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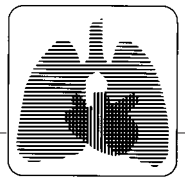

bronchoscopy

American College of Chest Physicians and American Association for Bronchology Consensus Statement*

Prevention of Flexible Bronchoscopy-Associated Infection

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Key words: bronchoscopy-associated infection; flexible bronchoscopy; infection prevention

Abbreviations: AER = automated endoscope reprocessor; BAI = bronchoscopy-associated infection; CDC = Centers for Disease Control and Prevention; FB = flexible bronchoscopy; FDA = US Food and Drug Administration; HEPA = high-efficiency particulate air; PAPR = power air-purifying respirator; SARS-CoV = coronavirus agent of the severe acute respiratory syndrome

Flexible bronchoscopy (FB) is one of the most common and useful procedures performed by chest clinicians, with > 500,000 procedures performed annually in the United States.[1] FB is performed frequently in immunocompromised patients and in health-care settings where exposures to increasingly virulent and drug-resistant microorganisms may occur. Recently reported bronchoscopy-associated infections (BAIs) and pseudoinfections[1–4] potentially affected > 800 patients and included instances in which clinically significant infections and fatalities might have been related to the procedure. Such outbreaks have generated major concerns regarding the possibility of iatrogenic infections due to FB and underscore the importance of reappraising this problem and optimizing preventive practices.[5,6] The potential sequelae of BAI and pseudoinfection are enormous. In addition to the possible morbidity and mortality associated with true infections, such events require expenditure of considerable time and resources for the careful assessment of the vast majority of instances in which no infections or harm to patients have occurred.

For many reasons it is remarkable that true infection due to FB appears to be an uncommon event. During performance of the procedure, host defenses are bypassed routinely as, most often, the bronchoscope is passed through the upper airways, which are invariably colonized by a myriad of potential pathogens. The patient's cough and other protective reflexes are attenuated purposefully with a variety of medications, ensuring aspiration of microbes, and these and other solutions are instilled routinely into progressively more distal airways, potentially soiling peripheral lung parenchyma. Normal mucosal barriers to infection are disrupted during lung biopsies and an increasing array of interventional procedures. With the latter, lengthier procedure times may increase opportunities for hematogenous as well as local infections. Simultaneously, the progressive

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miniaturization of bronchoscopes and accessories introduces potential difficulties in effective cleaning and disinfection of these structurally complex instruments. In addition, the prevalence of HIV, multidrug-resistant tuberculosis, hepatitis B, and newly emerging pathogens such as the coronavirus agent of severe acute respiratory syndrome (SARS-CoV) heighten concerns about the relative risks posed by bronchoscopy.

Prakash[7] has described several scenarios in which the bronchoscope may propagate infection. These include intrapulmonary or extrapulmonary spread of infection within the same patient, pathogen transmission from one patient to another, and the spread of infection from the patient to participating medical personnel.[8,9] Each of these possibilities poses unique challenges in implementing effective infection control practices. Other inherent difficulties also relate to meaningful definitions of infection or pseudoinfection, their accurate recognition in individual patients, appropriate monitoring of cleaning and disinfection of bronchoscopy instruments, laboratory maintenance, bronchoscopy staff education, and longitudinal monitoring and documentation of effective practices.

The exact incidence of infections caused by FB is unknown. Their apparent low frequency might reflect a truly uncommon occurrence. Alternatively, such events might be systematically underrecognized because of multiple factors. For example, new infection (patient-to-patient) induced by the procedure may be easily masked by the primary signs and symptoms for which FB was performed. In an individual patient, interpretation of a positive culture from a bronchoscopy specimen and the precise differentiation of colonization or infection from instrument contamination may be extraordinarily difficult. This dilemma may be especially problematic in the sickest patients. An individual bronchoscopist may not have access to the comprehensive experience of a bronchoscopy suite in order to discern whether telltale patterns of microbiologic isolates exist among patients undergoing bronchoscopy, and whether these are inappropriate for the patient's clinical presentation. Other reasons for underrecognition of endemic infection may include inadequate surveillance of outpatient procedures, asymptomatic infection or prolonged incubation period prior to the development of the symptoms, and fear of medicolegal ramifications of reporting/publishing device-related transmission of infection.

At an institutional level, recognition of BAI requires regular systematic review of all aspects of the procedure, rigorous adherence, reinforcement and monitoring of well-established infection control practices, and established mechanisms for timely objective epidemiologic evaluation whenever a potential problem occurs. Such resources (and the funding needed to support such efforts) may not be consistently available at many centers.

While prevention of infection caused by FB is an obvious concern for all chest clinicians, several observations suggest that there is a widespread unfamiliarity with practice guidelines and that potentially consequential variations in primary and secondary prevention of BAI and pseudoinfections may occur. Although reprocessing guidelines exist, their focal point has been on GI endoscopes. Guidelines addressing bronchoscope reprocessing, for the most part, are derived from those dealing with the GI endoscope. Guidelines for reprocessing of flexible endoscopes, including bronchoscopes, have been promulgated by the Association for Professionals in Infection Control, Association of PeriOperative Registered Nurses, and the British Thoracic Society, among others.[10–13] Data suggest that these guidelines have not been effectively disseminated and/or followed by many clinicians. A comprehensive survey[14] of bronchoscopists in the United Kingdom revealed that national guidelines for bronchoscope reprocessing were not followed consistently. Minimum disinfection times recommended before and after routine bronchoscopies were often (35%) not achieved, and no disinfection was carried out in 34% of medical centers before emergency bronchoscopies and in 19% of units after suspected cases of tuberculosis. Adequate rinsing of the bronchoscope with sterile or filtered water was not carried out by 43% of units. Staff rarely (7%) wore recommended protective clothing during bronchoscopy. In another survey involving US bronchoscopists, nearly two thirds of respondents, including medical directors of bronchoscopy suites, acknowledged that they were unfamiliar with national reprocessing recommendations. Interestingly, this survey was carried out just following a widely publicized Pseudomonas outbreak involving bronchoscopes.[15] Moreover, many (39%) were not aware of the approaches to reprocessing at their own institutions! Although specific data are unavailable, anecdotal observations suggest that bronchoscope reprocessing techniques are inadequately emphasized during the training of many pulmonary fellows, and many bronchoscopists may take it for granted that the instruments they use are safe.

