Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Follow-Up
Colonoscope Reprocessing at
VA Medical Facilities

Report No. 09-02848-218 **September 17, 2009**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations

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Executive Summary

Introduction

The Secretary of Veterans Affairs requested that the VA Office of Inspector General (OIG) conduct an inspection of endoscopy reprocessing at Veterans Health Administration (VHA) facilities in follow-up of OIG's initial report, *Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities*, Report No. 09-01784-146, published June 16, 2009. Several VHA medical facilities had been found to deviate from recommended procedures in the reprocessing of endoscopes, in some cases necessitating patient recalls. The June report described those incidents, VHA's responses to them, and results from an unannounced OIG inspection of a sample of facilities in May 2009. In May we conducted unannounced inspections at 42 facilities. Colonoscopes were reprocessed in 38 reprocessing units at 36 of these facilities. We found that 42.5 per cent of reprocessing units had adequate standard operating procedures (SOPs) and documentation of demonstrated competence for reprocessing staff

This current follow-up inspection provides results for all facilities not previously inspected and provides follow-up results for facilities previously found to be not compliant with VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*, issued February 9, 2009.

This inspection was limited to colonoscope reprocessing. For facilities not previously inspected, inspections involved all reprocessing locations at each facility. For facilities previously inspected, this follow-up inspection addressed only reprocessing locations previously found to be not fully compliant at the initial inspection in May. VHA was informed that this inspection would occur and the criteria to be used, but visits to all facilities were unannounced and unscheduled.

Among the 129 facilities inspected in August, all 129 were compliant with respect to SOPs; 128 facilities had adequate documentation of demonstrated competence for reprocessing staff.

In our initial report, we recommended that the Acting Under Secretary for Health ensure compliance with relevant directives regarding endoscope reprocessing, explore possibilities for improving the reliability of endoscope reprocessing with VA and non-VA experts, and review the VHA organizational structure and make the necessary changes to implement quality controls and ensure compliance with directives. The Acting Under Secretary for Health concurred with the recommendations and provided a plan of corrective action. OIG will follow up on actions until all recommendations have been fully implemented.

Introduction

Purpose

The Secretary of Veterans Affairs requested that the VA Office of Inspector General (OIG) conduct an inspection of endoscopy reprocessing at Veterans Health Administration (VHA) facilities in follow-up of OIG's initial report published June 16, 2009. On June 16 OIG received a request from the Chairman and Ranking Member of the House Committee on Veterans' Affairs Subcommittee on Oversight and Investigations to assess within 90 days whether "endoscopic procedures are being followed and that all personnel are following VHA Directives."

Background

Several VHA medical facilities have been found to deviate from recommended procedures in the reprocessing of endoscopes, in some cases necessitating patient recalls. A recent OIG report described those incidents, VHA's responses to them, and results from an unannounced OIG inspection of a sample of facilities in May 2009.[1] The current report provides results for all facilities not previously inspected and provides follow-up results for facilities previously found to be not compliant with VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*, issued February 9, 2009.

Scope and Methodology

Procedures for the initial inspection in May are described in detail in the June report. Briefly, in April 2009 we requested information from all VA medical facilities identified as sites for colonoscopy or ENT endoscopy. The study population for colonoscope (or ENT endoscope) reprocessing consisted of all reprocessing units in VHA facilities as of April 27, 2009. A VHA facility may have more than one reprocessing location, and each of the reprocessing units was counted. In May we conducted unannounced inspections at 42 facilities. Colonoscopes were reprocessed in 38 reprocessing units at 36 of these facilities. We found that 42.5 per cent of reprocessing units had adequate standard operating procedures (SOPs) and documentation of demonstrated competence for reprocessing staff.[2]

[1] *Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities,* Report No. 09-01784-146, June 16, 2009. Available at http://www.va.gov/oig/publications/reports-list.asp.

[2] In the initial report, one facility was inadvertently described as being compliant when in fact it was not. When this facility was inspected again in August it was found to be in compliance.

The current follow-up inspection was limited to colonoscope reprocessing. For facilities not previously inspected, inspections involved all reprocessing locations at each facility.

