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Recommendations for Biomonitoring of Emergency Responders: Focus on Occupational Health Investigations and Occupational Health Research

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Abstract

The disaster environment frequently presents rapidly evolving and unpredictable hazardous exposures to emergency responders. Improved estimates of exposure and effect from biomonitoring can be used to assess exposure–response relationships, potential health consequences, and effectiveness of control measures. Disaster settings, however, pose significant challenges for biomonitoring. A decision process for determining when to conduct biomonitoring during and following disasters was developed. Separate but overlapping decision processes were developed for biomonitoring performed as part of occupational health investigations that directly benefit emergency responders in the short term and for biomonitoring intended to support research studies. Two categories of factors critical to the decision process for biomonitoring were identified: Is biomonitoring appropriate for the intended purpose and is biomonitoring feasible under the circumstances of the emergency response? Factors within these categories include information needs, relevance, interpretability, ethics, methodology, and logistics. Biomonitoring of emergency responders can be a valuable tool for exposure and risk assessment. Information needs, relevance, and interpretability will largely determine if biomonitoring is appropriate; logistical factors will largely determine if biomonitoring is feasible. The decision process should be formalized and may benefit from advance planning.

INTRODUCTION

The disaster setting presents many challenges for protecting emergency responders, including prioritizing critical response activities, having limited access to incident

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leadership, marshaling necessary resources quickly and having timely situational awareness of important occupational safety and health events. The environment and conditions can be dynamic, frequently hazardous, and highly charged with competing demands, political pressures, and often with conflicting response strategies. The dynamic aspect of an emergency response may include fluctuations and changes in hazards and exposures. Protecting the health and safety of the emergency responders throughout all phases of an emergency response (i.e., preparedness, response, mitigation, and recovery) is an important component of any response. Exposure and risk assessment are critical activities in protecting the health and safety of emergency responders. As part of these assessments, questions about the need for biomonitoring often arise in disaster response.

Occupational health investigations in disaster settings focus strictly on the health and safety of the emergency responders and are under the control of the Incident Command. During disasters, the goal is to provide rapid, useful, and actionable information that will have a direct impact on the health and safety of emergency responders involved in response and recovery activities. These investigations are intended to determine the scope and burden of work activities, exposures, and risks, so that prevention can be implemented and determination of short- and long-term risk to emergency responders can be made. Occupational health investigations may involve site-specific investigations to assess individual or group exposure and health effects and may involve descriptive, analytic, applied, or exposure/disease-specific epidemiology. Occupational health investigations differ from clinical care in that health investigations are conducted when there is a concern about a workplace hazard. These investigations may evaluate an exposure or a health concern and are not necessarily conducted by clinicians, a physician–patient relationship is not necessarily established, and clinical care is not necessarily being provided. Biomonitoring may be used to evaluate an exposure or health concern and may or may not be diagnostic in nature. Occupational health investigations are also distinguished from occupational health research in this article.

Occupational health research related to disasters is intended to develop generalizable information[1] that addresses a specified scientific hypothesis or a set of hypotheses during or after a disaster. Hypotheses can be generated from health investigations, but also from data produced by surveillance and health monitoring or from information gaps identified in the published literature. This research may not provide immediate benefit to the emergency responders involved in the response or recovery, but may address important questions pertinent to future emergency response activities or risk assessments in general, such as potential health effects, exposure methodology, or exposure control strategies.

Exposure assessment is a critical component of occupational health investigations and occupational health research studies. Although this article generally focuses on chemical exposures, the framework could be applied to other types of exposure, including biological, physical, radiological, or psychological stressors. Chemicals can be measured in samples collected from various environmental media (i.e., air, water, or surfaces) to predict personal exposure. However, in some cases, the only way to evaluate personal exposure is to identify which chemicals have been absorbed into the body, the magnitude of chemicals absorbed, and their contribution to total body burden. This can sometimes be accomplished through

the use of biomarkers. Biomarkers have been defined by the National Academy of Sciences as measurable indicators in a biological system or organism, such as the presence of a chemical or its metabolite within biological specimens, measured alterations in structure or function, or identifiable genetic variations.[2] Three categories of biomarkers have been identified: exposure, effect, and susceptibility.[2,3] Some overlap in these categories is possible. For the most part, biomarkers of exposure provide a measure of body burden of a contaminant or its metabolite. Examples of biomarkers of exposure include blood lead, urinary cadmium, and serum dioxin.

