

Report of the Public Health Standing Committee of the NJDEP-Science Advisory Board

NJ Human Biomonitoring Charge Question

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NJ Human Biomonitoring Charge Question

Executive Summary

There were two related charge questions dealing specifically with human biomonitoring:

- What are the needs and scope of a NJ- specific human biomonitoring program?
- What are the appropriate structures and mechanisms for collecting and interpreting representative biomonitoring data?

Human Biomonitoring is defined by the CDC as, “The sampling and analysis of human samples, usually, but not exclusively, urine, blood, and hair, to determine the internal exposure and body burden to environmental chemicals.” Biomonitoring is a well-established tool in the federal government and in several states. Biomonitoring can provide important information about environmental exposures and risk that is not obtainable by other types of environmental assessment. This information can be used to assess the effectiveness of current regulations and guidance in reducing human exposure to toxic substances and to disclose exposures not currently recognized or addressed.

There are several persuasive arguments for conducting systematic human biomonitoring in New Jersey:

- NJ is not adequately represented by existing national biomonitoring.
- NJ has large scale multiple industries emitting a wide variety of chemicals.
- NJ has the highest population density of any U.S. state.
- NJ has a highly non-uniform spatial distribution of population likely resulting in highly asymmetrical distribution of chemical exposures not predictable on the basis of averaging assumptions.
- NJ has a legacy of chemical contamination some of which is likely still unknown.
- Because of the extent and nature of NJ’s industries, NJ is a prime venue for the appearance of emerging environmental contaminants that have not yet been addressed at the federal level.
- NJ is culturally and ethnically diverse. Diverse diets, lifestyles and exposure patterns predispose the NJ population to a wide range of exposures.

NJ Government and academia have expertise, experience and capability to conduct meaningful biomonitoring. These include the NJDEP's Office of Science, the NJDOH and Rutgers/EOHSL.

Conclusion and recommendations regarding human biomonitoring approach for NJ

As described below, there are many possible approaches and combinations of approaches that could be pursued in NJ. Each has the capability to address different issues of human exposure and each can provide different types of information of use to the NJDEP. Likewise, there are many different kinds of information, very valuable to NJ, that could be generated through human biomonitoring. The choice of which approach(es) to follow will depend on the specific biomonitoring goals the DEP chooses to address as well as on the availability and extent of funding available to support those goals. The Committee notes that the direct statewide sampling approach is the most inclusive and provides a sound basis upon which to assess the public health context of population and location-specific studies. Such an approach is not only extremely informative in its own right, but a foundation upon which other biomonitoring studies can be built.

In August of 2014, the NJDOH was awarded a biomonitoring grant from the CDC. The specific biomonitoring goals and programs that will be pursued are still under consideration. The Public Health Standing Committee recognizes this as a prime opportunity for collaboration between the NJDOH and the NJDEP to address important and large scale biomonitoring goals for New Jersey. The Committee strongly recommends that the NJDEP work with the NJDOH (and that NJDOH be encouraged to work with NJDEP) to implement the strategies described in this report. In particular, the Committee recognizes that this grant provides an opportunity (that may not recur) to design and implement the beginning of a statewide biomonitoring program.

Given both its interest and expertise in human biomonitoring and closely related scientific areas, the Public Health Committee of the SAB believes that it can be of important service to the NJDEP going forward and encourages the NJDEP to include the Committee (as well as the SAB in general) in its biomonitoring planning and programs going forward.

I. Charge to the Committee

What are the needs and scope of a NJ- specific human biomonitoring program?

What are the appropriate structures and mechanisms for collecting and interpreting representative biomonitoring data?

II. Introduction

Committee members

In general, there are 9 members of the Public Health Standing Committee (henceforth, the Committee). However, in preliminary discussions of this charge question, it became clear that if NJ were to implement a biomonitoring program as a result of the recommendation of the NJDEP-SAB, it is likely that such a program would require significant support from academia. Therefore, to maintain the eligibility of Rutgers University to participate in such a program, the Committee members with Rutgers appointments (including the Chair of the Committee) all recused themselves from further deliberations in order to avoid an appearance of a conflict of interest.

The remaining Committee members consisted of:

Judith Klotz, Dr.P.H. (independent consultant)

Mark Maddaloni, Dr.P.H. (USEPA)

Gerald Kennedy, M.S. (Dupont)

Judith Zelikoff, Ph.D. (NYU School of Medicine)

Alan Stern, Dr.P.H. served as the NJDEP Office of Science liaison to the Committee.

At the request of Alan Stern, Dr. Klotz agreed to serve as the interim Chair of the Committee for the duration of the deliberations on this charge question.

History of meetings

The initial meeting of the Committee was on 12/4/13. Following that meeting the Rutgers-affiliated members recused themselves. The remaining meetings with the reduced Committee as noted above occurred on the following dates, all by teleconference: 3/20/14; 4/30/14; 7/31/14 and 10/14/14.

III. Rationale and Goals for New Jersey-Specific Human Biomonitoring Program

What is biomonitoring?

