Quality Assurance and Endoscopic Reprocessing: The Clinical Application of HACCP

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Contents

- Endoscopies and Risk
- Managing Risk – QA/QC
- PRPs and HACCP
- Clinical Application of HACCP; endoscope reprocessing
What is safe?

Life is a risky business.............
Evolution of HACCP

- Food Manufacturing
- Clinical HACCP
- Catering Retailing
- Codex Principles
- Risk Management Nuclear Industry

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HACCP

“A risk management system based upon identified, named and validated control measures, implemented at critical control points”

Griffith 2006
Endoscopies

Are there hazards and risks associated with using endoscopes and if there are what can we do about it?
Endoscopies

“Approximately 5 million gastrointestinal endoscopies performed each year in the USA. Each procedure involves contact by a medical device or surgical instrument with a patient’s sterile tissue or mucous membrane. A major risk of all such procedures is the introduction of pathogens that can lead to infection.”

Guidelines for Disinfection and Sterilization CDC 2008
Endoscopies

OK so there maybe a risk – how great is that risk and are we likely to find out about it?
Risk Management

One can mitigate, control, transfer, or evade risk but can never eliminate it even with the greatest effort

Huihui 2010
Exogenous Endoscopy-Related Infections

- There is a potential risk and this can be managed using “Risk Management “ strategies
- The potential Endoscopy Infection Risk can be described as EIR and is based on

$$\text{EIR} = \text{IR} \times \text{CR} \times \text{DR}$$
Exogenous Endoscopy-Related Infections

- **EIR = IR x CR x DR**

- **IR** = Inherent Risk ie severity of hazards, probability of endoscope contamination

- **CR** = Control Risk ie effectiveness of decontamination procedures x compliance (consider types of errors and consistency)

- **DR** = Detection risk ie to know and record IF an infection occurs –higher for outbreaks
Endoscopy Related Risk: Inherent Risk (IR)

- Many patients maybe colonised or infected with a range of transmissible pathogens
- The consequences of some of these can be severe
## Microorganisms Transmitted by (or Shown to Contaminate) Endoscopes

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Cleaning procedure</th>
<th>Disinfection process</th>
<th>Rinsing process</th>
<th>Automated processor</th>
<th>Contaminated processing or water bottle</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacteria</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>P. aeruginosa</em></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><em>Klebsiella sp.</em></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Enterobacter sp.</em></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Serratia marcesens</em></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Salmonella sp. Incl. typhi</em></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><em>Helocobacter pylori</em></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><em>Bacillus sp.</em></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Proteus sp.</em></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Mycobacterium tuberculosis</em></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atypical mycobacteria</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Fungi</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Trichosporon sp.</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><em>Rhodotorula sp.</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>Parasite</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Strongyloides</em></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>Virus</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
Multidrug Resistant Outbreak of *Klebsiella pneumoniae*

- 16 patients identified with post ERCP *Klebsiella pneumoniae* (CTX-M-15.) 8 blood stream infections, 4 biliary tract infections, 4 fecal carriage
- Routine surveillance of endoscopes were negative – outbreak strain finally found after repeated flushing and brushing of the channels of one duodenoscope
- Strict adherence to reprocessing procedures ended the outbreak

Endoscopy 2010 : 42(11) 895-899
Inherent Risk

• Between 1966 and 2005 70 outbreaks were described in 64 papers
• Bronchoscopy accounted for 50% of reported outbreaks
• Inadequate decontamination practices leading cause of contamination
• 91% could have been prevented with improved QC procedures

• Seoane-Vazquez et al 2006 Curr Med Res Opin
Exogenous Endoscopy-Related Infections

• Reports and analysis are based on outbreak information and these may only represent a small fraction of the actual cases
“The problem in infection prevention does not lie with new control measures or the need for wonder chemicals BUT it is a behavioural problem and requires the consistent, full and correct implementation of known infection prevention practices and management is the key.”

