Training and Clinical Best Practices for Using CAD Systems

Ronald M. Summers, M.D., Ph.D.
Senior Investigator
Imaging Biomarkers and Computer-Aided Diagnosis Laboratory
Radiology and Imaging Sciences
NIH Clinical Center
Bethesda, MD

Financial Disclosure

- Patent royalties and CRADA support from iCAD Medical, Inc.
- License fees from Translational Sciences Corporation

Disclaimer

- Opinions expressed herein are not necessarily those of HHS or NIH

Group 4 Members

- Matthew Friedman, Georgetown Univ.
- Jesse Lin, FUJIFILM Medical Systems
- Ben Shih-Chung Lo, Georgetown Univ.
- Julian Marshall, Hologic, Inc.
- Pat Milbank
- Stephen Vastagh, MITA
- Samuel G. Armato III, University of Chicago
- Heang-Ping Chan, University of Michigan
- Berkman Sahiner, CDRH, FDA
- Nicholas Petrick, CDRH, FDA

Learning Objectives

- Understand benefits of PACS integration of CAD.
- Identify potential issues with off-label use of CAD.
- Understand the importance of user training relating to CAD devices.
- Learn about areas of CAD user training and QA that could benefit from further research.

What is the Problem We are Trying to Address?

- Improvement in radiologist performance with CAD is poor, even when the CAD performs well in the lab
- Examples from the recent literature:
  - Fenton et al.
  - Dachman et al.

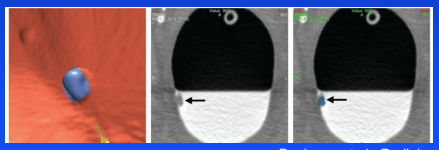
The Problem

- 684 956 women who received more than 1.6 million film-screen mammograms
- "CAD use … is associated with decreased specificity but not with improvement in the detection rate … of invasive breast cancer"
- CAD led to increased detection of DCIS
- Were radiologists using CAD as a crutch & not reviewing the mammograms as diligently?

Fenton et al., JNCI 2011

The Problem

- 100 CTC cases, 19 radiologist readers
- CAD sensitivity in the lab: 91.8%
- Sensitivity of the radiologists without and with CAD: 46.6%, 52.1%



Dachman et al., Radiology 2010

Overview

- To achieve the highest possible benefit from CAD systems, best practices are required for clinical implementation and use of CAD
- Summary of opinions of the AAPM CAD Subcommittee

CAD best practices – Important issues

- Importance of training in the use of CAD devices
- Pitfalls of off-label use
- Research opportunities

Rationale for CAD

- Reduce interobserver variability
  - Level the playing field
  - Less trained can perform closer to experts
- Reduce perceptual error
  - Find abnormalities missed by radiologists
  - Improve reproducibility

User training - Topics

- Importance of understanding the effect of improper use of CAD on sensitivity and specificity
- Frequency and type of training
- Training the vendors: Feedback on CAD performance
- Storing CAD marks long term for training/auditing purposes

CAD best practices – User training

- Training is important for reading images without CAD:
  Residencies, fellowships, special certifications
- Inexperienced readers benefit more from CAD
- Training for reading images with CAD
  - Little published research
- Educate the physicians on the intended use of the CAD

CAD User training – It Helps!

- Mammography CAD in the United Kingdom National Breast Screening Program
  - FJ Gilbert et al., Radiology 2006
  - CADET II Trial, FJ Gilbert et al., NEJM 2008

CAD User training

- 2 month training of radiologists
  - Initial training by vendor
  - Practice using 6 sets of 75-100 cases
  - Truth provide after each set to improve performance
  - Cancer prevalence progressively reduced from 25% to 5%
- Results
  - Single reader with CAD had comparable sensitivity to double reading without CAD

CAD User training – Other Results

- Short-term feedback may not help
  - Lung nodules on CXR with CAD, De Boo *et al.*, Eur Radiol 2012
- Focused training with CAD may reduce training requirements
  - Polyps on CTC, Taylor *et al.*, Br J Radiol 2008

Training Occurs During CAD Use

- Learning curve for radiologist use of CAD changes over the course of a year
- Breast radiologists initially doubled their recall rate when using CAD (6.2% to 13.4%), but over a year, the recall rate decreased to near the level before CAD implementation (6.75%)
  - Dean and Ilvento AJR 2006

User training – Important Questions

- How can we encourage radiologists to spend time getting trained?
- Does the absence of training impair CAD performance in the clinic?
- Is there an association between radiologist performance and attitudes towards CAD before and after training?

