# GUIDELINES

# INFECTION

# CONTROL

# IN

# ENDOSCOPY

## 2nd Edition

**GESA**
Gastroenterological
Society of Australia

# Acknowledgements

**TABLE OF CONTENTS**

# INTRODUCTION

The Editor of a Lonely Planet Travel Guide once enquired of the Curator of one of the world's great museums if the layout of exhibits would remain the same when the museum reopened after major refurbishment. The Curator replied "Everything will remain as it has always been except for those things which have changed". From the perspective of the Second Edition of "Infection Control in Endoscopy" the central tenets remain unchanged. There have however been significant changes, developments and problems. These include:

. A recognition of the core role of biofilms in water quality. The relatively simplistic concept of simple filter banks to produce high quality rinsing water for endoscopes has proved impractical in many areas. Delivery of bacteria-free water for endoscope rinsing is now a highly complex and frequently expensive undertaking.

. The problems of effective reprocessing to avoid risks of CJD transmission have become even more complicated with the recognition that there may be significant prion concentrations in lymphoid tissue in variant CJD. The implications for endoscope reprocessing are as yet unclear.

. Disease transmission associated with automated flexible endoscope reprocessors (AFER) failures continues. Epidemics of Pseudomonas transmission associated with bronchoscopes appear to relate to inappropriate port devices and AFER connector problems.

. Bacteriological surveillance of water supplies, AFERs and endoscopes has become much more widely accepted than at the time of publication of the First Edition. We make no apologies for stating that it should now be mandatory.

. We have encountered increasing difficulty obtaining well-researched and documented evidence of the mechanism of endoscopy-associated infection transmissions. This appears to relate both to the fear of litigation and also to confidentiality requirements imposed during and after actual litigation. It will be most unfortunate if these constraints increase the risk of similar events occurring because of a lack of information dissemination.

. We have received widespread reports complaining of some AFER and endoscope manufacturers' secrecy. There is increasing concern at the reluctance of companies to notify potential and real defects. Individual instrument and device tracing and warnings are likely to be ineffective because instruments and devices may have been on-sold or transferred to other facilities within large health care organizations.

Beth Wardle has joined the Editorial Panel following the tragic death of Trudy Rayner.  Trudy had worked tirelessly in the field for a number of years and her outstanding contributions will be sorely missed.  We again thank the Australasian Society for Infectious Diseases,and the Thoracic Society of Australia and New Zealand for the contributions from Peter Collingnon, Michael Whitby, and David Fielding.  The development of the Queensland Health hosted web site on endoscope reprocessing under the project management of Louise Davis drew extensively on the previous edition of this monograph and in turn that information has contributed to this edition.

This will be the last edition as Editor for Alistair Cowen.  This will be the 6th Monograph published for the Gastroenterological Society of Australia over the last 19 years.  I would like to thank the few medical colleagues who have had an interest in this area, particularly Anthony Speer.  Thanks to the many GENCA members who have contributed so heavily over the years.  Particular thanks to all the whistle blowers who have told us about many things which have happened that should not have, and many things that should have happened and have not.  We hope that we have managed to correct the majority of them.


**Alistair Cowen**                    **Di Jones**                    **Beth Wardle**

**The three most important rules of any effective cleaning and disinfection schedule are:**

CLEAN IT

CLEAN IT

CLEAN IT

## NON IMMERSIBLE ENDOSCOPES
## SHOULD BE NOT BE USED

*Scrupulous manual cleaning has been shown to remove all H.I.V. infective material from endoscopes used in A.I.D.S. patients or artificially contaminated with aqueous H.I.V. viral suspensions.*

*Patients have died from Serratia Marcescens infection acquired from a bronchoscope inadequately cleaned and then Ethylene oxide "sterilised".*

*In several endoscopy-associated serial clinical infections, increasing chemical immersion time has NOT solved the problem. Infections have only ended when inadequate manual cleaning (e.g. failure to ultrasonically clean spiral-wound wire forceps, failure to adequately clean spring-loaded biopsy port valves) has been recognised and corrected.*

*Aldehyde chemical disinfectants and alcohol "fix" proteinaceous material, making it harder to remove and preventing chemical contact with the organism.*

*Dried biological material is much harder to remove and chemical disinfectants, including aldehydes, penetrate much more slowly.*

*Organic material may inactivate the majority of disinfectants including aldehydes, resulting in a rapid reduction of effective chemical concentration.*

# STERILISATION AND DISINFECTION

## 1. STERILISATION

Sterilisation is a term describing the use of a physical or chemical procedure to destroy all microbiological life including bacterial spores. Major sterilising processes include dry heat sterilisation, steam sterilisation under pressure, low temperature hydrogen peroxide plasma sterilisation, automated peracetic acid systems and ethylene oxide gas[1,2] A number of chemical germicides are capable of achieving sterilisation if used for prolonged periods. To achieve sterilisation with aldehyde based products, depending on use temperature, a contact time exceeding three hours may be required. At present modern flexible endoscopes cannot be regularly sterilised, either because processes such as heat and steam are incompatible with the materials of which they are composed or because processes such as ethylene oxide and extremely prolonged chemical immersion are impractical and unlikely to achieve full sterilisation for the reasons subsequently outlined. A few newer model endoscopes are proposed as capable of undergoing low temperature gas plasma sterilisation but the long term effect on materials from repeated use of this process is not yet clear.

## 2. DISINFECTION

Disinfection is different from sterilisation. Disinfection is a process that only removes or kills organisms that are regarded likely to cause disease. Many organisms are relatively resistant to disinfection. In general they are regarded as low virulence organisms, e.g. bacterial spores. Other forms of microbial structures designed to allow survival in hostile environments, e.g. protozoal cysts, are also resistant.

Any item that comes into contact with sterile body sites needs to be sterile. Sterilisation is also preferable for instruments that come in contact with an intact mucous membrane, but unfortunately because of the structure of many instruments (including endoscopes), this is not achievable either because the instrument cannot withstand heat or the impracticable logistics of using other sterilisation processes (e.g. gas sterilisation).

Disinfection can be achieved by a number of means that include heat and chemicals. The cleaning process itself is a very efficient means of achieving disinfection. Cleaning removes or destroys more organisms than a chemical disinfectant is likely to do over a similar period of time (e.g. a 5 minute contact time). Organic material binds and inactivates many chemical disinfectants. Some disinfectants such as glutaraldehyde and alcohol fix protein. Thus chemical disinfectants may create a physical barrier of denatured protein that can protect organisms coated by organic material. Obviously no agent can be effective against microorganisms it cannot reach. An advantage of heat as a disinfecting agent is that it is conducted and is able to penetrate better than chemicals. The action of heat will also be compromised by inadequate cleaning, but to a lesser extent than with chemical disinfectants. With high levels of wet heat and pressure

(autoclaving) sterilisation is achieved. When heat is used at lower temperatures, e.g. boiling water or pasteurisation (70°C for 100 minutes - 90°C for 1 minute), heat is a very effective disinfectant.

For instruments that come in contact with mucosal surfaces, a high level disinfectant is required. Disinfecting agents need to kill all forms of bacteria (gram positive, gram negative and mycobacteria), viruses (both the more sensitive lipid coated viruses such as HIV and relatively resistant viruses such as the polio virus), fungi (e.g. Candida) and protozoa (e.g. Giardia). High level disinfectants are able to kill the more resistant forms of microbial life such as bacterial spores and cysts but only with prolonged contact times (usually over 3 hours).

No sterilising or disinfection agent works instantaneously. They all require sufficient contact times. The ability to achieve complete killing of microorganisms is dependent on a number of factors.

1.      **Initial number of organisms present**.

This is a critical factor as there is a log kill with time.  Therefore the higher the number of organisms present, the longer it will take to achieve a complete kill. This is a further reason why cleaning is a critical step in any cleaning disinfection protocol.  A log five reduction or more in the number of organisms present can certainly be achieved by scrupulous cleaning.

2.      **Temperature**

In general the higher the temperature, the quicker the disinfecting agent will destroy organisms.  This concept is used to allow rapid cycle times in AFER's, including machines which use glutaraldehyde and those which use peracetic acid. For manual reprocessing, the use temperature is provided on the product label. The use temperature for glycolated glutaraldehyde (Aidal Plus) is 25 degrees or 35 degrees whilst OPA is used at 20 degrees.  Biocidal activity is likely to be reduced at temperatures lower than those recommended for use  and recommended soaking times will thus be inaccurate.

3.      **Concentration**

Concentration of a chemical disinfectant is critical. In general the lower the concentration of the agent, the longer it will take to kill the same number of organisms. It is particularly important to ensure that disinfectants do not become diluted with excess water remaining on endoscopes after rinsing. Concentration of an agent (e.g. 2% glutaraldehyde) may be more than halved with repeated use and the activity of the disinfection process significantly compromised. The chemical concentration should be checked using test strips at the beginning of each day.

4.      **Contact time**

There is no specific soaking time that will guarantee that all agents present are killed by chemical disinfectants. It is dependent on the number of organisms present, the presence of inactivating compounds (e.g. organic materials), the pH, the temperature, the concentration of a disinfectant and the relative resistance (and therefore kill rate) of the organism involved. Recommendations given are for an adequately cleaned endoscope. If cleaning is compromised, even prolonged contact time (in excess of 60 minutes) is unlikely to kill pathogenic organisms present on or in the endoscope. It has been shown that ten separate full disinfection cycles failed to kill *Mycobacterium tuberculosis* present in an inadequately cleaned bronchoscope[3].

## 3.      BIOCIDES FOR ENDOSCOPE REPROCESSING

Agents, which can achieve high level disinfection, include 2% glutaraldehyde, 0.55% *ortho*-phthalaldehyde (OPA), peracetic acid, high concentrations of hydrogen peroxide and some chlorine releasing agents. In general peracetic acid and high concentrations of hydrogen peroxide can only be used in automated processors which prevent staff exposure. Glutaraldehyde and OPA can be used in either manual processing or in automated processors. Ethylene oxide achieves sterilisation with prolonged contact time. However, it must be recognised that gas sterilisation with ethylene oxide is subject to the same limitations as liquid chemical disinfectants. Gas sterilisation cannot be achieved in inadequately cleaned instruments.

Other chemicals such as quaternary ammonia compounds (e.g. Cetrimide) are only low level disinfectants and are inactive against many bacteria (pseudomonas, mycobacteria). They have little or no activity against viruses. Alcohol and iodine, while more effective than quaternary ammonia compounds, do not kill some forms of micro-organisms and are therefore not regarded as high level disinfectants.

It is customary to state that endoscopes undergo high level disinfection[4]. In practical terms, however, endoscopes cannot always be rendered free of all bacterial contamination by standard cleaning and disinfection processes.

Endoscopes subjected to the full cleaning and disinfection protocols advocated in this monograph and then having their channels filled with culture medium and stored in sterile bags, may still grow bacteria after several days. This is particularly so in older instruments where irregularities at junctions, minor cracking or splitting of the surface layers of the internal channels may allow protection of organisms[5,6,7]. The realistic aim, therefore, of any reprocessing protocol is to have an endoscope, which will not transmit pathogens from one patient to the next, nor hospital environmental contaminants from the endoscope or accessories to the patient. In addition, it is important to recognise there are a wide variety of other factors which influence whether or not significant clinical infection will occur when endoscopic procedures are undertaken. It is critical to have an appreciation of all the factors involved.

## 4. STERILISATION VS HIGH LEVEL DISINFECTION: PRACTICAL ASPECTS

Sterility is a simple theoretical concept. Demonstrating its existence in practice is rather more difficult. It is impossible to test each item; batch testing of large production lines provides little assurance. In practice, the concept of Safety Assurance Levels (SAL) is used[8]. A selected microorganism (usually a bacterial spore) is tested under fixed conditions in a sterilising process and the chance of live organisms remaining extrapolated from the kill graph. The usual convention is that a device labelled as sterile has an SAL of $10^{-6}$ [9,10]. This means that there is a less than 1 in 1 million chance that live organisms remain on the device. Over time there has been a progressive demand for higher Safety Assurance Levels to apply to devices labelled "sterile". Indeed, there is now a push to increase this SAL to $10^{-8}$. This is despite the fact that there is no evidence of worse clinical outcomes when devices with SAL's of $10^{-3}$ are compared with SAL's of $10^{-6}$, let alone $10^{-8}$! [11,12]

There are increasing pressures demanding that endoscopes should be "sterile". At least one State in America is considering legislation to this effect. There is no evidence anywhere that patients have suffered infections with organisms which would be eliminated by a sterilising process but not by a high level disinfection process.

The facts are:-
1  No currently available technique of reprocessing flexible endoscopes can guarantee sterility of every endoscope on every occasion.
2  Passing "laws" or publishing standards which are simply impossible to comply with in practice is deceptive to the public, exposes the reprocessor to possible litigation and offers a false sense of security to the ill-informed.
3  Safety in endoscope reprocessing is the sum of its component parts. No sterilising process can be effective if the instrument has not been meticulously cleaned or is mechanically defective. The sterilising process itself will only work if all parts of the endoscope are exposed to the chemical for an appropriate time and at an appropriate temperature, and rinsed with sterile water. It is truly farcical to suggest that a sterilising

process with no flow alarms, defective self-sterilising cycle, and using unsterile, possibly contaminated rinse water is guaranteed to achieve a better clinical outcome than a properly applied high level disinfection process which does not suffer the above defects.

American and British guidelines on bronchoscopy continue to state that high level disinfection is the recommended procedure with no comments regarding full sterilization. Bronchoscopy like endoscopy is a procedure which does not breach into a body cavity. Note that because biopsy forceps do breach the mucosa they should be sterilized or discarded if disposable. [13,14]

Recent Pseudomonas cross infection from flexible bronchoscopes in two separate reports was shown to be due to faulty bronchoscope design. It was not due to the use of high level disinfection rather than sterilisation[15,16]. Some studies report water filtration systems are not able to reliably provide bacteria-free water.[17] In this study no mycobacterial contamination of bronchoscopes was observed but the water sampled over a period of months from a filter in an automated flexible endoscope reprocessor (AFER) repeatedly grew mycobacteria. From this aspect alone, the impracticalities of attempting to perform a fully sterile procedure are demonstrated.

# MECHANISMS OF INFECTION AND MAJOR RISK FACTORS

## 1.   MECHANISMS OF INFECTION

1. Clinical infections associated with endoscopy may occur because infective agents are transmitted from one patient to the next via the endoscope or its accessory equipment.

2. Hospital environment pathogens may contaminate the endoscope or accessory equipment and be introduced into the patient during subsequent examination. Contamination may be from the general hospital environment, the water supply or disinfecting machines. Previously the risks of clinical infection from this mechanism related mainly to E.R.C.P. but with the increasing use of disinfecting machines it is rapidly becoming a more general problem.

## 2.   RISK FACTORS

The important risk factors are:

1. The number and particular type of bacteria, virus or other infecting agents present on or in the endoscope, its water-feed system, diagnostic or therapeutic accessories.

2. The particular type of endoscopic procedure to be undertaken and whether tissue penetration, damage or ischaemia occurs as a result of the procedure.

3. Patient factors:

   a) Immune status.

   b) Endovascular surface integrity.

   c) Indwelling foreign material, e.g. prosthesis within tissues.

   d) The presence of intrinsic infective foci.

# THE INFECTING ORGANISMS

## 1. BACTERIA

### (a) Salmonella and Related Species

Historically, salmonella and related species have been the infections most commonly transmitted by endoscopy[18,19,20,21]. Many of the older literature reports of such infections occurred with cleaning and disinfection regimens which would not be considered acceptable by today's standards. The majority of outbreaks were only recognised when bacteriological laboratories reported unexpectedly large clusters of unusual salmonella species triggering epidemiological investigation. The fact that these outbreaks were not recognised by the endoscopy unit concerned but only on epidemiological investigation suggests infections due to more conventional salmonella organisms may have been significantly under-reported. Some reports of salmonella outbreaks[22] have been associated with inadequate cleaning of accessories, particularly the failure to ultrasonically clean spiral wire wound accessories. Increasing chemical immersion time was ineffective in at least one of these outbreaks and the problem was only terminated when proper cleaning procedures were employed.

### (b) Mycobacteria

Mycobacteria are relatively resistant to most chemical agents including aldehydes[23]. Atypical mycobacteria are even more resistant and there are reports of atypical mycobacteria totally resistant to glutaraldehyde [24,25].

There is no proven case of transmission of tuberculosis by gastrointestinal endoscopy. Numerous reports of mycobacterial transmission by flexible bronchoscopy, however, have been reported[26,27,28,29,30,31] Mycobacterial infections during bronchoscopy have been related to contaminated suction valves[26], cracked biopsy channels[27], contaminated topical anaesthetic solutions[28] and contaminated disinfecting machines[29,30]. Epidemics of pseudoinfection associated with contaminated disinfecting machines have also been a cause of considerable confusion[32]. The term "pseudoinfection" means that organisms cultured from respiratory secretions taken at the time of bronchoscopy are actually organisms contaminating the bronchoscope or accessories, not organisms infecting the patient's respiratory tract. Hanson[33] has shown in a study using bronchoscopes heavily contaminated with *Mycobacterium tuberculosis* that adequate cleaning reduced contamination by a mean of 3.5 $\log^{10}$ colony forming units. All bronchoscopes were free of detectable mycobacteria after ten minutes in 2% glutaraldehyde. Nonetheless, the sheer number of cases of flexible bronchoscopic transmission of tuberculosis indicates that this is a significant clinical hazard. **The Centre for Disease Control and Prevention recommends that bronchoscopy should not be performed on patients with active T.B. unless absolutely necessary[34].** Bronchoscopy should not be regarded as a first line investigation in the diagnosis of TB and repeated sputum smears should be negative for acid fast bacilli before bronchoscopy is considered. Avoiding bronchoscopy in these patients is important not only from the point of view of

reducing contamination of bronchoscopes for subsequent patients, but also by way of avoiding contamination of either staff or other items in the bronchoscopy suite when patients cough excessively. Mehta[14] has recommended that to minimise airborne infection in the bronchoscopy suite clearly defined areas should be designated for contaminated, clean and sterile equipment. Furthermore, bronchoscopy suites should be equipped with an air filter that can provide at least 14 air exchanges per hour.

Nowhere, but nowhere, has the critical role of cleaning been better demonstrated than with *Mycobacterium tuberculosis* and fibreoptic bronchoscopes. Nicholson[3] showed that a bronchoscope, which had undergone ten separate complete disinfection cycles with 2% glutaraldehyde but had been poorly cleaned, was still contaminated with *Mycobacterium tuberculosis*.

Rinsing of bronchoscopes after disinfection should be with sterile or filtered water. Atypical mycobacteria are frequently present in tap water. Full air/alcohol drying at the end of lists is critical. (See also section on Pseudomonas, Bronchoscopy, and AFER's)

A further disturbing development in the mycobacterial area is the development of multidrug-resistant tuberculosis (MDRTB)[35]. In this paper by Agerton one patient became the point source for infection of three subsequent patients, two of whom had a benign clinical course, but in a third patient multi drug resistant tuberculosis proved fatal. Note in this outbreak the point source patient was already 4+AFB smear positive and culture positive for M*ycobacterium tuberculosis* on three sputum specimens but bronchoscopy was still done because of his worsening clinical condition despite anti-tuberculous therapy.

Indirectly this case reinforces the importance of avoiding bronchoscopy in either suspected or proven cases of tuberculosis wherever possible. DNA fingerprinting of the isolated mycobacteria proved the connection between the four patients. These strains have been reported principally from the eastern U.S.A. and infection transmission has largely been by respiratory aerosols. In the outbreak reported by Agerton the authors commented that the observations revealed that the cleaning & disinfection of endoscopic equipment did not follow the hospital's guidelines or the published guidelines.[35] The difficulty of tracing the bronchoscopic source of infection is well indicated in the report by Michele et al. In this study a patient developed tuberculosis six months after bronchoscopy. It was shown by DNA fingerprinting that infection was from a strain of tuberculosis from a patient bronchoscoped two days earlier[36]. The cleaning and disinfection schedule was inadequate in another study leading to infection[37].


METICULOUS DETAILED MECHANICAL CLEANING BY STAFF PROPERLY TRAINED IN BRONCHOSCOPE REPROCESSING REMAINS THE BEST AND INDEED PROBABLY THE ONLY DEFENCE AGAINST TRANSMISSION OF MYCOBACTERIAL DISEASE BY FLEXIBLE BRONCHOSCOPY. IT HAS BEEN UNEQUIVOCALLY DEMONSTRATED THAT EVEN EXTREMELY PROLONGED BRONCHOSCOPE IMMERSION

IN 2% GLUTARALDEHYDE WILL NOT PREVENT DISEASE TRANSMISSION IN INADEQUATELY CLEANED INSTRUMENTS AND ACCESSORIES.

**(c) Serratia marcescens**

If more evidence is required of the pivotal role of adequate mechanical cleaning in endoscope reprocessing then it is provided by *Serratia marcescens*. Several outbreaks of *Serratia marcescens* infection have been tracked to bronchoscopic transmission [16,38 39]. In an outbreak involving three fatalities[38], the instrument had been inadequately cleaned but then subjected to a full ethylene oxide sterilizing process, underlining the fact that any attempts at sterilization or disinfection are likely to be ineffective in the presence of inadequate cleaning.

**(d) Helicobacter pylori**

There is clear historical evidence that *Helicobacter pylori* was transmitted by research studies involving gastric tubes, endoscopy and biopsy, long before the organism was clinically recognised (epidemic achlorhydria)[40]. Retrospective examination of biopsies demonstrated the presence of *Helicobacter pylori*. *Helicobacter pylori* transmission by contaminated biopsy forceps was demonstrated using restriction enzyme analysis of bacterial DNA[41]. It is probable that endoscopic transmission of helicobacter has been more frequent than has been recognised because of:

(i)      the high background prevalence of symptoms similar to *Helicobacter pylori* infection in the population examined;

(ii)     the high background prevalence of *Helicobacter pylori* infection;

(iii)    the non-specific nature of symptoms associated with *Helicobacter pylori*-induced gastritis; and

(iv)    the frequency of asymptomatic infection

It has been suggested that a significant proportion of "adult reinfection" in some research studies is due to reinfection by inadequately processed biopsy forceps.

**(e) Clostridium difficile**

There are several reports of possible endoscopic transmission of *Clostridium difficile* but none have been definite[42]. *Clostridium difficile* spores are less resistant to a variety of chemical disinfectants than test spores used in standard analytical chemical sporicidal tests[42]. Exposure for 10 minutes to 2% glutaraldehyde has been shown to inactivate *Clostridium difficile* spores[43].

**(f) Pseudomonas**

Pseudomonas is a common hospital environmental pathogen. Endoscope and accessory contamination has almost invariably been acquired from the hospital environment rather than from previous patients. Pseudomonas is the archetypal biofilm-forming organism (see section on biofilms). Pseudomonas biofilms are extremely difficult to remove from plumbing, AFERs and damaged endoscope channels. Recently pseudomonas infection has been associated with flexible bronchoscopy [13,14,15]. Apparent defects include non-removal of biopsy valves, ill-fitting or wrong AFER-endoscope connectors and defective AFERs. Two outbreaks of Pseudomonas infection reported included the death of three patients [13,14]. These two reported outbreaks have reportedly necessitated the company recall of approximately 14,000 bronchoscopes worldwide. Modification of the bronchoscopes to solve a problem with biopsy port caps has been proposed. Given the magnitude of concern in relation to these outbreaks the authors referenced a paper by Colt from 2000 discussing the use of a sheathed bronchoscope. However at this stage the practicality of such sheaths is not known. The authors called for new standards to be developed to test and review the design of these instruments.

Historically, endoscopy-associated pseudomonas infections have largely been confined to E.R.C.P. and this problem is considered in more detail under that section. Clinical infections with pseudomonas may become significant in the severely immuno-compromised patient, particularly when procedures involving tissue disruption are undertaken. Even simple diagnostic procedures not usually associated with mucosal trauma such as diagnostic upper gastrointestinal endoscopy have been associated with pseudomonas septicaemia in severely immuno-compromised patient with gross oropharyngeal mucositis[44,45] (e.g. leukaemia, bone marrow transplantation). Colonisation of automated reprocessors has resulted in serious disease transmission to patients.

## 2. VIRUSES

### (a) Human Immunodeficiency Virus (HIV)

Infective HIV particles are present in the blood, semen and other body fluids of infected individuals. Needle stick injury with H.I.V positive blood has resulted in

sero conversion ranging from 0-0.42% in various studies[46,47,48,49,50]. The concentration of HIV in serum varies widely with the stage of the infection. High viral concentrations can be found associated with all stages of HIV/AIDS  HIV is sensitive to many chemical disinfectants including aldehydes [51,52,53]. A variety of studies has shown that when the virus is protected within a dried protein coagulum, some chemical disinfectants including 1% glutaraldehyde will fail to inactivate the virus within 5 minutes[51], emphasising the absolute necessity to ensure that scrupulous manual cleaning removes all traces of blood and proteinaceous material.  Such cleaning should be undertaken without delay.  In a series of studies Hanson et a1 [54,55] contaminated the surface and internal channels of endoscopes with high titre HIV serum.  Simple manual cleaning removed HIV activity from all except a single endoscope and the remaining viral activity was removed from this endoscope after 10 minutes or less in 2% glutaraldehyde. Where endoscopes were sampled after removal from HIV positive patients, all HIV present on endoscopes was removed by manual cleaning alone.

To date there has been no unequivocal demonstration of transmission of human immunodeficiency virus by gastrointestinal endoscopy.  It is difficult to interpret the rare reports suggesting that some human immunodeficiency viral material may remain on endoscopes after recommended reprocessing protocols.  The PCR techniques used may identify remaining nucleic acids, which do not constitute infective viral particles.  Deva et al[56] has shown that in the Duck Hepatitis B model, positive PCR material remaining on scopes does not correlate with infective transmission.

However the extremely long incubation time for clinical AIDS would make the detection of a very isolated instance of HIV transmission difficult to detect.

