BRIEF REPORT

Correction of Deficiencies in Flexible Fiberoptic Sigmoidoscope Cleaning and Disinfection Technique in Family Practice and Internal Medicine Offices

Frank W. Jackson, MD; Marilee D. Ball, RN, CGRN

To assess whether deficiencies exist in the processing of contaminated flexible fiberoptic sigmoidoscopes in family practice and internal medicine offices and whether training of office personnel results in a correction of identified deficiencies, we conducted a prospective review of sigmoidoscope processing in family practice and internal medicine offices before and after a training course. Participants were questioned on their current endoscope processing for 17 standards before and 2 months after receiving training. The 19 offices had between 4 and 11 deficiencies per office before training, with an average of 6.8 deficiencies per office. After training, deficiencies ranged from 0 to 8, with an average of 0.9 deficiencies per office ($P \leq .001$; Student *t* test). Personnel responsible for processing flexible sigmoidoscopes in family practice and internal medicine offices are insufficiently trained for this function. Endoscopes are not being processed according to current standards. After a 2-hour training period, these persons maintain their equipment close to or according to standards. *Arch Fam Med. 1997;6:578-582*

Colorectal cancer screening begins in the primary care physician's office. Flexible fiberoptic sigmoidoscopy (FFS) has become a standard for part of this surveillance and for the evaluation of other anal, rectal, and sigmoid colon disorders. A 1988 survey of the American Academy of Family Physicians disclosed that 48% of family practitioners performed this examination in the office.[1] Medicare paid for 894 531 FFS examinations for their clients in 1993.[2] Assuming that Medicare billing represents 40% of the total FFSs performed each year, the total number of examinations performed in the United States exceeded 2 million that year, most of which, by general consensus, were done in generalists' offices. A survey of the medical literature found 281 instances of documented transmission of infections by inadequately processed flexible endoscopes.[3] Other studies have confirmed that inadequately processed fiberoptic endoscopes leave significant bacterial loads within endoscopes when deficiencies in processing technique occur.[4,5] In addition, there are reports of glutaraldehyde-induced proctocolitis when endoscopes were not properly processed.[6] These reports were from hospital gastroenterology endoscopy units, where standards and practices of endoscope processing are expected to be highest. There are no reported studies evaluating the technique of FFS processing in generalists' offices. This report prospectively evaluated FFS processing in 19 generalists' offices before and after a 2-hour training program.

MATERIALS AND METHODS

The West Shore Endoscopy Center is an ambulatory gastrointestinal (GI) endoscopy center in Camp Hill, a suburb of Harrisburg, Pa. This central Pennsylvania community has a population of more than 300 000 and includes the Hershey Medical Center and 3 other hospitals of 150 to 600 beds. As a service to referring primary care physicians, the center conducted a 2-hour didactic (1-hour) and hands-on (1-hour) course in FFS processing. Processing in this report means the entire range of endoscope care, which includes manual cleaning, high-level cold

From the West Shore Endoscopy Center, Camp Hill, Pa.

disinfection, rinsing, drying, and storage of the endoscope and accessories. Twenty-five persons from 19 offices attended 3 separate sessions. Each of the 3 sessions involved 7 to 10 enrollees. Four registered nurses, 4 licensed practical nurses, and 17 medical assistants attended. The course instructor was a certified gastroenterology registered nurse (M.D.B.) with experience in hospital infection control.

COURSE CONTENT

The course was divided into 2 sections. A 1-hour didactic instruction period included printed course materials and a question-and-answer period. This was followed by a 1-hour hands-on demonstration by the course instructor in which enrollees could observe directly how to process a presumed contaminated endoscope. This combination of didactic, hands-on, and reference materials was believed to be the best method of presentation for retention of course material. The endoscope-processing guidelines of the Society for Gastrointestinal Nurses and Associates (SGNA) and the Association for Practitioners in Infection Control (APIC) were used to develop the course content.[7,8] Olympus and Pentax flexible endoscopes were used for demonstration purposes. The principles of endoscope design were explained, with special attention to the internal channels. Course participants were encouraged to handle the endoscopes and to disassemble and reassemble the removable parts. Endoscope processing was reviewed and demonstrated with emphasis on leak testing, meticulous manual cleaning, brush cleaning of all channels, filling of all channels with high-level disinfectant, and adequate rinsing of all channels. Alcohol flush and forced-air drying were demonstrated. Miscellaneous equipment was reviewed, including maintenance of the light source and care and disinfecting of the water bottle, biopsy forceps, and suction apparatus.

