III. Evaluation of appropriate DR parameters in other DR systems

As far as the taskforce has known, the DR systems produced by Philips, Siemens, GE, Toshiba, Hitachi, and Shimazu were available in Japan. Each of these venders was asked to submit a few typical pneumoconiosis cases for the evaluation by the DR Taskforce. Various sets of parameter modification were assessed by the same manner described above. After the evaluation in section **II**, the taskforce concluded that the spatial frequency processing should be off for the pneumoconioses screening. The multi-frequency processing that enable differential processing at the areas with the high and the low frequency was not allowed for the judgment of presence of pneumoconiotic opacities. The DR Taskforce's recommendation was, therefore, revised as the right side column in **Table 1**. Also the gray-scale processing on the mediastinum was omitted from the previous one.

Table 6 Applicable imaging parameters for each vender to match the recommendation by the DR Taskforce for MHWL-J in 2007

Canon	E		* or 1
	D		*****
	Brightness	17 - 20	
	Contrast		14 - 17
Philips	Density (D)	15 - 17	
	Gamma (G)		40 - 45
	NC (N)		00 - 03
	DCE		0.0
Siemens	SF		0/***
	H		0/***
	LUT		8
	W		2300 – 3300
	C		1900 – 2300
GE	Contrast (C)		119 - 130
	Brightness (B)		152 - 157
	Edge (E)		1
Toshiba	WL		1800 - 2400
	WW		1200 - 2800
	G		7
	E		0
	D		0
	I		0
Hitachi	Filter		0 - 3
	Mask size		5
	DRC		0
	γ		3
	WL		2100
	WW		3850
Shimazu	W		11500 - 12500
	L		6000 - 6500
	E		0

Note *, *****, *** are off.

As stated in the note of the table, the taskforce have reviewed CXDI hardcopies and accepted the use of Enhancement, a parameter for the spatial frequency processing, up to 1, while the CR Taskforce's recommendation is equivalent to the CXDI's Enhancement up to 4 as shown in the vender's recommendation in **Table 3**. For the other venders' DR, the taskforce only reviewed the hardcopies produced as the Spatial Frequency Processing OFF and the images were acceptable. The sharpness of the opacities' edge may largely affected by the Enhancement, but other factor like the distance between the subject and the film-screen or the flat-panel detector may also affect the sharpness of the images.

In order to perform a group review, the taskforce requested the venders to submit the hardcopies produced according to the recommendation shown in **Table 1**. **Table 6** summarized the parameter set for the each vender which is compatible to the DR Taskforce's recommendation for the processing of FPD DR. The contrast, the density, and the edge enhancement seem to be the comparable parameters for the majority of the venders, although there is no detailed explanation. Some of the venders include the window width and level, while the others do not.

Discussion

For the most of the physicians using CR or DR at their clinics may not realize the importance of the present study to ensure the comparability to the FS radiograph. What they are viewing on the medical monitor or laser printed hard copy on the view box is routinely produced images according to the pre-decided parameters, maybe recommended by its vender or by the hospital's chief radiologist, and in the black box to most of the physicians. As the storage medium is not infinite, the PACS system only carries the compressed data of the clinical images. After the compression, any pre-storage modified parameters for the gray scale processing and the spatial frequency processing cannot be re-modified. It is not the window level or width of the stored image but the pre-storage parameter setting that is critical to the visualization of the appropriate image.

Therefore, the images stored on the PACS system are usually different from the raw data and re-modification is not possible. In order to guarantee the compatibility of the data on the medical monitors or the medical laser printers, the DICOM Part 14 will be the format to use. The DICOM Part 14 provides the standardized format for gray scale display, the P-value, *i.e.* the pixel value after all DICOM defined gray scale transformations have been applied (8). We have experienced that when certain DICOM formatted CR image cannot be properly visualized on the high-resolution medical monitor, which is probably caused by not applying the DICOM Part 14. Such standardized format for gray scale will be the minimum requirement for the data collection. For the research purposes the image data should be obtained as the parameters modifiable data stored uncompressed or by reversible compression. Such data will not be usually available without the venders' assistance. It will not be practical to demand all the CR or DR data should be stored as raw data, but it is essential to demand all the digital radiograph data to be stored using P-value as defined in DICOM Part 14.

