DATA SCIENCE INSTITUTE

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# Fostering a Strong Ecosystem for AI in Medical Imaging

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# Disclosures [Blank]





Al presents a once-in-a-generation opportunity to dramatically improve patient care and lower the costs of high quality healthcare.





Not because AI is going to create a genius robot that is a far superior replacement to the radiologist.

But, to quote Stanford AI researcher Sebastian Thurn:

"[The way] machines made the human muscle 1000 times stronger, AI is going to make the human brain 1000 times smarter" Inertia Hype that can't live up to reality

Fear of change

Misalignment of financial incentives

Complex AI and medical informatics

Decentralized healthcare

The path doesn't look like an expedition party climbing Mt. Everest.



X-Ray as a Case Study in Rapid Adoption

Innovation in healthcare can be lightning fast but often fraught with errors and missed opportunities that cost lives.



# First x-ray image in Ohio 4 months later

Wilhelm Roentgen discovers X-rays Wuerzburg Germany - 1895





Thanks to Dr. Jeffrey Duerk





# No innovation is without risk or unintended consequences

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Apple Ecosystem



**Primary Beneficiary** Apple's Shareholders

#### **Other Beneficiaries**

Apple's Users, Partners and Employees

Al in Medical Imaging Ecosystem



#### **Primary Beneficiary**

Patients

#### **Other Beneficiaries**

Those who serve the patients (Providers and Provider Organizations, Vendors, Insurers, Regulators, Associations/Societies)





## Doing *Better* With Less...



... Through Medical Imaging.



Imaging 3. for provide

Imaging 3.0 is a vision and game plan for providing optimal imaging care.

"Our goal is to deliver all the imaging care that is beneficial and necessary and none that is not."



#### Radiologists: Medicine's earliest (and best known) data scientists

2004-07-30 오전 11:50:50

Index :

Improving care for 100+ years by embracing new technologies and approaches to medicine.

ocument mode

Since 1895, to name just a few innovations we've adopted...

• X-Ray

• Contrast Agents

Ultrasound

Nuclear Medicine

• Computed Tomography (CT)

Magnetic Resonance Imaging (MRI)

• Interventional Radiology (IR)

• Evidence-Based Clinical Guidelines

• Picture Archiving and Communications Systems (PACS)

Computerized Voice Recognition and Transcription

• Electronic Health Records

• Value-Based Medicine

• Artificial Intelligence & Data Science

146 mm

















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Radiologists who use AI will replace those who don't.





### Image interpretation

- Quantification of findings
- Quantified comparison between multiple studies
- Multiparametric analysis across multiple modalities
- Volumetric analysis
- Textural analysis
- Automation of Region Of Interest targeting and measuring





### Patient care and safety

- Detection and prioritization of potentially critical results
- Radiation dose optimization
- Pre-test probability assessment of patient risk of positive findings and contrast reactions
- Cancer and mammography screening
- Automatic protocoling of studies from EMR data





### Practice optimization for productivity and quality

- Automated transcription of audio narration
- Automated population of structured reports
- Optimization for case assignment across teams
- Increased accuracy of coding
- Smarter PACS hanging protocols and synchronization protocols
- Communication and tracking of primary and incidental findings
- Decreased patient waiting times
- Quality improvement in scanning
- Prediction and prevention of missed patient appointments
- Preventing imaging machine outages









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## Diagnostic Imaging, AI & Population Health



## **Diagnostic Imaging, AI & Population Health**



A challenge to radiologists embracing AI in practice is that we don't really understand how AI arrives at a particular conclusion.





## Neonatal Intraventricular Hemorrhage

Why is the algorithm effective? What's inside the black box?






June 26, 2018, 4:00 AM CDT

Corrected June 26, 2018, 10:20 AM CDT

## A.I. Has a Race Problem

• Facial recognition software still gets confused by darker skin tones.

By Lizette Chapman and Joshua Brustein

## MIT Researcher: Artificial Intelligence Has a Race Problem, and We Need to Fix It

The next generation of AI is poisoned with bias against dark skin, Joy Buolamwini says.

### Some rewards that computer has a hard time weighing:

- The patient's prior radiation dose exposure is unknown, which can this impact a decision of CT vs. MRI?
- Does the patient have to drive 3 hours to get to a more advanced imaging machine?
- Does the patient have claustrophobia that makes it hard to go in certain machines?
- The patient is losing her insurance at the end of the month, so a follow-up exam in the future may not be feasible.
- The patient suffers from multiple, co-morbid conditions so how sure can we be that any one condition is the cause of the finding?
- How much might we learn from an immediate follow-up study and what are the cost-benefit factors of how this might impact decisions about the course of treatment?





