CURRENT LANDSCAPE

GARTNER HYPE CYCLE - 2017
Geoff Hinton - October 2016: “What do you think is the most exciting work to come?”


“Let me start by just saying a few things that seem obvious.

If you work as a radiologist, you’re like the coyote who’s already over the edge of the cliff that hasn’t yet looked down, so he doesn’t yet realize there’s no ground underneath him.

People should stop training radiologists now. It’s completely obvious that within 5 years deep learning is going to be better than radiologists, because it’s going to be able to get a lot more experience.

It might be 10 years, but we’ve got plenty of radiologists already.

“The role of radiologists will evolve from doing perceptual things that could probably be done by a highly trained pigeon to doing far more cognitive things.”
DATA SCIENCE AND ARTIFICIAL INTELLIGENCE: A RAPIDLY EMERGING MEGATREND IN BUSINESS AND SOCIETY

Financial Power: Corporate Valuations by Sector

Financial Power: Corporate Valuations
### Examples of Recent FDA Clearances

<table>
<thead>
<tr>
<th>Company</th>
<th>Product/Feature Description</th>
<th>Month Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterys</td>
<td>Cardio DL perform editable ventricle segmentation (cardiac MRI)</td>
<td>Jan-17</td>
</tr>
<tr>
<td>iCAD</td>
<td>PowerLink Texo Detection tool for improved breast cancer detection and workflow solution</td>
<td>Mar-17</td>
</tr>
<tr>
<td>EnsoData</td>
<td>EnsoSleep to analyze sleep quality and aide in diagnosis of sleep or respiratory related sleep disorders</td>
<td>Apr-17</td>
</tr>
<tr>
<td>Quantitative Insights</td>
<td>QuantX evaluation of breast abnormalities</td>
<td>Apr-17</td>
</tr>
<tr>
<td>Viz.ai</td>
<td>Proactive Stroke Pathway Detect and directly alert the on-call stroke physician about suspected large vessel occlusions (CTA)</td>
<td>Feb-18</td>
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<tr>
<td>IDx</td>
<td>Idx-DR to identify patients with “more than mild” diabetic retinopathy</td>
<td>Apr-18</td>
</tr>
<tr>
<td>Densitas</td>
<td>DENSITAS</td>
<td>density to produce breast density reports (digital mammography)</td>
</tr>
<tr>
<td>Imageon</td>
<td>OsteoDetect to detect wrist fractures in adult patients (XRAY)</td>
<td>May-18</td>
</tr>
<tr>
<td>Zebra Medical Vision</td>
<td>Cardiovascular to automate coronary calcium scoring (CTA)</td>
<td>Jul-18</td>
</tr>
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**EXAM PLES OF RECENT FDA CLEARANCES**
These advances in technologies and growth in data have spurred:

- Powerful new applications for established and evolving AI techniques (e.g., deep learning)
- Advances in hardware led by GPU Computing
- A global, online community of AI practitioners sharing advances (e.g., ImageNet)
- Open source software from the community and tech giants (e.g., Google’s TensorFlow, Amazon/Microsoft’s Gluon)
- Huge AI spending by investors and tech companies who see AI as a significant disruptor

**CHALLENGES**

**AI IN DIAGNOSTICS**
WELL CHARACTERIZED DATA SETS

The market for humans training AI could hit $5 billion in five years.

— McKinsey Global Institute

$5B/Year just for tagging!
The Role of the ACR

• Founded in 1924, the American College of Radiology has been at the forefront of radiology evolution
• More than 38,000 radiologists, radiation oncologists, nuclear medicine physicians and medical physicists.

Core Purpose:

To serve patients and society by empowering members to advance the practice, science and professions of radiological care.
AI and Next Generation Technology

- The ACR Data Science Institute established May 2017
- Core Purpose:
  ACR Data Science Institute (DSI) empowers the advancement, validation, and implementation of artificial intelligence in medical imaging and the radiological sciences for the benefit of our patients, society, and the profession

ACR DSI Mission

- Ensure the value of medical imaging professionals as AI evolves through the development of appropriate use cases and workforce 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
POSSIBLE APPLICATIONS OF AI IN MEDICAL IMAGING

- Image interpretation
  - Quantification of findings
  - Quantitative comparison between studies
  - Multi-modality analysis across multiple modalities
  - Volumetric analysis
  - Texture analysis
  - Identification of Region Of Interest targeting and re-measuring

- Patient care and safety
  - Detection and prioritization of potentially critical results
  - Radiation dose optimization
  - Percutaneous probability assessment of patient risk of positive findings and contrast reactions
  - Assessment of malignancy of lesions
  - Automated transcription of audio narration

- Imaging/Physician and practice optimization for productivity and quality
  - Automated interpretation of positive reports
  - Automated population of structured reports
  - Optimization for case assignment across teams
  - Automated organization of radiology
  - Radiologist case prioritization
  - Automated protocoling of studies from EMR data

