Digital X-ray Imaging in Pneumoconiosis Screening: Future Challenges for the NIOSH B Reader Program

Commissioned Paper

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INTRODUCTION/OVERVIEW

Pneumoconiosis can be defined as the accumulation of inorganic dusts in the lungs and tissue reaction to their presence (1). Pneumoconioses are a major occupational health problem, and standard posterior-anterior (PA) film-screen chest radiography (FSR) is the leading method for screening, diagnosing, medical monitoring, and epidemiological study of pneumoconioses (2, 3). The most widely used system for classifying the abnormalities on chest radiographs due to inhalation of pathogenic dusts (e.g., asbestos, silica, and coal) is promulgated by the International Labour Organization (ILO) (4). In the United States, the National Institute for Occupational Safety and Health (NIOSH) manages the B reader program, a program that certifies physicians in the application of the ILO system for classifying chest radiographs.

Chest radiography constitutes up to 40% of conventional radiographs in many departments (5). During the last two decades, many medical centers have introduced digital x-ray imaging into clinical practice. The 'market penetration' of digital x-ray imaging has progressed to the point that in many centers it has become the 'standard,' and it has become difficult to obtain traditional FSRs. It is anticipated that this trend will continue. The widespread adoption of digital x-ray technology has numerous implications for NIOSH and the B reader program. For example, because there are limited data to indicate whether digital x-ray imaging is equivalent to FSR in identification and quantification of radiographic findings due to interstitial fibrosis, and pleural abnormalities (e.g., thickening, plaques, and/or calcification), digital x-ray imaging currently is not used widely in studies of interstitial lung disease due to pneumoconiosis such as the NIOSH-sponsored coal workers' pneumoconiosis surveillance program (3). This paper is intended to provide an overview of what is known about digital x-ray imaging with respect to interstitial lung disease, specifically pneumoconiosis and the ILO system, and to outline the challenges and opportunities that the advent of digital x-ray imaging presents to NIOSH in the future management and direction of the B reader program.

BACKGROUND

Since the early decades of the 20th century, standard PA chest radiography (FSR) has been the primary method for screening, diagnosis, medical monitoring and epidemiological study of pneumoconioses. In the 1930s, the ILO, based in Geneva, Switzerland, became involved in the development and evolution of a system for standardizing the classification of radiographs for pneumoconioses (6). The system has undergone a number of revisions, most recently in 2000. (7) The ILO system remains the most widely used method for scoring chest radiographs for pleural and parenchymal abnormalities related to inhalation of dusts (2, 4).

The ILO scheme is designed to allow for the classification of the appearance of PA radiographs, based on a comparison with 'standard' radiographs and written instructions. The system classifies the size, shape, and location of small and large parenchymal opacities and ordinal ranking of the profusion of such opacities in the lung zones. The ranking system for small opacities is comprised of 4 major categories (“0”, or normal, and “1,” “2,” and “3,” representing increasingly severe disease), which are each further divided into three ordered subcategories, resulting in a 12-point ordinal scale. Pleural abnormalities are graded according to location, thickness, extent, and calcifications (if any).

Beginning with the passage of the Federal Coal Mine Health and Safety Act in 1969, workers at underground coal mines in the United States have been eligible for periodic chest radiographs via the Coal Workers’ X-ray Surveillance Program. These radiographs have been interpreted according to the ILO system. The passage of the Occupational Safety and Health Act (OSHA) in 1970 created the National Institute for Occupational Safety and Health (NIOSH) and authorized NIOSH to create a program for certification of physicians in the application of the ILO system in order to support the Coal Workers’ X-ray Surveillance Program, and other programs (e.g., the Black Lung Benefits Program).

The first commercially available systems for digital x-ray imaging appeared in the 1980’s (8). These systems were based on storage phosphor technology and are usually described as computed radiography (CR). Subsequently, so-called digital radiography (DR) detector systems have become available, including active matrix flat panel images (AMFPI), charged couple devices (CCD), and selenium drum radiography. Though CR remains in place since it has advantages with respect to cost and with respect to portable imaging, most DR systems have been shown to produce images of superior quality and are projected to dominate the market once costs become more competitive.

