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Artificial Intelligence (AI) in medicine and medical education

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3) Uitgenodigd expert werkgroep Kwaliteit Hoge Raad van Artsen-specialisten en van Huisartsen
Expert invité groupe de travail Qualité du Conseil Supérieur des médecins spécialistes et des médecins généralistes

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Artificial Intelligence in European Medical examinations

- The presenter does absolutely not claim to be an expert in artificial intelligence...

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Part 1. AI in medicine

Application of Artificial Intelligence in daily medical practice

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1ST WAVE

Describe

Explicit knowledge presentation

2ST WAVE

Categorize

Statistical Learning

3ST WAVE

Explain

Hybrid systems
Human-centric AI

First AI Programs
Playing, learning, solving problems, planning
Language understanding

Knowledge based systems
Inference formalisms
Expert systems
Lips, Prologue

Maschinelleres Lernen
v.a. statistisches ML
Random forest, neural networks, SVM, Naive Bayes, AdaBoost

Lighthill Report
AI will never get past game problems

Knowledge Engineering
Bottleneck
Failure of AI languages

AI with another name
Cognitive systems
Intelligent systems

1956

1974-1980
1st AI Winter

1987-1993
2nd AI Winter

2000-2008
Winter without an end

2008
Big Bang of Deep Learning

1994
IBM's Deep Blue World Chess Champion

2011
IBM's Watson wins Jeopardy

2012
Google Brain re

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History of AI

Neural Networks

1950-1970

Machine Learning

1980-2010

Deep Learning

Today

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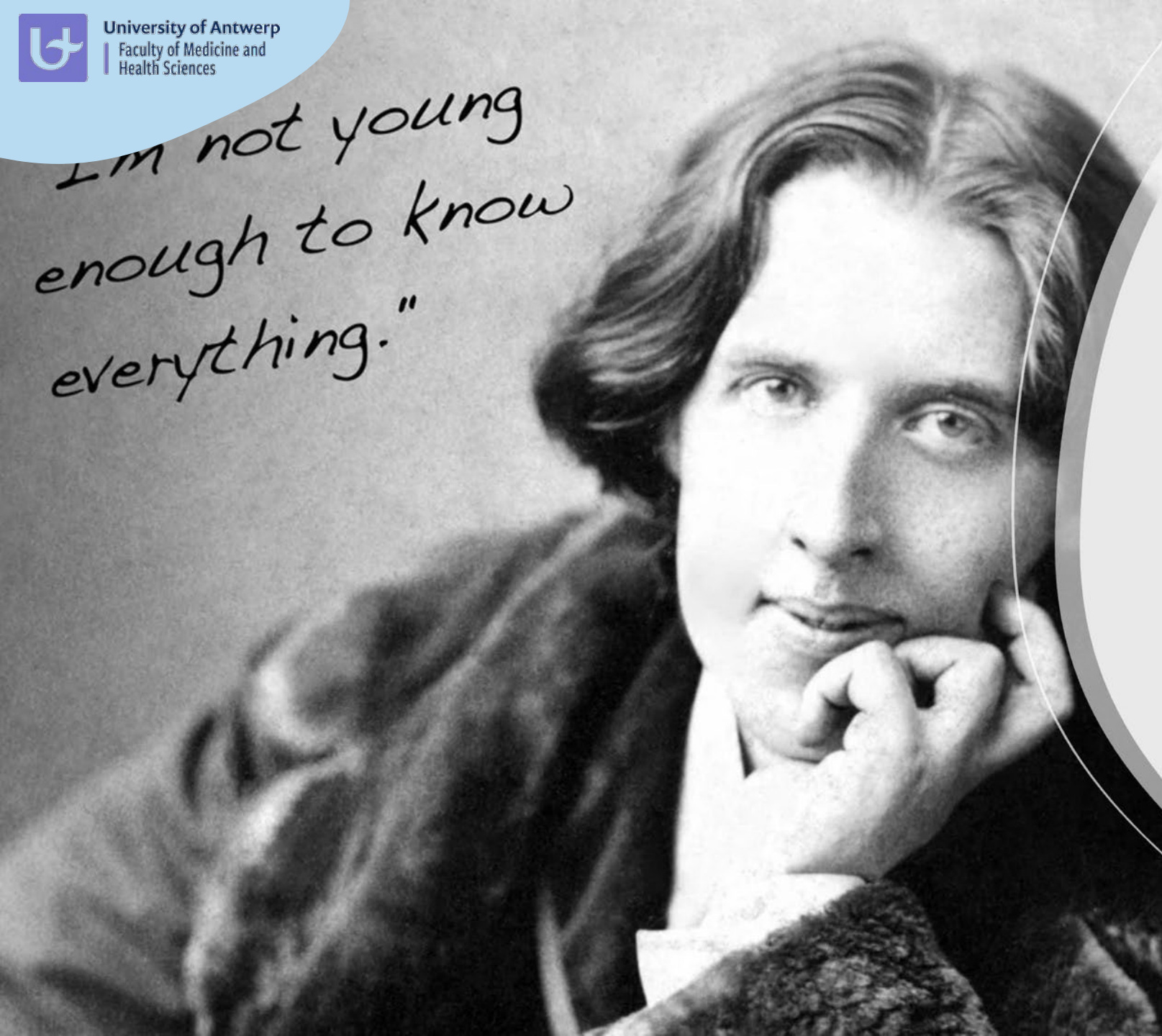

