Artificial Intelligence in Radiology
Clinical Trial of AI Product

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How to Become a Radiologist?

- 4 Year College with Bachelor’s Degree
- 4 Years of Medical School with MD
- 1 Year of Internship
- State Licensing Exam
- 4 Years of Radiology Residency
- Board Certification
- 1-2 Years of Fellowship for Specialty
  - Neuro, Vascular and Interventional, Pediatric, Nuclear, Mammo……
- Total: 12-13 Years

What Does a Radiologist Do?

- Determine the Imaging Protocol
- Interpret the results of medical imaging tests, New and Previous
- Create plans for additional tests and/or treatment of the patient
- Explain their findings to other doctors, family members, and/or patients.
- Write reports about test results and treatment plans
- Offer additional consultations

Before the AI Hype

Lo, S.B., Lin, J.S., Freedman, M.T., and Mun, S.K., "Computer-Assisted Diagnosis of Lung Nodule Detection using Artificial Convolution Neural Network" SPIE Proc. Med. Imag. VII, 1993, vol. 1898, pp. 859-869.

Diagnosis (CADx)	**Detection (CADe)**
• CADx outputs the likelihood that a known lesion is malignant.	• CADe outputs the location of potential cancers

CAD + Screening Digital Mammography Reimbursement

- Dramatic Increase of Screening Mammo- Women's Health
- Shortage of Mammo Expert Readers, Low Reimbursement Rates
- High Rate of False Positives
- CAD was Advocated for Additional Reimbursement

CPT/HCPCS Code[9]	Reimbursement Component	Medicare Physician Fee Schedule Payment[10]
Mammography, 2D – Screening/Diagnostic		
77065*** Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral	Professional (-26)	$40.32
	Technical (-TC)	$96.12****
	Global	$136.44 ****

