The NIOSH B Reader Certification Program:

Looking into the Future

Department of Health and Human Services
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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The authors thank: Jennifer Keller, Lea Pyles, Molly Pickett-Harner, Janet Hale, Lou-Ann Morris and Kim Clough Thomas for support and assistance with the B Reader workshop and this resulting report.

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THE NIOSH B READER CERTIFICATION PROGRAM:
LOOKING TO THE FUTURE

MARCH 5, 2004
MCLEAN, VIRGINIA

NIOSH B Reader Certification Program: Looking to the Future

Anita L. Wolfe

BACKGROUND

Chest radiographic imaging is a widely applied and important tool for assessing lung health in workers exposed to dusts capable of producing pneumoconiosis and other diseases. Accurate and precise categorization of chest radiographic images requires close adherence to standard methods of radiograph classification and adoption of procedures for quality assurance. For over 70 years, the International Labour Office (ILO) has provided a standardized system for classification of chest radiographs for the pneumoconioses that has been widely used by physicians and epidemiologic researchers concerned with occupational respiratory diseases.

Since 1970, under the U.S. Code of Federal Regulations [42CFR37], screening chest radiographic examinations have been provided to underground coal miners. As part of this mandated Coal Workers' Health Surveillance Program (CWHSP), the National Institute for Occupational Safety and Health (NIOSH) arranges for the interpretation of these radiographs. The presence and degree of dust-related radiological changes are determined by physicians who have demonstrated proficiency in using the ILO classification system. To determine proficiency, NIOSH developed and currently administers the B Reader Certification Program, a unique quality assurance program for training and certifying physicians who classify chest radiographs of the pneumoconioses. Under this Program, physicians who wish to obtain B Reader Certification must successfully pass a comprehensive examination, and to maintain certification, they must continue to demonstrate competence by passing a recertification examination every four years.

In 2002, the ILO, with NIOSH involvement and support, completed a revision of their chest radiographic classification system (1). To ensure that the NIOSH B Reader Program is maintained as a relevant and effective quality assurance program for occupational lung disease research and prevention, and to maintain adherence to the revised ILO classification system, modifications are required to the B Reader examinations and related training activities and materials. Moreover, in the 30 years since the development of the B Reader Certification process, the field of radiology, as well as the discipline of professional competency testing, have experienced considerable advances in knowledge, techniques, and methodology. In short, the B Reader Certification Program could benefit from a critical evaluation in order to ensure optimal utility of the Program.

Toward this end, NIOSH planned and held a scientific workshop-NIOSH B Reader Certification Program: Looking to the Future-March 5th, 2004, to discuss the important issues related to radiological surveillance for lung diseases. Background papers were commissioned from national experts on the topics of Quality Assurance, Computerized Tomography (CT) Scanning, and Digital Radiography. These proceedings include the following documents: NIOSH B Reader Certification Program: Looking to the Future; Occupational Lung Disease Among Coal Miners; Commissioned papers on "Alternative Approaches to B Reader Quality Assurance," "The Role of CT Scanning in Pneumoconiosis Screening," "Digital X-ray Imaging in Pneumoconiosis Screening: Future Challenges for the NIOSH B Reader Program"; Discussion pertaining to the commissioned papers; Results from Survey's sent to A, B, and Former B Readers; and

NIOSH Responds to the Challenges. Recommendations from this workshop are not consensus statements, but individual opinions of some, not necessarily all, of the participants.

KEYWORDS

Chest Radiographic Imaging, National Institute for Occupational Safety and Health, Pneumoconiosis, Quality Assurance

WORKSHOP OBJECTIVES

The workshop was structured such that three major objectives could be met.

1) To discuss the impact of recent technological advances in radiological imaging

2) To discuss current NIOSH and extramural activities and practices in this area

3) To gain input from participants on NIOSH activities and the impact of technological advances in radiological imaging

The Federal Coal Mine Health and Safety Act of 1969 (as amended by the Federal Mine Safety and Health Act of 1977) directs NIOSH to study the causes and consequences of coal-related respiratory disease and, in cooperation with the Mine Safety and Health Administration (MSHA), to carry out a program for early detection and prevention of coal workers' pneumoconiosis. At NIOSH these activities are administered through the CWHSP, as specified in Federal Regulations, 42 CFR 37, "Specifications for Medical Examinations of Underground Coal Miners."

The CWHSP consists of three components: (1) Coal Workers' X-ray Surveillance Program, (2) National Coal Workers' Autopsy Program, and (3) B Reader Certification Program. NIOSH staff, located at the Division of Respiratory Disease Studies (DRDS) in Morgantown, WV, are responsible for conducting the CWHSP. The B Reader Certification Program component of the CWHSP was the major focus of this workshop. The areas of Quality Assurance in film classification and the potential Roles for Digital Radiology and CT Scanning in lung imaging for dust diseases were specifically addressed.

In the 30 years since the development of the B Reader process, the field of radiology, as well as the discipline of professional competency testing, have experienced considerable advances in knowledge, techniques, and methodology. By facilitating this workshop, NIOSH was able to gather feedback from experts in these fields. The workshop's participants were asked to provide a critical evaluation of the current B Reader Program in order to ensure its optimal utility in today's workplace environment. Input was gathered during three concurrent breakout sessions, each beginning with the presentation of commissioned background papers to focus discussion.

ALTERNATIVE APPROACHES TO B READER QUALITY ASSURANCE

Quality assurance is a crucial component of the current NIOSH B Reader Program. Consequently, NIOSH contracted with Dr. Ralph Shipley, a member of the American College of Radiology Pneumoconiosis Committee and NIOSH B Reader from the University of Cincinnati to provide an overview regarding "Alternative Approaches to B Reader Quality Assurance. Dr. Shipley's paper addresses inter-reader and intra-reader variability and presents proposals for further study of methods to improve uniformity of interpretation. Assuring quality through innovative methods and inquiry into improved reading practices is important to maintain and improve the stature of the B Reader Program.

THE ROLE OF CT SCANNING IN PNEUMOCONIOSIS SCREENING

Drs. Cecile Rose and David Lynch, from the National Jewish Medical and Research Center, in Denver, Colorado, were requested by NIOSH to provide an overview regarding the "The Role of CT Scanning in Pneumoconiosis Screening." There is an increasing body of literature aimed at standardizing interpretation and validating the usefulness of high-resolution computed tomography (HRCT) in screening and surveillance for the pneumoconioses. The purpose of the commissioned paper was to review the published literature on the role of HRCT in pneumoconiosis screening, assess the current state-of-the-art regarding standardized technique and scoring of HRCTs, comment on directions in the use of high-resolution lung imaging, and outline future research needs.

DIGITAL X-RAY IMAGING IN PNEUMOCONIOSIS SCREENING

Dr. Al Franzblau from the University of Michigan was requested by NIOSH to provide an overview regarding "Digital X-ray Imaging in Pneumoconiosis Screening." Conventional screen-film chest radiographic imaging has been widely applied in assessing lung health in dust-exposed workers, but this technique is being replaced by digital radiography systems. Dr. Franzblau is currently the Principal Investigator for a NIOSH funded project assessing the equivalency of traditional radiography and digital radiography with respect to pneumoconiosis classification, using conventional and digital images from patients with a spectrum of dust-related lung disorders and chest pathology. Results of the project will assist in defining the utility of current digital imaging systems in the assessment of occupational dust diseases and will be used as part of the bases for ensuring that the NIOSH B Reader Program and Coal Workers' X-ray Surveillance Program effectively utilize current technology.

NIOSH is aware that each year brings new and improved systems for generating diagnostic images. These emerging technologies result in the capture, storage, and manipulation of vastly larger amounts of data. Programs such as the NIOSH CWHSP face difficult challenges as they must prepare to manage and adapt to these technologies. Though challenging, these new technologies present opportunities for improvement that NIOSH embraces.

REFERENCE

1. International Labour Office. Guidelines for the Use of ILO International Classification of Radiographs of Pneumoconioses. Revised Edition 2000. Geneva:ILO; 2002.

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Alternative Approaches to B Reader Quality Assurance
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Agenda

NIOSH B Reader Certification Program:
Looking to the Future

Scientific Workshops:
Alternative Approaches to B Reader Quality Assurance
The Role of CT Scanning in Pneumoconiosis Screening
Digital X-ray Imaging in Pneumoconiosis Screening

Friday, March 5, 2004, 8:00 a.m. - 12:00
Potomac, Chesapeake, and Old Dominion Rooms
Courtyard Marriott
1960-A Chain Bridge Road
McLean, VA 22102

7:30 - 8:00 a.m. Registration

8:00 - 8:30 a.m. Charges/Instructions to Workgroups

Alternative Approaches to B Reader Quality Assurance
- Moderator -Ralph Shipley
- Recorder - Greg Wagner
- Support - Anita Wolfe

The Role of CT Scanning in Pneumoconiosis Screening
- Moderator - Cecile Rose/David Lynch
- Recorder - Jack Parker
- Support - Jennifer Keller

Digital X-ray Imaging in Pneumoconiosis Screening
- Moderator - Alfred Franzblau
- Recorder - Lee Petsonk
- Support - Lea Pyles

8:30 - 9:00 a.m. Presentation of Background Papers
Shipley, Rose/Lynch, Franzblau

9:00 - 10:30 a.m. Workgroup Discussion of Papers

10:30 - 10:45 a.m. Break

10:45 - Noon Continued Workgroup Discussion/Summaries

Occupational Lung Disease Among Coal Miners

Edward L. Petsonk, M.D.

BACKGROUND

Since the beginning of the industrial revolution, coal has been the fuel that provided the energy for industry. In the United States, coal production is at near record levels and in 2003 1,972 active mines and about 70,000 working coal miners (1) were engaged in the commercial exploitation of the major U.S. coal deposits in 38 states (2, 3) (Figure 1). After World War II, mechanization in the U.S. coal mining industry brought an end to most pick-and-shovel mining, and resulted in dramatic increases in productivity and consequent sharp and progressive declines in mine employment. However, recent increases in energy prices have led to an increased interest in coal, and current industry figures suggest that coal mine employment is now increasing. (Coal mine employment statistics are available at http://www.msha.gov/stats/statinfo.htm) To maintain the required high levels of production with a small workforce, modern miners commonly operate powerful and sophisticated mining equipment. Despite extensive mechanization, however, coal mine work often involves strenuous manual labor in cramped and hazardous conditions. The high levels of production that are being achieved in confined spaces present continuing challenges for controlling dust and assuring the safety of miners.

RESPIRATORY DISEASE

Knowledge of the diseases of coal miners has progressively accrued since the early 1800s, when Laennec differentiated ‘melanosis’ or what was later called ‘miners black lung’ from malignant melanoma. During the early applications of the roentgenogram, it was noted that the lungs of coal miners demonstrated abnormalities that were not seen in unexposed workers. Chest radiography emerged as an essential tool for the investigation, diagnosis, and monitoring of health risks among coal miners, and, by 1930, the International Labour Office had published a system of classification for the radiographic appearances of pneumoconiosis (4). Over the last fifty years, investigators have undertaken comprehensive laboratory, clinical, and epidemiologic studies of coal miners, and it is now known that inhalation of dust during underground or surface coal mine employment can result in at least eight distinct respiratory tract conditions: chronic bronchitis; mineral dust airways disease; centrilobular emphysema; silicosis; silicotuberculosis; simple coal workers’ pneumoconiosis; complicated coal workers’ pneumoconiosis or progressive massive fibrosis; rheumatoid pneumoconiosis. Not all of these are reliably detected using radiographs (5). Despite evidence that coal miners are at risk of silicosis and obstructive airway diseases and that both of these conditions are risk factors for lung cancer, current epidemiologic evidence does not demonstrate an increased risk of lung cancer from the inhalation of coal dust (6).

RECENT TRENDS

In the United States, current federal regulation of working conditions in underground coal mines was initiated following the passage of the Coal Mine Health and Safety Act of 1969. The success of the Act in reducing underground coal mine dust exposures has been corroborated by the reduction in radiographic evidence of pneumoconiosis seen among participants in the U.S. National Coal Workers’ X-ray Surveillance Program (Program) (7, 8). This Program, administered by the National Institute for Occupational Safety and Health (NIOSH), was established under the 1969 Act and requires all operators of underground coal mines to offer chest radiographic examinations to working miners every five years. Under current coal mine regulations, miners who are determined by the Program to exhibit evidence of pneumoconiosis have the legal right to transfer to a job with reduced dust exposure, if available. To enhance the quality and reliability of the examinations, Program chest films must be taken in NIOSH-approved facilities and interpreted by NIOSH-certified physician readers. (See website at http://www.cdc.gov/niosh/topics/chestradiography/.)

Figure 2 illustrates the progressive decline in the tenure-related risk of radiographically-evident pneumoconiosis among coal miners who have participated in the Program. Whereas in 1974-8, over 1 in 3 participating miners with at least 25 years tenure demonstrated changes consistent with pneumoconiosis, the prevalence declined to 1 in 5 by 1987, and by 2002 only about 1 in 20 of these miners showed radiographic evidence of disease. The number of persons dying with coal workers' pneumoconiosis has also declined in recent years, although at least in part this has been a result of the reduction in the number of individuals employed in coal mining jobs. From 1990 to 1999, coal workers' pneumoconiosis was listed as the underlying or contributing cause of death for an average of 1504 deaths per year in the United States. (9).

FUTURE CHALLENGES

Despite remarkable progress in controlling pneumoconiosis in the United States, a number of difficult challenges remain in achieving the goal of preventing occupational lung disease among coal miners. First, although the overall progress has been impressive, recent studies have indicated that the improvement has not been uniform (8, 10). Program data have demonstrated that the prevalence of radiographic evidence of pneumoconiosis among working miners in certain states is 3-5 times the national average. Miners currently working in smaller mines (less than 50 employees) and in certain jobs at the coal mining face demonstrate significantly greater disease prevalence. Of particular concern, a number of cases of advanced and rapidly progressive disease have recently been reported among younger miners whose entire working career has been under current dust regulations (10). Explanations for these "hot spots" of pneumoconiosis must be sought.

A second concern relates to the occurrence of dust-related lung diseases among surface coal mine workers. Mandated surveillance does not cover employees or contractors at surface coal mines, and thus there is much less data regarding this group of miners. However, severe cases of pneumoconiosis have been reported among surface coal mine workers, and recent health surveys taken at surface coal mines have documented radiographic evidence of disease (8).

A third concern has been raised regarding the risk for chronic obstructive pulmonary disease (COPD) from inhalation of coal mine dusts (7, 11). Although pneumoconiosis was the initial focus of study in relation to miners' respiratory health, extensive epidemiologic investigations and supporting pathologic studies have demonstrated that chronic airflow limitation, including chronic bronchitis, emphysema, and mineral dust airways disease may result from coal mine dust exposures (5, 7). The current enforceable dust exposure limits, implemented in 1973, were targeted at the prevention of disabling pneumoconiosis, but were not intended specifically to address airways diseases. More recent evidence indicates that coal miners exposed at the current dust exposure limits (2 milligrams of respirable coal mine dust per cubic meter of air, mg/m3) may experience important dust-related lung function declines (7, 12). To address this risk, NIOSH has recommended the addition of pulmonary function monitoring to the currently-required coal mine radiographic health surveillance, in addition to recommending a reduction in permissible exposures to 1 mg/m3 in order to prevent all the respiratory diseases associated with coal mining (7).

A final issue in the control of occupational lung disease among coal miners, as well as among individuals in other dusty work, relates to the application and interpretation of chest imaging studies in diagnosis, monitoring, and research. Developments in imaging technology, including digital imaging systems and computerized axial tomography, present challenges to the traditional film screen approaches to chest radiography. The optimal role of these newer modalities requires clarification. Additionally, in spite of standardized classification methods and efforts in training and certification, considerable variability remains among physicians interpreting chest images for pneumoconiosis (13). It is the objective of these workshop proceedings to address the current status and future directions in the application of chest imaging in occupational lung disease. Recommendations from this workshop are not consensus statements, but individual opinions of some, not necessarily all, of the participants.

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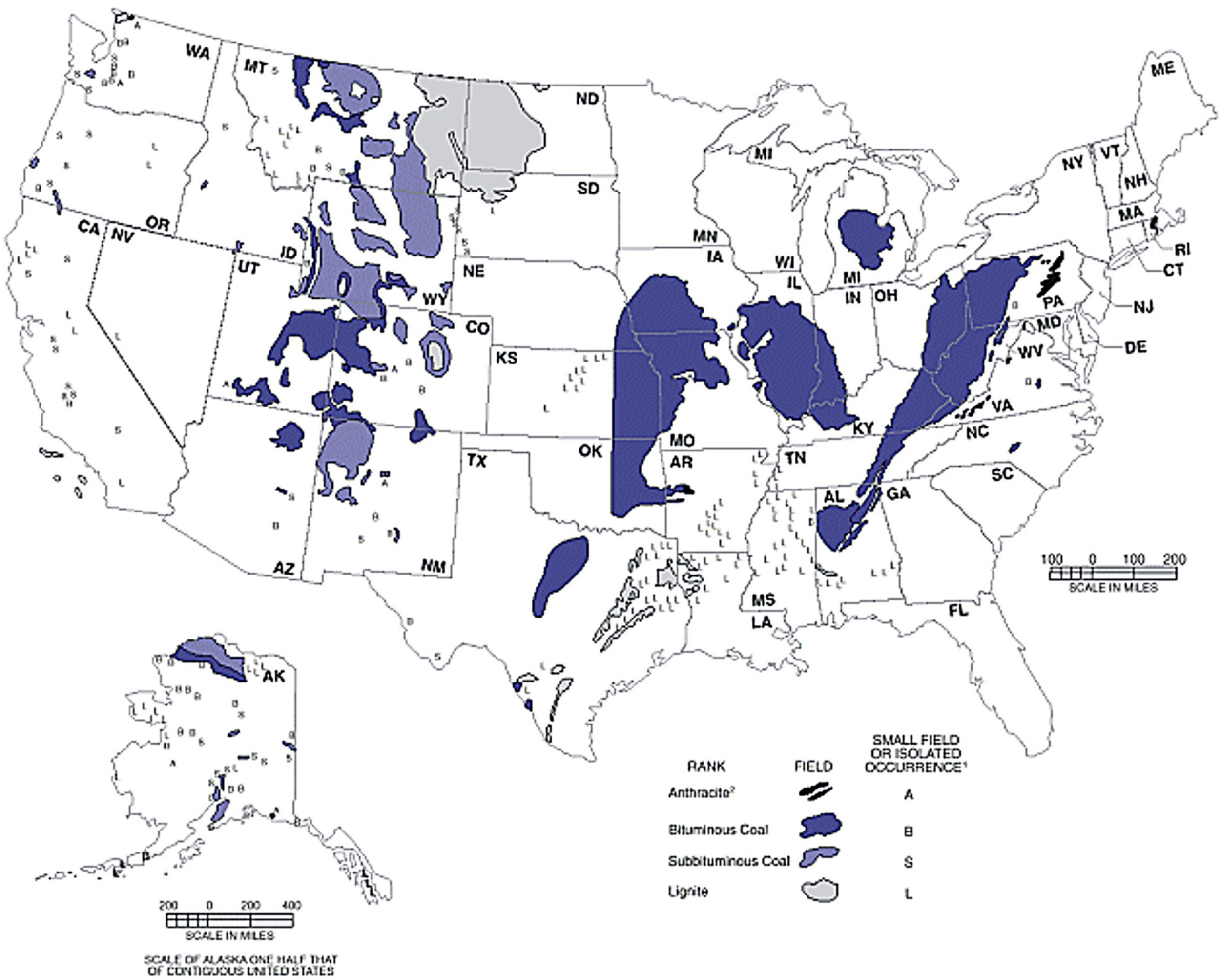
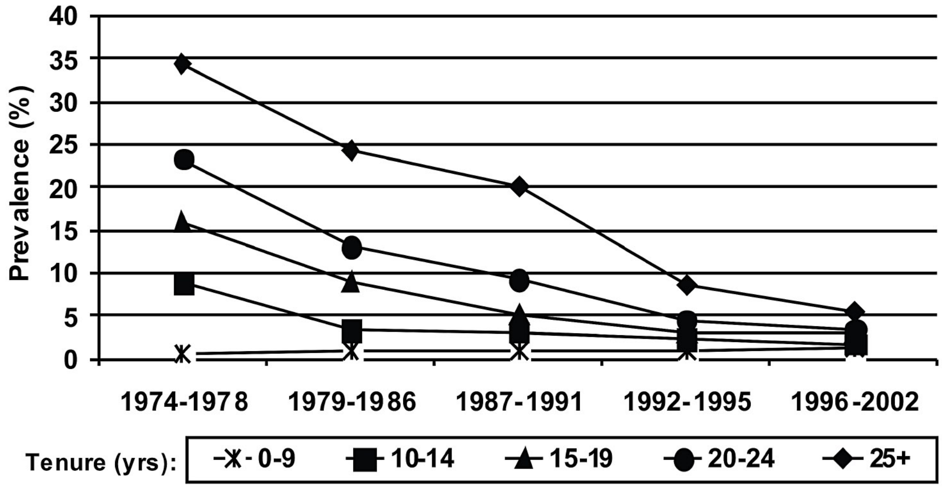
Figure 1. Coal-Bearing Areas of the United States



Source: See reference 3

FIGURE 2. Trends in coal workers' pneumoconiosis prevalence by tenure among underground miners examined in the U.S. National Coal Workers' X-Ray Surveillance Program, 1973-2002



Source: See references 8 and 9

Alternative Approaches to B Reader Quality Assurance

Commissioned Paper

Ralph T. Shipley, M.D.

