The challenging future of AI in Medical Devices

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„IoT, economic and management challenges for e-health integration in the enlarged Europe“

Introduction

- There are 2 crucial aspects concerning medical devices
  - Safety
  - Effectiveness
- Ensuring safety & effectiveness results from a shared understanding and responsibility among key stakeholders in healthcare (medical device‘s manufacturers, healthcare professionals, patients, regulatory authorities, importers, distributors, etc.)

Artificial Intelligence

- The science and engineering of making intelligent machines, especially intelligent computer programs

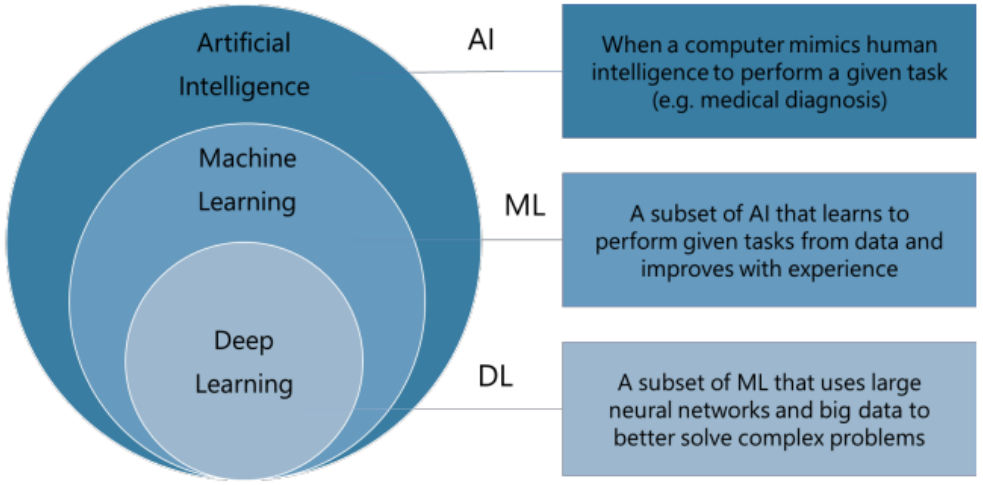
  John McCarthy

- AI can use different techniques to produce intelligent behaviour
- Machine Learning is an AI technique that can be used to design and train software algorithms to learn from and act on data (i.e. methods that learn to perform given tasks, such as prediction or classification, based on existing data)

Artificial Intelligence

- Deep Learning is the ability for machines to autonomously mimic human thought patterns through artificial neural networks composed of cascading layers of information

Figure 1 – Relationship between artificial intelligence, machine learning and deep learning



https://www.europarl.europa.eu/thinktank/en/document/EPRS_STU(2022)729512

AI – Real-world Examples

- *Targeted marketing*: group customers based on buying habits or demographic similarities, and by extrapolating what one person may want from someone else's purchases
- *Facial recognition and automatic photo tagging*: people previously received name suggestions for their mobile photos and Facebook tagging, but now someone is immediately tagged and verified by comparing and analyzing patterns through facial contours

AI – Real-world Examples

- *Fighting inappropriate content on social media*: ML has become helpful in fighting inappropriate content and cyberbullying on platforms from Facebook to Instagram and Twitter, which pose a risk to platforms in losing users and weakening brand loyalty

AI in healthcare

- AI is quickly being adopted in healthcare
  - From primary care to rare diseases, emergency medicine, biomedical research and public health
  - Covid-19 has expedited the process of digitalising healthcare, including the need for smarter medical devices
- Many medical devices are starting to incorporate AI capabilities

AI in healthcare: Rationale

- Increasing mismatch between demand and capacity
  - Ageing population, chronic diseases, long-term care needs
  - Shortage of skilled staff
- Increasing expectations as to what quality healthcare looks like

