# The EU regulatory framework on medical AI tools: the patients' rights perspective

**Hannah van Kolfschooten**
Law Centre for Health and Life
University of Amsterdam

# How does AI work?

## UMC Utrecht: AI predicts long-term neurodevelopmental outcomes in preterm babies

**Goal**: Predict which 28-week old infants will develop intellectual disability issues to develop a care plan.

**Training data**: EEG data of 369 babies in the first 3 days after birth data + data about their development after 2-3 years and 5-7 years

**Input**: New EEG of preterm baby X

**Output**: Baby X has a 95% chance of having a severe intellectual disability at the age of 5

**Recognize patterns in big datasets**

**Make predictions in new situations**

**Learn from new situations**

# How is AI used in healthcare?

News-Medical

## New, interpretable AI model can predict 5-year breast cancer risk from mammograms

Researchers have developed a new, interpretable artificial intelligence (AI) model to predict 5-year breast cancer risk from mammograms,...

19 mrt 2024

Trend Hunter

## AI Diaper Care Solutions

MECS - The MECS AI diaper care solution was created to prevent elderly people from experiencing UTI, IAD and pressure ulcers with complex...

31 dec 2021

TechCrunch

## Zoe Care uses existing Wi-Fi signals to detect falls in care homes

Fall detection and autonomy for the elderly is front-and-center at CES in Las Vegas this year. Cherish Health introduced the $300 Serenity...

10 jan 2024

Sifted

## Meet the AI chatbot therapists filling the gaps in Europe's mental health care shortfall

It's the first AI mental health chatbot in the world to achieve UKCA Class IIa medical device status — a product marking that signals its...

3 mrt 2024

www.amsterdamumc.org

## Groundbreaking: Artificial intelligence supports ICU physicians in patient discharge decision

Doctors at the Intensive Care Unit of Amsterdam UMC are now supported by artificial intelligence in their patient discharge decision,...

31 aug 2022

# What are the challenges for patients' rights? (1)

**1. Right to access to healthcare**

High-quality

Non-discrimination

**2. Right to privacy and confidentiality**

Privacy

Medical confidentiality

Medical data protection

**3. Right to information**

Information about one's health status

Access to medical records

Information about treatment options

# Visualizing bias (1)

# Visualizing bias (2)

Prompt: Traditional African healer is helping poor and sick White children.

# What are the challenges for patients' rights? (2)

**4) The right to self-determination**

Physical and mental integrity

Informed consent

Human dignity?