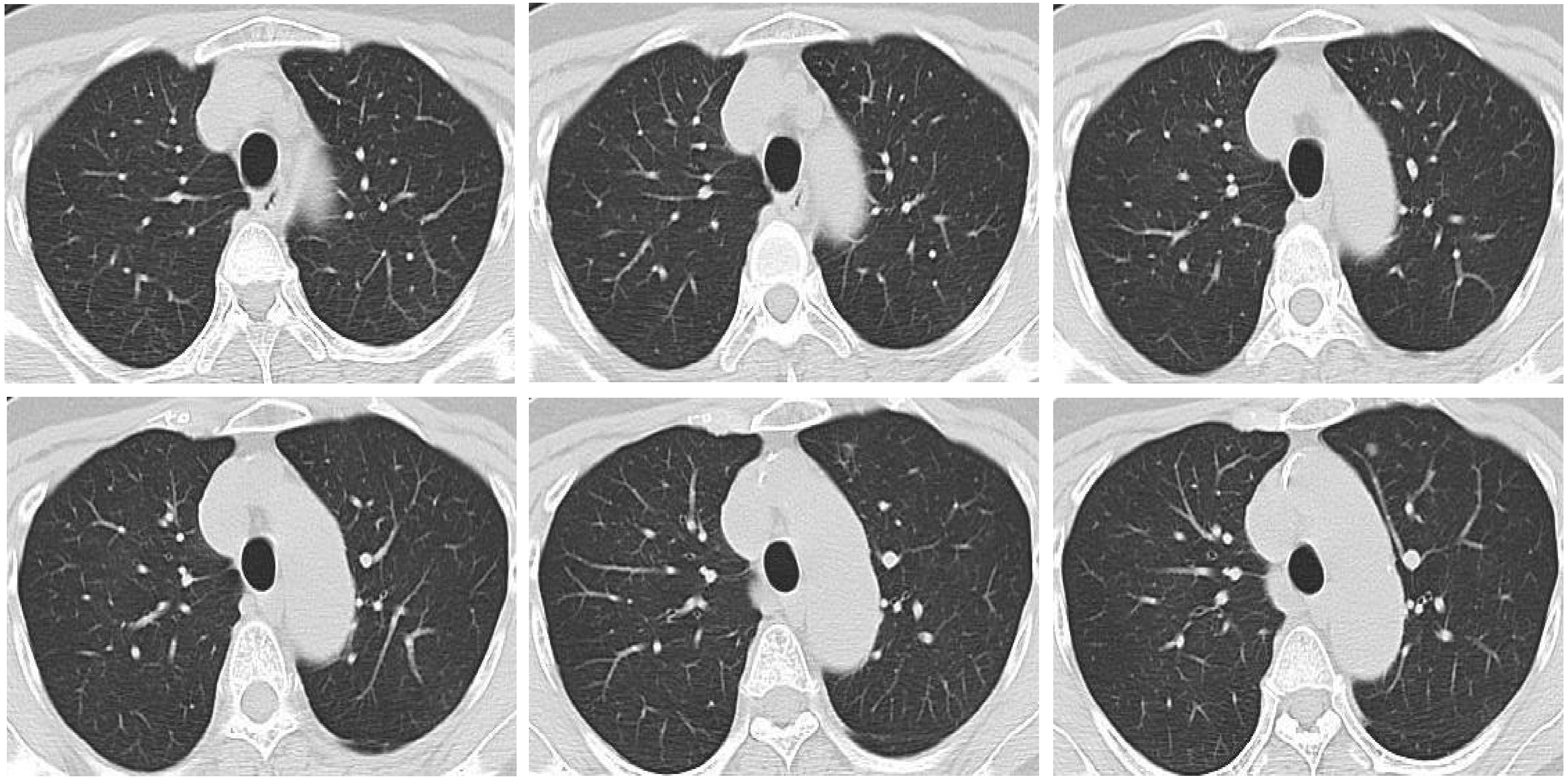
Digital Mammography CAD vs W/O CAD

DMIST (Studied by Cole et al)	Modality	Computer Performance	Radiologists' AUC w/o vs. w/	Remarks
iCAD	Digital Mammography	75% @ 3.16 FP/Case	0.71 vs 0.72	No statistically significant effect
Hologic R2	Digital Mammography	73% @ 3.08FP/Case	0.71 vs 0.72	No statistically significant effect

Studied by Lehman et al	Modality	Sensitivity w/o vs w/	Specificity w/o vs w/	Remarks
w/o n=495818 w/ n=129807	Digital Screening Mammography	87.3% vs 85.3%	91.4% vs 91.6%	No statistically significant effect

❖ AL Tools Do Not Offer Better Detection in BCa Screening

Detect Nodule in Thoracic CT: >1/3 Cancer are Missed



- **Low dose helical CT**
- **Images and Data Collected by NCI**
- **26,722 participants from 2002 to 2004**
  11.3 TB of DICOM Images
  Public National Archive

15% to 50% lung nodules in CT are missed clinically.

(1) >1/3 cancer were missed in NLST.
(2) Our reader study showed.

Optimize Open Source ML CNN → Train with Test Data → Trial with Test Data for FDA → Clinical Deployments → Scalable Validation → Successful Business Models

Obtaining FDA Clearance
CAD System for in Lung Cancer Screening

JOURNAL CLUB:

Computer-Aided Detection of Lung Nodules on CT With a Computerized Pulmonary Vessel Suppressed Function

AJR FOCUS ON:

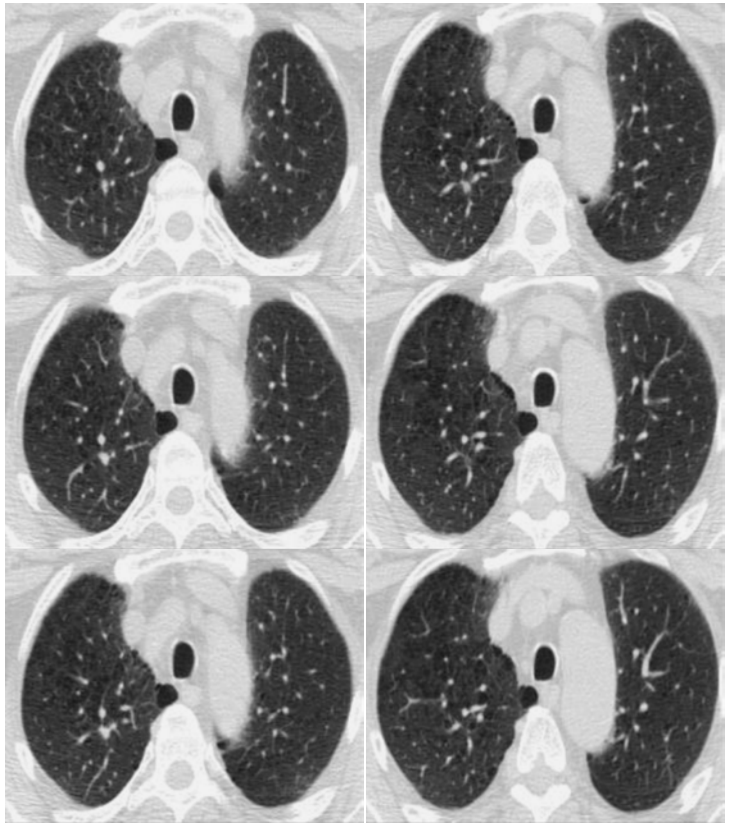
AJR JOURNAL CLUB

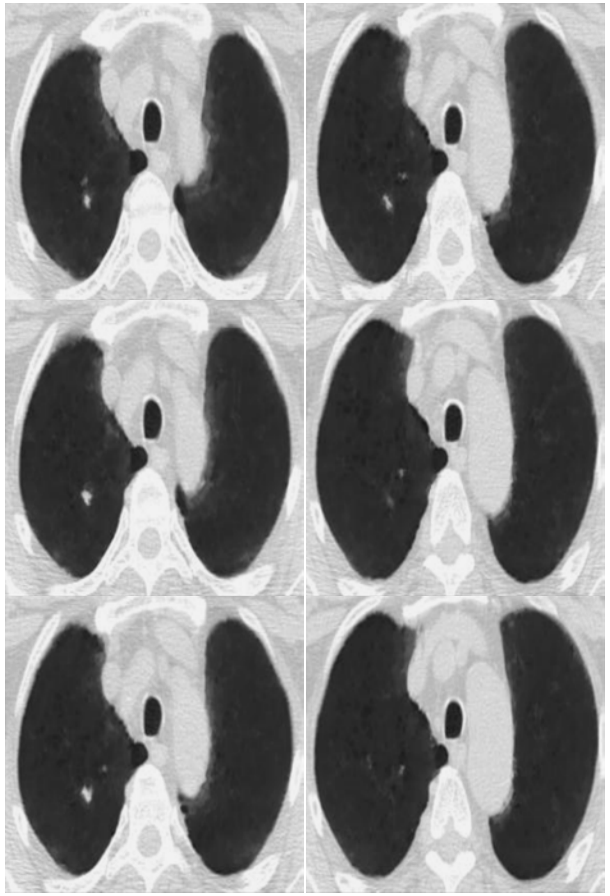
ShiChung B. Lo, Matthew Freedman, Lara B. Gillis,
Charles White and Seong K. Mun
AJR:210, Page 480-488 March 2018
With Study Guide

* CIO Statement: We at Virginia Tech Conducted the Clinical Trial Funded By Riverain.

- Problem Definition Business Model
- Data Collection
- Data Profiling
- Improving Data Quality
- Feature Engineering
- Training and Testing Data

Product Development and AI Training Set 1,000 Cases





Problem Definition Business Model → Data Collection → Data Profiling → Improving Data Quality → Feature Engineering → Training Data

Clinical Trial

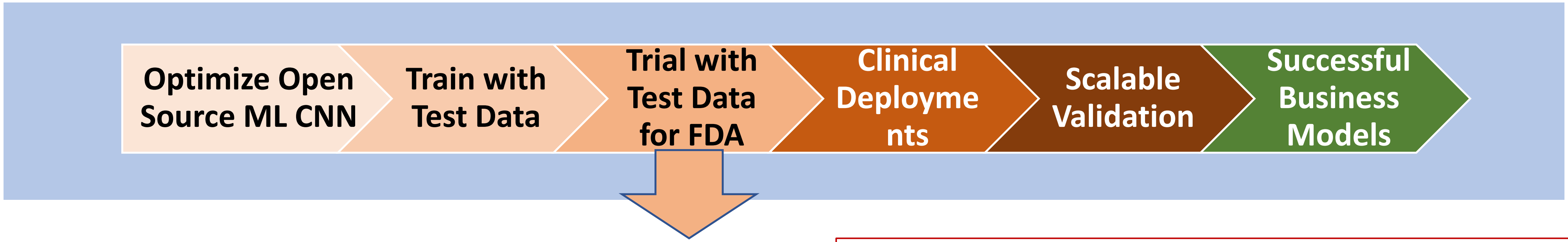
Selection of 324 Test Cases

- 273 cases from NLST Image Database
- 45 from University Hospital Cleveland
- 6 from University of Maryland