The DICOM Part 14 guarantees the standardization of gray scale, but it does not guarantee the standardization of other parameters of spatial frequency processing, multi-frequency processing and dynamic range control. The multi-frequency processing enables differential processing at the areas with the high and the low frequency. The dynamic range control, a pre-storage processing to allow showing the back of heart and diaphragm shadow less white while keeping the gray-scale of the lung field, would be useful for other clinical purposes but not allowed to use for legal medial judgment of pneumoconiosis at least in Japan. These parameters were tool for better visualization of DR images and may enable to show pathologic lesions more clearly, but standardization of those parameters has not been achieved yet.

Film-based hard copy of FPD DR was evaluated concerning imaging parameter appropriateness and consistency of classification results to the conventional FS radiograph. The hard copy of FPD DR was similar in brightness and contrast of gray-scale when produced applying the decided parameter range. Authors conducted similar study including comparison with CR using 10 definite, 10 borderline and 10 negative cases with HRCT proof (9). After optimization with venders' engineer's help the FPD DR could produce very similar image as the FS radiograph, while the CR hard copies produced by the CR vender's recommended parameter was not as similar as the FS radiograph when compared to the FPD DR, according to the study. However, the study did not able to detect the difference among the three modalities' area under the curve (AUC) of the ROC analyses when the HRCT proven FS radiograph reading results were considered as the gold standard.

The present study performed by the DR Taskforce started from the parameters that the previous CR Taskforce for MHWL-J has recommended. The conclusion that the DR Taskforce has reached, as stated above, is more rigorous than the former recommendation, not allowing the use of the spatial frequency processing for the DR. This new report may urge reconsideration of the former recommendation made by the previous CR Taskforce.

The FPD DR was officially approved for the pneumoconiosis judging purpose in December 2007. Evaluation of the image or soft copy on the CRT or LCD monitors was not in the scope of the evaluation performed by the MHWL-J taskforce. For its use as soft copy, rigorous evaluation of monitor spec, maintenance and calibration of the monitor, data storage, data compression rate, and pre-storage data processing should be done before implementation. This report may covers come part of the pre-storage data processing assuming the conventional film-screen radiograph is the best image to compare.

Conclusion

The MHWL-J DR Taskforce has concluded that the DR chest radiography with appropriate settings as presented in this article can be used in the legal management of patients with pneumoconiosis. Accordingly, the FPD DR was officially approved for the pneumoconiosis judging purpose in December 2007 in Japan. The pre-storage parameters, both gray scale processing and spatial frequency processing, are important to decide the image output as well as the post-storage parameters like window level and width. Those influences on the output image are universal to both hard copy and or soft copy. The DICOM Part 14 should be included as the grayscale format compatible to the DICOM monitors. Evaluation of the image or soft copy on the CRT or LCD monitors was not in the scope of the evaluation performed by the MHWL-J taskforce. For its use as soft copy, rigorous evaluation of monitor spec, maintenance and calibration of the monitor, data storage, data compression rate, and pre-storage data processing should be done before implementation.

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Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images

A NIOSH Scientific Workshop
March 12-13, 2008
Washington DC, USA

Workshop Summary

On March 12–13, 2008, the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) hosted a workshop to address issues for classifying digital chest radiographs for patients with pneumoconioses. The international group of scientists in attendance heard from representatives of the International Labour Organization (ILO), the American College of Radiology (ACR), NIOSH, and academia. Expert presenters described current and future issues in digital radiography, especially as they relate to classification. The workshop participants broke into smaller groups to discuss (1) image acquisition, (2) image presentation, and (3) file interchange, and to develop recommendations for advancing digital classification for pneumoconioses.

Introduction

David Weissman, M.D., Director of NIOSH's Division of Respiratory Disease Studies, welcomed the workshop participants and emphasized the background of the meeting—that is, the transition of radiologic surveillance from film to digital methods. Gregory R. Wagner, M.D., NIOSH Senior Advisor, also welcomed the workshop participants and introduced the plenary speakers.

