Minimizing Glutaraldehyde Use

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Hospital: Tools may have been contaminated patients notified of possible HIV, hepatitis exposure

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MANHASSET, New York (AP) -- A hospital notified 177 patients that they may have been exposed to HIV or hepatitis because equipment used to check their digestive systems might not have been properly cleaned.

North Shore University Hospital spokesman Terry Lynam said doctors believed the risk of transmission was "minuscule" and that the letters were a precautionary measure.

Of the 177 people sent letters last week, 86 have already undergone tests and none have tested positive for either virus, the hospital said. All of them are supposed to be retested in six months.

The hospital said it did not have records that medical instruments used for upper endoscopies or colonoscopies were properly disinfected for procedures performed from April 28 to May 10.

Workers apparently failed to test disinfectant levels in the water used in a cleaning machine, the hospital said. One of the workers was fired and a second has been suspended without pay, it said.

The procedures involve inserting a flexible tube through the patient's mouth or rectum to check the upper or lower digestive system for abnormalities.

Take Home Messages

1. Balance sporicidal, virucidal, and bactericidal effectiveness vs. human health effects and environmental toxicity of wastes
2. Check material compatibility with delicate medical devices and equipment repair costs
3. Consider cost per cycle, useful life of product, and cycle time

First Consider the Device*…

- Critical

  Enters sterile tissue or vascular system (e.g., surgical instruments, cardiac and urinary catheters, implants)

  STERILIZATION

- Semi-Critical

  Contacts mucous membranes or non-intact skin (e.g., endoscopes, respiratory therapy and anesthesia equipment, diaphragm rings)

  HIGH LEVEL DISINFECTION

- Non-Critical

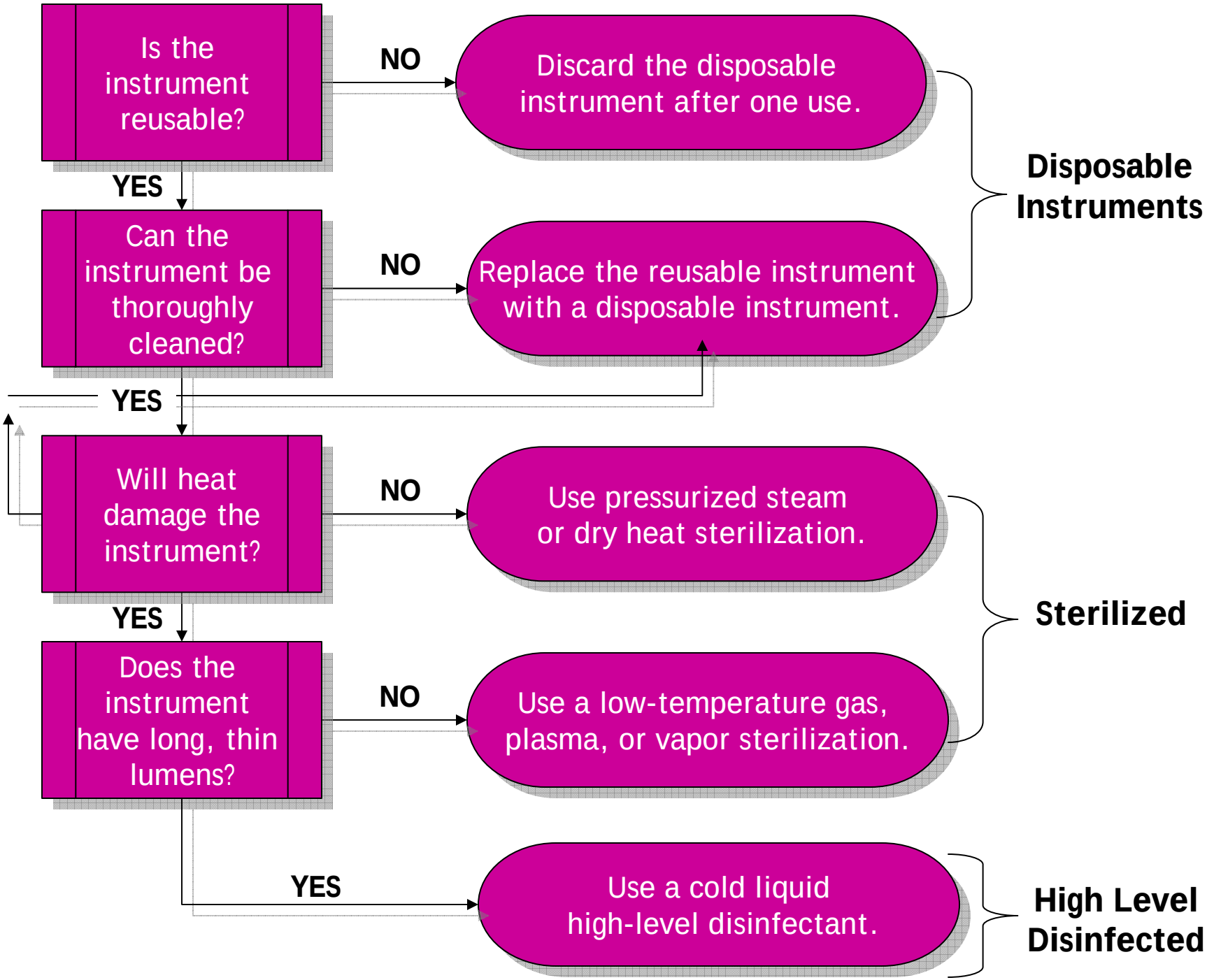
  Contacts intact skin (e.g., bedpans, blood pressure cuffs, crutches)

