

Medical Device Decontamination

(Incorporating the IDSc Journal)



Journal of the Institute of Decontamination Sciences

■ Patient Safety

■ Residual Contamination

■ Role of Decontamination Lead



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Cover picture: Conference 2007, Hilton Hotel

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Susan Meredith
Editor

Having listened to several colleagues debate the role of the 'Decontamination Lead', I was asked by my line manager to produce a paper on the same subject. I have chosen to include it within this issue explaining my understanding of what the role should encompass and I will be interested to hear if colleagues feel differently. I'm afraid I find those that consider the role to only apply to Sterile Services and Endoscopy have rather missed the point.

At long last the winter is becoming a distant memory, I was beginning to think it would never end rather like the extra work for reducing 'waiting times', the days when weekend work was restricted to trauma and catching up on the internal housekeeping of my department also feels like 'the good old days'.

By the time we issue the next edition, we will know who our political masters are going to be, will policy change or not? Will we finally have a version of HTM 01 06 that we can follow with ease? Will we ever reach a time when the NHS can provide a service without having to meet targets? Time alone will tell, or will it just be a question of changing words, so that the current targets become outcomes?

I look forward to an interesting spring & summer, for those that are hoping to go to the world congress in Brazil this year, information is as normal on the WFHSS website. Our own website continues to go from strength to strength and is a really useful reference site; we are at last getting the resources we need in a readily accessible format.

Finally, may we all bear in mind the following statement, we can only change ourselves and our world effectively if we follow it and if you know anyone standing for office anywhere, please pass it on.

Our lives improve only when we take chances - and the first and most difficult risk we can take is to be honest with ourselves.

Walter Anderson ■

Medical Device Decontamination
Journal of the Institute of Decontamination Sciences
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Val O'Brien
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As soon as the clocks moved forward last week-end I knew spring had arrived! This reminded me that April sees all acute hospitals having to register with the Care Quality Commission. Some Trusts have already been told that their registration is conditional on improving certain aspects of their services and in the Health Service Journal recently it was reported that, of the first registrations announced recently, 64 Trusts are registered as fit to provide services with no conditions, with the status of the second of the three sets of registered Trusts due to be announced shortly. It will be interesting to see just how many meet the infection prevention and control aspects including decontamination practices. The Care Quality Commission has published - the **'Code of Practice for the NHS on the prevention and control of healthcare associated infections and related guidance'**, which includes decontamination related issues. It contains nine criteria that are used to judge each trust's compliance with the regulation and I would recommend reading this valuable document. The IDSc were amongst other professional organisations which contributed to discussions on its content and were involved throughout its development.

As an organisation, we have worked hard on providing comments on all of the draft Health Technical Memoranda and my thanks go to all those who took the time to contribute. My knowledge of these long awaited documents suggests that we will now have to wait until after the general election before we see any further publications. HTM 01-01B incorporates recommendations from NICE and it is anticipated that the DH may well suggest a two year phasing in period for the practice of keeping instruments moist after use and prior to

decontamination. Whilst some organisations already do this in one form or another, there is still a huge debate as to the most effective and safe means of achieving this end. I suspect Trusts together with Sterile Services Departments will have to agree how and by what means this recommendation will be achieved. This is an area where further collaboration is required between theatres and SSDs

I have just attended the Central Sterilising Club conference at Kings College Cambridge where the organisation was celebrating its 50th Anniversary. The content was excellent, the location historic and the company convivial. We have close affiliations with CSC and many IDSc members remain members of this multidisciplinary club. Many of you will know that the IDSc was born out of the CSC when a group of sterile services managers formed their own association which went through a series of name changes to reflect the changing roles finally transforming into the Institute of Decontamination Sciences in 2004. I would like to congratulate the CSC on reaching this anniversary and look forward to another 50 years of collaboration between our organisations. ■

Anyone care to imagine what life would be like if this hadn't happened?

The BBC News series on British computer pioneers and pioneering British computers continues with the story of the Ace computer, which brought together a team who would go on to design the technology that underpins the internet.

Towards the end of the war, Alan Turing - the father of the computing age - had hid himself away in a hut at Hanslope Park in rural Buckinghamshire where, he told his assistant, he was *"building a brain"*. At the end of fighting, Turing took his plans with him to his new post at the National Physical Laboratory (NPL) in Teddington. In March 1946 he handed over a report (which went unpublished during his lifetime) which contained detailed plans, including circuit diagrams, for the Automatic Computing Engine (Ace). But when the engineers and scientists at NPL saw the plans they blanched at its complicated design.

Instead of building the whole thing, they decided to put together a smaller pilot machine. By this time, Turing had left NPL for a sabbatical at Cambridge and it fell to Jim Wilkinson, Harry Huskey and, later on, Donald Davies to get on with the construction. The machine ran for the first time on 10 May 1950. By modern standards it was sluggish but in its day was the fastest in the world.

Error correction

Turing's vision for Ace was that it would complete entire calculations for scientists and researchers, rather than do the bits and bobs of mathematical jobs that computers typically did before Ace came along. This made programming Ace a formidable task. And, whilst investigating how it could be used, the team uncovered another problem that looked set to dog greater use of computers - how accurate were they? *"When you put decimal numbers in a computer they have to be converted to binary,"* said Professor Maurice Cox, who also worked on Ace and its descendants. *"The conversion is not exact."* Binary is method of representing numbers using only the digits 0 and 1, used by all modern computers.

"Errors in the data can build up," said Professor Cox. *"Those errors can explode if you have an unstable method of calculation."*

Jim Wilkinson took on and defeated that uncertainty. Remembered with affection by everyone that worked with him, his work has been overshadowed by Turing.

"He was brilliant in his own right," said Clive Hall, a former colleague of Mr Wilkinson and who oversees some of the computer archives at NPL. *"The problem was that he came to NPL when Alan Turing was there."*

Wilkinson produced algorithms that could demonstrate the accuracy of computer calculations. *"It's work that became vital to all engineering and scientific calculation,"* said Professor Cox. It still is through the Numerical Algorithms Group, which produces libraries of algorithms used in hundreds of modern software packages.

Network man

Another NPL pioneer, Donald Davies, also cut his teeth on the Ace. He joined NPL at the same time as Jim Wilkinson and was, for a while, Turing's assistant. Much later, when he was head of the computer section at NPL, he did ground-breaking work on the best way to organise computer networks. At the time making a phone call meant literally creating an electrical circuit between the two people in the conversation. That tied up the entire line for the length of that chat, even though for most of the time the connection will go unused because of the silences and gaps that punctuate conversation.

Rather than mimic this and tie up computer links for a long time as data was sent back and forth, Mr Davies realised that the spaces could be used. By splitting data into packets and threading them on the same line, the carrying capacity of that link could be boosted and the whole network made more powerful. Roger Scantlebury, who worked with Dr Davies, presented the ideas about 'packet switching' to a conference in the US, where they were picked up by the creators of the nascent Arpanet, the fledgling internet.

Does that mean Britain invented the internet? *"Yes and no,"* said Mr Scantlebury. *"Certainly the underlying technology of the internet, which is packet switching, we did invent."* The NPL network ran at multi-megabit speeds in the late 1960s, faster than any network at the time. The network was not just an academic toy either. Real work was done across it.

David Yates was project manager of a program called Scrapbook which rolled together word processing, e-mail and hypertext - a system that incorporated many elements of the World Wide Web.

Scrapbook went live on 28 April 1971 and became something of a 'minor cult' among its growing user base. "We had a community of reasonably bright people that were interested in new things," said Mr Yates. "They were good fodder for a system like Scrapbook."

Scrapbook helped people across the 28 acres of the NPL campus collaborate on projects without having to sit next to each other. "When we had more than one scrapbook and hyperlinks we went across the network without the user knowing what was happening," he said. "I cannot make claims for precedence for it," said Mr Yates. "But it was certainly an early use and a very flexible use of hypertext." Whilst it is stretching the truth to say that Britain did invent the internet, there is no doubt that the history of the network is more complex than anyone ever thought.

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History made at the 2009 Inverness College award ceremony

Karen Tweed, Trust Decontamination Advisor, Leeds Teaching Hospital Trust

I think it's the first time I've ever made history but on the 13th November 2009 I did. I was one of the first people to graduate with a degree awarded from the University of the Highlands and Islands (UHI) Inverness College and the very first person to attain the degree of Master of Science (MSc) Medical Device Decontamination (MDD).

It did seem a long time since I read the article in the IDSc Journal in July 2006 on a degree course which was linked with the UHI, after a very swift phone call I was informed that I could attend the induction week end held over the August bank holiday and subsequently enrol on the degree. It was during this weekend I met existing students on the infection prevention course and the new students on the medical device decontamination course. This weekend was an excellent opportunity to meet other students as well as get a sound introduction to WebCT (now Blackboard) which was the IT learning system for the course and the UHI library service. It also gave me the chance to investigate the Inverness hostelries which I somewhat regretted on the following Sunday morning facing a 400 mile drive home. I decided to take the option to complete the degree in 3 years which meant taking on 4 modules for the first two years. This seemed very daunting at the start but once the interactive blackboard and WebCT was mastered and I was able to set myself a study time table and it became very enjoyable. At this point I must stress I have never been a perfect student and frequently I spent the weekends prior to handing in the assignments sat at the computer wishing I'd done things a lot sooner.

The first year's core modules took me a little out of my comfort zone. Because of my educational background I had only covered microbiology to A level standard and I found the microbiology modules were a challenge; but even so I also found them very interesting. The modules walked you through the subject step by step and by doing the section tasks I was able to make sure I was covering the correct information and hopefully keeping up with the time table.

A huge benefit was getting to know the tutors and the other students through blackboard and WebCT; we used this not only for course work but also to discuss problems in the work place and a little bit of social networking. It was quite comforting to find

out other student were struggling with the same aspects as myself and that the tutors helped by giving that little extra information and guidance.

The modules I took in year 1 were:

Micro-organisms & Disease (MAD)

Host Defence & Protection (HD&P)

Control & Administration of Decontamination (CAD)

Decontamination Processes and Their Control (DPC)

The decontamination modules in year 1 really helped me professionally, the CAD module allowed me to compare relevant standards such as the Health Technical Memorandum documents against the British Standards institution ISO standards. As a department we had tried to integrate the two but by doing the module I was able to understand the differences and this made implementation a lot easier.

The Leeds Trust started a project in 2007 reviewing different manufacturers of automatic endoscope reprocessors with a view to up grading some of our endoscopy units. The DPC module really helped with this evaluation process as I was able to look at the process cycle and internal workings to ensure the machines we looked at were fit for our purpose.

I looked forward to the second year and was expecting to find it a little easier, as most of the modules focused on aspects of medical device decontamination. But it was not without its pit falls as during the module MOD I had to re sit an assignment. My weakness was on calculating Fo values relating to autoclave cycles and I had to do extra work to make sure my second attempt was better, once again the UHI stepped in and offered all the support they could give.

Year 2 modules:

Decontamination Facilities, Utilities & Consumables (DCUF)

Microbiological Aspects of Decontamination (MOD)

Other Decontamination Processes and an Integration module

Other decontamination processes was an excellent module for me, I had to look into gas plasma sterilisation and ethylene oxide sterilisation

systems. Both these forms of sterilisation are used by the Leeds Trust for our equipment and I knew the basics but the assignment allowed me to understand exactly how they work and ensure I had a fuller understanding not just on the process but the regulatory requirements.

I think students on both the MSc's found the Integration module a challenge but this module did prepare me for the dissertation. I found that when reviewing research papers I was able to see their value towards my research and results.

