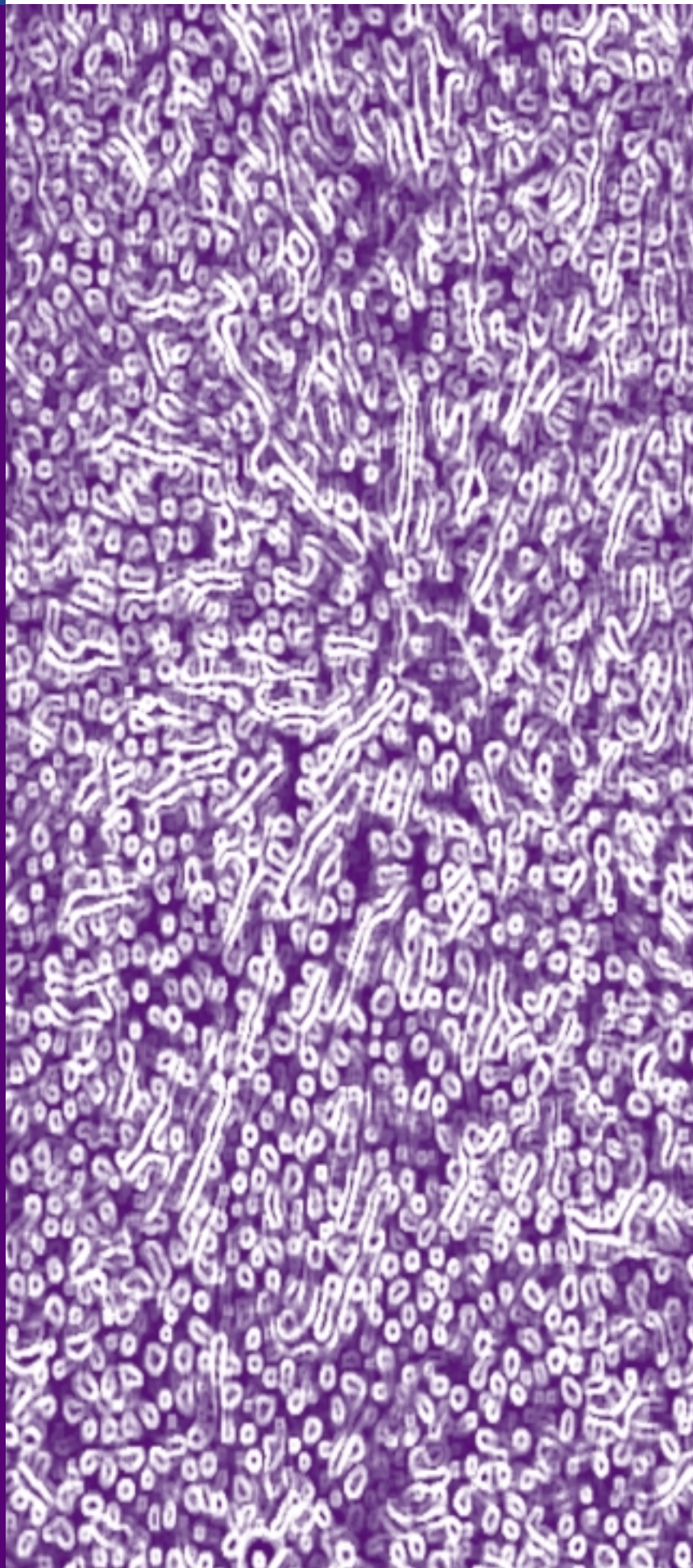


# Is there an alternative to glutaraldehyde?

*A review of agents  
used in cold  
sterilisation*



Royal College  
of Nursing





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Information for RCN stewards and RCN safety representatives,  
occupational health nurses, and nurses involved in endoscopy

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1

## Introduction

This publication is a review of the health and safety profile of agents used for reprocessing heat sensitive instruments and the implications for occupational health.

The majority of laparoscopic, urological and arthroscopic telescopes and their accessories are now heat tolerant and thus can be autoclaved. However, all flexible fiberoptic endoscopes are not heat tolerant and alternatives to autoclaving have to be used.

In the UK, the most common method of decontamination of endoscopes is immersion in two per cent activated alkaline glutaraldehyde for 10 to 20 minutes<sup>1</sup>. However, adverse reactions to glutaraldehyde are common among people involved in endoscopy and the Health and Safety Commission has recommended substantial reductions in atmospheric levels of glutaraldehyde in order to comply with the Control of Substances Hazardous to Health Regulations (COSHH), 1999.

This report is aimed at RCN safety representatives, RCN stewards, occupational health nurses, and all nurses involved in endoscopy and covers the following:

- ◆ the legislative background to assignment of a Maximum Exposure Limit (MEL) to glutaraldehyde
- ◆ the use of glutaraldehyde for reprocessing endoscopes and a review of alternative agents
- ◆ the legal framework relating to the management of risk in the workplace environment.

2

## Government health and safety framework

### Introduction

The English white paper *Saving Lives: Our Healthier Nation* (1999)<sup>2</sup>, the Scottish Executive's white paper *Towards a Healthier Scotland*<sup>3</sup> and Wales' strategy called *Better Health: Better Wales*<sup>4</sup> all set out proposals to save lives, promote healthier living, reduce inequality in health, and highlight exposure to risks in the workplace as a contributory factor to ill health.

