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The U.S. National Biomonitoring Network – Enhancing Capability and Capacity to Assess Human Chemical Exposures

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Abstract

Background: With the increased use of biomonitoring in public health, biomonitoring networks are forming worldwide. The National Biomonitoring Network (NBN), created in 2018, is an interconnected system of U.S. government laboratories in collaboration with public health partners, to advance human biomonitoring science and practice. The NBN aims to harmonize biomonitoring data for use in routine public health practice.

Methods: The NBN has taken a systems approach to provide high-quality biomonitoring data by establishing quality standards, mentoring nascent programs, and enhancing analytical capability and capacity through technical assistance. Guided by a multi-disciplinary Network Steering Committee (NSC), the NBN has developed an organizational framework, membership criteria, and guidance practices related to study design, quality management and analytical measurements. To facilitate the production of these resources, the NSC established interdisciplinary workgroups of subject matter experts.

Results: To date, 20 state public health laboratories have joined the NBN. Differences in land-use practices, state and local laws and availability of resources resulted in considerable variability in the design and approach of NBN member biomonitoring programs. By contributing technical guidance, technical training, examples and templates for analytical and epidemiological practices and opportunities for collaboration and interaction, the NBN addressed some of these challenges. Important challenges remaining are to define minimum data variables for laboratory measurements, demographic and exposure information, and to identify an appropriate national repository for biomonitoring data.

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Conclusion: The current NBN membership has greatly benefited from the resources, collaboration and engagement with other state and federal scientists. The NBN hopes to expand membership and increase interaction with biomonitoring networks internationally. While the objectives of biomonitoring networks around the world may differ, understanding their structures, advantages and limitations inform the NBN and provide opportunity for cross-network collaboration.

Keywords

Human biomonitoring; data harmonization; laboratory networks; public health practice; health surveillance; chemical exposure; risk assessment

Introduction

People are exposed to chemicals daily through food, their indoor and outdoor environments, work, lifestyle, and recreational activities. Measurement of chemical toxicants in the environment provides valuable information regarding potential sources and pathways of exposure and the external dose to which individuals may be exposed. These measures estimate the absorption of a contaminant by considering its chemical and physical properties, routes of exposure and uptake kinetics (National Research Council, 2006). By contrast, human biomonitoring, the measurement of chemicals and or their metabolites in biological specimens, quantifies the internal dose of a contaminant by integrating exposure from all sources and routes resulting in an accurate assessment of individual body burden (Sexton et al., 2004). Biomarkers of exposure (e.g. blood lead levels) complement environmental monitoring measures (e.g. lead in drinking water) to provide the most accurate exposure estimates when assessing human health risks from exposures to environmental chemicals. Biomonitoring data are also used by the US Environmental Protection Agency, the federal agency responsible for setting regulatory standards in water, air and environmental media, in the risk assessment process. By choosing the appropriate biomarkers of exposure, investigators may assess acute (short-term or high dose) or chronic (long-term or persistent) exposure.

Biomonitoring data are increasingly used in routine public health practice to investigate general and specific populations' exposures, communities' concerns (Daly et al., 2018), guide emergency response activities (Weibrecht et al., 2012), inform public health decision-making, and evaluate the efficacy of public health interventions (Abrams et al., 2006). In the United States, the National Center for Environmental Health (NCEH) at the Centers for Disease Control and Prevention (CDC) through the National Health and Nutrition Examination Survey (NHANES) provides nationally representative estimates of human exposure to select environmental chemicals (Calafat, 2012). NHANES data inform the risk assessment process and protect environmental health. However, within the USA, states vary significantly in demographics, industry (e.g. agricultural vs. manufacturing), geography, exposure sources, and regulation, potentially leading to considerable environmental health disparities. Therefore, state or local population-based surveillance is necessary for public health officials to understand the unique risks faced by their residents and evaluate the effectiveness of mitigation measures.

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So far, a relatively small number of U.S. public health laboratories have developed analytical capability and capacity for biomonitoring on occasional basis to investigate environmental health concerns in their respective jurisdictions. These targeted investigations conducted in collaboration with environmental epidemiologists and health officials in their states had typically focused on exposed or affected populations and were time and resource limited (Barton et al, 2020, Daly et al, 2018, Gibson et al, 2020, Graber et al, 2019, Landsteiner et al, 2014, Nair et al, 2014, Rogatsky et al, 2017).