The B reader program certifies experts in the interpretation of chest radiographs of the pneumoconioses. The program began in the 1970s as a means to identify physicians to participate in national programs for epidemiological research and for compensation of coalminers and others with disabilities related to dust inhalation (1). It is based on the International Labour Office (ILO) "Classification of Radiographs of the Pneumoconioses," and a "Revised Edition 2000" has recently been published. The goals of the Classification are to standardize classification methods and facilitate international comparisons of data collected on pneumoconiosis for screening and surveillance, epidemiological investigations, and clinical purposes (2).

The ILO Classification provides a standard way of describing and quantifying the changes seen on chest radiographs of workers exposed to dusty environments. It was designed to be used as an epidemiological tool to facilitate international comparability of pneumoconiosis statistics (3), but wider uses have been found for it, including medico-legal and clinical applications.

INITIAL GOALS AND HISTORY

For over 70 years, the ILO has published systems, periodically revised, for the classification of radiographs of the pneumoconioses (4). The early editions were designed to classify changes of silicosis only and used a four-point scale of severity. In 1959, standard films were incorporated. In 1971, the gradation of severity was expanded to a 12-point scale, and provisions were added to include pleural and parenchymal changes related to asbestos inhalation. In 1980, an expanded set of standard films illustrating the types and profusion of small opacities, large opacities, and pleural changes was added. The 2000 revision included additional symbols, simplified the pleural classification, and added another standard film option, the "Quad Set." This consists of 14 films, including nine of the most commonly used standards from the Complete Set, plus five films which are "composite reproductions of quadrant sections from the other radiographs in the Complete Set (2)." The Quad Set is wholly compatible with the Complete Set, and was intended both to reduce the cost of purchase of the standard films and to improve compliance with the requirement for direct comparison of the radiographs being classified to the standard films, by reducing the number of films that must be handled.

B reader certification is accomplished by passing a practical examination which consists of classifying 125 radiographs according to the ILO system. This test is administered by the National Institute for Occupational Safety and Health (NIOSH) in Morgantown, WV and selected other locations. To maintain certification, every four years B readers must pass a recertification test comprising 50 radiographs. The correct answers to the test have been determined by an expert panel of readers (5).

READER VARIABILITY

Inter- and intra-reader variation in radiographic interpretation has been an ongoing issue with the B reader program, despite the introduction of revised classification systems and standard films (6-19). Reader variability occurs throughout the Classification including small and large rounded opacities, but most of the current controversy involves pleural thickening and the reading of small irregular opacities at low profusion levels.

The causes of reader variability are many, and include film quality, reader training and experience, and bias, as well as the variability inherent in the act of individuals interpreting chest radiographs. Variability in classifying radiographs is accentuated by the use of the detailed 12-point scale. Any approach to B reader quality assurance should begin with an analysis of the causes of reader variability.

Film quality is an important component of interreader variation (20). Light films promote over-reading, whereas dark films promote underreading (21). Digital radiography and soft copy interpretation at a workstation will affect this issue, because with this technology it is possible for the reader to control density and contrast independently of the exposure factors used to acquire the image. Classification of digital images, compared to hard copy radiography interpretation, is reviewed elsewhere in these proceedings (see Franzblau paper included in this publication); one preliminary study found no significant differences in the two approaches (22). However, technical defects due to underinflation, mottle, scatter, and positioning are not solved with digital imaging, and proper comparison with the ILO standard films may be logistically difficult unless an electronic edition of the standard films is published.

The training and experience of the reader strongly influences inter- and intra-reader variability. Inexperienced readers tend to over-read when compared to recognized experts (18). Experience with both the wide variation of normal in chest radiography as well as the typical patterns of involvement by pneumoconiosis may reduce the misinterpretation of non-pneumoconiotic opacities as pneumoconiosis. A survey of a group of candidate B readers attending a training course in 1990 indicated that 70% were reading between zero and 10 films for pneumoconiosis per month (1). This finding raised the question of whether some readers are classifying insufficient numbers of films to maintain proficiency.

Conditions other than dust inhalation may be associated with the appearance of small opacities. Male sex, cigarette smoking, obesity, age, underinflation, and other factors can produce the appearance of irregular opacities on chest radiographs, generally at low levels of profusion (23-26). When utilizing the Classification and the standard films in epidemiologic studies, readers are not generally asked to distinguish between the small irregular opacities considered a result of interstitial fibrosis (e.g., asbestosis) and those thought to arise from airway inflammation or other causes. The ILO does state that when the Classification is used for some clinical purposes, the reader may be instructed to "classify only those appearances which the reader believes or suspects to be pneumoconiotic in origin (2)." It is a common clinical exercise when reading chest radiographs to differentiate non-fibrotic "increased markings" from interstitial fibrosis. When this differentiation cannot be made with confidence using the routine radiograph, high resolution computerized tomography (HRCT) may be recommended (see Rose and Lynch paper included in this publication).

This combination of fibrotic and non-fibrotic irregular opacities in one profusion level may contribute to variation in classification. For epidemiologic studies, readers are generally instructed to use the classification as a "pure" tabulation of radiographic appearances and to classify irregular opacities regardless of presumed etiology. In other settings, readers who anticipate that a Classification indicating irregular opacities will be construed as showing parenchymal asbestosis may choose to not classify those opacities which they judge are unlikely to be related to asbestos inhalation. The ILO has recognized in the Revised Edition 2000 that the Classification is used differently in epidemiological than in clinical studies (2). Differences between readers may be amplified by the fact that some observers consider the standard films themselves to be ambiguous in this sphere. Several of the standard films for irregular opacities show changes that are typical of interstitial fibrosis (e.g., 3/3 s/s), whereas others show an increase in irregular opacities that is not particularly typical of interstitial fibrosis (e.g., 1/1 s/t).

One reader might record "increased markings" as "s" or "t" opacities potentially due to pneumoconiosis, whereas another reader might interpret the same opacities as age or smoking related and not classify them. To further add complexity, many believe that occupational dust exposure produces irregular opacities on chest radiographs without interstitial fibrosis, perhaps by causing inflammatory or fibrotic changes in airways.

The argument has been made that reader variability will be minimized if the reader does not interpret the findings but merely records them (27). Consistent with that view, the 1980 edition of the Classification instructed the reader to classify all appearances that "might be due to pneumoconiosis," and the 2000 revision retains that instruction for classifying radiographs in epidemiologic studies (2, 3). However, the 2000 edition of the Classification acknowledges that, in some clinical settings, medical readers may classify only those appearances, which they believe or suspect to be dust-related. To avoid confusion, individuals who utilize and interpret reports of ILO Classifications should be familiar with the published guidelines and the protocol used in generating the specific results.

In the absence of calcification and using standard radiographic approaches, the chest radiograph is neither sensitive nor specific for pleural plaques. Extra-pleural fat deposition and muscle shadows produce thickening of the pleural stripe that can mimic asbestos-related pleural plaques (28), while plaques may be present and not visible on the PA radiograph (10, 29, 30). Oblique views may help increase certainty of plaques and aid discrimination from pleural fat (7), but are not part of the ILO Classification. The Revised Edition 2000 adds a requirement that pleural thickening be at least 3mm to be classified, and there is evidence that this minimum threshold will improve reader agreement (31). Readers who classify an area of pleural thickening because it might be plaque would be expected to disagree with readers who interpret a pleura opacity as fat and therefore do not classify it. Specification of the role of etiologic judgments in reading protocols should assist in the interpretation of situations in which a reader, for example, classifies pleural shadows as changes that "might be pneumoconiosis," but records under comments that the shadows are deemed due to "adipose tissue."

Bias is an important component of inter-reader variability. Knowledge of the exposure history, prevalence of abnormality in a given set of radiographs for classification, employment of the reader by plaintiff or defense counsel, and sympathy for the plight of either the worker or the industry, among other issues, all have the potential to influence a reader's tendency to under- or over-read. The local reading environment, such as location on the east or west coast versus mid-continent has been noted to affect the outcome of Classifications (11).

The inherent qualities of chest radiography and the ILO Classification, and the human element of interpretation make variation in reading inevitable (32). The extensive literature detailing inter-reader variability indicates that not all the disagreement can be from bias related to the implications of a positive or negative reading. The great variation of normal in chest radiographs, the asymmetric distribution of small opacities within lung zones, and the contribution of non-pneumoconiotic factors lead to variation in interpretation. Numerous studies have been published in which experienced readers with no financial incentives have significant disagreements. To improve precision in epidemiological studies using the chest radiograph, it is recommended to employ three readers representative of general reading practices (that is, they should not fall at the extremes of the range of variability between readers) and use the median reading (9, 16). In clinical situations, the radiographic reading should be interpreted in the context of a complete clinical evaluation (33).

STANDARD FILMS

To enhance calibration among readers, the ILO guidelines require a side-by-side comparison to the standard set of radiographs for each chest image being classified (34). However, the standard film set is expensive and can be cumbersome to handle. As a consequence, compliance with use of the standards during classifications has been inconsistent, although the availability of a lower cost Quad Set of standards, with fewer films, may encourage their use. An additional source of variability derives from the different published versions of the Standard Radiographs, which were produced using differing copy techniques and resulted in dissimilar appearances for the Standard Radiographs from the various sets. As of this writing, the ILO has not provided an approved digitized version of the Standard Radiographs for use with soft copy interpretation, and until such images are available, NIOSH recommends that readers "should continue to use traditional film screen radiographs and standards (35)."

The standards are mid-category examples, so that each exemplifies the center of each major category from 0/0 to 3/3. Unfortunately, the standard films are copies of radiographs, the originals of which used dated techniques. Their quality is variable, and several contain excessive contrast. In addition, the two 0/0 standards are really quite normal, closer to 0/- in the 12-point scheme, in the author's opinion. Thus, the gap between the standard for normal and the standard for mild involvement is greater than it appears, and this leads to greater difficulty in distinguishing 0/1 and 1/0. Boundary standards, or radiographs that illustrate the boundary between categories rather than the mid-categories, may improve reader agreement (36, 37). There is evidence that the mid-category standards bias the reader toward mid-category classification (38).

The pleural standards require revision. The standard for diffuse thickening does not conform to the Revised Edition 2000, which requires blunting of the costophrenic angle. In fact, this standard most likely illustrates pleural fat. The standard image for noncalcified, circumscribed plaque shows an en face plaque, but there are other appearances of plaque that should be illustrated.

FUTURE DIRECTIONS

It is not clinical practice for workers with a question of occupational lung disease to undergo open lung biopsy, so that radiologic-pathologic correlation studies are limited (39). For non-pneumoconiotic interstitial lung disease where biopsy is not possible or appropriate, current clinical practice is to integrate computerized tomography/high-resolution computerized tomography (CT/HRCT) with clinical assessment for diagnosis. Thus, the best "gold standard" readily available for investigation of pneumoconiosis is CT/HRCT.

Because the chest radiograph is inexpensive and easy to acquire, its use in surveys of workers at risk for pneumoconiosis will continue despite its well-documented limitations. Outside the B reader program, it is common experience that the advent of CT scanning has improved our ability to interpret chest radiographs. For these reasons, I propose two areas for inquiry: The categorization of small irregular opacities and the accurate detection of pleural plaques.

While there has been radiographic-HRCT correlation (40, 41), there has been little interest in using HRCT to "go backward" to improve chest radiographic interpretation. We know that "increased markings" with coarsening of bronchovascular shadows can be seen on chest radiographs that does not reflect interstitial fibrosis. On the other hand, interstitial fibrosis usually produces peripheral, subpleural irregular opacities that are confirmed with HRCT. A set of guidelines for distinguishing these opacities on the chest radiograph could be drawn up and tested on a cohort of workers who have both chest x-rays (CXR) and HRCT available for review. The HRCT images could be used as the gold standard to determine the accuracy of the guidelines for interpretation. The inter- and intra-reader variability could be compared to conventional classifications. Non-fibrotic opacities could be studied to identify any correlation with chronic bronchitis or other clinical condition that might not be fibrosis but still be occupationally related.

Similarly, classification of pleural thickening should be studied. A set of guidelines could be drawn up to distinguish pleural fat from pleural plaques on the chest radiograph and tested on a suitable cohort of workers who have both CXR and CT/HRCT available for review.

QUALITY ASSURANCE

The current system of quadrennial recertification is designed to periodically test the individual B reader's adherence to conformity with the level of reading defined by an expert panel. The underlying assumption is that the reader will read similarly in practice as he/she does in the testing situation. However, B readers are influenced by local standards (12) that may not apply to the testing situation, and experience suggests that bias may modify readers' interpretations when not in the testing environment (42).

A 1990 workshop was held to discuss the status of the B reader program (43). Among other ideas, proposals for quality assurance included (1) instituting a mandatory program of checks on readers, (2) initiating a core group of expert readers, (3) making provision for readers to voluntarily calibrate themselves with expert readers.

In order for mandatory checks of readings to identify bias, they would have to be random, not chosen by the individual B reader. Comparing the B reader's reports to the experts' could promote consistent reading patterns between recertifications, but if the B reader chose the radiographs to be monitored, bias could be maintained. The difficulty in mandatory audits is the wide variety of reading activity, which includes clinical, medico-legal, industrial, and governmental settings. While auditing would be easy in a large-scale surveillance project like the NIOSH Coal Workers X-ray Surveillance Project, it would be difficult to achieve in the day-to-day readings done for clinical and legal purposes.

Limiting the total number of B readers or appointing a core group of expert readers would have the effect of containing the variability problem to a smaller number of readers than the current group. The smaller number would ensure that each B reader would maintain a larger experience in interpreting radiographs for pneumoconiosis. The number of current B readers who read a low volume of films would suggest that reducing the total number would not have a detrimental effect on the program. However, the elitist nature of such a proposal, the intrusion upon local practices, and the financial implications will make this proposal unpopular and difficult to implement.

Voluntary calibration of readers has been successfully reported in Canada (44). This was accomplished by periodically circulating batches of radiographs to physicians reading films for pneumoconiosis. Their interpretations were sent to a central location, and feedback from an expert was provided in return. This led to improved agreement over time, indicating a learning effect. The logistical issues of mailing radiographs were recognized and addressed, but the advent of digital radiography and the ability to make images available on-line or on CD-ROM discs may make this approach even practical and economical. CT/HRCT correlation could be included to provide validation of the expert reading. Since the B reader would be well aware of which radiographs were being reviewed, the problem of bias would not be addressed. However, the feedback would be more frequent than recertification every 4 years, perhaps leading to greater uniformity.

SUMMARY

In summary, reader variability is multifactorial. If reducing bias is a priority, random review of B reader interpretations with feedback and a mechanism to enforce compliance with expert reading standards must be developed. Requiring B readers to maintain a minimum volume of reading would eliminate the problem of the outlier, low volume, B reader. Circulating CD-ROM discs or creating a website with cases available for interpretation with feedback would be an inexpensive way to provide continuing education to B readers between recertification exams. Inter-reader agreement could improve as a result.

Further research into chest radiograph interpretation with HRCT correlation may reduce the variability related to combining fibrotic and non-fibrotic small irregular opacities in the Classification. Differentiating pleural fat from pleural thickening may be improved through further study, or we may determine that, in the absence of diaphragmatic plaques or calcification, the chest radiograph is not effective for this purpose. The pattern of use of the Revised Edition 2000 of the ILO Classification with its acknowledgement of both epidemiological and clinical approaches needs to be clarified.

Reader variability is inherent in chest radiographic interpretation. This is present where no financial incentives are involved, but accentuated when they are. Proposals for further study of methods to improve uniformity of interpretation have been presented. Effective quality assurance designed to eliminate bias will be difficult to implement. Assuring quality through innovative new methods and inquiry into improved reading practices through CT/HRCT correlation will help maintain and improve the stature of the B reader program.

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Discussion of Alternative Approaches to B Reader Quality Assurance

The NIOSH B Reader testing and certification program is intended to assure professional competence in the classification of chest radiographs for the pneumoconioses and in particular to identify readers capable of supporting the NIOSH-mandated coal workers' health surveillance program (CWHSP) as well as other programs (e.g., Occupational Safety and Health Administration (OSHA) mandated health surveillance for workers with asbestos exposure).

Following an overview of the commissioned paper, "Approaches to B Reader Quality Assurance," by Dr. Shipley, the workgroup engaged in spirited dialog, exploring the needs for improved quality assurance and options for attempting to improve quality. Recommendations from this workshop are not consensus statements, but individual opinions of some, not necessarily all, of the participants.

Four common uses of B Readers/ILO Readings were identified, each with their own quality assurance needs:

- Medical surveillance and screening (as in the CWXSP)
- Research/epidemiology
- Clinical services (as part of disease diagnosis in an individual)
- Legal settings (workers' compensation; third party litigation; case finding)

Four leading questions regarding the B Reader Program also emerged:

1) What are the quality issues/problems?
2) What are the proposed responses/solutions?
3) Are the responses/solutions sufficient to take care of the issues/problems?
4) What should NIOSH do?

During the Quality Assurance (QA) workgroup's deliberations, various anecdotes were presented suggesting that source of payment can affect the perception of the presence or absence of abnormality in chest x-rays. Participants generally felt that there have been no effective mechanisms for NIOSH to supervise readers who may have been intentionally misusing their certification, and therefore the group chose to focus on QA issues relating to those who are motivated to classify x-rays accurately.

It was also acknowledged that there can be many sources of variability in readings-film quality, reader skills and experience, inadequacies in the standard films-among others. With respect to x-rays for worker monitoring, improvements are needed regarding validity to ensure consistent information is provided to the worker. One important goal of any QA effort should be to increase accuracy and reduce variability both among different readers and within a single reader. This would ensure that workers with dust exposure have a high probability of getting the same information (the same reading) from multiple readers or from the same reader who is looking at the film at different times.

Discussion continued regarding the fact that, although accuracy is the primary goal in all settings, the emphasis in QA may vary depending on the purpose of the examination. For example, surveillance requires a sensitive test, while addressing legal and clinical issues requires a more specific test; these may be competing needs. HRCT is already used to inform/qualify B Readings and might make the diagnosis more specific. However, using HRTC to confirm cases in the 0/0 0/1 boundary is problematic because the "gold" standard is not well defined. There is a continuum of abnormality on both pathology and HRCT. Showing correlations is useful for groups, but when the ILO classification is applied to individual films, it enters the arena of individual diagnosis for which the ILO system is less well suited. To demonstrate absence of bias when reading films that are used for litigation, readers can be asked to read the films in question along with others with known abnormalities, without being told which films have known readings.

Supplemental training for assessing ongoing performance was not discussed, inasmuch as NIOSH does not certify readings, just readers. However, candidates can pass the whole test but do poorly in one section (e.g., the pleural section) and then proceed to classify films requiring that competency. The certification test was developed before reading for asbestos was such a prominent issue, although classification of pleural changes is a larger component of the recertification examination. This issue could be addressed by requiring minimum competency scores for each section. The balance of films in the examinations may need to be reassessed. It was suggested that the NIOSH teaching syllabus films be reworked to include evaluation of quality issues and to obtain more information about them. There is a continuum of abnormality as shown by pathology (for nodules in 0/0 films). The cut-point around 0 and 1 is very important. Adding HRCT does not solve the problem, because the continuum exists on HRCT and on pathology as well. More clarity is needed in relation to the issues of validity versus reproducibility. A discussion ensued about convincing those taking the test to use the 0/1 category, compared to 0/0. Highlighting findings demonstrating exposure and pathologic correlations with subcategory 0/1 could be useful for this.

NIOSH approves x-ray facilities for the CWHSP (coal) but there is no federal evaluation of facilities providing radiographs for individuals at risk for asbestosis and silicosis. This process needs to be improved and potentially extended to all facilities. Some participants suggested that factors affecting the quality of readings could be mitigated by the creation of a master panel for blinded readings by those with no financial or other interest. However, this would require national legislation and could limit access to the expert witnesses that exists now.

Further discussion centered on the value of multiple-choice questions on the B reader examinations for technical aspects. A caution was voiced regarding non-technical aspects (e.g., issues regarding ethics would not be appropriate for multiple-choice questions). There was general agreement on this, but there were questions as to how such an approach would help solve any of the inherent problems. For example, some participants thought that each of the test component skills should be separately evaluated as having been passed or failed (and then all components should be passed for a reader to be certified).