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CHALLENGES – AI AT SCALE

- Use cases
- Regulatory
- Economics
- Standards
- Ethical
- Legal
- Commercialization
- Education
- Validation
- Content
- Compute
- Implementation
- Regulatory

CONSIDERATIONS

- Use cases
- Ethical
- Legal
- Commercialization
- Education
- Standards
- Economics
- Content
- Compute
- Implementation
- Regulatory
- Validation
Challenges in the AI Life Cycle

- How generalizable is the inference model?
- Is there hidden sample bias?
- What is the appropriate threshold for clinical use?
- How do we ensure ongoing performance?
- How robust is the model to changes in the environment?

Challenges in the AI Life Cycle

- Do models solving the same problem yield consistent, comparable outputs?
- Does the customer understand potential differences in the implicit use cases?
- How do we establish standard, consistent performance metrics?

Lung Nodule Detection Algorithms
Establish Standards & Certification Criteria

- Establish common expectations for addressing specific clinical scenarios (e.g., BI-RADS)
- Create well-qualified data sets that address explicit concerns about bias
- Define standard performance metrics that establish a quality threshold
- Validate models that address a specific clinical condition against these standards

Establish Standards & Certification Criteria

- Monitor ongoing performance to ensure ongoing quality and safety
- Provide monitoring for regulators
- Continuous feedback loop to vendors and content creators
- Match continuous learning with continuous assessment, monitoring, and feedback

TOUCH-AI
Detecting Lisfranc Joint Injury

Lisfranc joint injury is common and easily missed. AI that segments and detects abnormalities would prove valuable and help reduce false negative rates, patient risk, and medical-legal risk for the radiologists.

DSI Use Cases Clinical Guidance for Developers

Example: Lisfranc Joint Injury

- Expected Clinical Inputs/Outputs
- Conditions for launch
- Data Considerations for Training/Testing

ACR DSI Use Case Development – ACR DSI Use Case Panels

Common use case framework (TOUCH-AI)

ACR DSI Use Case Creation Process

ACR DSI Use Case Panels
TOUCH-AI USE CASES

- Approximately 50 Use Cases in Draft Form
- Currently Under Industry Review
- Anticipated Release Fall 2018

VALIDATION & REGULATORY CONSIDERATIONS

REGULATORY CONSIDERATIONS (FDA)

- Objectives
  - Protect the public health
  - Help speed safe and effective innovation

- Medical Device Classification
  - Based on Risk
  - Based on Intended Use (what does your label say)
  - Based on Indications for Use (under what conditions will the product be used)

<table>
<thead>
<tr>
<th>Class</th>
<th>LOW Risk</th>
<th>Class II</th>
<th>Class III</th>
<th>HIGH Risk</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>General Controls</td>
<td>General Controls + Special Controls</td>
<td>General Controls + Pre Market Approval</td>
<td></td>
</tr>
</tbody>
</table>
Where Does AI fall?

• CADe – Detection
  Devices intended to identify, mark, highlight, or in any other manner direct attention to portions of an image, or aspects of radiology device data, that may reveal specific abnormalities during interpretation of patient radiology images or patient radiology device data by the clinician.

• CADx – Diagnosis
  Devices go beyond CADe and include those that are intended to provide an assessment of disease or other conditions in terms of the likelihood of the presence or absence of disease, or are intended to specify disease type (i.e., specific diagnosis or differential diagnosis), severity, stage, or intervention recommended.

• 9/17 – Ruling classified CADx with AI as Class II. Vendors with similar products can apply for 510k clearance and avoid Pre-Market Approval (PMA)
• 6/18 – Request for Comment on Plan to Move Remaining CADe devices to Class II

Opportunities to Accelerate the Process

• Software as a Medical Device (SaMD)
  • 21st Century Cures Act provides guidance of medical device software
  • FDA is developing guidance for implementation

• Medical Device Development Tools
  • Promotes innovation in medical device development and regulatory science to help bridge the gap between research of medical devices and the delivery of devices to patients.

