National Institute for Occupational Safety and Health Nanomaterials and Worker Health Conference—Medical Surveillance Session Summary Report

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Objectives: The goal of these sessions was to identify current practices and recommendations regarding medical surveillance for nanomaterial workers. **Methods:** Conference participants met in three discussion groups. **Results:** There were few existing programs directed to nanomaterial workers. Participants expressed a range of views, from feeling that comprehensive medical surveillance is important currently to suggesting that targeted medical surveillance will become important when more complete data are available to assess risks. **Conclusions:** Results of health outcomes research for ultrafine air pollution and toxicological information about specific nanomaterials should inform the design of medical surveillance programs. Groups with high exposures should be identified and targeted. Overall, because of uncertainties in the health effects of concern, investments in control measures, exposure assessment efforts, and exposure registries are currently most likely to be important prevention strategies.

In an effort to address questions about the appropriate role of medical surveillance in an overall preventive program for workers with nanomaterials, approximately 120 participants at the National Institute for Occupational Safety and Health conference broke up into three discussion groups after some presentations on this topic. The participants were diverse in terms of their primary discipline (eg, physicians, epidemiologists, and health and safety specialists), affiliation (eg, academic, consulting, public health, industry, and labor), region or country of origin, and their experience with health concerns related to nanomaterials. The following summary distills the feedback received in these breakout sessions. These breakout sessions were useful in brainstorming ideas and approaches and permitting some preliminary discussion. The statements that follow should not be construed to represent the viewpoints of all or most of the participants, but they do reflect opinions of some speakers.

CURRENT SITUATION

Of the participants' organizations, some were conducting general medical surveillance on employees, though this was not specific to potential health effects from nanomaterial exposures. Input from the groups suggested that represented organizations were not performing specific medical screening or surveillance, either directed primarily to nanomaterial exposures or with endpoints chosen because of concerns about particular nanomaterials.

One organization's representative reported that he and other members had a medical surveillance program directed, at least in part, to nanomaterial concerns, although it was not specific to nanomaterials. This representative noted that a requirement from their governmental funding agency drove this program. This surveillance included baseline examinations, including routine laboratory tests, and annual surveys. The annual surveys included job hazard questionnaires that would capture work with nanomaterials and some medical questions regarding pulmonary conditions that might result from nanoparticle exposures. Interestingly, detailed responses regarding the types of nanomaterials used were part of a separate industrial hygiene survey/database, which was not connected with the medical survey.

Similarly, many individuals who work with nanomaterials are enrolled in occupational health surveillance programs, which include annual medical history, pulmonary function tests, and, in some case, other tests, such as chest radiography, as a result of other aspects of their work and other hazardous exposures. In some countries, for example, Germany and Switzerland, occupational health surveillance is mandatory for all workers with at least annual examinations, although the focus is on general workplace exposures, not specifically on nanomaterial exposures.

Some organizations did exposure tracking only at this point (with no medical surveillance or screening component). This approach potentially permits future medical evaluation of exposed workers, should a hazard be identified.

IMPLICATIONS OF LIKELY EXPOSURES AND EXPOSURE DOCUMENTATION

Several participants provided a rationale for not conducting occupational health surveillance for nanomaterial workers based upon some evidence that the use of nanomaterials did not result in any exposure, largely because of engineering controls in place, the use of personal protective equipment, and/or knowledge regarding the physical form of materials (i.e., in solution or suspension). These participants did acknowledge that there is some uncertainty regarding the efficacy of controls, such as fume hoods, in preventing any exposures.

There was some agreement that careful documentation of potential exposures to nanomaterials with specificity as to type is essential and should be a part of the health record or accessible to occupational health professionals, permitting an awareness of potential exposures when evaluating workers. Business units in some organizations currently report some information about nanomaterials being handled in the workplaces, but the definition of which parameters (eg, size, shape, agglomeration, and coating) ideally need to be reported is unclear. A goal should be to have improved tracking of where nanomaterials are in use. Optimally, appropriate exposure

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The findings and conclusions in this report/presentation are those of the author(s) and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

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measurements should be conducted for potentially exposed workers. Ultimately, appropriate quantification of exposures, combined with adequate information about exposure–response relationships, is necessary for health risk assessment and to design appropriate targeted medical surveillance programs. Much of this information is not currently available. Some organizations reported that they use a control-banding approach, a method of estimating exposure and hazard, when precise exposure and hazard information is not available.

PROS AND CONS EXPRESSED REGARDING MEDICAL SURVEILLANCE FOR NANOMATERIALS CURRENTLY

Pros

- In the face of uncertainties, conduct of medical surveillance would be viewed as proactive and represent a commitment to employee health and safety.
- Conduct of medical surveillance may help to establish boundaries on the nature and occurrence of potential problems and uncertainty.
- Data collected may serve a risk management function.

