

An evaluation of chemical disinfecting agents used in endoscopy suites in the NHS

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This research report looks at alternatives to glutaraldehyde for the disinfection of endoscopes. It highlights their benefits and limitations.

The work was commissioned because of the historically high number of cases of occupational asthma caused by glutaraldehyde.

There is no single system for disinfection and no single most appropriate disinfectant. Many users are moving away from glutaraldehyde towards other products, some of which are regarded as potential asthmagens.

The report presents the control approaches for disinfecting agents based on HSE's COSHH Essentials. This is summarised as follows:

Chemical Base	Example of Product	COSHH Essentials Hazard Group	COSHH Essentials Control Approach
Chlorine base	Sterilox	A (low hazard)	1 (general ventilation)
Chlorine base	Tristel	A (low hazard)	1 (general ventilation)
Peroxygen	Virkon S (1% liquid)	A (low hazard)*	1 (general ventilation)
Peracetic Acid	Nu-Cidex/Aperlan	C (medium hazard)*	3 (containment)
Ortho-phthalaldehyde	Cidex-OPA	C (medium hazard)*	3 (containment)
2% Glutaraldehyde	Cidex	E (special case)	4 (special case)

*Cidex-OPA is subject to requirement for self-classification within EU legislation. This assessment is based on manufacturer data.

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CONTENTS

EXECUTIVE SUMMARY	2
1. Introduction and Background	5
2. Methods	6
3. Findings	7
<i>3.1. Literature Review</i>	9
<i>3.2. Legislation and Standards</i>	9
<i>3.3. Reprocessors</i>	10
<i>3.4. Endoscopes</i>	11
<i>3.5. Disinfectants</i>	11
3.5.1. Disinfectants based on Alkylating Agents	11
3.5.2. Disinfectants based on Oxidising Agents	12
3.5.3. Other Types of Disinfectants	13
4. Discussion and Conclusions	13
<i>4.1 Concept of time line</i>	15
<i>4.2 Communication</i>	15
<i>4.3 Users experiences</i>	15
<i>4.4 Validation</i>	16
<i>4.5 Hierarchy of control</i>	16
<i>4.6 Draft selection guide</i>	18
Appendix A: Detailed Reference List	20
Appendix B: Detailed Table of Products and their Properties	25
5. References	28

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Executive Summary

The overall aim of the project was to develop guidance for users, which highlights the benefits and limitations of use for chemical disinfectants in endoscope decontamination. It is intended that the guidance could be used as part of the decision-making process to select a suitable endoscope disinfectant where exposure to hazardous chemicals is either prevented or adequately controlled.

In order to inform the project a review of the current National and International scientific literature was conducted and interviews were conducted with relevant stakeholders. Findings were grouped to enable identification of products, differences between them and issues with their use.

Key findings:

- There exists no single system for disinfection of endoscopes and no single most appropriate disinfectant;
- The use of disinfectant formulations based on 2%-activated glutaraldehyde (e.g. trade names Cidex, ASEP, Totacide 28) is likely to be significantly reduced in the UK by spring 2005. This is because the manufacturer with the major market share, Advanced Sterilization Products, initiated replacement of Cidex activated glutaraldehyde solution Cidex in 2003 and, in the experience of the author; the availability of the other two products has since declined. This situation has effectively forced users to seek alternatives, although the decision-making has little National consistency;
- It is not currently possible to gauge the pattern of disinfectant use across the UK so it is not known how many users are moving away from a known asthmagen (glutaraldehyde) towards other products, which are currently regarded by HSC as potential astmagens (e.g. Ortho-phthalaldehyde (OPA) and Succinic Dialdehyde (SDA)[1]);
- The legislation and standards, which apply to the use of disinfectants with endoscopes, can be confusing to line managers and others responsible for developing local disinfection strategies and protocols. This is because, firstly, although there is currently no definitive guidance, from an infection control perspective, on endoscope reprocessing, National, European and International standards apply and, within the healthcare sector, there is an expectation that they are complied with. Secondly, the UK COSHH Regulations require substitution of hazardous substances with the least hazardous chemical, as part of its hierarchy of control. Finally, protocols relating to the procurement of Automatic Endoscope Reprocessors (AERs) are governed by EU legislation, which does not currently encourage selection based on the hierarchy of control;
- Authorised Persons (AP) can have a major influence on choice of disinfecting equipment within hospitals, offering the potential to establish a more consistent interpretation of HTM2030 on a National basis;

- Not all endoscopes are compatible with every disinfectant. Generally, disinfectants based on oxidising agents may produce deleterious effects on endoscopes manufactured by Olympus and Pentax;
- Most disinfectants can be categorised as either alkylating or oxidising agents. The table below summarises the key differences:

Disinfectant Base	Properties	Examples
Alkylating agents	<ul style="list-style-type: none"> ○ Superior materials compatibility ○ Tend to be in higher COSHH Essentials^a hazard group than oxidising agents ○ Micro-organisms can become resistant to glutaraldehyde ○ Their ability to fix protein may limit use of some products (e.g. glutaraldehyde) 	<ul style="list-style-type: none"> ○ Glutaraldehyde (Cidex, ASEP, Totacide) ○ Ortho-phthalaldehyde (OPA) (Cidex-OPA) ○ Mixtures (Gigasept rapid, Septo DN)
Oxidising agents	<ul style="list-style-type: none"> ○ Superior sporicidal activity ○ Tend to be in lower COSHH Essentials hazard group than alkylating agents ○ May be incompatible with some endoscopes 	<ul style="list-style-type: none"> ○ Chlorine-containing compounds (Sterilox, Tristel) ○ Peroxygen compounds (Virkon S) ○ Peracetic Acid (Nu Cidex, Steris, Aperlan)

Key recommendations:

- A two-stage selection process has been developed which directs users to consider methods which do not use chemicals at all before proceeding. Consideration should be given to the least hazardous substances before consideration of more hazardous groups. Selection of substances that fall into the most hazardous group should be considered only if the other products are unsuitable. The selection process also takes into account, other important factors such as infection control issues and equipment compatibility.
- The HSE's product COSHH Essentials includes toxicological information in its evaluation. The selection process developed uses this approach to take into account

^a <http://www.coshh-essentials.org.uk/>

the legislative requirement for the need to apply a hierarchy of control of exposure to hazardous substances. This is summarised in the table below^b.

