

# **Quality Assurance and Endoscopic Reprocessing: The Clinical Application of HACCP**

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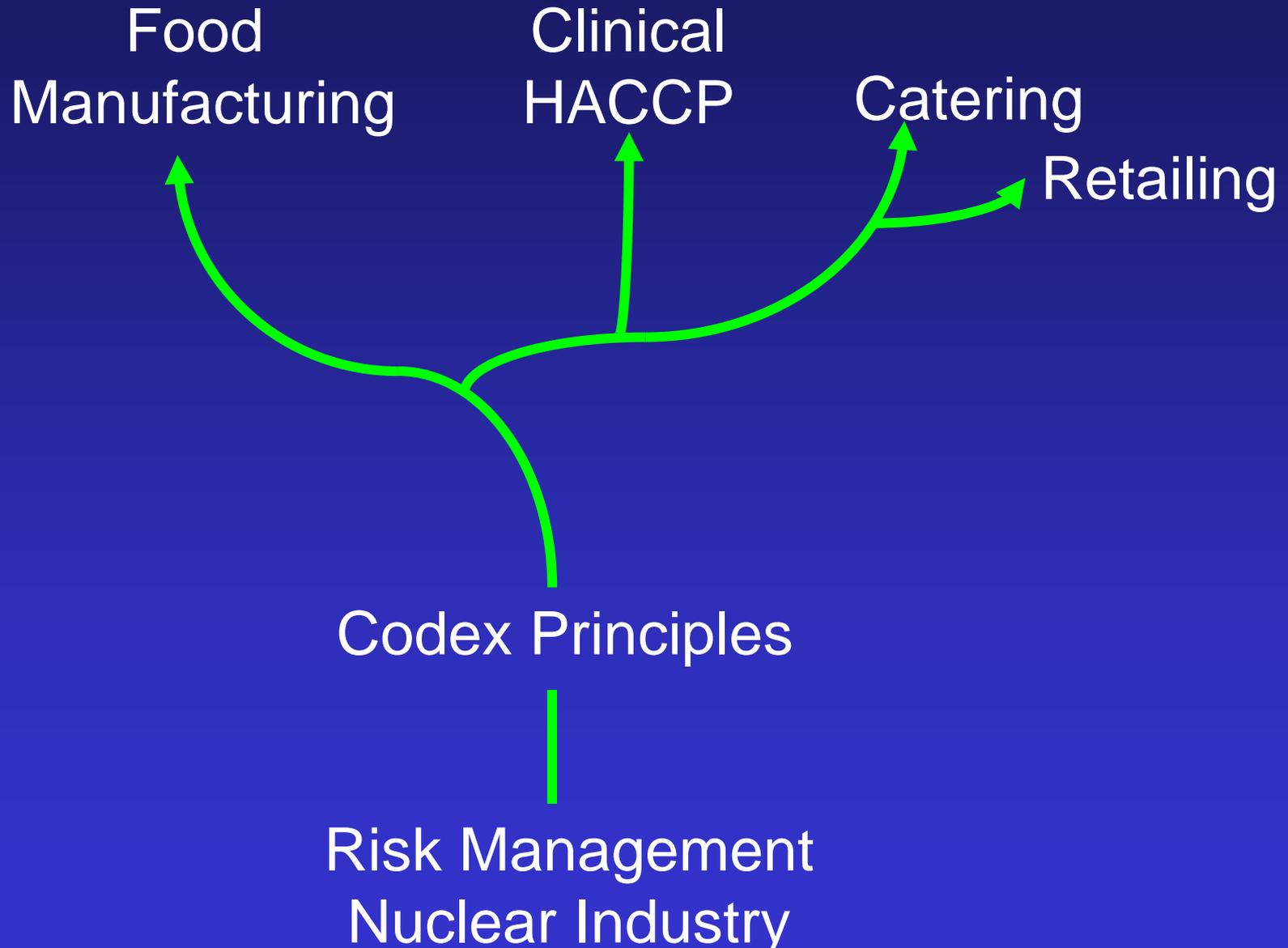
What is safe?

Life is a risky business.....

# Codex Risk Analysis Framework



# Evolution of HACCP



# HACCP

## 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
- $EIR = IR \times CR \times DR$

# Exogenous Endoscopy-Related Infections

- $EIR = IR \times CR \times DR$
- 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

	Cleaning procedure	Disinfection process	Rinsing process	Automated processor	Contaminated processing or water bottle
<b>Bacteria</b> <i>P aeruginosa</i>	X	X	X	X	X
<i>Klebsiella sp.</i>	X	X			
<i>Enterobacter sp.</i>	X	X			
<i>Serratia marcesens</i>	X	X			
<i>Salmonella sp. Incl. typhi</i>	X	X			X
<i>Helocobacter pylori</i>	X	X			X
<i>Bacillus sp.</i>	X	X			
<i>Proteus sp.</i>	X	X			
<i>Mycobacterium tuberculosis</i>	X	X			
Atypical mycobacteria	X	X	X	X	
<b>Fungi</b> <i>Trichosporon sp.</i>		X		X	X
<i>Rhodotorula sp.</i>	X			X	X
<b>Parasite</b> <i>Strongyloides</i>	X	X			
<b>Virus</b> Hepatitis B	X	X			
Hepatitis C	X	X			

