



UNITED STATES GENERAL ACCOUNTING OFFICE WASHINGTON, D.C. 20548

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MANPOWER AND WELFARE DIVISION

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The Honorable Donald E. Johnson Administrator Veterans Administration



Dear Mr. Johnson:

We visited three Veterans Administration (VA) hospitals in California to determine whether disposable catheters and guidewires were being reused in vascular studies. We found that two of the three hospitals reused these devices to some extent despite the manufacturers' cautions that reuse of the devices may endanger patient safety.

USE OF CATHETERS AND GUIDEWIRES

Both the radiology and cardiology departments of a hospital use catheters and guidewires in vascular studies. The guidewires are inserted through a blood vessel to the study site, such as in the aorta, heart, or brain. The catheter is placed over the wire which is used to guide the catheter to the study site. Once the catheter is in place, the guidewire is removed. The catheter is then filled with a contrast medium for use in active catheterization and filming. Guidewires in current use are stainless steel or stainless steel with a teflon coating. Catheters are plastic tubes which may be constructed in combination with various types of material, such as stainless steel or teflon.

DEVICES REUSED DESPITE MANUFACTURERS' CAUTIONS

Guidewires and certain catheters are manufactured as disposables, and the manufacturers label the products as such, or state on the packaging, the accompanying literature, or the catalog that they are recommended, or intended, for one-time use.

The manufacturers and users are concerned about the reuse of these devices, because complete cleaning is virtually impossible and because reuse weakens them. Therefore the

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possibility of infections, allergenic reactions, and product breakage are increased when catheters and guidewires are reused.

Following is a statement made by one manufacturer in its product catalog about the reuse of guidewires:

"EXPLANATION FOR PRECAUTION--USE ONCE AND DISCARD

"A wire guide is a delicate and fragile instrument. Any time that a wire guide is reused, the hazard of damage is increased.

"An acute bend or kink of the coil wire weakens the guide. Physiological saline may be of sufficient concentration to start stress corrosion, and rusting of the stainless steel wire at room or elevated temperature. Complete internal cleaning of the guide after use is nearly impossible even with an ultrasonic cleaner. Several users have become concerned with possible allergenic reactions in patients which could be caused by blood left inside guides after cleaning."

Manufacturers also caution that catheters be used only once. One manufacturer in its product catalog states that:

"To avoid all risks of re-infection the catheter should be discarded after use."

Similar warnings and precautions are also stated by the manufacturers in their catalogs and in the product packaging.

A representative of a manufacturer of catheters and guidewires said that disposable guidewires and catheters should not be reused and emphasized the dangers as given in the manufacturer's literature. He stated that the president of the firm he represented was very concerned about dangers in the reuse of these disposable devices and was considering a price reduction in the product as a way of discouraging reuse.

We also visited the radiology departments in two non-profit hospitals serving the private sector. Personnel of both hospitals said that (1) catheters and guidewires were used once and discarded and (2) they believed it was virtually impossible to get the devices clean. They said also that the vascular procedure was sufficiently complicated without adding additional risk. Although we were told that some hospitals in the private sector reused these devices, we do not know the extent to which reuse occurred.

REUSE OF CATHETERS AND GUIDEWARES AT VA HOSPITALS

Our inquiries at the three hospitals showed that there was no overall policy on the appropriateness of reusing disposable catheters and guidewires in vascular studies. Although reuse of the devices was limited at two of the three hospitals we visited, such reuse may be more extensive at other hospitals.

The Palo Alto hospital was not currently reusing the devices, although it had done so in the past. Hospital officials said that reuse was discontinued because of the difficulty of adequately cleaning the devices and that savings from reuse were questionable because considerable time and effort were being used trying to clean the devices without assurance of success.

The San Francisco and Martinez hospitals reused the devices only in the radiology departments. The cardiology departments did not reuse the devices because personnel were concerned with the dangers of blood clots and infections. The San Francisco hospital limited reuse to guidewires used in certain types of procedures. These guidewires were reused two or three times.

The Martinez hospital reused guidewires and catheters one time. However, we were told that it might reuse both devices several times if there was a shortage of funds for supplies or if the supplier was slow in making delivery.

We discussed our observations with the Deputy Director of the VA medical service. He told us that the matter of reusing disposable catheters and guidewires had recently come to his attention during a meeting of the Association of VA Cardiologists. The consensus of opinion of the VA doctors attending this meeting was that disposable catheters and guidewires should not be reused. During this meeting the VA doctors were encouraged to use these devices only once and were asked to notify the VA central office if they encountered any financial difficulty as a result of not reusing disposable catheters and guidewires.

We believe that the practice of reusing disposable guidewires and catheters is of sufficient significance to patient care for VA to establish overall guidance on the appropriate use of these devices in vascular studies.

RECOMMENDATION TO ADMINISTRATOR

We recommend that overall guidelines be established on the appropriate use of disposable catheters and guidewires in vascular studies.

AGENCY COMMENTS

VA's Deputy Director of medical service concurred with our recommendation and stated that action would be taken to bring this matter to the attention of the VA Professional Service Staff.

We appreciate the cooperation and assistance given to us by VA personnel and shall appreciate being advised within 60 days of actions taken or planned as a result of our observations on the reuse of guidewires and catheters. If you have any questions on our observations, we shall be glad to discuss them with you or your representatives.

We are sending copies of this report to the Chairmen, House and Senate Committees on Appropriations, on Government Operations, on Veterans' Affairs; and to the Director Office Selface of Management and Budget.

Sincerely yours,

Gregory J. Ahart

Director