In order to help organize and disseminate information regarding validated practices for bronchoscope reprocessing and infection prevention and control, this committee was jointly convened by the American College of Chest Physicians and the American Association for Bronchology. In this document, we summarize data from the literature regarding the

extent of the problem and specific risk factors (generally discovered during the comprehensive investigation of outbreaks). We also present principles related to the specific maintenance and disinfection of instruments together with provisional recommendations. Since many important factors extend beyond the purview of individual bronchoscopists and relate to the milieu in which the procedure is performed, we also address institutional aspects of the infrastructure and processes essential to bronchoscopy infection prevention and control.

The readers of this article should recognize that this is a consensus statement and does not represent evidence-based recommendations. Because of the relative absence of prospective investigations in this area, most of these recommendations are based on clinical experience and consensus opinion, rather than the higher grades of evidence generally required for true clinical practice guidelines. Accordingly, our recommendations represent an evolving perspective that provides numerous important opportunities for clinical outcomes research and that will require future critical refinement. In addition to general principles, the implementation of effective programs is institution specific and requires local modification through continued active dialogue among bronchoscopists, staff, and infection control teams.[16] We would also like to highlight that these recommendations are not intended to ensure the inactivation or removal of causative agents of transmissible spongiform encephalopathies (prion proteins).

Literature Review

The true incidence of BAI is unknown, due in part to episodic reporting and lack of specific monitoring or institutional surveillance of such events. A review of the English-language literature from 1970 to 2003 revealed over three hundred references to endoscopy-related transmissions of infection. Sixty-two were specific to FB. Despite published guidelines for the reprocessing of endoscopes, reports of "true infections" and "pseudoinfections" or "pseudoepidemics" related to FB seem to be increasing. Most citations refer to pseudoinfections and pseudoepidemics as the isolation of organisms in bronchoscopy specimens due to colonization or contamination of the bronchoscope rather than true patient-to-patient transmission ("true infection") [Table 1].[1–4,17–72] The majority of reports are descriptive, with few case-controlled investigations. Typically, episodes can be traced to inadequate cleaning techniques or disinfection processes. Occasionally, the infection is due to contamination of water supplies, reprocessing equipment, or accessories such as stopcocks or cleaning brushes. Defects within the bronchoscope itself (suction valve port) have also been implicated in transmission of organisms from patient to patient (Table 2).[17–42,69–71,73,74]

Only 18 publications have suggested "true" infection: the transmission of a specific pathogen associated with a clinically significant illness in a patient undergoing FB (Table 3).[1,2,18–20,31,32,42,46,49,53,66–70,73,75,76] Two of the accounts were reported in 2003, involving 33 patients with three possible deaths.[1–2] The use of DNA probes was helpful in identifying patterns of transmission. In these reports, the FBs were cleaned using automated endoscope reprocessors (AERs) and the recommendations for disinfection of endoscopic equipment were strictly followed.

The most common organisms implicated in bronchoscopy-related pseudoinfections include bacterial pathogens such as *P aeruginosa* or *S marcescens*, contagious and noncontagious mycobacteria, and environmental fungi[4] (Table 1). Pseudomonas and Serratia species, and *M tuberculosis* are among the most common organisms reported in true infections (Table 3).

Viruses can be nominally classified into two groups based on the presence or absence of a lipid bilayer envelope. The latter provides a barrier to external digestive enzymes and therefore more resistance to disinfection. Patient-to-patient transmission of viral infections during bronchoscopy has not been reported, however. Interestingly, transmission of hepatitis B as well as hepatitis C has been previously reported in the setting of inadequately disinfected gastroendoscopes.[77] While HIV is readily inactivated using standard disinfection techniques, HIV-RNA can be isolated from the bronchoscope after its use in patients with the virus. In addition, intact papilloma virus DNA can be isolated in the vapor plume from laser photoresection.[78–81] These observations further illustrate the potential for viral transmission during the FB procedure.

Reports of the transmission of airborne infections such as *M tuberculosis* or influenza to health-care providers suggest that there may be an additional occupational risk for bronchoscopy personnel. Recently, the outbreak of SARS-CoV afflicting health-care providers during the severe acute respiratory syndrome epidemic illustrated the risks of communicable airborne diseases. New evidence suggests that although transmission appears to occur from infectious droplets, there are occasional episodes in which airborne transmission cannot be excluded, including "aerosol"-generating procedures such as intubation, bilevel positive airway pressure ventilation, and bronchoscopy.[82–85] Cases of direct transmission of infectious diseases to staff during bron-