There are two classes of DR systems-direct, in which the x-rays passing through the patient are converted immediately to electrons to form the image and indirect, in which the x-rays are first converted to light photons and then to electrons (8). Each technology has its proponents and, at present, neither has been definitively shown to be superior to the other. Both classes of DR systems have improved image contrast and noise properties compared to screen-film. They also have a much wider dynamic range and can therefore display better contrast between tissues in low exposure (e.g., mediastinum) and high exposure (e.g., lung) regions of a chest image. Furthermore, the contrast and brightness of the displayed image can be adjusted to maximize perception of details-something that is not possible with screen-film images.

CR and DR offer a number of potential advantages over conventional chest radiography:

- numerical image manipulation for improved contrast perception (9);
- rapid transmission of digital images over long distances (e.g., for real-time off-site interpretation [teleradiology]) (10);
- potential to achieve ‘filmless’ radiology with reduction of unit costs and storage space and the elimination of ‘lost films’;
- production of unlimited, high quality ‘hard’ copies;
- wide ‘latitude’ with reduction in frequency of ‘marginally acceptable’ films and retakes, particularly with portable radiographs (11, 12).

Another long-hoped for advantage is that digital or computed chest radiography will achieve equal or better test performance (i.e., sensitivity, specificity, positive predictive value, and negative predictive value) than conventional radiography in identification of specific diseases (5). Studies have examined and evaluated computed chest radiography for a variety of chest conditions:

- blunting of the costophrenic angle (13);
- atelectasis (13);
- bullous disease (14);
- pneumothorax (13, 15-21);
- pulmonary nodules (20, 22-24);
- chest bone lesions (19);
- mediastinal abnormalities (13, 25).

Many of the studies’ results have been promising and have demonstrated the potential of digital x-ray imaging to equal the test performance of traditional FSR imaging for selected clinical conditions. More pertinent to the present discussion, there have been a number of investigations that have explored the application of CR or DR for identification of fibrotic lung diseases, or, more generally, interstitial diseases. Studies that address interstitial diseases and digital or computed radiography will be reviewed in more detail below.

LITERATURE REVIEW OF DIGITAL X-RAY IMAGING AND PNEUMOCONIOSIS OR INTERSTITIAL LUNG DISEASE

A number of studies have investigated the role of digital x-ray images in the diagnosis of interstitial lung disease, or pulmonary fibrosis (9, 13, 17, 18, 20, 21, 26, 27). Most of these studies have been small in terms of the number of images, or the number of readers, or both. Only one study used true CR images; the others were based on digitization of conventional films, usually without numerical image processing. Only one of these studies explicitly incorporated the ILO scoring system into the study design. Overall, these studies support the conclusion that images constructed using smaller pixel sizes tend to yield better results.

While there have been many studies that have examined agreement among and within observers in the interpretation of chest radiographs, older studies have reported only raw percentage agreement and have not employed statistical analyses that would correct for agreement beyond chance alone, such as the kappa (?) statistic (28). The first studies that examined inter-observer agreement using the kappa statistic and the ILO system for classifying radiographic abnormalities were by Musch (6, 29, 30). Subsequently, there have been only a limited number of studies that have examined observer agreement based on ratings using the ILO system and a statistical approach that corrects for chance agreement (31-33). Furthermore, only one study has involved a comparison of DR with FSR images (34).

Zähringer compared digital selenium radiography (a form of DR) to traditional FSR (34). Chest images were obtained on 50 patients and interpreted according to the ILO system by 4 readers. The DR images were laser printed and interpreted via 'hard copy'; 'soft copy' readings were not employed as part of the study. The parenchymal profusion scores ranged from "0/-" to "1/2," but 95% were less than or equal to "1/0." Approximately 25% of films were interpreted as showing some degree of pleural changes. It was concluded that ratings using the two modalities were similar: DR did not result in over- or under-reading compared to FSR, though image quality of DR was rated significantly better than FSR. All statistical tests consisted of t-tests comparing the mean counts or percentages of findings among the 4 readers. There was no direct statistical assessment of inter-rater agreement, such as kappa, and there were no data on intra-rater agreement. The study did not provide an assessment of its power to detect differences, which was probably low given the modest number of subjects (n = 50), and the low prevalence of increased profusion of small parenchymal opacities. As stated, the study did not involve soft copy images. However, this is the only published study that directly compares true digital x-ray images to FSR.

The literature on observer agreement using the ILO system for scoring images supports the following conclusions:

1. Only a few studies have directly examined inter-rater and/or intra-rater agreement of interpretation of FSR images using the ILO system and appropriate statistical techniques such as kappa.