The dissertation I chose was to support a project within the Leeds Trust on reviewing the storage of theatre sets and assessing the way the surgical equipment was wrapped. I found this work very interesting and because it was of use to the Trust there was a lot of encouragement for me to spend time doing the work. I must admit my motivation did take a dip around Christmas time and then I found I had a very steep hill to climb with the write up and assessment of the results.

During this time I always had support from my UHI supervisor and Trust supervisor to gently push me and keep me on track and by looking at my original

time table submitted to UHI. It is never easy to keep to time table especially when working on your own but the feeling when you post the final version to the university is worth it all. My advice to all students at this point is to make sure you have a good proof reader, I did let myself down a little bit with this and it showed in my final marks.

Over all I have really enjoyed doing this MSc and would recommend it all sterile services managers and decontamination leads. The MSc was a much needed professional qualification which will help managers in the field of decontamination pull together many different aspects of their work. It has certainly given me a much greater dept of knowledge and helped me view certain areas of my work much more ably.

The distance between my home in Yorkshire and the UHI in Inverness has not been a problem the interaction between student and tutors couldn't have been better via WebCT and blackboard.

And my graduation? It was a fantastic day with my brother in attendance and yes we followed it by once more enjoying the hostelries of Inverness. ■

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Patient Safety - communication and teamwork are the key

Diane Gilmour, President AfPP

For both Sterile Services Departments (SSD) and Operating Theatres the impact of other Government targets such as 18 week referral to treatment, compounded with recruitment concerns and staff shortages has meant that both departments have had to deal with more patients, more quickly and in a more streamlined process resulting in increased demand and workloads.

Over the past few years changes to Government policy and global events such as the Safe Surgery Saves Lives campaigns have and are influencing the working relationships between SSD and the Operating Theatre. This article will review two whose impact has had the greatest affect and will highlight the importance of teamwork and collaboration.

The move to centralised sterile services arose from the National Health Service (NHS) survey in 1999 which uncovered evidence that some decontamination processes did not meet recognised standards. In 2007 the first of the super centres/ off-site sterile units in England was opened.

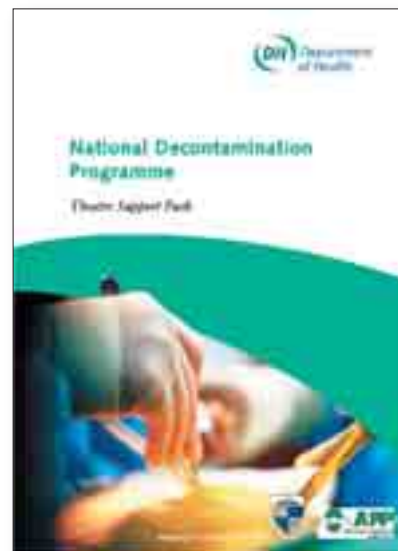
Professional bodies recognised that the investment to move off-site would be beneficial for some Trusts and healthcare organisations as they could not sustain their own services but were concerned about availability, timeliness, and standardisation within contracts. Moving to an offsite sterile service had implications not only for the staff in both SSD and Operating Theatres but also potentially for the safety of the patient. Anecdotal evidence and feedback during an Association for Perioperative Practice (AfPP) survey of members in 2007 detailed examples of lists being changed, instruments being returned with blood and bone visible, and lack of instruments. (*Gilmour and Cooper 2008*).

Within any aspect of change management communication is fundamental to the success (or failure) of any project. Giving the people involved information that is open, honest and factual will meet their expectations and allows individuals to recognise and deal with their reaction to change. (www.teamtechnology.co.uk accessed 17/02/2010).

After much debate and discussion, and together with the Department of Health (DH) National

Decontamination Programme, members of AfPP and IDSc wrote and launched the Theatre Support Pack in 2008. (Picture One) Produced for SSD and Theatres it aimed to provide clinical teams with clear and concise advice on the processes and procedures required when transferring instrument decontamination services. (*DH 2008*).

PICTURE 1 - Theatre Support Pack DH 2008



Within the document it identifies that a designated Theatre Lead is essential. This person with their extensive theatre background will be the link to SSD from pre-planning through transition to final sign over. They will be the communication link, the conduit for information between SSD and practitioners and co-ordinate activities such as instrument inventories, training and preparation of standard operating procedures.

Patient safety too has dominated health and media headlines. In 2004 the World Health Organization launched the World Alliance for patient Safety and in 2008 they set their second global patient safety challenge- Safe Surgery Saves Lives. The Alliance acknowledged that whilst surgical procedures are intended to save lives, the problem of surgical safety is a global and significant one. An estimated 234 million major operations are performed annually

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around the world yet complications for inpatients occur in up to 25% of cases. The Challenge aimed to reduce deaths and complications during surgery through a number of measures including the introduction of a Surgical Safety Checklist. (WHO 2008).

The House of Commons Health Committee Patient Safety report July 2009 identified that as many as 10% of patients admitted to hospital suffer some form of harm, most of which is avoidable. Systems for the reporting and learning from incidents as well as the new culture of openness has gone some way to addressing some of the safety issues but the Select Committee identified significant deficiencies

remain within current policy highlighting the need for involvement of front line clinicians in addressing patient safety. (House of Commons 2009).

“The quality of outcome and the safety of the patient during a surgical procedure relies on everyone involved in the surgical pathway.”

(World Health Organization (WHO) 2008 pg 9)

In January 2009 the National Patient Safety Agency (NPSA) launched the checklist (adapted for England and Wales) as a Patient Safety Alert with all actions to be implemented by all Acute Trusts by 1st February 2010. (Picture two).

PICTURE 2 - WHO Surgical Safety Checklist NPSA 2009

WHO Surgical Safety Checklist
(adapted for England and Wales)

SIGN IN (to be read out loud)
Before induction of anaesthesia

- Has the patient confirmed their identity, site, procedure and consent?
- Is the surgical site marked?
- Has the patient been a known allergy?
- Has the patient been a difficult airway/rapid extubator risk?
- Has the patient been a known allergy?
- Has the patient been a difficult airway/rapid extubator risk?
- Has the patient been a known allergy?
- Has the patient been a difficult airway/rapid extubator risk?

TIME OUT (to be read out loud)
Before start of surgical intervention
In theatre, OR, ORCA

- Has the team verified essential elements by name and role?
- Surgeon, Anaesthetist and Registered Practitioner verbally confirm:
- What is the patient's name?
- What procedure, site and position are planned?
- Essential critical items:
- Surgeon:
 - Have I read the case & consented?
 - Are there any specific equipment requirements or special requirements?
 - Are there any critical or unannounced risks associated with the team to know about?
- Anaesthetist:
 - Are there any patient-specific concerns?
 - What is the patient's ASA grade?
 - What monitoring equipment and other specific risks or support are required, for example blood?
- Registered Practitioner:
 - Has the safety of the environment been confirmed including indicator results?
 - Are there any equipment issues identified?
- Has the surgical site infection (SSI) bundle been undertaken?
 - Hand hygiene
 - Antibiotic prophylaxis within the last 60 minutes
 - Hair removal
 - Drummed barrier
- Are all preparations been undertaken?
 - Wound care
 - Pre-warmed drapes
 - Pre-warmed blankets
 - Pre-warmed gowns
 - Pre-warmed linens

SIGN OUT (to be read out loud)
Before any member of the team leaves the operating room

- Registered Practitioner verbally confirms with the team:
- Has the time of the procedure been recorded?
- Has it been confirmed that instruments, swabs and sponges counts are complete for site and position?
- Have the specimens been labelled (including patient consent)?
- Have any equipment problems been identified that need to be addressed?
- Surgeon, Anaesthetist and Registered Practitioner:
 - What are the key concerns for recovery and management of the patient?

PATIENT DETAILS

Last name: _____
First name: _____
Date of birth: _____
NHS Number: _____
Trust name: _____

This checklist contains the core content for England and Wales

www.npsa.nhs.uk/nrls

A simple checklist designed to be adapted locally incorporates three phases- **Sign in** (prior to anaesthesia induction); **Time out** (Prior to skin incision) and **Sign out** (prior to any staff leaving the operating theatre and prior to the patient being transferred to the post-anaesthetic care unit, post procedure) (AfPP 2009). The checklist can be expanded to incorporate briefing (prior to the commencement of any operating list) and debriefing (at the end of every operating list) to assist the multi-disciplinary

perioperative team to improve communication and teamwork.

One of the core elements identified within the checklist is for confirmation at Time Out-

“Has the sterility of the instrumentation been confirmed including indicator results?”

(NPSA 2009)

Theatre staff routinely assure themselves and the team that instruments and associated equipment are ready and fit for purpose to be used on that or each patient. Therefore preparation and remedy of any problems prior to the commencement of surgery is essential and avoids last minute chaos and “panic” if an instrument or set is not ready. The checklist is a tool that can assist but also facilitates greater planning ahead enabling the effective and efficient coordination of an operating list. Many teams now use the briefing to clarify with the surgeon what equipment is available for which case and the debriefing to discuss and prepare for the next scheduled list for that surgeon. By adopting such techniques this potentially allows for greater involvement with SSD staff.

Communication as practitioners plan ahead, informing SSD staff if an operating list is altered and why, working with SSD staff to understand the pressures for set turnaround, enable the SSD staff and management to manage the workload accordingly.

Whilst changes will affect practice constantly there is much that we as theatre practitioners and SSD staff can do to support and understand one another’s role, responsibilities and expectations of each other. We need to continually work together, improve openness between departments, integrate training and development opportunities for all – instruments themselves are the tools of our trade. ■

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Investigations of the recovery of residual contamination in the validation of washer-disinfectors pursuant to EN ISO 15883 Part 1

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Keywords:

- Instrument preparation
- Cleaning
- Residual contamination

Background:

EN ISO 15883 defines minimum cleaning requirements for reprocessing surgical instruments in washer-disinfectors.

Objective:

Determination of recovery rates for residual contamination using elution method on processed medical devices according to EN ISO 15883. Optimization of the elution method by increasing recovery rates.

Methods:

Determination of residual contamination and its recovery rate by elution using the radionuclide method.

Results:

For surgical instruments, it could be shown that using SDS elution recovery rates of no more than 0 to 40% can be obtained. After optimization of the recovery method under experimental conditions using test plates, the recovery rate can be increased to almost 100%.

Introduction

According to EN ISO 17664 ("Information to be provided by the manufacturer for the processing of resterilizable medical devices"), manufacturers of medical products are required to present a suitable procedure to assure ability to clean and sterilize reusable instruments ("type testing"). That includes a validated cleaning procedure with corresponding legal liability.

The central points of this validation are regulated by the new EN ISO 15883-1 ("Washer-disinfectors – Part 1: General requirements, terms and definitions and tests") and substantiated by the guideline compiled by DGKH (German Society for Hospital Hygiene), DGSV (German Society for

Sterile Supply) and AKI (Working Group Instrument Preparation) Two different procedures are used to test the cleaning: the use of test instruments with defined contamination, and the use of instruments contaminated by clinical use. The evaluation of the test instruments is accomplished first visually and then by at least semi-quantitative protein detection methods such as the biuret/BCA method. However, "aside from the protein analysis methods mentioned above for detection of residues (...) other physical-chemical detection procedures that provide appropriately sensitive quantitative results are carried out (1)." For the real contaminated instruments, a quantitative analysis can optionally be performed after the visual examination.

continued on page 14

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The evaluation follows corresponding acceptance criteria from the guideline. If the threshold limit of 100 µg protein (as bovine serum albumin) per ml of eluate from each instrument is exceeded, the washer-disinfector will have to be decommissioned.

