

# Fairness, Transparency, and Responsibility in Artificial Intelligence



# Healthcare Strategy *Review*

Doctors go to jail. Engineers Don't.

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**“Until the liabilities and responsibilities of AI models for medicine are clearly spelled out via regulation or a ruling, the default assumption of any doctor is that if AI makes an error, the doctor is liable for that error, not the AI.”**

Polevnikov, 2024

“Soon, it will be a violation of your Hippocratic Oath NOT to use AI in your medical practice.”

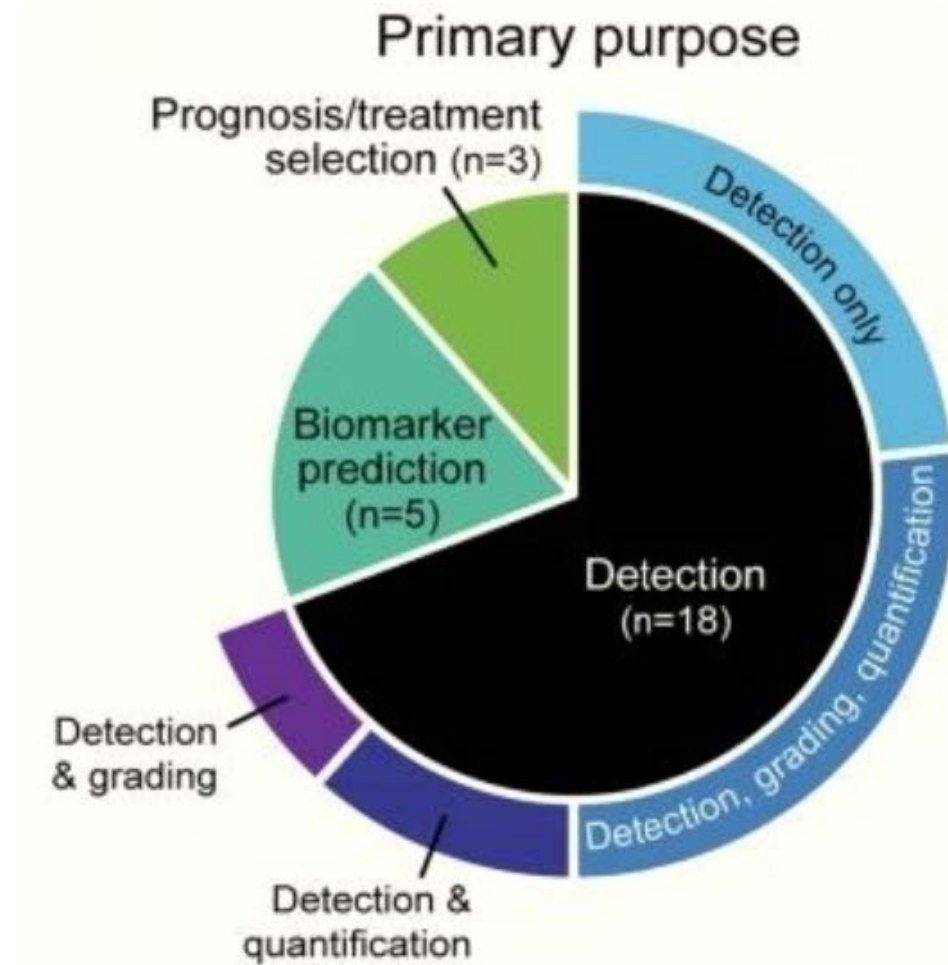
Neal Khosla, 2024

**“When AI-based technology becomes the standard of care, the liability of medical providers for failing to adopt it, especially when it could have prevented harm to a patient, can be significant under malpractice law.”**

Froomkin, Kerr and Pineau, 2019

# Review of approvals for AI-enabled medical devices

- Only **38%** had peer-reviewed internal validation studies (in UK and EEA); **40%** in US
- Validation studies often **lacked diversity**; many datasets were small or used limited scanner platforms
- Only **17%** were independently conducted without vendor involvement



# Weak Post Market Surveillance (Netherlands)

4. Data		
#	Requirement	Result
4.3	Provisions for serious incidents	✘
4.4	Provisions for non-serious incidents	✘
4.5	Provisions for reporting trends	✘
4.6	Provisions for literature review	✘
4.7	Provisions for customer feedback	!
4.8	Provisions for similar medical devices	✘
4.2	Proactive and systematic procedures	✘
4.9	PMCF/PMPF plan	!
4.1	Appropriate data sources	✓

- ✓ More than 75% of the manufacturers met the assessment criterion.
- ! 50 - 75% of the manufacturers met the assessment criterion.
- ✘ Less than 50% of the manufacturers met the assessment criterion.