Griffith RSPH 2009
Endoscopes and Infections

- But we have guidelines eg
  - BSG working group 1997, 2003
  - Multi society 2003
  - ASGE 1999
- But guidelines are NOT management systems and they do disagree on some aspects eg drying (Muscarella 2006 Am J Gastroenterol)
- And people do not always comply with them
Compliance with Guidelines

“Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization”

“Audits show personnel do NOT consistently adhere to reprocessing guidelines”

CDC 2008
Report on Endoscopes Decontamination in NI

• More active approach to training
• In too many locations the area for decontamination was inadequate
• Unclear lines of communication
• Small number had developed audits
• Guidance available “Disappointing”
• One trust comprehensive IC manual
• Lack of awareness and confusion over decontamination / cleaning
• Steps missed out
Management of Reprocessing

• Tend to be collection of procedures drawn up by Infection Control staff which are often not communicated/well known to or consistently practised by staff

• QA rather than QC

• Range of management options
Management

_Infection Prevention Management:_ Coordinated activities to direct or control infection prevention.

The attainment of infection prevention goals in an effective and efficient way through planning, staffing, organizing, directing and controlling organizational resources.
Quality Control (QC)

- Planning inspection operations, identifies errors
- Inspection: sorts good from bad
- Assessing if quality achieved

Quality Control = defect detection
How to Achieve Quality

Quality Assurance (QA)

- All planned and systematic actions necessary for a service or product to satisfy quality requirements
- Confidence that quality requirements are fulfilled

Quality Assurance = defect prevention
Operational Performance: What happens?

Infection Prevention Management Systems
A formalised system that documents the structure, responsibilities, activities, resources, events and procedures required to achieve effective quality management.
Management Systems

- Technically adequate and appropriate
- Be seen/perceived by staff as important
- Be a “living breathing part of the day to day activities”
- Be understandable
- Not just focus on processes but also people
- Based upon HACCP?
HACCP, Hazards and Risk
Managing Food Safety: 2006 Approach

PRPs + HACCP = SF
Reprocessing Endoscopes

PRPs + HACCP = SP?
### PRPs versus HACCP

<table>
<thead>
<tr>
<th>PRPs</th>
<th>HACCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indirectly with food safety <em>(patient health)</em></td>
<td>Directly with food safety <em>(patient health)</em></td>
</tr>
<tr>
<td>General</td>
<td>Product: Process Specific <em>(procedure specific)</em></td>
</tr>
<tr>
<td>Lower risk FP <em>(HAI)</em></td>
<td>High risk FP <em>(HAI)</em></td>
</tr>
</tbody>
</table>
Pre-Requisite Programmes (PRPs)

Describes all those activities other than specific HACCP plans, which affect food (patient) safety.

Universal steps or procedures that control the operational activities within a food establishment allowing production of safe food (clinical environment to minimise patient infection).

Managed and documented
Healthcare Environment: Buildings

- Work + people flows
- Single rooms?
- Design and construction materials
- Implication new builds: PFI
Tygerberg’s toilet shame

Hygiene should be a major priority at a hospital, but you wouldn’t think so if you’re unfortunate enough to answer nature’s call at this health facility.

A patients’ toilet at the Tygerberg hospital is littered with animal droppings on the floor, dirty nappies in a cupboard and sanitary holders in the sink.

The Western Cape Health Department says the toilets in the hospital’s cardio unit are cleaned twice a day, but photographs taken by Bellville attorney Janine Myburgh refute this. She says a visit to the hospital toilets left her disgusted.

“I had taken my mother to the unit last week. She’d had a heart attack last year and needed a check-up. She was at the hospital in Worcester and for her check-up she was asked to go to Tygerberg because they have the cardio unit. She had heard there were long queues at the hospital so made sure they were there at 6.15am. “There were a few others before us. I soon noticed we were not being helped in the order that we’d come in. I was told patients who came for the first time were given priority. “I said it was the first time and was informed that couldn’t be. Then I was told that patients from rural areas were helped first and again I said my mother qualified as she’s from Prince Alfred Hamlet. In addition she’s in her 70s and should qualify for priority.”