Chemical Base	Example of Product	COSHH Essentials Hazard Group	COSHH Essentials Control Approach
Chlorine base	Sterilox	A (low hazard)	1 (general ventilation)
Chlorine base	Tristel	A (low hazard)	1 (general ventilation)
Peroxygen	Virkon S (1% liquid)	A (low hazard)	1 (general ventilation)
Peracetic Acid	Nu-Cidex/Aperlan	C (medium hazard)	3 (containment)
Ortho-phthalaldehyde	Cidex-OPA	C (medium hazard) ^c	3 (containment)
2% Glutaraldehyde	Cidex	E (special case)	4 (special case)

- There is a need for teamwork between the wide range of relevant professionals who contribute to the debate on selection of disinfectant, with demarcation of roles and responsibilities and clear mechanisms and processes for communication. In all relevant NHS organisations there should be a “disinfection co-ordinator”, whose role is to bring together the diverse groups with a relevant professional interest in disinfection of endoscopes;
- There is a need for further development of validation standards to which manufacturers and users can work. This is because some manufacturers use different microbiological tests from others, making comparisons between products confusing;
- Decision-makers should specify that any equipment or AERs that are considered for purchase are validated for use with a range of disinfectant types, so that a change of product, if required can be done without incurring large expenditure;
- A UK database of disinfectant use should be developed and regularly updated to track changes in use;
- HSE and the Health Protection Agency (HPA), should work more closely together perhaps by an initial joint exploratory workshop, to explore common ground on staff and public health and safety issues.

^b It should be noted that the table shows general examples of assessments. During the selection process it will be important to ensure that the assessment takes account of the actual product in use, taking into account factors such as multi-shot or single-shot and whether there are any precursor products to be handled.

^c Cidex-OPA is subject to requirement for self-classification within EU legislation. This assessment is based on manufacturer data.

1. Introduction and Background

Revitalising Health and Safety[2] and Securing Health Together[3] sets out targets for improvements in occupational health and safety including a 20% decrease in incidence of all occupational ill health by 2010, and specifically a 30% decrease in occupational asthma (OA). Within this group there are 1,500-3,000 new cases of OA each year with 7,000 cases “made worse by work”.

Glutaraldehyde has been commonly used as a chemical disinfectant in healthcare, particularly for use with endoscopes. The Health and Safety Commission (HSC) have however identified it as the 5th highest cause of asthma. They have recommended substantial reductions in workplace exposure to glutaraldehyde to comply with the Control of Substances Hazardous to Health (COSHH) Regulations. There has been a progressive number of alternative disinfectants to glutaraldehyde entering the UK market in the past few years and many endoscopy units are thought to have chosen one of these alternatives for their endoscope decontamination procedure. As part of their Asthma Compliance Programme initiative targeted at reducing OA, HSE wishes to encourage the use of alternatives to glutaraldehyde where practicable to do so. As well as this the HSE Asthma Project Board aim to eliminate glutaraldehyde induced asthma by 2005^d.

Consequently there is a need for information on the various disinfectants in use and the potential impact of change from glutaraldehyde to alternative disinfectants to help inform HSE policy on chemical disinfection in healthcare.

The research described in this report provides an insight into the issues surrounding current practice and use of chemical disinfecting agents, which can be used to inform a risk assessment of options, to help produce prioritised strategies to control risks. This appraisal takes into account risks to health and safety, infection control, plant, equipment and maintenance, and economic and legislative considerations.

The overall aim of the project was to develop guidance for users, which highlights the benefits and limitations of use for chemical disinfectants in endoscope decontamination. It is intended that the guidance could be used as part of the decision-making process to select a suitable endoscope disinfectant where exposure to hazardous chemicals is either prevented or adequately controlled.

To achieve this aim the project had four main objectives:

- To improve the knowledge base on the types of products/formulations in use;
- To gather data on their costs, benefits and risks of use;
- To compare products with one another in an option appraisal;
- Develop guidance for selection and use.

^d source: <http://www.hse.gov.uk/asthma>

2. Methods

In order to inform the project and ensure the most up to date background information on available products a review of the current National and International scientific literature was conducted. The main information gathering was carried out by HSE with the author reviewing the main papers found (this complete list is in Appendix A. The references cited in this report are at the end of the report). The findings of the literature review were used to inform the products and formulations, which were included in the project.

In order to gauge opinion, interviews were conducted with representatives of a limited number of relevant stakeholders. These included^e:

- Product manufacturers and formulators;
- Infection Control Specialists;
- Users of products;
- NHS support workers (such as estates managers, supplies departments etc.);
- Health and safety specialists;
- NHS organisations.

These data were of a qualitative nature, intended to give a flavour of the different types of product and issues with their use. Findings were grouped to enable identification of products, differences between them and issues with their use. This initial analysis was used to inform the comparison of products and the development of the guidance for the selection of methods for disinfecting endoscopes.

As a precursor to developing the guidance, glutaraldehyde was used as a baseline comparator. This was so it would be possible to readily identify whether alternatives to glutaraldehyde could be regarded, taking all relevant factors into account, as a better or worse option.

^e Note: This list was not intended to be definitive and may not include all stakeholders.

3. Findings

There were two main “headline” findings from the research.