Organizational Perspectives

Igor A. Fedotov, M.D., Ph.D.; Edward L. Petsonk, M.D.; and Daniel Henry, M.D.

Dr. Igor Fedotov, of the International Labour Organization (ILO), reviewed advances in conventional chest radiography (film screen) during the past 20 years—for screening and health surveillance, clinical care, diagnosis, evaluation of response to treatment, and epidemiological research. Film screen radiography is easy to perform, cost-effective, and relatively specific for some conditions, including advanced coal-workers' pneumoconiosis. Chest radiography is the most commonly applied tool for the screening and surveillance of dust-exposed workers. It can indicate failure in dust control and can help establish exposure-response relationships. Yet there are limitations. For example, conventional radiography may miss some airway disorders and may not correlate with functional impairment.

Dr. Fedotov stated that new digital techniques for chest radiography produce better-quality images, allow easier manipulation, and afford easy access and storage. Digital methods can allow for teleradiology—transmitting images through network connections. They allow the use of Picture Archiving and Communication Systems (PACS). Two digital radiographic methods are in use—computed radiography (CR), which uses an imaging plate and scanner, and digital radiography (DR), which uses a flat-panel detector. Digital methods feature high equipment costs, and they lack standardization. Trials must be conducted to establish the comparability of the various digital imaging techniques with film-screen classifications, and the ILO must produce standard digital images for comparisons. Legal aspects have slowed the introduction of digital systems—for example, state and Federal laws and qualifications for compensation for lung injury. Dr. Fedotov suggested a future medical-screening scheme featuring the use of digital subject films and standard digital images and the use of CT classification of pneumoconiosis as a supplementary method.

Dr. Fedotov presented the case for revising the ILO 2000 classification scheme, which has served to improve international comparisons of data on pneumoconiosis. The revision will feature increasing use of new soft (image) standards as opposed to hard copies. A draft text of the revision will be completed in 2008. It will address many technical issues, such as standardization of file formats, the use of different brands of equipment, and ensuring image quality for classification.

Dr. Edward Petsonk, of NIOSH's Division of Respiratory Disease Studies, provided background on the ILO classification, which was defined as "a means for describing and recording systematically the radiographic abnormalities in the chest provoked by the inhalation of dusts." He noted that incidence of pneumoconiosis in coal miners declined steadily in the 1970s and 1980s, yet has risen since the 1990s. Challenges for the ILO revision of classification include a need to ensure detailed and uniform images for classification and a need to merge science and practicality. Dr. Petsonk described the NIOSH perspective, based on surveillance programs, compensation and clinical evaluations, and epidemiological and clinical research. NIOSH requires the uniformity and integrity of digital images. Migration to digital imaging will require specifications for acquisition and formation of digital chest radiograph images, as well as procedures for classification of images based on the ILO system, local and disseminated systems for managing images, and a capacity to examine and approve B readers.

Dr. Daniel Henry, of the Medical College of Virginia and Chair of the American College of Radiology Pneumoconiosis Committee, provided an ACR perspective, stressing the need to create an environment in which to view images. ACR's mission includes education and technical development and support. Dr. Henry reviewed the ACR's history in this field, including the development of guidelines and support for B readers. The ACR has incorporated the Digital Imaging and Communication in Medicine (DICOM) standard to promote the communication of images and support PACS. Dr. Henry stated the ACR's goal of moving away from traditional viewboxes and creating a new logistical paradigm for image viewing. One trend today is the use of 3-D color rendering. Color LCD monitors may be more versatile for cross-sectional imaging and CR/DR. There is a need to integrate digital acquisition and display guidelines with elements of chest radiography. The ACR has constructed a new facility in Reston, Virginia, known as the ACR Education Center. The site likely will host future teaching seminars and B-reader testing. Dr. Henry described a plan to transition the ACR's Pneumoconiosis Committee into a task force that can move beyond issues of education to a role of working with NIOSH and ILO to support the transition to digital media.