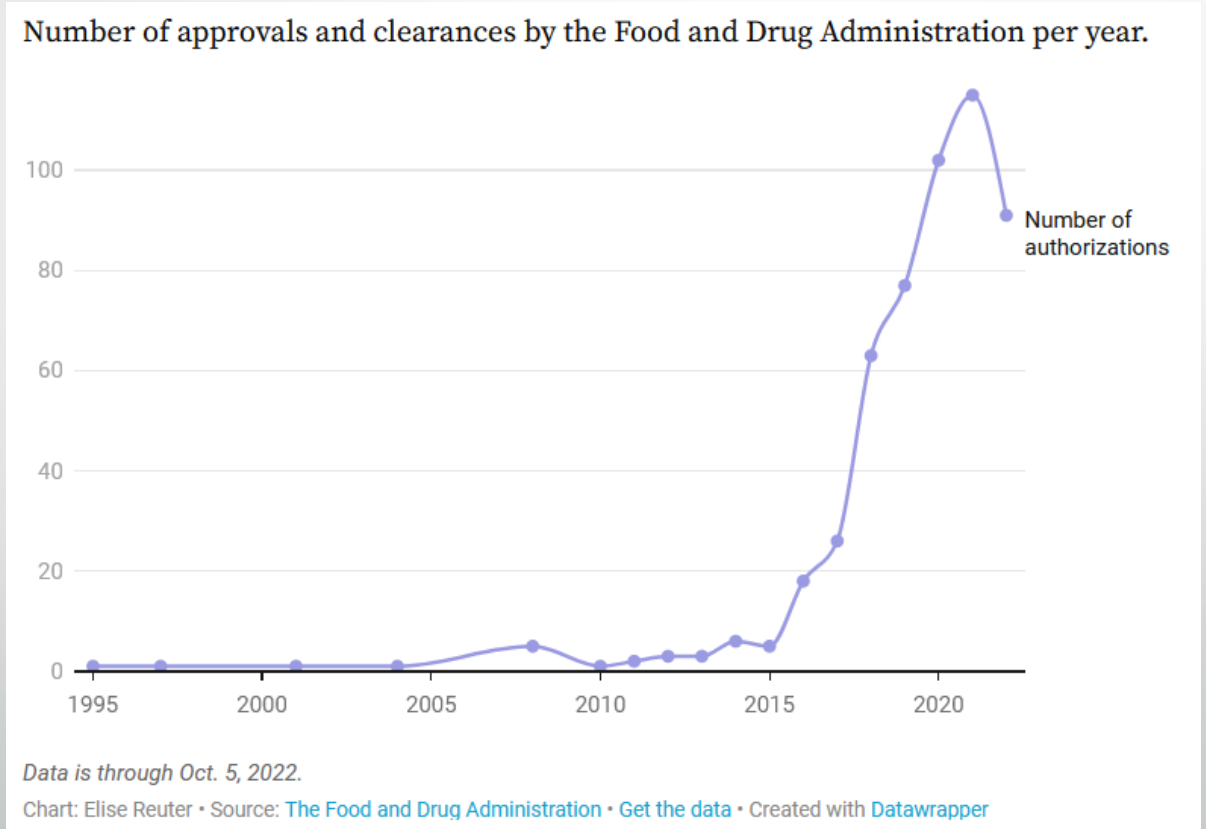
AI in healthcare: Rationale

- Healthcare inequities
  - Lack of transparency on how waiting list priorities are set
  - Inadequate availability of services, particularly in rural areas
  - Difficulties in reaching particularly vulnerable communities who have limited access to qualitative healthcare such as ethnic minorities and socioeconomically disadvantaged people
  - Racial bias and unequal healthcare provision

AI in healthcare: Rationale

- Ideally, AI might be able to provide:
  - super-human performance,
  - free of human error and inconsistency,
  - and scalable at will to provide expert-level care across health systems
- This has been the impetus for health systems (and their funders) to invest, research, and apply AI in healthcare

