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Infection control of lung function equipment: a practical approach

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Summary The degree of risk of cross-infection of patients via lung function testing equipment has yet to be quantified. Based on current evidence, elaborate precautions are not justified for the majority of patients attending the laboratory, but attention to appropriate routine cleaning and disinfection protocols is important.

Disinfection and sterilization can be achieved by a variety of methods, although chemical methods should be used with caution. Identification of factors increasing the susceptibility or infectivity of particular patients is important in determining appropriate precautions. Where patients are known to be infectious or are immuno-compromized, additional precautions such as using a barrier filter may be appropriate. However, because of cost constraints, the routine use of barrier filters is difficult to justify based on current evidence of minimal cross-infection associated with lung function equipment. Until further studies have been conducted to quantify the degree of risk of cross-infection that lung function test equipment poses, the recommendations given in this review provide a practical approach to dealing with this problem. © 2003 Elsevier Ltd. All rights reserved.

Introduction

Within the lung function laboratory, expensive testing equipment is used, with sometimes large numbers of patients being tested on the same day. A patient may undergo a range of tests, including measurement of expiratory flow and volume, invasive blood gases, sleep studies and the assessment of response to inhaled medication or bronchial provocation agents using nebulizers. Lung function measurements are not, however, just restricted to the laboratory, as a range of assessments and treatments can be carried out in the patients own home, including sleep studies, treatment for breathing disorders during sleep and expiratory flow.

Patients attending the laboratory may be infectious, whilst others may be more vulnerable to infection, such as those undergoing immunotherapy. Organisms may persist within the equipment, and in some cases the equipment itself is difficult to clean thoroughly. There is therefore a potential risk of cross-infection between patients undergoing lung function tests, including arterial blood gases. Whilst this potential risk exists, there is little evidence that lung function equipment poses a significant risk, and case reports of cross-contamination are exceptional. Whilst the potential risk is recognized, the experts themselves cannot agree on the magnitude of the potential risks or on how to deal with them, with some of the recent recommendations being empiric rather than being based on scientific data.[1–3]

With the increasing awareness of patients, patient advocate groups and healthcare workers to the possible risks, there is a need for clear procedures to be in place to reduce possible risks to

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a realistic minimum. It is therefore surprising that few recommendations exist.[1–9] Furthermore, even when they exist, lung function laboratories and infection control departments appear to adopt different approaches to solve the same problem, as illustrated by two published audits.[10,11]

This review outlines the potential sources of cross-infection; our current understanding of cross-infection risks in the lung function laboratory and equipment used in the home, the methods of disinfection and sterilization available and concludes with practical recommendations and suggestions for future research.

Organisms possibly implicated in cross-infection

Communicability of a disease within a lung function laboratory is determined by numerous factors. These include: (a) the source of the organisms, e.g. blood, saliva; (b) the persistence of viability outside the host; (c) the routes of infectivity; and (d) the actual infective dose required to infect the host and cause disease. Many factors further affect the dose required to result in disease, including the clinical condition and immune status of the subject and the particle size of aerosols encountered during respiratory testing.

Tuberculosis

Transmission occurs from organisms suspended in droplets. These droplets may be produced by coughing and possibly via forced expiratory manoeuvres by patients with pulmonary tuberculosis.[12,13] Droplets containing *Mycobacterium tuberculosis* may remain infectious for many hours. Droplets will remain airborne longer if small, but in general, organisms will remain viable longer in larger droplets. In view of the increase in multi-drug resistant tuberculosis infections, cross-infection of these organisms is causing concern.[14]

Burkholderia (Pseudomonas) cepacia

This motile gram-negative bacillus is not normally a pathogen in humans, but it is associated with marked respiratory function deterioration in cystic fibrosis (CF) patients. In CF patients, there is considerable patient-to-patient spread.[15,16] The CF Trust of Great Britain has recommended that *B. cepacia* positive patients be separated from those who are *B. cepacia* negative. Furthermore the Trust has defined medium risk (handshaking, social kissing) and high risk (sharing eating or drinking utensils and intimate contact) activities.[17] As these patients need to have lung function monitored regularly, the risks of cross-infection between patients must be assessed.[17]

Methicillin-resistant Staphylococcus aureas (MRSA)

This presents particular problems in lung function laboratories with the relative ease of transmission from patient-to-patient, potentially via fomites including equipment. Whilst recommendations exist for controlling the spread of MRSA,[18] it has been argued that trying to control the spread is unlikely to be cost-effective in many situations and is either unrealistic or ineffective in many cases.[19,20] Measures to minimize transmission are based on good basic hygiene, including hand washing, good-quality cleaning and ensuring that the work surfaces, floors and walls of the department are suitable for cleaning with appropriate cleaning agents. Lung function equipment also needs to be easily cleaned on the outside. Carpets, curtains should be kept to a minimum in laboratories.

Acquired immune deficiency syndrome (AIDS)

Whilst the possibilities of transmission of pathogens via respiratory function equipment were recognized,[21] the perceived risks were magnified with the concerns about infection by the human immunodeficiency virus (HIV). This led to considerable anxiety and the drive for "safer" lung function laboratories and equipment.[22,23] The reality, however, is somewhat different. Although fragments of the HIV virus are found in human saliva,[24] there is no current evidence to suggest that HIV is transmitted from saliva or expired gases or via respiratory expirates.[25] The few reported cases of transmission between patients and dental workers are more likely to have occurred through transmission via blood rather than via saliva.[26] In the "Florida Dentist" outbreak, the mode of transmission remains unknown.[27] Despite these observations, salvia is unlikely to a medium for transmission of HIV infection, as the infection is not acquired by kissing.

Hepatitis

There are five recognized hepatitis viruses (A, B, C, D and E). Of these, hepatitis B (HBV) poses the main risk to healthcare workers. In its acute form, it is transmitted via blood that contains a high

concentration of viral antigens. The risk of transmission is about 12–17% via accidental needle-stick injuries, but may exceed 30% in unvaccinated individuals. Healthcare workers with frequent blood contact are at greatest risk.[28]

HBV may occasionally also be transmitted via saliva as the HBV antigen has been identified in saliva.[29,30] Acquisition of HBV infection by oral ingestion has been described, but only if the viral dose is high.[31] There is no current evidence that HBV is transmitted via expired breath.