### (b) Hepatitis B

Hepatitis B is a highly infectious virus and high concentrations of viral particles are found in the blood of symptomatic hepatitis B sufferers and asymptomatic hepatitis B carriers, particularly those who are HBeAg positive.  Clinical hepatitis B may occur as frequently as 1 in 3 following needle stick [57,58,59,60,61] (compared with 1 in 400 becoming HIV positive after needle stick injury with HIV infected blood).  Despite the high infectivity of hepatitis B, there is only a single well documented case of transmission of hepatitis B by endoscopy[62].  Clinical studies following up patients who have been endoscoped on the same endoscopy list as known hepatitis B positive patients have produced no evidence of

infection[63,64,65,66,67,68,69,70].   Hepatitis B virus is moderately sensitive to the majority of chemicals[71,72].   However, chemical inactivation requires that the germicide comes in contact with the virus and failure to remove blood, mucus and protein coagulums will allow the virus to be protected from chemical inactivation.


## (c) Hepatitis C


Human body fluids including saliva, ascites and urine, all contain significant concentrations of Hepatitis C virus in infected patients.  The risk of infection following needle stick injury with HCV positive blood is around 3%.  Given the known physical characteristics of the virus, its infectivity under general clinical conditions and its known sensitivity to disinfectants, it was assumed that the risks of endoscopic transmission would be similar to Hepatitis B.

Unfortunately this appears not to be the case.  There is now convincing evidence of transmission of Hepatitis C associated with endoscopic procedures.  In many cases this seems related to inadequate cleaning.  Tennenbaum et al reported the transmission of Hepatitis C following endoscopic sphincterotomy in 1993[73.] Andrieu et al[74] found in a gastroenterology hospitalised population in patients over the age of 45, endoscopic biopsy appeared to be the second highest risk factor for Hepatitis C, an odds ratio of 2.7 compared with an odds ratio of 1.8 for blood transfusion.  A national blood transfusion survey in France reviewed over two and a half million blood donations and found 30 anti HCV positive blood donors who had made a previous donation but had screened anti HCV negative. Six of 26 donors had a history of endoscopy between negative and positive donations in the absence of any other identifiable risk factor[75].

Bronowicki et al[76] also reported from France HCV transmission during colonoscopy from a known infective patient to the two subsequent patients on the list.  It appears likely that the cause of endoscopic transmission was a totally inadequate cleaning protocol including failure to brush the biopsy channel. However the biopsy forceps and polypectomy snare were also inadequately processed.

Transmission of Hepatitis C during gastroscopy has also been reported by Crenn et al[77].  Single strand conformational polymorphism analysis of the hypervariable region of HCV RNA confirmed the patient to patient transmission.  It is claimed that adequate reprocessing protocols were followed for the endoscope.   It is unclear in this patient whether the anaesthetic procedure or the endoscope was the cause of the transmission.  Becheur et al[78] have shown that HCV is detectable by PCR in 28% of endoscope biopsy channels and on 6% of biopsy forceps after use in patients with non-treated replicative chronic hepatitis C.  They again found that conventional reprocessing techniques removed all HCV infected material.   In contrast to some of the above findings, Goudin et al in a study in Lyon, France tested all patients referred for endoscopy for HCV and could find no definite evidence of HCV transmission and only one possible case[79].

Proven transmissions of Hepatitis C by endoscopy remain confined to France. It is unlikely that this geographical restriction will continue. There are very few studies around the world which have prospectively examined the possibility of endoscopy as a risk factor for Hepatitis C transmission. A study by Kim et al[80] from Korea could not identify endoscopy as a risk factor. In French epidemiological studies it is impossible to know what may have been the cause of Hepatitis C transmission.

In all except one clinical report there have been clear and gross deficiencies in the endoscope and accessory reprocessing. This is not altogether surprising since Raymond in 1990[81] found that 73% of all units surveyed in France had gross protocol deficiencies. This, however, should not lead to any sense of complacency elsewhere. Reynold's survey in the U.S.A.[82] in 1992 showed that 40% of units surveyed had inadequacy in some aspects of their protocols. There are no recent Australian surveys but past surveys were little better and there is recent anecdotal evidence that the very protocol failures associated with transmission of Hepatitis C at colonoscopy had been present until recently in a small number of Australian endoscopy units.

At present the overwhelming evidence is that cleaning and disinfection protocols when properly applied during endoscope and accessory reprocessing will render instruments and accessories free of the risk of transmission of Hepatitis C. Failure to prevent endoscopic transmission of Hepatitis C has been due to wilful or inadvertent deficiencies in appropriate cleaning and disinfection protocols or (possibly) inadequate anaesthetic techniques.

7 cases of Hepatitis C appear to have been transmitted at a Brooklyn endoscopy clinic because of reuse of syringes or needles[83,84].

52 cases (possibly more) of Hepatitis C appear to have been transmitted by a similar mechanism in an Oklahoma day surgery setting[85].


**(d) Enteroviruses**


Polioviruses are more resistant to many chemical disinfectants than the viruses which have a high lipid content (e.g. HIV). Hanson et al[86] studied the elimination of entero viruses from endoscopes using polio virus as the pilot agent. Endoscopes were artificially contaminated with high levels of polio virus and subjected to standard cleaning and disinfection protocols. In further studies the effectiveness of glutaraldehyde against cell free and cell associated polio viruses dried to a surface in a protein coagulum was also studied. Cleaning and disinfection was totally effective against a heavy viral contamination and glutaraldehyde rapidly inactivated polio virus even when dried to a surface in serum.

# 3. OTHER INFECTIONS

A wide variety of other bacteria, viruses, fungi and protozoa could potentially be transmitted by endoscopy. Relatively little investigation has been undertaken in this area although candidal infection of immunocompromised patients has been reported[87]. An epidemic of pseudoinfection with the yeast *Rhodotorula rubra* has been reported in bronchoscopy patients[88].

The sensitivity of many unusual organisms to chemical disinfectants is largely unknown. However some agents such as the oocysts of cryptosporidia are highly resistant to a variety of chemical disinfectants including 2% glutaraldehyde[89,90]. It is unlikely that such organisms pose a significant threat to patients with normal immune systems. However they could be responsible for serious and even fatal infections in the immunocompromised.

## Creutzfeldt Jakob Disease (CJD - Prion Disease)

Spongiform encephalopathies are a family of aggressive neurological disorders whose symptoms include dementia, ataxia, myoclonus, pyramidal and extrapyramidal damage[91,92,93,94,95,96,97,98,99,100,101,102,103,104,105,106,107,108]. These diseases are characterized by the accumulation of a modified prion protein $PrP^{res}$ which is an isoform of a normal protein $PrP^c$. The abnormal form has an identical amino acid sequence but the two isoforms differ in their three dimensional conformation and glycosylation patterns. The protein appears to be encoded by PRNPG on chromosome 20. Mutations of Codon 200 result in familial forms of CJD and polymorphism at Codon 199 may influence susceptibility to the infection.

The disease occurs in classical (sporadic, familial, iatrogenic, occupational) and new variant forms (vCJD). Sporadic disease accounts for 90% of known cases and the mode of acquisition and/or transmission is not known. Less than 10% of cases are familial. The "new variant" disease suggests that the prion source may be BSE contaminated beef.

There are approximately 160 cases worldwide of iatrogenic or occupationally acquired classical CJD[91,92,93,94,100,105,106]. The vast majority of these relate to dura mater transplant (66) or the use of human cadaveric growth hormone (76). Other sources include contaminated neurosurgical instruments (4), human cadaveric pituitary gonadotrophin (4), brain electrodes (2) and corneal transplants (3). Occupationally acquired classical CJD has been documented in only three workers, all of whom had percutaneous exposure to high risk tissues in laboratory settings.

21.

The risk of classical CJD transmission is a function of the relative concentration of the abnormal prion protein in a particular tissue[93,99,105]. Brain, dura mater and cornea are high risk tissues.

Prion proteins are highly resistant to a variety of chemical and physical processes which normally inactivate microbiological agents. In addition, the catastrophic nature of the disease has engendered such an emotional response that many recommended risk containment strategies have been grossly excessive. It again needs to be stressed that no iatrogenic or occupationally acquired classical CJD has occurred from exposure to low to no risk tissues.

A conservative endoscopic approach, therefore, is:

- Seek alternative diagnostic studies or therapeutic approaches in patients with known or suspected classical CJD.

- Where such procedures are totally unavoidable, refer such patients to a large centre where specific endoscopes are reserved for patients with classical CJD.

- Discard all endoscopic accessories used in patients with known or suspected classical CJD.

- No change can be recommended to the indications for endoscopy or current cleaning and disinfection protocols in patients who are not known to have or suspected to have classical CJD.

**New Variant CJD (vCJD)**

New variant CJD is a rapidly progressive human spongiform encephalopathy which is due to a prion strain identical to that causing bovine spongiform encephalopathy in cattle (Mad Cow Disease)[109]. The clinical course in vCJD shows a shorter incubation time, a more rapid onset often presenting with psychiatric symptoms followed by a rapid progression to death. In new variant CJD, large quantities of the abnormal prion ($PrP^{sc}$) are found in lymphoid tissue.[110] vCJD can be regularly diagnosed by tonsillar biopsy. This high concentration of prions in lymphoid tissue raises the possibility that endoscopes coming in contact with alimentary lymphoid tissue could become contaminated with material containing high levels of prions[111]. Presently, the quantitation of this risk is hampered by a lack of knowledge about the absolute prion titres in various alimentary lymphoid tissue and the absence of any experimental work demonstrating transmission by this mode in animals. Some experiments suggest the possibility of transmission of vCJD or similar animal spongiform encephalopathies by concentrated blood products.

VCJD poses a more complex problem as prion protein in this disease appears to be connected with gut lymphoid tissue. Thus transmission via endoscopes and accessories may be possible. However, at this time, vCJD has not been recorded in Australia. The potential for such transmission reinforces the need for instrument tracking. [112,113]

# THE PROCEDURES

## 1.     DIAGNOSTIC ENDOSCOPY

Bacteraemia occurs in any situation where there is mucosal trauma[114,115,116,117,118,119,120,121,122,123,124,125,126,127,128] (even vigorous teeth cleaning). The presence of bacteraemia after an endoscopic procedure does not necessarily indicate that a risk of serious clinical infection is present, but it does provide an index of the degree of mucosal trauma. Significant rates of bacteraemia have been reported where older style large diameter endoscopes have been studied[117,118,119,120,121,122,123]. The organisms found on blood culture were largely oropharyngeal commensals with a low level of pathogenicity and the quantitative number of organisms recovered was small[118,120]. ANTIBIOTIC PROPHYLAXIS IS THEREFORE NOT INDICATED FOR ROUTINE UPPER ENDOSCOPY WHERE STANDARD PANENDOSCOPES ARE USED IN HEALTHY PATIENTS, THE IMMUNOCOMPROMISED, THOSE WITH CARDIAC VALVE PROBLEMS, ARTIFICIAL INDWELLING VASCULAR DEVICES, JOINT PROSTHESES, SILICONE TISSUE IMPLANTS OR PACEMAKERS. **THE SINGLE EXCEPTION TO THIS MAY BE TRANSPLANT OR CHEMOTHERAPY PATIENTS WITH SEVERE MUCOSITIS.** Pseudomonas septicaemia has been reported in leukaemia patients undergoing routine endoscopy[44] and one study has reported a high rate of bacteraemia following endoscopy in bone marrow transplant patients[45], although a subsequent study was unable to confirm this[129]. It is likely that the risk in this situation depends upon the degree of mucositis present.

## 2.     OESOPHAGEAL DILATATION

Disruption of the oesophageal mucosa invariably occurs during dilatation; indeed, endoscopic inspection following dilatation can show quite frightening tissue trauma. It is not surprising that significant levels of bacteraemia have been recorded in association with oesophageal dilatation[130,131]. Organisms recovered at blood culture have sometimes been oropharyngeal commensals but more pathogenic organisms contaminating the endoscope or accessory equipment have also been recovered. ANTIBIOTIC PROPHYLAXIS IS RECOMMENDED FOR OESOPHAGEAL DILATION IN IMMUNOCOMPROMISED PATIENTS OR THOSE WITH SIGNIFICANT CARDIAC OR VASCULAR ABNORMALITIES.

## 3.     ENDOSCOPIC SCLEROTHERAPY/ BANDING

The degree of tissue damage occurring at the time of endoscopic sclerotherapy will depend upon the volume of sclerosant injected and whether this is intra or extra-variceal[132]. Very significant tissue destruction can occur with extra-variceal injection. The majority of patients in whom endoscopic

sclerotherapy is undertaken have a compromised immune system and it is not surprising that SERIOUS CLINICAL INFECTIONS AND FATALITIES HAVE BEEN RECORDED IN ASSOCIATION WITH INJECTION SCLEROTHERAPY[133,134,135,136,137,138,139]. Some of these complications have been local, e.g. mediastinal abscess, others have been more generalised including septicaemia or distant abscess, e.g. brain abscess. New needle catheters with covered tips for endoscopic injection therapy have been reported[140]. The distal tip of the catheter is covered with rubber and the needle only punctures the rubber when insertion of a needle into the varix or other tissue being injected (e.g. bleeding ulcers) is imminent. Investigations show this covered needle catheter system reduces the number of contaminating bacteria and may be useful in preventing bacteremia. Bacterial endocarditis has been reported following variceal sclerotherapy[138,141].

Again, the organisms recovered have varied widely but have included organisms contaminating endoscopes and accessory equipment. It is recommended that ANTIBIOTIC PROPHYLAXIS BE GIVEN IN SEVERELY IMMUNOCOMPROMISED PATIENTS WHERE SIGNIFICANT ASCITES IS PRESENT OR SIGNIFICANT EXTRA-VARICEAL INJECTION HAS OCCURRED. Oesophageal banding is associated with significantly less tissue trauma and antibacterial prophylaxis is not usually indicated[142,143].

Where latex allergy is known or suspected, latex free bands should be used (see section on Latex Allergy).

## 4. COLONOSCOPY

Low levels of bacteraemia have been reported in association with diagnostic colonoscopy[144,145,146,147,148,149,150,151,152,153,154,155] but the organisms recovered have been more pathogenic than those associated with upper gastrointestinal endoscopy. There appears to have been an association with Streptococcus bovis endocarditis in some patients with villous adenoma[156]. It is important to recognise that manipulation of the sigmoid in patients with acute peridiverticular inflammation or abscess formation is likely to result in gross bacteraemia. WHERE COLONOSCOPY IS UNDERTAKEN IN THE PRESENCE OF ACUTE PERIDIVERTICULAR ABSCESS, ANTIBIOTIC THERAPY IS INDICATED EVEN IN PATIENTS WITH NORMAL IMMUNE COMPETENCE. ANTIBIOTIC PROPHYLAXIS IS INDICATED IN COLONOSCOPY FOR THOSE WITH CARDIAC OR VASCULAR ABNORMALITIES, PERITONEAL DIALYSIS OR SEVERELY COMPROMISED IMMUNE STATUS.

## 5. E.R.C.P

ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY IS THE ONLY ENDOSCOPIC PROCEDURE WHICH HAS BEEN ASSOCIATED WITH A SIGNIFICANT RATE OF PROCEDURE INDUCED INFECTION[157,158,159,160,161,162,163,164,165,166,167,168,169]. Infections have occurred both sporadically and in mini epidemics. It is an unfortunate fact that most of the mini

epidemics have only been detected by hospital infection control processes, mainly as a result of phage typing of pseudomonas found in bile recovered at operation.

> *Endoscopic retrograde cholangiopancreatography is the only endoscopic procedure, which has been associated with a significant rate of procedure-induced infection.*

There are a number of reasons why E.R.C.P. is associated with this increased level of procedure-induced infections:

## (i)    Contamination of instrument and accessory equipment

INFECTIONS INDUCED AT E.R.C.P. HAVE ALMOST INVARIABLY BEEN WITH PSEUDOMONAS OR SIMILAR ORGANISMS (including Proteus spp.) These are ubiquitous commensal organisms which colonise almost any damp surface.  The usual source of pseudomonas has been the channels within the endoscope itself although occasionally contamination of accessory equipment has been responsible.  The major causes of infection that have been traced as a result of single clinical cases of infection or mini epidemics have included:

(a) Inadequate disinfection of the endoscope with particular faults being related to inadequate cleaning and disinfection of the forceps raising channel[170,171].

(b) Failure to rinse the channels at the end of the post-session cleaning and disinfection process with alcohol and to subsequently dry the channels with forced air[170,,172].

> *Because of the risk of residual dampness allowing proliferation of remaining organisms, duodenoscopes must always undergo full disinfection prior to the commencement of a list.*

(c) Contamination of the water feed system and water[172,173].  The water bottle and connecting tube must be sterilised before the commencement of each E.R.C.P session.  Sterile water must be used in the water bottle.  Use autoclavable water bottle and tubing to eliminate the possibility that glutaraldehyde residue may contribute to pancreatitis.

(d) Contamination of disinfecting machines by Pseudomonas (see Disinfecting Machines section).

Routine bacteriological surveillance of duodenoscopes and accessories should be performed monthly (see Microbiological testing of endoscopes).

**(ii)** **Patient related factors**

Obstruction of the bile or pancreatic duct will greatly increase the risk of infection following E.R.C.P. and if duct obstruction is demonstrated at the time of examination, then every attempt should be made to ensure adequate drainage by sphincterotomy and stone extraction, sphincterotomy and stenting, or naso-biliary drainage. If drainage cannot be achieved by these methods then consideration should be given to early surgical or percutaneous transhepatic intervention. Significant tissue damage is likely to occur if the pancreatic duct is over-filled or during manipulation to place stents. The clinical risks of infection will be compounded if the patient has a compromised immune status. WHEREVER INTERVENTIONAL E.R.C.P PROCEDURES ARE LIKELY TO BE UNDERTAKEN OR WHERE THERE IS A SIGNIFICANT LIKELIHOOD OF DUCT OBSTRUCTION, THEN CONSIDERATION SHOULD BE GIVEN TO PROPHYLACTIC ANTIBIOTICS. It is important to obtain significant tissue levels of antibiotics at the start of the procedure. Antibiotics are therefore generally administered intravenously commencing one hour before the start of the procedure.

# 6. PERCUTANEOUS ENDOSCOPIC GASTROSTOMY

Bacteraemia may occur during percutaneous endoscopic gastrostomy insertion from the necessary endoscopic manoeuvres. The passage of the inevitably contaminated end of the gastrostomy appliance through the stomach and abdominal wall makes the risk of local infection significant and antibiotic prophylaxis is recommended for all patients[174,175].

# 7. ENDOSCOPIC ULTRASOUND

There are conflicting reports of the rate of bacteremia during endoscopic ultrasound, one study[176] reporting no evidence of bacteremia, another claiming significant bacteremia in 6.3% of patients[177]. The longer distal segment without bending may result in some ultrasonic endoscopes causing more tissue trauma during manipulation. Until more evidence is available it may be prudent to offer antibiotic prophylaxis to patients undergoing endoscopic ultrasound who have HIGH RISK cardiac lesions.

## 8.    BRONCHOSCOPY


Flexible bronchoscopy represents only a very small fraction of all flexible endoscopic procedures, in some countries as low as 1/1000th . Bronchoscopy therefore has the highest <u>rate</u> of disease transmission and pseudo transmission of any flexible endoscopic procedure. Transmission of *Mycobacterium tuberculosis*[178], a*typical mycobacteria* and the problems of pseudo epidemics are discussed in the section on Mycobacteria (page 14).

More recently, there have been several epidemics of *Pseudomonas* transmission[15,16,179,180]. There is conflicting evidence as to the mechanism of transmission in at least two of these outbreaks. Details of the complex and conflicting arguments can be followed on the web site www.myendosite.com

From the evidence available on the net, in limited publications, from our own observations and from nursing staff reports in Australia the following observations seems appropriate:-

1.    Non-removable accessory devices (eg some channel valves and caps) should be viewed with extreme caution. Attempts to obtain positive cultures from these devices are difficult and may only be successful with reverse flow sampling.

2.    Instrument companies seem reluctant (presumably on the basis that it would be bad publicity) to issue warnings about real or potential instrument and accessory problems. Further, they seem reluctant to accept that individual instrument tracing and warnings are likely to miss many potentially affected instruments. (eg where they have been on-sold or transferred to another facility within a large health care organization.

4. Numerous problems associated with reprocessing flexible endoscopic instruments in automatic flexible endoscope reprocessors (AFER's) are considered in that section.

Critical points include:-

   a)  AFER's frequently become colonised with a*typical mycobacteria*, *Pseudomonas* and related organisms. The risks of serious colonisation are related to the unit water quality, the age and particular design of the AFER.
   b)  Claims that AFER's can regularly sterilise instruments in the absence of flow alarms on all channel connections, demonstrable sterility of rinsing water and demonstrable effective terminal self-sterilising cycles are simply untrue.

5.  Users and reprocessors of flexible bronchoscopes are strongly advised to:-

    a)  Comply <u>STRICTLY</u> with bacteriological surveillance of instruments, accessories and AFER's.

    b)  Review on a <u>REGULAR</u> basis that connecting tubes and devices are correct for the instrument manufacturer and AFER, and more specifically for the particular endoscope model. It may be necessary to purchase a separate cleaning adaptor from the endoscope manufacturer as these are not supplied with all models of AFERs. LEAKAGE AROUND INAPPROPRIATE OR WORN CONNECTORS MAY TOTALLY INVALIDATE THE WHOLE REPROCESSING PROTOCOL.

# THE PATIENT WITH INCREASED SUSCEPTIBILITY TO INFECTION

A variety of clinical circumstances may increase the danger of infection associated with endoscopy.  These will include:

1. Compromised immune status.
2. Procedurally induced tissue damage.
3. Intrinsic sources of bacteraemia.
4. Increased susceptibility to bacterial lodgement associated with septicaemia.

## 1. COMPROMISED IMMUNE STATUS

Impaired immune status is a major risk factor for significant clinical infection associated with endoscopic procedures[44, 129,134,135].  The most important clinical conditions associated with impaired immune status include:

(a) Infections, particularly Human Immunodeficiency Virus infection.

(b) Neoplastic disease (especially malignancy associated with the lymphoreticular system (lymphomas and leukaemias).

(c) Cancer therapy (radiotherapy, chemotherapy).

(d) Transplant patients (particularly bone marrow transplantation).

(e) Advanced systemic disease including advanced liver and renal disease.

(f) Specific disorders of immune response (e.g. hereditary hypogammaglobulinaemia).

Patients with compromised immune status are more susceptible to infection with ordinary pathogens but are also at significant risk from organisms not ordinarily considered pathogenic.  In addition they may, themselves, harbour unusual organisms which may be difficult to detect and resistant to chemical disinfectants (e.g. Cryptosporidia).  While such atypical organisms pose a relatively minor risk to patients with normal immune systems they may constitute a serious threat to other immunocompromised patients.  Hospital water supplies when contaminated with Pseudomonas or atypical mycobacteria, even at low levels, may be sufficient to pose a significant threat to the immunocompromised.

## 2. PROCEDURALLY-INDUCED TISSUE DAMAGE

Endoscopic procedures that result in tissue disruption or damage due to mechanical, chemical or inflammatory processes render the patient at even greater risk of infection. Significant tissue disruption occurs during oesophageal dilatation, removal of sessile polyps and in difficult bile duct stone extraction associated with sphincterotomy. Major tissue damage due to chemical factors occurs during injection sclerotherapy if significant paravariceal injection has taken place. It may also occur where absolute alcohol or sclerosing agents are injected into tumours or in attempts to arrest bleeding from chronic ulcers or Dieulefoy's abnormalities. Inflammatory processes such as post E.R.C.P. acute pancreatitis also increases the risk of infection. CONSIDERATION SHOULD BE GIVEN TO PROPHYLACTIC ANTIBIOTIC ADMINISTRATION IN PATIENTS WITH IMPAIRED IMMUNE STATUS AND EVEN THOSE WITH NORMAL IMMUNE STATUS WHERE MAJOR TISSUE DAMAGE HAS OCCURRED.

## 3. INTRINSIC SOURCES OF INFECTION

Intrinsic sources of infection which may be activated by endoscopic procedures will include acute peridiverticular abscess, E.R.C.P in the presence of cholangitis or infected pseudocysts or any other situation where infected lesions are present in or adjacent to the organ being examined. Consideration must be given to prophylactic antibiotic administration.

## 4. INCREASED RISK OF BACTERIAL LODGEMENT FOLLOWING SEPTICAEMIA

### (a) Endovascular integrity

Any abnormality of the endovascular surface, particularly if a high flow rate is associated with turbulence, will render the patient more susceptible to bacterial lodgement. The highest risk will be associated with prosthetic or incompetent valves. Other high risk factors will include stenotic valves, arteriovenous shunts and previous endocarditis.

### (b) Foreign material

Indwelling intravascular devices such as long term venous access systems (e.g. portacaths, Hickmann catheters) will constitute a high risk group. Foreign material within the body, but not in the intravascular space, carries a very substantially lower risk. Septic arthritis of artificial joints has been reported only very rarely in association with endoscopic procedures[181,182] and does not warrant antibiotic prophylaxis after the first 6 months post-insertion.

# ENDOSCOPY AND ANTIBIOTIC PROPHYLAXIS

## 1. INDICATIONS

There is no evidence to suggest that patients undergoing routine upper gastrointestinal endoscopy require antibiotic prophylaxis. Patients undergoing procedures, which have a higher incidence of bacteraemia, e.g. those involving the biliary tract, sclerotherapy or oesophageal dilatation may benefit, although this remains unproven. Prophylactic antibiotics are of proven value in E.R.C.P.

For this reason recommendations from both cardiac and microbiological societies vary quite widely[183]. As a generalisation, antibiotic prophylaxis can be recommended for:

(a) All procedures in patients with previous endocarditis.

(b) Patients with prosthetic heart valves, major valvular damage, arteriovenous shunts and indwelling vascular devices in all endoscopic procedures except simple diagnostic upper gastrointestinal endoscopy using a slim panendoscope.

(c) Patients with seriously impaired immune status having colonoscopy or any therapeutic procedure where tissue disruption is likely. If severe mucositis is present antibiotic prophylaxis may be appropriate for even simple diagnostic endoscopy.

(d) E.R.C.P. and associated pancreatobiliary procedures where there is duct obstruction, tissue disruption or impaired immune status.

(e) Patients having endoscopic procedures adjacent to intrinsic infective foci (e.g. colonoscopy and peridiverticular abscess, E.R.C.P with cholangitis, or infected pseudo cyst).

(f) Percutaneous endoscopic gastrostomy.

