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Re: Review of Current Intelligence Bulletin

Dear Dr. Weston,

Thank you for the opportunity to review the Current Intelligence Bulletin: A review of information published since 1995 on coal mine dust exposures and associated health outcome. Please see my comments on the review form below.

With greatest respect,

Review of Current Intelligence Bulletin: A review of information published since 1995 on coal mine dust exposures and associated health outcomes

By way of introduction I would like to commend NIOSH on taking the time and investing the effort to produce this bulletin at this crucial time. We have witnessed a significant resurgence of disease related to exposure to coal mine dust which has created impetus for a redesign of dust control regulations. This review of the scientific literature on the health effects of coal mine dust exposures will be of great use, and is quite timely.

1) Assessment of whether the Current Intelligence Bulletin has fully included all relevant material in its evaluation that is pursuant to its aims

I believe the current intelligence bulletin has included the vast majority of all materials relevant to the questions that have been asked – were the conclusions of the CCD supported and confirmed by the medical literature published since 1995.

Since this review was published, an additional article – Wade et. al. [<http://chestjournal.chestpubs.org/content/early/2010/09/28/chest.10-1326>] has been published in Chest and I believe should be included in the review as it supports the surveillance information showing increased rates of PMF.

In addition there has been more information published about diffuse interstitial fibrosis resulting from exposure to coal mine dust. This was not touched on in the review, perhaps because there is no good surveillance data on the prevalence of this form of coal worker's pneumoconiosis. Consideration might be given to mentioning this as a small sentence or two as another manifestation of CWP under the section: "Other Respiratory Disease Outcomes". Two articles by A. Brichet [Rev Mal Respir 1997; 14:227-285, and Sarcoidosis Vasc Diffuse Lung Dis 2002; 19:211-219 as well as a more broad discussion of environmental interstitial fibrosis, Taskar VS et. al. [Proc Am Thorac Soc 2006; 3:293-298] have described this.

There has been other information on the health effects of dust – particularly silica in causing lung cancer that while interesting do not add to the discussion of whether or not the recommendations of the CCD have been supported. The data comes from other silica exposed work forces and not necessarily coal miners. [For example Finklestein, M.M. et. al. Am J. Ind. Med. 2000:38:8-18, Lacasse Y, Martin S, Gagné D, Lakhil L. Dose-response meta-analysis of silica and lung cancer. Cancer Causes Control. 2009 Aug;20(6):925-33.]

2) Evaluation of whether the presentation and summarization of that material is fair and unbiased

I believe the presentation to be quite fair and exhibits no bias, rather is a dispassionate discussion of the recent medical literature. It has been performed in a scholarly fashion and is quite comprehensive.

3) Determination of whether the overall conclusions are accurate and supportable, including those relating to support for the 1995 conclusions and recommendations

I believe that the body of evidence presented in the update, in addition to the evidence summarized, particularly in Chapter 4 of the CCD strongly support the 1995 conclusions and recommendations. It is clear from the data presented in the update, that miners working entirely under the current dust control standards, are developing a higher prevalence of disease, as well as advanced disease, and rapidly progressive disease. In addition they are continuing to develop lung function impairment, emphysema, and high prevalence of respiratory symptoms.

These findings as documented quite nicely in the update add significant support, and in my opinion a sense of urgency to the recommendations.

4) Evaluation of whether the organization and format of the material as presented is satisfactory for the intended purpose

The information is very well organized into relevant sections.

One suggestion is consideration of re-stating the core recommendations of the 1995 Criteria Document explicitly, or at least a general summary of the most important recommendations including:

- 1) 1 mg/m³ standard for 10 hour day, 40 hour week TWA for respirable coal mine dust
- 2) .05mg/m³ standard for 10 hour day, 40 hour week TWA – for respirable silica
- 3) Adding spirometry to medical surveillance for coal workers
- 4) Adding respiratory questionnaire and occupational history questionnaire.
- 5) Including surface miners

5) Other comments you might have:

I have reviewed the public comments submitted by 2 individuals during the public comment period. I would like to respond to those comments briefly.

- 1) Comments by Dr. James L. Weeks.

I agree with Dr. Weeks that the inclusion of spirometry as an essential component of the diagnosis of COPD is necessary. I would update the reference that he gave to use the GOLD COPD document of 2009. "A clinical diagnosis of COPD should be considered in any patient who has dyspnea, chronic cough, or sputum production, and/or a history of exposure to risk factors for the disease. The diagnosis should be confirmed by spirometry." Page 33. [Global Initiative For Chronic Obstructive Lung Disease. Updated 2009.

I think Dr. Weeks' other suggestions are quite useful.