FFS PROCESSING STANDARDS

We carefully reviewed the standards published by the SGNA, APIC, American Society of Gastrointestinal Endoscopy (ASGE) and the Centers for Disease Control and Prevention (CDC).[7-10] There is remarkable uniformity in the standards from these 4 agencies. Seventeen standards for the study were chosen by the authors, selecting those considered most critical in endoscope processing. These standards are given in **Table 1**. No office did endoscopic biopsies, so the processing standard of this accessory equipment was not evaluated.

DATA COLLECTION

A questionnaire was completed by all participants prior to the course. Yes/No and fill-in-the-blank questions were asked for the 17 standards. Two months after attending the course, all participants were contacted in writing and offered an on-site visit to review cleaning and disinfecting practices, with only 1 office accepting. The others said they did not believe it was necessary. The rest of the participants were contacted by telephone and the original questionnaire was repeated.

Table 1. Standards for Flexible Fiberoptic Sigmoidoscopic Processing

1. Leak testing of endoscope after procedure
2. Use proteolytic enzymatic detergent for cleaning cycle
3. Manual cleaning with sponge or gauze pad, including brushing and flushing of suction-biopsy channel
4. Flush air-water and suction-biopsy channel with water
5. Use high-level disinfectant
6. Immerse insertion tube or entire endoscope in disinfectant
7. Fill suction-biopsy channel with disinfectant
8. Fill air-water channel with disinfectant (immersible endoscopes only)
9. 20-Minute or longer disinfectant soak
10. Water rinse suction-biopsy channel
11. Water rinse air-water channel (immersible endoscopes only)
12. Alcohol flush air-water and suction-biopsy channels
13. Forced-air dry air-water and suction-biopsy channels
14. Vertical endoscope storage
15. Use of sterile water bottle
16. Change water in water bottle daily
17. Sterilize and disinfect water bottle daily

RESULTS

DISINFECTION TECHNIQUE

All offices used the manual immersion or soaking technique with the disinfectant contained in a soaking tub. None had automated machine-processing equipment.

TYPES OF ENDOSCOPES

There were 9 nonimmersible and 10 immersible endoscopes in the 19 offices. Nonimmersible endoscopes were manufactured before 1983. This equipment allows soaking of only the insertion portion of the endoscope. Totally immersible endoscopes allow soaking of the entire endoscope.

PREVIOUS TRAINING OF PERSONNEL IN FFS PROCESSING

The personnel in 2 offices were self-taught from the equipment manual, in 12 they were trained by a co-worker, and in 5 by a sales representative. No participant had taken a formal course on FFS processing. Furthermore, none of the participants were aware of endoscope-processing guidelines or standards as published by SGNA, APIC, ASGE, and CDC.

TYPES OF MEDICAL PRACTICE

Fourteen family practice offices participated in the study, with a total of 28 physicians, all of whom were board certified in family practice medicine. Five internal medicine offices participated in the study, with a total of 15 physicians, all of whom were board certified in internal medicine.

AVERAGE NUMBER OF FFSs PER WEEK

In 12 offices, 0 to 2 FFSs a week were performed; in 2 offices, 3 to 4 FFSs were performed; in 2 offices, 5 to 6 were performed; and in 3 offices, more than 6 were performed.

Table 2. Endoscope Processing Standards*

	Before Training													
	Family Practice													
Standard	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Leak testing														
Proteolytic detergent	X	X	X	X	X	X	X	X	X					
Manual cleaning	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Channel water flush		X	X	X	X	X	X	X	X	X	X		X	
High-level disinfectant	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Insertion tube or endoscope immersion	X	X	X	X	X		X	X		X	X	X	X	X
Suction-biopsy channel disinfectant fill	X	X	X	X	X	X			X	X	X	X	X	
Air-water channel disinfectant fill		NA	X	X	NA	NA					NA	NA	NA	NA
>20-min endoscope immersion	X		X	X		X		X	X	X	X	X	X	X
Suction-biopsy channel rinse	X	X	X	X	X	X	X		X	X	X	X	X	X
Air-water channel rinse		NA	X	X	NA	NA					NA	NA	NA	NA
Alcohol flush all channels									X					
Forced-air drying			X		X				X					
Vertical endoscope storage		X	X	X	X	X	X			X			X	X
Sterile water									NA					
Change water daily		X	X	X	X	X			NA	X	X	X	X	X
Disinfect water bottle daily		X			X				NA		X	X	X	
Total No. of Deficiencies	**10**	**5**	**4**	**5**	**4**	**6**	**10**	**11**	**5**	**8**	**6**	**7**	**5**	**8**

