

UNITED STATES DEPARTMENT OF LABOR

+ + + + +

ADVISORY BOARD ON TOXIC SUBSTANCES AND WORKER HEALTH

+ + + + +

SUBCOMMITTEE ON SITE EXPOSURE MATRICES (AREA #1)

+ + + + +

MEETING MINUTES

+ + + + +

MONDAY
JULY 11, 2016

+ + + + +

The Subcommittee met telephonically at 1:00 p.m.
Eastern Time, Laura Welch, Chair, presiding.

MEMBERS

SCIENTIFIC COMMUNITY:

JOHN M. DEMENT
MARK GRIFFON

MEDICAL COMMUNITY:

STEVEN MARKOWITZ
LAURA S. WELCH, Chair

CLAIMANT COMMUNITY:

KIRK D. DOMINA
GARRY M. WHITLEY

OTHER ADVISORY BOARD MEMBERS PRESENT:

FAYE VLIEGER

DESIGNATED FEDERAL OFFICIAL:

CARRIE RHOADS

Introductions and review of charge to the subcommittee

Ms. Rhoads opened the meeting at 1:05 p.m. The charge of the subcommittee is to advise the Department of Labor (DOL) on the Site Exposure Matrices (SEM). The Institute of Medicine has already done a review of the SEM. That review is available to the board. DOL has asked the board to provide policy guidance on links between exposure and disease. The areas are 1) policy guidance on linkages between toxins and occupational disease; 2) specific diseases for which the DOL wants guidance about causation; 3) how to modify the SEM to better convey information and help DOL set up priorities for contractors and adding new data to the SEM.

Defining issues and scope

The subcommittee toyed with the notion that they should change their name from the SEM Subcommittee to the Exposure Assessment Subcommittee. The subcommittee wants to look at the totality of the information that goes into the exposure assessment. The subcommittee should look at everything from the occupational history process to the process of obtaining that history and how the history is used in connection with the SEM for exposure assessment. The SEM also includes links to diseases. So, the subcommittee can go beyond exposure assessment to disease linkage as well. Member Domina pointed out that at the full board meeting, the board asked if it could have access to the version of the SEM used by claims examiners, not just the public SEM. There are also sites without SEMs. As far as getting disease-specific claims data, Ms. Rhoads said that DOL is still working on getting that information to the board.

Regarding the Procedure Manual, the subcommittee wanted to emphasize the probative value of information that may not be in the SEM as it relates to particular claims. There can be exposures reported by workers that are not in the SEM and those types of instances need to be looked at by the subcommittee. Subcommittee members want to look at a number of claims to see how things work and identify the various pieces that are used to construct exposures and the role of the personnel in using and interpreting information from start to end. The subcommittee must examine the totality of the process. If the subcommittee were to try to fix something related to the

common diagnoses, it would probably end up improving the process for all of the claims. The subcommittee would really like to see statistics on the kind of claims that are coming in and how many of those have been approved or denied.

Member Dement said the subcommittee should get the database on claims in its totality. With this database, the subcommittee can look at the frequency of acceptances and denials based on ICD codes. Then, stratified samples can be taken of the ones in the major categories. Some of the less common diseases that people make claims for should also be looked at. Member Griffon proposed taking stratified samples based on sites. Within a few weeks, and before the next full board meeting, the subcommittee hopes to request a certain number of de-identified claims to read. The goal of looking at a sample is to help the board understand how the claims process works, what is going into the assessment of the individual exposures and then the exposure/causation link. Additionally, the subcommittee wants to understand what data points exist within the claims. Ideally these claims could be examined before the next meeting on September 20th.

Chair Welch said that either the subcommittee could say that it wants to look at so many files of the top three diagnoses and so many files of the shorter list. Or, Chair Welch could choose some files once the spreadsheet becomes available. Or, once the data becomes available, Ms. Rhoads could send it to everyone and then individual subcommittee members could send Ms. Rhoads requests of what files they would like to review. Member Vlieger said it would be helpful if the entire subcommittee got a chance to look at the data. It's up to Ms. Rhoads to figure out how to pressure DOL to get the ICD code-specific data analysis of the claims. It was agreed that the subcommittee should move ahead on looking at presumptions.

The subcommittee will look at the same cases and select a representative number of Department of Energy (DOE) sites. A COPD case from Rocky Flats may look very different than one from Los Alamos. Some of the smaller sites do not have a SEM. Some of the claims that the subcommittee will look at should come from non-SEM sites. Member Dement said that the occupational histories appear to be very incomplete. There is very little information with regard to description of tasks performed during exposure. Member Vlieger said that the information one would expect workers to know about their exposures does not exist, and that regardless of what a worker

puts on the questionnaire, it is not considered probative. Member Vlieger stated that the only information that the DOL considers valid is what they pull from the SEM. Member Dement thought that it would be helpful if an occupational history could provide some cues with regard to the worker, as to the tasks that are known to increase the risk of intense exposure. Member Markowitz thought that it would be very ambitious to get high-quality information from people's memories about job tasks. It will be a challenging undertaking. As the subcommittee moves forward, it should think about making recommendations to DOL about how to improve the questionnaire.