AI in healthcare



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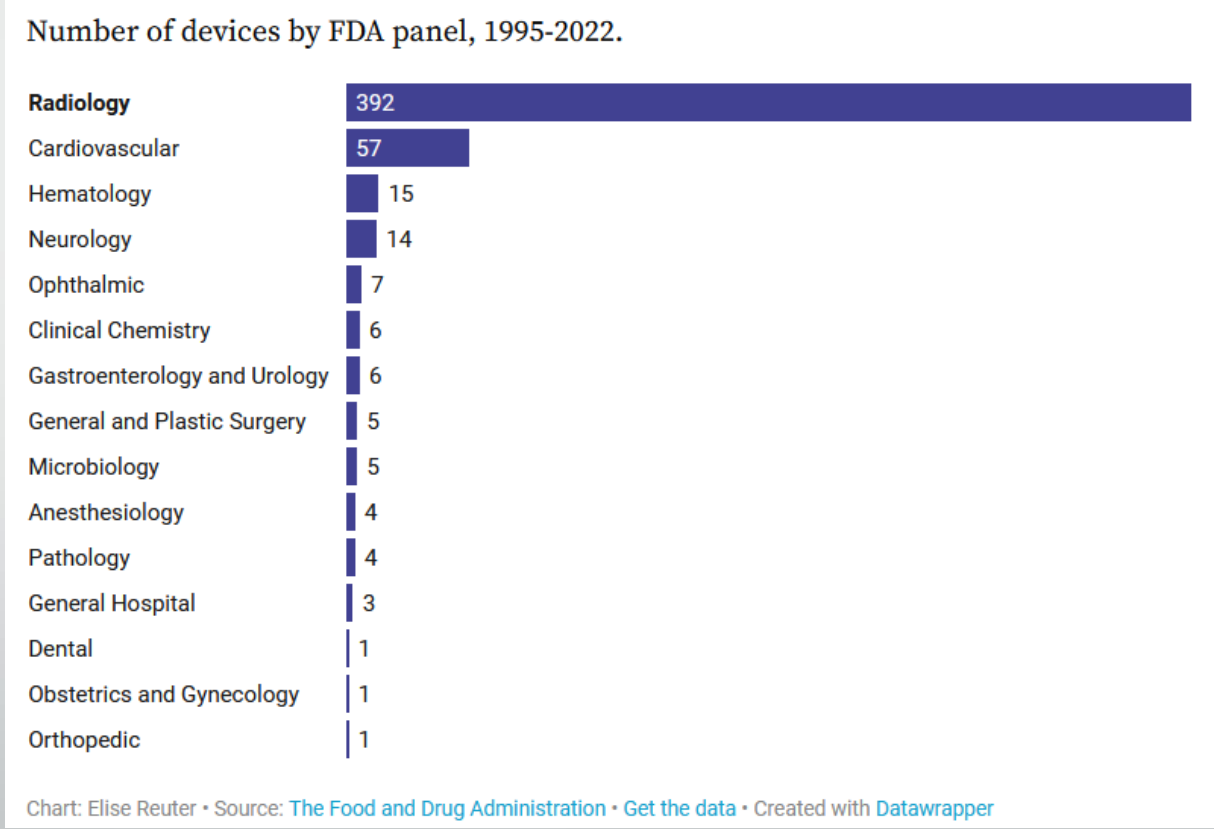
AI-based Medical Devices



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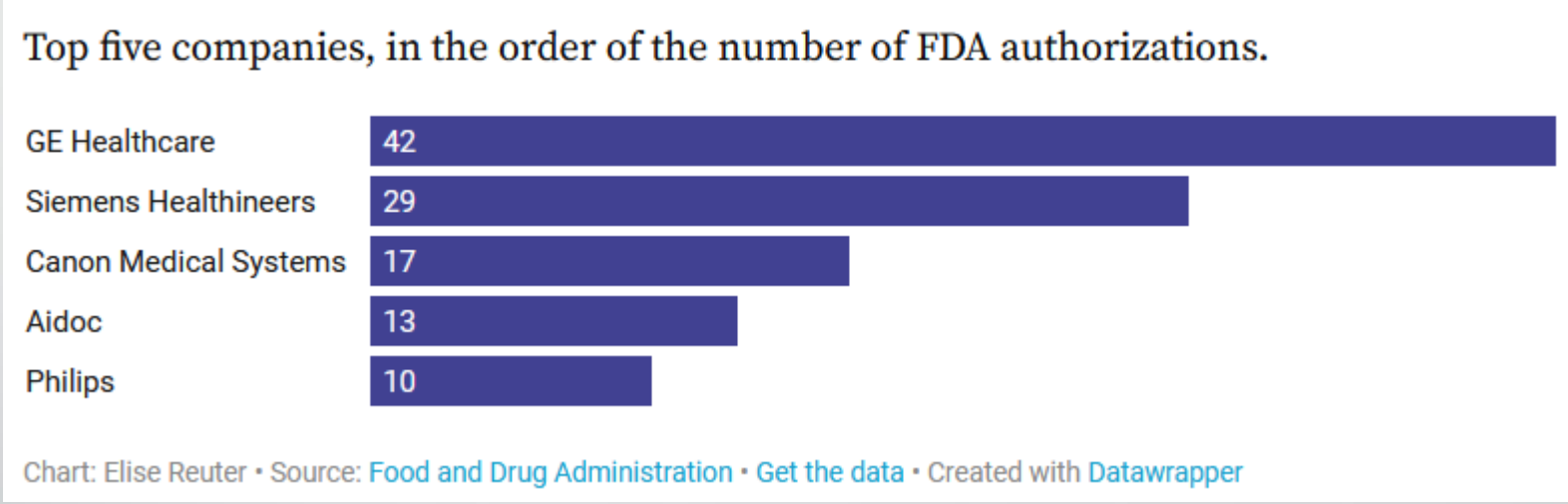
AI-based Medical Devices