Hepatitis C has a similar mode of transmission to HBV but is less infectious.[32] The other bloodborne hepatitis virus, D, can only infect individuals with HBV infection. It is prevalent in the Mediterranean area, Africa, South America and the Middle East but rare in Western Europe.

Rhinovirus

Transmission of rhinovirus generally results from deposition of the virus on surfaces during sneezing or coughing and subsequent hand-to-nose manoeuvres, although aerosol transmission between subjects in close proximity has been observed.[33]

Other upper respiratory tract flora

The upper respiratory tract of healthy children and adults contain a wide range of flora including *Haemophilus influenzae, Branhamella catarrhalis and Streptococcus pneumoniae*. Whilst not presenting a major problem to the majority of patients undergoing lung function tests, they may pose problems to immuno-suppressed patients, or those compromised by other respiratory illness.

Hospital water supplies

It is well documented that hospital water supplies can be contaminated with Mycobacteria and *Pseudomonas aeruginosa* organisms.[34–39] There is potential for patients and healthcare workers to deposit microorganisms onto equipment surfaces, which may subsequently come into direct or indirect contact with other patients. Where patients have competent immune systems, this is unlikely to be an appreciable threat from drinking water used for hand washing.[38] However, in some patients, such as those with cystic fibrosis, there may be increased risks.[36]

Legionella

This is a gram-negative bacillus found worldwide in lakes, air conditioning cooling towers[40] and water systems.[41–43] Patients at risk are the elderly and those with compromized cellular immunity or respiratory function, such as smokers. Its mode of transmission is by inhalation of aerosols. To this extent, care needs to be taken when using nebulizers as these have been shown to act as a source of transmission.[42,43]

Current knowledge regarding lung function equipment

The potential to grow pathogens in lung function equipment and the subsequent transmission of pathogens via this equipment has been reported in few studies. Up to 1980, no reports of nosocomial transmission of disease via lung function equipment had been reported to the Center for Communicable Disease.[4] This may be because few, if any, cases have been linked to cross-infection caused by lung function equipment, publication bias, the impracticality of performing large scale monitoring studies, and probably the lack of enthusiasm for this type of study. This has resulted in no evidence base to demonstrate risk at the clinical level.

Spirometers

Houston et al.[44] assessed the Vitalograph tubing using discrete swabs from various locations and observed a range of flora, none of which were significantly pathogenic. Leeming et al.[45] carried out a similar study using Vitalograph tubing but washed the inside of the tube with a broth. No significant pathogens were obtained. Similarly, Rutala et al.[46] and Marchant et al.[47] observed that low numbers of respiratory flora were present in spirometers. In contrast, Singh et al. reported significant bacterial contamination of spirometer tubing, including *Aspergillus* and acid-fast bacilli.[48] Marchant et al.[47,49] suggested the use of apparatus similar to that recommended by Denison et al.[23] in patients with cystic fibrosis where an inspiratory flow-volume curve is required.

Burgos et al.[50] noted that colonization of water-filled spirometers occurred within 3 days of use, mainly in the distal tubing, the water and the bell itself. They could not demonstrate any transmission sequence from machine to patient. A few colonies of microorganisms were obtained from a heated Lilly pneumotachograph.

Recently, Hiebert et al.[51] demonstrated that *Escherichia coli* introduced as an aerosol into spirometry tubing could be recovered from air drawn from the proximal end of the spirometry

tube only transiently (1–2 min after inoculation). No *E. coli* was recovered after 5 min. No assessments of flow-based systems were performed, and this remains an area for further investigation.

Ultrasonic spirometers, where the parts of the flow head are in contact with the patient and their exhaled air are replaced after each patient do not appear to become contaminated.[52] Similarly, some newer spirometers are employing disposable, pre-calibrated flow heads, thus reducing the risk of cross-infection. There is no data currently available on unheated pneumotachographs, turbine spirometers or hot-wire spirometers.

Two publications have presented circumstantial evidence of the transmission of infection by respiratory function testing equipment, although in neither case was the aetiological agent recovered from the implicated instrument.[12,53] In the first case, one of 22 patients who used the test device after use on a patient with pulmonary tuberculosis converted from tuberculin skin test negative to positive within 10 weeks. The organism was not isolated from the secondary case or the spirometer.[12] In the study by Gough et al.[53] intermittent outbreaks of infections on a ward with a specific strain of *H. influenzae* did not recur after a one-way valve and barrier filter were used in the spirometer circuit. Again, no organisms were recovered from the spirometer tested before insertion of the filter.

Peak flow meters

Despite their common use, only one study has assessed the contamination of Mini-Wright peak flow meters.[54] This study found fungal contamination in regularly used meters although their mechanical operation was not affected and no incidents of cross-infection were reported. Whether there are any long-term effects of repeated use of contaminated meters is unclear, particularly since they now form an integral part of self-management. Other commercially available peak flow meters have not been assessed.

Meters such as the Mini-Wright often include a plastic flap which prevents subjects from inhaling from these devices, thereby reducing the potential for cross-infection where these devices are used in hospitals with different patients.

Lung volumes and gas transfer equipment

There are few reports assessing the microbiological contamination of equipment used to measure static lung volumes.[21,46] Whilst these reports have shown that mouthpieces and proximal tubing are likely to

be contaminated neither showed evidence of contamination of the interior surfaces of a volume displacement spirometer.

No reports appear on the potential for cross-infection from body plethysmographs or gas transfer equipment. Whilst the parts of the test circuit directly in contact with the patient will be contaminated with condensation, the internal surfaces of both rolling-seal spirometers and heated pneumotachographs appear to be free from contamination. With heated pneumotachographs, this may be due to maintaining a dry environment hostile to microorganisms and may reduce the time period organisms remain viable. This would concur with the findings of Burgos et al.[50] However, in unheated pneumotachographs, condensation can form on the resistive screen, thereby providing a suitable environment for organisms to grow.