In March 1999 the Health and Safety Commission, the Health and Safety Executive and the Department of Health (England) jointly launched the Healthy Workplace Initiative with the aim of improving productivity, generating lower rates of sickness absence, and resulting in fewer accidents and less illness. The National Plan for the NHS<sup>5</sup>, launched in July 2000, set out the establishment of a national agency called NHSplus which will provide a portfolio of occupational health services to small and medium sized businesses.

The Government is giving a clear signal that the management of health and safety is considered to be a key issue and is encouraging a partnership approach between employees, employers and local communities.

There are a number of bodies that provide advice and guidance to the Government on health and safety. The key groups are reviewed below.

### The Health and Safety Commission (HSC)

In England, Scotland and Wales the HSC reports to the Secretary of State for Environment, Transport and the Regions. The HSC for Northern Ireland reports to the Department of Enterprise, Trade and Investment in Northern Ireland. The HSC is responsible for the administration of the Health and Safety at Work Act 1974 and has oversight of the work of the Health and



Safety Executive (HSE) and has power to delegate to the Executive any of its functions.

Membership of the HSC is by nomination from organisations representing employers, employees, local authorities and others.

Its functions include the protection of the public against risks arising from work activities and to secure the health, safety and welfare of persons at work. It also reviews the adequacy of health and safety legislation and will submit new or revised regulations and approved codes of practice to government.

## The Health and Safety Executive (HSE)\*

The HSE provides the HSC with the policy, scientific and professional advice that is required to carry out its functions and responsibilities.

The work of the HSE involves making sure:

- ◆ employers look after the health and safety of their employees
- ◆ employees and the self-employed look after their own health and safety
- ◆ all take care of the health and safety of others.

The HSE develops new health and safety laws and standards, and plays a full part in international developments, especially in the European Union. The HSE also:

- ◆ inspects workplaces
- ◆ investigates accidents and cases of ill health
- ◆ enforces good standards by advising people how to comply with the law and by ordering them to make improvements by prosecuting them if necessary
- ◆ publishes guidance and advice
- ◆ provides an information service
- ◆ carries out research.

HSE inspectors enforce health and safety legislation. Cases of occupational asthma, like those caused by exposure to glutaraldehyde, are reportable by the employer to the HSE under the Reporting of Injuries, Diseases and Dangerous Occurrence Regulations

\* The HSC for England, Scotland and Wales and the HSC for (Northern Ireland).

1995 (RIDDOR)<sup>6</sup>. Such reports are used for epidemiological information and may be investigated by HSE staff.

## The role of advisory committees

The HSC also takes expert advice from a network of 25 advisory committees, which recommend standards and provide guidance and comment on policy issues facing the HSC. Each committee includes members nominated by employer and employee organisations and, where appropriate, members may also be public interest representatives and scientific and professional experts.

### The Health Services Advisory Committee (HSAC)

The HSAC is one of the advisory committees to the HSC, advising on health and safety protection of people working in the health services. The HSAC also provides advice and guidance to the health services and acts as a stimulus for identifying and meeting research needs.

In February 1998 the HSAC revised the leaflet *Glutaraldehyde and You – Guidance for the Healthcare Sector* with updated advice on measures to protect employees' health, with emphasis on the need to use a substitute disinfectant. The leaflet also explains the measures to be taken following the reclassification of the exposure limit for glutaraldehyde under the COSHH regulations.

Single copies of the leaflet<sup>7</sup> are issued by the HSC and are available free of charge, HSE Books, PO Box 1999, Sudbury, Suffolk, CO10 2WA, order code IACL64. Alternatively order through their web site, [www.hsebooks.co.uk/homepage.html](http://www.hsebooks.co.uk/homepage.html).

### The Advisory Committee on Toxic Substances (ACTS) and occupational exposure limits

Occupational exposure limits are set on the recommendations of the Health and Safety Commission's Advisory Committee on Toxic Substances (ACTS) and its subcommittee, the Working Group on the Assessment of Toxic Chemicals (WATCH).

**Maximum Exposure Limits (MELs)** are set for hazardous substances that have been shown to cause significant ill health in humans and for which a No Observed Adverse Effect Level (NOAEL) can be set. These substances may cause the most serious health effects, such as cancer and occupational asthma.

## 3

**Occupational Exposure Standards (OESs)** cover substances where a NOAEL can be set below the exposure limit to which a substance is considered to be safe.

The HSE publication EH40 Occupational Exposure Limits<sup>8</sup>, which is revised annually, contains a list of substances for which occupational exposure limits have been set.

## Control of Substances Hazardous to Health (COSHH)

The Control of Substances Hazardous to Health (COSHH) regulations came into force in October 1989 and were last updated in 1999<sup>9</sup>. They provide a comprehensive and systematic approach to the control of exposure to hazardous substances at work. COSHH requires employers to take all reasonable steps to protect workers from risks to their health from hazardous substances. Where prevention is not possible employers must adequately control the risks. The two types of exposure limits set out under COSHH, MELs and OESs, are intended for use in normal working conditions.