  DISINFECTION

*Spaulding scheme

Reprocessing Algorithm* and Pollution Prevention Crosswalk

- Must maintain strict infection control standards to ensure patient safety while also being mindful of environmental impacts.
  - Based on use and construction of instrument
  - Disposal considerations
  - Chemical requirements
  - Available P2 opportunities



* Reprinted with permission from: Muscarella LF, "Automatic Flexible Endoscope Reprocessors," *Gastrointestinal Endoscopy Clinic of North America*, 2000 April;10(2):245-257

Reprocessing Algorithm* and Pollution Prevention Crosswalk

Q1 | Is the instrument reusable?
If **NO**, discard after each use.

Q2 | Can the instrument be thoroughly cleaned?
If **NO**, replace with disposable instrument.

Q3 | Will heat damage the instrument?
If **NO**, sterilize using pressurized steam or dry heat

Q4 | Does the instrument have long, thin lumens?
If **NO**, sterilize using a low pressure gas, plasma or vapor technologies
If **YES**, use cold-process high-level disinfectant

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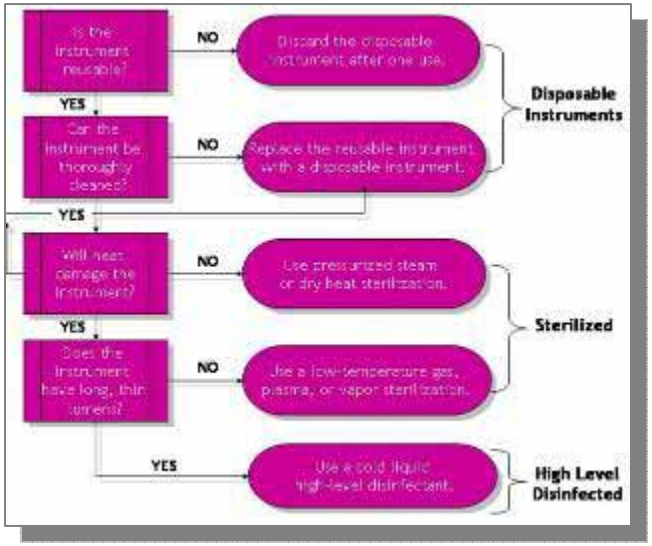
Now, making the P2 connection…

- **Disposable Instruments**
  - Know where to throw!
  - Opportunities for reprocessing single-use devices



- **Sterilization**
  - Avoid using Ethylene Oxide (EtO)
  - Disposal considerations

- **High-Level Disinfection**
  - Minimize Glutaraldehyde Use

Disinfection Levels

- High-level

  Capable of killing bacterial spores, and is therefore expected to kill all other microorganisms

- Intermediate-level

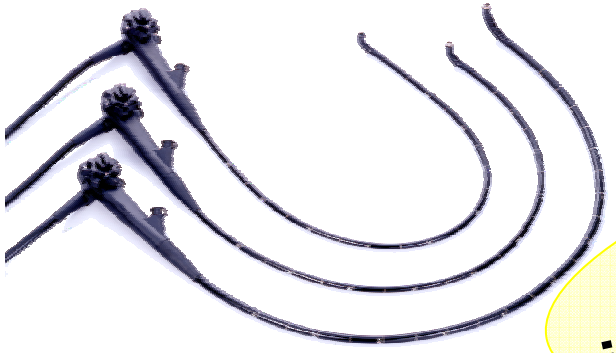
  Destroys all vegetative bacteria, including tubercle bacilli, viruses, and fungus spores