2. The range of inter-rater agreement using kappa and the ILO system has varied considerably among the studies [kappa = -0.04 (31) to 0.73 (30)]. It is not possible to combine

the kappa values from different studies because they are not equivalent (e.g., some studies only reported pair-wise agreement among readers, some reported an overall kappa involving more than 2 readers, some reported weighted kappa values and some reported kappa values for only parenchymal profusion, and others reported kappa values for only pleural findings). Despite these limitations, it would appear that agreement generally has been fair to good [i.e., kappa values from 0.40 to 0.75 (28)], with most kappa values in the lower end of this range (kappa = 0.4 to 0.5).

3. There are no published studies that have employed the ILO system to compare FSR and digital x-ray images with appropriate statistical analyses of results (i.e., use of kappa or similar statistics to properly assess inter-rater and/or intra-rater agreement with adjustment for chance agreement).

4. The results of the DR vs. FSR study by Zähringer are reassuring, but the power was not assessed and was probably low (34). Therefore, based on this study it is not possible to exclude a type II error (i.e., a false negative conclusion).

5. There have been no studies that have employed DR in epidemiological investigations of pneumoconiosis among dust-exposed workers (i.e., dose-response analyses of dust-exposed workers).

FUTURE CHALLENGES AND RECOMMENDATIONS

1) Hardware and software issues related to digital x-ray imaging

a) Picture Archiving and Communication Systems (PACS) - Should NIOSH and other agencies acquire/adopt a PACS system for acquiring and managing chest images for research, hazard evaluations, and surveillance?

b) Digital Imaging and Communications in Medicine (DICOM) Standards -Should NIOSH adopt the DICOM standards for image format and display?

c) Should NIOSH designate minimum requirements for digital x-ray technologies for image capture in the investigation and monitoring of individuals exposed to dust hazards?

d) Should NIOSH be concerned with encryption and the security of long-distance electronic transmission of images?

e) Should NIOSH designate minimum standards for the display of soft copy images of pneumoconiosis (e.g., for workstations and monitors)?

The transition to digital x-ray imaging that is presently occurring throughout the world presents many future challenges to NIOSH and other agencies concerned with lung diseases, in terms of both the hardware and software for image capture, archiving, and display. As listed above, many decisions related to these issues will be required. Based upon this review, the recommended answers to all of the listed questions are 'yes.'

a) In order to archive and display the digital x-ray images that will be used for pneumoconiosis screening, NIOSH will need a picture archiving and communications system (PACS). The ideal PACS would have the following features: it should be compatible with others that are in general use; it should include a fast network for minimal delay in querying the images from the archive; it should include redundancy so images are not lost if a component fails; it should require minimum oversight and upkeep, and have almost 100% uptime; it should have adequate storage for the anticipated number of images that might be acquired in the next 5 to 10 years and include a simple upgrade path for adding storage capacity; it should include high quality display monitors; and it should include workstations with interfaces that are user-friendly and fast (e.g., for image display and manipulation, such as positioning of present and past images and standard images, variation of contrast and brightness, zoom and roam).

b) The Digital Imaging and Communications in Medicine (DICOM) standards (http://medical.nema.org/) have been accepted and implemented for x-ray image interpretation in Radiology departments throughout the United States. These standards specify a common format for the storage and transfer of digital x-ray images and they specify brightness and contrast levels for the display monitors. Adoption of these standards by NIOSH will guarantee that the NIOSH PACS is compatible with those employed in Radiology departments and that the images are displayed in the same manner and have the same quality as those in Radiology departments.

c) To guarantee that the digital x-ray images employed in research and screening are of sufficient quality and that patient doses are reasonable, NIOSH should establish minimum requirements for the digital x-ray devices. These requirements should include spatial resolution, contrast detectability, and patient skin-surface radiation dose. Medical Physicists should be consulted regarding these requirements.

