In this particular patient, the repeated administration of successive doses of TcSC increased the period of circulating radiopharmaceutical, allowing sufficient time to identify the radiotracer that had extravasated into the viscus. Also, the radiotracer sequestration into the reticuloendothelial system eliminated the obscuring collateral vessel blood pool, allowing the bleeding site to be localized.

Therefore, TcSC allows more accurate localization of a gastrointestinal bleeding site in patients with abundant collateral vessels, and may be the radionuclide of choice in such patients.

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Validation of Diagnostic Software

TO THE EDITOR: Computers and the software that drives them are assuming an increasing importance in nuclear medicine and all of radiology. While the software is generally of very high quality and facilitates rapid and accurate diagnosis, we have experienced a growing number of computer software errors that have, on occasion, misrepresented diagnostic information and that might lead to misinterpretation of clinical data. For example, images have been displayed as a mirror reflection of the original orientation. Other examples include the incorrect video plotting of a time-activity curve to demonstrate disease when no pathology existed. Technologists who process data on a regular basis are probably familiar with other similar examples.

To our knowledge, there are no formal criteria for the validation of software for diagnostic application.* Our profession has relied on the vendor of the software to verify the integrity and accuracy of the product. In consideration of the vast amount of software that is available, vendors have done a good job of error trapping and validation, but there is a clear trend to increasing dependence on diagnostic software with the increased technology of medical care. As the complexity of software increase, clinicians must depend more heavily on computer software for patient management.

Concerns for the validation of software is mounting in all areas. The military (and the public) wish to be sure that the software which controls our defense system actually works as planned. In industry, there has been a significant investment of resources on development and validation of software (*1*). In the medical field, the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) has become involved in diagnostic software to the point of classifying clinical software as a medical device. The CDRH has also moved to encourage the reporting of software related problems through the USP-FDA Problem Reporting Program.†

Classification of diagnostic software as a medical device raises a host of questions as to the future restrictions and requirements of using the software. For example, what kind of testing or validation will be required in order to release the software for medical application? What training requirements and qualifications will be required in order to clinically use the software? Must each updated release of software be subject to complete revalidation?

Another question applies to the liability for personal injury when diagnosis is made using medical software. Brannigan and Dayhoff address this issue in an article (*2*) discussing the tort law doctrines of negligence and strict product liability applied to medical software. After a thorough examination of the issue they concluded that medical software will be treated as products which will subject their manufacturer (whoever it be) to strict liability in tort for any defects that cause medical injury. They also state that if a physician "unreasonably" relies on a program, liability would be based on negligence.

In summary, the issues of validation and use of medical software are becoming increasingly significant. The responsibility and possible consequences of the medical application of computer software apply to the producers and users of the product alike. These issues are so new that no formal group has been formed by the nuclear medicine profession to study and advise on the specific situation. It may be a propitious time for our profession to establish a task force under the direction of the Computer Council to further research the problem and to open communication with vendors and governmental agencies and to assure the continued integrity and development of new software to aid diagnosis.

FOOTNOTES

* Second draft of informational guidelines has been sent from Center for Devices and Radiological Health to selected vendors in July 1985.

†United States Pharmacopia, 12601 Twinbrook Parkway, Rockville, MD 20852.

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