- Low-level

  Destroys all vegetative bacteria (except tubercle bacilli), some viruses and fungi

Instruments Often Cleaned with Cold Process High-Level Disinfectants

- Flexible Endoscopy
  - Gastroenterology
  - Gynecology
  - Head & Neck Surgery
  - Urology
- Rigid Endoscopy
  - Operating Room
- Ultrasound Transducers
  - Obstetrics
  - Radiology
  - Cardiology
  - Urology
- Miscellaneous
  - Cryo probe tips
  - Diaphragms



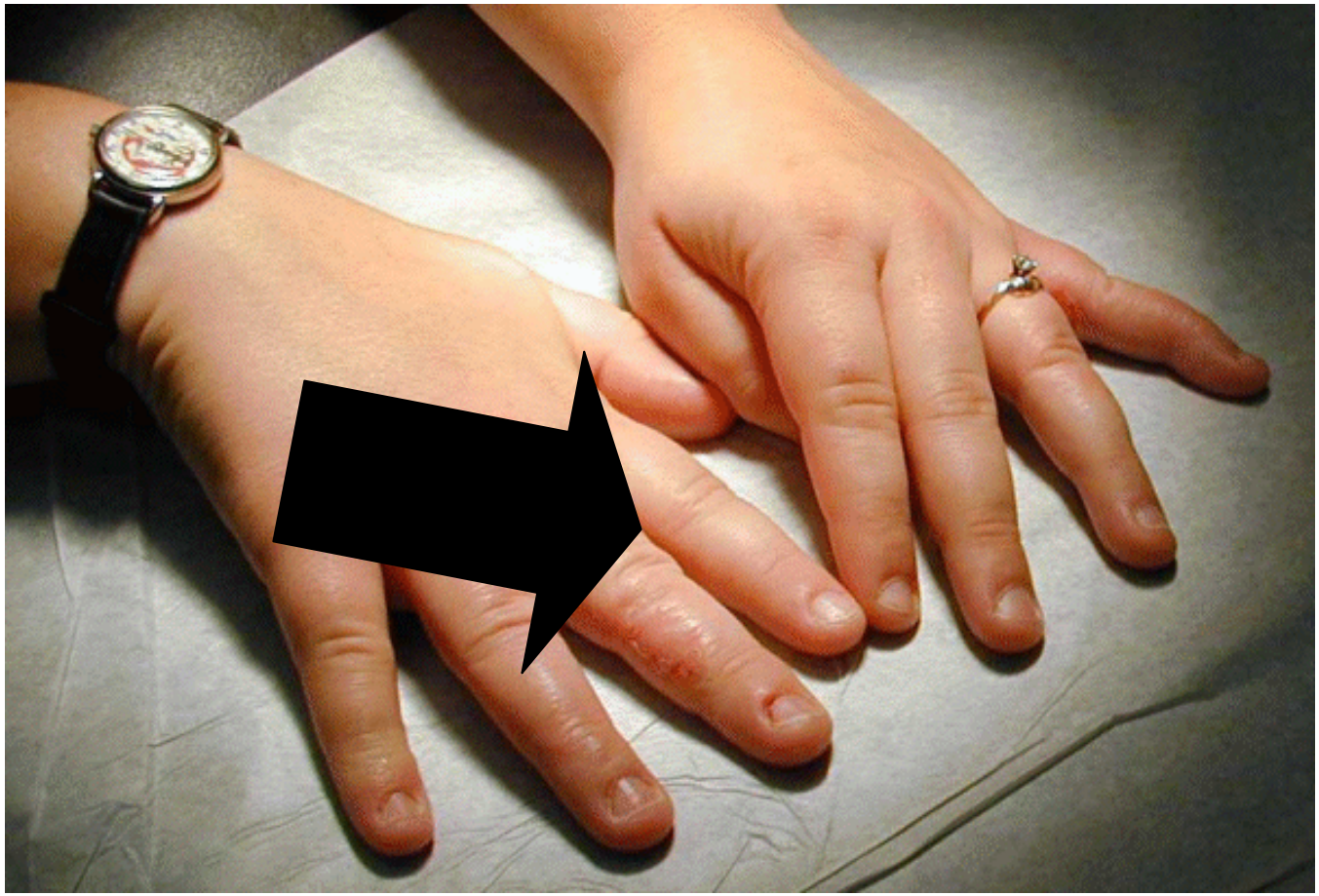
Heat and moisture sensitive instruments with long, thin lumens.

