EndoSheath® Technology
Infection Control Considerations

The reasons to consider using EndoSheath® Technology rather than conventional flexible scopes requiring high level disinfection between uses are numerous. The material in this binder relates to minimising the risk of cross-infection.

The Vision Sciences flexible endoscopes do not incorporate a working channel. Instead, following a prescribed aseptic protocol, they are fitted with a disposable sterile sheath which incorporates the working channel. In this way the patient is not exposed to a contaminated surface.

The following pages comprise:

1) A leaflet explaining EndoSheath® Technology

2) Aseptic EndoSheath technique (wall charts)

3) A 21st century nosocomial issue with endoscopes
BMJ 2014; 348 doi: http://dx.doi.org/10.1136/bmj.g2047 (published 19 MArch 2014)

4) Decontamination Risk Assessment
Diane Lumley BArnet and Chase Farm Hospitals

5) A comparison between "sterilised" cystoscopes and disposable sterile sheaths
Steve McCombie, Sarah J. Wood et al. (Norfolk & Norwich University Hospital)
Journal of Clinical Urology Feb 2013

6) Outpatient Flexible cystoscopy using a disposable slide-on Endosheath system
M Kimuli, S Lloyd Ann R Coll Surg Eng, 2007: 89: 426-430

7) Microbiologic Assessment of Disposable Sterile Endoscopic Sheaths
Alvarado CJ et al Am J Infect Control 2009;37:408-13

8) Endoscope Sheaths as Viral Barriers: Laboratory FDA Study
Baker KH et al Laryngoscope 1999;109:636-9

Contact Genesis Medical for further information, a PowerPoint presentation on the Infection Control considerations, copies of referenced papers, a bibliography of relevant peer reviewed papers. Much material is available on the website: www.genmedhealth.com

September 2014

VISION® sciences

VISION® sciences

Infection Control
with EndoSheath® Endoscopy

EndoSheath® Technology

The sterile, disposable solution for flexible endoscopy

EndoSheath® Technology is not your typical barrier. Designed to offer a strong, durable, proven effective microbial barrier, this is not just a simple cover. By providing a barrier between the endoscope and patient, EndoSheath® Technology allows for less complicated cleaning and disinfection routines, and improves equipment turnaround time. All the difficult-to-clean endoscope components with EndoSheath® Technology are disposable, including: the barrier, the channels, the ports, and the seals. Clinically proven, EndoSheath® Technology allows for efficient, effective endoscope reprocessing in any setting.

With *EndoSheath® Technology* there is strength in numbers…

- **20+** years on the market
- **30+** FDA clearances
- **37+** systems with CE Mark
- **9+** systems with HealthCanada license
- **5+ million** procedures performed worldwide
- **0 cross-contamination complaints**

Reusable Endoscope

with sterile, disposable EndoSheath® Technology

EndoSheath® Technology

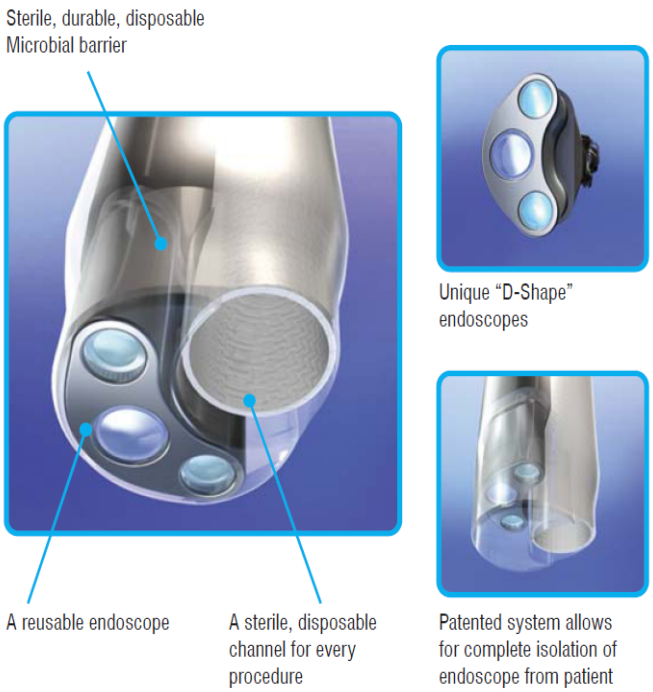
A brand with strength.
A name you can trust.

Pioneering Infection Control
with EndoSheath® Endoscopy

EndoSheath® Advantages:

- EndoSheath® Technology is a proven effective barrier to organisms as small as 27 nanometers per FDA requirements and testing
- Over 5 Million EndoSheath® products sold over 20 years without a single reported complaint of patient-to-patient cross contamination
- EndoSheath® Technology is designed to stretch and maintain its integrity, and not to tear or break during procedures
- All EndoSheath® disposables are 100% leak tested during manufacturing with a 0% acceptable failure rate for production
- All barriers, channels, ports, seals, and tubing are sterile and disposable
- Concerns over biofilm, bioburden, and issues of improperly rinsed devices are eliminated for patient contact areas, as they are always new, sterile, and disposable
- Easy to use and prepare limiting the complexity of endoscopy preparation routines
- Compatible with standard accessories such biopsy forceps, needles, and other endoscopic devices
- Over 30 research studies performed on EndoSheath® Technology since 1992
- Disposables feature a 3-year shelf life
- EndoSheath® Technology is FDA cleared and CE marked

Innovative Solutions:



About Vision-Sciences, Inc.

Vision-Sciences,Inc. has brought pioneering concepts to the world of flexible endoscopy for over 20 years. With the patented EndoSheath® Technology and innovative endoscope designs, Vision-Sciences,Inc. has transformed the economics of flexible endoscopy while enhancing patient safety for Otolaryngology, Gastroenterology, Urology, and Pulmonology practitioners. Vision-Sciences has made a commitment to help physicians transform their practices with the EndoSheath® Technology.

Currently available for:
Bronchoscopy, Cystoscopy, Esophagoscopy, and Laryngoscopy

Request a **Clinical Research Summary** or an Official EndoSheath® Technology **Infection Control package:**

Call **800-874-9975** or visit **www.visionsciences.com**

Vision-Sciences, Inc.
40 Ramland Road South / Orangeburg, NY 10962
Telephones: 800-874-9975 / 845-365-0600 / Fax: 845-365-0620
E-Mail: info@visionsciences.com

CE 0843

www.visionsciences.com

© Vision-Sciences, Inc. Vision Sciences, EndoSheath, and Slide-On are registered trademarks of Vision-Sciences, Inc. Covered by one or more of the following U.S. Patents: 5,337,734; 5,443,781; 5,520,607;6,350,231;6,530,881; 6,579,582; 6,733,440; 7,025,923. Other U.S. and international patents pending.

PL13203 Rev B 06/2011

genesis ENDOSCOPY

for innovation, for reliability, for peace of mind

Vision Sciences Endoscopes and EndoSheath ® Technology Preparation Wall Chart

PRECAUTIONS:

- Endoscopes and EndoSheath® Technology should not be used without a thorough review and understanding of the User's Manual.
- Before inserting the Endoscope into the Sheath, ensure that the insertion Tube is Clean, Dry and Undamaged.
- Review the User's Manual for Recommended Cleaning procedures for the Endoscope.
- If setting up for sterile field, double-glove with sterile gloves.

BEFORE THE PROCEDURE - SET UP

STEP 1

Carefully place Sheath contents in sterile field.

STEP 2

Double glove, Sterile. Apply drape bag to installation stand

STEP 3

Place Sheath into installation stand with accessory port facing out

STEP 4

Gently insert Scope into Sheath with the endoscope label facing forward and the flat edge of the insertion tube against the flat edge of the Sheath connector opening

IMPORTANT NOTE

The tip of the scope MUST be straight when placing into Sheath. If there is any resistance in loading, verify that the Sheath channel is properly aligned. If the channel is misaligned / twisted, straighten the channel before continuing scope insertion

STEP 5

Lock Sheath to Scope by turning knob 90⁰ (horizontal)

STEP 6

Deflect Scope tip to ensure Sheath window is seated properly.

STEP 7

When applicable insert irrigation/suction tube through the flow control valve.

STEP 8

Attach the end of the irrigation/suction tube to an irrigation/ suction source.

IMPORTANT NOTE

When using a CV-1.5 Sheath, attach the irrigation source tubing directly to the sheath connector accessory port.

STEP 9

If setting up sterile, remove outer gloves. Unfold cover over control body of Scope and secure with clips.

STEP 10

Ready for use. Verify angulation function and water flow/suction before use.

