Digital Mammography: Planning, Implementation, Integration

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Why Get Into FFDM?
After All……

• New DMIST study - 26% increase in cancer on SFM?
• Analog – better spatial resolution
  – SFM, 17 – 20 LP/mm
  – FFDM, 5 – 10 LP/mm
• 15 - 60% longer interpretation time for FFDM
• May 2007 – only 20% of facilities FFDM
Growth of FFDM Units and Facilities in US (1st of each month)

- 3.3% of all units
- 3.7% of all facilities
- 13.8% of all units
- 14.8% of all facilities

Date: Oct-03 to Oct-06
Female Breast Cancer Rates by State
Female Breast Cancer Death Rate by State
The ACR’s Mammography Accreditation Program: Ten Years of Experience Since MQSA

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The ACR’s Mammography Accreditation Program has been helping facilities improve the quality of mammography through peer review and professional feedback since 1987. Initially conceived as a voluntary program, accreditation became mandatory when the Mammography Quality Standards Act (MQSA) of 1992 required all U.S. mammography facilities to become accredited and certified by October 1, 1994. Currently, the ACR is the largest of four accrediting bodies approved by the U.S. Food and Drug Administration, accrediting 12,729 units at 8325 facilities by October 1, 2004. Between 1987 and 1991, 70% of the mammography units applying for accreditation with the ACR passed on their first attempts, indicating a marked improvement in the quality of mammography in the United States since MQSA went into effect 10 years ago.

Key Words: Breast radiography, quality assurance

The Challenge

- Prompt annual mammography has shown the ability to decrease the mortality rate from breast cancer in a population by almost 50% *
- As many as 20% of breast cancer will be missed by mammography
- Sensitivity decreases as breast density increases

* Tabar
FFDM Advantage

- Improved contrast resolution
  - Offsets compromise with spatial resolution
- Image manipulation
- Ability to transmit images worldwide
  - Any image, any where, any time
First DMIST Study

Digital Mammography offers a cancer detection benefit for specific subgroups of women:

- Women < 50 years of age
- Pre and Peri menopausal women
- Women with dense or heterogeneously dense breast tissue
Further FFDM Justification

• Improved visualization of calcs
• Lower radiation dose
• Analog – a fully mature modality
• Ability to manipulate images
• Documented 35% decrease in exam time
• Last film based modality
• CAD efficiency
• Elimination of wet processing!
• Standard of care for our facility (market leader)
• Reclaim valuable department space
• Platform for future applications
Getting Started

- CR vs DR – cost vs efficiency
  - CAD in CR environment
- All or nothing (film and digital world)
- Vendor evaluations
  - Site Visit
  - MD Buyline or other
  - Image Quality – phantoms
  - Service history
  - Physicist experience
  - Interface capability – DICOM conformance
  - Image file size
  - Cost; unit and service
Project Planning - Document

- Power and Network drops
- Tech workstation set-up and placement
- PACS Vendor vs Vendor Review Station
  - 5K Monitors
- Environment
- Report/orders interface - MIS
- “Send ID” (SCW) interface
- Home for mamm parts and pieces?
- Laser printer
- Delivery, install and applications
- Room Renovations – esthetics
- Radiologists digitally qualified
Esthetics
Governing Bodies Notification

- Room shielding plan
- State radiation protection
- ACR
  - New or Existing facility
- MQSA
  - Review of film based and digital Q/C
ACR Accredited Facilities Process

• Physics Evaluation
  – Laser Printer up and running
• Send Application fee and physics pass/fail form
• Do not have to wait 4 days
• Make sure ACR receives and approves application – transmits to CMS
• Timeframe dictates whether you will enter the re-accreditation phase or not
Mammographer Readiness

- PACS - unfamiliar territory for many
  - Training
- Tech Workstation Location
  - In room
  - Outside room
- Keep them informed
  - Targeted in-service
  - Explain the set-up
- Vendor training schedule
- Push back regarding scheduling time slot
Radiologist Efficiency (or not!)

- Vendor Webex
- PACS vs Vendor SCW
- Handling prior exams and reports
  - Hang analog images?
  - Digitize Priors (CAD Vendor)
    - Available in reading room
- Reading Preferences
  - Cheat sheet
- CAD
  - Separately Accessed?
  - Overlay?
- Interfaces
- Q/A exams on PACS
- Become a resource/advocate – paradigm shift
BTW.....
What’s Wrong With This Picture?
Don’t Forget the Details
PACS Decisions

• Understand workflow
• Tech Workstations
  – Auto DICOM?
  – Auto import CAD?
• Publish to Web?
  – Images
  – CAD
• Compression
  – Primary - Lossless only, acquisition & archive
  – Web
  – CAD
• Archive CAD?
• Plan storage needs (30mb, 90mb)
• Upgrade reading stations; monitors, RAM, 64 bit
• Network bandwidth
Marketing FFDM

- Get word out to referring’s
- Informational piece - FFDM
- Patient recall letter
- Breast cancer case manager
- Cancer treatment center manager
- Breast conference
Mammography has been practiced since the 1930’s until it has reached the exquisite image quality produced by today’s state of the art equipment and highly trained imaging professionals. Two basic types of systems are in use today – traditional or film/screen (analog) and the newer digital systems which take electronic images of the breast and store them directly in a computer allowing the recorded data to be enhanced, magnified or manipulated for further evaluation. Which one is right for you?

