Environmental Health Tracking & Biomonitoring

Report to the Minnesota Legislature on the pilot program for biomonitoring

Minnesota Department of Health

January 15, 2008

MINNESOTA MDH DEPARTMENT OF HEALTH

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EXECUTIVE SUMMARY

The 2007 Legislature established the Environmental Health Tracking & Biomonitoring (EHTB) program, directing the Minnesota Department of Health (MDH), in consultation with an advisory panel of scientists, to develop and implement, among other activities, a biomonitoring pilot program. The biomonitoring pilot program, as described in statute, consists of four pilot projects to assess communities' exposure to arsenic, perfluorochemicals, mercury, and a fourth chemical to be selected by MDH in consultation with the advisory panel.

The EHTB statute states, "By January 15, 2008, the commissioner shall submit a report on the results of the biomonitoring pilot program to the chairs and ranking members of the committees with jurisdiction over health and environment." While pilot project results are not yet available, this report provides a summary of the progress made in developing biomonitoring program guidelines in general, and the four pilot projects specifically, since the legislation creating the EHTB program went into effect on July 1, 2007.

Arsenic:
South Minneapolis has been selected as the community for the pilot project. The specific population that will be sampled in this community is children (ages 3 through 10), due to their higher risk of being exposed to arsenic in contaminated soils. Collection of biospecimens (urine and/or hair) is likely to begin in the summer of 2008.

Perfluorochemicals (PFCs):
Two communities in Washington County have been selected for the pilot project. These communities are defined by their source of drinking water and will include households served by the Oakdale municipal water supply (community one) and households with PFC-contaminated private wells in Lake Elmo and Cottage Grove (community two). Collection of biospecimens (blood serum) in adults in these communities is likely to begin in the summer of 2008.

Mercury & a chemical to be designated:
Planning is in an early stage for biomonitoring for mercury and a fourth chemical. In light of limited resources, EHTB staff and the EHTB advisory panel are considering a range of options for proceeding with these projects, including collaborating with other planned or existing studies.

INTRODUCTION

Biomonitoring means directly measuring the amount of a chemical (or the products that a chemical breaks down into) in people's bodies. Biomonitoring measurements are a good way to determine exposure to a chemical, because biomonitoring indicates the amount of the chemical that actually gets into people, rather than the amount that could potentially get into people. Biomonitoring can be used to identify populations who are most at risk for exposure, to track changes in exposure over time, and to help target programs and interventions to reduce exposures.

Though biomonitoring projects have been carried out occasionally at the Minnesota Department of Health (MDH) in the past, biomonitoring has not been conducted on an ongoing basis. In 2007, the Minnesota Legislature passed a law creating the Environmental Health Tracking and Biomonitoring (EHTB) program at MDH. This legislation directed MDH to develop four biomonitoring pilot projects and, based on the results of those projects, to make recommendations for establishing an ongoing biomonitoring program in Minnesota.

Since July 2007, when the legislation went into effect, MDH has assembled an advisory panel, as required by statute, to advise program staff in the planning and implementation of the biomonitoring pilot program.

The call for nominees for the panel was publicized by the Secretary of State. The Commissioner of Health appointed nine members to the panel, the commissioners of the Pollution Control Agency and the Department of Agriculture each appointed one member, and the Speaker of the House and the Senate Majority Leader each appointed one member (see appendix for more information).

As required by statute, the panel is made up of scientists and citizens who have a background or training in designing, implementing, and interpreting health tracking and biomonitoring studies or in related fields of science. The panel is comprised of members representing nongovernmental organizations, statewide business organizations, the University of Minnesota, Minnesota's interests "at large," and state agencies.

The advisory panel has met twice (in October and December 2007) and has discussed the biomonitoring projects that are described in this report. At each of the meetings of the advisory panel, panel members will be encouraged to discuss and comment on the planning and implementation of the pilot projects. Panel members are also expected to participate in interpreting the results of the projects.

During the first six months of the program, EHTB program staff, in consultation with the advisory panel, began deliberations to establish biomonitoring program guidelines. A task force of the advisory panel has been formed to draft a set of program guidelines, which will be presented to the full panel for discussion at its meeting in March 2008.

The development of scientifically sound biomonitoring projects requires a significant amount of time and financial resources. Careful planning ensures that the pilot projects are carried out in an ethical and rigorous manner and that the projects are conducted in ways that are acceptable to the communities involved. Planning also makes sure that the projects are implemented in accordance with the EHTB legislation and that they follow state and federal laws for the protection of data privacy and human subjects in research.