Continued on page 3
### Testing Requirements and Interpretation of Results for Endoscopy Final Rinse Water

<table>
<thead>
<tr>
<th>Hazard/Hygiene Indicator</th>
<th>Timing/ Frequency of Testing</th>
<th>Result</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerobic Colony Count</td>
<td>Weekly</td>
<td>&gt;100 in 100 ml</td>
<td>UNACCEPTABLE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;10 - ≤100 in 100 ml</td>
<td>UNSATISFACTORY</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 - ≤10 in 100 ml</td>
<td>ACCEPTABLE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 in 100 ml</td>
<td>SATISFACTORY</td>
</tr>
<tr>
<td>Environmental mycobacteria</td>
<td>Annually (or more frequently, depending on risk assessment)</td>
<td>&gt;10 in 100 ml</td>
<td>UNSATISFACTORY</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 in 100 ml</td>
<td>SATISFACTORY</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>Optional – to be determined in discussion with local microbiologist</td>
<td>&gt;10 in 100 ml</td>
<td>UNSATISFACTORY</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 in 100 ml</td>
<td>SATISFACTORY</td>
</tr>
</tbody>
</table>
Section 2.9

• Winning Ways recommend HACCP

• Consider use of HACCP
Possible Clinical Applications: Where?

- Any healthcare process with increased patient risk
Clinical HACCP

Has it been applied? - Yes in following:

- Handling of expressed breast milk 1991
- Airborne contamination in clean rooms 1995
- Infant formula 1999
- Enteral tube feeds 2000
- Post-operative endophthalmitis 2001
- General IC, 2002
- Pharmaceutical product 2003
- Clinical engineering 2003
- Endoscopes 2005
- Bundling 2006
Will HACCP be Used in Healthcare?

• Interest from:
  – UK
  – Germany
  – US
  – Brazil
  – Australia

• Use recommended in UK epic 2 guidelines

• HACCP medical alliance in US

• 10 years time?
Possible Clinical Applications: What does it do?

• Does not tell you NEW control measures but HOW TO MANAGE them
  i.e. management tool

• QA

• Scientific systematic approach
HACCP Case Study: Endoscopes
HACCP

7 Codex Principles:

1. Conduct Hazard Analysis
2. Determine CCPs
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Verification Procedures
7. Establish Documentation
Codex HACCP Logic Sequence

1. Assemble the HACCP Team
2. Describe Product
3. Identify Intended Use
4. Construct Flow Diagram
5. On-site Verification of Flow Diagram
6. List all Potential Hazards
   - Conduct a Hazard Analysis
   - Determine Control Measures
Codex HACCP Logic Sequence

Assemble the HACCP Team

Describe Product

Identify Intended Use

Construct Flow Diagram

On-site Verification of Flow Diagram

List all Potential Hazards
Conduct a Hazard Analysis
Determine Control Measures

Identification of what can go wrong
Codex HACCP Logic Sequence

1. Determine CCPs
2. Establish Critical Limit for Each CCP
3. Establish a Monitoring System for Each CCP
4. Establish Corrective Action for Deviations that may occur
5. Establish Verification Procedure
6. Establish Record Keeping and Documentation

Managing the process of preventing things from going wrong
Clinical HACCP LS1 P1

Assemble Team

• Nurses
• Specialist practitioners
• Administrators / Domestic Managers
• Doctors
• Infection Control / Microbiologist
• External consultants?

Typically 4-6

Training

Chair
Clinical HACCP LS2 P1

Define, describe process / procedure: equipment, consumables, etc.
An endoscopy is a test that enables a clinician to look inside the body. Different types of endoscopes can be used to examine different parts of the body. The most common use of endoscopes is to look inside the oesophagus, stomach and duodenum. In addition, biopsies (samples) can be taken of any abnormal looking tissue.

The endoscope itself (see diagram) consists of a number of component parts, one of which is a long tube which contains a light and camera and can be swallowed. This transmits an image of the inside of the organ examined. The scope may also allow air to be blown (e.g. into the stomach) expanding the tissue and making examination easier, or can be used to stop bleeding. Patients may receive mild anaesthetic, analgesics or sedatives during the procedure.

The procedure typically takes 20-60 minutes, depending on the site examined.