It was pointed out that some organizations are moving away from certifying competence to certifying performance -- more like the NIOSH model. Continuing Medical Education (CME) credit for assessment of a NIOSH-compiled set of films with feedback - all done on a voluntary basis - was discussed and advocated. B Readers could be asked to review a set of twenty films every six or twelve months and provided with reference readings of films separately, in order to assess the accuracy of their readings.

The analogy of respirator testing was offered as an example. Is there anything in this analogy for the B Reader program, such as field audits? It was questioned how any of these procedures could be done and what the legal implications might be. Such things are done with mammography, but that system is confidential and no lawyers are involved.

Various individuals made recommendations regarding QA activities, but no consensus was sought or reached. Following are some of the recommendations that the individuals suggested NIOSH should take into consideration for the B Reader Program. Note that these are not consensus recommendations by all participants but a collection of different suggestions that one or more participants offered for improving the B Reader Certification program.

1. Training could be improved if:
   a. Training films were "validated" using either HRCT findings and/or pathology
   b. The NIOSH home study syllabus and the American College of Radiology (ACR) courses were updated to reflect thecurrent state of practice
2. The B Reader examination could be improved if:
   a. The films used in the examination were "validated" by HRCT
   b. The scores were distributed proportionately to the desired competencies (particularly, increased focus on accurate recognition of pleural abnormalities)
      i. A suggestion that each of the subcomponents of the test be "passed" did not receive much support; it was felt that the ability to accurately test each of the sub-components was limited by the time available
   c. The examination frequency, for those who participate in a voluntary periodic (annual) quality assurance and continuing education program, was lessened
   d.Testing on issues other than film classification were included (e.g., written test on the guidelines; public health reporting requirements; conduct of surveillance systems)
3. The performance of B Readers between certification exams could be improved if:
   a. An opportunity for assessment by circulating unknown films and providing feedback was provided
   b. Continuing education modules for the various component skills were provided -- these could be done in conjunction with a partner (e.g., ACR or ATS) who is skilled in the development and delivery of CMEs
   c. CD-based or internet-based educational approaches were used
4. The role in epidemiology/research could be improved if:
   a. NIOSH could develop and disseminate a recommended approach to assuring the quality of research x-ray readings
5. Film quality could be improved if:
   a. Facility certification was expanded to include all facilities where films are taken for ILO Classification
   b. The ACR "red book" for radiology technicians was updated
6. Other suggestions included:
   a. Intentionally reducing the number of B Readers (however, no mechanism was proposed)

At the conclusion of the workshop each participant was asked a final question. If NIOSH could change one thing pertaining to the B Reader Program, what should it be? Following are the answers that were given:

- De-certify readers who have a conflict of interest
- Provide ongoing quality assurance with mailings and educational materials
- Establish a national surveillance program for other diseases
- Provide ongoing surveillance of classification results by B Readers
- Provide comparison with HRCT
- Provide quality assurance more frequently
- Fix the reliability problems in the current examination
- Expand the self-study syllabus to include HRCT

Finally, it was repeatedly noted that the B Reader training and certification program is a valuable effort that could benefit from adjustment but should not be abandoned because of its important role in occupational lung disease surveillance, research, and intervention.

The Role of CT Scanning in Pneumoconiosis Screening

Commissioned Paper

Cecile Rose, MD, MPH, and David Lynch, MD

BACKGROUND

The purpose of screening is to identify diseases early in their course, before an individual would ordinarily seek medical care and when existing interventions may favorably affect disease outcome (1). Screening tests should be acceptable to those at risk for disease; have reasonable cost, effectively separate those with and without disease; and be sufficiently standardized to be performed with accuracy, consistency, and reproducibility. For pneumoconiosis screening, chest radiographs are acceptable, widely available and relatively inexpensive. However, the insensitivity of chest films for detection of early or moderate pneumoconioses limits their efficacy in screening. The ILO classification system, developed initially for epidemiologic purposes, is limited for purposes of clinical screening and diagnosis by high intra- and interobserver variability. Further, chest radiography is widely recognized as an ineffective tool for detection of airways abnormalities such as emphysema from dust exposure.

Within the past 20 years, newer imaging techniques such as conventional and high-resolution computerized tomography (HRCT) have enhanced visualization of the lung. Kreel and Raithel were pioneers in the use of CT to evaluate asbestosis and silicosis, with several papers from the 1970s documenting the enhanced ability of CT to show pleural plaques, subpleural parenchymal abnormalities, parenchymal bands, and micronodules in exposed workers with normal chest radiographs (2, 3). A further advance in the mid-1980's was the use of thin section, high resolution CT (thin collimation slices performed with a small field of view and reconstructed with a high spatial frequency algorithm) with both supine and prone images to more precisely characterize the extent and type of parenchymal disease (4-6). These techniques have improved the detection of early pathological changes and increased sensitivity and specificity in detecting occupational pleural and parenchymal abnormalities.

There is an increasing body of literature aimed at standardizing interpretation and validating the usefulness of HRCT in screening and surveillance for pneumoconioses. Our purpose in this working paper is to review the published literature on the role of CT in pneumoconiosis screening, assess the current state-of-the-art regarding standardized technique and scoring of CTs, comment on directions in the use of high-resolution lung imaging, and outline future research needs.

METHODS

After performing a MEDLINE literature search using the OVID search engine, we identified 762 peer-reviewed articles published between 1966 and 2003 using the exploded Medical Subject Heading terms asbestosis, silicosis, and coal workers pneumoconiosis. From these we selected all English-language papers using thin-section (? 3 mm) CT to evaluate populations of patients with asbestos, silica, or coal mine dust exposure. We included only those articles examining nonmalignant respiratory sequelae of these exposures. We systematically reviewed the findings of these papers under the following headings: (1) sensitivity of CT vs. CXR for pneumoconioses; (2) CT findings and lung function abnormalities; (3) correlation between CT findings and histopathology; and (4) CT scanning and disease progression. We initially summarized the data under multiple separate headers in tables (including details of CT technique used in each study, study design, specific occupations, smoking histories, and particular physiologic parameters), but later collapsed several of these categories for ease of presentation.

RESULTS

Technical differences in CT scanning between studies.

We found some variability in the technical approach to CT scanning in all of the articles reviewed. These technical differences probably affect generalization of findings, especially in earlier studies. About half the studies obtained contiguous 5-10 mm images in addition to HRCT images. In patients with asbestos exposure, the use of contiguous scans increased the likelihood of detection of pleural plaques. Scanning in the prone position is standard in almost all studies, and many also included supine imaging. Supine CT scans do not enhance sensitivity for asbestosis when prone scans are available (7). Scan collimation ranged from 1-2 mm but most recent studies have used 1 mm collimation. The number and spacing of scans has varied widely, but there is general agreement that at least 5 HRCT scans are usually obtained. In suspected asbestosis, several studies have tailored the scan acquisition to the expected site of disease, with scans being obtained only through the bases in the prone position to optimize depiction of the posterior subpleural lung. In a study of the CT dose required to detect asbestosis, it was found that a CT exposure of less than 200 mAs impaired detection of short lines (8).

Sensitivity of chest radiograph vs. CT scan.

Table 1 contains summary findings from major articles regarding the sensitivity of CT vs. chest radiograph in the recognition of asbestosis, silicosis, and coal workers pneumoconiosis (CWP). CT was generally found to be more sensitive in detecting early dust diseases of all types, particularly in workers with normal or 0/1 profusion chest films. However, this finding was not uniform. Investigations by Bergin and Remy-Jardin describe a significant number of chest films positive for simple silicosis that were negative on CT scan (9, 10). Poor concordance between chest film and HRCT in the early stages of silicosis was also found by Talini et al. (11). Friedman found that HRCT showed fewer parenchymal and pleural abnormalities in an asbestos-exposed population with chest radiograph B-readings showing interstitial and pleural changes (12). Of note, reader agreement (interobserver variability) is consistently higher for CT than for B-readings of chest radiographs for all pneumoconioses, even in the absence of a standardized scoring system.

In the majority of studies on silicosis and coal workers pneumoconiosis, CT was more sensitive and specific than chest film in the early detection of parenchymal opacities. In workers with normal chest radiographs, HRCT shows pneumoconiosis in 23-27% of cases. Additionally, CT was found to be better in the detection of coalescent and conglomerate opacities compared to plain film, and CT has been recommended in patients with simple silicosis on radiograph who may have conglomerate disease amenable to additional therapy (e.g., treatment for tuberculosis) or requiring more frequent medical follow-up and assessment for progression (10). CT is also superior to chest radiograph in the detection of emphysema and other airway effects of dust exposure, which are often also associated with cigarette smoking.

For asbestos-related pleural disease, several papers have demonstrated that CT is more sensitive and more specific than chest radiograph. Extrapleural fat on the chest films leads to over-diagnosis of pleural disease (particularly on oblique radiographs), while posterior plaques are not usually visible on chest radiograph (13). In patients with normal lung parenchyma by chest film, HRCT will show lung fibrosis in 13-54% of cases, depending on the population being screened. When the chest radiograph shows abnormal lung parenchyma, CT will confirm abnormality in 67-97% of cases. CT scoring is associated with less inter-observer variation than chest radiograph scoring.

CT findings vs. pulmonary function abnormalities. Table 2 contains information on the relationships between CT findings and lung function abnormalities in workers exposed to fibrogenic dusts. Most of these studies obtained complete pulmonary function tests on dust-exposed workers, including lung volumes, spirometry and diffusion capacity for carbon monoxide (DLCO). Several articles also evaluated exercise physiology in the context of CT findings.

A number of studies have shown that in silica or coalmine dust-exposed patients with obstructive lung disease, CT defines the presence of emphysema not evident on chest radiograph. CT findings are much better predictors of lung function abnormalities than are B-readings of chest films, particularly in the evaluation of emphysema associated with many of the functional abnormalities found in silicosis. Ooi et al. found that complicated silicosis on HRCT is an independent predictor of airflow obstruction and that HRCT mean lung attenuation is associated with restrictive physiology in silicotics (14).

The presence of asbestosis on CT is associated with decreased lung volumes, even in those with normal lung parenchyma by chest radiograph (15). The presence of diffuse pleural thickening on CT is usually associated with restriction (16). The extent of pleural plaque on CT is not usually associated with significant restriction once the extent of underlying parenchymal disease is accounted for.

Quantitative measurements derived from the CT density histogram have attracted increased interest as indices of the severity of parenchymal lung diseases (17-19). In patients with pneumoconiosis, primarily asbestosis, there have been several studies evaluating the relationship between quantitative CT-based measures of parenchymal abnormality and physiologic impairment (17, 20, 21). CT-determined lung density and other quantitative measures are correlated with decreased lung volumes and diffusion capacity.

CT findings vs. lung histopathology.
An obvious limitation to the use of CT as a screening tool is the absence of a gold standard for verifying the accuracy of CT findings. The gold standard for interpretation of imaging studies would ideally be morphology of the lung parenchyma obtained via necropsy or surgical biopsy. There are few published articles on the relationship between lung histologic findings in association with abnormalities on high resolution CT scans in individuals with pneumoconioses (Table 3). Several of these studies are limited by lack of quantitative information on severity and extent of CT abnormalities compared to histologic severity of disease. However, studies generally show that findings on HRCT reflect the pathologic description of pneumoconioses, and provide insights into the specific relationships between radiologic and pathologic findings. Limited data suggests that HRCT is less sensitive than biopsy in the detection of pneumoconiosis.

CT as a tool to monitor disease progression.
In the context of screening, the utility of CT as a tool to identify workers at risk for disease progression has important implications, as such workers would in most cases be well-served by changing to low exposure jobs if they are still exposed. For those workers with disease who are no longer exposed, the application of CT as a screening tool for progression would, if reliable, provide a valuable clinical tool. Table 4 summarizes the few available studies addressing this issue. These studies suggest that CT findings of early pneumoconiosis usually progress over time, particularly in workers with high cumulative dust exposures. The appropriate interval for follow-up of such abnormalities probably depends on the severity of exposure, but is likely 2-4 years.

DISCUSSION

Knowledge Gaps
While there is an expanding literature regarding

the utility of CT scanning as a screening tool for pneumoconioses, there are notable remaining gaps in knowledge that must be addressed before this technique can be recommended for widespread use. Major questions persist regarding (1) validity of CT screening (based on lung histology, physiology, and natural history of disease); (2) clinical management of both work-related and incidental CT findings; and (3) standardization of CT technique and scoring systems.

The utility of HRCT as a screening tool depends heavily on the populations targeted. The yield of CT screening probably varies depending on cumulative exposure dose, job description (e.g., underground coal mine work at the face), and latency since first exposure. Likewise, the appropriate interval for surveillance of high risk populations remains unclear. Further investigation of high-risk cohorts with carefully characterized exposure parameters is needed to address questions of efficacy and frequency of screening with this modality.

A number of studies show poor concordance between chest radiograph and HRCT in early stages of pneumoconioses. This discrepancy is partially attributable to overdiagnosis of pleural or parenchymal abnormalities on the chest radiograph. Extrapleural fat deposits commonly simulate pleural thickening on the chest radiograph, while changes of smoking-related respiratory bronchiolitis may simulate interstitial parenchymal abnormality. Additional explanations for the discordance between chest radiograph and CT include inadequate CT sampling or other technical issues or variability in reader interpretation due in part to the lack of an HRCT standardized scoring system. Despite the absence of a gold standard for diagnosing pneumoconiosis, it is likely that CT is more accurate in the early detection of parenchymal lung disease than the chest radiograph. This assumption is supported by the improved concordance between readers for HRCT compared to ILO chest radiograph scoring; the better correlation between HRCT findings and pulmonary function parameters suggests that HRCT is more accurate than chest radiograph. Additional studies assessing the correlation between imaging findings and lung pathology are required before a definitive answer will emerge.

With the increased sensitivity of HRCT, algorithms for appropriate clinical management of imaging findings need to be developed. It is probably reasonable to suggest that all interstitial findings of pneumoconiosis should prompt referral for further evaluation such as pulmonary function testing, risk communication, and interval surveillance. Pleural CT abnormalities suggesting previous asbestos exposure should prompt counseling regarding increased risk for other sequelae of asbestos exposure, minimizing further exposure, and smoking cessation if appropriate. Questions remain as to whether early findings of a pneumoconiosis should prompt removal of a worker from further exposure so as to decrease risk for disease progression. As seen in studies of high risk populations screened for lung cancer, a high prevalence of incidental findings is to be expected if contiguous CT imaging is performed. Noncalcified nodules were found in 111 of 602 asbestos workers screened by CT in a study by Tiitola et al. (22). A more limited HRCT sampling technique should lead to detection of fewer nodules, but would also lead to concern regarding missed lung cancers. These issues will need to be considered before HRCT is likely to gain widespread use as a screening tool.

A number of efforts to standardize the technical approaches and classification of CT for pneumoconioses have been proposed (23-25). The system described by Kraus et al, has been applied in over 2000 CT studies, with excellent intra and interobserver variance (70 to 90%). Their recommendations for standardized protocols for occupational lung disease surveillance using CT include:

- Examination from lung apex to base
- 1 mm slice thickness, 10 mm distance between slices
- Examination in supine position at

maximum inspiration
• 2 sections in prone position, slice thickness 1-2 mm
• Technical data: >130 kV; 180-300 mAs; high or ultra-high resolution kernel; scan time, 2 sec preferably <1 sec
• Window parameters: In lung window, W = 1500-2000HU; C = -300 to -500 HU; additional soft tissue window W= 200-500 HU; C = 40-10 HU
• Obligatory documentation on film or disk
• Internal quality control with obligatory B-reader evaluation
• Extended evaluation when malignant lesion suspected (spiral CT, additional slices)

Our only recommended changes to this protocol would be to perform the entire scan in prone position and to reduce the CT exposure parameters to 100 mAs or less.

In addition to standardizing image acquisition techniques, it is important to the science of occupational lung disease that imaging experts agree to standard methods for CT interpretation. Various standardized protocols for recording the presence and extent of abnormalities have been proposed, but none has gained widespread acceptance or endorsement. Descriptions of the CT findings in pneumoconiosis are reasonably standardized but scoring of the extent of these findings will require a standardized system of visual estimation. Whatever scoring system is adopted should be reasonably simple and associated with low inter-observer variation even in non-expert hands.

Barriers to the use of HRCT screening for pneumoconioses

There are a number of current barriers to the use of CT scanning as a screening tool for pneumoconioses. The six-fold higher cost of CT (high resolution images with interpretation, Medicare rate = $468) compared to chest radiographs (PA and lateral with interpretation and B-reading, Medicare rate = $76) is an obvious consideration. Some may question whether screening CT scans would be a windfall for owners and operators of CT scanners, for radiologists who interpret them, and for clinicians to whom many more patients are likely to be referred for medical management and follow-up. It is likely that the "downstream" evaluation of both screening-detected pneumoconiosis as well as incidental findings such as indeterminate lung nodules will add to the costs of health care. To justify the higher cost of CT, populations with a relatively high pre-test probability of disease should be selected for screening.

An additional consideration is the increased radiation dose associated with CT (1000-2000 mRads) compared to chest radiograph (5-10 mRads). Modern multi-channel scanners should allow substantial decrease in the effective CT dose. Scanning at selected non-contiguous slice intervals is associated with a lower effective dose than contiguous CT acquisition. Low dose thin section CT screening protocols are currently being used for lung cancer screening, and should also be considered for further investigation of dust diseases.

A major issue is geographic and financial access to CT scanning services. Unlike chest radiographs, there is limited availability of mobile CT units that would enable convenient, high quality and accessible service to miners and other workers at risk for dust diseases who often live and work in rural areas at long distances from medical centers. Likewise, the importance of assuring standardized approaches to imaging techniques and interpretation by trained and certified readers cannot be over-stated.

In the United States, there remains a paucity of comprehensive, confidential medical screening and surveillance programs available to workers. Rather than expanding to include costly and poorly accessible imaging techniques, would workers be better served if we focused on improving medical surveillance programs in other ways? For example, perhaps chest radiograph screening programs such as the "Miner's Choice" program should be extended to include surface coal miners and metal/nonmetal miners at risk for silicosis who are not currently served by federally-funded and sponsored efforts. Perhaps expanding the use of more sensitive tests of lung function (e.g., spirometry, diffusion capacity and/or exercise physiology) as well as detailed histories using validated respiratory symptom questionnaires would better improve early disease detection in workers at risk for dust diseases of the lung. Indeed, one approach to improved screening might be to eliminate the chest radiograph as a primary screening tool to be replaced by some combination of questionnaire, functional assessment, and CT.

The field of occupational lung disease is characterized by an intense and often adversarial legal environment. While the ILO system for standardizing chest radiographs arose with the intent of improving epidemiologic investigations, the system has been widely used in the assessment of workers for purposes of compensation and benefits eligibility. It is likely that the addition of CT scan findings to the criteria for defining pneumoconiosis would lead to the same contentiousness within the legal and regulatory environments that exists currently for chest radiograph interpretations. Moreover, earlier disease detection, likely with less impairment than is seen with abnormal chest films, may have the effect of labeling asymptomatic workers for early lay-offs and other risks for loss of employment and insurability. Alternatively, CT may be of benefit if it is normal or if it shows another cause for symptoms or functional impairment that require other approaches to medical management.

Need for further targeted research and demonstration projects

Despite significant knowledge gaps and barriers, our review suggests that HRCT scans are more sensitive and specific in the early detection of fibrosis and emphysema associated with dust exposures than chest radiographs. Table 5 summarizes the advantages of CT scans in the context of pneumoconiosis screening and diagnosis. While we cannot recommend routine CT screening for all at-risk worker populations, there probably is a role for CT in the screening of some high risk worker populations, e.g., in those with adequate exposure dose and latency who have normal or equivocal chest radiographic findings, particularly if these individual exhibit functional abnormalities and/or unexplained respiratory symptoms In workers exposed to silica and/or coal mine dust who have evidence of simple pneumoconiosis, HRCT appears to have a role in screening for conglomerate masses that may require further medical management. HRCT should also be considered in those with lung function abnormalities, particularly obstructive defects that are poorly demonstrated on plain film.

Further research and demonstration projects are needed in order to better validate the use of HRCT as a screening and surveillance tool in these settings. CT images need to be correlated with histopathologic findings for all interstitial and airway lung diseases, including those caused by inhalation of inorganic dusts. Multi-center, federally funded research studies using standardized low dose CT scanning protocols and scoring systems are essential. Additional longitudinal studies will be necessary to determine the natural history of these lung diseases as reflected by changes on CT. Finally, it will be important to develop computer-based methods for quantitative imaging of the lung to identify disease early, to follow disease progression over time, and to evaluate results of therapeutic interventions.