Excesses over the warning limit of 50 µg of protein require measures to attain the guide value of < 50 µg of protein. The validation is not considered completed until that is accomplished (2).

If analytical methods are used to detect residual contamination on surgical instruments, the first question that arises is that about the manner in which the sample being examined is obtained. For this purpose, EN ISO 15883 describes an elution of the instrument with a sodium dodecyl sulphate solution (SDS), which dissolves proteins from the instrument surface and unfolds their spatial structure. This eluate is then used for quantitative methods of determination.

It is necessary to investigate the extent to which such a process can wash off protein residues that defy a far more expensive cleaning procedure

under optimized thermal (cleaning temperature), chemical (cleaning agent) and mechanical (washing pressure) parameters.

It must be noted in this respect that SDS solution is unable to dissolve fibrin. SDS is used industrially to separate fibrin and plasma.

Fibrin is the principal problem in instrument cleaning because of its insolubility in water. It is particularly relevant for judging the cleaning.

A physical process using the radionuclide method (RNM) is used to investigate the recovery. The results allow valid declarations. By radioactive labelling of human albumins, the principal protein components of human blood, in the form of macroaggregates, we have a basis for quantitative examination for proteins (3) not only in the eluate, but also as a nondestructive test for the entire instrument.

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Materials and methods

Test soil

There has not yet been any European consensus about a uniform composition for test soils. Recommendations range from heparinized sheep blood (Germany) and egg yolk (UK) to wheat flour (Austria). Given the required ability to quantify and standardize and the additional requirement of relevance to practice, the test soil in this study was done in a single process using sheep blood. Investigations confirm comparable properties with human blood with respect to removability (3). First, 10 ml of sheep blood, stored cold, is warmed to room temperature. Then it is mixed at high speed, using a magnetic stirrer, with 100 MBq of labelled Pulmocis (99mTc macroalbumin, used in lung perfusion scintigraphy), equivalent to about 1.3 ml of solution. After reactivating ability to clot by adding 1000 IE protamine sulphate per ml, the instruments are contaminated for a maximum of 5 minutes.

For the surgical clamps investigated, 10% isotonic NaCl solution was added to the reactivated sheep blood and the joint region was contaminated with 100 µl contaminant. Then distribution comparable to actual practice was accomplished by opening and closing them five times. That is necessary to get the test contaminant into the surfaces that are the most difficult to clean (the inner branches of the joint).

For tubular instruments, 10% isotonic NaCl solution is added to the test contaminant. The test contaminant is introduced with a sterile disposable syringe connected through a Luer-Lok fitting to wet the internal surfaces completely. The test contaminant is added slowly into the instrument, held vertically, until the test contaminant issues at the distal region.

For test plates, the addition of isotonic NaCl solution is increased to 50% to prevent flaking of the coagulated test contaminant off the smooth surface (stainless steel, mat. no. 1.4021) on drying. The amount of contaminant used depends on the nature of the test, and is described in the accompanying individual sections on results.

Each test contaminant is followed by a drying period of 60 minutes at 45 °C in a heated chamber to give defined conditions, as well as to make cleaning more difficult (worst-case conditions).

Cleaning process

After the drying period, the instruments are cleaned in a Miele Type G 7735 CD washer-disinfector. Each tubular instrument is connected through the

Luer-Lok to a separate flushing channel of the washer-disinfector. Clamps and test plates are placed on screen pans for cleaning.

The instruments are cleaned with the following cleaning program:

- 4 minutes pre-rinse with cold tap water
- Emptying
- 5 minutes cleaning with Neodisher FA at 55 °C (0.5%)
- Emptying
- 5 minutes cleaning with Neodisher FA (0.5%) and V4067 (0.35%)
- 1 minute neutralizing with Neodisher Z
- Emptying
- 20 seconds neutral flushing
- Emptying
- 3 minutes intermediate flushing.

Recovery process

As the inner lumens of tubular instruments, and covered surfaces of surgical instruments, are not accessible for any direct chemical detection process for residual contamination, the substances to be detected must first be brought into solution. This step will be called "recovery". Then the eluate obtained is analyzed with the various detection procedures.

The process used in the standard/guideline describes flushing the instruments with 1% SDS solution to dissolve protein residues on the instruments (1). Here it is important to process the instrument after the cleaning step before any disinfection or sterilization process, because proteins are denatured at high temperatures and so escape the quantitative determination. The volume of SDS solution to be used is another problem. The volume must be great enough to reach the entire surface of the instrument being examined. On the other hand, it should be as small as possible so as not to dilute below the limit of detection.

In the following tests with clamps and tubular instruments, 2 ml of SDS solution was used for each instrument.

To recover sample from the clamps, each instrument is placed in a 50 ml beaker and then 2 ml of the SDS solution is pipetted over the joint area. The beaker is held tilted so that the instrument, held at

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¹Code of Practice for Decontamination of RIMD. Version 1.0, HSE 2007
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the lip of the beaker, is wetted up to just above the joint. Then the joint is opened as wide as possible in the solution and closed five times. Then the instrument is left to stand in the beaker for 10 minutes (“digestion”), and the procedure is repeated in the same solution. The procedure is repeated still a third time.

The tubular instruments are equally placed in a beaker, however the SDS solution is flushed through the flushing channel using a syringe.

To optimize recovery rates, test plates are placed into individual test tubes containing SDS solution and are exposed to varied parameters (exposure time, SDS concentration, pH value, temperature, ultrasound as well as addition of urea).

Radionuclide method as the reference method

The radionuclide method makes it possible to state the residual contamination remaining in or on surgical instruments, by means of the quantitative measurement of gamma-ray photons from Tc99m-labeled human albumin macroaggregates (MaA) removed from their location (3). That is possible, in

principle, after each individual reprocessing step. To do so, heparinized sheep blood is mixed homogeneously with radioactively labelled Pulmocis. Immediately after addition of protamine sulphate, it is placed on the instrument being examined as the standardized test contaminant. The gamma radiation emitted is measured with a gamma camera.

Because the natural half-life of Tc99m is 6.03 hours, all the values must be normalized so that the digital measurements will be comparable.

The function for the normalized measurement (Zr) is:

$$Zr = ((Zg + (Zg \times 0,01 : 5 \times tr) / t0) \times sf) - (nc \times nHz)$$

Measurements of 5 counts/second or less are taken as the criterion for a clean test instrument (3). This limit is based on correlations with limited-area analytical methods such as scanning electron microscopy (SEM) with energy-dispersive X-ray microanalysis (EDX) and X-ray photoelectron spectroscopy (XES), which were done at the Institute of Natural Sciences and Medicine (NMI) of the University of Tübingen, in Reutlingen (4).

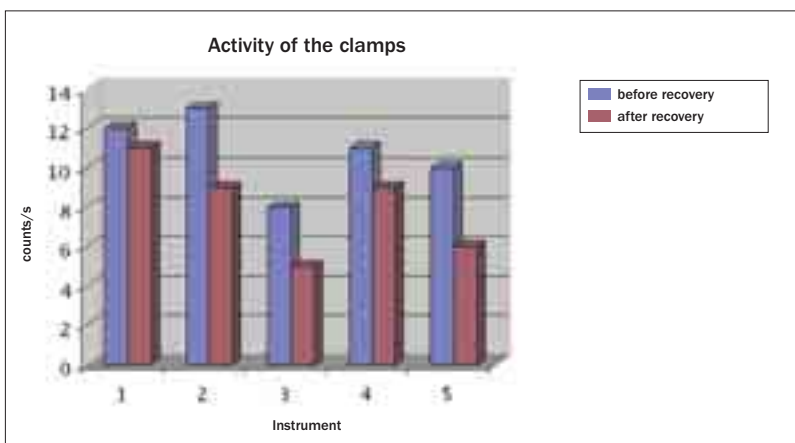


FIGURE 1: Plot of the activity on the arterial clamps before and after the recovery process according to Standard EN DIN ISO 15883-1.

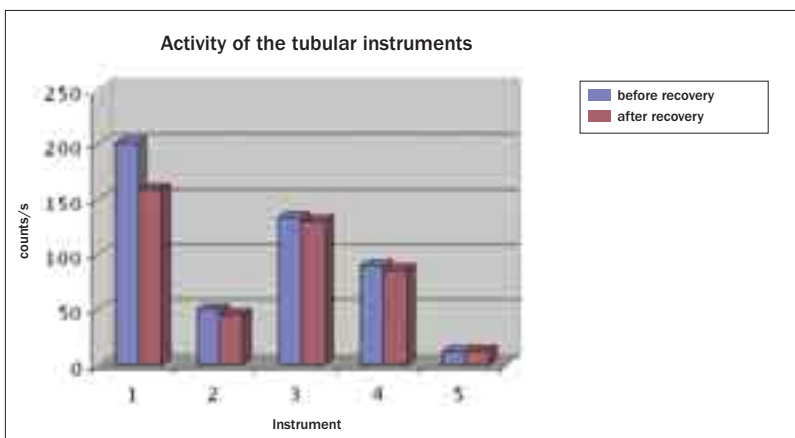


FIGURE 2: Plot of the activity on the tubular instruments before and after the recovery procedure according to Standard EN DIN 15883. Instruments 1 to 3 are test objects, instruments 4 and 5 are needle holders.

Results

The following results were determined by measurements with the radionuclide method. For better comparability of the measurements, the activities determined are shown first as the calculated percentage reduction and then as a graph of the decay results (counts/second).

Recovery according to the standard/guideline

Arterial clamps

In the recovery, 5 instruments attained reductions between 8.33% and 40%. The percent reduction is based on the value before the recovery.

The mean of the measurements of all five instruments gives a reduction of 26.96%.

Tubular instruments

All three test bodies attained reductions between 2.3% and 20.9%, compared to the initial contamination.

In the investigation of the MIS needle holders, there was no reduction for one instrument, and a reduction of 4.4%, compared with the initial contamination, for the second instrument. The average for all five instruments is 7.42%.

Optimization of the recovery with test plates

Soil volumes

With an identical recovery process, the average of the initial activity that could be brought into solution for the 3 samples contaminated with 50 µl was 5.82% of the initial activity (sample 1: 3.57%; sample 2: 10.71%; sample 3: 3.17%).

The average for the test plates contaminated with 40 µl was 9.88% (sample 4: 2.17%; sample 5: 23.91%; sample 6: 4.17%).

The average for the test plates contaminated with 30 µl was 4.81%. The average is based on just two measurements, as sample 8 was no longer available for any further measurements because the test tube was broken (sample 7: 3.57%; sample 9: 6.06%).

The average for the test plates contaminated with 10 µl was 6.06% (sample 10: 0%; sample 11: 18.18%; sample 12: 0%).

pH of the SDS solution

No improvement of the percentage recovery can be gained by adding sodium hydroxide to the SDS solution and adjusting to a pH of 11.

In recovery by a SDS solution at pH 11, samples 1 to 3 (with 50 µl test contaminant) had an average of 6.88% recovery (sample 1: 6.78%; sample 2: 9.09%; sample 3: 4.76%).

The percentage recovery in the triplicate determination from samples 4 to 6 (with 40 µl test contaminant) was 4.58% (sample 4: 0%; sample 5: 2.38%; sample 6: 11.36%).

The percentage recovery in the duplicate determination with samples 7 and 9 (with 30 µl test contaminant) was 16.57% (sample 7: 13.79%; sample 9: 19.35%).

The percentage recovery in the triplicate determination from samples 10 to 12 (with 10 µl test contaminant) was 6.06% (sample 10: 15.38%; sample 11: 0%; sample 12: 11.11%).