Cons or Difficulties

- Medical surveillance may pose resource issues (cost, time involved, etc) for occupational health/environment, health, and safety programs.
- There is lack of clarity as to the health endpoints of concern, particularly in the medium and long term, making design of rational surveillance programs particularly challenging.
- While nonmalignant and malignant pulmonary conditions and certain cardiovascular conditions have been appropriately suggested as potential health effects of exposure to nanomaterials based on other scientific knowledge, such conditions would likely be common in the populations engaged in this work as they age, independent of nanomaterial exposures. There would be difficulties in sorting out the cause of any abnormalities identified through medical surveillance. Participants expressed concern related to separating abnormalities that might be related to nanoparticle exposures from those associated with nonoccupational (or other occupational) causes.
- Markers of physiological changes or health effects that may be related to nanomaterial exposure are nonspecific, with multiple potential causes. Similarly, markers of exposure or of inflammation may be affected by exposures to other small particles, such as ultrafine particles, for example, diesel exhaust. Confounding effects of other exposures need to be taken into account in designing surveillance schemes that attempt to evaluate short- and long-term effects of engineered nanoparticles.
- Concern was expressed regarding the use of medical screening tests, which subject workers to potential harm, such as computed tomographic scans with consequent radiation, or which generate data of uncertain significance, leaving the occupational health care professional and the worker without guidance as to the appropriate action in the face of a "positive" result. The cost of false-positive results, in terms of unnecessary anxiety and costs of follow-up tests, should be considered.
- Assessment of endpoints that may reflect potential central nervous system effects of exposures, if warranted, will likely raise employee concerns as to the kinds of information that should be collected in surveillance programs at baseline and throughout employment. Some of this information would likely be perceived as falling within the realm of mental health, with the attendant sensitivities to the collection and management of this kind of information.
- Medical surveillance may provide a false sense of security for employees, suggesting, perhaps incorrectly, that testing is sufficiently sensitive to detect all potential adverse health effects from nanomaterial exposures.

OTHER CONSIDERATIONS RELEVANT TO MEDICAL SURVEILLANCE FOR NANOMATERIAL EXPOSURES

Recognizing many data gaps regarding workplace exposures and likely health effects, some participants expressed concern that the expanding development, production, and the use of engineered nanomaterials could be considered a large and largely uncontrolled experiment, engaging increasing numbers of workers across the United States and the globe. This recognition suggests a need for proactive assessment and control of exposure and serious consideration of medical surveillance for potential health outcomes, especially when exposures may not be fully controlled.

It was pointed out that many workers, particularly those working for smaller employers, have no access to occupational health care services and are not currently participating in any form of medical surveillance. Exposure assessment is likely nonexistent in these settings as well. Discussions of the need for medical surveillance or registries need to take these workers into account. These underserved workers may, in fact, account for the largest number of potentially exposed workers, based on survey data presented at the conference.

There is likely a perception that the work environment is safe and free of risk among large segments of the nanomaterials workforce, particularly among those in research and development, who have available engineering controls and personal protective equipment. Such individuals will likely have little interest in participating in medical surveillance programs. Training programs that provide a strong rationale for participation in medical surveillance will be needed for these groups. Engaging the workforce, with a clear explanation of the potential risks and the levels of uncertainty, is essential to establishing meaningful surveillance programs and ensuring compliance with them. A partnership between those potentially exposed and those interested in assessing risk and outcome needs to be the context for work in this area.

The point was made that the legal status of health records needs to be carefully set out. Any connection between employer-collected records and larger state or national registries needs to be explicit with clear safeguards for confidentiality and job security. Confidentiality and privacy concerns that may arise, for example, with prolonged retention of data, problems in securing data, and appropriately limiting access to data, must be addressed.

Some participants felt that it is important, when designing medical surveillance programs, to avoid making assumptions about mechanisms of disease, dose–response relationships, and latency in an area of new and evolving exposures. Given the situation in the United States in which medical surveillance programs tend to end at the conclusion of employment, it was suggested that a European approach be considered, in which information about exposures/jobs and medical examination results is provided to employees leaving employment.

SUGGESTED APPROACHES

The experience with research regarding ambient air pollution and cardiovascular and pulmonary effects should inform the design of medical surveillance programs for nanomaterials. Similarly, toxicological information of concern about the adverse effects of specific types of nanomaterials, for example, carbon nanotubes, should be considered in the decision to initiate and design the medical surveillance programs. It was suggested that groups with high exposures be identified, based on air monitoring. Such groups could be initially targeted for medical surveillance.

Participants indicated that efforts to identify and test for appropriate markers for likely or known effects, for example, targeting certain inflammatory mediators, would be more promising

than untargeted general medical surveillance programs, for example, questionnaires and physical examinations. Some participants indicated that, when medical surveillance will be utilizing methods of unproven utility, sensitivity, and specificity, it should be done in a research mode with full, informed consent and appropriate oversight.

Generally, participants felt that efforts are warranted now to identify and contemporaneously document the salient features of work activities, work areas, types of nanomaterials used, and controls, ideally in a consistent and easily retrievable fashion across organizations. Such efforts will facilitate the conduct and interpretation of medical surveillance for groups of nanomaterial workers, whether it is initiated now or in the future. Moreover, these efforts will be of great value to any future implementation of exposure registries and epidemiologic studies.

Some participants suggested that surveillance of these populations of workers for morbidity and mortality patterns is essential. Observation of differences in rates or age of onset of certain conditions that may be plausibly connected to nanomaterial exposures may be informative, particularly if there is accompanying exposure information.

Many participants felt that investments in control measures, exposure assessment efforts, and exposure registries are likely to be more effective prevention strategies at this time than investments in medical surveillance and that these approaches should probably be of higher priority currently, especially if resources are limited.