The first was that there exists no single system for disinfection of endoscopes and no single most appropriate disinfectant. This is because there exist a number of complex interactions (i.e. between health and safety and infection control issues; between local circumstances and National and International legislation and guidance; and compatibility between equipment and disinfectant). This interaction is illustrated below in **Figure 1**:

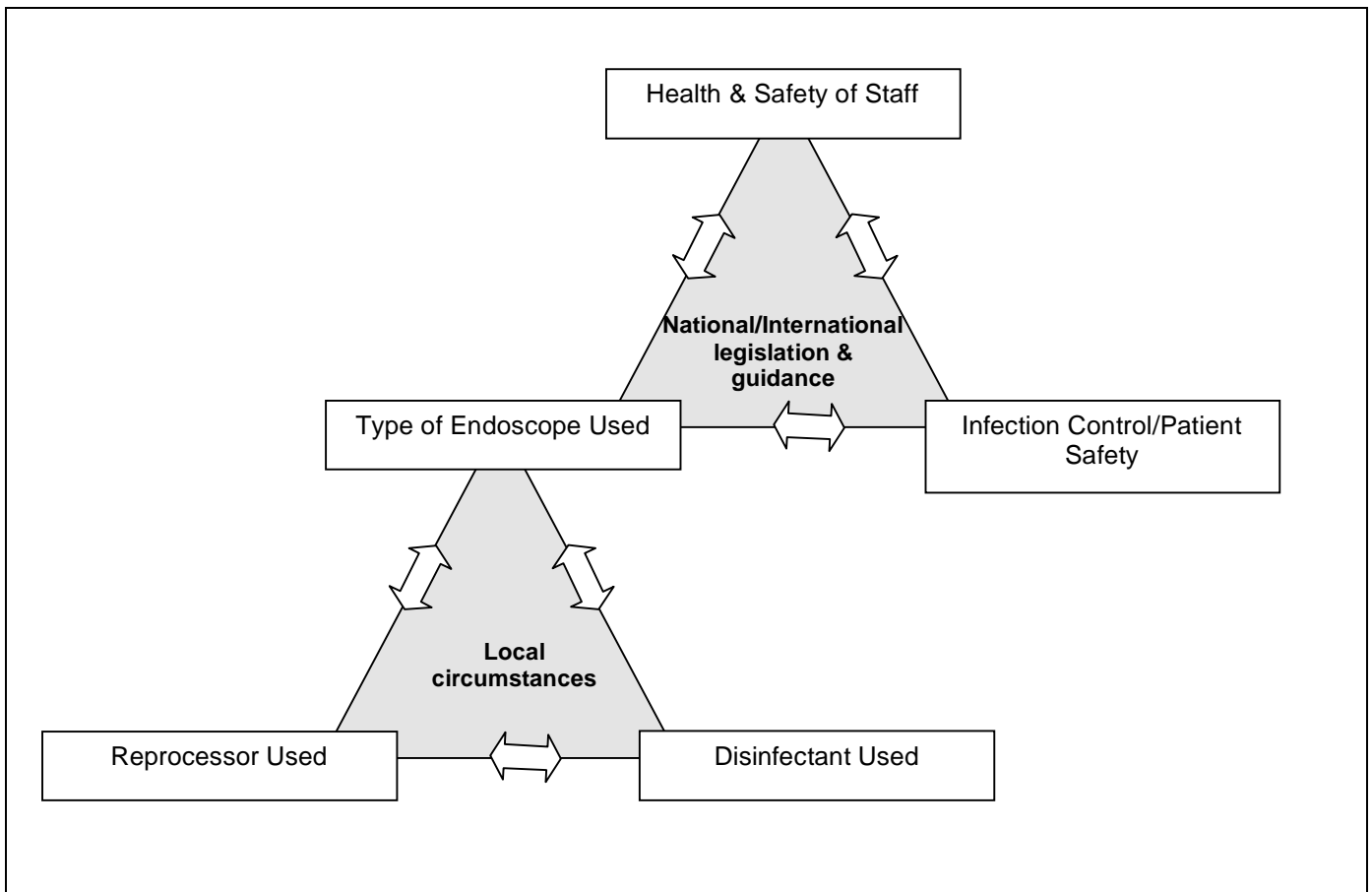


Figure 1: Interactions Between Key Aspects of Endoscope Use

Theoretically the choice of endoscope, reprocessor and disinfectant is straightforward and made to maximise the safety of staff, patients and the endoscopy equipment itself. It has been found that, in practice, it is currently not possible to achieve this. Examples are given below to illustrate this.

Example 1: The health and safety of both staff and patients are covered by the requirements of the Control of Substances Hazardous to Health (COSHH) Regulations 2002. This means choosing a disinfectant and method of disinfection that does not adversely affect either group. One of the available type of disinfectants, based on the generation of hypochlorous acid, so-called “super oxidised water”, is low hazard for staff, at the concentration used, and an effective high level disinfectant thus controlling the risk of cross-infection for patients^f but is incompatible with some makes of endoscopes. Although measures have been introduced to mitigate this damage (e.g. the disinfectant manufacturer underwriting the cost of replacement of damaged endoscopes, and the introduction of a manual procedure to regularly apply a protective coating to the scopes), this still represents a situation that is less than ideal.

Example 2: Some disinfectants are incompatible with some reprocessors and some buildings are restricted in the type of reprocessors they can use, because of space and other demographic or estates-related constraints. Thus, although it is possible to devise general guidance for selection, local circumstances must be included in the decision process. There is also a likely difference in selection outcome if the choice is being made as part of a new-build or to fit in with existing accommodation.

The second important finding was that use of disinfectant formulations based on 2%-activated glutaraldehyde (e.g. trade names Cidex, ASEP, Totacide 28) is likely to be significantly reduced in the UK by spring 2005^g. This is because the manufacturer with the major market share, Advanced Sterilization Products, initiated replacement of Cidex acitivated glutaraldehyde solution Cidex in 2003 and, in the experience of the author; the availability of the other two products has since declined.

This situation has effectively forced users to seek alternatives, although the decision-making appears to be a local process, with little National consistency. It is not currently possible to gauge the pattern of disinfectant use across the UK so it is not known how many users are moving away from a known asthmagen (glutaraldehyde) towards other products, some of which are also currently regarded by HSC as potential asthmagens (e.g. OPA and SDA)[1].

