



PAVING THE WAY FOR

I**F** all goes well, by March of 2007 Mallinckrodt Institute of Radiology (MIR) will have a catalogued computed tomography (CT) image library that could contain more than 12 million images from the National Lung Screening Trial (NLST)—some of those images may hold keys to breakthroughs in diagnosis and treatment.

by Mary Jo Blackwood, RN, MPH, CHES

LIFESAVING RESEARCH

A NATIONAL
CT IMAGE LIBRARY
FINDS A HOME
AT MALLINCKRODT
INSTITUTE.

As David Gierada, MD, associate professor of radiology and coprincipal investigator for the Washington University NLST site explains, the purpose of the archive is to make particular types of CT images readily available so that investigators involved in future approved research studies can look at the data from different perspectives and with different premises in mind. One possible application would be to use the images for computer-assisted diagnosis software programs, to test their validity and the algorithms used to design them. "It's an active research field: developing better ways to assist radiologists by refining computer programs to help identify potential lesions. A roadblock has been the lack of collections of scans available to develop and test the algorithms. This library will make an enormous number of scans available," says Gierada.

David Gierada, MD, and (right) Fred Prior, PhD, are shown in the atrium of the Scott Avenue Imaging Center.

NATIONAL LUNG SCREENING TRIAL UPDATE

The NLST began in 2002, with a goal of comparing spiral CT and chest X-ray studies for their effectiveness in reducing deaths from lung cancer. Thirty sites across the country have been collecting data from 50,000 smokers and former smokers. Enrollment was completed in February 2004, with nearly 3,800 participants from the Washington University site. Data come from two different sources: the Prostate, Lung, Colorectal, and Ovarian (PLCO) trial network, which started more than 10 years ago, and the American College of Radiology Network (ACRIN). According to Gierada, the NLST screening phase will be completed in about six months, then the ongoing process will continue for several years.

According to Gierada, Mallinckrodt Institute was already managing imaging quality control for the study, so MIR was a logical facility to house the CT Image Library (or CTIL, as it will be known). The CTIL project involves only the PLCO side of the NLST. Over 34,000 volunteers are enrolled in the PLCO arm of the NLST study, and half of those volunteers received CT scans. Each participant in the CT group receives

one scan a year for three years; each CT scan has an average of 250 slices (or images), making for an enormous potential library of scans available for further study.

The other half of the NLST images are chest X rays and are not being centrally archived at this point. There are two concerns with the chest radiographs. "Those images are being obtained in two formats: film medium and digital," says Gierada. "If we were to archive all images electronically, we would have to digitize all the film radiographs by a standard method to make them comparable. That would involve a tremendous amount of equipment, storage, and cost. We had some discussions with our contacts at NCI [*National Cancer Institute*] about setting up a similar library for those images, but it is not being pursued at the present time due to the cost involved and the fewer potential research applications. Currently, all the X-ray studies are being housed at the individual enrollment sites. However, there may be future discussion of an X-ray library."



ESTABLISHING THE CT LIBRARY

Kenneth Clark is a research associate in the Institute's Electronic Radiology Laboratory (ERL) and the data coordinator for the CT library. According to Clark, after only a year, about one third of the images, which are housed in the ERL, have been received. Image-study collection at the enrolling sites, delivery of the image studies to the CTIL, and image-study check-in and archiving are complicated laborious processes, involving multiple steps and requiring great attention to detail.

"This library will make an enormous number of scans available."

—David Gierada, MD

To help with the collection process, MIR provided each enrollment site with a laptop computer, a high-capacity external hard drive, software for image collection and transmission, and software for image study de-identification. Testing centers download image studies from their Picture, Archive, and Communications Systems (PACS) to the laptops. The DICOM [*Digital Imaging and Communications in Medicine—an established standard for distributing and viewing any kind of medical image, regardless of the origin*]

Left, top: Paul Koppel, PhD, and (right) David Maffitt



Left, bottom: Mary Wolfsberger and (seated) Joan Moulton scan images for complete coverage of the lungs.

headers of the image studies are then de-identified of protected health information and re-identified only with anonymous participant identifiers (PIDs). PIDs are assigned by Westat, an independent central management and data collection service contracted by NCI to supervise the NLST/PLCO project. De-identified image studies are then delivered to the CTIL either on DVD, on the external hard drive, or transmitted over a Virtual Private Network (called a VPN) on the Internet.