Organisms do not appear to survive inside rolling seal spirometers. It has been suggested that where soda lime absorbers are used, the soda lime is sufficiently caustic to kill contaminants as they pass through the absorber. However, the circuit proximal to the absorber may still be contaminated.

Nebulizers in therapeutic use

Large volume nebulizers and humidifiers have frequently been associated with the episodes of hospital-associated pneumonia and outbreaks of nosocomial disease. Small volume nebulizers are increasingly used in respiratory laboratories, hospital wards and in the home, in both adult and paediatric practice and in acute and domiciliary settings for a variety of respiratory disorders.[55,56]

There is no direct evidence that these nebulizers are responsible for the acquisition of infecting organisms that lead to increased length of hospital stays or increased hospital admissions when guidelines for use and cleaning have been followed. However, studies have shown that nebulizers can harbour a variety of microorganisms, even when patients and hospital staff have cleaned the devices correctly.[43,44,56–67]

Of prominence are the studies on patients with cystic fibrosis.[57–60] Pitchford et al.[58] observed contamination of home inhalation equipment with *Pseudomonas* species. Furthermore, they noted that there was reinfection in patients with CF colonized with *S. aureus* and *P. aeruginosa*. This reinfection appeared to be reduced by regular changing of equipment and use of cleaning agents. Kuhn et al.[59] investigated nebulized drugs used by CF patients and observed *Bacillus cereus* contamination of these dispensed solutions for home used

within 5 days of dispensation. Hutchinson et al.[60] isolated *B. cepacia* from about 10% of home nebulizers, but whilst *P. aeruginosa* was present in virtually all patients, it was not observed in their nebulizer chambers. In most cases, the heaviest contamination appeared beneath the baffles. This appeared to be reduced in patients with good nebulizer hygiene, including drying the nebulizer after washing. It was concluded that nebulizers are likely to be the primary source rather than sites of secondary contamination derived from the patients' secretions. This is in contrast to nebulizers in mechanical ventilator circuits, which tend to be used for shorter periods but which have been observed to become contaminated with bacteria from patients' respiratory tract.[61]

In patients with asthma and COPD, most of who will be using nebulized bronchodilators, few studies in the home have been performed.[62–66] Higgs et al.[62] noted contamination and observed that cultures were composed of non-pathogenic organisms. Jones et al.[63] observed about two-thirds of nebulizer solutions were contaminated with pseudomonads, whilst Barnes et al.[64] and Childs and Dezateux[65] observed home nebulizers were contaminated with various flora, including *B. cepacia*.

Recently, we have observed that nebulizer chambers returned during normal outpatients' assessments were contaminated with mixed gram-negative bacilli.[66] In this study of 23 patients with COPD or asthma, only 11 patients cleaned their nebulizer chambers after each use and six cleaned them fortnightly or less. Comparing visual inspection with microbiological assessment showed agreement with the level of contamination in only 7/23 chambers. In particular, many chambers yielded heavy microbiological growths, but appeared visibly clean. In a review of their nebulizer service, Smyth et al. observed that only 29% of patients washed their chamber after every use and 21% had never washed the chamber over the previous 12 months.[67]

To date there is no data investigating the problems of colonization of small volume nebulizer chambers in hospital wards or lung function departments. Since many patients admitted to respiratory wards will stay for extended periods, there is the potential for significant contamination to occur.

Environmental contamination: The sources of contamination of nebulizers in home use have not been fully established in CF, asthma or COPD, and in particular, the areas used for cleaning nebulizers and dispensing drugs. In the hospital environment, no data is available on the range of microorganisms already present in the environment surrounding the site of nebulization or in the drug preparation and cleaning areas.

Risks of contamination: There is no evidence that nebulizers are responsible for the acquisition of infecting organisms that lead to increased length of hospital stays or increased occurrence of hospital admissions for patients with CF, asthma or COPD. Clearly, there is a potential risk of infection of patients from nebulizers, and possibly from nebulizers to other patients or family members. With the increasing awareness of patients and health-care workers to the possible risks, there is a need for procedures to be in place to reduce these risks to a realistic minimum.

Nebulizers in diagnostic use

Nebulizers are used for a variety of diagnostic procedures, of which the principle one in lung function laboratories will be bronchial challenges.[68] No recommendations were given on cleaning nebulizers used in these challenges. It was recognized that some laboratories use the same nebulizer solutions and the same nebulizers on different patients. In some set-ups, this may result in patients inhaling a previous patient's exhalate or an aerosol of their secretions. Again, there is no data on this being a risk factor for cross-contamination, but is of obvious concern.

Blood gas analyzers

Blood gas analysis poses specific risks, mainly of needle-stick injuries. There are a few reports of infections resulting from contaminated equipment used for collecting and analyzing blood gas samples.[69–74] Care must be taken in the handling of the blood samples, maintenance of the blood gas analyzer and its surrounding environment must be regularly cleaned and any spillages mopped-up immediately.

Methods of disinfection and sterilization

A variety of methods exist for the disinfection and sterilization of equipment (Table 1). Having determined whether disinfection is sufficient or sterilization is required, the choice will depend upon ease of use, compatibility with equipment and ultimately cost. Despite the trend to centralize decontamination services to improve process control, methods that are available within and under the control of the laboratory are often preferred by users since costs can be minimized and turn-around of equipment is rapid. This obviates the need for large stocks of reusable items.

Table 1 Comparison of decontamination methods.

