Autonomous AI and Ethics: lessons from real world implementation
Role of Physicians

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Conflicts of Interest IDx – Founder, Director, Employee, Patents and Investor.
Revenge of the machines

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ies should be performed to validate the work of
these computers, they anticipate that this ap-
proach will result in “cost-effective early detec-
tion of [diabetic retinopathy] in millions of people
with diabetes to [perform] triage [in] those pa-
tients who need further care at a time when they
have early rather than advanced [retinopathy].”

At a time when obesity is a worldwide epi-
demic, and the number of patients with vision
This ophthalmologist is doing health care AI the right way

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Full Bio

Physician-scientist and AMA member Michael Abramoff, MD, PhD, identified a problem and then painstakingly spent eight years building an augmented intelligence (AI) solution to fix it.

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The Food and Drug Administration (FDA) and a quartet of venture capital firms say he forged a path that others seeking to develop health care AI systems can follow.

A professor of ophthalmology at the University of Iowa’s Carver College of Medicine, Dr. Abramoff was disturbed by how long it often takes for patients with diabetes to see an eye-care specialist for a diabetic retinopathy exam. And he was bothered by how specialists’ schedules are frequently crammed full of routine eye-exam visits that did not require their level of expertise.

“Clearly, the standard practice is not working, and people are not getting the exams they need,” Dr. Abramoff said, citing various studies finding that between 15% and 50% of patients who need a diabetic retinopathy
2017: First ever Preregistered Clinical Trial for Autonomous AI

Pivotal trial of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary care offices

Michael D. Abràmoff, Philip T. Lavin, Michele Birch, Nilay Shah, and James C. Folk

Artificial Intelligence (AI) has long promised to increase healthcare affordability, quality and accessibility but FDA, until recently, had never authorized an autonomous AI diagnostic system. This pivotal trial of an AI system to detect diabetic retinopathy (DR) in people with diabetes enrolled 900 subjects, with no history of DR at primary care clinics, by comparing to Wisconsin Fundus Photograph Reading Center (WFP RC) widefield stereoscopic photography and macular Optical Coherence Tomography (OCT), by FPRC certified photographers, and FPRC grading of Early Treatment Diabetic Retinopathy Study (ETDRS) and Diabetic Macular Edema (DME). More than mild DR (mtmDR) was defined as ETDRS level 35 or higher, and/or DME in at least one eye. AI system operators underwent a standardized training protocol before study start. Median age was 59 years (range: 22-84 years); among participants, 47.5% of participants were male; 16.1% were Hispanic; 83.3% not Hispanic; 28.6% African American and 63.4% were not 198 (23.8%) had mtmDR. The AI system exceeded all pre-specified superiority endpoints at sensitivity of 87.2% (95% CI, 81.8-91.2%) (85%), specificity of 90.7% (95% CI, 88.3-92.7%) (>82.5%), and imageability rate of 96.1% (95% CI, 94.6-97.3%); demonstrating AI’s ability to bring specialty-level diagnostics to primary care settings. Based on these results, FDA authorized the use by health care providers to detect more than mild DR and diabetic macular edema, making it, the first FDA authorized autonomous AI diagnostic system in any field of medicine, with the potential to help prevent vision loss in thousands of people with diabetes annually. ClinicalTrials.gov NCT02963441

2018: First ever Autonomous AI authorized by FDA (510k de novo pathway)

“IDx-DR is the first device authorized for marketing that provides a screening decision without the need for a clinician to also interpret the image or results, which makes it usable by health care providers who may not normally be involved in eye care.”
2019: Autonomous AI in Clinic

- Point of care diagnosis in real time
- High safety, efficacy, equity
- Prescription device: requires physician order
- Company assumes liability
- Operated by high school graduate
- No physician oversight of the medical decision

www.npr.org/sections/health-shots/2019/04/14/711775543/how-can-we-be-sure-artificial-intelligence-is-safe-for-medical-use
2019 Autonomous AI CPT codes and payments

- AMA CPT® Editorial Panel created first ever CPT® category 1 code for autonomous AI, on May 15, 2019: 9225X to go into effect Jan 1, 2021

- 9225X vignette may describe a rigorously validated autonomous AI system, authorized by FDA, operated in primary care physicians to diagnose diabetic retinopathy and diabetic macular edema, without eye care provider involvement.

