

General Principles of Medical Surveillance

Implications for Workers Potentially Exposed to Nanomaterials

Douglas B. Trout, MD, MHS

Objective: As potential occupational exposure to nanomaterials becomes more prevalent, it is important that the principles of medical surveillance be considered for workers in the nanotechnology industry. **Methods:** The principles of medical surveillance are reviewed to further the discussion of occupational health surveillance for workers exposed to nanomaterials. **Results:** Because of the rapid evolution of nanotechnology, information may not be available to make a well-informed determination of all factors needed to evaluate risk of health effects from occupational exposure to nanomaterials. **Conclusion:** Every workplace dealing with engineered nanomaterials should conduct hazard and exposure assessments as part of an overall surveillance needs assessment for nanotechnology workers. In workplaces where risk is felt to be present, or at least cannot be ruled out, initiation of medical surveillance is prudent to protect workers' health.

The principles of medical surveillance are an essential component of occupational health practice.¹⁻³ As the production of (and potential occupational exposure to) nanomaterials becomes more prevalent, it is important that these principles be considered for workers in the nanotechnology industry.

DEFINITIONS AND BACKGROUND

Occupational health surveillance is the ongoing systematic collection, analysis, and dissemination of exposure and health data on groups of workers for the purpose of preventing illness and injury. Occupational health surveillance can help to define the magnitude and scope of occupational health issues among groups of workers, with the ultimate goal of prevention; occupational surveillance data are used to guide efforts to improve worker safety and health and monitor trends over time. The general term *occupational health surveillance* includes hazard and medical surveillance. Although the focus here concerns medical surveillance, integration of hazard and medical surveillance is key to an effective occupational health surveillance program, and surveillance for disease or other health endpoints should not proceed without having a hazard surveillance program in place.⁴

The terms *medical surveillance* and *medical screening* have sometimes been used interchangeably (and sometimes inconsistently) in the past, and it is important to understand distinctions between these activities.⁵ *Medical surveillance* describes activities that target health events or a change in a biologic function of an exposed person or persons. A surveillance program involves recurrent longitudinal examinations and data analysis over time. *Medical screening* is a complementary activity, sometimes considered one form of medical surveillance, that is designed to detect early signs

of work-related illness by administering tests to apparently healthy persons in a cross-sectional approach.⁵ The term *medical monitoring* has been assigned different meanings in the past, but it is most appropriately seen as analogous to screening. Screening activities generally have a more clinical focus when compared to surveillance (the screened person may be directly treated in response to the screening test), but medical screening data, collected in a standardized manner, aggregated, and evaluated over time, can also be evaluated as a part of a surveillance program.

Both medical surveillance and screening are second lines of defense behind the implementation of engineering, administrative, and work practice controls (including personal protective equipment). Surveillance and screening activities should be seen as mechanisms that occupational health care professionals can use to determine whether the usual prevention activities in the hierarchy of occupational health controls are effective.⁶ Although both are the examples of secondary prevention, if the results of surveillance and screening efforts are extended to make interventions in the workplace, both may also represent primary prevention activities.

ELEMENTS OF A MEDICAL SURVEILLANCE PROGRAM

The elements of a medical surveillance program generally include the following:

1. Identification of the group(s) of workers for which surveillance or screening activities will be appropriate.
2. An initial medical examination and collection of medical and occupational histories.
3. Periodic medical examinations at regularly scheduled intervals, including specific medical screening tests when warranted.
4. More frequent and detailed medical examinations, as indicated on the basis of findings from these examinations.
5. Postincident examinations and medical screening after uncontrolled or nonroutine increases in exposures such as spills.
6. Ongoing data analyses to evaluate collected information for surveillance and/or screening purposes.
7. Worker training to recognize symptoms of exposure to a given hazard.
8. A written report of medical findings.
9. Employer actions in response to the identification of potential hazards and risks to health.

These elements are present in many surveillance programs currently in use, including those based on medical screening and surveillance recommendations from the National Institute for Occupational Safety and Health (NIOSH). General information concerning surveillance may be found at the NIOSH Web site: www.cdc.gov/niosh/topics/surveillance/. Examples of specific information from NIOSH related to surveillance can be found in resources devoted to specific hazards, such as coal mining (www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html). The Occupational Safety and Health Administration also places great emphasis on surveillance and screening. Mandatory and nonmandatory medical surveillance programs used by the Occupational Safety and Health Administration are

From the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Cincinnati, Ohio.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

Address correspondence to: Douglas B. Trout, MD, MHS, Associate Director for Science, DSHEFS, NIOSH, R-12, 4676 Columbia Parkway, Cincinnati, OH 45226; E-mail: dtrout@cdc.gov.

Copyright © 2011 by American College of Occupational and Environmental Medicine

DOI: 10.1097/JOM.0b013e31821b1e45

compiled at the following Web site: <http://www.osha.gov/SLTC/medicalseveillance/>.