Discussion

In response to a question, Dr. Henry noted that newer color monitors are cheaper and faster than the older black-and-white monitors. However, during a period of transition, we do not want to exclude people because of the PACS systems in place. Availability of technologies is a key. Dr. Michael Flynn stressed the importance of pixel size and field of view. Dr. Carl Ravin encouraged the group to consider converting from B readers to A+ readers, which might include computerized reading. It was noted, however, that attempts at computer automated readings a decade ago were less than successful. Dr. Henry suggested that a first step be the development of computer standards for opacity and profusion. Dr. David Clunie wondered whether CT would be a better imaging strategy because of its success with computer evaluation.

Plenary Presentations

Comparison of Digital Radiographs with Film-Screen Radiographs for Classification of Pneumoconiosis – Alfred Franzblau, M.D.

Dr. Alfred Franzblau, of the University of Michigan School of Public Health, described a study that assessed the impact of image format on the ILO classification as performed by experienced readers. The study compared the use of DR and film-screen radiograph (FSR) images. Study participants read both hard copy (printed out) and soft copy (on the monitor) DR images. The images featured abnormalities of lung parenchyma and pleura resulting from inhalation of dust. Dr. Franzblau reviewed the study methods, including recruitment of subjects, capturing of images, reading of images, data cleaning, and statistical analyses. The cases included all major ILO small opacity profusion categories, with both rounded and irregular small opacities, large opacities and pleural abnormalities.

The investigators captured images from 107 subjects. Six B readers classified each image in random order based on the ILO 2000 system and ILO standard films and digitized images for comparison. Subsequent analyses compared inter-reader reliability, using the kappa statistic. The investigators also analyzed marginal rating differences across image formats. Dr. Franzblau presented the following conclusions from the study:

- There were few significant differences in reliability of image classifications across formats, and the differences were solely among classifications of image quality.

- Parameter estimates for image format in adjusted models were similar to results for unadjusted models, indicating that covariates (age, gender, etc.) were not acting as confounders of the effect of image format on prevalence of findings.

- For film quality, classifications for FSR and digital soft copy images did not differ significantly. Hard copy images tended to be classified as worse than FSR and soft copy images.

- For parenchymal abnormalities and small opacity profusion, classifications of FSR and digital soft copy images did not differ significantly. Classifications of digital hard copy images demonstrated significantly greater prevalence of parenchymal abnormalities and small opacity profusion.

- For large opacities, the three image formats differed significantly. (When "ax" were included, the difference between FSR and soft copy disappeared.)

- For the presence of pleural abnormalities, all three formats differed significantly.
- There were no significant differences among the formats with regard to costophrenic angle obliteration and diffuse pleural thickening, although the study power was low for these outcomes.

Dr. Franzblau cautioned that the study did not employ a gold standard. When there was a difference in prevalence by image format, one could not determine which was closer to the "truth."

Discussion

In response to questioning by Dr. John Balmes, Dr. Franzblau concluded that there is little reason to read digital hard copies. He noted that readers of soft copies were allowed to manipulate the images on the screens. In the analyses, kappa values were not weighted. The workshop participants noted that, despite drawbacks, digital hard-copy reading likely will be used throughout the world. That might not matter for pleural disease, for which clinicians can use CT. The workshop participants wondered whether inter-reader variability might have played a role in the results. Dr. Franzblau noted that techniques (e.g., different times spent in reading different formats) might have led to differences. One key for future studies may be the optimizing of reader processing. Dr. David Lynch noted that the results do not rule out the possibility that both hard- and soft-copy DR may be more sensitive than film-screen.

Acquisition of Digital Chest Images for Pneumoconiosis Classification: Methods, Procedures, and Hardware – Ehsan Samei, Ph.D.

Dr. Ehsan Samei, of Duke University Medical Center, reviewed the conventional film-screen process and listed the benefits of digital radiography (improved dynamic range, post-processing for visualization, analytical capability, archiving). Digital radiography features analog image capture followed by digitization. It can suffer from x-ray scatter and requires pre-and post-processing of the image. Digital radiography systems can differ in detector technology, image quality, reported and required exposure, and the image post-processing and appearance. Dr. Samei reviewed the physical bases of the technologies (sensitive layer, coupling layer, collection layer).