## Issues related to the use of glutaraldehyde

### Glutaraldehyde in health care settings

Glutaraldehyde is a volatile dialdehyde and it has been used in the health service as a disinfectant and sterilising agent since the 1960s<sup>10</sup>. It is used in the following settings:

- ◆ endoscopy units
- ◆ general surgical theatres
- ◆ sterile device departments
- ◆ urology departments
- ◆ catheterisation laboratories
- ◆ dental practices
- ◆ histological fixing
- ◆ X-ray film processing.

Exposure to glutaraldehyde liquid or vapour has been known to cause a range of health problems<sup>11,12</sup> including:

- ◆ irritation of the eyes, nose and throat
- ◆ skin sensitisation
- ◆ occupational asthma where the symptoms in affected individuals include chest tightness and difficulty in breathing<sup>13</sup>.

The use of glutaraldehyde has potential cost implications in terms of staff health, sick leave, litigation and workforce compensation<sup>3</sup>. Once an individual has been sensitised, further exposure to glutaraldehyde makes the symptoms worse. In the case of occupational asthma, removal from exposure can still result in symptoms for years after, or even indefinitely<sup>14</sup>. Studies have shown that once occupational asthma develops it is important not to delay action and to remove the worker from exposure immediately<sup>15</sup>. This may mean removing the worker from the workplace and perhaps redeployment to another clinical area.

## How the COSHH regulations apply to glutaraldehyde

Until January 1998, exposure to glutaraldehyde was controlled to an Occupational Exposure Standard (OES) of 0.2 parts per million. The OES is a time-weighted average concentration of glutaraldehyde in air measured over a 10-minute interval. It was set at this level to prevent mucous membrane irritation. However, this level did not prevent cases of sensitisation and occupational asthma occurring<sup>16</sup>.

In 1999 the HSC approved a proposal that exposure to glutaraldehyde should be controlled to a Maximum Exposure Limit (MEL) of 0.05 parts per million, for both short-term (15 minutes) and long-term (8 hour time-weighted average) exposure. Peak vapour concentrations should not exceed this level. This change was prompted because of the impossibility of determining a safe exposure limit for glutaraldehyde. MELs require employers to prevent exposure to the substance, but if this is not feasible, employers should aim to reduce exposure as far below the limit as is reasonably practicable.

The HSE, as part of their inspection process, will be making an assessment of compliance with the glutaraldehyde MEL. Employers will have to show that all the required systems are in place if they are to carry on using glutaraldehyde. Failure to do this may result in the HSE factory inspectors issuing improvement notices, prohibition notices or undertaking 'enforcement action', such as prosecution.

## The role of employers

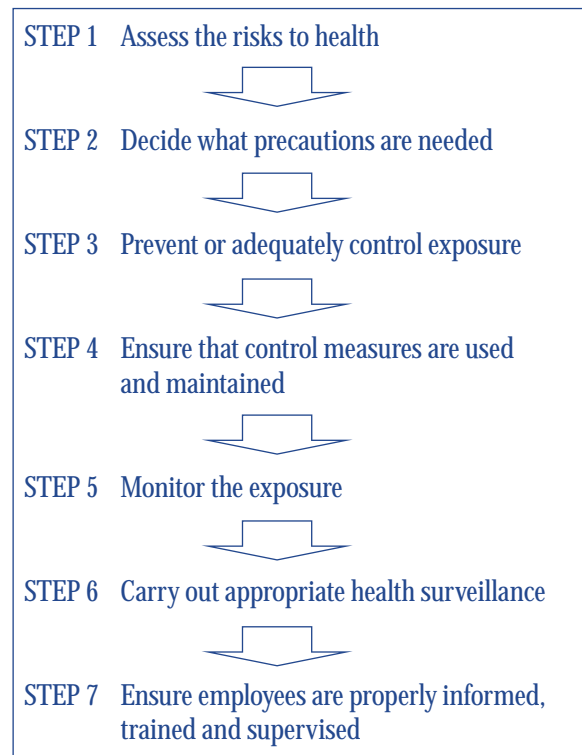
A substance that is governed by a MEL places a requirement on employers<sup>17,18</sup> to reduce exposure as far below the limit as is practicable or replace it with a less hazardous substance if possible, as defined in COSHH 1999.

It is thought that most hospitals could meet the MEL for glutaraldehyde by tightening up operational guidelines, by improving automated washer-disinfectors and installing appropriate fume extraction. However, a cost benefit analysis carried out by the HSE<sup>19</sup> indicated that there would be significant costs for many trusts if they were to provide the facilities and equipment to meet the MEL.

## The management and control of risk

The law requires employers to control exposure to hazardous substances in order to prevent ill health. There are seven basic measures that employers must take to assess risks, control exposure and establish good working practices. The COSHH regulations require the risk of exposure to glutaraldehyde to be controlled. This may include air monitoring to ensure that concentrations of glutaraldehyde remain below the MEL. There is a duty on the employer to exercise due diligence and to take all reasonable precautions to protect the health of employees. The following guide outlines the steps to be taken in carrying out a COSHH assessment.