^f See Sections 3.5.2; 4.4; 4.5; and Appendix A for further discussion of this aspect

^g There is currently no UK-wide database of disinfectants used in endoscopy so this conclusion is assumed.

Therefore the remainder of this chapter will concentrate on summarising the findings from the literature review and interviews with stakeholders so far as they apply to reprocessors, endoscopy equipment and disinfectants used. The subsequent chapter will look at these findings in the context of various generic factors, which emerged during the data collection. The information in both of these chapters will be used to draw conclusions, make recommendations and to develop a proposed generic decision process that can be used at local level.

3.1 Literature Review

The literature review was conducted by HSE. Several key references[4-12] were selected from this review and used to help inform the detailed table of products and their properties, which is included in **Appendix B**. A full review of the literature was beyond the scope of this project. However, for information, a full reference list is included at the end of this report, in **Appendix A**.

3.2 Legislation and Standards

There are numerous pieces of legislation and standards, which apply to the disinfection of endoscopes. The situation can be confusing to line managers and others responsible for developing local disinfection strategies and protocols, particularly as guidance relating to control of infection is regularly refined and modified.

The main workplace health and safety-related legislation, which regulates the health and safety of staff is the Control of Substances Hazardous to Health Regulations 2002 (COSHH)[13]. As well as chemical exposure to staff, patient safety is also covered by COSHH, so far as exposure to infective agents is concerned. Regulations 7(1) and 7(2) of COSHH (Prevention or control of exposure to substances hazardous to health) requires that exposure to hazardous substances be prevented or, if not reasonably practicable, adequately controlled. Prevention may be by substitution of hazardous substances, which either eliminates or reduces the risk to health. The Approved Code of Practice (ACoP) to Regulation 7 further clarifies that the overriding duty is to prevent exposure, and that this option must be considered first. If this assessment process concludes that it is still necessary to use a hazardous substance, the ACoP suggests that the use of an alternative safer substance should be considered. This might be a substance of less toxicity but the ACoP also draws attention to the need to consider all relevant factors in the decision-making process.

There is currently no definitive legislation, from an infection control perspective, on standards for endoscope reprocessing. However, National, European and International standards apply and, within the healthcare sector, there is an expectation that they are complied with. These include:

- Standards which concentrate on cleaning and disinfecting validation, such as the prEN ISO 15883 series and BS EN 13727 (2003)[14].
- Relevant NHS Estates Health Technical Memoranda, such as HTM2030[15].
- Standards where the emphasis is on sterilisation validation, such as HTM2010[16] and ISO 14937:2000[17].
- Various UK Medical Devices Agencies circulars which cover issues of contraindications between devices and disinfecting agents (e.g. [18-20]).

Authorised Persons (AP) can have a major influence on choice of disinfecting equipment within hospitals. These individuals are familiar with the standards and relevant issues. As a group, they offer the potential to establish a more consistent interpretation of HTM2030 on a National basis. More information about AP's can be found at www.iheem.org.uk.

3.3 Reprocessors

So far as Automatic Endoscope Reprocessors (AERs) is concerned there are a number of manufacturers and models available. AERs are a major capital investment for a healthcare establishment and the procurement process is governed by EU legislation. A detailed specification is used, which covers all relevant factors. Although occupational health and safety issues are included, they are of a general nature and do not encourage selection based on the hierarchy of control. The selection process is dependant on a number of factors such as:

- Physical size of AERs, which may be compromised by available space;
- Size and number of baths for reprocessing endoscopes, which will be determined by local need;
- Compliance with standards, in particular HTM 2030 and prEN ISO 15883.

Manufacturers known to produce AERs, which either have been, or are in use in the UK are as follows. The list is not intended to be exhaustive, merely to illustrate the extensive choice available (alphabetical):

- Afos
- Astec
- Dawmed (Wassenberg)
- Keymed
- Labcaire
- Lancer
- Medipur
- Plade
- SAL
- Soluscope
- Sterilox
- Steris

Each AER manufacturer has validated their machines for use with either a single or limited number of disinfectants. From the information currently available to the author there is no AER manufacturer that offers validation data across the full range of disinfectant types. This means that users are generally restricted to the types of disinfectants available to them depending on the AER that they purchase.

3.4 Endoscopes

There are four main manufacturers of endoscopes in the UK market. They are (alphabetical):

- Fujinon
- Olympus Keymed
- Pentax
- Storz^h

Not all endoscopes are compatible with every disinfectant. Generally, disinfectants based on oxidising agents can present incompatibility issues with endoscopes manufactured by Olympus and Pentax. Local users reported to the author that they regard this as a problem because:

- a). There are major selection issues relating to local “custom and practice”. This includes the impact of the personal preference of the treating clinician, reluctant to change from equipment they regard as otherwise excellent;
- b). Olympus currently has the largest market share and there are therefore a large number of endoscopes currently in use with disinfectant incompatibilities. It is hoped that future research and development by the manufacturers can identify solutions to this, in the long-term;
- c). Although manufacturers of oxidising agents, which are known to damage endoscopes, underwrite any damage caused, there is still a need for endoscopy unit staff to coat and wipe the scopes with disposable wipes provided by the manufacturers. This was reported by staff involved with the process to be time consuming.

3.5 Disinfectants

As well as numerous manufacturers of AERs and endoscopes and their range of incompatibilities, there is also a variety of disinfecting agents available. All have good virucidal activity. Most can be categorised as either alkylating or oxidising agents, leaving a small group of products that can be classified as “Other”. These categories will be explored below, in Sections 3.5.1. to 3.5.3. A table listing the detailed properties of each of the main disinfectants is also included at the end of this report, in **Appendix B**.

3.5.1 Disinfectants based on Alkylating Agents

These products generally are AER and endoscope compatible. However, they tend to have greater toxicity. Micro-organisms can also become resistant to them and their ability to fix protein can limit their use (for example, in situations where prions might be present).

^h It should be noted that Storz mostly provides rigid instruments, which can be autoclaved.