OTHER CONSIDERATIONS FOR MEDICAL SURVEILLANCE PROGRAMS

Clear Definitions of Purpose and Availability of Tests/Tools

A medical surveillance program should have a clearly defined purpose/objective and a defined target population, and testing modalities must be available to accomplish the defined objective. Testing modalities may include such tools as questionnaires, physical examinations, and medical testing. These types of evaluations are used within the target population to gain data concerning specific organ system(s) and more general information concerning potential health effects or exposure. Consideration given to potential routes of exposure is a logical means of helping to target medical evaluations. For example, if the route of potential exposure is thought to be inhalation, the pulmonary system may be targeted for medical evaluation. When considering specific testing modalities, existing toxicity information about a given nanomaterial on a larger scale can provide a baseline for anticipating the possible adverse health effects that may occur from exposure to that same material on a nanoscale.

Test Characteristics

Data collected in a surveillance program should be interpreted with some knowledge of the characteristics of the tools being used. Typically, ideal medical screening tests have high sensitivity (the test is positive in a high percentage of persons with the disease). Nevertheless, tests with high sensitivity often have low specificity (some workers with positive test results are actually free of disease [false positives]). In interpreting nonspecific tests, a careful examination with attention to occupational as well as known nonoccupational factors is necessary. The positive predictive value of a test is also of particular importance and will be dependent on the prevalence of the condition being evaluated in the target population.

Ongoing Data Analysis

Those conducting medical surveillance and screening should understand the concepts of sentinel events^{4,7} and should be alert for unusual patterns of findings. In some instances, results of data analyses will alert practitioners to elevated rates of common diseases or common symptoms that warrant follow-up investigation. In other instances, data analyses will signal when a disease or illness occurs in excess or in a “cluster” in time and space. Expertise in epidemiologic principles is essential when analyzing and interpreting medical surveillance data and disease rates.^{3,8,9}

Availability of Intervention

The availability of effective interventions is an important consideration in establishing a medical surveillance or screening program. The importance and effectiveness of a medical surveillance or screening program may be assessed by determining whether it was successful in leading to interventions that could decrease disease or illness.

Communication

An effective medical surveillance or screening program will require communication with a number of individuals or groups. On the basis of the identified purpose of the program, a clear plan should be established for interpreting the results and presenting the findings to workers and management of the affected workplace(s) in a manner that avoids creating false anxiety or false assurance. An explanation of the level of uncertainty associated with measurements should be routinely included in presentations to workers and management.

Workers should be given a summary of the information in accordance with appropriate privacy and confidentiality protections.

Program Evaluation

An important part of any medical surveillance or screening program is assessing the overall program efficacy by evaluating the program in a number of ways. Quality assurance and control should be considered for all workplace sampling and medical testing. For medical tests, review or direct assessment of the laboratory's quality assurance procedures should be considered. Another component of program evaluation is assessing the appropriateness of the target populations. For example, for those workers at risk of exposure to nanomaterials, what percentage actually participated in the medical surveillance program? Conversely, how much excess testing was done on workers without specific risk factors warranting the testing?

Management, Coordination, and Integration With Other Programs

Hazard or medical surveillance or screening and its individual components will not provide for effective occupational health surveillance without coordination of all aspects by a program manager. The occupational health surveillance program manager has the duty of integrating the surveillance components and providing input to maximize the effectiveness of all aspects of the program.

CHALLENGES TO MEDICAL SURVEILLANCE/SCREENING OF NANOTECHNOLOGY WORKERS

A number of the elements of a standard medical surveillance program represent unique challenges when applied to surveillance for nanotechnology workers. Identification of workers potentially exposed to a hazardous substance, an important first step in the initiation of a surveillance program, may be challenging in the “field of nanotechnology.” A standard approach for the initiation of surveillance with known hazards (such as substances with a documented evidence base related to biomedical effects and an occupational exposure limit [OEL]) is to utilize the concept of an “action level,” which is some fraction of the OEL. Common practice has included triggering of various preventive actions such as a medical surveillance program based on worker exposure at or above the action level. Currently, in many situations, data concerning exposure are not available for properly assessing the need for medical surveillance or screening related to occupational exposure to nanomaterials. In the absence of OELs and attendant action levels for nanomaterials, medical surveillance for groups of potentially exposed workers should be considered on the basis of qualitative job hazard exposure analyses.⁸ In workplaces where risk (based on an assessment of the best-available information concerning hazard and exposure) is felt to be present, or at least cannot be ruled out, initiation of medical surveillance is prudent to protect workers' health. Such medical surveillance may consist, at a minimum, of collecting medical history information on a targeted population. A determination of whether medical surveillance is instituted, the components of the medical surveillance, and how frequently data are collected should be made on a workplace by workplace basis, influenced by the possible nature of the health effects associated with the nanomaterial, as derived from available information. When information concerning the degree of hazard associated with a nanomaterial is not known, as with many nanomaterials, various other approaches may need to be utilized—for example, by determining whether toxicity information exists for a similar type of nanomaterial or larger-scale particles of the same composition that can be used as a surrogate for triggering action.¹⁰ Periodic reassessment of hazard and exposure will be a critical part of this needs assessment for a medical surveillance program.