Method	Applications	Advantages	Disadvantages	Range of kill
Hand-hot soapy water	Small items—tubing, mouthpieces, facemasks	(1) In department (2) Removes organic & inorganic debris	(1) Requires clean area (2) May require additional use of alcohol-impregnated cloths	Physically removes microorganisms
Commercial washer disinfector	Small items—tubing, mouthpieces, facemasks	(1) In department (2) Easy to use (3) Pre-cleaning not normally required (4) Dries items	(1) High initial cost (2) Requires specific electric supply	Vegetative bacteria, most viruses, TB (equivalent to pasteurization)
High-temperature steam (usually 134°C or 121°C)	Heat-stable items—items with lumen if vacuum cycle used	(1) Items can be wrapped Dries item	Not "on site" (necessitates large stock of items)	Sterilizing method
Low-temperature steam (LTS; approx. 73°C)	Moderately heat-stable items—items with lumen (vacuum cycle), e.g. tubing, mouthpieces, facemasks	(1) Items can be wrapped (2) Dries item	Not "on site" (necessitates large stock of items)	Vegetative bacteria, most viruses, TB, not hepatitis B
Alcohol-impregnated cloths	Small items that can be easily wiped and work-surfaces	(1) Easy to use	(1) Efficacy dependent on thoroughness of user (parts of article easily missed) (2) Exposure times achieved usually very short	Vegetative bacteria, enveloped viruses (if contact time is sufficient)
Chlorine-releasing agents	Items immersed for 15–30 min	(2) In department (3) Rapid process	(1) Items not dried (2) Corrodes most metals (3) Inactivated by organic matter	Vegetative bacteria, viruses
Activated 2% gluteraldehyde	Items damaged by heat or other chemicals (e.g. flexible endoscopes)	(1) In department (2) Very good material compatibility	(1) Items not dried (2) Respiratory and cutaneous toxicity (requires fume cupboard)	Vegetative bacteria, viruses including HIV and hepatitis TB after 40–60 min exposure Bacterial spores after 3 h

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				Sterilizing process	(1) & (2) used as chemical sterilants (3) Vegetative bacteria, TB viruses
Ethylene oxide	As gluteraldehyde	(1) Items can be wrapped (2) Items left dry	(1) Limited availability + long turn around (necessitates large stock of items)		
(1) Chlorine dioxide	As gluteraldehyde		Relatively expensive (1) & (2) more corrosive than Gluteraldehyde		
(2) Peracetic acid	Similar to gluteraldehyde, but less toxic				
(3) Orthophthal-aldehyde					

A commercial dishwasher, providing disinfected, clean and dry items may be a suitable long-term investment. In the UK, performance specifications and maintenance schedules for washer-disinfectors are given in HTM 2030.[75]

Whatever method is used to decontaminate equipment, it is important to note the manufacturer's recommendations on material compatibility, the number of times each piece of apparatus can be decontaminated before significant structural deterioration is experienced, and any other cautionary notes. Where chemical methods are used, the correct dilution for the application must be determined, and the length of time each item is immersed should be followed with care. Working solutions of chlorine-releasing agents should be discarded immediately after use, or at the least on a daily basis, even if unused. Gluteraldehyde (2%) may, within limitations, be reused for up to 2 weeks, but its effectiveness declines due to dilution when used in a washing machine. At 1% or less, adequate disinfection cannot be guaranteed.

Health and safety issues must also be considered. Gluteraldehyde, for instance, must be used with good extract ventilation and personal protective equipment since up to 30% of exposed staff become sensitized. The low occupational exposure limits that have recently been introduced mean that the use of gluteraldehyde is no longer practicable in most respiratory departments. A number of less-irritant alternatives to gluteraldehyde for high level disinfection are now available.[76,77]

Barrier filters

Barrier filters have been heralded by some as the solution to reducing the risk of infection from lung function equipment, where the subject has to breathe via a mouthpiece from a breathing circuit.[49,78] Filters have been used for many years in intensive care units, but their use in lung function laboratories has occurred only recently.

The choice of filter is important. Early filters were reported to have high bacterial retention rates.[79] However, the methods used to assess bacterial retention have been questioned, and these filters were subsequently shown to have a bacterial retention efficiency of about 67%.[80] Recently, filters using more efficient filter media, have been demonstrated to be about 99.9% efficient using flow rates up to $750\,l\,min^{-1}$ and about 97% efficient at removing bacterial colony forming particles when patients perform forced expiratory manoeuvres through them.[81] In a comparison of six filters, the efficiency of removal of

P. aeruginosa from air containing 1×10^4 CFU ml^{-1} ranged from 27.7% to 100%.[82] The threshold above which some bacteria passed through the filters ranged from 1×10^8 to $<1 \times 10^4$ CFU ml^{-1}.

Placing an efficient barrier filter between the patient and the respiratory circuit will not only provide protection to the entire circuit from contamination with exhaled microorganisms, but will also protect the patient from inhaling particles from within the circuit. Furthermore, as sensors are now being placed closer to the patient, they will provide protection to these delicate components from exhaled particulates. However, no filters are 100% effective, and their use does not preclude the need for adequate cleaning of the equipment.[83]

Barrier filters have been shown to reduce peak flow, but have little effect on measures of timed forced expiratory volume.[84–89] The reductions in peak flow and in dynamic lung volumes are small (2–4%) and clinically insignificant. There are no reports of the effectiveness of filters in reducing or eliminating nosocomial transmission of disease during measurements of absolute lung volumes, gas transfer or during exercise. However, if filters minimize risks during forced respiratory manoeuvres, then they should work for these other test procedures.

For measurements of CO transfer factor, the additional dead-space of the filter will need to be included in the calculations. Similarly, where airways resistance is assessed, either in a body plethysmograph or using forced oscillometry techniques, then the added resistance of the filter needs to be taken into account. During exercise tests, the aim will be to keep both the circuit resistance and dead-space as low as possible, especially when assessing perception of breathlessness.[90]

There is also no data on the effects of these filters when used over a series of test procedures on a single patient, although repeated expiratory blows do not appear to increase flow resistance.[91] This is important as some laboratories use a new filter for each patient, whilst others use a single filter for a whole day or week. Use of the same barrier filter for multiple patients could result in patients inhaling organisms entrained in the filter medium following previous use. Thus, there is an argument for the routine, single patient use of filters for respiratory function tests.[91]

Costs

One factor in deciding which methods of infection control to apply in a laboratory will be cost. Whilst everyone is aware of this, there is little data comparing the costs of the various forms of infection control available to lung function laboratories.

