worldwide, and this population is often the most difficult to include in longitudinal studies and biomonitoring efforts.
- Children in agricultural communities have unique and greater exposure to pesticides, and in partnership with communities; we can carry out rigorous scientific studies and translate the results into action.

I wish I could have talked more about that last piece because that's why we are biomonitoring, because we want to make better the people we are working with. Unfortunately, that's where we are- translating into action. We haven't done a lot of that because it takes so long to get results back, we are just now starting to get results back after five years, so maybe in two years, I'll be invited back to talk about that.

Dianne Quigley, MA

Dianne Quigley is a Researcher and Doctoral Candidate, concentrating in Ethics in the Religious Studies department at Syracuse University. Ms. Quigley is the Principal Investigator of a grant from the National Institute on Health titled "Collaborative Initiative for Research Ethics in Environmental Health" (Year 2000-2006). With an interdisciplinary team of academic and community professionals from five community-university research partnerships, she is developing innovative approaches for dealing with environmental health research ethics. To date, the project has produced fourteen new case studies/articles from the field experience of researchers on such topics as: developing community rights in research, valuing multiple, cross-cultural knowledge systems, and using rituals and qualitative research methods as a means to develop and sustain community partnerships.

Ms. Quigley holds a Master's Degree from Clark University, Worcester, MA in the Environment, Science and Policy Program. At Clark University, for seven years, she was the Principal Investigator of several major government and private foundation multi-year grants to assist community populations across the country in dealing with the health impacts of nuclear contamination.

Ms. Quigley was also the Executive Director of the Childhood Cancer Research Institute (CCRI) for twelve years, a national public health organization which assisted communities with the health impacts of nuclear contamination. At CCRI, Ms. Quigley produced over fifteen national newsletters, conducted over sixty workshops in community, academic and federal settings; organized a national conference, "Meeting Community Needs – Improving Health Research and Risk Assessment" and produced numerous educational materials on the health risks of radiation exposure.

<u>Excerpts from Dianne Quigley: "Ethical Issues Related to Biomonitoring"</u>
It's my honor to be here to and to deal with some of the complexities I have been hearing buzzing around with ethical issues related to biomonitoring. My background is mostly dealing with communities on environmental health issues. Recently in our collaboration, we learn a lot from the public health field and we hope we are giving back so we are mixing audiences around the issue of research ethics and communities.

I want to give you training in basic research ethics. What are ethical issues that guide medicine and public health research? They are the very well known principles that came out of the Belmont Report, as it is called. These are called principle ethics that come from understanding individual rights and the greatest good for the greatest benefit. They came in response to the horrors of the Nazi war crimes and other research horrors.

Principles of Beneficence and Nonmalificence include:

- One ought not to inflict harm
- One ought to prevent harm or evil
- One ought to remove evil or harm
- One to do or promote good
- Remove conditions that will cause harm of other
- Rescue persons in danger and
- Help persons with disabilities

Additionally beneficence requires truth telling, confidentiality, privacy, fidelity and technical excellence (scientific probity, objectivity, conscientiousness).

Respect for autonomy ensures a right to informed consent including (many of these principles relate to biomonitoring in particular):

- Disclosure: full information about the intervention being used to participants who are engaging in this.
- Comprehension: understanding what this intervention can and cannot do. This has been done very incompletely in a lot of environmental research, i.e., helping people understand what research studies can or can do. Often it means looking at case studies to see what did and did not work as examples.
- Voluntaries: this is often an issue for communities who do not want to volunteer their community for research they may find harmful or burdensome to the community. An individual has the right to volunteer or not volunteer.
- Competence: in regards to your mental state in that you are competent in deciding about research and about being a part of that research.
- Consent: The actual signing or written or verbal approval to consent.

Justice includes (this is one we are always working on):

- Equitable distribution of burdens and benefits.
- Whatever respects are relevant; persons equal in those respects should be treated equally.
- Varied approaches to justice are found in utilitarian, egalitarian, communitarian and libertarian ethical philosophies.

Now these are principle ethics that just relate to individuals. The problem is that we do not have a set of ethical principles for communities, and lots of research harms occur with community research that come from not thinking about communal needs or communal issues and just thinking about the individuals needs.

What are ethical harms that can occur without good ethical communal principles?
These include:

- Research approaches that are academically controlled- academic teams inexperienced with community needs and rights with no provision for community participation.
- Research designs and methods that are scientifically interesting to academics but irrelevant and sometimes damaging to the community needs.
- Serious inequities in the research process in terms of acquisition, interpretation and dissemination of knowledge for research effort, hence leading to exploitation of community member/resources.
- The lack of development of community or group rights in western scientific research practices. This produces ethical inadequacies in research obligations of community consent, involvement, comprehension and benefits from a research effort (sometimes resulting in harm such as community stigmatization in publications).
- Expert driven research that excludes the observations, the local knowledge and experience reported by community members. This illegitimates human subjective experience for 'value free' objective knowledge determined by expert scientific methods. It leaves out the emotional and the cultural, and other types of knowledge values, problems, and needs that community members talk about. These include direct observations of community contamination or excess disease by community members: multi-dimensional impacts of contamination on community life. Information provided by community members is considered less credible than that which comes from experts. That has been a very big problem in environmental health research.
- Long-term commitment by researchers to the community; researchers often do "parachute research" in and out with no commitment to community needs over time.
- Issue of proprietary rights to community research data.

- Community consent procedures are not well developed for research dissemination, publication or uses of community archives of local knowledge or community data. All of these have become problematic.

Where is the impetus for us to develop collaboration to work on communal rights and communal needs? Surprisingly, very little work has been done on this in the past decades, and the closest we have come to any kind of guidelines are out of the Council for International Association of Medical Sciences. This is for international epidemiological studies with international populations. It does try to extend individual rights to communities.

CIOMS guidelines for ethical review of Epidemiological Studies-Provisions for Community Protections:

1. Informed consent-Community agreement:
   - "When investigators work with communities, they will consider communal rights and protections as they would individual rights and protections: Collective will of the community, how the community defines itself and who represents or speaks for the community will need to be determined."
2. Maximizing benefits: when you are doing a research intervention you might want to think of some benefits to the community that they will have despite what the findings are.
   - Provision for communication of study results.
   - Treatment or referral for health care needs.
   - Training local personnel.
3. Minimizing Harm:
   - Causing harm and doing harm: (transgressing values, exploiting scarce community resources, avoiding the risks of stigmatization or economic and social status being harmed in harmful publicity) through analysis of risk verses benefits by researcher with the community.

This is really important because I have read in a number of case studies, how important it is, that researchers don't think they know what all the risks are going to be, and just say what they are to the community. Risks need to be decided in collaboration with the community because community people will identify risks that researchers can't see. Just as an example, I mentioned earlier with native tribes, researchers doing some of the genetic research might declare that the cultural origins are different than what the tribe always believed. This may bring great harm to our community. It is so important to work closely with communities to identify what the risks are. Communities may not always be ready for that. They need again, some training on similar studies that have been done in other communities, and what the risks and benefits of that were. It might be a better dialogue giving them this background in order to identify what risks there might be to themselves as well.

Cultural competency is very important in dealing with different racial and ethnic groups. You must have cultural sensitivity training so that you understand values and beliefs, so that you are sensitive and understand that there are problems of language, and you're not dominating discourse. There are several case studies that are helpful in understanding social mores and sensitivity.

- Protection of confidentially, linked and un-linked information.
- Conflicts of Interest should be avoided and we are familiar with those types of issues.

I know that people talked about CBPR this morning. What I hoped to do was talk about implementation of principles. These are a collective list of research ethics for CBPR. This is based on the collective work of people who have been in the field:

Collective List of Research Ethics and CBPR recommendations: With these recommendations, we are using a communitarian ethical approach to research as opposed to a principle approach to research.

A communitarian approach to research focuses on sharing core values for developing a morality for the practice of research. I am just mentioning a few ethical frameworks that are helpful for people engaged in complex problems like health research.

There are also postmodern ethnics that help us deal with power or issues when we come together to share social values and develop guidelines with each other, it is important to understand who has power and who does not, acknowledging that and trying to level the playing field. This is a lot of work, particularly if you are working with a lot of different ethic groups. The academic, white scientific model tends to dominate too much. We need to develop a lot of openness and self-awareness, so we are not unconsciously taking over discourse and the development of communal procedures for research.

Preparation by researchers for Community Health research:

- Contacting community leaders about health research intentions.
- Understanding community conditions: sub cultural contexts, values, beliefs, socio-economics, geography, and demographics.

Developing the Collaboration or partnership:

- Recruiting Community Advisory Committees.
- Initial administrative arrangements between researchers and community members.
- Representation and involvement of community members in all stages of the research process.
- Equity reimbursement or incentives for the Community for involving Community in the research process.

How is the community defined? From some case studies, there are common themes that define a sense of community:

- A sense of belonging.
- Common experiences and history linked to place and emotional/spiritual connection.
- Fulfillment of individual and social need.
- Influence-the individual and the community feel they matter.
- Positive valuing of unity, diversity and cultural pluralism.
- Commitment to shared values and meanings.
- Social ties-interpersonal relationships family, classmates, co-workers, support groups, friends, neighbors, other local associations.
- CIOM Guidelines: When members of a community are naturally conscience of their activities as a community and feel common interests with other members, the community exists, irrespective of the study proposal.

In an ideal community, these are the types of community members who come together to form advisory boards:

- Representatives from existing community health or environmental organizations.
- Representatives of affected groups (by disease, exposures proximity to pollution source).
- Mixed community leaders-positional and reputation (political, religious, social, etc).
- Social and political activists (health, environmental, peace, arts, etc.).
- Keeper of cultural knowledge, local traditions, history or related knowledge (elder, local specialists).
- Representation of marginal groups (cultural, racial, disabled, gender issues, other).
- Community representations linked to regional, state, national and international networks with environmental health issues.

There is also the issue of equity. An important element that works in the NIEHS social justice grants is that there is sharing of the budgets. Community expenses often include the costs of building

participation of the community through advisory communities, building comprehension, and building rich input into the study. There is the other issue of qualitative local knowledge collecting, incorporating community knowledge into the research collection and designs, so that the entire agenda is not dictated by the scientists. Community members can be trained as community researchers to assist in interview data collection.

These are the scientific steps you may want to take. I have a special talk that I don't have time to go into which is about embedded knowledge that comes out of indigenous ethics. They define knowledge very different than western science does. All their knowledge is about participation and relationships. It is process and relationships dependent. Knowledge embedded is in all kinds of relationships. The objective and the subject have merged together and problems and disease come from a break down from all these relationships that are often embedded in community. So knowledge is often getting to where there is a lowering of morality. Relationships should be full of a high moral content, so Native people have a large understanding of their natural environment in terms of their relationship with it. The fact that we push out embedded knowledge and subjective knowledge is very damaging to our science. Our science should be the opening up to this kind of model. I think that communities are doing this more but the native communities are doing it a lot more. I could give you a talk on a risk assessment done with the Yakama and Mohawk tribes that show all these different outcomes- in cultural, social life, spirituality, ecology and health from their scientific approaches which then was more beneficial to the community. So that is something to be keeping in mind.
Philosophical foundation of Indigenous Science:

- Knowledge as participation and relational
- Knowledge as process and context dependent
- Perceiving and opening to the flow/spirit of knowledge
- Knowledge as Embedded-Traditional Ecological Knowledge

Native Science is based on subjective experience:

- To gain inner sensibilities
- To experience the essence of nature
- To acquire metaphoric and transcendent understanding of the experience

Finally, Richard Sharp wrote a good article on ethical issues one needs to consider in conducting environmental health research within a community. This is good information on how we are addressing the moral dimensions of these common technical risk decisions (Sharp, Environmental Health Perspectives, 2003) Here are some important to biomonitoring:

- Determining levels of risk sufficient to regard a substance as a potential health or ecological threat.
- How to disclose this information to those who are at risk from this toxicant with effective communication strategies?
- How are we choosing who and where to sample (choosing subjects or areas for environmental sampling or monitoring)? Are social justice issues considered in these choices, disparities in power and privilege that are underlying deeper ethical problems in social relationships?
- Assessing biological mechanisms through which environmental toxicants influence health outcomes (ethical issues surrounding the use of animal experiments and modeling).

Lori Copan, RPH, MPH

Lori Copan is the former Project Manager for the Biomonitoring Planning Project. She has spent the past 18 years developing and implementing both public and environmental health projects with core orienting values of participation and transparency. Such projects have included the participatory

design of HIV educational materials with low-literate linguistic minorities; the development of a waste reduction program in Latin America to include social and economically disenfranchised trash collectors; and most recently a decision-making process for the selection of biomonitoring projects that included community stakeholders' concerns. Ms. Copan is currently Program Director at the Asthma Education Center in San Rafael.

Excerpts from Lori Copan: "Decision Making and Responsible Research"

Thank you for inviting me here to represent the biomonitoring planning project that ended a year ago. Most of what I will be speaking about today is criteria we developed to make decisions two years ago. The information is certainly practical and as I listen to the conversations this afternoon, I realize we used a lot of embedded knowledge when we developed the criteria to do this work. When Christine asked me to come and speak about this work I had a very hard time separating, of course, we are talking about ethics, criteria that we developed that would be considered ethical criteria from the decision making process itself. So you'll probably hear a little bit of both of those things.

Before beginning, I wanted to acknowledge the biomonitoring program staff: Peter Flessel was the PI, and Bill Draper. Many of the people in the room comprised the advisory committee; Thu Quach and Christine were staff people as well as my self.

The Responsible Research Subcommittee consisted of:

- Sharyle Patton, Commonweal
- Marty Kharrazi, DHS Genetics Disease Branch
- Patricia Clary: Californians for Alternatives to Toxics
- Margaret Reeves, PANNA
- Michael DiBartolomeis, Cal/EPA OEHHA
- Jane Williams, Californians Communities Against Toxics

Background:

- Biomonitoring planning initiative in CA State Laboratory that involved 33 states, and we were one of them. When we began the initiative we were told there would be 5 to 6 million dollars in funding probably divided among five states who won the grants. However, a year and a half later, the funding changed to 2 million dollars in funding. We didn't win the grant, but being here today and being able to have the opportunity to share what we did truly means we did a good process and hopefully some of this work will be used as we go on.
- Plan needed to involve Laboratory and Non-Laboratory partners, but which partners? There was much interest from an array of investigators.
- Subcommittee was charged with examining and providing guidance on ethical issues arising from biomonitoring.