AFTER THE PROCEDURE - REMOVAL

STEP 11

Double glove before starting removal process. Re-insert Scope into stand, detach clips and move control Body Cover without contaminating handle. Remove outer gloves.

STEP 12

Detach irrigation/ suction Tube from the Flow Control Vale and Water Source.

STEP 13

Unlock Sheath rom Scope by Turning the Locking Knob to the Vertical Position.

STEP 14

Remove Scope from Sheath.

IMPORTANT NOTE

If resistance is felt during removal. STOP, Make sure the sheath and Scope are STRAIGHT and ensure the channel is not wrapped around the insertion tube. Use the drape bag as a barrier between the fingers and sheath, gently grasp the window of the Sheath and remove the Scope WITHOUT rotating the Scope

STEP 15

Deposit used Sheath and gloves into drape bag and dispose as per hospital policy.

EndoSheath® Technology

VISION® sciences

Vision-Sciences, Inc.
40 Ramland Road South / Orangeburg, NY 10962
Telephones: 800-874-9975 / 845-365-0600 / Fax: 845-365-0620
E-Mail: info@visionsciences.com

Genesis Medical Ltd
7 Trojan Business Park
Cobbold Road
London NW10 9ST
Tel: +44 (0)20 8451 4100
Fax: +44 (0)20 8451 4115
Website: www.genmedhealth.com

genesis ENDOSCOPY

for innovation, for reliability, for peace of mind

Endoscope with EndoSheath® Technology

Reprocessing Chart for Recommended Cleaning Procedure

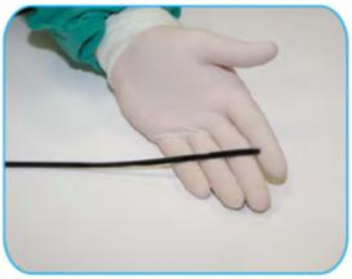
The EndoSheath® Technology is a sterile, disposable, durable protective barrier which isolates an endoscope from patient contact, and limits the need for elaborate chemical disinfection or EtO sterilization procedures after every endoscopy procedure. EndoSheath® Technology allows for fast and effective reprocessing of an endoscope and ensures a sterile Insertion Tube for every patient.

IMPORTANT NOTES:

1. Users should review complete manufacturer's guidelines for equipment disinfection/sterilization found in the user's manual.
2. Users should review EndoSheath® Technology installation/removal process found in the user's manual.

WARNING: This chart is only for reprocessing of Vision Sciences® endoscopes using EndoSheath® Technology

Remove endoscope from Sheath and place in a clean/Sterile area. Do not handle the endoscope with contaminated gloves



After removing the Sheath, Inspect the endoscope insertion tube and distal bending section and confirm these areas are dry and undamaged.

NOTE

If the endoscope was dry when the sheath was fitted it will be dry when removed. If moisture is observed, this could indicate a breach of the sheath and high level disinfection can be considered. If high level disinfection is decided upon, the endoscope must be prepared according to instructions in the user manual.

CLEANING AN INTERMEDIATE LEVEL DISINFECTION (after each procedure)

Gently wash all external surfaces of the endoscope with an appropriate instrument grade detergent or EndoWipe™ Enzymatic sponge

After washing thoroughly rinse the outside of the Endoscope with clean lukewarm water.

Wipe down the entire Endoscope with Gauze soaked in 70% ethyl/isopropyl alcohol or an EndoWipe™ Towelette . Ensure full coverage of alcohol

Ensure all external surfaces of the Endoscope are dry prior to installing another Sheath.

LEAK TESTING (If a leak is suspected & if high level disinfection is needed)

Connect the leak tester to the endoscope's EtO/vent valve. Push down and rotate the leak tester connector clockwise until it is secured.

Pressurise the Endoscope. Ensure leak tester's valve is closed. Pump the hand bulb until the needle reaches the green section. Maintain pressure for 10 seconds, observing the needle position. Endoscope may require several pumps of the bulb to completely pressurise

If the needle position remains steady. Immerse the entire scope in water and observe if for 30 seconds. Angulate the distal bending section up and down while the Endoscope is immersed. The absence of air bubbles confirms the scope is air tight. Remove from water and open the leak tester's valve. Ensure the needle on the pressure gauge fails to zero and disconnect the leak tester from the endoscope.

NOTE

If the pressure decreases the leak tester connection may be loose or the pressure valve on the leak tester may be open Re-attach the leak tester. If the symptoms persists, contact Genesis Medical. A small stream of bubbles indicates a leak in the endoscope that was not detected by pressure gauge. Do not continue to use a leaking endoscope and contact Genesis Medical for repair.

EndoSheath® Technology

In the event that high level disinfection/sterilization is required, please refer to the protocols in the user's manual for proper steps to ensure complete and efficacious reprocessing.

Vision-Sciences, Inc.
40 Ramland Road South / Orangeburg, NY 10962
Telephone: 800-874-9975 / 845-365-0600 / Fax: 845-365-0620
E-Mail: info@visionsciences.com

Genesis Medical Ltd
7 Trojan Business Park
Cobbold Road
London NW10 9ST
Tel: +44 (0)20 8451 4100
Fax: +44 (0)20 8451 4115
Website: www.genmedhealth.com

This site uses cookies. By continuing to browse the site you are agreeing to our use of cookies. Find out more here

LUPUS SCIENCE & MEDICINE™

LUPUS FOUNDATION OF AMERICA / BMJ

BMJ

Feature

Feature

A 21st century nosocomial issue with endoscopes

BMJ 2014; 348 doi: http://dx.doi.org/10.1136/bmj.g2047 (Published 19 March 2014)
Cite this as: BMJ 2014;348:g2047

Anne Marie Noronha, senior associate[1],
Steve Brozak, president[1]

Author Affiliations

1WBB Securities, 67 Walnut Avenue, Clark, NJ 07066, USA

sbrozak@wbbsec.com

Endoscopic procedures provide lifesaving diagnostic information, but do they put patients at unnecessary risk of deadly infection from cross contamination?

On 3 January 2014 the results of a year long investigation by the US Centers for Disease Control (CDC) into an outbreak of New Delhi metallo-β-lactamase (NDM)-producing carbapenem resistant Enterobacteriaceae (CRE) were released. Of 69 patients with confirmed CRE infections, 29 went to Advocate Lutheran General Hospital (ALGH) for the same procedure—an endoscopy.[1] The endoscopy itself is not dangerous, but the current cleaning process used between procedures leaves patients susceptible to infection and troubles many healthcare practitioners.

With more than 18.6 million gastrointestinal endoscopies and at least a half million bronchoscopies every year in the US alone,[2] medical practitioners must take the utmost care during the cleaning process between patients, especially with the emergence of superbugs such as CRE. But the safety profiles of the cleaning protocols are less than acceptable in preventing life threatening outbreaks. The endoscopes are frequently the means for facilitating pathogenic cross contamination between patients—making the case at ALGH far from unique.

The threat of cross contamination may not be visible to a clinician from personal experience alone, but broader and more comprehensive studies show that the cleanliness of endoscopes varies greatly. A mid 2013 study reported that about 15% of endoscopes in US hospitals failed to achieve an accepted standard of cleanliness after liquid reprocessing (the prevailing disinfection process used between patient procedures).[3] In this study, duodenoscopes were the dirtiest at a 30% contamination rate, and colonoscopes were the cleanest at a 3% contamination rate.[3]

All in all, reprocessing is time consuming, labor intensive, expensive and, most importantly, susceptible to failure. Among the most problematic features of an endoscope are the luminal channels, which often become contaminated by endoscope accessories.[4] The lumen are difficult to access and can easily harbor pathogens through multiple reprocessing procedures,

even when the protocol is followed correctly.4 Not only must the cleaning protocol be followed strictly, but the equipment and reprocessing environment also must be well maintained.5 Disinfectants and cleaning materials for endoscopes are often contaminated themselves in these incidents.6

Ironically, the commonly used liquid reprocessing procedure is sometimes called "liquid sterilization" even though it does not sterilize the instrument. According to guidelines from the Society of Gastroenterology Nurses and Associates, Inc. (SGNA) the protocol requires up to 43 steps and, according to another study, over half an hour of labor. 5 7 To begin, debris is removed during pre-cleaning. Next, leak testing makes sure that all internal channels are intact and that no holes contribute to instrument contamination. The scope then must be taken apart to allow access for manual cleaning, which removes any foreign material that may interfere with disinfection. The endoscope is then immersed in a high level disinfectant.5 The disinfectant must be potent enough to remove contaminants, yet gentle enough to preserve the integrity of the instrument, since a disinfectant that is too concentrated may decrease the life span of the instrument.8 The scope is then rinsed, dried, and stored.5 The SGNA also offers several guidelines for maintaining the cleaning reprocessing environment to help make reprocessing as effective as possible.5