Although the term, biomonitoring is sometimes used to describe the sampling of biota in ecological studies, this charge question deals specifically with human health biomonitoring (henceforth, simply, biomonitoring).

Human Biomonitoring is the sampling and analysis of human samples, usually, but not exclusively, urine, blood, and hair, to determine the internal exposure and body burden to environmental chemicals (CDC, 2014). Sampling of the external environment (air, water, soil, food) provides information on the overall quality of the environment. However, such samples

cannot account for the important differences among individuals in how they interact with the external environment, as well as the important differences in how they absorb, metabolize, retain, and eliminate the chemicals to which they are exposed.

Furthermore, since the concentration of contaminants in biomonitoring samples integrates exposures from all routes (air, water, soil food), biomonitoring data can reveal important information about exposure that is not provided by the usual environmental sampling of independent media.

Biomonitoring can reveal medically significant exposures in individuals, but the primary use of biomonitoring is for the sampling and description of exposures within a population of which, only a small fraction of the total are actually sampled.

As discussed below, human biomonitoring is a well-established tool in the federal government and in several states.

Goals of human biomonitoring

Biomonitoring can provide important information about environmental exposures and risk that is not obtainable by other types of environmental assessment. These include:

- The description of the range of exposures throughout the population;
- Comparison of a population (e.g., NJ) to other populations, including the U.S. population as a whole;
- Detection of exposures that are not otherwise obvious through environmental measurements (air, water, soil, biota);
- A focus on specific sub-populations such as disproportionately impacted groups, children, and geographically specific populations whose exposures may not be recognized or well defined by other environmental data;
- Detection of changes in patterns of population exposure over time;
- Assessment of the overall efficacy of guidance, regulations, policies that are intended to reduce exposure.

Rationale for creating a NJ-specific human biomonitoring program

NJ is not adequately represented by existing national biomonitoring - Although the CDC has been conducting national biomonitoring through its NHANES ongoing study (CDC, 2014), state-specific data cannot be disaggregated from the national data.

NJ has large scale multiple industries emitting a wide variety of chemicals - The variety and extent of NJ industries, notably including, but not limited to chemical and pharmaceutical creates

many opportunities for exposure. Populations are potentially exposed to common products, but also to unusual products, intermediates and waste materials.

Population density - NJ has the highest population density of any U.S. state and 14 times that of the U.S. as a whole (U.S. Census Bureau, 2014). High population density means that significant numbers of people can be exposed to contaminants from a single source, even if that source might not otherwise be categorized as large. High population density also means individuals expose each other to chemicals emitted during daily activities (transportation, heating, pest control, gardening/lawn care, personal care products, pharmaceutical elimination and disposal, etc.).

NJ has a highly non-uniform spatial distribution of its population - Twenty nine percent of NJ's population lives in just three of its 21 counties (Bergen, Middlesex and Essex) (NJ Dept. Labor, 2014). These counties are also areas of concentration of chemical and pharmaceutical manufacture and transportation. Thus, chemical exposure in NJ is likely to be highly asymmetrical and not predictable based on simple averaging assumptions.

NJ has a legacy of chemical contamination - NJ's long history of industrialization that has not only resulted in the largest number of current federal NPL hazardous sites (113) (http://www.epa.gov/region2/cleanup/sites/njtoc_name.htm) as well as numerous state priority sites, but also widespread diffuse contamination in soil and water, including urban background soil levels that are routinely higher than non-urban levels.

Emerging Contaminants – Because of the extent and nature of NJ's industries, NJ is a prime venue for the appearance of emerging environmental contaminants that have not yet been addressed at the federal level, or are unlikely to be addressed on the federal level because of the specific NJ impact. Some, like PFOA (perfluorooctanoate) and PFOS (perfluorooctane sulfonate) are not confined to NJ, but occur at higher concentration in NJ than in other parts of the US. Others, like PFNA (perfluorononanoic acid) appear to be largely a NJ issue.

Culturally/Ethnically Diverse Population - NJ is one of the most culturally and ethnically diverse states. Each distinct population group has diverse diets, lifestyles and exposure patterns that predispose them to being exposed to different environmental contaminants and to common contaminants to varying degrees.

NJ Government and academia have expertise, experience and capability to conduct meaningful biomonitoring

NJDEP's Office of Science and its collaborators at the Rutgers University Environmental and Occupation Health Sciences Institute (Rutgers/EOHSI) have a long history of conducting a linked series of focused biomonitoring studies of chromium exposure in Jersey City over two decades assessing chromium in urine and its relationship to chromium in household dust. These studies showed that children's exposure to chromium was occurring prior to remediation of

chromium waste sites and returned to background exposure post-remediation (Stern et al., 2013). The Office of Science/EOHSI also conducted a groundbreaking biomonitoring study of methylmercury exposure in NJ pregnant women in the mid-1990's (Stern et al., 2001).

The NJDOH conducted a medical screening in Jersey City in the mid-1990's, a key portion of which involved chromium biomonitoring (Fagliano et al., 1997). In addition, the NJDOH laboratories have extensive capability for trace chemical analysis in blood, urine, etc.