Each case reviewed by 3 radiologists

- At least two have to agree
- 216 studies revealed normal
- 108 cases with nodules considered actionable

Realistic Mix of Types of Case Essential



Clinical Trial - FDA

Recruitment of 12 Radiologists as Readers

Trial Begins (About 3 days for 324 cases)

1. First Review Images **without** AI
2. Gap of 6 to 8 weeks
3. Review Images **with** AI Support

Trial Result Data Collection

1. Location of Nodule
2. Level of Suspicion (scale 1 – 100)
3. Follow up Recommendations
   CT follow up, PET/CT or biopsy

Results:

Increased sensitivity: **24% for cancer,**

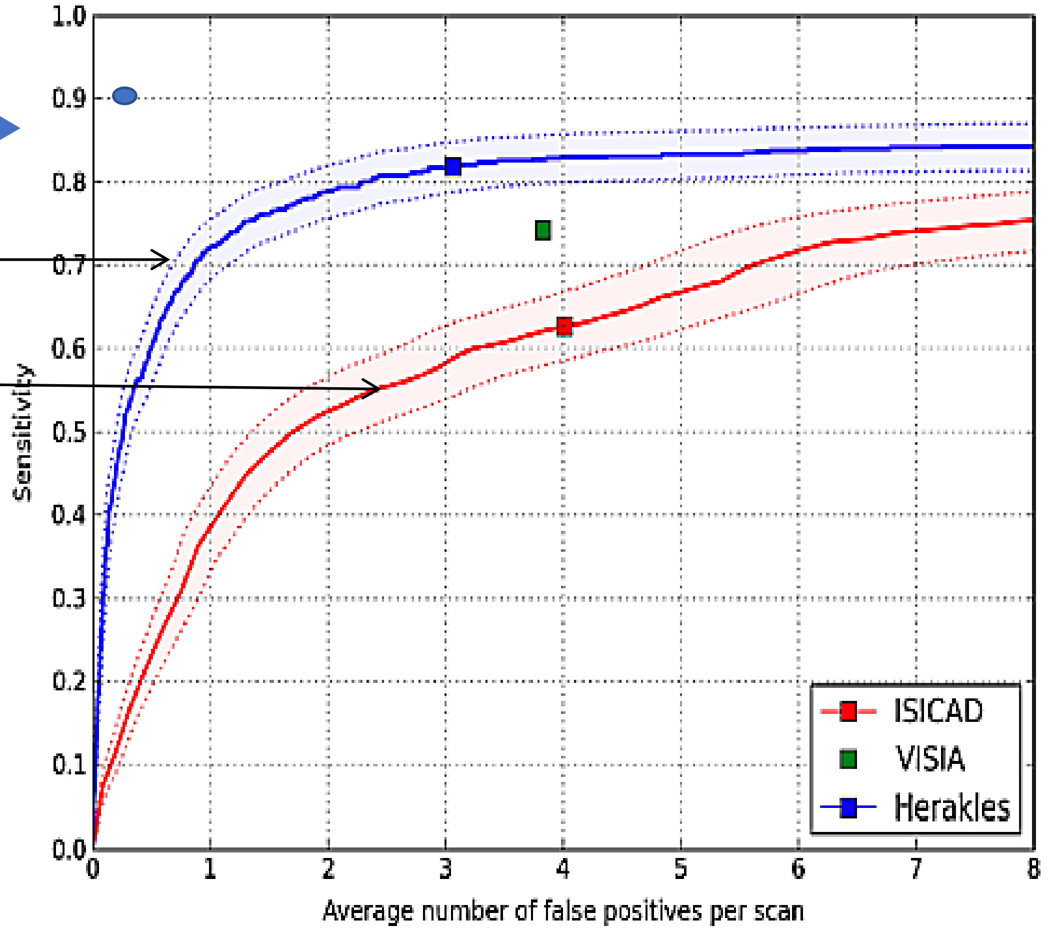
Decreased reading time: **26%**

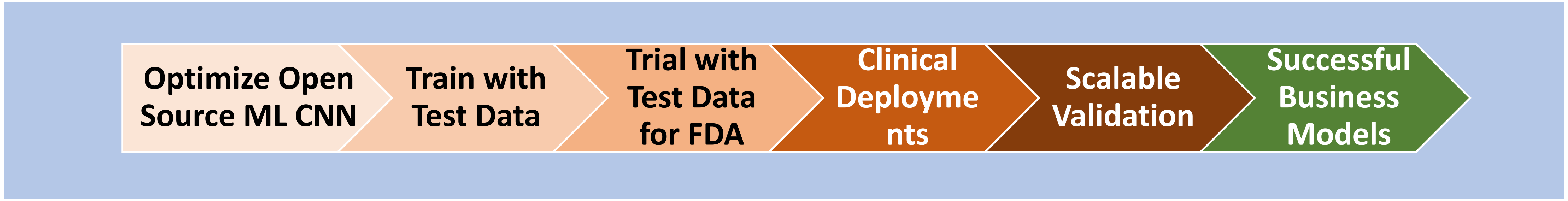
Many Levels of AI Performance in Radiology