Regrettably, endoscope contamination is not a new phenomenon. In 2006 Seoane-Vazquez and colleagues reported meta-data analysis on all available contamination incidents in the US during the 30 year period between 1974 and 2004.6 Research showed that 10 989 patients were exposed to a contaminated instrument and 740 patients were contaminated (although not all reports stated how many were exposed).6 The implicated types of endoscopy varied. Bronchoscopy and gastrointestinal endoscopy contributed the highest numbers of incidents (see table 1⇓); and upper GI endoscopy infected the most patients per patients exposed (see table 2⇓).6 The infectious agents identified the most were *Mycobacterium tuberculosis* and *Pseudomonas aeruginosa*, both of which are life threatening and have associated antibiotic resistant strains.6

Table 1 Patients exposed to endoscope related contamination by type of intervention (1974-2004

Intervention	Outbreaks reporting patients contaminated
Arthroscopy	1
Bronchoscopy	35
Cystoscopy	3
Endoscopic retrograde cholangiopancreatography	7
Lower gastrointestinal endoscopy	12
Upper gastrointestinal endoscopy	10
Gastrointestinal endoscopy*	1
Total	69

*Outbreaks not included in lower or upper GI endoscopy.

Data only include outbreaks that also report patients exposed.

Adapted from: Seoane-Vazquez E, Rodriguez-Monguio R, Visaria J, Carlson A. Exogenous endoscopy-related infections, pseudo-infections, and toxic reactions: clinical and economic burden. *Curr Med Res Opin* 2006;22:2007-21.

Table 2 Ratio of patients exposed to patients contaminated by type of intervention

Intervention	Number of outbreaks	Number of patients exposed	Number of patients contaminated	% contaminated
Arthroscopy	1	352	7	2.0
Bronchoscopy	15	4001	270	6.7
Cystoscopy	2	773	25	3.2

Endoscopic retrograde cholangiopancreatography	4	554	38	6.9
Lower gastrointestinal endoscopy	4	4179	42	1.0
Upper gastrointestinal endoscopy	3	1130	107	9.5
Total	29	10<thin>989	489	4.4

Note: Data only include outbreaks that report patients exposed and patients contaminated.

Adapted from: Seoane-Vazquez E, Rodriguez-Monguio R, Visaria J, Carlson A. Exogenous endoscopy-related infections, pseudo-infections, and toxic reactions: clinical and economic burden. *Curr Med Res Opin* 2006;22:2007-21.

Owing to limited surveillance, limited reporting, and lack of immediate clinical symptoms of patients, experts agree that the endoscopic cross contamination is significantly under-reported and its incidence cannot be accurately determined.6 Outbreaks that are recognized usually involve severe or unusual pathogens, which then prompt thorough investigations.6 If an older patient contracts tuberculosis, a doctor is not likely to suspect that the patient's latest endoscopy is implicated, even though *M tuberculosis* transmission represents a significant proportion of recent outbreaks.6 Even so, since 2000, several outbreaks of life threatening pathogens have been traced to contaminated endoscopes in facilities throughout the US and Europe.9 10 11 12 13 14 15 16 17

In 2009, 11 000 patients were notified of possible infection after the US Department of Veterans Affairs (VA) learned through an internal investigation that only 42.5% of its endoscope reprocessing units were adequately cleaning endoscopes.18 Because US government agencies are generally required to publicly divulge their findings, the VA's information may provide better representation of all endoscope facilities, including those that are not subject to the same mandated reporting.

Infections resulting from scope contamination break the trust between patients and doctors and place a financial burden on healthcare institutions. Two VA patients (one with hepatitis C and the other with HIV) successfully sued the federal government.19 20 The statute of limitations meant an unfortunate veteran who was infected with hepatitis B could not seek compensation because the time limit had expired before he learned that he had been infected.20

Following an outbreak last year at the Neosho Memorial Regional Medical Center, substandard scope cleaning was detected and 244 patients were notified of possible exposure to HIV, hepatitis B, and hepatitis C.17 In 2002, an outbreak of *P aeruginosa* infected at least 32 of 414 exposed patients at Johns Hopkins Hospital and may have played a role in three deaths.10 At an unnamed Texas hospital in 2009, an arthroscope transmitted the same bacteria to seven patients.11

Among those healthcare organizations that were able to determine the exact cause of their disease outbreaks, the lumen of the endoscope was most often found to be the chief culprit.4 The lumen, through which auxiliary equipment such as biopsy forceps can be threaded, is difficult to clean and inspect, making it an easy place for bacteria to hide.4 In 2001, three consecutive outbreaks in one French hospital were caused by a loose port at the entrance of one luminal channel.12 The resulting infection rates were 117 out of 418 scoped patients.12 In 2003, two implicated bronchoscopes in a different French hospital had damaged lumens, which were promptly replaced. In this incident, 4 of 16 scoped patients were infected.13

Despite the high rate of endoscope contamination and published outbreaks resulting from such contamination, the medical community tends to attribute mishaps to negligent cleaning and human error. The Emergency Care Research Institute, which lists inadequate reprocessing of endoscopes as one of its "2014 Top 10 Technology Health Hazards," asserted that guidelines should be continuously reviewed and technicians should be better trained.21 However, this advice is over two decades old and the problem still persists. The CDC has also been warning about cross contamination since 199122 and other medical organizations have concurrently tightened procedural guidelines.23 24 Meanwhile, the proportion of incidents caused by equipment defects and cleaning equipment contamination (not human error) has since risen, according to the 30 year US based study.6 Additionally, not all incidents covered in the study were reported to have had an in-depth investigation into the causality of events; thus, human error could be an assumption in many of the cases.6

As past experience demonstrates, even the most stringent liquid reprocessing guidelines do not prevent outbreaks. The complexity of reprocessing protocols and the intricacy of endoscope design are inherent flaws, because they foster statistically predictable failures that allow pathogens to persist on the endoscope, particularly in the luminal channels[4 12 13] and in the cleaning equipment and detergent.[6]

One of the very few positive outcomes of a contamination incident is the change of disinfection practices that follows. After its superbug outbreak, the ALGH switched to ethylene oxide gas sterilization.[1] Alternatively, several other facilities in the US and the UK have begun using sterile disposable sheaths on scopes and have reported improvements in safety.[7 25 26 27]

The sheath provides a single use sterile barrier between the scope and the patient without hindering functions such as visualization and biopsies. The device incorporates a sterile "working channel" that allows equipment such as biopsy forceps to pass through unhindered.[27] Studies show that using the sheath, along with a simple alcohol wipe down between uses, guarantees sterility, offering a vast improvement over current decontamination procedures.[26 28] Even if there is a defect in the integrity of a single sheath, research confirms that the second sheath prevents contaminants from infecting the next patient.[25] The central idea behind the sheath is that a pathogen cannot overcome it. Because each sheath is used only once, pathogens cannot hide on the outside of sheaths or become resistant to disinfecting liquids. One added benefit to using sheaths, which no other decontamination protocol offers, is protection against prions, such as that which causes Creutzfeldt-Jakob disease.[28]

By using sheathed endoscopes, healthcare facilities will spend less on labor and equipment[7 27] and avoid exposure to noxious chemicals.[7 26] Although acquiring new endoscopes that accommodate sheaths may require an initial investment, the scopes are less expensive than unsheathed models and better in terms of long term benefits in patient care, efficiency, and lower operating costs.[27] The sheath eliminates unreliable and cumbersome reprocessing, condensing the protocol into just a few steps, and reduces reprocessing time by up to 31 minutes.[7] It also is more cost effective, reduces repair costs, and decreases investment in multiple scopes that are out of operation while being cleaned.[7 26 27]

Other sterilization methods exist for endoscopes, but each has its drawbacks in terms of safety, efficiency, and cost. Ethylene oxide gas sterilization is a toxic and carcinogenic process, requiring additional time for a post-sterilization aeration period.[8] Hydrogen peroxide gas plasma sterilization also has a long processing time, is expensive, and can be corrosive to certain materials. Neither of these methods protects against prions.[8]

The advent of antibiotic resistant bacteria such as CRE and deadly viruses requires that cleaning standards be continuously improved. Just about every invasive instrument we use is sterilized better than the endoscope. Syringes and needles are almost universally disposable and many surgical instruments are subjected to intense heat and pressure between uses. Endoscopy demands the same standards, because the instruments come into contact with or break the delicate mucosal membranes.