### From COSHH – a brief guide to the regulations<sup>20</sup>



A recent study has shown that intervention in the workplace, training people who handle glutaraldehyde, and accurate health surveillance may reduce the risks of developing occupational asthma<sup>21</sup>. Employees also need to be trained on coping with predictable, untoward incidents such as spills and machine failures.

## 4

## The role of Occupational Health Services (OHS) and health surveillance

Occupational Health Services (OHS) can play a key role in identifying health problems at an early stage. Pre-employment screening that includes enquiries regarding asthma, dermatitis, rhinitis, conjunctivitis, and lung function testing<sup>22</sup>, may help to identify at-risk individuals so that appropriate advice can be given. Similarly, this can be repeated for members of staff who are moving into any area where they will be using glutaraldehyde for the first time.

Regular and appropriate arrangements should be made for health checks/surveillance<sup>23</sup> on an ongoing basis and employees should be instructed on how to recognise the symptoms of sensitisation<sup>24</sup>. The checks should be safe, easy to perform, non-invasive and acceptable to employees. Appropriate procedures on health surveillance for an individual working with glutaraldehyde should include an enquiry seeking evidence of respiratory symptoms related to work, and a skin inspection by a responsible person (for example, an occupational health nurse).

Health surveillance will always include keeping an individual's health record<sup>25</sup>, which must be kept for 40 years from the date of the last entry and be available for inspection with the permission of the individual concerned.

It is important that the results of health surveillance lead to action that will benefit the health of employees. This is emphasised by the International Labour Office<sup>26</sup> and under COSHH regulations.

## Disinfection and sterilisation

### Key definitions

**Immersion** in disinfectants can be criticised as inadequate because this is not a sterilisation process. However, thorough cleaning will remove most organisms from endoscopes and accessories<sup>27, 28</sup>, but it is inappropriate to use the terms decontamination, sterilisation and disinfection interchangeably. Some simple definitions of key terms are given below:

**Cleaning** is a process that removes contaminants, including organic matter (for example, body fluids and faeces) and most microorganisms. Cleaning is always required before disinfection or sterilisation, especially when processing at low temperatures as the presence of proteins protect microorganisms from destruction by chemical agents. Ultrasonics can also be used to process rigid instruments. A specific frequency compatible with these instruments needs to be selected.

**Decontamination** is a general term used for the removal or destruction of microorganisms and other unwanted contaminants that may prejudice the safe use of a medical device. It includes cleaning, disinfection and sterilisation.

**Disinfection** is a process that reduces the number of viable microorganisms present on a surface or medical device to a level previously specified as appropriate for handling or for its intended further use. It does not necessarily kill or remove all microorganisms (particularly spores), but reduces them to a safe level. In laboratory tests, disinfectants should kill at least  $10^5$  organisms (for example, *Pseudomonas aeruginosa*, *Escherichia coli*, *Clostridium difficile*) over a time period similar to that used in practice, usually 10 minutes or less. Tests that mimic in-use conditions should be carried out before a disinfectant is accepted. Disinfectants should also be compatible with instrument components and processing equipment. All disinfectants have the disadvantage that recontamination can occur during rinsing to remove toxic residues, and instruments cannot be packaged to



prevent re-contamination during storage. Sterile (autoclaved) or bacteria free (filtered) water is necessary for rinsing.

**Sterilisation** is a process that renders an object free of all viable microorganisms including spores. Prions (infectious proteins), the probable causative agents of Creutzfeldt-Jakob disease (CJD), scrapie and bovine spongiform encephalopathy (BSE), are the only relevant exceptions and are resistant to the usual sterilising processes. However, the risk of transmission in a well-cleaned endoscope is minimal.

## Agents used for disinfection

The pressure to reduce the use of aldehydes is likely to increase over the next few years as a result of the MEL of 0.05 parts per million for glutaraldehyde, as well as the desire to seek safer alternatives that do not pose a risk to users. There is also a trend to move from alkylating agents to oxidising agents, as these can be biocidal very quickly. The ideal agent should be at least as effective as glutaraldehyde and non-irritating to users.

The following section provides a brief overview of agents that could be used as an alternative to glutaraldehyde. It includes some references to compatibility with metals. There may be other compatibility issues that this paper does not address because published information is not available. This is a complex area which is beyond the scope of this review.

### Glutaraldehyde

The common method of decontamination of endoscopes is immersion in two per cent activated alkaline glutaraldehyde for 10 to 20 minutes. Glutaraldehyde (for example, Cidex, Asep, Totacide 28) is highly effective for the disinfection of endoscopes, but as discussed earlier it is irritant and allergenic<sup>22</sup>.

Most bacteria and viruses, including HIV and hepatitis B virus (HBV), are killed or inactivated in less than five minutes of immersion in two per cent glutaraldehyde<sup>29</sup>.  
<sup>30, 31, 32, 33, 34, 35, 36</sup> *Mycobacterium tuberculosis* is more resistant, but is killed in 20 minutes<sup>37, 38, 39, 40</sup>. It must only be used in a well-ventilated room, exhaust-vented cabinet or an enclosed automated processor<sup>41</sup>.