**High Risk Cardiac Conditions**[189]
- Prosthetic heart valves
- Previous history of endocarditis
- Complex cyanotic congenital heart disease
- Surgically constructed systemic pulmonary shunts or conduits

**Moderate Risk [189]**

- Uncorrected shunt defects
- Bicuspid aortic valves
- Coarctation of the aorta
- Acquired valvular dysfunction

**RECOMMENDATIONS FOR ANTIBIOTIC PROPHYLAXIS**

| ENDOSCOPIC PROCEDURE | CARDIAC CONDITIONS | | OTHER SITUATIONS REQUIRING SPECIAL CONSIDERATION |
|---|---|---|---|
| | HIGH RISK | MODERATE RISK | |
| Diagnostic endoscopy | NO | NO | YES - Chemotherapy/bone marrow transplant |
| Oesophageal Dilatation | YES | YES | YES - severely immunocompromised |
| Injection Sclerotherapy | YES | YES | YES - severely immunocompromised |
| Oesophageal Banding | YES | +/- | +/- - severely immunocompromised |
| Mucosectomy | YES | YES | YES - severely immunocompromised |
| Endoscopic Ultrasound | YES | +/- | +/- - severely immunocompromised |
| P.E.G. | YES | YES | YES - ALL PATIENTS |
| Routine Colonoscopy | YES | YES | YES - Ascites / Severely immunocompromised |
| Colonoscopy with Peridiverticulitis | YES | YES | YES - ALL PATIENTS |
| Traumatic Procedures e.g. foreign body removal, difficult stent placement | YES | YES | YES - IMMUNOCOMPROMISED |

# 2. ANTIBIOTIC REGIMENS

Protocols for antibiotic prophylaxis in endoscopy have been recommended by a number of bodies[183,184,185,186,187,188,189,190,191,192,193,194] including the Committee on Rheumatic Fever and Endocarditis and the Council on Cardiovascular in the Young, Endocarditis Working Party of the British Society for Antimicrobial Chemotherapy and Australian Therapeutic Guidelines on Antibiotics (available from Therapeutic Guidelines, North Melbourne, Victoria).

While there is little agreement on details of prophylactic regimens, the general principles are accepted. It is important to ensure adequate antibiotic concentrations in the serum during and after the procedure. To reduce the likelihood of microbiological resistance it is important that prophylactic antibiotics are given only during the peri-operative period.

COMMONLY USED PROPHYLACTIC ANTIBIOTIC REGIMENS

Standard Regimen – not allergic to Penicillin

ADULTS:  Ampicillin or Amoxycillin 1-2 g IM/IV   ) Before commencement
      and  Gentamicin 3mg / kg IV    ) of procedure

CHILDREN: Ampicillin or Amoxycillin 50mg/Kg IM/IV  ) Before commencement
       and Gentamicin 3 mg / kg IV    ) of procedure

Allergic to Penicillin / on Long Term Penicillin / Recent Penicillin

ADULTS:  Vancomycin 1g over 60-120 minutes IV
   ) One hour
        and  Gentamicin 3mg / kg IV    )  before procedure

CHILDREN: Vancomycin 20mg/kg IV       ) One hour
       and Gentamicin 2mg/kg IV     ) before procedure

   OR

Replace Vancomycin with Teicoplanin 6 mg/kg.


CLINICAL PROBLEMS WHERE A WIDE DIVERGENCE OF OPINION ON THE NEED FOR ANTIBIOTIC PROPHYLAXIS EXISTS.

    Indwelling vascular devices - antibiotic prophylaxis may be of value for patients undergoing endoscopic procedures with a high rate of bacteraemia, particularly if they have a compromised immune system

    Recent coronary artery stenting – antibiotic prophylaxis has been recommended by some authorities in the first 3-4 months following stenting until epithelialization has occurred.

    Orthopaedic prostheses – there are isolated case reports of orthopaedic prosthetic infection associated with endoscopic procedures[181]. However, the risk is extremely low. A recent survey of programme directors of infectious disease training programmes found that more than 50% or respondents felt that antibiotic prophylaxis was not indicated for any endoscopic procedures in patients with artificial joints[195]. However, there were wide variations in recommendations and there appeared to be little scientific basis for some views. The risk is certainly highest immediately after joint replacement and many would recommend antibiotic prophylaxis for the first six months after joint replacement, particularly if the patient has any impairment of immune competence.

# 3. ANTIBIOTIC PROPHYLAXIS FOR E.R.C.P.

The value of antibiotic prophylaxis for E.R.C.P. is also controversial[196,197,198,199] Some of this confusion has arisen because of the inappropriateness of the use of the term "prophylactic". There can be little argument that patients with clinical cholangitis or other evidence of biliary or pancreatic sepsis should be on appropriate antibiotics. Ther is also general consensus that patients who have undergone traumatic procedures with major tissue manipulation, incomplete drainage of obstruction, or widely dilated duct systems should continue to receive appropriate antibiotics.

The area of controversy is whether patients with minimal or no bile duct dilatation undergoing simple procedures such as endoscopic sphincterotomy and stone removal require antibiotics commencing before the procedure. A recent meta-analysis of studies examining antibiotic prophylaxis prior to E.R.C.P. concluded that while it may reduce the incidence of bacteraemia, it did not substantially reduce the incidence of clinical sepsis/cholangitis. One of the difficulties in deciding for or against antibiotic prophylaxis commencing before the procedure is that the complexity and outcome of the procedure cannot always be accurately predicted.

Optimum benefit of antibiotics will only be obtained if therapeutic levels are present in the bile and tissues at the time of examination. Patients should commence antibiotic prophylaxis intravenously at least one to two hours before the procedure. The common pathogenic organisms encountered in the biliary tree are *Pseudomonas aeruginosa, Klebsiella spp, E. coli, Bacteroides spp* and *Enteroccocci.*

**Prophylactic Antibiotic Regimens for E.R.C.P.**

Ciprofloxin    oral 750 mg – 2 hours before procedure
                    IV   200 mg – 2 hours before procedure

Piperacillin    4.5gm IV- 30 minutes before procedure

**OR**

Piperacillin $\pm$ Tazobactam  4.5gm IV 30 minutes before proceedure

**OR**

Ticacillin +/- Clavulinic Acid 3.1gm 30 minutes before proceedure

The reason for giving antibiotics needs to be clearly borne in mind. Is the risk simply of cholangitis or is there also a significant risk of endocarditis because of valvular damage or other abnormalities? Cephalosporins, ciprofloxacin and extended spectrum penicillins (e.g.ticarcillin, piperacillin) have very poor activity

against enterococci and are generally considered inappropriate for endocarditis prophylaxis.

Many infectious diseases physicians would not agree with the above choices for antibiotic prophylaxis for ERCP as there is wide-spread concern that the use of broad spectrum agents such as ciprofoxacin may have long term detrimental effects from the point of view of antibiotic resistance.

# 4.  BRONCHOSCOPY AND ANTIBIOTIC PROPHYLAXIS

Bacteraemia following fibreoptic bronchoscopy has a very low incidence.  Blood cultures taken after bronchoscopy were negative in all 100 cases in one study and were positive in 1 out of 50 cases in a second study[200,201].  There is only one case report of infective endocarditis following fibreoptic bronchoscopy that occurred in a 24 year old HIV positive patient[202]. Fever following bronchoscopy is not uncommon particularly in patients having bronchoalveolar lavage and is thought to be due to release of pro inflammatory cytokines from alveolar macrophages[203]. It can also occur following transbronchial needle aspiration.  Recently a study has found that during bronchoscopy bacteraemia rates can be 6.5%[204].

The Thoracic Society of Australia and New Zealand Guidelines state prophylaxis is not recommended for routine flexible bronchoscopy. However, it is recommended for rigid bronchoscopy, particularly those with high risk cardiac lesions, previous endocarditis, prosthetic valves, left sided major valve abnormalities, or surgically constructed systemic pulmonary shunts or conduits[205]. The British Thoracic Society recommends antibiotic prophylaxis before bronchoscopy in patients who are asplenic, have a heart valve prosthesis, or a previous history of endocarditis[13].  The American Heart Association recommends prophylaxis in a more exhaustive range of disorders; other subgroups of patients to be offered antibiotics prior to bronchoscopy include those with cyanotic congenital heart disease, rheumatic and other acquired valvular dysfunctions including mitral valve prolapse with regurgitation, surgically constructed systemic pulmonary shunts or conduits, and hypertrophic cardiomyopathy.  Because of the risk of haematogenous joint infection the following patients should also have antibiotic prophylaxis; joint replacement within the past two years, previous prosthetic joint infection. Those with inflammatory arthropathies including Rheumatoid Arthritis and Systemic Lupus Erythematosus disease, drug or radiation-induced immunosupression, haemophilia, malnutrition, and insulin dependent diabetes mellitus should also be considered for prophylaxis[206,207].

# PRINCIPLES OF EFFECTIVE DECONTAMINATION PROTOCOLS

## 1. INTRODUCTION

**THE MOST IMPORTANT STEP IN THE PROCESS OF ENDOSCOPE DECONTAMINATION IS SCRUPULOUS MANUAL CLEANING PRIOR TO DISINFECTION**

---

*DEFINITION*

*"Manual cleaning" refers to the physical task, performed by hand, of removing secretions and contaminants from the endoscope with appropriate brushes, cloths, detergents and water. <u>It should NOT be confused with</u> "mechanised cleaning" (where a cleaning process is performed by a machine) or "mechanised disinfection" (when a clean endoscope is placed in a machine which disinfects and rinses the instrument).*

*Mechanised cleaning has not been validated as a suitable method of cleaning endoscopes*

---

In order for manual cleaning to be effective it must:

1. Be performed by a person conversant with the structure of the endoscope and trained in cleaning techniques;

2. Be undertaken **immediately** after the endoscope is used so that secretions do not dry and harden;

3. Follow a protocol which, using appropriate detergents and cleaning equipment, allows all surfaces of the endoscope, internal and external, to be cleaned;

4. Be followed by thorough rinsing to ensure that all debris and detergents are removed prior to disinfection.

2. **EFFECTIVENESS OF RECOMMENDED PROTOCOLS**

Hanson et al[54,55] has shown that recommended protocols removed all microbiological contamination from endoscopes used to examine patients with HIV and HBV infection. They have also confirmed that endoscopes artificially contaminated with serum containing high titres of these viruses have all microbiological activity removed by appropriate reprocessing. These results have been confirmed by a number of other studies. One of the most important is that of Deva et al[208]. This excellent study made three critical findings:

1. When followed meticulously, recommended reprocessing protocols removed microbiological contamination.

2. That bacterial contamination was an accurate index of viral contamination.

3. That even minor deviations from cleaning protocols resulted in persistent microbiological contamination after disinfection.

Chu et al[209] has quantitated the dramatic reduction in bio burden levels following effective cleaning of colonoscopes. They have also confirmed the contamination of endoscopes during the cleaning process by water borne organisms including pseudomonas and enterobacteriaceae.

Not all investigators have been able to confirm such satisfactory results in reprocessing. Kovacs et al[210] reported a strain of *Pseudomonas aeruginosa* responsible for three separate clinical episodes of E.R.C.P. associated cholangitis over an 11 year period. They concluded the organism developed adaptive chemical resistance to glutaraldehyde because it could be recovered from the instrument after stringent recommended reprocessing protocols. Kovacs et al[211] found that endoscopes artificially contaminated with *Mycobacterium chelonei* did not have all bacteria removed by recommended reprocessing. The clinical implications of this study are less clear since clinical disease is unlikely to occur from *Mycobacterium chelonei.* Cronmiller et al[212] contaminated colonoscopes with *Enterococcus faecalis* and found some remaining contamination after ten minutes of glutaraldehyde immersion. Bordas et al[213] found that "in use" tests demonstrated not all bacterial contamination was removed by recommended protocols. Van der Voort et al[214] and other authors have found remaining HIV RNA on endoscopes when using PCR techniques. However the significance of this was extremely doubtful, particularly since the study of Deva et al[56] using the duck hepatitis B model has shown that duck hepatitis virus remaining on instruments detected by PCR was not infective when injected into ducks and therefore is likely to represent remaining viral RNA rather than intact infective particles. The number of organisms detected in most of these studies has been extremely small and of doubtful clinical significance.

A standard for testing of cleaning efficiency in endoscope reprocessing protocols has not yet been yet been developed though several studies have examined

methods such as ATP bioluminescence in an endeavour to provide a marker of cleanliness.

Several studies have shown that when followed meticulously, recommended reprocessing protocols removed microbiological contamination; however, even minor deviations from cleaning protocols resulted in persistent microbiological contamination after disinfection.  **This emphasises that present reprocessing techniques are less than ideal and have a lower margin of safety than is desirable.  It reinforces the need for all steps in reprocessing protocol to be carried out meticulously**.

## 3.  ENDOSCOPE STRUCTURE

There are at least fifty different models of flexible endoscopes available in Australia. An instruction book is supplied with each endoscope by the manufacturer.


**IT IS ESSENTIAL THAT EVERY PERSON RESPONSIBLE FOR ENDOSCOPE DECONTAMINATION READS THESE INSTRUCTION BOOKS AND IS FAMILIAR WITH THE PARTICULAR CHARACTERISTICS OF EACH MODEL OF ENDOSCOPE REQUIRED TO BE CLEANED.**


**COMMON FEATURES**

**External**

All flexible fibrescopes have a light guide plug, an umbilical cable (cord), a control head and an insertion tube.

**(a) The Light Guide Plug**

The light guide plug connects into the light source.  The air/water and suction channels have ports in the light guide plug.

The light guide plug of a video endoscope is larger and  heavier than that of a fibrescope and needs to be handled with care.  The size differential is also important with some AFERs with some instruments not fitting into reprocessing trays.

**(b) The Umbilical Cable/Universal Cord**

The umbilical cable connects the light guide plug to the body of the endoscope. The external surface may be contaminated by splashes or hand contact during endoscopic procedures.

**(c) The Control Head**

The control head contains the angulation control handles, which allow the operator to flex the instrument, and suction and air/water valves for control of air and water flow from the distal tip. Fibreoptic endoscopes have an eyepiece on the control head. Video endoscopes are similar in construction to fibreoptic endoscopes, except that they do not have an eyepiece - the image is seen on a video screen. The control head is contaminated during endoscopic procedures by the operator's hands. The control handles have grooved surfaces, which must be carefully brushed during cleaning. The hollow structure of some control handles should be noted and care taken to ensure that the undersurface is thoroughly rinsed and emptied of fluids. The seats, which house the suction and air/water valves (buttons), must be thoroughly cleaned with appropriate brushes. The biopsy channel port is located at the base of the control handle near its junction with the insertion tube. This port must be brushed carefully during the cleaning process.

**(d) The Insertion Tube**

The insertion tube enters the patient's body and is grossly contaminated during the procedure. The distal tip of the insertion tube houses the microchip (in video endoscopes), the openings for the suction and air/water channels and the lens covering the flexible fibreoptic light guides. The section of the insertion tube adjacent to the distal tip is known as the bending section. The outer covering is made from soft flexible material and is particularly vulnerable to damage especially if handled carelessly.

**Common Internal Features**

The suction and air/water channels and the fibreoptic light guide extend from the light guide plug to the distal tip. In non-video models an additional fibreoptic bundle, the image guide, extends from the control head to the distal tip. The cables, which allow the tip to be flexed, run through the insertion tube. Any damage to either the umbilical cable or the insertion tube can potentially damage any of the internal structures. Care must be taken during cleaning procedures to ensure that the umbilical cable and insertion tube do not become kinked or acutely bent. KINKS IN BIOPSY CHANNELS TRAP DEBRIS AND LEAD TO FAILURE OF THE CLEANING PROCESS. Suspected damage should be referred to the supplier for assessment and repair. A negative leakage test does NOT exclude damage to internal endoscope structures.

**Special Internal Features**

Most duodenoscopes have an additional channel - the forceps elevator (raiser) which is extremely fine (capacity 1-2 mls) and requires scrupulous attention during the cleaning process. Cleaning adaptors for this channel are provided with each duodenoscope AND MUST BE USED.

Some colonoscopes have a carbon dioxide channel ($CO_2$) that is connected to the air/water channel. Cleaning protocols should include individual flushing of this channel.

Flushing (jet) channels are found in some endoscopes. These are usually grossly contaminated during procedures and must be independently flushed during cleaning whether or not they have been used.

## 4. CLEANING EQUIPMENT

All endoscopes are supplied with appropriate cleaning adaptors. It is vital that persons cleaning endoscopes are conversant with these adaptors and use them correctly. Rubber "0" rings on the adaptors must be inspected regularly for defects or looseness and should be replaced as required. Substitute cleaning equipment should not be used unless approved by the supplier of the instrument, e.g. using a syringe to squirt fluid into a port which requires a screw thread adaptor is not safe practice.

Cleaning brushes for both channels and valve ports are also supplied. These have a limited life. They should be inspected regularly and replaced when worn or kinked. Metal wear from abrasion by cleaning brushes and other endoscope accessories may occur on the edge of the biopsy valve or suction button ports.

Soft toothbrushes are useful to clean grooved control handles and to brush the distal tip and biopsy ports. Cotton buds may be used to clean the biopsy valve caps but should not be used in the air/water port as threads may become caught and cause blocked channels.

Adequate supplies of disposable cloths should be available.


## 5. CLEANING FLUIDS

Detergents assist in wetting of and penetration into soil and in containment of the removed material in suspension. Enzymes digest biological contaminants, enhancing removal by brushing and flushing. These products should be used for endoscope cleaning. The study by Cheetham and Berentisveig[215] where deliberately inactivated enzyme cleaners showed reduced cleaning activity confirms the effectiveness of enzymatic detergents. The Cheetham study also highlighted the importance of enzyme stability during storage, with significant negative effects on both amylase and protease activity in some products from storage.

Manufacturers of enzymatic solutions report optimum efficacy when used in warm water ($35^0$C). However, enzymes will continue to be active in water that has cooled to room temperature ($20^0$C). The use of hot water ($>60^0$C) denatures proteins and inactivates enzymes. Heavy contamination may exceed the enzyme's activity capacity.

The use of enzymatic detergents may pose a workplace safety hazard. Occupational asthma and allergy have been documented with the use of proteolytic enzymes in the manufacture of detergents[216] and anecdotal reports over recent years have questioned whether such problems may be arising in endoscope reprocessing. It is likely that enzyme-free products currently undergoing evaluation and trials will be available in the near future.


## 6. BIOFILM

A biofilm is formed when some bacteria adhere to a surface and secrete large amounts of polysaccharide[217,218,219,220,221,222,223,224,225,226]. A typical biofilm will contain around 85% polysaccharide matrix and only 15% bacterial mass. Many bacteria are capable of only existing in a planktonic state (free suspension). Other bacteria, including Pseudomonas species, Legionella species and atypical mycobacteria have the ability to exist either in a planktonic state or to form biofilms. Examined under a confocal scanning laser microscope biofilms are shown to be complex systems with polyform towers and elaborate internal structures including water reticulation systems. Amazingly, bacteria with identical genotypes will exhibit marked differences in phenotype depending on whether they are in the planktonic or biofilm state. This has profound clinical implications discussed later. The ability to form biofilms confers significant survival advantages on bacteria. It offers a major defence system against physical and chemical forces, allowing bacteria to survive under adverse conditions of drying, chemical and antibiotic exposure. The biofilm is able to adapt its physical structure in response to alteration in environmental forces. For example, biofilms may exhibit a soft frond-like structure with relatively weak attachment in a slowly

flowing water stream.  If the velocity of water flow increases markedly then the biofilm will change to a firm to hard structure with much more secure surface attachments.

The ability to reticulate water within the biofilm allows a much greater extraction of nutrients.  A nutrient poor natural stream only able to support 8-12 planktonic bacteria per ml may have a bacterial density in a biofilm growing on a stream edge rock of $5x10^8/m^3$.[217]

Many biofilms also afford bacteria physical protection against natural enemies.  Amoebae and bacterial phages are unable to penetrate the polysaccharide matrix which shields bacteria from attack.   Under adverse conditions, biofilms are capable of disintegrating and releasing their bacterial population into a planktonic state.  Many signaling systems must exist within biofilms to allow these structural and chemical modifications.  These systems include quorum sensing (the release of signal chemicals in response to increasing population density), biosignal blockers, pheromones and butyrylhomoserine lactone.  These systems may in the future offer valuable avenues for impeding biofilm formation.  Even such an elementary description of the physical and chemical complexities of biofilms should lead to some appreciation of just how formidable adversaries biofilm-producing bacteria are.


**Areas of Biofilm Importance in Endoscopy Reprocessing**


Hospital Water Quality

If the endoscopy unit is the end receiver of highly contaminated water from old iron pipes with heavy biofilms, the problem may be insurmountable at a unit level and a total hospital water supply policy must be in place to ensure a reasonable quality of water to its various departments.  The degree of difficulty of preventing contamination of AFER's will thus be directly related to the quality of the municipal water and the plumbing system in the hospital.  Where the plumbing system has been subject to alteration, particularly with presence of dead runs, biofilm formation is likely to be a significant problem.  With reasonable water quality delivered to the unit, local measures such as filter banks with isolation loops are usually effective.   Initial biofilm removal within filter banks and isolation loops is best achieved with repeated applications of oxidising agents.  Once this has been achieved, frequent sometimes daily, applications of physical (hot water) or chemicals (lower concentrations of oxidising agents particularly chlorine releasing agents) are then likely to be able to maintain acceptable control of biofilm growth.   Solutions to hospital water supply problems must be a multidisciplinary approach involving engineers as well as water filtration experts, clinical microbiologists and endoscopy staff.

Removal of Biofilms

Oxidising agents are the most effective chemicals currently available for killing and removing biofilms. However, large quantities of the oxidising agent are consumed in destroying the biofilm and repeated applications at relatively high concentrations may be necessary, particularly in old or corroded pipes. Unfortunately, the concentration of oxidising agents required can itself have a serious corrosive effect on metal pipes and indeed endoscope parts. Glutaraldehyde is also an effective agent but requires a much greater time to kill the biofilm and is less effective in causing shedding of the biofilm from the surface. It is however much less damaging to metals.

Water Filters

A filter life and efficacy will be highly dependent on delivered water quality. Iron fragments from old iron pipes are quite literally capable of shooting holes in filters. When filters are removed they should be examined and cultured. If there is any suggestion of iron contamination then their physical integrity should be tested. Frequent clogging or gross contamination of the filters will only be overcome by presenting water of a more acceptable quality at the filter bank inlet.

AFERs

It may be impossible to remove biofilms once they become established in AFERs without major replacement of hoses, worn seals etc. Many bacteria are capable of developing resistance to glutaraldehyde. This applies particularly to some species of atypical mycobacteria. Glutaraldehyde will then be ineffective in removing the biofilms, and high concentrations of oxidising agents may be required as well as partial rebuilding of the machine.

**Some Clinical Implications of Biofilms**

(1)  Implications of Differing Phenotypes
There may be major differences in phenotype expression between the planktonic and biofilm states of genetically identical bacteria. This means that sensitivities both to chemicals and antibiotics determined on planktonic bacteria may be totally different from the sensitivities of the genetically identical bacteria in the biofilm state.

(2) Biofilm Implications of Positive Cultures
The recovery of organisms from AFER's or endoscopes may be totally dependent upon the timing of physical events to the culture. For example, if there is biofilm formation within the channel of an endoscope then cultures are likely to be apparently sterile by any technique if taken shortly after a full cleaning and disinfection regimen. Unfortunately, this does not prove that there are not viable bacteria at deeper layers of the biofilm. Further, the culture on one particular organism does not necessarily exclude that other organisms in the same or different biofilms exist within the endoscope.

**Biofilms within the Endoscopy Environment**

The removal of biofilms must be approached with care[217]. Shedding large chunks of biofilm into the air or into the bloodstream of patients is highly undesirable. For example, a single Legionella organism expelled into the atmosphere from an airconditioner will rarely cause clinical disease. However, when large chunks of a Legionella biofilm are inhaled then the risk of serious clinical disease is much higher. It is worth considering hospital areas where aerosols or biofilms can be formed within the endoscopy environment. This could include air conditioning systems, spa baths, ultrasonic cleaners and within AFER cabinets.

# 7. RINSING WATER

Where an instrument has undergone a "sterilising process" and is rinsed in water which is not sterile or where the sterility of the water has not been validated, then it is clearly wrong and misleading to claim that the instrument is sterile[227,228]

Where an instrument that has undergone a high level disinfection process is rinsed with water which is not of high level disinfection quality or where the water quality has not been validated, then it is clearly wrong and misleading to claim that the instrument has achieved high level disinfection[228,228]

The final rinse water for bronchoscopes and duodenoscopes should be bacteria free. It is desirable that the final rinse water for other endoscopes should be of high quality and free of bacteria known to cause invasive clinical disease including Pseudomonas species[229,230,231,232].

Water quality (ALSO SEE BIOFILMS) is a whole hospital issue and not simply an endoscopy unit problem[230,231,232,233,234,235,236,237,238,239].
>    (a) Hospitals should determine the quality of the delivered municipal water. The quality will depend on numerous factors including geography, municipal water filtration and disinfection systems, age of municipal piping etc.
>    (b) Hospitals must assess the intrahospital factors affecting water quality. These will include holding tanks, plumbing (age, plumbing alterations **NB** dead runs), the temperature of the hot water used, etc.
>    (c) The endoscopy unit must insist that water delivered to the unit is of acceptable quality. Unit water management efforts will become an expensive, ineffective waste of time if the whole of hospital issues are not addressed.

Even where unit delivered water quality is acceptable many problems can still occur. Old endoscopy units and those with water quality problems must have an effective isolation system, indeed these are recommended for all endoscopy units. This should include an access point at the beginning of water delivery to the unit and an access point immediately prior to the entry into AFER's. The line between these two points will include the filter banks and if necessary other water processing systems. This isolation loop must be easily and preferably automatically accessible to the particular water processing system used. Many

individual systems have been used[240]. These include biofilm removal by oxidising agents or Glutaraldehyde, line and filter sterilisation by physical agents such as hot water[241], and chemicals including chlorine-releasing agents. The chosen method must be compatible with filters, some of which can resist certain chemicals but not others, some can be backwashed, some cannot, etc.