To help answer this question we can refer to the Digital Mammographic Imaging Screening Trial (DMIST) the findings of which were recently reported. Conducted by the American College of Radiology Imaging Network (ACRIN) and funded by the National Cancer Institute (NCI) the trial included researchers at 33 sites across the United States and Canada. This four year project enrolled 49,528 women who had no signs of breast cancer. Women in the trial were given both digital and film mammograms. Mammograms were interpreted independently by two different radiologists. Four different equipment vendors systems were tested during the trial.

The DMIST study showed that digital mammography detected significantly (up to 28%) more cancers than screen film mammography in women who were:

- 50 and younger
- premenopausal
- perimenopausal and
- those with dense breasts

Yet the study showed no difference between digital and film mammography in detecting breast cancer for the general population of women.

In 2005 approximately 211,000 women were diagnosed with breast cancer and 40,000 women died of the disease in the United States. You owe it to yourself to take advantage of the best, most appropriate technology available today to potentially detect this serious disease. At Cascade Medical Imaging, LLC we offer the first digital mammography system in Central Oregon as your breast imaging option.
FFDM Equipment Evaluations, Annual Surveys and QC

FDA regulations require facilities to follow FFDM manufacturer’s QC – this makes life interesting for everyone
900.12(e)(6) QC Tests-Other Modalities:
“the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in this section”

- The “image receptor manufacturer” would be GE, Fischer, Lorad, Siemens or Fuji
MQSA Final Regulations

• Published October 28, 1997
• Required April 28, 1999
• Digital receptors not in use
• FDA could not include detailed FFDM q/c in rules
• FDA charged responsibility of FFDM q/c to manufacturers
• This will be standardized
Our Vendor’s Quality Control

• Laser Printer – daily
  – Artifact Evaluation
  – Printed Phantom Weekly
• SMPTE – weekly
• Artifact Evaluation, Detector, weekly
• SNR/CNR, weekly
• Flat Field Calibration, bi-weekly
• Compression Thickness Indicator
• Reading station(s)
  – Phantom
  – Q/C - photometer
  – Viewing Conditions
Standardize and streamline QC tests, performance criteria and frequencies across all systems
  - Will apply to all manufacturers and models
  - When ready, draft will be sent to manufacturers for their input before it is final

When final, ACR will apply for FDA alternative standard
  - When approved, facilities will have the option of following ACR QC or manufacturer’s QC

Provide input to FDA for new regulation development
• Tech QC
  – Laser printer density consistency (dry lasers) – monthly –
    • ACRIN data shows it rarely fails
  – Darkroom fog test – eliminate
  – MTF/System Resolution – only for systems with moving parts (e.g., slot-scan, CR) – quarterly

• Medical Physicist QC
  – Eliminate annual kVp testing
    • ACRIN data shows it rarely fails with modern generators
Transferring Digital Mammograms

- Must be able to provide **hardcopy of final interpretation quality**
- Softcopy original or lossless compressed images, *if acceptable by receiving party*
- Charging for hardcopies
  - May not charge for 1\(^{st}\) hardcopy
  - May charge for additional copies (actual costs)
Potential of Digital Mammography

“Perhaps the true strength of digital mammography lies not in its conventional use but rather in its ability to serve as a platform for the development of other mammography based breast imaging applications.”

Elizabeth Rafferty, MD
Future Mamm Applications

- Digital Tomosynthesis
- Contrast enhanced mammography
- Dual Energy Subtraction
- Fusion with ultrasound and PET
- CAD subtraction
Tomosynthesis Data Set
Key Talking Points for Tomosynthesis

• Big Four Digital vendors working on technology
• Dose equivalent to four view exam
• Screening vs Diagnostic tool?
• Reduce recall rate by 40%
• File size – 1 gig!
• Longer read time?
• Expensive modality with no reimbursement today
• Upgrade path?
Potential Future PACS/Digital Mamm Enhancements

• 3K monitor – FDA
• Lossy compression - FDA
• Digitize & discard priors??
Questions/Comments
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