Concentration of the SDS solution:

The triplicate determination of samples 1 to 3 with an SDS concentration of 1% gave a 15.15% recovery (sample 1: 2.7%; sample 2: 18.75%; sample 3: 24%).

The triplicate determination of samples 4 to 6 with an SDS concentration of 3% gave a 2.3% recovery (sample 4: 6.9%; sample 5: 0%; sample 6: 0%).

The triplicate determination of samples 7 to 6 with an SDS concentration of 5% gave a 2.95% recovery (sample 7: 2.78%; sample 8: 6.06%; sample 9: 0%).

Variable shaking time

Extension of the recovery procedure from 20 to 60 minutes improved the average recovery percentage from 4.79% for 20 minutes to 11.92% for 60 minutes. Both percentages are averages of the triplicate determinations done.

Samples 1 to 3 show the following measurements for 20 minutes recovery time: Sample 1 gives a reduction of 5.56%; sample 2: 8.82%; no reduction for sample 3.

Samples 4 to 6 show the measurements for 60 minutes recovery time: Sample 4 shows a reduction of 3.13%; sample 5: 23.53%; sample 6: 9.09% of the initial contamination.

Effects of ultrasound and temperature

When the temperature was increased with constant ultrasound action, there was a definite increase in removal from 70.75% at 22 °C to 100% at 80 °C. The duration of the ultrasound treatment remained constant at 20 minutes.

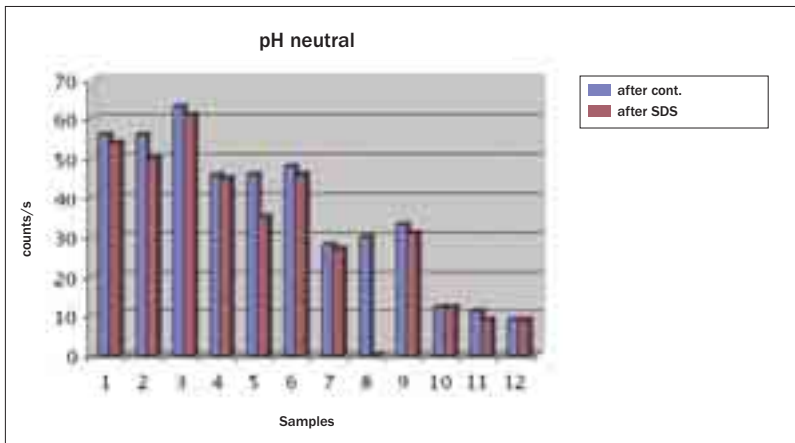


FIGURE 3: Plot of the activity on the test plates after contamination and after recovery in neutral pH SDS solution. samples 1 to 3 contaminated with 50 μ l, samples 4 to 6 with 40 μ l, samples 7 to 9 with 30 μ l and samples 10 to 12 with 10 μ l of test contaminant.

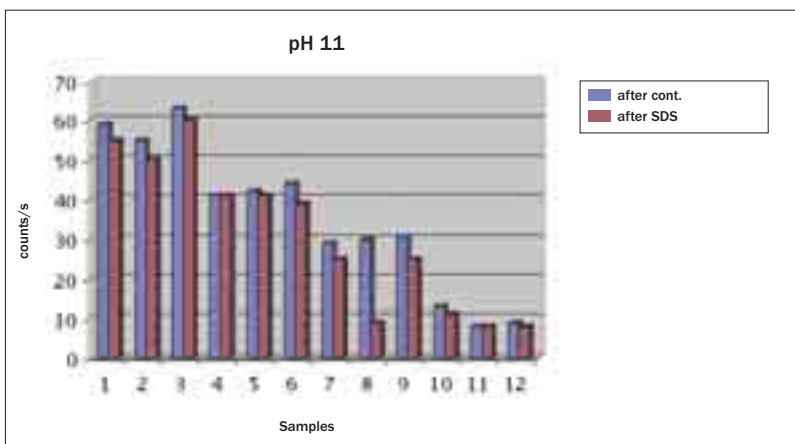


FIGURE 4: Plot of the activity on the test plates after contamination, and after recovery in SDS solution at pH 11; samples 1 to 3 contaminated with 50 μ l, samples 4 to 6 with 40 μ l, samples 7 to 9 with 30 μ l, and samples 10 to 12 with 10 μ l of test contaminant.

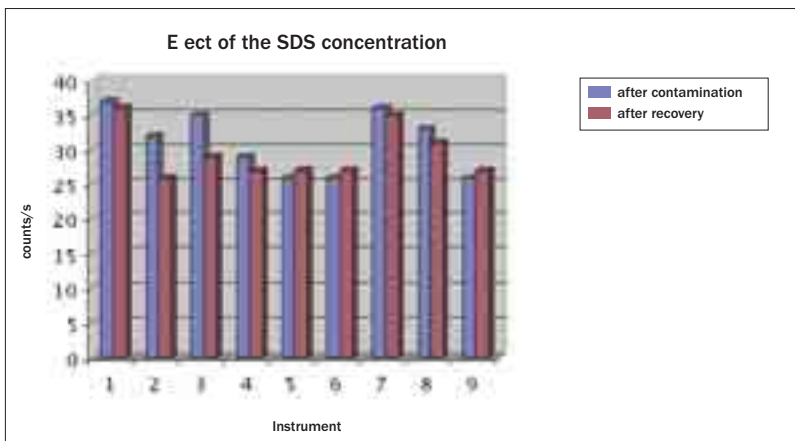


FIGURE 5: Plot of the activity on the test plates after contamination and after recovery in neutral pH SDS solution. The SDS concentration was 1% for recovery from instruments 1 to 3; 3% for recovery from instruments 4 to 6; 5% for recovery from instruments 7 to 9.

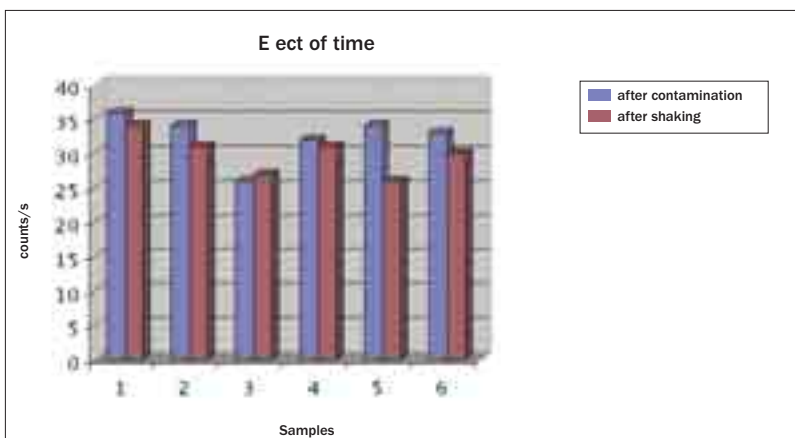


FIGURE 6: Plot of the activity on the test plates after contamination, and after recovery in neutral-pH SDS solution. The recovery time was 20 minutes for samples 1–3 and 60 minutes for samples 4–6.

Samples 1 to 3 show the measurements at 22 °C in the ultrasound bath: Sample 1 shows a reduction of 62.86%; sample 2: 75.86%; sample 3: 73.53% of the initial contamination. This triplicate determination gives an average of 70.75%.

Samples 4 to 6 show the measurements at an ultrasound bath temperature of 30 °C: Sample 4 shows a reduction of 75.76%; sample 5: 60%; sample 6: 65.79% of the initial contamination. This triplicate determination gives an average of 67.18%.

Samples 7 to 9 show the measurements at an ultrasound bath temperature of 50 °C: Sample 7 shows a reduction of 97.37%; sample 8: 77.78%; sample 9: 72.73% of the initial contamination. This triplicate determination gives an average of 82.63%.

Samples 10 to 12 show the measurements at an ultrasound bath temperature of 70 °C: Sample 10 shows a reduction of 94.74%; sample 11: 100%; sample 12: 100% of the initial contamination. This triplicate determination gives an average of 98.25%.

Samples 13 to 15 show the measurements at an ultrasound bath temperature of 80 °C: Sample 13 shows a reduction of 100%; sample 14: 100%; sample 15: 100% of the initial contamination. This triplicate determination gives an average of 100%.

Addition of urea

Reduction cannot be increased by adding urea to the SDS solution (5% concentration by volume).

Reduction of 100% still requires a temperature of 80 °C with 20 minutes of ultrasonication.

Samples 1 to 3 show the measurements at room temperature, 22 °C, in the ultrasound bath: Sample 1 shows a reduction of 38.24%; sample 2: 58.06%; sample 3: 27.78% of the initial contamination. This triplicate determination gives an average of 41.36%.

Samples 4 to 6 show the measurements at an ultrasound bath temperature of 30 °C: Sample 4 shows a reduction of 37.50%; sample 5: 38.71%; sample 6: 76.32% of the initial contamination. This triplicate determination gives an average of 50.85%.

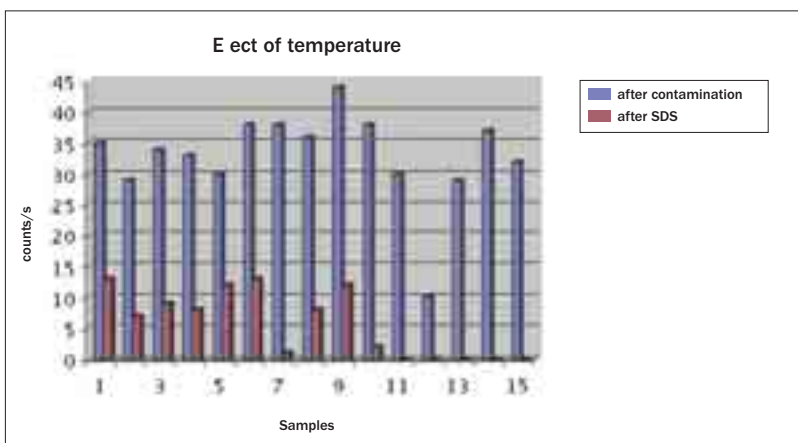


FIGURE 7:

Plot of the activity on the test plates after contamination and after completion of recovery in a neutral pH SDS solution in the ultrasound bath: ultrasonic treatment of samples 1 to 3 at 22 °C; of samples 4 to 6 at 30 °C; samples 7 to 9 at 50 °C; samples 10 to 12 at 70 °C; samples 13 – 15 at 80 °C.

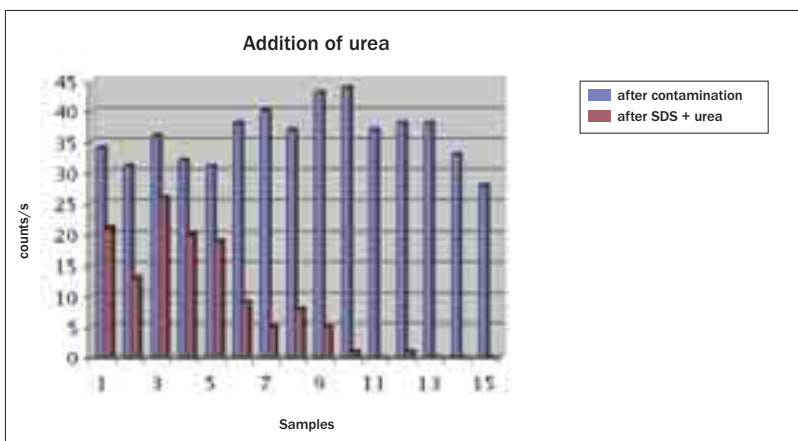


FIGURE 8:

Plot of the activity on the test plates after contamination and after completion of recovery in neutral pH SDS solution with added urea in the ultrasound bath. Ultrasound treatment of samples 1 to 3 at 22 °C; samples 4 to 6 at 30 °C; samples 7 to 9 at 50 °C; samples 10 to 12 at 70 °C; samples 13 to 15 at 80 °C.