What we wanted to do was actually identify the chemicals that were important to Californians and would be used to build methods within the state laboratory. This was a process that was in the context of a state laboratory. This is pretty significant in terms of the amount of participation we had in that process given that it was a laboratory based process. The plan had to involve, and obviously it needed to identify, the chemicals that we wanted to develop methods for. It needed to involve the laboratory for which we were building methods and also non-laboratory partners, i.e., people who had research projects ongoing or had samples, were going to collect new samples or they had banked samples that we could actually use to develop these methods with. The Responsible Research Subcommittee was a subcommittee in the process that was charged with examining and providing guidance on ethical issues arising from biomonitoring.

The first meeting that we had of the Responsible Research Committee, which was an ethical subcommittee at the time, one person, I believe it was Geoff Lomex, introduced us to the term responsible research because up until that time we were talking about ethics. And ethics implied that you needed this specific knowledge base and expertise in ethics to actually be able to do this stuff. We didn't have an ethicist so to speak; we had a lot of people with good information and experience and so we adopted the term responsible research (RR).

I want to say again that it is difficult for me to separate the planning process from the responsible research committee, in that I think for me personally as the former project manager, they really go hand in hand. I think the responsible research subcommittee perhaps wouldn't have been as strong in what we were actually able to do if we didn't have ourselves embedded in a process that also had principles, values, and ethics in and of itself. I am going to say it was a participatory planning process as much as we can use that phrase. It was not a community-based, research action approach in the planning process, but we did our absolute best to make sure that the decision we made was based on real situations in California.
Responsible research fits into decision-making framework. These four values guided the entire process:

- Transparency: Assure transparency by explicating criteria upon which the decision was made.
- Values: Integrate values and concerns of different stakeholders into the process.
- Consistency: Represent all potential project alternatives in a consistent and equable manner.
- Objectivity: Safeguard that projects are not judged against each other but rather against a list of objective selection criteria.

We received call from members of areas such as Richmond and Bay View Hunter's Point asking to be biomomitored. We wanted to make sure that when we thought about comparing large institutional projects that were collecting samples with small community-based projects that had the potential to collect samples, we were looking at those projects through the same lens. That was part of the objectivity. Also that we would discreetly state what it is that we are making the decision on therefore stakeholders could come back and say how was that decision made? There was a trail to show as to how that decision was made.

I think being expressive about values is very important in making decision-making because we all have values and whether they all get written down as scientific evidence or knowledge base, they are still values decision-makers use in deciding what gets done. This really forced people to write down their values. Before I get on to the responsible research, I need to tell you that the criteria I will discuss is not just as explicit, is as explicit in the research sub-committee research project. Equally explicit is the other criteria we looked at. People had to be committed to looking hard at how to make a decision that was right for the state.

Criteria based structure:
Step 1: Scientific Criteria

1. Toxicity, exposure and preliminary laboratory results
2. Hypothesis and study design
3. Study population
4. Biomonitoring Impact Evaluation

Step 2:

1. Evaluate collaborator infrastructure

Step 3

1. Responsible Research Subcommittee evaluate the projects

Step 4
1. Evaluate public health benefits and impact

Step 5
1. Evaluate public support

Step 6
1. Human Sampling and laboratory-testing feasibility

Scientific criteria are the hard data we can measure: laboratory feasibility, toxicity, and study population. We had inter-collaborator infrastructure and we needed to know that people had the resources to collect the samples. We looked at public health benefits and public support for projects. We also looked at human sampling and laboratory-testing feasibility.

What I will be focusing on now is the Responsible Research Subcommittee. Here is a little chronology around that. At the very first meeting of the advisory board that was comprised of 24 members, people spoke up and said this is a loaded issue; we need to think about ethics as we think about going forward in this process. Therefore, we had a subcommittee formed and we completed a very extensive literature search that did not help us very much. There were two articles from all the articles we looked at that were helpful. One was about communicating results to individual participants in an environmental exposure study.

Deck W. & Kosatshy T., Communicating Their Individual Results to Participants in an Environmental Exposure Study: Insights from Clinical Ethics, Environmental Research Section, 1999, A80: 8ss3 8229. National Bioethics Advisory Commission. Research involving Human Biological Materials. Ethical Issues and Policy Guidance. Executive Summary. Aug 2001

Just looking through those articles yesterday, I thought those articles didn't help us either.

So in echoing what Dianne has said, we really did look at embedded knowledge to develop these criteria. We developed guidelines and approved them. As the projects went through the six steps, when they got down to the third step which was the ethical framework, the responsible research subcommittee, we had eight projects that we were thinking about using those guidelines. So these criteria are divided into five groups; recruitment, use of specimens, results communication, community participation, and study implications.

Responsible research criteria:
Recruitment: We are echoing things we heard today. Practice and Theory. We wanted to make sure that:

- During the research, the nature of the research and participation is explained to the potential study participant.
- Appropriate educational materials are provided to the potential study participant at the time of recruitment.
- Investigators explain to the potential study participants that refusal to participate in the study would not jeopardize access to health care services.

In terms of the use of specimen:

- Informed consent for future us of specimens for specified and/or unspecified research purposes by an approved groups(s) is obtained at the time of collection.
- There is a mechanism for the participant to ask for withdrawal of his/her specimens(s) from research at any time.
- For Banked specimen, if no informed consent for future use was obtained at the time of collection, investigators will request individual consent before use.

Those of you who are investigators think we're crazy. No project could meet all of the specifications or criteria, but these were a list of best practices in the real world. This is what we wanted to see- the most ethical approaches to do a study.

Results communication:
Disclosure of individual laboratory results with acknowledgement of scientific validity and limitations is offered to all participants. This was very important. The subcommittee felt that disclosing individual results was the standard we wanted to apply. Epidemiologists may shudder at the suggestion, especially when we do not know the clinical implications. We did not get to tease out what this would actually mean if we could have actually applied it to a research process because we didn't get funded. Which is really unfortunate because it would have been an interesting case study to see how we would have communicated those results, or how we would have thought about the need to communicate those results. Obviously any program that would communicate results of studies without knowing the clinical implications would need to be very well thought out, very thorough and very thoughtful in terms of how to accomplish that.

If the individual results do have clinical implications, the participant will be informed and referrals provided. We want to give people the option. It doesn't mean everyone wants their individual results, perhaps some people could be happy with group results, but lets start by giving people the option of individual results.

When possible, face-to-face results will be done through face-to-face encounters that are culturally sensitive and allow for counseling if needed. Results would be disclosed to participants to understand the significance and limitations of the findings through use of lay, literacy appropriate materials and resources.

Community participation: One criterion was:

- Mechanisms exist for community input in the planning, implementation and results communication stages of the study. Using this as the best practice, you would need to have a community based project to really try to see how this would play out in using community at all stages, as a source of knowledge and integrated at all stages of the planning of the research process.

Study implications:

- Knowledge and experience learned from the study can be used to inform policy and public health actions.
- Knowledge can inform the community to take action. This was a very important point for us in terms of the relationship between the right to know individual results and the ability to take action. That people were very firmly planted in the fact that if you do not know what your individual result was, clinical implications or not, then as an actor for the future you are limited. This has implications in terms of using bank samples verses newly collected samples given that with banked samples, even if you could go back and contact people, most times you will have a fairly significant loss rate. Study implications and right to know were very predominate in this decision-making.

In conclusion:

- Responsible Research fits well into formal values-oriented, decision-making structure.
- Process needs to be balanced against type of decision, i.e. biomonitoring feedback.
- RR consideration may be used as 'best practices' approach for future.

Robert Hiatt, MD, Ph.D.

About three or four times this morning, the Bay Area Breast Cancer and Environment Research Center was mentioned. Mary Wolff mentioned it; Janice Barlow mentioned it and a couple of other people mentioned it. Dr. Robert Hiatt, Director of Population Science at the UCSF Comprehensive Cancer Center is the PI of that Center. Although he is not on the agenda, it is important for those people not familiar with the Center to have some information about it.

Excerpts from Robert Hiatt

While I appreciate the opportunity, this will be a rapid data download about the Breast Cancer and Environment Research Centers, including the regional Bay Area Center. This new research effort is mentioned on page 42 of the State of the Evidence in your information packets. Let me elaborate for a couple of seconds on what this Center does and who is involved. It's important in this forum to recognize that many people in the room are involved in this project.

The Bay Area Breast Cancer and Environment Research Center is one of four Centers funded by NIEHS and the NCI. This study is looking at a particular aspect of breast cancer. We have known for a long time that women who go through menarche earlier are at higher risk of breast cancer. This has all been ascertained through retrospectively administered questionnaires, asking women with breast cancer, usually in case-control setting or cohort setting, about their past history. We know little of the determinants of pubertal maturation, especially the physical environmental determinants. The reason this is important is because puberty is the time of life that the breast is developing and the cells of the breast are dividing rapidly. This is a time when the breast may be particularly susceptible to potential environmental toxicants and other influences. So the way to understand this phase of development better, is to actually study young girls prospectively as they go through pubertal maturation.

The Centers have been funded for seven years, which is longer than the usual five-year NIH funding cycle. It was an RFA that was fairly specific on what was wanted. One of two projects that each Center was asked to put forward was a study of sexual maturation in young girls. The idea would be to recruit and track young girls around the age of seven and follow them for five years to understand their dietary practices, physical activity, their family structure, their environmental exposures ascertained both through analyses of biospecimens (biomonitoring in a sense) and through self-reported exposures. There are many other aspects of data collection which I do not have time to go into. But these girls will be followed at least once a year for over five years. Through this research study, we will be able to better understand the determinants of early sexual maturation.

Paired with this study of young girls are animal studies: in two cases looking at mouse models and two cases looking rat models in order to understand, not just the timing of pubertal maturation, but also the effects of environment over the lifespan from the neonatal period, through the pubertal period, to pregnancy and old age. This will give us a chance to look at different influences of the environment in these animal models so we can better understand what is going on in human populations. It's a very exciting project and the first time something of this focus and magnitude has been done. Like all studies of this nature, the results will be in some time in coming and remember that we are not looking at breast cancer as the outcome, but at the influence of environmental factors on pubertal maturation. It is a piece of a larger puzzle.

The study is important to describe as a result of advocacy and of community-expressed needs in this area. It was presented as a national issue to Dr. Kenneth Olden and Dr. Andrew von Eschenbach at the NIEHS and NCI with a very strong input from local advocacy groups including those in the SF Area. In my view it is a very good example of two things:

1. The involvement of community at the beginning- defining their needs.

2. The high level of integration of groups and individuals in the research.

There is two way communication, where community participants are part of the meetings of the researchers and are able to hear what is going on and better able to translate it back to their communities. In addition, we sponsor research community forums like this one today. We now have had 3-4 forums of various sorts in the Bay Area and we will continue to use this Center as a platform for issues that go beyond the actual research questions.

It's not only important for you to know about this project but also to know who is involved and attending this conference. Janice Barlow is the principal investigator of the Community Outreach and Translational Core. Karen Pierce, Kathy Koblick and Fern Orenstein, who you heard from earlier, are all members of the COTC. Mary Wolff is an epidemiologist with the Center at Mt. Sinai in New York. Larry Kushi from Kaiser Permanente leads the local center's puberty cohort study. Of note, we have a special advantage in recruiting girls locally because we have access to birth records and can track the girls over time through their medical records. I don't think there is anyone else in the core group, but I would like to mention Jeanne Rizzo who was important in advocating for this project in the beginning and is one of our community advisors.

So we are you, you are us. We hope this project will be enlightening as well as exciting as we go forward, both in terms of the interdisciplinary mix that we have in conducting the science and in the integrated community participation that is part of it.

Benefits of Biomonitoring

Biomonitoring has the potential to make unique contributions to our understanding of the role environmental exposures play in the development of disease, including breast cancer. Biomonitoring is a tool that can be used to:

- Measure environmental chemicals that are actually in the body, which is the best way within the public health paradigm to associate exposure to health outcomes.
- Validate models designed to assess exposures from air, water and the workplace.
- Capture unique individual exposures from food (such as mercury, persistent organic pesticides), from products (such as phthalates), and from the work place (such as lead).
- Evaluate exposures to environmental hazards not easily measured through direct environmental sampling or modeling.
- Identify unrecognized routes of exposure.
- Identify unrecognized exposures.
- Provide policy direction without risk analysis.
- Develop public policies to ban lead and exposure to cotintine from second hand smoke.
- Evaluate intervention strategies, such as the phasing out of lead in gasoline, paint, and industrial processes and polybrominated diphenyl ethers (flame retardants)
- Achieve policy changes at the local, state, national and international level (such as the passing of California legislation to ban PBDEs, the Stockholm International Treaty banning 12 of the most persistent organic pollutants and the current safe personal care product initiative)
- Classify individuals according to risk for a positive or negative health outcome from environmental exposures.
- Validate the degree to which people are classified as more or less exposed or have a higher or lower risk from environmental exposures.
- Provide, in combination with environmental monitoring, detailed information about differences in exposure across geography, race/ethnicity and socio-economic status. For example, the CDC report demonstrated that DDE is three times higher in Mexican-Americans living in the United States. Also DDE is still measurable in adolescents aged 12 to 19 years of age demonstrating that despite having been banned in 1973, children are still being exposed to low levels of DDT and DDE.
- Study the workplace environment which is important for many reasons, i.e., most individuals spend at least 8 hours a day in the workplace, workers are more highly exposed to chemicals and occupational studies are the primary means by which chemicals (such as asbestos and benzene) have become identified as human carcinogens.
- Assess workplace exposures within the context of the larger picture such as the human factors that effect susceptibility (genetic and behavioral) and impact and interact with environmental factors leading to clinical disease.
- Detect failures in environmental control measures in the workplace leading to corrections and improvements.
- Provide workers information about their personal health status in relation to internal chemical doses.
- Identify harmful workplace exposures through other pathways, such as skin and ingestion, not necessarily picked up by air monitoring.