# 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

# Control Risk

“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 “

# Endoscopes and Infections

- But we have guidelines eg
  - BSG working group 1997, 2003
  - Multi society 2003
  - APIC 1997, 1998, 1999
  - 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

## 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**

# Quality Management System

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

## PRPs

Indirectly with food safety (patient health)

General

Lower risk FP (HAI)

## HACCP

Directly with food safety (patient health)

Product: Process Specific (procedure specific)

High risk FP (HAI)

# Pre-Requisite Programmes (PRPs)

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

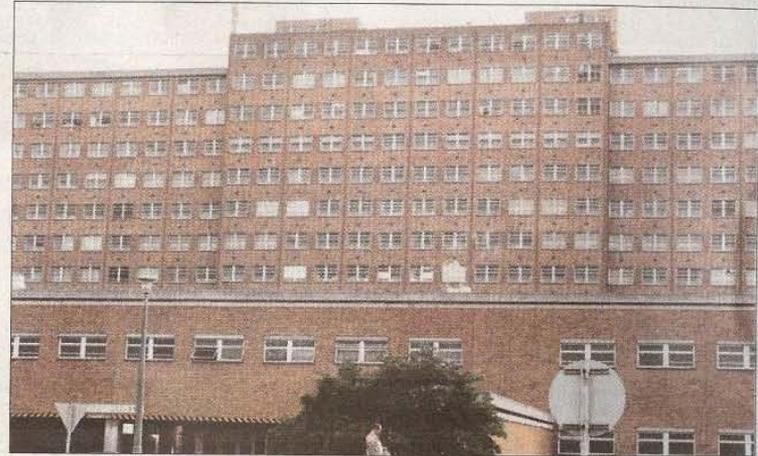
Universal steps or procedures that control the operational activities within a food establishment allowing production of safe food (clinical environment to minimise patient infection).

Managed and documented

# Healthcare Environment: Buildings

- Work + people flows
- Single rooms?
- Design and construction materials
- Implication new builds: PFI

■ The single woman's toilet in the cardio unit of Tygerberg Hospital is disgusting, says a visitor.



# 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.

VENNESSA SCHOLTZ

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

Hazard/Hygiene Indicator	Timing/Frequency of Testing	Result	Interpretation
Aerobic Colony Count	Weekly	>100 in 100 ml	UNACCEPTABLE
		>10 - ≤100 in 100 ml	UNSATISFACTORY
		0 - ≤10 in 100 ml	ACCEPTABLE
		0 in 100 ml	SATISFACTORY
Environmental mycobacteria	Annually (or more frequently, depending on risk assessment)	>10 in 100 ml	UNSATISFACTORY
		0 in 100 ml	SATISFACTORY
<i>Pseudomonas aeruginosa</i>	Optional – to be determined in discussion with local microbiologist	>10 in 100 ml	UNSATISFACTORY
		0 in 100 ml	SATISFACTORY