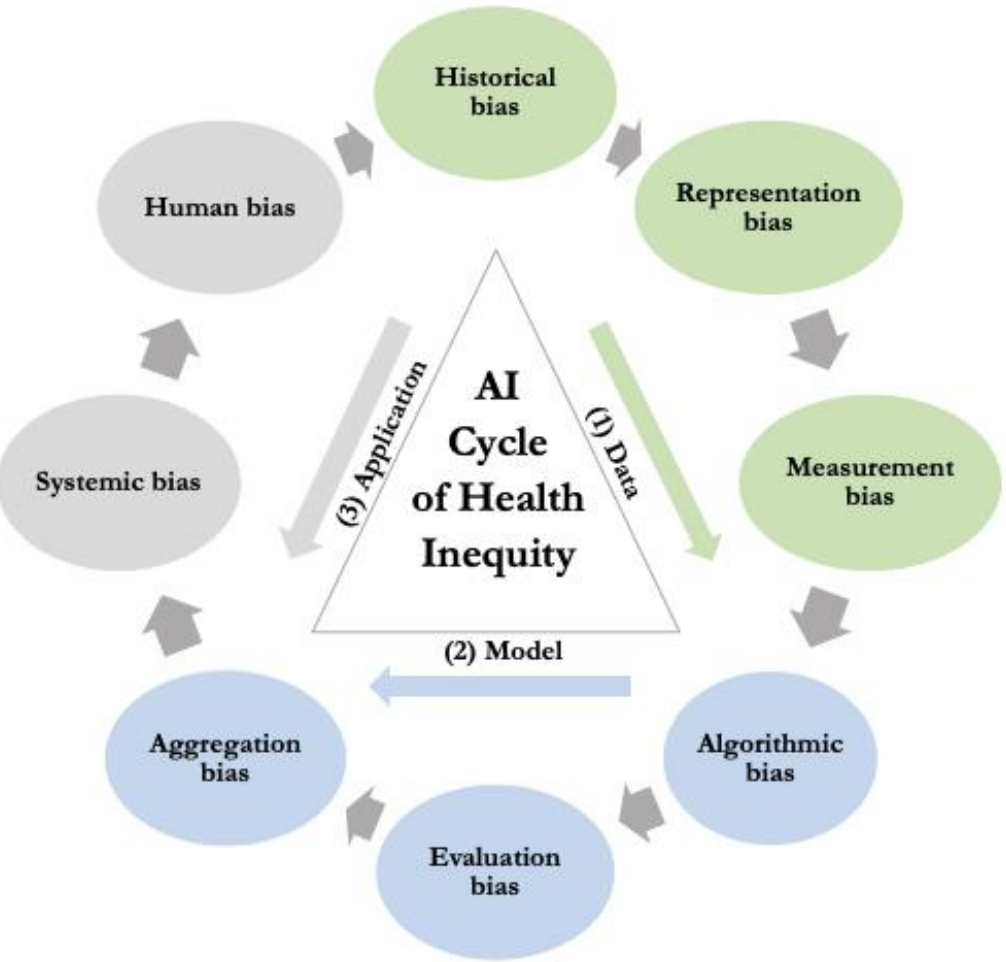
**5) The right to justice**

Post-treatment information

Complaint systems

Harm compensation

# Concerns for health inequity




**Data phase:**

- **Historical:** algorithms may be trained with data that no longer accurately reflect reality
- **Representation**: when certain population groups are underrepresented in the training dataset
- **Measurement**: inaccurate input data or labels

**Model phase:**

- **Algorithmic:** biased variable/proxy in the model
- **Evaluation:** testing data does not represent target population
- **Aggregation:** general model is used for groups with different conditional distributions

**Application phase:**

- **Systemic:** institutions advantage certain social groups and disadvantage others
- **Human:** unconscious biases and stereotypes in interpretation

# EU legal framework (1)

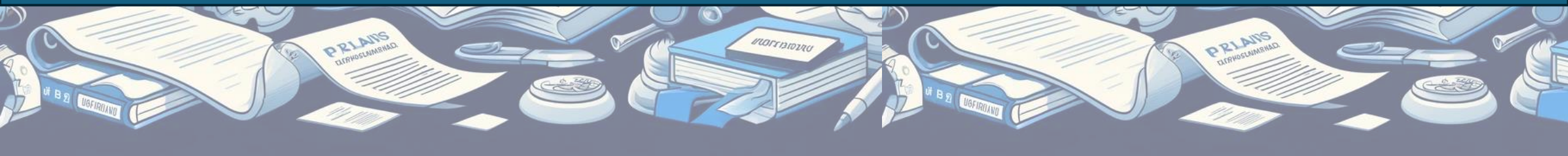
1) Charter of Fundamental Rights of the European Union
2) General Data Protection Regulation
3) Current legal framework: Medical Devices Regulation (MDR)
4) Product regulation / consumer protection
*5) New AI Act*

NB:

1) EU has limited legislative competences in healthcare;
2) AI apps are often no MDR medical devices

# EU legal framework (2)

1) Artificial Intelligence Act was adopted 21 May 2024
2) Regulates the development, placing on the market, putting into service and use of AI systems in the EU
   -> *Brussels effect?*
3) Aims: safety; respect for fundamental rights; promoting trust in AI; support innovation; enhance EU competitiveness in AI
4) Horizontal application
5) Risk-based approach: the higher the risk, the stricter the rule
   **High risk**: AI medical devices; pricing for health insurance; classifying emergency calls…
   **Low risk**: AI medical chatbots; AI sensors and camera's in elderly care
   **Minimal risk**: AI in pharmaceutical research; hospital administration



# How *should* we regulate AI to protect patients' rights?

- Now: standardisation process; national implementation
- EU *Medical* AI Act?
- Amend the Medical Devices Regulation – data quality, transparency, regulatory oversight?
- "Human rights impact assessments" by hospitals?
- "*Good AI*"-labels; Minimum accuracy percentages?

- …New human rights?

# Questions?


Hannah van Kolfschooten
h.b.vankolfschooten@uva.nl

@hvkolfschooten

Hannah van Kolfschooten