Challenges Associated with Biomonitoring

Although biomonitoring may be a powerful tool in closing the gaps in our current understanding of the role environmental exposures plays in the development of disease, including breast cancer, it is still an emerging science. There are many challenges, uncertainties and limitations associated with the use of biomonitoring. These include:

- Predicting adverse health outcomes following human exposure is problematic because people respond differently to similar exposures. The efficiency in which individual's absorb, distribute (throughout the body), metabolize and eliminate the same chemical differs from individual to individual. Factors associated with differing responses include: genetic factors, demographic factors (age, sex, geographic location), nutritional status, and cumulative environmental and behavioral factors.
- Non-persistent chemicals, such as pesticides and phthalates, have very short half-lives, less than one day so there is a very short window of time that we can assess these exposures. However, if you are constantly exposed to a non-persistent chemical a sustained, measurable dose can be measures.
- Just because we can measure a chemical in the body doesn't mean it has an adverse health outcome. The presence of a chemical does not mean it causes disease. The CDC report provides each year new exposure data but doesn't identify levels that lead to disease.
- Just because you can measure a chemical it does not mean it is useful in cancer etiology. Two problems associated with measuring persistent and non-persistent biomarkers are of timing (when you measure these biomarkers) and have the reliability and validity of the measurements. Are persistent biomarkers really good indicators for chronic disease assessment? Are non-persistent biomarkers relevant for risk assessment?
- Biomonitoring study populations are often not representative of the population at large.
- The latency of the some diseases, such as breast cancer, is such that the window of risk is not the period of time biospecimens are being collected, but may be much earlier in development such as in utero or during adolescence. How do we assess exposures throughout a lifetime? How do we access exposures form conception through birth? Under NHANES are assessing exposures in children six years and older?
- Timing of exposure is important. There are windows of exposure that are directly related to risk.
- Sustained exposures (peak verses average exposures) make a difference in interpreting biomonitoring results.
- Environmental exposures are ubiquitous, cumulative (multiple exposures to different chemicals at once), aggregate (having multiple pathways of exposure) and multiple.
- Cost and logistics of collecting samples is expensive. Often need to collect multiple specimens over a period of time as opposed to a single sample.
- Obtaining informed consent from individuals and communities is challenging when collecting human samples are part of the study.
- Respondents cannot report ambient exposures from their environment.
- Biomonitoring is not just measuring environmental exposures but is also measuring host factors and genotypes in terms of people who are better able or less able to metabolize specific types of environmental exposures.
- "Mis-Measures" pose a biomonitoring challenge. Potential mis-measures include: Monitoring the wrong thing, at the wrong time among the wrong people and/or measuring too few samples, the wrong samples for chemicals of interest or chemicals too hard to detect.
- Chemical formulations change, i.e.; may not be studying what is currently relevant to health.
- Are still unsure as to what biomarkers we should be using, when should we be measuring and how do we apply the information?

- Is mistrusted by both employers (i.e., liability issues and no regulatory mandates) and employees (i.e., associated with drug testing, linked to the individual in a way environmental monitoring isn't, privacy issues and potential for job discrimination.
- It provides a direct measure of body burden at a given point in time. However, due to variables excretion rates among populations, the short retention period of certain chemicals, the lack of relevant and reliable biomarkers for many types of pollutants and the inability to trace how a person actually got the chemical into their body biomonitoring does not necessarily capture all the relevant information about human exposure
- Unanswered questions include: What biomarkers do we use? When should we be measuring? How do we apply them to future biomonitoring studies?
- Haven't answered many of social and ethical questions associated with biomonitoring.
- Challenges associated with risk communication are considerable, given all the limitations and challenges, given what we know and do not know.

Speaker and Panelist Recommendations

These recommendations are a synthesis of the many recommendations related to biomonitoring research and ethics, risk communication and community participation and public policy made by speakers and participants at the forum.

Recommendations related to research approaches and methods:

1. Speakers and participants emphasized the importance of using a community-based participatory research approach when conducting biomonitoring and environmental research studies. Specifically:
   - A Community Based Participatory Research (CBPR) should be utilized in all aspects of the research process, including developing the research questions, collecting and analyzing the data and disseminating the findings.
   - Community members and community-based organizations should be regularly engaged in establishing research priorities and in conducting research.
   - Create funding mechanisms and incentives that facilitate collaborative partnerships between community-based organizations and academic researchers.
2. Biomonitoring cross-discipline coalitions and other networks should be built, including the breast cancer and environmental movements, the environmental justice and occupational health movements.
3. Community and/or State biomonitoring projects should use the same methodology and protocols used in the National Health and Nutrition Examination Survey, which than allows for the direct comparison of a community, county and/or state population data with the national data collected on an ongoing basis.
4. When planning a community or state biomonitoring project start small. The operational aspects of the survey when combined with human sampling expand the complexity involved.
5. Improve exposure assessment in population studies. Develop better biomarkers for exposure, particularly, for non-persistent chemicals.
6. Investigate what matrices, what measures are most appropriate to us when looking at environmental exposures in uteri, the neonatal period and/or early childhood (before the age of six)

Recommendations related to responsible and ethical research:

1. A set of ethical principles for communities be developed that address communal needs, rights and protections.
2. People should be given the option of receiving their individual level results acknowledging the scientific validity and limitations of the results.
3. Individual results having clinical implications should be communicated face to face, if possible, and necessary medical or counseling referrals be made.
4. Risks verses benefits need to be decided in collaboration with the community.
5. Provide a clear and precise statement of the purpose of monitoring before sampling. Want to be able to clearly say, “These samples will tell us “this’ and these samples will not tell us “that”.
6. Observations, local knowledge and experiences as reported by community members should be respected.
7. Cultural competency is very important in working with different racial and ethnic groups. Researchers and community members have cultural sensitivity training so they understand values and beliefs and understand the problems of language and literacy and are not dominating the discourse.
8. Protocols are developed with the community for data ownership, dissemination and publication.
9. Agreements on procedures for conflicts in data determination are developed.

10. Responsible research requires an assessment of the public health benefits and public support for the project as well as the feasibility of collecting human samples and doing laboratory evaluations.
11. During recruitment, the nature of the research and participation is explained to the potential study participant, appropriate educational materials are provided and the potential study participant is informed that refusal to participate in the study would not jeopardize access to care.
12. Informed consent for future use of the specimens for specified and/or unspecified research purposes by an approved group(s) is obtained at the time of collection.
13. There is a mechanism for the participant to ask for withdrawal of his/her specimen from the research at any time.
14. For banked specimens, if no informed consent for future use was obtained at the time of collection, investigators will request individual consent before use.

Recommendations related to communication and community-involvement:

1. Communication should be improved among scientists, advocates, providers and community members.
2. Contact community leaders about health research intentions.
3. Understanding community conditions; sub cultural contexts, values, beliefs, socio-economics, geography, demographics, etc.
4. Based on an initial community assessment, developing a community infrastructure (both a building, a place and a staff of community members/research partners) and forming community advisory boards is one of the first steps to take.
5. Be visible in the community explaining who you are, what is research, what is this particular research study about, etc?
6. Have hands-on demonstration materials.
7. Employ tracking and retentions strategies.
8. Regularly disseminate research findings to communities, supported by a variety of methods, such as community forums and brief reports/newsletters.
9. Anticipate issues with language translation and literacy.
10. Messages need to be simple and clear and linked to information about action.
11. Ensure researchers and community members are adequately trained in cultural competency and sensitivity. A lack of cultural sensitivity toward study participants can create barriers to participation in biomonitoring studies.
12. Use the media to draw public attention to biomonitoring. Conduct policy and media advocacy to initiate a continued public dialogue about the issue.
13. Develop and implement effective methods of sharing, transmitting and dissemination research findings to communities in a way that promotes action and/or changes in public policy.
14. Education and continuous outreach is critical to the success of a community-based, biomonitoring and/or environmental research study
15. Need to understand the context of the exposures in order to communicate them. We should strive to ensure meaningful involvement of the person, who contributed the specimen, lives in the community or is otherwise at the receiving end of the exposure assessment.

Recommendations related to public policy issues:

1. A preventive approach to individual and population exposure to environmental contaminants as expressed in the “precautionary principle” should be integrated into all levels of policy as it affects biomonitoring research, the environment and human health.
2. When crafting a piece of legislation, keep it simple. Simplicity is the key. Proponents need to be able to describe the bill in 30 seconds. Review the Federal Funds Participation register

because if you can find federal matching funds you have a better chance at the state level to advance a successful bill. A bill should be based on good science and valid data.

3. In some instances, biomonitoring alone can provide policy direction without risk assessment.
4. Biomonitoring data can be used to achieve policy changes at the local, state, national, and international level. (See Benefits of Biomonitoring for examples)
5. A coordinating office for all California. There is an urgent need for a coordinating office of all CA databases that track environmental health.
6. Environmental health data needs to be shared and integrated in a standardized manner and communicated to the public in a timely manner.
7. Public health and environmental agencies lack adequate staff and resources to respond to environmental health threats.
8. Industries that produce, import or store chemical, biological or physical agents in CA should be required to report:
    - Full chemical/toxic properties.
    - Location and quantity of manufacturer.
    - Lab methods for environmental and biological sampling.

8. State laboratory biomonitoring capabilities need to be enhanced.
9. California needs NHANES and CAL-HEXAS surveys. HEXAS (couples environmental samples such as dust and air monitoring to nutritional exam and health exam from NHANES).
10. Surveillance systems for asthma, childhood neurodevelopmental and neurological diseases need to be developed and enhanced.
11. Need to develop standardized protocols for investigating disease clusters/build health education capability.
12. Hazard, exposure and health data to be reported by race and income.

Small Group Discussions

Topics

Following the presentations and questions and answer sessions, speakers and participants broke out into four self-selected groups. The topics posed for the discussion were:

1. How can we incorporate the concept of uncertainty, based on the current limitations in using biomonitoring data to establish health outcome/toxic chemical linkages, when communicating results to individuals and communities who are participating in research studies, which involve biomonitoring?
2. What are the advantages and disadvantages of using breast milk as a biospecimen to advance scientific knowledge and promote public policy changes?
3. How can biomonitoring be used as an effective surveillance tool in defining public health priorities in the state of California and in local communities?
4. How can we design biomonitoring programs and/or research projects that incorporate the principles of community-based, participatory research, i.e., that equally involve researchers, health professionals and community members in the decision-making processes regarding the design, implementation, analysis of data and publication of results?

The small discussion groups included a mix of community advocates, presenters and researchers and had both a facilitator and a recorder. Each group was given a list of potential discussion suggestions. The recorder summarized discussion points and in the closing session of the forum, summaries and recommendations were presented to the entire group regarding potential next steps and future action.

Discussions

Group 1: How can we best incorporate the concept of uncertainty when communicating risk?

Questions to guide the discussion:

Discussion Order:

1) Are there any additional questions for Peggy Reynolds regarding her experience with conducting an epidemiological study that included biomonitoring?
    - Based on your experience, do you think there is value in using biomonitoring in studies given all its drawbacks?
    - What would be an ideal study you would design using biomonitoring?

2) Based on the different presentations and discussions today, what are the different types and sources of uncertainties regarding biomonitoring?

TYPE		SOURCE(S)
o Measuring right people at right time		study design
o Representative sample		
o Ability to measure at low levels	l	laboratory capabilities
o Accurate measures		
o Meaning of results		interpretability results
o Comparison to other groups		
o Not knowing the health impacts		
o What can be done to reduce levels.		source of exposure known body burden

3) *Scenario:* A governmental agency partnered with a community health clinic to conduct a small 2-year breast milk biomonitoring study with a community in the San Francisco Mission District. Different members of the community, advocates and service providers participated in the planning and implementation of the study. The study participants were breastfeeding mothers who also belonged to a support group providing education and counseling. The breast milk samples were analyzed by a laboratory using a newly developed method analyzing for several chemicals, which have not been previously biomonitored before. The study did not focus on any specific health outcomes.

List some of the uncertainties related to this study: (possible answers: no background level for comparison, no health links, lab uncertainties b/c this is a new method, possible deterrence from breastfeeding, who the results are generalized to, what is the source of the chemical body burden, what are behaviors which would reduce the level of chemical body burden).

- How (and when) do we communicate these uncertainties to the study participants?
- How do we communicate the uncertainties to the public?

4) What are some concerns/ suggestion s for considerations in respect to the concept of uncertainty and communicating risk that you would make to the following people:
   - Researchers
   - Policy-makers
   - Community advocates

Group 1 Recorder sheet:
1. Please record comments related to each of the questions discussed. This can be done on the accompanying sheet.

Types of uncertainty:

- Uncertainty in knowing how to engage communities.
- How to disclose findings – ethical/moral responsibilities
- Communicating risk
  - Meaningful/relevant comparisons
- Interpretation/translation of results
  - Statistical uncertainty
  - What does a body burden mean?
- Indeterminate clinical results
  - Reliability and validity of clinical results
  - Errors in lab measurements
  - Limits of detection
- Limitations of what results can reveal
  - Results can only show correlation/association, not causation
  - Source of exposure is unknown
  - Time of exposure (and window of vulnerability) is unknown
  - There are confounding factors in disease (causes of disease are multifactorial)
- Study design and sample size
- Epidemiology studies are based on statistics/probability

Sources of uncertainty:

- One size does not fit all for communities
- There are many caveats when communicating results/findings
- Variability in community knowledge and capacity
- Variability or insufficiency in study design and size

- Variable susceptibility and vulnerability of individuals
- Media
- The need for burden of proof
- Politics
- Opposition (industry)
- The world is uncertain
- Communication/outreach component is under-funded and under-appreciated. At the same time, it is also very difficult and expensive.
- Biomonitoring and risk communication are complex issues
- Scientific uncertainty
- Latency of diseases
- Weight of evidence

Recommendations:

- Involve stakeholders
  - Involve/engage them early
  - Especially the study community
- Acknowledge that there rarely is CERTAINTY when it comes to science and human beings
  - Therefore, precautionary approaches are needed
- It takes both science and people to achieve change
  - Activities/initiatives must involve a broad range of stakeholders
  - Buy-in is necessary from various stakeholders including the community, media, scientists, and community leaders
- Communication needs to happen early and often
- There needs to be more one-on-one communication
- Increase cultural competency among researchers, scientists, and funding agencies
- Know your audience
- Increase capacity/skill in social marketing
  - Including visual presentations
  - Social math techniques
  - Meaningful comparisons
- Increase transparency in methods/process related to biomonitoring
- Need to understand and incorporate community values as well as different philosophical perspectives

For report back:
2. What are some of the main topics discussed in the session? Summarize 2-3 of the important issues discussed. Please check with the group to be sure you have captured these correctly. (For example, what are the different types of uncertainty that are encountered in research and/or surveillance?)