Cold Liquid High-Level Disinfection Methods

- Glutaraldehyde
  - Cetylcide-G (3.2%)
  - Cidex (2.4, 2.5, 3.4%)
  - MedSci (3%)
  - Metricide (2.5, 2.6, 3.4%)
  - Omnicide (2.4, 3.4%)
  - Procide (2.4%)
  - Rapidcide (2.5%)
  - Sporicidin (1.12/1.93% glut/phenol)
  - Wavicide-01 (2.5%)
- Hydrogen Peroxide
  - Sporox (7.5%)
- Hydrogen Peroxide/ Peroxyacetic Acid
  - EndoSpor Plus (7.5/0.23%)
  - Peract 20 (1.0/0.08%)
- ortho-Phthalaldehyde
  - Cidex OPA (0.55%)
- Peroxyacetic Acid
  - Steris S-20 (35%)

Disadvantages of Glutaraldehyde

- Skin sensitizer – rashes and dermatitis



Disadvantages of Glutaraldehyde

- Severe irritant - may cause asthma and respiratory sensitization
  (although not cancer or reproductive harm)
- Burning eyes and conjunctivitis
- Headaches and nausea
- Low exposure limits
  - 0.2 ppm NIOSH REL
  - 0.05 ppm ACGIH TLV
  - Proposed 0.015 ppm Ceiling Limit in CA

Kaiser Woodland Hills Case Study:

OPA vs. Glutaraldehyde

- Low vapor pressure, therefore minimal inhalation risk
- Switch can be accomplished relatively quickly compared to installing engineering controls

- Reduces disinfection time to 12 min. manual and 5 min. automated processing (from 20 min. for glutaraldehyde)
- Allows twice the disinfection cycles before solution failure

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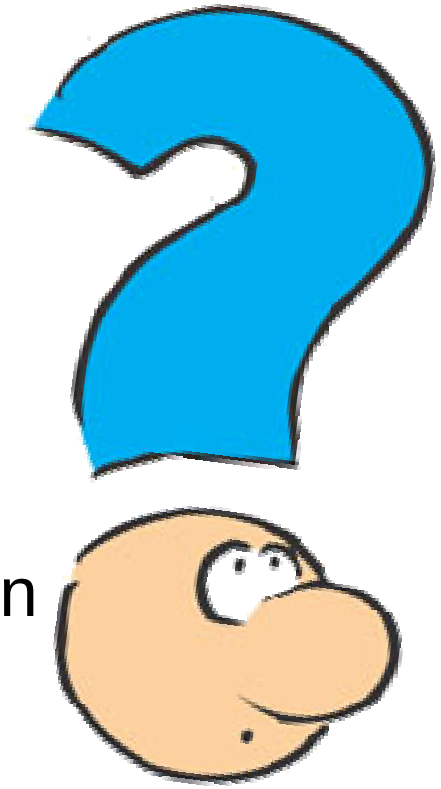
OPA Considerations

- Unknown long-term health effects or cross-sensitivity to other aldehydes
- No validated air sampling method
- No exposure limits set – so for now, requires same engineering controls as glutaraldehyde
- Contact with CIDEX® OPA may stain skin or clothing. Solution may also stain surfaces such as walls, floors and countertops.
- Product more expensive than glutaraldehyde



June 2004 Product Notification

- Possibility of sensitization to CIDEX OPA Solution with repeated exposure.
- In rare instances CIDEX OPA Solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies.
- CIDEX OPA Solution should not be utilized to process instrumentation for patients with known sensitivity to CIDEX OPA Solution or any of its components.