There are three main types of disinfectants based on alkylating agentsⁱ:

- Those based on **glutaraldehyde** (e.g. CIDEX Activated Glutaraldehyde solution, ASEP, Totacide). These products have been withdrawn from supply in the UK and their use should cease entirely from mid 2005.
- Those based on **ortho-phthalaldehyde (OPA)** (e.g. CIDEX-OPA). This is the main product that has thought to have largely replaced CIDEX. No studies reporting on the potential for OPA to cause asthma have been reported. However, the HSC/HSE Working Group on Action to Control Chemicals (WATCH) concluded that OPA may have the potential to cause OA[1]. This was based on knowledge about the asthmagenic properties of other dialdehyde molecules and information suggesting that OPA is reactive towards protein molecules. There have also been reports of adverse reactions in some urology patients[18, 20].

Laboratory studies have shown that OPA causes severe skin and gastro-intestinal irritation following dermal and oral dosing respectively. Although there are no studies into the potential for OPA to cause eye and respiratory tract irritation, the evidence for severe skin and gastro-intestinal tract irritation strongly suggests that OPA will also cause eye and respiratory tract irritation if it comes into contact with these tissues.

- Those based on **mixtures** (e.g. Gigasept Rapid (a mixture of glutaraldehyde and formaldehyde), SEPTO DN (a mixture of glyoxal and glutaraldehyde)).

3.5.2 Disinfectants based on Oxidising Agents

These products generally offer superior sporicidal activity. However, although generally less toxic than those based on alkylating agents, their use can be limited because of incompatibility with equipment such as AERs and endoscopes.

There are three main types of disinfectants based on oxidising agents:

- Those based on **chlorine containing compounds** (e.g. Sterilox, Tristel).
- Those based on **peroxygen biocides** (e.g. Virkon S)
- Those based on **peracetic acid** (e.g. Nu Cidex, Aperlan, Steris)

ⁱ In theory there are also products containing Succinic Dialdehyde (SDA) although currently there are no commercial formulations available in the UK

3.5.3 Other Types of Disinfectants

These products can be regarded as belonging to one of two categories.

- Those containing **chemical** agents such as those based on quaternary ammonium compounds, alcohols or gas plasma (e.g. Sterrad);
- Those based on a **non-chemical** process (e.g. autoclaving or ultra-high pressure^j)

It is important that selection of a disinfection procedure takes account, where possible, of methods, which do not rely on hazardous substances. For example, some endoscopes, or their components, may be able to be decontaminated by autoclave sterilisation. Where possible this option should be considered in the first instance.

4. Discussion and Conclusions

The HSEs aim to eliminate glutaraldehyde-induced OA by 2005 would appear to be achievable, at least in an endoscopy setting^k. However, the supplementary aim, to encourage elimination or substitution of hazardous substances, is still potentially confounded by a number of factors. Examples are given below:

^j Generally restricted to the food industry

^k It is also worth noting the International situation, whereby glutaraldehyde is still freely available and extensively used, particularly in North America and the Far East.

Example 3: As noted in Section 3.3, some AER manufacturers advocate use of their machines with either a single disinfectant (e.g. Lancer and Aperlan) or a restricted number. This can complicate selection. Very few, if any, reprocessor manufacturers have validated their equipment against a full range of disinfectants.

Example 4: Endoscopes are complex instruments with long lengths of narrow lumens, which must be cleaned thoroughly prior to reprocessing. There have been adverse incidents relating to this issue[19] and there is detailed guidance on how this pre-cleaning should be done to avoid the risk of transmission of infection because of inadequate decontamination. Although the efficacy of all disinfectants is reduced by the presence of organic matter, some are more rapidly de-activated in the presence of organic matter than others (e.g. those products based on oxidising agents). This is another relevant factor in the selection process. There is a need for a more clearly defined specification for validation of new products prior to launch.

Example 5: Some disinfectants do not adequately inhibit the rapid growth of bio film, which can grow in the pipe work of the AER (e.g. those based on succinic dialdehyde (SDA) and ortho-phthalaldehyde (OPA). This can occur after only a few hours use and usually the AER is treated by a “self-disinfect” cycle at regular intervals (e.g. once a day). Some microorganisms can become resistant to certain disinfectants (e.g. those based on alkylating agents) and, in this case it is usually accepted as best practice to use a different disinfectant for the self-disinfection cycle, usually one based on a different active agent (e.g. alkylating vs. oxidising agent).

Other emerging issues are discussed below.

4.1 Concept of time line

It was noticeable during the data collection that local choices about AERs, endoscopes and disinfectant had not only been affected by their compatibilities and the various issues discussed above, but also by when the choice about their use occurred in time. This is because there has been new information on a regular basis on products new to the market^l and emerging issues with others, use of which is already established (e.g.[20]). This complicating factor means that decisions made several years ago might be different to those taken more recently.

It is foreseeable that, in time, additional data will therefore become available on adverse health effects with the use of certain disinfectants and caution is advised, particularly with new products. There is potentially a need for a validation standard to which manufacturers and users can work.

It may also be advisable for decision-makers to specify that any equipment or AERs that are considered for purchase are validated for use with a range of disinfectant types, so that a change of product, if required can be done without incurring large expenditure.

4.2 Communication

Communication can and should be improved in two main areas, to ensure the interests of all stakeholders are adequately and appropriately represented:

a). Despite the major importance of both the health and safety and the infection control aspects of endoscopy disinfection procedures, it was found that there was little dialogue between HSE and organisations such as the Health Protection Agency (HPA)^m, which is an independent body charged with ensuring the protection of the health and well being of everyone in England and Wales (the equivalent body in Scotland is Health Protection Scotland (HPS)ⁿ). The Agency plays a critical role in protecting people from infectious diseases and in preventing harm when hazards involving chemicals, poisons or radiation occur. It is suggested that efforts by both organisations to work together on this issue could be beneficial, perhaps by an initial joint exploratory workshop;

b). It has been found that the use of glutaraldehyde in the UK would have ceased by mid 2005, at the latest. However, this was because of the knowledge that supplies will no longer be available in the UK. However, the picture is less clear regarding prevalence of use of other disinfectants. This is because there is currently no UK database of use. It is therefore impossible to know who is using what. This is unfortunate because, not only is it impossible to track changes in usage over time, but also there remains a risk that lessons being learned at local level might not be passed to the National community, who might benefit (i.e. avoidance of “Reinvention of the wheel”).