Table 1—*Bronchoscopy-Related Pseudoinfections

Organisms	Total Reports, No.	Affected Patients, No.	Reference(s)
Bacteria			
Proteus sp	2	8	3,43
Bacillus sp	2	23	44,45
Serratia marcescens	5	33†‡	40,42,46–48
Pseudomonas aeruginosa	8	220†§	1,2,48,49,66–71
Legionella pneumophilia	1	5	38
Klebsiella pneumonia	2	19	3,48
Methylobacterium mesophilicum	2	25	27,34
Morganella morganii	1	1	3
Fungi			
Aureobasidium sp	1	9	23
Rhodotorula rubra	3	56	21,28,41
Blastomyces dermatitidis	1	2	17
Trichosporon cutaneum	1	8	4,5,29
Penicillium sp	1	8	29
Cladosporium sp	1	1	29
Phialospora sp	1	1	29
Mycobacteria			
Mycobacterium tuberculosis	9	24†‡	18,20,31,32,49–53
Mycobacterium avium-intracellulare	4	11†‡	20,22,39,49
Mycobacterium xenopi	2	13†‖	25,35
Mycobacterium chelonae	15	304†‡‖	19,24–27,33,54–62
Mycobacterium fortuitum	2	4†‖	25,61
Mycobacterium gordonae	3	59†¶	24,30,36,72
Mycobacterium abscessus	2	33	63,64
Various nontuberculous mycobacteria	3	17†	37,60,65

*Modified from Culver et al.[6]

†The precise number of pseudoinfections is not specified. The number of affected cases are estimated from the excess positive bronchoscopy culture results compared to control periods.[2,48,60,69]

‡The exact number of total pseudoinfections is unclear in these reports.[39,42,49,52,61]

§One report[69] described 35 excess cases but did not differentiate the proportion of pseudoinfections and true infections. The same outbreak is described elsewhere.[49,70]

‖One report[25] described 15 patients with *M xenopi*, *M chelonae*, and/or *M fortuitum* pseudoinfections but did not specify the numbers of each.

¶Six patients with culture-positive *M gordonae* and two additional patients with smear-positive acid-fast bacilli only.[36].

choscopy are apparently rare. However, the increased incidence of latent tuberculosis among respiratory therapists and pulmonary fellows compared with other health-care providers suggests that there may be an increased risk to health-care providers who are involved in bronchoscopy procedures.[86,87]

Recommendations

We reemphasize that our review of the literature reveals that the infrequent and sporadic recognition of bronchoscopy-related infection hinders development of evidence-based guidelines for this topic. However, review of the available literature suggests that all episodes are preventable. Many of the following recommendations are based on accumulated clinical experience and expert opinions involving several disciplines. The following recommendations have taken into account guidelines published by other societies and organizations.[6,10–12,88,89] Review of the literature also points out several flaws in current practices; we highlight measures to avoid such mistakes.

General Recommendations

All bronchoscopy personnel, including technical staff, physicians, and fellows should be educated in infection control practices including "sharp precautions," all reprocessing steps, and material handling. All bronchoscopy personnel should be vaccinated against influenza as well as hepatitis B and should undergo a surveillance purified protein derivative test every 6 months as long as they are not tested positive at a prior testing interval.

All bronchoscopes should be properly maintained according to the recommendations of the manufacturer. The user manual should be easily accessible and provide information on the use of specific bronchoscope models. Use of bronchoscopes that are fully immersible and have disposable suction and

Table 2—*Major Sources of Contamination*

Source of Contamination	Reference(s)
Ineffective cleaning	
Inadequate cleaning	17,71
Damaged internal channel	18,19
Poorly mated internal components	74
Reusable suction valve	20
Suction channel	20,21
Biopsy port	71
Accessories	
Sample collection tubing	22
Reused stopcocks for BAL fluid aspiration	23
Contaminated reprocessing equipment	
Automated washer	69
Rinsing tank	24
Tubing	25
Filter	26
Biofilm in reprocessor	27,69
Cleaning brushes	28
Instilled solutions	
Topical anesthesia (cocaine)	29
Green dye (additive to anesthetic)	30
Atomizer	31
Disinfectant	
Inadequate activity	32
Incorrect disinfectant concentration dispensed by automated reprocessor	73
Contaminated glutaraldehyde	23,33
Improper connector to reprocessor	70
Recontamination after disinfection	
Rinsing tap water (hospital supply)	34–37
Contaminated water filters	38,39
Reuse of "sterile water" for rinsing	40
Reassembly of valves prior to storage	41
Storage in coiled position/in cases:	42

biopsy valves is highly recommended. Nonimmersible bronchoscopes and those with a reuseable valve should be replaced as soon as possible.

There are no reports of subacute bacterial endocarditis or that of joint infections resulting from a bronchoscopy procedure. However, prophylactic antibiotic therapy should be considered for patients at high risk for these complications (Table 4).[7,90] Patients with joint replacement within the past 2 years, history of previous prosthetic joint infection, inflammatory arthropathy, hemophilia, malnutrition, insulin-dependent diabetes mellitus, and immunocompromised status are susceptible to hematogenous total joint infection and, therefore, may benefit from prophylactic antibiotics.[91] In view of the lack of data, application of such a practice could be recommended only on an individual basis.

Infection control precautions ("standard precautions") should be mandated for every procedure and should include full barrier clothing (gown, gloves, mask, and eye shields) and needle precautions for the bronchoscopist (Fig 1). Use of a fit-tested N95 particulate respirator by the bronchoscopist or a higher-grade respiratory precaution are recommended when mycobacterial infection is suspected. For highly contagious agents (*eg*, SARS-CoV), a power air-purifying respirator (PAPR) hood should be used (Fig 2).[82–85,92] Prior to their use, medical clearance of proper fit-testing and familiarity with these masks is essential for all bronchoscopy personnel. There must be compelling indications for bronchoscopy in patients suspected of having highly contagious infections (see "Patient Selection"). When bronchoscopy is to be performed in such patients, it should be performed in a negative pressure-ventilated room, if one is available. These patients should also be required to wear a surgical mask so that the risk of dissemination of airborne infection can be minimized (Fig 3).