User training – What?

- Sensitivity and average false positives per image
- Characteristics of false negatives and false positives (knowledge of latter benefits efficiency)

User training – What?

- Unique strengths and weaknesses of a particular CAD (target lesions; susceptibility to artifacts)
- Meaning of the various CAD marks
- Absence of CAD mark should not discourage recall
- Learning curve for use of CAD in actual clinical use

User training – When?

- At initial installation
- Annually or via CME
- At time of CAD updates or modifications
- During residency (currently implemented for breast imaging rotations under ACR guidelines)

User training – How?

- Web-based
- One-on-one
- Case-based

User training – Implementation

- Case-based examples of changes in CAD behavior after updates or modifications
- Technologist training, especially if radiation dose or patient positioning affect CAD

Training the CAD Vendor

- Continuous feedback about missed lesions, false positives
- Recording callbacks that have no CAD marks, CAD marks that cause additional callbacks, recalling CAD marks on prior exams when current exam is being read

Storing CAD Marks

- Controversial
- Medicolegal aspects have been emphasized, patient benefits have not
- CAD has been used in the courtroom and has helped defendant radiologists
  - Brenner *et al.*, AJR 2006

Storing CAD Marks - Benefits

- Facilitate automatic monitoring of the stability of the CAD system performance over time
- Help the radiologist learn the characteristics of dismissed CAD marks on prior exams that turn out to be true lesions in current exams
- Enable CAD system to use previous readings to improve its current performance
- Enables CAD prospective performance evaluation in large populations

Storing CAD Marks - Implementation

- Some CAD operates on raw data or processed images not shown to the radiologist
- Example: ultrathin CT images for CTC
- Such raw data would also need to be stored along with CAD marks
- Record CAD metadata in DICOM header or using Annotation Imaging Markup (AIM)

Off-label Use

- Use of device in a manner that is not specifically stated in the FDA-approved indications for use
- Physicians may use any FDA-approved product off-label according to their professional judgment concerning the needs of their patients
- Potential problem: CAD used off-label to improve productivity rather than sensitivity
- Second reader > Concurrent reader > First reader

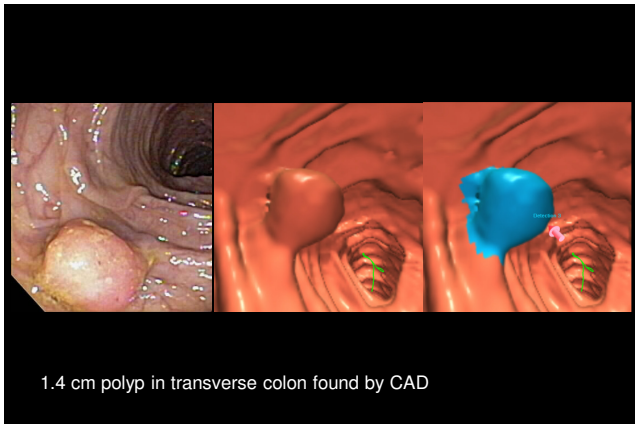
Off-label Use

- CAD should be used on ALL cases, not just selected ones, since radiologist cannot know in advance which cases will be false negatives without CAD

Colon Cancer in Americans

- 2nd leading cause of cancer death
- 131,000 diagnosed annually
- 55,000 annual mortality
- 6% will develop colon cancer during their lifetime (40% die)

Image source: Wikipedia



1.4 cm polyp in transverse colon found by CAD

Reading Paradigm

- First read
- Concurrent read
- Second read

First Read

- Radiologist reviews only CAD results, not entire colon
- Fast interpretation time
- High specificity
- Lower sensitivity
- Presently unlikely to be used clinically
- Sometimes used for mammography CAD (microcalcifications)