Biomarkers of effect (also known as biomarkers of response) measure effects or responses in the body to an exposure. These changes may be early precursors of disease, specific clinical changes, or markers for clinical disease. An example of biomarkers of effect is the decline of blood levels of the enzyme acetyl cholinesterase (AChE) in persons exposed to organo-phosphate pesticides. The results of biomonitoring of blood AChE levels can be used to determine possible illness and treatment implications. Biomarkers of effect tend to be less specific than exposure markers, as a number of chemicals or agents may cause similar responses. For example, measuring blood AChE levels provides evidence of exposure to organo-phosphate pesticides, but does not identify the precise pesticide responsible for the decrease in blood enzyme.

Biomarkers of susceptibility indicate when an individual may be at increased or decreased risk for developing a disease after an exposure has occurred. Susceptibility biomarkers may also identify individuals whose body burden may be increased or decreased relative to other individuals because of differences in metabolic or other biological processes. Biomarkers of susceptibility, for example, could include the activity of the Cytochrome P450 2E1 (CYP2E1) enzyme as determined by genotyping studies that modify benzene toxicity.[4] Other factors also affect risk including lifestyle, genetics, health status, and diet.

This article limits the discussion of biomonitoring to the emergency response context. All three categories of biomarkers are likely to be used in disaster research studies. However, for occupational health investigations, some types of biomarkers have more utility than others. For example, susceptibility biomarkers are unlikely to be monitored in an initial emergency response unless there are predeployment evaluations of emergency responders. This type of biomarker has more utility in research studies to determine risk factors for potential health outcomes. Biomarkers of exposure would have the most utility in occupational health investigations as these markers measure body burden, whereas biomarkers of effect would be most useful when associated with a known health outcome.

A number of benefits may arise from conducting biomonitoring in an emergency response (Table I). Although most workplace exposures can be anticipated based on process or job conditions, emergency response often involves unexpected or unpredictable exposures making exposure and risk assessments difficult. Biomonitoring can augment environmental exposure assessment methods, such as personal breathing-zone air monitoring and surface sampling, and may determine the usefulness of these methods as surrogates for capturing the individual burden of exposure. If a substance has a sufficiently long half-life, biomonitoring can be used to estimate cumulative dose after repeated exposures and can help characterize

the contribution from multiple exposure routes (e.g., inhalation and dermal). Sampling of environmental media focuses on a single route.

Biomonitoring can be especially useful for assessing dermal exposure because (1) skin sampling methods are not readily available for many chemicals, (2) criteria or standards for comparison are not generally available, and (3) results do not provide information regarding the amount of chemical absorbed through the skin. Biomonitoring may also be useful in assessing the biological effects from breach or improper use of personal protective equipment (PPE) and may allow for comparing exposure/doses associated with different work practices.

Certain limitations may also affect the use of biomonitoring in emergency response (Table II). Limitations related to interpretation of results, communication, logistics, and method availability need to be considered. Exposures may not be specific to the incident, so attribution of body burden to the disaster may not always be possible. Because the presence of a chemical in the body does not necessarily indicate harm, results must be interpreted and communicated with care. Implementation of biomonitoring is contingent on successfully anticipating and fulfilling a variety of requirements, such as ensuring the protection of human subjects (including Institutional Review Board [IRB] approval), consideration of ethical issues, and obtaining other organizational approvals. Failure to anticipate these requirements can impair the ability to carry out the project, particularly when collection of biomonitoring specimens is time-sensitive.

The purpose of this article is to provide a decision framework on when to perform biomonitoring in an emergency response, either as part of a health investigation or for research purposes. Both the appropriateness and feasibility of biomonitoring during a disaster are key factors in the decision process and will be discussed in detail.

METHODS

Upon review of the response related to the Deepwater Horizon oil release, the National Institute for Occupational Safety and Health (NIOSH) identified multiple processes that could be improved to better ensure the safety and health of emergency responders, while still maintaining an effective and efficient response. A chief concern was the need for a systematic decision-making process to determine when biomonitoring should be initiated, both within the context of an occupational health investigation and for research initiatives.[5]

In response to this need, the NIOSH director convened a work group consisting of NIOSH scientists experienced with disaster response, biological monitoring, and risk assessment, representing the disciplines of toxicology, occupational medicine, and industrial hygiene. Drawing on direct experience from multiple large emergency/disaster responses, including terrorist attacks of September 11, 2001, anthrax events, severe acute respiratory syndrome, Hurricane Katrina, the H1N1 pandemic, and the Deepwater Horizon oil release, the work group collaborated to devise a comprehensive rationale for determining when to conduct biomonitoring in workers responding to a disaster.