The Built Environment

- Isolation of cleaning and disinfection process from clinical procedure areas
- Separation of clean and dirty areas
- Process flow from dirty to clean, with no cross-over encouraged between the two
- Engineering controls of vapor-generating activities and equipment
- Safety equipment (eyewash, shower, spill containment, emergency shut-off)

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Local Exhaust Ventilation

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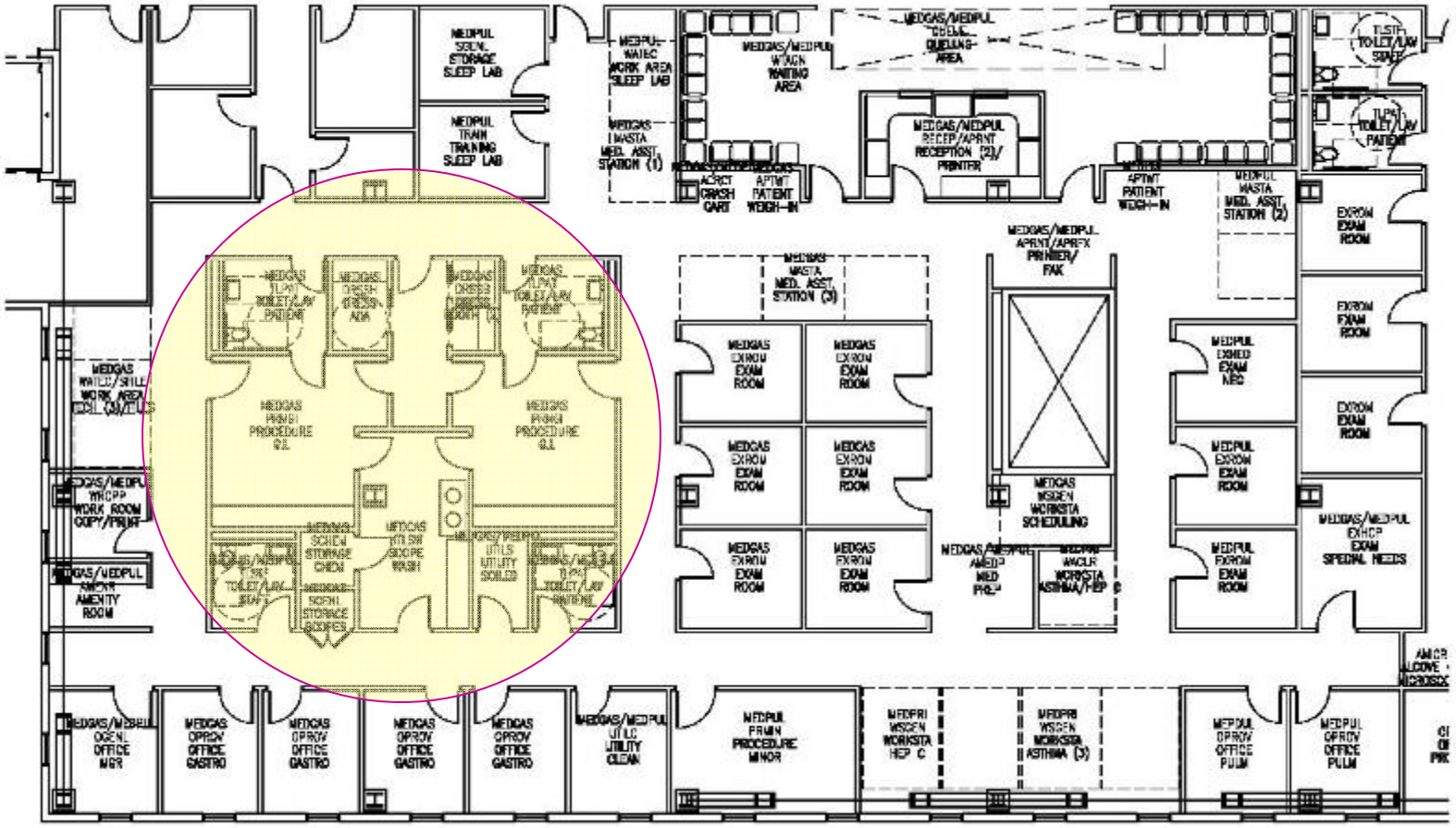
Scope Wash Room



Time Out: Comparing Cycle Times

Glutaraldehyde *($5 per bottle)*

- **20 minutes per cycle**

  = 24 cycles per 8 hour shift

Cidex OPA *($25 per bottle)*

- **12 minutes per cycle (manual)**

  = 40 cycles per 8 hour shift

- **5 minutes per cycle (automated)**

  = 96 cycles per 8 hour shift

Benefits of Quicker Process Time

- **Increased availability of instruments and medical devices**
- **Decreased inventory requirements**
- **Increased personnel availability**

Patients get treated sooner!

Relative Cost Considerations

$20 **Difference in cost of OPA vs. glutaraldehyde-based products**

$15,000 **Cost of each reprocessor**

$30,000 **Cost of each endoscope**

Take Home Messages

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