For facilities previously inspected, this follow-up inspection addressed only reprocessing locations previously found to be not fully compliant at the initial inspection in May. VHA was informed that this inspection would occur and the criteria to be used, but visits to all facilities were unannounced and unscheduled.

As in the initial inspection, we assigned each colonoscope to one of the following five categories based on information provided by facilities:

- Olympus with an auxiliary water system.
- Olympus without an auxiliary water system.
- Pentax.
- Fujinon.
- Storz.

We considered a facility to be compliant if at each reprocessing location model-specific reprocessing SOPs and at least one competence record were present for applicable colonoscopes.

We performed the inspection in accordance with *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Findings

During August 3–6, 2009, reprocessing locations at 128 medical facilities were inspected. An additional facility with one reprocessing unit was inspected on August 12. All 129 facilities were compliant with respect to SOPs. All facilities had adequate documentation of demonstrated competence for reprocessing staff except for the White River Junction VA Medical Center, Vermont.

Conclusions

Based on unannounced inspections at probability-based samples of endoscope reprocessing facilities, we previously estimated that fewer than half of all VHA facilities were compliant with requirements for standard operating procedures and documentation of staff competence. This follow-up report describes results from all facilities performing colonoscopy which were not previously inspected and also includes those facilities previously inspected and found to not be in compliance. Among the 129 facilities inspected in August, one did not have documentation of demonstrated competence for reprocessing staff.

In our initial report, we recommended that the Acting Under Secretary for Health ensure compliance with relevant directives regarding endoscope reprocessing, explore possibilities for improving the reliability of endoscope reprocessing with VA and non-VA experts, and review the VHA organizational structure and make the necessary changes to implement quality controls and ensure compliance with directives. The Acting Under Secretary for Health concurred with the recommendations and provided a plan of corrective action. OIG will follow up on actions until all recommendations have been fully implemented.

Comments

The Acting Under Secretary for Health concurred with the report and stated his confidence that endoscope reprocessing in VHA is on the right track. However, he disagreed with the finding that the White River Junction VA Medical Center did not have adequate documentation of demonstrated competency. (See the complete text of his comments in Appendix B.) He stated he disagreed with the conclusion that the facility did not have adequate documentation of demonstrated competency for reprocessing staff which he believed was based only on the fact that the competency record in question contained a typographical error which included the word “cystoscope” rather than the correct “colonoscope.”

In the case of the documentation presented by White River Junction VA Medical Center, even if the label had been “colonoscope” rather than “cystoscope,” the documentation still lacked adequate detail. It did not contain the specific manufacturer and model number, and it did not include any documentation of scopes with auxiliary water channels. While we were onsite, the facility was invited to submit any record or other evidence that would document the demonstrated competency of any staff member as required in VHA’s own policies.

VHA was well informed that this inspection would occur, but the specific facilities and dates of the visits were unannounced and unscheduled. We considered a facility to be compliant if, at each reprocessing location, model-specific reprocessing SOPs and at least one competence record were present for applicable colonoscopes. We have not questioned whether the staff in question had the competency. Notwithstanding VHA's assertions to the contrary, we stand by our conclusion that the facility could not provide appropriate documentation.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

VA Facilities Visited During May and August 2009

Facility Type	Location	State
Outpatient Clinic	Anchorage	AK
VA Medical Center	Birmingham	AL
VA Medical Center	Montgomery	AL
VA Medical Center	Fayetteville	AR
VA Medical Center	Little Rock	AR
VA Medical Center	Prescott	AZ
VA Medical Center	Phoenix	AZ
VA Medical Center	Tucson	AZ
VA Medical Center	Los Angeles	CA
VA Medical Center	Fresno	CA
VA Medical Center	Long Beach	CA
VA Medical Center	Loma Linda	CA
VA Medical Center	Sacramento	CA
Outpatient Clinic	Redding	CA
Outpatient Clinic	Martinez	CA
VA Medical Center	Palo Alto	CA
VA Medical Center	Livermore	CA
VA Medical Center	San Francisco	CA
VA Medical Center	San Diego	CA
VA Medical Center	Denver	CO
VA Medical Center	Grand Junction	CO
VA Medical Center	West Haven	CT
VA Medical Center	Washington	DC
VA Medical Center	Wilmington	DE
VA Medical Center	Bay Pines	FL
Outpatient Clinic	Fort Myers	FL
VA Medical Center	Miami	FL
Outpatient Clinic	Sunrise	FL
VA Medical Center	West Palm Beach	FL
VA Medical Center	Gainesville	FL