Administration of adequate topical anesthetic agents or cough suppressants is recommended to minimize coughing resulting in dissemination of airborne pathogens. Sharp metal objects or needles should not be used to remove biopsy specimen from the forceps, because this may increase the risk of transmission of blood borne pathogens.[77]

A procedure log should be kept that includes the patient's name and medical record number, the bronchoscope used, the name of the bronchoscopist(s), and the automated endoscope reprocessor (AER), if used, to assist in outbreak investigation. In addition, a maintenance record must be maintained for each bronchoscope and AER in use.

Patient Selection

To prevent contamination of the instrument and aerosolization of highly pathogenic organisms such as *M tuberculosis* or SARS-CoV,[82–85] every effort should be made to confirm the diagnosis by other techniques. Bronchoscopy for the purpose of diagnosis should be postponed until at least three sputum or gastric aspirate smear findings are negative for acid-fast bacilli in patients suspected of having pulmonary tuberculosis.[93]

Bronchoscopy Suite

The bronchoscopy suite as well as the postprocedure recovery areas should have engineering controls that will allow ≥ 12 air exchanges per hour for new construction as of year 2001 or 6 exchanges per hour for construction before 2001 and be under negative pressure.[94] The air must be either discharged directly to the outside or to a monitored high-efficiency particulate air (HEPA) filtration system before recirculation. The adequacy of these air

Table 3—*Bronchoscopy-Related True Infections**

Organism	Mechanism	Outcome	Reference(s)	Year
S marcescens	Inadequate cleaning and disinfectant (alcohol)	Three true infections, 1 probable death, and 103 pseudoinfections	46	1975
Psudomonas sp	Suction attachment not detached prior to attempted disinfection	One true infection and five pseudoinfections	66	1978
Burkholderia pseudomallei†	Unknown (rigid bronchscope)	Causality tenuous	67	1979
P aeruginosa	Inadequate disinfectant (povidone-iodine) Insufficient disinfection time (5 min); reintroduction of cleaning brush after disinfection	One true infection and 10 pseudoinfections	68	1982
M tuberculosis	Inadequate disinfectant (povidone-iodine)	One patient each with true infection and pseudoinfection	32	1983
M chelonae	Damaged suction channel prevented adequate disinfection	Two true infections and 70 pseudoinfections	19	1983
M tuberculosis	Use of nondisposable suction valves	One patient acquired active TB, and two pseudoinfections each with *M tuberculosis* and MAI	20	1989
S marcescens	Regimen inadequate at multiple steps	Six cases (five possible true infections); causality tenuous	42	1993
M tuberculosis	Multiple deviations from APIC guidelines	One patient acquired active TB	75	1997
Multidrug-resistant *M tuberculosis*	Multiple deviations from APIC guidelines	One patient each with active TB (died due to TB) and skin test conversion, and one patient with pseudoinfection	53	1997
P aeruginosa	Contaminated AER	Number of true infections and pseudoinfections not specified	69	1997
P aeruginosa	Contaminated AER/not routinely serviced or cleaned	Two or more of eight total patients with true infection	76	2000
P aeruginosa	Inadequate disinfectant concentrations from automatic dispenser	Six ICU patients with colonization	73	2001
M tuberculosis	Reuse of lidocaine atomizers (?)	One patient each with lung and ocular TB	31	2001
P aeruginosa	Wrong connectors used for lumen disinfection by AER	Three true infections, and 14 pseudoinfections	70	2001
M tuberculosis	Punctured sheath/leak test not done	Two patients acquired active infection, and six patients had pseudoinfection	18	2002
P aeruginosa	Unclear (?) loose biopsy port cap prevented cleaning and disinfection	Twenty to 43 possible infections; pneumonias, sinusitis, bacteremias; and three possible deaths	2	2003
P aeruginosa	Same as Srinivasan (above)	Probable pneumonia; details scarce and/or causality tenuous in these reports.	1	2003

*APIC = Association for Professionals in Infection Control and Epidemiology; MAI = *M avium-intracellulare*. Used with permission from Culver et al.[6]

†Formerly known as *Pseudomonas pseudomallei*.

exchanges should be monitored on a regular basis with appropriate documentation by the engineering and/or infection control personnel of the institution. Designated "clean" and "dirty" (reprocessing) areas should be maintained in the bronchoscopy suite to separate used instruments from clean ones. Bronchoscopy supervisory staff should strictly implement and monitor such practices. No special preparation is required prior to the reuse of a well-ventilated facility after performing a procedure in a patient suspected of having infection with a virulent, airborne pathogen. All furniture and equipment used during the procedure should be wiped down following each procedure using hospital-approved cleaning solutions. The bronchoscopy suite floor should also be wiped with hospital approved cleaning solutions at the end of each working day, following the procedure appropriate for the soiling. If a procedure is being performed in a nondesignated area, a portable HEPA filter should be used when appropriate (high suspicion for airborne pathogens).

Reprocessing of the Bronchoscope

The sequence of reprocessing should be as follows.