Samples 7 to 9 show the measurements at an ultrasound bath temperature of 50°C: Sample 7 shows a reduction of 87.50%; sample 8: 78.38%; sample 9: 88.37% of the initial contamination. This triplicate determination gives an average of 84.75%.

Samples 10 to 12 show the measurements at an ultrasound bath temperature of 70°C: Sample 10 shows a reduction of 97.73%; sample 11: 100%; sample 12: 97.37% of the initial contamination. This triplicate determination gives an average of 98.37%.

Samples 13 to 15 show the measurements at an ultrasound bath temperature of 80°C: Sample 13 shows a reduction of 100%; sample 14: 100%; sample 15: 100% of the initial contamination. This triplicate determination gives an average of 100%.

Application of recovery optimization to arterial clamps

The clamps were subjected to the optimized recovery process under identical contamination and cleaning conditions.

The clamps were ultrasonicated at 35 kHz for 20 minutes in specially prepared test tubes at an

ultrasound bath temperature of 80°C and storage in 5 ml 1% SDS solution (without alkalization).

Five clamps examined showed reductions between 90 and 100%, with an average of 96.57%, under the optimized recovery.

Discussion

Test soil

Blood is the contaminant most closely related to practice for surgical instruments. The fibrin that it contains is considered the component of the contamination that is the most difficult to remove.

Blood, as a suspension of different components, offers the possibility of investigating them independently of each other with various quantitative analytical methods. That makes it possible to state which components place special requirements on the cleaning process.

Cleaning process

The optimum temperature for cleaning cycles is discussed controversially in the literature (5, 6).



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Observations from practice on cleaning of surgical instruments show a superiority of higher cleaning temperatures (up to 90°C) over lower ones (50°C). However, experimental studies with filter papers contaminated with blood exhibit denaturation and fixation effects with rising temperatures, resulting in poorer cleaning results (5).

For standardization, identical parameters (temperature, rinsing pressure, addition of cleaner, and duration of cleaning) were used in experiments with a previous cleaning cycle, and were monitored with data loggers. The cleaners were added manually. Only one cleaning agent was used. Here it must be noted that different cleaning chemicals can leave behind different components of the contamination on the instrument surfaces. That situation must be considered in interpreting the results of the measurements.

Recovery process

The EN ISO 15883-1 recovery process allows quick recovery of residual contamination on small instruments with small elution volumes (2–5 ml). The small elution volume minimizes the dilution effect. The standard does not make any statements about

examination of large instruments or instruments with lumens. The only limit there to the practical procedure is that it is nearly impossible to get to all the surfaces of the instrument being examined with a small volume of flushing solution. That results in even lower recoveries. Required recoveries of > 90% have been published, but they cannot be confirmed by the present study.

Optimization of recovery for test plates with stainless steel surfaces takes near practice conditions into consideration. Direct examination of the contaminated test objects, without a previous cleaning cycle, gives comparable starting conditions with respect to the degree of contamination. This method does require a supplemental test, based on instruments that were subjected previously to a cleaning process. A publication in preparation (5) will show how fixation effects can also occur due to the cleaning process under the influence of temperature and cleaning chemistry.

It is necessary to use glass vessels in the studies on recovery of eluate under the influence of ultrasound, because glass has low absorption, allowing a stronger ultrasonic action on the instrument itself.

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Effect of SDS on fibrin

In instrument cleaning, fibrin is considered a blood component that is particularly difficult to remove because of its poor water solubility. At present, addition of hydrogen peroxide to the usual cleaning agents is being utilized to destroy the polymeric structure of fibrin by oxidation and to bring it into solution.

The fact that SDS does not hydrolyzed polymerically crosslinked fibrin is well known.

The results clarify this situation. Centrifuging at 400 rpm for 20 minutes with 1% SDS solution removes only about 50% of the activity from the fibrin clot. As technetium is not bound to fibrin, but to albumin, we must assume that all the other blood components are also concealed in polymerically crosslinked fibrin.

Even storage in SDS solution for 24 hours shows visually only reduction in size and slight decolorization of the fibrin clot.

Recovery according to the standard

Three instrument types of different designs were used for the investigations. The recovery conformed to the standard by elution with 1% SDS solution, with evaluation through comparative measurements of radioactivity (radionuclide method) before and after the elution. For one thing, Crile arterial clamps, which are difficult to clean because of their joints, were examined. For another, needle holders from minimally invasive surgery, which also have a flushing channel, were examined. Furthermore, specially designed test instruments that can be disassembled, with tubes, internal push rods, and a threaded screw connecting the two parts together, and having a flushing channel, were examined. The arterial clamps are mentioned both in the standard as test instruments, and also presented as test instruments in a widely applied "Collaborative

experiment on testing the minimum cleaning requirement according to the guideline compiled by the DGKH, DGSV and AKI" (8) to establish acceptance criteria. An increase in the cleaning requirements and thus also in the recovery process is taken into consideration by testing the needle holders and the disassembly test instruments with push rods.

With an average recovery of about 27% for five arterial clamps examined, the high range of scatter, 8% to 40%, is striking.

Two MIS needle holders exhibited the lowest recoveries, with an average of only about 2%. The results reflect the drop in recovery with increasing complexity of the instrument design, with a large internal volume having a greater effect than an added push rod with lower internal volume. That is presumably due to the SDS solution not being able to wet all the surfaces with a large internal volume, under the given conditions. Furthermore, small separations between push rod and tube could increase the flow rate of the SDS solution during elution, increasing the recovery.

Optimization of recovery on test plates

Different thicknesses of the contamination have no effect on the percentage recovery under the existing standardized conditions. With averages from triplicate determinations between 4.82% and 10.08%, no distinct tendencies for increase or decrease with more contamination can be detected.

No significant improvement in recovery can be found on comparison of the results of a standardized recovery (neutral pH SDS solution versus SDS solution alkalized to pH 11). Averages from 7 samples show a minimal improvement from 6.86% (neural pH) to 8.55% (alkalized).

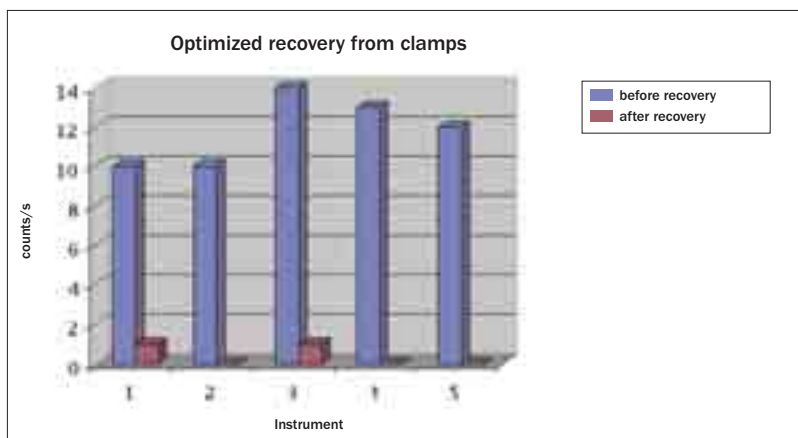


FIGURE 9: Plot of the activity on the arterial clamps before and after the optimized recovery procedure.

Increasing the SDS concentration results in a distinct reduction of the recovery: 15%, on average, with 1% SDS solution, compared with barely 3% when a 5% SDS solution is used make that clear. No studies were done with SDS concentrations above 5% for reasons of material incompatibility and interference with the chemical detection procedure.

Extension of the elution time under standardized conditions from 20 to 60 minutes resulted in an increase of the recovery from just under 2% to just under 12%. The results do not meet expectations, considering the great expenditure of time, the scatter of the measurements, and the desired recovery of 100%.

Use of ultrasound at a frequency of 35 kHz for 20 minutes in the water bath at 22 °C raised the recovery to more than 70%. Increasing the temperature gave further stepwise improvement of recovery to 67% at 50 °C and finally 100% at 80 °C.

Addition of urea to SDS at a total concentration of 1% cannot compensate for a reduction of the ultrasonic bath temperature. That is, it cannot remove all the residual contamination from the instrument surface. Addition of urea actually has a negative effect in the temperature range below 30 °C. Even after addition of urea, a temperature of 80 °C combined with a 20minute ultrasonic treatment is still required for complete recovery.

The processes tested for potential optimization of the recovery (increasing the concentration of the 1% neutral pH SDS solution, making it alkaline, extension of the elution time, and addition of urea) do not contribute to a significant improvement.

A further attempt at optimization, which combines the ultrasonic action with a high bath temperature of 80 °C results in a 100% recovery, and so to complete dissolution of the radioactively labelled contamination from the instrument surface into the sample solution.

Application of recovery optimization to arterial clamps

Arterial clamps, because of their covered surfaces, present significantly higher requirements to a recovery process than the test plates previously investigated.

As described, severe scattering of the measurements from about 8% to 40%, with an average recovery of 27%, is observed with five arterial clamps examined using the standardized

recovery process. Optimization of the recovery process can bring about 96% of the residual contamination into solution, with minimal scatter in the measurements, under identical contamination and cleaning conditions. Thus it can make other quantitative analytical methods accessible.

Conclusion

Considering the far-reaching and manifold consequences of inadequate cleaning, it is necessary to develop a test procedure that yields valid test results for the cleaning process. In view of the results presented here, and of the results from the "Collaborative experiment on testing the minimum cleaning requirement according to the guideline from DGKH, DGSV and AKI" (8), refinement of methods for detecting residual contamination, combined with lowering the detection limits is not necessary, as a substantial proportion of the departments may have problems in reaching the required acceptance criteria at all.

Given the low and, especially, the severely scattered, recoveries, it appears more important to establish a process for getting samples that assures high and stable recovery.

In the present study, for example, arterial clamps were examined successfully by an optimized recovery process. Only further studies will show the extent to which these results can be transferred to more complexly designed instruments (e.g. MIS instruments). In particular, tubular instruments and endoscopes will present problems because of increasing eluate volumes with increasing dilution effects, and because of the less reliable action of ultrasound in such instruments.

Summary

Because of the increasing importance of non-thermal sterilization processes and the problem of prions and heat-stable endotoxins, attention in instrument cleaning is being directed increasingly to the cleaning process. The standard EN ISO 15883-1 recommends, for that purpose, an elution procedure to detect residual contamination on surgical instruments.

In the present studies on test objects or instruments cleaned in the standard manner with known residual contamination, the elution process using SDS proves to be not sufficiently effective. On the average, only about 27% of the residual contamination could be recovered, with a scattering range of 8% to 40%. Fibrin in the coagulated blood, which is not dissolved by SDS, is responsible for that.

It is possible to dissolve all the contamination from the surfaces of test plates of instrument steel after optimizing the recovery process using ultrasonic action and temperature increased to 80 °C. Testing the instruments used with the optimized recovery process gives average recoveries greater than 96%, distinctly above the required minimum of 90%. ■

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The role of the Decontamination Lead

Susan Meredith, Director of Publications, IDSc

As I said in my introduction - I believe there is a lot of confusion around this particular role, my line manager requested a paper on the subject, I spoke to colleagues and searched the internet. I also think I may have missed some definitions too, my point is that I do not think that everyone understands the legal requirements around this post or how far reaching the remit is. I was recently invited to an external audit to discuss my understanding of the bed pan washers on site, they should have a programme of pre-planned tests just like our washer disinfectors. The other topic was that of physiotherapy exercise equipment, I am not the decontamination lead on my site but I was expected to know the answer. This is my interpretation of what the role covers and it is around this document that we are developing our understanding of on site decontamination.

