Emerging Telehealth and Artificial Intelligence Policy

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  • Research to Prevent Blindness

• No commercial relationships
Overview

• An introduction to telehealth
• Different types of telehealth and example cases
• Changes in relation to the COVID-19 Pandemic
• Ongoing challenges
• Opportunities for artificial intelligence
Telehealth – Definitions

• “Telemedicine” coined in the 1970s: “Healing at a distance”
• “The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities” (WHO)
• “The use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration” (HealthIT.gov)
Telehealth – Key Principles

• Providing clinical support
• Overcome geographical barriers
• Involves use of information and communication technologies
• Goal of improving health outcomes

• “Telehealth” intended to be more broad than “telemedicine” but often used interchangeably
Forms of Telehealth

**Synchronous**
- Phone calls, Video Visits

**Asynchronous**
- Patient messages, image interpretation, data portals, remote sensing
Diagnosis of an internal carotid artery aneurysm via telehealth

- 59 yo F called triage line complaining of double vision associated with vertigo and headache
- Underwent video visit evaluation (patient declined in-person evaluation due to COVID-19 pandemic) using Doxy.me
- At home tools to gain ophthalmic data:
  - Snellen visual acuity chart (Safe Eyes America)
  - Extraocular movements (9Gaze app)
  - Dynamic examination also conducted during videoconference

Findings consistent with acute CN6 palsy and referred for emergent neuro-imaging
Diagnosis of an ICA aneurysm via telehealth

Figure 2. Giant internal carotid artery (ICA) aneurysm visualized on neuroimaging. The white arrows highlight various views of the partially thrombosed giant aneurysm arising from the right cavernous ICA, which measured $3.4 \times 3.1 \times 2.6$ cm, on both magnetic resonance images (a) and computed tomography angiography (b). There was also a 2 mm aneurysm projecting posteriorly from the left ICA terminus (blue arrow in (b)).
Case Report

Internal carotid artery aneurysm presenting as diplopia via telemedicine during COVID-19

Sally L Baxter, David E Kuo and Shira L Robbins

Abstract
A patient presented with acute onset of double vision during the start of the COVID-19 pandemic when elective medical care was restricted. Initially declining an in-person evaluation, she was examined using a telehealth video visit, incorporating multiple technological modalities to ascertain ophthalmic examination elements. Her findings prompted emergent neuroimaging, revealing a giant internal carotid artery aneurysm, which was successfully embolized to prevent debilitating and possibly fatal intracranial haemorrhage. This case report illustrates the successful use of telemedicine and remote patient data acquisition to make a life-saving diagnosis.

Keywords
Remote consultation, tele-ophthalmology, telehealth, telemedicine, teleneurology

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Diabetic Retinopathy Screening Programs

Installing cameras at primary care clinics and screening patients at primary care visits to improve access to diabetic retinal exams

Images read and interpretations provided asynchronously (i.e., not in real time)
Diabetic Retinopathy Screening Programs

38-year-old man with Type 2 diabetes and no visual complaints, had never seen ophthalmology before

Imaging at primary care office found to have evidence of diabetic retinopathy
Diabetic Retinopathy Screening Programs

Found to have neovascularization on ultra-wide field retinal imaging upon follow-up visit to ophthalmology

New diagnosis of proliferative diabetic retinopathy thanks to teleretinal program
Diabetic Retinopathy Screening Programs

Afshar et al. • UWF Imaging for DR Screening

Figure 1. Photographs showing the mobile ultra-widefield imaging (UWFI) program: (A) the University of California, San Francisco, mobile eye service van; (B) an Optos Daytona (Optos Plc, Dunfermline, United Kingdom) camera bolted to a custom, adjustable-height table on the van; (C) patient being screened with mobile UWFI unit; and (D) map of San Francisco including 3 fixed cameras (red tabs) and 7 primary care clinic stops through the city for the mobile eye van screenings (blue tabs).
Growing Digital Health Environment
The Impact of COVID-19 on Telehealth

- 2019
- % change in telehealth encounters 2019 to 2020
- 2020
- % change in ED visits 2019 to 2020

First U.S. case of COVID-19 announced Jan 20, 2020
First community spread of COVID-19 in the United States Feb 26, 2020
CMS telehealth waivers go into effect Mar 6, 2020
CARES Act enacted Mar 27, 2020