Table 1: Sensitivity of CT vs CXR in diagnosis of pneumoconiosis

Reference	Reference Summary	
Bergin 1986 (9)	Disease	Silicosis
	Mean Exposure	30 years
	Population	58 workers, 90% current or former smokers
	CT Scoring System	ILO system
	CXR vs CT # Abnormal	6 vs 12 normal 30 vs 13 simple 22 vs 33 complicated
	Conclusions	CXR is superior to CT in early detection of silicosis. Recommend CT in workers with simple silicosis on CXR to identify treatable conditions and severe disease.
Akira 1989 (26)	Disease	CWP, silicosis, talcosis, graphite and welders lung
	Mean Exposure	NA
	Population	61 silicosis; 12 CWP; 6 welders lung; 6 graphite; 5 talcosis on CXR
	CT Scoring System	2 independent readers
	CXR vs CT # Abnormal	NA
	Conclusions	Focal dust emphysema and low attenuation areas more commonly found with p opacities. CXR p opacities show on HRCT as binary branching opacities and small areas of low attenuation with central dot, not as distinct rounded opacities.
Remy-Jardin 1990 (10)	Disease	CWP
	Mean Exposure	23 years
	Population	170 coal dust exposed workers; 86 miners with CXR CWP and 84 miners without CWP CXR
	CT Scoring System	Micronodules (< 7mm); Nodules (8-20 mm); Progressive Massive Fibrosis (PMF) >20 mm; emphysema honeycombing, LN
	CXR vs CT # Abnormal	0/48 (CXR) vs 11/48 (23%) with abnormal HRCT. In 72 with normal HRCT 36 (50%) had abnormal CXR.
	Conclusions	CT better than CXR for silicosis, emphysema, necrosis, cavitation.

Table 1: Sensitivity of CT vs CXR in diagnosis of pneumoconiosis (continued)

Reference	Reference Summary	
Begin 1991 (27)	Disease	Silicosis
	Mean Exposure	29 years
	Population	49 workers referred to compensation board; 2 normal Controls
	CT Scoring System	ILO system; 3 independent chest MD readers
	CXR vs CT # Abnormal	32 vs 22 normal, 6 vs 1 indeterminate, 10 vs 19 simple, 3 vs 9 confluent.
	Conclusions	13 (27%) abnormal by CT alone. HRCT better than comparison of conventional CT (CCT) (added 10% new cases). Better reader agreement for CT than CXR. CT more sensitive than CXR for opacities & confluence.
Begin 1993 (28)	Disease	Asbestosis
	Mean Exposure	22 years
	Population	N= 61 Referral for evaluation for asbestos related disease
	CT Scoring System	Similar to ILO 5 readers
	CXR vs CT # Abnormal	27% (CXR) vs 39% (HRCT)
	Conclusions	Reader agreement was higher for CT than for CXR. CT is more sensitive and specific.
Gamsu 1995 (29,30)	Disease	Asbestosis
	Mean Exposure	52.5 years
	Population	N=30 HRCT and histologic material available
	CT Scoring System	4-point scale of extent and severity 6 features
	CXR vs CT # Abnormal	Asbestosis present in 10/14 patients with CXR $\leq$0/1, and in all 11 of those with CXR $\geq$1/0.
	Conclusions	NA

Table 1: Sensitivity of CT vs CXR in diagnosis of pneumoconiosis (continued)

Reference	Reference Summary	
Friedman 1988 (12)	Disease	Asbestosis, pleural disease
	Mean Exposure	> 1 year
	Population	N=60 Chest radiograph showing pleural disease
	CT Scoring System	Presence or absence of lines, bands, subpleural curvilinear lines, honeycombing
	CXR vs CT # Abnormal	CXR: 23 (38%) had asbestosis; 38 (63%) had pleural disease. CT: 21 (35%) had asbestosis (2 without pleural disease); 31 (52%) had pleural disease.
	Conclusions	Selection bias?
Aberle 1988 (4,5)	Disease	Asbestosis, pleural disease
	Mean Exposure	21 years exposure 37 years mean latency
	Population	N=100 Disagreement over presence of asbestosis or pleural disease on CXR
	CT Scoring System	Type, location, thickness of pleural disease. Parenchymal abnormality scored as low, medium or high probability of asbestosis. Thickened lines, subpleural density, and parenchymal bands were major contributors to CT diagnosis.
	CXR vs CT # Abnormal	CT high probability in 39/45 with clinical asbestosis, in 20/55 who did not meet clinical criteria, and in 28/65 with normal CXR. Pleural disease present in 93/100 (minimal in 29).
	Conclusions	CT more sensitive than CXR for pleural and parenchymal disease; it is appropriate criteria for minimal disease.
Ameille 1993 (13)	Disease	Asbestos pleural disease
	Mean Exposure	NA
	Population	23 workers with pleural disease on oblique CXR
	CT Scoring System	Comparison of PA and oblique CXR with HRCT diagnosis of pleural plaque.
	CXR vs CT # Abnormal	CXR: 6/23 (PA radiographs) 23/23 (oblique radiographs) HRCT: 3/23
	Conclusions	Pleural disease absent on CT in 2 of 6 in whom it was diagnosed on PA CXR and in 17 of 23 in whom it was diagnosed on oblique radiographs. Extrapleural fat simulates pleural disease, particularly on oblique radiographs.

Table 1: Sensitivity of CT vs CXR in diagnosis of pneumoconiosis (continued)

Reference	Reference Summary	
Oksa 1994 (31)	Disease	Asbestos pleural disease and asbestosis
	Mean Exposure	≥15 years
	Population	21
	CT Scoring System	Evaluation of CT findings in asbestosis
	CXR vs CT # Abnormal	CXR: 5 abnormal CT: 27 abnormal
	Conclusions	CT should be performed in those with normal CXR and functional impairment.
Gevenois 1998 (32)	Disease	Asbestos-related diseases
	Mean Exposure	≥10 years
	Population	159 exposed, with normal CXR
	CT Scoring System	CCT and HRCT
	CXR vs CT # Abnormal	CCT: Pleural disease 58/159 Fibrosis 9/159 HRCT: pleural disease 49/159, fibrosis 20/159
	Conclusions	CCT more sensitive for pleural disease. HRCT more sensitive for parenchymal abnormality.
De Raeve 2001 (33)	Disease	Asbestos pleural disease
	Mean Exposure	≥10 years
	Population	100 civil servants in office building with asbestos
	CT Scoring System	Intra- and interobserver variation;-3 readers
	CXR vs CT # Abnormal	18/100 had plaques on HRCT.
	Conclusions	Consensus plaques in 18/100, diagnosed by all 3 observers in only 8. Good intraobserver variation $\lambda=0.68$, moderate to fair interobserver variation $\lambda=0.26$-0.48 Diagnosis of subtle plaques requires strict definition of plaques.

Table 1: Sensitivity of CT vs CXR in diagnosis of pneumoconiosis (continued)

Reference	Reference Summary	
Gevenois 1998 (32)	Disease	Asbestosis, asbestos pleural disease, diffuse pleural thickening
	Mean Exposure	≥10 years
	Population	231 compensation-seekers Excluded those with obvious calcified plaques and with ILO score>1/1
	CT Scoring System	Consensus reading; two radiologists
	CXR vs CT # Abnormal	CT normal in 132 (57%). Plaques in 72 (31%). Diffuse thickening in 32 (14%). Parenchymal bands in 35 (15%), septal/intralobular lines in 11 (5%), honeycombing in 6 (3%), round atelectasis in 8 (3%)
	Conclusions	Plaques or diffuse pleural thickening were not statistically associated with signs of asbestosis. Three distinct clusters of abnormality were identified: plaques, diffuse pleural thickening (with parenchymal bands and round atelectasis), and asbestosis.
Al-Jarad 1993 (34)	Disease	Asbestosis
	Mean Exposure	11 years
	Population	53 asbestos workers Profusion >1/0 in 32 ≤1/0 in 21
	CT Scoring System	Comparison of CXR, CT, and time expanded waveform analysis of auscultation
	CXR vs CT # Abnormal	32>1/0 on CXR 42 with HRCT parenchymal abnormalities
	Conclusions	HRCT abnormal 31/32 with CXR profusion > 1/0, 8/11 with 1/0, 2/4 with 0/1, and 1/17 with 0/0 Time expanded waveform analysis about similar in detection rate Lower specificity Waveform analysis is more sensitive than auscultation for detection of asbestosis

Table 1: Sensitivity of CT vs CXR in diagnosis of pneumoconiosis (continued)

Reference	Reference Summary	
Topcu 2000 (35)	Disease	Asbestosis
	Mean Exposure	53 years
	Population	26 environmentally exposed (Turkey) Profusion $\leq$1/0 in 24 Extensive plaques on CXR obscuring lungs
	CT Scoring System	Prevalence study.
	CXR vs CT # Abnormal	2/26 on CXR vs 24/26 on HRCT
	Conclusions	Parenchymal bands in 92%, interlobular lines in 81%, intralobular in 46%, subpleural lines in 46%, fine honeycombing 38%, coarse honeycombing 27%, round atelectasis 19%, apical pleural thickening 35%. High prevalence of parenchymal abnormalities in those with extensive pleural disease. Apical pleural thickening may be increased, but no control group.
Tiitola 2002 (36)	Disease	Asbestos-related pleural disease
	Mean Exposure	26 years
	Population	602 exposed 50 controls (30 with possible asbestos exposure). Diagnosis of asbestos related pleural disease (N=601) or asbestosis (N=85, and 20 were nonsmokers).
	CT Scoring System	Observer agreement study, comparison with controls
	CXR vs CT # Abnormal	NA
	Conclusions	Observer agreement moderate to good λ=0.75 for disease extent. Bilateral pleural disease seen in 64% of controls and 95% of workers. Extent, thickness, and prevalence of calcification were all greater in the exposed group. Bilateral pleural plaques may occur in unexposed or minimally exposed individuals. Extent of pleural abnormality > 45 cm^2 was best discriminant between controls and exposed.

Table 1: Sensitivity of CT vs CXR in diagnosis of pneumoconiosis (continued)

Reference	Reference Summary	
Huuskonen 2001 (37)	Disease	Asbestosis
	Mean Exposure	26 years
	Population	602 exposed, 49 controls (30 with possible asbestos exposure) Diagnosis of asbestos related pleural disease (N=601) or asbestosis (N=85, of whom 20 were nonsmokers)
	CT Scoring System	Receiver operating characteristic (ROC) curve for CT criteria vs clinical diagnosis of asbestosis
	CXR vs CT # Abnormal	NA
	Conclusions	Area under ROC curve for CT was 0.89, compared with 0.76 for ILO score of CXR. Highest score seen in insulators.
Vehmas 2003 (38)	Disease	Asbestos-related CT changes
	Mean Exposure	26 years
	Population	587 exposed: 18 never smokers, 406 ex-smokers, 163 current smokers
	CT Scoring System	Prevalence of findings among smoking groups
	CXR vs CT # Abnormal	NA
	Conclusions	Emphysema and airway wall thickening were related to smoking. Curvilinear lines and septal thickening appeared less frequent in smokers. Difficult to interpret this study because of lack of prone images, and small number of nonsmokers.
Harkin 1996 (39)	Disease	Asbestosis
	Mean Exposure	Exposure > 5 years Latency > 20 years
	Population	107 subjects, of whom 37 also agreed to pulmonary function testing (PFT) and broncho alveolar lavage (BAL). 37 exposed: 8 nonsmokers, 12 exsmokers, 17 current smokers
	CT Scoring System	Correlate ILO score, CT, physiology, lavage
	CXR vs CT # Abnormal	9/37 CXR vs 11/37 HRCT

Table 1: Sensitivity of CT vs CXR in diagnosis of pneumoconiosis (continued)

	Conclusions	26 were normal by HRCT- CXR was concordant in 23. 11 were abnormal by HRCT- CXR was concordant in 6. Pleural disease correlated with lung volumes. ILO score performed about as well as CT score. Small sample size; results difficult to interpret.
Murray 1995 (7)	Disease	Asbestosis
	Mean Exposure	NA
	Population	49
	CT Scoring System	Comparison of scan readings based on more or less limited sampling
	CXR vs CT # Abnormal	CXR showed < 50% of abnormalities on CT
	Conclusions	Supine scans do not add to detection of asbestosis. Use of single scan increased observer disagreement.
Majurin 1994 (8)	Disease	Asbestosis
	Mean Exposure	Exposure > 20 years
	Population	45 clinical suspicion asbestosis
	CT Scoring System	Comparison of visibility of findings at different mAs
	CXR vs CT # Abnormal	CT confirmed parenchymal abnormality seen on CXR in 37/45 (82%)
	Conclusions	Visibility of short (reticular) lines decreases progressively below 200 mAs. Lower dose scans may be useful. Study needs to be repeated with newer equipment.
Jarad 1992 (24)	Disease	Asbestos-related pleural and lung disease
	Mean Exposure	Exposure >10 years Latency > 20 years Mean 34 years
	Population	60 CXR showed lung or pleural disease.
	CT Scoring System	Observer variation in scoring, correlation with PFT
	CXR vs CT # Abnormal	Pleural disease 54/60. Fibrosis (>0/1) 51/60. Pleural disease 59/60. Fibrosis 45/60.
	Conclusions	Observer variation was lower for CT than for CXR. Correlation with physiology was similar, but CT has advantage of detecting emphysema. 9/51 patients with fibrosis by CXR had no fibrosis on CT

Table 1: Sensitivity of CT vs CXR in diagnosis of pneumoconiosis (continued)

Reference	Reference Summary	
Klaas 1993 (40)	Disease	Asbestosis
	Mean Exposure	Exposure 23 years Latency >14 years Mean 37 years
	Population	75 of whom16 met clinical criteria for asbestosis (including CXR≥ 1/1).
	CT Scoring System	Evaluation of gallium scanning and HRCT
	CXR vs CT # Abnormal	Pleural disease 53/75 Fibrosis (≥1/0) 34/75 Fibrosis 59/75
	Conclusions	CT high probability in 44/59 (88%) without clinical asbestosis and in 15/16 with clinical asbestosis. Gallium scan positive in 52/59 without asbestosis and 15/16 with asbestosis.
Staples 1989 (15)	Disease	Asbestosis
	Mean Exposure	> 10 years
	Population	169 asbestos-exposed with profusion <1/0 on CXR
	CT Scoring System	Comparison of workers with normal or near-normal parenchyma on CT and those with abnormal CT.
	CXR vs CT # Abnormal	HRCT abnormal in 57/167 (54%)
	Conclusions	NA

Table 2: Relationship between CT findings and functional abnormalities in pneumoconiosis

Reference	Reference Summary	
Bergin 1986 (9)	Disease	Silicosis
	Mean Exposure	19 years
	Population	17 men (15 smokers); 6 controls without exposure
	CT Scoring System	Grade 0=no nodules Grade 1=small number of nodules Grade 2=many nodules Grade 3 = confluence of nodules Grade 4 = confluence of nodules over 2 slices (PMF)
	Study Design	Comparison of CXRs vs CTs in known silicotics. Slightly impaired lung function – means forced expiratory volume in one second (FEV1), total lung capacity (TLC), DLCO > 80%).
	Results	Good correlation between mean attenuation values and visual CT scores vs ILO profusion.
	Conclusions	CT better for detection of emphysema associated with silicosis than CXR.
Begin 1988 (41)	Disease	Silicosis
	Mean Exposure	All > 20 years
	Population	94 workers (80 granite workers) referred to compensation board; analyzed by smoking history
	CT Scoring System	ILO system
	Study Design	Patients grouped by results: 1=normal, 2=simple silicosis, 3=simple on CXR but comp on CT, 4=both show complicated Lung volumes, DLCO, compliance, exercise gas exchange
	Results	Group 3 had significantly worse PFTs than Group 2; including lung volumes, gas exchange and airflow obstruction.
	Conclusions	Recommend CT scan in those with CXR simple silicosis since more likely to show complicated disease associated with decreased lung function.

Table 2: Relationship between CT findings and functional abnormalities in pneumoconiosis (continued)

Reference	Reference Summary	
Collins 1993 (42)	Disease	CWP
	Mean Exposure	26 years
	Population	29 coal miners; smoking histories examined; excluded those with airflow limitation
	CT Scoring System	2 independent radiologists: 0=no nodules 1=1-5 nodules 2=6-10 nodules 3=TNTC; focal emphysema
	Study Design	CXR profusion: 9 had 0/0; 5 had 0/1; 6 had 1/0; 1 had 2/1 Spirometry, lung volumes, resting ABG
	Results	HRCT more sensitive than CXR in showing nodules and focal emphysema; no correlation with PFT abnormalities.
	Conclusions	Selection bias to healthy miners
Cowie 1993 (43)	Disease	Silicosis
	Mean Exposure	29 years
	Population	70 older gold miners with and without silicosis
	CT Scoring System	Cat 0=no nodules Cat 1= few nodules Cat 2 = intermediate # Cat 3 = innumerable nodules
	Study Design	70/242 with exposure randomly selected to have CT
	Results	Association with diffuse emphysema and silicosis: 14% without silicosis vs 50% with silicosis had CT emphysema; increasing % with higher profusion; emphysema significantly associated with decreased FEV1/forced vital capacity (FVC).
	Conclusions	NA

Table 2: Relationship between CT findings and functional abnormalities in pneumoconiosis (continued)

Reference	Reference Summary	
Lamers 1994 (44)	Disease	CWP
	Mean Exposure	> 20 years underground
	Population	35 retired coal miners with normal CXR ($\leq$0/1); cumulative dose calculated; 20 healthy controls
	CT Scoring System	2 independent radiologists; 4 categories: 0=normal 1=few nodules 2=moderate opacities 3=numerous
	Study Design	FEV-1, TLC, DLCO
	Results	Tendency to higher cumulative dust exposure between HRCT groups 1 and 4; PFTs did not differ between groups.
	Conclusions	Small numbers; one of the few studies to examine cumulative dust exposure and HRCT score.
Begin 1995 (45)	Disease	Silicosis Asbestosis
	Mean Exposure	NA
	Population	207 consecutive workers referred to compensation board (66 silicosis, 45 silica exposed; 37 asbestosis, 59 exposed); low CXR profusion
	CT Scoring System	3 readers ILO system for opacities Presence, type, extent, severity by zone, and severity score for emphysema
	Study Design	Lung volumes; spirometry, DLCO, rest arterial blood gases (ABG)
	Results	Nonsmokers: emphysema in 1/20 without pneumoconiosis and 8/11 with pneumoconiosis. Smokers: emphysema in 55% silica exposed and 29% asbestosis exposed.
	Conclusions	Significant CT emphysema and abnormal PFTs in workers with pneumoconiosis and in smokers with silica exposure.

Table 2: Relationship between CT findings and functional abnormalities in pneumoconiosis (continued)

Reference	Reference Summary	
Talini 1995 (11)	Disease	Silicosis
	Mean Exposure	29 years
	Population	27 workers (8 smokers, 13 ever smokers, 6 non-smokers) diagnosed with silicosis by history and CXR $\geq$ 1/0.
	CT Scoring System	2 independent readers Categories 1-4 nodules scoring per Bergin; grades 1-4 proportional area with emphysema.
	Study Design	Spirometry, lung volumes, diffusion capacity
	Results	HRCT grade of emphysema and higher profusion score associated with reduced DLCO Significant correlation between HRCT grade emphysema and profusion score.
	Conclusions	Higher reader concordance with HRCT than CXR. Poor concordance with CXR and HRCT in early stage silicosis. Profusion of opacities on HRCT correlated with PFTs, irrespective of smoking or bronchitis.
Gevenois 1998 (32)	Disease	Silicosis, CWP
	Mean Exposure	17 years
	Population	48 coal miners, 35 silica exposed referred to compensation board; 40 unexposed
	CT Scoring System	2 independent readers; no profusion scoring of Micronodules
	Study Design	Comparison of CXR vs CT vs PFTs
	Results	Micronodules on CT scan are not associated with PFT abnormalities; CT detected micronodules in 23/46 (50%) with CXR<1/1.
	Conclusions	NA

Table 2: Relationship between CT findings and functional abnormalities in pneumoconiosis (continued)

Reference	Reference Summary	
Ooi 2003 (14)	Disease	Silicosis
	Mean Exposure	28 years
	Population	Recruited 76 patients with silicosis based on history and CXR $\geq$ 1/0.
	CT Scoring System	2 radiologists; 5 CT parameters: Begin scale nodular profusion (NP), PMF (>1.5 cm opacity), NP plus emphysema (NPI), emphysema index (EI) , mean lung attenuation
	Study Design	Quantified pack years and exposure years; Borg scale dyspnea grade Spirometry, lung volumes, DLCO
	Results	HRCT showed 18 with simple silicosis; 58 with PMF. PMF and EI were best independent determinants of FEV1, FEV1/FVC and TLC. Mean lung attenuation was best determinant of FVC, DLCO and Borg scale dyspnea.
	Conclusions	PMF is an independent predictor of airflow obstruction. Neither duration of silica exposure nor cigarette consumption had effect on lung function. Mean lung attenuation is an indicator of lung restriction in silicosis.
Wollmer 1987 (20)	Disease	Asbestosis
	Mean Exposure	NA
	Population	33 workers (27 smokers), 39 controls (19 smokers) Shortness of breath ≥ Grade 1, or crackles, or CXR profusion ≥ 1/0, or abnormal spirometry
	CT Scoring System	Density measurements at periphery of lung
	Study Design	Comparison of lung density in workers vs controls, stratifying for smoking Lung volumes, resistance, elastic recoil
	Results	Lung density lower in nonsmoking asbestos workers than in nonsmoking controls.
	Conclusions	Lung density correlates with TLC in exposed group.