Within the Health and Social Care Act 2008

Decontamination lead - The senior member of staff with responsibility for managing all aspects of decontamination. It is expected that this officer will report directly to the chief executive or registered provider. It is not intended that this post should always be filled by a technically competent individual, merely that their level of seniority within the organisation is sufficient to encompass all aspects of delivery and thus ensure compliance with best practice.

The Decontamination Lead is defined within HTM 01- 01: Decontamination of Reusable Medical Devices as:

- 5.14** Every healthcare organisation must have a nominated Decontamination Lead with responsibility for decontamination, either at board level or who has line management responsibility to a senior responsible person at that level (see 'The Health Act 2006: Code of practice for the prevention and control of healthcare associated infections' (Department of Health, 2006).
- 5.15** The Decontamination Lead should report directly to the Executive Manager.

5.16 The Decontamination Lead is organisationally responsible for the effective, and technically compliant, provision of decontamination services.

5.17 The Decontamination Lead is responsible for the implementation of an operational policy for decontamination. He/she should ensure that the operational policy clearly defines the roles and responsibilities of all personnel who may be involved in the use, installation and maintenance of decontamination equipment. The Decontamination Lead is also responsible for monitoring the implementation of the policy.

5.18 The Decontamination Lead may delegate specific responsibilities to key personnel; the extent of such delegation should be clearly set out in the operational policy together with the arrangements for liaison and monitoring.

The Health Act 2006: Code of practice for the prevention and control of healthcare associated infections' (Department of Health, 2006).

Part 2A Public Health Protection

45A Infection or contamination

- (1) The following provisions have effect for the interpretation of this Part
- (2) "Contamination" includes radiation
- (3) Any reference to infection or contamination includes a reference to infection or contamination which presents or could present significant harm to human health
- (4) Any reference to the spread of contamination includes a reference to the spread of any source of contamination
- (5) Any reference to disinfection or decontamination includes a reference to the removal of any vector, agent or source of the infection or contamination
- (6) Related expressions are to be read accordingly.



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The Health and Social Care Act 2008

Code of Practice for the NHS on the prevention and control of healthcare associated infections and related guidance

Part 3: States that compliance by a provider with the statutory requirement set out in Part 2 will be judged against the following criteria and the Annex.

This refers to HCAI's and to maintaining a clean and appropriate environment and in Part 6 Relevant sections from the Health & Social Care Act there is a reference to reusable medical devices.

The Central Sterilizing Club issued the following advice in June 2009 –

A reusable medical device is a device that is intended for multiple use and requires processing (or 'reprocessing', which may include cleaning,

disinfection, packaging and/or sterilization) to ensure that it is safe for reuse. The processing cycle can include a series of steps such as device preparation, disassembly, inspection, pre-cleaning, cleaning, disinfection (thermal and/or chemical), rinsing, drying, packaging, sterilisation (thermal and/or chemical), and storage. The level of processing required varies according to the specific piece of equipment and its intended use and in some cases this may only include simple instructions such as cleaning and routine maintenance, while in other more detailed instructions are required. See *Spaulding Classification on page 29*.

It is the responsibility of the device manufacturer to provide detailed instructions to users regarding the safe and effective processing of their devices, when those devices are claimed to be reusable. This is essential to ensure that the devices can be safely reprocessed and re-used; to continue to meet their performance specification (as defined by the manufacturer) textiles are not currently included in this.



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Definitions

Device or Medical Device. Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories (including the software intended by its manufacturer), to be used specifically for diagnostic and/or therapeutic purposes.

Note: this definition includes medical, dental and out-patient devices used for surgery or investigations, as well as other devices such as wheelchairs, beds, mattresses, and decontamination equipment (such as washer-disinfectors and sterilizers) with associated cleaning chemistries. For a full definition, refer to the European Medical Device Directive (93/42/EEC).

So, what is a 'Medical Device'?

According to the European Medical Device Directive (93/42/EEC), a Medical Device is;

“...any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of;

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means...”

Decontamination Defined:

Decontamination is a process which removes or destroys contamination and thereby prevents infectious agents or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response. Differing levels of decontamination are available. They are: cleaning followed by high level disinfection; or cleaning followed by sterilization, depending on the procedure and chemicals used.

Or

Decontamination, the combination of processes (including cleaning, disinfection and sterilization) used to render a reusable item safe for further use on patients and handling by staff. – *“A guide to the decontamination of reusable surgical instruments – NHS Estates 2003”*

Alternatively, the ‘*Spaulding Classification*’ may be used,

In the mid-1960s Dr. Earl Spaulding developed a framework as a guide for reprocessing decision making. He based his system on the probability of risk to the patient of contracting an infection that various types of instrument or equipment contact can cause. ■

Spaulding’s Classification

Classification	Definition	Level of processing required
Critical Equipment/Device	Equipment/device that enters sterile tissues, including the vascular system.	Cleaning followed by sterilization.
Semi Critical Equipment/Device	Equipment/device that comes in contact with non intact skin or mucous membranes but does not penetrate them.	Cleaning followed by high level disinfection (HDL) as minimum. Sterilization if preferred.
Non-Critical Equipment/Device	Equipment/device that touches only intact skin and not mucous membranes, or does not directly touch the client/patient.	Cleaning followed by low level disinfection. In some cases, cleaning alone is acceptable.

A brief overview of the HCAI Technology Programme

This is a synopsis of a document produced by the Department of Health, Feb 2010.

The Healthcare Associated Infection Technology Innovation Programme provides a proactive new strategy for the identification, development and adoption of innovative technological solutions to combat Healthcare Associated Infections in the NHS.

Programme initiatives

HCAI Technology Innovation Programme initiatives identify and support the development and adoption of innovative and exciting new technologies with the potential to prevent or reduce HCAs. These initiatives and some of the technologies and equipment they have helped to advance are outlined below. Further information is available at www.clean-safe-care.nhs.uk

“The idea with the Rapid Review Panel was to look at the materials and kit that companies were promoting to see if any of it was to any real advance and benefit. What we’ve been able to do now is not only to review their products but also to give them product surgeries and set up advice systems for them, so we can get them expert advice about what is really needed in the clinical setting.”

Professor Brian Duerden, CBE, Inspector of Microbiology and Infection Control, Department of Health.

The Rapid Review Panel (RRP)

The Rapid Review Panel (RRP) was set up in 2004, to provide expert advice to the Chief Medical Officer. It is run by the Health Protection Agency (HPA). The RRP provides a prompt assessment of new and novel products, equipment, materials and protocols to determine their potential to improve hospital infection control and reduce HCAs. It meets four times per year and without charge provides expert assessment advice to innovators who can make use of its services as many times as appropriate.

How does it work?

- The Panel, made up of experts in microbiology, infection control and design, reviews written information and evidence about new technologies and makes recommendations to the Department of Health regarding their potential to prevent or reduce HCAs.

- Each technology is assigned one of seven recommendations. Recommendation 1 is the highest and means that basic research and development, validation and recent in-use evaluations for the technology in question have shown benefits that should be available within the NHS.
- Technologies achieving an RRP recommendation 1 are placed in the Supply Chain catalogue as soon as possible, making them rapidly available to the NHS.
- These technologies automatically gain entry to the Showcase Hospitals Programme, where a service evaluation is undertaken within a clinical context and an outcome report is made available to all hospitals in the NHS to promote awareness. Showcase events are undertaken locally to stimulate adoption.
- The HCAI Technology Innovation Programme provides support and guidance to innovators whose technologies and products have received RRP recommendations 2 and 3, helping them improve their RRP recommendation and assisting them to further evidence their products where appropriate.
- In this way, the effort and investment of industry are directed on the basis of good scientific advice and according to NHS need, helping save time and money.

The Showcase Hospitals Programme

The HCAI Technology Innovation Programme has recruited eight NHS Trusts from around the country to act as ‘Showcase Hospitals’. Showcase Hospitals evaluate and promote new HCAI technologies, allowing:

NHS professionals around the country to see them in use; learn from the experiences of those trialling them and discuss barriers to their adoption.

Further information is available at www.showcasehospitals.com

“It’s very easy to overlook the importance of getting robust adoption strategies in place as part of the A-Z process of getting new and novel HCAI related

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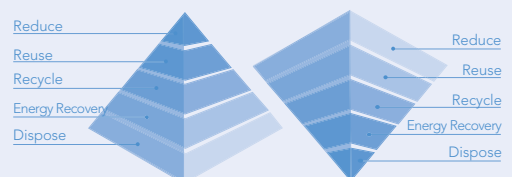
* Fichet et al. Prion inactivation using a new gaseous hydrogen peroxide sterilisation process. J. Hosp. Infection (2007) 67, 279-287

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technologies into the NHS. We need to make sure that helping NHS staff to understand this process and the upsides to them and their patients is given the same importance as the invention of the technology in the first place"

Margaret Parton, Chief Executive, NHS Technology Adoption Centre.

"We've been given time to trial these products. Often with trials you'll have it for a week and then it's gone... the experience we've had here has given us much more time to find out the good, the bad and the ugly about the product."

Cheryl Etches, Director of Nursing, Royal Wolverhampton NHS Trust.

- An evaluation report is prepared, which provides information on the technical and in-use value and business case for each RRP 1 recommended technology.
- Evaluation reports are made freely available on the www.clean-safe-care.nhs.uk website and can be used to help local NHS staff make the case for adoption in their own Trusts.
- Showcase Hospitals also have a role in raising awareness of new technologies by reaching out into their local health economies through twice yearly educational and awareness conferences for local colleagues and through occasional targeted promotional days.

How does it work?

- Technologies with a Rapid Review Panel Recommendation 1 are placed in Showcase Hospitals, where they are evaluated in practice for up to 6 months.

Current Showcase Hospitals

- Calderdale and Huddersfield NHS Foundation Trust
- Country Durham and Darlington NHS Foundation Trust
- Imperial College Healthcare NHS Trust



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Local Technology Reviews at Showcase Hospitals – evaluating HCAI technologies that show promise

In addition to evaluating technologies with an RRP recommendation 1, each Showcase Hospital has undertaken to service evaluate infection related products or technologies in which they have a specific interest and adopt them as ‘local’ projects.

Local Technology Reviews

- Ultrasonics as an aid to hospital cleaning
- A training and awareness DVD on the transmission of infection
- Rapid screening for *C. difficile* compared to conventional screening methods
- Steam cleaning technology for the disinfection of ward equipment, furniture and the built environment
- Disposable blood pressure cuff covers
- A website for the public and patients providing information and advice on HCAI issues
- An IT system which allows data from a number of infection prevention and management-related hospital systems to be brought together, giving comprehensive information about patients with infections
- A 2% chlorhexidine-based infection-resistant lines protector
- A new sterile mat for use when dressing wounds and undertaking other clinical procedures
- A new hand hygiene awareness campaign.

Related ventures

- A London centre of expertise in infection prevention and cleaning related activities
- A study of challenges to the adoption and diffusion of new HCAI technologies in the NHS
- An investigation to gain a better understanding of procurement activities at Trust level.

“I have seen for myself the temporary infection prevention facilities designed as part of the Smart Ideas programme and feel sure that it will add real value in the fight against infection. I am delighted that this has been developed so quickly, with such a wide range of input from frontline staff in the NHS and such a close association with industry.”

David Nicholson, CBE Chief Executive

“The kits improved the usage of beds on wards where patients with MRSA could not all be accommodated in single rooms. Patients could be discharged from intensive care to the ward more rapidly. This flexibility means the additional efforts to get the design right for both staff and patients is well worth the effort.”