After use the endoscope should undergo high level disinfection, this is usually performed in an automated cleaner / disinfector. The chemical used for the process can be quite toxic. Guidelines exist on how this process should be performed.
Endoscope Structure
Stages in C & D After Leak testing

- Cleaning: mechanically clean internal and external surfaces (brushing and flushing)
- Disinfection: immerse scope in high level disinfectant (remove air pockets) and ensure contact of all surfaces with biocide for required time
- Rinse: rinse all channels with high quality water
- Dry: rinse insertion tube and inner channels with alcohol and dry with forced air
- Storage: prevent recontamination and allow drying
Automated Endoscope Reprocessor
Identify intended use

• Risk of abuse
• Vulnerable groups
Construct process flow diagram (PFD)

- Outline process
- All stages
Endoscope Decontamination Flow Diagram

Risk of endoscope contamination from environment

- Endoscope storage in cupboard at ambient (20°C) for >3 hours
  - Leakage Test
  - Autodisinfection (1) cleaning cycle for 45 minutes
  - Trolley – re-use scope if <3hrs
  - Scope Used
  - Wipe down to remove external secretions
  - Depress air / water valve, suck in enzymatic detergent
  - Leakage testing
  - Manual clean (bowl)
  - Manual cleaning (sink)
  - Autodisinfection (2)
  - Drying

Risk of environmental contamination from dirty scope

Risk of endoscope contamination from environment

- Air
- Disposable cloth
- Enzymatic detergent
- Filtered Tap Water
- Disinfectant e.g. Glutaraldehyde
- Non sterile paper towels, swabs, lubricant
- Tap Water
- Disposable/ reusable brushes and toothbrush
- Alcohol

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Verify flow diagram

- Check accuracy / repeatability
- Different shifts / managers / weekends, etc.
- Amend, record, sign and date
Conduct hazard analysis

The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for patient safety and therefore should be addressed in the HACCP plan.
Clinical Hazard Analysis

• Hazard Identified Stage 1
  – in house records
  – epidemiology
  – patient complaints
  – decision trees / C + E analysis

• List of all hazards for each step of PFD
Potential Hazards And Sources Associated with Endoscopes

- Patient – Colonoscopes; Campylobacter, Helicobacter, Salmonella, C diff., Rotavirus, etc. parasitic, worms, blood borne-HIV etc

- Environment – water, skin, e.g. Pseudomonas, Staphylococcus aureus
Clinical Hazard Analysis

- Hazard Evaluation Stage 2
  - probability
  - Severity

- Level of concern – prioritise

- **Reported** incidence of infection is low (1 in 1.8 million)

- More HCAIs outbreaks associated with scopes than any other medical device (CDC 2008)
Clinical Hazard Analysis

- Bioburden found on USED scopes varied from $10^6$ to $10^{10}$ CFU/ml highest in suction channels
- Suggested 1.9% cont. after reprocessing (AJIC June 2006)

- Identify control measures
Clinical Hazard Analysis

Identify Control Measure

Any action and activity that can be used to prevent or eliminate a food (patient) safety hazard or reduce it to an acceptable level
Determine CCPs

A step at which control can be applied and is essential to prevent or eliminate a food safety (patient) hazard or reduce it to an acceptable level.
Endoscope Decontamination Flow Diagram

Endoscope storage in cupboard at ambient (20°C) for >3 hours

Leakage Test

Autodisinfection (1) cleaning cycle for 45 minutes

Trolley – re-use scope if <3hrs

Scope Used

Wipe down to remove external secretions

Depress air / water valve, suck in enzymatic detergent

Leakage testing

Manual clean (bowl)

Manual cleaning (sink)

Autodisinfection (2)

Drying

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## Case Study Hazard Analysis

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Hazard</th>
<th>Control Measure</th>
<th>CCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning</td>
<td>Presence of organic matter, Biofilms, Pathogen survival</td>
<td>Effective cleaning</td>
<td>?</td>
</tr>
</tbody>
</table>
Determine CCPs

- Decision trees
  - Codex

- No control measure?
Determine CCPs: Codex Decision Tree

Q1. Do control measures exist?  
- YES  
  - Do preventative measures exist?  
    - YES  
      - CCP  
    - NO  
      - Modify step, process or product

- NO

Q2. Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an acceptable level?  
- YES  
  - CCP

- NO  
  - Not a CCP  
    - Thought required about processing, handling, etc.