CR, developed in 1975, works by using x-rays to stimulate a layer containing phosphor, producing a latent image. Laser scanning then produces light emission, which is collected in the form of digital signals. The inherent image quality is governed by the lateral spread of laser light and the phosphor thickness. Flat panel technology was developed in the late 1990s and, although expensive, outperforms CR in quality and speed. It makes use of discrete pixel capacitors—and there are two types—photoconductor detection and phosphor detection. Charge-coupled systems, which also were developed in the 1990s, use phosphors in combination with discrete charge-coupled devices (CCDs) and metal-oxide semiconductor light sensors. Image quality is comparable to CR. Scatter, which reduces image quality, is an ever-present attribute of chest radiography, whether analog or digital. Dr. Samei explained the technique of slot-scanning DR, which can reduce scatter significantly.

Dr. Samei concluded that digital radiography offers advantages over film screen, that current technologies offer varying image quality, and that an initiative is needed to address the different systems and to unify conditions. He recommended that the radiography field:

- Standardize image acquisition and processing protocols
- Institute robust quality control and preventive maintenance programs
- Develop facility and equipment accreditation programs

CR and DR Chest Radiographic Image Parameters for the Pneumoconioses: The Japanese Approach and Experience – Narufumi Suganuma, M.D., Ph.D.

Dr. Narufumi Suganuma, of Kochi University Medical School, stated that because the Japanese Pneumoconiosis Law uses radiographic classification as a scale to determine administration class of dust-exposed workers and compensation, revision of the law is socially sensitive. A Japanese digital radiography taskforce began the revision process by defining appropriate digital radiography parameters for classification. They built upon an earlier task force's recommended parameters for grayscale and spatial frequency and developed parameters for the Canon digital radiography system.

The task force conducted a reading trial of the classification of pneumoconiosis using a film-screen system compared to hard copy images from the same individual but produced using a digital radiography system. The study found that, for profusion, about 15 percent of cases were over-read by digital radiography and about 6 percent were under-read. About 80 percent were classified as the same.

Conclusions of this trial were that (1) there was crude agreement between digital radiography and FSR for pneumoconiosis classification, (2) inter-reader agreement for FSR and digital radiography were $\kappa = .6072$ and .6968 respectively, and (3) digital radiography can be considered to have a capability of classifying pneumoconiosis changes in the chest equal to that of FSR. The task force recommended a digital radiography grayscale imaging parameter equal to the previous parameter for FSR (1.6–2.0). It recommended that spatial frequency processing be turned off for digital radiography. The task force investigators subsequently studied other vendor systems (Philips, Siemens, GE, Toshiba, Hitachi, and Shimazu). They concluded that parameters for grayscale processing and spatial frequency processing must be standardized.

The task force concluded that digital radiography with appropriate settings could be used for legal management of patients with pneumoconiosis. The pre-storage parameter settings are more critical than the window level or width of stored image for the visualization of the appropriate image. It will not be practical to require that all CR or DR images be stored as raw data files. However, all digital radiograph data should be stored using a P-value as defined by DICOM. The use of soft copy (onscreen) images has yet to be evaluated, and users of soft copies are advised to consider appropriate variables for monitors and data.

Discussion

Dr. Yukinori Kusaka noted that readers in Japan tend to use hard copies and controls that were adopted over time. There is a need to establish standard parameters. Dr. Suganuma stated that a Japanese committee continues to evaluate parameters for different vendor monitor systems for quality assurance. Japan has adopted three control schemes and integrated them for calibration. Dr. Elizabeth Krupinski wondered why the Japanese study recommended no edge enhancement. Dr. Suganuma responded that this was because of the use of an analog standard (a preference).

Dr. Franzblau noted that a study being performed in Montana is collecting film and DR chest images, as well as CT images of pleural disease to be used as the gold standard. Dr. Fedotov wondered whether the diversity of systems will jeopardize the development of international standards. Dr. Samei stated that the solution is to have access to "for processing" data—that is, data that are ready for processing. It will also be important to know the system that produced the data, to have a gold standard, and to maintain a central Web server to load raw images. However, there are serious challenges to collecting raw image data.