**Dr Peter Wilson, Consultant Microbiologist
University College London Hospitals**

An innovative way of procuring innovation

The Department of Health emphasises innovative procurement as one key strategy for improving the quality and efficiency of healthcare while securing better value for money for the taxpayer.

‘Necessity – not nicety: A new commercial operating model for the NHS and Department of Health’ states the need for a new commercial operating model which addresses past deficiencies to optimise the procurement of goods and services in order to maximise value, quality and patient benefit. Furthermore, the recent **‘Life Sciences Blueprint’** calls for radical action to bring about greater quality, innovation, productivity and prevention (the QIPP agenda) in order to establish the NHS as an innovation Champion.

The HCAI Technology Innovation Programme has made a pioneering contribution to the visions laid out in these documents by introducing the following radical new strategies to drive procurement.

- **Pre-commercial procurement**

Stimulated the development of future products by helping inform industry about what is needed and how best to develop and launch new technologies.

- **Front-end engagement**

Improving communication with the NHS front-line to identify unfulfilled needs and engaging NHS experts and industry specialists from the start of the innovation process.

- **Foster innovation**

Driven innovation by providing a space in which collaboration with experts and access to insider-knowledge is easily accessible, thereby reducing the risk to innovators and strengthening the foundations for successful development.

- **Fast-track new products**

Reduced the time taken to develop useful technologies and accelerating new products to market in record time.

- **Maximise private sector investment**

An open innovation model has stimulated innovators and companies to invest in technological development.

- **Demonstrate success**

Provided a successful model for open innovation for the NHS and potentially for the public sector more broadly and demonstrated how public procurement can be leveraged to help meet UK innovation requirements and stimulate UK industry.

"Innovation produces quality and productivity. Identify the need; evaluate if the needs were fulfilled (and what the beneficial impact would be) and then use pre-commercial procurement techniques to get it into the NHS as rapidly as possible. This plays straight into the Quality, Innovation, Productivity and Procurement agenda which is now being mainstreamed in the NHS."

Brian Winn Head of Technology & Product Innovation

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Geoff Sjogren, IDSc Director of Technical Support

Introduction

The recent 'draft' decontamination guidance, HTM 01-01 (series – excluding part A), and HTM 01-06 have been delayed. At the moment there is no release date, although I am told there were many comments submitted in relation to the endoscopy guidance.

The Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection – guidance from the Advisory Committee on Dangerous Pathogens TSE Working Group have updated and revised several parts of their guidance.

- Annex A1: Distribution of TSE infectivity in human tissues and body fluids (updated March 2010). This document states *“There is evidence that the distribution of the disease-specific partially protease-resistant form of prion protein (PrPTSE) in tissues is more widespread in the body in variant CJD (vCJD) patients than in patients affected by sporadic CJD. In sporadic CJD, the presence of abnormal prion protein in patients with clinical disease appears to be restricted to the central nervous system (CNS). However, abnormal prion protein has been detected in various lymphoid tissues, including tonsils, spleen, gastrointestinal lymphoid tissue (appendix and rectum). Lymph nodes, thymus and adrenal gland of patients with clinical vCJD. Abnormal prion protein has also been detected in lymphoid tissues within the appendix removed from 2 patients some 8 and 24 months before they developed vCJD suggesting that abnormal prion protein could be present in the lymphoid tissue of people incubating vCJD for some time before the onset of clinical disease.”*
- Annex J: Assessment to be carried out before surgery and/or endoscopy to identify patients with, or at increased risk of, CJD or vCJD (revised and updated 25 January 2010).
- Part 4: Infection control of CJD, vCJD and other human prion diseases in healthcare and community settings (revised and updated 25 February 2010).

These documents give very important information in relation to the management of surgical instrument decontamination. These documents will no longer be uploaded on to the IDSc Website as they are available on the Department of Health’s Website.

To find these documents please use the link below:
www.dh.gov.uk/ab/ACDP/TSEguidance/index.htm?ssSourceSiteId=en



Website

The new IDSc Website is working well. The forum does not seem to be used by members, and maybe a debate amongst the IDSc branches is necessary to discuss the use and need for this forum. If there are any comments about the Website and/or forum, could branch representatives please raise them at the next Board and Council meeting?

BSi Standards

Many more members have asked for access to the BSi Standards Collection, making it ever more popular. There are currently 49 standards freely available to members. In April, the IDSc is able to remove standards that are no longer current (under the terms of the BSi contract, changes to the site are only permissible in April of each contract year), and update the collection. If there are any standards that members would like to see on the site, please contact me. As mentioned previously: *“This is the most comprehensive decontamination standards collection for decontamination professionals that is available free. It is hoped that we will be able to seek further sponsorship to continue our IDSc subscription into 2013.”*




IDSc word search

The winner of the word search competition in the February edition is Karen Tweed, Leeds Teaching Hospital Trust, Leeds, LS1 3EX - congratulations and an iPod Shuffle will be winging its way to you thanks to Uniplex.

Win an iPod Shuffle by solving this wordsearch. All you have to do is:

- 1 identify all the words listed below.
- 2 identify the HIDDEN word.
- 3 add your name and address.
- 4 return the completed quiz to: Susan Meredith, Editor IDSc Journal, c/o Sterile Services, Southend Hospital, Pritwell Chase, Westcliff on Sea, SSO 0RY.

The first correct answer drawn from the hat by 18th June will win an iPod Shuffle donated by Uniplex UK Ltd 

General Enquiries: enquiries@beepo.co.uk or Phone: 0114 272 6858

Words to find:

barrier, capacity, centralised, challenge, choice, complex, compliant, corroded, diagnosis, effective, ethics, indicator, infection, matron, planning, process, records, technical, treatment, verify.

Use your powers of observation to find the **TWO HIDDEN** words:

CLUE 'Outside our control but impacts on everything we do' - 6 & 6 letters.

e	v	i	t	c	e	f	f	e	a	i	c	d	n	p
c	r	n	n	n	s	e	c	a	n	r	a	i	o	l
o	e	o	a	l	e	c	o	d	g	t	p	a	i	a
m	i	r	i	o	a	m	i	r	f	i	a	g	t	n
p	r	t	l	u	e	c	t	h	g	a	c	n	c	n
l	r	a	p	s	a	e	i	a	t	i	i	o	e	i
e	a	m	m	t	d	c	g	n	e	e	t	s	f	n
x	b	e	o	o	n	r	o	n	h	r	y	i	n	g
k	r	r	c	l	a	t	o	m	e	c	t	s	i	d
c	o	r	r	o	d	e	d	c	h	l	e	e	e	d
d	e	s	i	l	a	r	t	n	e	c	l	t	o	e
p	r	o	c	e	s	s	e	s	i	r	r	a	n	v
v	e	r	i	f	y	i	e	o	n	f	w	s	h	i
n	g	i	s	e	d	s	h	n	h	n	w	y	f	c
y	a	t	a	y	r	c	o	t	e	n	e	t	r	e

HIDDEN WORDS ARE: _____

Name: _____ Work tel. no. _____

Address: _____

Postcode: _____

Product News

These news items are provided by companies with an interest in decontamination products and services. The views expressed do not necessarily reflect the views of the Institute of Decontamination Sciences.

Work-based Medical Technologies Degree proves a winner

The first group of students to complete Eastwood Park's two year Medical Technologies Foundation Degree will all graduate in January next year. Those currently interested in joining the next course need to apply swiftly as the March intake closes mid-February.

One of the top students, Stuart Eccles, not only passed with distinction but also made the greatest contribution. He was recently recognised by IHEEM with the presentation of the "William E Schall Award for excellence in medical technologies". Stuart Eccles is part of the EBME team at the Countess of Chester Hospital.

This first student group on the work-based degree course came from all over the country with twelve on the medical equipment pathway and three on the decontamination pathway. Currently Eastwood Park has 44 students progressing through the degree course as it has grown in popularity.

According to Steve Dickson, Eastwood Park's Learning and Development Manager, the students played a key role in providing feedback on all aspects of the delivery of the Foundation Degree: "I was impressed by the enthusiasm of all the students and how they provided support for each other. We have been very appreciative of their feedback which has helped us to improve the experience for those following them."

The Medical Technologies Foundation Degree is still relatively new, having been established in 2007 by Eastwood Park in

partnership with Kingston University and in association with the Department of Health, Sector Skills Councils, SEMTA & Skills for Health, the MHRA, IHEEM, IPEM & IDSc. It was created to meet the needs of employers to ensure their skill requirements were being met, while enabling employees to remain in full-time employment yet with the opportunity to progress. The Degree is the next level on from NVQ level 3 in decontamination and medical equipment technology and enables students to access the Medical Technologies Management BSc honours degree. The majority of Eastwood Park's first student intake has continued their studies with Kingston University.



For more information about Eastwood Park's Foundation Degree, visit: www.eastwoodpark.co.uk/training or call 01454 262777.

Amsco® V-Pro™ 1 - a new solution for infection control



The Amsco V-Pro 1 Low Temperature Sterilization System provides infection control professionals with a convenient new solution for easily, safely and economically processing heat sensitive instruments.

BASINGSTOKE, UK - March 31st, 2010 - STERIS Ltd. has launched the innovative V-Pro 1 Sterilization System for low temperature processing of delicate instruments and electrical items without any risk of damage. Sterilisation is based on a relatively dry process designed to operate at low temperature using vaporised hydrogen peroxide (VHP®), and is effective against a full spectrum of pathogens, meeting the EN ISO 14937 standard for sterilisation processes.

The V-Pro 1 is a low overall cost solution for sterile processing as major installation, drainage or special environmental ventilation are not required and consumables are minimal. VHP is generated

by a single-use Vaprox™ cartridge in a completely enclosed system, preventing any user contact with hydrogen peroxide, and there are no toxic by-products, only water and oxygen, making the process truly environmentally friendly.

The system sterilises packaged instruments in wraps or pouches, maintaining sterility and fitting well into existing departmental processes. V-Pro 1 can process a large number of heat sensitive devices in one cycle, increasing productivity, and has been designed to tolerate moisture in dried loads where items can be difficult to dry completely. The user-friendly, easy-to-operate touchscreen controls a standard, pre-validated 55 minute cycle, and a countdown timer allows easy monitoring of the sterilisation process.

The Sterile Services Department at Southend University Hospital NHS Foundation Trust was the first UK department to benefit from the V-Pro 1. Susan Meredith, Sterile Services Manager, explained: "Previously we decontaminated our endoscopes in automated reprocessors but could not wrap them, which gave us a completely restrictive lifespan of only three hours before they had to be used. The V-Pro 1 is different from other sterilisers because it can sterilise flexible endoscopes without any detrimental effects, helping us to meet our CE registration requirements. The endoscopes can be wrapped and sealed as sterile packs, giving a shelf life of up to a year, which is ideal for transporting to off-site facilities, clinics and theatres."

For further information, contact:

Sarah Pilbrow
STERIS, STERIS House, Jays Close, Viables, Basingstoke, Hampshire, RG22 4AX.

Tel: +44 (0)1256 840 400 Fax: +44 (0)1256 866 503
Website: www.STERIS.com

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PRIORCLAVE renew their partnership with BioCote



Linda McKeaveney, BioCote's Customer Relations Manager, and Priorclave's MD Tony Collins, seal a partnership for a further two (three?) years.

Priorclave Ltd. manufacture quality autoclaves and offer solutions to the more complex problems of effective sterilisation, in particular, applications synonymous with laboratory requirements.