^l Two current examples include **Supprox** (<http://www.medipureonline.com>) and **G-Cide** (<http://www.medicapro.com>)

^m www.hpa.org.uk

ⁿ <http://www.show.scot.nhs.uk/scie/h/>

4.3 Users experiences

There is a wide range of relevant professionals who contribute to the debate on selection of disinfectant. For example, the occupational health and safety and infection control specialists are essential participants but there is also need for representatives from disciplines such as nursing, medical, estates, maintenance, and supplies. It was found that the role of these various specialist advisers could become confused and to avoid this there was a need for strong leadership with demarcation of roles and responsibilities and clear mechanisms and processes for communication.

Some NHS organisations had appointed a “disinfection co-ordinator”, whose role was to bring together the diverse groups of professionals, with a relevant professional interest in disinfection of endoscopes. Those who had, found the post to be highly valuable. It is recommended that this approach be adopted by all NHS organisations.

With the increasing complexity of procedures for ensuring the adequate disinfection of endoscopes (e.g.[14, 15, 17]), there was a sense that nursing staff perceived that their role was changing and that they were becoming more like technicians than carers. The risks of this outcome are beyond the scope of this report but need to be further evaluated.

4.4 Validation

As mentioned in 4.1, there is a need for a validation standard to which manufacturers and users can work. This conclusion was reached because there was evidence that some manufacturers had used different microbiological tests from others, making comparisons between products potentially confusing.

In addition, many AERs were validated with or were only compatible with specific disinfectants. This is understandable, given the high cost of undertaking validation. However, it means that, in practice disinfectant choice can be restricted. An industry federation might be able to offer standardised validation against a range of disinfectants and equipment.

Within HTM 2030[15] there is a requirement for so-called “single-shot” disinfectants (i.e. use once and discard). This would remove the need to validate the active concentration of disinfectant, such as currently done using, for example, test strips. This is because the disinfectant is purchased in a ready-to-use form. This move away from the use of concentrate would also remove the need for staff to mix chemicals and is therefore a positive feature from the perspective of controlling exposure to hazardous substances.

4.5 Hierarchy of Control

The legislative requirement for the need to apply a hierarchy of control of exposure to hazardous substances has already been discussed, in Section 3.2. Any selection process must therefore take this into account at every stage. HSE's product COSHH Essentials^o takes account of this hierarchy by including toxicological information in its evaluation.

The author has used material safety data sheets (MSDS) for the products and the COSHH essentials process to rate the various products currently in common usage in the UK. When this was done the following groups emerged:

Chemical Base	Example of Product	COSHH Essentials Hazard Group	COSHH Essentials Control Approach
Chlorine base	Sterilox	A (low hazard)	1 (general ventilation)
Chlorine base	Tristel	A (low hazard)	1 (general ventilation)
Peroxygen	Virkon S (1% liquid)	A (low hazard)	1 (general ventilation)
Peracetic Acid	Nu-Cidex/Aperlan	C (medium hazard)	3 (containment)
Ortho-phthalaldehyde	Cidex-OPA	C (medium hazard) ^p	3 (containment)
2% Glutaraldehyde	Cidex	E (special case)	4 (special case)

The draft selection guide (see section 4.6 below) is intended to direct users to consider firstly hazard groups of the least hazardous substances (i.e. group A), before consideration of more hazardous groups (i.e. groups C and D). Selection of substances that fall into group E (special case) should be considered only if the other products are unsuitable.

The outcome of the COSHH Essentials process includes guidance on all aspects of control, (e.g. maintenance, treatment of spillages etc.) and this detailed advice can be printed out and used locally. It is therefore recommended that those responsible for selecting disinfecting agents and procedures for endoscopy adopt the COSHH Essentials approach as part of the decision-making process.