# epic 2: Evidence Based Guidelines

## February 2007

### 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

**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**



# Codex HACCP Logic Sequence

**Assemble the HACCP Team**



**Describe Product**



**Identify Intended Use**



**Construct Flow Diagram**



**On-site Verification of Flow Diagram**

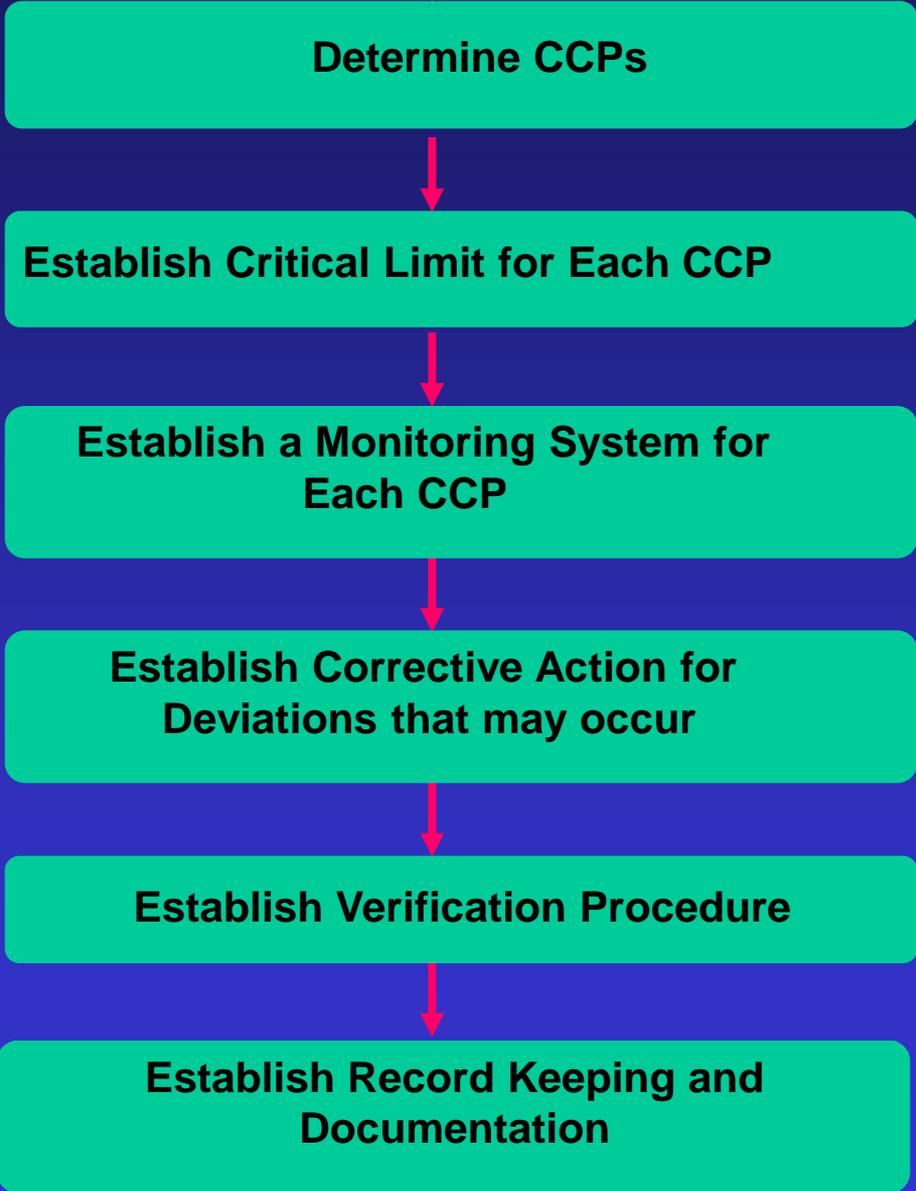


**List all Potential Hazards  
Conduct a Hazard Analysis  
Determine Control Measures**



**Identification of  
what can go wrong**

# Codex HACCP Logic Sequence



```
graph TD; A[Determine CCPs] --> B[Establish Critical Limit for Each CCP]; B --> C[Establish a Monitoring System for Each CCP]; C --> D[Establish Corrective Action for Deviations that may occur]; D --> E[Establish Verification Procedure]; E --> F[Establish Record Keeping and Documentation];