An extensive literature search on biomonitoring during disaster/emergency response was performed in Medline (Ovid), Embase (Ovid), Health and Safety Science Abstracts, TOXLINE, Web of Science and OSH References Collection for articles between 2001 and 2011. Major search terms included, but were not limited to, chemical incident or disaster, emergency response, emergency responder, disaster planning, emergencies, biomonitoring, biomarker, and biological marker.

RESULTS

Use of Biomonitoring for Emergency Response: A Decision Process

Biomonitoring often provides valuable information not available through other means. However, certain factors must be considered when evaluating biomonitoring proposals in the disaster/emergency response setting and the importance of these factors varies depending on the purpose of the biomonitoring. Numerous practical and scientific challenges must be considered when evaluating whether biomonitoring can provide information in an emergency response setting that is unattainable by other means. As noted above, the goal of biomonitoring during an emergency response investigation is to provide actionable information that will have a direct impact on the health and safety of current emergency responders. A decision process was designed to provide occupational health and medical experts with a well-defined, logical framework for determining if biomonitoring should be conducted during an emergency response. The issues or factors within the decision process are categorized under two broad questions: (1) Is biomonitoring appropriate? and (2) Is biomonitoring feasible? Under each question are factors or issues to consider in determining if biomonitoring should be conducted (Table III).

Is Biomonitoring Appropriate?

Do Information Gaps Exist That Biomonitoring Can Address?—In disasters, information gaps should first be assessed to determine whether they are amenable to biomonitoring. If the information gap is related to work-site exposure, biomonitoring might provide direct and unambiguous demonstration of exposure, which could only be inferred by alternative monitoring methods. For example, an emergency response worker with considerable dermal exposure to a compound with low vapor pressure should be considered for biomonitoring because other methods of determining exposure will not provide useful exposure information for the individual. Biomonitoring is of particular importance when exposures occur through multiple routes (e.g., dermal and inhalation).

Biomonitoring also could improve decision-making about exposure controls, including the requirements for PPE, as well as remediation strategies. In other instances, biomonitoring may be used to evaluate the efficacy of initial control measures or PPE recommendations. At times, biomonitoring may be the only effective means of determining whether PPE or engineering controls are performing as expected. During the anthrax attacks in 2001, an immunochemical test for anthrax exposure was developed. This biomonitoring test was used to determine if remediation workers who took the anthrax vaccine were immunized and if PPE worn by unvaccinated remediation workers was sufficient.[6]

A key use of biomonitoring is to determine health risks at the individual and group levels. However, the ability to detect chemicals by biomonitoring has outpaced the ability to predict health risks based on their measured concentrations.[7] Where the information gap is related to potential future data interpretation, biomonitoring could provide important baseline exposure or effect information needed to assess future exposure or health data. For example, biomonitoring before exposure and postexposure may be able to establish whether exposure has occurred and whether health monitoring should be conducted postevent to evaluate potential long-term effects.

Will Biomonitoring Provide Information Directly Applicable to Emergency Responders/Remediation Workers Involved in the Ongoing Response?—This second consideration pertains directly to conducting occupational health investigations. It is important to determine whether information derived from biomonitoring would likely have a direct and immediate impact on the health and safety policies and procedures of an ongoing emergency response. This determination must consider whether the proposed biomonitoring activity will primarily support an investigation that will yield timely information related to current actions to protect emergency responders as opposed to a research study which would assess health impacts and actions to inform future emergency responses.