Answered in above summary:
3. What are the specific benefits and challenges of incorporating the concept of uncertainty when communicating risk?

Benefits and challenges:

- Incorporating a cultural understanding of “risk” and “uncertainty” is essential
- Must really know the audience
- Results need to be given in a context/acknowledging and understanding that we don’t know answers to everything
- Make sure media gets the message right

- Can build alliances with community leaders and learn from them what is the best way to communicate

4. What recommendations would the group make related to this topic? (Please check these with the group)

Answers to this question are above.

Group 2: Biomonitoring using breast milk as a biospecimen.

Questions to guide discussion:
Introductions all around or take time to identify groups of individuals present (community members, researchers, local and state government, environmental organizations, etc) Sharyle Patton will give some additional background on breast milk monitoring.

Questions for group discussion:

1. Is breast milk monitoring a good idea?
2. If you were a breast feeding mother or your partner was…what would you want to know about breast milk monitoring before you would be involved in a study?
3. Given that breast milk monitoring is going to be happening, what do you think should be included in such a biomonitoring project? What recommendations would you make regarding information and education for the study participants and for the larger community? What is the appropriate use of breast milk monitoring in education or policy campaigns?
4. What are some recommendations that could be made to policy makers regarding breast milk monitoring?

Group 2 Recorder sheet:
1. Please record comments related to each of the questions discussed. This can be done on the accompanying sheet.

Summary of discussion:
Sharyle asked "given what we know about the contamination in breast milk and the way the discussion regarding this can be alarming with parents/breast feeding mothers, is it a good idea to do breast milk monitoring?"

- Some folks recommend using meconium, but that isn't as fatty and there isn't as much of it.
- Could use cord blood because are really measuring the contamination to the baby/fetus when measure breast milk; so wouldn't this be just as good to use cord blood? Again there isn't as much of it and cord blood is already used for many other things.
- Breast cancer advocates want it because they see it as connected to breast cancer and may provide some answers; can also shine the light on the problem in a way that will get attention.

However, there is dissension in the ranks; some individuals think it will discourage breast feeding so shouldn't be used; for example, 25% of breast milk wouldn't pass as food under FDA standards and this would discourage breast feeding.

So, is it worth it then? One participant said this is the wrong question. The right way to frame it is that we have to look at what we want to do- we want to monitor what happens to newborns and before birth, so this is the best window to look at what the baby and fetus has been exposed to and breast milk is a large volume with ease of collection. Breast milk contamination is the evidence of

contamination in our community and it must be stopped but we need to keep saying that breast milk is still the best food source for babies.

One participant noted that the levels are such that we should recommend breast feeding for 2 years since the damage has already been done in utero and what is added from breast feeding is more benefit than harm. However, if we were in the Arctic with the levels there, then recommending breast feeding wouldn't be good. Also, children that are breast fed are different emotionally, intellectually, socially. In addition, in tribal communities, breast feeding has a sacred significance. And formula which has been shown in some cases to have magnesium and lead isn't that great.
Also, if we don't monitor breast milk we don't know what's in it and we can't really be making any decisions. Knowledge is ultimately better than not.

We need to be thinking about how to message this so that we know the real problem here is that we even have to be having this conversation. We need to engage the lactation community. Other things about messaging include:

- Have press workshops so that the message to the press is clear- call it a fetal contamination study for example.
- Educate the public about the need to act now so that your children and grand children will be better off.
- When doing breast milk monitoring- accompany the study with lots of information to be sure that the message about continuing breast feeding is clear.
- Use headlines of formula contamination to show that it isn't the greatest either.
- Have sensitive information accompanied by disclosure of all that is known about levels and what the levels mean.
- Be sure to always advocate for funding the advocate part of a grant.

If one were doing a study, would need:

- Results back to the community and the individual
- Don't call it breast milk monitoring
- Confidentiality
- Look at the community as the "in charge" group- follow their advice and lead about how to go about the study and reporting

The question of calling it "fetal contamination study" raised concerns in the group about whether or not we might find ourselves allied with groups that we wouldn't want to be with (like, right to life groups).
For report back:
2. What are some of the main topics discussed in the session? Summarize 2-3 of the important issues discussed. Please check with the group to be sure you have captured these correctly.

- There is some dissension in the ranks because of advocating breast feeding vs. right to know issues.
- This is an issue about the fetus getting a lot of chemical exposure so doing the breast milk monitoring really just lets us know what they have already gotten- maybe explaining this better would shift the focus to getting chemicals out of the environment rather that being alarmed about breast feeding per se.
- We should see this as a regulatory failure.

3. What are the specific benefits and challenges of breast milk monitoring?
Benefits include big sample and easy to collect/can monitor newborns.
Challenges including the controversy/turning away mothers from breast feeding.

4. What recommendations would the group make in relation to this topic? What recommendations could be made to policy makers? To researchers when designing breast milk monitoring studies?

- One recommendation is to rename from breast milk monitoring to something more to the point and possibly less controversial.
- Could also work specifically with breastfeeding groups
- Think about the messaging issue

This group took the additional step of deciding that they would continue this discussion as part of an email list serve.

Group 3: How can biomonitoring be used as an effective surveillance and research tool in setting public health priorities at the federal, state and community level?
Questions to guide discussion:

1. How can biomonitoring be used in research/in surveillance (refer back to the discussions of the day)?
2. What is the difference between using biomonitoring for research and surveillance?

Also:

- One time only vs. ongoing
- Amount of resources necessary to do the project and the timing of the biomonitoring effort
- How to fit into research protocols vs. not having the same kinds of timing restrictions
- If with a research project, design and sample size are critical to the hypotheses and whether the research question can be answered with biomonitoring
- If surveillance, what kind information does this provide?

Is the use of biomonitoring an effective way to set public health priorities?

- Why or why not
- Add discussion of whether is just environmental focus or more broad
- In either case, how could it be incorporated into priority setting?

What recommendations would the group make about this issue? Under what circumstances could/should biomonitoring be used in setting priorities?

Group 3 Recorder sheet:
1. Please record comments related to each of the questions discussed. This can be done on the accompanying sheet.

Biomonitoring can be used in surveillance as part of a long term data gathering process; provides background levels/ temporal and geographic differences and can identify hot spots and prompt specific research.

Research and biomonitoring is bounded in time and focus; on a specific hypothesis question/research; might be hypothesis evaluation.

What is the extent of biomonitoring at the federal, state and local level? Need to strengthen federal program and support state biomonitoring also with strong local partnerships. States need geographic data for specific distribution (like alpha protein and Alzheimer's using GIS).

Specific benefits and challenges include:

- Surveillance good for hypothesis generation; use in research for hypothesis evaluation.
- Do the biomonitoring data support clear and definitive regulations and support strict enforcement and support lawsuits (e.g. restrictions to trade provisions).

- Could use NHANES for GIS analysis on big geographic units/need state data for local GIS/hot spots/census tracts.

Recommendations:
- Include biomonitoring (including breast milk) in public health infrastructure as an important tool.
- Need to strengthen state biomonitoring capacity.
- Is it an effective tool? Depends – in the public health story, it worked well in some situations. Need more data for regional assessment of regulatory compliance (PBDE removal due to biomonitoring).
- Communities need to speak strongly for biomonitoring support
- Need comprehensive plan for protection from toxic chemicals and biomonitoring can play a part in this.

For report back:
2. What are some of the main topics discussed in the session? Summarize 2-3 of the important issues discussed. Please check with the group to be sure you have captured these correctly.
- We discussed the difference between the use of biomonitoring for surveillance and for research. These are complimentary but are not the same.
- We discussed the need for biomonitoring at the federal, state and local level providing different information that fits into a big picture.

3. What are the specific benefits and challenges of incorporating biomonitoring into research studies, into surveillance and/or into priority setting?

Benefits: Surveillance for hypothesis generation; research for hypothesis evaluation; Ask whether the biomonitoring data support clear and definitive regulatory actions/law suits; success of biomonitoring in the lead reduction case.

4. What recommendations would the group make related to this topic? (Please check these with the group) For example, should biomonitoring be incorporated into priority setting?
- Include biomonitoring in public health infrastructure
- Communities need to speak strongly for biomonitoring support
- Need a comprehensive plan for protection from toxic chemicals with biomonitoring as a tool in the plan and used in conjunction with other approaches in priority setting.

Group 4: How can we design community biomonitoring surveillance and research studies that reflect and incorporate the principles of community based participatory research?

Questions for discussion:
1. What principles of CBPR stand out from the presentations?
2. What are some of the additional concerns specific to biomonitoring (refer to Dianne's earlier talk and ethical concerns and Lori's earlier talk and 'responsible research criteria')
3. Have any of the group participants been involved in community based studies where biomonitoring was a component of the study? If so, what were some of the approaches that were used to incorporate CBPR goals into the study?
4. What are the benefits of an approach that utilizes CBPR and what are the possible challenges?
5. What steps would need to be taken by a community group or a researcher to ensure community participation in studies?

6. What kind of criteria or protocol would be appropriate to ensure community participation in biomonitoring studies?
7. What recommendation or set of recommendations would the group make regarding this topic? (Utilize the responsible research criteria if appropriate but these could also be advocacy recommendations, policy change, among others).

The following question could be used to stimulate additional discussion if needed: Are there any differences in incorporating community participation in surveillance vs. research studies?

Group 4 recorder sheet:
1. Please record comments related to each of the questions discussed. This can be done on the accompanying sheet.

- The primary principles/issues are incorporation of community values and community representation. Biomonitoring should be used in that context to prevent exposures and as a tool to point to problems. It is important to build consensus (for instance, in relation to the biomonitoring bill which was too complex partially because of trying to build with so many different people).
- Serious ethical concerns can be addressed by CBPR.
- There needs to be money dedicated to the pursuit of community input and participation- it is expensive, takes a long time and is resource intensive.
- Biomonitoring in a state structured program needs to include community or it will miss the mark.

There are numerous IRB issues that need to be addressed:

- Who is at the table at the start of a project will determine how well the project will look ahead to potential ramifications/social justice issues and possible exploitation of communities.
- At what point must the researchers involve the community? Scientists often respond from a reductionistic approach rather than asking what might be the outcome and how can we open this up to be most responsive to the needs of the community. This difference could be seen in the “writing up a report vs. generating a model from a community perspective”.
- If the communities are generating the data, they need to know what it means.
- CBPR should be elevated as a credible science to learn participants concerns and community concerns.
- There is high potential benefit of demonstrating harm from chemicals specifically. There are ethical considerations with the results- how to avoid negative community impact. Questions arise about how information from such biomonitoring studies will be used. This needs to be addressed early on.
- Also need to question who the community is so that there is appropriate representation.
- Ownership of the data is a concern as well as the future use of the data and how to interpret the data. There are some standardized agreements in the public domain on ownership and use and these could be consulted as models.

There is a lot of complexity in the issue- ways to address control, ethical concerns, ways to open access to data and make it freely available, how to interpret to the community so that it can be used as the community wants- for action or information or whatever, need to examine opportunities for transferring the skills and knowledge required to individuals and communities. Develop models of ownership and sharing while maintaining confidentiality.

For report back:
2. What are some of the main topics discussed in the session? Summarize 2-3 of the important issues discussed. Please check with the group to be sure you have captured these correctly.

- Uses of data- impacts on the community and requests to bring in other experts- sociologists, etc.
- How to deal with the impacts
- Building community consensus
- Discussing ownership of the data

3. What are the specific benefits and challenges of incorporating CBPR approaches with biomonitoring in studies?
   - Biomonitoring is a useful tool but there are all the problems/issues of using it in research studies- how to use it most effectively regarding the specific hypothesis.
   - Issues with explaining to individuals why we are collecting body specimens for the study and how the results will be used/confidentiality and right to know/informed consent.

4. What recommendations would the group make related to this topic?
   - Put information in the public domain- open data bases- and train and educate the community group on maintenance and confidential data.
   - Scientific researchers share budgets as well as data.
   - Make it professionally beneficial to publish the data.
   - Call in experts in other fields as soon as it seems relevant so can get a broad understanding of the problem and the possible approaches.
   - Standardize agreements so that all research includes comprehensive agreements with individuals and communities.

Summary of Small Group Recommendations

Group 1: How can we incorporate the concept of uncertainty, based on the current limitations in using biomonitoring data to establish health outcome/toxic chemical linkages, when communicating results to individuals and communities who are participating in research studies, which involve biomonitoring?

- Acknowledge that there rarely is certainty when in comes to science and humans; therefore precautionary approaches need to be communicated and adopted.
- Cultural competency training for researchers, community members and funding agencies. Incorporating a cultural understanding of "risk" and "uncertainty" is essential as is incorporating community values into the study design. Know your audience.
- Develop *early and effective* communication strategies, including one-on-one frequent meetings with community leaders and study participants.
- Study results should be given in context with meaningful comparisons using multi-sensory approaches (i.e., visual, auditory, etc). Regularly disseminate findings to communities.

Group 2: What are the advantages and disadvantages of using breast milk as a biospecimen to advance scientific knowledge and promote public policy changes?

- Reframe/rename "breast milk monitoring" in a way that is less controversial and more to the point.
- Develop innovative ways to message the need for breast milk monitoring, including press workshops, sensitive information for parents accompanied by full disclosure of what is known and not about breast milk biomonitoring, reinforce the benefits of breast feeding.
- Continue to engage the lactation community.

Group 3: How can biomonitoring be used as an effective surveillance tool in defining public health priorities in the state of California and in local communities?

- Include biomonitoring in the public health infrastructure
- Communities need to speak up strongly for biomonitoring support
- Need a comprehensive plan for protection from toxic chemicals with biomonitoring as tool in the plan, used in conjunction with other approaches in priority settings.

Group 4: How can we design biomonitoring programs and/or research projects that incorporate the principles of community-based, participatory research, i.e., that equally involve researchers, health professionals and community members in the decision-making processes regarding the design, implementation, analysis of data and publication of results?

- Make data sources more accessible to community researchers and members for their own interpretation, analysis and use, while ensuring the confidentially of those on whom the research is based through community trainings and education programs.
- Create funding mechanisms and incentives that facilitate collaborative partnerships between community-based organizations and academic researchers.
- Develop standardized agreements regarding ownership of data, future use of data and interpretation of data that can be used as models.