Other methods of improving water quality within the loop have included reverse membrane osmosis, ultraviolet irradiation, Sterilox systems, etc. Whatever method is chosen then this must be a multidisciplinary approach with involvement of hospital engineers, AFER's representatives, clinical microbiologists, infection control officer, as well as endoscopy unit personnel[17,242,243,244].

No system is foolproof and water quality delivered to the AFER must be monitored by bacterial culture on a regular basis.

## 8. RINSING

Rinsing should take place under running water so that all traces of detergent and disinfectant are flushed away. Failure to adequately rinse glutaraldehyde from endoscopes has been reported to cause severe post colonoscopy colitis[245] and may be responsible for some cases of post E.R.C.P. pancreatitis. Residual OPA stains protein and has been reported staining patients lips following upper GI endoscopy and transoesophageal echocardiography. Static rinsing, i.e. rinsing in bowls of water should not be used.

The amount of water required to thoroughly manually rinse an endoscope after disinfection will vary according to the design and length of the instrument. Manufacturers instructions for volume of rinse water should be followed. It is unlikely that volumes of less than 150mls of fresh water in each channel will be effective in removing glutaraldehyde reside and 250 ml in removing OPA residue[246].

## 9. DISINFECTANT

Disinfectants for use in endoscope reprocessing are regulated by the Therapeutic Goods Administration (TGA)[247]. Worldwide, glutaraldehyde is the most frequently used chemical disinfectant for use in unsealed systems either in 2% alkaline glutaraldehyde (e.g. Cidex) or 2% neutral complexed glutaraldehyde (e.g. Aidal Plus) formulations. The recent entry into the market of *ortho*-phthalaldehyde (OPA) is an alternative. In Australia, peracetic acid is used in closed systems.

**Soaking time**

Effective manual cleaning of the item to be soaked is critical in determining the effectiveness of chemical disinfection.

*Endoscopes which are not adequately cleaned will not be adequately disinfected even with prolonged soaking times.*

Chemical manufacturers are regulated by the TGA to provide disinfectant contact times on the product label. Many professional organisations have published guidelines which recommend a shorter soaking time. Those recommendations are based on evidence that significantly less time is needed if the instrument has first been manually cleaned. Soaking times of 10-20 minutes for glutaraldehyde are common, with other chemicals having similar ranges of time. Other factors which effect soaking time include temperature and concentration of the biocide.

Chemical disinfection must take place in an area with adequate physical controls such as forced air extraction. Soaking bowls must have close fitting occlusive lids. Forced air extraction should extend to the rinsing sink. Post disinfection rinsing should be performed in COLD running water (warm or hot water increases the amount of fumes generated).

**ENDOSCOPY SHOULD NOT BE PERFORMED IN CENTRES WHERE ADEQUATE FACILITIES FOR CLEANING AND DISINFECTION ARE NOT AVAILABLE.**

Staff required to chemically disinfect endoscopes must be provided with education in the safe use of the biocide and with personal protective clothing which includes impervious gowns (or gowns and plastic aprons), gloves which have been approved for use with the chemical used and face shields (see Occupational Health and Safety).

## 10. GENERAL MAINTENANCE

Leak testing of endoscopes should be performed after use as per manufacturers' instructions. Removal of control buttons will assist in detection of minor leaks arising from cracks in the channel. Flexing of the distal tip whilst the instrument is pressurised will assist in detection of leaks in the A rubber. Failure to detect a

leak prior to thorough cleaning and disinfection may result in major damage to the instrument.

Examination of the instrument lens and outer sheath should be performed following each session to detect any signs of cracking or damage. The function of angulation cables should be checked.

Inspection of "0" rings on valves for sign of wear should be performed at the end of each session. "0" rings should be changed when signs of wear are detected. Biopsy caps should be checked for signs of wear and replaced as required.

## 11.   LUBRICATION

Lubrication is used to ensure optimal functioning of both endoscopes and accessories. The "O" rings on suction and air/water control buttons require lubrication to prevent the buttons sticking in the depressed position. Traditionally silicone oil supplied with the endoscope has been used. Silicone oils can be either petroleum based or in a water-soluble base. There is evidence that both preparations may impair reprocessing[248]. Biological fluid can be entrapped within oil globules and protected from disinfectant action. The choice is therefore to either take particular pains to ensure complete removal of silicone-based lubricants or to use surgical instrument lubricant.

**Recommendation**

(a) Accessory items processed in ultrasonic cleaners should be lubricated with an instrument lubricant following completion of the ultrasonic cleaning. They should then be wiped with a clean, lint-free cloth and allowed to air dry prior to packaging for steam sterilisation.

(b) Where silicone oil lubricants are used for suction and air/water control buttons, they should be applied immediately before use (after chemical disinfection). It is essential to remove lubricant residue to allow germicide contact. Ultrasonic cleaning will remove any small remaining amounts of lubricant.

## 12.   WORK AREAS

Work areas should be planned carefully. The areas should be well ventilated and the cleaning area should include the following:

1. At least one sink designated for the cleaning of instruments, referred to as the "dirty" sink. This should be made of materials which are impervious to solution, such as stainless steel, porcelain or of a plastic bonded material. The sink must be of sufficient dimensions to adequately hold a coiled full length

colonoscope without causing the instrument damage. The sink should be supplied with running hot and cold water.

2. An area adjacent to this sink where the components of the instrument are removed for cleaning. The "dirty" bench is then suitable for holding instruments awaiting chemical disinfection.

3. An area for disinfection of instrument. In the case of automated reprocessors the dimensions and requirements are dictated by the make and model of the machine to be installed. For manual disinfection, a container of solution of sufficient dimensions to hold an instrument without damage to the instrument would need to be available. It is preferable that this container be a fixed sink placed under an appropriate fume extraction system. Otherwise a container especially designed for liquid chemical disinfection of instruments is available. This must be placed in a fume extraction cupboard.

4. Where an automated disinfector is used, rinsing is performed within the machine. Where manual rinsing occurs, a sink designated for rinsing only clean instruments must be available and contained within the fume extraction cover.

# DECONTAMINATION REGIMENS

**Introduction**

It is known that stored endoscopes may become colonised with vegetative bacteria during storage, especially if the drying process is not adequate[249]. Unfortunately the complex structure and fine channels of endoscopes preclude absolute certainty that drying processes are always effective. Therefore endoscopes must have a full disinfection process performed prior to use **on the day** and at the end of the list.

At the end of a list, using 70% isopropyl alcohol to enhance the drying process, the endoscope must be thoroughly forced air dried prior to storage. Methylated spirits is NOT suitable for this process.

## 1.  MANUAL CLEANING

**<u>Pre Cleaning</u>**

The following steps should be performed immediately following a procedure. Bronchoscopes do not have air/water channels but should otherwise be processed according to these steps.

> **1.1**     **IMMEDIATELY** after each procedure with the endoscope still attached to the light source, grasp the control head. Using a disposable cloth soaked in detergent solution, wipe the insertion tube from the control head to the distal tip. Discard cloth.

> **1.2**     Place distal tip in detergent solution. Aspirate through suction channel - depress and release suction button rapidly to promote debris dislodgement. Continue aspiration until clean fluid is seen.

> **1.3**     Depress and release air/water button several times to flush water channel. Occlude air button to force air through the air channel.

> **1.4**     Depending on the brand of endoscope, either (1) insert the special air/water channel feed button and depress the button to flush with water then release for air flow to expel the water; OR (2) move the lever on the water feed connector to close off the water supply, then depress the water feed button until water is expelled; OR (3) disconnect the water bottle connector from the endoscope taking care not to contaminate its end, then occlude water connector port on the light guide plug and depress the water feed button until all water is expelled.

> **1.5**     The endoscope should be removed from the light source and taken to the cleaning area. Ensure protective caps are applied before immersing in solutions. (If due to local circumstances there is a delay prior to thorough cleaning first leak test the instrument then place the endoscope in

a bowl of enzyme detergent solution and soak).  **IT IS ESSENTIAL THAT THE ENDOSCOPE IS NOT ALLOWED TO DRY PRIOR TO CLEANING AS THIS WILL ALLOW ORGANIC MATERIAL TO DRY MAKING REMOVAL FROM CHANNELS DIFFICULT OR IMPOSSIBLE.**

### Leak Testing

**1.6**    Remove all valves and buttons prior to leak testing. Leak test the instrument as per manufacturer's instructions.

### Cleaning

**1.7**    Make up cleaning solution (page 41) as per manufacturers instructions.

**1.8**    Brush and clean buttons and valves paying particular attention to internal surfaces.  Place buttons in an ultrasonic cleaner.

**1.9**    Place endoscope in cleaning solution and using the brushes provided by the manufacturer brush all sections of the suction/biopsy channel and air/water channels if the instrument design allows.  Some twin channel instruments will require brushes of differing sizes.  If the brush contains obvious debris it should be cleaned before being withdrawn.  Each channel should be brushed until all visible debris is removed.  Wash all outer surfaces.

**1.10**    Using a soft toothbrush, gently clean the distal tip of the endoscope.

**1.11**    Brush control handles and biopsy port.  Brush around valve seats.

**1.12**    Clean valve seats thoroughly - check that all visible debris has been removed.  Use special brushes if provided by manufacturer.

**1.13**    Fit cleaning adaptors.  Thoroughly flush all channels with cleaning solution.  Ensure all air from the channels has been displaced then leave solution in contact for product specified time.

**1.14**    Purge cleaning solution from all channels.

**1.15**    Rinse outer surfaces.  Flush all channels thoroughly with fresh water.  It is essential that all detergent be removed prior to disinfection.

**1.16**    Purge channels with air to remove rinsing water.

**1.17**    Disinfect as per section 2 or reprocess in AFER.

## 2. MANUAL DISINFECTION

**2.1** After manual cleaning immerse endoscope in disinfectant so that the entire endoscope is submerged. Fill all channels with disinfectant so that all air bubbles are expelled. All channel entrances must be under the surface of the disinfectant during this procedure to ensure that no air enters the channel. Remove the buttons and valves from the ultrasound, rinse, dry and then immerse in disinfectant as per 2.2 or autoclave if applicable. It is preferable to have extra supplies of buttons and valves to ensure that adequate cleaning is performed prior to immersion in disinfectant.

**2.2** Soak instrument for required time at the required temperature in disinfectant of choice (see page 46). A timer with an alarm is essential to ensure that accurate soak times are achieved and digital timers are more accurate. A fluid thermometer with digital readout is recommended to constantly monitor temperature of biocide solution.

**2.3** Purge disinfectant from all channels with air and remove endoscope, valves and buttons from disinfectant, taking care to avoid drips and splashes.

**2.4** Rinse exterior of endoscope thoroughly and flush channels with fresh water to remove traces of chemical (for rinse volumes, see page 50). Rinse all valves and buttons thoroughly.

**2.5** Purge all rinsing water from channels.

**2.6** Dry instrument channels with pressurised air.

**2.7** If the instrument is being prepared for reuse, remove the cleaning adaptors. Dry exterior surfaces with a soft cloth and reassemble endoscope.

*If the instrument is to be stored do not remove cleaning adaptors and refer to point 3.1.*

## 3. AT THE END OF THE LIST

**3.1** Flush all channels with 70% Isopropyl alcohol (approximately 2mls for elevator channels, approximately 20m1s for each other channel)[249]. If using a multi-channel cleaning adaptor the quantities of alcohol may need to be increased.

**3.2**    Force air dry all channels.  Ensure that the air source has a flow regulator and use lower pressure on fine channels.  Use bayonet  (leur slip) fittings rather than luer lock to attach the air tubing to the cleaning adaptors and fit securely but not tightly - if safe pressure is exceeded the bayonet fitting will give way.  Use of excessive air pressure may cause damage to the instrument.

**3.3**    Remove all channel adaptors.

**3.4**    Ensure that all outer surfaces are dry.

**3.5**    Check the instrument for any sheath or lens damage.  Polish the lens with the cleaner provided by the manufacturer.  DO NOT REASSEMBLE ENDOSCOPE.

**3.6**    Store endoscope (disassembled) in a well ventilated storage cupboard, which permits full length hanging on appropriate support structures.

*Endoscopes should not be stored in transport
cases as these may themselves become
contaminated.*


## 4.  ENDOSCOPIC ACCESSORY EQUIPMENT

The cleaning and disinfection or sterilisation of reusable endoscopic accessories is equally as important as that of the endoscope as endoscopic accessories have been implicated in the transmission of infection.

***As with endoscopes, the cleaning of accessories as a pre-requisite to sterilisation is mandatory.***

 **(a)    Cleaning**

1.  All equipment should be immersed in enzymatic detergent immediately following use until cleaning can be performed.

2.  The equipment should be dismantled as far as possible and all visible soiling removed.

3.  Any spiral coil, hinged or complex structured accessories should be placed in an ultrasonic cleaner and processed according to manufacturers' recommendations. **NB** Keep hands out and lid on.  (Refer Aust. Std 2773)

4.  Any fine bore cannulae or tubing accessory items will require thorough flushing with enzymatic detergent.  Other accessory items, depending on design, will require a combination of flushing and brushing to clean surfaces.

**5.** Following cleaning by either of these methods, accessory items should be thoroughly rinsed and dried prior to disinfection, autoclaving or ethylene oxide sterilisation. ***High level disinfection should not be used for equipment which can be steam sterilised.***

## (b)  Disinfection

In general, accessory equipment used in gastroenterological procedures requires high level disinfection.  However, accessories that enter sterile tissue or the vascular system must be sterile.  This includes biopsy forceps, injection sclerotherapy needles and all accessories used for E.R.C.P.  Where an alternative exists, all non-autoclavable reusable accessories should be phased out.

1.  All autoclavable equipment must be cleaned thoroughly prior to sterilisation process.

2.  All non-autoclavable equipment should be immersed in disinfectant ensuring all cavities are filled.  The soaking time will depend on whether the accessory item will be required to enter sterile tissue (see section on Disinfection).

**Some accessory items require specific comment.**

**Sclerotherapy needles** are difficult to clean and reprocess to a sterile state. Therefore it is recommended that only single use sclerotherapy needles be used.

**Water bottles and connectors**.  These accessory items should be autoclaved at the beginning and end of each session as they have been implicated in the transmission of infection.  All non-autoclavable bottles and connectors should be replaced with those that are fully autoclavable.

**Dilators** are likely to come in contact with tissue that has been abraded or otherwise damaged by the dilation process.  They should therefore have undergone high level disinfection immediately before the session.  Note the operative field will not be sterile as the patient's own microbiological flora will contaminate the area.  Dilatation is also frequently performed using an endoscope that has undergone high level disinfection.

# 5. VARIATION IN CLEANING AND DISINFECTION REGIMENS DEPENDING UPON THE SUPPOSED INFECTIVE STATUS OF THE PATIENT

A number of surveys have shown that the practice of varying the cleaning and disinfection regimen according to the supposed infective status of the patient is widespread[81,82,250,251,252]. Reynolds et al[82] reported that in up to half the endoscopy units surveyed in Massachusetts, hospitals changed their reprocessing techniques after use in patients with known HIV infection, tuberculosis or hepatitis. Common practices include using ethylene oxide "sterilisation" or prolonging chemical immersion times for endoscopes used in patients with these diagnoses. Such an approach is totally unscientific and illogical. Many patients who have these disorders and do not know or conceal such knowledge will be subjected to endoscopic procedures. It is therefore totally unacceptable to have a cleaning and disinfection schedule that does not effectively deal with such unrecognised cases. By logical extension, if the cleaning and disinfection regimen is adequate to deal with unknown cases, then it is also adequate to deal with known cases. Conversely, the use of special precautions in known infected cases clearly implies that the regimen used under routine circumstances is thought to be inadequate to prevent transmission of these diseases. There is clear, adequate evidence to show that the cleaning and disinfection schedule recommended in this review is adequate to prevent the transmission of infectious disorders including HIV infection, hepatitis and tuberculosis. There is therefore NO JUSTIFICATION to alter the cleaning and disinfection regimen if patients are known to have these disorders.

It must be noted these statements apply to common pathogens such as human immuno deficiency virus, hepatitis viruses and bacteria. Special and unusual hazards do exist. The problems associated with modified Prion Protein diseases (Creutzfeldt Jakob Disease and other spongiform encephalopathies) are considered on pages 21-23. These agents are highly resistant to conventional forms of microbiological destruction and the containment measures outlined in that section should be followed.

There is no evidence that *Mycobacterium tuberculosis* can develop adaptive chemical resistance. A special problem with *Mycobacterium tuberculosis*, however, exists in relation to staff and patient cross infection from contaminated aerosols. As noted in the section on *Mycobacterium tuberculosis*, the Centre for Disease Control strongly recommends that bronchoscopy is not undertaken in patients with known active tuberculosis. Where open cavitating tuberculosis exists the risk of aerosol spread is extremely high. Persistent and explosive coughing is frequent during and following bronchoscopy and the risk of mycobacteria containing aerosols is significant even with closed tuberculosis. Appropriate precautions in the examination room will include negative air pressure ventilation with operating theatre levels of air exchange together with appropriate personal protective measures for the staff.

Adaptive chemical resistance to a wide range of disinfectants has been convincingly shown for atypical mycobacteria and problems associated with the decontamination of automated reprocessors are considered on page 57.

# 6. REUSE OF MEDICAL DEVICES LABELLED 'SINGLE USE ONLY'

The annual cost to the United States health services alone of devices labelled 'Single Use Only' is estimated to exceed three billion dollars. It is therefore hardly surprising that in a climate of progressive fiscal restraint, health care facilities will attempt to restrain costs by reusing devices labelled 'Single Use Only'. The safety, ethical and legal issues involved in such reuse have proved to be complex and divisive, various stakeholders viewing the problem from one perspective only[253,254,255,256,257,258,259,260,261,262,263,264,265,266,267,268].

Major physical issues in reprocessing 'Single Use Devices' are clearly stated in the compliance policy guide of the F.D.A.:

1. That the device can be adequately cleaned and sterilised.

2. That the physical characteristics or quality of the device will not be adversely affected; and

3. That the device will remain safe and effective for its intended use.

Less clear are the ethical and legal issues raised in reprocessing. The underlying issues revolve around the opposing arguments of utilitarianism and contractarianism. Does the maximisation of benefit to society as a whole from the more efficient use of medical financial resources outweigh a small but essentially unquantifiable increase in risk to the individual patient in whom a 'single use only' device is reused?

Institutions proposing to reuse 'single use only' items will face the necessity of developing and validating protocols which can ensure the safety and efficacy of reprocessed items.

Endoscopists have until recent years dealt with these problems with the convenient but highly unsatisfactory device of simply ignoring them. Major problems remain in the reprocessing of endoscopes themselves, let alone accessory devices. Fortunately recent advances in design and manufacture of accessories have resulted in significant improvement. Biopsy forceps can now be autoclaved and there can be no justification for failing to use either disposable or sterilised reusable biopsy forceps[264,265,266,267,267,268]. Relatively low cost disposable items are now available for a number of other accessories where clinical usage/design mitigate against effective reprocessing (e.g. endoscopic injecting needles). The main area of debate in the reuse of 'single use only' items in endoscopic practice centers around the relatively expensive E.R.C.P. accessories, particularly catheters, sphincterotomes, guidewires and balloons. Fortunately for the majority of these items, device failure during operation is unlikely to have major clinical consequences. Major debate therefore centers around the efficacy of cleaning and sterilisation.

The available literature provides no clear evidence that reprocessing can be achieved safely or that there is significant cost benefit. The prudent course appears to be either not to reuse items that are labelled 'single use only' or to do so under the strictly controlled conditions outlined above.

# AUTOMATED FLEXIBLE ENDOSCOPE REPROCESSORS (AFER's)

Machines designed to disinfect and rinse endoscopes have been available for more than 20 years and are now widely used in the western world[251,269]. Surveys in America in 1988 and 1999 showed around 70% of units employ AFERs[270,271]. Machines reduce unpopular arduous repetitive tasks and reduce occupational exposure to irritant chemicals. A survey of practices in the United States in the early 90's showed widespread lack of knowledge of the potential problems with machine contamination[252,269], and although there is a wider recognition in recent surveys of the problems associated with AFERs, there still remains widespread ignorance of the importance of machine colonisation, the proper methods of decontaminating machines and the need for bacteriological surveillance. AFERs have been responsible for many serious clinical infections which have included deaths[15,16,272,273,274,275,276,277,278,279,280,281], and have also been responsible for epidemics of pseudo-infection. The enthusiastic and largely uncritical acceptance of AFERs may pay more to their convenience than clinical safety. There are numerous AFER models with widely varying quality, durability and effectiveness[282]. Perceived advantages of disinfecting machines include:

- Standardisation of endoscope reprocessing.

- Reduced exposure of staff to chemicals

- Reduction in staff time spent on disinfection.

- Reduced occurrence of occupational strain injury to workers hands

None of the currently available machines negate the need for thorough manual cleaning. This is an essential prerequisite to disinfection. Claims by manufacturers of some models of automated endoscope reprocessors that manual pre-cleaning is unnecessary are not supported by published literature in respected peer reviewed journals. Working parties in Europe are currently developing standards for AFERs under the European Committee for Standardisation and the International Standards Organisation. When completed, Parts 1 & 4 of these documents will hopefully provide a reasonable international machine standard which will specify requirements for manufacturers as well as guidance on routine and periodic tests for users to perform.

## Machine Design and Principles

AFERs will rarely show contamination when new. Unfortunately this is when most machines are tested. Problems with bacterial contamination rarely become apparent in machines before six months and become progressively more likely as the machine ages. Common predisposing causes include the development of biofilms, valve wear, surface irregularity, line fissuring and filter failures.

The following are ideal design features and principles which should underlie the selection and use of AFERs.

1. Water Supply:  Machines should be plumbed into the water supply rather than use manual filling.  It will be necessary to install pre-filters, i.e. filters in the water supply prior to its entry into the automated reprocessor.  Membrane cartridge filtration of 0.2 micron is necessary for final rinsing. Once filter systems are installed they in turn must be regularly serviced and monitored. It is all too easy for filters themselves to become a source of contamination[17,243,243,244, 276,281].

2. Water reuse: Fresh water should be used for each cycle to avoid disinfectant contamination of rinse water.

3. Fume Containment: Provision should be made for the extraction of disinfectant fumes from within the machine or the machine should be contained within a fume extraction hood.

4. Disinfectant Supply:  Machines which use a concentrated solution and in-use dilution for a single cycle (e.g. STERIS System, Soluscope) avoid the problem of dilution of the disinfectant with rinsing water.  Machines which contain a tank of disinfectant for re-use should be monitored for disinfectant concentration to determine appropriate disinfectant change schedules. Machines which require filling of a disinfectant reservoir must incorporate a pump mechanism to obviate the need for pouring of solutions into the machine.

5. Cycle Counter:  Visual display and a permanent record of the cycle number should be available to indicate the appropriate time for disinfectant change. Automatic recording of disinfection activity is desirable.

6. Self-disinfection:   All machines should have a cycle for auto-disinfection. Unfortunately this term is used loosely and in many machines the so called "auto-disinfection cycle" does not extend to all parts of the machine which may allow significant contamination to develop.   Heat is the preferred choice for self disinfection. Alternatively, it is preferable that the auto-disinfection cycle should use a disinfectant alternative to that which is routinely used in the reprocessing cycle.  A number of organisms including atypical mycobacteria (particularly *Mycobacterium chelonae*) can become extremely resistant to glutaraldehyde[30,276].   Elimination of such colonising organisms may require purging of the whole system with alternative agents including chlorine-releasing disinfectants, peroxide compounds or absolute alcohol.

7. Drying:   A drying cycle using filtered air should be complemented by a facility that irrigates the channels of the endoscope with alcohol.

8. Leak Testing:  Machines should perform leak testing of the endoscope at least once during the reprocessing cycle.

9. **Warning Systems:  Measurement of all channel flow rates and pressures should be monitored and an audible warning alert should be incorporated for changes in these parameters to detect channel blockage preventing**

**adequate perfusion of disinfectant solutions, dislodged connectors, water filter blockage, and leakage from split channels.**

10. Proof of Process:  A printout of cycle parameters should be incorporated. Ideally this information should be electronically transferable to computer based record systems.

11. A heating facility allows for lower in-use concentration of disinfectant and shorter contact time.  The temperature should be monitored if heated disinfectant is used in the machine and the disinfectant chosen be licensed by the TGA for use at the elevated temperature.

**12. Individual Channel Perfusion: Fluid flow through each channel should be ensured by a design which does not permit diversion of flow to a channel of lower resistance. Machines which are to be used for reprocessing duodenoscopes must allow for the differential pressures required to perfuse the widely differing sized channels.  The forceps elevator channel in duodenoscopes is a particular problem because of the extremely fine bore and similar issues arise with perfusion of jet channels.**

13. Maintenance:  A maintenance schedule which ensures tanks, pipes, strainers and filters of both the machine and water treatment system are kept free of biofilms and other deposits should be instituted.

14. Strict bacterial monitoring of disinfecting machines and endoscopes is essential wherever endoscope reprocessing machines are used.  Machines which are shown to be contaminated should not be used until cleaned and proven to be microbiologically safe (see Microbiological Testing of Endoscopes).

15. Quality features:  AFERs cannot guarantee to sterilise endoscopes despite some manufacturers claims to the contrary (see Sterilisation and Disinfection Practical Aspects).  Endoscopes that have been inadequately cleaned and subjected to "sterilising processes" have caused serious clinical infections and deaths, and this includes processors using ethylene oxide and peracetic acid exposure. AFERs cannot claim to sterilise instruments if they do not have flow alarms on all channels, appropriately fitting connection devices which prevent excessive leakage and sterile rinse water, the sterility of which can be verified by in-use tests.

# PROOF OF PROCESS

## Proof of Process

Quality control is fundamental to the delivery of safe and effective clinical services. Endoscopy is hindered by the inability to use sterilisation techniques with clearly defined parameters (e.g. steam under pressure sterilisation) in the reprocessing of flexible endoscopes.

There is substantial evidence that endoscope and accessory reprocessing procedures are often not fully followed. The reprocessing of flexible endoscopes is a difficult and complex task therefore:
- Endoscopy should only be undertaken in centres that have adequate facilities for cleaning and disinfection.
- All centres that reprocess endoscopes and accessories should have clear and detailed quality management systems to ensure there is full compliance with all aspects of the cleaning, disinfection and sterilisation protocols.
- Only staff who have been formally trained and certified to perform the vital tasks of cleaning, disinfection and sterilisation, or those undergoing supervised training, shall carry out these tasks.
- The laboratory that performs the microbiological testing must be NATA accredited and may have ISO 17025 or ISO 9007 certification.