Rutgers/EOHSI has deep expertise in population-based sampling, and state-of-the-art laboratory capability for trace chemical analysis in blood, urine, etc.

In 2003, NJDEP, NJDOH and Rutgers/UMDNJ/EOHSI worked intensively together to submit a large-scale biomonitoring grant proposal to the CDC. Although this proposal was highly rated by CDC, there were only three grants awarded nationwide and NJ's proposal was not funded. However, the exercise provided a strong understanding of biomonitoring goals, resources and strategies, and demonstrated the collaborative potential of these groups.

Looking forward, NJDEP, NJDOH and Rutgers/EOHSI working collaboratively, could carry out a variety of highly useful biomonitoring programs.

IV. Biomonitoring Programs at the State and Local Level Elsewhere in the U.S.

Several states and NY City already have formal biomonitoring programs in place. These are summarized briefly below. Details of these programs are in Appendix A.

California

(<http://www.biomonitoring.ca.gov/>)

- Created by legislation in 2006
- Partially funded by CDC
- Analyses by in-house laboratories
- External scientific guidance panel – mostly academics
- Mostly focused studies of specific populations – e.g.:
 - phthalates and environmental phenols in Salinas teenage girls
 - flame retardants in mothers
 - flame retardants and other persistent chemicals in blood of teachers with breast cancer

Minnesota

(<http://www.health.state.mn.us/divs/hpcd/tracking/biomonitoring/index.html>

<http://www.health.state.mn.us/divs/eh/risk/studies/biomonitoring.html>)

- Created by legislation 2007
- State funding

- Analyses by in-house laboratories
- External scientific guidance panel from academia, state and local government, NGOs, industry
- Specific populations/specific areas – e.g.:
 - PFCs in blood of East Metro residents exposed in drinking water before interventions.
 - Mercury and Lead in Newborns in the Minneapolis area.
 - Arsenic in urine of children in South Minneapolis areas with soil contamination.

Washington State

(<http://www.doh.wa.gov/DataandStatisticalReports/EnvironmentalHealth/Biomonitoring.aspx>)

- Funding from 5-yr 2009 CDC grant for \$1.34 million/yr
- Analyses in State DOH labs
- External advisory committee from academics, state, federal and local government and NGO
- State-wide, general population cross-sectional study
 - 1 year 2010-2011
 - 1,422 urine samples
 - 12 metals
 - pyrethroid and organophosphate pesticide metabolites
 - bisphenol A (BPA) and phthalates
- Specific populations/specific areas – e.g.:
 - Pesticides and plastics-related compounds in residents of subsidized housing
 - Residents of South Whidbey Island with high naturally occurring arsenic

New York City

(<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2022653/>)

- City-wide, population-based, cross-sectional - Modeled on national NHANES
- Funding largely through philanthropic organizations
 - Robin Hood
 - New York State Health Foundation
 - Quest Diagnostics
 - Doris Duke Charitable Foundation
- Significant collaboration with CUNY School of Public Health
- 2,000 randomly selected New Yorker adults
- Blood and urine samples
 - Mercury
 - Lead
 - Cadmium
 - Cotinine (passive smoking exposure)
 - organophosphate pyrethroid pesticide metabolites
 - PCBs, PBDEs (anticipated analysis of archived samples)

V. Past and Current NJ Grant Proposals to CDC

2003 NJ proposal to CDC

- Collaborative proposal – NJDOH, NJDEP, EOHSI
- Largely statewide, population-based
- Sample collection from blood bank and clinical lab “wastage”
- Some focused, population-specific studies – impacted communities
- Addressed lab capacity, sample collection
- Not funded

2014 CDC grant

- Approval Aug. 2014
- \$1 million per year for 5 years
- Create/enhance laboratory capacity – 1st year
- Initial goals and sampling strategy under revision
 - Specific populations/locations – waste sites, water supplies
 - DEP involvement assumed
 - ***Opportunity to work with NJDOH to modify goals and strategy per SAB recommendations***

VI. Possible Biomonitoring Approaches for NJ

The following presents a menu of possible biomonitoring approaches with a discussion of their advantages and disadvantages. Following this discussion, the report presents its recommended approach.

1. Direct sampling approaches

Direct sampling approaches refers to strategies in which samples are obtained directly from the individuals participating in the study. The direct nature of the sampling allows for the collection of related information (demographics, lifestyle, residential history, possible sources of exposure). With all types of direct sampling approaches, follow-up is required to inform participants of their results and to explain the context of their results.

1. a. Statewide, representative random sampling

This approach is similar in concept to the approach utilized by CDC-NHANES and NYCHANES. This approach is designed to create a picture of various exposures across the

entire State by designing the sample collection strategy so as to represent the NJ population as a whole. This means that all ages, sexes, races, incomes, and regions will be represented in the sample in proportion to their occurrence in the population. However, as in NHANES, selected groups of particular interest (e.g., overburdened communities, populations defined by race, ethnicity, income, or residence in proximity to specific sources of contamination) can be oversampled so as to allow a more in-depth focus on them.