Given that biomonitoring in health investigations should directly impact emergency responders, it is possible to anticipate some of the health and safety issues likely to develop during a response that could be addressed by biomonitoring. Such issues include:

- Determining if a hazardous exposure (exposure of concern) has occurred or providing assurance if no significant exposures are occurring
- Quantifying exposure from all sources and routes (integrated exposure)
- Assessing the possibility of unanticipated health effects
- Clarifying the results of clinical testing
- Determining the adequacy of PPE and other control measures
- Clarifying whether a health effect may be related to an occupational exposure
- Using data for health monitoring or surveillance

These issues also can directly impact the safety and health policies and procedures for a given event. If a given body burden is associated with health effects, measures may need to be implemented to reduce or monitor exposures. Actions would include engineering controls, changes in work practices, use or changes in PPE, other administrative controls (i.e., temporary removal of worker) or increased frequency of health monitoring and/or health surveillance.

As an example of using biomonitoring during an emergency response, firefighters were called to the scene of a manufacturing facility because of an ill employee and concerns of a gas leak in the building.[8] Environmental monitoring instruments found elevated carbon monoxide (CO) levels, but could not identify the CO source. After evacuation of employees, fire-fighters quickly assessed the carboxyhemoglobin levels of employees through CO pulse

co-oximetry, and questioned them on their principal location in the plant that day. Employee location and carboxyhemoglobin results were mapped out, which then allowed firefighters to identify the CO source and implement mitigation measures.

Will Biomonitoring Provide Interpretable Results?—This third criterion is also most appropriately applied to occupational health investigations, as biomonitoring for research purposes may include biomarkers that are still being explored for their relationship to a health outcome. When conducting biomonitoring during an occupational health investigation, results of the biomonitoring should provide interpretable information relevant to the emergency responders, and have the potential to lead to control measures that could reduce exposure risk and improve emergency responder health.

For most chemicals of concern, health-based biomonitoring criteria do not exist. This leads to the question of interpretability or usefulness of results. A limited number of workplace exposure criteria based on toxicity or on health outcome or exposure levels have been calculated. For example, Biological Exposure Indices have been determined for some chemicals by the American Conference of Governmental Industrial Hygienists.[9] The German Commission has developed biological tolerance values, known as biologischer arbeitsstoff-toleranz-wert.[10] For certain chemicals, such as lead, cadmium, mercury, and CO, regulatory health-based action levels exist and are related to specific urinary or blood values associated with well-defined toxicity endpoints.[7,11,12] Under the European Registration, Evaluation and Authorisation and Restriction of Chemicals Program, establishment of derived, no-effect levels are an important component.[13] The concept of Biomonitoring Equivalents that represent safe or acceptable levels has also been recently developed using established reference values and toxicokinetic data.[14] Guidelines on risk communication issues related to Biomonitoring Equivalents have also been developed; these include issues related to confidence and uncertainties associated with the risk assessment.[15] Scheepers et al[16] defined levels of concern to be equivalent to Acute Exposure Guideline Level-2 to ensure that detected exposures were higher than background or occupational settings. In many chemical emergencies, exposures of concern are several fold higher than occupational exposure limits and usually exceed short-term exposure limits or immediately dangerous to life or health values.

Because biological exposure guidelines or standards have been set for so few chemicals, most often during an occupational health investigation no action levels or occupational exposure limit-based biological indices exist. Although the absence of specific standards or criteria increases the uncertainty as to the meaning of biomonitoring results, other approaches can be used to interpret or place biomonitoring results into context. For example, reference values (i.e., levels of certain chemicals within a defined “reference” group) may be helpful in interpreting the measured biomarker levels. Reference values may be obtained from sources such as the Centers for Disease Control and Prevention, National Health and Nutrition Examination Survey Program, and published research studies.[17] A limitation of using reference values is that levels found in a population from a specific geographic location do not necessarily represent levels in the underlying population from which the emergency responders were drawn. In addition, certain chemicals are likely to be detected in biological samples from nearly all people attributable to ubiquitous dietary and/or

environmental sources (i.e., background levels). These background levels need to be taken into consideration when interpreting biomonitoring data. Animal and human toxicity values found in the published literature may also be considered when biomonitoring criteria or reference values are unavailable. Often, information about no observed adverse effect levels (NOAELs) or lowest observed adverse effect levels (LOAELs) are available. NOAEL and LOAEL values, along with acute toxicity and pharmacokinetic data, can be used to interpret biological monitoring data.[18]

Conducting biomonitoring in an emergency response setting without biomonitoring interpretation criteria can be a complicating factor requiring expertise in biomonitoring and risk assessment communication. Conducting such risk assessments during the urgency of a response poses the possibility of developing a less detailed appraisal about the quality of the available literature, the applicability of health endpoints, etc., and therefore could be harder to defend in a politically charged atmosphere. Such risk assessments might therefore be preferably conducted in the context of a research study, where more in-depth consideration can be given to the complexities and interpretability of the biomarker in question.