Q3. Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could they increase to unacceptable level(s)?  
- YES  
  - Not a CCP

- NO

Q4. Will a subsequent step eliminate or reduce the likely occurrence of the identified hazard to an acceptable level?  
- YES  
  - CCP

- NO  
  - Not a CCP

For each hazard:
- Question forces consideration or growth or contamination
- Focuses team on realistic use of product
## Determine CCPs: Output from use of Codex Decision Tree

<table>
<thead>
<tr>
<th>PROCESS STEP</th>
<th>HAZARD</th>
<th>CONTROL MEASURES</th>
<th>DECISION TREE QUESTIONS</th>
<th>CCP Y/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning</td>
<td>Residual soil / microorganisms</td>
<td>Effective cleaning</td>
<td>1 1a 2 3 4</td>
<td>Y</td>
</tr>
</tbody>
</table>

Application of the decision tree for the chemical processing stage of an endoscope. The results of the individual questions are recorded as indicated to provide transparency of decision making and can be auditable. Question 1a refers to the question “Do preventative measures exist?”. Copyright © Prof Chris Griffith, UWIC 2007
“Amongst the most challenging medical devices to clean”

“Instruments from “hell””

“Cleaning crucial to prevent transmission”

“Capable of 99.99% reduction bioburden”
“Maximum effectiveness from disinfection and sterilization results from first cleaning and removing organic and inorganic materials “

Guidelines for Disinfection and Sterilization
In Healthcare Facilities    CDC 2008
Cleaning Endoscopes: Quotations

“Thorough cleaning is ESSENTIAL before high level disinfection and sterilization “

Guidelines for Disinfection and Sterilization
In Healthcare Facilities    CDC 2008
“Meticulous cleaning must precede any sterilization or high level disinfection. Failure to perform good cleaning can result in disinfection failure and outbreaks of infection “

Guidelines for Disinfection and Sterilization
In Healthcare Facilities    CDC 2008
“2% of patient ready endoscopes returned +ve cultures”

“All 12 smaller air / water channels had extensive biological soil”

“Presence of biofilms increases risk of decontamination failure”

Pajkos et al., J. Hosp Infection, 2004
Determine CCPs: Output from use of Codex Decision Tree

<table>
<thead>
<tr>
<th>PROCESS STEP</th>
<th>HAZARD</th>
<th>CONTROL MEASURES</th>
<th>DECISION TREE QUESTIONS</th>
<th>CCP Y/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disinfection</td>
<td>Survival of vegetative pathogens</td>
<td>Effective Chemical Disinfection</td>
<td>Y - Y - - -</td>
<td>Y</td>
</tr>
</tbody>
</table>

Application of the decision tree for the chemical processing stage of an endoscope. The results of the individual questions are recorded as indicated to provide transparency of decision making and can be auditable. Question 1a refers to the question “Do preventative measures exist?”.
Summary So Far: Identified

• All important hazards within process

• Control measures

• Where control measures implemented
  i.e. focus attention

• Next P 3, 4, 5 How to manage CCPs
• Critical limits
  Criteria which separate acceptability and unacceptability

• Target Level
  Values of a parameter, at a critical control point, which have been shown to eliminate or control a hazard

• Deviation
  Failure to meet a critical limit
Establish Critical Limits

• Setting CLs
  – in house validation
  – published data - models
  – expert advice
  – Microbiological / rapid tests
  – SPC
Establish Monitoring LS9 / P4

• Show CCPs controlled

Detects loss of control at CCP

• Monitor

The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control
Table 1: Results of bacteriologic and bioluminescence sampling.
Mean values, data ranges and percentage of failures against set levels for both methods at two units.
Number of endoscopies examined: Unit A n=25, Unit B n=38