Dr. David Clunie suggested recognizing and creating reference images that are appropriate to uses. He stated that it will be impossible to create an algorithm to consolidate data from various vendors/detectors. Yet, Dr. Samei noted we could readily adjust for such differences. Dr. Wagner noted that some hard-copy standards were developed using film stocks that have since been replaced. Dr. Petsonk proposed identifying parameters that are essential and creating minimum standards for them. Dr. Krupinski noted that the ACR guidelines provide such standards. They need to be adopted.

Dr. Daniel Henry cautioned that persons in far-flung places might have difficulty accessing a central site for standard references. Dr. Fred Prior suggested that we define a physics-based standard that vendors could apply to produce a certain quality. Dr. Eliot Siegel noted that experts in the field of digital mammography have proposed creating a harmonized raw data set and the use of a phantom that would be scanned to produce values for standards for data acquisition.

Image Presentation: Implications of Processing and Display – Michael Flynn, Ph.D.

Dr. Michael Flynn, of Henry Ford Health System, reviewed steps in processing images, which are used to transform digital radiographic data into display values for presentation at a workstation or film printer. A first processing step is preprocessing, in which raw data based on detected radiation energies are treated to create an image suitable for processing. The results are referred to as "for processing" data.

Display processing refers to subsequent steps in which "for processing" data are treated in five ways: grayscale rendition, exposure recognition, edge restoration, noise reduction, and contrast enhancement. Dr. Flynn described each of these processes. Grayscale rendition converts signal values to display values. Exposure recognition adjusts for high/low exposure. Edge restoration sharpens edges while limiting noise. Noise reduction features the reduction of noise while maintaining sharpness. Contrast enhancement entails increasing contrast to produce detail and produces the most dramatic and visible effects.

A final step, display presentation, refers to aspects related to the human visual system. Dr. Flynn reviewed the elements of viewing that affect the human interpretation of radiographic images. For example, the viewer is affected by viewing distance, display size, pixel size, and equivalent contrast, which refers to the role of brightness in the detection of contrast. Observer performance is best when the visual system is adapted to the average scene luminescence. Dr. Flynn listed the following display specifications: a luminance response of 350, a maximum brightness of 450 candelas per square meter or more, a pixel pitch of 0.210 mm or less, a diagonal size of 20–24 inches with a 4:3 or 5:4 aspect, and an ambient luminance that is less than 1 /4 of the minimum display luminance.

Dr. Flynn provided sample presentations of a chest image, showing, for example, the effects of tone-scale changes and edge restoration.

Discussion

In response to a question by Dr. Wagner, Dr. Flynn noted that, for edge restoration, the effects for nodules and irregular opacities are the same. The tradeoffs in adjusting parameters might be different for different detectors. Dr. Krupinski cited the factor of reader age in setting levels of enhancement for viewing. Dr. Lynch cited a need to study how processing affects the perception of pathology. The prettiest image might not be the most optimal in producing a perception of pathology. Perhaps we should develop digital standards with and without aggressive enhancement. Dr. Flynn envisioned a day when NIOSH and ILO support, based upon accepted observations, a standard data processing engine. It would seem to be possible to produce similar results using the various vendor systems and adjusting parameters. The workshop participants cited phantoms currently in use.

Dr. Franzblau wondered about a possible benefit in developing settings for different abnormalities. That idea, noted Dr. Siegel, suggests a benefit in performing processing at the workstation, varying the image. Prior to that, a unified "for processing" image could be helpful in, for example, relating to CT images. In any event, we will need guidance in comparing across vendor systems. Dr. Flynn agreed with that need but cited a difficulty in establishing settings among vendors. It would be helpful to obtain a set of images for a disease state. Dr. Henry proposed placing an indicator on the image (something imaged as the patient is imaged) to guide subsequent adjustment for display. The workshop participants considered this to be a good idea, although perhaps difficult to implement.

Ensuring Image Quality for Classification of Digital Chest Radiographs – Ehsan Samei, Ph.D.