Side et al.[91] published a cost comparison of filters versus the current Thoracic Society of Australian & New Zealand (TSANZ) guidelines.[8] This analysis showed that in a busy laboratory the cost per test of using a barrier filter was on average about 5 times cheaper than the implementation of the guidelines. If, as the authors assume, we accept that the universal precautions approach taken by the TSANZ guidelines offer a comparable degree of protection to the use of barrier filters, then the use of filters is a sensible cost-effective alternative to cleaning and disinfecting equipment between patients.

An alternative approach is to use a commercial instrument dishwasher that provides disinfected, dry items.[92] Although the initial installations costs are high (approximately £11,700) this may be a cheaper option than the use of barrier filters. Based on our current throughput of patients over a 5-year period (21,960 patients) and including maintenance and consumable costs, the overall cost of using a dishwasher would be about £20,600, or £0.94 per patient. This compares favorably with the cost of £1.18 per bacterial filter.[93] Furthermore, it should be remembered that the use of filters does not eliminate the need to clean breathing circuits on a regular basis.[83]

What are we protecting from what?

When deciding what we are trying to protect, it is important to look at the environment, the equipment and the patient. Hospitals by their nature, are dealing with sick, infected and immuno-compromised patients and transmission of pathogens a regular occurrence.[94–99] Individuals walking along a hospital corridor or sitting in a crowded waiting room will incur a finite risk of exposure to a wide range of pathogens.

For the majority of patients, there will be no significant risk of cross-infection from having lung function tests, and they will pose little risk to other patients through contamination of the equipment. As with any risk assessment exercise, the severity of the consequence of cross-infection is important in determining appropriate interventions. In some patients, a common cold may be acquired, but although inconvenient, this would be categorized as a low risk. Tuberculosis would normally be considered a higher risk, regardless of the relative risk of acquisition, because it is a serious infection.

The problem faced by many laboratories is identifying who is infected with significant pathogens and who is at increased risk. One approach is to request this information at the time of referral.

In a recent audit of two teaching hospital laboratories, both of whom request this information before performing any breathing tests, approximately 84% of patients were referred with "no known infection", 10% where immuno-compromized, 2% had a chest infection and the remaining 4% were MRSA+, HEP B/C+, or TB+.[100]

"At risk" patients

Immuno-compromised patients are potentially at greater risk of acquiring a variety of infections, although there is a no evidence that they have an increased morbidity or mortality after lung function testing. It is important, however, to minimize the risks. Precautions can range from the elaborate[21,23] to the simple.[47,78] One approach is to assess these patients at the start of the day when the apparatus has been thoroughly cleaned and dried.

Patients with cystic fibrosis tend to be more susceptible to the risks of cross-infection by certain organisms and precautions should be taken to reduce these risks, although the evidence for cross-infection from respiratory function equipment is not proven. Guidelines to deal with this have been published.[27,101]

Infected patients

Patients with identified infection transmissible by the respiratory route, or who would require isolation if the patient were an inpatient (consult local infection control guidelines), require precautions to be taken. It would be appropriate to question the need for lung function tests, and possibly to limit the range of tests. Where the tests are considered essential for the clinical management of the patient, then the tests should be performed at the end of the day or similar precautions taken for those "at risk".

Overly concerned patients/patient advocate groups

A very small number of patients demand information on the risks of cross-infection from the breathing circuits being explained to them and what precautions are being taken to eliminate all risks of cross-infection. Similarly, some patient advocate groups expect precautions to be taken, despite there being no evidence to suggest a risk exists. For these patients, protocols need to be in place to satisfy them that the risks are reduced to an absolute minimum. Use of a bacteria-retentive filter is normally sufficient to reassure such patients.

Approaches to infection control

Infection control practices adopted by laboratories, and their underlying assumptions might be categorized as follows:

1. *Universal precautions*: All patients are treated as if they were infective to other patients and susceptible to infection carried by these patients. Consequently, it is appropriate to take *stringent universal precautions* to prevent the patient coming into direct contact with the test equipment, either by using specifically designed equipment[12,14] or the use of a barrier filter with every patient.[49,78] There is little current evidence supporting this approach.
2. *Minimal precautions*: Patients are considered to be at no significant risk, regardless of clinical state. With this assumption we would take minimal precautions, cleaning the breathing circuits on a "when it looks dirty" basis or when the equipment surface has visible condensation. Despite the lack of persuasive evidence that respiratory function testing equipment transmits infection, this approach would be considered by many to be inadequate, particularly for potentially susceptible patients such as those with cystic fibrosis.
3. *Evidence-based approach*: Although there is scant evidence of cross-infection in respiratory laboratories,[44–51] risk assessments justify enhanced infection control precautions for some patient groups, including those with an identified respiratory infection or in those who are immuno-compromized. For most patients, simple routine precautions are taken, with additional precautions introduced only for these identified high-risk patients.

Recommendations based on limited evidence are likely to prove controversial. Some guidelines, such as those from the TSANZ[8] have been criticized as impracticable or costly.[91,102] The TSANZ guidelines are summarized in Table 2. It is important that guidelines are readily implemented and cost effective whilst reducing any real or perceived risks of cross-infection to a level acceptable to staff and patients.

Recommendations

The following recommendations cover the range of equipment used in a typical respiratory laboratory, and has proved practical and cost-effective approach to infection control. We have graded these

Table 2 Summary of the TSANZ guidelines for infection control in lung function laboratories from reference 91.