In 2013, the UK Department of Health (DH) recommended a "tracking, traceability and audit trail" designed to systematically expose instances of cross contamination before becoming widespread.[21] US outbreaks between 2000 and 2004 lasted an average of 84 days,[6] and the recent CRE outbreak at ALGH lasted the full year,[1] highlighting the importance of a vigilant surveillance system. The system proposed by the DH will provide the medical community with a more accurate and active survey of epidemiology, and hopefully push its constituents to replace liquid decontamination with a more effective alternative.

The *BMJ* is an appropriate venue for this discussion because of its undeterred criticism of conformist practices with the intent of improving healthcare. In 2012, the *BMJ* addressed nosocomial infection in an article titled "Dirty, deluded and dangerous" by Gary L French,[29] which exposed the recent trend of doctors who wash their hands much less frequently than expected.[30]

The issue of scope cross contamination and the growing incidence of negligence in hand washing have a common historical background. In the 1800s, most European physicians rejected the theories of Ignaz Semmelweis,[31] who proposed that hand washing would lower the postpartum mortality rate.[32] Since the advent of antibiotics, doctors have paid less attention to the value of meticulous sterilization.[29] However, with the recent appearance of superbugs, we need to be more mindful of careful

sterilization.

We must not make the same mistake as Semmelweis's contemporaries, who remained passive as their patients suffered the consequences of doctors with dirty hands while a simple, lifesaving alternative was sensible, affordable, and available. Like hand washing in Semelweis's day, better procedures for cleansing and even sterilizing scopes between uses are mandatory to prevent cross contamination, prevent infection, and potentially save lives.

Notes

Cite this as: *BMJ* 2014;348:g2047

Footnotes

- Competing interests: I have read and understood the BMJ Group policy on declaration of interests and have no relevant interests to declare.
- Provenance and peer review: Not commissioned; externally peer reviewed.

References

1. ↵
Centers for Disease Control and Prevention (CDC). Notes from the field: New Delhi metallo-ß-lactamase–producing Escherichia coli associated with endoscopic retrograde cholangiopancreatography. 3 Jan 2014. *www.cdc.gov/mmwr/preview/mmwrhtml/mm6251a4.htm.*
2. ↵
Peery AF, Dellon ES, Lund J, Crockett SD, McGowan CE, Bulsiewicz WJ, et al. Burden of gastrointestinal disease in the United States: 2012 update. Gastroenterology2012;143:1179-87.
CrossRefMedlineWeb of Science
3. ↵
Bommarito M. A multi-site field study evaluating the effectiveness of manual cleaning of flexible endoscopes with an ATP detection system. Abstract #040 APIC 2013 annual conference, 9 June 2013.
4. ↵
Hervé R, Keevil CW. Current limitations about the cleaning of luminal endoscopes. J Hosp Infect2013;83:22-9.
CrossRefMedline
5. ↵
Society of Gastroenterology Nurses and Associates, Inc. Standards of infection control in reprocessing of flexible gastrointestinal endoscopes. 2012. www.sgna.org/Portals/0/sgna_stand_of_infection_control_0712_FINAL.pdf.
6. ↵
Seoane-Vazquez E, Rodriguez-Monguio R, Visaria J, Carlson A. Exogenous endoscopy-related infections, pseudo-infections, and toxic reactions: clinical and economic burden. Curr Med Res Opin2006;22:2007-21.
CrossRefMedline
7. ↵
Krebs A, Borin JF, Kim IY, Jackson DJ, McDougall EM, Clayman RV. Evaluation of practice efficiency with a novel sheathed flexible cystoscope: a randomized controlled trial. Urology2007;70:883-7.
CrossRefMedlineWeb of Science
8. ↵
Sabnis RB, Bhattu A, Vijaykumar M. Sterilization of endoscopic instruments. Curr Opin Urol2014;24:195-202.
CrossRefMedline
9. ↵

Department of Veterans Affairs Office of Inspector General. Healthcare inspection: follow-up colonoscope reprocessing at VA medical facilities. 17 Sept 2009. www.va.gov/oig/54/reports/VAOIG-09-02848-218.pdf.

10. ↵

Srinivasan A, Wolfenden LL, Song X, Mackie K, Hartsell TL, Jones HD, et al. An outbreak of Pseudomonas aeruginosa infections associated with flexible bronchoscopes. N Engl J Med2003;348:221-7.

CrossRefMedlineWeb of Science

11. ↵

Tosh PK, Disbot M, Duffy JM, Boom ML, Heseltine G, Srinivasan A, et al. Outbreak of Pseudomonas aeruginosa surgical site infections after arthroscopic procedures: Texas, 2009. Infect Control Hosp Epidemiol2011;32:1179-86.

CrossRefMedline

12. ↵

Cêtre JC, Nicolle MC, Salord H, Pérol M, Tigaud S, David G, et al. Outbreaks of contaminated broncho-alveolar lavage related to intrinsically defective bronchoscopes. J Hosp Infect2005;61:39-45.

CrossRefMedline

13. ↵

Corne P, Godreuil S, Jean-Pierre H, Jonquet O, Campos J, Jumas-Bilak E, et al. Unusual implication of biopsy forceps in outbreaks of Pseudomonas aeruginosa infections and pseudo-infections related to bronchoscopy. J Hosp Infect2005;61:20-6.

CrossRefMedlineWeb of Science

14. ↵

Gonzalez-Candelas F, Guiral S, Carbo R, Valero A, Vanaclocha H, González F, et al. Patient-to-patient transmission of hepatitis C virus (HCV) during colonoscopy diagnosis. Virol J2010;7:217.

CrossRefMedline

15. ↵

Larson JL, Lambert L, Stricof RL, Driscoll J, McGarry MA, Ridzon R. Potential nosocomial exposure to Mycobacterium tuberculosis from a bronchoscope. Infect Control Hosp Epidemiol2003;24:825-30.

CrossRefMedlineWeb of Science

16. ↵

Aumeran C, Poincloux L, Souweine B, Robin F, Laurichesse H, Baud O, et al. Multidrug-resistant Klebsiella pneumoniae outbreak after endoscopic retrograde cholangiopancreatography. Endoscopy2010;42:895-9.

CrossRefMedlineWeb of Science

17. ↵

Ryan K. Patients at Chanute hospital possibly exposed to hepatitis, HIV. Wichita Eagle 16 Jul 2013. www.kansas.com/2013/07/16/2890467/patients-at-chanute-hospital-possibly.html.

18. ↵

U.S. Department of Veterans Affairs. VA continues notification process for veterans affected by reprocessing issues. Press release. 3 April 2009. www1.va.gov/opa/pressrel/pressrelease.cfm?id=1661.

19. ↵

Smiley D. Vet who contracted Hep C wins malpractice suit against VA hospital. Miami Herald 21 November 2012. www.miamiherald.com/2012/11/21/3108483/vet-who-contracted-hep-c-wins.html.

20. ↵

Hall KM. Court rules against Tenn. vet in colonoscopy case. Associated Press 1 June 2012. http://bigstory.ap.org/article/court-rules-against-tenn-vet-colonoscopy-case.

21. ↵

Emergency Care Research Institute (ECRI). 2014 top 10 health technology hazards. Health Devices. 2013. www.ecri.org.

22. ↵

From the Centers For Disease Control (CDC). Nosocomial infection and pseudoinfection from contaminated endoscopes and bronchoscopes—Wisconsin and Missouri. JAMA1991;266:2197-8.

CrossRefMedlineWeb of Science

23. ↵
ASGE Standards of Practice Committee, Banerjee S, Shen B, Nelson DB, Lichtenstein DR, Baron TH, et al. Infection control during GI endoscopy. Gastrointest Endosc2008;67:781-90.
CrossRefMedlineWeb of Science
24. ↵
U.K. Department of Health. Choice framework for local policy and procedures 01-06—decontamination of flexible endoscopes: operational management. 2013.
www.gov.uk/government/uploads/system/uploads/attachment_data/file/192522/Decontamination_of_flexible_endoscopes.pdf.
25. ↵
Baker KH, Chaput MP, Clavet CR, Varney GW, To TM, Lytle CD. Evaluation of endoscope sheaths as viral barriers. Laryngoscope1999;109:636-9.
CrossRefMedlineWeb of Science
26. ↵
Lawrentschuk N, Chamberlain M. Sterile disposable sheath system for flexible cystoscopes. Urology2005;66:1310-3.
CrossRefMedlineWeb of Science
27. ↵
Gupta D, Srirajakalidindi A, Wang H. Reduced turnover times make flexible optical reusable scope with EndoSheath® Technology significantly cost-effective. J Biomed Res2012;26:241-7.
CrossRefMedline
28. ↵
Winter SC, Thirwell A, Jervis P. Flexible nasendoscope with a disposable-sheath system versus standard nasendoscopy: a prospective, randomized trial. Clin Otolaryngol Allied Sci2002;27:81-3.
CrossRefMedline
29. ↵
French GL. Dirty, deluded, and dangerous. BMJ2012;345:e8330.
FREE Full Text
30. ↵
Boyce JM, Pittet D. Guideline for hand hygiene in health care settings. Recommendations of the Healthcare Infection Control Practice Advisory and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Infect Control Hosp Epidemiol 2002;23:S3-40.
31. ↵
Carter KC, Carter BR. Childbed fever: a scientific biography of Ignaz Semmelweis. Transaction Publishers, 2005.
32. ↵
Routh CH, Loud MD. On the causes of the endemic puerperal fever of Vienna. Lancet1848;2:642-3.