## Using Representative/Diverse Training Data: Multiple Dimensions of Image Variation





## Using Representative/Diverse Training Data: Multiple Dimensions of Image Variation



#### Modality

(e.g., X-Ray, MRI, CT, PET, Ultrasound)

#### **Modality-specific variations**

- MRI For example:
  - Techniques (Pulse Sequences, Field of View)
  - Anatomic planes (axial, sagittal, coronal)
  - Equipment variation (Manufacturer, Product Version and Firmware/Software Version, Field Strengths, Signal-to-Noise Ratio)

- CT For example:
  - Exposure parameters
  - Slice thickness
  - Number of detectors
  - Equipment variation



The Triangulation Approach to Radiographic Diagnosis

Correlation of radiographic findings and Gamut with patients' clinical and lab findings to arrive at the most likely diagnosis

Step #3



DATA SCIENCE INSTITUTE AMERICAN COLECE OF RADIOLOG

www.gamuts.net contains:



Unique imaging findings



Linkages between findings and conditions



Unique conditions that cause findings

PCL Tear Use Case

	COMPUTED TOMOGRAPHY	MAGNETIC RESONANCE	POSITRON EMISSION	RADIOGRAPHY	ANGIOGRAPHY	ULTRASOUND	FLUOROSCOPY	
ABDOMINAL IMAGING								
BREAST IMAGING			N					
CARDIAC IMAGING		(1)						
EMERGENCY IMAGING								
MUSCULOSKELETAL								
NEURORADIOLOGY								
NUCLEAR MEDICINE								
PEDIATRIC IMAGING								
THROACIC IMAGING								
INTERVENTIONAL								
	ANATOMY	ANATOMY	ANATOMY	ANATOMY	ANATOMY	ANATOMY	ANATOMY	





What will it be like when AI is an indispensable tool for radiology professionals?









• Partnered with company developing algorithms looking for five findings on chest, abdomen, and pelvis CT scans:

1) coronary calcium scores, 2) pulmonary emphysema, 3) liver steatosis, 4) spine compression fractures, and 5) bone mineral density

- Automatically scans images when received by the PACS and notifies radiologists when they enter the case with a green light/red light indicator if it identifies something
- Phased testing and adoption to obtain confidence in software and buy-in from clinicians
- Benefits found with:
  - Incidental findings that can be overlooked
  - Potentially problematic bone mineral density readings that are too early stage to be identified by the human eye





*"It's like having an extra set of eyes* to help us provide additional information to referring physicians for optimal patient care."

– Dr. Arun Krishnaraj





MASSACHUSETTIS GENERAL HOSPITAL



Deep Learning: A Modern Approach to Early Breast Cancer Detection

Connie Lehman MD PhD

Professor of Radiology Harvard Medical School Director of Breast Imaging Massachusetts General Hospital

ENTRANCE





Figure 2. Paired unadjusted and multivariable-adjusted percent of patients with dense breasts (heterogeneously or extremely dense), by radiologist.





## Density



## Deep Learning density assessment to reduce human variation

Connie Lehman MD PhD MGH Regina Barzilay PhD MIT

Bahl et al, Radiology (2017)

# **High-Risk Breast Lesions:** A Machine Learning Model to Predict Pathologic Upgrade and Reduce Unnecessary Surgical Excision<sup>1</sup>

Purpose:

To develop a machine learning model that allows highrisk breast lesions (HRLs) diagnosed with image-guided needle biopsy that require surgical excision to be distinguished from HRLs that are at low risk for upgrade to cancer at surgery and thus could be surveilled. **Radiology** 



### **Reducing Overtreatment: High Risk Lesions**



100% Excised | 87% Benign





**Surgery Reduction** 



Bahl et al, Radiology (2017)

How can we make AI an <u>indispensable tool</u> for radiology professionals, referring physicians and patients?







- Industry vendors
- Data scientists
- Physicians
- Informaticists
- Patient advocates
- Healthcare executives
- Regulators and policy makers
- Insurers
- Patients













NRDR DDSE INDEX REGISTRY





The Tragedy of the Commons



ACR Data Science Institute: Participation



## DATA SCIENCE INSTITUTE AMERICAN COLLEGE OF RADIOLOGY

http://www.acrdsi.org/

**Ensure the value of radiologists as AI evolves** through the development of appropriate use cases and workflow integration **Establish industry relationships** by providing credible use cases, help with FDA and other government agencies, and pathways for clinical integration

**Protect patients** through leadership roles in the regulatory process with government agencies and validation of algorithms **Educate** radiologists, other physicians and all stakeholders about AI and the ACR's role in data science for the good of our patients

Clinical Data Science: Considerations





## **Protecting Patients From Unintended Consequences Of AI**

- Algorithms useful, safe and effective
- Clinically validated
- Transparency in algorithm output
- Monitored in practice
- Free of unintended bias
- Medicare and insurance coverage issues