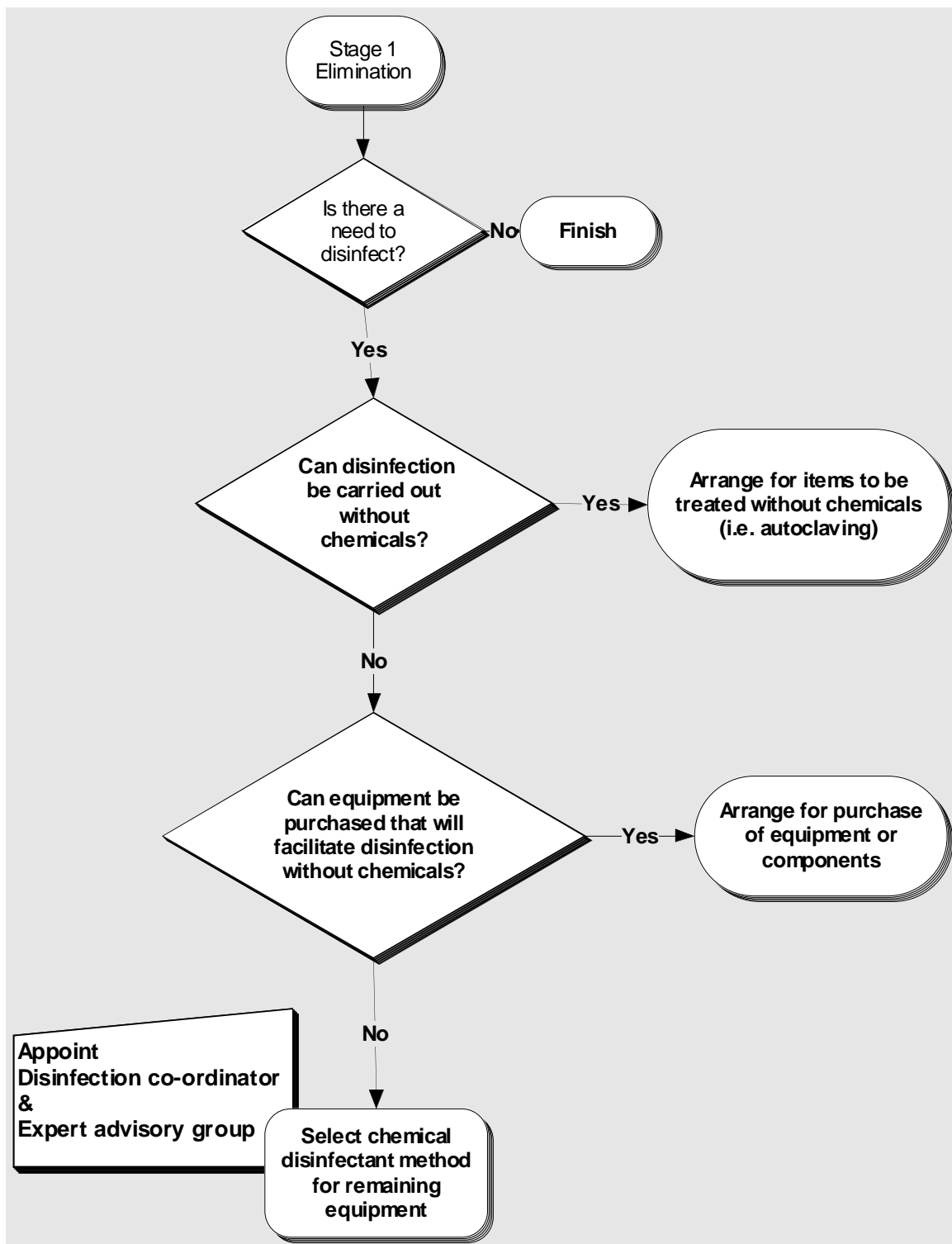
As has already been discussed, the selection process will also require taking other important factors into account, such as infection control issues and equipment compatibility plus disinfectant factors such as multi-shot or single-shot and whether there are any precursor products to be handled. However, using the COSHH Essentials framework, suggested above will allow these other factors to be taken into account in a structured fashion.

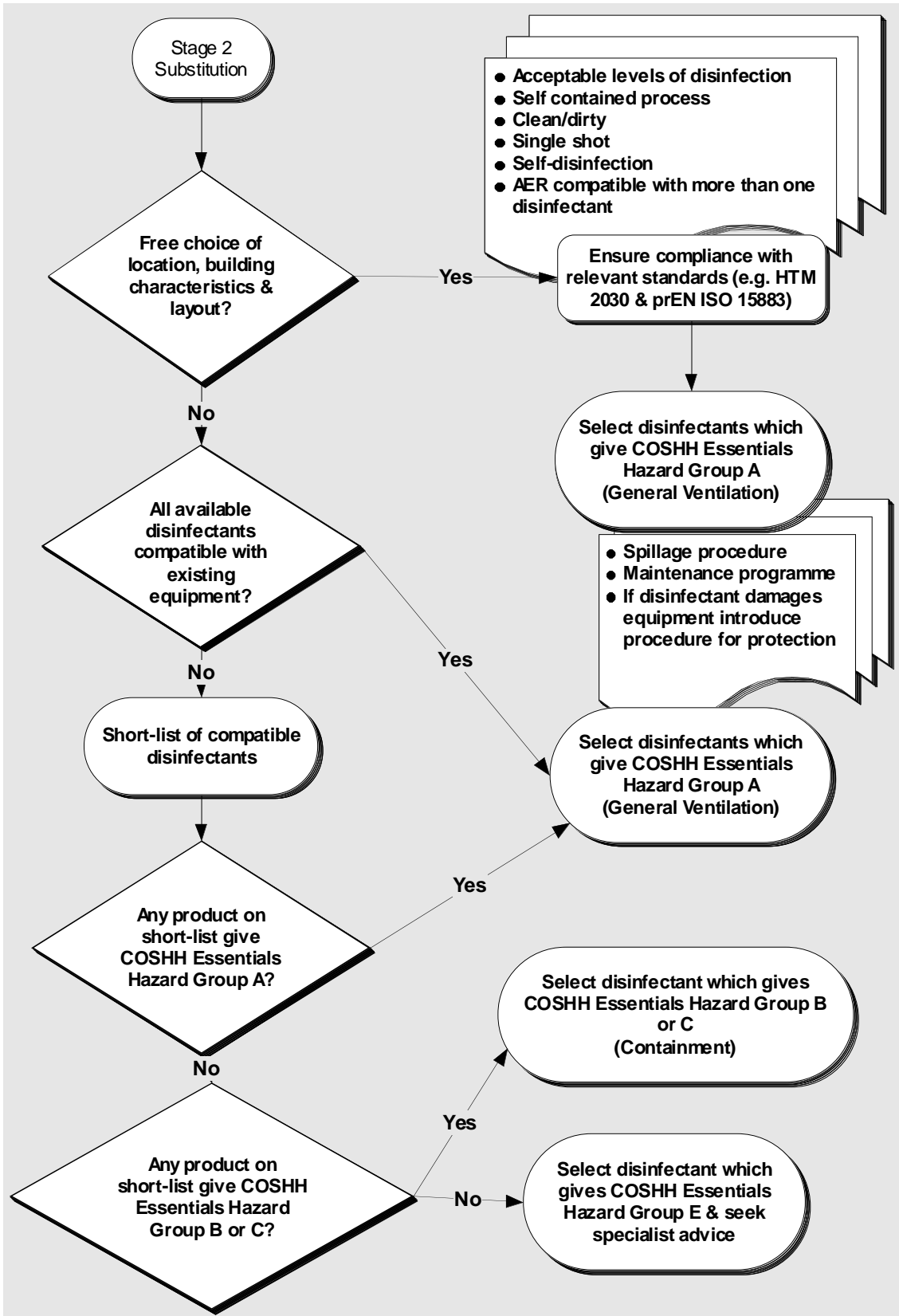
^o Its web-based equivalent e-COSHH essentials (<http://www.coshh-essentials.org.uk/>)

^p Cidex-OPA is subject to requirement for self-classification within EU legislation. This assessment is based on manufacturer data.