BMJ Group
Privacy and Cookie Policy
Website T & Cs
Revenue Sources
HighWire Press
Feedback
Help
© 2014 BMJ Publishing Group Ltd

DECONTAMINATION RISK ASSESSMENT FOR USE OF ENDOSHEATH TECHNOLOGY IN AN OUTPATIENT OR DAY SURGERY SETTING

Report Author: Diane Lumley, Head of Decontamination

1.0 Aim

To provide an overview of the benefits to the Trust for implementation of the Vision Science Endosheath Flexible Cystoscopy System (EFCS) and ensuring that uniformed standards of safe decontamination within an outpatients or day surgery theatre setting are maintained.

2.0 Objectives

To ensure that there are systems in place that as far as reasonably practicable, all cystoscopes are effectively decontaminated prior to use and that any risks associated with the decontamination environment and processes are adequately managed.

2.1 Inspection of decontamination environment
2.2 Identify applicable statutes
2.3 Identify hazards
2.4 Make recommendations to achieve compliance
2.5 Review information provided to staff, contractors, patients and visitors

3.0 Methodology

To ensure that the potential benefits to the Trusts of the implementation of the EFC System provides uniformed standards of safe decontamination enabling risk reduction, as far as possible balanced against the expected benefits.

4.0 Introduction

The Trust has accepted the use of Vision Sciences Cystoscopes covered by sterile sheaths following the prescribed US Foods and Drug Administration (FDA) protocol, however questions were raised by the Trust Infection Prevention & Control Team and Infection Control Doctor (Microbiologist) as to whether the procedure can be safely carried out in a standard operating theatre or day outpatient setting.

This report is based on Decontamination guidelines and statutory compliance.

4.1. Cystoscopy

Cystoscopy is the most frequently performed urological procedure and provides an invaluable tool for both diagnostic and surveillance in identifying lower urinary tract pathology and is currently performed in a clinical theatre setting.

Cystoscopy procedures are classified as *'Minor Procedures'*, (H. Humphrey et al. / Journal of Hospital Infection 80 (2012) 103-109) (Appendix I).

4.2 Cystoscope EndoSheath System

The EFCS is an alternative to conventional cystoscopy procedures and is designed to never come into contact with the patient. The reusable scope is protected from cross-contamination by a single-use sterile sheath. Also when used correctly the sheath eliminates the need to high-level disinfect between procedures.

The Vision Science cystoscopes are essential exactly the same as cystoscopes currently used within Barnet & Chase Farm provided by Olympus. There is however one exception, Vision Science cystoscopes do not have a working channel instead they are covered which provides a durable, protective barrier between patient and scope, as well as operating a disposable working channel. The scope has a lever to lock onto the disposable sheath and a depression valve for irrigation, the sheath incorporates a working channel for biopsy and ureteric stent removal.

4.3 Sterile Sheath

The use of a sterile sheath is supported within the Choice Framework for Local Policy and Procedure 01-06 (CFPP) (3.60 page 17), *'cleaning and disinfection is required even if single-use sheaths are used'.*

The EFCS is designed to reduce the risk of cross-contamination by providing a sterile, single-use barrier between the patient and the device. The cystoscope is covered by a sterile sheath incorporating the working channel which is the insertion tube that enters a body cavity.

The FDA have cleared the endosheath as a protective and proven barrier to micro-organisms as small as 27nm, which has been demonstrated to be an effective barrier to viral passages and states that *'the use of a disposable sheath eliminates the need for high-level disinfection between procedures'*.

Endoscopes used are contaminated with various types of microorganisms, if these organisms are not removed before subsequent use there is a risk of disease transmission to other patients. One method of decreasing this risk is the use of a sterile sheath that covers the insertion tube portion of an endoscope.

Following each procedure, it is recommended that the insertion part of the cystoscope is inspected together with the sheath to confirm their integrity. If a tear has occurred then the cystoscope will require decontamination through an automated process (EWD). No leak in a sheath has been reported.

4.3. Chlorine Dioxide Wipes

With the use of a disposable sheath research has concluded that the reprocessing step for the EFCS need not be high-level disinfected, but rather meticulous cleaning of the endoscope, followed by an intermediate-level disinfection step, combined with careful aseptic techniques.

The use of the three wipe system as confirmed as a compliant method of decontamination on non-lumened endoscopes, such as nasendoscopes in the CFPP provides a practical and highly effective way to decontaminate heat sensitive, non-lumened instruments. The three wipe system uses chlorine dioxide acting as a powerful oxidising agent providing an effective disinfection agent killing all organisms on a pre-cleaned surface within 30 seconds of the first application. The process is currently adopted for all nasendoscope reprocessing, transoesophageal echo TOE Probes, Transrectal and Transvaginal probes and provides high-level disinfection in a busy outpatient clinic setting in a relatively short time.

Chemical decontamination by the chlorine dioxide wipe system has been widely used by many hospitals for several years and episodes of cross- infection have not been reported, and neither is there any evidence to show that the use of chlorine dioxide leads to greater risk of cross-infection compared to processing endoscopes in a central decontamination unit. However, this system must be carried out according to a set protocol with standard operating procedures.

The application of the wipe system is subject to regular user training and comes complete with a fully traceable tracking system, which is externally audited providing a quality management audit trail. All users, doctors and consultants will be provided with Three Wipe decontamination training, which will be certificated.

Each stage of the three wipe process will be timed to ensure accurate application of the product.

4.4 Current Position

The six cystoscopes currently in use and under the existing PFI contract have reached the end of their useful life. The Trust PFI Partners Siemens are in agreement to replace them with the Endosheath System.

5.0 The Legal Environment

The Trust and its partners have a duty of care to patients, staff and visitor's.

Relevant statutes on this subject include:

5.1. The Choice Framework for Local Policy and Procedure (CFPP) - Decontamination of Flexible Endoscopes 01-06: offers best practice guidance on the management and decontamination of flexible endoscopes (14304 Page 6) and supersedes the relevant parts of HTM2030 (Page 7).

The CFPP is a suite of guidance documents that has replaced previous guidance supplied in the form of Health Technical Memorandum (HTM). The CFPP supports local decision making in the commissioning, regulation, management, use and decontamination of medical devices in acute care. It has been designed to support continuous improvements in the efficiency and outcomes in terms of safety, clinical effectiveness and patient experience with core principles centred on having an evidence base working with engineering standards applying a risk control approach with a view to *'progressive improvement'*, therefore risk assessment is essential in determining the decontamination of invasive medical devices. This is directly in line with the health policy direction being taken by the UK government for the modernisation of the NHS in England as outlined in the Health and Social Care Act 2012.

The Health and Social Care Act gives power to clinicians to make commissioning decisions and therefore advocates the adoption of an 'Essential Quality Requirements' (EQR) leading to 'Best Practice' (BP) approach to allow greater choice for commissioners across providers both within the NHS and private sector, using a risk-control approach to the management and decontamination processes for reusable medical instruments.

This risk assessment has been produced taking into account the requirements of BS EN ISO 14971:2012 *'Risk Management for Medical Devices'*, a key standard specifying a process for a manufacturer to identify the hazards associated with medical devices, to estimate and evaluate the associated risks, enabling control of the risks and to monitor the effectiveness of the controls. The requirements of this standard are applicable to all stages of the life-cycle of a medical device.

