Diana, Sherri A. (CDC/NIOSH/EID) (CTR)

From: McKernan, Lauralynn Taylor (CDC/NIOSH/EID)
Sent: Monday, November 21, 2011 12:56 PM
To: Diana, Sherri A. (CDC/NIOSH/EID) (CTR); Miller, Diane M. (CDC/NIOSH/EID)
Subject: FW: Brief comments on the NIOSH diacetyl criteria document

Importance: High

PLEASE ADD this email to the docket....

From: Mary C. Townsend, Dr.P.H. [mailto:mct@mctownsend.com]
Sent: Monday, November 21, 2011 12:55 PM
To: McKernan, Lauralynn Taylor (CDC/NIOSH/EID)
Subject: Brief comments on the NIOSH diacetyl criteria document
Importance: High

Lauralynn,
I have listed comments below that I made at your August public meeting as well including another comment or two. Please include these remarks in the NIOSH Diacetyl Criteria Document Docket.

1. FEV1s are distributed with constant variability around the predicted values as people age, so that a worker who remains at a constant position relative to his predicted value (e.g., 1 L below it) will have an FEV1 %pred that gets smaller as he ages since the denominator of this index gets smaller. Therefore, for risk analysis, FEV1 % of pred does not fully remove the effect of age, and if you have independent variables that are time-related, use of %pred may exaggerate the impact of those variables if the age range is big. If all workers are about the same age, the impact will be negligible. I would recommend using deviation from the NHANES FEV1 predicted value as your dependent variable, which will remove the effects of age as well as height, sex, and ethnicity so that you don't need to consider those variables in your model. I would think that at least verifying the conclusions of your analyses using this alternative approach is a good idea.

2. If you have a number of non-smokers, I would perform the risk analysis for that group alone and then for all smoking statuses combined using a dummy variable for smoking status. The thing that has struck me about diacetyl exposure-related cases is that a high number of them have occurred in non-smokers - this is unusual in the occupational setting and means that you don't need to worry about any part of the effect in those workers being caused by the big personal exposure - smoking.

3. You may be doing this already, but I would limit the definitive risk analyses to spirometry measurements performed by NIOSH techs using volume spirometers which are routinely leak-tested and cal-checked since the data are pretty reliable, particularly when compared with non-NIOSH clinic measurements. Spirometries performed by clinics and contractors may suffer from poor technique, but also (and perhaps more insidiously) from varying spirometer configurations (e.g. some older software versions rate tests as acceptable when the repeatability is 0.25 L, which will likely allow sub-maximal inspirations to be accepted as valid) and end-of-test criteria. Some spirometers also have FEV6 settings which you must be certain are not used while testing is conducted since expirations will not proceed to the FVC with those settings.

The end-of test criteria will impact the ratios (falsely making them too large and "non-obstructed" since the FVC will be under-recorded.) None of these concerns are present when NIOSH's teams of well-trained techs go out to do spirometry using their well-maintained volume spirometers - however, it would be wise to investigate all of these issues if you plan to put much weight on non-NIOSH measurements. Since the need for accuracy is great in performing these risk analyses and you have the luxury of having many tests performed by NIOSH teams, I also would not use results from non-NIOSH testing unless I was able to review the graphs generated by non-NIOSH sources.

Thanks for accepting these comments and good luck with this important project.

Best regards,

Mary C. Townsend, Dr.P.H.
M.C. Townsend Associates, LLC

289 Park Entrance Drive
Pittsburgh, PA 15228
412/343-9946
Fax: 412/343-9947
Cell (only when traveling): 412/680-1107
Web page: http://www.mctownsend.com