No. of encounters
Surveillance week
Percentage change 2019 to 2020

Image Credit: CDC
The Impact of COVID-19 on Telehealth

Image Credit: JAMA Surgery
The Impact of COVID-19 on Telehealth

States Expanding Telehealth in Medicaid In Response to COVID-19 By Adjusting Key Areas

- **Populations**
  - Expanding the Medicaid populations that can use telehealth

- **Technology**
  - Expanding the technologies used to deliver telehealth
  - Allowing more types of distant and originating sites

- **Services & Payment Rates**
  - Allowing new services to be delivered via telehealth
  - Adjusting payment rates and cost sharing

- **Providers**
  - Broadening provider types that may deliver services via telehealth

Image Credit: Kaiser Family Foundation
Ongoing Challenges

• Evolving policies as the pandemic restrictions are easing – how will access and reimbursement be affected?
• Digital Divide

Disparities in broadband access → Disparities in access to technology → Disparities in education and digital literacy
Ongoing Challenges

- Time delays
- Possible communication gaps
- Loss to follow-up
Other industries have undergone digital transformation...

Analog → Digital

“Dumb Digital” → Continuously Improved Digital
Opportunities for Artificial Intelligence

• Ability to scale
• Managing large volume of data from both traditional clinical encounters and telehealth encounters
• Enhanced predictive models and risk stratification
• Autonomous AI can provide point-of-care results without waiting for clinician input
• AI can also facilitate synchronous telehealth interactions (e.g. chatbots)
• Opportunities to streamline/automate workflows
Our Changing Vision
Implications in the adoption of AI during the COVID-19 pandemic

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The Watzke Professor of Ophthalmology and Visual Sciences
University of Iowa
Founder and Executive Chairman, Digital Diagnostics
Fellow, ARVO
Choosing Autonomous AI
Reduce physician burned and improve patient outcomes

Autonomous AI
- Medical decision made by the AI
- No human oversight
- Point of Care
- Primary care
- Liability with AI creator

Assistive AI
- Medical decision made by the clinician
- Clinician needed
- Time to review
- Specialty care
- Liability for clinician
Healthcare problems to be solved by Autonomous AI

Healthcare Cost - Access

Healthcare Cost - Productivity

Productivity in healthcare
(2000 = 100%)

Productivity in all other industries
(2000=100%)

Healthcare demand - workforce gap

Lam et al, The effect of electronic health records adoption on patient visit volume at an academic ophthalmology department BM Health Serv Res, 2016
Redd et al, Electronic health record impact on productivity and efficiency in an academic pediatric ophthalmology practice, JAPOS 2014
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Focus on Eye Health Summit: Our Changing Vision | July 14–15, 2021
Diabetes health inequities & disparities in access

Affects groups differentially, resulting in large differences in:

» Diabetes incidence and prevalence
» Diabetic retinopathy incidence
» Compliance w/ eye exams
» Visual loss from diabetic retinopathy

Examples:

» In Black Americans, diabetes prevalence 20.4% (95% CI, 18.8%-22.1%), almost twice that of white Americans
» Diabetes prevalence U.S. Hisps 22.1% (95% CI, 19.6%-24.7%)
» Black Americans 2.5x risk of developing DR at equal A1C levels
» Compliance among the Black American population to have diabetic eye exams is less than all other groups

Shift from referral-based to instantaneous POC A1C testing increases compliance from <50% to 95% in people with diabetes1,2,3

Citations:

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Examples:
- In Black Americans, diabetes prevalence U.S.
- Black Americans 2.5x risk
- Compliance among the Black population

Shift from retinopathy increases death

WHO: Biased AI health tech could disadvantage poorer countries

**BY ASHLEIGH FURLONG** 05/28/2021 08:59 AM EDT

LONDON — Artificial intelligence poses great possibilities in streamlining health care, but with these products developed mostly by using data from wealthy nations, their deployment in low- and middle-income countries raises concerns of bias and inequitable provision of health care, according to new guidance from the World Health Organization.

The guidance, published Monday, on AI in health care follows two years of consultation by a panel of experts appointed by the WHO, and finds that AI holds great promise in improving patient care, providing more accurate diagnoses and increasing access to health care in settings where the provision of these services is limited.

However, the WHO cautions that in these same settings, AI systems may not work as well. That’s due to contextual bias, which is a result of AI systems being designed using data from individuals in high-income countries. “Algorithms may not recommend safe, appropriate or cost-effective treatments for low-income or low-resource settings or for countries that have resources but in which segments of the population still have poor health outcomes,” states the guidance.