(continued)

Facility Type	Location	State
VA Medical Center	Lake City	FL
Outpatient Clinic	Jacksonville	FL
VA Medical Center	Tampa	FL
VA Medical Center	Orlando	FL
Outpatient Clinic	Viera	FL
VA Medical Center	Decatur	GA
VA Medical Center	Augusta	GA
VA Medical Center	Dublin	GA
VA Medical Center	Iowa City	IA
VA Medical Center	Des Moines	IA
VA Medical Center	Boise	ID
VA Medical Center	North Chicago	IL
VA Medical Center	Chicago (Jesse Brown)	IL
VA Medical Center	Danville	IL
VA Medical Center	Chicago (Hines)	IL
VA Medical Center	Marion	IL
VA Medical Center	Indianapolis	IN
VA Medical Center	Fort Wayne	IN
VA Medical Center	Topeka	KS
VA Medical Center	Leavenworth	KS
VA Medical Center	Wichita	KS
VA Medical Center	Lexington	KY
VA Medical Center	Louisville	KY
VA Medical Center	Alexandria	LA
VA Medical Center	Shreveport	LA
VA Medical Center	Jamaica Plain	MA
VA Medical Center	West Roxbury	MA
VA Medical Center	Baltimore	MD
VA Medical Center	Augusta	ME
VA Medical Center	Ann Arbor	MI
VA Medical Center	Detroit	MI
VA Medical Center	Iron Mountain	MI
VA Medical Center	Saginaw	MI
VA Medical Center	Minneapolis	MN
VA Medical Center	St. Cloud	MN

(continued)

Facility Type	Location	State
VA Medical Center	Kansas City	MO
VA Medical Center	Columbia	MO
VA Medical Center	St. Louis	MO
VA Medical Center	Poplar Bluff	MO
VA Medical Center	Biloxi	MS
VA Medical Center	Jackson	MS
VA Medical Center	Fort Harrison	MT
Outpatient Clinic	Missoula	MT
Outpatient Clinic	Billings	MT
VA Medical Center	Durham	NC
VA Medical Center	Fayetteville	NC
VA Medical Center	Asheville	NC
VA Medical Center	Salisbury	NC
Outpatient Clinic	Charlotte	NC
VA Medical Center	Fargo	ND
VA Medical Center	Omaha	NE
VA Medical Center	Manchester	NH
VA Medical Center	Lyons	NJ
VA Medical Center	East Orange	NJ
VA Medical Center	Albuquerque	NM
VA Medical Center	Reno	NV
VA Medical Center	Bronx	NY
VA Medical Center	Buffalo	NY
VA Medical Center	Syracuse	NY
VA Medical Center	Albany	NY
VA Medical Center	Castle Point	NY
VA Medical Center	New York	NY
VA Medical Center	Brooklyn	NY
VA Medical Center	Northport	NY
VA Medical Center	Cleveland	OH
VA Medical Center	Chillicothe	OH
VA Medical Center	Cincinnati	OH
VA Medical Center	Dayton	OH
Outpatient Clinic	Columbus	OH
VA Medical Center	Muskogee	OK
VA Medical Center	Oklahoma City	OK

(continued)

