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Ethics and Principles in Medical Monitoring of Populations Exposed to Environmental Hazards

Michael Gochfeld, MD, PhD,

Department of Environmental and Occupational Medicine and Environmental and Occupational Health Sciences Institute, Consortium for Risk Evaluation With Stakeholder Participation, UMDNJ-Robert Wood Johnson Medical School, Piscataway, NJ

John D. Bogden, PhD, and

Department of Preventive Medicine and Community Health, UMDNJ-New Jersey Medical School, Newark, NJ

Donald B. Louria, MD

Department of Preventive Medicine and Community Health, UMDNJ-New Jersey Medical School, Newark, NJ

In this issue Wones et al.¹ describe a comprehensive medical monitoring program (MMP) for community residents in proximity to the Fernald facility, long operated for the Department of Energy as part of the nuclear weapons complex. The extensive contamination of the thousand acre Fernald facility has been remediated, though much of the contamination is confined in place, but the legacy of community exposure has weighed heavily on people's minds. The MMP described in this issue is a pioneering example of how such a program can operate and how it should be evaluated.

The principle underlying medical monitoring programs (MMP) for individuals or groups exposed to environmental contaminants is for early detection and correction of adverse health conditions or risk factors related to the exposure, thereby reducing the likelihood of premature morbidity, disability, or mortality. Medical monitoring programs can consist of a screening phase (one time assessment for all exposed) and a surveillance phase (longitudinal examinations for those with high level exposure)(see Ref 2 for discussion of definitions and semantics). Often people who have been exposed to hazardous substances or conditions in the home, community, or workplace environment, have been placed at increased risk of premature morbidity, disability or mortality. They seek legal redress that includes an MMP, so that medical monitoring can become a central part of a toxic tort case. Neighbors of contaminated sites, abandoned gas stations, and other environmental hazards, may have had years of hazardous exposure, often without knowing the exposure details, and early detection of diseases will be important. Courts vary greatly in how they handle claims for medical monitoring, screening or surveillance. Wones et al.¹ provide a detailed description of the Fernald MMP, one of the first and certainly the largest MMP for a community

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exposed to hazardous environmental contaminants. Moreover, theirs is the first publication of the results of such an MMP.

In this editorial, we articulate epidemiologic and ethical principles which clarify some of the challenging issues around MMPs, particularly for household or community exposures. Familiar scenarios include communities with drinking water contaminated by industrial solvents, vapor intrusion from underground plumes, or homes contaminated with gasoline from leaking underground tanks. In such cases of hazardous exposures, disease risk has increased, but the magnitude of risk may be difficult to estimate. In many cases, even in most published epidemiologic studies of toxic exposures in workplaces or communities, only a qualitative estimate of exposure such as “low”, “medium” or “high” can be constructed—even then with substantial uncertainty. The Fernald paper¹ provides an excellent example of the qualitative nature of exposure information, using distance from the source of exposure as a surrogate.

Usually by the time people become aware of their increased chemical or radiation risk, the exposure has already existed, perhaps for many years, and in some cases has ended some time in the past. The exposed people may have increased risk for more than one disease in more than one organ. With such historic exposures the risks can neither be erased nor always specifically quantified, and the outcomes may be sufficiently uncommon to render screening for them difficult. Nonetheless, in some legal cases, courts have required that medical monitoring be restricted to only those markers or endpoints specific to the exposure. We argue that this strict requirement is medically unsound, statistically invalid, and ethically indefensible.

Such restricted or targeted monitoring is characteristic of medical surveillance in the occupational setting (e.g. Mroz et al 2009)³, particularly where exposures are known and potentially ongoing. Outside of the workplace there are remarkably few publications describing how an MMP is planned or might work. There is a large scale monitoring program for workers responding to the 9/11 World Trade Center (WTC) attack,^{4,5} and many papers on medical surveillance of other occupational groups have been published.

Testing people only for the specific consequences of their known exposures can be difficult to design, costly to execute, and may entail secondary risks related to false negatives (unwarranted reassurance) or false positives (unwarranted confirmatory procedures and tests). In our view, it is also unethical to restrict MMPs to specific endpoints. People are whole organisms with inter-related organ systems and risk factors. Therefore an MMP that will truly benefit participants must be aimed at an overall reduction of premature morbidity, mortality, and disability by identifying correctible risk factors and disease conditions. Certainly an MMP must include a quest for specific markers or endpoints of toxic exposures, where appropriate, but it must also address those risk factors most commonly associated with premature morbidity, mortality and disability (for example smoking, obesity, hypertension, diabetes, and depression). This idea recognizes that even workers exposed for years to hazardous chemicals may be more likely to die from common degenerative chronic diseases (stroke, heart disease, other cancers) than from their specific exposures, although chemical exposures may hasten morbidity and mortality from these common causes. This

principle recognizes that some chemical exposures may render individuals more susceptible to those common diseases.

Where people have been placed at increased risk due to environmental contamination, their overall risk can be addressed beneficially as Wones et al. show.¹ Thus we consider it unethical for an MMP to look only for specific exposure-related outcomes, particularly where exposures cannot be corrected or undone. These people placed at increased risk, share more common risk factors that can be modified or eliminated by well-established approaches. And by addressing common risk factors, an MMP can compensate individuals for the excess specific risks from past exposures.

As a reminder, screening must be conducted in a context that takes into account sensitivity (the ability to find something that is there), specificity (the ability to not find something that is not there), and predictive value (if we find something how likely is it to be real and conversely if we don't find something how confident are we it is not there)(see Table 1). All this hinges on the underlying prevalence of whatever it is that we are looking for. In a chemical workplace, the probability that workers have been exposed to a chemical may be high (high prevalence of exposure). In a community where drinking water is contaminated, the prevalence of exposure is also likely to be great, however, in the same community, the prevalence of exposure to vapor intrusion from an underground plume may be more sporadic. The rarer the exposure (the lower its prevalence), the greater the likelihood that a positive screening test result will be a false positive (hence the lower the specificity and the lower the positive predictive value).

