Controlling procedures for reprocessing flexible gastrointestinal endoscopes
The value of g-control charts

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Objectives

In our quality control (QC) program and in the international literature, infection has been related to high-risk flexible gastrointestinal endoscopes (FE).

Especially after over night proliferation of micro organisms in FE channels, patients can be at infection risk.

We looked for unstable FE reprocessing procedures using a Number-Between g-Type statistical Control Chart and associated statistical methods.

Methods

Microbial counts from flush water from the water channel obtained immediately before an endoscopy were used in our QC program. Clean, critical and high-risk FEs were defined.

Definitions for the Quality Control Program		
Bacteria from flush water from the water channel of flexible endoscopes		
Clean FE	**Critical FE**	**High-risk FE**
0-4 CFU per 0.2 ml	5-50 CFU per 0.2 ml	>50 CFU per 0.2 ml

Washer-disinfectors (WDs)

Cold-chemical WDs:

Fibro Cleaner (Lancer France) - 2% glutaraldehyde (GA) for 10 min at room temperature

Thermo-Chemical WDs:

ETD and ETD 2(+) (Olympus, Europe) - 0,12% detergent and 0,24% GA between 59 and 60 °C.

g-Control Charts

- **X-axis** represents the consecutive number of identified critical or high-risk FE.
- **Y-axis** represents the number of clean FE between critical or high-risk FE.
- **CL** (the centre line) illustrates the central tendency of the y-axis values.
- **UCL** (the upper control limit) is CL + 3 x standard deviation. (the lower control limit is zero).

Criteria for lack of statistical control

1. Control values above the UCL.
2. Eight consecutive control values on the same side of the CL.
3. Any 12 of 14 consecutive control values on the same side of the CL.
4. Eight consecutive values exhibiting either an increasing or decreasing trend.

CL was determined for the three different WDs (**CLwd**) and for the manual cleaning (**CLmc**) from previous experiments.

g-control charts were produced for each endoscopy unit allowing out of control evaluation in relation to occurrence of critical and high-risk FEs.

13 endoscopy units from 8 hospitals in Copenhagen Hospital Corporation (H:S) and Copenhagen County (KAS) participated in the program.

(Infect Control Hosp Epidimiol 1998;19: 265-283)

Table 1: CLmc from previous experiments and CLwd from evaluating of 7458 QC samples from the water channel of FE after reprocessing in tree different

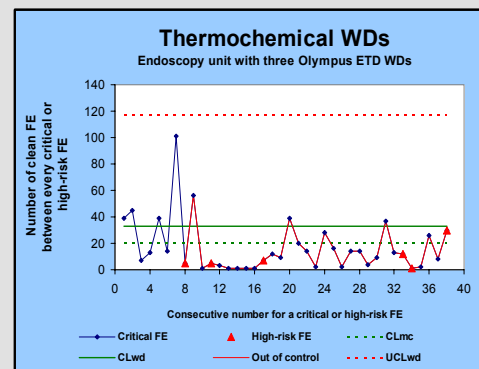| Manual cleaning or Washer-disinfector	Detergent and Disinfectant	CLmc or CLwd
Manual cleaning (No proliferation of micro organisms in FE)	Enzymatic detergent.	20
Fibro cleaner WDs (Procedure optimized)	Original products from Lancer, France	20
ETD WDs (ETD cleaner and disinfectant	Original products from Olympus	32
ETD 2(+) WDs	Original products from Olympus	46

Figure 1: g-Control chart with results of 651 samples through five years from the water channel of FE immediately before an endoscopy.

Results

7358 QC samples from FE were evaluated. Table 1 shows CLwd for three WDs respectively and CLmc for manual cleaning.

Figure 1 shows a g-control chart over a 4-year period from a department using three 6-10 year-old Olympus ETD WDs.

The FE reprocessing went from in control to out of control

- with eight or 12 of 14 consecutive control points below the CLwd and CLmc.
- with a occasional observation of high-risk FE during the last two years.

Control charts from all departments

If defective FEs were excluded:

- Out of control situations with high-risk FE could only be detected if eight or 12 of 14 consecutive control points fell below the CLwd or CLmc.

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Conclusion

- The g-control chart was found to be a valuable statistical tool allowing identification of out of control procedures for reprocessing FE.
- These data can show out of control manual cleaning and early signs of WDs in need of repair or are in such bad condition they should be replaced.