Have Ethical Issues Been Identified, Vetted, and Evaluated?—Ethical issues pertinent to biomonitoring in a research setting are also applicable to biomonitoring in a health investigation.[19] The design of a biomonitoring study needs to take into account participant recruitment and informed consent. Privacy and confidentiality concerns need to be addressed. Risks and benefits need to be explained. The strategy for data handling, data analysis, interpretation, communication, and dissemination of the biomonitoring results to affected workers, comparison groups, and others are all issues of concern. In an emergency response, additional concerns may arise, such as a desire for all emergency responders to be included in a particular biomonitoring study, when only specific and targeted emergency responders are the focus. For example, tasks that place certain workers at higher potential exposures are selected for biomonitoring instead of those selected at random.

Clinicians who are asked to participate in a biomonitoring program, particular as part of an occupational health investigation, also need to be cognizant of the risks of not adhering to professional standards of care in situations where biomonitoring methods are less well established. Considerations for participation in such biomonitoring activities may include whether the physician will have a physician–patient relationship and will be providing medical care to the patient as part of the overall biomonitoring effort.

Is Biomonitoring Feasible?

Is There is a Validated Method for Biomonitoring?—The availability of a validated method is especially important for occupational health investigations where time is critical. During an emergency response, it is unlikely that sufficient time will be available to develop a biomonitoring method for an occupational health investigation. Some published methods might be quickly put into place in a laboratory setting with little to no modification, assuming that the method has been validated for the intended analytical matrix (blood, urine, etc.). If a biomonitoring method is available, analytical parameters, such as limit of detection, specificity, sensitivity, accuracy, and precision, need to be evaluated in the

context of the expected exposure to ensure that the method can detect the chemical at levels observed during the emergency. Often, the levels of exposure or potential interferences may not be known initially, but based on professional judgment, it may be possible to predict whether the selected biomonitoring method will have sufficient sensitivity and specificity for a biomarker of interest. It should be noted that a method being analytically valid does not presuppose that valid clinical information can be derived from the biomonitoring. When validated methods are not available, this may be the appropriate time to consider conducting biomonitoring research for the purpose of method development and validation.

Are There Significant Logistical Issues?—Health investigations and research can have similar logistical issues, although timeframes can differ in terms of funding acquisition, method development, and protocol development. Ideally, preplanning for emergency response activities should include the development of an exposure assessment protocol that considers the possibility of biomonitoring. Since not all exposures can be anticipated, the first step would be to modify the protocol to include the biomarker(s) of interest. The protocol would most likely need IRB approval and perhaps other organizational and Incident Command approvals. It may be possible in preplanning exercises to develop sections of the protocols to decrease the time needed for IRB approval. Political or legal implications may also need to be addressed, which could lead to delays in conducting biomonitoring. These and other logistical issues, some of which are common to any biomonitoring effort, are summarized in Table III.

Communicating Biomonitoring Efforts—Biomonitoring of emergency workers will require a risk communication component. Emergency response operations can include individuals with a variety of backgrounds, education levels, and languages. Furthermore, an emergency responder's ability to evaluate or recognize risk may be impaired, especially in stressful life-saving situations.[20] Many principles of effective crisis and emergency risk communication, including simplicity, credibility, and tailoring of messages[21] can be applied to appropriately inform emergency responders about biomonitoring efforts. When developing communications materials, it is important to address a number of issues, such as Why conducting biomonitoring is the correct decision, how investigators are collecting specimens, how investigators are ensuring privacy and confidentiality, how results will be used and by whom, and limitations of the biomonitoring and how those limitations apply to interpreting results and predicting future health outcomes. Communicating with emergency responders early can address their concerns, prevent rumors and misinformation, and improve the overall quality of the investigation. Considering the complexity of factors that affect results, significant attention should be given to the interpretation of findings. Emergency response environments are often chaotic and can sometimes span very large distances. Thus, it is important to develop strategies for disseminating information to emergency responders and maintaining contact with participants throughout the investigation. Pre-existing channels of communication developed as a part of the larger emergency response may provide effective means of distributing information and updates to the workers during the response.

