IMDRF /DITTA joint workshop
Artificial Intelligence in Healthcare
Opportunities and Challenges

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AI in Healthcare & Regulatory Developments
(An Industry Perspective)

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• Introduction into AI & its unique characteristics
• Concrete examples by industry of AI software in different application areas
• What does AI bring to healthcare from a clinician’s perspective
• Development of AI based software causes both new opportunities as well as new challenges
• Terminology is still to be defined globally
  • Artificial Intelligence, Machine Learning
  • Learning – Supervised, Unsupervised
  • Locked/Unlocked Algorithms – Discontinuous/Continuous Learning

• Standards & Regulatory requirements are still being defined globally
  • AAMI, BSI, ISO, USA FDA, AMA, CHI, Xavier University, DITTA/MITA, etc.

• Clinical Utility (incl. acceptance/adoption) is still being defined globally

• Reimbursement/Payment varies by country

• Entry by non-traditional medical device mfg. – Apple, Google, etc.
EXAMPLE: USA
• AI application & relevant medical discipline vary...

• Monitoring (many smartphone enabled)
  • Apple: A-fib detection
  • Empatica: Epilepsy detection
  • AliveCor: ECG

• Triage
  • IDx: Diabetic retinopathy referral
  • Viz.ai: Stroke detection referral

• Clinical Decision Support
  • Arterys: Liver & lung cancer diagnosis
  • Aidoc: Pulmonary embolism diagnosis
USA FDA APPROVALS OF AI APPLICATIONS

FDA APPROVALS FOR ARTIFICIAL INTELLIGENCE-BASED ALGORITHMS IN MEDICINE

[Diagram showing various AI applications and their FDA approvals dates.]
• Better integration of clinical data
• Aid in monitoring, triage, clinical decision support
• Improved clinical outcomes
• Enhanced resource management – clinician fatigue/burnout, availability, specialization, etc....
• Simply put, AI can be leveraged to augment:
  • Repetitive & creative activities
  • Highly interactive & data-driven activities
AI OPPORTUNITIES

**WILL DIGITAL HEALTH TECHNOLOGY REPLACE PHYSICIANS?**

Digital Health Technologies will play a limited role in these professions mostly serving as auxiliary tools.

- Geriatrics
- Dentistry
- Otorhinolaryngology
- Pulmonology
- Gastroenterology
- Oncology
- Dermatology
- Radiology
- Sports Medicine

Many repetitive components of the jobs will be replaced by technologies to create space for creative tasks.

- Psychiatry
- Neurology
- General Practice
- Pediatrics
- Infectology
- Emergency Medicine
- Forensic Medicine
- Toxicology

These professions will be heavily dependent on digital health technologies. Medical professionals will work with them on a daily basis.

Data-based (requires both data about or observed from the patient)

Interaction-based (interacts with the patient in person or remotely)
Opportunities:

• Improved clinical outcomes
• Aid in monitoring, triage, clinical decision support
• Better integration of clinical data

• Meets all of the goals of the Quadruple Aim
  • Improving the patient experience (incl. prevention of loss of health, satisfaction with care)
  • Improving the health of populations
  • Reducing the cost of healthcare
  • Improving the Clinical Providers experience (incl. clinicians, nurses, technologists, etc.)
DEVELOPMENT OF AI BASED SOFTWARE CAUSES BOTH NEW OPPORTUNITIES AS WELL AS NEW CHALLENGES...

Challenges:

• AI-dependent
  • Explainability/Explicability
  • Transparency
  • Trustworthiness

• Industry/Regulatory
  • Aligning terminology
  • Nascent standards & regulations
  • Developing clinical evidence requirements
  • Integrating Risk into R&D & regulatory activities (incl. autonomy-driven concerns)
  • Commercialization processes need multiple/branched pathways sensitive to risk (based on Risk, e.g. autonomy)
General assistance

System adjusts to static presets
Operator performs fine-adjustment
Physician reads all images

Partial automation
System adjusts to individual situation
Operator triggers adjustment
Physician reads selected data

Conditional automation
System semi-autonomously acquires data
Operator takes control in emergency
Physician reads selected data

High automation

Full automation
System fully autonomous, connected
Physician only needed for complex cases

Level of USER autonomy
Level of SYSTEM autonomy
• Much is still yet to be defined & implemented
• Many key aspects to commercialization & adoption remain to be addressed:
  • Right-sizing requirements to Risk (patient, clinician, etc.)
  • Aspects of Explainability/Explicability, Transparency, Trustworthiness, etc.
  • And last, determining how to reimburse/pay manufacturers for R&D & products – purchase vs. pay for use models
• International convergence of regulatory approaches is needed
The Doctor will see you now...
Thank you!
Спасибо!

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