Table 2: Relationship between CT findings and functional abnormalities in pneumoconiosis (continued)

Reference	Reference Summary	
Begin 1993 (28)	Disease	Asbestosis
	Mean Exposure	NA
	Population	61 referral for evaluation for asbestos related disease
	CT Scoring System	Similar to ILO
	Study Design	Correlation with physiology, comparison with CXR Lung volumes, P(A-a)O2 DLCO
	Results	Similar correlations for CXR and CT
	Conclusions	NA
Eterovic 1993 (21)	Disease	Asbestosis
	Mean Exposure	NA
	Population	Histologically proven asbestosis 7 early asbestosis (profusion ≤1/0), 15 late asbestosis, 13 controls, all nonsmokers
	CT Scoring System	CT histogram parameters (applied to raw data) 3-point visual probability score for asbestosis
	Study Design	Comparison of controls, early, late disease Volumes, DLCO, ABG
	Results	Histogram parameters separated controls, early and late disease. Correlations with DLCO slightly stronger for histogram than for visual score.
	Conclusions	Unclear why expiratory images were used, small n
Neri 1996 (46)	Disease	Asbestos pleural and lung disease
	Mean Exposure	Mean 21.6 Latency 21.6 years
	Population	119 shipyard workers with normal CXR (no pleural disease, profusion ≤1/0)
	CT Scoring System	Presence or absence of parenchymal or pleural abnormally.
	Study Design	Prevalence study; comparison of exposure groups
	Results	50 had plaques only, 31 had plaques and parenchymal abn, 7 had parenchymal abn only. All 22 workers exposed 15 years had pleural abnormalities, 50% had parenchymal abn. Parenchymal abn increased with smoking history, and with duration of exposure.
	Conclusions	Type of parenchymal abn not specified

Table 2: Relationship between CT findings and functional abnormalities in pneumoconiosis

(continued)

Reference	Reference Summary	
Schwartz 1990 (47)	Disease	Asbestos-related pleural and lung disease
	Mean Exposure	NA
	Population	Asbestos-exposed with normal parenchyma on CXR and varying levels of pleural disease on CXR
	CT Scoring System	NA
	Study Design	Evaluation of pleural and parenchymal disease and lavage findings as determinants of restrictive lung function Lung volumes, DLCO
	Results	Pleural disease (by CXR) was the strongest determinant of pulmonary restriction.
	Conclusions	Small n
Staples 1989 (15)	Disease	Asbestos
	Mean Exposure	> 10 years
	Population	169 asbestos-exposed with profusion < 1/0 on CXR
	CT Scoring System	Group 1 (n=76): normal or mild focal abnormalities at ≤ 2 levels Group 2 (n=57): multifocal/ diffuse, bilateral, multiple Levels Group 3(n=36) indeterminate-excluded
	Study Design	Lung volumes, DLCO, dyspnea grade
	Results	Those with abnormal CT had significantly lower vital capacity and DLCO, and higher dyspnea grade.
	Conclusions	NA

Table 3: Relationship between CT findings and histopathologic findings in pneumoconiosis

Reference	Reference Summary	
Akira 1989 (26)	Disease	Silicosis
	Mean Exposure	NA
	Population	2 postmortem specimens from patients with silicosis
	CT Scoring System/Design	HRCT performed on 2 inflated and fixed post mortem lung specimens
	Results	Low attenuation on HRCT=focal dust emphysema. Central dot=fibrous nodule surrounded by vesicular emphysema. P opacities=irregular fibrosis around respiratory bronchioles
	Conclusions	Focal dust emphysema (small areas of low attenuation) more common with p opacities. Study qualitative.
Lee 1999 (48)	Disease	DMLD (diffuse micronodular lung disease)
	Mean Exposure	4/40 with silicosis, 2/40 with CWP
	Population	40 patients with biopsy proven DMLD due to HP(3), DPB(4), sarcoidosis(2), TB(12), infectious bronchiolitis 4), dust disease(6)
	CT Scoring System	3 independent radiologists: Scored nodule location, size, margin definition, coalescence, cavitation, distribution Correlated HRCT findings with biopsy (TBBX, VATS, thoracotomy)
	Results	Centrilobular micronodules found in 1 CWP; perilymphatic micronodules in 5/6; mediastinal LN enlargement in 2/6; upper and middle zone predominant in 2/6. Pathology in dust disease showed gray-black 0.5-5.0 mm fibrotic nodules-peribronchiolar, perivascular and subpleural interstitium
	Conclusions	HRCT findings correlated with pathologic description of pneumoconiosis. Nodules mainly perilymphatic in location on CT (also true for sarcoidosis and amyloidosis).

Table 3: Relationship between CT findings and histopathologic findings in pneumoconiosis (continued)

Reference	Reference Summary	
Akira 1990 (49)	Disease	Asbestosis
	Mean Exposure	Exposure 21 years Latency 31 years.
	Population	7 with asbestosis at autopsy
	CT Scoring System	4-point scale In vitro post-mortem CT-Direct rad-path correlation
	Results	Intralobular lines=peribronchiolar fibrosis Interlobular lines=fibrosis or edema Pleural-based opacities=subpleural fibrosis Ground glass=edema or fibrosis Subpleural curvilinear lines=confluent peribronchiolar fibrosis
	Conclusions	CT reflects pathology in established asbestosis.
Gamsu 1995 (29,30)	Disease	Asbestosis
	Mean Exposure	Exposure 21 years Latency 53 years
	Population	30 with asbestosis exposure, HRCT and histologic material available
	CT Scoring System	4-point scale of extent and severity; 6 features Relationship between CT scores and histologic DX of asbestosis
	Results	Histologic asbestosis present in 9/14 patients with normal or near-normal CT, and in all 16 of those with CT scored as consistent with or probable asbestosis. Asbestosis more likely with increasing number of different types of abnormality.
	Conclusions	CT will not detect all asbestosis. Multiple CT findings, present bilaterally and at multiple levels, usually indicate asbestosis.
Ren 1991 (50)	Disease	Asbestosis
	Mean Exposure	NA
	Population	29 patients with pleural plaques at autopsy
	CT Scoring System	Probability score for asbestosis In vivo study of lungs
	Results	Only 8/29 with plaques had documented asbestos exposure, and only 2 had asbestosis. CT showed equal prevalence of abnormalities in control and plaque groups.
	Conclusions	Very difficult to interpret because of inadequate documentation of exposures, heavy selection bias.

Table 4: Progression of CT abnormalities in patients with early pneumoconiosis

Reference	Reference Summary	
Bourgkard 1998 (51)	Disease	CWP
	Mean Exposure	NA
	Population	80 miners, >10 yrs face work, with 0/1 or 1/0 CXR profusion >10 yrs. with normal CXRs and 80 miners <2 yrs. with normal CXRs
	CT Scoring System	2 independent readers; profusion by zone (0=absent, 1=rare, 2=intermediate, 3=high)
	Study Design	Longitudinal, 1990, 1994; cumulative coal mine dust exposure calculated
	Results	Progression over 4 years associated with micronodules on CT, wheeze, high cumulative dust exposure.
	Conclusions	CT improved diagnostic precision and predicts evolution to pneumoconiosis.
Akira 1991 (52)	Disease	Asbestosis
	Mean Exposure	Exposure 24 years Latency 31 years
	Population	NA
	CT Scoring System	4-point scale for peripheral and central extent of 6 types of abnormality-2 observers
	Study Design	2 scans taken 12-37 months apart
	Results	21 patients had abnormal CT. Progression of findings occurred in 9/23—more common in smokers and in those scanned at 2-3 year interval. Centrilobular nodules became confluent.
	Conclusions	Findings of early asbestosis may progress over time. Appropriate followup interval is probably 2-3 years.

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Discussion of Role of CT Scanning in Pneumoconiosis Screening

Drs. Lynch and Rose presented summary slides for discussion based on the draft manuscript. There was extensive and animated discussion from workshop participants, as outlined below. Recommendations from this workshop are not consensus statements, but individual opinions of some, not necessarily all, of the participants.

REVIEW: CONCLUSIONS OF THE WORKSHOP PAPER

Many participants suggested the following modification to the summary:

- HRCT is more sensitive than chest radiograph in detection of interstitial abnormalities.
- HRCT is more sensitive than chest radiograph in detection of emphysema.
- HRCT improves detection of coalescent/ conglomerate opacities in silicosis and CWP.
- Among experienced readers, HRCT appears to be associated with less interobserver variability (better reader concordance) than the chest radiograph
- Lung function deficits are more strongly associated with abnormalities on HRCT than on chest radiographs.
- HRCT is more sensitive and specific than the chest radiograph for identification of asbestos-related pleural disease.

KNOWLEDGE GAPS

Specific knowledge gaps were reviewed and discussed, including the validity of HRCT findings in pneumoconiosis, the optimal imaging technique, and CT scoring system, the optimal frequency or interval for screening, and the clinical management of CT findings.

BARRIERS TO USE OF CT

Barriers to more widespread use of CT include cost (including social costs), difficulty with access, radiation dose, and the possibility that alternative screening approaches may be preferable. It was reiterated several times during the workshop that screening should be done with well-defined purposes in mind, either treatment or prevention. This core concept is particularly important in evaluating screening tools for pneumoconioses, long latency diseases with limited treatment options. It was felt that CT probably fits best with a multi-pronged clinical approach, perhaps as a secondary measure following symptom/exposure questionnaires and/or measures of lung function. Regarding cost, it is possible that a limited CT acquisition approach might decrease the cost of examination. Regarding radiation, the participants reflected that breast is the critical at-risk organ, which may be less of a concern in predominantly male workers, and that addition of a lateral chest radiograph to the standard PA screening film increases radiation dose three-fold.

CT TECHNIQUE

Many participants felt that the optimal method would be a contiguous prone acquisition with a multi-channel scanner, using as low a radiation dose as possible. Both thin and thick sections would be reconstructed from this acquisition. However, further validation of low-dose acquisition techniques in evaluation of the lungs and pleura will be important. A limited number of expiratory images should be included in conditions where obstructive lung disease is a prominent feature (e.g., black lung, silicosis, and hypersensitivity pneumonitis).

APPROPRIATE POPULATIONS FOR SCREENING

Because of limited options for prevention and/or treatment of asbestosis, it was felt that the benefit of CT screening in asbestos-related disease was primarily in detection of asbestos-related lung cancer. However, further insight into the value of CT in this context awaits the outcome of ongoing U.S. national lung screening trials. In patients with suspected silicosis or coal workers' pneumoconiosis, where detection of disease may result in medical removal from the environment and/or treatment of exposure-related complications such as infection, it was felt that there was a role for CT in "secondary screening" of workers in several specific contexts: workers with boundary chest radiographs (0/1, 1/0), those with abnormal spirometry, and those with higher profusion radiographs in whom conglomerate masses are more likely to be detected on CT.

CT SCORING METHODOLOGY

The most important role for the use of CT in pneumoconiosis screening or diagnosis is determination of the presence or absence of pleural or parenchymal abnormalities. Reference images will probably be necessary, primarily with reference "boundary images" for minimal disease. Determination of extent of disease may be based on semiquantitative estimation of percentage of lung involved or on quantitative imaging techniques. Any scoring system adopted should also be applicable to non-pneumoconiotic occupational interstitial diseases such as hypersensitivity pneumonitis, chronic beryllium disease, etc.

ACTION ITEMS/SUGGESTIONS FOR TARGETED RESEARCH:

Workshop participants discussed ways to address the knowledge gaps and cost considerations that included the following suggestions for further research.

(1) Information on the correlation between CT and pathologic findings in pneumoconioses is currently very limited, and should be expanded. With this in mind, some workshop participants recommended that NIOSH explore research collaboration with the lung tissue registry currently being established by NHLBI.

(2) Given concerns about CT radiation dose and cost, further efforts should be made to evaluate the efficacy of lower dose CT techniques for identifying parenchymal and pleural disease.

(3) Additional investigation should focus on the efficacy of quantitative CT for determining extent of disease.

(4) NIOSH should communicate with investigators in other countries (Finland, Germany, Japan, Belgium, etc.) to identify CT algorithms, protocols, and scoring systems currently in use elsewhere.

(5) NIOSH should consider convening a follow-up workshop or working group to address and expand the research questions and hypotheses outlined. ACR and ATS/ACCP should be urged to co-sponsor this effort, and NIOSH should continue to play a leadership role in fostering necessary collaborations between radiologists and occupational lung disease experts to facilitate further investigation.

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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Discussion of Digital X-ray Imaging in Pneumoconiosis Screening

Dr. Franzblau presented summary slides for discussion. There was extensive discussion from the workshop participants, as outlined below. Recommendations from this workshop are not consensus statements, but individual opinions of some, not necessarily all, of the participants.

Need for adoption of digital imaging

Many participants observed that the 'market penetration' of digital x-ray imaging has progressed to the point that, in many centers, it has become the standard. It has become difficult to obtain traditional film-screen radiographs in many areas. Inasmuch as the ILO system is the most widely used system for classifying abnormalities due to inhalation of pathogenic dusts in the workplace, we must consider the implications for NIOSH and the B Reader program if digital radiography is not soon adopted. Many participants expressed a clear need to establish 1) if there is equivalence of digital and FSR regarding the recognition and classification of pneumoconiosis, 2) under what circumstances is there such equivalence, and 3) what parameters should be specified, and what can remain flexible, regarding the application of the ILO classification system to digital chest images.

Multiple issues were discussed in relation to the implementation of digital x-ray imaging for occupational lung disease:

- Hardware/software issues
  - o PACS systems will be needed that are capable of storing, viewing, and transferring images to facilitate connectivity, and accurate image transfers
  - o Network, workstation/monitor standards should specify conditions for viewing and classifying images
- Specific parameters and file formats may need to be specified for image processing, as well as the recording and transfer of the images and pneumoconioses classifications and interpretations
  - o Facility approvals may be able to apply DICOM and ACR specifications for digital soft and hard copy images, room lighting, and numerical processing of ILO classification categories
  - o The selection and dissemination of digital images for the ILO standard films will need to be specified (three somewhat different sets are now used) as well as a description of the procedures for comparisons between the digital unknown images and the standards
- Digital versions of the ILO standard films and B Reader certification examinations will be required, and procedures for training readers to maximize effectiveness in the evaluation of digital images.
- Archiving systems - may need to store the raw/linear image rather than processed files to assure compatibility between systems, and to assure that image processing does not affect classification outcomes
- DICOM® standards - subcategories of the standard may be needed, including specification of factors that are required or not, including an image display standard
- Requisite technologies/requirements for image capture may be needed
- Encryption/security of long-distance electron transmission of images may be required to assure medical confidentiality and privacy protections
- Specifications may be needed for image size and other factors which can assure equivalence of soft and hard copy digital x-ray images with FSR
- Can traditional hard copy ILO standard films be used when viewing digital images and if so, is there an impact on classifications?

Urgent, flexible update of NIOSH B Reader Program

NIOSH must remain current to serve the needs of workers now and into the future and to fulfill its legislative mandate. Consequently, many of the participants stated that the Institute must move rapidly to adopt digital x-ray radiographic technology for the B Reader program and remain flexible so as to be able to adapt to new technologies as they inevitably become available.

Results from Surveys sent to A, B, and Former B Readers - Summary

Anita L. Wolfe

Introduction:
The Federal Coal Mine Safety and Health Act of 1969, as amended by the Federal Mine Safety and Health Act of 1977, PL-95-164, directs the National Institute for Occupational Safety and Health (NIOSH) to study the causes and consequences of coal-related respiratory disease, and in cooperation with the Mine Safety and Health Administration (MSHA), to carry out a program for early detection and prevention of Coal Workers' Pneumoconiosis (CWP), also called Black Lung. The 1977 Act mandates that all underground coal miners be offered a chest x-ray examination, at no cost to the miner. The x-rays must be taken at approved facilities and interpreted using a standardized classification system by certified physician readers. The presence of definite evidence of CWP on the x-ray determines a miner's eligibility for specified rights to work in a mining job with a reduced dust exposure. NIOSH administers these mandates through the Coal Workers' Health Surveillance Program (CWHSP) as outlined in 42 CFR Part 37, "Specifications for Medical Examinations of Underground Coal Miners," at the Appalachian Laboratory for Occupational Safety and Health (ALOSH) in Morgantown, West Virginia.

The CWHSP carries out the following activities related to the administration of chest x-ray examinations specified in the 1977 Act: 1) Testing and certification of physicians as B Readers qualified to interpret and classify x-rays using the International Labour Office (ILO) International Classification of Radiographs for Pneumoconioses; 2) Evaluation and certification of x-ray facilities; 3) Approval of coal mine operator plans for providing chest x-rays to miners; 4) Arrangement and reimbursement for requisite B Reader interpretation of chest x-rays; 5) Notifying participating miners of the results of chest x-rays interpreted for the presence or absence of CWP; 6) Notifying miners of the results of chest x-ray interpretations where abnormal findings other than CWP are identified; and 7) Maintaining a database of information related to all aspects of the CWHSP for purposes of assessing effectiveness, identifying disease trends, and assessing the value of dust exposure limits for the mining industry.

NIOSH developed and currently administers the B Reader Certification Program - a unique quality assurance program for training and certifying physicians who classify chest radiographs for the pneumoconioses. Physicians who wish to obtain B Reader certification must successfully complete an extensive initial examination. To demonstrate ongoing competence and maintain certification, a recertification examination is required every four years. Prior to sitting for the examination, candidate B Readers are strongly encouraged to adequately prepare by completing the NIOSH Self-Study Syllabus and/or attending the American College of Radiology (ACR) Symposium on Radiology of the Pneumoconioses. The Self-Study Syllabus was developed by NIOSH in 1980 under a contract with the ACR and includes 80 example chest radiographs with associated explanatory text. The ACR Symposium on Radiology of the Pneumoconioses, developed jointly with NIOSH in the 1970s, is held every 2-3 years. As part of the CWHSP, NIOSH obtains and processes B Reader interpretations regarding the presence and degree of dust-related changes on the screening chest radiographs. These radiographs are provided to underground coal miners approximately every five years.

The ILO, with NIOSH involvement and support, has recently completed a revision of its radiograph classification system (ILO 2000). With the publication of these revisions, NIOSH had the opportunity and obligation to improve and update the B Reader Program. Input from physicians having practical experience interpreting x-rays for findings consistent with occupational illnesses was sought. A survey was designed and distributed in May 2003, to solicit and document input from physicians regarding program revisions. Three survey instruments were developed appropriate for soliciting input from current B Readers, former B Readers, and A Readers. A Readers are those physicians who have completed a training course or otherwise demonstrated competence in use of the ILO Classification, but who are not currently certified as B Readers.

Purpose:
These surveys address the goal of enabling NIOSH to retain and enhance its national and international leadership by maintaining the B Reader Program as a unique, contemporary, relevant, and effective quality assurance program for the classification of chest radiographs for occupational lung disease screening, surveillance, research, and prevention.

Two specific aims were addressed by conducting the surveys: 1) to evaluate the overall strengths and weakness of the current B Reader Program in ensuring and extending the utility of occupational chest radiographic imaging for occupational lung disease research and surveillance; and 2) to evaluate NIOSH publications, electronic and print communications, forms, and related materials (including the Self-Study Syllabus/Film Set for candidate B Readers and the examination images) for consistency and adherence to the revised ILO system and overall program goals.

To ensure that revisions to the B Reader Program are guided by input from stakeholders, surveys were sent to all currently certified B Readers, A Readers, and former B Readers. Respondents were asked to describe the current use of their B Reader certification in their practice. They were asked to comment on specific proposed revisions to the B Reader Program, and opinions were solicited regarding quality assurance activities and digital radiography.

Logistics:
Paper-based survey instruments were initially mailed along with a pre-addressed, postage-paid return envelope. Instructions included an option for web-based electronic submission. Only one completed survey was accepted per reader, and in the event that an individual completed both the paper-based and the electronic survey, the first survey received was used for analysis.

