Learning Objectives

- To appreciate the sources and consequences of errors in digital radiology systems
- To consider processes for avoiding, detecting, and recovering from errors
- To become familiar with how automation minimizes some errors but aggravates others
How can errors arise in such a wonderfully automated system?

- Mistakes in configuration of PACS
- Improper calibration of PACS devices
- PACS design flaws
- Inherent limitations of human operators
- Discrepancies between PACS and hospital processes
- Inadequate training and documentation of PACS and hospital processes
- Insufficient planning for PACS service interruptions

Mistakes in configuration of PACS

- Inappropriate software settings and values
- Outdated or inconsistent version of software
- Incompatible combinations of software and hardware

Improper calibration of PACS devices

- Includes monitors, Computed Radiography (CR), film digitizers, laser cameras, analog interfaces, phototimers, etc.
- Methodology for calibrations not well-established
- Frequency of calibrations not well-established
- Consequences of im-calibration not widely acknowledged
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“The best electronic image, improperly displayed is terrible.”

- CRT monitors degrade over time.
- The wrong display Look-up-table (LUT) can spoil a great electronic image.
- Test patterns, notably the SMPTE, can make display problems obvious.

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**PACS design flaws**

- Some software and hardware features either do not function, or act in an undesired manner (bugs).
- Some processes that are absolutely required for clinical practice are not supported.
- Limited connectivity
  - Incomplete implementation of DICOM
  - Incompatible interpretations of DICOM
- Lack of adherence to software design principles
- Lack of application of Reliability Engineering

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**Inherent limitations of human operators**

- Every process that depends on a human is a source of random errors; every process that automation performs independently is source of systematic errors.
- Human errors increase exponentially with the complexity of the system and operator interface.
- Quality Control (QC) processes must be in place to detect and rectify errors.
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Differences between PACS and hospital processes: fallacious assumptions!

- Patient identification data is invariant.
- Only one radiologist is associated with a report.
- Only one physician is associated with a request.
- Images are used in surgery in the same manner as images are used in clinics.
- The patient scheduled for an exam in Room 4 will be examined in Room 4.
- The exam started in Room 4 will be completed in Room 4.
- Outpatients are only examined in the Outpatient Center.
- The same supervisors of exams on 1st shift are also present on 3rd shift.

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Inadequate training and documentation of PACS and hospital processes

- Limited knowledge of hospital processes
  - Who are my customers?
  - Where are they looking at images?
  - What are they doing with the images?
  - How many look at images at one time in the same place?
  - How is an exam scheduled, performed, interpreted, and reported?
- Limited knowledge of PACS processes
  - varied operator background
  - High personnel turnover
  - Rapid advancements in technology
  - Sketchy technical documentation

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Insufficient planning for PACS service interruptions

- How is PACS affected by loss of utility services, i.e., power, HVAC, or network?
- How do I maintain continuity of clinical operations during downtime of an individual PACS component?
- Can local components operate during downtime of a central PACS component (database, archive, gateway, RIS or RIS interface)?
- How does PACS recover after service is restored?
- How does PACS recover after service is restored?
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So, it’s not a perfect world ...

Quantifiable Consequences of Degraded Performance:
- Loss of Contrast Sensitivity
- Loss of Sharpness/Spatial Resolution
- Loss of Dynamic Range
- Increase in Noise
- Decrease in System Speed
- Geometric Distortion
- Artifacts

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So, it’s not a perfect world ...

Clinical Consequences of Degraded Performance:
- Increase in non-diagnostic/repeated examinations
- Increase in patient radiation dose
- Increase in misdiagnosis
- Increase in equipment downtime
- Delay of diagnosis
- Loss of images
- Decreased confidence in the system

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The best image, improperly identified, is useless.

Consequences of misidentification:
- Incorrect information can cause image unavailability
- Incorrect exam info can affect image development
- Mis-association complicates error correction
- Proliferation of digital images complicates correction

Automation of association:
- RIS interfaces
- Bar code scanner augmentation
- DICOM Modality Worklist Management
- Unscheduled exams
- Resource re-allocation
Which image is worse?