5.1.1 CFPP 01-06 Operational Management: Executive Summary

Scope**:** *'This document covers flexible endoscope management and decontamination only. Clinical issues relating to endoscopy or the manufacture of EWDs are not discussed. In addition this document does not cover the processing of flexible endoscopes used to examine sterile body tissues. These endoscopes should be sterile, possibly using low temperature gas sterilisation and may be the subject of future guidance'*

All cystoscopes pass through a non-sterile urethra which may or may not contain pathogens. The bladder is commonly believed to be sterile but work published in 2012 by the Journal of Clinical Microbiology showed this not to be the case (Appendix II).

5.1.2 CFPP Decontamination of Flexible Endoscopes Policy and Management – Decontamination Environment

'Examples of Essential Quality Requirements' (Page16)
States: *'Lumened instruments should be reprocessed using a validated automated process (where applicable) following the manual cleaning stage'*

- **The Endosheath cystoscope system is non-lumened therefore this 'Best Practice' requirement does not apply**

'Examples of Best Practice' (Page 17)
States: *'In Essential Quality Requirements, the environment where the decontamination process is carried out should be such as to minimise the risks of recontamination of instruments or the inadvertent use of incompletely decontaminated endoscopes and of cross-contamination of clean and dirty areas'*

- **This applies to the Endosheath cystocope decontamination process: Decontamination can be carried out in one environment provided the area has a dirty to clean flow**

There must be a clearly designated flow from dirty to decontamination (clean) which demonstrates the stages of the decontamination of the cystoscope. It is essential that the room floor area be adequate to support the full process of endoscope management and decontamination without compromising quality.

-

Single-Room decontamination unit for low throughput units is supported within the CFPP (Appendix VI)

It is important to ensure that the workflow within the department is from dirty to clean to avoid the possibility of recontamination of reprocessed endoscopes from surfaces contaminated by unprocessed devices, whilst using the Three Wipe System.

5.1.3 Theatre Setting: Bronchoscopy Theatre Day Surgery Barnet

The proposed theatre at Barnet is currently used to carry out Bronchoscopies for the therapeutic endoscopic procedures involving the airway. The theatre is at negative pressure as these procedures carry an increase of risk for air contamination with M. Tuberculosis in patient with known or undiagnosed tuberculosis, a disease spread by the airborne route. Negative pressure must be maintained in order to protect the worker and the environment. However, cystoscopy procedures are classed as a 'Minor Procedures', therefore special ventilation is not required, the only requirement is for both theatre and outpatient settings are: *'Natural ventilation, including the presence of opening windows but with a fly screen, is acceptable'*. (Appendix VII Table 1: H. Humphreys et al / Journal of Hospital Infection 80 (2012) – 'Other', page 107). HTM03-01 Part A Design and Validation 2007: Appendix 2 – Recommended Air-Change rates: 'Cystoscopy ventilation is not a critical factor in Infection Prevention'.

The theatre at Barnet is also used to carry out Transrectal procedures involving the use of probes, which are non-lumened. These are currently decontaminated using the three wipe system within the theatre environment.

An area has been identified adjacent to the theatre which would provide an adequate decontamination area but will require upgrading.

5.1.4 Outpatient Setting:

By nature outpatient environments can be crowded and poorly controlled. The EFCS does not have lumens and therefore in accordance with the CFPP can be reprocessed in an outpatient procedure room environment, provided dirty to clean flows are established. There are no special ventilation requirements for negative or positive pressure rooms.

5.1.5 CFPP Decontamination of Nasendoscopes (Non-Channelled Scopes)

Nasendoscopes are used for the examination of naspharynx, larynx and hypopharynx. They are short flexible endoscopes usually without lumens. The decontamination of these endoscopes requires the same standards of cleanliness and disinfection as other flexible endoscopes. All 'EQR' outlined in the CFPP 'Policy and Management' volume apply, except that nasendoscopes without lumens can be manually decontaminated using wipes and procedures validated for that purpose (3.59 Page 17).

Vision Science Cystoscopy Endoscopes are non-channelled so these guidelines apply.

Currently all Trust nasendoscopes are reprocessed in an outpatients setting, in one room with clearly defined clean to dirty flow.

5.1.6 Infection Control Asepsis Protocols

It would be advisable for the Infection Control Team to oversee the Aseptic EndoSheath technique applied by the Urology Team.

5.2 US Food and Drug Administration (FDA)

The FDA is an agency within the Department of Health and Human Resources. Companies that design, manufacture, repackage, re-label, and/or import medical devices into the United States are regulated by the FDA's Center for Devices and Radiological Health (CDRH). UK equivalent: Medicines and Healthcare Products Regulatory Agency (MHRA). The FDA's organisation consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency:

- Medical Products and Tobacco
- Foods
- Global Regulatory Operations and Policy
- Operations

The Vision Science EndoSheath Technology system (Video Cystoscope) manufactured by Vision Science has been approved by the FDA (December 2007) under Regulatory Class II demonstrating that it can be legally marketed for use on urology patients (Appendix III).

In addition a Laboratory FDA Study (Appendix V) researcher's recommended: *'that an endoscope reprocessing step be combined with the use of a disposable sheath'* and data indicated: *'that the step need not be high-level disinfection'.* Instead, they concluded that meticulous cleaning of an endoscope followed by intermediate-level disinfection should provide a safe instrument for otolaryngologic endoscopy'. The disposable EndoSheath has been cleared by the FDA as providing a protective barrier and has been demonstrated to be an effective barrier to viral passages.

6. The Health and Safety at Work etc. Act 1974

Places general duties on the employer under sections 2 and 3

7. The Management of health and Safety at Work Regulations

Requires duty holders to *'undertake a suitable and sufficient risk assessment'*

8. The Workplace Health, Safety and Welfare Regulations 1992

Encourages a more systematic and better organised approach to dealing with health and safety in all workplaces

9. Health & Social Care Act 2008: Code of Practice on the Prevention & Control of Infections and related guidance, supporting the NHS as set out in the Health & Social Care Act 2012

The Code of Practice Health and Social Care Act 2008 on the prevention and control of infections and related guidance, provides the standards for this aspect of patient care. Complementing this is the Department of Health guidance CFPP which will assist the Trust in complying with the decontamination guidance set out in the above Code of Practice and in meeting the Care Quality Commission (CQC) registration requirement on hygiene and infection control.

10. Joint Advisory Group on GI Endoscopy (JAG)

Joint Advisory Group Accreditation Unit, Royal College of Physicians confirmation of decontamination requirements (Appendix VI).
The letter clearly states that there are no JAG requirements regarding the use of EndoSheath cystoscopes, should the Trust decide to use this technology to improve patient care and service delivery there would be no restraints or conditions imposed upon them from JAG.

11. Identify Hazards

Cystoscopy is classified as a *'Minor Procedure'*, which under various disciplines may be performed outside a ventilated operating theatre.

11.2. CJD/vCJD

The greatest fear with regard to cross contamination is a prion-related disease such as vCJD. However, none of the decontamination systems, including washing, high-level decontamination using an automated process or autoclaving is 100% effective at eradicating prions. The risk of inducing disease using a sterile sheath process is likely to be extremely low.

It is advisable to monitor immuno-compromised patients undergoing cystoscopy procedures using the endosheath technology. Should an endoscope be used in a patient with suspected vCJD the cystoscope must be placed in quarantine immediately until the condition of the patient is known. If the patient is subsequently shown to be positive for vCJD the cystoscope should be destroyed.

11.3. Ineffective Use of Chlorine Dioxide Wipes

There is no evidence to show that a risk exists after following the protocol for endosheath cystoscope cleansing and disinfection with chlorine dioxide. As long as hospital personnel are properly trained in performing and adhering to this protocol, the risk of an endoscope being contaminated is extremely low.

11.4. Risk of Damaging the Endosheath Cystoscopy or sheath

Chlorine Dioxide will not impair the optical image resulting in mis-diagnosis of important pathology of the cystocope as the working channel forms part of the sheath. In the event of a tear to the sheath, the cystoscope must be processed using an automated endoscope washer disinfector.

11.5. Manual Cleaning Process

A manual cleaning process is not a validated process and does not form part of the CFPP. There is no requirement for the endosheath cystoscope to be manually cleaned before use, however manufacturer instructions recommend that the scope be manually wiped with an enzymatic cleanser, which forms part of the three wipe process.

11.5.1. Manual Cleaning Sink – Leak Testing

Leak testing is only required if a leak is suspected, or there is damage to the scope and it needs to be returned for repair. A fully decontaminated dry cystoscope is inserted into the sheath and it will remain dry. So after removal from the sheath, the scope must be inspected to ensure that it remains dry and not damaged. If the cystoscope is wet this will indicate that the sheath was perforated (although this has never been reported) before, during or after the procedure. If the scope is damaged then Vision Science requests that it must be leak tested and high-level disinfected before return. Leak testing can be carried out in any location.