```

Determine CCPs

Establish Critical Limit for Each CCP

Establish a Monitoring System for Each CCP

Establish Corrective Action for Deviations that may occur

Establish Verification Procedure

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.

# Endoscopy

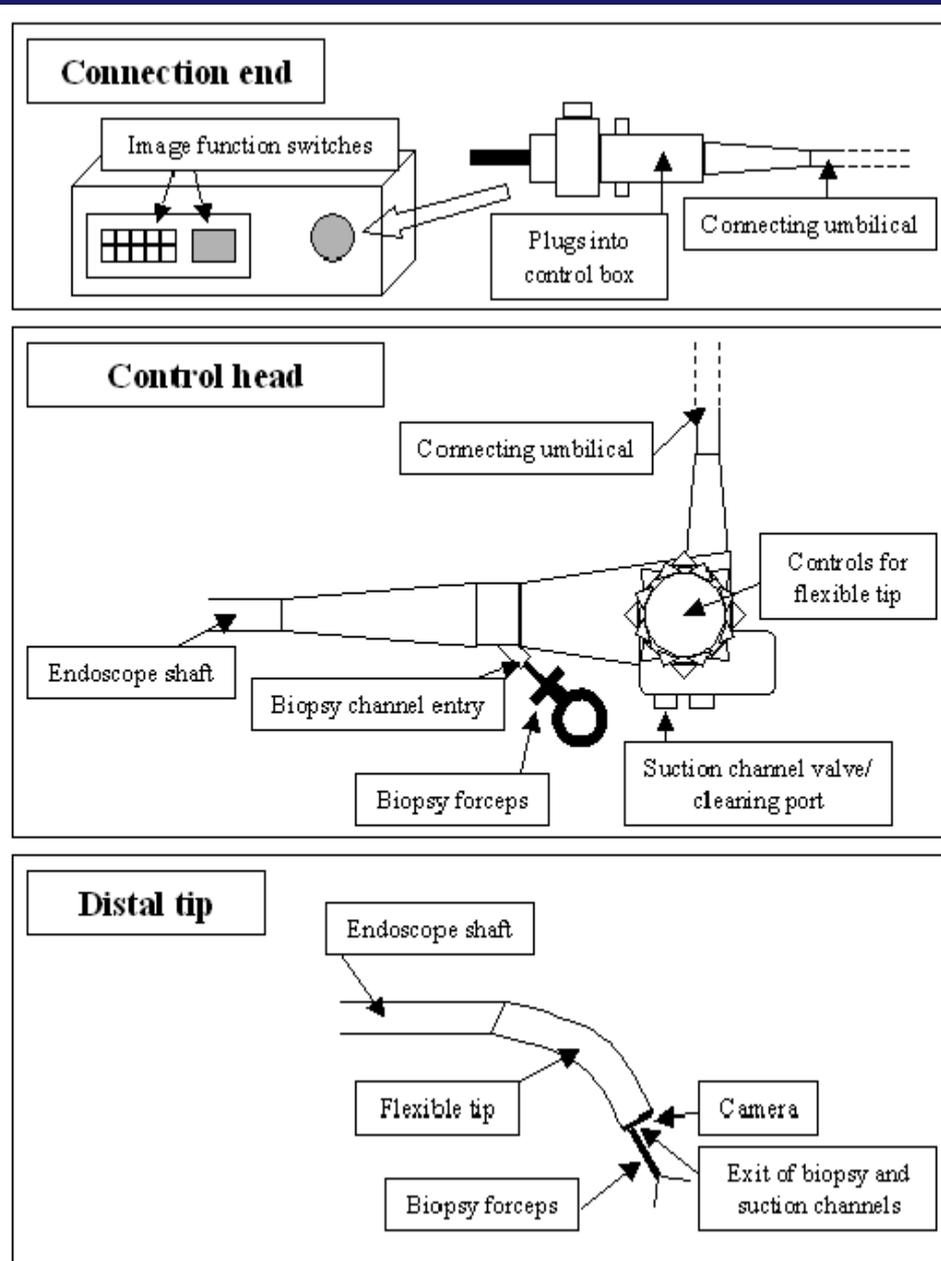
An endoscopy is a test that enables a clinician to look inside the body. Different types of endoscopes can be used to examine different parts of the body. The most common use of endoscopes is to look inside the oesophagus, stomach and duodenum. In addition, biopsies (samples) can be taken of any abnormal 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 / disinfectant. The chemical used for the process can be quite toxic. Guidelines exist on how this process should be performed.

