Artificial Intelligence in Breast Screening Program: 
*The Art Of The Possible In Future State Solutions*

Clinical, Technical and Regulatory Considerations

Presenter:
Lisa M. Baumhardt, MT(ASCP), MS, MJ, RAC, FRAP
Sr. Regulatory Manager of Global AI Strategy
IBM Watson Health Imaging

IBM Watson Health Team Members:
Danielle MacLean, Sr. Principal Offering Manager
David Richmond, Ph.D., Sr. Data Scientist
Margaret Kusano, Sr. Software Developer
David Gruen, M.D., Chief Medical Officer
IBM’s Principles of Trust and Transparency in the AI Era

Purpose
• To augment human intelligence – *systems embedded in processes, systems, product and services by which business and society function should remain within human control.*

Transparency
• People need to have confidence in AI’s recommendations, judgments and uses.
• IBM will make clear:
  - When and for what purposes AI is being applied
  - Major sources of data and expertise that inform the insights
  - Methods used to train those systems and solutions
  - Clients own their own business models and intellectual property
  - IBM will help clients to protect their data and insights

Skills
• IBM will work to help students, workers and citizens acquire skills and knowledge
  - To engage safely, securely and effectively in a relationship with AI cognitive systems
  - To perform the new kinds of work and jobs that will emerge in a cognitive economy

Breast cancer is the second-leading cause of cancer-related deaths in women across the globe.

Mortality due to breast cancer every year is 21.5 per 100,000 women.

2.2 million women will be diagnosed by 2025 with breast cancer.

~1 in 8 women will develop breast cancer.

Over 33 million screening mammograms are performed each year in the United States.

Only 30% of mammograms in US are interpreted by breast imaging specialists.

Breast cancer awareness for early detection is rising.

Demand for better screening and cancer prediction is rising.

Source: A Portrait of Breast Imaging Specialists and of the Interpretation of Mammography in the United States.
A.I. Is Learning To Read Mammograms

... AI Bested Doctors in Detecting Breast Cancer in Mammograms

A.I Shows Promise for Breast Cancer Screening

Ripped from the headlines...
People and Technology

Human + machine = greater than the sum of its parts

Humans excel at:

Common Sense  Dilemmas  Morals  Compassion  Imagination  Dreaming  Abstraction  Generalization

AI systems excel at:

Natural Language  Pattern Identification  Locating Knowledge  Machine Learning  Eliminating Bias  Endless Capacity

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Artificial Intelligence’s Potential Use and Impact in Breast Cancer Screening

- **Patient Presents for Screening Mammography**
  - Tech Takes Images
  - Radiologists Opens & Interprets Study
  - Radiologists Finalizes Screening Report

- **Intake Screening Mammography Questions**
  - Quality Control Preliminary Assessment
  - Triage & Worklist Prioritization

- **Screening Recommendations**
  - Risk Prediction
  - Breast Density Reporting
  - Prior Comparison
  - Autonomous Reading & Reporting (e.g. BI-RADS 1)

- **Increase Screening Participation**
  - Lesion detection, classification, characterization

- **Suggestions Based on Patient Cohort**
  - Final Reports

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Primary Reader – Independent Reading and Reporting

Reading screening mammography studies

Autonomously reporting on negative/benign studies

What would be needed

Performance equal to or better than an average MQSA-qualified interpreting physician OR performance equal to or better than a breast imaging specialist
Building an AI Algorithm

Define success
Acquire data
Train
Internal tests
REAL WORLD data and tests
Clinical study

Measure success
Market release & adoption
Regulatory submission

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Clinical evidence: Multi-prong approach

- Bench testing
- Pilot Studies
- Standalone Testing
- Pivotal Studies
- Post-Market Surveillance

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Workflow with AI as a Primary Reader

Acquisition device

PACS/DICOM

Radiologist / Interpreting Physician
Assesses remainder of studies

Artificial Intelligence Assessment
Ingests DICOM from PACS, reads screening studies, and output assessments for exams

Reporting system
Screening exam outcomes are captured in the reporting system

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Implementing AI into the clinical workflow for a screening study

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Technical Considerations and Challenges

- Generalizability of Data
- Transparency / Explainability / Descriptive Reporting
- Validation of Model
  - Performance Requirements
  - Standardized Testing & Comparison
- Workflow & Integration
- Changes In Clinical Reporting
Clinical Considerations and Challenges

- Performance
- Reimbursement
- Workflow & Integration
- Enhancing Quality Using the Inspection Program (EQUIP)
- Peer Review / Audits
- Patient Acceptance
- Medical-legal aspects
Regulatory Consideration and Challenges

- Risk Benefit Analysis
- Regulatory Pathway
  - Classification
  - Clinical Study
  - Modifications
- Standards
- Global Regulatory Guidance on AI
- Mammography Quality Standards Act

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Combination of People and Technology to improve healthcare
Thank You