Endoscopic Cleaning and Disinfection Procedures for Preventing Iatrogenic Spread of Human Immunodeficiency Virus

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With estimates as high as 1.8 million individuals infected with human immunodeficiency virus (HIV) in the United States, the majority asymptomatic, it is crucial that all physicians routinely use adequate disinfection procedures for medical instruments. The protosigmoidoscopic disinfection procedures used by US family physicians were evaluated for adequacy in inactivating HIV. Sixty-seven percent of 1,585 randomly selected American Academy of Family Physicians members completed a mail survey regarding these procedures. Comparing procedures used with those recommended by the Centers for Disease Control or documented to inactivate HIV, 32.4 percent were judged to be appropriate procedures; 54.4 percent of the procedures were not tested or recommended; and 13.2 percent used appropriate solutions but at inadequate concentrations or exposure times. Therefore, a substantial proportion of US family physicians performing endoscopic procedures use disinfection procedures that may not inactivate HIV. The ever-increasing prevalence of HIV demands that standardized adequate disinfection procedures be implemented by all physicians to prevent the potential nosocomial spread of HIV.

Epidemiologic data regarding the transmission of the acquired immune deficiency syndrome (AIDS) and identification[1] of the etiologic agent firmly support the infectious nature of AIDS. In keeping with this conclusion, infection control guidelines were established[2] to prevent the nosocomial or iatrogenic spread of the human immunodeficiency virus (HIV). Strict recommendations concerning sterilization and high-level disinfection of medical instruments that come into contact with mucous membranes were outlined by the Centers for Disease Control (CDC).[3-5] The CDC guidelines[3] recommend the following:

> Decontamination can be accomplished by machine or by hand cleaning by trained personnel wearing appropriate protective attire and using appropriate chemical germicides. Instruments or other nondisposable items that touch intact mucous membranes should receive high-level disinfection. . . . When decontaminating instruments or medical devices, chemical germicides that are registered with and approved by the U.S. Environmental Protection Agency (EPA) as 'sterilants' can be used either for sterilization or for high-level disinfection depending on contact time; germicides that are approved for use as 'hospital disinfectants' and are mycobactericidal when used at appropriate dilutions can also be used for high-level disinfection of devices and instruments. . . . When chemical germicides are used, instruments or devices to be sterilized or disinfected should be thoroughly cleaned before exposure to the germicide, and the manufacturer's instructions for use of the germicide should be followed. . . . Information on specific label claims of commercial germicides can be obtained by writing to the Disinfectants Branch, Office of Pesticides, Environmental Protection Agency, 401 M Street SW, Washington, DC, 20460.

The effectiveness of certain agents against HIV has also been documented in the research literature.[6-9]

These guidelines have been strongly adhered to in the disinfection of endoscopes used on patients known to be

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infected with HIV,[10] but may not be strictly applied to the disinfection of endoscopes used on routine patients. That some of the latter group of patients may be harboring the virus is a valid concern, with current estimates placing the number of HIV-infected asymptomatic Americans at 1 to 1.8 million.[11–13] In addition, documented prevalence rates as high as 1 per 100 individuals in certain regions of the United States have been reported.[14] Therefore, there may be a potential risk of noscomial transmission of HIV to uninfected individuals by improperly disinfected endoscopes previously used on asymptomatic and unrecognized infected individuals.

Until recently any concern of iatrogenic HIV transmission by endoscopy was widely discounted on the basis of the supposed fragility of the virus outside the human body. A recent report[9] that cell-free viable HIV can be recovered from dried material at room temperature for up to three days, however, does not support this position. The present study was therefore undertaken to assess the potential risk of transmission of HIV by endoscopy by addressing the following research question: What proportion of the routine proctosigmoidoscopic cleaning and disinfection procedures used by US family physicians are known to be adequate to inactivate HIV? Although no case of endoscopy-mediated HIV transmission has been documented, transmission of hepatitis B by this avenue has been documented in at least one case,[15] and a second patient is known to have become HBsAg positive[16] subsequent to the procedure.

METHODS

A questionnaire regarding the cleaning and disinfection of proctosigmoidoscopic equipment was designed by the investigators. This initial form was subjected to three series of pilot testing and revision based on personal interviews with five nurses who routinely assist in the disinfection of flexible sigmoidoscopes, telephone interviews of 20 Georgia physicians who perform flexible sigmoidoscopy, and, finally, personal interviews with two additional nurse technicians.