Table 4—*Factors Associated With Bacterial Endocarditis

Patients susceptible to bacterial endocarditis
Individual factors†
History of bacterial endocarditis
Prosthetic heart valves including bioprosthetic and homograft valves
Cyanotic congenital heart diseases
Rheumatic valve disease
Hypertrophic cardiomyopathy
Mitral valve prolapse with regurgitation
Surgically corrected systemic-pulmonary shunts or conduits
Immunocompromised patients with lower respiratory tract infection
Procedural factors
Diagnostic tests that would induce mucosal trauma (brushing, endobronchial or bronchoscopic lung biopsy, transbronchial needle aspiration)
Therapeutic bronchoscopy causing mucosal trauma: laser photoresection, endobronchial electrosurgery, balloon bronchoplasty, stent placement
Patients susceptible to hematogenous total joint infection
Joint replacement within past 2 yr
Previous prosthetic joint infection
Inflammatory arthropathy
Immunocompromized patient
Hemophilia
Malnutrition
Insulin-dependent diabetes mellitus

*There are no reports of bacterial endocarditis or joint infections caused by the FB. Prophylaxis against these conditions should be considered in susceptible patients on individual basis.

†Many center administer antibiotics during or immediately after bronchoscopic lung biopsy in lung transplant recipients to prevent BAI. To date, there are no data to support such practice.

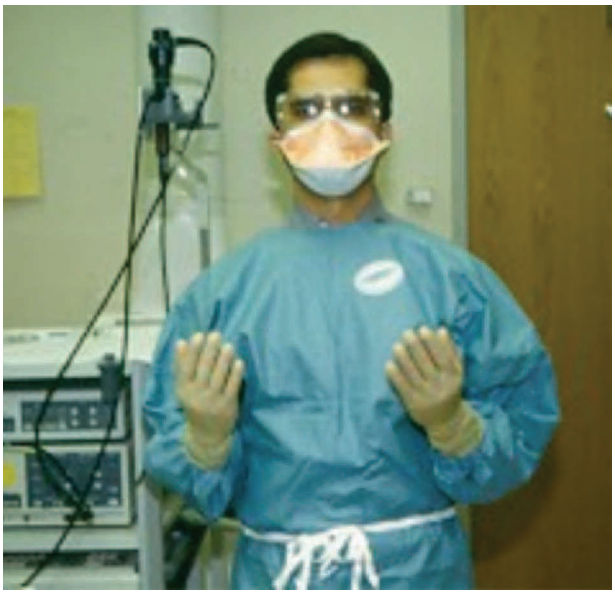

FIGURE 1. Standard precautions for bronchoscopy, showing bronchoscopist with gown, gloves, mask, and eye gear.

Mechanical Cleaning

Mechanical cleaning begins immediately after the procedure to prevent drying or hardening of organic debris.[10,95] Personal protective equipment (gown, gloves, mask, and eye shields) must be worn while processing the contaminated bronchoscope. The outside of the bronchoscope should be wiped with a detergent-soaked gauze piece and detergent solution suctioned through the channel. All suction ports or biopsy attachments should be detached prior to leak testing, further cleaning, and inspecting the instrument for any damage. All disposable items must be discarded. The instrument should then be pressurized with a leak tester to detect any damage that could have occurred during the procedure. The bronchoscope is then fully immersed in water to confirm or to rule out any air leaks. Flexion and extension of the bending section should be performed under water to detect any minute leaks that may not be visualized otherwise. The presence of a leak indicates a breach in the integrity of the external or the luminal surface of the instrument. Such puncture sites and breaches will develop concretions of debris (blood, mucus) that cannot be disinfected. Any instrument with a positive leak test result should not be reused until fully repaired (Fig 4). Only after ensuring that there are no air leaks should an enzymatic cleaner be added to the water. Next, the bronchoscope should be soaked in cleaning solution for approximately 5 min. The external surface of the bronchoscope should be cleaned/wiped manually with an enzymatic detergent. Detergent solution or water is then flushed through all ports to loosen organic debris. The detergent preparation should not be reused. A cleaning brush of an appropriate size then should be passed multiple times through all ports of the instrument. Meticulous cleaning alone achieves a 3.5- to 4-log reduction in the organism load.[96] After brushing, channels should be flushed again to remove all loosened material. Cleaning brushes should either be for single use or should receive mechanical cleaning followed by sterilization or high-level disinfection after each use.[28] Finally the instrument and its channel should be rinsed with water to remove the enzymatic cleaner and prepare it for disinfection.

Following a procedure performed in a nondesignated area (*ie*, in the ICU), the external surface of the bronchoscope should be wiped and its channel flushed with water. The instrument should then be placed in a water-tight polyethylene bag and returned to the bronchoscopy suite as soon as possible for a formal reprocessing. The bronchoscope reprocessing should not be performed in the procedure area.