Facility Type	Location	State
VA Medical Center	Portland	OR
VA Medical Center	Roseburg	OR
VA Medical Center	Altoona	PA
VA Medical Center	Erie	PA
VA Medical Center	Lebanon	PA
VA Medical Center	Philadelphia	PA
VA Medical Center	Pittsburgh	PA
VA Medical Center	Wilkes-Barre	PA
VA Medical Center	San Juan	PR
VA Medical Center	Providence	RI
VA Medical Center	Charleston	SC
VA Medical Center	Columbia	SC
VA Medical Center	Sioux Falls	SD
VA Medical Center	Fort Meade	SD
VA Medical Center	Hot Springs	SD
VA Medical Center	Memphis	TN
VA Medical Center	Mountain Home	TN
VA Medical Center	Nashville	TN
VA Medical Center	Murfreesboro	TN
VA Medical Center	San Antonio	TX
VA Medical Center	Kerrville	TX
VA Medical Center	Amarillo	TX
VA Medical Center	Big Spring	TX
VA Medical Center	Dallas	TX
VA Medical Center	Houston	TX
VA Medical Center	Temple	TX
Outpatient Clinic	El Paso	TX
VA Medical Center	Salt Lake City	UT
VA Medical Center	Salem	VA
VA Medical Center	Hampton	VA
VA Medical Center	Richmond	VA
VA Medical Center	White River Junction	VT
VA Medical Center	Seattle	WA
VA Medical Center	Walla Walla	WA

(continued)

Facility Type	Location	State
VA Medical Center	Tacoma	WA
VA Medical Center	Spokane	WA
VA Medical Center	Madison	WI
VA Medical Center	Milwaukee	WI
VA Medical Center	Beckley	WV
VA Medical Center	Clarksburg	WV
VA Medical Center	Huntington	WV
VA Medical Center	Martinsburg	WV
VA Medical Center	Cheyenne	WY
VA Medical Center	Sheridan	WY

Appendix B

Acting Under Secretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: September 10, 2009

From: Acting Under Secretary for Health (10)

Subject: OIG Draft Report, *Healthcare Inspection, Follow-Up Colonoscope Reprocessing at VA Medical Facilities,* Project No. 2009-02848-HI-0158 (WebCIMS 437849)

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report, and I concur with it. I am very encouraged that out of 129 unannounced and unscheduled site visits to VA medical facilities across the country, there was only one location with an adverse finding. While there is still much work to be done, I am confident that endoscope reprocessing in VHA is on the right track.

2. While I technically agree with your report and the finding that a staff member at White River Junction, Vermont VA Medical Center did not have a competency record present for applicable colonoscopes, I disagree with your conclusion that the facility did not have adequate documentation of demonstrated competency for reprocessing staff in the Gastroenterology (GI) Clinic. As pointed out during your site visit to White River Junction, the competency record in question contained a typographical error which included the word "cystoscope" rather than the correct "colonoscope." It is important to note that the flexible cystoscope is typically reprocessed in the same manner as a flexible GI endoscope.

3. To certify that GI Clinic personnel at White River Junction were in fact competent to reprocess flexible endoscopes, the VHA Office of Medical Surgical Services conducted an independent external site visit on August 18, 2009. Under direct observation, White River Junction personnel demonstrated the correct method for pre-cleaning, leak testing, cleaning, and reprocessing a used flexible endoscope. The Office of Medical Surgical Services concluded that with the exception of the typographical error, White River Junction fully complied with the intent of the original competency assessment for reprocessing flexible GI endoscopes, and all

OIG Draft Report, *Healthcare Inspection, Follow-Up Colonoscope Reprocessing at VA Medical Facilities,* Project No. 2009-02848-HI-0158 (WebCIMS 437849)

critical elements were identified. In the end, while the word “cystoscope” was in the competency assessment reviewed by OIG inspectors, the correct sequence and critical elements for reprocessing GI endoscopes were in the document. As such, while the competency did not technically meet your inspection standard, a deeper examination suggests that White River Junction did have adequate documentation of demonstrated competency for reprocessing staff.

4. Thank you for the opportunity to review the report and provide comments. I would be pleased to discuss any concerns or comments you may have about this response. If you have any questions, please have a member of your staff contact Margaret Seleski, Director, Management Review Service (10B5) at (202) 461-7245.

(original signed by:)

Gerald M. Cross, MD, FAAFP

Appendix C

OIG Contact and Staff Acknowledgments

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