

Conversion to use of Digital Chest Images for Surveillance of Coal Workers' Pneumoconiosis (Black Lung)

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Abstract:

To protect the health of active U.S. underground coal miners, the National Institute for Occupational Safety and Health (NIOSH) has a mandate to carry out surveillance for coal workers' pneumoconiosis, commonly known as Black Lung (PHS 2001). This is accomplished by reviewing chest x-ray films obtained from miners at approximately 5-year intervals in approved x-ray acquisition facilities around the country. Currently, digital chest images are not accepted. Because most chest x-rays are now obtained in digital format, NIOSH is redesigning the surveillance program to accept and manage digital x-rays. This paper highlights the functional and security requirements for a digital image management system for a surveillance program. It also identifies the operational differences between a digital imaging surveillance network and a clinical Picture Archiving Communication Systems (PACS) or teleradiology system.

Introduction

The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC) is mandated by the U.S. government to monitor the health of active underground coal miners. The NIOSH Coal Workers' X-ray Surveillance Program (CWXSP) carries out this responsibility. Coal workers' pneumoconiosis, also known as Black Lung, is caused by inhaling coal mine dust. Federal law mandates that new miners working in underground coal mines are entitled to a chest radiograph as part of a pre-placement physical or during the first six months after being hired. Experienced miners are entitled to a chest radiograph at approximately five year intervals to monitor for development or worsening of pneumoconiosis (PHS 2001). All chest radiographs submitted to the CWXSP were obtained at approximately 200 approved x-ray facilities located throughout the U. S., preferably in sites that are convenient to coal miners. NIOSH manages the interpretation process and permanent storage of the chest radiographs received from the facilities along with associated miners' records.

Since its inception, the CWXSP has been a film-based operation; however, approximately one-third of the approved x-ray facilities no longer use film and acquire

only digital chest exams. Subsequently, these facilities have been removed from the list of approved facilities where miners can receive their chest exams, drastically reducing the number of convenient locations where miners can receive x-rays. Consequently, NIOSH is acquiring the technology to manage digital images and redesigning well established film-based activities to support the digital conversion.

The digital conversion of CWXSP is complex. It must take into account published regulations that dictate the operations and procedures of CWXSP that might need to be updated, along with a number of standard operating procedures for managing the program. Working with digital protected health information introduces its own constraints and requirements which add levels of security that did not exist in the film-based environment. Lastly, the digital interpretation process varies from the film-based process.

To ensure that all critical aspects of the conversion process were considered, a systems engineering approach was undertaken that included:

- *Workflow analysis* of the film-based environment and identification of those activities that will remain unchanged versus those that will change in a digital environment. This analysis includes identification of existing regulations that might need to be updated to accommodate newer digital technologies,
- Defining functional requirements for a *digital CWXSP* that support the surveillance activities required by federal law,
- Defining a *secure image transfer* mechanism that accepts digital images from the x-ray facilities and is compliant with evolving government networks security rules.

Work-flow Analysis

The CWXSP is currently based on the acquisition and management of film-based chest radiographs of miners' lungs. Existing published regulations dictate the procedures to be followed by approved x-ray facilities in acquiring chest radiographs. Film size, x-ray projection, focal spot size, generator ratings, exposure time, and other parameters are specified in federal regulations "Part 37 of the Public Health

Service 42 CFR Part 37 - Specifications for Medical Examinations of Underground Coal Miners” (PHS 2002). Even the length of time between acquisition of the film and receipt of it by NIOSH for interpretation is dictated in the regulation.

When a film-based chest x-ray is received by NIOSH, it is matched with accompanying documentation and a quality control check performed. It is then assigned to a B Reader, a physician who has passed a NIOSH certification examination in “classification” of chest x-rays according to an International Labour Office (ILO) classification system. The film is placed in a queue for mailing, and eventually packaged with other films to be sent to the B Reader. When the B Reader receives the package, s/he classifies all the films, records each film’s results on a form, and returns the package to NIOSH. Consensus on classification of pneumoconiosis is required; thus, each chest film needs to be classified at least twice. At a minimum, each film is classified by an initial reader at the approved x-ray facility and a NIOSH B Reader. If there is no consensus, the film is then assigned to a second B Reader, packaged with multiple films and mailed. When the second B Reader completes her/his interpretation, the film will either be filed in the film archive or sent for a third review if there is insufficient agreement between the readers. This process of receiving multiple readings is time consuming, costly, and carries inherent risk of loss of the film.

