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"Quality Control in Picture Archiving and Communications Systems (PACS)"

Texas Children's Hospital

COLLEGE OF MEDICINE • SCIENCE • EDUCATION • RESEARCH • CARE

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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

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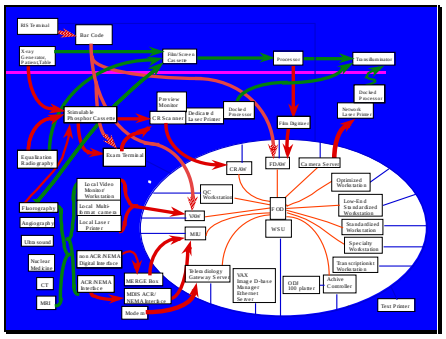

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How can errors arise in such a wonderfully automated system?

- 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

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Mistakes in configuration of PACS

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- Outdated or inconsistent versions of software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

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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 mis-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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Discrepancies 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?

Software upgrade is a service interruption!

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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 detection*
  - *proliferation of digital images complicates correction*
- Automation of association:
  - *RIS interfaces*
  - *Bar code scanner augmentation*
  - *DICOM Modality Worklist Management*
    - unscheduled exams
    - resource re-allocation

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Which image is is worse?

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

- Electronic images are imperfect: they are subject to deletion, mis-association, mis-routing, and mis-interpretation.
- Electronic devices and media are im-permanent records: the consequence of loss is greater than one film or one film jacket.
- A single bad electronic image can be proliferated: a single bad film image can be controlled.
- Bad electronic images can disappear without a trace: bad films disappear, but leave a signature. How many films were in the box at start-of-shift?

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"Bad practice still translates into bad images."

- Automation has not been invented to correct for patient motion, poor inspiration, bad positioning, improper collimation, incorrect alignment of x-ray beam and grid, wrong exam performed, 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.

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Countermeasures:

- Quality Assurance
  - *an active effort, 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*

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"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.

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"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 ***(note: an image count of two does not necessarily mean both the PA and LAT views!).***
- Technologists must recognize images that are non-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.

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"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.
- Radiologist must demand accountability for image quality and availability, and must enthusiastically support the QA effort.

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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 reconsidered:

Continuity of Care must be maintained!

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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.

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Table I. Single Points of Failure

- Image database (Oracle)
- Radiology Information System (RIS) – IDXrad
- RIS interface (PACS Broker)
- Hospital Information System (HIS) – IDX
- Web Server (Web1000)
- Network Interface Adapter (NIA) – Medical Gateway 3000
- Network Gateway
- Archive Server
- Magneto Optical Disk or Tape media
- Main Data Center
- Hospital Broadband Network

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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.

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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
- A.K.A. "Downtime Procedures"
- 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.

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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?

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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, DSI, MR, CT, US, FD)
- Loss of RIS connection

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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

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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

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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

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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
- RIS 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

- Roehrig, H., Willis, C.E., and Damento, M.A.: Characterization of Monochrome CRT Display Systems in the Field. *Journal of Digital Imaging.* 12(4): 152-165, 1999.
- Willis, C.E. Computed Radiography: QA/QC. in *Practical Digital Imaging and PACS.* Medical Physics Monograph No. 28. Madison: Medical Physics Publishing pp 157-175. 1999.
- Willis, C.E., Mercier, J., and Patel, M.: Modification of conventional quality assurance procedures to accommodate computed radiography. *13th Conference on Computer Applications in Radiology.* Denver, Colorado. June 7, 1996. pp. 275-281.
- Willis, C.E., Leckie, R.G., Carter, J., Williamson, M.P., Scotti, S.D., and Norton, G.: Objective measures of quality assurance in a computed radiography-based radiology department. *SPIE Medical Imaging 1995: Physics of Medical Imaging.* Paper #2432-61. vol. 2432. 588-599. San Diego, CA. February 27, 1995.

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References

- McBiles, M. and Chacko, A.K. Coping with PACS downtime in digital radiology. *J. Dig. Imag*. 13:3 pp. 136-142. 2000.
- Ramthun, S., James, E.M., Hangiandreou, N., and Bender, C.E. Electronic imaging system implementation at Mayo Clinic Rochester: downtime procedures and communication plans. *J. Dig. Imag.* 13:2 (Suppl 1) pp.206-207. 2000.
- Avrin, D.E. Andriole, K.P., Yin, L., Gould, R., and Arenson, R.L. Simulation of disaster recovery of a picture archiving and communications system using off-site hierarchal storage management. *J. Dig. Imag*. 13:2 (Suppl 1) pp. 168-170. 2000.
- Behlen, F.M., Sayre, R.E., Weldy, J.B., and Michael, J.S. "Permanent records": experience with data migration in radiology information system and picture archiving and communications system replacement. *J. Dig. Imag.* 13:2 (Suppl 1) pp.171-174. 2000.

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References

- Willis, C. E.; McCluggage, C.W.; Orand, M.R., and Parker, B.R. Puncture Proof Picture Archiving and Communications Systems. *Journal of Digital Imaging* Vol 14 No 2 Suppl 1 (June) 2001: pp 66-71.
- Groth, D.S.; Bernatz, S.N.; Fetterly, K.A., and Hangiandreou, N.J. Cathode Ray Tube Quality Control and Acceptance Testing Program: Initial Results for Clinical PACS Displays. *RadioGraphics* 2001;Vol 21:719-732.
- Willis, C.E. Quality Assurance: An Overview of Quality Assurance and Quality Control in the Digital Imaging Department. in *Quality Assurance: Meeting the Challenge in the Digital Medical Enterprise*. Great Falls: Society for Computer Applications in Radiology. pp.1-8. 2002.
- Honea, R.; Blado, M.E., and Ma, Y. Is Reject Analysis Necessary after Converting to Computed Radiography? *Journal of Digital Imaging* Vol 15 Suppl 1 2002: pp 41-52.