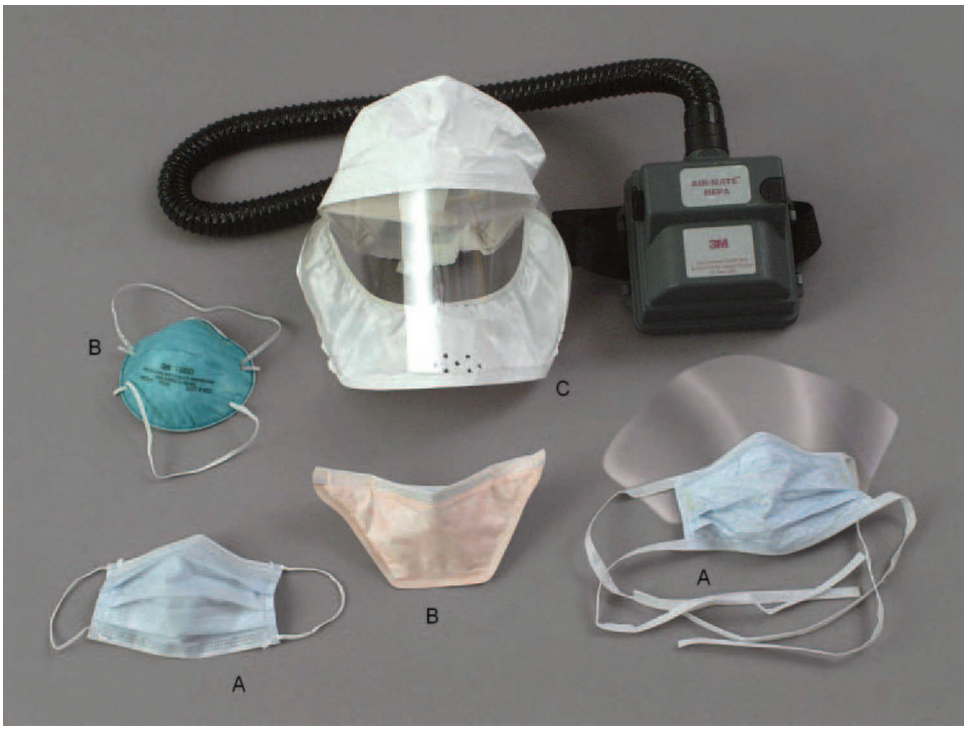

FIGURE 2. Facial masks used during bronchoscopy. *Left*, *A*, and *right*, *A*: The surgical mask helps prevent spread of droplet infection from the surgeon into the open surgical wounds. *Left*, *B*, and *center*, *B*: N95 particulate respirators help prevent spread of airborne infection from patient to the bronchoscopy personnel, and filter 95% of particles > 0.3 μm. Prefitting is required. *Top*, *C*: PAFR hood.

The decision to process a bronchoscope with high-level disinfection vs sterilization is based on a classification system for medical devices that divides them by the risk of infection transmission. The Spaulding classification[97] groups medical devices into three groups, allowing determination of the level of disinfection for each. The following is a description of each group.

Critical Devices: Devices that normally enter sterile tissue or the vascular system (*eg*, cardiac catheters, biopsy forceps). They should undergo sterilization, defined as the destruction of all microbial life.

Semicritical Devices: Devices that come in contact with intact mucous membranes and do not normally penetrate sterile tissue (*eg*, endoscopes). They should undergo high-level disinfection, defined as the destruction of all vegetative microorganisms, mycobacteria, viruses, fungal spores, and some, but not all, bacterial spores.

Noncritical Devices: Devices that do not ordinarily touch the patient or touch only intact skin (*eg*, stethoscopes or patient carts). These items may be cleaned by low-level disinfection.

Disinfection

According to the above scheme, the FB is a semicritical device, as it seldom comes in contact with breached mucosa or open surgical wounds.[98] A minimum of high-level disinfection is required before its reuse. Sterilization with ethylene oxide gas, while highly effective, is likely to be associated with unacceptable delays between procedures due to the prolonged sterilization process and the need to aerate the instrument afterwards.

Disinfection is carried out either manually or by using an AER. Activated alkaline gluteraldehyde, peracetic acid, and orthophthaldehyde are the acceptable chemicals for disinfection.[99–101] A complete list of approved disinfectant formulations and maximum reuse time can be found at www.fda.gov/cdrh/ode/germlab.html.[89]

All currently approved agents are effective high-level disinfectants in experimental conditions, by definition achieving a 6-log reduction in mycobacterial burden.[95] The choice of specific disinfectant can vary by institution, depending on cost, volume of procedures, availability of AERs, and the number of bronchoscopes in use. Disinfection for 20 min in 2% alkaline gluteraldehyde at 20°C ("20–2-20") provides

FIGURE 3. Bronchoscopy personnel wearing a PAPR. The respirator circulates filter air through the hood.

adequate disinfection if cleaning with detergent precedes disinfection.[7,96,98,100] Meticulous cleaning and assiduous adherence to an appropriate protocol are much more important determinants of successful disinfection than the choice of a specific approved agent.[100] It is important to note that dilution of disinfectants occurs over time.[103] Depending on the formulation, the solutions may be reused for 14 to 28 days.[89] Potency of the solution should be periodically tested with commercially available test kits and documented for proper record keeping.

Gluteraldehyde solution should be discarded after 14 days or 20 cycles and should not be used if the concentration is $< 2\%$; the solution should be tested at the beginning of every day of use. Even if the concentration is adequate, the disinfectant should not be used longer than the recommended period, since the aldehyde moeity will polymerize over time attenuating its microbiocidal activity.[102] If the AER use is the primary mode of disinfection, the advisory issued by the US Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) should be followed closely (Table 4).[89] It is essential to ensure compatibility between bronchoscopes and AERs.[49,65,70] Chemical and biological indicators (sporicidal tests) should be strictly followed during the use of AERs. Automated reprocessors can be used for endoscopes other than FB, provided all AER users adhere to acceptable reprocessing protocol. All AERs should be properly maintained according to the recommendations of the manufacturer. User manuals should be easily accessible and provide information on which specific bronchoscope models have been tested for compatibility with the AER.

Postprocessing Procedure

Since many pathogens isolated from the bronchoscopes are from recontamination after disinfection,[34–40] it is imperative to properly dry and store the instrument. Following disinfection or sterilization, thorough rinsing of the internal channel with sterile or filtered tap water is essential to prevent toxic effects of residual chemicals. Ideally, the instrument is dried by purging the channel with 70% alcohol and compressed air.[97]

Proper storage of the bronchoscope is an important step to prevent pathogen growth. Flexible bronchoscopes should be hung vertically without valves attached, in a roomy cabinet with adequate ventilation to prevent moisture accumulation. An additional step to decrease moisture is to place the bronchoscope in a drying cabinet that utilizes a desiccant to reduce relative humidity. The instrument should not be stored in its carrying case, which should be used only for long-distance transportation. Since the carrying case itself cannot be disinfected, it is unsuitable to maintain the bronchoscope in a "patient-ready" condition. All instruments transported in the case must be reprocessed before and after being placed in the case. For procedures performed at locations other than the bronchoscopy suite, a sterile sealed polyethylene bag should be used for transportation of the disinfected instrument.