Recognizing the need for biomonitoring capacity at the state level, in 2001, NCEH funded 25 states to design biomonitoring plans (CDC 2001), and select states to develop state-based capacity (CDC 2003, CDC 2009, CDC 2014, CDC 2019). Concurrent with these activities, CDC transferred to the states advanced analytical technology and capacity for high-throughput testing for chemical threat agents in clinical specimens through the Laboratory Response Network for Chemical Threat Agents (LRN-C) (CDC 2002–2020) (https://emergency.cdc.gov/lrn/chemical.aspdone. Emergency response activities provided the opportunity to engage new partners in the clinical and medical toxicology communities directly. Leveraging these analytical capabilities and enhanced collaborations, additional state public health laboratories and their public health partners became engaged in biomonitoring efforts and explored the implementation of population-based environmental health surveillance.

Understanding the increased prominence of biomonitoring for exposure and risk assessment, the Association of Public Health Laboratories (APHL) in collaboration with CDC developed two successive 5-year plans beginning in 2009 which culminated with the development of the National Biomonitoring Network (NBN) in 2018. The NBN goals are to promote quality management directives and opportunities for connection and collaboration among public health programs to produce high quality biomonitoring data for use in public health practice (APHL 2009, APHL 2012, APHL 2014, APHL 2019a, Latshaw et al, 2017). This paper aims to provide an overview of the objectives, structure, governance and implementation of the National Biomonitoring Network.

Methods

The implementation of the NBN was modeled upon the structure and development of other laboratory networks (Kirk et al., 2010, Astes, 2010, CDC LRN-C 2002, Villanueva et al, 2019). It is a performance based network that affords jurisdictional flexibility to the state biomonitoring programs in designing and operationalizing their work, allowing for programs that meet the current needs for community investigation, environmental health surveillance and evaluation of public health policy and intervention. This approach results in several challenges such as the need to harmonize laboratory measurements, nomenclature, questionnaire development and study design. The NBN provides technical assistance and guidance towards these objectives. Since resource constraints limit the scope of many state programs, APHL also works to educate partners and legislators about the value and uses of biomonitoring data in public health practice.

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Recognizing that human biomonitoring is a multi-disciplinary endeavor, the NBN is guided by a Network Steering Committee (NSC) of subject matter experts in analytical chemistry, epidemiology, exposure science, public health, risk communication, and toxicology. These experts represent several CDC programs (Division of Laboratory Sciences, Environmental Public Health Tracking Program, the National Institute of Occupational Safety and Health), the Agency for Toxic Substances and Disease Registry, the Environmental Protection Agency, the National Institute of Environmental Health Sciences, the National Institute of Standards and Technology, and multiple state programs (currently Massachusetts, Minnesota, New Jersey, New York, Texas and Wisconsin; New Hampshire and Arizona were former representatives). NSC members, who are selected based on their subject matter expertise, commit to at least a two-year term, extended as needed to ensure continued engagement. Additional members can be added as specific expertise needs are identified.

In the few years since its inception, the NSC has defined the governance structure, established a tiered network format, and developed a five-year timeline and implementation plan. The NSC has also identified multiple areas requiring focused attention and authorized the establishment of topic-specific work groups to research and draft recommendations that are presented to the NSC for consideration. This is an iterative process designed to maximize stakeholder input and perspective.

- Governance – the NSC is co-chaired by subject matter experts representing the Division of Laboratory Sciences at CDC and a state public health laboratory with considerable biomonitoring experience. The NSC works under the auspices of the APHL Environmental Health Committee and is ultimately accountable to the APHL Board of Directors. The NSC, which meets monthly via teleconference and at least annually in-person, is empowered to establish and dissolve ad hoc work groups and to provide recommendations related to specific topics (e.g., study design and membership.
- Network structure – the NBN has tiered architecture based on the public health laboratory capabilities, demonstration of biomonitoring methods proficiency and experience at the time of application; there is flexibility and opportunity to change tiers as appropriate (Figure 1). Membership is currently limited to government laboratories working within the public health system. Laboratories reapply for membership in the NBN every three years, at which time their capabilities and proficiencies are reviewed, as is the Tier designation. Applications are reviewed by a panel comprised of one representative each from the NBN Steering Committee, CDC and APHL. The NSC may consider expansion of the NBN membership to include non-government laboratories and/or non-laboratory partners in subsequent years.
- Engagement and scientific exchange opportunities – the NBN provides frequent and regular engagement opportunities for member laboratories to share experiences, successes and challenges via an online electronic platform and quarterly conference calls. Every two years, the network convenes the National Biomonitoring Meeting which affords the opportunity to share progress on

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analytical methodology, current biomonitoring investigations and a forum for advanced technical training.