DISCUSSION AND CONCLUSIONS

Our literature search identified few examples addressing specific considerations for biomonitoring in the emergency response setting. Most articles addressed the use of biomonitoring in the conduct of research. Notable examples were publications by the National Research Council and by Manno et al[22,23] Of the 115 articles identified, only one publication by Scheepers et al[16] attempted to develop a decision matrix for conducting biomonitoring during chemical releases. This article, primarily addressed general populations at risk, described a stepwise procedure that considered exposure, biomarkers and their half-lives, analytical methods, and feasibility of sampling times, but did not focus on the appropriateness of conducting biomonitoring for occupational health investigations directed at emergency responders. Another article described lessons-learned and recommendations from biomonitoring efforts initiated in the first Gulf War, Operation Desert Storm.[24] The National Biodefense Safety Board, an advisory committee to the Assistant Secretary of Preparedness and Response within the U.S. Department of Health and Human Services, recently engaged on the topic of inclusion of scientific investigations as a component of disaster planning, but their report did not specifically address biomonitoring.[25]

The approach in our article differs from the existing literature in that it focuses on biomonitoring of emergency responders and clearly delineates the differences in the decision process between health investigations and research studies. We further describe in detail the logistical and interpretability concerns of performing biomonitoring in the context of a disaster.

The various factors to consider for biomonitoring of emergency responders are summarized in Table III. Items under each question may be considered in a stepwise manner or concurrently. Addressing these factors will help ensure a careful, measured approach to the conduct of biomonitoring. Conversely, inability to adequately address these factors suggests that biomonitoring needs to be reconsidered, or should not proceed, particularly for the health investigation context. In these situations, the project may alternatively proceed in a research context, with the understanding that the results may not be actionable for current emergency responders.

The use of biomonitoring in health investigations (as opposed to its use in research studies) calls for different approaches, goals, and time frames. To develop an optimal biomonitoring strategy, the formation of a working group by organizations coordinating the conduct of science in disaster response is recommended for both health investigations and research. This working group would operate in the emergency response preplanning stage and during actual emergencies, and would integrate into existing Incident Command Systems. It should include experts in occupational health/medicine, industrial hygiene, toxicology, biomonitoring, epidemiology, chemistry, laboratory science, communication, and other specialty areas, as needed. In the preplanning stage, the work group would develop a framework for biomonitoring protocols and informed consent documents, which would then necessitate only minor modifications to the basic protocol and would help minimize delays in seeking IRB approval. Once an emergency response begins, the work group would then

evaluate the various factors listed in Table III with the objective of making a recommendation on whether to proceed with a biomonitoring effort. A recommendation would also be made on whether a potential biomonitoring effort should be conducted as part of a health investigation or research initiative context (or both). The work group will need to re-evaluate the need for biomonitoring as the response proceeds and more information becomes available. Logistical issues, such as those involved with collecting, shipping, and storing specimens could be considered as part of this decision process.

This decision process is designed to be used by occupational health and medical experts when considering biomonitoring during both occupational health investigations and research activities in the context of emergency response. The primary decision on whether to proceed with biomonitoring should begin with the decision on whether to conduct an occupational health investigation or a research study. Then, the factors critical in determining whether biomonitoring should proceed can be assessed based on the given decision process. Several conditions are provided that must be satisfied to determine whether a health investigation or research study is to be initiated. The recommended framework should ensure that biomonitoring will be scientifically sound, needed, and able to be justified in emergency response efforts.

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TABLE I

Benefits of Biomonitoring in Emergency Response

Benefits
Measures actual body burden
Augments other exposure monitoring tools
Captures all exposure routes, including dermal
May detect unexpected exposures or unexpected routes of exposure
Evaluates the effectiveness of control measures, including PPE
May provide biomarkers of potential health risks
Enhances individual or group risk assessments
Provides valuable information regarding risk communication to emergency responders, including reassurance in cases where exposure is insignificant

TABLE II

Limitations of Biomonitoring in Emergency Response

Limitations
Difficulty in interpreting exposure levels in terms of human risk
Absence of standards or reference values to evaluate risk
Biomonitoring methods may not be available
Difficulty in attributing exposures to the event because of confounding from nonevent exposures
Difficulty in communicating risk and uncertainties in the results
Complications from political pressures arising during a response
Delays related to approvals needed to conduct biomonitoring
Logistical difficulties in the disaster environment
Interference with life-saving activities or other critical response actions