Bronchoscopic Accessories

All nondisposable bronchoscopic accessories (such as forceps) that breach the bronchial mucosa require sterilization following a thorough mechanical cleaning.[20,23] Because they cannot be properly sterilized, needles used for aspiration biopsy are for single-patient-use only. All ancillary equipment (atomizers, filters, washers) must be cleaned and maintained according to the recommendation of the manufacturer. Reuse of atomizers between patients is unacceptable.[31] Multiuse vials (*eg*, canisters of benzocaine) used for topical anesthesia should be wiped down with a hospital-approved disinfectant between use.

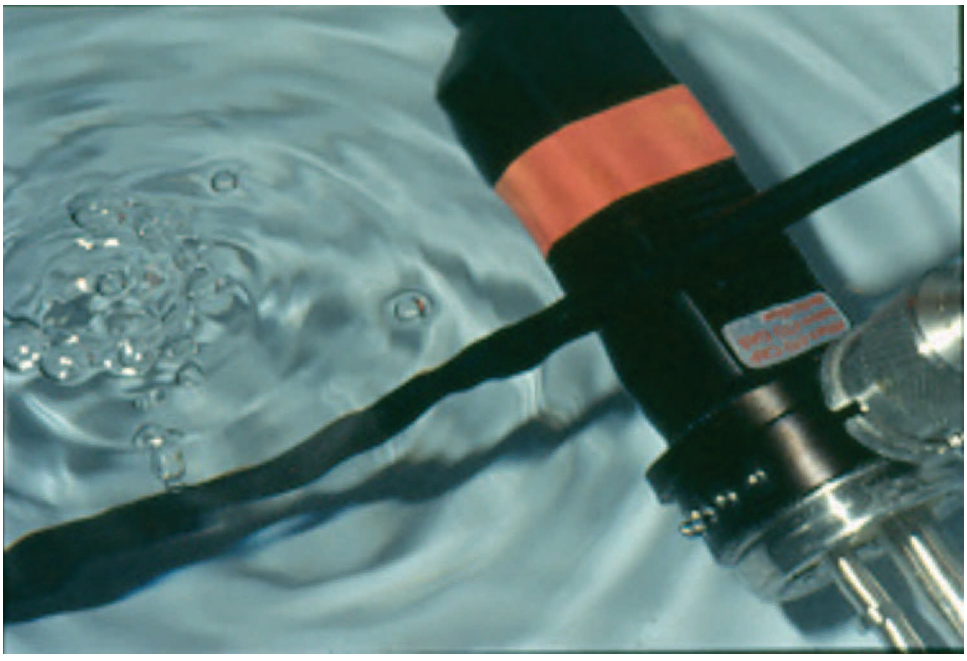

FIGURE 4. Positive leak test result. Air bubbles emitting from the surface of the bronchoscope indicate a breach in its exterior.

Rigid Bronchoscope

The rigid bronchoscope and ancillary equipment are made of durable steel or other metals. They can be steam-sterilized using standard autoclave methods of sterilization. Therefore, the potential for a rigid bronchoscope to be a vector of infection is minimal to nonexistent.

SECONDARY MEASURES OF INFECTION PREVENTION

Secondary measures of infection prevention are often overlooked but become increasingly important for infection control during FB since total interdiction of pathogen transmission is impossible. Factors that increase the propensity for infection to be spread by bronchoscopy include increasing frequency of the procedure, duration and complexity of the procedure, the expanding population of immunosuppressed patients, economic pressures, and the hardiness of the pathogens. A review of prior outbreaks suggests that a large proportion of cases in each instance might have been prevented with earlier recognition of the problem. The mainstay of recognition, therefore, is effective pathogen surveillance. Each institution should develop bronchoscopy-specific protocols for surveillance for microbiological

Table 5—*FDA and CDC Public Health Advisory

1. Follow the instructions for cleaning the endoscope provided by the manufacturer.
2. Check with the manufacturers of the endoscope to determine whether the endoscope can be reprocessed in an AER. Also, check with the manufacturer to determine whether any specific steps are required prior to a specific type of endoscope being reprocessed in an AER.
3. Compare the reprocessing instructions provided by the endoscope and AER manufacturers and resolve any conflicting recommendations.
4. In the absence of specific technical instructions on automated reprocessing for each model of endoscope used in the facility, be sure to follow the manual reprocessing instructions of the endoscope manufacturer as well as the recommendations of the manufacturer of the chemical germicides at the facility.
5. Regardless of manual reprocessing of the endoscope or use of an AER, consider incorporating a final drying step in the protocol.
6. Ascertain that the instructions of the facility for preparing endoscopes for patient contact are appropriate and that the staff is adhering to these instructions.
7. Provide comprehensive and intensive training for all staff assigned to reprocessing endoscopes to ensure that they understand the importance of proper reprocessing of all endoscopes used in the facility.
8. Implement a comprehensive quality control program.

*Infections from endoscopes inadequately reprocessed by an AER system.

isolates. Input from bronchoscopists, infection control specialists, and microbiologists is ideal. Relying solely on individual practitioners to quickly identify trends in isolate patterns will prolong outbreaks, especially for users of shared facilities.