The security of patient information must be a high priority both at the workstations and for long-distance electronic transmission of the images (i.e., teleradiology). Radiology departments are working with digital x-ray imaging, teleradiology, and PACS vendor companies to address these issues at the present time. NIOSH should consult with Radiology departments and companies to determine the best ways to guarantee patient confidentiality.

d) Just as NIOSH should establish minimum requirements for the digital x-ray capture devices, it should also establish minimum standards for the workstations and display monitors. The overall image quality that is perceived depends on the weakest link in the image acquisition and display chain. One would not want to view an image acquired with one of the best digital x-ray imaging devices on a lower quality display monitor. The monitor requirements include the number of lines (e.g., 2000 lines for high quality), the brightness level (the American College of Radiology (ACR) recommends that monitors used for primary diagnosis exhibit a maximum brightness [luminance] that is at least 171 cd/m2), and the monitor contrast (the ACR recommends monitors used for primary diagnosis should have a contrast or maximum to minimum brightness ratio that is greater than or equal to 250). As discussed above, NIOSH should adopt the DICOM display standards (in particular the DICOM Grayscale Standard Display Function) to guarantee that the monitor gray levels are set properly. In addition, NIOSH should establish minimum ambient light levels in the image reading rooms (the ACR recommends that the ambient room light have a brightness that is less than 25% of the minimum brightness level on the display monitor.) It has been found that very low ambient light levels are required for optimum perception of subtle contrasts in x-ray images displayed on monitors and view boxes. The ACR practice and technical standard guidelines can be found at: http://www.acr.org/dyna/?doc=departments/stand_accred/standards/standards.html.

e) Finally, to guarantee that the image acquisition and display are consistent and optimal, NIOSH should establish quality control (QC) test procedures and minimum frequencies of those test procedures for digital x-ray image devices and display monitors. NIOSH should consult with Medical Physicists regarding the requirements for these QC tests. (See American Association of Physicists in Medicine (AAPM) Task Group 18 Assessment of Display Performance For Medical Imaging Systems, latest draft version available at: http://deckard.duhs.duke.edu/~samei/tg18).

2) Chest image interpretation for pneumoconioses
   a) Is hard copy digital x-ray imaging equivalent to FSR?
   b) Is soft copy digital x-ray imaging equivalent to FSR?

c) Is digital x-ray imaging (either hard or soft copy) 'better' than FSR?
d) Is reduced size, hard copy digital x-ray imaging acceptable?

These questions are critical in assessing the adoption of digital x-ray imaging for the B reader program. The only published study that directly addresses these questions, and actually only the first question, is by Zähringer (34). As discussed above, this study suffers from a number of limitations. The authors currently are engaged in a study, funded by the Association of Schools of Public Health and the Centers for Disease Control and Prevention that will address the first 3 questions and other issues (e.g., is intra-rater agreement equivalent for digital x-ray imaging compared to FSR?). However, this study is not scheduled for completion until the fall of 2005.

In many centers hard copy digital x-ray images are laser printed in reduced format (e.g., 66% scale hard copy) (35) .This practice primarily serves to save money. However, it has been shown that reduction of image size by 50% or more leads to loss of detection accuracy (36). Therefore, reduced format, hard copy digital x-ray images are almost certainly not acceptable if the reduction is 50% or more, but this does not address whether any larger scale format is acceptable (e.g., is 66% scale hard copy acceptable?). Clearly, more research in this area is needed.

3) Digital Image Processing
a) What is optimal or even acceptable numerical processing of digital x-ray images for identification of pneumoconiosis?
b) Should submission of 'raw' or unprocessed digital x-ray image data be required for the NIOSH Coal Workers' or other compensation programs?

For a variety of reasons, all digital x-ray images are processed numerically before display and interpretation (37). Processing is necessary and clearly can improve the appearance of chest images compared to 'raw' or unprocessed images. However, the choice of processing parameters is critical since the processing can also produce distortions. Processing can lead to over enhancement of the normal background profusion of small parenchymal opacities, leading to false-positive interpretation of chest images. Processing also can diminish the apparent profusion of small opacities, leading to false-negative conclusions. The lack of standardization of numerical processing of digital x-ray images is somewhat analogous to variation in film characteristics and exposure techniques with FSR. However, the potential for image manipulation with digital x-ray image processing is much greater than with FSR and can be harder to detect (e.g., processing parameters may not be displayed explicitly in the final digital x-ray image). Unfortunately, at present, there is no empirical basis for the choice of numerical processing parameters for chest digital x-ray images for optimal identification of interstitial lung disease and/or pleural abnormalities potentially related to pneumoconiosis. There needs to be research directed toward determining 'optimal' numerical image processing parameters for digital x-ray chest images for pneumoconiosis.