Advantages:

This approach yields the largest amount of useful information, such as: comparison to the US population; the characteristics of the most/least exposed; what factors are predictive of exposure, as well as information that can aid in interdicting exposure.

Disadvantages:

This approach is the most expensive and resource dependent. However, cost can be reduced by limiting the number of samples, thus reducing predictive ability for the upper percentiles of exposure, while still providing reasonable estimates of the mean exposures. The number of samples necessary under this approach will depend on the desired level of precision for the mean estimate of exposure and on the anticipated variability in exposure across the population.

1. b. Pilot/demonstration project with representative random sampling (e.g.) of two counties

This study would have the same goals and follow the same strategy as the statewide approach (above), but instead of attempting to characterize the NJ population as a whole, this approach would focus on (e.g.) two counties selected on the basis of populations or exposure of particular *a priori* interest such as one or more overburdened urban areas. Because the base populations of counties are smaller than for the whole state, greater precision in estimating the highest levels of exposure can be obtained at lower cost.

Advantages

This option would provide detailed information about exposures in the target counties, and would provide a useful opportunity to develop and refine strategies and methods. In addition, such an approach would be a powerful pilot/demonstration that could be leveraged to seek additional funding for larger-scale (e.g., statewide) projects.

Disadvantages

The results from individual counties would not be particularly useful in generalizing to the state as a whole.

1. c. Pilot/Demonstration project with representative sampling based on ecologically-defined areas

This approach is similar to the county-based approach, but instead of a focus on a population defined by political boundaries, this approach would focus on a population defined by

ecologically defined boundaries such as a watershed. Such an approach would be particularly appropriate for investigating exposure issues related to consumption of fish and shellfish.

Advantages

This approach has similar advantages to the county-based approach, and in addition would support and would be supported by ecological biomonitoring studies of aquatic biota.

Disadvantages

This approach has limited applicability for human exposures other than those occurring primarily or specifically from consumption of aquatic biota. In addition, the interpretation of the relative significance of exposure levels measured in an ecologically defined population would still need to be based on a comparison to a cross-sectionally defined population distribution (e.g., county, state) for the same contaminants

1. d. Hybrid – statewide/county-specific approach

This approach would combine aspects of the statewide random sampling approach with information from random sampling of two or more counties (or an ecologically defined area). In contrast to the full statewide approach described above, this approach would utilize a relatively small statewide sample that could provide a reasonable estimate of the mean statewide exposures, but that would be insufficiently large to allow a reasonable estimate of the upper percentiles of exposure. However, the reduced statewide sample would be combined with more intensive sampling of the populations of a few counties (or ecologically defined areas) selected to represent the diversity of the state with respect to specific *a priori* criteria (e.g., income, ethnicity, race). This more intensive county sampling would provide reasonable estimates of the upper percentiles of exposure for those counties that could, in turn, be used to estimate the upper percentiles of the state as a whole.

Advantages

The advantage of this approach is that it could provide an overall estimate of the range of exposures statewide at a lower cost than a full statewide approach.

Disadvantages

The disadvantage of this approach is that the estimates of the upper range of exposures from the selected counties would only indirectly reflect the upper range of the state as a whole.

2. Population-specific sampling designs

Population-specific designs would not focus on the state (or county) populations as a whole, but would address individual populations identified on the basis of specific characteristics of interest. These could include: proximity to emissions or waste sources; low-income populations; overburdened communities; and communities with specific ethnic or racial characteristics.

While the focus of this type of sampling would be the individual communities/populations, the exposure results from these groups would only be meaningful and interpretable if they were compared to the exposures of a reference population (e.g., NJ as a whole, the resident county as a whole). This would require having, at a minimum, a reasonable estimate of the corresponding mean exposures of the appropriate reference population. Thus, population-specific approaches would require some level of broader random sampling.

Advantages

Provides focused information on a specific population(s) of interest in a relatively time and cost-limited fashion.

Disadvantages

This option is narrow in scope. In addition, in order to be interpretable, results from sampling of a specific population would still require comparison to broader population distribution of the same exposure(s). Unless there was little or no exposure to the same contaminant among other populations and locations in the state, such a comparison would still require comparison based on some level of large-scale cross-sectional sampling (e.g., countywide, statewide).

3. Indirect sampling approaches

Indirect sampling approaches obtain samples by means other than by direct contact with the individuals comprising the population that is being characterized. Instead, indirect sampling would obtain samples of blood and/or urine from existing pools of these media such as blood banks and clinical laboratories. This was the approach proposed in NJ's 2003 proposal to the CDC. As part of the 2003 proposal, several major NJ blood banks and at least one major NJ clinical laboratory agreed to provide "wastage" samples that would otherwise be disposed of. With renewed agreement by these (or additional) organizations, this approach could be pursued for biomonitoring in the future.

Advantages

The major advantage of this approach is that because it would not require sample collection from individuals, it would be much less expensive and resource intensive than direct sample acquisitions approaches while still allowing useful estimates of population distributions of exposure.