### Superoxidised water

Superoxidised water (known as Sterilox) is a mixture of mild oxidants that includes hypochlorous acid. The microbiological profile has shown that it is highly effective in killing spores, mycobacteria and other potentially pathogenic microorganisms associated with diagnostic and therapeutic endoscopy procedures<sup>42, 43, 44</sup>. Sterilox acts faster than glutaraldehyde, being sporicidal in five minutes compared to six hours for glutaraldehyde. The Sterilox formulation also includes a proprietary corrosion inhibitor. A contact time of five minutes or less is effective in giving a five log reduction or greater against a range of microorganisms. As the active agents in Sterilox decompose slowly to harmless species, it has to be generated on-site, on-demand and has a life of 24 hours. It is non-toxic and non-irritant. A dilute solution of Sterilox can be used as bacteria-free rinse water, requiring no maintenance or filters.

### Alcohol

Alcohol, (ethanol [IMS] and *isopropanol*) at 60 to 70 per cent, is sometimes used for the disinfection of endoscopes, but an exposure time in excess of five minutes may damage the lens' cements. Alcohol rapidly destroys most non-spore forming bacteria, including mycobacteria, but is less effective against enteroviruses<sup>31</sup>. However, as it is flammable it is not recommended for use in automated processors where large volumes are used. Alcohol is useful for the disinfection of external surfaces of the camera and fiberoptic cables because it evaporates rapidly without leaving any residue and without the need for subsequent rinsing.

### Peracetic acid

Peracetic acid (such as Steris 0.2 per cent used at 50-56°C or Nu-Cidex 0.35 per cent used at room temperature) has an advantage over glutaraldehyde as it becomes effective very quickly; it is sporicidal in 10 minutes and effective against non-spore forming bacteria (including *Mycobacterium tuberculosis*<sup>40</sup>) and viruses in less than five minutes. However, in-use solutions are unstable and the disinfectants and processing equipment are expensive. Corrosion of certain metals can occur unless a suitable inhibitor is included. There are occupational exposure standards for the components of peracetic acid solutions (hydrogen peroxide and acetic acid) and control measures need to be in place. Peracetic acid is being looked at by ACTS/WATCH who recommend OESs and MELs to the Health and Safety Commission.

### Chlorine dioxide

Chlorine dioxide (Tristel, Dexit and Medicide) is sporicidal and is active against non-spore-forming bacteria, including mycobacteria and viruses, in less than five minutes<sup>45</sup>. It is potentially corrosive but commercial preparations contain an inhibitor. If chlorine dioxide is approved by the instrument and processor manufacturers, it is another possible alternative to glutaraldehyde. A respiratory irritant, chlorine dioxide has an OES set under COSHH and it is recommended that facilities provide enclosed and/or exhaust ventilated systems.

### Quaternary ammonium compounds

These are relatively non-toxic and non-damaging but usually have deficiencies in their antimicrobial spectrum. Dettox (now Dettol ED) cannot be recommended for routine use because of poor virucidal activity. An improved product, Sactimed (Sinald), shows a moderate mycobactericidal effect, but evidence of effectiveness against enteroviruses is lacking. Therefore, it is not recommended as a disinfectant for gastrointestinal endoscopes.

To order a copy contact the Medical Devices Agency (MDA) on 020 7972 8203.

The MAC is formed from specialist representatives from the NHS, Public Health Laboratory Service (PHLS) and academia. The MAC advises the Department of Health, through the MDA, on disinfection and sterilisation practices relevant to the Health Service. The MAC also advises on the preparation and approval of departmental guidance on microbiological aspects of equipment for use in the Health Service.

## Agents used for sterilisation

Flexible endoscopes will not tolerate high processing temperatures (in excess of 60°C) and cannot be autoclaved or disinfected using sub-atmospheric steam<sup>1</sup>. Sterilisation options include ethylene oxide, low temperature steam formaldehyde and gas plasma. However, current processing methods for these options take a long time to complete making them impractical for routine processing of most gastrointestinal instruments.

## Further reading

The Microbiology Advisory Committee (MAC) has produced a document which will prove useful when considering alternative agents. *Sterilisation, Disinfection and Cleaning: Guidance on Decontamination* discusses the principles of decontamination, provides suggested protocols for various decontamination regimes, and covers the Medical Devices Directive and CE marking, as well as recommended regimes for the decontamination of particular types of medical devices, such as endoscopes.

## 5

# Influencing the workplace and minimising the risks from glutaraldehyde

## The legal basis for a safe working environment

Health and safety laws ensure rights and responsibilities for both employers and employees. In campaigning for a safer workplace the following acts and regulations are important:

- ◆ The Health and Safety at Work Act (HASWA) 1974
- ◆ Management of Health and Safety at Work Regulations 1999
- ◆ Personal Protective Equipment at Work Regulations 1992
- ◆ Control of Substances Hazardous to Health Regulations (COSHH) 1999
- ◆ Reporting of Injuries, Diseases and Dangerous Occurrence Regulations (RIDDOR) 1995
- ◆ Disability Discrimination Act 1995.

## The role of safety representatives

Employers must consult safety representatives appointed by recognised trade unions<sup>46,47</sup>. Employees not covered by such arrangements must be consulted, either directly or indirectly, through elected representatives of employee safety<sup>48</sup>.

It is good practice to develop an awareness of the importance of health and safety issues and to consult with both union and non-union safety representatives on safety measures, information, training and the effects of new technology.