“To err is human: to really mess up requires a computer!"

- Electronic images are impermanent: they are subject to deletion, misregistration, misrouting, and misinterpretation.
- Electronic devices and media are impermanent records: the consequence of loss is greater than one film or one film jacket.
- A single bad electronic image can be prevented: a single bad film image can be controlled.
- Bad electronic images can disappear without a trace: bad film images leave a signature. How many films were in the box at start-of-shift?

“Bad practice still translates into bad images.”

- Automation has not been trivial to correct for patient motion, poor inspiration, bad positioning, improper filtration, incorrect alignment of x-ray beam and grid, wrong, manufactured, wrong patient examined, or double exposure.
- Image processing is a poor substitute for proper examination technique.
- This implies that we must provide a guide for appropriate technique.
Countermeasures:

- Quality Assurance
  - an active, not passive, and unfortunately, you have to measure stuff
- Training
  - initial, incidental, refresher, and you have to create it, conduct it, and keep it up-to-date
- Reliability Improvement
  - assemble components to bias for continuity of clinical care
- Disaster Recovery
  - plan, prepare, practice

"Quality assurance (QA) means never having to say you're sorry."

- QA means making sure that the devices are properly operated; the devices operate properly, and the devices are properly maintained.
- QA must consider the entire imaging chain from acquisition to display.
- QA must regard the human operator as an integral part of the system.

"Someone has to reconcile the checking account."

- The technologist/supervisor must accept responsibility for appropriate delivery of all images to the physician.
- Processes must be in place to verify that all exams performed and all images acquired reach their intended destinations. Simply noting that two images were acquired does not necessarily mean that both the PA and LAT views were acquired.
- Technologists must recognize images that are not diagnostic.
- Processes must be in place to correct errors when detected.
- Errors must be recorded and reviewed.
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“Human operators have a right to know what is expected of them.”

- Vendor applications training is not sufficient.
- Local policies and practice must be developed, communicated, documented, reinforced, and enforced.
- Clinical Competency Criteria are helpful for standardizing and documenting basic proficiency training.
- Training must be tailored for technologists, radiologists, referring physicians, clinical engineers, and PACS personnel.

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“Commercial film-less imaging systems are not designed to support comprehensive QA”

- QA costs time and money.
- QA is not required to obtain FDA approval of PACS products (although ISO9000 is incorporated by reference).
- The user bears the burden of developing and implementing QA, because the user suffers the consequences of its absence.

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“The best maintenance is preventive maintenance.”

- Calibrations need to be performed on schedule.
- Operators need to clean, inspect, and document.
- Start-of-shift routines or checklists are helpful.
- Schedule PM to occur at convenience of clinical operation.
- Software upgrades are major service events that demand re-verification of proper function.
“Without emphasis by the radiologists, QA is just spinning its wheels.”

- Resources and priorities are controlled by the radiologists.
- Radiologists set the standard; hospital staff can only produce the lowest level of quality that is acceptable to the radiologists.
- Radiologists must demand accountability for image quality and availability, and must enthusiastically support the QA effort.

Physicians depend on PACS ...
... like a race driver depends on tires.

- While the crew chief can't preclude failures, he can take action to improve reliability.
- Recent literature describes efforts to minimize PACS downtime.
- Early PACS reliability requirements based on acquisition modality experience.
- PACS Reliability should be reevaluated:
  - Dependability of PACS must be measured.