# Endoscope Structure

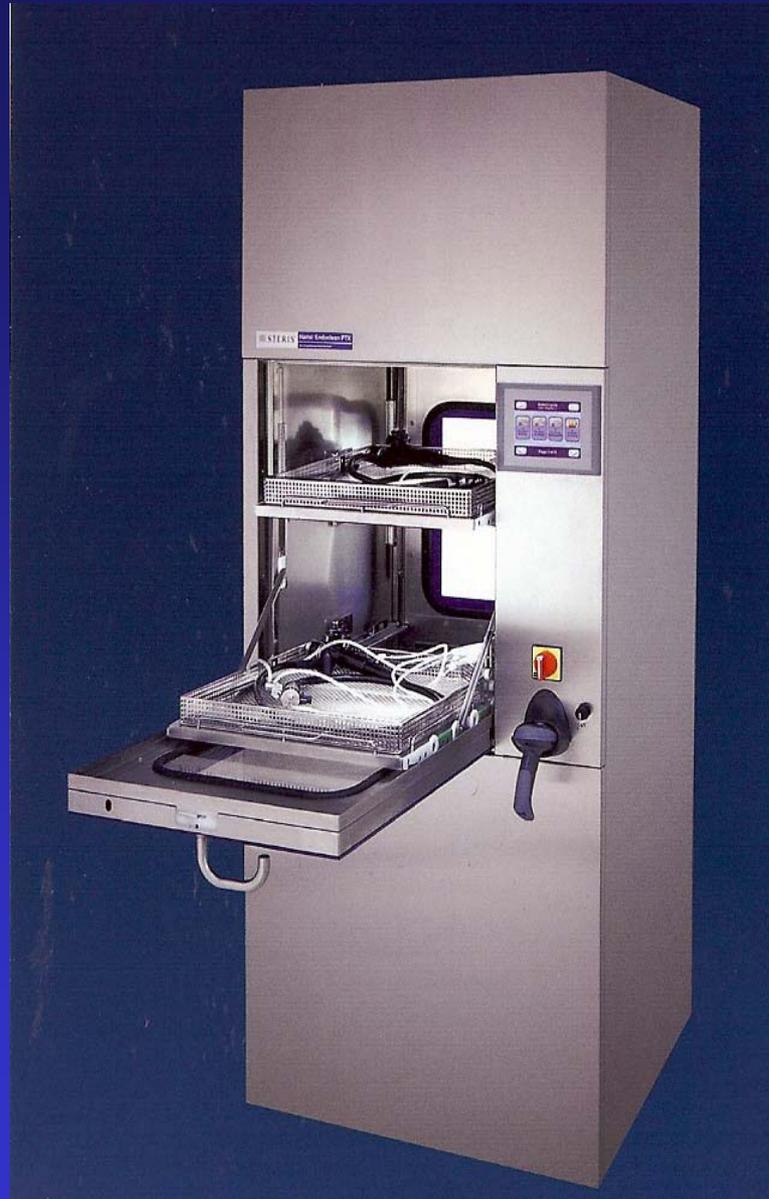


# Stages in C & D After Leak testing

- 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





# Clinical HACCP LS3 P1

Identify intended use

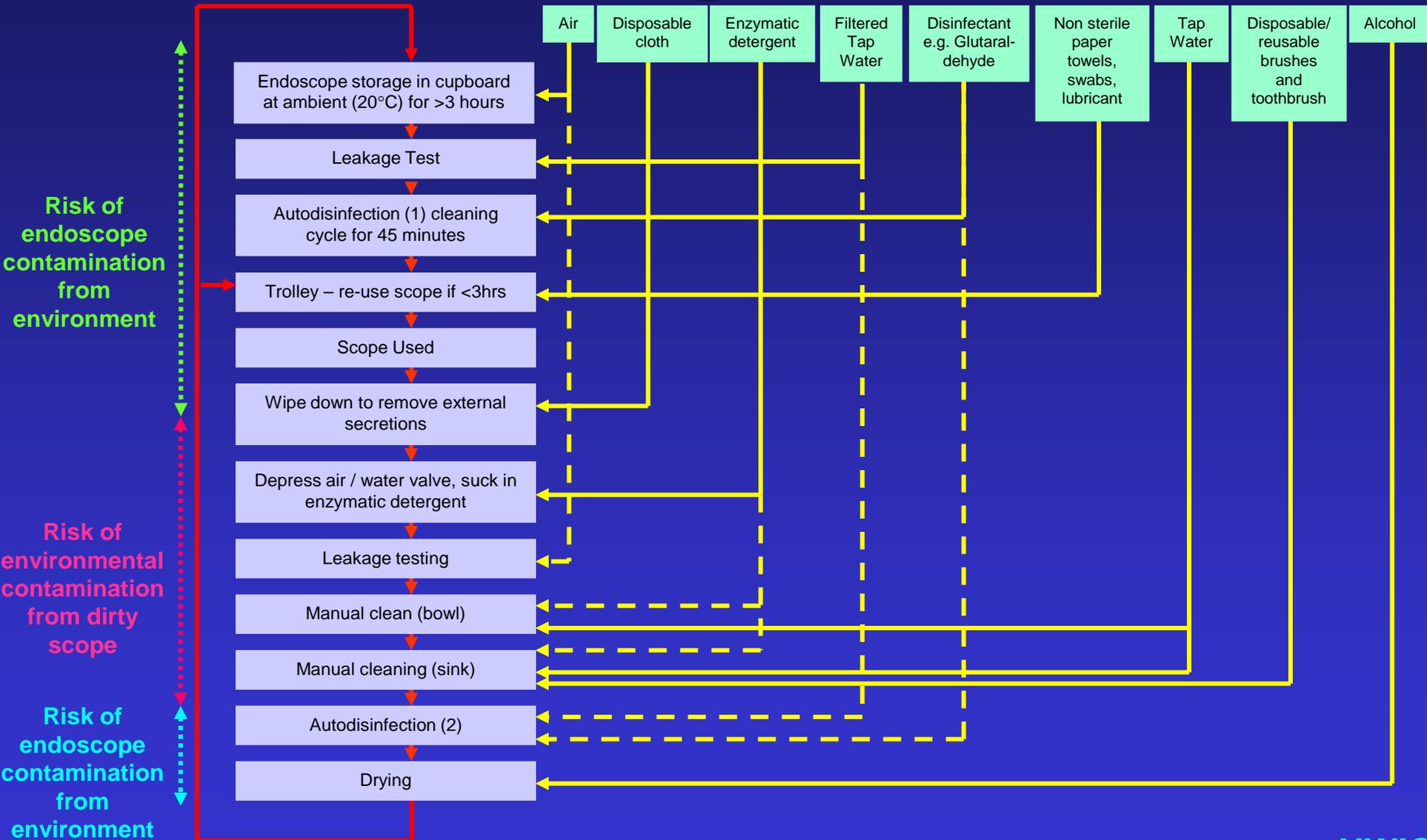
- Risk of abuse
- Vulnerable groups

# Clinical HACCP LS4 P1

Construct process flow diagram (PFD)