A leak within a sheath will not result in cross-infection, the cystoscope would have been highly disinfected using the three wipe system and should a contaminated scope be aseptically covered by a sterile sheath following the correct protocol, then contamination could not pass on to the next patient through the sheath. This was shown in an FDA study: Laryngoscope: Volume 109(04) April 1999 – (636-639) Evaluation of Endoscope Sheaths As Viral Barriers.

Users will be trained to follow the correct protocol by Genesis and this should be overseen by Infection Control.

Theatre Setting: Ideally in a decontamination area with a double sink used for manual cleaning and leak testing, this is situated in the Day Surgery Endoscopy Decontamination Area. The side room once upgraded will provide a full decontamination area.

Outpatient Setting: The only manual sink area in the outpatient area of Barnet is situated in the Sluice Room. This is currently used to analyse and dispose of urine sample down the sluice. There is a sink available which would provide an adequate manual cleaning facility however the process of disposal of urine and manual cleaning or leak testing could not occur at the same time. Rigid local protocols will need to be written and adhered to so that the users of the cystoscope and nursing staff analysing and disposing of the urine sample both understand and work together. This will involve a minor change of the layout of the room and arrangements for access.

A letter of confirmation has been provided by the Trust AE(D), Peter Rust.

11.6. Transporting

All contaminated and decontaminated scopes will require transporting in sealed containers.

12 Recommendations

12.1 Weekly Ninhydrin Testing

Manual pre-cleaning is essential to remove deposits from lumens and around the controls of an endoscope and provides a critical step during the decontamination process. The endosheath cystoscope does not have lumens, but still requires cleaning this is completed by the first process of the three part wipe system. The cystoscope does have control buttons and requires specific attention to these areas when applying the wipe system, however in order to assess the level of contaminants that might remain on the cystoscope after the three wipe system has been applied, this is usually achieved by measuring qualitatively or quantitively the extent of protein residue. Residual protein detection is currently recommended by the Department of Health CFPP as a gauge of cleaning efficacy.

Technology providing levels of residual protein detection after washing and disinfection are available and the Ninhydrin Testing method is widely used within endoscopy and sterile service departments. It will provide accurate and reliable proteinaceous residue detection based on reagents strongly binding to amino acids and short peptides the constitutes of protein residues, this is neatly demonstrated by the use of ninhydrin testing. However, with most of these test they should be used caution owing to their lack of sensitivity but data provided by the manufacturers and training will ensure that the trust is provided with a protein detection process for the endosheath cystoscopes on a weekly basis of those difficult to clean area including all control buttons. This process will be closely monitored and audited. Training will be provided by the manufacturers.

SUMMARY

The CFPP supports local decision making, these documents are considered risk-control-based, allowing the 'user' to make active local choices on the precautionary strategies that are most suitable for both their local circumstances and the patient.

Whilst the trust must always strive towards achieving 'Best Practice', the endoscopy equipment within the trust has reached the end of it's useful life, although plans are in place for a modular unit with new endoscopy equipment the need for an alternative method of reprocessing to support the urology service is clearly evident.

- The CFPP recognises nasendoscopes as non-lumened and confirms that using a three wipe system is an adequate means of decontamination. Nasendoscopes used within the Trust are currently being decontamination using the three wipe system

- Nasendoscope reprocessing is carried out in an outpatient setting, with dirty to clean flow using one entrance

- The EndoSheath Cystoscope is non-lumened, therefore can be decontamination in accordance with the CFPP by using the three wipe system

- The CFPP supports the use of sheaths

- The CFPP allows decontamination in one room. There must be clear evidence of dirty to clean flow

- The EndoSheath Cystoscope does not require manually cleaning in a sink

- There is no requirement for cystoscopies to be carried out in pressurised settings

The outpatient environment provides a one-room decontamination environment, with use of the sluice area. It is advised that configuration of this room is carried out to allow both urine sample nurses access and decontamination processes should the need arise. Manual sink access within this area would provide a dedicated place for manual cleaning processes or leak testing should the need arise.

The day theatre environment provides a perfect opportunity for decontamination to be carried out in the adjacent room, this would require some enabling works and upgrade with manual sink and hand wash basin.

Both areas within Barnet Hospital, Outpatients and Day Surgery Theatre were visited by the Trust AE(D) Peter Rust, who is in agreement that there is no reason why this EndoSheath Cystoscope System cannot be adopted immediately within either setting.

All consultants have been provided with Tristel Three Wipe Training, refresher training will be provided.

RISK ASSESSMENT for ENDOSHEATH TECHNOLOGY

WARD / AREA / DEPARTMENT : Barnet Hospital	**TASK ASSESSED** : EndoSheath Cystoscopy
RISK ASSESSMENT NUMBER : 001	**DATE :** June 2014 **REVIEW DATE :** July 2014
Assessors : Diane Lumley Head of Decontamination	

Activity	Hazard and possible	Who or what is at risk and	Existing controls	Risk Rating (RR) Score S	L	(SxL)RR	Additional controls required
Only one Cystoscope must be used in the room at one time			Written Local Protocol				
Check all Cystoscope documentation to confirm its number, date, time and status of decontamination			Written Local Protocol				
Ensure patients details are identified and accompany the cystoscope to the decontamination room and the three wipe system is traceability book is correctly filled in			Written Local Protocol				
Cystoscopes must only be handled by staff trained in handling them. Staff must be regularly assessed as competent by means of documented training and assessment by an appropriate person. Competency documentation must be			Written Local Protocol				
retained by a Manager and copies available in the decontamination area							

Cystoscopes must only be used once fully decontaminated using the three wipe system			Written Local Protocol				
There must be a clearly defined clean and dirty demarcation area within the procedure room			Written Local Protocol				
Staff must wear full PPE at all times when undertaking the decontamination process			Written Local Protocol				
Cystoscopes must be wiped down immediately after the procedure			Written Local Protocol				
Staff must comply with the requirements of the COSHH Policy			Written Local Protocol				
Health Screening must be undertaken for all staff decontaminating the cystoscopes			Written Local Protocol				

Published online before print February 25, 2013

Journal of Clinical Urology **February 25, 2013**

Urinary tract infection following flexible cystoscopy: a comparison between sterilised cystoscopes and disposable sterile sheaths

Steve P McCombie; Jack P Carmichael; Srijit Banerjee; Sarah J Wood

Department of Urology, Norfolk and Norwich University Hospital, UK

Abstract

Objective: The objective of this article is to compare the incidence of post-cystoscopy urinary tract infections (UTIs) between cystoscopes sterilised between patients and cystoscopes that use removable sterile sheath technology.

Patients and methods: A total of 200 patients undergoing flexible cystoscopy at the Norfolk and Norwich Hospital (Norwich, UK) between November 2011 and March 2012 were identified prospectively as part of an ongoing audit of the department's services. One hundred patients were recruited from day procedure lists, using KeyMed® cystoscopes sterilised between patients (sterilised scope, SS); 100 patients were recruited from a 'one-stop' urology clinic, using a Vision Sciences® CST-5000 cystoscope with disposable sterile Endosheath® technology (removable sheath, RS). Mid-stream urine (MSUs) samples and patient symptoms were recorded prior to the cystoscopy and at least three days following the cystoscopy.

Results: No significant difference was found in the incidence of new MSU-confirmed UTI (2.7% (SS) vs. 2.0% (RS)). In those undergoing their first cystoscopy, no significant differences were found in either new symptoms (34.1% (SS) vs. 36.7% (RS)) or requirement for antibiotics (13.6% (SS) vs. 13.0% (RS)).

Conclusion: Flexible cystoscopy using removable sterile sheath technology does not have a higher incidence of UTI compared to a cystoscope sterilised between patients. The introduction of cystoscopes using this technology can therefore safely transform flexible cystoscopy into an outpatient clinic procedure.

Acknowledgements

This was an independent audit carried out by the authors with no involvement or funding being provided by KeyMed®, Vision Sciences ®, Tristel®, Sani-Cloth®or any other external sources.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of interest

The authors declare that there are no conflicts of interest.

The Royal College of Surgeons of England

UROLOGY

Ann R Coll Surg Engl 2007; **89**: 426–430
doi 10.1308/003588407X183346

Out-patient flexible cystoscopy using a disposable slide-on™ endosheath system

MICHAEL KIMULI, STUART N LLOYD

Pyrah Department of Urology, St James's University Hospital, Leeds, UK

ABSTRACT

INTRODUCTION The aim of this study was to investigate the feasibility of out-patient flexible cystoscopy.