<table>
<thead>
<tr>
<th></th>
<th>Unit A</th>
<th></th>
<th>Unit B</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bacteriology (cfu/sample)</td>
<td>ATP (RLU/sample)</td>
<td>Bacteriology (cfu/sample)</td>
<td>ATP (RLU/sample)</td>
</tr>
<tr>
<td>Suction channel</td>
<td>0.8 (0 - 7)</td>
<td>192 (26 - 531)</td>
<td>1.2 (0 - 8)</td>
<td>1191 (22 - 10030)</td>
</tr>
<tr>
<td>pre-disinfection</td>
<td>4%</td>
<td>4%</td>
<td>18%</td>
<td>42%</td>
</tr>
<tr>
<td>Biopsy channel</td>
<td>0.3 (0 - 2)</td>
<td>683 (29 - 3829)</td>
<td>1.7 (0 - 14)</td>
<td>1389 (69 - 12436)</td>
</tr>
<tr>
<td>pre-disinfection</td>
<td>0%</td>
<td>16%</td>
<td>18%</td>
<td>45%</td>
</tr>
<tr>
<td>Suction channel</td>
<td>0.3 (0 - 6)</td>
<td>60 (24 - 103)</td>
<td>0.1 (0 - 1)</td>
<td>70 (17 - 354)</td>
</tr>
<tr>
<td>post disinfection</td>
<td>4%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Biopsy channel</td>
<td>1.1 (0 - 14)</td>
<td>82 (20 - 502)</td>
<td>0.1 (0 - 1)</td>
<td>67 (20 - 374)</td>
</tr>
<tr>
<td>post disinfection</td>
<td>8%</td>
<td>4%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Endoscope exterior and tip</td>
<td>0.2 (0 - 2)</td>
<td>1387 (20 - 12102)</td>
<td>0.0 (0 - 0)</td>
<td>353 (38 - 2715)</td>
</tr>
<tr>
<td>post disinfection</td>
<td>0%</td>
<td>44%</td>
<td>0%</td>
<td>16%</td>
</tr>
<tr>
<td>Post rinse water</td>
<td>0.4 (0 - 4)</td>
<td>53 (26 - 128)</td>
<td>0.0 (0 - 0)</td>
<td>51 (24 - 110)</td>
</tr>
<tr>
<td>Endoscope resting surfaces</td>
<td>0.4 (0 - 3)</td>
<td>264 (25 - 1861)</td>
<td>1.7 (0 - 14)</td>
<td>355 (119 - 839)</td>
</tr>
<tr>
<td>Image function switch panel</td>
<td>0.5 (0 - 3)</td>
<td>5322 (111- 74457)</td>
<td>0.03 (0 - 1)</td>
<td>401 (88 - 3677)</td>
</tr>
<tr>
<td>switch panel</td>
<td>4%</td>
<td>92%</td>
<td>0%</td>
<td>13%</td>
</tr>
</tbody>
</table>

**Key:**
- Mean (Range)
- Failure levels set at >=3cfu/sample for microbiology and >500 RLUs for ATP bioluminescence
- % above benchmark values
Monitoring Activities

- Checks (e.g. records)
- Inspections: Processing equipment
- Inspections: Endoscope itself
- Measuring
Establish Monitoring

• Real time data!
• Continuous: discontinuous
• When and frequency
• Who
• How
• With what
Corrective action

Any action to be taken when the results of monitoring at the CCP indicate loss of control, i.e. deviation outside critical limit.
Establish Corrective Actions

- Who has responsibility / informed
- What actions
  - process control
  - product control
  - prevent recurrence
Verification

Application of methods, procedures, tests and other evaluations in addition to monitoring to determine compliance with the HACCP plan
Validation Obtaining evidence that elements of the plan are effective

i.e. is the CM or plan capable of controlling all relevant hazards or will it work?

ALSO

At time of initial formulation the plan is effective
Q  Don’t we manage the process already?

A  Yes and No – variability
   - NI June 2004
   Management Failures
Comparison Between HACCP and Management Systems in Two Endoscopy Units

<table>
<thead>
<tr>
<th>HACCP LS</th>
<th>UNIT A</th>
<th>UNIT B</th>
</tr>
</thead>
<tbody>
<tr>
<td>LS1</td>
<td>No</td>
<td>Partial</td>
</tr>
<tr>
<td>LS2</td>
<td>No</td>
<td>Partial</td>
</tr>
<tr>
<td>LS3</td>
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</tr>
<tr>
<td>LS12</td>
<td>No</td>
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</tbody>
</table>
Operational Performance: What happens

Infection Prevention Management

Infection Prevention Culture
Summary

There is a risk associated with endoscopies and HACCP can and in some parts of healthcare is being applied in a clinical setting.