1.	Disassemble equipment to allow the physical removal of particulate matter
2.	Clean thoroughly with a suitable detergent to reduce microbial load
3.	Rinse with tap water to remove traces of detergent
4.	Disinfect according to the Centres for Disease Control (CDC) category of the item—semi-critical items—those coming into contact with mucous membranes such as non-disposable mouthpieces, pneumotachographs and breathing valves should be cleaned and disinfected between consecutive patients; most suitably by immersion in a 70% solution of either ethanol or isopropyl alcohol for 20 min (modified CDC recommendation). Non-critical items—those coming into contact with intact skin or have no direct contact with patients such as closed or open breathing hoses distal to the breathing valve. These should be cleaned daily with a suitable detergent.
5.	Rinse thoroughly with water
6.	Air dry

The effectiveness of the TSANZ guidelines in eliminating the possibility of cross-infection has not been evaluated.

recommendations based on the levels of evidence available in each case[103,104] as follows:

(A) Randomized control trial data.
(B) Well-conducted study, but no randomized control trial.
(C) Expert committee reports or opinions and/or clinical experience of respected authorities.

There are no grade (A) studies in the literature. The majority of opinion comes from expert committees or clinical experience, and that itself appears to be based on empiric rather than experimental or trial-based evidence. To this extent, we have marked those recommendations as (C). The recommendations are summarized in Table 3, with the relevant explanation and evidence given in the following review.

Single-use, single-patient use and reusable items

Equipment used in departments and in patient's homes, such as nebulizers, are usually classified as single-use, single-patient use or reusable and in Europe manufacturers are required to mark their products as such. Single-use items should be used once only and then discarded.[105] Single-patient use items may be used by the same patient repeatedly, with cleaning taking place after each use. Reusable items can be used on different patients as long as appropriate reprocessing, as indicated by the manufacturer, is followed. This categorization means that both the manufacturer and the laboratory manager need to define the extent and the methods by which "single-patient use" and reusable devices should be used and reprocessed. Advice should be obtained from the manufacturer as to appropriate methods of reprocessing and the number of times each device should be reprocessed.

Adherence to the stated category of equipment use should occur at all times. Where this is impracticable, changes can only be made based on consultation and agreement with the manufacturer and employers' safety committee (C).

Determining infectivity and susceptibility of referred patients

Where a patient has a known infection, such as MRSA, TB or a chest infection, or the patient is immuno-compromised this should be indicated on the form requesting respiratory function tests. Space should be allocated for this on the request form and must be completed by the referring clinician to the best of their knowledge. The reliability of information given on request forms would be a suitable topic for local audit to ensure that the system is identifying as many high-risk patients as is practical. Where the patient does have a known infection, it may be appropriate to question the urgency and need for these tests. If the tests are essential for the clinical management of the patient, then additional precautions may be required, over and above normal laboratory practice. Precise precautions, including the use of barrier filters, gowns, gloves, etc., and the disposal or sterilization of equipment should be formulated in conjunction with the local Infection Control department and the equipment manufacturer, and should be appropriate for the infectivity and severity of the potential infection.

According to local circumstances, patients with known infections may be tested: (a) on equipment that is easily disinfected, (b) at the end of the day, (c) in their own room or in rooms specifically designed for such patients, or (d) using of a barrier

Table 3 Summary of recommendations on infection control in lung function departments.

	Recommendation	Grade
Single-use, Single-patient use and re-usable items	Adhere to the stated category of equipment use at all times. Category changes can only be made after consultation and agreement with the manufacturer and employers' safety committee	C
Precautions for infectious patients	Patients with known infections may be tested (a) on disease-specific equipment, (b) at the end of the day, (c) testing the patients in their own room or in rooms specifically designed for such patients, or (d) use of a barrier filter in combination with (a)–(c). Use of barrier filters is highly recommended for patients with serious infections spread by the airborne route such as TB	C
Handwashing	Wash hands between patients with soap and water or antiseptic preparation	B
Cleaning of surfaces, sanitary and washing facilities	Clean at least daily, using appropriate cleaning agents	B
Nebulizers and cone spacers	Should be cleaned and dried between use, where single-patient use or reusable chambers are used	B
	Patient education for home use is essential	C
Medications and fluids	Use single-dose drug preparations, single-patient use devices, sterile water and rigorous protocol	B
Blood gas analysis and blood gas analyzers	Use national guidelines for the handling and processing of blood samples and the use of blood gas analyzers	B
Mouthpieces	Change between patients. Clean appropriately or discard	B
Noseclips	Use rubber noseclips and clean with alcohol wipes between patients	C
Peak flow meters	Use as single-patient use at home. In laboratories use one-way mouthpieces or filters where inspiration is not required	C
Breathing circuits	Tubing—clean regularly. Patient valves—clean between patients with alcohol wipes. A barrier filter may be useful for infectious or immuno-compromised patients where patients handle equipment there is an increased risk of cross-infection	C
	Wipe equipment with alcohol-impregnated wipes between patients	B
Water-sealed spirometers	Change water every 2 days for water-sealed spirometers	B
	Rolling seal, heated pneumotachographs—minimal cleaning required, remove dust	B
Exercise testing equipment	Wipe down treadmill or bicycle at the end of each testing session	C
	With invasive blood gas analysis—as for blood gas analyzers	B
	Breathing circuits—as above. Replace breathing valves between patients and clean using appropriate techniques for the heat sensitivity and chemical sensitivity	C
Sleep study equipment	Clean probes and reusable electrodes between patients using alcohol wipes	B
	Washable components—chest wall belts, CPAP head caps, etc., should be washed in a washing machine to the highest temperature possible	C
	CPAP components—reuse within the manufacturers guidelines, e.g. low-temperature steam treatment	C
Domiciliary equipment	Patient education on the handling and cleaning of equipment is essential	C

filter in combination with (a)–(c). Use of barrier filters is highly recommended for patients with serious infections spread by the airborne route such as TB (C).

Handwashing

This is the single most important step in preventing nosocomial infections. After dealing with each

patient, hands should be washed thoroughly with soap and water or with an appropriate antiseptic soap (B).