Evaluation Process

Following the conference, participants and speakers were asked to complete an evaluation form to assess to what extent personal goals were met, questions were answered, information was exchanged, mutually respectful relationships were formed and communication channels were created through participation in this process.

Evaluation will be both qualitative, describing the forum processes and analyzing the small group discussion groups and quantitative analyzing and reporting out the results of the evaluation questionnaire.

How early two way communication process between researchers, etc and community members can influence individual and group:

- Perceptions
- Knowledge
- Attitude
- Beliefs about biomonitoring

Extent to which attendees were satisfied with the community forum as a method for:

1. Informing community members about individual and group risks and benefits of biomonitoring.
2. Educating a broad audience of interested and concerned researchers, Public health professionals, health providers, breast cancer advocates, environmentalists, scientists about the current state of the science of biomonitoring.
3. Engaging in informed and shared decision-making activities with individuals representing diverse perspectives, experiences and expertise.
4. Involving community members in setting priorities for future biomonitoring studies and forums.
5. Identifying partnerships interested in collaborating on community-based, participatory breast cancer research studies through biomonitoring.
6. Disseminating information from the forum, as well as the results of assessments and evaluations, to relevant stakeholders, including the media, health care providers, community organizations, environmental groups, public health professionals, breast cancer advocates, researchers and community members.

Other evaluation measures should comment on:
A majority of participants indicated they choose to attend because the topic of biomonitoring was important and relevant which demonstrates the appropriateness of the community forum theme.

- The success and relevance of the community forum and small group discussions, as measured by attendance and participant comments after the forum. Did the forum draw a wide range of participants from varied perspectives?
- Demographic information on who attended and the usefulness of the information to their own work
- Geographic areas represented –Was the forum a bridge between communities?
- Comments contributed by participants in question and answer periods and in small groups. Quality of discussion and recommendations that came out of the process by their participation.
- Content of the forum sessions and the comments by participants regarding the comprehensibility and relevance of the material presented.

Specifically:

- Did the forum draw a wide range of participants from varied perspectives?
- Did participants report a clearer understanding of the individual verses group risks and benefits of biomonitoring?
- Did participants demonstrate increased understanding of research using biomonitoring, environmental risk and the issues involved in these areas of research?
- Were any initial steps taken in identifying partnerships interested in collaborating on CBPR breast cancer studies using biomonitoring?
- Did presenters and participants come to some consensus about specific action steps for the future?
- Was there a lively discussion in small discussion groups?
- How participants will use the information from the forum? What was the outcome of the meeting for those that attended?
- Did the participants feel the forum was interactive, i.e. people were there to listen to and respond to their input?

Evaluation Form

Marin Breast Cancer Watch

COMMUNITY FORUM EVALUATION FORM

Please answer the following questions at the end of the session. Your participation is greatly appreciated and is an important part of improving future community forums. Please hand it in on your way out today. Thank you for your time and effort.

Overall, how would you rate the following items?

		Excellent	Very Good	Good	Fair	Poor
1.	The quality of the keynote speaker					
	a. Content of presentations.....	1☐	2☐	3☐	4☐	5☐
	b. Quality of presentations	1☐	2☐	3☐	4☐	5☐
2.	The quality of the other speakers					
	a. Content of presentations.....	1☐	2☐	3☐	4☐	5☐
	b. Quality of presentations	1☐	2☐	3☐	4☐	5☐
3.	The range of topics	☐	☐	☐	☐	☐
4.	The conference venue	☐	☐	☐	☐	☐
5.	The effectiveness of the small group discussions in eliciting dialogue & developing recommendations for next step activities.	☐	☐	☐	☐	☐

Next, please indicate how strongly you agree or disagree with each of the following statements about this forum.

		Strongly Agree	Agree	Disagree	Strongly Disagree
6.	I feel satisfied after attending this forum.	1☐	2☐	3☐	4☐
7.	The attendees were given enough opportunity to voice their concerns.	☐	☐	☐	☐
8.	Holding a community forum is a good way to involve community members in the research process.	☐	☐	☐	☐
9.	I feel more connected to community members after attending this forum.	☐	☐	☐	☐
10.	The people in charge of this forum care about the opinions of attendees.	☐	☐	☐	☐

11. I feel frustrated after attending this community forum. ☐ ☐ ☐ ☐

If yes, Why?

12. I am not willing to attend another community forum on this topic ..... ☐ ☐ ☐ ☐

If yes, why?

13. I am not willing to attend another community forum on <u>any</u> topic. ☐ ☐ ☐ ☐

If yes, why?

14. The people in charge of the meeting worked hard to bring all the issues related to biomonitoring into the open. ☐ ☐ ☐ ☐

15. Alternative viewpoints were encouraged at this community forum. ☐ ☐ ☐ ☐

16. Community forums are a good way to get information to the community on topics such as biomonitoring. ☐ ☐ ☐ ☐

17. I learned many new things about the risks of biomonitoring from this community forum. ☐ ☐ ☐ ☐

18. I learned many new things about the benefits of biomonitoring from this community forum. ☐ ☐ ☐ ☐

19. Did attending this forum make you feel more concerned about environmental contamination in your community, less concerned about environmental contamination in your community, or did it have no effect on your level of concern?

1☐ More concerned 2☐ Less concerned 3☐ No effect

20. Why do you feel that way?

_____

21. People have many reasons why they attend community forums. What were your main reasons for attending this forum?

Next, we would like to know how you feel about whether or not there might be a breast cancer risk associated with living in the Bay Area. Please indicate how strongly you agree or disagree with each of the following statements.

	Strongly Agree	Agree	Disagree	Strongly Disagree
22. I believe I am exposed to breast cancer risk by living in the Bay Area.	1☐	2☐	3☐	4☐
23. Getting breast cancer is something I am frequently worried about.	☐	☐	☐	☐
24. Being exposed to environmental contaminants is something I frequently worry about.	☐	☐	☐	☐
25. I have little or no control over the breast cancer risk that might be caused by living in the Bay Area.	☐	☐	☐	☐
26. I believe that breast cancer risk possibly posed by living in the Bay Area is increasing.	☐	☐	☐	☐
27. I believe that while living in the Bay Area, exposures to environmental contaminants have caused me to get breast cancer.	☐	☐	☐	☐
28. I believe that while living in the Bay Area, exposures to environmental contaminants have caused someone close to me to get breast cancer.	☐	☐	☐	☐

Please indicate which, if any, of the following apply to you or to your organization as a result of attending the community forum.

	Yes, this applies	No, does not apply
29. I/We plan to bring back information from this community forum to my organization.	1☐	2☐
30. I/We plan to hold subsequent community meetings or community education projects focused on biomonitoring.	☐	☐
31. I/We plan to form partnerships to do community-based, participatory research using biomonitoring.	☐	☐
32. I/We plan to disseminate information on biomonitoring to the press or to my organization's constituency.	☐	☐
33. I learned new things about the risks of biomonitoring that I was not aware of before attending this community forum.	☐	☐
34. I learned new things about the Benefits of biomonitoring that I was not aware of before attending this community forum.	☐	☐
35. I/WE plan to become more involved in policy level activities related to biomonitoring as a result of attending this Forum.	☐	☐

Finally, we would like to know a little about you to help us analyze the results of this evaluation.

36. Are you male or female?

1☐ Male 2☐ Female

37. What was your age at your last birthday? Age: _____

38. What is the highest level of education you have received?

1☐ 0 to 11 years of school 2☐ High school diploma 3☐ Some college
4☐ Associates or bachelor's degree
5☐ Advanced degree (Masters, Ph.D., JD, DDS, etc.)
6☐ Other (*SPECIFY*: _____)

39. What is your race or ethnic background?

1☐ White/Caucasian/European American 2☐ Black/African-American/African
3☐ Hispanic/Latino/Chicano 4☐ Asian/Asian-American
5☐ Pacific Islander Or Hawaiian Native 6☐ American Indian Or Alaskan Native
7☐ Other (*SPECIFY*: _____)

40. What is your current employment status?

1☐ Retired 2☐ Student 3☐ Looking for work
4☐ Employed (*PLEASE SPECIFY JOB TITLE*: _____)
5☐ Something else

41. In what community do you live?

1☐ San Francisco 2☐ Oakland 3☐ Berkeley 4☐ Alameda
5☐ Marin County 6☐ Other (*SPECIFY*: _____)

42. For how many years have you lived in this community?

Number of years: _____

43. What is your approximate household income before taxes?

1☐ Less than $20,000 2☐ $20,000 to $34,999 3☐ $35,000 to $74,999
4☐ $75,000 to $99,999 5☐ $100,000 to $199,999 6☐ $200,000 or more

44. Are you associated with an environmental organization?

1☐ Yes 2☐ No

45. Do you work for a governmental agency?

1☐ Yes 2☐ No

46. Do you work at a university?

1☐ Yes 2☐ No

47. Are you a health care provider or health educator?

1☐ Yes 2☐ No

48. Are you associated with a breast cancer advocacy group or any other community based organization?

1☐ Yes 2☐ No

49. Are you a breast cancer survivor?

1☐ Yes 2☐ No

50. Have you changed your opinion or beliefs regarding biomonitoring as a result of attending this forum?

1☐ Yes 2☐ No

If yes, please explain.

Thank you very much for taking the time to complete this questionnaire! Your assistance in providing this information is very much appreciated. If there is anything else you would like to add, please feel free to do so in the space below.

Evaluation Results

CRITICAL ISSUES IN BIOMONITORING
A COMMUNITY FORUM

October 9, 2004

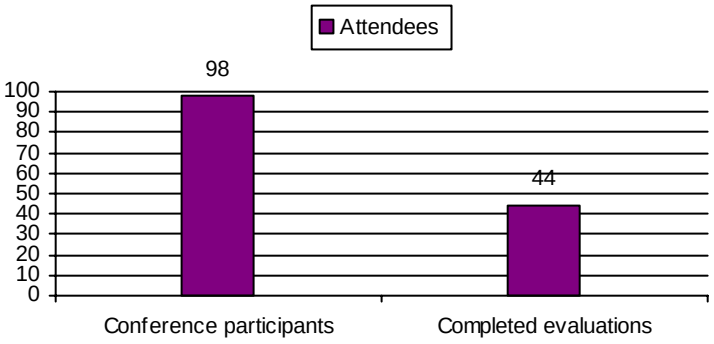
UCSF Mission Bay Campus
San Francisco, CA

Sponsored by Marin Breast Cancer Watch
A non-profit organization dedicated to finding the causes of breast cancer through community participation in the research process.

Co-Sponsored by
Marin County Department of Health and Human Services

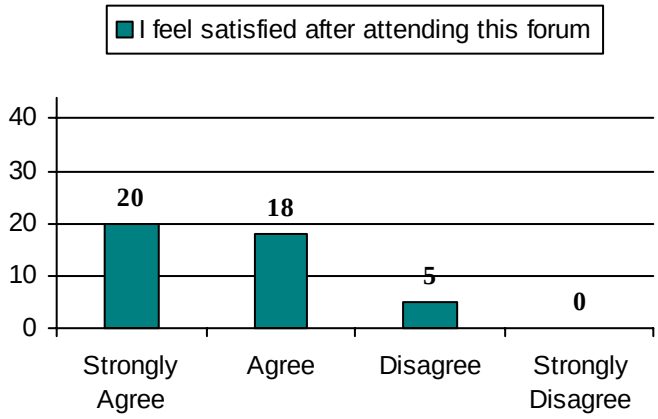
The Bay Area Breast Cancer and Environment Research Center

California Environmental Health Tracking Program



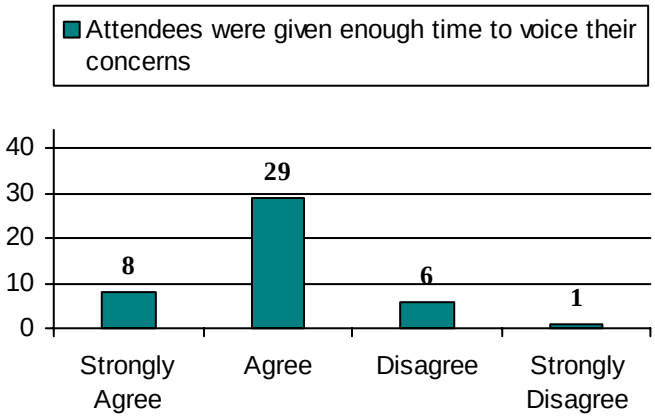
45% of attendees completed the evaluation.

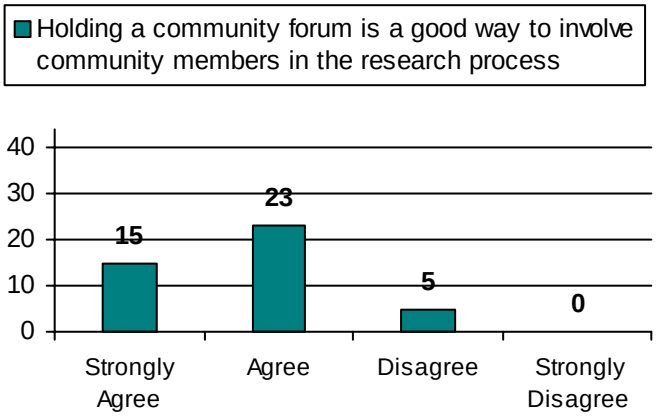
Community Forums



88% of respondents felt satisfied after attending Critical Issues in Biomonitoring.

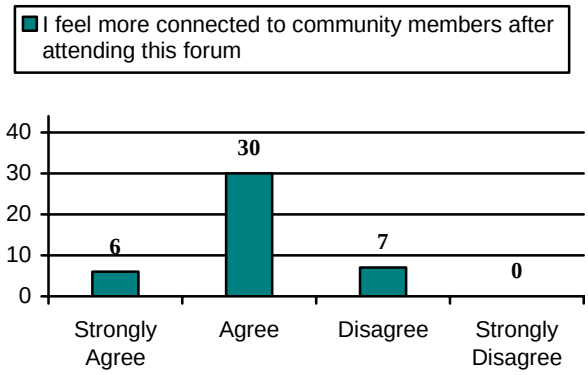
84% of respondents believed that attendees were given enough time to voice their concerns.