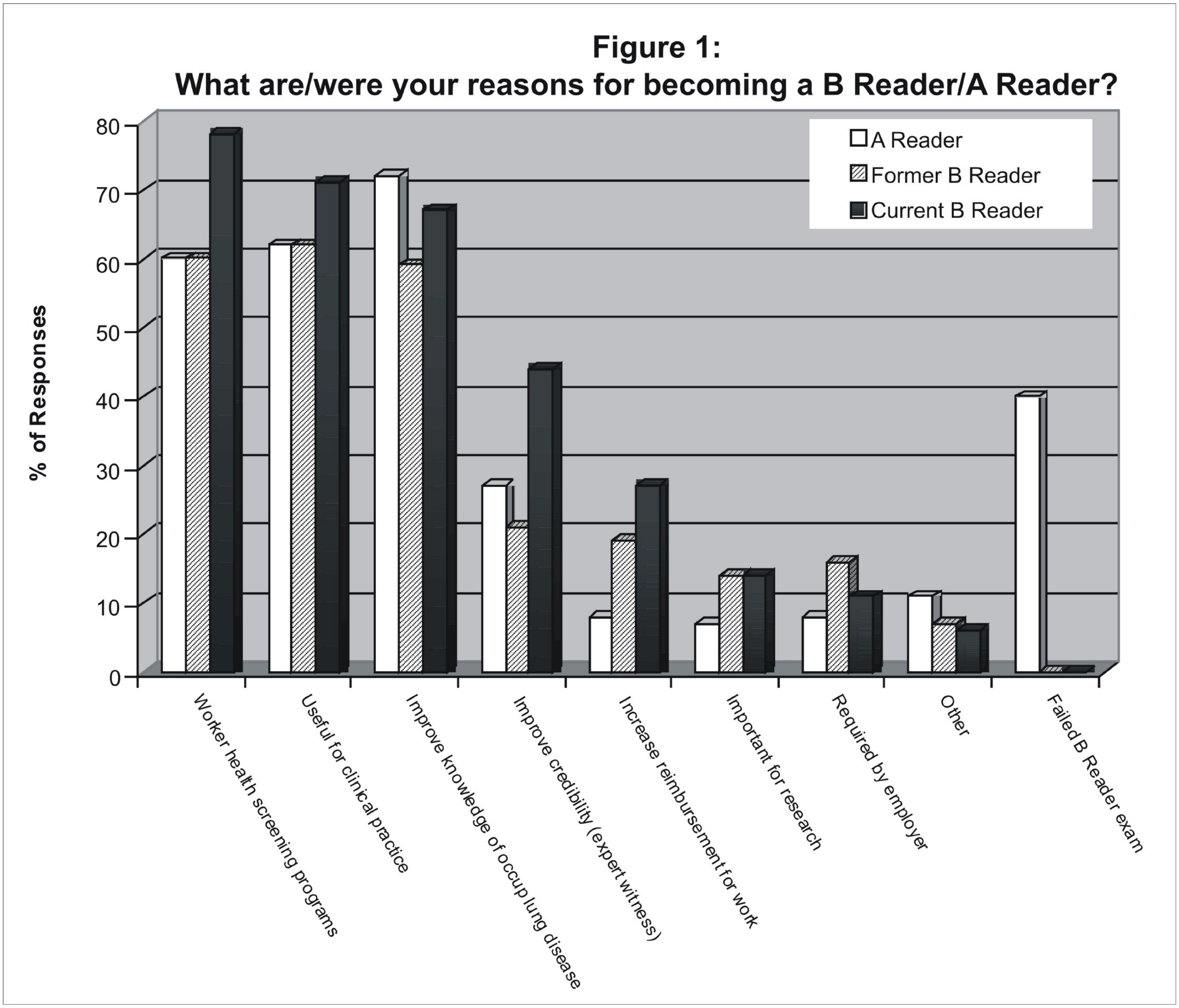
Surveys were mailed to 471 current B Readers, 318 former B Readers, and 1417 A Readers. Responses were received from 215 current B Readers, 58 former B Readers, and 154 A Readers, for an overall response rate of 19%. The individual response rates were: current B Readers = 46%; former B Readers = 18%; and A Readers = 11%.

Results:
Reasons for Becoming/Remaining an A/B Reader
Q: What are/were your reasons for becoming a B Reader/A Reader? (check all that apply)

Possible answers included:

- To improve knowledge of occupational lung disease
- Useful for clinical practice
- To aid in reading films for worker health screening/surveillance programs
- To improve my credibility as an expert witness in medical-legal cases
- Important for research
- Required by my employer
- To increase reimbursement for work
- Failed B Reader exam
- Other

Of the responding current B Readers, 78% (168/215) chose the answer "to aid in reading films for worker health screening/surveillance programs." Of the responding former B Readers, 62% (36/58) chose, "useful for clinical practice." Of the responding A Readers, 72% (111/154) chose "to improve knowledge of occupational lung disease," and 40% (61/154) reported that they became A Readers because they "failed B Reader exam." Some of the "other" responses included: for teaching; to provide a needed service; as a convenience to local industries; for professional status; and as requested by clients. (See Figure 1)

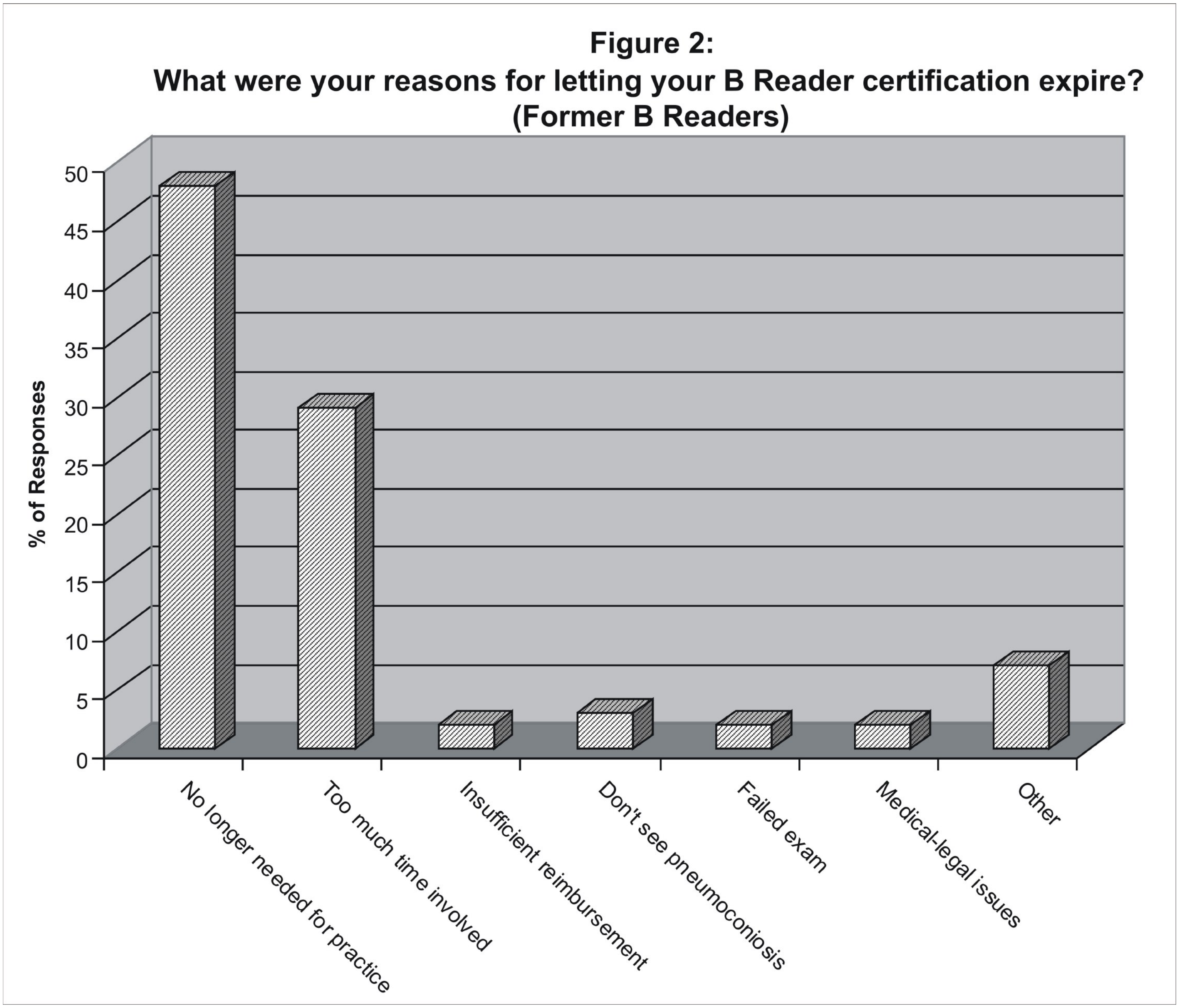


Q: What were your reasons for letting your B Reader certification expire?

Possible answers included:

- No longer needed for my practice
- Too much time required to study/and or travel
- Insufficient reimbursement
- Don't see enough pneumoconiosis
- Failed the exam
- Medical-legal issues
- Other

Almost half, 48% (28/58), of former B Readers who responded reported that B Reader certification was "no longer needed for my practice" as their reason for not recertifying. (See Figure 2)



Digital Issues:

As outlined in the Introduction Section, in order to become a NIOSH-certified B Reader, the physician must pass a test that includes correctly classifying a set of 125 traditional film-screen x-rays in accordance with the guidelines for the ILO classification system. These guidelines currently prescribe side-by-side viewing of subject and standard radiographs and state that the standard (traditional film-screen) comparison films take precedence in defining profusion categories. The CWHSP requires that x-rays must be taken in accordance with the requirements of federal regulations (42 CFR Part 37). These regulations specify the use of film no less than 14 x 17 inches in size, as well as other requirements associated with traditional film-screen techniques. Therefore, NIOSH does not currently accept radiographic images obtained using digital techniques for this program. However, increasing numbers of x-ray facilities are adopting digital technology, a question related to digital chest imaging was included in the survey.

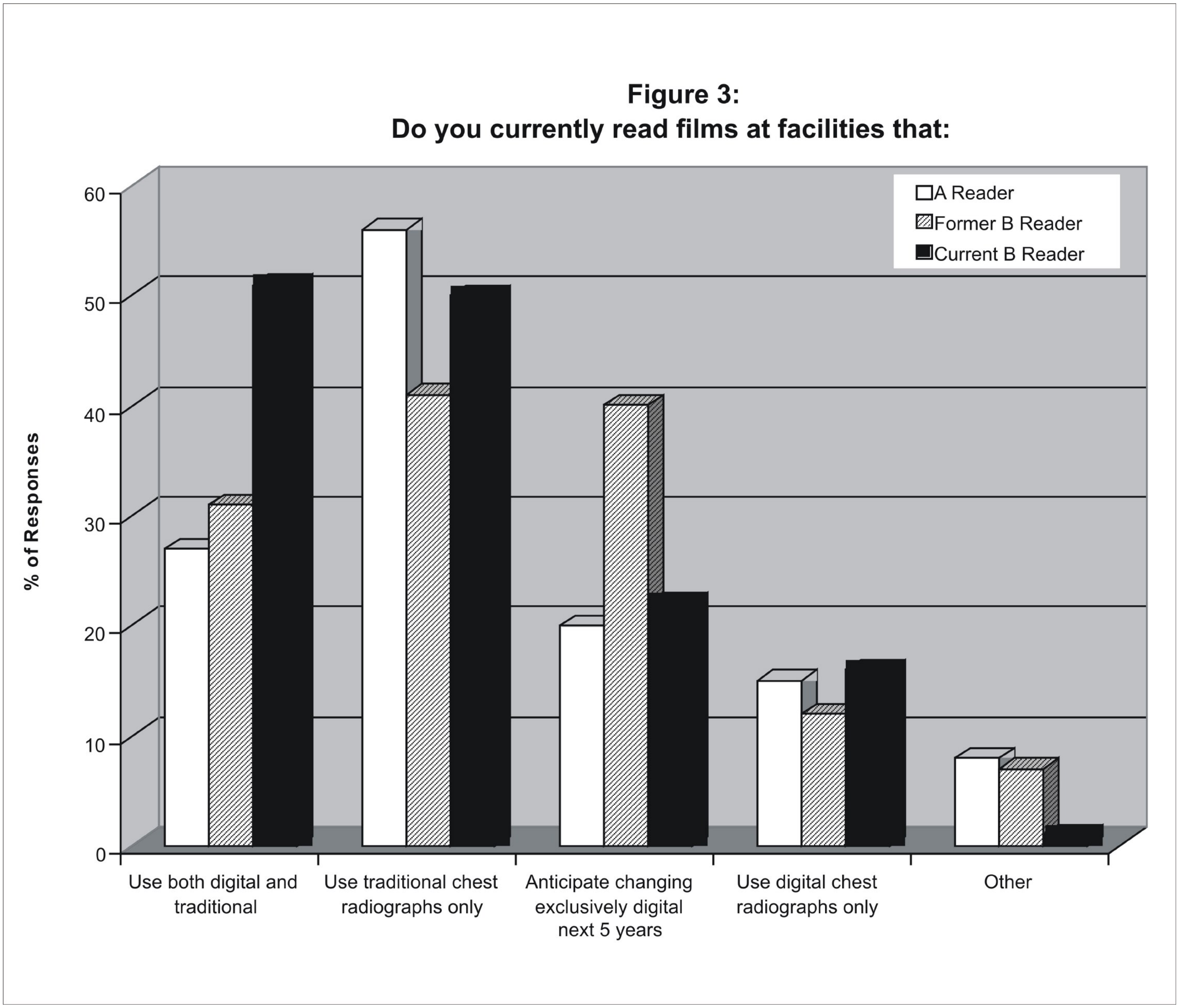
Q: Do you currently read films at facilities that: (check all that apply)

Possible answers to choose from included:

- Use digital chest radiographs only
- Use traditional chest radiographs only
- Use both digital and traditional chest radiographs

• Anticipate changing to an exclusively digital system within the next 5 years
• Other

Of the responding current B Readers, 51% (110/215) responded "use both digital and traditional chest radiographs." Both former B Readers and A Readers most often indicated "use traditional chest radiographs only" at 41% (24/58) and 57% (87/154), respectively. Former B Readers also reported that they "anticipate changing to an exclusively digital system within the next 5 years" with 40% (23/58). Most of the "other" responses involved comments such as: retired or no longer classifying films. (See Figure 3)



Quality Assurance Alternatives
The next several questions were prompted by the goal of maintaining the B Reader Program as a unique, contemporary, relevant, and effective quality assurance program for the classification of chest radiographs for occupational lung disease research and prevention.

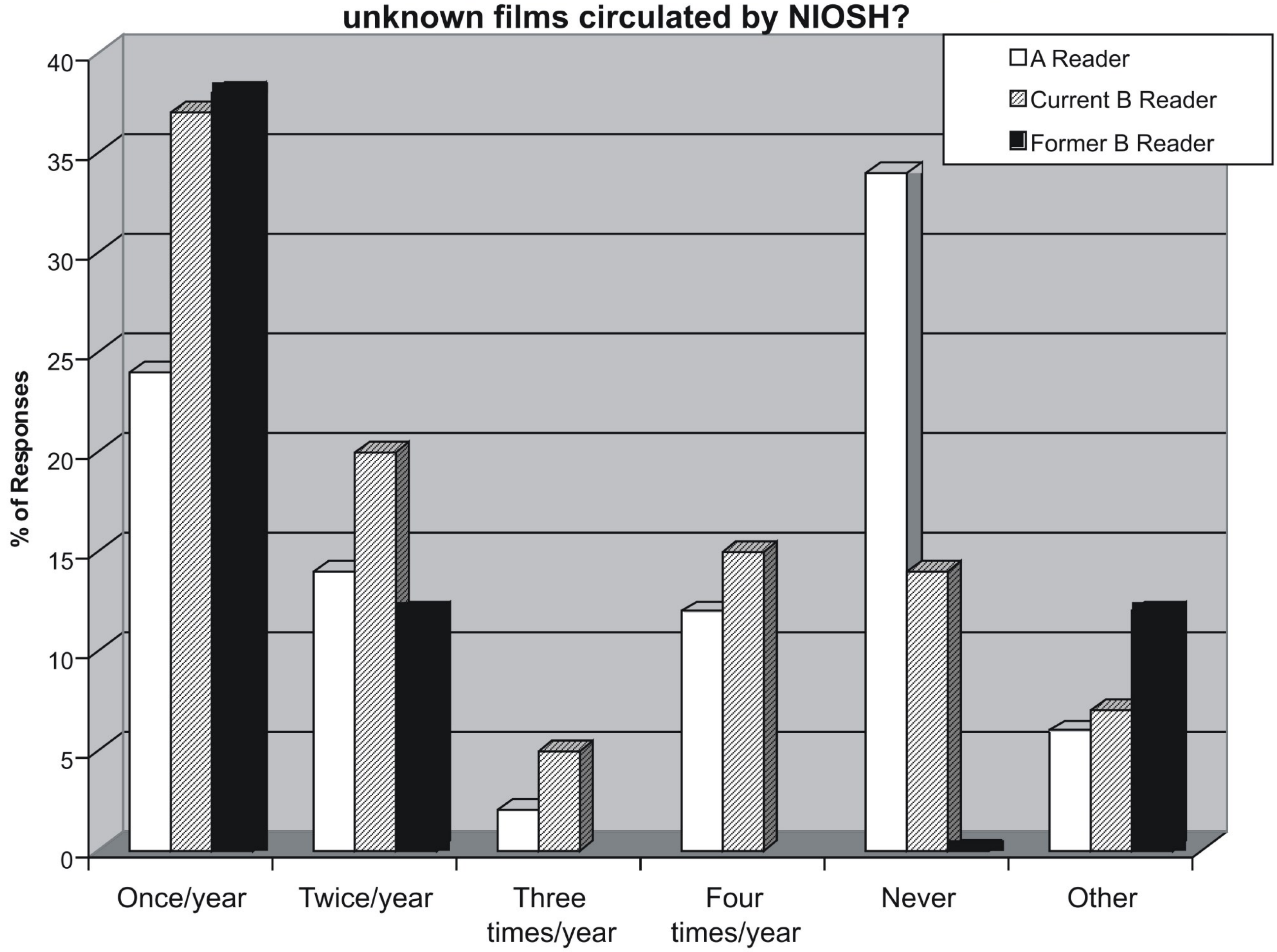
Q: Would you be willing to participate in (do you think a quality assurance program would be beneficial requiring) reading of unknown films circulated by NIOSH? If yes, or undecided, how often?

Q: Would you be willing to participate in (do you think a quality assurance program would be beneficial in which you) voluntarily submit a certain number of films per year to a core group of expert readers for comparison of readings?

Q: Would you be willing to participate in (do you think a quality assurance program would be beneficial in which) your reading patterns are compared with other readers and you are supplied with the results of a statistical analysis?

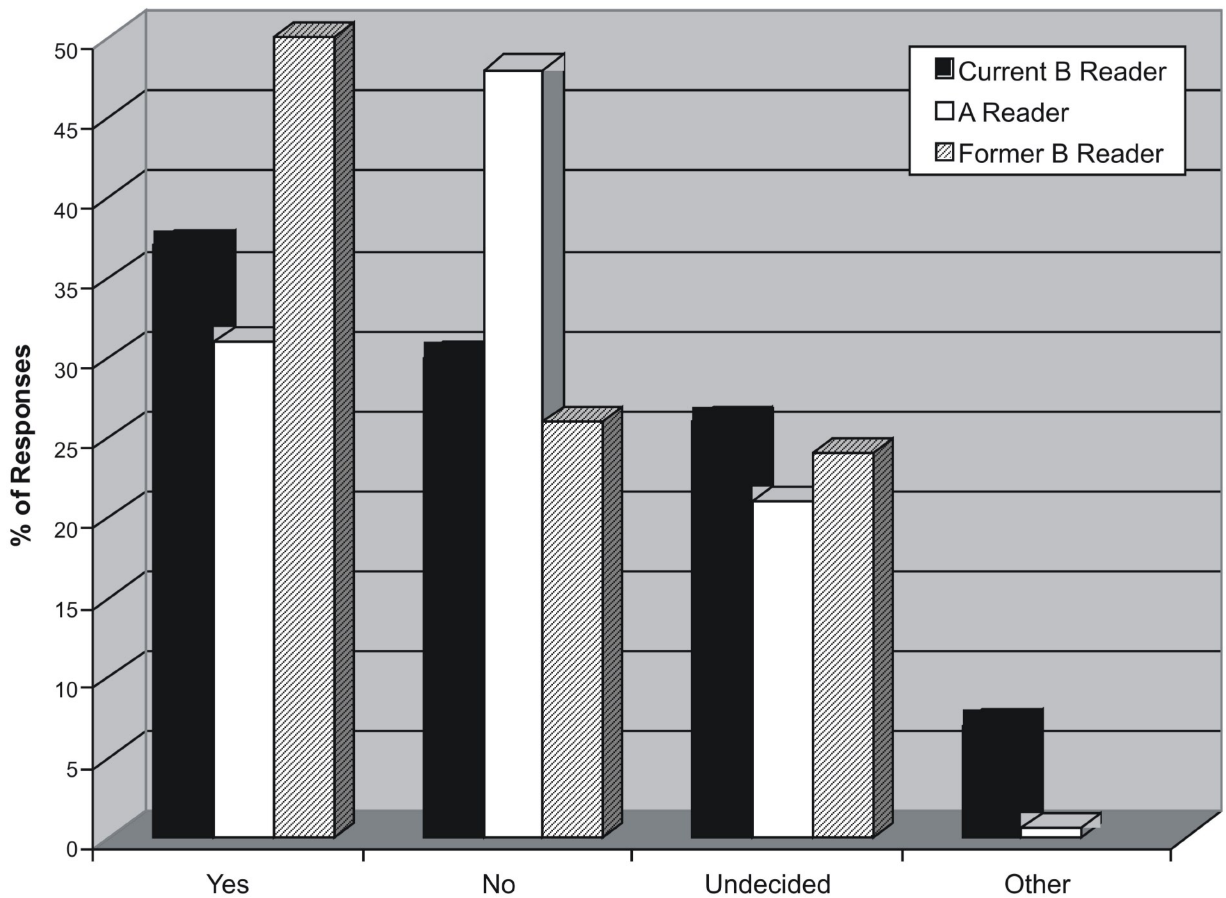
For the first quality assurance question, 37% (80/215) of the responding current B Readers answered "yes," that they would be willing to participate in a yearly program requiring reading of unknown films. However, 34%, (52/154) of responding A Readers reported that they were "never" willing to participate in this type of reading program. Former B Readers were asked an alternate question, "do you think a quality assurance program would be beneficial…," and 38% (22/58) responded "yes" this type of program would be beneficial on a yearly basis. (See Figure 4)

Figure 4: Would you be willing to participate in/do you think a quality assurance program would be beneficial requiring reading unknown films circulated by NIOSH?