# Walking the tightrope between stifling innovation and doing harm through under-regulation



1. **Industry self-governance:** Voluntary ethical business standards
2. **Soft law:** Non-binding principles and technical standards provide agility but may lack clear rights or responsibilities.
3. **Regulatory sandboxes:** Controlled environments allow testing of innovative regulatory approaches but can be very resource-intensive to run.
4. **Hard law:** Binding frameworks like the EU AI Act or country-level legislation provide consistency and legal certainty but must be adapted to local context keeping in mind existing capacity and resources.





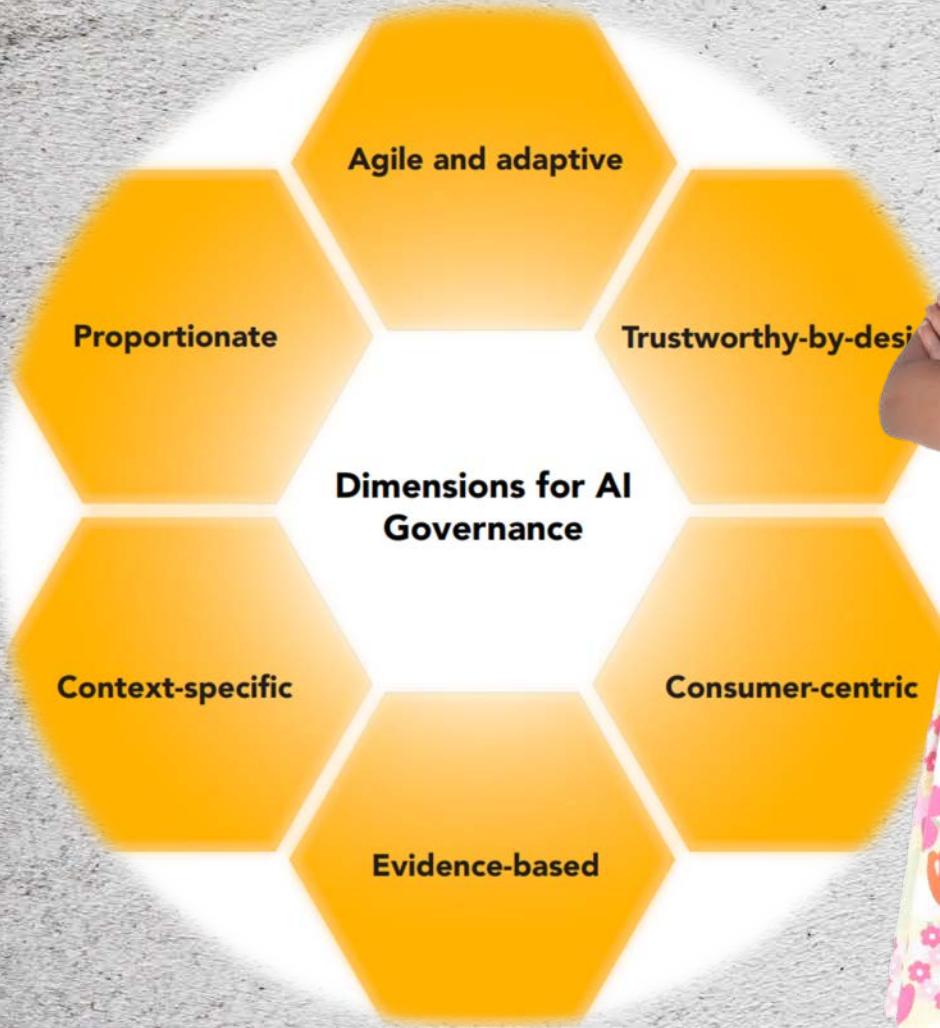
LOW

HIGH

**Human-out-of-the-loop**  
AI makes the final decision without human involvement, e.g. recommendation engines.

**Human-over-the-loop**  
User plays a supervisory role, with the ability to take over when the AI encounters unexpected scenarios, e.g. GPS map navigations.

**Human-in-the-loop**  
User makes the final decision with recommendations or input from AI, e.g. medical diagnosis solutions.



**Digital Infrastructure:** Providing reliable internet, advanced data systems, and computational power.

**Human Capital:** Upskilling workers and building AI talent pipelines.

**Local Ecosystems:** Fostering innovation through public-private partnerships and supportive policies