• National Evaluation System For Health technology (NEST)
  • Intended to shorten the time to market for new technology health care products by developing a system for more robust post-market surveillance

Establishing NEST Will Enable The Pre-Post Market Shift

Graphic courtesy of Greg Pappas, Assistant Director FDA NEST
NEST Demonstration Project: Lung-RADS Assist

LungRads Assist - Demonstration Project

Use Case
**Certification Data Sets** (e.g. LDCT for Lung Screening)

- **Inclusion/Exclusion Criteria**
- **Sample Size** (number of cases, % positive)
- **Data Dictionary**
- **Dataset Stratifications**
- **Annotation**

- Inclusion criteria:
  - Performed for lung cancer screening
  - Non-contrast CT
  - Low dose CT scanning technique
  - Full inspiration study
  - Patient weight < 90 kg (to avoid excess noise or artifacts)
  - 1-1.25 mm in section thickness
  - Any CT vendor or equipment
  - Pathology proof of diagnosis (cancer type) for the Lung RADS 3 and/or 4.
  - Follow up LDCT for non-biopsied nodules

- Exclusion criteria:
  - Motion artifacts
  - Metal hardware
  - Confounding findings: LDCT must not have diffuse lung disease or other abnormalities apart from nodules, or smoking related features (emphysema, bronchial wall thickening)

- Sample Size:
  - Detection: with AUC of 0.5, effect size of 0.06, and two subunits per patient (right and left lungs), 50 patients (LDCT) with nodules and additional 50 patients (LDCT) without nodules.
  - 50% with 2 or more nodules, 50% with no nodules

- Measurement:
  - A 95% CI to estimate the size of the lesion to within .2mm assuming a standard deviation of 2.2mm, requires 465 patients

- Data Dictionary:
  - Per patient:
    - Patient weight
    - Smoking history
    - Presence of nodule (yes/no)
    - Number of nodules (integer)
  - Per nodule:
    - Image number for each nodule
    - Location (side and lobe; parenchymal, fissural, and endobronchial)
    - Attenuation (solid, subsolid, part-solid, calcified (pattern), cavitary, cystic)
    - Margins
    - Size (maximum, minimum and average size in mm)
    - Lung RADS category
    - Pathology proof of diagnosis (cancer type) for the Lung RADS 3 and/or 4.
    - Follow up LDCT for non-biopsied nodules with stability of nodules or resolution of nodules when n is not met

- Image markup:
  - Location
  - Margins
  - Size (maximum, minimum)

- Criteria for establishing ground truth:
  - Detection - Controlled reader study
  - Size - Controlled reader study
  - Lung RADS - Pathology proof of diagnosis (cancer type) for the Lung RADS 3 and/or 4.
  - Follow up LDCT for non-biopsied nodules with stability of nodules or resolution of nodules when n is not met

- Data stratifications:
  - Lung RADS category:
    - 50% Lung RADS 1
    - 30% Lung RADS 2
    - 30% Lung RADS 3
    - 20% Lung RADS 4A
    - 20% Lung RADS 4B
  - Gender:
    - 50% Male
    - 50% Female
  - Age:
    - 10% 40s
    - 20% 50s
    - 30% 60s
    - 30% 70s
    - 10% 80s+
Threshold Considerations for Certification

<table>
<thead>
<tr>
<th>Algorithm</th>
<th>Examples</th>
<th>Eval Method</th>
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</thead>
<tbody>
<tr>
<td>Classification</td>
<td>LungRads, Nodule Type</td>
<td>AUC, logloss, MeanScore</td>
</tr>
<tr>
<td>Segmentation</td>
<td>Nodule or organ seg.</td>
<td>Dice COefficient</td>
</tr>
<tr>
<td>Estimation</td>
<td>Nodule Size, Nodule Shift</td>
<td>RMSE, RMSE, NMMRSE</td>
</tr>
<tr>
<td>Location Detection</td>
<td>Nodule Detection</td>
<td>Dice COefficient</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Evaluation Method</th>
<th>Prediction Evaluation Framework</th>
<th>Certification Data Set</th>
<th>Certification Status</th>
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<tbody>
<tr>
<td>AI</td>
<td>Dice COefficient</td>
<td>Retrieval</td>
<td>Assess Performance</td>
<td>AI</td>
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<th>Risk Assessment</th>
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<tr>
<td>Clinical Use</td>
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<tr>
<td>Risk</td>
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<tr>
<td>Prioritization in Work list</td>
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<tr>
<td>Detection and Classification</td>
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<tr>
<td>Diagnosis</td>
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<tr>
<td>High</td>
</tr>
</tbody>
</table>

LungRads Assist - Demonstration Project

Monitoring and Feedback

n = 2405  Kappa = .74
WORKFLOW INTEGRATION

AI Opportunities Across the Imaging Life Cycle

Data Science Center
Diagnostic Radiology Interpretation/Reporting

Recommendations
Classifications
Findings
Structured Information
 PACS
EHR
• AI will persistently and pervasively enhance all aspects of radiology
  • It’s not about Human vs AI.
  • It’s about Human augmented by AI vs. Human working without AI

• AI will expand today’s decision-making capabilities
  • Earlier and better detection leads to better treatment options and improved outcomes

• Meaningful AI will improve quality, efficiency and outcomes
  • Utilizing all available data to optimize patient care

Summary
2018 Combined Quality and Safety And Artificial Intelligence Meeting

- Practicing Physicians
- Radiology Informaticians
- Developers

THANK YOU!