The lack of specific screening tests for exposure or health endpoints related to nanomaterial exposure is a second important challenge. The utility of nonspecific medical screening is limited, because the health endpoints that may be linked to nanomaterials are not well known or confirmed at this time. Nonetheless, general medical screening may serve as an early warning system for possible, yet to be determined, health effects linked to exposure. This determination will require that the data be continually analyzed on a group basis and, if possible, linked to exposure and compared to appropriate comparison population rates. The limitation of this approach is that it may identify health effects unrelated to nanomaterial exposure (and in some cases, false positives, which may require follow-up and further diagnostic evaluation). It may also give screened employees a false sense that such procedures would be sensitive to any health risk associated with exposure to nanomaterials.

Our ability to address these and other challenges will be improved as our knowledge related to occupational exposure to nanomaterials grows. Some of these challenges can be partially addressed in current worksites where workers are monitored through existing programs whether they work in areas with both regulated hazards (or hazards which may not be regulated but for which well-accepted medical monitoring procedures exist) and nanomaterials. For example, three such types of medical surveillance that may be occurring in a workplace include assessment of the worker's ability to wear or use required respiratory or other personal protective equipment, medical examinations pertaining to job placement, and medical examinations as part of emergency medical care after a work-related exposure or incident. Employers should continue using these established applications of medical surveillance as appropriate and keep in mind that analyses of these data in the future with respect to current nanomaterial exposure may provide useful information concerning health effects potentially related to exposure to those nanomaterials.

CONCLUSIONS

Application of the principles of medical surveillance is essential in creating appropriate occupational health surveillance programs to fit the needs of workers and organizations involved with nanotechnology. Every workplace dealing with nanomaterials should conduct hazard and exposure assessments as part of an overall

surveillance needs assessment for nanotechnology workers. In many situations currently, because of the rapid evolution of nanotechnology, information may not be available to make a well-informed determination of all the factors needed to evaluate risk of health effects from occupational exposure to nanomaterials. In workplaces where risk is felt to be present, or at least cannot be ruled out, initiation of medical surveillance is prudent to protect workers' health. Periodic modifications to any initial medical surveillance programs for nanotechnology workers are likely to be necessary, as the knowledge base relative to potential hazards of occupational exposure to nanomaterials grows.

REFERENCES

1. Halperin WE, Ratcliffe JM, Frazier JM, Wilson L, Becker SP, Schulte P. Medical screening in the workplace: proposed principles. *J Occup Med.* 1986;28:522–547.
2. Ashford NA, Spadafor CJ, Hattis DB, Caldort CC. *Monitoring the Worker for Exposure and Disease.* Baltimore, MD: The Johns Hopkins University Press; 1990.
3. Baker EL, Matte TP. Occupational health surveillance. In: Rosenstock L, Cullen M, Brodtkin CA, eds. *Textbook of Clinical Occupational and Environmental Medicine.* Philadelphia, PA: Elsevier Saunders Company; 2005:76–82.
4. Redlich CA, Froines J, Wegman D, Eisen E. Hazard surveillance in occupational disease. *Am J Public Health.* 1989;79:26–31.
5. Gochfeld M. Medical surveillance and screening in the workplace: complementary preventive strategies. *Environ Res.* 1992;59:67–80.
6. Halperin WE. The role of surveillance in the hierarchy of prevention. *Am J Ind Med.* 1996;29:321–323.
7. Rutstein D, Mullan R, Frazier T, Halperin W, Melius J, Sestitio J. Sentinel health events (occupational): a basis for physician recognition and public health surveillance. *Am J Public Health.* 1983;73:1054–1062.
8. Harber P, Conlon C, McCunney RJ. Occupational medical surveillance. In: McCunney RJ, ed. *A Practical Approach to Occupational and Environmental Medicine.* Philadelphia, PA: Lippincott, Williams, and Wilkins; 2003:582–599.
9. Sundin DS, Frazier TM. Hazard surveillance at NIOSH. *Am J Public Health.* 1989;79:31–37.
10. Kuempel ED, Geraci CL, Schulte PA. Risk assessment and research needs for nanomaterials: an examination of data and information from current studies. In: Simeonova PP, Opopol N, Luster MI, eds. *Nanotechnology—Toxicological Issues and Environmental Safety: Proceedings of the NATO Advanced Research Workshop on Nanotechnology—Toxicological Issues and Environmental Safety, Held in Varna, Bulgaria, 12–17 August 2006.* New York, NY: Springer; 2007: 119–145.