Expert

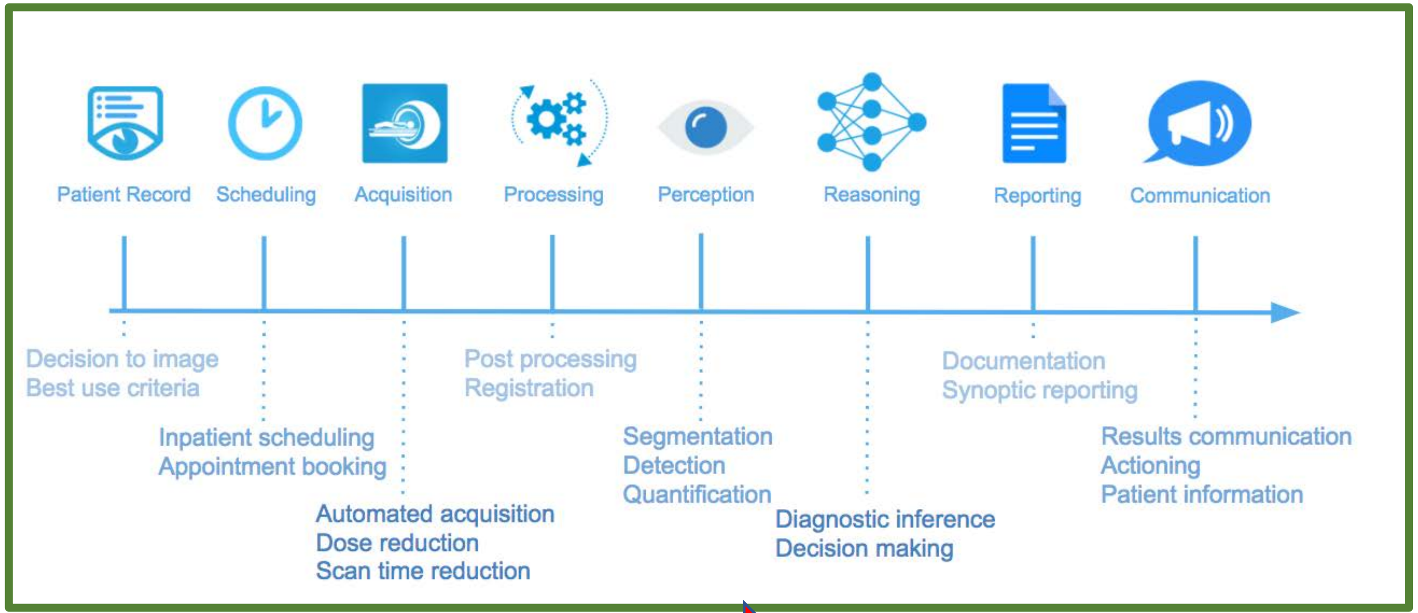
Fellow

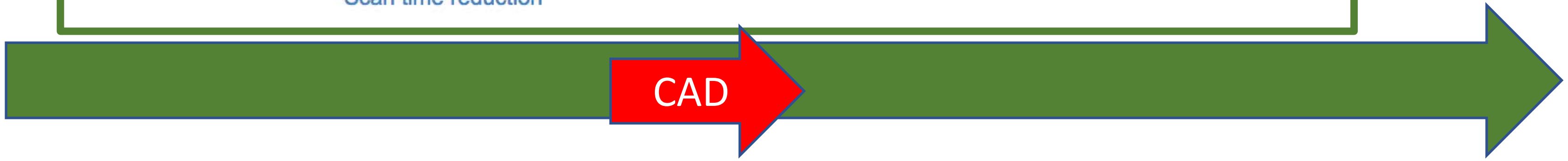
Resident





CAD/AI : Only A Limited Partial Solution





“ Productivity gains will drive demand.” Hugh Harvey, MD, NHS, UK

Current State of AI in Radiology

Doing Well- AI Today

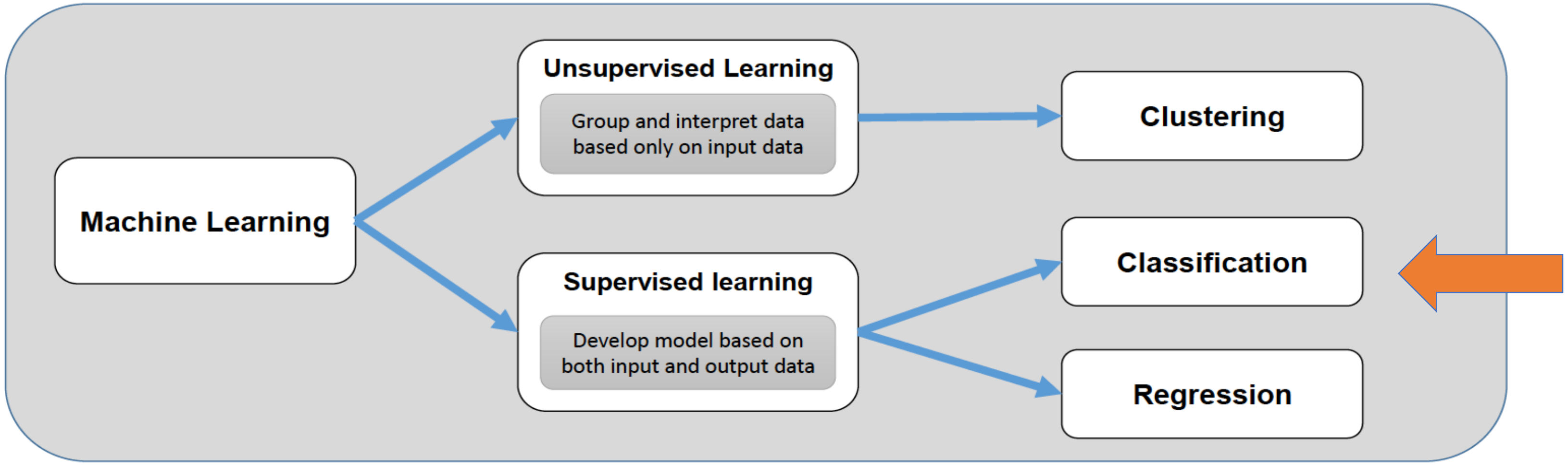
- **Detection of Inconspicuous abnormalities**
- **Make abnormalities more conspicuous**
  - Contract, Brightness, Edge adjustments,….
- **Differentiation of types of abnormalities**
- **Benign vs. Malignant, Infection vs. Malignancy**

Needs Improvements

- **Measurements**
  - Size, Volume, Radiodensity, Heterogeneity, ….
- **Measures of growth/shrinkage: serial images**
- **Comparisons with Library of Images**
  - Unusual and rare diseases
- **Integration of Image Features with**
  - Clinical history, Lab results, patient demographics
- **Guidance toward optimized next steps**

More focus should be on end-to-end productivity improvements

Two Types of ML/AI



- ***Supervised learning,*** which trains a model on known inputs and output data to predict future outputs
- ***Unsupervised learning,*** which finds hidden patterns or intrinsic structures in the input data
- ***Semi-supervised learning,*** which uses a mixture of both techniques; some learning uses supervised data, some learning uses unsupervised learning

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Almost Intelligent (AI) → Meaningful Intelligent (MI)

- Today’s AI in Imaging: Brittle and Limited
- AI Will Not Replace Radiologists
- AI Will Empower Radilogists
- Radiology will become
  - better and more efficient
- Medical Imaging - More Ubiquitous
- Medical Imaging – Precision Therapy

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