PATIENTS AND METHODS Twenty-seven patients awaiting diagnostic or check cystoscopy in Leeds, UK were invited to undergo out-patient flexible cystoscopy using a CST-2000 Flexible Cystoscope (Vision Sciences; Natick, MA, USA) using the sterile single-use slide-on™ disposable endosheath endoscope system (EndoSheath®; Vision Sciences). The performance of the cystoscope was evaluated, and the patients' experiences were documented using a questionnaire.

RESULTS The out-patient setting proved to be ideal for flexible cystoscopy. The cystoscope was rated highly for image quality, ease of use and handling. All patients complimented us on the service and preferred out-patients to a day-ward or theatre attendance.

CONCLUSIONS This study demonstrates that it is possible to perform out-patient flexible cystoscopy safely, economically and efficiently with the aid of a disposable endoscope system.

KEYWORDS

Flexible cystoscopy – Vision Sciences – Disposable endoscopy sheaths – Slide-on™ endosheath system

CORRESPONDENCE TO

Stuart N Lloyd, Consultant Urologist, Pyrah Department of Urology, St James's University Hospital, Leeds LS7 9TF, UK
E: slloyd140@btinternet.com

Flexible cystoscopy is the most frequently performed urological procedure both as a diagnostic and surveillance tool. Freely available facilities to flexible cystoscopy is fundamental to modern urological practice but this is often limited by access to facilities, sterilisation and instrumentation resulting in significant waiting times for the procedure delaying diagnosis and treatment. Most units perform flexible cystoscopy in a day-ward theatre setting, others in purpose-built endoscopy units, few in the out-patient setting. Within our unit, flexible cystoscopy is performed in day-ward theatres, waiting times for non-urgent flexible cystoscopy has reached 9 months. Purchasing and servicing a large number of instruments was considered costly. Moving flexible cystoscopy into an out-patient setting with the implementation of the new Vision Sciences flexible cystoscope using slide-on™ endosheath system may overcome these difficulties and provide an opportunity to improve efficiency.

This paper reports our initial experience with this new device comparing it with standard flexible cystoscopy in an out-patient setting.

Patients and Methods

Twenty-seven patients on the day-case waiting list for diagnostic flexible cystoscopy were randomly chosen to be part of the pilot for the out-patient flexible cystoscopy list. Initially, small numbers were listed to establish the processes; the last list accommodated 10 patients comfortably. All patients were given an information sheet in the waiting area prior to the procedure. They were interviewed using a simplified assessment sheet and consented by the operator (Appendix 1). Patients did not fully change as in the day-ward setting but removed their lower half garments in the treatment room behind a screen.

The Vision Science CST-2000 flexible cystoscopy was used for all procedures. At first glance, the flexible cystoscope looks similar to existing instruments but closer inspection reveals several key differences (Fig. 1A–D). The cross-section of the instrument is crescenteric and measures 13.8-F by 16.8-F. It has a lever to lock onto the disposable sheath and a depression valve for irrigation. The sheath incorporates a 6-F working channel for biopsy and ureteric stent removal.

Key Points:-

- To demonstrate that Outpatient flexible cystoscopy was a feasible practice
- 27 patients awaiting diagnostic or check cystoscopy in the Leeds area were invited to attend an Outpatient Clinic to evaluate the Vision Sciences CST2000 scope that uses the Endosheath system
- The performance of the system was evaluated and patient feedback obtained through questionnaire
- The results were positive indicating Outpatients scenario was ideal for flexible cystoscopy of this nature
- The system was rated highly for image quality, ease of use and handling
- Patients complimented the service and preferred Outpatient setting to day-ward or theatre based procedure

Conclusions:-

- The Vision Sciences system makes it possible to perform outpatient flexible cystoscopy, economically and efficiently with the aid of a disposable Endosheath system

Microbiologic Assessment of Disposable Sterile Endoscopic Sheaths: Prospective Clinical Trial

Alvarado CJ, Anderson AG, Maki DG. Microbiologic assessment of disposable sterile endoscopic sheaths to replace high-level disinfection in reprocessing: a prospective clinical trial with nasopharyngoscopes. *Am J Infect Control* 2009;37:408-13.

In this article, Alvarado et al described a clinical trial that included a microbiologic assessment of the ability of the Slide-On® EndoSheath® Technology (Medtronic ENT, Jacksonville, FL) to provide protection against bacterial contamination of flexible nasopharyngoscopes. Three 30-mm Olympus nasopharyngoscopes (ENF Type P4, Olympus America, Melville, NY) were used while covered with an EndoSheath® barrier to examine the nasopharynx and larynx of 100 different, randomly selected patients. The surface of the head and shaft of each nasopharyngoscope was wiped to obtain two samples for culture at each of the following times: before application of the EndoSheath® Technology and the endoscopic examination, immediately after the examination and removal of the EndoSheath® disposable, and after a disinfection procedure consisting of the following steps: vigorous wiping of the endoscope with an enzymatic detergent, rinsing with running tap water, drying with gauze, wiping with gauze soaked in 70% ethanol, and air drying in a vertical position. All samples were plated on 5% sheep blood agar and incubated for 72 hours at 37°. Bacterial colony types were enumerated and identified by using standard methods. The study also included leak testing of the 100 used disposable sheaths removed from the nasopharyngoscopes and of 20 unused sheaths taken from the clinic inventory. The barrier integrity of the EndoSheath® Technology was assessed by using a pressure decay system (138 ± 2 inches of water [5 lb per square inch]).

Bacteria grew in cultures of 16 head and 6 shaft samples obtained before the endoscopic procedure, 13 head samples and 1 shaft sample taken immediately afterward, and no samples obtained after the disinfection procedure. The contamination found was low level (2 to 100 colony-forming units) and due primarily to skin commensals, mainly coagulase-negative *Staphylococcus* and *Bacillus* species. One sample was positive for *Staphylococcus aureus*; none showed gram-negative bacilli or fungi. None of the 120 used or new sheaths lost barrier integrity on leak testing. Alvarado et al noted that not a single leak or tear had been detected in the total of 755 sheaths in their study and all previously reported clinical trials in which the EndoSheath® Technology was used.

In light of their findings, the researchers concluded that use of the EndoSheath® Technology followed by proper cleaning and intermediate disinfection with 70% ethanol can provide a safe, patient-ready nasopharyngoscope, with reliable protection against contamination by virulent bacteria pathogens such as methicillin-resistant *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and mycobacteria species and by viruses likely to be present in the respiratory tract. Alvarado et al also suggested that the acquisition costs of disposable sheaths would be offset by avoidance of high-level reprocessing of flexible endoscopes, which is expensive and may expose health care workers to toxic disinfectants; by reductions in endoscope downtime; and, possibly, by a decrease in costs associated with inadequate high-level reprocessing practices.

Endoscope Sheaths as Viral Barriers: Laboratory FDA Study

Baker KH, Chaput MP, Clavet CR, Varney GW, To TM, Lytle CD. Evaluation of endoscope sheaths as viral barriers. *Laryngoscope* 1999;109:636-9.

The aim of this bench study conducted by scientists at the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA) was to characterize virus transmission through otolaryngologic endoscope sheaths in which a hole or tear had been made with an excimer laser or acupuncture needle. EndoSheath® Technology (n = 22) with a hole or tear ranging from 2 to 84 µm were applied to an endoscope, which was then submerged in a high-titer virus suspension (108 viruses/mL). The inside of each EndoSheath® barrier and the endoscope on which it had been placed were then rinsed separately to determine the amount of any virus that had penetrated through the hole.

A sequential test was also conducted. In this experiment, a virus challenge was first performed outside an EndoSheath® disposable in which a 30-µm hole was created before it was applied to an endoscope. The EndoSheath® Technology was then removed from the possibly contaminated endoscope, and a second EndoSheath® barrier, in which a 20-µm hole had been made in the same location as the 30-µm hole in the first EndoSheath® disposable, was placed on the endoscope. Another virus challenge was conducted to determine whether any virus would pass outward through the second sheath.

The first experiment found that small volumes of virus-containing fluid penetrated through the holes or tears in the EndoSheath® Technology and that up to 45% of passed virus particles could be recovered from the endoscope after removal of the EndoSheath® Technology. In the sequential test, virus was found on the second disposable barrier in only one case. Most important, according to the researchers, no virus was found outside the second sheath.

The FDA researchers recommended that an endoscope reprocessing step be combined with use of disposable sheaths. They also said, however, that their data indicated that the step need not be high-level disinfection. Instead, they concluded that meticulous cleaning of an endoscope followed by intermediate-level disinfection should provide a safe instrument for otolaryngologic endoscopy.