## ACR<sup>®</sup> TOUCH-AI

## **Radiology's Value Proposition**

- Trusted partnerships with industry and regulators
- Ensure patient safety
- Increase radiology professionals' value in healthcare

### **Use Case Development**

- Use case authoring platform
- Human language to machine language



## Al Data Elements

## **KSNA** Informatics<sup>®</sup>



Projects		
<ul> <li>ACR LI-RADS: Liver Imaging Reporting and Data</li> <li>ACR TI-RADS: Thyroid Imaging Reporting and D</li> <li>Annotation and Image Markup (AIM) (12 elements)</li> <li>C-RADS: CT Colonography Reporting and Data</li> <li>CAD-RADS: Coronary Artery Disease Reporting</li> <li>CAR/DS Adrenal Nodule (9 elements)</li> <li>CT Stroke (4 elements)</li> <li>Glasgow Coma Scale (GCS) (4 elements)</li> <li>MR Rectal Tumor Imaging (16 elements)</li> <li>Neck Lymph Nodes (1 element)</li> <li>Pediatric Bone Age (3 elements)</li> <li>SAR: MRI Primary Rectal Cancer Staging (22 elements)</li> </ul>	ta System (12 elements) Data System (2 elements) A System (5 elements) and Data System (1 element)	
Traumatic Brain Injury (35 elements)		





### **Specifications For Data Access**

- Standardized definitions and data elements allow multiple institutions to use these standards to create datasets that developers can use for algorithm training and testing.
- Specifications include standardized tools and methods for image annotation.
- Using multiple sites as data sources for these datasets provides technical, geographic and patient diversity to prevent unintended bias in algorithm development.
- Allows more individuals and institutions to participate in Al development.
- The ACR DSI will house a freely available **public directory** of institutions that have created these datasets around ACR DSI Use Cases to inform the developer community.





## **Specifications For Algorithm Validation**

- Centralized assessment of algorithm performance will be performed according to the statistical metrics metrics specified in the use case using novel datasets.
- These validation datasets are created **at multiple institutions** to ensure geographic, technical and patient **diversity** within the validation dataset.
- Multiple readers and guidelines for data quality to ensure "ground truth" consistency between sites, consistent metrics for measuring performance across sites and standards to protect developers' intellectual property, ensure patient privacy and diminish bias.
- Reports are generated for developers

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#### **AI Monitoring Program**

- Patient safety and FDA surveillance
- Algorithm transparency and radiologist acceptance
- Developer improvements

## **Specifications For Monitoring In Clinical Practice**

- Data elements in each use case specify how the algorithm will be monitored in clinical practice.
- Radiologist input is gathered as the case is being reported, and if the radiologist does not incorporate the algorithm inferences into the report, this change is captured in the background by the reporting software. If the radiologists agrees changes the output of the agrees with algorithm, this is also noted and transmitted to the registry.
- Specified metadata about the exam such as equipment vendor, slice thickness and exposure exposure are also transmitted to the registry.
- Algorithm assessment reports include algorithm performance metrics and the exam parameters affecting the algorithms' performance.
- These reports are used by the developers to report to the FDA and for algorithm improvement.





#### Working Example of Monitoring Algorithm Performance Using An AI Data Registry

- This example is from a pediatric bone age classification algorithm. The reporting software, PACS or the modality transmits information about the radiologist's agreement or disagreement with the algorithm along metadata about the examination to the AI data registry.
- The raw data are complied in the registry and reports are aggregated and developer specific reports are generated for developers for use in FDA post-market surveillance reports and to improve the algorithm.
- Site reports are provided to provide AI performance metrics to the clinical practices.




### Office of Science And Engineering Labs



#### **FDA Center For Devices And Radiological Health**

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Office of Device Evaluation	ODE is responsible for the program areas through which medical devices are evaluated or cleared for clinical trials and marketing. This page provides summary information about the major programs administered by ODE and includes a brief description of the promoted program superior period.									
Office of In Vitro Diagnostics and Radiological Health	exemption, investigational device exemption, and premarket notification programs.									
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## **Moving AI From Concept To Clinical Practice**

Use Cases	Content	Validation	Implementation	Regulatory	Safety
Economics	Standards	Education	Facilitation	Legal	Ethical



#### **DSI and Healthcare AI Industry**

Services to assist industry deliver successful AI solutions to clinical practices

- AI Use Case Development (ACR TOUCH-AI)
- AI model Certification (ACR CERTIFY-AI)
- AI model Integration (ACR ASSIST)
- AI model Assessment (ACR DSI ASSESS and ACR AI REGISTRY)





## **Summary Of ACR DSI Objectives**

- Useful
- Safe and effective in clinical practice
- Performance monitored and improvements made based on real world data
- Transparent
- Ensure diversity and preventing unintended bias

# *"The future is already here. It's just not evenly distributed."*

William Gibson