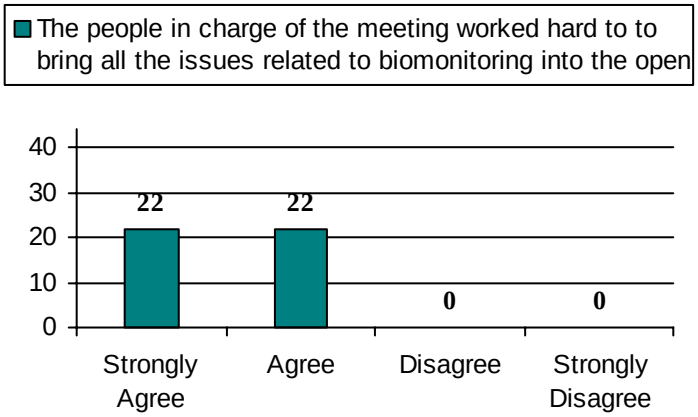




88% of respondents agreed that holding a community forum is a good way to involve community members in the research process.

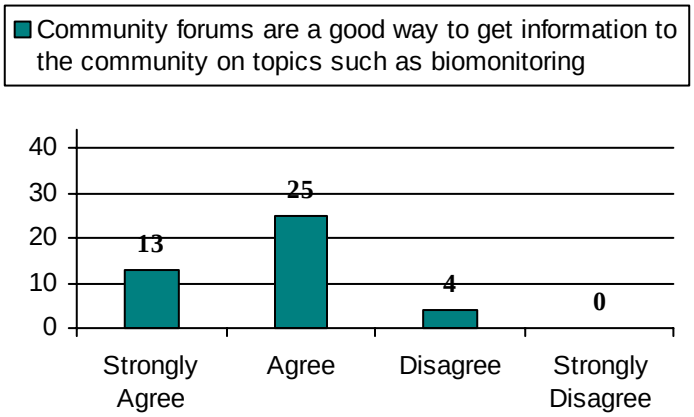
84% of respondents felt more connected to community members after attending this forum.

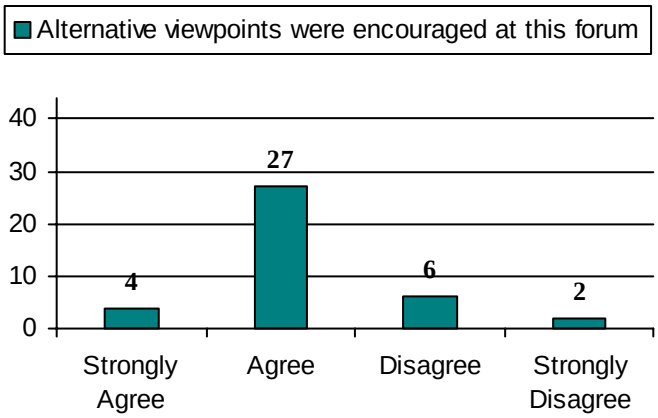




100% of respondents stated that the people in charge of the meeting worked hard to bring all of the issues related to biomonitoring into the open.

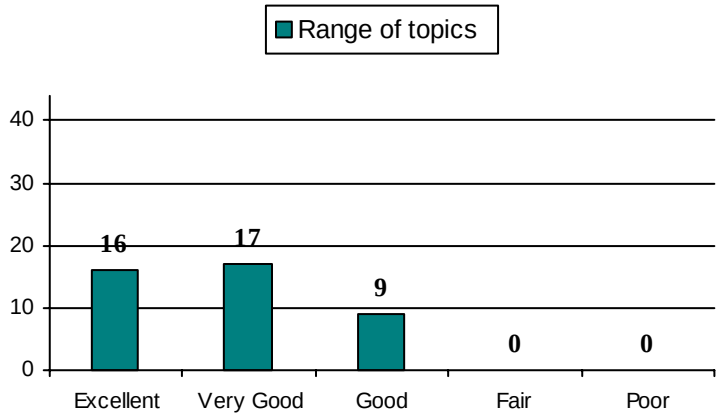
90% of respondents stated that community forums are a good way to get information to the community on topics such as biomonitoring.

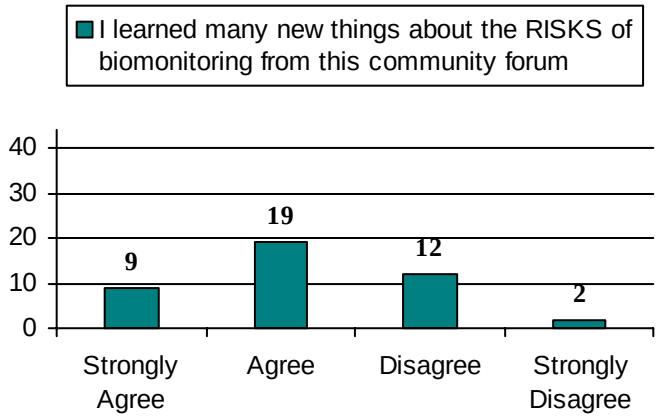




79% of respondents felt that alternative viewpoints were encouraged at this forum.

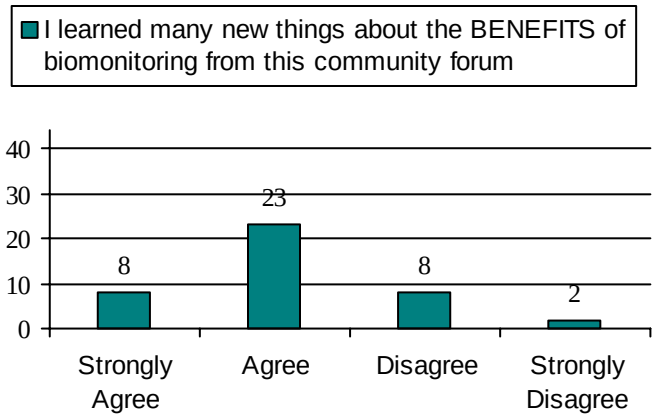
There was a 100% positive response rate to the range of topics discussed at this forum.

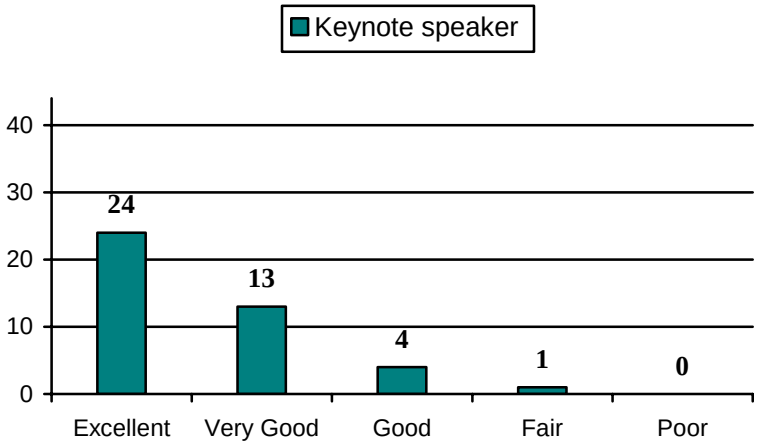




67% of respondents agreed that they learned many new things about the risks of biomonitoring. Several of the respondents commented that they were already aware of the risks, so it was not new information.

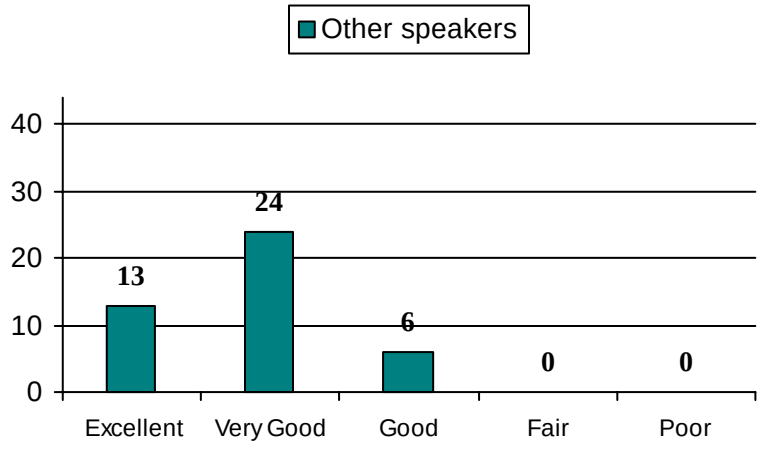
76% of respondents agreed that they learned many new things about the benefits of biomonitoring. Again, many of the attendees were already knowledgeable about this topic so the information was not deemed as new.

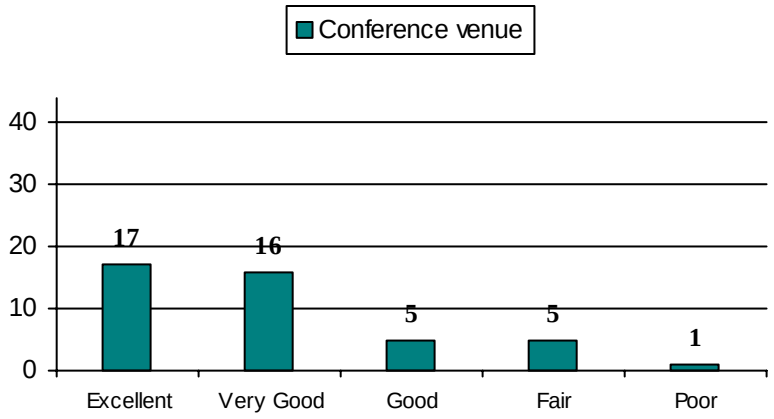




98% of respondents reported a positive response to the keynote speaker, Richard Jackson.

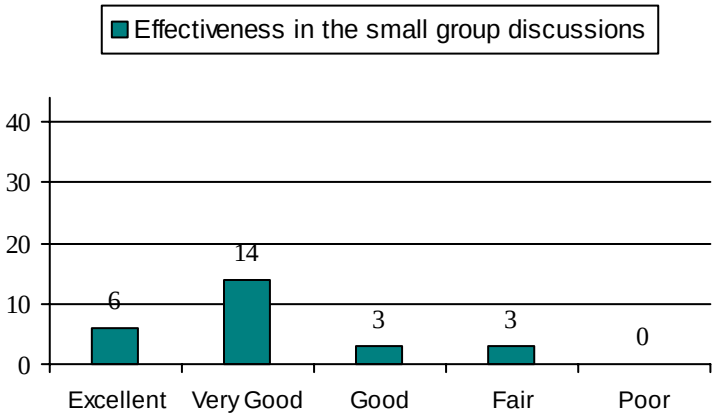
100% of respondents enjoyed the other speaker's presentations.

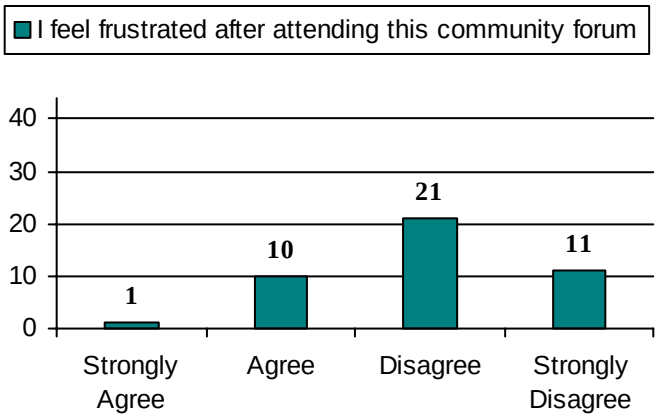




86% of respondents had a positive response to the conference venue. Comments by the remaining 14% included lack of signage, as it is new construction, and not being familiar with the area. Also, several participants would have liked more places to sit and converse during breaks.

88% responded positively in regards to the effectiveness of the small group discussions. However, only 26 out of 44 (59%) respondents answered this question. This indicates that almost half of the respondents did not stay and participate in the small group discussions. Comments included that it was a lot of information to absorb in one day, it was held on a sunny weekend-day, and participants would rather have had more time for discussion in large group format with all of the speakers present.





74% of respondents disagreed that they felt frustrated after attending this forum. Comments from the remaining 26% are listed below.

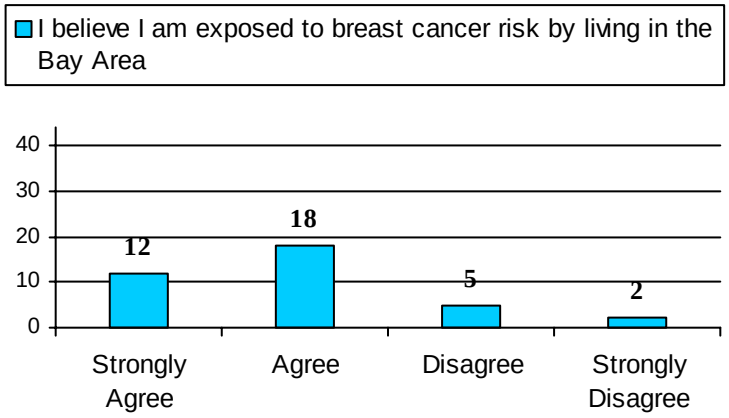
Comments:

- Public health is not really a scientific problem particularly in an era of corporate industry. It is a political problem, and the politics were not addressed.
- Too much emphasis placed on scientific research and the need for more of it. We need to apply the precautionary principle in regulatory agencies and laws passed to protect the public.
- Too rushed, no time to absorb and get references or copies of slides.
- Still grappling with the challenges of understanding biomonitoring implementation.
- Too much to do.
- Did not stay on time, not enough time for questions & answers.
- Overwhelmed by the extent of the content, did not leave with the best sense of how all the pieces fit together, but the small group discussions helped me feel better about that.
- Too much content to absorb at once.
- Information overload- too many speakers. Fewer speakers and more time for discussion would help.
- In the biographies of the speakers, I would like to have their websites and email addresses and phone numbers. I would have also liked to have copies of the literature that the speakers presented.
- Too much being talked at and too little time for interaction.
- Not enough community involvement.