- Outline process
- All stages

# Endoscope Decontamination Flow Diagram



# Clinical HACCP LS5 P1

Verify flow diagram

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



# Clinical HACCP LS6 / P1

## 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 HCAs 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

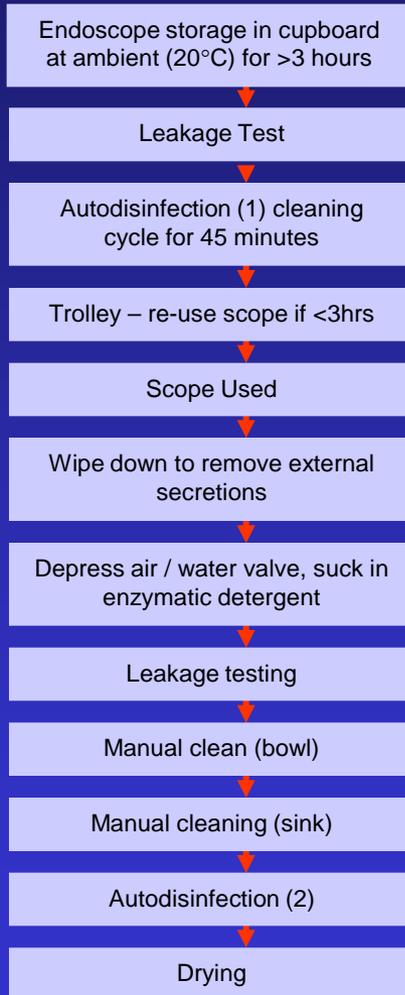
Any action and activity that can be used to prevent or eliminate a food (patient) safety hazard or reduce it to an acceptable level

# Clinical HACCP LS7 P2

## 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



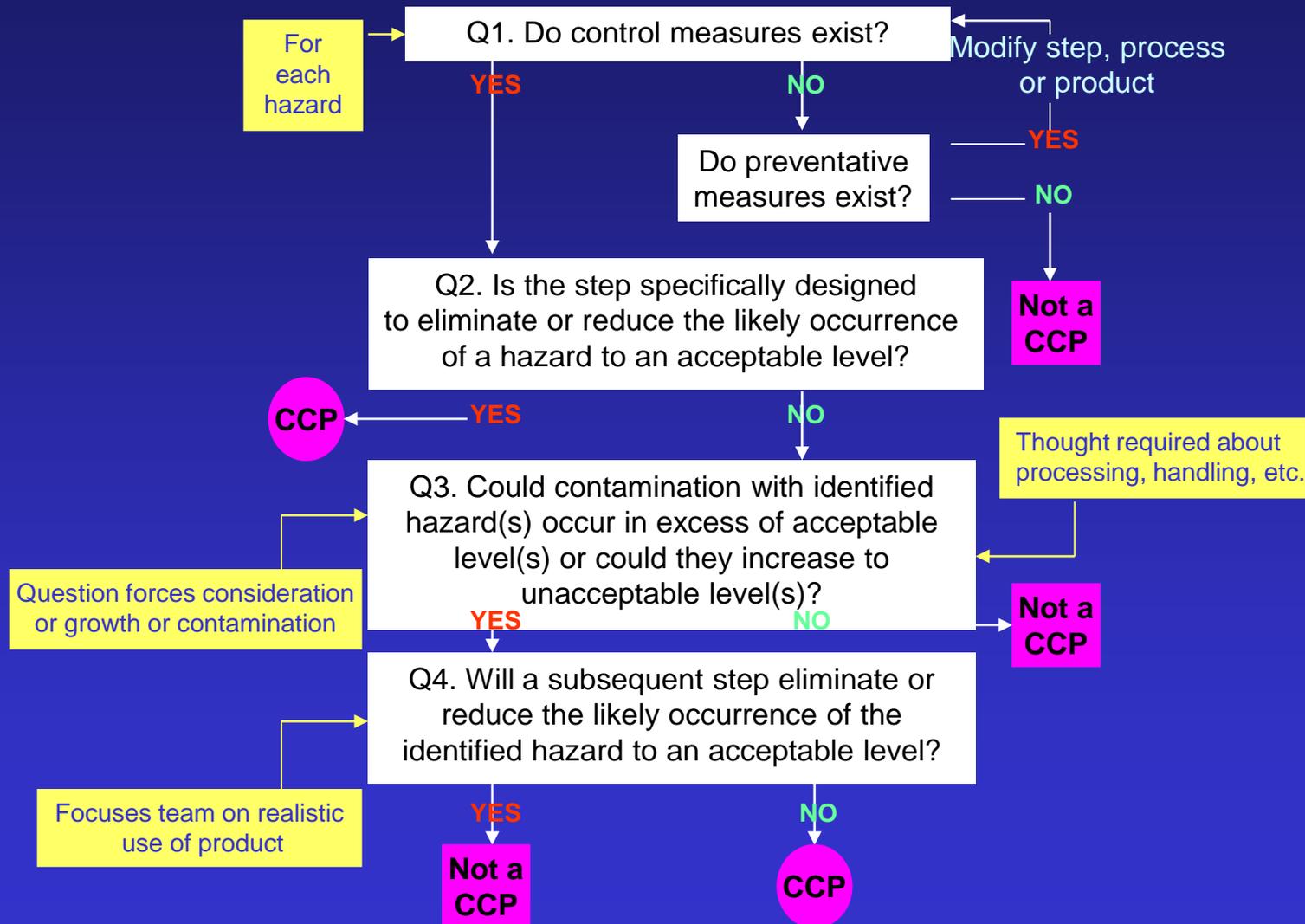
# Case Study Hazard Analysis

Process Step	Hazard	Control Measure	CCP
Cleaning	Presence of organic matter Biofilms Pathogen survival	Effective cleaning	?