The procedures used in the development and distribution of the questionnaires were modeled after those outlined by Dillman.[17] The initial mailing consisted of a cover letter and a numbered survey questionnaire sent to 1,585 randomly selected members of the American Academy of Family Physicians (AAFP), representing approximately 5 percent of the active membership of 35,002.[18] Physicians who do not disinfect the proctoscope were instructed to ask the nurse or technician who performs the disinfection to complete the questionnaire. One week after the initial mailing, a postcard reminder was sent to all participants. Two weeks later a second cover letter and replacement questionnaire were sent to all nonrespondents. Seven weeks after the initial mailing, questionnaires were sent by certified mail to 375 individuals, approximately 50 percent of those who had not responded to the first two mailings. About four months after the initial mailing, a research assistant attempted to contact 20 of the nonrespondents to the certified mailing, asking them to provide the information requested on the mail questionnaire.

TABLE 1. CLASSIFICATION SCHEME FOR CLEANING PROCEDURES BY EFFICACY AGAINST HIV

Procedure	Disinfection	Air Drying
Appropriate	Appropriate	—
	—	Appropriate
Questionable	Questionable	Inappropriate
	Questionable	Questionable
	Inappropriate	Questionable
Inappropriate	Inappropriate	Inappropriate

Each disinfection procedure reported was reviewed and classified according to the method employed by the respondent: autoclaving, boiling, gas sterilization, or disinfection by solution. All endoscopes that were autoclaved, boiled, or gas sterilized were deemed appropriately disinfected. Those procedures that employed a disinfectant solution were further classified according to appropriateness on four variables: the type of solution, the concentration used, the minimum length of exposure time, and the minimum length of air-drying time between patients. Decisions regarding the appropriateness of various solutions, concentrations, and exposure times were based on the recommendations of the CDC[4,5] and studies of additional high-level disinfectants.[6–9] In the absence of adequate disinfection by any other means, air drying of greater than three days' duration was judged appropriate,[9] although not a realistic method for disinfection.

For each of the four variables, each disinfection procedure was coded as appropriate, inappropriate, or questionable (Table 1). For the variable solution type, solutions that have been neither tested nor recommended against HIV were coded as questionable, since there are insufficient data upon which to base a judgment of the adequacy of these solutions; therefore, no solutions were coded as inappropriate. These questionable solutions include substances that are unlikely to be adequate against HIV (eg, Dawn dishwashing detergent), substances that are widely used but neither documented as effective against HIV nor recommended by the CDC or the product manufacturer, and substances that may be effective but for which completed details of their evaluation against HIV are pend-

TABLE 2. APPROPRIATENESS OF CLEANING PROCEDURES BY RESPONSE GROUP

Cleaning Procedures	First Mailings No. (%)	Certified Mailings No. (%)	Telephone Survey No. (%)	Totals No. (%)
Appropriate	145 (30.7)	13 (29.5)	2 (40.0)	160 (31)
Questionable	301 (63.8)	27 (61.4)	1 (20.0)	329 (63)
Inappropriate	26 (5.5)	4 (9.1)	2 (40.0)	32 (6)
Totals	472	44	5	521 (100)

$\chi^2 = 11.158$ ($\alpha = .05$, df = 2)

ing.[19] Disinfectant concentrations were classified as questionable if the respondent failed to report the concentration used or reported using varying concentrations of the disinfectant. Disinfectant exposure times and air-drying times not reported were also coded as questionable.

Taking the individual procedures as the unit of analysis, the frequency of procedures in each of the three appropriateness categories was determined. To compute estimates of the true proportions in the entire population that take into account the differences in response rate among the three response groups, the proportion in each appropriateness category was multiplied by the proportion of the total population covered by that response group (eg, for the first mailings described below: .570/.919). The proportions within each appropriateness group were then summed across response groups to produce weighted estimates of the proportions in the total population of disinfection procedures being used.

To ascertain trends in the type of responses that were obtained within each response group, a chi-square analysis was performed comparing the number of inappropriate procedures and the number of appropriate or questionable procedures across response groups (Table 2).