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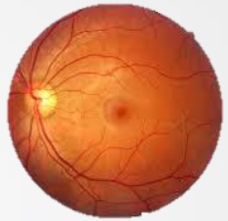
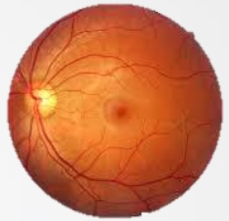
AI in healthcare – Case 1



- IDx-DR
  - A software program using an AI algorithm to analyze images of the eye taken with a retinal camera
  - A doctor uploads the digital images to a cloud server on which IDx-DR software is installed
  - The software provides the doctor with one of two results:
    - "more than mild diabetic retinopathy detected: refer to an eye care professional", or
    - "negative for more than mild diabetic retinopathy; rescreen in 12 months

AI in healthcare – Case 1

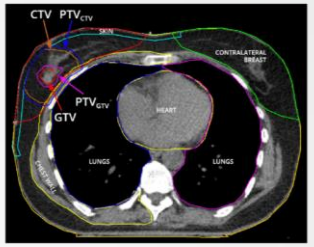


- IDx-DR
  - Early detection of retinopathy is an important part of managing care for the millions of people with diabetes, yet many patients with diabetes are not adequately screened for diabetic retinopathy since about 50 percent of them do not see their eye doctor on a yearly basis
  - It can be used in a primary care doctor's office, as it 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

AI in healthcare – Case 2

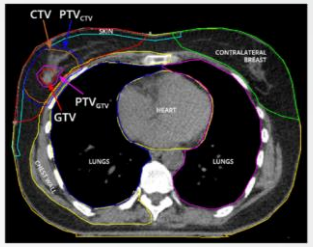
- Atrial Fibrillation (Afib) History Feature is intended for use with the Apple Watch and the Health app on iPhone
- The AFib History Feature acquires platform sensor data from Apple Watch. After acquisition, the Afib History Feature algorithms analyze pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and aggregates those episodes to provide the user with an estimate of atrial fibrillation burden during watch wear
- It empowers users to observe and understand the impact of lifestyle on their AFib burden, and to better understand their condition generally

AI in healthcare – Case 3



- Contour delineation is a crucial treatment planning process that involves outlining target(s) and organs at risk (OARs) to guide radiation therapy plans that optimize tumor control and reduce radiation toxicity
- ART-Plan is a software for multi-modal visualization, contouring and processing of 3D images of cancer patients for whom radiotherapy treatment has been prescribed

AI in healthcare – Case 3



- ART-Plan allows the user to view, create and modify contours for the regions of interest. It also allows to generate automatically, and based on medical practices, the contours for the organs at risk and healthy lymph nodes and to register combinations of anatomical and functional images.
- Contours and images require verifications, potential modifications, and subsequently the validation of a trained user with professional qualifications in anatomy and radiotherapy before their export to a Treatment Planning System

AI in healthcare – n Cases

- https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices?utm_medium=email&utm_source=govdelivery

Challenge: Data availability and quality

- Medical data is known to be unstructured and noisy
- Formats and quality of clinical data vary significantly between centres/region/countries
- Data are fragmented across several EHRs and software platforms, and collectingdata to test AI becomes challenging
- Most existing datasets are not exploitable in AI without first having significant and costly human revision, quality control, cleaning and relabelling

Challenge: Methodological Research Flaws

- There are not enough established methodologies, prospective research, or peer-reviewed studies
- Most of studies have been retrospective and based on historical patient medical records
- To realize the true value of AI in real-world, physicians must study current patients over time, which means prospective research