# Determine CCPs

- Decision trees
  - Codex
- No control measure?

# Determine CCPs: Codex Decision Tree



# Determine CCPs: Output from use of Codex Decision Tree

PROCESS STEP	HAZARD	CONTROL MEASURES	DECISION TREE QUESTIONS					CCP Y/N
			1	1a	2	3	4	
Cleaning	Residual soil / microroganisms	Effective cleaning	Y	-	Y	-	-	Y

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?”.

# Cleaning Endoscopes: Quotations

“Amongst the most challenging medical devices to clean”

“Instruments from “hell””

“Cleaning crucial to prevent transmission”

“Capable of 99.99% reduction bioburden”

# Cleaning Endoscopes: Quotations

“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

# Cleaning Endoscopes: Quotations

“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

# Quotations

“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

PROCESS STEP	HAZARD	CONTROL MEASURES	DECISION TREE QUESTIONS					CCP Y/N
			1	1a	2	3	4	
Disinfection	Survival of vegetative pathogens	Effective Chemical Disinfection	Y	-	Y	-	-	Y

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

# Establish Critical Limits LS8 / P3

- 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

	Unit A		Unit B	
	<b>Bacteriology (cfu/sample)</b>	<b>ATP (RLU/sample)</b>	<b>Bacteriology (cfu/sample)</b>	<b>ATP (RLU/sample)</b>
<b>Suction channel pre-disinfection</b>	0.8 (0 - 7) 4%	192 (26 - 531) 4%	1.2 (0 - 8) 18%	1191 (22 - 10030) 42%
<b>Biopsy channel pre-disinfection</b>	0.3 (0 - 2) 0%	683 (29 - 3829) 16%	1.7 (0 - 14) 18%	1389 (69 - 12436) 45%
<b>Suction channel post disinfection</b>	0.3 (0 - 6) 4%	60 (24 - 103) 0%	0.1 (0 - 1) 0%	70 (17 - 354) 0%
<b>Biopsy channel post disinfection</b>	1.1 (0 - 14) 8%	82 (20 - 502) 4%	0.1 (0 - 1) 0%	67 (20 - 374) 0%
<b>Endoscope exterior and tip Post disinfection rinse water</b>	0.2 (0 - 2) 0%	1387 (20 - 12102) 44%	0.0 (0 - 0) 0%	353 (38 - 2715) 16%
<b>Endoscope resting surfaces</b>	0.4 (0 - 3) 4%	264 (25 - 1861) 12%	1.7 (0 - 14) 26%	355 (119 - 839) 18%
<b>Image function switch panel</b>	0.5 (0 - 3) 4%	5322 (111- 74457) 92%	0.03 (0 - 1) 0%	401 (88 - 3677) 13%

<b>Key:</b>	Mean (Range)	Failure levels set at $\geq 3$ cfu/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

# Establish Corrective Actions LS10 / P5

- 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 LS11 / P6

- Verification

Application of methods, procedures, tests and other evaluations in addition to monitoring to determine compliance with the HACCP plan

# HACCP Terms

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

-Problems with private practice(2003)

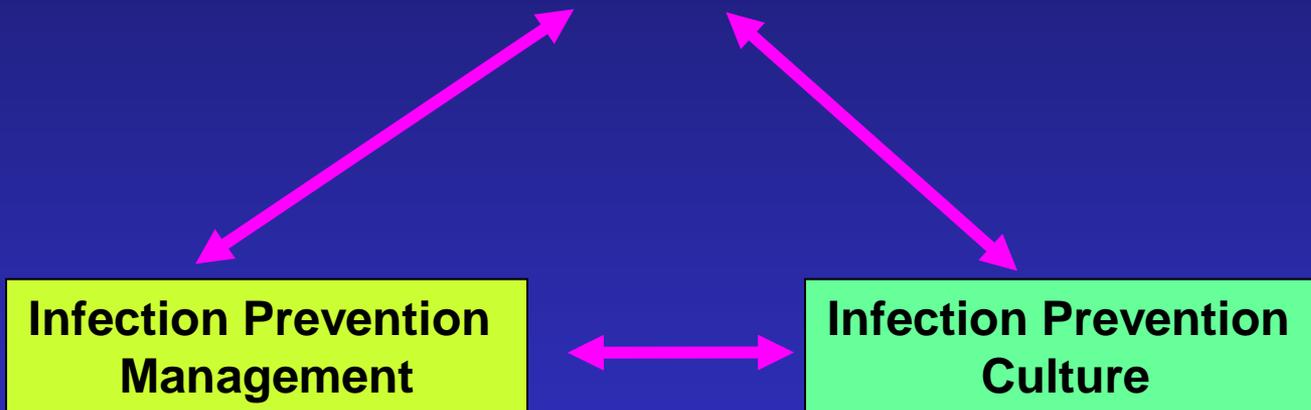
- NI June 2004

Management Failures

# Comparison Between HACCP and Management Systems in Two Endoscopy Units

HACCP LS	UNIT A	UNIT B
LS1	No	Partial
LS2	No	Partial
LS3	No	No
LS4	No	No
LS5	No	No
LS6	No	Partial
LS7	Partial	Partial
LS8	Partial	Partial
LS9	No	No
LS10	No	No
LS11	No	Partial
LS12	No	Partial