Member Whitley thought that developing presumptions would be the most helpful step toward assisting the claims examiners. In order to get the right information out of a worker, the program would need interviewers who understand the particular sites and the processes that were used there. Even if a claimant does not meet the presumption, his case can be adjudicated based on more specific individual information. Member Vlieger said that at some point the subcommittee needs to address the fact that workers will describe exposures and the SEM describes exposures linked with those, and diseases linked with those exposures and the timeframe for when the exposures occurred. Member Domina said that sites often didn't monitor for certain exposures because those substances weren't considered hazards at the time or the site was in a Cold War effort.

Member Markowitz said that the presence or absence of monitoring data post-1995 is not going to be determinative of what needs to be done. Member Vlieger said that DOE did not provide DOL any exposure information for the post-1995 Toxic Exposure Circular. The subcommittee's recommendations as to how to improve exposure assessment is going to apply to the post-1995 exposures as well as to the pre-1995 exposures.

IOM Report

Chair Welch summarized the IOM report. DOL wanted IOM to focus on the link between exposure and disease in the SEM (which is derived from Haz-Map). IOM said that the Haz-Map was not meant to be used for the purpose of an establishing exposure/disease link as required by EEOICPA. Haz-Map and SEM do not handle complex mixtures or exposures well and Haz-Map is not very systematic. One point the report made was to urge incorporation of information from other sources beyond Haz-Map like the ATSDR Toxprofiles, data from EPA, IRIS, substance-specific reports

from the National Toxicology Program, and information specifically from the California EPA. The report stated that the functionality of SEM could be improved in several ways: 1) there are ways to improve the search option for a worker that worked at multiple sites; 2) introducing quality assurance into the SEM; 3) there should be an expert advisory panel for SEM. The IOM report makes a case for having exposure links in SEM be created by more than one person and that there be a transparent process and expert review of such links. There are some recommendations out of IOM that DOL said cannot be implemented. The subcommittee is going to ask DOL to make a presentation of what they have and have not implemented from the IOM report at the next full board meeting. However, what the totality of what IOM recommends goes beyond the scope of the Toxic Substances Board. The full board should decide what it can feasibly do and recommend a plan. Member Markowitz noted that the IOM recommendations encompass an immense set of tasks. The board needs to describe how the tasks can be accomplished, what resources are required, and what the structure should look like. The Veterans Administration has an advisory board that only focuses on Agent Orange, and the people on that board struggle with this single agent. The IOM report is talking about 17,000 chemicals. How to move forward in this daunting process is going to require a lot of thought.

Haz-Map may not be up to date on some cancers. In order to get into Haz-Map, causality for a cancer has to be in a textbook versus more contemporary literature. The subcommittee wants to look at what kind of delay there is between an excellent review coming out and when that information gets into SEM. DOL should have its own unit that monitors the literature or does some sort of expedited peer review with some supervision and then directly modifies its exposure/disease database so that it doesn't have to rely on Haz-Map. Having a disease link in the SEM is not enough unless there is also a presumption. In theory, a claimant could provide information that is not in the SEM, then that information could go to a contract medical consultant and they could award the claim based on their own review process. Member Whitley said that the subcommittee should review the training material that DOL provides to claims examiners and others: PowerPoints, written guidance, instructions, or procedures beyond those that are available on the website used by claims examiners, physicians, industrial hygienists, and whatever personnel process claims. Member Griffon agreed and said that it would be useful to look at the procedures claims examiners go through when assessing a claim.

Also, the subcommittee might want to think about the role of professional judgement and how DOL is assuring consistency in quality. Member Dement said that if the board does a dataset for Part E, he would like to get the description of the reasons for denial.

The subcommittee also wants to look at how DOL evolved toward using presumptions so that the board can understand DOL's thinking. If the board gets around to developing presumptions, there would need to be an outline for a peer-review process for doing that. Chair Welch said that she would work with Ms. Rhoads to get all the items from the DOL that the subcommittee has requested. The meeting was adjourned at 2:53 p.m.

I hereby certify that, to the best of my knowledge, the foregoing minutes are an accurate summary of the meeting.

Submitted by:



Laura S. Welch, MD
Chair, Subcommittee on the Site Exposure Matrices (SEM)
Advisory Board on Toxic Substances and Worker Health
Date: _____