Miller, Diane M. (CDC/NIOSH/EID)

From: Ross, Robert M [rross@bcm.edu]
Sent: Saturday, March 05, 2011 1:05 PM
To: NIOSH Docket Office (CDC)
Subject: 215 - NIOSH Guideline: Application of Digital Radiography for the Detection and Classification of Pneumoconiosis

I would like to compliment you on your work for the new NIOSH guidelines. It is well researched and I understand its intent. Further, I recognize that you mention under "Objective" that "The Guideline should not be considered a mandate for medical practice". However, as the document stands, I have significant reservations unless this comment is strengthened to make it clear that digital radiographs on CD or film are essentially no different than analog radiographs. There may be variability in technical quality and image display. NIOSH is providing some guidelines. However, the ultimate decision as to the value of the image for interpretation for pneumoconiosis according to the ILO scale should be left to the b-reader. These Guidelines should not be used to exclude readings or readers without the specified equipment.

I am a Board Certified Pulmonary physician and a NIOSH Certified B-Reader and have been for many years. I have been actively involved in assessing people for pneumoconiosis and have assessed many thousands of radiographs in accordance with the ILO classification system. I have also had an article published in CHEST in 2003 which looked into the sensitivity, specificity and positive predictive value of a chest radiograph compatible with asbestosis according to the ILO scale. I believe I have a good, "real world" understanding of the strengths and weakness of the system for evaluating pneumoconiosis.

I understand that a major purpose of the ILO system is to create uniformity in the interpretation of workers' chest radiographs. However, another critical purpose is to determine if an individual actually has (or is likely to have) pneumoconiosis. For many years the radiographs were analog radiographs printed on film. These radiographs were taken by many different technicians and x-ray equipment. The resulting radiographs did not have identical "technique", either one to another, among groups or compared to the ILO standards. However, B-readers were aware of this and took these factors into account when evaluating individual or serial radiographs. Further, many x-rays were taken by treating physicians for various reasons. These, also often provide useful information for determining if there is radiographic evidence of pneumoconiosis. They have also been used for ILO interpretation where possible. The ILO has allowed interpreters to take these factors into account by grading them 1-3 or unreadable. This is a simple but effective approach. Lastly, for several years now digital radiographs have been available on film or CD. These also have been assessed in an "ILO-like" manner.

I am concerned about codifying a specific method how digital radiographs must be taken and particularly how the images must be displayed for interpretation. Although I understand the purpose is to create as uniform conditions as possible in order to minimize any differences due to technical factors, this approach has many drawbacks. These include:

- New advances cannot be foreseen and will not comply.
- Radiographs taken under different conditions may be of good quality but could be excluded for ILO evaluation.
- Many physicians may not be able to obtain the hardware configurations required.
- Physicians already have extensive experience using their monitors or view boxes in interpreting analog and digital radiographs for evaluation of pneumoconiosis according to the ILO standards. The B-readers have proven their competency by passing the examination.
- The purpose of assessing a chest radiograph for profusion is not to determine how much "gray" is present. It is for a skilled physician to determine if the radiograph shows parenchymal

abnormalities consistent with pneumoconiosis. It is unnecessary for all radiographs to be technically identical. Efforts to do this such as these "Guides" creates unnecessary "overhead" and limits the usefulness of the system to the detriment of those it is trying to serve.

I suggest the following:

- What you have proposed is fine to use as an example of how to apply digital radiography for the detection and classification of pneumoconiosis but do not make it a requirement.
- Instead add introductory sentences such as "A good quality digital chest radiograph should be utilized for screening for pneumoconiosis such as produced by the radiology departments of an American Hospital Association accredited (or professionally accredited) hospital. The following is an example." This will allow any facility with good quality clinical digital radiographic equipment to be used. It will also keep the document useful as technology improves.
- Similarly, for Image display do not require specific standards but recommend that good quality monitors be used and that if the monitor or digital image has factors that limit interpretation that be considered when scoring the technical quality 1-3 or unreadable. Remember, this is what has to occur anyway with transparencies that have been acquired using digital systems and printed for display on a traditional view box.

As you rightfully point out, the essential elements of the ILO system are reader competency and commitment to ethical classification. These elements cannot be codified. The determination of proper image collection, radiographic reading methods and viewing follow from competency and ethics. If the B-reader feels the radiograph is ILO interpretable, he or she should interpret it and classify its quality 1-3 or unreadable in accordance with the existing ILO scheme. We do not want to add bureaucracy that increases overhead and that limits readers and worthwhile radiographs. A more flexible system will help assure that the NIOSH/ILO program serves the welfare and best interests of the patients, workers and society in an efficient, effective manner.

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