The guidance also warns of differing liability regimes for AI, with liability rules sometimes being the “only line of defense against errors made by machine-learning technologies.” Some low- and middle-income countries may not have the regulatory capacity to assess these new products, with the guidance warning that individuals harmed by these AI systems may also face little recourse to justice.

The guidance sets out six principles to prevent situations such as these, including ensuring inclusiveness and equity, as well as promoting human well-being, safety and the public interest.
Clinical requirements for Autonomous AI

» Make medical decision without human oversight
  • Autonomous AI
  • Creator assumes liability
  • Easy-to-understand diagnostic output

» Minimal changes to clinic/lab workflow
  • Make diagnosis within minutes
  • Minimal footprint to fit clinic space, power outlet only requirement
  • High diagnosability

» Use existing staff
  • Operable by existing staff (high school diploma)
  • Robotic camera with assistive AI

» Automatic claims, billing and care gap closure
  • Real time, immediate claims and ICD-10 generation
  • Aligned w Standards of Care and Preferred Practice Patterns
Ethical framework for Autonomous AI requirements

Ethical principles
- Non-maleficence
- Autonomy
- Justice

Legal principle
- Accountability

Mitigating bias through AI design


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Validation against clinical outcome

- Evidence based markers for diabetic retinopathy
  - Studies from 70s and 80s and today
  - Highly reproducible and consistent over decades
  - Used today for FDA drug trials: ETDRS, DRS and DRCR
  - Cannot be created again ethically

- Clinicians not validated against this standard
  - Low diagnostic accuracy and diagnostic drift
  - Lack of consistency

Rigorous Validation of AI Against Prognostic Standard

<table>
<thead>
<tr>
<th></th>
<th>FDA Superiority Endpoint</th>
<th>IDX-DR(n=819)</th>
<th>Remote Reading Network / Telemedicine</th>
<th>Board Certified Ophthalmologist in Clinic</th>
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<tr>
<td>Sensitivity</td>
<td>85%</td>
<td>87% (81% - 91%)</td>
<td>72% (65%-79%) 6</td>
<td>33%-33%-34%</td>
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<tr>
<td>Specificity</td>
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<td>90% (88% - 93%)</td>
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<tr>
<td>Repeatability</td>
<td>99%</td>
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<tr>
<td>Reproducibility</td>
<td>99%</td>
<td></td>
<td>83% 4</td>
<td>83%</td>
</tr>
</tbody>
</table>

Equity: No significant effects for sex, race, ethnicity, HbA1C, lens status, or site

Surrogate outcome:
Stereo imaging: ETDRS level 43
- 1-year risk of early PDR 26.3%
- 1-year risk of high-risk PDR: 8.1%
OCT: DRCR level no ci-DME
- No benefit from treatment
Creation of a new industry: Autonomous AI in Healthcare

300+ papers (2008)
Ethical Foundations (2020)

First FDA de novo clearance (2016)
Second FDA clearance with 510k (2020)

First ever CPT Code 92229 (2019)
Coverage $55.66 (2020)

American Academy of Ophthalmology
USPTO 11,004,565

Preventing blindness and visual loss
Resolving health disparities and closing care gaps

Case Study: Improving access in New Orleans

- Largely Black population
- Hardly any eye care providers
- 805+ patients w care gaps for diabetic eye exam
- > 4-month appointment wait time

9 months post IDx-DR

- Eliminated care gaps for 805+ patients
- Same day appointments if eye exam needed

25% had a potentially blinding disease

Case Study: Reducing COVID backlog in Iowa

- 100 patients not tested
- 70 patients tested
- 30 patients tested
- Backlog cleared

Diabetic eye exams halted due to lack of access
IDx-DR added to address eyecare backlog/eliminate extra visits
Routine use of IDx-DR

17% had a potentially blinding disease

"With IDx-DR we stayed on top of closing care gaps even during a pandemic. Access to diabetic eye exam is not a problem anymore because of the highly scalable capacity."

Michelle Havinga (Director Population Health & ACO Ops UIHC)
References

11. Lam et al. The effect of electronic health records adoption on patient visit volume at an academic ophthalmology department BM Health Serv Res, 2016
12. Redd et al. Electronic health record impact on productivity and efficiency in an academic pediatric ophthalmology practice, JAAPOS 2014