**Average deficiencies per office before training, 6.8; after training, 0.9. Letter X indicates standard satisfied; blank space, standard not satisfied; NA, not applicable.*

DEFICIENCIES BEFORE AND AFTER TRAINING

Table 2 gives the results by office before and after training. Before training, there were an average of 6.8 deficiencies per office. After training, this incidence fell to 0.9 deficiencies per office. This low incidence was achieved despite 1 office with 8 deficiencies reporting that no corrective change had been made because of an imminent office move. These changes were highly significant ($P \leq .001$; Student t test).

Before training, no office was leak testing to protect the endoscope from fluid damage. Eight offices were not using a recommended proteolytic enzymatic detergent solution for cleaning before disinfection. All offices were using a high-level glutaraldehyde disinfectant. Three did not use the recommended 20-minute soak time. Two offices were not soaking the insertion tube, but merely wiping it with the disinfectant. Of the 11 immersible endoscopes, 4 offices filled the air-water channel with disinfectant. It is impossible to disinfect the air-water channel in nonimmersible endoscopes. After the disinfection and water rinse, 1 office flushed the channels with alcohol and a few used forced air to dry the channels. The care of the water bottle was inconsistent. No office used sterile water in the water bottle, 1 office used distilled water, and a few sterilized or disinfected the water bottle daily. Finally, vertical endoscope storage was used in just 10 offices.

COMMENT

Over the years, many generalists have become trained in performing flexible sigmoidoscopy, often by local gastroenterologists. The present study indicates that the processing of contaminated FFSs in generalists' offices has not kept pace with procedure performance. In 1988, Katner et al[1] published a survey of 5% of the membership of the American Academy of Family Physicians. Sixty-seven percent of 1585 questionnaires were returned. Using the CDC processing guidelines available at that time and knowledge of which chemicals inactivated the human immunodeficiency virus, 32.4% were judged to be disinfecting instruments appropriately. Of interest, 65 different cleaning and disinfectant solutions were recorded, most of which by today's standards are ineffective and/or not recommended for cleaning or high-level disinfection. In 1992, an on-site survey of 8 Massachusetts hospitals examined the processing technique for contaminated endoscopes.[4] Considerable variability of technique, lack of processing protocols, and unawareness of guidelines and standards by processing personnel were documented. In another report, 22 hospitals and 4 ambulatory care centers were studied by culturing processed endoscopes.[5] Cultures of the internal channels of 71 endoscopes disclosed that 21% grew more than 100 000 colonies of bacteria. As in the Massachusetts study, inappropriate cleaning and disinfecting solutions were found in these cases. It is likely that for many generalists' offices, the risk of disease transmission is considerably less than in a hospital setting. Still, the standard in the entire medical community is that of universal precautions, assuming that any and every patient is a potential human immunodeficiency virus carrier or a transmitter of other infectious agents.

Although the literature does not report cases of transmitted infections due to improperly processed FFSs in generalists' offices, the potential certainly exists. Hospital GI endoscopy units are an available knowledge source for endoscope processing in many communities. The results of this study indicate that this knowledge has not been disseminated to and implemented in generalists' offices. Undue reliance was placed on the use of outdated endoscope manuals

	After Training																				
Internal Medicine					Family Practice													Internal Medicine				
15	16	17	18	19	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
					X	X	X	X		X	X		X	X	X				X		X	X	X
		X	X		X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X
X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X
X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
X			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X
	NA		X	X	X	NA	X	X	NA	NA	X	X	X	X	NA	NA	NA	NA	X	NA	X	X	X
X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	NA		X	X	X	NA	X	X	NA	NA	X	X	X	X	NA	NA	NA	NA	X	NA	X	X	X
					X	X	X	X		X		X	X	X	X	X	X		X	X	X	X	X
	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X
X				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
					X	X	X	X	X	X		X	NA	X	X	X	X		X	X	X	X	X
X	X	X	X	X	X	X	X	X	X	X	X	X	NA	X	X	X	X	X	X	X	X	X	X
					X	X	X	X	X	X	X	X	NA	X	X	X	X		X	X	X	X	X
9	7	10	5	5	0	0	0	0	3	0	2	1	0	0	0	1	1	8	0	1	0	0	0

that provided inadequate or even wrong information relevant to current endoscope-processing guidelines. Likewise, sales representatives sometimes gave sketchy or incorrect information on endoscope processing. No office in this study was aware of manufacturers' free training programs on endoscope processing, which are given regularly around the country, and none were aware of national guidelines on endoscope cleaning. Finally, several family practice physicians stated that they believed they should follow manual instructions and/or sales representatives' advice because of liability considerations.