Concurrent Read

- CAD marks visible during radiologist's primary image interpretation
- Radiologist evaluates CAD marks as they appear in the image

Concurrent Read

- Reduced interpretation time
- CAD marks may distract radiologist from other findings in vicinity ("satisfaction of search" error)

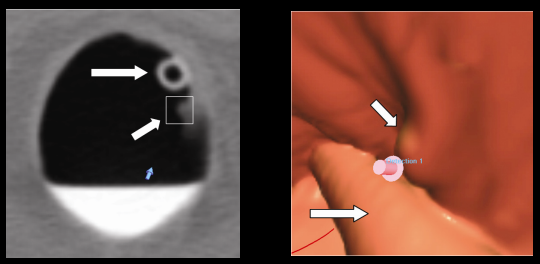
2nd Reader

- Radiologist reviews images and arrives at preliminary diagnosis
- Then evaluates CAD marks, revises preliminary diagnosis to arrive at final diagnosis
- Used for mammography CAD (masses)

2nd Reader

- Highest sensitivity (↑ 9 - 25%)
- Lowest specificity (↓ 2 - 14%)
- Longest interpretation times (↑ 2 - 4 min.)

CAD as 2nd Reader



7 mm TA in rectum found by 3 readers with CAD

N. Petrick et al., Radiology 2008

Discouraging Off-label Use

- Hard to see how off-label use of CAD benefits patients rather than physicians
- Record or track reading behavior
- Record radiologist's findings prior to displaying CAD output (auditing; RIS integration of CAD)
- Control the workflow by modifying the display protocols (requires PACS integration of CAD)

PACS Integration of CAD

- Improves usability
- Increases reader sensitivity with minimal impact on interpretation time
  - Lung nodule study, Bogoni *et al.* J Digital Imaging 2012
- Integration hampered by deficiencies in IHE
  - Welter *et al.* Comput Methods Programs Biomed. 2011
  - Le et al. IJCARS 2009

Standardization

- File formats and reported data elements
- APIs for PACS/RIS integration of CAD
- Quality control
- Reporting
- Limited to encourage buy-in from vendor community

CAD best practices – Research opportunities

- Assessment of radiologist performance and training methods
- Monitoring CAD performance changes and effectiveness over time using large electronic health records
- Funding opportunities

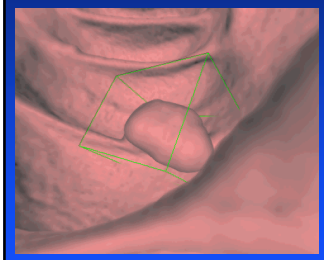
Research opportunities - Training

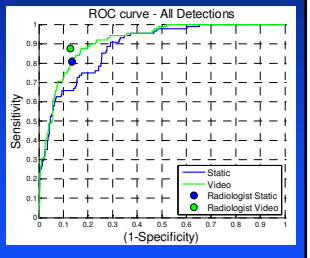
- Number of cases
- Generalizability: local or global cases
- Re-training requirements
- Overcalls, recall rates, FNs, FPs, efficiency, subtle lesions, pitfalls, radiation exposure
- Patient preparation and acquisition-specific issues
- Reading paradigms
- Content-based image retrieval

Research opportunities

- Effect of CAD marks (shape, type) on performance
- Human perception research
- Estimating the likelihood of malignancy of a lesion
- Automated lesion size measurement and segmentation

Distributed human intelligence for observer performance assessments





Summers et al. MIPS Conference 2011; McKenna et al., MedIA 2012

Future Directions

- CAD keeps improving
- Reimbursements on downward trend
- Physician extenders will increasingly provide care
- First-read paradigm will ultimately prevail
- Satisfaction of search errors (i.e., the Fenton paper) could become more prevalent

Conclusions

- Use of best practices optimizes benefit of CAD
- Areas of improvement to be had in training users, discouraging off-label use
- Consensus from members of the CAD community
- Has to be done in a way that is not punitive …
- … but that keeps a sharp focus on benefiting the patient

To Learn More …

www.cc.nih.gov/drd/summers.html

Acknowledgment:
Viatronix provided V3D visualization software