Eliminate Single Points of Failure

- Local loss of service has global consequences.
- "Critical PACS components" is a subset of single points of failure.
- Includes associated information systems.
- Includes utilities.
### Table 1. Single Points of Failure

<table>
<thead>
<tr>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Image database (Oracle)</td>
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<tr>
<td>Radiology Information System (RIS)</td>
</tr>
<tr>
<td>RIS interface (PACS Broker)</td>
</tr>
<tr>
<td>Hospital Information System (HIS)</td>
</tr>
<tr>
<td>Web server (Web1000)</td>
</tr>
<tr>
<td>Network Interface Adapter (NIA)</td>
</tr>
<tr>
<td>Medical Gateway 3000</td>
</tr>
<tr>
<td>Network Gateway</td>
</tr>
<tr>
<td>Archive Server</td>
</tr>
<tr>
<td>Magnet Optical Disk or Tape media</td>
</tr>
<tr>
<td>Main Data Center</td>
</tr>
<tr>
<td>Hospital Broadband Network</td>
</tr>
</tbody>
</table>

### Redundancy - multiple or backup components

- Strategy to eliminate Single Points of Failure
- Components in parallel fail at the product of individual failure rates.
- Components in series fail at the sum of individual failure rates.
- RAID, a Redundant Array of Inexpensive Disks, is an enabling technology for PACS.
- Redundant server technology was demonstrated at RSNA 2000.

### Emergency Power - inside and outside the data center

- What PACS components must operate during emergency?
- What components require UPS for orderly shut-down?
- What components require Line Conditioner to compensate for transients when switched to generator power?
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**Distributed Redundancy**
- Similar display or acquisition components, geographically separated.
- Operator may have to travel outside normal area to use.
- Clinical operations continue uninterrupted.

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**Manual workarounds**
- Allow continued operation during unavailability of automated system.
- Reversion to Conventional Film/Screen radiography, the PACS workaround of last resort.

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**Recovery**
- Restored automated system requires update.
- May involve transmission of images acquired during downtime.
Failure Modes and Effects Analysis

- What natural and man-made disruptive events could reasonably occur?
- Is the imaging department expected to continue operations despite the event?
- What effect would disruptive events have on PACS components?

Table II. Disaster Scenarios

- Loss of a single image or exam
- Loss of a single piece of media (MOD or tape)
- Loss of a single core component (NG, AS, OS, Broker, or Web Server)
- Loss of a single display component (RS or laser camera)
- Loss of a single NIA (MG 3000)
- Loss of a single QA Workstation (PS, or VIPs)
- Loss of a single acquisition device (CR, DSL, MR, CT, US, FD)
- Loss of RIS connection

Table II. Disaster Scenarios (continued)

- Loss of power to the datacenter
- Loss of network connectivity to the datacenter
- Loss of HVAC to the datacenter
- Loss of physical access to the datacenter
- Loss of all components in the datacenter
- Relocation of the datacenter
- Interruption of service during major upgrade of software requiring database migration
Reliability Improvement Plan

- Need to operate during adverse conditions
- Need to recover rapidly from interruptions in service
- Modified number, configuration, and location of PACS components

Reliability Improvements

- CR Clusters
- Secondary Data Center
- Independent Outlying Health Centers
- Niche PACS in Ultrasound and Nuclear Medicine
- Multiple Gateways
- Capabilities to produce and interpret hardcopy images

Baptism Under Fire:
actual circumstances test reliability

- Hospital-wide power outages
- Hospital network infrastructure reconfiguration
- Relocation of the imaging department
- Relocation of the primary data center
- HIS periodic maintenance
- Software upgrades
- Tropical Storm Allison
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**Special notes on the image database**

- Absolutely critical for continued operations and recovery.
- Daily backup to tape insufficient:
  - Most critical exams are most recent.
- Reconstruction from physical media too slow.
- Parallel databases at Health Centers
  - "Near-realtime", not concurrent.
- Cache management problem
  - Disconnected client = "least busy".

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**Conclusions**

- Unfortunately, errors will always occur in PACS.
- QC is key to detecting and correcting errors.
- Training is key to averting errors.
- Reliability engineering is key to continuity of clinical operations.
- Disaster recovery is key to restoring normal clinical operations.

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**References**

References


References