Disadvantages

Because there would be no contact with the individuals from whom these samples originated, there would be minimal and de-identified demographic information available – perhaps limited to sex and age. Little or no information would be obtained that could aid in identifying sources of exposure or lifestyle characteristics associated with exposure. In addition, data obtained from these sources would not be truly random. This is because blood banks and clinical labs do not

proportionally collect samples from all age groups, socio-economic strata, or geographic locations. Thus, estimates of means and upper percentiles of exposure will be biased in ways that cannot be easily adjusted.

4. Hybrid indirect/direct sampling

By combining indirect sampling (blood banks, clinical labs) with a drastically scaled-down direct statewide sampling approach on a scale adequate only to provide estimates of the central tendency of exposures, the direct sampling results could be used to statistically adjust the inherent bias in the indirect sampling results resulting from the non-random nature of the blood bank and clinical lab samples. This would increase the utility of the indirect sampling approach, while providing significant information on sources or characteristics of exposure.

Advantages

Reduced cost compared to more intensive direct sampling approaches. Ability to statistically correct some of the bias inherent in indirect sampling approaches

Disadvantages

While reduced, the cost of the direct sampling component would still be significant. The information obtained from the direct sampling component would be limited in not providing information on the most highly exposed and at-risk populations.

Conclusion and recommendations regarding human biomonitoring approach for NJ

As outlined above, there are many possible approaches and combinations of approaches that could be pursued in NJ. Likewise, there are many different kinds of information that would be very valuable to NJ that could be generated through biomonitoring. The choice of which approach(es) to follow will depend on the specific biomonitoring goals the DEP chooses to address as well as on the availability and extent of funding available to support those goals.

Since it is not within the Science Advisory Board's purview to address DEP's policy priorities, the Committee is not in a position to recommend any particular approach to the exclusion of the others. However, the Committee notes that the direct statewide sampling approach is the most inclusive and provides a sound basis upon which to assess the public health context of population and location-specific studies. Such an approach, therefore, is not only extremely informative in its own right, but a foundation upon which other biomonitoring studies can be built.

VII. Guidance for Selecting Target Chemicals

The Committee has identified several chemicals and classes of chemicals that are common environmental contaminants and are thus, likely candidates for biomonitoring in general. In addition, perfluorinated chemicals (PFCs) (e.g., PFOA, PFOS, and PFNA) are a particular NJ issue and are also likely candidates. One of the important uses of biomonitoring is to identify chemicals of emerging concern that may be causing human exposure before they become regulatory issues. Thus, this list should not be viewed as inclusive. Additionally, CDC has an increasing list of chemicals that it has identified for longitudinal biomonitoring through its NHANES program. This list is based on prevalence, health risks and information on emerging chemicals of potential concern. CDC has developed state-of-the-art analytical methodologies for these chemicals in blood and urine and these methods can greatly facilitate analytical efforts in NJ. The list of target chemicals for NJ biomonitoring should, therefore, be informed by the list of NHANES analytes. However, CDC currently analyzes for more than 300 chemicals as part of NHANES biomonitoring. This list is considerably larger and broader in scope than is likely to be appropriate for NJ at this point. The Committee recommends that chemicals for population-based biomonitoring in NJ should be selected on the basis of their hazard potential, degree of prevalence in the environment, and the feasibility of achieving useful detection limits.

For biomonitoring that is focused on specific populations that are defined by their proximity to specific sources of exposure (e.g., waste sites, contaminated water supplies) the list of analytes of interest will be defined by the specific sources of exposure.

Therefore, rather than supply a prescriptive list of chemicals that should necessarily be addressed by NJ biomonitoring, the Committee is providing the following list as possible examples of chemicals that fit the criteria of hazardous, prevalent, and analytically feasible. However, this list should be seen as neither required in total, nor complete.

Perfluorinated chemicals (PFCs) such as PFOA, PFNA and PFOA have rapidly emerged as chemicals of concern in NJ. Their recent detection at relatively elevated levels in drinking water in specific locations has led to efforts to define the magnitude and spatial extent of exposure. It is likely that exposure to PFCs in NJ has both a site-specific and a more ubiquitous background component. The long half-life of these chemicals in the human body makes biomonitoring an ideal approach to assessing the extent and level of both of these aspects of exposure in the NJ population.

NJ has a long history of addressing contamination with metals in hazardous waste, sites, urban environments, homes, as well as naturally occurring levels of some toxicologically important metals in soil water. Lead, arsenic, chromium and mercury, and to a lesser extent, cadmium are all obvious metals to consider. Most metals, however, including more exotic metals that have not been historically addressed, are accessible through the same analytical techniques and can be obtained as a suite for little additional cost compared to analysis of individual targeted metals.

Classic persistent organic pollutants (POPs) such as PCBs, dioxins, and structurally related halogenated organics have been found in fish and shellfish consumed by anglers and to a lesser extent sold commercially in NJ. These chemicals are also ubiquitous at relatively low levels in urban soils and dusts as well as in aging building materials such as older fluorescent light ballasts, and some caulking materials.