RESULTS

Of the 1,585 family physicians surveyed, 1,057 (66.7 percent) responded. Of these, 903 (57.0 percent) responded to one of the first three mailings, 140 (8.8 percent) responded to the certified mailing, and 14 (0.9 percent) of the individuals surveyed by telephone provided data. The 140 respondents by certified mail represent 16.1 percent ([140/375] × [1 − .570]) of the total population. The 14 telephone respondents represent 18.9 percent ([14/20] × [1 − .570 −.161]) of the total population. The data obtained in the present study, therefore, represent a coverage of 91.9 percent of the population.[20,21]

Of all the respondents, 507 (48.0 percent) reported performing endoscopy, with 450 (42.6 percent) reporting the disinfection procedure(s) used. Of these, 71 reported a disinfection procedure for both flexible and rigid endoscopes, for a total of 521 disinfection procedures to be analyzed in this study. There were 65 different identifiable cleaning and disinfectant solutions reported (Table 3). Cidex (2 percent glutaraldehyde) and ethyl alcohol were the most frequently reported appropriate disinfectants. Betadine was the most frequently reported questionable solution, followed by Hibiclens. Only a small minority air dried their endoscopes for the three days assured to be the minimum necessary to inactivate the virus.

Of the 521 reported disinfection procedures, 160 (31 percent) were judged appropriate against HIV; 329 (63 percent) were questionable; and 32 (6 percent) were inappropriate (Table 2). The proportions of procedures in each category grouped according to their response group (first mailings, certified mailing, telephone survey) are also presented in Table 2. Weighted estimates of the proportions in the total population were appropriate 32.4 percent, questionable 54.4 percent, and inappropriate 13.2 percent (Table 4).

There is a statistically significant difference in the proportion of inappropriate procedures across response groups (Table 2; $\chi^2 = 11.158$). Pair-wise chi-square analyses of response groups revealed that the difference is between the proportion of inappropriate procedures in the telephone respondents as compared with that proportion among the first-mailings respondents ($\chi^2 = 10.82$, $df = 2$), the proportion of inappropriate procedures being greater among the telephone respondents than that among the first-mailings respondents.

No statistically significant difference was observed in the proportion of appropriate, questionable, and inappropriate procedures among physicians serving different-sized populations (Table 5; $\chi^2 = 9.27$, $df = 8$; $\chi^2_{crit\ .05} = 15.5$). When the data were collapsed into two population groups of less than 100,000 and 100,000 or more, however, a statistically significant difference was observed, with the proportions of both inappropriate and questionable procedures being greater in the less urban populations ($\chi^2 = 6.92$, $df = 2$; $\chi^2_{crit\ .05} = 5.99$).

TABLE 3. DISINFECTANT AND CLEANING SOLUTIONS REPORTED

Tested or recommended against human immunodeficiency virus			
Alcohol	Glutarex	Omnicide	Wescodyne
Amphyl	Lehn Germicide	Sonaside	Wexcide
Bleach	Lysol	Sporocidin	
Cidex/Cidex7	Metricide	Sterilize	
Neither tested nor recommended against human immunodeficiency virus			
Alconox	Detergents:		
Amerse	ABCO	Hyperclens soap	
Banacide	Dawn	Hydrogen peroxide	Pursue
Betadine	Ivory	Instastan	Radiol
Beaucoup	Palmolive	Kleero	Robark
Benzalkonium chloride	Detergiclene	LOC	Salt (NaCl)
	Dermascrub	Manu-Klenz	Septisol
BioKleen	Endozyme	Mill-Rose instrument cleaner	Sklar-Kleen
Buel Cleaner	Edisonite/superedisonite	Organisol	Staphene
Cetylcide	Germafect	O-Syl	Stella-Kleen
Chlorophense	Green soap	Parachlorometaxylenol	Sterisol
Clinidine	Hemocol soap	Pheneen	Vesphene
Coleo	Hibiclens	Phisohex	Weck
Control III	HI-TOR	Protozyme	Zepharin

TABLE 4. ESTIMATES OF THE POPULATION PROPORTIONS

Procedure	Gross Proportion	Weighted Proportion	Standard Error (%)	95% Confidence Interval (%)
Appropriate	30.7	32.4	4.2	±8.2
Questionable	63.2	54.4	3.8	±7.4
Inappropriate	6.1	13.2	3.9	±7.7

DISCUSSION

Though there has been no documented case of transmission of HIV by endoscopy, there is clearly a finite potential for iatrogenic transmission. With the numbers of asymptomatic infected individuals growing daily, this potential risk is rapidly increasing. This study was designed, therefore, to determine the proportion of family physicians who disinfect their proctoscopes or flexible sigmoidoscopes adequately on a routine basis to inactivate the virus.

The response data revealed that 48 percent of all practicing family physicians perform proctosigmoidoscopy; 43 percent reported their disinfection procedures. The large number of different solutions used revealed little homogeneity in the disinfection procedures. More than one half of these physicians used procedures of questionable efficacy against HIV while less than one third used acceptable procedures. The remaining 13 percent used appropriate disinfectant solutions at concentrations or exposure times that are not documented as effective against HIV. Extrapolating from the data gathered to the 92 percent of the population covered, these data suggest that of the approximately 14,500 family physicians represented in this study who perform endoscopy disinfection, some 1,900 disinfect their instruments in a manner that has not been shown to inactivate HIV. This number may in fact be low, since the study was purposely designed to produce the most conservative estimate of this proportion, underestimating the parameter in at least two ways.

The use of a coding scheme that includes a questionable category, which likely includes both appropriate and inappropriate procedures, results in underestimates of the proportion of appropriate and inappropriate procedures. Also, since this classification procedure identifies as inappropriate only those procedures using appropriate disinfectant solutions at inappropriate concentrations or exposure times (in conjunction with inappropriate air-drying times), the proportion of inappropriate procedures is likely to be further underestimated.

The larger proportion of inappropriate procedures in the telephone survey group suggests that individuals who were less likely to respond were more likely to use inappropriate disinfection procedures. This conclusion further suggests that within that part of the population not covered by this survey, the proportion of individuals who use inappropriate procedures may be higher than the proportion evidenced by the respondents in this study. The weighted estimate of the proportion of inappropriate procedures in the population computed above may therefore further underestimate the true proportion in the population.

IMPLICATIONS AND RECOMMENDATIONS

Ever increasing numbers of individuals are becoming infected with HIV [11-14] It has been shown that HIV is iso-

TABLE 5. APPROPRIATENESS OF CLEANING PROCEDURES BY SIZE OF THE PATIENT POPULATION SERVED

Cleaning Procedures	Population Size 0–24,999 No. (%)	25,000–49,999 No. (%)	50,000–99,999 No. (%)	100,000–499,999 No. (%)	500,000+ No. (%)	Totals No.
Appropriate	52 (27)	24 (28)	26 (33)	37 (43)	17 (35)	156
Questionable	123 (65)	57 (66)	47 (59)	47 (54)	30 (61)	304
Inappropriate	15 (8)	5 (6)	7 (9)	3 (3)	2 (4)	32
Totals	190	86	80	87	49	492*

$\chi^2 = 9.271$ ($\alpha = .05$, df = 8)

* An additional 29 procedures are omitted from this analysis, since they were reported by physicians who did not respond to the population size item in the study

lated from up to 50 percent of healthy asymptomatic individuals in known risk groups and more frequently from individuals with AIDS-related complex than from those with AIDS.[22,23] Moreover, culture-positive individuals who are both asymptomatic and seronegative have been identified.[24] With the majority of infected individuals showing no outward sign of the infection, there is clearly reason for concern that invasive procedures may be performed on infected individuals, placing subsequent patients at risk. The issue is further complicated in that physicians rarely obtain adequately detailed sexual or drug abuse histories on their patients to determine a patient's risk of HIV infection. Procedures for disinfecting endoscopes that are adequate against HIV must be routinely implemented, therefore, since identifying all HIV-infected patients is a practical impossibility.

Appropriate disinfection is a relatively simple task. An example of an appropriate procedure is the physical removal of all organic debris followed by a ten-minute exposure to a solution of 2 percent glutaraldehyde, followed by adequate rinsing. This concentration of glutaraldehyde is higher than necessary to inactivate HIV but is the concentration necessary to inactivate hepatitis B,[25] a common pathogen in many HIV risk groups and one that is known to be transmitted by inappropriately cleaned endoscopes.[15,16]

Since education is currently the only means of combating the spread of AIDS, the findings of this study warrant a nationwide effort to make physicians aware of the CDC guidelines and to encourage all physicians to routinely follow these guidelines for disinfecting instruments used on all patients. These educational efforts should include especially those physicians in less urban settings.

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