4.6 Draft Selection Guide

This is shown in the following diagrams, as a two-stage process. The first part involves consideration of the extent to which disinfection using chemicals can be eliminated. Stage two looks at the selection process on aspects that remain after stage one.





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Appendix B: Table of products and their properties

Chemical Base	Product Names	Product Preparation	Disinfection Time	Features of Use	Comments
Chlorine Containing	Sterilox	Sterilox-generated solution at point of use by the electrolysis of salt solution Activity depends on pH and Available Free Chlorine (AFC) values	5 mins Rapidly sporicidal	* Solution generated at point of use * Single use	* scopes may be sensitive * not portable * more sensitive to presence of organic matter than products based on alkylating agents * May cause damage to the lacquer coating of some endoscopes * Protective coating added weekly to scopes * Used within 24 hours of generation * Requires space to house generators * Apparatus expensive to purchase, therefore most users lease the system. * Low running costs.
Chlorine Containing	Tristel (The Tristel Company)	Generated from the acidification of Sodium Chloride (activator)	5 mins Rapidly sporicidal	* Test kit available * Colour change when sterilising capacity is compromised * Disposal to drain	* May be damaging to some instrument components * Odour of Chlorine * more sensitive to presence of organic matter than products based on Alkylating agents
Glutaraldehyde	Cidex (ADVANCED STERILIZATION PRODUCTS) ASEP (Galen) Totacide 28 (Coventry Chemicals)	2% buffered aqueous solution	Approx 10 minutes (variable depending on level of disinfection required) Slow sporicidal activity Glutaraldehyde-resistant mycobacteria	* Non damaging to equipment * Not adversely affected by organic matter	* Asthmagen and moderate contact sensitiser * HSE aims to reduce workplace exposures from glutaraldehyde as part of their Asthma Compliance Programme * UK supplies withdrawn by two major suppliers. Reduced availability in the UK * Relatively inexpensive to buy but workplace equipment controls expensive

Chemical Base	Product Names	Product Preparation	Disinfection Time	Features of Use	Comments
Mixtures	Gigasept Rapid (Schulke & Mayr)	Formaldehyde & SDA dilute concentrate by 10%	10 mins		
Ortho-phthalaldehyde (OPA)	Cidex-OPA (ADVANCED STERILIZATION PRODUCTS)	0.55% 1,2-benzenedicarboxaldehyde Good bactericidal activity Poor sporicidal activity	10 mins	* No activation required * Excellent stability over pH range 3-9 * Low odour	* Regarded as a potential asthmagen * Biofilm growth not prevented * Skin turns black on contact * Risk of adverse reaction (anaphylaxis after repeated cystoscopy) * Possible allergic reactions in NHS staff
Peracetic acid	e.g. Nu Cidex (ADVANCED STERILIZATION PRODUCTS) PeraScope (Medichem) Adaspor (Minntech) Gigasept PA (Schulke & Mayr) Perasafe (Antec International) Aperlan (Lancer UK)	Various concentrations, pH, and contact time; Good bactericidal and sporicidal activity	5 mins	* Colour change at activation	* Damages copper alloys in some AERs * Affected by organic matter * Only stable for 24 hours * Strong odour of acetic acid, which may be unpleasant * In some cases the Aperlan (Lancer) process involves heat * Relatively expensive, when compared to glutaraldehyde
Peracetic acid	Steris System (Steris)	0.2% peracetic acid at 45° in a sealed chamber Good bactericidal and sporicidal activity	Sterility in 12 mins	* Benchtop totally sealed system	* Has to be used with the dedicated machine * Relatively expensive compared with glutaraldehyde - one container of disinfectants required per cycle

Chemical Base	Product Names	Product Preparation	Disinfection Time	Features of Use	Comments
Peroxygen Biocides	Virkon S	Powder supplied in pre-weighed sachets	Approx 10 minutes		* The Working Party of the European Society of Gastroenterology (ESG) does not recommend peroxygen disinfectants for gastrointestinal endoscopy (2003)
Succinic Dialdehyde (SDA)	Gigasept FF (Schulke & Mayr)	dilute concentrate by 10%	Approx 10 minutes (variable depending on level of disinfection required)		* Not currently available commercially in the UK

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An evaluation of chemical disinfecting agents used in endoscopy suites in the NHS

This research report looks at alternatives to glutaraldehyde for the disinfection of endoscopes. It highlights their benefits and limitations.

The work was commissioned because of the historically high number of cases of occupational asthma caused by glutaraldehyde.

There is no single system for disinfection and no single most appropriate disinfectant. Many users are moving away from glutaraldehyde towards other products, some of which are regarded as potential asthmagens.

The report presents the control approaches for disinfecting agents based on HSE's COSHH Essentials. This is summarised as follows:

Chemical Base	Example of Product	COSHH Essentials Hazard Group	COSHH Essentials Control Approach
Chlorine base	Sterilox	A (low hazard)	1 (general ventilation)
Chlorine base	Tristel	A (low hazard)	1 (general ventilation)
Peroxygen	Virkon S (1% liquid)	A (low hazard)	1 (general ventilation)
Peracetic Acid	Nu-Cidex/Aperlan	C (medium hazard)*	3 (containment)
Ortho-phthalaldehyde	Cidex-OPA	C (medium hazard)*	3 (containment)
2% Glutaraldehyde	Cidex	E (special case)	4 (special case)

*Cidex-OPA is subject to requirement for self-classification within EU legislation. This assessment is based on manufacturer data.

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