Planning for all four biomonitoring pilot projects is underway. The proposals for the arsenic and perfluorochemicals (PFCs) pilot projects have been drafted and reviewed by the advisory panel, and data collection is expected to begin by summer of 2008, after the necessary approvals have been obtained. Options for the pilot projects for mercury and a fourth chemical (to be designated) are still being explored.

Limited resources are available for the biomonitoring pilot program; therefore choices regarding the most effective way to allocate funds among the four pilot projects will be necessary. As one way to extend biomonitoring funds, opportunities are being explored for collaborating with other planned and existing studies for conducting the biomonitoring projects for mercury and/or a chemical yet to be determined. Decisions about the best ways to proceed with the pilot projects will be made in consultation with the EHTB advisory panel, which exists to ensure that the biomonitoring projects are based on sound science.

In conducting the pilot projects, MDH expects to gain valuable information – for the individuals exposed to chemicals in the environment, for the communities in which those individuals live, and for the state. At the individual level, participants will receive their own results, and may be able to take new steps to reduce their exposure and protect their own or their children's health. At the community level, MDH may learn whether these exposed communities have elevated levels of chemicals in their bodies compared to other populations in which these same chemicals have been measured. This knowledge may guide future efforts to develop, implement, or evaluate interventions to protect people's health. And at the state level, MDH will learn valuable lessons about the feasibility and usefulness of conducting biomonitoring and will be able to make recommendations about continuing biomonitoring as a base program.

The biomonitoring project has made significant progress during the first six months of funding and is poised to move ahead quickly in the remaining months of the pilot program timeframe.

A detailed progress report on each of the four pilot projects and the development of biomonitoring program guidelines is included below.

This report does not discuss the other major activity provided by the EHTB legislation, development of an environmental health tracking program for the state. The Minnesota Environmental Health Tracking System is currently being developed alongside the biomonitoring program, and in collaboration with the Minnesota Pollution Control Agency and the Minnesota Department of Agriculture. For more information on the tracking program, the biomonitoring pilot projects, and the advisory panel, go to http://www.health.state.mn.us/divs/eh/tracking/.

DEVELOPMENT OF BIOMONITORING PROGRAM GUIDELINES

Biomonitoring has great potential to provide valuable information about Minnesotans' exposures to chemicals in the environment. However, in order to carefully direct this work, program guidelines need to be established. Guidelines will also aid the panel in making recommendations for an ongoing biomonitoring program in Minnesota.

Program staff and advisory panel members will look to a number of sources for guidance in developing the biomonitoring program guidelines, including the Centers for Disease Control and Prevention's National Biomonitoring Program and recommendations developed by the National Research Council.

In establishing biomonitoring program guidelines, many issues must be considered. Some of these issues are common to all biomonitoring projects, while others are unique to the purposes of public health agencies.

A task force of the advisory panel has been formed to draft a set of program guidelines. The task force, in conjunction with program staff, will address the following questions in developing the guidelines, which will be presented to the full panel for discussion at its meeting in March 2008:

What are the primary goals and objectives of a state biomonitoring program?
The biomonitoring program guidelines will seek to define the most appropriate uses of biomonitoring in Minnesota, as biomonitoring programs can be established for the purposes of ongoing public health surveillance, the assessment of risks related to specific environmental exposures, as a support for research activities, and/or as a service to individuals who would like to know what chemicals they have been exposed to. Also at issue will be the extent to which the program should be designed to meet the needs of the Environmental Health Tracking program activities.

How should specific biomonitoring studies be designed?
Decisions must be made about how scientifically rigorous state biomonitoring studies should be. Guidelines related to study design include consideration of the choice of biospecimens collected to assess exposure to specific chemicals, sample size, and generalizability of the results to the population sampled.

How should data from biomonitoring studies be interpreted?
Results from biomonitoring studies can be difficult to interpret, particularly because the ability to measure chemicals in the body in many cases exceeds our knowledge about the health effects of exposure to those chemicals, particularly at low levels. Guidelines will need to be established for identifying comparison values (which can indicate how an individual's or a community's exposure compares to other populations) or other methods for approaching data interpretation.

How should results of biomonitoring studies be communicated?
There are many audiences that might be interested in learning the results of state biomonitoring projects, including individual participants, the general public, policy makers, and members of the scientific community. In developing program guidelines, recommendations will be made for how results should be communicated with these audiences.

How can communities be involved in biomonitoring studies?
Biomonitoring can benefit greatly from community participation in the design of specific studies. Guidelines will be considered for how and when to best involve community members in biomonitoring.

How can we ensure that biomonitoring studies are conducted ethically?
While formal processes are already in place to protect the rights of participants in these and other research projects, biomonitoring projects present additional legal and ethical issues that must be considered, including the rights of participants to have access to biomonitoring results and the use of biomonitoring samples for other purposes. Program guidelines will be developed to address these issues.