Exposure to diesel exhaust, particularly in urban settings and particularly in communities that can be described as environmentally overburdened is an ongoing issue of concern in NJ. The particulate portion of diesel exhaust is not easily addressed through biomonitoring. However, polycyclic aromatic hydrocarbons (PAHs) are an important (and potentially carcinogenic) constituent of diesel exhaust that may be addressed with biomonitoring. In addition, recent work on diesel-specific biomarkers of exposure (Laumbach et al., 2009) may provide a biomonitoring approach to assessing diesel exhaust exposure within populations.

Awareness of bisphenol-A and phthalates exposures and their potential for adverse developmental effects has greatly increased in recent years. While a significant portion of these exposures appears to arise from consumer products, including personal care products, the presence of these chemicals in wastewater, drinking water and food also poses a potential for population exposure that has not been addressed in NJ to date.

Concerns regarding human exposures to various pesticides in NJ is complicated by the difference in their uses between agricultural and urban areas and by the continued presence in environmental media of the residue of historic pesticide use. While pesticide use and occurrence is to some extent monitored in environmental media, it is not known to what extent data on environmental occurrence of various pesticides is indicative of the internal body burden of pesticides throughout NJ.

In addition to the specific and classes of chemicals listed above, having a biomonitoring sample collection strategy in place will allow the state to rapidly respond to concerns about new, and currently unanticipated exposures to emerging contaminants to assess the extent of these exposures in NJ.

VIII. Cost

Given the variety of possible biomonitoring approaches and goals in NJ and given the wide range of options within many of these approaches, one, or even several different cost estimates would not be meaningful. However, as noted above, the NJDOH has been awarded a major biomonitoring grant by the CDC. The initial grant was for \$1 million a year for five years. It now appears that this has been somewhat reduced, but remains substantial. A portion of this grant is budgeted for increasing NJDOH laboratory capacity and capability. Nonetheless, the Committee notes (as documented above and in Appendix A) that the State of Washington

utilized a grant of \$1.34 million to conduct a statewide, representative, random biomonitoring sampling employing direct sampling that collected urine samples from 1,422 individuals (<http://www.doh.wa.gov/DataandStatisticalReports/EnvironmentalHealth/Biomonitoring.aspx>). These samples were analyzed for arsenic, 12 other metals, a variety of pesticide classes, phthalates, and bisphenol-A.

IX. Funding sources

Consideration of funding sources can be divided into two categories that are not necessarily mutually exclusive: initial funding sources; and ongoing funding sources. Initial funding sources are those that can be used to establish the structure of a biomonitoring program and to provide initial results. These initial results, either from a pilot study, or from a full scale study can then be used to make the case for larger and more extended funding in order to produce more representative data and/or to establish a baseline of exposure. Such a baseline could form the starting point for longitudinal sampling that can show changes over time in the manner of the CDC's NHANES ongoing biomonitoring. Following exposures over time in NJ (and identifying emerging exposures) will require ongoing funding. However, a track record of successful and useful results from an initial large scale or pilot project can be leveraged to secure funding from government (e.g., CDC) and/or private foundations for continued work.

An obvious, available, timely and extremely useful source of initial (and to some, extent, ongoing) funding is the very recent CDC's grant to the NJDOH. The use of even a portion of this funding for a successful and informative initial biomonitoring program would make a strong case for future funding from CDC or elsewhere for ongoing sampling.

Private non-profits with a longstanding interest in environmental and public health issues, such as the Robert Wood Johnson Foundation, and the Pew Charitable Trust, may be a source of funding in addition to or as an alternative to the CDC-NJDOH grant. The Committee notes that the NY City HANES project was entirely funded through non-governmental sources.

Another supplement or alternative to the CDC biomonitoring grant to the NJDOH is a special appropriation from the NJ Legislature. While the Legislature may not be amenable to the cost of a full-scale effort, a modest appropriation for initial funding, possibly in the form of a pilot project in two or more counties or a scaled-down statewide project (both discussed above) could serve as the basis for securing additional funding from CDC and/or from private non-profits for more extensive ongoing and follow-up work.

X. Recommendation for Collaboration with NJDOH

The specific biomonitoring goals and programs that will be pursued under the recent CDC grant to NJDOH of \$1 million per year for five years are still under consideration and have not yet been set. The Public Health Standing Committee recognizes that there is now a critical window for collaboration. This is a prime opportunity for NJDOH and NJDEP to address important and large scale biomonitoring goals for New Jersey. The Committee strongly recommends that the NJDEP work with the NJDOH and that NJDOH be encouraged to work with NJDEP to implement the strategies described in this report in the current window of opportunity. In particular, the Committee recognizes that this grant provides an opportunity (that may not recur) to design and implement the beginning of a statewide biomonitoring program.

Future Involvement of the NJDEP-SAB

Given both its interest and expertise in biomonitoring and closely related scientific areas, the Public Health Committee of the SAB believes that it can be of important service to the NJDEP going forward and encourages the NJDEP to include the Committee (as well as the SAB in general) in its biomonitoring planning and programs going forward.