## The role of employers

Undertaking risk assessment is a mandatory part of an employer's legal obligation to employees. Given that the MEL for glutaraldehyde is strict, it is appropriate to consider the hierarchy of controlling risks:

- 1 Remove the hazardous substance by changing the process.
- 2 Control exposure by enclosing the process.
- 3 Control exposure by using extraction and ventilation equipment.
- 4 Control exposure by adopting safer working and handling processes.

Having considered step 1 (using an alternative agent) and deciding to continue with glutaraldehyde, the employer must put in place appropriate precautions to control risk. Step 2 would require the installation of washer-disinfectors, in conjunction with step 3 to provide extraction and ventilation equipment. Additionally, personal protective equipment (PPE) should be provided.

COSHH limits the use of PPE to those situations where other measures cannot adequately control exposure. The use of PPE should be considered as a last line of defence and other measures should be taken to minimise the level of glutaraldehyde in the atmosphere. When handling glutaraldehyde, gloves (nitrile not latex), aprons, goggles, respirators are all suitable PPE, however these are not foolproof and steps should be taken to ensure that equipment is regularly inspected, maintained and validated for effectiveness. If enclosed systems for glutaraldehyde are not in place it may be necessary for staff to wear fully enclosed suits supplied with an individual air supply.

Other measures that can be taken to control exposure to glutaraldehyde include:

- ◆ keeping lids on all containers
- ◆ safe disposal procedures (rather than pouring down the drain)
- ◆ monitoring exposure to glutaraldehyde
- ◆ the provision of health screening that identifies individuals who are becoming sensitised and have a mechanism in place to prevent further exposure.

## The responsibilities of employees

Employees have a duty to follow control measures, use the protective equipment provided, and to report any problems with them. Training, support and advice must be provided by the employer<sup>17,18</sup> on the measures that must be taken when working with glutaraldehyde. Any concerns on working with glutaraldehyde should be discussed with a direct line manager and trade union or employee health and safety representative.

## Workplace assessments

Union safety representatives and employee representatives have the right to carry out workplace inspections to investigate potential hazards, incidents and complaints about employee health and safety at work. They may inspect statutory records kept by employers, such as COSHH assessments, and make a judgement on their adequacy.

These assessments are a way of ensuring that a workplace is fulfilling all requirements for the safe use of glutaraldehyde.

## Evaluation of alternative agents

The implications of using safer alternative agents to glutaraldehyde should also be considered. As a first step in this evaluation process form an expert group of interested parties who can consider the alternatives and have a stake in making a change, such as:

- ◆ risk management representatives
- ◆ a head of facilities management
- ◆ a consultant surgeon
- ◆ a consultant physician
- ◆ a consultant microbiologist
- ◆ a directorate manager
- ◆ an endoscopy nurse
- ◆ safety representatives
- ◆ an infection control nurse
- ◆ occupational health representatives.

Questions to be considered during the process of finding a replacement for glutaraldehyde include:

- ◆ What alternative agents exist?
- ◆ What is their microbiocidal profile?
- ◆ What safety measures would be required?
- ◆ What have colleagues in other trusts used?
- ◆ Would the new agent be compatible with the equipment and procedures that are currently in use?
- ◆ Would the new agent provide other benefits such as swifter set up/finish and could more patients be seen per session?
- ◆ What costs would be involved with making the change?
- ◆ Would staff already sensitised to glutaraldehyde be able to work with a new agent (therefore increasing the number of experienced and trained staff available)?

## Staff redeployment

Under the Disability Discrimination Act (1995) disability is placed within the legal framework of equal opportunities<sup>49</sup>. It requires an employer to make reasonable adjustments to the working conditions of an employee who develops a disability<sup>50</sup>. In the case of glutaraldehyde sensitisation it may be appropriate to redeploy to another clinical area to remove the possibility of exposure. The RCN's publication *Workability – Injured, ill and disabled nurses can return back to work*<sup>51</sup>, will help with advice on these issues. Also consider changing to another agent that does not cause sensitisation. The new generation oxidising agents such as Sterilox or peracetic acid may offer a solution to this problem.

If a member of staff has to leave their job or give up work as a result of glutaraldehyde sensitisation they may be eligible for Industrial Injuries Benefit (temporary or permanent) from the NHS. Sufferers of prescribed diseases due to exposure to glutaraldehyde (non-infective dermatitis (D5), occupational asthma (D7) and allergic rhinitis (D4)) may be eligible for compensation from the DSS<sup>52</sup>.

Occupational dermatitis and asthma due to glutaraldehyde are diseases reportable under RIDDOR 1995<sup>6</sup>. The employer should designate a responsible



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person to inform the enforcing authority, this is usually the “person for the time being having control of the premises” where the exposure occurred. It is NOT the responsibility of the occupational health service to report the occurrence of the disease. Before reporting the disease, the responsible person should have received a written statement from a registered medical practitioner diagnosing the disease.

## The role of Occupational Health Services (OHS)

Occupational Health Services (OHS) is an integral part of risk management. It must take a population view and provide collective results to the employing organisation in a form that prevents individuals from being identified. This organisational overview can lead to action on controlling any risks being taken. There is also a responsibility to inform individual workers of abnormal results of screening. It must be noted that health surveillance by an occupational health professional is NOT a substitute for preventing and controlling exposure to glutaraldehyde.