- Primary care physicians are billing and collecting successfully

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<th>Retinal Imaging</th>
<th>Accepted addition of code 9225X to report retinal imaging with automated point-of-care; and revision of codes 92227, 92228 to include imaging of retina for detection and monitoring</th>
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• 11.17 [...] Artificial intelligence systems that detect more than mild diabetic retinopathy and diabetic macular edema authorized for use by the FDA represent an alternative to traditional screening approaches (115). [...] 

Ethical Framework for Autonomous AI

From the ethical principles *Non-maleficence, beneficence, autonomy, and justice*

- **Improve** patient outcome as shown either by direct evidence linked clinical literature, and aligned with evidence based clinical standards of care/practice patterns from quality of care organizations, professional medical societies and patient organizations, while accounting for safety, efficacy and equity.

- **Design** so the Autonomous AI’s operations are maximally reducible to characteristics aligned with scientific knowledge of human clinician cognition, rather than proxy characteristics.

- **Maximize** traceability of patient derived data, and commensurate data stewardship, accountability, and authorization; including by adherence to accepted standards.

- **Validate rigorously** for safety, efficacy and equity, using preregistered clinical studies, by comparing the AI against clinical outcome, or outcome surrogates in the case of chronic diseases, in the intended clinical workflow and usage, as shown by either direct or linked evidence.

- **Align** liability or other protections commensurate with indications for use and autonomy, without unduly burdening with liabilities beyond other comparable entities.
Policy

The American Medical Association House of Delegates has adopted policies to keep the focus on the need for proper regulatory intelligence (AI) in health care.

"Medical experts are working to determine the clinical

Regulation, payment, liability and other key policies
Annual 2019

Our AMA supports the use and payment of AI systems that advance the quadruple aim. Specifically, AI systems must be based on risk of harm and benefit accounting for a host of factors, including but not limited to: intended and reasonably expected use(s); evidence of safety, efficacy and equity, including addressing bias; AI system methods; level of automation; transparency; and conditions
Improve patient outcome as shown either by direct evidence or linked clinical literature, and aligned with evidence based clinical standards of care/practice patterns from quality of care organizations, professional medical societies and patient organizations, while accounting for safety, efficacy and equity.
Design so the Autonomous AI’s operations are maximally reducible to characteristics aligned with scientific knowledge of human clinician cognition
Design of Autonomous AI:
build in invariance to ethnic, racial and sex bias

Simplistic use of CNNs leads to black box

Mimic cortical processing of clinicians as much as possible

Abramoff et al, IOVS 2007
Abramoff et al, Nat Dig Med, 2018
Design of Autonomous AI: maximally reducible to characteristics aligned with scientific knowledge of human clinician cognition

Biomarker detectors: semi-dependent and primarily CNNs

- Robust against catastrophic failure
- Robust against racial / ethnic bias

Abramoff et al, IOVS 2007
Abramoff et al, IOVS 2016, Nat Dig Med 2018
Lynch et al, ARVO 2017
Shah et al, Proc ISBI 2018
Finlayson et al, Science, 2019

• 9,814,386
• 9,782,065
• 9,155,465
• 10,140,699
• 10,115,194
• 9,545,196
Autonomous AI is mainstream in healthcare

- 2017: First preregistered clinical trial for autonomous AI
- 2017: First trial comparing autonomous AI to patient outcome markers
- 2018: First autonomous AI system *de novo* 510k authorized by FDA
- 2018: First to introduce medical liability for autonomous AI creators
- 2018: 2019: First Category 1 CPT® code for autonomous AI: 9225X with “AI work”
- 2019: NCQA bridging solution for HEDIS 2019 CDC compliance
- 2020: Autonomous AI in ADA’s Standard of Diabetes Care

All based on

- physician leadership
- specialty organization support