In many, if not most digital x-ray systems the 'raw' or unprocessed image data are discarded once the image is processed, interpreted, and stored in the PACS. It is not possible mathematically to recover the 'raw' data from the processed image data that are stored. This means that, under normal operating procedures, it is not possible to re-examine digital x-ray images based on an alternative image processing protocol applied to the original, or raw, data. Since digital x-ray image processing parameters can vary among centers, and possibly among radiologists within centers, considerable variation in image appearance and interpretation may occur due to differences in image processing. A surveillance system that seeks consistency of digital x-ray image interpretation across many institutions (such as the NIOSH Coal Workers' X-ray Surveillance Program) may need to enforce standard criteria for image processing. However, given that there are many vendors of digital x-ray systems, it would be difficult to define psychophysically-equivalent image processing protocols across all systems. Alternatively, NIOSH could require that digital x-ray images submitted to the Coal Workers' X-ray Surveillance Program must be DICOM compatible and must be 'raw' or unprocessed (i.e., a 'linear look-up table', etc.). This latter alternative would allow NIOSH to process images using whatever protocol(s) it considers optimal, and NIOSH would not be dependent on the varying numerical processing preferences of outside institutions or physicians. However, this approach needs to be considered carefully since the definition of unprocessed or 'raw' data may vary among hardware vendors.

DIGITAL VERSIONS OF THE ILO STANDARD FILMS OR IMAGES

Use of the ILO standard films is a required element of interpretation of FSR films for the presence of changes that may be due to inhalation of pathogenic dusts (7). DR and CR can involve 'hard copy' and 'soft copy' interpretation of chest images. Use of the ILO standard films in interpretation of hard copy images does not present a problem since both images are on film and can be read side-by-side on standard radiographic view boxes. However, as noted above, many departments are moving to 'filmless' systems, and the full advantages of digital x-ray imaging cannot be realized unless the primary image viewing modality is soft copy. Interpretation of soft copy chest images, which is also the preferred mode in many Radiology departments, creates a number of challenges for use of the ILO system:

a) If the ILO standards films were not digitized for viewing in soft copy format, then, on a practical level, work stations for viewing soft copy images would need to be adjacent to traditional radiographic view boxes so that the ILO standard films and soft images could be viewed side-by-side for comparison purposes. This physical configuration may not be available in many departments. Even if it were, it may create problems with respect to ambient light, glare, and luminance (35).

b) Alternatively, the ILO standard films could be digitized, thus allowing for direct viewing and comparison of soft copy chest images and soft copy ILO standard images side-by-side on adjacent monitors. Side-by-side monitors at workstations have become relatively common, if not the norm in practice (35). The current ILO standard films could be scanned and digitized for use in soft copy format. However, the current ILO standard films are based on old technology. Most of the current standard films are less than 'good quality' by today's technical criteria (7). Digitizing the current standards perpetuates these problems, and also creates additional problems (e.g., issues related to numerical processing of the scanned, digitized images). Ideally, there should be new standard images that are obtained as digital images, not digitized versions of FSR images. It is recognized that the current ILO standard films are invested with considerable historical and practical significance, and to create new digital standard images would be a major challenge with respect to consistency of ILO readings with 'old' and 'new' standard images. It also is not clear who would undertake the challenge of creating new standard images using digital x-ray technology - the ILO, NIOSH, the American College of Radiology, or possibly some other entity.

B READER CERTIFICATION

DR and CR images can be viewed in both hard copy and soft copy format, and in many centers with digital x-ray imaging, most chest images are only interpreted in soft copy. The NIOSH B reader certification examination is based on interpretation of hard copy images using two adjacent view boxes. To reflect modern radiological practices, the certification examination probably should incorporate soft copy (in addition to reading hard copy images), in which case, NIOSH would need a number of high-quality workstations. It could be expensive to acquire and operate such equipment for testing purposes.

CONCLUSIONS

Digital x-ray imaging will soon become dominant in the United States. The advent of digital x-ray imaging offers a number of opportunities and challenges to organizations and individuals involved in evaluating lung images for occupational lung disease. In addressing these challenges, NIOSH needs to remain current, to be able to serve the needs of workers now and into the future and to fulfill its legislative mandates. NIOSH must move rapidly to adopt digital x-ray radiographic technology for the B reader program, and yet, it must remain flexible so as to be able to adapt to new technologies as they inevitably become available. These decisions will require appropriate expertise, resources, administrative commitment, and leadership of the agency.

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DHHS (NIOSH) Publication No. 2009-140