Because the diagnostic bronchoscopy is often performed to evaluate patients with fever, abnormal radiographic findings, and/or other signs of possible infection, it is not always possible to conclude with confidence that FB has caused an infection since these clinical indexes may wax and wane. If either a "true" or a "pseudo" infection is encountered, the bronchoscopy team must inform the institutional infection control officer, the bronchoscope manufacturer, the state health department, the FDA MedWatch program, and the CDC, as well as the patient(s) and referring physicians. If contamination is suspected, the instrument must be removed from service immediately and an investigation begun by culturing parts of the bronchoscope, hospital tap water, and reprocessing equipment. On the basis of this initial assessment, the infection control team and bronchoscopy personnel should proceed as needed to assess and ameliorate any breach in infection control practices. The use of routine environmental microbiological testing of bronchoscope for quality assurance has not yet been established.

Conclusions

Spread of infection during FB is underrecognized and underreported. Unless proper infection control practices are observed, the increasing numbers of procedures performed are likely to be associated with more frequent episodes of infections attributed to bronchoscopy. Even though the reported incidence is quite low, lethal outcomes can result. Prevention of BAI requires increased vigilance by physicians, assiduous implementation of reprocessing protocols, and closer collaboration between bronchoscopy personnel, infection control practitioners, microbiology laboratories, and instrument manufacturers. Formalized institutional monitoring of isolate patterns and epidemiologic analysis may aid in the early detection of potential epidemics. The use of molecular biology techniques such as DNA fingerprinting can help confirm such occurrences. Finally, future innovations in bronchoscope design will require attention to the principles of infection control. The bronchoscopist, health-care providers involved in bronchoscopy, and equipment manufacturers should actively continue to develop techniques and systems to prevent infections from FB. The following definitions and discussion are useful.[104]

Definitions

Critical Devices: Devices that normally enter sterile tissue or the vascular system (eg, cardiac catheters, biopsy forceps).

Semicritical Devices: Devices that come in contact with intact mucous membranes and do not normally penetrate sterile tissue (eg, endoscopes).

Noncritical Devices: Devices that do not ordinarily touch the patient or touch only intact skin (*eg,* stethoscopes or patient carts).

True Infection: Transmission of organisms during bronchoscopy causing new related illness in the patient under going the procedure.

Pseudoinfection and Pseudoepidemic: Isolation of transmitted organisms in the bronchoscopy specimens obtained from the patient or patients, without evidence of specific infection.

Low-Level Disinfection: Process that inactivates most bacteria, some viruses, and some fungi.

Intermediate-Level Disinfection: Process that inactivates *M tuberculosis*, vegetative bacteria, most viruses, and fungi

High-Level Disinfection: Process that achieves 6-log reduction in mycobacterial burden.

Sterilization: Complete elimination of all forms of microbial life, including bacterial and fungal spores.

Recommendations for Precleaning, Disinfection, and Postprocessing of the FB

The following prerequisites are required: (1) proper education and training, and (2) personal protective equipment must be worn.

Precleaning

Immediately After Use (at the Bedside): (1) Flush water or saline solution through the channel for 20 s, making sure that the distal tip of the scope does not rest in the fluid without suction being applied; (2) wipe external surface of scope with wet gauze to remove any loose debris; and (3) place contaminated scope loosely in a sealed water-tight bag labeled biohazard, for transportation to the cleaning area, if necessary.

Cleaning, Disinfection, and Preparation

The following procedures should be followed: (1) Immediately after use (at beside), flush water or saline through the channel for 20 s making sure that the distal tip of the scope does not rest in the fluid without applying suction. (2) Transport the instrument to a processing area as soon as possible to avoid drying of debris over the instrument. (3) With proper personal protective equipment worn, remove the instrument from the bag and place it in the basin for precleaning after placing water-tight caps on to protect electrical components. (4) Remove all disposable parts (suction/biopsy valve). (5) Perform leak test before immersing the instrument in water. (6) Any instrument that fails the leak test must be removed from service until repaired. (7) Add enzymatic cleaner to the water and soak the instrument for 5 min. (8) Using the enzymatic solution, wipe external surfaces with wet gauze and flush the suction channel. (9) Insert an appropriate-size cleaning brush through the channel of the instrument and brush all ports until there is no more visible debris being removed from the instrument. Flush the channel again to remove all loosened material. (10) Drain the enzymatic solution from the basin. (11) Rinse all internal as well as external surfaces with water to prepare the instrument for disinfection.

High-Level Disinfection: For high-level disinfection, do the following: (1) Place the bronchoscope in either an AER or a basin used for manual disinfection. (2) Use only detergents and FDA-cleared disinfectants that are compatible with the bronchoscope as well as the reprocessor. Minimum effective concentration of the disinfectant solution must be checked with each cycle using the available test strips. (3) While using the AER, ascertain that proper connections are made with the internal channel of the instrument for the flushing of the disinfectant. (4) The bronchoscope is fully immersed in the disinfectant solution, exposing all surfaces to the solution for the proper time required. With the manual system, the channel is filled with the disinfectant using a syringe containing the solution.

Postprocessing Procedure: The following steps should be followed: (1) Once the proper time for the is met for high-level disinfection, the bronchoscope and its channel are rinsed with either sterile or filtered tap water according to the recommendations disinfectant supplier. (2) Proper drying of the channel is accomplished by purging 70% alcohol with forced air. (3) Remove the water-tight caps from the instrument and hang vertically in a storage cabinet devoid of any valves. (4) Proper documentation related to the use and the disinfection of the instrument (medical record number of the patient, date of the procedure, bronchoscopist performing the procedure, model and the serial number of the scope, and the date of reprocessing) is maintained for infection control purposes.

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