**Operational Performance:  
What happens**



# 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

# Basic Control Measures Used in Infection Prevention

- Relatively well documented
- US and UK
  - New epic 2: National Evidence Based Guidelines Feb, 2007
- 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

# HIS 2006: Lowbury Lecture (W Jarvis)

## 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

# 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

## Checklist Continues To Stop Bloodstream Infections In Their Tracks, This Time In Rhode Island

Friday, 03 December 2010 18:05

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 (CLABSIs) fell by 74 percent across Rhode Island's 23 ICUs over two and a half years. Researchers estimate the interventions prevented 42 CLABSIs, 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

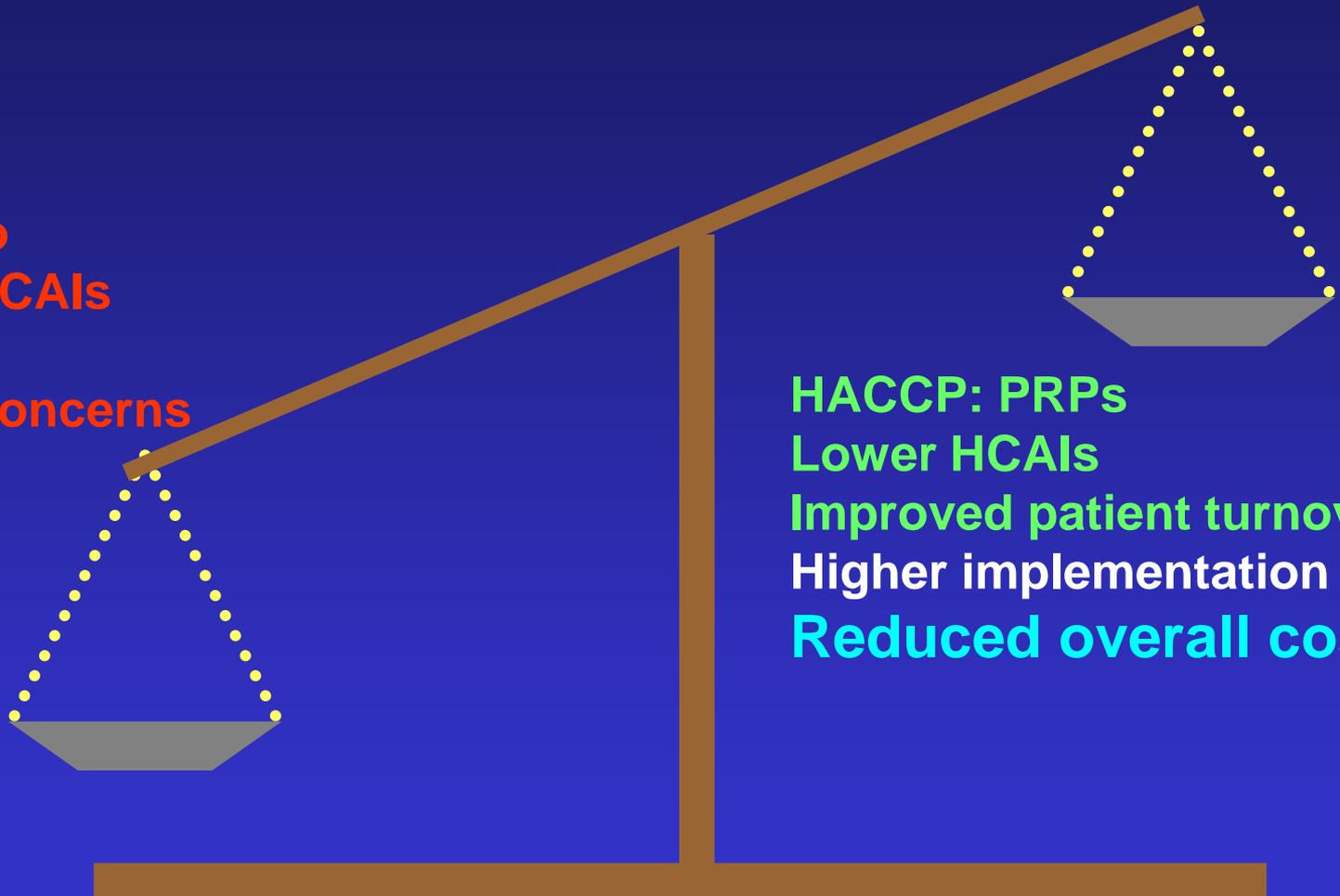
## Implementation Costs - Ongoing

- 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?**