Even in a population that has had very high exposure to a highly hazardous substance, many individuals may not succumb. For example, cigarette smoking and lung cancer probably provides the most universally recognized environment-disease linkage, yet most smokers, even many heavy smokers, die of something other than lung cancer. Thus, even among smokers, the lifetime prevalence of lung cancer is about 10%. Hence screening for lung cancer, even with new technologies (spiral CT) and new therapies, is controversial,^{6,7} while radiation exposure risks of radiologic screening must be considered.⁸ However, including smokers in health promotion programs aimed at all their identifiable and controllable risk factors is more likely to be beneficial and will benefit all.

Therefore, a comprehensive MMP for smokers would entail focus on health outcomes other than lung cancer, for it is often the early signs or symptoms of a heart attack rather than a scary cough that persuades smokers to stop smoking. Thus a quest for the specific exposure-related outcome (lung cancer) makes sense when integrated into a comprehensive preventive program of risk factor recognition and reduction. Smokers who have good diets, engage in regular exercise, have lower serum cholesterol and LDL, monitor and control their blood pressure, and participate in recommended cancer screening programs, particularly those recognized by the U.S. Preventive Services Task Force,⁹ will live longer and be healthier than smokers who ignore these risk factors. And of course, such a program would address the smoking behavior itself. Our concept of how an MMP may improve health, even when the contaminant exposure cannot be undone, is shown in Figures 1a–1d.

As an example, underground solvent plumes, such as trichloroethylene (TCE) are common features around industrial sites. TCE is known to cause kidney and probably liver cancer.¹⁰ Volatile materials may penetrate upwards through the soil into buildings (vapor intrusion), allowing occupants to suffer long-term low-level exposure, perhaps producing an elevated cancer risk. Once this exposure pathway is discovered, interdiction may be difficult and costly; people may leave or stay; many will voice concerns about their current health and future health risk.¹¹ These people will benefit from an MMP which in addition to detecting early stages of cancer, addresses additional risk factors shared by many. An MMP targeted only to kidney cancer, will be less cost effective, than a comprehensive program which addresses risk factor identification and reduction for all exposed. Thus the residents who have suffered vapor intrusion exposure can all benefit from the comprehensive program.

Therefore we conclude and recommend that any MMP designed to protect people who have had significant exposure to a hazardous agent in their home, community, or workplace environment should address all common correctable risk factors. Participants placed at risk by an involuntary toxic exposure will benefit from a comprehensive program much more than from a program that only seeks the exposure-specific outcome(s).¹² Although such programs would be beneficial for anyone in the general public, including their doctors, lawyers, and judges, it becomes a specific and justified remedy for people who have been placed at increased risk of morbidity, mortality, and disability through an involuntary exposure to a hazardous substance or condition. Persons with disease detected at an early stage can be referred for appropriate treatment (usually outside the MMP). The complete risk-factor reduction program compensates the victim for the added risks they have accumulated due to their exposure. As in figure 1d it restores the hypothetical health and risk balance or in legal terminology, renders the person “whole”.

We also recommend that any MMP have an evaluation component funded as part of the budget. Wones et al. exemplify this.¹ This approach will allow a summary of risk factors, other exposures, and significant medical conditions identified, as well as periodic follow-up to track outcomes. Not all members of an exposed community will opt to participate in an MMP. In some cases the MMP will be part of a class action with an opt-in or opt-out provision. In some cases eligible persons may have the option of accepting a cash payment in lieu of participation. Those who do enter the MMP will not be a random sample of those actually exposed, but they will represent a population receptive to preventive medicine interventions, or as Wones et al. call them “healthy volunteers”.¹

Legal decisions that restrict medical monitoring recovery to the specific diseases caused by toxic exposures are too narrow, ignore the documented benefits of preventive medicine, and compromise health ethics, while denying exposed individuals the benefits of additional good healthful interventions. In such circumstances the ethical principles of beneficence, justice, and responsibility support the provision of a comprehensive MMP.

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b

C

d

Figure 1.

The combination of disease state (DZZ), lifestyle risk factors (LIFE), and environmental contaminant exposure (CONT) weigh down upon us as our body maintains a healthful balance between good health and bad. (Used by Permission © EOHHSI).

- a Shows a person at average risk, with relatively low weights for CONT, LIFE and DZZ, maintaining a balance between good health and bad health.
- b. The burden of excessive exposure to contamination tips the balance upwards towards high risk and bad health.
- c. Unhealthful lifestyles and disease enhance the risk. Tipping balance further upward.
- d A comprehensive medical monitoring program can identify early disease states that can be treated and modifiable risk factors that can be corrected, thereby restoring the person's risk to the average or baseline level, or making him "whole" in a legal sense.

TABLE 1

The relationship between true negatives and positives, false negatives and positives, and sensitivity, specificity and predictive value.(© EOHSI)

	Exposure low and risk NOT increased	Exposure high and/or risk increased	
Test NEGATIVE DOES NOT detect elevated exposure, risk or disease	TN=True Negative	FN=False Negative	Negative predictive value $NPV = TN / (TN + FN)$
Test POSITIVE, DOES DETECT elevated exposure, risk, or disease	FP=False Positive	TP=True Positive	Positive predictive value $PPV = TP / (TP + FP)$
	Specificity $TN / (TN + FP)$	Sensitivity $TP / (TP + FN)$	