### Purpose of Quality Control

The general purpose of the quality control system is to:
- ensure that HCWs responsible for reprocessing endoscopes and accessories have a clear understanding of the important principles involved and fully understand each of the steps necessary in reprocessing
- record measurable parameters, such as disinfectant immersion time and disinfectant concentration
- maintain accurate records of each reprocessing encounter that allows appropriate retrospective linkage analysis e.g.
  - investigation of possible transmission of diseases by endoscopy
  - investigation of low levels of bacterial contamination of endoscopes

### Information required

Records shall be kept and shall include, but are not limited to the following:
- Every list
  - order of patients on the list
- Every endoscope reprocessed
  - date of procedure
  - patient details – this could be formatted on a facility label
  - instrument details
  - temperature of the biocide
  - immersion time in the biocide

- signature of person who
  - manually cleaned the instrument
  - rinsed the instrument
  - disinfected the instrument
  - final rinsed the instrument
  - tested the temperature of the biocide
  - timed the immersion of the instrument in biocide
  - connected the instrument to the automated flexible endoscope reprocessor (AFER)
- Daily (at least)
  - minimum effective concentration (MEC) of the biocide
  - signature of the person who tested the biocide
- Other
  - batch number of biocide
  - date biocide decanted into tank
  - date biocide changed or topped up (to maintain volume)

A unit-based record shall be kept regardless of whether the information is in the patient's health care record. Computer print-outs from an AFER shall be attached to the unit record and a copy may be attached to the patient's health care record.

It is recommended that one person perform the full manual cleaning of an instrument. If a change in personnel occurs then the process should be recommended to completion.

All accessory items that have been sterilised, e.g. biopsy forceps, shall have a chemical indicator to demonstrate that they have been subjected to the sterilisation process.

Accessories which breach sterile surfaces and are difficult to reprocess, such that sterility cannot be regularly achieved, should be single use only, e.g. sclerotherapy needles.


**Monitoring the biocide**

Concentration of a biocide is critical. In general the lower the concentration of the agent, the longer it will take to kill the same number of organisms. It is particularly important to ensure that biocides do not become diluted with excess water remaining on endoscopes after rinsing.

To achieve the minimum high-level disinfection required for reprocessing endoscopes the concentration and temperature of the biocide and the contact time with the instrument must be in accordance with the biocide's TGA registration. This is reflected in the manufacturer's instruction on the biocide's label.

The most critical factor in the use of any biocide is thorough meticulous manual cleaning. If the flexible endoscope or its accessories are not clean then high level disinfection or sterilisation cannot be achieved.

**Minimum effective concentration (MEC***)*
The challenges of microbes and organic matter, dilution by rinse water and age of the chemical solution result in a gradual reduction of the effectiveness of reusable biocides. The appropriate number of reuses must be determined by testing that the solution is at or above its MEC.

- The MEC of the biocide must be checked at least daily depending on the numbers of instruments being reprocessed.
- It is important that a test strip or other approved device specific for the brand and MEC of the active agent be used in the appropriate manner to monitor the potency of the biocide.
- A log of the results of the MEC testing and the signature of the person performing the test should be maintained.
- The biocide must be changed when the solution fails to meet the MEC or if it exceeds the manufacturer's recommended use life, whichever comes first.

**In-use life**
The in-use life of the biocide should not be extended beyond that recommended by the manufacturer.

The MEC should not be used as a means of extending the in-use life of the biocide. Equally the in-use life should not be utilised as a means of re-using the biocide if the MEC of the solution is not adequate.

 A record should be maintained of:
- the batch number of the biocide
- the date decanted (ie. date of first use)
- the expiry date of the biocide

**Ultrasonic cleaners**

An ultrasonic cleaner enables thorough cleaning of equipment by ultrasonic agitation that dislodges soil from instruments.

**Routine cleaning**
Cleaning the ultrasonic cleaner and replacement of the cleaning solution is necessary at least daily or more frequently if solution soiled.

This should include:
- checking filters
- checking base plates
- wiping of external surfaces,
- emptying the tank

**Performance testing**
The efficacy of the ultrasonic cleaner should be tested daily or when used. Testing should be performed according to the manufacturers instructions and in keeping with AS2773.2 section 6. The results of the testing shall be documented as part of the proof of process.

According to AS 2773 either of the following two tests can be used to check the performance of the ultrasonic cleaner.

Pencil Load test
This is also known as the ceramic disc test. The surface of an unglazed ceramic disc or plate having a matt finish and a diameter of approximately 50 mm (thickness is not critical) is rubbed with a standard HB lead pencil and then immersed in the cleaning tank. A ground glass stopper, a sheet of ground glass, or an aluminium sheet with a thickness of 2 – 3mm may be substituted for the ceramic disc. A kit using an aluminium disc is now commercially available.

The Ultrasonic Cleaner should completely remove the pencil lead within 3 minutes or the time specified on the kit instructions.

Aluminium foil test
Vertically suspend pieces of aluminium foil in the ultrasonic tank, so that they are evenly spaced between the ends of the cleaning tank. Each piece of foil should be approximately 0.025mm thick and extend to approximately 6mm clear from the sides and bottom of the tank.

Operate the ultrasonic cleaner for 10 seconds. Remove the sheets of foil and observe the number and distribution of perforations and wrinkles.

Ideally, all sheets of foil should be similarly perforated and wrinkled. That is, if the holes are primarily in the middle sheet of foil, or if the pieces of foil are only wrinkled but without holes, the equipment is considered to have failed the test.

It may be necessary to provide a simple wire frame to support each sheet of foil during the test.

On completion of the test, ensure that the tank is drained and thoroughly cleaned, to remove the foil residue.

**TEMPLATES**

Each unit should develop their own register that is suitable to their own particular needs.

Some samples templates are included in Appendix A.  They have been developed by particular units for their own use and are included as examples for units to use as a guide to developing their own documentation system.  For example if your facility sends accessory items to the sterilising department, then Sample 5 may not need to be used, as the sterilising department maintains their own quality assurance documentation.

# INVESTIGATION OF POSSIBLE INFECTION TRANSMISSION BY ENDOSCOPY

Transmission of Hepatitis C by colonoscopy, endoscopy and ERCP together with transmission by errors of anaesthetic technique of other serious **VIRAL** infections including HIV have occurred during minor surgery raising public concern. Increasingly, patients will question the possibility of serious viral disease being acquired as a result of endoscopic procedures. The aim of this section is to provide general advice for endoscopy units when the possibility of disease transmission arises. The most likely viruses involve Hepatitis C, Hepatitis B and HIV. In some cases these claims will be opportunistic, seeking financial gain or seeking to divert attention from the real source of infection. However, it is important to realize that in some patients the source of infection will be genuinely unknown and these patients may sincerely believe that endoscopy is the most likely cause of their disease. If your unit has followed the recommendations laid down in this manual it is extraordinarily unlikely, indeed it will be unique, if your unit has transmitted a serious viral disease by endoscopy.

Unfortunately the likelihood of a patient acquiring a significant **BACTERIAL** infection as a result of endoscopic transmission is significantly higher (see section on Infecting Organisms, Bronchoscopy, AFERs and Water in the Endoscopy Unit).

Investigation of a possible transmission incident usually arises because:-
- self-recognition of protocol errors
- defective machines and devices
- AFER colonisation
- inadequate or otherwise improper use of biocide.

In Australia, the relevant State Health Department should be notified of any incident requiring investigation. Authorities will commonly allow the unit to investigate self-recognised protocol failures which are deemed to have a low risk of disease transmission. Investigation of patient complaints and potentially serious incidents should be conducted by an independent appropriate regulatory authority. The proper approach to investigating an incident will depend upon the particular circumstances. Obviously, the investigation of a patient's claim that they have acquired Hepatitis C after an endoscopy will be rather different from the finding of atypical mycobacteria in an AFER. In general, for any potential serious breach the investigation will:-

1. Demand evidence of compliance with registration, licensing and credentialling requirements.
2. Evidence of medical and nursing qualification with an acceptable continuing education program.
3. Unit assessment to evaluate endoscopic equipment, accessories, AFERs and safety equipment.
4. Conduct an inspection to ensure that internationally accepted reprocessing protocols are used and that protocol compliance is documented.
5. Review evidence of bacteriological surveillance programs.

6.   Identify involved at-risk patients, endoscopes, accessories and equipment.
7.   Examine anaesthetic procedures
8.   Conduct appropriate patient surveillance usually including serological testing for HIV, HCV and HBV of at-risk patients.

The following principles are strongly recommended:-
1. Inform the relevant State Health Department immediately a problem is recognised.
2.   Document patient complaints and refer them to the State Health Departments.
Do not attempt to argue with the patient, suggest alternative sources of infection or belittle fears of possible infection transmission.
3.   For potentially serious incidents obtain independent advice.  Contributors to this monograph have extensive experience in investigating such incidents and are always available for initial advice.
4.   Do not try to avoid investigation and do not attempt to undertake investigation of serious patient complaints yourself.
5.   Ensure that the information required for investigating authorities is readily available.

There is no current evidence that serious viral diseases such as HIV, HBV, HCV have been transmitted from one patient to another by endoscopy if all details of the reprocessing protocols and other measures recommended in this monograph have been followed.

# MICROBIOLOGICAL TESTING OF ENDOSCOPES (INCLUDING BRONCHOSCOPES) AND AUTOMATED FLEXIBLE ENDOSCOPE REPROCESSORS

## 1. INTRODUCTION

Appropriate bacteriological surveillance of endoscopes and automated processors has proved one of the most difficult and controversial areas of infection control in endoscopy. It is therefore appropriate to state the principles involved together with the details of sample acquisition, processing and interpretation.

Microbiological contamination of endoscopes may occur if:

1. Reprocessing has been inadequate or otherwise deficient.

2. The endoscope is damaged.

Reprocessing deficiencies may occur during:

1. Manual cleaning. This will include all aspects of proper cleaning, from allowing biological material to dry on or in the endoscope through failure to carry out each of the numerous cleaning steps properly. Deva et al[57] has shown that failure to brush even the short segment of the biopsy channel between the suction button and the biopsy forceps port resulted in persistent viral and bacteriological endoscope contamination even after an otherwise adequate manual reprocessing and full disinfection. The colonoscopic transmission of Hepatitis C in France may well have resulted from failure to brush colonoscope channels adequately[76].

2. Disinfection failures may occur because of the use of inappropriate disinfectants, inadequate immersion time or more frequently the use of contaminated automatic processors.

Endoscope Damage:

It is not possible to adequately inspect the internal channels of endoscopes. Cracking, splitting, fissuring, joint disruption, actual channel wall holes can all be the source of bacterial contamination within the scope which can be difficult to impossible to detect by routine inspection and testing. BACTERIOLOGICAL SURVEILLANCE OF ENDOSCOPES IS FREQUENTLY THE ONLY MEANS OF DETECTING THESE PROBLEMS AT THIS TIME.

## 2. TESTING SCHEDULES

The frequency of bacteriological screening for standard endoscopes and colonoscopes remains controversial. On the other hand regular microbiological monitoring of duodenoscopes, bronchoscopes and AFER's is essential. The presence of potentially transmissible bacterial pathogens on gastrointestinal endoscopes following inadequate cleaning is usually accompanied by the inadequate removal of other enteric bacteria. Thus microbiological monitoring of endoscopes should be viewed as an indirect marker of adequacy and completeness of the cleaning and disinfection process, i.e. is a marker of rigorous adherence to the recommended protocol and also as a measure of structural integrity of the instrument. Assessment should focus on the acceptability of the total number of organisms remaining. Detailed taxonomic identification is not indicated except where microbiological failure persists after a rigorous review of compliance with both cleaning and disinfection protocols, after review of the structural soundness of the endoscope or where clinically recognised cross-infection is apparent. Numerous studies document the transmission of infection by contaminated duodenoscopes during E.R.C.P. (see E.R.C.P section). In many of these outbreaks the endoscopy units involved were unaware of the instrument contamination and the serious clinical infections being caused. The outbreaks were frequently overlooked for prolonged periods and only came to light as a result of investigation of a series of infections with similar or unusual organisms.

### WHAT TO LOOK FOR

**Viruses**

It is frequently asked why microbiological surveillance does not extend to viruses. The principles involved here are:

1. Viruses can only proliferate within cells. Therefore proliferation in the internal channels of endoscopes or in automated reprocessors does not occur.

2. Deva et al[208] have shown that bacterial contamination after reprocessing is an accurate reflection of viral contamination. Where bacteria remained on or in an endoscope after reprocessing there was also frequently remaining viral material. Conversely however, in no case where all bacterial contamination had been removed were remaining intact viruses demonstrated.

3. The detection of intact infective viruses is extraordinarily complex, prolonged and expensive, indeed, prohibitively expensive for routine surveillance purposes. Many viruses, e.g. HBV, cannot be cultured in vitro. The detection of viral nucleic acid by PCR techniques (see Hepatitis C section) certainly does not necessarily reflect the presence of intact infective viral particles[56].

**Bacteria**

Bacterial cultures should be directed to the detection of:

- **Endoscopes and Colonoscopes**
  Common pathogens, including pseudomonas, klebsiella, proteus, E coli and salmonella.

- **Automated Processors and Bronchoscopes**
  Pseudomonas, similar organisms and atypical mycobacteria.

Previous recommendations that other common tap water contaminants, including legionella and cryptosporidia should be looked for do not appear to be clinically useful and are difficult and expensive. We do not recommend routine cultures for these organisms.

# 3. RECOMMENDATIONS

Because of differential risks of infection transmission, recommendations which are themselves empiric, vary with both the proposed use of endoscopes and with the method of disinfection and cleaning:

1. Automated reprocessors (AFER's) and endoscopes processed in these should be monitored every four (4) weeks.

2. Duodenoscopes should be monitored every 4 weeks.

3. Bronchoscopes should be monitored every 4 weeks.

4. All other gastrointestinal scopes should be routinely monitored every four months.

5. The frequency of the monitoring of the water supply will depend on the bacteriological quality of the water delivered to the unit.

6. If major changes are made in the Endoscopy Unit personnel responsible for cleaning or if there is a clinical suspicion of cross-infection related to endoscopy, then further microbiological screening should be undertaken in conjunction with a Clinical Microbiologist.

# 4. MICROBIOLOGICAL TESTING PROTOCOLS

These protocols are primarily instituted to detect an increased residue of bacteria following routine cleaning and disinfection which represents a surrogate marker of inadequate cleaning or of structural damage to the channels of the endoscope. Instruments should be sampled following cupboard storage of not less than 12 hours.

**Method of Sampling**

1. 10mls of sterile water (or Ringer's solution) is withdrawn from a freshly opened bottle using a sterile needle and syringe and put into a sterile universal container.

2. A second 10mls of sterile water (or Ringer's solution) is flushed to fill the channel to be sampled.

3. A sterile endoscope brush is passed down the biopsy channel, withdrawn and swirled in the universal container containing the sterile water (or Ringer's solution). The brush will need to be handled using sterile gloves. The endoscope brush should be sterilised by autoclaving or gas sterilisation.

4. A further 10mls of sterile water (or Ringer's solution) is flushed through all of the channels (air-water, suction) by using a sterile syringe. The rinse fluid (20 to 30 mls) is collected in another sterile universal container.

5. Both containers are labelled and sent with a request form detailing the following:

   a. Type of scope sampled and serial number.

   b. Name of person to whom report should be sent.

   c. Test request - Endoscope routine culture.

*Note:*
*Organisms (especially pseudomonas) can multiply in fluids. Therefore it is essential that the sample is promptly processed after collection. If there is likely to be any delay the sample should be refrigerated. Any delay, such as samples being collected in the late afternoon and not processed until the following day, may lead to erroneous results.*

**Laboratory Procedure - Infection Control**

1. The collected sample is centrifuged down to lml.

2. All specimens – blood agar and MacConkey agar under aerobic conditions only.

3. Semi quantitation of bacterial growth should be performed, e.g. no growth, 10 to 100 colonies, 100 to 10,000 colonised, $> 10^4$ colonies.

## 5.  INTERPRETATION OF CULTURES

Each endoscopy unit in conjunction with a clinical microbiologist must set its own threshold for the initiation of action if cultures are positive.  Some examples are given below:

1.  Low numbers of environmental type organisms, e.g. *Staph epidermis*, may be encountered not infrequently.  These are most likely to represent collection process contamination rather than a significant problem with the disinfection or cleaning process.  The most appropriate initial response is to review the sample processing technique to reduce the chance of contamination.

2.  A growth of *Pseudomonas spp* from a duodenoscope or an automatic processor that processes duodenoscopes would be cause for serious and immediate concern.  This is a high risk clinical situation and the immediate responses would include removing the automatic processor and duodenoscope from service, careful culturing of the automatic processor to see if it is the source of contamination, careful inspection of the duodenoscope for defects and repeated cultures after manual reprocessing to see if infection persists and clinical follow up of patients recently undergoing E.R.C.P. and related procedures with that duodenoscope.

3.  Significant numbers of enteric organisms, e.g. E coli or *Enterococcus faecalis* being recovered from one instrument only.  This suggests that there is a mechanical defect in the instrument and careful inspection with replacement of the insertion tube if no other defect can be identified.

4.  Significant or borderline numbers of enteric organisms such as E coli, *Enterococcus faecalis* being recovered from a variety of instruments within the unit. This is strong evidence of inadequate reprocessing. It is most likely to be due to defects in the manual cleaning program. Much less likely is a problem in an automated reprocessor, (e.g. worn valves, serious biofilm accumulation etc). The appropriate response here would be a detailed review of <u>all</u> staff's cleaning and disinfection techniques, if necessary by an independent assessor.

5.  Culture of *Mycobacterium tuberculosis* organisms from a flexible bronchoscope.  This is a serious problem.  Responses would include removal of the bronchoscope from service, mechanical review of the instrument by the manufacturer, review of any automated reprocessor used including detailed cultures and clinical surveillance of patients recently bronchoscoped with that instrument.

6.  Growth of *Mycobacterium chelonae* from a bronchoscope.  It is almost certain that this will prove to be due to a contaminated automated reprocessor that needs to be taken out of service and decontaminated.

7.  <u>ANY</u> isolation of salmonella or shigella should cause concern.

# 6. MICROBIOLOGICAL SURVEILLANCE OF AUTOMATED FLEXIBLE ENDOSCOPE REPROCESSORS

The method of sample collection for AFER's will vary depending upon the design of the individual machine. It is therefore appropriate to seek advice from the manufacturers or consult with your hospital clinical microbiologist. Commonsense would suggest that the most appropriate point of the machine to sample is the attachment of the machine to the endoscope. For machines with a single point of attachment (e.g. Medivator) this is relatively simple. Where there are multiple endoscope connections the problem becomes more complicated. Further, it is essential to know the design of the machine to determine which is the optimum part of the cycle to collect the sample. In most cases this will be in the rinsing cycle. Positive cultures require immediate assessment. Interventions should be undertaken if necessary with follow-up cultures to assess effectiveness. A review of the post incident monitoring plan should be made to confirm its adequacy.

Early detection of machine contamination is best effected by a concentration process. For example, a technique which works well with the Medivator is to connect a sterile sealed Millipore filter to the outlet of the machine where it normally attaches to the endoscope and to cycle at least 200ml of fluid through the filter in the rinse cycle mode. The disc can then be removed and plated directly. Since the principal contaminants of automated reprocessors are Pseudomonas and related species and various forms of atypical mycobacteria, cultures should be directed towards these organisms.

Positive cultures require immediate assessment. Intervention should be undertaken if necessary with follow up cultures to assess effectiveness. A review of the post incident monitoring plan should be made to confirm its adequacy.

# WORKPLACE HEALTH AND SAFETY IN ENDOSCOPY

## Legislation

In each jurisdiction (Commonwealth, State or Territory) there is a principal occupational health and safety Act that gives broad duties to the workplace parties. Commonly included in each Act are requirements for:
- Ensuring the workplace health and safety of employees at work;
- providing systems of work that are safe and without risk to health;
- preventing occupational injuries and diseases;
- protecting the health and safety of others in relation to work activities, e.g. visitors.

The Act may also include requirements for:
- providing a safe working environment;
- providing information, instruction and training;
- maintaining plant in a safe condition
- rehabilitation and maximum recovery from incapacity of injured employees.

The key principle in each Act is the 'duty of care'. This imposes obligations on employers to ensure the workplace health and safety of employees at work. This obligation extends to others such as contractors, patients and visitors. There is also an obligation on employees to ensure their own workplace health and safety and that of others, and to co-operate with employers on workplace health and safety matters.

Below are websites of the various State, Territory and Commonwealth government workplace health and safety sites.

Division of Workplace Health and Safety, Queensland
www.whs.qld.gov.au

WorkCover New South Wales
www.workcover.nsw.gov.au

Australian Capital territory WorkCover
www.workcover.act.gov.au

Victorian Workcover Authority
www.workcover.vic.gov.au

Workplace Standards Tasmania
www.wsa.tas.gov.au

WorkCover Corporation, South Australia
www.workcover.com

WorkSafe Western Australia
www.safetyline.wa.gov.au

Work Health Authority, Northern Territory
www.nt.gov.au/wha

Comcare Australia
www.comcare.gov.au

National Occupational Health and Safety Commission (NOHSC)
http://www.nohsc.gov.au/

Occupational Health and Safety Service, New Zealand
http://www.osh.dol.govt.nz/

As well as the sites listed above it is possible to link to copies of State/Territory legislation via the Australian Legal Information Institute at www.austlii.edu.au

## Risk Management

This is the process that underpins health and safety management. It involves systematically identifying hazards, assessing and controlling risks, and monitoring and reviewing activities to make sure that risks are effectively managed.

Effective consultation, training and information management are essential parts of the risk management process and it can be applied to all workplaces.

## BIOLOGICAL HAZARDS

One of the main hazards to those reprocessing endoscopes and accessories is that posed by the risk of acquiring an infectious disease from blood and other body fluid exposure. For a discussion of the infectious agents that can contaminate endoscopes see the section on Infecting Organisms.

The risk relates to the handling of a used endoscope and the potential for splashing and the production of aerosols during manual cleaning. Aerosols create three risks during cleaning:
- the risk of exposure to infectious microorganisms contained in the aerosol
- the risk of exposure to chemicals contained in the aerosol
- the risk of environmental contamination due to aerosols from the cleaning process being dispersed and deposited throughout the area

It is imperative that techniques of cleaning should be designed to avoid splashing and the generation of aerosols.

## STANDARD PRECAUTIONS

When cleaning and handling used items, follow Standard Precautions at all stages of handling to prevent exposure to blood and body substances. Standard Precautions involve treating blood and body substances of all persons as potential sources of infection independent of diagnosis or perceived risk. If you are unsure how Standard Precautions impact on your practice discuss this with your facility's infection control practitioner or the state or territory's infection control practitioner.

Appropriate PPE, such as gloves, specifically designed fluid repellent masks/eye protection/face shields and fluid resistant aprons or gowns should be worn when handling used endoscopes and accessories.

The reprocessing area is potentially a contaminated area and as such non-essential personnel should be excluded and food should not be consumed in this area.

## MANAGEMENT OF SHARPS AND SHARPS INJURIES, BLOOD AND BODY FLUID EXPOSURE

All endoscopy units should have an appropriate sharps disposal policy. Sharps injury poses a very real threat of disease and careless practices by medical or nursing staff should not be tolerated.

All endoscopy units should have a clearly defined policy for sharps injuries and blood and body fluid exposures. In general this should follow the protocols laid out in state health department Infection Control Guidelines

It is essential that prompt action be taken to report an occupational exposure so that immediate counselling, evaluation and treatment can be instigated. When it has been recommended, anti-retro viral therapy is most effective when commenced as soon as possible.

## MYCOBACTERIUM TUBERCULOSIS

Bronchoscopy should be avoided wherever possible in patients with known or suspected tuberculosis[34]. There is a significant risk of nursing and medical staff contracting *Mycobacterium tuberculosis* when bronchoscopy is carried out on tubercular patients without proper precautions.

Where this is unavoidable Additional Precautions should be utilised:
- the procedure should be carried out in a room with negative pressure ventilation;
- a close fitting, disposable, P2 (N95) particulate filter respirator should be worn by endoscopy room staff during the bronchoscopy (this is not the same as a surgical mask), staff should receive instruction and training in the use of these respirators[283];

- during recovery phase if coughing, patients should be provided with a close fitting, disposable particulate filter respirator that does not have an exhalation valve.

Strict adherence to the appropriate standard precautions when reprocessing all bronchoscopes and accessories will prevent occupational exposure.

**IMMUNISATION**

Immunisation is a measure by which some protection from infection due to occupational exposure can be given to health care workers (HCWs).  It is important that you are aware of your own immune status.

The National Health and Medical Research Council (NHMRC) in their most recent edition of 'The Australian Immunisation Handbook 7th ed. provides detailed information on immunisation schedules and vaccines.  Staff vaccination programs should comply with these procedures which acknowledge that there may be some circumstances that require special consideration before vaccination, for example, where a HCW is pregnant.

The NHMRC recommendations state that HCWs should be vaccinated against infections they may encounter.  These may include hepatitis B, hepatitis A, measles, mumps, rubella, influenza and varicella.

Section 22 of The Communicable Diseases Network Australia (CDNA) publication 'Infection Control Guidelines' sets out more specific guidelines for immunisation of HCWs[284].

From this document a recommendation of particular importance in endoscopy is:
- Hepatitis B vaccine - particularly to those with potential exposure to blood or body substances (with post immunisation testing to identify non-responders) as soon as possible before or after starting work.

In some special circumstances these may also apply:
- Mantoux tuberculin test negative HCWs at high risk may be offered BCG vaccination.
- HCWs likely to encounter hepatitis A (e.g., in communities with substantial indigenous populations, custodial carers and carers of the intellectually impaired) should be immunised.

Each State or Territory may also have their own guidelines for immunisation of HCWs that should also be followed.

# HAZARDOUS SUBSTANCES

Hazardous substances are chemicals and other substances that can cause injury, illness or disease.  The health effects may be acute or chronic.