Challenge: Errors leading to harm

- AI can fail
  - Noise and artefacts in AI‘s clinical inputs and measurements
  - Data shift between AI training data and real-world data
  - Unexpected variations in clinical contexts and environments

Challenge: Errors leading to harm

- AI failures can potentially lead to safety concerns
  - Missed diagnoses of life-threatening disease
  - Unnecessary treatments due to false positives
  - Incorrect prioritisation in emergency care
  - …

Challenge: Privacy & Security

- „The price of innovation does not need to be the erosion of fundamental privacy rights“
- AI demand vast amount of data which increases the possibility of leakage and misuse of such data
- Informed consent shall remain a crucial and integral part to the patient's experience in healthcare
- There can be harmful and potentially fatal cyberattacks on AI solutions

Challenge: Lack of Transparency

- AI is still considered to be complex and obscure
- Transparency is closely linked to
  - Traceability
  - Explainability
- Seeing AI as „black-box“ should not be anymore acceptable

Challenge: Bias & Discrimination

- Most common biases:
  - Sex and gender
  - Age differences
  - Ethnic groups
  - Geographic locations
  - Socioeconomics
- AI systems are only as unbiased as the data they are trained on
  - If data is biased, the resulting system will be too

Challenge: Bias & Discrimination

- Oxygen administration and pulse oxymeter [*]
  - Pulse oxymeter is known to systematically overestimate oxygen saturation levels in nonwhite patients
  - Black patients are three times more likely to suffer from an occult hypoxemia
  - Disparities may start at the level of clinical measurements, which can ultimately shape erroneous medical decisions for entire patient groups, and can be amplified with the development of AI technologies
- Cardiovascular disease has different patterns in male VS female [*]
  - AI trained on dataset prevalently containing data from male individuals may not perform accurately on female

[*] Torori et al., 2021, *Patterns*

Challenge: Bias & Discrimination

- AI is designed by humans, and may reflect human biases [*]
  - Lack of diversity in engineering and biomedical teams can replicate unconscious bias and power imbalances
  - AI is often designed to tackle what their developers consider the most urgent problems to solve
  - These problems might not be the same challenges faced by the individuals that are concerned by that AI

[*] Torori et al., 2021, *Patterns*

Challenge: Continuous learning

- Typically, legally marketed devices have only included algorithms that are "locked" prior to marketing
  - „Locked" algorithm: an algorithm that provides the same result each time the same input is applied to it and does not change with use. Examples of locked algorithms are static look-up tables, decision trees, and complex classifiers
- Not all AI/ML-based MD are locked; some algorithms can adapt over time
- The power of these AI/ML-based MD lies within the ability to continuously learn, where the adaptation or change to the algorithm is realized after the MD is distributed for use and has "learned" from real-world experience
- These types of continuously learning and adaptive AI/ML algorithms may provide a different output in comparison to the output initially cleared for a given set of inputs

Challenge: Accountability

- There are multiple actors involved with AI, from developers to healthcare professionals
- There are current gaps in regulation concerning concerning who should be held accountable or liable for errors or failures of AI
- Healthcare professionals are left vulnerable, especially if the AI they are using is not entirely transparent

Challenge: Humans

- AI can learn from big data (such as incommunicable silos of unstructured information stored in an EHR) more efficiently than healthcare professionals
- AI can perform predefined tasks with higher precision
- AI can be in a continuous active state without compromising its performance - it does not suffer from burnout as humans do
- „In bot we trust“
  - People are actually more willing to trust a computer than their fellows

Challenge: Humans

- Never forget that AI is going to be tool in the hands of healthcare professionaly – not the other way around
  - Art of medicine: the creative process of understanding the uniqueness of each and every patient and tailoring treatments according to the arisen needs
  - Think outside the box
- Patients shall be engaged
  - Patients were shown to be excited about healthcare AI but wanted assurances about safety [*]
  - Patients expect their clinicians to ensure AI safety[*]

[*] Richardson et al., 2021, *npj Digital Medicine*

Conclusions

- Is AI good or bad?
- Can AI be used in healthcare whilst ensuring safety and effectiveness?

Conclusions

- AI is a tool
- It is neither good nor bad per se, but its uses can lead to both positive and negative outcomes
- „*With great power comes great responsibility*“