There have been 3 major stages of fiberoptic flexible endoscope development. The first stage produced the nonimmersible endoscope that allowed disinfection by immersion of only the insertion tube portion of the endoscope and filling of only the suction-biopsy channel. The air-water channel, holding head, and umbilical portion could not be disinfected. Manufacturers of GI endoscopes stopped making these endoscopes in 1983-1984 (C. Hotaling, Pentax Precision Instrument Corp, personal communication, March 9, 1995). The second stage of endoscope design produced the immersible fiberoptic endoscope. The third stage used video, optically sensitive, computer chip technology. Both of these latter 2 designs allow total immersion of the endoscope and filling of all internal channels, resulting in high-level disinfection of the entire endoscope.

The ASGE, SGNA, and APIC have recommended rapid phasing out of use of nonimmersible endoscopes. Few hospital gastroenterology endoscopy units still use first-stage endoscopes. The older, hospital-retired endoscopes seem to have found their way into generalists' offices. The economic reasons are understandable. Used nonimmersible endoscopes can be obtained for a fraction of the cost of a new endoscope. This nonimmersible equipment should be phased out of use in an expeditious manner. As video endoscopes replace immersible, stage 2 hospital endoscopes, these later endoscopes should become more available for use in generalists' offices.

KEY STEPS IN PROCESSING

Although the detailed processing of fiberoptic instruments is beyond the scope of this report, certain important aspects of processing should be mentioned.

Step 1. Cleaning: Manual cleaning of the outside of the endoscope with disposable gauze pads or sponges, and brushing of the channel parts and the suction-biopsy channel. A proteolytic enzyme solution is recommended.

Step 2. Disinfection: 20-minute soak in a 2% glutaraldehyde solution. Both the air-water and suction-biopsy channels should be filled in immersible endoscopes. The suction-biopsy channel should be filled in nonimmersible endoscopes.

Step 3. Rinsing: Thorough water rinsing, including both internal channels.

Step 4. Drying: Use of 70% alcohol rinse of internal channels followed by forced-air drying.

Step 5. Storage: Endoscopes should be stored vertically to allow gravity drainage and drying of residual water in the endoscope.

Step 6. Biopsy forceps: These should be manually cleaned and steam autoclaved.

Several points need stressing. Manual cleaning, using a proteolytic enzyme solution, of outside and internal channels is a critical first step in endoscope cleaning. No other solution should be used for the first step. For high-level disinfection by soaking technique, only a 2% glutaraldehyde solution is approved by the Food and Drug Administration. Alcohol flush of the internal chan-

nels allows for subsequent rapid forced-air drying. Adequate drying and vertical endoscope storage are especially important when use is infrequent, as is common in generalists' offices.

It was gratifying to see the remarkable improvement in processing technique after the 2-hour training program. We found office personnel to be sensitive to the need for high-quality endoscope processing. The rapid change in processing performance attested to this fact. Subsequent discussion with enrollees disclosed a high level of satisfaction and comfort with this knowledge. The uniform reaction was that they were unaware of standards and did not realize how deficient they had been. We judged this to be the primary reason for the remarkable change in performance. We received virtually no feedback from physicians aside from thanks for presenting the course. This suggests that physician knowledge and awareness of standards are lacking.

The most outstanding source of knowledge in most communities is the gastroenterology endoscopy department of local hospitals. Gastrointestinal endoscopy nurses are highly trained persons with a national organization, SGNA, whose charter and ongoing activities address these evolving standards of endoscope processing. Primary care physicians and hospital endoscopy and ambulatory surgical centers should work together to bring endoscope-processing standards in generalists' offices up to acceptable standards. The directors of the family practice and internal medicine residencies and the GI endoscopy unit should formulate procedures whereby this information can be readily taught to the personnel who perform endoscope processing. Physicians in rural communities or areas where a hospital resource is unavailable need to become more involved in the cleaning process. The simplest solution would be to arrange for a training session for the processing assistant at a distant site. Hospitals that receive these physicians' patient referrals should feel an obligation to provide this training. The remaining alternative is for the physician and, especially, the assistant to carefully learn and perform the various steps in processing endoscopes through self-teaching.