Workplace health and safety regulations exist in each State or Territory to protect against exposure to hazardous substances at the workplace.  You should notify workplace health and safety personnel at your workplace if you suspect that exposure to a hazardous substance is causing health effects.

In this section the examples used will be for glutaraldehyde but the same principles apply for all hazardous substances.  A great deal of information about glutaraldehyde is available at the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) website[285].

The manufacturer or importer of a substance is responsible for determining whether or not it is hazardous.  A substance is deemed hazardous if:
- it is listed on the NOHSC 'List of Designated Hazardous Substances'
- it meets the criteria in the NOHSC 'Approved Criteria for Classifying Hazardous Substances'

If a substance does not meet either of these criteria and you consider that it is causing adverse health effects in your workplace then the avenues for the investigation and reporting of this are:
- supervisor
- workplace health and safety representative
- workplace health and safety officer
- state/territory workplace health and safety department
- NOHSC

Workplace health and safety regulations exist in each State or Territory for hazardous substances.  These regulations place duties on people including suppliers, manufacturers and employers for hazardous substances.  Hazardous substances regulations differ between each State or Territory, and therefore the following discussion only provides an overview of the legislation.  You should refer to the regulations in your particular State or Territory to find out what its specific requirements are.

Suppliers of hazardous substances must:
- produce a current Material Safety Data Sheet (MSDS) for each hazardous substance they supply
- provide the MSDS to the purchaser at least the first time that the substance is supplied and when the MSDS is amended or revised
- label the substance in accordance with the regulations

The employer is required to:
- obtain a current MSDS for all hazardous substances used in the workplace
- keep a register that includes a list of all hazardous substances used in the workplace and the current MSDS for each one

- ensure that all containers of hazardous substances are appropriately labelled
  - if a hazardous substance is decanted from its original container into a second container this must also be appropriately labelled with the product name and relevant risk phrases and safety phrases as they appear on the original container's label e.g. 'R36 Irritating to eyes', 'R38 Irritating to skin'
- conduct and keep records of a risk assessment
- conduct and keep records of environmental monitoring and health surveillance if indicated by the risk assessment
- provide and keep records of induction and on-going training

## MATERIAL SAFETY DATA SHEET (MSDS)

An MSDS provides information about the hazardous substance that will assist with the risk assessment. It contains information about the substance such as:

- a statement indicating whether it has been classified as hazardous to health in accordance with NOHSC criteria
- the contents
- what it should be used for and how to use it safely
- its health effects
- first aid instructions
- advice about safe storage and handling

The information you need about any hazardous substances used in your workplace is:

- the ways in which the substance enters the body, e.g., skin absorption, inhalation or ingestion
- what the acute and chronic health effects are
- the NOHSC exposure standard for the substance
- the recommended control measures

## RISK ASSESSMENT OF A HAZARDOUS SUBSTANCE

The risks involved in using the hazardous substance need to be assessed and managed following the process outlined in the risk management section.

In order to make an assessment of the risks involved in the use of this substance some more information is needed. As well as the information identified from the MSDS it is necessary to identify:

- where and how the substance is used
- who is likely to be at risk from exposure to the substance
- the tasks which may cause exposure
- whether monitoring or health surveillance is required
- whether anyone is showing health effects from exposure
- what controls are already in place, whether these controls are effective in managing the risk and if they should be reviewed

For more information on this process a good place to start is the Hazardous Substances Case Study No.8) on glutaraldehyde found on the Queensland Division of Workplace Health and Safety's website.

A risk assessment should be conducted and documented every 5 years or earlier if:
- a work practice involving a hazardous substance is significantly changed
- new information about the substance is available
- health surveillance or monitoring shows control measures need to be reviewed]
- new or improved control measures are implemented

If you need to perform a risk assessment of any hazardous substances used in your workplace it would be advisable to contact your WH&S personnel who will provide you with some assistance. Examples of the risk assessment process as applied to the use of glutaraldehyde, peracetic acid or orthophthalaldehyde are provided in Appendices B, C & D respectively.


Reproductive hazards

Reproductive hazards can arise from hazards such as biological hazards and hazardous substances. Hazardous substances that are teratogenic are able to produce abnormalities in a developing foetus.

If you have any concerns regarding reproductive risks you should discuss this with WH&S personnel or your medical practitioner for advice on fitness to work with any hazardous substances whilst pregnant.

**PERSONAL PROTECTIVE EQUIPMENT**

The possibility of splashing by blood, bodily fluids and hazardous substances is not necessarily predictable and all those likely to encounter splashing should wear PPE.

It is also important to use work practices that can minimise the likelihood of splashing and the production of aerosols.

CLOTHING

Fluid repellent gowns that provide full skin protection for arms and legs should be worn when reprocessing flexible endoscopes and accessories. They should be changed if soiled.

The relevant Australian Standards are:
- AS 3789.2 Textiles for health care facilities and institutions – Theatre linen and prepacks
- AS 3789.3 Textiles for health care facilities and institutions – Apparel for operating theatre staff

EYE PROTECTION

For handling hazardous substances, where splashing of the concentrated solution may occur, chemical safety goggles should be used.

For handling small quantities of dilute solutions, chemical safety spectacles with side shields may suffice.

When reprocessing endoscopes, face shields should be used to protect from exposure to biological hazards as well as hazardous substances.

The selection and use of eye protection should be in accordance with the Australian Standards:
- AS 1336 Recommended practices for occupational eye protection
- AS 1337 Eye protectors for industrial applications

RESPIRATORY PROTECTIVE EQUIPMENT

As aerosol production or splattering is likely a fluid-repellent, deflector mask is most appropriate when reprocessing flexible endoscopes and accessories.

Where there is a risk of airborne infection, as in bronchoscopy, close fitting, disposable, particulate filter respirators should be worn. In the absence of an Australian Standard it is recommended in 'Infection Control Guidelines' Section 13.4 that respirators which meet the United States N95 standard be used. The Australian equivalent is a P2 respirator.

In case of spills of hazardous substances where respiratory protection is required a half-face respirator with organic vapour cartridge should be available. Cartridges should be replaced at regular intervals in accordance with the manufacturer's recommendations.

The relevant Australian Standards are:
- AS/NZS 1715: Selection use and maintenance of respiratory protective devices
- AS/NZS 1716: Respiratory protective devices


GLOVES

Gloves used when reprocessing endoscopes must be impervious to the cleaning agents and biocides being used. If single use gloves are not used then the reusable gloves should be washed in soapy water, rinsed and dried after use, otherwise they may become permeable. They should be stored dry after use and replaced if torn, cracked, peeling or showing signs of deterioration.

The permeability of different gloves to increasing concentrations of glutaraldehyde has been assessed by permeation tests. PVC and neoprene gloves have been found to retain or absorb glutaraldehyde on extended exposure. Nitrile rubber or butyl rubber provide the best protection. Latex gloves provide protection for approximately 45 minutes. However, the issue of latex allergy will impact on the choice of gloves.

Latex allergies are an increasing occupational health and safety problem and can vary from mild to very severe. For more information about latex allergy go to the CDC website http://www.cdc.gov/niosh/latexpg.html .

As aerosolisation of latex particles is a major route of sensitisation the use of powder free gloves is advisable.

For latex sensitive individuals gloves made from alternative products such as nitrile, butyl rubber, vinyl and neoprene are available. However, consideration needs to be given to the suitability of the material for use with the biocides and cleaning agents used for reprocessing.

The Australian Standards for gloves are:
- AS/NZS 4179: Single-use sterile surgical rubber gloves – Specification
- AS/NZS 4011: Single-use examination gloves – Specification
- AS/NZS 2161.2: Occupational protective gloves - General requirements

**Guideline Application Statement**

These guidelines have been prepared by the Gastroenterological Nurses College of Australia and the Gastroenterological Society of Australia and every care has been taken in their compilation. The guidelines are intended to be used as a guide only and not as an authoritative statement of every conceivable step or circumstance which may or could relate to the performance of the procedures outlined. Practitioners should use these guidelines as an aid in relation to disinfection and not as a complete or authoritative statement of such procedures.

The Gastroenterological Society of Australia, the Gastroenterological Nurses College of Australia and the compilers of these guidelines shall not be liable to users of these guidelines nor to any other person, firm, company or other body for any loss, direct, indirect or consequential, on whatsoever account for any omission or negligent mis-statement contained herein, or by reason of, arising from or in relation to any such user, by any other person, company or body relying or acting upon or purporting to rely or act upon any matter contained therein or arising thereout.

## APPENDIX A          Proof of Processing Templates

**Sample 1**

**Record of Reprocessing Parameters**

| A | Date: | Time: |
|---|-------|-------|

| B | **<u>Biocide Concentration</u>** |
|---|---|

Signature_____

| Sink 1 | Sink 2 | Sink 3 | Sink 4 |
|--------|--------|--------|--------|
|        |        |        |        |

| C | **<u>Biocide</u>** |
|---|---|

| Sink 1 | Sink 2 | Sink 3 | Sink 4 |
|--------|--------|--------|--------|
| **Batch No._____** | **Batch No. _____** | **Batch No. _____** | **Batch No. _____** |
| **Expiry date _____** | **Expiry date _____** | **Expiry date _____** | **Expiry date _____** |
| **Date of 1$^{st}$ use_____** | **Date of 1$^{st}$ use _____** | **Date of 1$^{st}$ use _____** | **Date of 1$^{st}$ use _____** |
| **Topped up** <br> **Date_____** | **Topped up** <br> **Date_____** | **Topped up** <br> **Date_____** | **Topped up** <br> **Date_____** |
| **Batch No._____** | **Batch No._____** | **Batch No._____** | **Batch No._____** |

 Signature: _____

**Additional Equipment (if used)**

| D | **<u>Ultrasonic Monitoring</u>** |
|---|---|

Pass signature: _____        Fail signature: _____

Action: _____

| E | **<u>Water filters reprocessed</u>** |
|---|---|

Signature: _____

**Sample 2**

# Record of Reprocessing Parameters for AFER (for high volume units)

Date:

**Machine Biocide Concentration**

Signature: _____

Machine Serial No. _____

| Tank 1A | Tank 1A | Tank 1B | Tank 1B |
|---|---|---|---|
| **Test Time**<br><br>**MEC**<br> **Pass / Fail**<br><br>**Action** | **Time changed**<br>**Batch No._____**<br><br>**Expiry date _____**<br><br>**Date of 1<sup>st</sup> use_____**<br><br>**Topped Up**<br>   **Date_____**<br><br>   **Batch No._____** | **Test Time**<br><br>**MEC**<br> **Pass / Fail**<br><br>**Action** | **Time changed**<br>**Batch No. _____**<br><br>**Expiry date _____**<br><br>**Date of 1<sup>st</sup> use _____**<br><br>**Topped Up**<br>   **Date_____**<br><br>   **Batch No._____** |

Machine Serial No.

| Tank 2A | Tank 2A | Tank 2B | Tank 2B |
|---|---|---|---|
| **Test Time**<br><br>**MEC**<br> **Pass / Fail**<br><br>**Action** | **Time changed**<br>**Batch No._____**<br><br>**Expiry date _____**<br><br>**Date of 1<sup>st</sup> use_____**<br><br>**Topped Up**<br>   **Date_____**<br><br>   **Batch No._____** | **Test Time**<br><br>**MEC**<br> **Pass / Fail**<br><br>**Action** | **Time changed**<br>**Batch No. _____**<br><br>**Expiry date _____**<br><br>**Date of 1<sup>st</sup> use _____**<br><br>**Topped Up**<br>   **Date_____**<br><br>   **Batch No._____** |

**Ultrasonic Monitoring**

Pass signature: _____     Fail signature: _____

Action: _____

## SAMPLE 3: 'PROOF 0F PROCESS' FOR FLEXIBLE ENDOSCOPES

| Date | Scope Number/ Item | Cleaned by | Rinsed by | Biocide | | | | | | Final Rinse by | Patient Name | Medical Records No. | Order on List |
|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | | | | Batch no. | Expiry date | Date 1st Use | Immerse Time | Temp | Sign | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |

**Instructions for using Sample 3**: 'Proof of Process for flexible endoscopes'

General instructions:
- Use a dark ink pen
- Do not use white out
- Do not use an eraser
- When the sheet is complete, store in a folder. It is suggested that a new folder is to be used for each half year or year. Label the folder and store in a safe, dry place in accordance with the local facility's established policy.

Date:
Date that the endoscope is processed

Endoscope number/item:
Utilise this column only if your facility processes more than one flexible endoscope
If your facility has more than one flexible endoscope, identify each of them by the serial number, or use a number, letter or colour

Cleaned by:
This is for recording the identity of the person who cleaned the flexible endoscope

Rinsed by:
This is for recording the identity of the person who rinsed the flexible endoscope after it was cleaned prior to disinfection.

Biocide batch number:
This is for recording the manufacturer's batch number of the container of biocide, which is to be used for disinfection of the particular endoscope. (This will remain the same until a particular solution of biocide is changed.)

Biocide expiry date:
This is for recording the expiry date, which is stated on the manufacturer's container from which the biocide solution in use was taken. (This will also remain the same until a particular solution of biocide is changed.)

Biocide date 1st use:
This is for recording the date of activation or commencement of use of the biocide solution to be used for endoscope disinfection

Biocide immerse time:
This is for recording the period of time during which the endoscope being reprocessed was continuously immersed in the biocide solution

Biocide temp:
This is for a record of the temperature of the biocide solution when the endoscope was reprocessed.

Biocide sign:
Signature/initial of the person responsible for disinfection of the endoscope

Final rinse by:
Sign against the items that are released for future patient use

Patient name or medical records no:

Record either the patient's name or the patient's medical record number so that there is a link between each processed instrument or tray and the particular patient on which it is used

Order on List:
This is for recording the position on the endoscopic procedure list that each particular patient receiving an endoscope(s) processed that day, is located

Each unit/facility is encouraged to develop a register suitable to their particular needs. The sample register as used at P.A.H. Brisbane is provided as an example which may be used in whole or in part, provided that all the principles and information are readily accessible and traceable. Computer printouts from automated machines will require either modification or be used within the register.

# APPENDIX B  - RISK ASSESSMENT FOR GLUTARALDEHYDE

**GLUTARALDEHYDE**

*What are the health effects?*
Glutaraldehyde is classified as hazardous to health in accordance with NOHSC criteria.

**Eye irritation**
Accidental splashes with glutaraldehyde may cause severe irritation, pain and light sensitivity.  Conjunctival and corneal irritation from excess vapour exposure can occur.

If you wear contact lenses you should consult your ophthalmologist regarding the suitability of your lenses in relation to potential exposure to glutaraldehyde vapour. Some lenses may become discoloured or impregnated with glutaraldehyde and cause eye irritation.

**Respiratory irritation/sensitisation**
Respiratory irritation is commonly reported as is irritation of the nose and throat. Asthma has also been reported.

**Skin irritation/sensitisation**
Glutaraldehyde is a skin irritant and sensitiser.  Contact dermatitis from skin irritation has been reported often.  It is important to note that this may be associated with deep skin  fissuring and cracking, resulting in an increased susceptibility to blood borne viruses (e.g., HIV)

**Other**
Current evidence does not suggest that glutaraldehyde is a reproductive hazard or a carcinogen.

*What level of exposure is hazardous?*

The NOHSC sets exposure standards for hazardous substances, and these concentrations are designed to not cause adverse health effects or undue discomfort to nearly all employees.

The national exposure standard for glutaraldehyde is :
Peak Limitation (Peak)                =      0.1 ppm

This means that the exposure must never be greater than 0.1 ppm (Peak Limitation) regardless of whether the average exposure is still below 0.1 ppm.

There is a very limited safety margin here as occupational health problems have been reported with exposure to vapour concentrations close to 0.1 ppm.  Sensitisation has been reported to occur at exposure levels below the odour threshold level of 0.04 ppm. and it can be difficult to be certain whether the peak values are exceeded from time to time.

A monitoring result that is half or more of the exposure standard should be taken to be an action level for review of control measures. It should also be noted that other countries have lower exposure standards (e.g., USA 0.05 ppm)

*How can exposure be monitored?*

It may be necessary to monitor the glutaraldehyde concentration in the workplace.

There are a number of methods available for determining glutaraldehyde concentrations in air. Some of the methods are subject to interference from a variety of other chemical compounds including alcohol and perfume and will give falsely elevated readings in their presence. This means that someone who is competent and trained in using these measurement methods should carry this out. Contact your WH&S personnel to arrange monitoring of glutaraldehyde level.

Monitoring can be used to establish a baseline level, determine if there is a problem in the workplace in the first place or it may be used to determine if the control measures in place are effective.

Monitoring should occur on the introduction of any hazardous substance into the workplace and when new work practices relating to the use of the hazardous substance are introduced (e.g. heating glutaraldehyde).

*What control measures are appropriate?*

***engineering controls*** – e.g., install ventilation systems
- it is essential to have good local exhaust ventilation to minimise exposure
- vapours generated should be contained in fume cabinets
- work stations should have properly constructed and maintained fume cabinets in which the glutaraldehyde is used
- the features of an effective fume cabinet for glutaraldehyde use include:
  - air directed from the front access of the cabinet, across the work area and extracted through a baffle at the rear of the cabinet
  - a fan above the work area with air extracted via ducting to a safe location outside the building
  - a face velocity of not less than 0.5 m/sec at the front of the cabinet

***administrative controls*** – those recommended by NICNAS for the use of glutaraldehyde are:
- clear labelling of all containers
- proper storage of solutions in designated cupboards away from heat sources
- use the minimum amount of glutaraldehyde for the task
- take care when soaking and using syringes to avoid splashing
- use work place design and work practices which prevent the transfer of glutaraldehyde out of the fume cabinet or onto clothing (e.g. inclusion of the rinsing sink in the fume cabinet.
- cover soaking containers at all times
- avoid transporting open containers
- properly rinse instruments and soaking containers with water after use
- don't decant glutaraldehyde back into bottles from soaking containers

- clean up spills immediately
- place used disposable equipment into appropriate containers
  - providing instruction and training
  - establishing policy and procedures

*PPE* – recommended for use with glutaraldehyde are:
- chemical safety goggles or safety spectacles with side shields or face visors
- gloves which cover any exposed skin and are not permeable to glutaraldehyde
- aprons/gowns made from impervious material and which cover exposed skin
- in case of spills and leaks, half-face respirator with organic vapour cartridge (store the organic vapour cartridge in a sealed container when not in use)

*What do I do in case of a spill?*

*Small spills*
- wear appropriate PPE
- absorb with cloth or towel and dispose of in a clean, sealable plastic container

*Large spills*
- wear appropriate PPE
- evacuate personnel from immediate area of spill
- spread neutralising agent over the spill
- allow 5 minutes for deactivation
- absorb with kitty litter or spill pillow
- scoop up and place into a clean, sealable, plastic container
- flush area and tools with soap and water solution followed by water

Part of the training provided to anyone working with glutaraldehyde should include instructions on how to clean up a spill and in the use of the spill kit. A spill kit should be available close to the area where the glutaraldehyde is used and should contain everything necessary to clean up the spill.

A spill kit should contain:
- half face respirator with an organic vapour cartridge (store the organic vapour cartridge in a sealed container when not in use)
- skin protection equipment
- eye protection equipment
- material to contain the spill
- material to neutralise the spill
- material to absorb the spill
- a means of disposal of the above materials

Your workplace should also have an emergency response plan in the event of a substantial (≥15 litres) leak or spill. Your WH&S personnel will be able to help you to prepare this response plan if necessary.

# APPENDIX C – RISK ASSESSMENT FOR PERACETIC ACID

This is currently only registered in Australia for use as a chemical sterilant with the Steris System1. It is supplied in a sealed container with a liquid part and a powder part. The liquid part contains peroxyacetic acid, acetic acid, hydrogen peroxide, sulfuric acid and water. The powder part or the buffers include nitrilotriacetic acid, trisodium salt monohydrate.

*What are the health effects?*
Peracetic acid is classified as hazardous to health in accordance with NOHSC criteria. Concentrated peracetic acid is safe only when used in totally enclosed systems. **The sealed container must never be opened manually.** Exposure to powder or concentrated liquid can cause severe burns and eye injury leading to blindness.

## Eye Irritation
Peracetic acid is corrosive and may cause lacrimation, burns, conjunctivitis, inflammation and permanent eye damage including blindness.

## Respiratory Irriation
Peracetic acid is corrosive by inhalation. Vapour/mist will irritate nose, throat and lungs, but will usually subside when exposure ceases. Coughing, sneezing, mucous production, nausea, headache and breathing difficulty may occur.

## Skin Irritation
Peracetic acid is corrosive and may cause severe burns. It is toxic by absorption through intact skin and may cause redness, stinging, swelling, defatting, burns and irritant contact dermatitis

## Swallowed
Peracetic acid is corrosive if swallowed and may cause nausea, vomiting and serious damage to tissues.

## Other
Studies do not confirm increased risk of cancer in exposed humans and peracetic acid is not listed as a carcinogen.

Some of the components of the powder part are classified as possibly carcinogenic but no significant hazards should occur when good personal hygiene and safety practices are followed.

*What level of exposure is hazardous?*
No exposure standard has been set for the Steris 20 Sterilant Concentrate, however exposure standards exist for its individual constituents.

*What do I do in case of a spill?*
- Ensure there are no sources of ignition nearby.
- Increase ventilation
- Wear appropriate PPE
- Flush spilled materials with large quantities of water until all materials are dissolved/diluted by at least 20 volumes

Part of the training provided to anyone working with peracetic acid should include instructions on how to clean up a spill and in the use of the spill kit.  Records must be kept of the details of staff induction and training.

A spill kit should contain:
- Respiratory equipment - for small spills, a half-face piece respirator or a single use respirator with an acid gas filter
- Skin protective equipment  - rubber or neoprene gloves or gauntlets, boots and protective gown or apron
- Eye protective equipment

An emergency response plan should be developed for large spills.

## APPENDIX D - RISK ASSESSMENT FOR *ORTHO-PHTHALALDEHYDE (OPA)*

**What are the health effects?**

OPA is not classified as hazardous to health in accordance with NOHSC criteria. However, OPA may be a good deal more toxic than has so far been recognised. Extensive anecdotal reports are now appearing of skin staining, inflammation of skin and mucous membranes in some instances progressing to frank ulceration. The reports include both accidental exposure to splashes and patient injury where rinsing of the endoscope has been inadequate. Significant volumes of rinsing water are needed to remove chemical residue. [246]

**Swallowed**

May irritate the tissues of the mouth, throat, oesophagus and digestive system. Symptoms of over exposure may include vomiting, diarrhoea and nausea

**Eye**

Direct eye contact may cause stinging, excess tearing and redness. Advice should be sought from an ophthalmologist or optometrist regarding use of contact lenses.

**Skin**

Direct skin contact may cause stinging and mild irritation after prolonged exposure. Prolonged and repeated skin contact may cause dermatitis

**Inhaled**

Inhaling mists and sprays may cause mild irritation of the nose, throat and respiratory system. Symptoms of overexposure are coughing and sneezing. Inhalation may aggravate pre-existing bronchitis and asthma conditions

*What control measures are recommended?*

*engineering controls* – e.g., install ventilation systems
- Use in a well-ventilated area. If general ventilation is inadequate use local exhaust hoods.

*PPE* – recommended for use with OPA are:
- latex or nitrile rubber gloves for routine handling – change latex gloves every 10 – 15 minutes during use of OPA. (Do not use polyvinyl gloves.)
- chemical safety goggles or a visor
- fluid resistant gowns or aprons

*What do I do in case of a spill?*

*Small spills*
- wear appropriate PPE
- wipe up with a sponge or mop and flush with large quantities of water down drain

*Large spills***:**
- wear appropriate PPE
- prevent solution from entering drains and waterways
- evacuate personnel from immediate area of spill
- neutralise by sprinkling 25 grams of glycine powder per 5 litres of estimated OPA spilled
- mix with mop or other tool and allow 5 minutes for deactivation
- scoop up and place into a clean, sealable, plastics container
- flush area and tools with soap and water solution followed by water

Part of the training provided to anyone working with OPA should include instructions on how to clean up a spill and in the use of the spill kit.  Records should be kept of the details of staff induction and training.

A spill kit should contain:
- respiratory protective equipment - full face respirator with an organic vapour cartridge (store organic vapour cartridge in a sealed container when not in use)
- skin protection equipment - heavy duty nitrile gauntlets and protective gown or apron and rubber boots
- material to contain the spill
- material to neutralise the spill
- material to absorb the spill
- a means of disposal of the above materials

## REFERENCES

[1] Favero MS, Bond WW.  Sterlisation and disinfection in the hospital. In: Manual of Clinical Microbioloby, 5th ed., American Society of Microbiology,Washington, DC, 1990.

[2] Favero MS, Bond WW.  Chemical disinfection of medical and surgical materials.  In: Block SS (Ed), Disinfection, Sterilisation and Preservation, 4th ed., Lea and Febiger, Philadelphia, 1990.

[3] Nicholson G,  Hudson RA,  Chadwick MV,  Gaya H.   The efficacy of the disinfection of bronchoscopes contaminated in vitro with *Mycobacterium tuberculosis and Mycobacterium avium-intracellulare* in sputum: a comparison of Sactimed-I-Sinal and glutaraldehyde.  J Hosp Infect 1995;  29: 257-64.

[4] Ridgway GL. Decontamination of fibreoptic endoscopes. J Hosp Infect 1985;6:363-8.

[5] Bond WW, Favero MS, Mackel DC, Mallison GE.  Sterilisation or disinfection of flexible fiberoptic endoscopes. Assoc Operating Room Nurses J 1979;30:350-1.

[6] Bond WW. Disinfection and sterilisation of flexible fiberoptic endoscopes (FFE) and accessories. Endosc Review 1987;5:55-8.

[7] Hedrick E. Gastrointestinal endoscopy: infection transmission and prevention. Asepsis 1987;9:2-5.

[8] Favero MS.  Sterility Assurance: Concepts for patient safety. In: Rutala, WA (ed). Disinfection, sterilization and antisepsis: principles and practice in health care facilities. Washington; Association for Professionals in Infection Control and Epidemiology. 2001: 110-119

[9] Bruch CW.  The philosophy of sterilization validation.  In: Morrisey RF, Phillips GB, editors.  Sterilization technology: a practical guide for manufacturers and users of healthcare products. New York; Van Nostrand Reinhold, 1993:17-35

[10] Kallings L, Ernerfeldt F, Silverstolpe L.  Microbiological contamination of medical preparations.  Report to the Swedish National Board of Health, Stockholm 1965.