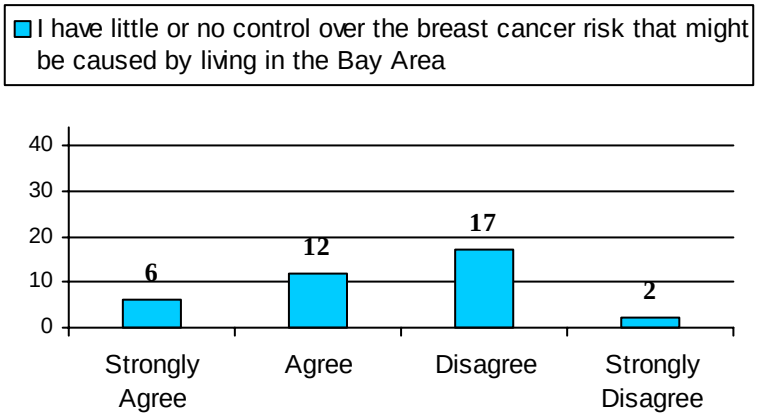
What was your main reason for attending this forum?

- To find out what people are actually doing about biomonitoring.
- Little funding and effort is being extended to serious environmental research. Any and all forums need to be attended and monitored.
- To network with community professionals and staff. To influence agency decision-making regarding important decision matters.
- I feel that I have a strong voice on behalf of the community and I am not afraid to speak out in decision-making places.
- I have a concern for community impacts that could be negative.
- Relevant to public policy work and outreach and education of the public.
- Environmental health and breast cancer concerns.
- Toxic exposure is a mystery to me. I wanted to understand how the subject could be studied scientifically. I wanted to understand the tools needed to document environmental abuses and pollution so as to take action to protect people's health.
- Among the advisory community and am also interested in the topic of biomonitoring.
- To learn more about biomonitoring to educate the management and leadership at the local health department where I work.
- To spend time with some of the keynote speakers and my colleagues that I see less frequently.
- Interested in working in PH biomonitoring.
- To get more information.
- Education.
- The invited speakers were of interest to me.
- I worked on the Asian-American Breast Cancer Project 20 + years ago. Wanted to update what are recent trends in biomonitoring.
- To meet some of the top scientists in the field doing this work and to figure out how we can make biomonitoring happen in California.
- To network with people in the scientific and public health communities and see how mainstream environmental groups can better represent the issue of biomonitoring in policy.
- Learn and network.
- Represent my community-based organization, educate myself and be a resource for my CBO.
- My work is in environmental health so I felt that biomonitoring is something important for me to learn about. There was also great networking here- great crowd.
- Issue focused.
- To learn about the state of science in this area.
- Generally interested in this topic and where this area is going.
- To learn the status of thinking and technology and policy with biomonitoring.

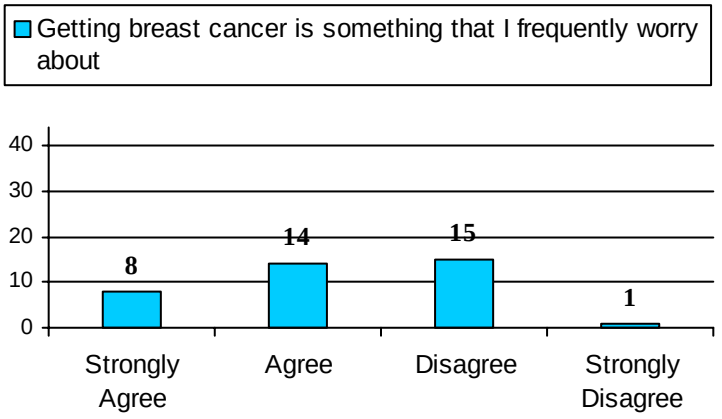
Breast Cancer



81% of respondents believe that they are exposed to breast cancer risk by living in the Bay Area.

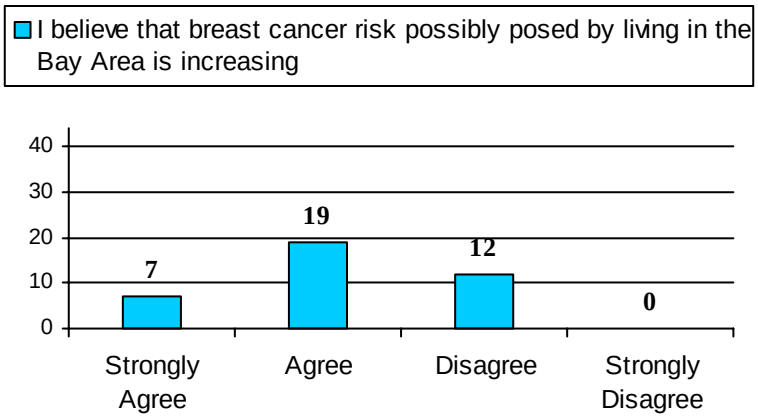


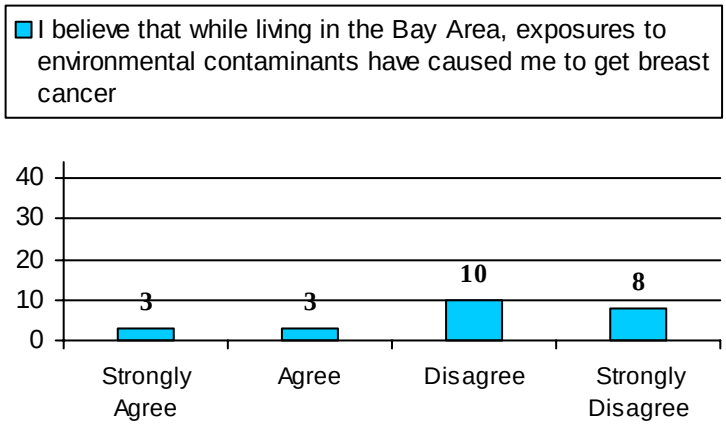
49% of respondents believe that they have little or no control over the breast cancer risk that might be caused by living in the Bay Area.



84% of respondents stated that getting breast cancer is something that they frequently worry about.

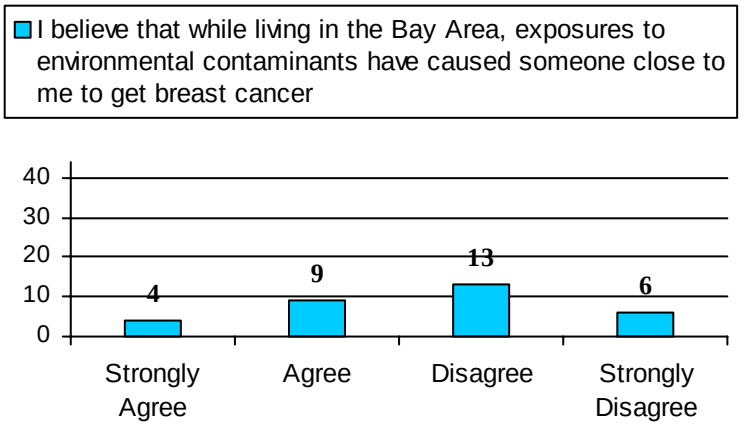
68% of respondents believe that breast cancer risk possibly posed by living in the Bay Area is increasing.



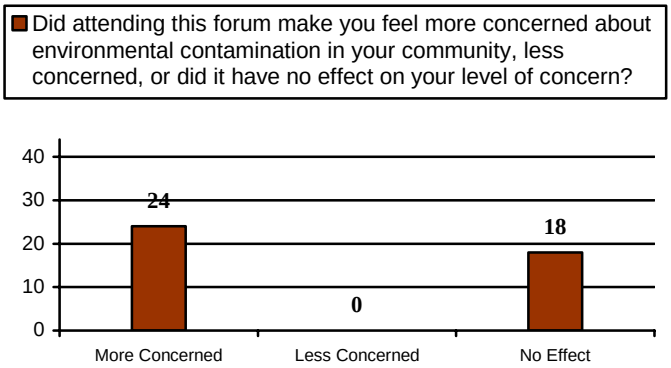


25% of the 24 respondents to this question reported that they believe that while living in the Bay Area, exposures to environmental contaminants have caused them to get breast cancer. Interestingly, the only 6 respondents to report having had a breast cancer diagnosis also were the 6 who agreed with this statement. All of the respondents who did not agree with this statement also reported not having had a breast cancer diagnosis and therefore most likely believed that this statement did not apply to them.

41% of respondents believe that while living in the Bay Area, exposures to environmental contaminants have caused someone close to me to get breast cancer.



Environmental Concerns



57% More concerned
0% Less concerned
43% No effect

Why do you feel MORE concerned about environmental contamination in your community after attending this forum?

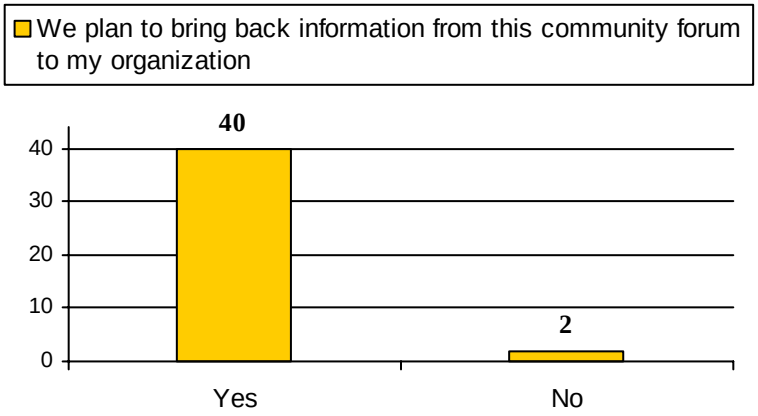
- Science is becoming part of the delaying process- delaying developing legal ways to force industry to stop poisoning us.
- We keep assessing and less asserting.
- Reminds me how real it is, seeing all of the experts concerns really drives the importance home.
- The results of the studies shown- especially phthalates.
- So powerful to hear both scientific explanation of body burden and impacted members.
- Because there is so much environmental contamination and so little biomonitoring being done to measure it at the individual level.
- How can any of us control our chemical intake and health? One of the speakers talked about living a relatively healthy lifestyle and then being biomonitored and thinking that she should have been relatively chemical free however that was not the case.
- Thinking about it more and hearing community members “testify”.
- Awareness of the problem, number of toxins, complexity of the problem.
- I learned even more about how contaminated our bodies are.
- To hear my concerns taken seriously by government health organizations. A high caliber of scientists is validating and encouraging.
- I learned many new things about community.
- Hearing the community voices is so powerful.
- Presentation of data showing exposures not just in my community but nation/world wide.
- Toxin dumping shipyard as I live in Bay View Hunter’s Point.

Why do you feel NO EFFECT about environmental contamination in your community after attending this forum?

- My level of concern has always been high.
- Already extremely concerned before today.
- I already knew too much.
- Because I began very concerned about this in my community.
- My opinions are deeply held.
- Already have a high level of concern.
- I was already concerned.
- Many more concerns regarding biomonitoring given how little concrete info about risks, both to individuals and the movement.

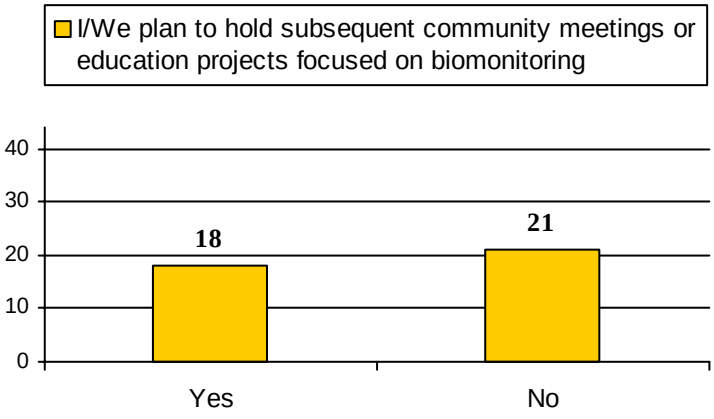
- For me there wasn't really any new information that I was not aware of.
- I was already concerned.
- Already concerned.
- I already knew a lot about it.
- My level of concern remains the same.
- I am a community representative and already know.

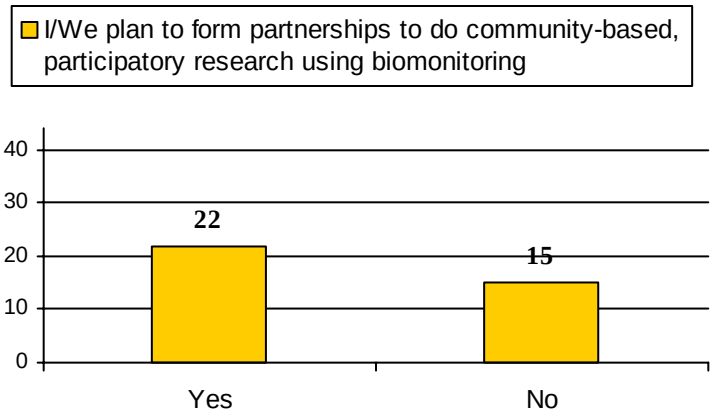
Dissemination of Information



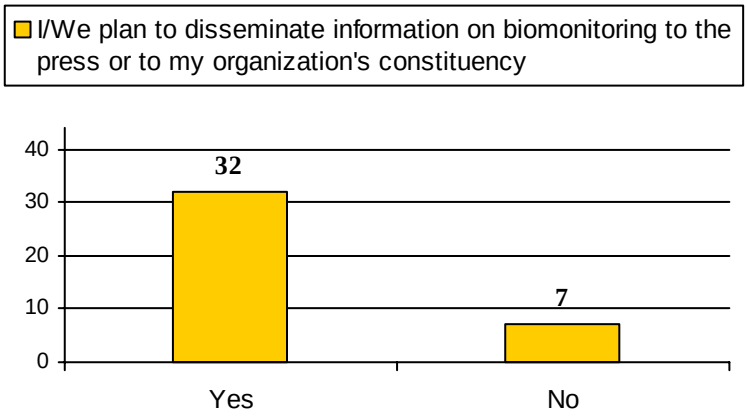
95% of respondents plan to bring back information from this community forum to their organization.

46% of respondents plan to hold subsequent community meetings or educational projects focused on biomonitoring.