Physicians need not know the step-by-step procedure required to achieve a clean instrument. They should, however, be aware that national guidelines exist, and that in their private office they are responsible for proper endoscope processing. If a physician is using an older and, in particular, a nonimmersible FFS, then it should be assumed that the processing part of the manual is out of date or in error in some respects. An updated manual should be requested from the company. For new equipment, the assistant needs to review the processing section assiduously and to maintain uniformity in all processing procedures. Likewise, a hospital that owns or manages primary care practices must have a single standard of care for hospital and outpatient activities. Joint commission inspection and liability considerations alone should be major incentives. A regular yearly course conducted by the GI endoscopy unit would seem to be adequate for achieving and maintaining this competence. We have found that in groups of 7 to 10 persons, a 2-hour course, half didactic and half hands-on, worked well.

If the present results are confirmed, corrective action is needed. It is appropriate that the American Academy of Family Practice, American College of Physicians, and the other national organizations publicize existing endoscope-processing guidelines to their members. In addition, residency training programs for these 2 specialties should incorporate processing standards into their programs.

CONCLUSIONS

Based on our findings, we consider the following recommendations to be appropriate.

1. Physicians, nurses, and medical assistants in offices where FFS is performed should be knowledgeable about national endoscope-processing standards published by SGNA, ASGE, APIC, and the CDC.
2. Hospital GI endoscopy units and ambulatory surgery and endoscopy centers should offer regular courses for the personnel in generalists' offices who process this equipment.
3. As part of flexible sigmoidoscopy training, family practice and internal medicine residencies should make each resident aware that processing standards exist and that these guidelines should be taught to and followed by their office personnel.
4. Nonimmersible endoscopes should be phased out of use because it is impossible to provide high-level disinfection for various components of these endoscopes.
5. Use of outdated endoscope manuals or sole reliance on endoscope sales representatives' recommendations for endoscope processing should be avoided.

Accepted for publication July 26, 1996.

We owe special gratitude to Joanna Shields for her editorial assistance. We are grateful to Michelle Houseknecht for her patience and support throughout this project.

Reprints: Frank W. Jackson, MD, West Shore Endoscopy Center, 423 N 21st St, Suite 102, Camp Hill, PA 17011.

REFERENCES

1. Katner HP, Buckley RL, Smith MU, Henderson AM. Endoscopic cleaning and disinfection procedures for preventing iatrogenic spread of human immunodeficiency virus. *J Fam Pract.* 1988;27:271-276.
2. Health Care Financing Administration, Bureau of Data Management and Strategy, Office of Health Care Information Systems. *1993 BESS Procedure Data by Type of Service Completed Year.* Washington, DC: Office of Health Care Information Systems; 1993. Publication BESS DS08.
3. Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Ann Intern Med.* 1993;118:117-128.
4. Reynolds CD, Rhinehart E, Dreyer P, et al. Variability in reprocessing policies and procedures for flexible fiberoptic endoscopes in Massachusetts hospitals. *Am J Infect Control.* 1992;20:283-290.
5. Kaczmarek RG, Roscoe MM, McCrohan J, et al. Multi-state investigation of the actual disinfection/sterilization of endoscopes in health care facilities. *Am J Med.* 1992;92:257-261.
6. Durante L, Zulty JC, Israel E, et al. Investigation of an outbreak of bloody diarrhea: association with endoscopic cleaning solution and demonstration of lesions in an animal model. *Am J Med.* 1992;93:476-480.
7. Society of Gastroenterology Nurses and Associates. *Recommended Guidelines for Infection Control in Gastrointestinal Endoscopy Settings.* Rochester, NY: Society of Gastroenterology Nurses and Associates; 1990.
8. Martin MA, Reichelderfer M, Association for Professionals in Infection Control and Epidemiology Guidelines Committee, et al. APIC guideline for infection prevention and control in flexible endoscopy. *Am J Infect Control.* 1994;22:19-38.
9. American Society for Gastrointestinal Endoscopy. *Infection Control During Gastrointestinal Endoscopy.* Manchester, Mass: American Society for Gastrointestinal Endoscopy; 1988.
10. Garner J, Favero MS. *Guideline for Handwashing and Hospital Environmental Control, 1985.* Springfield, Va: National Technical Information Service; 1985. Publication 85-923404.