Dr. Samei noted downsides in the use of digital radiographs, including the following:

- Wide dynamic range can lead to over- or under-exposure of the patient
- Image post-processing can lack utility for physicians, reduce reading efficiency, and produce ad hoc images
- The digital format can lead to lost patient data and security problems

The potential advantages of digital radiography are not automatic. For full realization of digital radiography, users must recognize nuances associated with features, implementation, and quality control (QC). Quality control procedures can enable standardized processing and appearance and enable automated and optimal quantification. Metrics of image quality include resolution, noise, and signal-to-noise efficiency. Resolution is the ability to resolve distinct features, usually characterized by the Modulation Transfer Function (the efficiency of reproducing contrast at different spatial frequencies). It varies among common imaging systems. Noise refers to unwanted signals that interfere with interpretation and is best characterized by the Noise Power Spectrum (variance in terms of spatial frequencies). Signal-to-noise efficiency can be determined by the detector quantum efficiency. This too varies among the common digital radiography systems.

Dr. Samei described a possible quality control system for digital radiography that featured acceptance testing, system calibration, preventive maintenance, and periodic assessments. He also described the use of phantoms for quality control. He listed the following requirements for classifying pneumoconiosis:

- A robust QC program
- Standardized image acquisition protocols
- A consistent exposure index
- Raw image data in "for processing" form
- Consistent processing and display for consistent visualization across systems and cases
- Consistent analysis for automated quantification of pneumoconiosis
- Archives of raw and processed data for further analyses

Dr. Samei concluded that digital radiography can provide standardized classification of pneumoconiosis because of its quantitative nature and tractable performance characteristics. QC is essential to ensure robustness and integrity of data and to enable a reliable classification scheme. Dr. Samei recommended that NIOSH-affiliated programs enact maintenance and QC programs and follow predefined acquisition and processing protocols. NIOSH may consider maintaining a central Web server for affiliated facilities. Affiliated facilities could register their imaging devices and performance metrics. NIOSH should consider accrediting affiliated facilities to ensure adherence to requirements.

Discussion

Dr. Alan Ducatman wondered whether phantoms offer consistency over time. Dr. Samei responded that facilities should be re-accredited following major changes. Dr. Vikas Kapil noted the problem of biases introduced in post-processing by readers. Dr. Samei suggested storing the raw images. Specific approaches to processing could be required for images to be classified. Dr. Krupinski suggested developing a program that could observe and save changes that are made during classifications—enabling future audits. Dr. Clunie suggested that there be quality control procedures for display systems. Dr. Flynn noted that the Modulation Transfer Function is not an issue in LCD systems with digital interfaces. He also wondered whether, because of the variety in acquisition devices, we should have a separate QC program for CR devices. Dr. Krupinski suggested that QC systems consider the reading environment (ambient lighting, etc.).

Standardizing File Formats, Security, and Integration of Digital Chest Image Files for Pneumoconiosis Classification – David A. Clunie, M.D., M.B.B.S.

Dr. David Clunie, of RadPharm Incorporated, noted that today there are no challengers to the DICOM standards for handling pneumoconiosis classification files. DICOM is supported by all modern devices in all countries. It has a bit depth suitable for the available sensors and features patient demographics, management information, and technique information in each header. It is the only inter-vendor standard in use. Dr. Clunie reviewed versions and features of DICOM, including limitations, and described DICOM as a system for thinking about interoperability. DICOM services include transfer across networks, querying for lists of patients and studies, retrieving studies, patients, series and images, creating work lists, and printing. Methods for transfer and workflow include the use of workstations, PACS, CDs, and networks.

Issues with CD viewers include the fact that images are often are burned to CDs with a viewer incorporated, the risk of transferring viruses on CDs, a need to be familiar with dozens of viewers, a possible lack of grayscale pipeline support, and other concerns. One solution is to import standard media into a PACS. Barriers to importing include formats, ID reconciliation, and viruses. Software compatibility issues include multiple DICOM SOP classes, a need for "ready to view" images, and the need for a GSDF-calibrated display.