Cleaning of surfaces

Despite the current practice of reducing costs on cleaning and hygiene,[97] work surfaces, floors and washing facilities should be washed daily with detergent. The surfaces of equipment should be cleaned daily, particularly parts that patients may handle during testing. Spills of blood or other body fluids must be cleaned up immediately according to local guidelines (B).

Nebulizers, Cone Spacers and metered dose inhalers

Nebulizer chambers are classified as single-use, single-patient use or reusable. Single-patient use devices may be used repeatedly by the same patient, with cleaning and drying taking place between each nebulization. Reusable chambers can be used on different patients as long as appropriate reprocessing occurs. The manufacturer should provide advice on the number of times that a chamber can be reprocessed and what agents should be used. Whatever agent is used, the effect of cleaning must not significantly affect performance.

Cone Spacers are either single-patient or reusable, and there is currently no evidence of a risk of cross-infection from cone spacers.

In general, most single-patient use and reusable chambers can be cleaned with hand-hot soapy water, rinsed thoroughly and then dried either with a tissue or by blowing air through the chamber.[106] A dishwasher also works very well, without any apparent effect on performance. Drying is probably the most important part of the process to prevent microbial colonization during storage.

Patient education is an essential component of the management of patients using such devices at home, and probably requires re-enforcing at each outpatient follow-up visit (C).

Recently there has been some concern about re-use of metered dose inhalers (MDI). There is no current evidence that there is a risk of cross-infection from the MDI and the suggestion that placebo MDI's should be single-patient use is highly questionable. Manufacturer's must provide evidence to support this.

Decontamination of the MDI holder can be achieved as for cone spacers above.

Medications and fluids

All medications and fluids should be used under aseptic conditions. Only sterile fluids should be used in nebulizers. Where feasible single-dose medication vials should be used for each patient. No medication should be used after the stated expiry date (B).

Blood gas analysis and blood gas analyzers

In view of the hazardous nature of blood, safety precautions on the taking, handling and analysis of blood are paramount. Procedures and safety precautions have been outlined in UK national guidelines on lung function testing[108] and these or equivalent national guidelines should be followed closely (B).

Respiratory function equipment

There is a range of equipment used in the laboratory, wards and outpatient clinics and at home. Recommendations cannot therefore be specific, but the manufacturer's instructions on cleaning equipment should be followed. The ease and costs of cleaning all equipment should be taken into account when new equipment is to be purchased.

Mouthpieces: Where barrier filters are routinely used, the filter itself can act as a mouthpiece. Where barrier filters are not used, disposable mouthpieces should be used. If only exhalation is required, such as for a volume–time curve, mouthpieces incorporating a high quality, low flow resistance one-way valve will help prevent inhalation from the spirometer (B).

More recently, some manufacturers have introduced single-patient use flow-heads that are disposed of at the end of the testing session. These may be pre-calibrated and appear to offer improved efficiency in terms of reducing the risks of cross-infection and the need to calibrate the equipment on a regular basis. Further evidence is needed regarding the accuracy and cost savings before they can be recommended over existing systems.

All reusable mouthpieces will come into direct contact with mucous membranes and must be cleaned, disinfected and dried before use with other patients. They do not need to be sterilized. Rubber or plastic mouthpieces should be washed first to remove extraneous substances and any lipstick, etc. attached to them. The choice of disinfection method depends on what is available,

but chemical (chlorine-releasing agent), a commercial dishwasher or low-temperature steam treatment are satisfactory (B).

Both used and clean mouthpieces should be handled using latex powder free, non-sterile gloves, which will provide suitable protection to both staff and to patients.

Noseclips: These come with sponge or rubber mounts. Sponge mounts should be discarded after each patient. Rubber mounts should be wiped with alcohol wipes after each patient. Of the two, rubber is preferable and will last longer (C).

Peak flow meters: The Mini-Wright peak flow meter is marked as single-patient use. However, it may be used in the hospital as a reusable item if it contains a one-way valve, which prevents patients from inhaling from the meter. Guidelines on the cleaning of the mini-Wright have recently been issued and covers not only the decontamination of these devices and the problems of multi-patient use.[109] Where peak flow meters do not have a one-way valve then either a one-way valve mouthpiece or a new barrier filter should be used for each patient (C).

Breathing circuits: In practice, disinfection at the end of each day, rather than between each patient, should be sufficient. Both internal and external surfaces of the tubing should be decontaminated. Barrier filters can also be used, either as required or on a regular basis, and offer the advantage of helping to protect all internal surfaces of complex breathing circuits.

Where patients handle the equipment, such as the flow heads of spirometers, there is a risk of cross-infection with organisms such as MRSA, which can be transmitted via fomites. To reduce potential risks, the outside of the equipment should be wiped between patients using ethanol or isopropanol-impregnated wipes (B).

Interior workings of lung function equipment: The complexity of the internal components of many measuring instruments makes routine dismantling and decontamination impractical. Manufacturers should be encouraged to produce equipment that is easily cleaned and disinfected. Whilst it may be possible to clean and disinfect the equipment there is no data on how often this should take place. Manufacturers should advise on the agents that can be used. The frequency of cleaning and disinfecting should be decided by each department in consultation with the Infection Control department. Soda lime dust should be removed from rolling seal spirometers by vacuuming (B).

The water in water-sealed spirometers should be changed regularly to maintain a low microbial load, and careful cleaning of the spirometer bell is required, probably every other day (B).

The use of barrier filter will provide further protection and may reduce the need for such regular changing of the water, although no data exists to guide operators under these circumstances. It may be more practical to avoid using such spirometers, unless there is no acceptable and practical alternative.

Exercise testing equipment: Treadmills and cycle ergometers should be wiped down at the end of each testing session (C).

Where blood sampling has occurred during testing, any spillages should be cleaned up as quickly as possible, and certainly at the end of each study, following appropriate guidelines[101] (B).

Where ventilation is measured, using a pneumotachograph or equivalent device located on the inspiratory side removes problems associated with condensation. If ventilation is measured on the expiratory side, using a heated pneumotachograph also reduces condensation. Cleaning of the inspiratory and expiratory tubes should be done at the end of each session and the tubes not reused until completely dry.