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## Conclusions

This report has considered the current use of glutaraldehyde and has set out alternative agents that can be adopted. The overwhelming conclusion of this report, based largely on a review of the Health and Safety framework, is that:

- ◆ employers should actively seek alternatives to glutaraldehyde that do not have the same risk profile and are free of health associated effects
- ◆ if glutaraldehyde is to be retained, employers must take steps to protect their workers from exposure and employees must take responsibility for their own welfare by following procedures and using the personal protective equipment provided.

# References

- <sup>1</sup> British Society of Gastroenterology. Cleaning and disinfection of equipment for gastrointestinal flexible endoscopy: interim recommendations of a working party. *Gut* 1998; 42: 585-593
- <sup>2</sup> Department of Health. *Saving Lives: Our Healthier Nation*. The Stationery Office, 1999
- <sup>3</sup> Scottish Executive. *Towards a Healthier Scotland*. The Stationery Office, 1999
- <sup>4</sup> Welsh Assembly. *Better Health: Better Wales*. The Stationery Office, 1999
- <sup>5</sup> Department of Health. *The NHS Plan*. The Stationery Office, 2000. [www.nhs.uk/nhsplan](http://www.nhs.uk/nhsplan)
- <sup>6</sup> Health and Safety Commission. *The Reporting of Injuries, Diseases and Dangerous Occurrence Regulations 1995*. London: HSE Books, 1995
- <sup>7</sup> Health and Safety Commission, Health Services Advisory Committee. *Glutaraldehyde and You*. Sudbury: HSE, 1998
- <sup>8</sup> Health and Safety Executive. *EH40/99 Occupational Exposure Limits*. London: HSE Books, 1999
- <sup>9</sup> Health and Safety Commission. *Control of Substances Hazardous to Health Regulations 1999*. London: HSE Books, 1999
- <sup>10</sup> Menzies D. Glutaraldehyde - Controlling the risk to Health. *Brit J Theatre Nursing* 1995;4:11
- <sup>11</sup> Department of Health. *Glutaraldehyde*. HSC 1998/208, [www.open.gov.uk/doh/coinh.htm](http://www.open.gov.uk/doh/coinh.htm)
- <sup>12</sup> Health and Safety Executive. Chemical Hazard Alert Notice 7 - Glutaraldehyde. *CHAN 7 (REV)* - February 1998
- <sup>13</sup> Gannon PF, Bright P, Campbell M, O'Hickey SP, Burge PS. Occupational asthma due to glutaraldehyde and formaldehyde in endoscopy and x ray departments. *Thorax* 1995; 50(2):156-9
- <sup>14</sup> Newman Taylor AJ. Occupational asthma. *Postgraduate Medical Journal* 1988; 64(753):505-10
- <sup>15</sup> Burge PS. New developments in occupational asthma. *British Medical Bulletin* 1992; 98(5 suppl):240S-250S
- <sup>16</sup> Burge PS. Occupational risks of glutaraldehyde. *British Medical Journal* 1989; 299: 342
- <sup>17</sup> Health and Safety Executive. *Management of health and safety at work regulations*. Sudbury: HSE books, 1999. [www.hse.gov.uk/press/c99058.htm](http://www.hse.gov.uk/press/c99058.htm); <http://www.hse.gov.uk/press/c00009.htm>
- <sup>18</sup> Health and Safety Executive. *Regulations and code of practice*. Sudbury: HSE books, 1999
- <sup>19</sup> Health and Safety Executive. *Glutaraldehyde cost benefit analysis*. London: HSE (Economics Department), 1997
- <sup>20</sup> Health and Safety Executive. *COSHH: A brief guide to the regulations*. London: HSE Books, 1999
- <sup>21</sup> Di Stefano F, Siriruttanapruk S, McCoach J, Burge PS. Glutaraldehyde: an occupational hazard in the hospital setting. *Allergy* 1999; 54(10):1105-9
- <sup>22</sup> British Society of Gastroenterology working party. Aldehyde disinfectants and health in endoscopy units. *Gut* 1993, 34: 1641-1645
- <sup>23</sup> Health and Safety Executive. *Guide to health surveillance*. Sudbury: HSE books, 1999
- <sup>24</sup> Royal College of Nursing. *Occupational health audit*. London: RCN, 1999 (publication order code 000 815).
- <sup>25</sup> Health and Safety Commission. *Approved codes of practice*. Sudbury: HSE Books, 1999
- <sup>26</sup> International Labour Organisation. Technical and ethical guidelines for workers' health surveillance. *Occupational safety and health series 72*. Geneva: ILO, 1998
- <sup>27</sup> Babb JR, Bradley CR. Endoscope Decontamination: where do we go from here? *Journal Hospital Infection* 1995; 30(supp):543-551
- <sup>28</sup> Chan-Myers H, McAlister D, Antonoplos P. Natural bioburden levels detected on rigid lumened medical devices before and after cleaning. *American Journal of Infection Cont* 1997; 25:185
- <sup>29</sup> Rutala WA, Clontz EP, Weber DJ, Hoffman KK. Disinfection practices for endoscopes and other critical items. *Infection Cont Hospital Epidemiology* 1991; 12:282-288
- <sup>30</sup> Sattar SA, Springthorpe VS, Karim Y, Loro P. Chemical disinfection of non-porous inanimate surfaces experimentally contaminated with four human pathogenic viruses. *Epidem Infect* 1989; 102:493-505