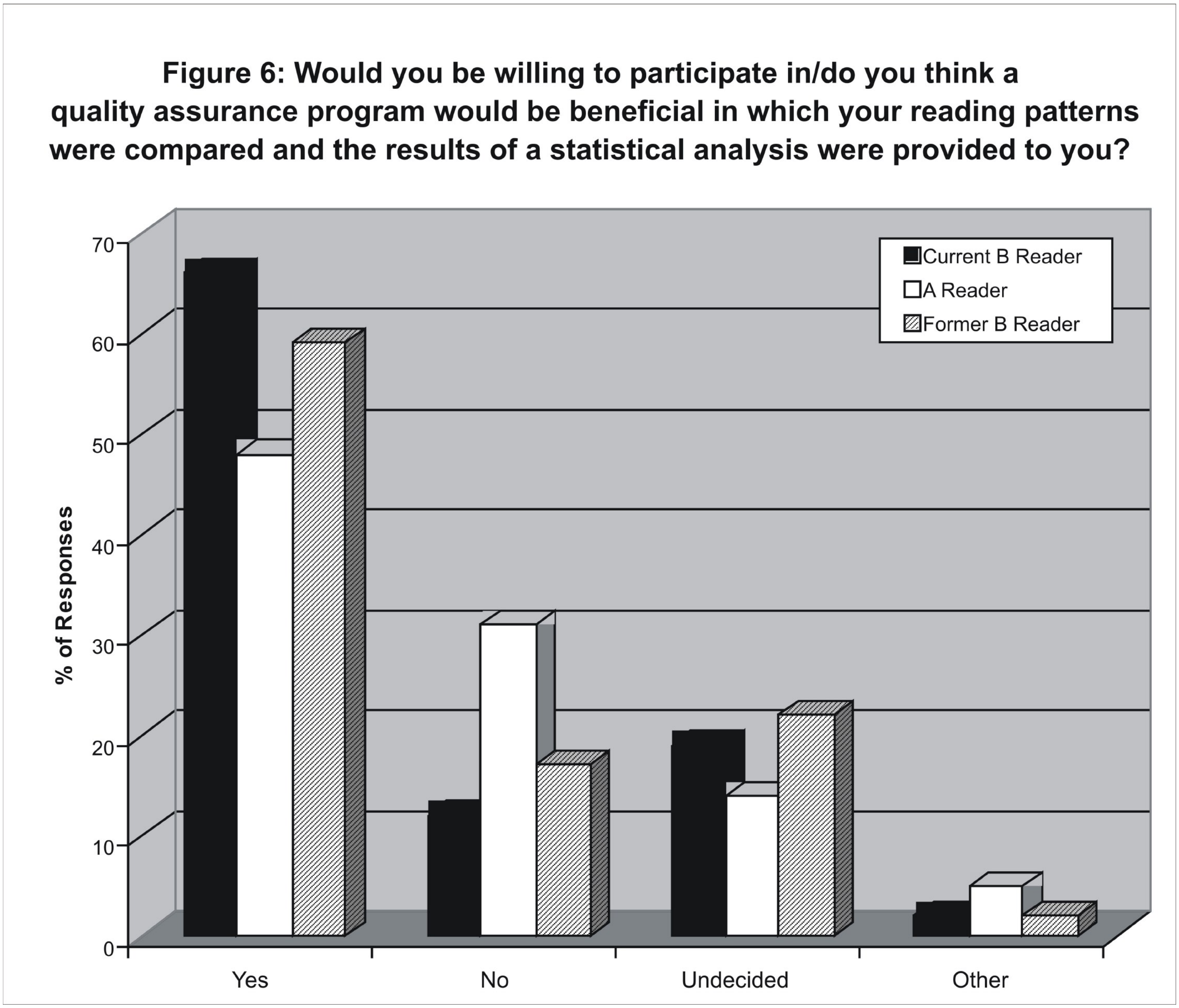
For the second quality assurance question, 37% (79/215) of responding current B Readers reported that "yes" they would be willing to participate in a quality assurance program in which there was voluntary submission of a certain number of films per year to a core group of expert readers for comparison of readings. Again, among the A Readers, the highest response was "no," (46%, 71/154) they would not be willing to participate. When the former B Readers were asked "do you think … would be beneficial," 50% (29/58) responded "yes." (See Figure 5)

Figure 5: Would you be willing to participate in/do you think a quality assurance program would be beneficial in which there was voluntary submission of a certain number of films per year to a core group of expert readers for comparison of readings?



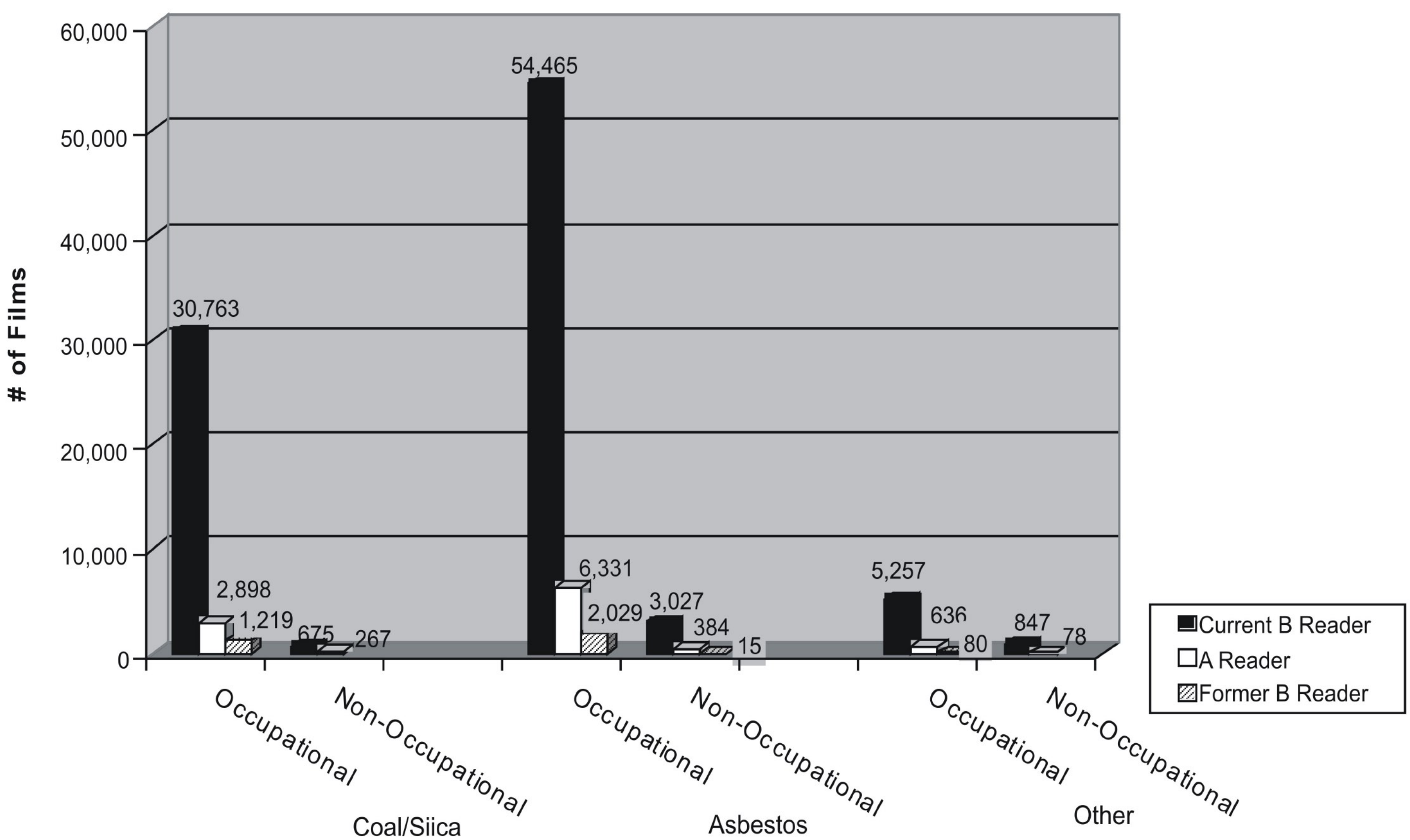
The last question concerning quality assurance issues, dealt with comparison of reading patterns between readers and then those readers being supplied with the statistical analysis. The majority of responding current B Readers (66%, 142/215) replied, “yes.” 48% (74/154) responding A Readers also replied “yes.” When asked if this sort of quality assurance program would be beneficial, 59% (34/58) of the responding former B Readers answered “yes” as well.

This type of quality assurance program was the one most favored by all three groups. (See Figure 6)



Types of Exposures for Readings:
The next question on the surveys asked about the number of films classified during the past year using the ILO system in relation to coal or silica, asbestos, or other exposures, and whether these exposures were occupational or non-occupational. Occupational asbestos cases accounted for the majority of classifications (62,825), while occupational coal/silica cases accounted for 34,880 cases. Most classifications were occupational (103,678 versus 5,293). (See Figure 7)

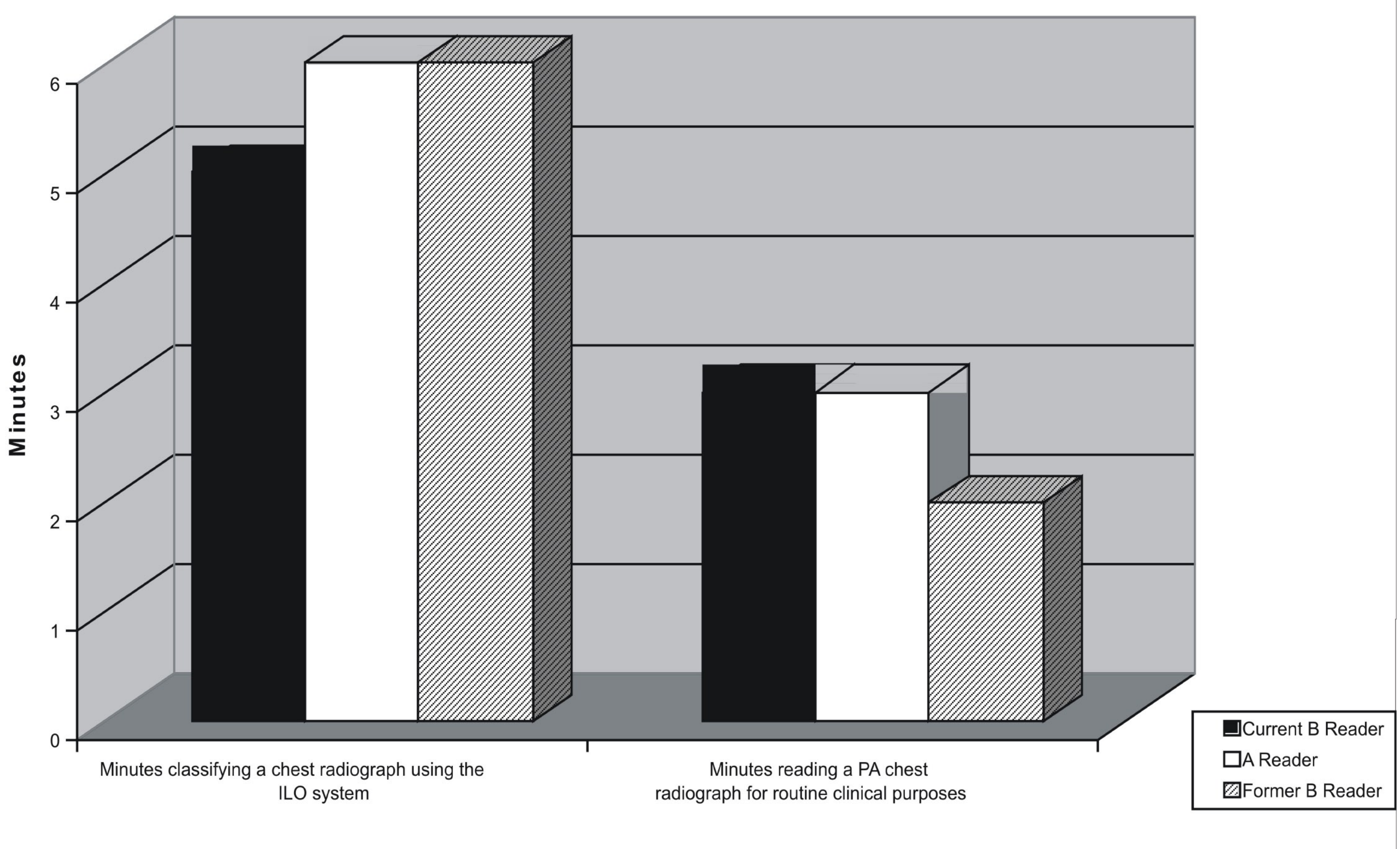
Figure 7: Indicate the approximate number of films which you classified during the past year using the ILO system in relation to suspected exposures :



Time Spent on Readings:

The respondents were asked to indicate how many minutes they spent classifying a chest radiograph using the ILO system for pneumoconiosis and how many minutes they spent reading a posteroanterior (PA) chest radiograph for routine clinical purposes. Across all three groups, the time spent classifying films using the ILO system was greater than the time spent reading for routine clinical purposes. A Readers and Former B Readers both reported an average of 6 minutes with the ILO system (with a range from 1-30 minutes), while Current B Readers averaged 5 minutes (with a range of 1-30 minutes). For routine clinical readings, both A Readers and Current B Readers averaged 3 minutes per film (with a range of 1-60 minutes), while Former B Readers averaged 2 minutes per film (with a range of 1-10 minutes). (See Figure 8)

Figure 8: On average, I spend approximately:



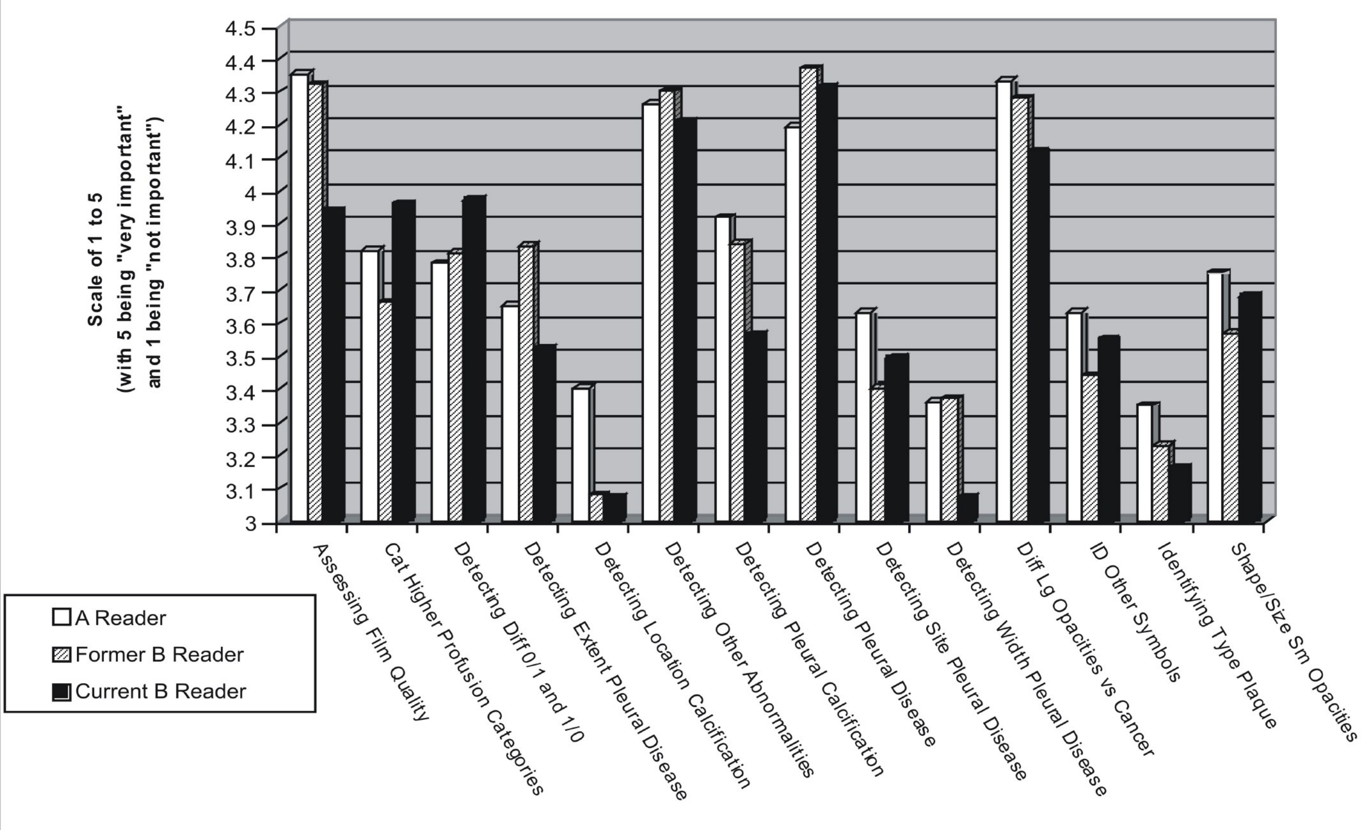
Important Areas to Assist in Recognition of Pneumoconiosis:

The NIOSH home study syllabus and the B Reader examination and recertification examination should reflect the important issues and difficulties encountered by readers in classifying films for pneumoconiosis. Survey respondents were asked to rate various issues regarding their importance in assisting in the recognition of these patterns. The areas they were asked to rate on a scale of 1 to 5 (with 5 being the most important) were:

- Assessing film quality
- Detecting differences between categories 0/1 and 1/0
- Shape/size of small opacities
- Accurately categorizing higher profusion categories (i.e. > 1/0)
- Differentiating large opacities vs. cancer
- Detecting pleural disease
- Detecting size of pleural disease
- Identifying type of plaque (inprofile vs. en face)
- Detecting extent of pleural disease
- Detecting width of pleural disease
- Detecting pleural calcification
- Detecting location of calcification
- Detecting presence of other abnormalities
- Identification of other symbols

Both Current B Readers and Former B Readers ranked detecting pleural disease as the most important with average scores of 4.31 and 4.37 respectively. A Readers ranked assessing film quality as most important, with an average score of 4.35. Figure 9 shows the ranking of these categories.

Figure 9: NIOSH home study materials and B Reader examinations should reflect the current distribution and patterns of pneumoconiosis. To assist in recognition of these patterns, based upon your use of the ILO system, rate the following:



The ILO 2000 revision requires the following list of symbols. Survey respondents were asked to identify those symbols which they felt should be included on the B Reader Examination.

- aa - atherosclerotic aorta
- at - significant apical pleural thickening
- ax - coalescence of small opacities
- bu - bulla(e)
- ca - cancer
- cg - calcified non-pneumoconiotic nodules
- cn - calcification in small pneumoconiotic opacities
- co - abnormality of cardiac size or shape
- cp - cor pulmonale
- cv - cavity
- di - marked distortion of an intrathoracic structure
- ef - pleural effusion
- em - emphysema
- es - eggshell calcification
- fr - fractureded rib(s) (acute or healed)
- ho - honeycomb lung
- id - ill-defined diaphragm border
- ih - ill-defined heart
- kl - septal (Kerley) lines
- me - mesothelioma
- od - other diseases
- pa - plate atelectasis
- pb - parenchymal bands
- pi - pleural thickening of an interlobar fissure
- px - pneumothorax
- ra - rounded atelectasis
- rp - rheumatoid pneumoconiosis
- tb - tuberculosis
- hi - enlargement of non-calcified hilar mediastinal lymph nodes

All three groups chose ca - cancer as the most important finding to be included, with ef - pleural effusion and hi - enlargement of non-calcified hilar mediastinal lymph nodes to follow. Figure 10 shows each symbol and the percentage of respondents who indicated the finding should be included on the examination.