Image contrast features include a single default presentation of image contrast, a linear window center and width, and a nonlinear contrast adjustment. Dr. Clunie described the use of look-up table data. He stated that reference images are the ILO reference set and they can be displayed digitally with patient images. Displays are traditional PACS double portrait 3-megapixel workstations. Classifications can be performed using existing infrastructures and remotely, with images provided by a central server. In the future, authorized B readers might be able to access patient-related images and documents in large national databases. Dr. Clunie reviewed security issues surrounding patient images and other patient information, noting that digital data are at risk when in physical form (CD) or online. Privacy can be maintained by, for example, replacing a patient's name and social security number with a pseudonymous identifier.

Dr. Clunie described the DICOM structured reporting methods, which feature a variety of templates, and their advantages. He summarized his talk with the following statements:

- An entire infrastructure already exists to support clinical use of digital projection x rays
- It is based on the use of the current DICOM standard between modalities, PACS, and workstations, using networks and CDs
- Most sites are now experienced with exporting and providing outside access to digital images (including "for presentation" digital x-ray)
- The correct choice of an appropriate image viewer should allow consistent display and reliable review of images side by side with ILO or equivalent reference images
- Expensive displays already installed can easily be reused
- Results can be stored as DICOM Structured Reports—DICOM can support the addition of templates and codes.
- Matters of security and privacy can and should be addressed through conventional means that are already widely used clinically

Dr. Clunie recommended the following:

- Both CR and DX DICOM images should be permitted
- Processed "for presentation" images should be required, and they should not be dependent on proprietary processing in a display workstation
- Display workstations should be qualified and certified for use of ILO classifications by B readers, working with test images from different vendors and software, supporting variations of encoding and grayscale pipeline, and capable of displaying subject and reference images side-by-side
- For privacy, images should be de-identified before sending for reading
- A digital (not digitized film) reference set should be created and released, comparable in contrast and resolution to CR and DX images
- NIOSH should consider the creation of a managed distributed or centralized infrastructure, with remote reading and an open archive

Discussion

Dr. Prior wondered whether the use of de-identified data will be feasible. Dr. Clunie suggested that it will be, and the export of data will be for further patient care. He added that the approach for file handling that he described could be applied on an international level. Dr. Wagner wondered whether implementing such a system might be overly cumbersome. Dr. Clunie noted that many of the issues, such as multi-vendor PACS, have already been addressed.

Dr. Flynn expressed concerns about data export on CDs. Some large centers running full PACS operations are likely to export CDs in a proprietary format, thereby leading to a problem in reading them remotely. Dr. Clunie suggested that this problem may not be widespread. One solution would be for such a center to forward the data to a third-party CD writer that uses a non-proprietary DICOM format. Dr. Clunie raised another problem—some PACS systems alter the images (pixels, headers, etc.). Internet transmission engenders policy issues.

Dr. Clunie noted that other digital images (CT, MR) are used routinely in litigation, so that digital radiography likely will be used as well. Regarding privacy, a general recommendation is to obtain consent for secondary use of de-identified data up front. Dr. Prior added that, for matters such as privacy and litigation, it will be important to determine the form of data (that is, the image) that was observed by the reader. Dr. Clunie suggested that archiving requirements, backed by NIOSH, could reduce the possibility of altering images (as for malevolent purposes). Software updates should be accompanied by facility re-accreditation. Dr. Petsonk noted that the use of film-screen images will persist for some time, necessitating two tracks.

SMALL GROUP DISCUSSIONS AND RECOMMENDATIONS

The workshop participants divided into three smaller groups to discuss separately the following areas and provide recommendations to NIOSH and ILO for steps to be taken in the shorter term and longer term:

- Digital chest radiograph image acquisition and formation, including QC
- Image presentation, including processing and display
- File interchange, including formats and interoperability

They then reconvened as a whole to hear the leader of each subgroup report on the separate discussions.

1 – Digital Chest Radiograph Image Acquisition and Formation, Including QC

Dr. Samei summarized the results of the first subgroup's discussion of acquisition and formation of images. The group members agreed that implementation should be left to a follow-up initiative. They agreed on a multi-phase approach that would be grounded on the use of "for processing" data and basic image metrics. The consistency of image appearance must be a main goal. The subgroup described a three-phase approach: