ORIGINAL ARTICLE

# Results from a Large-Scale Epidemiologic Look-Back Investigation of Improperly Reprocessed Endoscopy Equipment

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**(See the commentary by Weber, on pages 657–660.)**

OBJECTIVE. To determine whether improper high-level disinfection practices during endoscopy procedures resulted in bloodborne viral infection transmission.

DESIGN. Retrospective cohort study.

SETTING. Four Veterans Affairs medical centers (VAMCs).

PATIENTS. Veterans who underwent colonoscopy and laryngoscopy (ear, nose, and throat [ENT]) procedures from 2003 to 2009.

METHODS. Patients were identified through electronic health record searches and serotested for human immunodeficiency virus (HIV), hepatitis C virus (HCV), and hepatitis B virus (HBV). Newly discovered case patients were linked to a potential source with known identical infection, whose procedure occurred no more than 1 day prior to the case patient's procedure. Viral genetic testing was performed for case/proximate pairs to determine relatedness.

RESULTS. Of 10,737 veterans who underwent endoscopy at 4 VAMCs, 9,879 patients agreed to viral testing. Of these, 90 patients were newly diagnosed with 1 or more viral bloodborne pathogens (BBPs). There were no case/proximate pairings found for patients with either HIV or HBV; 24 HCV case/proximate pairings were found, of which 7 case patients and 8 proximate patients had sufficient viral load for further genetic testing. Only 2 of these cases, both of whom underwent laryngoscopy, and their 4 proximates agreed to further testing. None of the 4 remaining proximate patients who underwent colonoscopy agreed to further testing. Mean genetic distance between the 2 case patients and 4 proximate patients ranged from 13.5% to 19.1%.

CONCLUSIONS. Our investigation revealed that exposure to improperly reprocessed ENT endoscopes did not result in viral transmission in those patients who had viral genetic analysis performed. Any potential transmission of BBPs from colonoscopy remains unknown.

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More than 23 million ambulatory diagnostic endoscopies and 2 million inpatient endoscopy procedures were performed in the United States in 2004.[1] In the Department of Veterans Affairs (VA), more than 277,000 colonoscopies and 81,000 laryngoscopies were performed in fiscal year 2009 (VA National Patient Care Database). Because the gastrointestinal (GI) and respiratory tracts have high bacterial burdens, endoscopes are generally heavily contaminated during use.[2,3] Flexible endoscopes are difficult to disinfect because they contain delicate fiber optic equipment and narrow lumens with channels and ports that must be meticulously cleaned prior to high-level disinfection.[2,4] Failure to perform proper cleaning can result in disinfection failure, and outbreaks of infection can occur.[2,3,5]

Many endoscopy-associated outbreaks are related to breaches in reprocessing techniques; therefore, it is imperative that cleaning and disinfection is performed correctly.[6] Because of their complex design, endoscopes will not withstand steam sterilization to eliminate microorganisms.[4,7] Instead, reprocessing requires manual outer surface cleaning, brushing to access inner channels and ports, and leak testing to ensure endoscope integrity followed by high-level disinfection, often performed in automated endoscope reprocessors (AERs).[2,8-10] AERs offer several advantages over manual reprocessing: they

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automate and standardize several important reprocessing steps, reduce the likelihood that essential reprocessing steps will be skipped, and reduce personnel exposure to high-level disinfectants or chemical sterilants.[2]

Because of the large variety of endoscopic equipment, no single standard procedure for reprocessing all reusable endoscope equipment exists. Furthermore, this equipment is constantly being updated, improved, and changed. Particularly challenging to those responsible for endoscope reprocessing is the growing plethora of complex equipment and components, which require unique reprocessing techniques that change as new equipment is introduced. Thus, manufacturers' recommendations as well as guidelines from multiple medical societies for cleaning and disinfecting endoscopes should be strictly followed.[8,9,11-14] Guidelines for conducting investigations if reprocessing failure occurs also exist.[15]

The incidence of endoscope-associated infection is reported to be very low, at approximately 1 in 1.8 million procedures.[2,9] However, this number is likely an underestimate, as many outbreaks are unrecognized or never reported.[2,4,6] Most reported outbreaks involve waterborne or enteric bacteria, including *Pseudomonas*, *Salmonella*, and *Mycobacteria* species.[2,4] Despite the low incidence of infection, endoscopes are often implicated in device-related healthcare-associated outbreaks.[2] Worldwide, hepatitis C virus (HCV) and hepatitis B virus (HBV) infection transmission has been attributed to GI endoscopy, but no cases of human immunodeficiency virus (HIV) transmission have been reported.[4,7] Documenting the transmission of viral infections is often more difficult than documenting the transmission of bacterial infections because of longer incubation periods and because patients may be asymptomatic or minimally symptomatic.[4,7] No cases have been identified in the literature of transmission of HIV, HBV, or HCV associated with contaminated flexible laryngoscopes, despite evidence that laryngoscopes can be contaminated with blood, organic debris, body fluids, and microorganisms during use.[16-20]

Current reprocessing guidelines have documented that HBV, HCV, and HIV are readily inactivated by commonly used cleansing mechanisms.[9,21-26] However, no simple method exists that ensures that adequate disinfection has occurred.[2] Major reasons for endoscope-related infections are reported to be inadequate cleaning, improper selection or dilution of disinfecting agents, failure to follow recommended cleaning and disinfection procedures, and flaws in endoscope design or AERs.[2,9,13] Failure to follow established reprocessing guidelines, inadequate staff training and quality assurance, and failure to use proper equipment during reprocessing continues to result in infections associated with endoscopes.[2] Here, we describe results from a large-scale epidemiologic investigation within the VA that took place following the recognition of improper reprocessing of endoscopic equipment at 4 VA medical centers (VAMCs).

## METHODS

### Facility-Specific Events

*VAMC 1.* From January 2008 to February 2009, ear, nose, and throat (ENT) endoscopes were cleaned using sanitizing cloths and did not undergo high-level disinfection in accordance with the manufacturer's and Centers for Disease Control and Prevention (CDC) recommendations. All 1,104 patients who underwent flexible laryngoscopy during that time were notified and invited for follow-up testing.

*VAMC 2.* From February 2004 to January 2009, ENT endoscopes were wiped off, placed on a clean towel saturated with a 1 : 6 Wexcide dilution for 10 minutes instead of the manufacturer's recommended 1 : 128 dilution for general disinfection, wiped with a clean cloth saturated with Hibiclens, rinsed under warm running tap water, dried, and wiped twice with 70% isopropyl alcohol. A total of 297 patients who had an ENT endoscopy procedure during that time frame were notified.

*VAMC 3.* On December 1, 2008, a patient underwent a colonoscopy, and clinicians noted blood in the auxiliary water tubing (AWT) system, which is used during procedures for irrigation. A required 1-way valve was absent during the procedure, and 2 components of the AWT system were not being disinfected or discarded according to the manufacturer's instructions. Although colonoscopes underwent appropriate reprocessing, AWTs were reprocessed at the end of the day rather than after each patient. Furthermore, irrigation tubes were not discarded at the end of each day in accordance with the manufacturer's instructions. It could not be determined with certainty how long the AWT had been in use. Consequently, all 6,805 patients who had undergone colonoscopy from the date those colonoscopes were received from the manufacturer (April 23, 2003) until the date the problem was identified and corrected (December 1, 2008) were notified.

*VAMC 4.* Colonoscope AWT was not reprocessed after each patient but was rather only flushed or rinsed with sterile water and was never sent to the Sterile Processing Department for reprocessing. None of the irrigation components had been changed or reprocessed since May 2004. In addition, clinicians connected the AWT system to colonoscopes after the procedure was already in progress in approximately half of all procedures. Therefore, all 2,531 patients who underwent colonoscopies utilizing AWT from May 1, 2004, to February 12, 2009, were notified.

### Epidemiologic Investigation

The primary goal of our investigation was to assess the risk of transmission of HBV, HCV, and/or HIV infection among veterans exposed to improperly reprocessed endoscopes. The investigation was considered an urgent public health response and, as such, was determined by the VA Office of Research Oversight as not requiring review by VA or facility institutional review boards.

TABLE 1. Seroprevalence of Hepatitis B Virus, Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV) Infection for All Patients Tested at 4 Veterans Affairs Medical Centers (VAMCs), January 2003–December 2008

| VAMC | Total no. of positive tests for HBsAg | Total no. of patients tested for HBsAg | HBsAg positive, % | Total no. of positive tests for HCV Ab | Total no. of patients tested for HCV Ab | HCV Ab positive, % | Total no. of positive tests for HIV Ab | Total no. of patients tested for HIV Ab | HIV Ab positive, % |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 48 | 2,692 | 1.78 | 706 | 7,964 | 8.86 | 74 | 3,175 | 2.33 |
| 2 | 57 | 30,401 | 0.19 | 2,042 | 37,423 | 5.46 | 32 | 2,012 | 1.59 |
| 3 | 85 | 17,939 | 0.47 | 2,503 | 39,239 | 6.38 | 49 | 8,013 | 0.61 |
| 4 | 239 | 10,502 | 2.28 | 2,507 | 22,129 | 11.33 | 435 | 7,577 | 5.74 |

NOTE. Ab, antibody; HBsAg, hepatitis B surface antigen.

Patients at risk were identified by electronic health record (EHR) data (procedure codes, encounter notes) or logbooks, and a look-back process was established at each site. Disclosure letters were sent to all veterans who were potentially exposed during endoscopic procedures and offered testing for HBV, HCV, and HIV. EHR look-back encounter notes documented that the patient was notified, test results if testing was performed, and whether the person agreed to follow-up testing. Standard enzyme immunoassays were used for hepatitis B surface antigen as well as HIV and HCV antibodies. Supplemental confirmatory testing was done on the basis of screening results. Laboratory and clinical data from the EHR were reviewed for all serologically positive patients to determine the preendoscopy serologic status for HBV, HCV, and HIV. In addition, a retrospective analysis of endoscopic procedures performed during the risk period was conducted, and the background seroprevalence of HIV, HCV, and HBV infection was determined at the 4 sites.

Patients ("case patients") were considered to have a possible case of viral transmission from their endoscopy procedure if they had undergone endoscopy at the facility during the time period described above; had a positive postendoscopy serologic test result for HBV, HCV, or HIV infection; and had no or negative preendoscopy serologic test results available. Potential source patients ("proximate patients") were those who were known to be chronically infected with HBV, HCV, or HIV and underwent endoscopy prior to a case patient on the same day or the day prior.

We reviewed case patient EHRs to obtain patient demographics, medical history, and laboratory data, including any prior testing and risk factors for HCV, HIV, or HBV (including but not limited to known sex partners infected with HIV, HCV, or HBV; intravenous drug use; transfusions; unprotected intercourse; tattoo(s); history of sexually transmitted disease or infection with another BBP; and sexual contact with sex workers). If available, a description of relevant endoscope procedure(s), including date, time, and endoscope number, and whether a biopsy was performed were obtained from the patient's EHR and/or procedure records or logbooks at each facility. Patient information was collected and recorded in an electronic database.

No case/proximate pairings for HBV or HIV infection were found. For HCV case patients with identified proximates, we determined whether sufficient HCV load was present in both patients for further testing. If patients agreed, HCV from patient plasma was genotyped and sequenced (HCV envelope 2 [E2] gene; hypervariable region 1 [HVR1]) to assess relatedness of viral isolates collected from endoscopy patients with chronic and incident HCV infection. All sequencing was performed at the Division of Viral Hepatitis, CDC, Atlanta, Georgia, using established methods as described elsewhere.[27-31] The E1-HVR1 quasispecies were isolated and amplified by a real-time polymerase chain reaction assay, and approximately 50 end-point dilution clones (length of 291 nucleotides) were sequenced from each sample. Phylogenetic analyses were conducted using MEGA, version 3.1 (Center for Evolutionary Medicine and Informatics, Tempe, AZ). HCV E1-HVR1 quasispecies sequences from patients' specimens were compared with each other and with sequences from randomly selected HCV-infected persons from the Third National Health and Nutrition Examination Survey.[28,30] To evaluate genetic relatedness, pairwise analysis of nucleotide sequences was performed, and a phylogenetic tree was constructed. Viral strains that demonstrated more than 95% nucleotide sequence homologies were considered possibly related.

## RESULTS

Background seroprevalences for the 3 viral infections among all veterans tested between January 1, 2003, and December 31, 2008, for each site are presented in Table 1 and ranged from 0.19% to 2.28% for HBV infection, from 5.46% to 11.33% for HCV infection, and from 0.61% to 5.74% for HIV infection. The prevalence of these infections within the look-back cohort were 0.00%–1.07% for HBV, 0.00%–12.14% for HCV, and 0.00%–2.45% for HIV (Table 2).

The total number of patients requiring look-back notification was 10,737 at 4 sites, of whom 9,879 (92%) completed testing. The total number of patients who were deceased or declined testing was 803, and 55 patients did not respond to look-back notification (Table 3 and Figure 1).

There were 90 patients with newly identified positive results for 1 or more of the 3 viral infections (92 infections total; Table 3). Ninety-three percent of these were male, and the median age was 59.5 years (range, 34–88). Among the group with newly identified positive results, 36 patients (40%) had

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TABLE 2. Seroprevalence of Hepatitis B Virus, Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV) Infection for All Cohort Patients at 4 Veterans Affairs Medical Centers (VAMCs) Tested as Part of the Endoscopy Look-Back Investigation

| VAMC | Total no. of patients tested | HBsAg positive, % | HCV Ab positive, % | HIV Ab positive, % |
|---|---|---|---|---|
| 1 | 1,028 | 1.07 | 4.76 | 0.68 |
| 2 | 276 | 0.00 | 0.00 | 0.00 |
| 3 | 6,172 | 0.19 | 3.69 | 0.09 |
| 4 | 2,403 | 0.81 | 12.14 | 2.45 |

NOTE. Ab, antibody; HBsAg, hepatitis B surface antigen.

1 or more risk factors for viral infections present, with a history of injection or noninjection drug use being most common. Eleven (30%) of 36 and 18 (33%) of 54 patients with and without risk factors present, respectively, had been tested previously for any of the BBPs.

We reviewed data from all patients who had undergone endoscopy procedures on either the same day or the day before a newly identified HCV-, HBV-, or HIV-infected case patient. We identified 24 case patients for whom proximate patients were also identified. In all case/proximate pairings, the BBP identified in both was HCV. No pairings of case/proximate patients for HBV or HIV infection were identified. Seven case patients and their associated 8 proximate patients had sufficient HCV load to conduct further genetic testing and determine strain relatedness. These 15 patients were distributed at 3 sites (proximate patients were approached first and 4 proximate patients refused testing or were not located, so the associated 5 case patients were not tested). In all, a total of 6 ENT endoscopy patients, 2 case patients, and 4 proximate patients at VAMC 1 agreed to molecular testing. Case patient 1 was associated with 1 proximate patient, and case patient 2 was associated with 3 proximate patients.

For case patient 1, the mean genetic distance between case and proximate patient HCV strains was 13.5% (Figure 2). For case patient 2, one of the 3 proximate patients was found after sequencing to have an HCV subtype different from that of the case patient (genotype 1b vs 1a). The mean genetic distance between the HCV strain of case patient 2 and the remaining proximate patients' HCV strains was 17.5% and 19.1%.

## DISCUSSION

Our findings suggest that improperly reprocessed ENT endoscopes did not result in documented viral transmission, at least in those patients for whom HCV genetic analysis was performed. Possible transmission of HCV from colonoscopy remains unknown since further case/proximate patient testing could not be performed. Although 8 and 13 patients were newly diagnosed with HIV and HBV infections, respectively, duration of infection was unknown, and no potential source patients were uncovered, making transmission during endoscopy unlikely. Although 71 patients were newly diagnosed with HCV infection, for only 24 was a proximate patient with known prior HCV infection identified, and only 10 had sufficient HCV load for strain comparison. In addition, 10 of 24 HCV-infected case patients had other documented HCV risk factors prior to their endoscopy, which argues against transmission related to endoscopy in these cases. Although in aggregate our findings do not provide evidence of viral transmission, we cannot definitively exclude the possibility that HCV transmission occurred in these 24 individuals as a result of endoscopy. Even if all newly diagnosed HCV-infected patients were infected via endoscopy, the infection rate would be no greater than 0.008%. Using risk measurement described by Rutala and Weber,[32] we determined the estimated risk of

TABLE 3. Patients Included in the Endoscopy Look-Back Investigation at 4 Veterans Affairs Medical Centers (VAMCs)

| | VAMC 1 | VAMC 2 | VAMC 3 | VAMC 4 | Total |
|---|---|---|---|---|---|
| No. of patients included in look-back notification | 1,104 | 297 | 6,805 | 2,531 | 10,737 |
| No. of patients who declined look-back testing or who were deceased | 74 | 21 | 598 | 110 | 803 |
| No. of patients who did not respond to look-back notification (ie, lost to follow-up) | 2 | 0 | 35 | 18 | 55 |
| No. of patients for whom look-back was completed | 1,028 | 276 | 6,172 | 2,403 | 9,879 |
| New HIV infections | 2 | 0 | 1 | 5 | 8[a] |
| New HCV infections | 6 | 0 | 40 | 25 | 71[a] |
| New HBV infections | 2 | 0 | 7 | 4 | 13[a] |

NOTE. HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus.

[a] Ninety total patients (1 patient each at VAMC 3 and VAMC 4 had both HCV and HBV newly identified).

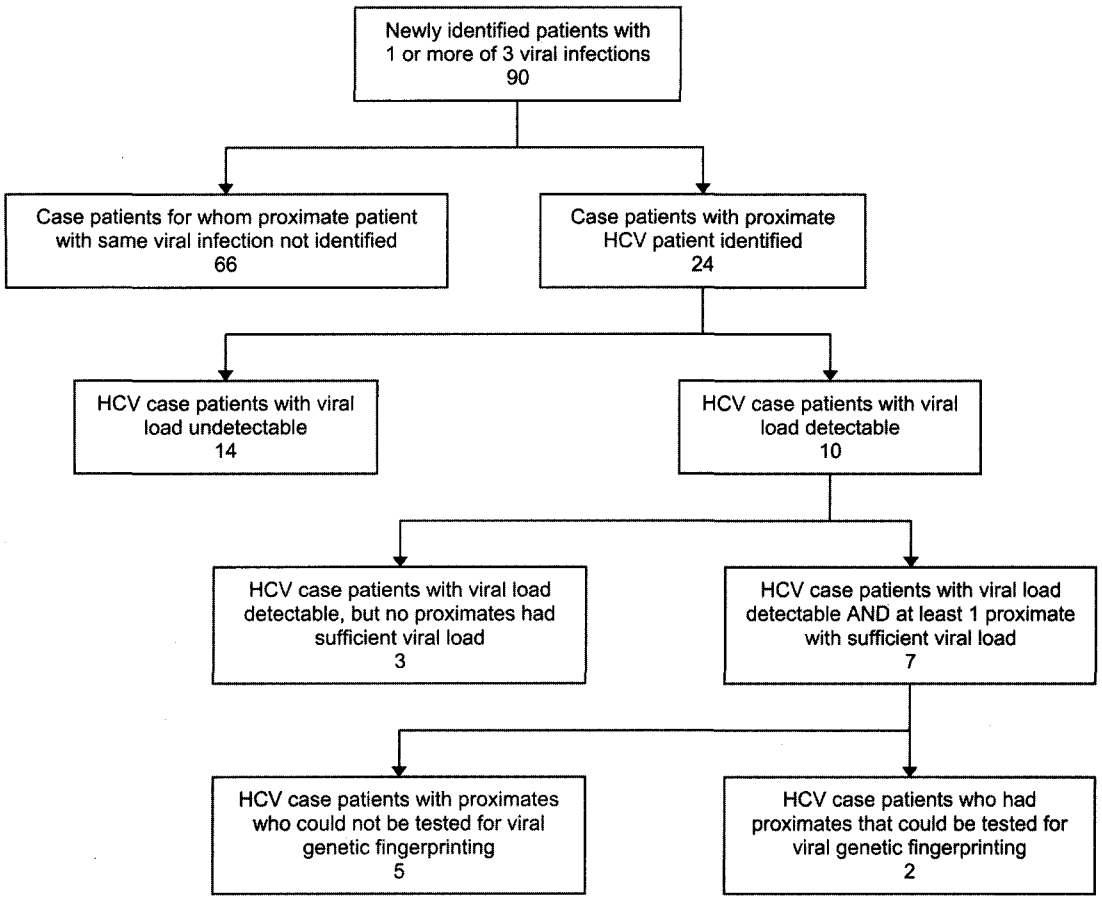


FIGURE 1. Flow diagram depicting testing results of the Veterans Affairs endoscopy look-back investigation at 4 Veterans Affairs medical centers. HCV, hepatitis C virus.

acquiring HIV infection during ENT endoscopy or colonoscopy in our cohort to be 7 in 10 trillion and 2.4 in 1 billion, respectively; for HBV infection, the risk was 1 in 1 billion and 8 in 10 million, respectively, with HCV risk falling between that of HIV and HBV.

Look-back investigations are often plagued by difficulties, which we also encountered. Given the extended risk period, some patients were deceased, difficult to find, or refused testing. Infection rates in those not tested may have been higher, resulting in some selection bias; however, 92% of all identified patients consented to and returned for testing, so this was felt to be a minor concern in this look-back investigation. Lengthy time intervals between the occurrence of failure and the recognition of the problem led to a large pool of patients being involved. Lack of documented preprocedure serologic testing made postprocedure positive viral test results difficult to interpret. In addition, there is little evidence in the published medical literature on whether failure to follow manufacturers' recommended decontamination or servicing procedures leads to a residual infectious bioburden that poses a risk of transmission to subsequent patients. We believe that at all 4 sites the errors in reprocessing were significant enough to warrant a large-scale look-back investigation; even though colonoscopes were reprocessed correctly, AWT systems were not, and laryngoscopes were only superficially cleaned. In addition, no uniform protocol existed within the VA for conducting look-back testing or documentation. One facility did not perform HCV confirmatory testing and misidentified some potentially newly infected patients, whereas other facilities documented only the endoscopy date and not the scope number. If scope type and number had been consistently recorded, we could have matched case/proximate pairs to specific scopes; instead, we took a more conservative approach and assumed that any scope could be implicated. As a result of this investigation, we recommended that all VA facilities implement scope-tracking protocols. Finally, when look-back testing took place, facilities did not collect or store extra blood for additional testing. Thus, when case/proximate pairs were identified, a protocol for repeat blood testing to conduct genetic fingerprinting analysis had to be developed. Some patients did not agree to repeat testing, which meant that an important piece of this investigation could not be completed.

We found a paucity of previous HIV, HBV, and HCV testing

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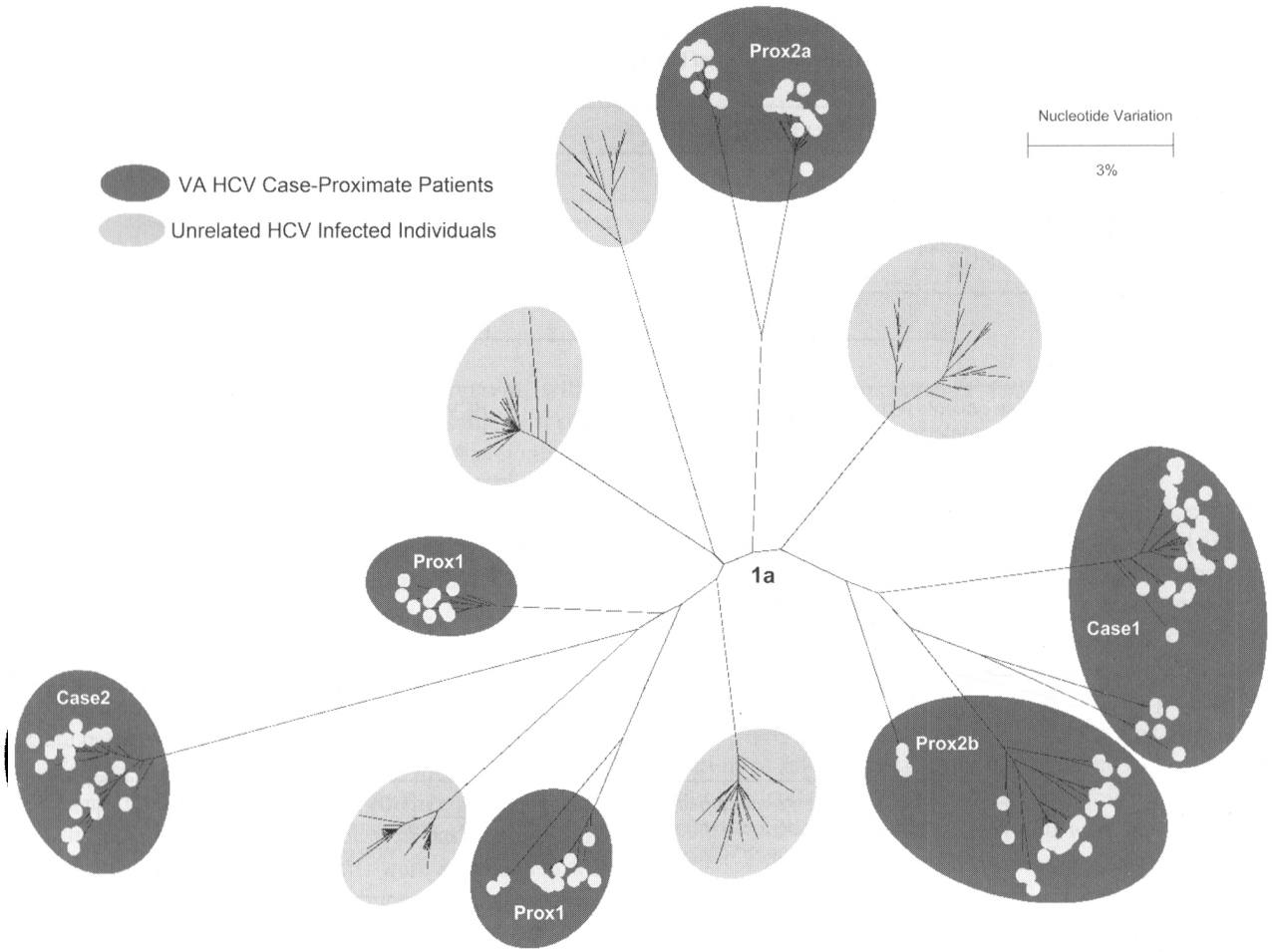


FIGURE 2. Phylogenetic consensus tree based on 291–base pair E1-HVR1-E2 "clonal" hepatitis C virus (HCV) sequences obtained by end-point limiting-dilution real-time polymerase chain reaction assay from the plasma of case and proximate patients compared with subtype 1a variants from US participants in the National Health and Nutrition Examination Survey. Case/proximate pairs = Case1/Prox1; Case2/Prox2a and Prox2b.

among look-back patients, despite documented risk factors and current BBP-screening recommendations in the VA. Many patients with 1 of the 3 viral infections were never tested for the other 2. The calculated seroprevalence rates for these viruses in our look-back cohort were generally lower than the background positivity rates for HBV, HCV, and HIV of 0.19%–2.28%, 5.5%–11.3%, and 0.6%–5.7%, respectively, at these VAMCs. We also reviewed the VA Clinical Case Registry, where the identified prevalence of known chronic HCV and HIV infections at these facilities was 1.5%–2.2% and 0.2%–1.0%, respectively.[33] Chronic HBV infection data are not routinely collected. Thus, additional emphasis must be placed on appropriate screening and testing for these infections in the VA.

Overall, the documented risk of transmission of BBPs from inadequate endoscope reprocessing is low.[1,7,13,34] The lack of transmission may be due to scarcity of reporting when a breach in reprocessing occurs or because on the whole facilities reprocess equipment appropriately. Although inadequate reprocessing practices are still considered to be the main reason underlying contamination from endoscopy procedures, no formal recommendations for surveillance of infections related to these procedures are published.[2] Lack of surveillance data makes it impossible to determine rates of postprocedure infections, and there is no formal mechanism for detecting when cases occur, which can lead to delays in the initiation of outbreak investigations. From a public health perspective, improved surveillance systems could identify adverse events earlier and reduce the clinical burden associated with endoscopy-related events.[6] Thus, reporting of endoscopy-related outbreaks and reprocessing failures will continue to rely on astute healthcare workers.

Standards are difficult to maintain given the numerous differences among reprocessing guidelines and manufacturers' recommended practices.[1] Surveys assessing compliance with current guidelines have indicated less than ideal com-

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pliance.[35-38] Consistent process recommendations and design features from manufacturers to promote effective reprocessing would have helped avoid reprocessing variance. This key issue will require further discussion between manufacturers and appropriate regulatory entities. In the interim, it is critical that reprocessing personnel are adequately trained in evidence-based procedures consistent with guidelines and manufacturers' recommendations and that adequate quality-assurance practices are put into place. Experts agree that when accepted reprocessing guidelines for GI endoscopes are routinely used, BBP transmission can be effectively prevented.[6,13]

Our investigation highlights important challenges in reprocessing endoscopy equipment. Following a large investigation of failure in reprocessing prostate biopsy equipment at 21 VA hospitals, the VA implemented a focused education program to ensure that all facilities were in compliance with recommended reprocessing procedures.[39] A similar effort aimed at endoscopy reprocessing procedures has now been undertaken. Prevention of similar endoscopy reprocessing errors in the future will primarily depend on maintaining strict adherence to published guidelines and manufacturer-specific cleaning recommendations as well as proper training and routine competency assessments for staff responsible for reprocessing endoscopy equipment and accessories.

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