Assessing the added value of algorithmic decision-making systems (ADS) in healthcare practices

A COMPARISON BETWEEN ADS AND PHARMACEUTICALS

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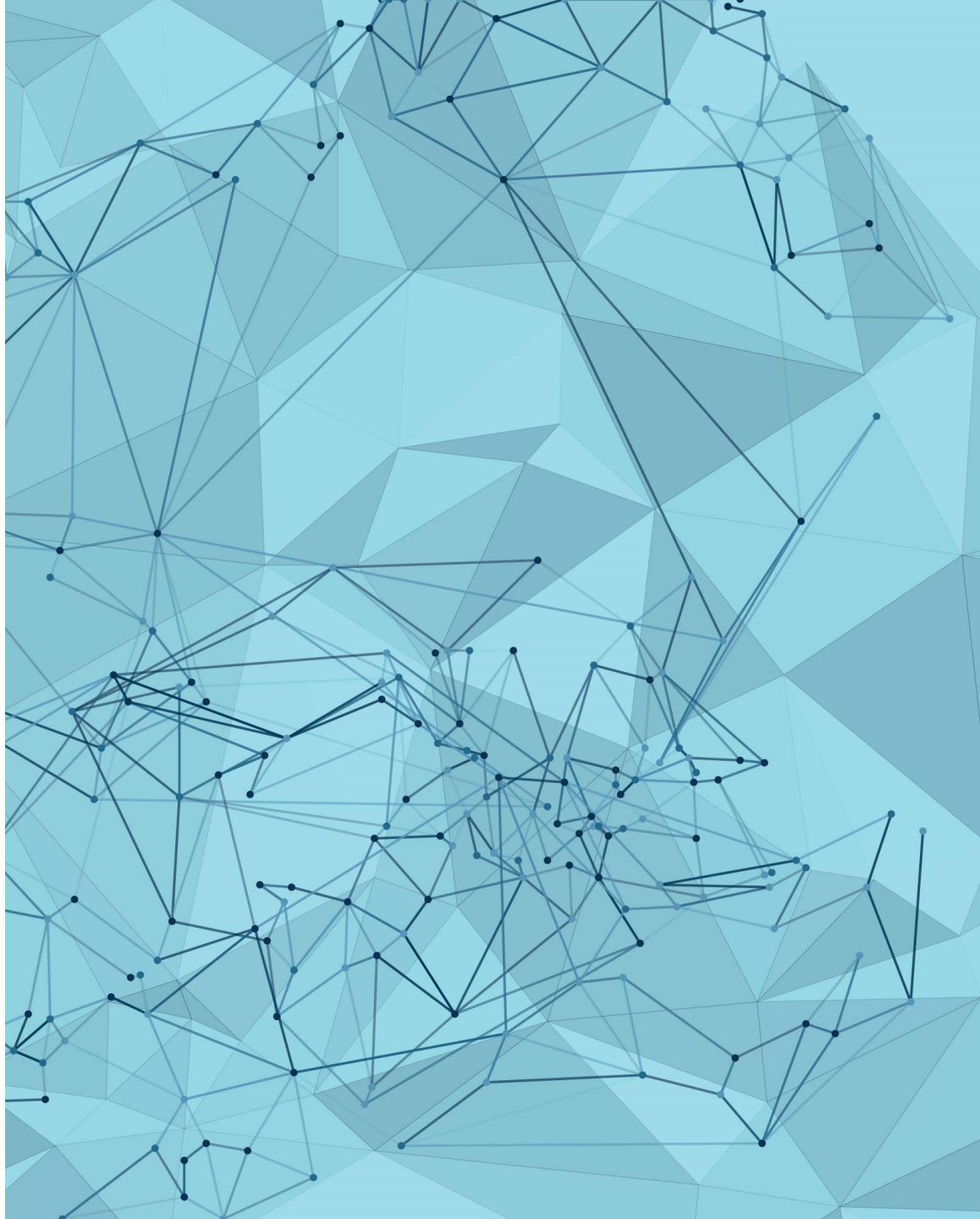

Context

"We won't be able to stop that AI will be used in healthcare. Healthcare systems are overloaded to such an extent that we seize all solutions, and we also must do so, because the situation is not sustainable how it is now. AI can provide solutions in many respects"

(Quote expert on AI in healthcare).

- Slow progress, low acceptance of algorithmic decision-making systems (ADS) in healthcare

→ often ascribed to uncertain added clinical benefits in local settings.

-The development of value assessment approaches for pharmaceuticals already has a long history.

Aim

To explain how added value of ADS (AIMD) in Dutch healthcare is evaluated and how this differs from evaluating added value of pharmaceuticals.

ADS: AI-medical devices

Jolien van de Sande

Methods

- Literature review of scientific research and policy documents on ADS in healthcare, and their regulation, funding/ reimbursement, and health technology assessment (HTA).

- Interviews with different experts on the development, use and regulation of ADS in healthcare (lawyers, computer scientists, and experts on health policy, HTA, and healthcare practice.

- Observations of a symposium of radiologists discussing the future of AI in the field of radiology.

Findings – Funding (HTA)

- Health technology assessment (HTA): value = cost-effectiveness: quality of care / costs

- HTA has become both an established scientific discipline and a broadly accepted standard practice for informing reimbursement and funding decisions, but mainly for outpatient pharmaceuticals.

- Broadening the focus of HTA towards other technologies requires flexible lifecycle- and early HTA approaches that can deal with uncertainty.

- Distinctive characteristics of ADS further complicate value assessment and require additional flexibility (e.g. through sandboxing)

Findings – regulation

- The market for AI-products in healthcare is rapidly developing; regulation is slowly catching up and becoming stricter (MDD->MDR), AI Act.

- Focus on ‘launch phase’, publicly available real-world evidence is limited. Stricter requirements for market access of pharmaceuticals.

- Regulation can also restrict ‘technology-driven innovation’ to ensure added value.

- Solutions from within the sector are challenging: biomedical R&D and ADS-development by healthcare organizations themselves.

Conclusions

- Many similarities between ADS and new pharmaceuticals to learn from for regulating, funding, developing and using ADS.

- New HTA approaches for ADS are similar as for new pharmaceuticals, but still developing.

- Specific characteristics that make ADS different from pharmaceuticals require even more flexible value assessment approaches (e.g. sandboxing).

- These new approaches come with a risk of too soft regulation fostering technology-driven innovation, driven by opportunities to making profits rather than to meet clinical needs.

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