BIOMONITORING FOR ARSENIC

The arsenic biomonitoring project will be conducted in south Minneapolis, where elevated levels of arsenic have been detected in the soil of several hundred residences. Though the U.S. Environmental Protection Agency is in the process of removing the soil from the yards with the highest levels of contamination (and has plans to expand the soil clean-up to hundreds of additional homes), neighborhood residents are understandably concerned about their – and their children's – exposure to the arsenic in the soil.

The arsenic biomonitoring pilot project will measure the arsenic levels in 100 children (ages 3 through 10) who live in homes where an elevated level of arsenic was found in the soil. Children are the emphasis of this project because they are more likely to be exposed to the arsenic in the soil through playing in the soil and are more likely to get soil in their mouths. Also, children's bodies may be more affected by exposure to the arsenic because they are going through stages of rapid growth and development and their bodies may break down the arsenic differently than adults.

Arsenic will be measured using urine and/or hair specimens. Because arsenic does not stay in the body for very long, the arsenic measurement will be just a snapshot of the children's recent exposure to arsenic through the soil and other sources.

Using soil sampling results, biomonitoring project staff will identify which households may be eligible to participate in the project and will then contact the residents to determine which of the households have children. One child per household will be randomly selected and invited to participate in the project until the total of 100 participants is reached. Priority will be given to children living in households with the highest levels of arsenic contamination. Because arsenic exposure needs to be recent in order to be detected, only households whose yards have not yet been remediated will be eligible to participate.

Participation in the project is voluntary, and written, informed consent will be obtained from the caregivers of each participant.

In the coming months, the project protocol will be further refined, based on feedback from community residents, the EHTB scientific advisory panel, and other stakeholders, and will then be submitted to MDH's Institutional Review Board (IRB) for approval. The IRB ensures that participants' rights are protected and that the project is conducted in an ethical way.

In order to ensure the project is conducted in a way that will be acceptable to and successful for the community, a priority has been placed on notifying the community about the project and offering opportunities for community stakeholders to provide input. For example, information about the project has been sent home with school children in the project area, posted at neighborhood parks and libraries, and listed in community newspapers. The assistance of neighborhood organizations has been enlisted and a community meeting was held on December 6 to describe the project and to solicit input from residents. Efforts to involve the community will continue as the project is further developed.

Collection of samples is planned for the summer of 2008. Collecting the samples in the summer ensures that children are more likely to be in contact with the contaminated soil in their yards than they would be during the school year. The measurement of arsenic levels in the biospecimens will be performed at the MDH Public Health Laboratory according to methodology developed by the Centers for Disease Control and Prevention.

All participants will receive their own results, along with information to help them interpret their result. Parents of the children who are found to have elevated levels of arsenic will be provided with information to help them identify all possible ways their children are exposed to arsenic and take steps to reduce the exposure. They will also be provided with information about following up with a medical provider for retesting. Participants' results will be grouped to determine whether the community as a whole has elevated levels of arsenic. The analysis will also look for any correlation between levels of arsenic in the soil and levels found in the participants' bodies. Data analysis is planned for the fall of 2008 and the release of pooled results is anticipated in early 2009.

BIOMONITORING FOR PERFLUOROCHEMICALS

The perfluorochemicals (PFCs) biomonitoring project will be carried out in two communities in Washington County, where the drinking water is contaminated with PFCs. The PFCs that have been detected in the water include perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA), and perfluorobutanoic acid (PFBA).

The two communities are defined not by geographic boundaries, but by their drinking water source. The first community is households that are served by the Oakdale municipal water supply. This includes not only Oakdale residents, but a small number of households in Lake Elmo as well. The second community is people with private wells contaminated with PFCs in Lake Elmo and Cottage Grove.

These communities were selected because testing has shown that the drinking water in these communities is contaminated not only with PFBA (which leaves the body relatively quickly due to its short half-life) but also with PFOA and PFOS (which have half-lives of three to six years and, as a result, stay in the body much longer). The project will measure the levels of these three PFCs in blood serum collected from 100 adults from each of the two communities.

Widespread PFBA contamination has been discovered in the drinking water in other parts of the east metro area, including Cottage Grove, St. Paul Park, Newport, Woodbury, Hastings, and South St. Paul. However, only a few of the wells in these areas contain more than trace levels of PFOA and PFOS. The short half-life of PFBA means it is less likely to be detected in a blood sample. Thus, in order to increase the likelihood of detecting PFCs, communities where the water is contaminated only with PFBA were not selected to be part of the pilot project.