Once films are archived at NIOSH, there are a number of situations where an old film may be required for final determination of pneumoconiosis if evidence of pneumoconiosis is presented based on other medical evidence but not identified by the B Readers from the classification of the x-ray films. Also, when an x-ray classification by the B Readers suggests the existence of abnormality in cardiac outline, pneumothorax, tuberculosis, complicated pneumoconiosis, or cancer, all x-rays available for that miner are compared side-by-side. The original films are used in both of these situations. There are also numerous requests made to NIOSH/CDC for past x-ray records of miners. Many of these requests are from miners’ families, lawyers, and physicians. Some requests are filled with copies of the original film, others require the original film.

The digital conversion of the CWXSP must consider the acquisition, interpretation, management, and storage of the chest x-rays as well as the B Reader certification process. The specifics of these processes are covered in the next section.

Digital CWXSP Requirements

NIOSH has estimated that over the last five years about half of all their acquisition facilities stopped

producing film-based x-rays and therefore were not able to participate in the CWXSP. They also have identified a number of approved x-ray facilities that only produce film-based images for the CWXSP and would like to cease their production of film and go to a completely digital environment. Therefore, NIOSH recognized the need to accept digital chest x-rays for the CWXSP.

While there are standards that make the conversion from a film-based to digital imaging environment easier, there are also special requirements of a Digital CWXSP that differ from those of a clinical Picture Archiving and Communication System (PACS) or Teleradiology System and therefore complicate the conversion process. Some of the key differences include:

Assignment of images: The CWXSP requires multiple classifications of each miner’s chest x-ray for presence of pneumoconiosis. In a digital CWXSP, a miner’s image will generally be assigned simultaneously to two separate B Readers’ work lists and the system will allow both of them to classify the image. A traditional PACS often assumes only a single review of a study.

Special Hanging Protocol: B Readers review a miner’s chest x-ray by comparing it to a standard set of 22 ILO reference images (ILO 2002). Traditionally, PACS or teleradiology workstations do not allow for concurrent viewing of an examination with a standard set of images or with an examination from a different person. Therefore, the digital CWXSP must be able to display the reference set and allow the B Reader to scroll or page through it while displaying the miner’s x-ray image.

Preservation of multiple presentation states: Since multiple B Readers must review and report on a single miner’s chest x-ray, the digital presentation state used to classify the image must be saved so that others can easily identify what the B Readers saw when making their determinations. This requirement in and of itself is not unique to the digital CWXSP. However, the fact that multiple presentation states from multiple Readers are required makes this function unique to the digital CWXSP.

Secure Image Transfer

NIOSH/CDC must comply with a set of government security and privacy regulations defined within the Federal Information Security Management Act (FISMA) (NIST 2009). NIOSH/CDC has firm directives not to allow social security numbers and other key protected health information to be transmitted across public networks if unprotected by The Federal Information Processing Standards (FIPS) 140-2 compliant

encryption algorithm (NIST 2002). CDC firewalls prohibit the transmission of this sensitive information through anything other than the CDC Secure Data Network (SDN).

The Digital Imaging and Communications in Medicine (DICOM) Standard is widely accepted for the transmission of medical images from digital acquisition devices like computed and digital radiography devices and to and from image management systems and workstations. The DICOM standard defines the formatting of messaging and/or images on removable media but does not have a security model that is compatible with the CDC SDN requirements. Therefore, the use of industry wide DICOM standards for transfer of images from the approved x-ray facilities to NIOSH is difficult to accommodate and requires additional software applications and hardware to accomplish this task (NIOSH 2008).

NIOSH/CDC also requires that the miner's identifying information, including their chest image, not remain on a B Reader's workstation after they have completed reviewing the chest x-ray.

Discussion

As discussed in this paper, the digital conversion of the CWXSP encompasses both engineering and procedural challenges. The acquisition and transfer of the digital image to NIOSH, requirements for classification of those images, reviewing features and security concerns must be carefully considered to achieve a fully integrated and successful digital CWXSP.

Standards and best practices employed by teleradiology and PACS serve as a foundation for transitioning to a digital program. However, the CWXSP has very specific requirements that are not found in the typical radiology or teleradiology workflow and thus, will not appear as standard features and functionalities in any commercial product. Additionally, federal security requirements impose strict constraints on the use of the commercially adopted DICOM standard for the transfer of digital images that will necessitate both strict procedural guidance and additional development to meet the security requirements.

While this paper does not address image quality issues between digital x-rays and traditional film-based chest x-rays in the classification of pneumoconiosis, there

has been some research in this area. Franzblau et al., (2008) found few differences in the reliability of image classification for pneumoconiosis between digital x-rays and screen film.

The digital conversion will increase the number of facilities that are approved to acquire chest x-rays for use by the CWXSP which, in turn, should improve coal miners' access to surveillance for early detection of pneumoconiosis and other lung diseases.

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