Image studies arriving at the

CTIL are checked to make sure they meet CTIL requirements: proper CT scanner reconstructions, image headers free of protected health

information, and the number of images received match the number of images sent from the originating site. The image studies also are visually inspected to ensure they are images of the lungs, are not corrupted, and contain no protected health information.

Failing image studies are discussed on an individual basis with the originating sites and remedies, where possible, are initiated. Certified image studies that meet all CTIL requirements are committed to the CTIL archive.

USING IMAGES FOR FURTHER RESEARCH

Obtaining approval to conduct a research study using NLST images or other data is another complicated process: The investigator must submit a study proposal with its protocol to the PLCO-NLST Presentations, Publications, and Associated Studies Committee.

If that group approves it, the proposal is forwarded to the NCI for approval. After it clears NCI, the proposal is sent to the NLST Data Safety and Monitoring Board (DSMB), an independent body that meets twice a year to review the progress of the NLST, insure data integrity, and protect the welfare of the study participants. As part of these responsibilities, the DSMB ensures no data are released to investigators conducting associated studies that would affect the conduct and integrity of the primary study—the NLST in this case. Every large clinical trial must have a DSMB.

Creation of the CTIL will transform virtually all of the screening CT examinations obtained at PLCO-NLST sites into a centralized database for use by imaging researchers who wish to conduct associated studies using CT scans from the NLST. Through anonymous identifiers, the CTIL scans will be linked to the database of clinical information maintained on all NLST participants by Westat. Together, these two databases will provide a powerful means to provide investigators with cases that meet the inclusion criteria of their associated studies. For instance, if a study requiring scans of patients with proven cancer is approved, Westat will be able to generate a list of all such cases and provide the CTIL with ID numbers of the scans to release to the researcher. Because NLST is such a large study, the amount and variability of the data also could be used for important research on other smoking-related diseases such as emphysema and coronary artery disease. The NCI encourages this but stipulates that appropriate safeguards must be kept in place.

MEETING FUTURE NEEDS

During the processing of the images received so far, Gierada says the CTIL team has learned that visual inspection of all images is necessary, yet prohibitively time-consuming. In order to meet the March 2007 goal of cataloguing the images, the team has added part-time film-viewing personnel. “Meeting our goal depends on two things: screening centers transmitting all their scans to us in a timely manner and the CTIL staff viewing every scan submitted. This has to be accomplished with the constraints of the funding allocated to the project. NCI has agreed that in case the scans cannot be completely archived by the target date, the clinically most significant scans should be viewed first so they will be accessible earlier. Our goal is to make all of the scans available at the earliest possible time, while still maintaining the quality control of the process.”

Kenneth Clark is shown in front of the equipment that manages NLST quality assurance. He's holding an external disk drive that can hold nearly 1,000 studies.



CTIL TEAM

- David Gierada, MD—NLST coprincipal investigator at Washington University in St. Louis
- Fred Prior, PhD—ERL codirector and CTIL systems architect
- Stephen Moore—Project manager, De-identification software author
- Kenneth Clark—Data coordinator
- David Maffitt—CTIL database management and Web site tracking software author
- Paul Koppel, PhD—Systems administrator
- Stanley Phillips—Network administrator
- Mary Wolfsberger and Joan Moulton—CTIL librarians
- Angelica Cosas, Patricia Rueweler, and Rochelle Williams—Part-time image viewers

Editor's note: In 1983, the American College of Radiology and the National Electrical Manufacturers Association formed a joint committee to create a standard method for the transmission of medical images and associated data. For more information about DICOM, go to <http://DICOM.nema.org>. Or you can go to www.rsna.org and click on "Technology" in the left-hand column.