As currently proposed, this project will use city water billing records and well sampling results to identify all of the households eligible to participate in the project. Residents will be contacted and surveyed to identify eligible adults living in the households. Among all eligible adults who return the survey, 100 in each community will be randomly selected and invited to participate. Because measures are now in place to contain the PFCs (e.g., filtration systems), participants must have been living at their homes before the PFCs were first detected to be eligible.

Participation in the project is voluntary, and written, informed consent will be obtained from each participant.

The project protocol will be further refined, based on feedback from community residents, the EHTB scientific advisory panel, and other stakeholders, and will then be submitted to MDH's Institutional Review Board for approval. The IRB ensures that participants' rights are protected and that the project is conducted in an ethical way.

Efforts are underway to inform community members and other stakeholders about the pilot project and to solicit their input on the project. Opportunities for community engagement will continue as the project progresses.

Collection of samples is planned for the summer of 2008, to allow for adequate planning and obtaining the necessary approvals. The measurement of PFC levels in the biospecimens will be performed at the MDH Public Health Laboratory according to methodology developed by the Centers for Disease Control and Prevention.

All participants will be given the opportunity to receive to their individual results. Values will be compared to results obtained through the National Health and Nutrition Examination Survey (NHANES) and other studies. Participants will be provided with information to help them interpret their results. Unfortunately, research on human health effects from environmental exposures to PFCs is sparse, so it may be difficult to fully explain what the results mean.

Results will also be grouped to determine whether the two communities have elevated levels of PFCs when compared to national data. Data analysis is planned for the fall of 2008 and the release of pooled results is anticipated in early 2009.

BIOMONITORING FOR MERCURY

Planning for mercury biomonitoring is in an earlier stage than for the two projects previously described.

Environmental Health Tracking & Biomonitoring staff recognize that the program has limited financial and human resources for implementing biomonitoring pilot projects yet also know the importance of ensuring that any biomonitoring pilot project conducted is done so in a scientifically valid and culturally appropriate way. To reconcile these competing realities, program staff are exploring a variety of low-cost options for carrying out a biomonitoring pilot project for mercury (for example, adding mercury analysis to a planned or existing study at the Minnesota Department of Health or another site).

The EHTB advisory panel has just begun consideration of this issue, and panel members will serve as valuable resources for identifying appropriate projects with which to collaborate and for ensuring that any collaborative effort adheres to as many of the biomonitoring program guidelines and legislative guidelines as possible.

At the March 2008 advisory panel meeting, panel members will be asked to formally consider the available options for conducting biomonitoring of mercury as required by statute, and to make a recommendation for proceeding with a pilot project.

BIOMONITORING FOR A CHEMICAL TO BE DESIGNATED

Efforts to identify a fourth chemical have just begun.

As with the mercury pilot project, resources constrain the ability to carry out a well-designed independent pilot for the fourth chemical. Program staff are exploring a number of options for proceeding with biomonitoring in this area, including tying into some other planned or existing study at the Minnesota Department of Health or another site. Another option being considered is to channel resources toward outreach and strategic planning to identify priorities for biomonitoring, including the selection and ranking of specific chemicals to study under the base biomonitoring program in future years.

The EHTB advisory panel has reviewed criteria that might be used in the selection of an appropriate chemical to be studied. The panel has also been briefed on financial and logistical considerations that might factor into the decision about how to proceed with an additional biomonitoring project.

At the March 2008 advisory panel meeting, panel members will be asked to formally consider the full range of options related to selecting a fourth chemical for biomonitoring as required by statute, and to make a recommendation for proceeding with a pilot project.

CONCLUSION

The EHTB program, in consultation with its advisory panel, will continue to plan and implement the biomonitoring pilot projects in the best ways possible. The program is committed to designing projects that are as scientifically valid, acceptable to the community, and in line with legislative requirements as existing resources (including both time and finances) will allow.

Because the biomonitoring projects are pilots, the projects will not be able to address all questions related to human exposures to chemicals in the environment. For example, detailed information about participants' potential current and past exposure to chemicals (such as water consumption, food consumption, occupational history, use of consumer products and other potential sources of exposure) will not be gathered.

However, these pilot projects will be useful for testing policies and methods for biomonitoring and for evaluating the feasibility of and identifying best practices for continued biomonitoring in Minnesota.

The next report describing the EHTB program, and the biomonitoring pilot program, will be submitted to the legislature on January 15, 2009. In addition to including preliminary results of the pilot program, the report will describe lessons learned from the pilot projects, which will ultimately form the basis for formal recommendations about establishing an ongoing biomonitoring program for the state.

APPENDIX: Environmental Health Tracking and Biomonitoring Advisory Panel

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