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TABLE III

Biomonitoring Decision Matrices for Occupational Health Investigations and Research

	Occupational Health Investigations	Occupational Health Research
Is Biomonitoring Appropriate?	**(1) Establish whether information gaps exist that biomonitoring can address.**	**(1) Establish existing information gaps that biomonitoring can address.**
	Will biomonitoring help resolve information gaps?	Will biomonitoring help resolve information gaps?
	Will biomonitoring help determine exposures?	Will biomonitoring help determine exposures?
	Will biomonitoring help determine adverse health effects?	Will biomonitoring help determine adverse health effects?
	Is it likely that biomonitoring will inform decision making?	Could biomonitoring provide answers to questions about the effectiveness of workplace controls or PPE?
	Could biomonitoring provide answers to questions about the effectiveness of workplace controls or PPE?	
	(2) Determine whether biomonitoring will provide information that is directly applicable, relevant and actionable to emergency responders/remediation workers.	**(Not applicable to research)**
	Will biomonitoring have a direct impact on decision making?	
	Will biomonitoring provide information directly applicable to health and safety procedures?	
	Will biomonitoring results directly address or improve emergency responder health?	
	(3) Establish whether biomonitoring will provide interpretable results.	**(Not applicable or necessary for research)**
	Will the biomonitoring provide information to enable scientifically justified decisions?	
	Does the biomonitoring method have sufficient sensitivity and specificity?	
	Can a background level be identified that existed before the event? Is a reference range available?	
	Is a recognized exposure index or criterion available, or are literature data available to aid in the interpretation of the results?	
	Is sufficient information in humans or animals available to establish a relationship between biomonitoring results and either external levels, internal dose, or toxicity?	
	(4) Identify and evaluate ethical issues.	**(2) Identify and evaluate ethical issues.**
	Do ethical issues exist that would preclude biomonitoring?	Do ethical issues exist that would preclude biomonitoring?
	Are there ethical issues related to interpretation and communication of test results?	Are there issues related to interpretation and communication of test results?
Is Biomonitoring Feasible?	**(1) Establish whether there is a validated method for biomonitoring.**	**(Not applicable; the research itself could involve the development of a biomonitoring method.)**
	Is a published method available to conduct biomonitoring?	
	Does the sampling and analytical method provide reproducible and reliable results?	

	Occupational Health Investigations	Occupational Health Research
	Has the biomarker been evaluated and is it biologically relevant?	
	(2) Determine whether there are significant logistical issues.	**Determine whether there are logistical issues.**
	Can specimens be collected within the required timeframe following exposure?	Can specimens be collected within a sufficient timeframe?
	Is the specimen type feasible to be collected (i.e., relatively non-invasive/ burdensome)?	Is the specimen type feasible to collect (i.e., relatively non-invasive/ burdensome)?
	Does the time required to collect, ship and analyze the specimens fit the required timeframe?	Does the time required to collect, ship and analyze the specimens fit the required timeframe?
	Is the cost of specimen collection and analysis prohibitive?	Is the cost of specimen collection and analysis prohibitive?
	Do multiple specimens need to be collected for optimal interpretation, and if so, is this logistically feasible?	Do multiple specimens need to be collected for optimal interpretation, and if so, is this logistically feasible?
	Do other tests/assays need to be conducted to interpret the result (e.g., creatinine, specific gravity)?	Do other tests/assays need to be conducted to interpret the result (e.g., creatinine, specific gravity)?
	Have laboratories been identified with sufficient experience to perform the analysis within the required timeframe?	Have laboratories been identified with sufficient experience to perform the analysis within the required timeframe?
	Have sufficient personnel been identified to collect the specimens?	
	Does the specimen have any specialized collection, shipping or storage requirements?	Does the specimen have any specialized collection, shipping or storage requirements?
	Have the types of quality control samples been identified?	Have the types of quality control samples been identified?
	Can human IRB approval be obtained within the required timeframe?	Can IRB approval be obtained within the required timeframe?” Is the population accessible and are the Incident Command and workers willing to participate?
	“Is the population accessible and are the Incident Command and workers willing to participate?	