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Appendix A

Description of State and Local (NY City) Biomonitoring Programs

I. California's Biomonitoring Program

(<http://www.biomonitoring.ca.gov/>)

- The California Department of Public Health (CDPH) www.cdph.ca.gov – Lead program
- Also, California Environmental Protection Agency's (Cal/EPA's) Office of Environmental Health Hazard Assessment (OEHHA) www.oehha.ca.gov and Department of Toxic Substances Control (DTSC). www.dtsc.ca.gov
- Created by Legislation Passed in 2006
 - o Senate Bill 1379
- Scientific Guidance Panel
- Scientific Guidance Panel (SGP), makes recommendations regarding the Program's design and implementation.
 - o specific recommendations regarding chemicals that are priorities for biomonitoring
 - o scientific peer review for Biomonitoring California.
 - o Mostly academics
- CDC
 - o **CDC funding to help support laboratory activities, field work and sample collection, and return of results to participants.**
 - o provides technical assistance and consultation to Biomonitoring California in the areas of sampling strategy, data collection methods, and data management systems.
 - o share chemical analysis methods with state laboratories and train state laboratory staff.

- Biomonitoring California Laboratories include:
 - o Environmental Health Laboratory Branch, California Department of Public Health
 - o Environmental Chemistry Laboratory, Department of Toxic Substances Control

Specific Projects

- California Childhood Leukemia Study (CCLS)
 - o Analysis of flame retardants and other persistent chemicals in blood samples from mothers of children with leukemia and mothers of children without leukemia
- Health and Environmental Research in Make-up of Salinas Adolescents (HERMOSA) Study
 - o Analysis of phthalates and environmental phenols in urine samples from teenage girls
- Biomonitoring Exposures Study (BEST) - Pilot
 - o Study of environmental chemical exposures in adults in the Central Valley
 - o This appears to be based on a random, cross-sectional design for the Central Valley
- California Teachers Study (CTS)
 - o Analysis of flame retardants and other persistent chemicals in blood samples for a study of women with and without breast cancer
- Center for the Health Assessment of Mothers and Children of Salinas (CHAMACOS)
 - o Analysis of phthalates in urine samples from 5-year-old children for a study in an agricultural community
- Firefighter Occupational Exposures (FOX) Project
 - o Study of environmental chemical exposures in Southern California firefighters
- Maternal and Infant Environmental Exposure Project (MIEEP)

- o Study of environmental chemical exposures in pregnant women and their infants
 - o The project measures environmental chemical exposures in **65 mother-infant pairs** and an additional **27 pregnant women**
- Three Generations Study (3Gs)
 - o Analysis of persistent environmental chemicals in archived samples from pregnant women in the 1960s and recent samples from their now-adult daughters in a study examining the risk of breast cancer and other diseases affecting women
 - UCSF Studies of Second-Trimester Pregnant Women
 - o Analysis of flame retardants and other persistent chemicals in blood samples for studies of ethnically diverse, low-income pregnant women

Comments

The CA biomonitoring effort differs fundamentally from the NHANES and NYCHANES efforts in not attempting to be cross-sectional for the State as a whole or for significant regions of the State (with the possible exception of the pilot Biomonitoring Exposures Study (BEST) in the Central Valley. Rather all or most of CA's biomonitoring projects are population, or disease-specific.

- California receives financial assistance and technical assistance from the CDC.
- Laboratory analyses appear to be mostly, or entirely conducted in CA government labs.
- There is a standing (mostly) academic advisory panel.

II. Minnesota's Biomonitoring Program

(<http://www.health.state.mn.us/divs/hpcd/tracking/biomonitoring/index.html>
<http://www.health.state.mn.us/divs/eh/risk/studies/biomonitoring.html>)

- Purpose
 - Identify differences in the levels of chemicals among Minnesota's diverse populations, which may differ by income, ethnicity, culture, or geographic location
 - Assess the need for public health policy and action
 - **Track changes over time to find out whether actions taken to reduce chemical exposures have been effective**
- **Advisory Panel**
 - o The Minnesota Department of Health (MDH) convenes an expert Advisory Panel that provides recommendations on environmental health tracking and biomonitoring priorities and activities. This panel was established by Minnesota state law. All meetings are open to the public for observation.
 - o Members from academia, state and local government, NGOs, industry
- **Authority**
 - o The Environmental Health Tracking Biomonitoring Program and its Advisory Panel were established by the Minnesota Legislature in 2007
 - o Under MN DOH
- **Projects**
 - o Minnesota Family Environmental Exposure Tracking (MN FEET)
 - MN FEET will measure mercury and other chemicals in newborns from at-risk Minnesota communities
 - Unclear how populations are selected or what the n is
 - o PFC Biomonitoring: East Metro
 - 2008 and 2010, studies measuring PFCs in the blood of East Metro residents. Designed to track PFCs in people exposed in drinking water before the interventions.

- In 2014, will conduct the East Metro PFC3 Biomonitoring Project Study will measure PFCs in 2008 and 2010 participants to determine changes associated with source reduction
- o Pregnancy and Newborns Exposure Study: Measuring Mercury and Lead in Newborns
 - A collaboration between MN and the University of Minnesota
 - Cord blood and newborn bloodspots were collected from 48 newborns in the Minneapolis area.
- o Mercury in Newborns in the Lake Superior Basin
 - Mercury in newborn bloodspots from 1,126 newborns born in the Lake Superior region
- o South Minneapolis Children's Arsenic Study
 - Arsenic in urine of 65 children in South Minneapolis neighborhoods with known soil contamination.
- o Riverside Prenatal Biomonitoring Pilot Project
 - Measured exposures to bisphenol, parabens and tobacco smoke in the urine of 66 pregnant women receiving care at an urban Minneapolis clinic.