Priorclave Ltd. and BioCote Ltd have had a long-standing, exclusive agreement to incorporate the revolutionary BioCote® powder coating technology into the manufacture of their entire range of laboratory autoclaves. As a result, such has been the success of the combined technologies, they have renewed their partnership for a further two years.

The silver based, BioCote® coating technology incorporated into the exterior surfaces of the Priorclaves aids the fight against cross-infection by inhibiting the growth of a wide

range of micro-organisms, including bacteria such as E-Coli, Pseudomonas and the superbug MRSA within hospital, biochemical and pharmaceutical laboratory environments as well as food industry, research sectors and many others.

Since the launch of BioCote® the reduced risk of cross-infection and cross-contamination has been dramatic and has been proven to work through many environmental studies across many disciplines, the most recent of which has been undertaken within the nursing home sector.

A refurbished care home in Leicester was kitted out with a bedroom and ensuite containing BioCote® protected products and compared to similar untreated products in another refitted bedroom and ensuite. The combined average reduction in microbe levels was an astonishing 94.6% fewer on the BioCote® treated surfaces, similar to that seen at the trial conducted at the outpatients clinics within the Heart of England NHS Foundation Trust, where BioCote® treated surfaces demonstrated an overall average of 95.8% reduction. Together, both of these studies have been published in the Journal of Infection Prevention and the British Journal of Community Nursing.

No less vital is the maintenance of the hygiene standards within a busy working laboratory where the Priorclave surface will

be touched, inevitably, by operatives handling organisms during normal shared use of the equipment and is, therefore, likely to be an area where cross-contamination might be an issue.

Typical sterilisation applications cover media preparation, glassware and instruments, and waste disposal. All are critical in the maintenance of good hygiene practice and sterile working conditions. In this arena Priorclave continue to have a unique range of autoclaves with the capacity to inhibit the growth of bacteria, not only on the inside - but also on the outside.

This technology however, should be regarded as an enhancement to, and not a replacement for, good cleaning and sterilisation practice.

For full details of the Priorclave range of Laboratory Autoclaves please visit their website: www.priorclave.co.uk

For further information contact:

Mr. Tony Collins, Managing Director
Priorclave Ltd., 129-131 Nathan Way,
Woolwich, London SE28 0AB.

Tel: +44 (0) 208 316 6620

Fax: +44 (0) 208 855 0616

e-mail: sales@priorclave.co.uk

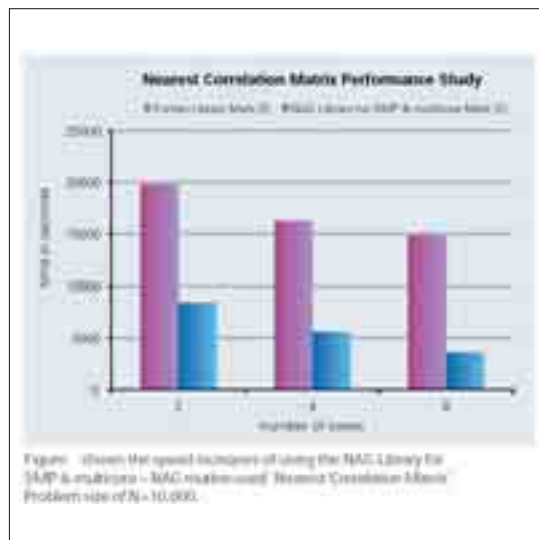
Web: www.priorclave.co.uk

New Numerical Algorithms for Medical Device Engineers - Release of the NAG Library for SMP and Multicore

Medical device engineers seeking better use of the processing power of multicore computer systems in addition to an easy way to migrate existing applications to multi processor architectures, can now download the **new NAG Library for SMP and Multicore** (http://www.nag.co.uk/downloads/downloads_entry.asp?pc=FS) from Numerical Algorithms Group (NAG).

Mathematical and statistical algorithms optimized for performance on multicore architectures have become key to progress in various aspects of instrumentation and sensor designs, advanced control engineering, materials' innovations and manufacture, and other aspects of medical device design and manufacture.

As Dr. Hartmut Schmider of the computational support team of the High Performance Computing Virtual Laboratory at Queen's University, Kingston, Ontario comments, "The NAG Library is very good for work on multiple cores because of the reliable parallel design of the algorithms. But it is also because of the common interface for both serial and multicore libraries. This enables users to speed up their code on many multiple core architectures with greatly reduced effort."



Product News

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Dental Decontamination opportunities for Audere Medical Services Limited



NHS and private dentists have been contacting Audere Medical Services Limited to advise and assist them in the implementation of the necessary processes and procedures to comply with the Essential Quality Requirements and Best Practice criteria of the recently introduced Department of Health Technical Memorandum 01-05.

Historically, the dental profession has not been required to adhere to the same strict standards of infection and decontamination control as other sectors of the healthcare industry. Manual decontamination processes were not monitored and the traceability of instruments was poor.

HTM 01-05 will raise the standard of infection control across the dental industry. One of the most demanding challenges dental clinics will face in the future to comply with HTM 01-05 is the requirement to properly sterilize all instruments and procedure equipment after ALL surgical procedures.

Audere Medical Services Limited are the largest independent service and validation organisation in the UK decontamination industry. Working with dental practices, Audere's multi-manufacturer trained team of engineers and technicians are servicing, validating and upgrading existing

equipment to the required HTM01-05 standards. They are also recommending suitable new or replacement equipment and training dental staff to ensure their safety when operating decontamination equipment.

Gareth Jones, director of Audere Medical Services Limited welcomes the new legislation and recognises the importance of enforcing infection control in dentistry. "This is a significant development for the dental industry. In 2000, a number of dental practices were visited as part of a survey of decontamination practices in the healthcare industry. The results of this survey identified a number of health and safety issues including the use of inappropriate decontamination processes and equipment. The introduction of HTM01-05 will make infection control an essential and regulated part of modern dentistry, minimising health risks to patients and dental staff."

Reusable and single use surgical instruments from Heeley Surgical Ltd

Heeley Surgical Ltd - Manufacturer of Surgical Instruments - Quality without compromise!

With unrivalled experience in the supply and design of surgical instruments - both single use and reusable, Heeley Surgical Ltd can be trusted to provide the very best quality products for all your surgical instrument requirements.

Our ultimate aim is to provide a solution to your needs whilst also saving you money.

We offer a unique service where an instrument maker/engineer is willing to discuss any technical problems that you may have and, where possible, provide you with a more suitable alternative.

As a highly skilled manufacturer we are also in the fortunate position to be able to re-engineer your Reusable items into Single Use - should the need arise.

Our Single Use instruments imitate their Reusable equivalents. All carry the wording Single Use and the worldwide Single use logo.

These can be supplied either Sterile (double peel pouched, with 3 or 5 years sterility, and tear off barcode providing full traceability) or Non Sterile.

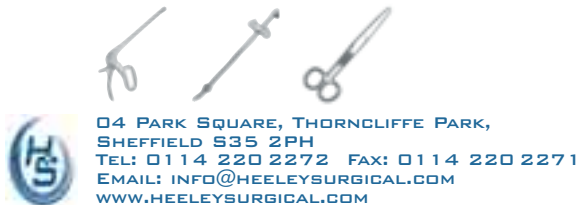
You, the customer, can also decide which instruments you would like to make up your sterile packs.

All products manufactured and supplied by Heeley Surgical Ltd comply with the requirements of recognised standards; these include British, European and International quality management systems ISO 13485.

All instruments carry the CE Mark and are made from the highest quality materials and carry replacement guarantees.

Managing Director, Alan Heeley, has 48 years experience in surgical instruments manufacturing and design - having been an instrument maker himself this provides Heeley Surgical Ltd with unrivalled expertise.

If Heeley Surgical Ltd can be of any help or service to you, or you would like to discuss any requirements you may have, please contact us - we would welcome the opportunity to provide you with any information or help you require.



Phoenix Surgical Instruments Limited



Phoenix Surgical Instruments Limited is a company specialising in the manufacture and supply of surgical instruments and have been trading for over 35 years. As well as being able to manufacture all types of general surgical instruments we also have the facility to manufacture one off and prototypes.

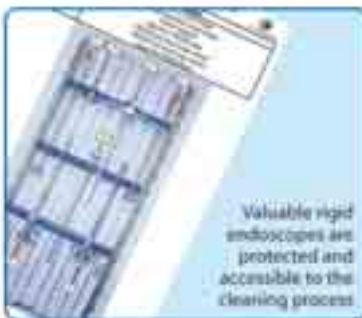
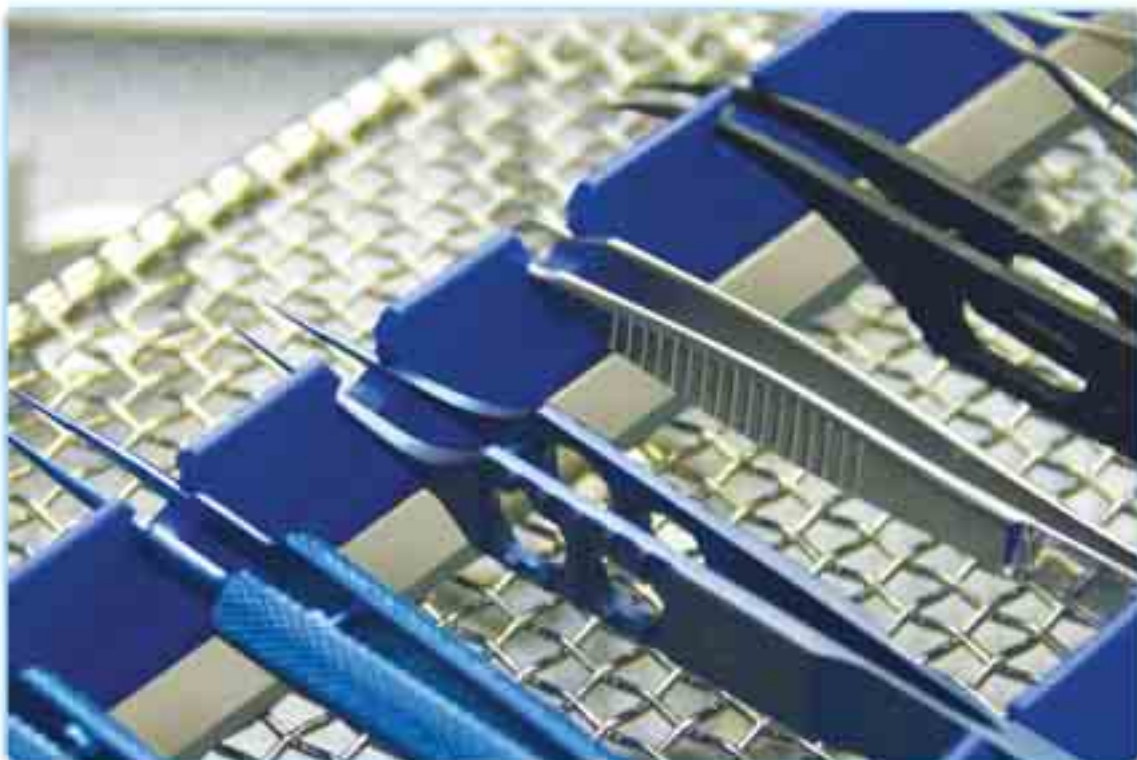
The repair of all types of instruments plays a major part of the business with many NHS and private hospitals on contract; we can repair all types of instruments including Monopolar & Bipolar equipment, Laparoscopic instrumentation, Telescopes and related instrumentation as well as air tools and dental drills.

If you are interested in using our services please contact the office:

Tel: 01992 479444. Fax: 01992 478878. Email: customerservices@phoenixsurgical.co.uk

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