- 2) Comments by Bruce Watzman, NMA.

- 1) Need for IQA (Information Quality Act) peer review: This appears to be a legal/regulatory argument which is questioning the process by which NIOSH peer reviews its bulletins and documents and asserts that this document cannot be published without a separate peer review process including the OMB's Bulletin for Peer Review.

I am not qualified to render a legal opinion as to whether or not the NIOSH process is appropriate, however I would note that this document is not presenting new data that has yet to undergo peer review. Instead, this article is a review of data that has been extensively peer reviewed and published in the medical literature since 1995. There is no reference to any data or studies that have not been peer reviewed internally in NIOSH and externally prior to publication as full manuscripts in peer reviewed journal.

There is one exception to this and that is reference #24 which is data that is to be presented at his year's APHA conference. Consideration may be given to removing this reference from the update since the data has not been reviewed and published in manuscript form.

2) Watzman then goes on to criticize the 1995 criteria document, stating that it relied on pre 1972 data. He also states that there was little data on lung function and COPD from the post 1972 era, thus questioning its validity. This is incorrect, and not relevant to the current update as well. The 1995 CCD did include data from NSCWP after 1972 as well as much other later data. These data formed the main foundation of the document's arguments. Clearly data from before this time was discussed as it does inform our understanding of the health effects of coal mine dust.

Watzman makes several generalities regarding the 1995 CCD including stating that there was poor control of smoking histories in the COPD studies and that research relied upon in the CCD was challenged by "some" as having poor designs. He does not refer to any published critiques of the CCD or allege that the data was not appropriately peer reviewed.

I do not think these comments are particularly relevant to the current document, other than to criticize the original CCD and its conclusions, undermining the basis for affirming those conclusions.

Watzman then moves on criticize the Surveillance Data – Section 2.1 of the update. He seems to question the NIOSH surveillance data showing an increase in the prevalence of CWP. He ignores the plateau in CWP prevalence first reported in 2003 (as well as concerning increases in some subsets of miners). He then attributes subsequent reports of increases in prevalence to the focused enhanced surveillance program. This criticism was explicitly and convincingly discussed in the update. There was a detailed discussion of this bias in the update which essentially rules out an upward bias. He is also not convinced by the author's discussion of weighting state specific prevalence of disease by participation rates, but does not state why. He also seems to discount or ignore the entire issue of hotspots of rapidly progressive and severe disease which were uncovered as part of the enhanced surveillance program.

Mr. Watzman also criticizes the reported increases in prevalence of CWP reported from CWXSP and the enhanced program because the populations are self selected, however the methodology of the regular program did not change and there is no data to support the notion that the population would change their pattern of self selection.

Mr. Watzman questions the data showing an increase in the prevalence of PMF, stating that it is often misdiagnosed, however there is no reason to assume that the rate of misdiagnosis would somehow be changing among the panel of NIOSH B-readers. There is also no evidence that the pattern of self selection of less healthy miners would somehow change as well. In addition, a targeted program only

means that the geographic areas were targeted, not those sicker miners were somehow targeted thereby falsely elevating the prevalence of this disease.

In addition, examination of other data sources – such as the west Virginia OP data [See Wade et al. <http://chestjournal.chestpubs.org/content/early/2010/09/28/chest.10-1326>], have confirmed the findings in the NIOSH surveillance data.

Watzman also criticizes the YPPL due to the unreliability of death certificate data. He cites the propensity of authors of death certificates to note black lung in order to help black lung claims, however this tendency would not be expected to have changed recently, and therefore the trend would not be affected.

Watzman finally makes broad criticisms of the data in the update relating coal mine dust to COPD. He incorrectly states that the articles in this section were not peer reviewed when they were and notes that there have been “critics” of these studies, however there are no citations to published data contradicting these findings.

Watzman concludes by reiterating his concerns that the document be peer reviewed by the IQA process noted above.

In summary, I am not persuaded that Watzman has raised any significant issues related to the quality of the articles reviewed and included in this update. He has not identified any peer-reviewed literature that was not included in this review, has not cited any literature which has been published which contradicts the conclusions of the articles in this review or is a valid criticism of the published literature.

There is only one reference that I noted that has not been published as a full peer reviewed manuscript, but has been peer reviewed for presentation at the APHA meetings.

In order to avoid any criticism in this regard, removing this reference may be expedient.

Editorial Comments:

Page 9 last paragraph, second to last sentence – I would recommend using the following, “This type of opacity is a radiographic manifestation of nodules in the lung having a typology often *associated* with excessive exposure to silica dust. (rather than arising from).

Page 10 – consider eliminating reference 24.