- <sup>31</sup> Tyler R, Ayliffe GAJ, Bradley CR. Virucidal activity of disinfectants: studies with the poliovirus. *Journal Hospital Infection* 1990; 15:339-345
- <sup>32</sup> Hanson PIV, Gor D, Jeffries DJ, Collins IV. Chemical inactivation of HIV on surfaces. *British Medical Journal* 1989; 298:862-864
- <sup>33</sup> Bond WW, Favero MS, Peterson NJ, Ebert JW. Inactivation of Hepatitis B virus by intermediate to high level disinfectant chemicals. *J Clin Micro* 1983; 18:535-538
- <sup>34</sup> Kobayashi H, Tsuzuki M, Koshimizu H et al. Susceptibility of Hepatitis B virus to disinfectants or heat. *J Clin Micro* 1984; 20:214-216
- <sup>35</sup> Deva AK, Vickery K, Zou J et al. Establishment of an in-use test for evaluating disinfection of surgical instruments using the duck hepatitis model. *Journal Hospital Infection* 1996; 33:119-130
- <sup>36</sup> Best M, Sattar SA, Springthorpe VA, Kennedy ME. Efficacies of selected disinfectants against Mycobacterium tuberculosis. *J Clin Micro* 1990; 102:493-505
- <sup>37</sup> Holton J, Nye P, McDonald V. Efficacy of selected disinfectants against mycobacteria and cryptosporidia. *Journal Hospital Infection* 1994; 27:105-115
- <sup>38</sup> Lynam PA, Babb JR, Fraise AP. Comparison of the mycobactericidal activity of 2% alkaline glutaraldehyde and "Nu-Cidex" (0.35% peracetic acid). *Journal Hospital Infection* 1994; 30:237-240
- <sup>39</sup> Hanson PJV, Chadwick MV, Gaya H, Collins JV. A study of glutaraldehyde disinfection of fiberoptic bronchoscopes experimentally contaminated with Mycobacterium tuberculosis. *Journal Hospital Infection* 1992; 22:137-142
- <sup>40</sup> Griffiths PA, Babb JR, Fraise AP. Mycobactericidal activity of selected disinfectants using a quantitative suspension test. *Journal Hospital Infection* 1999; 41:111-121
- <sup>41</sup> Bradley CR, Babb JR. Endoscope decontamination: automated vs manual. Where do we go from here? *Journal Hospital Infection* 1995; 30(supp) 537-542
- <sup>42</sup> Selkon JB, Babb JR, Morris R. Evaluation of the antimicrobial activity of a new super-oxidized water, Sterilox, for the disinfection of endoscopes. *Journal Hospital Infection* 1999; 41:59-70
- <sup>43</sup> Shetty N, Srinivasan S, Holton J, Ridgway GL. Evaluation of microbiocidal activity of a new disinfectant: Sterilox 2500 against Clostridium difficile spores, Helicobacter pylori, vancomycin resistant enterococcus species, Candida albicans and several Mycobacterium species. *Journal Hospital Infection* 1999; 41:101-105
- <sup>44</sup> Middleton AM, Chadwick MV, Sanderson JL, Gaya H. Comparison of a solution of superoxidised water (Sterilox) with Glutaraldehyde for the disinfection of bronchoscopes, contaminated in vitro with Mycobacterium tuberculosis and Mycobacterium avium-intracellulare in sputum. *Journal Hospital Infection* 2000; 45:278-282
- <sup>45</sup> Babb JR, Bradley CR, Ayliffe GAJ. Sporicidal activity of glutaraldehyde and hypochlorites and other factors influencing their selection for the treatment of medical equipment. *Journal Hospital Infection* 1980; 1:63-75
- <sup>46</sup> Royal College of Nursing. *Safety representatives manual: a guide for RCN safety representatives*. London: RCN, 1994
- <sup>47</sup> Health and Safety Executive. *Safety representatives and safety committee regulations*. Sudbury: HSE books, 1977
- <sup>48</sup> Health and Safety Executive. *Health and Safety (consultation with employees) Regulations*. Sudbury: HSE books, 1996
- <sup>49</sup> Royal College of Nursing. *Guide to the Disability Discrimination Act 1995*. London: Labour Relations Department, 1996 (for copies contact RCN Employment Relations Department, 020 7409 3333)
- <sup>50</sup> Royal College of Nursing's Work Injured Nurses Group (WING). *Guide for injured, ill or disabled nurses*. London: RCN, 1998 (publication order code 001 006)
- <sup>51</sup> Royal College of Nursing. *Workability - Injured, ill and disabled nurses can return to work*. London: RCN, 2000 (publication order code 001 159)
- <sup>52</sup> Harrington JM, Gill FS, Aw TC, Gardiner K. *Occupational health (4th edition)*. London: Blackwell Science, 1998.



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