- Cross-network collaboration- The NBN works collaboratively and learns from international biomonitoring programs through joint presentations at scientific conferences, analytical performance exercises and participation in the newly formed International Biomonitoring Network.

Results and Discussion

The NBN aims to develop and enhance biomonitoring science through the sharing of quality management practices and tools, technical assistance and training, and peer mentorship. The performance-based network allows for innovation and improvement in recruitment practices, questionnaire development, analytical technology, data analysis and communication. A network toolkit includes resources such as accreditation guidance, method validation templates, study participant recruitment strategies, human subjects review guidelines, examples of questions to be asked to study participants, data analysis practices, and model study participant reports. The toolkit can assist members through the pre-analytical, analytical, and post-analytical phases of a biomonitoring program. Updated technical guidance for laboratory biomonitoring programs, training videos on specimen collection and results reporting and CDC's biomonitoring specimen collection guidance are available to NBN members in the network resource center on the APHL website (www.aphl.org). Defined performance metrics are assessed annually to evaluate the efficacy and impact of the technical resources offered.

As of June 2021, 20 laboratories are NBN members (Figure 1). The network is currently exploring opportunities for greater network interaction through mentorship and twinning relationships. More experienced laboratories could volunteer to mentor laboratories who would benefit from that experience while honing their own training and technology transfer skills. Laboratory twinning is a concept that has been used internationally for capacity building, networking and to bring communities together (Mills et al., 2019). The NSC is considering a twinning program that would enable members to collaborate in a mutually beneficial way.

Harmonization of human biomonitoring data is exceptionally challenging given differences in individual program design, purpose, and approach (https://www.aphl.org/aboutAPHL/publications/Documents/EH-2020-NBN-Harmonization.pdf). Other programs domestically and internationally strive to harmonize biomonitoring measures by creating analytical centers of specialized excellence (Balshaw et al., 2017, Haines et al, 2017) or standardizing biomarkers and methodology (Hond et al., 2015, Schwendler et al, 2017). These strategies for data harmonization are customized to meet the objectives of the individual biomonitoring programs: surveillance vs targeted investigations, biomarkers common to multiple programs vs biomarkers specific to select jurisdictions, targeted assays vs non-targeted screening.

Data harmonization efforts are dependent upon rigorous quality management of all phases (pre-analytical, analytical, and post-analytical) of testing and data analysis. The NBN membership requires demonstrated capability through documented method

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validation, demonstration of technical competency, independent certification or accreditation (e.g., Clinical Laboratory Improvement Amendments (CLIA), College of American Pathologists (CAP), and International Organization for Standardization (ISO)), and successful participation in external quality assessment (EQA) programs at the concentrations expected in the target populations. EQA programs, such as those administered by the Centre de Toxicologie du Québec (CTQ, https://www.inspq.qc.ca/en/ctq/eqas) and the University of Erlangen-Nuremberg (http://www.g-equas.de/default.htm), allow for comparison of a laboratory's testing to a peer group of laboratories or a reference laboratory to assess method accuracy and estimate inter-laboratory bias. As novel analytes of concern emerge, there may be a lag time in the development and implementation of proficiency panels for these biomarkers. As an interim measure, network laboratories may consider alternate ways to demonstrate analytical proficiency such as comparing results obtained from the analysis of the same sample by different laboratories (APHL 2019b).

A significant challenge ahead for the nascent National Biomonitoring Network is to identify a national centralized data repository for state biomonitoring data. Complexities include establishing data standards, incorporating data from known exposed populations as well as population-based surveillance values, defining data access protocols and identifying resources to accomplish these tasks. The NBN began by evaluating existing data platforms such as CDC Environmental Public Health Tracking Network (Kearney et al., 2015), NIEHS Children's Health Exposure Analysis Resource (Balshaw et al, 2017) and Human Health Exposure Analysis Resource (https://www.niehs.nih.gov/research/supported/exposure/hhear/index.cfm), and the APHL Informatics Messaging Services (www.aimsplatform.com) to assess their suitability, limitations, and willingness to accept biomonitoring data. The assessment identified system gaps and resource requirements for implementation. A small pilot effort is planned to assess the practicality of a data lake, a storage repository where vast amounts of raw data are held in its native format until it is needed, for state biomonitoring results which integrate with available resources for data visualization, ideally producing a dashboard similar to the HBM4EU platform (https://www.hbm4eu.eu/eu-hbm-dashboard/).