Benefits:
- Consistency: Documentation and records
- Transparent: Auditability
- Comprehensive and specific
- Pro-active / preventative

Barriers
- Attitudes
- Behavioural Change

Costs
- Potential to save money and improve health

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Basic Control Measures Used in Infection Prevention

• Relatively well documented

• US and UK

• MANAGEMENT procedures NOT well defined BUT they are KEY
Clinical Application of HACCP

• Commodity dominated: HACCP
  – Surgical equipment
  – Endoscopes
  – Re-usable items

• Patient dominated: HACCP Principles
  – Intravenous infusion
  – SSIs
  – VAP
  – UTI
  – LRTI

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Bundling: What is Involved

- Collection of practices or process steps
- Based on solid evidence
- All steps need implementing
- Monitored
- Outcomes evaluated and recorded
Comparison of HACCP Based Systems and Care Bundles

HACCP Based System

- Multidisciplinary
- Documentation needed
- Managerial support / leadership
- Process related
- Validated control measures
- Monitoring implementation
- Series of CM
- Real time

Care Bundles

- Multidisciplinary
- Documentation needed
- Managerial support / leadership
- Process related
- Evidence based guidelines / measures
- Checking implementation
- Collection/ bundles of activities
- Real time

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Comparison of HACCP Based Systems and Care Bundles

HACCP Based System

- Outcome / end product is successful criterion
- Works in conjunction with PRPs
- Success requires implementation of all control measures
- Designated responsibilities

Care Bundles

- Outcome / end product is successful criterion
- Works in conjunction with good general hygiene and infection control practices
- Success requires implementation of the “whole bundle”
- Designated responsibilities
Bundling Lacks

Formalised

• Details of monitoring
• Hazard Analysis
• Specified Corrective Actions
• Validation and Verification
• International definitions and agreement
Does Bundling Work?

Cocanour et al., J of Trauma (2006)61: 122-130

VAP 22-32 Infection / 1000 ventilation days

Bundle of activities – no decrease
Bundle and auditing and feedback 0-12 infections / 1000 ventilation days

Average costs of VAP $50,000
Using a widely heralded Johns Hopkins checklist and other patient-safety tools, intensive care units across the state of Michigan reduced the rate of potentially lethal bloodstream infections to near zero.

The new study, published in the December issue of the journal *Quality and Safety in Health Care*, found that the rate of central-line associated bloodstream infections (CLABSI) fell by 74 percent across Rhode Island's 23 ICUs over two and a half years. Researchers estimate the interventions prevented 42 CLABSI, saved 10 lives, reduced ICU stays by 608 days and saved $2 million.
“Nearly all of these infections are preventable,” Pronovost says. “Unlike breast cancer, we have a cure. Yet some hospital infection rates are 10 times what they should be.”

The safety program developed at Johns Hopkins includes the much-heralded, cockpit-style checklist for doctors and nurses to follow when placing a central-line catheter. Along with the checklist, the program promotes a “culture of safety”.
Berenholtz Sm et al. Critical Care Medicine, 2004; 32: 2014-20

- CVC rate decreased from 11.0 to 0/12000 cvc days
- Savings
  - 43 infections
  - 8 deaths
  - $1.95m
Will HACCP based approaches succeed in healthcare?
Managing Patient Safety: Potential Benefits

• Reduced risk of illness

• Less wastage / shorter stays

• Better turnover

• Improved confidence
Managing Patient Safety: Barriers

- Lack of real commitment
- Lack of legal requirement
- Financial constraints
  - Short term
- Human resource constraints
- Human nature
- Lack of expertise/technical/support/data
- Inadequate infrastructure/facilities/PRPs
- Inadequate communication
Managing Patient Safety: Cost Balance

Failure Costs

• Illness / death
• Loss of revenue
• Increased infection costs
• Compensation
Cost Balance

Implementation Costs - Initial

- Preparation/planning - time
- Consultants?
- Training
- Equipment
- Changes to layout
- Documentation

Deduct from the above any financial incentives
Managing Patient Safety: Cost Balance

Implementation Costs - Ongoing

- Cleaning?
- Monitoring/recording
- Updating/training
Cost Balance: See Dispelling the Myths

Satus Quo
- Higher HCAIs
- Waste
- Patient concerns

HACCP: PRPs
Lower HCAIs
Improved patient turnover
Higher implementation costs
Reduced overall costs
Operational Performance: What happens?

Infection prevention Management Systems

Infection Prevention Culture