Comments

- Similar to CA in having individual (and largely unrelated) studies with a narrow population focus.
- Funding source(s) not stated, but given legislative authorization and no mention of other sources, appears to be funded from general revenues.

III. Washington State's Biomonitoring Program

(<http://www.doh.wa.gov/DataandStatisticalReports/EnvironmentalHealth/Biomonitoring.aspx>)

- Funded by 2009 CDC grant for 5 years for \$1.34 million.
- Goals
 - o Increase the ability of the Washington State Department of Health's Public Health Laboratories to conduct biomonitoring testing.
 - o Measure the amounts of chemicals in the urine, blood and other tissues in a sample of Washington residents. This includes people at average risk and those at high risk for exposure.
 - o Compare levels in Washington to those in the United States as a whole.
 - o Use this information to reduce exposures.
- Advisory Committee
 - o Combination of academics, state, federal and local government and NGO.
 - No industry
- Projects
- Statewide General Population Study
 - o May 2010 through June 2011 - collection (by WA-DOH) of 1,422 urine samples from a **statewide representative sample** of Washington residents age six and older.
 - o Urine samples analyzed at the Washington State Department of Health Public Health Laboratories for
 - Total and speciated arsenic
 - 12 metals,
 - Pyrethroid and organophosphate pesticide metabolites.
 - Subset of samples for bisphenol A (BPA) and phthalates.

- Survey of Residents of Subsidized Housing in King County
 - o The purpose of this study was to measure and better understand exposures to pyrethroid pesticides and plastics-related compounds (bisphenol A and phthalates) among residents of subsidized housing.
 - o May 2013 to April 2014 collected urine samples from 585 people living in subsidized housing in King County.
 - o Compare results with state and U.S. levels and plan to use survey findings to help reduce these chemicals in people.
- Pyrethroid Exposure Survey and Testing (PEST) Study
 - o Licensed pesticide applicators from King, Pierce, Snohomish, Clark or Thurston counties who used pyrethroid products at work were eligible. The purpose was to learn how work practices affect their exposures.
 - o May through October 2012, 56 participants completed a questionnaire and gave urine samples after a work day of applying pyrethroid pesticides.
 - o Results will be used to improve continuing education for these professionals.
- High Arsenic Area Study: South Whidbey Island
 - o South Whidbey Island has high, naturally occurring arsenic in groundwater.
 - o July through September 2011, collected urine and drinking water samples from residents on private wells or small water systems (less than 15 connections).
 - o Households with arsenic at or above EPA's drinking water standard were invited to participate.
 - o A total of 172 residents from 82 households participated in this study.

Comments

- o WA appears to have the only state biomonitoring program that has so far undertaken a population-based representative biomonitoring study. The scope, however, is similar to that of the NY City effort
- o Sample collection appears to be done by dedicated WA DOH employees, analytical work is done in WA DOH labs

- o Presumably, this is facilitated by the CDC grant
- o Other studies are focused based on
 - o Geographic location relative to known sources of contamination
 - o Occupation
 - o Disadvantaged/impacted communities

IV. Summary of NY City Biomonitoring Program

(<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2022653/>)

- Modeled on national NHANES
- Funding
 - Funding largely through philanthropic organizations
 - Primarily provided by the de Beaumont Foundation
 - With additional support by:
 - Robin Hood,
 - New York State Health Foundation,
 - Quest Diagnostics,
 - Doris Duke Charitable Foundation
- Collaborators
 - NYC Dept. Health and Mental Hygiene
 - CUNY School of Public Health
- Population-based, cross-sectional
- Two rounds to-date
 - 2003
 - 2014
- Biomonitoring conducted as part of larger NYCHANES program
 - Assess various health indicators
 - Body-mass index
 - Blood pressure
 - Diabetes
 - Hypercholesterolemia
 - etc.

- Representative sample of 2,000 randomly selected New Yorker adults
 - o Household-based sampling
 - o Designed to provide citywide estimation
- Blood and urine samples collected for biomonitoring
 - o Biomonitoring foci
 - Mercury
 - Lead
 - Cadmium
 - Cotinine (passive smoking exposure)
 - Organophosphate pyrethroid pesticide metabolites
 - PCBs, PBDEs (anticipated analysis of archived samples)
- Biomonitoring portion of program so far has produced important information about disproportionately high methylmercury exposure among Asians
 - o Unexpected
 - o Not obvious from national or other NYC data

Comments

- NYCHANES is the only non-federal biomonitoring program that focuses exclusively on the population as a whole
- Funding has been entirely non-governmental
 - o However, appears that NY State will be supplementing additional analysis of archived samples through CDC funding
- Significant collaboration with CUNY