[11] Sjoberg L.  Scandinavian regulatory viewpoint-sterile medical products. In:Gaughran ERL, Morrissey RF, editors.  Sterilization of medical products.   Multiscience Publications 1981,   Montreal Canada; 2:294-9.

[12] Jarvis WR and Epidemiology Branch.  Nosocomial Outbreaks. The Centers for Disease Control's Hospital Infections Program Experience 1980-1990.  In: Marrone WJ, Garner JS, editors.  Proceedings of the 3rd decennial international conference on nosocomial infections. Am J Med 1991; 91(3B):101S-106S.

[13] British Thoracic Society.  Guidelines in diagnostic flexible bronchoscopy. Thorax 2001; 56 (suppl 1): i1-i21.

[14] Mehta AC, Minai OA.  Infection control in the bronchoscopy suite. Clin Chest Med 1999; 20: 19-32.

[15] Srinivasan A, Wolfenden LL, Song X,  Mackie K, Hartsell T,  Jones H et al.  An outbreak of Pseudomonas aeruginosa infections associated with flexible bronchoscopes NEJM 2003;  348: 221-7.

[16] Kirschke DJ,  Jones TJ,  Craig  AS,  Chu PS,  Mayernick GG,  Patel JA,  Schaffner W.  Pseudomonas aeruginosa and Serratia marcescens contamination associated with a manufacturing defect in bronchoscopes.  NEJM  2003; 348: 214-9

[17] Cooke RP, Whymant-Morris A, Umasankar RS, Goddard SV.  Bacteria-free water for automatic washer-disinfectors: an impossible dream?   J Hosp Infect 1998;39:63-65.

[18] O'Connor BH, Bennett JR, Alexander JG, Sutton DR, Leighton I. Salmonellosis infection transmitted by fibreopic endoscopies. Lancet 1982;2:864-6.

[19] Tuffnell  PG.  Salmonella infections transmitted by a gastroscope.  Can J Public Health  1976; 67: 141-2.

[20] Chmel H,  Armstrong D.  Salmonella oslo – a focal outbreak in a hospital.  Am J Med 1976; 60: 203-8.

[21] Beecham HJ,  Cohen  ML,  Parkin WE. *Salmonella typhimurium.*  Transmission by fiberoptic upper gastrointestinal endoscopy.   JAMA 1979; 241: 1013-5

[22]  Dwyer DM,  Klein EG,  Istre GR,  Robinson MG,  Neumann DA,  McCoy GA. *Salmonella Newport* infections transmitted by fiberoptic colonoscopy.  Gastrointest Endosc 1987; 33: 84-7.

[23] Bond WW.  Disinfection and endoscopy: Microbial considerations.  J Gastroenterol Hepatol  1991; 6:31-6

[24] Hanson PJV, Chadwick M, Nicholson G et al. Mycobacterial resistance to disinfection in AIDS: whither infection control policies now? Thorax 1988;43:850.

[25] van Klingeren B, Pullen W. Glutaraldehyde resistant mycobacteria from endoscope washers (letter). J Hosp Infect 1993;25(2):147.

[26] Wheeler PW, Lancaster D, Kaiser AB. Bronchopulmonary cross-colonisation and infection related to mycobacterial contamination of suction valves of bronchoscopes. J Infect Dis 1989;159:954-8.

[27] Pappas SA, Schaaff DM, DiCostanzo MB, King FW, Sharp JT. Contamination of flexible fiberoptic bronchoscopes. Am Rev Respir Dis 1982;127:391-2.

[28] Leers WD. Disinfecting endoscopes: how not to transmit *Mycobacterium tuberculosis* by bronchoscopy. Can Med Assoc J 1980;123:275-83.

[29] Bryce EA, Walker M, Bevan C, Smith JA. Contamination of bronchoscopes with *Mycobacterium tuberculosis.* Can J Infect Control 1993;8(2):35.

[30] Fraser VJ, Jones M, Murray PR et al. Contamination of flexible fiberoptic bronchoscopes with *Mycobacterium chelonae* linked to an automated bronchoscope disinfection machine. Am Rev Respir Dis 1992;145:853.

[31] Reeves DS, Brown NM. Mycobacterial contamination of fibreoptic bronchoscopes. J Hosp Inf 1995;30:531-536.

[32] Gubler JG, Salfinger M, von Graevenitz A. Pseudoepidemic of nontuberculosis mycobacteria due to a contaminated bronchoscope machine. Chest 1992;101(5):1245-9.

[33] Hanson PJV, Chadwick MV, Gaya H, Collins JV. A study of glutaraldehyde disinfection of fibreoptic bronchoscopes experimentally contaminated with *Mycobacterium tuberculosis.* J Hosp Infect 1992;22:137-42.

[34] Centres for Disease Control and Prevention Core Curriculum on Tuberculosis: what the clinician should know. 3rd ed. Altanta, GA. Us Dept of Health and Human Services. 1994

[35] Agerton T, Valway S, Gore B. et al. Transmission of a highly drug-resistant strain (strain W1) of *Mycobacterium tuberculosis*. JAMA 1997;278(13):1073-1077.

[36] Michele TM, Cronin WA, Graham NMH et al. Transmission of *Mycobacterium tuberculosis* by a fibreoptic bronchoscope. JAMA 1997;278(13):1093-1095.

[37] Wenzor RP, Edmond MB. Tuberculosis infection after bronchoscopy. JAMA 1997;278(3):111.

[38] Webb SF, Vall-Spinosa A. Outbreak of *Serratia marcescens* associated with the flexible fiberbronchoscope. Chest 1975;68:703-8.

[39] Vandenbroucke-Grauls CM, Baars AC, Visser MR et al: An outbreak of *Serratia marcescens* traced to a contaminated bronchoscope. J Hosp Infect 1993;23(4):263-70.

[40] Gledhill T, Leicester RJ, Addis B, et al. Epidemic hypochlorhydria. Br Med J 1985;289:1383-6.

[41] Graham DY, Alpert LC, Smith JL, Yoshimura HH. Iatrogenic *Campylobacter pylori* infection is a cause of epidemic achlorhydria. Am J Gastroenterol 1988;83:974-80.

[42] Patterson DJ, Johnson EH, Schmulen AC, Fulminant pseudomembranous colitis occurring after colonoscopy. Gastrointest Endosc 1984;30:249-53.

[43] Hughes CE, Gebhard RL, Peterson LR, Gerding DN. Efficacy of routine fiberoptic endoscope cleaning and disinfection for killing *Clostridium difficile.* Gastrointest Endosc 1986;32:7-9.

[44] Greene WH, Moody M, Hartley R, et al. Oesophagoscopy as a source of *Pseudomonas aeruginosa* sepsis in patients with acute leukemia: The need for sterilisation of endoscopes. Gastroenterology 1974;67:912-9.

[45] Bianco JA, Pepe MS, Higano C, Applebaum FR, McDonald GB, Singer JW. Prevalence of clinically relevant bacteremia after upper gastrointestinal endoscopy in bone marrow transplant recipients. Am J Med 1990; 89(2):134-6.

[46] Marcus, R and the CDC Cooperative Needlestick Surveillance Group. Surveillance of health care workers exposed to blood from patients infected with the human immunodeficiency virus. N Engl J Med 1988;319:1118-23.

[47] Henderson DK, Saah AJ, Zak BJ, et al. Risk of nosocomial infection with human T-cell lymphotropic virus type III/ lymphadenopathy-associated virus and in large cohort of intensively exposed health care workers. Ann Int Med 1986;104:644-7.

[48] McEvoy M, Porter K, Mortimer P, Simmons N, Shanson D. Prospective study of clinical, laboratory, and ancillary staff with accidental exposures to blood or body fluids from patients infected with HIV. Br Med J 1987;294:1595-7.

[49] Geberding JL, Moss AR, Bryant CE, Levy J, Sande MA. Risk of acquired immune deficiency syndrome (AIDS) virus transmission to health care workers (HCW) (Abstract). In: Program and Abstracts of the TwentyFifth Interscience Conference on Antimicrobial Agents and Chemotherapy Washington, DC: American Society for Microbiology; 1985: 131.

[50] Henderson DK, Fahey BY, Willy ME, et al. Risk for occupational transmission of human immunodeficiency virus type 1 (HIV-1) associated with clinical exposures: a prospective evaluation. Ann Intern Med 1990;113:740-6.

[51] Hanson PJV, Gor D, Jeffries DJ, Collins JV. Chemical inactivation of HIV on surfaces. Br Med J 1989;298:862-4.

[52] Martin LS, McDougal JS, Loskoski SC. Disinfection and inactivation of the human T lymphotropic virus type III/ Lymphadenopathy-associated virus. J Infect Dis 1985;2:400-3.

[53] Resnick L, Veren K, Salahuddin SZ, Tondreau S, Markham PD. Stability and inactivation of HTLV III/LAV under clinical and laboratory environments. JAMA 1986;255:1887-91.

[54] Hanson PJV, Gor D. Clarke JR, et al. Contamination of endoscopes used in AIDS patients. Lancet 1989;2:86-8.

[55] Hanson PJV, Gor D, Jeffries DJ, Collins JV. Elimination of high titre HIV from fibreoptic endoscopes. Gut 1990;31:657-9.

[56] Deva AK, Vickery K, Zou J, West RH, Harris JP, Cossart YE. Establishment of an in use testing method for evaluating disinfection of surgical instruments using duck Hepatitis B model. J Hosp Infect 1996;33:119-30.

[57] Seeff LB, Wright EC, Zimmerman HJ, et al. Type B hepatitis after needle-stick exposure. Prevention with hepatitis B immune globulin. Final report of the Veterans Administration cooperative study. Ann Intern Med 1978;88:285-93.

[58] Grady GF, Lee VA. Prevention of hepatitis from accidental exposure among medical workers. N Engl J Med 1975;293:1067-70

[59] Mast EE, Alter MJ. Prevention of Hepatitis B virus infection among health care workers. In: Ellis RW ed Hepatitis B Vaccines in Clinical Practice New York, Marcel Dekker, 1993;295-307.

[60] Gerberding JL. Management of occupational exposures to blood-borne viruses. N Engl J Med 1995;332:444-51.

[61] Werner BG, Grady GF. Accidental Hepatitis B surface antigen positive inoculations. Use of e antigen to estimate infectivity. Ann Intern Med 1982;97:367-9.

[62] Birnie GG, Quigley EM, Clements GB, Follet EAC, Watkinson G. Endoscopic transmission of hepatitis B virus. Gut 1983;24:171-4.

[63] Ayoola EA. The risk of type B hepatitis infection in flexible endoscopy. Gastrointest Endosc 1981;2:60-2.

[64] Bond WW. Moncada RE. Viral hepatitis B infection risk in flexible fiberoptic endoscopy. Gastrointest Endosc 1978;24:225-30.

[65] Ferrari AR Geocze S, Ferraz MLG, Silva AEB, Vilela ME. Lack of evidence of upper gastrointestinal endoscopy as a risk factor for transmission of Hepatitis B virus. Endoscopy 1991;23:353-4

[66] Galambos JT. Transmission of hepatitis B from providers to patients: How big is the risk? Hepatology 1986;2:320-5.

[67] Hoofnagle JH, Blake J, Buskell-Bales Z, Seeff LB. Lack of transmission of type B hepatitis by fibreoptic upper endoscopy. J Clin Gastroenterol 1980;2:65-9.

[68] Lok ASF, Lai C-L, Hui W-M, et al. Absence of transmission of hepatitis B by fibreoptic upper gastrointestinal endoscopy. J Gastroenterol Hepatol 1987;2:175-80.

[69] McClelland BDL, Burrell CJ, Tonkin RW, Heading RC. Hepatitis B: absence of transmission by gastrointestinal endoscopy. Br Med J 1978;8:23-4.

[70] Moncada RE, Denes AE, Berquist Kind regards,, Fields HA, Maynard JE. Inadvertent exposure of endoscopy patients to viral hepatitis B. Gastrointest Endosc 1978;24:231-232.

[71] Bond WW, Favero MS, Petersen NJ, Ebert JW. Inactivation of hepatitis B virus by intermediate to high level disinfectant chemicals. J Clin Microbiol 1983;18:535-8.

[72] Kobayashi H, Tsuzuki M, Koshimizu K, et al. Susceptibility of hepatitis B virus to disinfectants or heat. J Clin Microbiol. 1984;20:214-6.

[73] Tennenbaum R, Colardelle P, Chochon M, et al. Hepatite C apres cholangiographic retrograde. Gastroenterol Clin Biol. 1993;17:763-764.

[74] Andrieu J, Barry S, Colardelle P, et al. Prevalence et facteurs de risque de l'infection par le virus de l'bepatite C dans une population hospitalisee en gastroenterologie. Role des biopsies per-endoscopiques. Gastroenterol Clin Biol 1995;19:340-345.

[75] Davis AJ, Pink JM, Kowalik AM, et al. Multiple endoscopies in a Sydney blood donor found positive for hepatitis B and C antibodies (letter). Med J Aust 1996;164:571

[76] Bronowicki JP, Venard V, Botte C. et al. Patient-to-patient transmission of Hepatitis C virus during colonoscopy. New Engl J Med 1997; 337(4); 237-240.

[77] Crenn P, Gigou M, Passeron J et al. Patient to patient transmission of Hepatitis C virus during gastroscopy on neuroleptanalgesia. Gastroenterology 1988; 114:4,A1229.

[78] Becheur H, Harzic M, Colardelle P, Deny P, Coste T, Dubeaux B, Chochon M, Roussin-Bretagne S, Doll J, Andrieu J. Hepatitis C virus contamination of endoscopes and biopsy forceps. Gastroenterol Clin Biol. 2000 Oct;24(10):906-10

[79] Goudin JL, Hot A, Dumont O, Bobichon R, Souquet JC. Systematic Hepatitis C virus (HCV) screening in patients with previous digestive endoscopy. Gastroenterology 1995;114-4, A15.

[80] Kim YS, Ahn YO, Kim DW. A case-control study on the risk factors of Hepatitis C virus infection among Koreans. J Korean Med Science 1996;11(1):38-43.

[81] Raymond JM et al. Evaluation des procédures de décontamination utilisées dans les centres d'endoscopie digestive de Gironde. Gastroenterol Clin Biol 1990;14:134-139.

[82] Reynolds CD, Rhinehart E, Dreyer P, Goldman DA. Variability in reprocessing policies and procedures for flexible fiberoptic endoscopes in Massachusetts hospitals. Am J Infect Control 1992:20:283-90.

[83] Muscarella LF. Recommendations for preventing Hepatitis C Virus infection: analyses of a Brooklyn endoscopy clinic outbreak. Infect Control Epidemiol 2001 Nov 22 (11): 669.

[84] Frieden TR. Dept of Health letter at www.nyc.gov/html

[85] Krisiunas E. Forum posting: warning issued on reuse of needles. ekrisiunas@aol.com

[86] Hanson PJ, Bennett J, Jeffries DJ, Collins JV. Enteroviruses, endoscopy and infection control: an applied study. J Hospital Infection 1994;27(1):61-7.

[87] Barthel JS. Sprouse RF, Dix JD, Sunderrajan EV Fatal *Candida* esophageal abscess and sepsis complicating endoscopic variceal sclerosis. Gastrointest Endosc 1987;33:107-10.

[88] Hoffmann KK, Weber DJ, Rutala WA. Pseudoepidemic of *Rhodotorula rubra* in patients undergoing fiberoptic bronchoscopy. Infect Control Hosp Epidemiol 1989;10:511-4.

[89] Angus KW, Sherwood D, Hutchison G. Campbell 1. Evaluation of the effect of two aldehyde-based disinfectants on the infectivity of faecal cryptosporidia for mice. Res Vet Sci 1982;33:379-81.

[90] Campbell 1, Tzipori S, Hutchison G, Angus KW. Effect of disinfectants on survival of Cryptosporidium oocysts. Vet Rec 1982;111:414-5.

[91] Berger JR and David NJ Creutzfeldt-Jakob disease in a physician: review of the disorder in health care workers. Neurology 1993;43:205-206.

[92] Brown P. Guidelines for high risk autopsy cases: special precautions for Creutzfeldt-Jakob Disease 1990. Autopsy Performance and Reporting 1990. College of American Pathologist, Northfield, IL:68-74.

[93] Brown P. Environmental causes of human spongiform encephalopathy. In Baker HF and Ridley RM (Eds), Prion Diseases, pp. 139-16=54. Himana Press, Totowa, NJ. 1996.

[94] Centers for Disease Control and Prevention. Creutzfeldt-Jakob disease associated with cadaveric dura mater grafts – Japan, January 1979 – May 1996. Morbidity and Mortality Weekly Report, 1997: 46 (45): 1066-9.

[95] Committee on Health Care Issues, American Neurological Association. Precautions in handling issues, fluids and other contaminated materials from patients with documented or suspected Creutzfeldt-Jakob Disease. Ann Neurology 1986; 19: 75-7.

[96] Ernst DR and Race RE. Comparative analysis of scrapie agent inactivation methods. J Virol Meth 1993;41:193-201.

[97] Favero MS and Bond WW. Chemical disinfection of medical and surgical materials. In Block, SS (ed), Disinfection, Sterilization and Preservation, Fourth Edition, pp. 617-641. Lea & Febeger, Philadelphia, 1991.

[98] Garner JS and Favero MS. Guideline for Handwashing and Hospital Environmental Control 1985. Centers for Disease Control, Atlanta, 1985.

[99] Geertsma, RE and van Asten JA. Sterilization of prions. Central Sterilization 1995;3:385-394.

[100] Holman RC, Khan ASK, Kent J, Strine TW and Schonberger LB. Epidemiology of Creutzfeldt-Jakob Disease in the United States, 1979-1990: Analysis of National Mortality Data. Neuroepidemiol 1995;14:174-181.

[101] Jarvis WR. Precautions for Creutzfeldt-Jakob Disease. Infect Control 1982;3:238-239.

[102] Steelman VM Creutzfeldt-Jakob Disease:Recommendations for Infection Control. Amer J Inf Control 1994;22:312-318.

[103] Taylor DM. Inactivation of the unconventional agents of scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob Disease. J Hosp Infect 1991;18 (supplement A): 141-146.

[104] Tyler KL. Prion Diseases of the Central Nervous System (Transmissible Neurodegenerative Diseases) In Mandell GL, Bennett JE, Dolin R (eds); Principles and Practice of Infectious Diseases, Fourth Edition, pp. 881-887. Churchill Livingston, New York, 1995.

[105] Asher MA. Spongiform Encephalopathies. In Murray, PR (ed): Manual of Clinical Microbiology, Sixth Ed, pp 1121-1130. American Society for Microbiology, Washington, DC, 1995.

[106] Bailes, BK. Creutzfeldt-Jakob Disease - A Fatal Neurodegenerative Transmissible Disorder. AORN Jour 1990;52:976-984.

[107] Will RG. Epidemiology of Creutzfeldt-Jakob Disease. Brit Med Bull 1993; 49:960-970.

[108] Transmissable Spongiform Encephalopathy in Infection Control in the Health Care Setting-Guidelines for the Prevention of Transmission of Infectious Diseases.(Draft-03/06/2003) http://www.health.gov.au/pubhlth/strateg/communic/review/index.htm

[109] Bruce ME, Will RG, Ironside JW, et al. Transmission to mice indicate that 'new variant' CJD is caused by the BSE agent. Nature, 1997; 389:498-501.

[110] Bruce ME, McConnell I, Will RG, Ironside JW. Detection of variant Creutzfeldt-Jakob disease infectivity in extraneural tissues. Lancet, 2001; 368: 208-9.

[111] Wadsworth JD, Joiner S, et al. Tissue distribution of protease resistant prion protein in variant Creutzfeldt-Jakob disease using a highly sensitive immunoblotting assay. Lancet, 2001; 358: 171-80.

[112] Collinge J. Variant Creutzfeldt-Jakob Disease. Lancet. 1999,354:314-23.

[113] Smith PG. The epidemics of bovine spongiform encephalopathy and variant Creutzfeldt-Jakob disease:current status and future prospects. Bull World Health Organ. 2003:81:123-30

[114] Reith AFR, Squier TL. Blood cultures of apparently healthy persons. J Infect Dis 1932;51:336-43.

[115] Cobe HM. Transitory bacteremia. Oral Surg 1954;7:609-15.

[116] Slade N. Bacteraemia and septicaemia after urological operations. Proc R Soc Med 1958;51:331-4.

[117] Richards JH. Bacteremia following irritation of foci of infection. JAMA 1932;99:1496-7.

[118] Shull HJ Jr, Greene BM, Allen SD, Dunn GD, Schenker S. Bacteremia with upper gastrointestinal endoscopy. Ann Intern Med 1975;83:212-4.

[119] Norfleet RG, Mitchell PD, Mulholland BS, Philo J. Does bacteremia follow upper gastrointestinal endoscopy? Am J Gastroenterol 1981;76:420-2.

[120] O'Connor HJ, Hamilton I, Lincoln C, Maxwell S, Axon ATR. Bacteremia with upper gastrointestinal endoscopy - a reappraisal. Endoscopy 1983;15:21-3.

[121] Mellow MH, Lewis RJ. Endoscopy-related bacteraemia. Arch Intern Med 1976;136:667-9.

[122] Baltch AL, Buhac I, Agrawal A, O'Connor P, Bram M, Malatino E. Bacteremia after upper gastrointestinal endoscopy. Arch Intern Med 1977;137:594-7.

[123] Liebermann TR. Bacteremia and fibreoptic endoscopy. Gastrointest Endosc 1976;23:36-7.

[124] Ritchie MT, Lightdale CJ, Botet JE Bilateral perinephric abscesses: a complication of endoscopic injection sclerotherapy. Am J Gastroenterol 1987;82:670-3.

[125] Nelson DB, Sanderson SJ, Azar MM. Bacteremia with oesophageal dilation. Gastrointest Endosc 1998;48(6):563-567.

[126] Stray N, Midtvedt T, Valnes K, Rosseland V, Pytte R, Hoivik B. Endoscopy-related bacteremia. Scand J Gastroenterol 1978;13:345-7.

[127] Stephenson PM, Dorrington L, Harris OD, Rao A. Bacteremia following oesophageal dilation and oesophago-gastroscopy. Aust NZ J Med 1977;7:32-5.

[128] Leitch DG, Collins JSA, Radhakrishnan S, O'Neill G, Dannatt J. Bacteraemia following endoscopy. Br J Clin Pract 1986;40:341-2.

[129] Kaw M, Przepiorka D, Sekas G. Infectious complications of endoscopic procedures in bone marrow transplant recipients. Dig Dis Sci 1993; 38(l):71-4.

[130] Zuccaro G, Richter JE, Rice TW, et al. Viridans streptococcal bacteremia after oesophageal stricture dilation. Gastrointest Endosc 1998;48(6):568-573.

[131] Yin TP, Ellis R, Dellipiani AW. The incidence of bacteremia after outpatient Hurst bougienage in the management of benign oesophageal strictures. Endoscopy 1983;15:289-90.

[132] Snady H, Korsten MA, Waye JD. The relationship of bacteremia to the length of the injection needle in endoscopic variceal sclerotherapy (abstract). Gastrointest Endosc 1984;30:136.

[133] Cohen FL, Koerner RS, Taub SJ. Solitary brain abscess following endoscopic injection sclerosis of oesophageal varices. Gastrointest Endosc 1985;31:331-3.

[134] Barthel JS, Sprouse RF, Dix JD, Sunderrajan EV Fatal *Candida* oesophageal abscess and sepsis complicating endoscopic variceal sclerosis. Gastrointest Endosc 1987;33:107-10.

[135] Lai KH, Tsai YT, Lee SD. Spontaneous bacterial peritonitis after endoscopic variceal sclerotherapy. Gastrointest Endosc 1986;32:303.

[136] Goenka MK, Thapa BR, Jethi SC, et al. Candidiasis complicating sclerotherapy-induced oesophageal ulcer presenting as recurrent hematemesis. Ind J Gastroenterol 1989;8:187-8.

[137] Barnett JL, Elta G. Bacterial peritonitis following endoscopic variceal sclerotherapy. Gastrointest Endosc 1987;33:316-7.

[138] Baskin G. Prosthetic endocarditis after endoscopic variceal sclerotherapy: a failure of antibiotic prophylaxis. Am J Gastroenterol 1989;84:311-2.

[139] Ritchie MT, Lightdale CJ, Botet JE Bilateral perinephric abscesses: a complication of endoscopic injection sclerotherapy. Am J Gastroenterol 1987;82:670-3.

[140] Uno Y, Munakata A. New needle catheters with covered tips for endoscopic injection therapy without bacteremia. First Dept of Internal Med, Hirosaki Uni School of Med, Hirosaki, Japan.

[141] Wong A, Rosenstein AH, Rutherford RE, James SP. Bacterial endocarditis following endoscopic variceal sclerotherapy. Clin Gastroenterol 1997;24/2:90-91.

[142] Stiegmann GV, Goff JS, Michaletz-Onody P, et al. Endoscopic sclerotherapy as compared with endoscopic ligation for bleeding oesophageal varices. N Engl J Med 1992;326:1527.

[143] Tseng C-C, Green RM, Burke SK et al. Bacteremia after endoscopic band ligation of oesophageal varices. Gastrointest Endosc 1992;38:336.

[144] Norfleet RG, Mulholland BS, Mitchell PD, Philo J, Walters EW. Does bacteremia follow colonoscopy? Gastroenterology 1976;70:20-1.

[145] Norfleet RG, Mitchell PD, Mulholland BS, Philo J. Does bacteremia follow colonoscopy? II. Results with blood cultures obtained 5, 10 and 15 minutes after colonoscopy. Gastrointest Endosc 1976;23:31-2.

[146] Dickman MD, Farrell R, Higgs RH, et al. Colonoscopy associated bacteremia. Surg Gynecol Obstet 1976;42:173-6.

[147] Farrell RL, Dickman MD, Higgs RH, Humphries THJ, Chappelka AR. Colonoscopy-associated bacteremia: a clinical entity? (abstract). Gastrointest Endosc 1975;21:187

[148] Rafoth RJ, Sorenson RM, Bond JH. Bacteremia following colonoscopy. Gastrointest Endosc 1975;22:32-3.