The establishment and implementation of a National Biomonitoring Network are challenging and ambitious activities that are the culmination of work by many dedicated public health scientists and partners working collaboratively. As with any process that develops organically, from the ground up, diverse approaches and solutions exist. Vast differences in resources, staffing and support for biomonitoring projects have contributed to the diversity of practices in the implementation of biomonitoring programs across the states. By encouraging and facilitating discussions across professional disciplines and among states conducting biomonitoring studies, the NBN has developed tools for chemists, epidemiologists, toxicologists, and risk communication specialists to design biomonitoring studies and programs that are more comparable to one another. Broad stakeholder engagement that contributed diverse expertise and perspective was critical in the crafting of these tools. One of the most important outcomes of the interactions among NBN members has been the development of trusted relationships and mutual respect, the cornerstone of a strong network.

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Despite the progress made, work remains to be done. For example, the development of an NBN centralized national repository for state biomonitoring data will be a long-term effort requiring considerable allocation of time and resources. Also, besides strengthening relationships within the NBN, learning from, and collaborating with international biomonitoring networks can further shape the implementation and success of the NBN system. Additionally, strategies for the sustainability and continued growth of the network need to be assessed and a strategic plan developed.

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Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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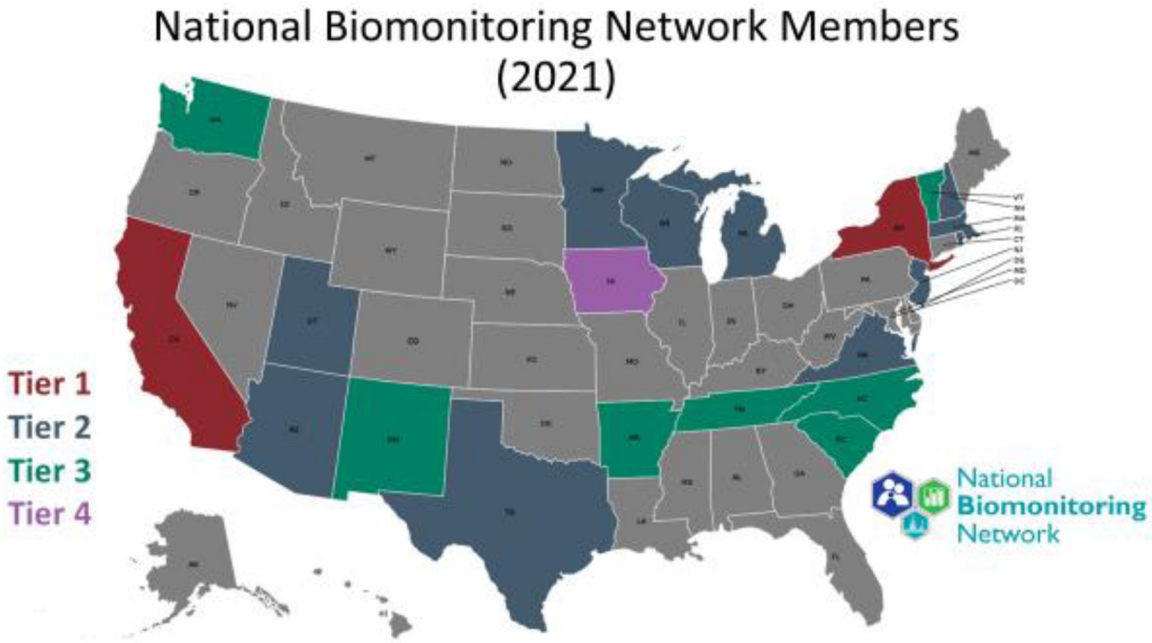

Figure 1. National Biomonitoring Network Member Laboratories

Tier 1

- Laboratories engaged in biomonitoring activities related to statistically representative population based surveillance, targeted investigations and emergency response.
- Demonstrated successful participation in an established quality assessment program.
- A well-established biomonitoring team integrated within the state public health system

Tier 2

- Laboratories engaged in biomonitoring activities related to targeted and emergency response.
- Demonstrated successful participation in an established quality assessment program.
- A well-established biomonitoring team integrated within the state public health system.

Tier 3

- Laboratories with biomonitoring capabilities and infrastructure but not actively conducting biomonitoring.
- Established implementation plan which includes a biomonitoring team integrated within the state public health system and a project timeline.

Tier 4

- Laboratories considering development of biomonitoring capabilities

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