Figure 10: Symbols and % of Respondents Indicating the Finding Should be Included on the Examination			
	Current B Reader	A Reader	Former B Reader
aa	14	23	19
at	31	45	52
ax	64	53	72
bu	61	53	66
ca	85	67	81
cg	38	46	47
cn	34	45	57
co	62	48	57
cp	35	38	48
cv	62	57	71
di	49	42	55
ef	71	60	78
em	66	50	64
es	52	54	60
fr	42	25	38
hi	68	60	72
ho	68	54	67
id	52	39	50
ih	51	37	47
kl	49	49	55
me	64	60	60
od	39	38	41
pa	30	30	38
pb	21	26	33
pi	38	42	41
px	60	56	69
ra	44	36	53
rp	20	29	43
tb	65	59	71

Improvement in the Examination process: Current B Readers and A Readers were queried on how the B Reader examination could be improved. The options they were given included:

- allow more time
- allow less time
- include fewer films
- include more films
- include better quality films
- provide more view boxes
- provide a better study syllabus
- provide better exam instructions
- have less frequent exams
- have more frequent exams
- provide different locations for exams
- other

Both groups chose "provide different locations for exams" as the top choice (Current B Readers = 55% and A Readers = 38%). Using the same options, we asked Former B Readers how the B Reader recertification examination could be improved. Again, "provide different locations for exams," was the top choice with 55% of respondents choosing that option. Figures 11 and 12 show these options and the percentage of respondents that chose each option.

Figure 11: How could the B Reader examination process be improved?

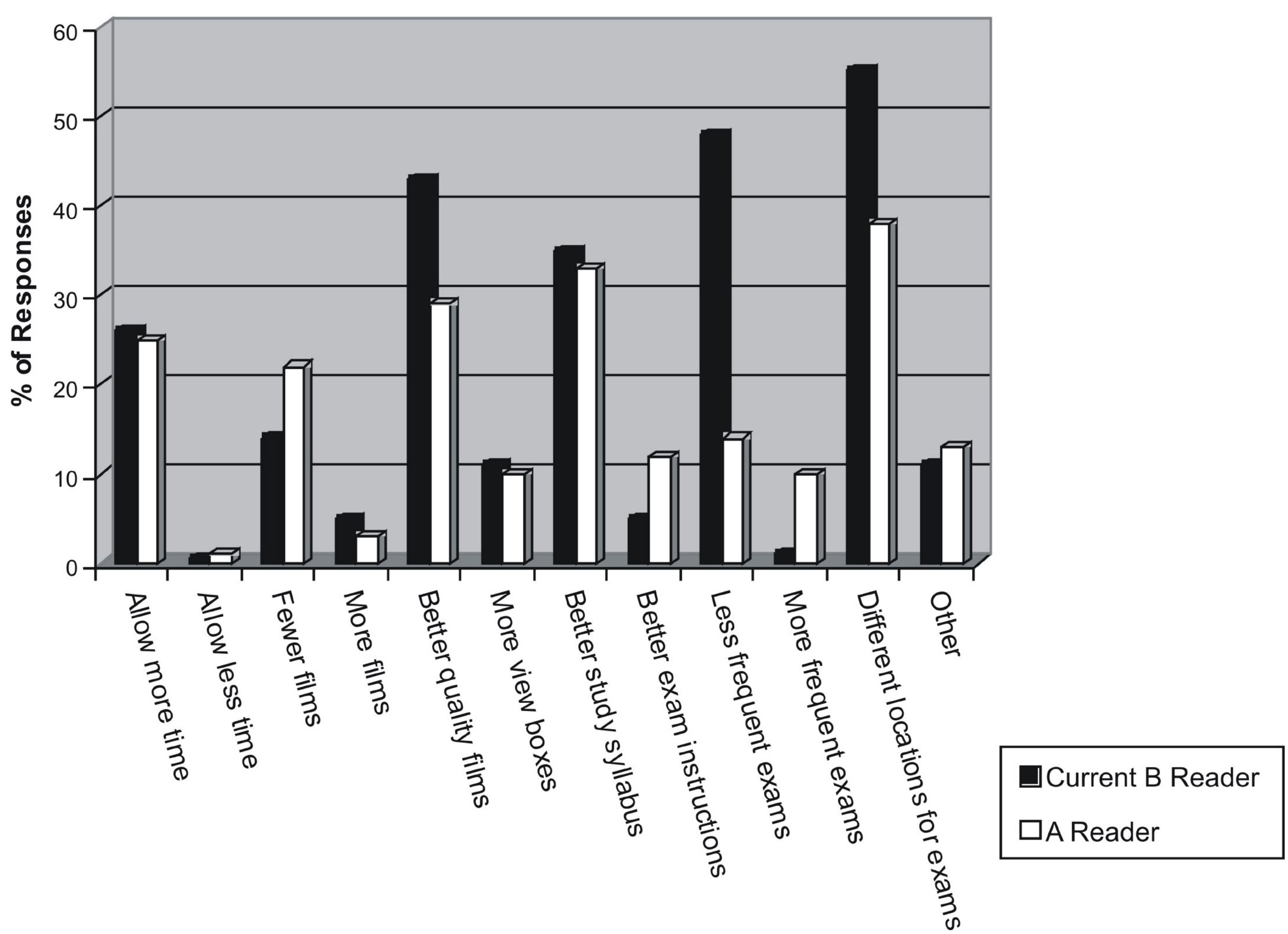
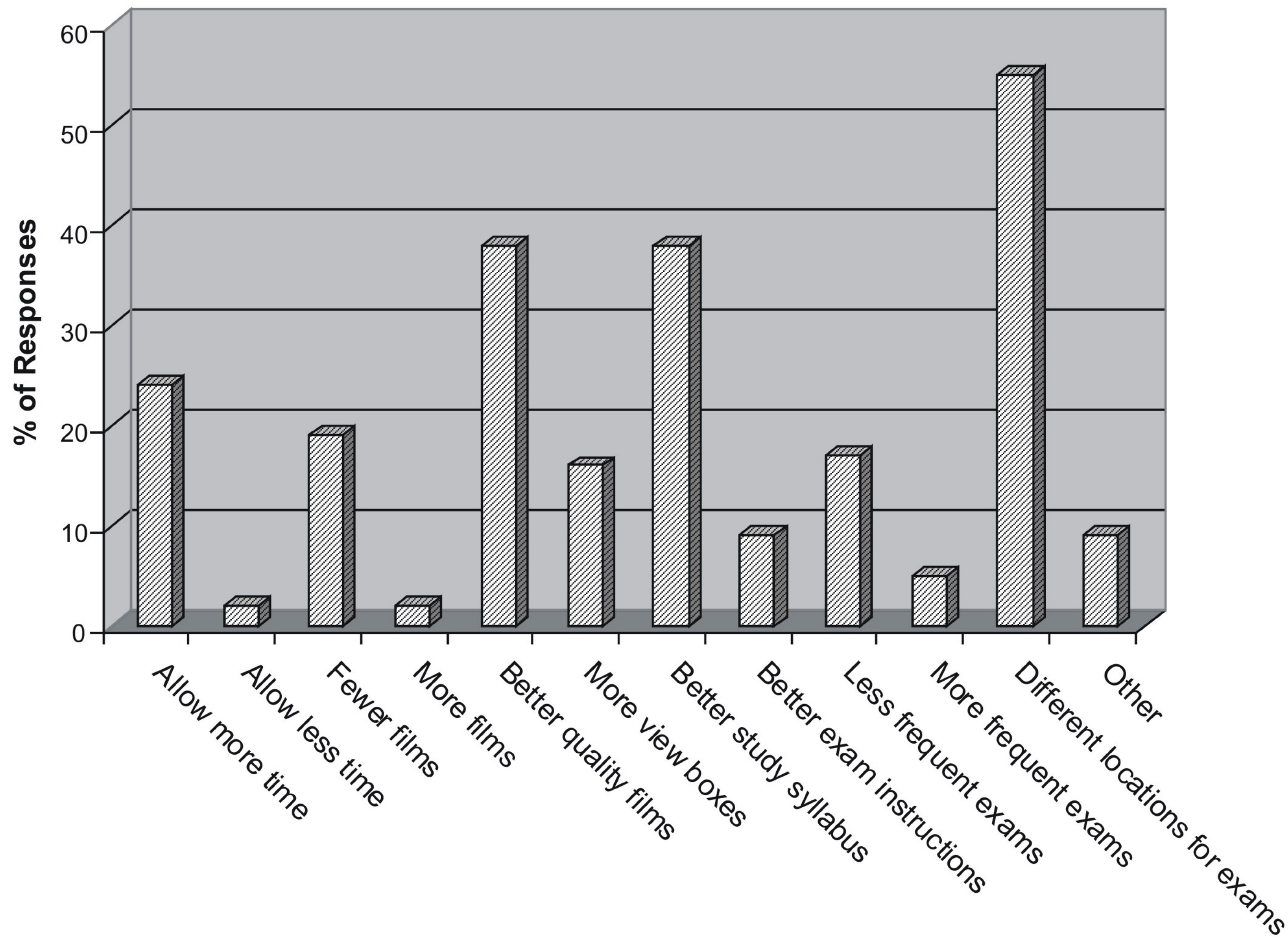
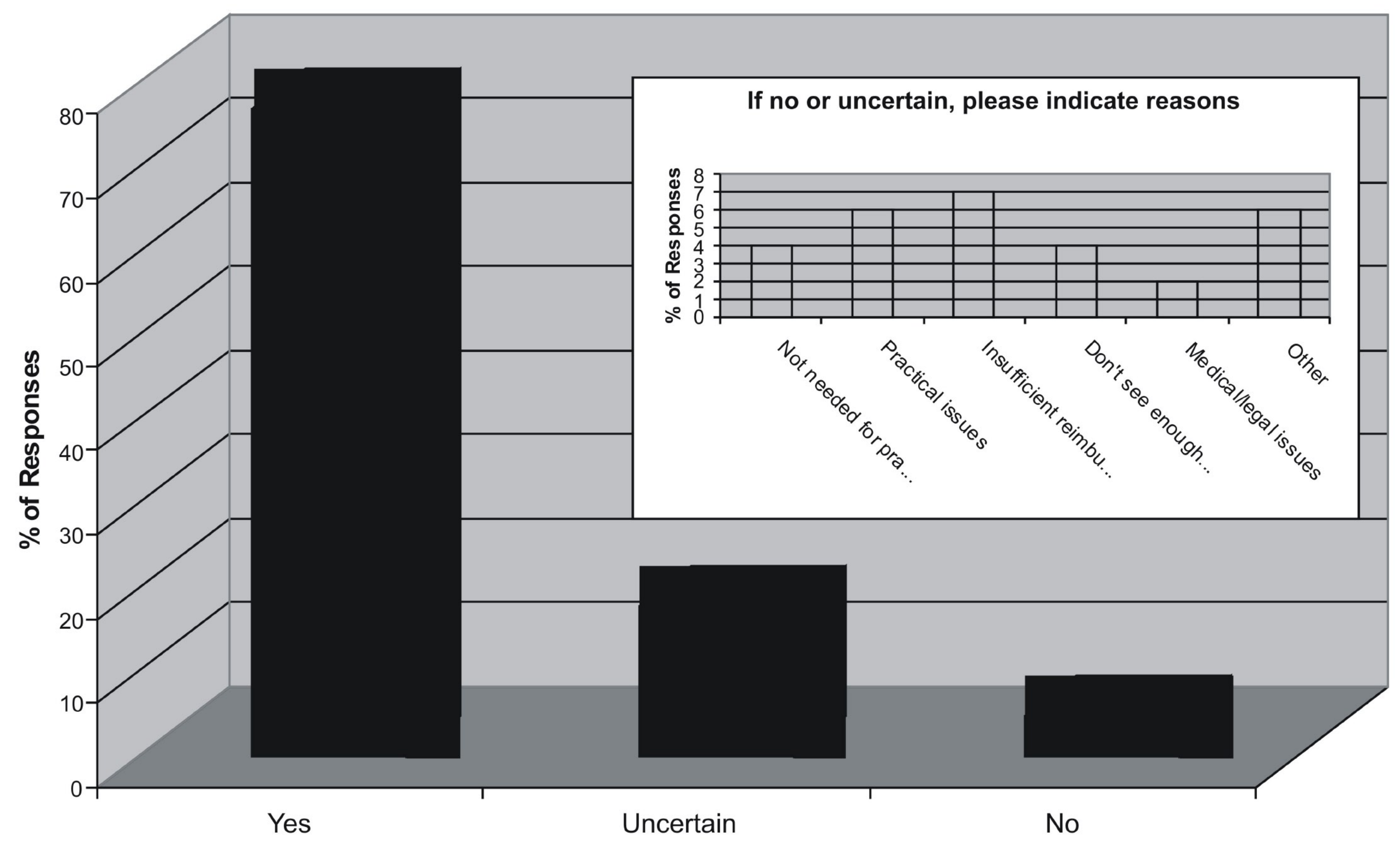


Figure 12: How could the B Reader recertification process be improved? (Former B Readers)



When Current B Readers were asked about their intent to recertify, 77% of the respondents reported that “Yes” they did plan to take the recertification exam. “Insufficient reimbursement” was the highest response (7%) for the remaining 23% who were “uncertain” or who responded “No.” (See Figure 13)

Figure 13: Do you currently plan to take the re-certification exam? (Current B Readers)



In conclusion, these surveys highlight key issues that are being reviewed and considered in updating the NIOSH B Reader Program.

NIOSH Responds to the Challenges

Edward L. Petsonk

In the past several years, NIOSH has been undertaking a review of its roles and responsibilities regarding the application of lung imaging for the pneumoconioses, and has sought input from interested stakeholders, health professionals, and the general public. This workshop has helped to highlight the critical issues in this area, and should enable the Institute to continue to focus actions on strengthening existing programs as well as evaluating new approaches in this changing field.

Quality Assurance

The workshop discussed one of the major challenges for NIOSH in the application of radiographs for research and surveillance: the enhancement of the quality and utility of pneumoconiosis classifications. Dr. Shipley's talk emphasized the important problem of reader variability, and current approaches to minimizing it. The B reader examination program and the related training activities comprise one important focus of action. The American College of Radiology, in partnership with NIOSH, completed a revision of the periodic training seminar on the radiology of the pneumoconioses in March 2004. NIOSH is seeking to migrate the current home study syllabus to a CD-based teaching program, and in 2004 awarded a contract to accomplish this. The psychometric performance of the examination items has been reviewed by a nationally recognized organization devoted to competency assessments, and an internal report has been prepared for NIOSH entitled "A Report on the Statistical Characteristics of the B Reader Certification Examination and the B Reader Recertification Examination." NIOSH is currently in the process of identifying additional candidate images for the examinations, and is also evaluating the existing approach to examination scoring, with the objective of enhancing the overall performance of the examinations.

Dr. Shipley's talk recognized the importance of film quality in inter-reader variability. The NIOSH radiographic facility approval process was established to address film quality issues. This process requires each candidate facility to submit a series of films, which are assessed for film quality criteria prior to approval of the facility. To further strengthen film quality for the Coal Workers' Health Surveillance Program, NIOSH initiated a pilot activity in which film quality is tracked, with specific feedback provided to all NIOSH-approved radiographic facilities. The impact of this voluntary program, which was initiated in 2002, is currently being assessed.

Another critical challenge addressed by Dr. Shipley, is reducing reader bias, particularly in relation to the classification of small opacities at low profusion levels and in the identification of localized pleural abnormalities. NIOSH is currently evaluating several approaches for reducing the potential for reader bias which may occur in readings performed between certification examinations while at the same time maintaining specificity and sensitivity to abnormality. Calibration and feedback were discussed as feasible by Dr. Shipley, but approaches that limit the total number of B readers or require auditing of individual readers were judged difficult to implement in routine readings done for clinical and legal purposes. To improve the availability of information regarding the appropriate application of chest radiography for evaluating occupational lung disorders, to emphasize procedures recommended for reducing bias, and to further inform occupational health professionals concerning the revisions in international criteria (see below), in April 2005 NIOSH posted a greatly expanded web page on this topic, http://www.cdc.gov/niosh/topics/chestradiography/breader-info.html

Dr. Shipley discussed the 2000 revision of the ILO International Classification of Radiographs of

Pneumoconioses, which includes an improved set of standard radiographs. NIOSH remains committed to working with the ILO in further enhancing both the hard copy standard images as well as developing a practical set of soft copy images for application of the classification to digital images.

Digital chest radiography

The paper by Dr. Franzblau documents the extensive market penetration of digital radiographic imaging in the U.S., and the transition to digital x-ray imaging that is presently occurring throughout the world. He provides an overview of what is known about digital x-ray imaging with respect to recognition and classification of the pneumoconioses using the ILO system. In response, NIOSH is working with its partners in developing a specification for the classification of digitally-acquired chest images for pneumoconiosis that is practical, valid, and science-based. In addition to these proceedings from the expert scientific workshop, NIOSH has sought input from stakeholders and experts on this topic in a variety of ways, including requests for comments published in the federal register on November 26, 2003 (Volume 68, Number 228) and June 5, 2006 (Volume 71, Number 107), a public meeting (held March 4, 2004 in McLean, VA). The opinions from surveys of active and former NIOSH-certified readers are also reported here (see page 9-1). Several activities have been initiated addresssing the future challenges and recommendations in Dr. Franzblau's paper. NIOSH has recently purchased hardware and software for the acquisition, storage, and display of digital radiographic images. External funding was announced and has been awarded for studies of the equivalence of digital and traditional radiography regarding the recognition and classification of pneumoconiosis. Discussions with other agencies are also underway to initiate additional collaborative research. NIOSH has initiated an intramural interdisciplinary workgroup to address the technical aspects and implementation of a specification for classification of digital chest images for pneumoconiosis, including image acquisition, transfer, display, archiving, and interpretation.

Computerized tomographic imaging

The commissioned paper by Drs. Rose and Lynch relates how CT images, particularly those using high resolution thin section protocols, have demonstrated a number of advantages over traditional imaging among workers with pneumoconiosis. As well, these authors relate that the approach also has significant shortcomings, such as the greater radiation exposure and higher cost. Much remains to be done to clarify the role of CT scans in research and monitoring of workers in dusty work environments, including clarification regarding the validity of CT screening in dust-exposed workers and clinical management of both work-related and incidental CT findings. At this time, it is important for NIOSH to define and prioritize its role in this process. The utility of traditional radiographs in the investigation of pneumoconioses was greatly enhanced by the application of the standardized classification system promulgated by the ILO; a similar widely accepted and validated standardized approach to categorizing dust-related findings on chest CT images would likely also enhance the application of CT scanning in occupational studies. Due the high cost of CT studies, additional research will require collaboration among funding agencies, and may also benefit from a coordinated multi-center approach, including international partnerships. Many workshop participants suggested that NIOSH could promote the emergence of such a classification, along with implementation protocols that improve comparability of images between facilities and minimize population exposure to radiation, while maintaining the diagnostic advantages of CT images.

Summary

Radiographic lung imaging continues to play a critical role in the recognition, investigation, assessment, and prevention of occupational dust diseases. As the technology and applications of lung imaging continue to evolve, the proceedings of this workshop should provide guidance to NIOSH and its partners in optimizing the role of this essential tool in protecting the health of workers.

Abbreviations within Proceedings Documents

ABG	arterial blood gases
ACCP	American College of Chest Physicians
ACR	American College of Radiology
ALOSH	Appalachian Laboratory for Occupational Safety and Health
AMFPI	active matrix flat panel images
ATS	American Thoracic Society
BAL	broncho-alveolar lavage
CCD	charged couple devices
CCT	conventional computerized tomography
CME	continuing medical education
COPD	chronic obstructive pulmonary dieseae
CR	computed radiography
CT	computerized tomography
CWHSP	Coal Workers' Health Surveillance Program
CWP	coal workers pneumoconiosis
CXR	chest x-rays
DICOM	Digital Imaging and Communications in Medicine trademark of the National Electrical Manufacturers Association (NEMA)
DLCO	diffusion capacity for carbon monoxide
DMLD	diffuse micronodular lung disease
DPB	diffuse panbronchiolitis
DR	digital radiography
DRDS	Division of Respiratory Disease Studies
DX	diagnosis
EI	emphysema index
FEV-1	forced expiratory volume in 1 second
FSR	film-screen chest radiography
FVC	Force vital capacity
HP	hypersensitivity pneumonitis
HRCT	high-resolution chest radiography
ILO	International Labour Office
LN	lung nodule
MSHA	Mine Safety and Health Administration
NA	not applicable
NHLBI	National Heart, Lung, and Blood Institute
NIOSH	National Institute for Occupational Safety and Health
NP	nodular profusion
OSHA	Occupational Safety and Health Administration
PA	posterior-anterior
PACS	picture archiving and communication system
PFT	pulmonary function test
PMF	progressive massive fibrosis
QA	quality assurance
ROC	receiver operating characteristic
TB	tuberculosis
TBBX	trans-bronchial biopsy
TLC	total lung capacity
TNTC	too numerous to count
VATS	video-assisted thoracoscopic surgery

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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