[149] Hartong WA, Barnes WG, Calkins WG. The absence of bacteremia during colonoscopy. Am J Gastroenterol 1977;67:240-4.

[150] Pelican G, Hentges D, Butt J, Haag T, Rolfe R, Hutcheson D. Bacteremia during colonoscopy. Gastrointest Endosc 1976;23:33-5.

[151] Kiss A, Ferenci P, Graninger W, Pamperl H, Potzi R, Meryn S. Endotoxaemia following colonoscopy. Endoscopy 1983;15:24-6.

[152] Kumar S, Abcarian H, Prasad L, Lakshmanan S. Bacteremia associated with lower gastrointestinal endoscopy: fact or fiction? I. Colonoscopy. Dis Colon Rectum 1982;25:131-4.

[153] Craner GE, Ogburn RM. More data on bacteremia and colonoscopy (letter). Gastrointest Endosc 1975;22:105.

[154] Vender R, Larson, J, Garcia J, Topazian M, Ephraim P. Appendicitis as a complication of colonoscopy. Gastrointest Endosc 1995; 41: 514-6.

[155] Coughlin GP, Butler RN, Alp MH, Grant K. Colonoscopy and bacteremia. Gut 1977;18:678-9.

[156] Watanakunakorn C. Streptococcus bovis endocarditis associated with villous adenoma following colonoscopy. Am Heart 1988;116:1115-6.

[157] Davis JL, Milligan FD, Cameron JL. Septic complications following endoscopic retrograde cholangiopancreatography. Surg Gynecol Obstet 1975;140:365-7.

[158] Elson CO, Hattori K, Blackstone MO. Polymicrobial sepsis following endoscopic retrograde cholangiopancreatography. Gastroenterology 1975;69:507-10.

[159] Thurnherr N, Bruhlmann WF, Krejs GI, Bianchi L, Faust H, Blum AL. Fulminant cholangitis and septicemia after endoscopic retrograde cholangiography (E.R.C.P) in two patients with obstructive jaundice. Dig Dis Sci 1976;21:477-81.

[160] Schousboe M, Carter A, Sheppard PS. Endoscopic retrograde cholangiopancreatography: related nosocominal infections. NZ Med J 1980;92:275-7.

[161] Noy MF, Harrison L, Holmes GKT, Cockel R. The significance of bacterial contamination of fibreoptic endoscopes. J Hosp Infect 1980;53-61.

[162] Low DE, Micflikier AB, Kennedy JK, Stiver HG. Infectious complications of endoscopic retrograde cholangiopancreatography: a prospective assessment. Arch Intern Med 1980;140:1076-7.

[163] Doherty DE, Falko JM, Lefkovitz N, Rogers J, Frornkes J. *Pseudomonas aeruginosa* sepis following retrograde cholangiopancreatography (E.R.C.P.). Dig Dis Sci 1982;27:169-70.

[164] Allen JI, Allen MO, Olson MM, et al. Pseudomonas infection of the biliary system resulting from use of a contaminated endoscope. Gastroenterology 1987;92:759-63.

[165] Bilbao MK, Dotter CT, Lee TG, Katon RM. Complications of endoscopic retrograde cholangiopancreatography (E.R.C.P) Gastroenterology 1976;70:314-20.

[166] Vennes JA, Jacobson JR, Silvis SE. Endoscopic cholangiography for biliary system diagnosis. Ann Intern Med 1974;80:61-4.

[167] Classen DC, Jacobson JA, Burke JP, Jacobson JT, Scott Evans R. Serious pseudomonas infections associated with endoscopic retrograde cholangiopancreatography. Am J Med 1988;84:590-6.

[168] Seigman-Igra Y, Isakov A, Inbar G, Cahaner J. *Pseudomonas aeruginosa* septicemia following endoscopic retrograde cholangiopancreatography with a contaminated endoscope. Scand J Infect Dis 1987;19:527-30.

[169] Godiwala T, Andry M, Agrawal N, Ertan A. Consecutive *Serratia marcescens* infections following endoscopic retrograde cholangiopancreatography. Gastrointest Endosc 1988;34:345-7.

[170] Nosocomial infection and pseudoinfection from contaminated endoscopes and bronchoscopes - Wisconsin and Missouri. JAMA 1991;266:2197.

[171] Struelens MJ, Rost F, Deplano A et al. *Pseudomonas aeruginosa* and *Enterobacteriaceae* bacteremia after biliary endoscopy: an outbreak investigation using DNA macrorestriction analysis. Am J Med 1993;95:489.

[172] Alfa MJ, Sitter DL. In-hospital evaluation of contamination of duodenoscopes: a quantative assessment of the effect of drying. J Hosp Infect 1991;19:89.

[173] Bass DH, Oliver S. Bornman PC. Pseudomonas septicemia after endoscopic retrograde cholangiopancreatography: an unresolved problem. S Afr Med J 1990;77:509.

[174] Hollands MS, Fletcher JP, Young J. Percutaneous feeding gastrostomy. Med J Aust 1989;151:328.

[175] Jain NK, Larson DE, Schroeder KW, et al. Antibiotic prophylaxis for percutaneous endoscopic gastrostomy: A prospective randomised double blind clinical trial. Ann Intern Med 1987,107:824.

[176] Bhutani M, Puterbaugh M, Davis L et al.  Does endoscopic ultrasound result in Bacteremia?  A prospective evaluation..Gastrointestinal Endoscopy Vol 45 No 4 April 1997.

[177] Weber Ch, Fabricius H, Klein D, Dancygier H.  Bacteremia following endoscopic ultrasonography of the upper gastrointestinal tract.  Dept Int Med II & Lab Med, Stadtische Kliniken Offenbach, Uni of Frankfurt, Offenbach/Main, Germany.

[178] Ramsey AH.  An outbreak of bronchoscopy-related *Mycobacterium tuberculosis* infection due to lack of bronchoscope leak testing. Chest 2002; 121: 976-81.

[179] Feigal D, Gardner S, McClellan M. Ensuring safe and effective medical devices. N Engl J Med 2003: 348 (3) 191-2.

[180] Vision Sciences Inc. "Vision Sciences Addresses Recent Bronchoscope Recall", a press release dated March 11, 2002: www.biz.yahoo.com/prnews/020311/nwm013_1.html

[181] Norfleet RG. Infective endocarditis and infections of orthopedic and vascular prostheses following gastrointestinal endoscopy and dilation (letter). Gastrointest Endosc 1990;36:546.

[182] Vanderhooft JE, Robinson RP.  Late infection of a bipolar prosthesis following endoscopy.  A case report.  J Bone & Joint Surg Am 1995 Jul;77(7):1129-30.

[183] Schulman ST, Amren DP, Bisno AL, et al. Prevention of bacterial endocarditis: a statement for health professionals by the Committee on Rheumatic Fever and Infective Endocarditis of the Council of Cardiovascular Disease in the Young. Circulation 1984;70:1123A-7A.

[184] Kaye D. Prophylaxis for infective endocarditis: An update. Ann Intern Med 1986;104:419-23.

[185] The antibiotic prophylaxis of infective endocarditis: report of a working party of the British Society for Antimicrobial Chemotherapy. Lancet 1982;2:1323-6.

[186] Meyer GW Prophylaxis of infective endocarditis during gastrointestinal procedures report of a survey. Gastrointest Endosc 1979;25:1-2.

[187] Meyer GW. Endocarditis prophylaxis for oesophageal dilation: A confusing issue? Gastrointest Endosc 1998;48(6):641-643.

[188] Simmons NA, et al. Antibiotic prophylaxis of infective endocarditis. Recommendations from the Endocarditis Working Party of the British Society for Antimicrobial Chemotherpy. Lancet 1990;1:88-9.

[189] Dajani AS, Tauburt KA, Wilson YU. Prevention of bacterial endocarditis: Recommendations by the American Heart Association. Clinical Infectious Diseases.1997; 25: 1448-58

[190] Infection control during gastrointestinal endoscopy: guidelines for clinical application. Gastrointest Endosc 1988;34 (3 Suppl):37S-40S

[191] Zuckerman GR, O'Brien J, Halsted R. Antibiotic prophylaxis in patients with infectious risk factors undergoing gastrointestinal endoscopic procedures. Gastrointest Endosc 1994;40(5):538-43.

[192] Meyer GW. Antibiotic prophylaxis for gastrointestinal procedures: who needs it? Gastrointest Endosc 1994;40(5):645-6.

[193] Wong A, Rosenstein AH, Rutherford RE, James SP. Bacterial endocarditis following endoscopic variceal sclerotherapy. J Clin Gastroenterol 1997, 24/2:90-91.

[194] Selby WS, Norton ID, Pokorny CS, Benn RA. Bacteremia and bacterascites after endoscopic sclerotherapy for bleeding esophageal varices and prevention by intravenous cefotaxime: a randomized trial. Gastrointest Endosc Nov-Dec 1994, 40(6):680-4.

[195] Meyer GW, Artis AL. Antibiotic Prophylaxis for Orthopedic Prostheses and GI Procedures: Report of a Survey. Am J Gastroenterology 1997; 92: 989-91.

[196] Alveyn CG, Robertson DAF, Wright R, et al. Prevention of sepsis following endoscopic retrograde cholangiopancreatography. J Hosp Infection 1991;19(Supp. C):65-70.

[197] Smith BC, Alqamish JR, Watson KJ, et al. Preventing endoscopic retrograde cholangiopancreatography related sepsis: a randomized controlled trial comparing two antibiotic regimes. J Gastroenterol Hepatol 1996;11:938-941.

[198] Van den Hazel SJ, Speelman P, Dankert J, et al. Piperacillin to prevent cholangitis after endoscopic retrograde cholangiopancreatography: a randomized, controlled trial. Ann Intern Med 1996;125:442-447.

[199] Byl B, Deviere J, Sturelens MJ, et al Antibiotic prophylaxis for infectious complications after therapeutic endoscopic retrograde cholangio-pancreatography: a randomised double-blind, placebo-controlled study. Clin Infect Dis 1995; 20: 1236-40.

[200] Pereira W, Kovnat DM, Khan MA, Lacovino JR, Spivak ML, Snider GL. Fever and pneumonia after flexible fibreoptic bronchoscopy. Am Rev Respir Dis 1975;112:59-64.

[201] Smith RP, Sahetya GK, Baltch AL, Ohern J, Gord D. Bacteremia associated with fibreoptic bronchoscopy. NY State J Med 1983;83:1045-47.

[202] Jurado RL, Klein S. Infective endocarditis associated with fibreoptic bronchoscopy in a patient with mitral valve prolapse. Clin Infect Dis 1998;26:769-70.

[203] Standiford TJ, Kunkel SL. Strieter RM. Elevated levels of tumour necrosis factor after bronchoscopy and bronchoalveolar lavage. Chest 1991; 99: 1529-30.

[204] Yigla M, Oren I, Bentur L et al. Incidence of Bacteraemia Following Fibreoptic Bronchoscopy. Eur Res J 1999; 14: 789-91.

[205] Wood-Baker R, Burdon J, McGregor A, Robinson P, Seal P. Fibreoptic bronchoscopy in adults: a position paper of the Thoracic Society of Australia and New Zealand Internal Medicine Journal 2001;31 479-487.

[206] Dajani AS, Bisno AL, Chung KJ et al. Prevention of Bacterial Endocarditis: Recommendations by the American Heart Association. JAMA 1990; 264: 2919-22.

[207] Prakash VBS. Prophylactic Antibiotic Therapy for Bronchoscopy: Indications. J Bronch 1997; 4: 281-5.

[208] Deva AK, Vickery K, Zou J et al. Detection of persistent vegetative bacteria and amplified viral nucleic acid from in-use testing of gastrointestinal endoscopes. J Hosp Inf 1998;39:149-157.

[209] Chu N, McAlister D, Antonopios P. Natural bioburden levels detected on flexible gastrointestinal endoscopes after clinical use and manual cleaning. Gastrointest Endosc 1998;48(2):137-142.

[210] Kovacs BJ, Aprecio RM, Kettering JD, Chen YK. Efficacy of various disinfectants in killing a resistant strain of *Pseudomonas aeruginosa* by comparing zones of inhibition: implications for endoscopic equipment reprocessing. Am J Gastro 1998; 93(11):2057-9.

[211] Kovacs BJ, Chen YK, Kettering JD et al. High-level disinfection of flexible GI endoscopes: are current recommendations adequate? Am J Gastroenterol 1999; 94 (6): 1546-50

[212] Cronmiller JR, Nelson DK, Salman G et al. Antimicrobial efficacy of endoscopic disinfection procedures: a controlled, multifactorial investigation. Gastrointest Endosc 1999

[213] Bordas JM, Marcos-Maeso A, Perez MJ, Llach J, Terés. High level disinfection of duodenoscopes: assessment using "in use" tests. Gastrointest Endosc 1999

[214] Vandervoort J,Tanasijevic M, Tham TCK et al. HIV detection on endoscopes after high level disinfection. Gastrointest Endosc 1999

[215] Cheetham NWH, Berentsveig V. Relative efficacy and activity of medical instrument cleaning agents. Australian Infection Control 2002; 7(3): 105-11

[216] Kizkin O, Suleyman GT, Hacievliyagil S, Gunen H. Proteolytic enzyme sensitivity and decrease in respiratory function (a 10-year follow-up). Int Arch Occup Environ Health. 2002 Aug;75(6):441-4. Epub 2002 Apr 13.

[217] Costerton W. Biofilms: a growing problem. Seminar transcripts at www.maunco.com/seminars/transcripts/biofilms.htm

[218] Costerton JW, Cheng K-J, Geesey GG, Ladd TI, Nickel JC, Dasupta M et al. Bacterial biofilms in nature and disease. Ann Review Microbiol 1987; 41: 435-64.

[219] Rogers J, Norkett DI, Bracegirdle P, Dowsett AB, Walker JT, Brooks T, et al. Examinaiton of biolilm formation and risk of infection associated with the use of urinary catheters with leg bags. J Hosp Infect 1996; 32: 105-15

[220] Schwank S, Rajacic Z, Simmerli W, Blaser J. Impact of bacterial biofilm formation on *in vitro* and *in vivo* activities of antibiotics. Antimicrob Agents Chemother 1998; 42: 895-8.

[221] Nichols WW, Evans MJ, Slack MPE, Walmsley HL. The penetration of antibiotics into aggregates of mucoid and non-mucoid *Pseudomonas aeruginosa.* J Gen Microbiol 1989; 135: 1291-33.

[222] Characklis WG, McFeters GA, Marshall KC. Physiological ecology in biofilm systems. In: Characklis WG, Marshall WC, (Eds). Biofilms. New York: John Wiley & Sons; 1990: 341-94.

[223] Davies DG, Parsek MR, Pearson JP, Iglewski BH, Costerton JW, Greenberg EP. The involvement of cell-to-cell signals in the development of a bacterial biofilm. Science 1998; 280: 295-8.

[224] Donlan RM, Elliott DL, Gibbon DL. Use of surfactants to control silt and biofilm deposition onto PVC fill in cooling water systems. Proceedings of the 1997 International Water Conference Annual Conference; Pittsburgh, Pa. Paper No 1WC-97-73.

[225] Johansen C, Gaholt P, Gram L. Enzymatic removal and disinfections of bacterial biofilm. Appl Environ Microbiol 1997; 63: 3724-8.

[226] Christensen BE, Tronnes HN, Vollan K, Smidsrod O, Bakke R. Biofilm removal by low concentrations of hydrogen peroxide. Biofouling 1990; 2: 165-75.

[227] Muscarella LF. Application of environmental sampling to flexible endoscope reprocessing: the importance of monitoring the rinse water. Infect Control Hosp Epidemiol 2002; 23 (5) 285-9.

[228] Muscarella, LF.  The claims of AERs and the importance of routinely sampling the rinse water used during endoscope reprocessing.  May 2002; www.myendosite.com

[229] Working Party Report. Rinse water for heat labile endoscopy equipment.  J Hosp Infect 2002; 51: 7-16.

[230] Working Party Report.  Decontamination of minimally invasive surgical endoscopes and accessories. J Hosp Infect 2000; 45: 263-77.

[231] Babb JR, Bradley CR.  Endoscope decontamination: where do we go from here? J Hosp Infect 1995; 30: 543-51.

[232] Rinse water for heat labile endoscopy equipment.  A joint working group of the Hospital Infection Society and the Public Health Laboratory Service.   Richards J (Ed) at www.his.org.uk/rhwlee.htm

[233] Langer BKT, Daniels-Haardt I, Fischeder R, Boschek HJ.  *Legionellen, P.aerugmosa* und atypische Mykobakterien in Haunsinstallationssystem von Althenheimen und Kreankenhdusern einer deutschen Gropstadt (Legionelle, P. aeruginosa and atypical mycobacteria in home water supply systems at convalescent homes and hospitals of a large German city). Forum Stadte-Hygiene 1990; 451:286.

[234] Lowry PN, Blankenship R, Gridley W, Tompkins L.  A cluster of Legionella sternal-wound infections due to post-operative topical exposure to contaminated tapwater. NEngl JMed 1990; 324: 109-13

[235] Nye K, Chadha DK, Hodgkin P, Bradley C, Hancox J, Wise R.  *Mycobacterium chelonei* isolation from broncho-alveola lavage fluid and its practical implications.  J Hosp Infect 16 (3): 257-61.

[236] Grange JM, Yates MI, Infections caused by opportunistic mycobacteria – a review. JR Soc Med 1986; 79: 226-9.

[237] Freije MR.  Legionellae control in health care facilities: a guide for minimizing risk. Indianapolis: HC Information Resources, Inc 1997 (xi); 131.

[238] Muder RR, Stout JE, Yee YC. Isolation of *Legionella pneumophilia* serogroup 5 from empyema following esophageal perforation: source of the organism and mode of transmission.  Chest 1992; 102 (5): 1601-3.

[239] Sniadack DH, Ostroff SM, Karlix MA, et al. A nosocomial pseudo-outbreak of *Mycobacterium xenopi* due to a contaminated potable water supply: lessons in prevention.  Inf Control & Hospital Epidemiol 1993; 14 (11): 636-41.

[240] Mackay WG, Leanord AT, Williams CL.  Water, water everywhere nor any a sterile drop to rinse your endoscope.  J Hosp Infect 2002; 51: 256-61.

[241] Pang J, Perry P, Ross A, et al.  Bacteria-free rinse water for endoscope disinfection. Gastrointestinal Endoscopy 2002; 56 (3): 402-6.

[242] Phillips G, McEwan H, Butler J.  Quality of water in washer-disinfectors.  J Hosp Infect 1995;31:152-154.

[243] McKnight A, Cadwallader H, Thomas L.  Is filtered rinse water for endoscopy sterile?  Australian Infection Control Association May 1998 12th National Conference, Poster No. 6, p.95.

[244] Peadon J.  Achieving filtered water with endocleaners.  Australian Infection Control Association May 1998, 12th National Conference, p.51.

[245] Durante L, Zulty JC, Isreal E, et al. Investigation of an outbreak of bloody diarrhea: association with endoscopic cleaning solution and demonstration of lesions in an animal model. Am J Med 1992;92(5):476-80.

[246] Wardle E, Jones D.  Determination of rinsing volumes following manual endoscope disinfection with *ortho*-phthalaldehyde (OPA) J.GENCA 2003; 12 (4): 7-9.

[247] Therapeutic Goods Administration.  Chemicals at http://www.tga.gov.au/

[248] Lewis DL, Arens M.  Resistance of microorganisms to disinfection in dental and medical devices.  Nature Medicine, 1995;1(9):956-958.

[249] Gerding DN, Peterson LR, Vennes JA. Cleaning and disinfection of fiberoptic endoscopes: evalution of glutaraldehyde exposure time and forced air drying. Gastroenterology 1982;83:613-8.

[250] Kaezmarek RG, Moore RM jr, McCrohan J et al. Multi-state investigation of the actual disinfection/sterilisation of endoscopes in health care facilities. Am J Med 1992;92:256-61.

[251] Van Gossum A, Loriers M, Serruys E, Cremer M. Methods of disinfecting endoscopic material: results of an international survey. Endoscopy 1989;21:247-50.

[252] Gorse GJ, Roberta L, Messner RNC.  Infection control practises in gastrointestinal endoscopy in the United States: a national survey.  Infect Control Hosp Epidemiol 1991; 12 (5): 289-96.

[253] Reuse of Single-Use Medical Devices: Making Informed Decisions.  ISBN 0-941417-52-2: ECRI 1996.

[254] The Reuse of Single-Use Medical Devices. Guidelines for Healthcare Facilities. Canadian Healthcare Association, Ottawa, Ontario. CHE Press, 1996.

[255] Report of the NHMRC expert panel on re-use of medical devices labelled as single-use. Australian Government Publishing Service, Canberra 1997.

[256] Reuse of single-use medical devices: NHMRC deliberations. MJA 1996; 164: 537.

[257] Collingnon PJ, Graham E, Dreimanis DE. Reuse in sterile sites of single-use medical devices: how common is this in Australia? MJA 1996; 164: 533-6.

[258] Ball CK, Schafer EM, Thorne D. Reusing disposables: Same old story – more characters added. Insight 1996; XXI; 3: 77-84.

[259] Disposable Endoscopic Accessories. Device Reprocessing Companies. Technology Status Evaluation. Gastroenterology 1988; 48: 717-22.

[260] Infection Control During Gastrointestinal Endoscopy. Technology Statement. Gastroint End 1988; 34(3): 37S-40S.

[261] Sterilizing Medical Devices in the Year 2000. An MD & DI Industry Roundtable. Medical Device and Diagnostic Industry December 1990; 137 –75.

[262] Melzera Buess G. Reusable, Re-posable and Disposable Instrumentation. End Surg 1995; 3: 127-8.

[263] Kozarek RA, Raltz SL, Ball TJ et al. Reuse of disposable sphincterotomes for diagnostic and therapeutic ERCP: a one year prospective study. Gastrointest Endosc 1999; 49 (1): 39-42.

[264] Lee RM, Kozarek RA, Raltz SL, Sumida SE. Risk of Contamination of Sterile Biopsy Forceps in Disinfected Endoscopes. Gastrointest Endosc 1998; 47 (5): 377-81.

[265] Kozarek RA, Raltz SL, Merriam LD, Sumida SE. Disposable versus reusable biopsy forceps: a prospective evaluation of costs. Gastrointest Endosc 1996; 43 (1): 10-3.

[266] Wilcox CM, Geels W, Baron T. How many times can you reuse a "single use" sphincterotome?: A prospective evaluation. Gastrointest Endosc 1998;48(1):58-60.

[267] Kozarek RA, Sumida SE, Raltz SL et al. In vitro evaluation of wire integrity and ability to reprocess single-use sphincterotomes. Gastrointest Endosc 1997;45(2):117-21.

[268] Reprocessing of Endoscopic Devices: To Use or Reuse. Clinical Symposium, ASGE, May 13, 1997, Washington Convention Center.

[269] Foss D, Monagan BA. A national survey of physicians and nurses attitudes towards endoscopic cleaning and the potential for cross infection. Gastroenterology Nursing 1992;15(2):59-65.

[270] Cheung RJ, Oritz D, DiMarino AJ. GI endoscopic reprocessing practices in the United States. Gastro Endoscopy 1999; 50 (3): 362-8.

[271] Muscarella LF. Current Instrument Reprocessing Practices. Result of a National Survey. Gastroenterology Nursing 2001; 24 (5): 253-60.

[272] Maloney S, Welbel S, Daves B et al. Mycobacterium abscessus pseudoinfection traced to an automated endoscope washer: utility of epidemiologic and laboratory investigation. J. Inf Dis 1994;169(5):1166-9.

[273] Alvarado CJ Stolz SM, Maki DC. Nosocomial infections from contaminated endoscopes: A flawed automated endoscope washer: An investigation using molecular epidemiology. Am J Med, suppl. 1991;91(3B):272S-80S.

[274] Reichert M. Automatic washers/ disinfectors for flexible endoscopes. Infect Control Hosp Epidemiol 1991;12:497-9.

[275] Struelens MJ, Rost F, Loriers M et al. Septicemia after ERCP: outbreak linked to an automatic endoscope disinfecting machine (abstract 73). In:Proceedings 3rd International Conference on Nosocomial Infections, Atlanta Georgia 1990. American Hospital Association, Chicago, 1990

[276] Griffiths PA, Babb JR, Bradley CR, Fraise AP. Glutaraldehyde-resistant *Mycobacterium chelonae* from endoscope washer disinfectors. J Applied Microbiology, 1997;82:519-526.

[277] Merighi A, Contato E, Scagliarini R, et al. Quality improvement in gastrointestinal endoscopy: microbiologic surveillance of disinfection. Gastrointest Endosc 1996;43(5):457-62.

[278] Favero MS, Pugliese G. Infections transmitted by endoscopy: an international problem (editorial; comment). Am J Inf Control 1996; 24 (5): 343-5.

[279] Gubler JG, Salfinger M, von Graevenitz A. Pseudoepidemic of nontuberculous mycobacteria due to a contamination bronchoscope cleaning machine: Report of an outbreak and review of the literature. Chest 1992;101:1245-9.

[280] Takigawa K, Fujita J, Negayama K, et al. Eradication of contaminating *Mycobacterium chelonei* from bronchofiberscopes and an automated bronchoscope disinfection machine. Respir Med 1995;89:423-7.

[281] Mitchell DH, Hicks LJ, Chiew R, Montanaro JC, Chen SC. Pseudoepidemic of Legionella pneumophila serogroup 6 associated with contaminated bronchoscopes. J Hosp Inf 1997;37(1):19-23.

[282] Lynch DAF, Porter L, Murphy L, Axon ATR. Evaluation of four commercial automatic washing machines. Endoscopy 1992;24:766-70

[283] Fennelly KP. Personal Respiratory Protection Against Mycobacterium Tuberculosis. Clinics in Chest Medicine 1997; 18: 1-17.

[284] Communicable Disease Network of Australia. Protection for Health Care Workers (Section 22). In: Infection Control Guidelines for the Prevention of Transmission of Infectious Diseases in the Health Care Setting. 2002. Available at http://www.health.gov.au/pubhlth/strateg/communic/review/draft.htm

[285] NICNAS (National Industrial Chemicals Notification & Assessment Scheme). http://www.nicnas.gov.au