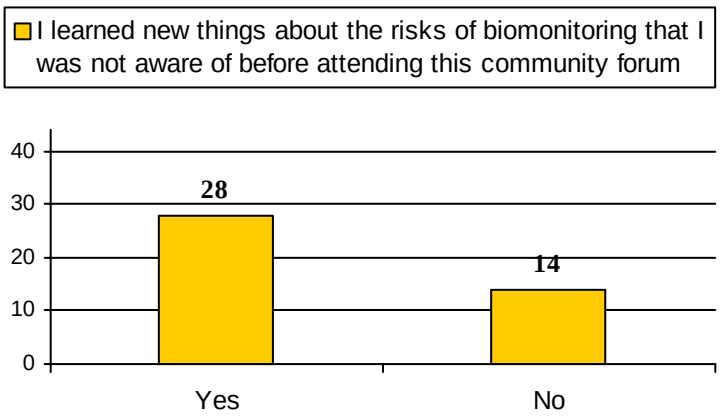




59% of respondents plan to form partnerships to do community-based, participatory research using biomonitoring.

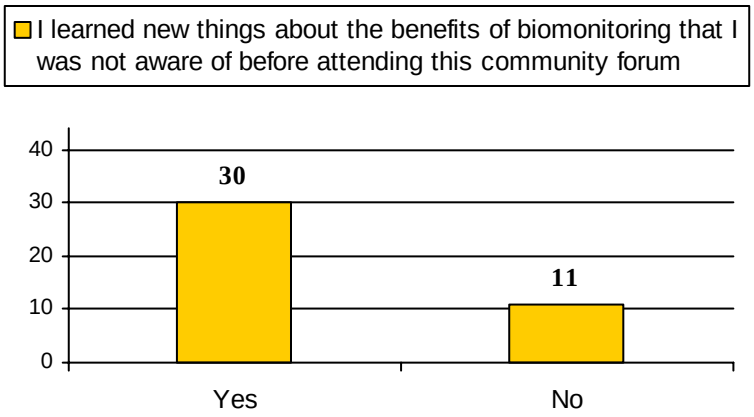


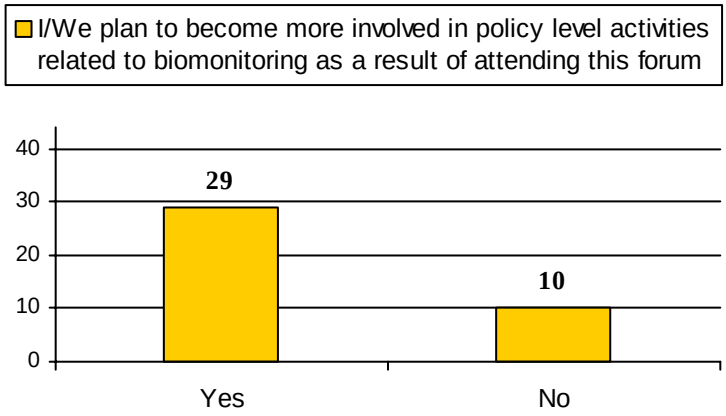
82% plan to disseminate information on biomonitoring to the press or to their organization's constituency.



67% of respondents stated that they learned many new things about the risks of biomonitoring.

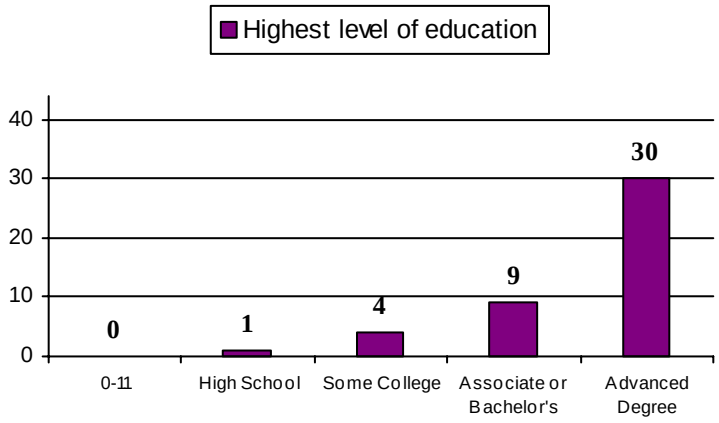
73% of respondents stated that they learned many new things about the benefits of biomonitoring.

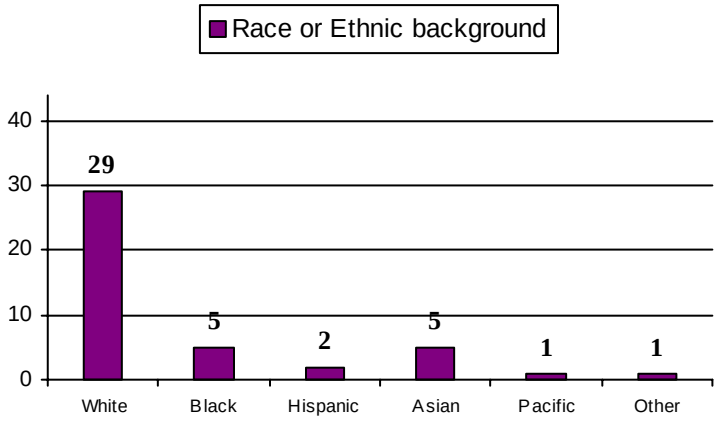


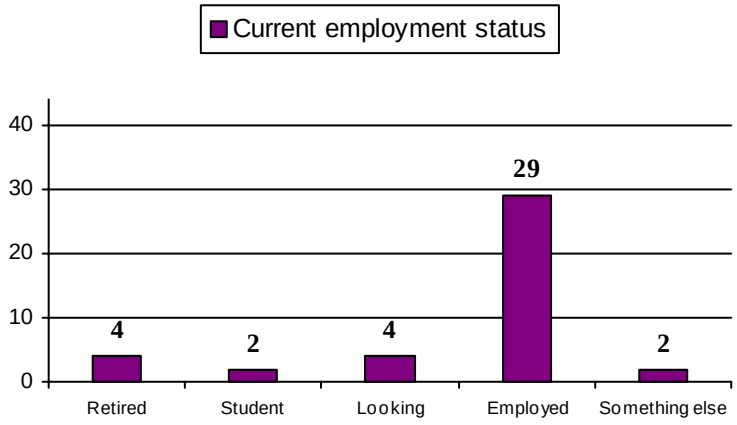


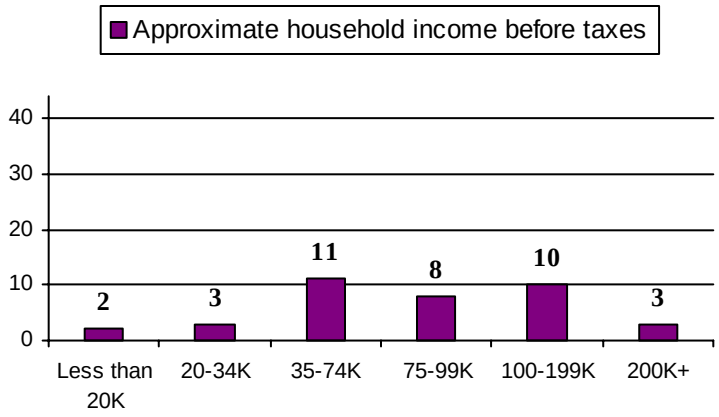
74% of respondents stated that they plan on becoming more involved in policy level activities related to biomonitoring as a result of attending this forum.

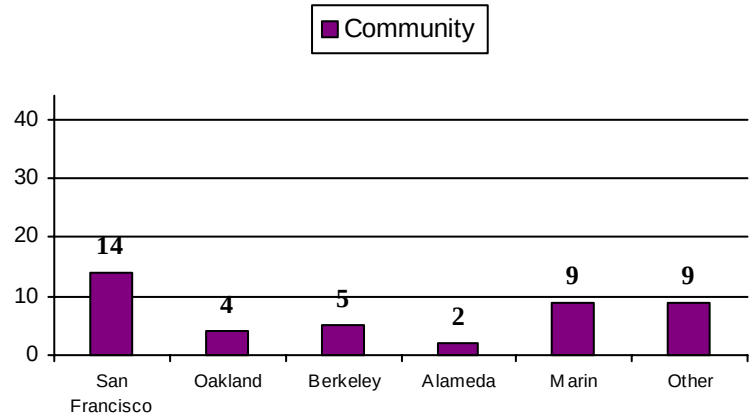
Demographics



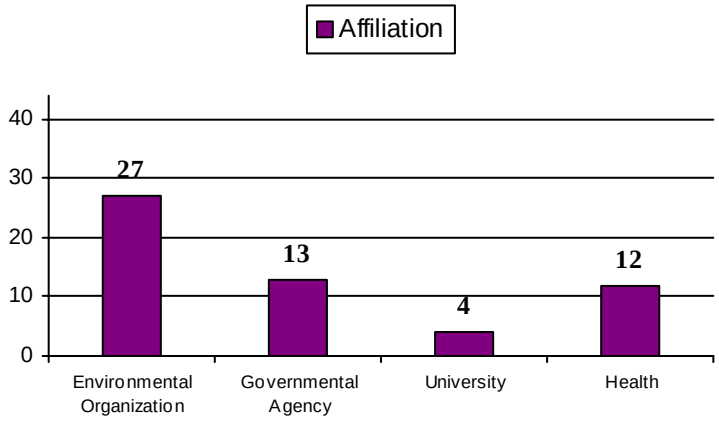


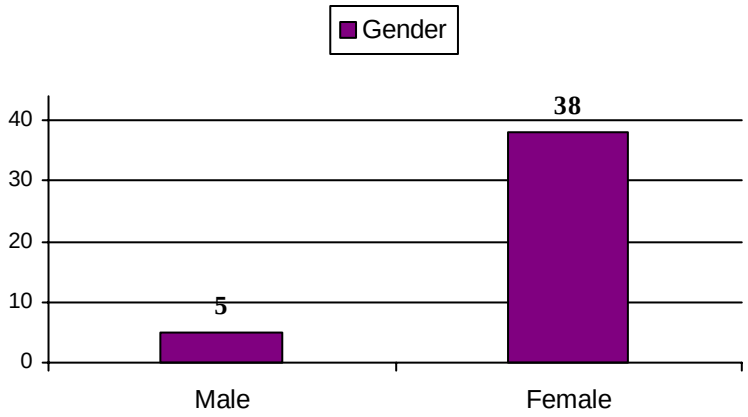






Average number of years residing in Bay Area = 4.22 years





As the data indicates, the majority of attendees that completed this evaluation were white, middle to upper class, highly educated, employed females.

Mean age of respondents = 30.73 years

Additional Comments

- Thanks.
- New campus is fabulous.
- Presentations were great and inspirational! I'd like to leave a time for discussion and the audience member's reaction and thoughts not just questions.
- I appreciate the difficulties or "challenges" associated with biomonitoring but also see the many opportunities.
- Good mix of speakers and attendees and conference was very well put together.
- Thank you for this great conference. I do wish that the meeting itself were more environmentally sustainable. It would be nice to have a list of attendees and affiliations in our packets.
- I have a lot more fears about biomonitoring now and how it is used by advocates and where and how it's the best tool. What is it's niche and how to use it strategically.
- I would liked a bit more discussion and opportunity to discuss how groups like mine (California League of Conservation Voters) can communicate to the public and educate voters about biomonitoring and community-based efforts.
- Thank you!
- Data must be made accessible to the community- communities must drive the process.

Lessons Learned

After holding a community forum, it is always possible to see what could have been improved, what should not have been done and what could have been done in a more successful way. Although the overwhelming majority of participants evaluated the forum as very successful, the following are a few things that if a Biomonitoring conference was done again, the planners would advocate for doing differently:

- The number of people speaking on panels reduced to allow for more dialogue between the speakers and the participants/speakers.
- Although community participant was evident, there could have been more community involvement by having longer question and answer dialogue.
- Poor attendance in the afternoon sessions was likely a result of the forum being held on a beautiful weekend day.

Suggested Action Plans

- Publication distribution of proceedings.
- Setting future priorities for future local biomonitoring studies
- Identifying partnerships interested in collaborating on CBPR studies using biomonitoring.
- Use information generated from the evaluation to develop relevant information for the community and press about the newly emerging technology of biomonitoring.
- To add to the literature on effective methods of risk communication to communities (can we do some kind of joint publication on our findings)
- Development of materials for the lay public and media about biomonitoring
- Track the number and type of presentations made to relevant groups and stakeholders at the forum following the project. Haven't done this, may want to, i.e. send out a survey to participants.
- Host a "Joining Together Conference" on Risk Communication and Translational Research. One suggestion was to incorporate a training component on how to discuss and translate the research information to non-scientists and lay-people.

Plans for Dissemination (Aim for visibility and being accountable to the public)

- MCHHS community forum scheduled for September 2005.
- Presentation at the Breast Cancer Coordinating Council, December 15, 2005.
- Develop additional presentations and collaborations based on participation process during the project year.
- Establish community-based networks to discuss and disseminate conference finding via community forums, brief reports, newsletters and presentations.
- Final report format and distribution: publication of proceedings, summaries of speakers, panelists and small group presentations and recommendations in printed documents.
- Entire document to be put on MBCW Website with appropriate linkage.
- DVD reproduction and distribution.
- Ensure the community forum results are sent to policy makers so that they can use the information when talking with constituents, reviewing legislation.
- Disseminate findings to health providers to ensure they will receive, understand and will be able to answer patients questions.
- Development of poster.

Forum Participants

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Moderator

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Diane Balma
Susan G. Komen Breast Cancer Foundation

Davis Baltz
Commonweal

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Betsy Barton, MA
Marin Breast Cancer Watch

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Flavia Belli
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Candace Brady

Judy Brody

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Collaborative on Health and the Environment

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Marin Breast Cancer Watch

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Silicon Valley Toxics Coalition

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Ola Donley
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Lawrence Berkeley National Laboratory

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Joe Guth
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UCSF Comprehensive Cancer Center

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Bruce Jennings
Speaker

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Marilyn Leigh

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Michael Lipsett, MD
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Geoff Lomex

Lori Low
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Michael Lowrie
California State Assembly

Barbara Materna
Speaker

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CA Breast Cancer Research Program

Katherine Mills
Pesticide Action Network

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Fern Orenstein, MED
Marin Breast Cancer Watch

Romel Pasqual, MA
Speaker

Sharyle Patton
Speaker

Karen Pierce
San Francisco Department of Health

Forum Participants Continued

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Marj Plumb & Associates

Anh Thu Quach, MPH
California Department of Health Services

Dianne Quigley, MA
Speaker

Marlene Quint
Women's Health Educator

Katy Rexford
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