If a two-way non-return valve or a bi-directional turbine device is used to measure ventilation, this should be replaced or cleaned between patients. Valves fitted with saliva traps are preferred as this reduces the potential for spillage of the excessive amounts of saliva produced by patients when exercising.

Cleaning of these valves, such as those from Hans Rudolf, poses some problems. These systems are heat sensitive to temperatures above 40°C and are damaged by prolonged exposure to hypochlorite solutions. Dismantling, washing in hand-hot soapy water, rinsing and drying should be sufficient to ensure adequate cleaning and disinfection.

Sleep study equipment: The majority of equipment used during sleep studies comes directly into contact with the patient's skin. Pulse oximetry probes have been shown to be contaminated following use.[110] It would be expected that nasal–oral temperature sensors used to assess flow, transcutaneous PCO_2 probes and reusable electrodes would also be contaminated. These should be cleaned between patients using alcohol-impregnated wipes and by wiping the outside surface of the equipment, including the leads (B).

Chest wall and abdominal belts used to assess breathing movements should be washed between patients (C).

Silver/silver chloride electrodes should be rechlorided between patients using domestic bleach, which should be handled with regard to appropriate

health and safety guidelines (Control of Substances Hazardous to Health regulations in the UK).

Masks, tubes, exhalation valves and head caps used with continuous positive airway pressure (CPAP) or nasal intermittent positive pressure ventilation (NIPPV) are expensive. Head caps can be washed in an ordinary washing machine. Most of the plastic and silicone-based components can be reprocessed by washing in hand-hot soapy water, wiping with alcohol-impregnated wipes and then drying. Most of the masks also tolerate low-temperature steam (73°C) reasonably well. However, some of the nasal masks, especially the full-face masks with plastic flap valves become deformed at this temperature, and manual cleaning can be difficult. It is therefore important to consider compatibility with available methods of decontamination before purchasing re-usable masks. CPAP tubes, mask frames and CO_2 exhalation valves can be disinfected with low-temperature steam. The number of times each component may be reprocessed is unclear, and close visual inspection of each component before use is essential.

In the acute setting of an HDU, where NIPPV is used, a mask fitting trolley can be used to determine the correct size of mask for a patient. The range of masks will be in contact with the patient for a couple of minutes and can be wiped with alcohol-impregnated wipes and returned to the trolley. The correct size mask can then be selected from the store (C).

Domiciliary equipment

The range of hospital-owned equipment used by patients at home is limited. Currently there is no evidence to suggest that failing to follow cleaning instructions of domiciliary equipment will lead to increased infections or hospital admissions.

Portable spirometers: These should be checked and cleaned after each patient and cleaning should be in accordance with the manufacturer's recommendations. Where possible, peak flow meters should be are prescribed in place of more complex spirometers, and the patient should retain the meter after use. Patients should not be required to disassemble and clean their peak flow meter because this practice often alters meter performance (D.P. Johns, unpublished observation).

Nebulizers: All patients should be given clear instructions on the cleaning and maintenance their nebulizers and compressors. This can be time-consuming, especially if the patients are receiving several different drugs via nebulization, each requiring a different delivery system. Nebulizers should be emptied at the end of each nebulization, rinsed in hand-hot water and dried, either using a soft paper towel or by blowing air from the compressor unit through the chamber. Providing a reusable chamber that is easy to dismantle and clean will aid patient compliance with cleaning.[106] Despite being given clear instructions, patients do not always appear to comply with cleaning requests.[107]

CPAP and NIPPV machines: As with nebulizers, patients using CPAP and NIPPV machines need to be given instructions on the cleaning of masks, head-caps and tubing and on changing of particulate filters. The masks, head-caps and tubing should be cleaned in hand-hot soapy water at least weekly and be allowed to dry before subsequent use. Depending on the local environment, patients will need to change the filters monthly, more often if the environment is particularly dusty. Most mask systems will last, on average, for about 6 months before they need replacing.

Future research

As has been highlighted in this article, evidence to support infection control interventions is hard to find in the medical literature. Ultimately the most valuable studies would measure the increase in probability of acquiring an infection following respiratory function tests and how particular interventions reduce this probability. However, the difficulty in adequately monitoring patients and selecting sufficient well-matched controls is likely to preclude definitive studies of this nature in the near future. This being the case, continued vigilance in monitoring infections such as TB in respiratory physiology patients is vital for gathering circumstantial evidence of equipment-associated acquisition.

There is clear evidence that respiratory equipment becomes contaminated with microorganisms of probable respiratory tract origin during use. It can reasonably be assumed that contaminants will include potential pathogens occasionally. The likelihood that these microorganisms are breathed in by subsequent patients has not been assessed experimentally. An apparatus which could simulate the breathing patterns of test patients and from which microbiological samples could be taken might be capable of resolving this issue and of assessing the value of interventions designed to minimize exposure.

A further area where research would be value would be the microbiological safety of reused single-patient-use devices. For example, it is well

documented that home use nebulizers are subject to substantial microbial contamination, but no studies have evaluated the time course of this contamination. Such studies, which should compare different cleaning protocols, would be comparatively straightforward and would permit an evidence-based recommendation of how long such devices should be reused before replacement. Studies evaluating the clinical consequence of domiciliary use of contaminated nebulizers by patients with asthma or COPD would also be useful, but would be difficult to conduct.

Finally, with the increasing use of barrier filters in respiratory function laboratories, there is a need for independent assessment of the various products available. Evaluations should include not only the ability of the filters to remove microorganisms, but their effect on the lung function indices being measured due to factors including flow resistance and low dead space. These parameters must be monitored over a number of test cycles to evaluate deterioration that is likely to be experienced if barrier filters are not replaced between tests.

Disclaimer

The statements and recommendations made in this review are based on current evidence. The authors accept no responsibility for the subsequent adoption of any recommendations made in this review. Final implementation must be the responsibility of the laboratory and its own infection control staff.

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