Oscar Wilde

(°16/10/1854 Dublin - †30/11/1900 Paris)

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Michael Hugh Mosley (°22/03/1957 Calcutta, India – †05/06/2024 Agia Marina, Greece)

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Isabel Solutions

Isabel DDx Companion

For healthcare professionals

Using just the minimal presenting clinical features, the Isabel DDx Companion enables clinicians to expand their differential and get

Isabel Self-Triage

For healthcare institutions and health platforms

Helps patients access the care they need more quickly.

Isabel Self-Triage asks just 11 standard questions and takes less than a minute to achieve

Isabel Clinical Educator

For clinical educators and learners

Teaches and assesses reasoning skills in clinical learners.

Isabel Clinical combines refl

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Example of bias introduced in AI diagnostic tools...

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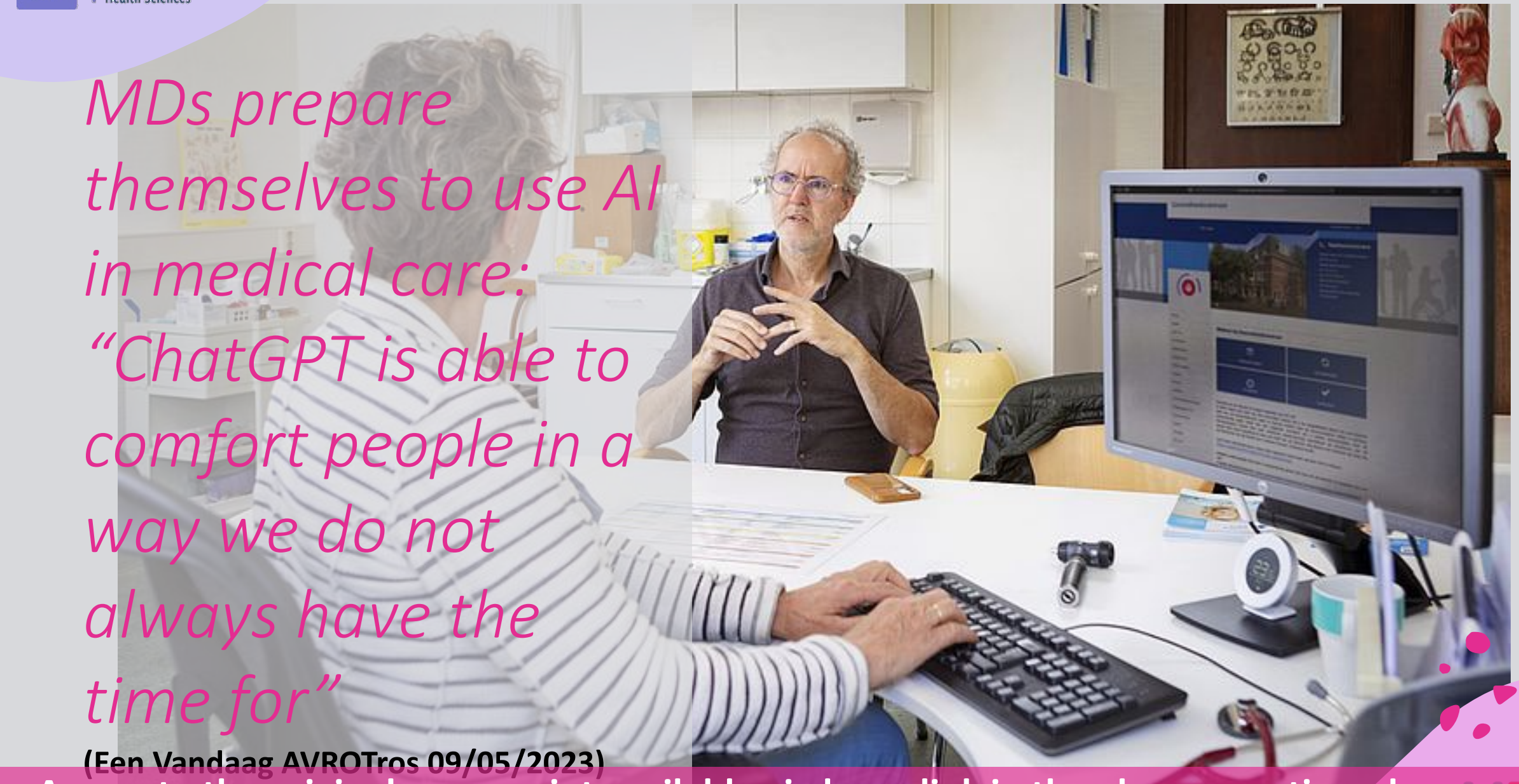
MDs prepare themselves to use AI in medical care: "ChatGPT is able to comfort people in a way we do not always have the time for"

(Een Vandaag AVROTros 09/05/2023)



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ARTIFICIAL INTELLIGENCE IN HEALTHCARE AND REGULATION CHALLENGES: A MINI GUIDE FOR (MENTAL) HEALTH PROFESSIONALS

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SUMMARY

Artificial intelligence (AI) offers new perspectives in the healthcare sector, ranging from clinical decision support tools to new treatment strategies or alternative patient remote monitoring. However, as a disruptive technology, AI is associated with potential barriers, limitations and challenges for appropriate integration in medical practice. To avoid potential patient safety risks and harm, a robust regulatory framework is crucial to guide health professionals in their AI adoption in clinical practice. The European Union offers a new legal framework for the development and deployment of AI systems, the AI Act. This regulation was approved in March 2024 and will be fully applicable by 2025 to ensure that AI technologies are safe, transparent, and respect fundamental rights. However, these new regulatory concepts may be obscure for clinicians. This article aims to provide health professionals with the preliminary key points of regulation needed to interact adequately with these new AI applications and consider the potential risks of AI systems to patient safety.

Key words: *Artificial Intelligence - AI Act – regulation - healthcare*

Abbreviations: *AI - Artificial Intelligence; GenAI - Generative Artificial Intelligence; Art – Article; FLOP - floating-po*

Gilbert A. et al. (2024). Artificial Intelligence in Healthcare and regulation challenges: a mini guide for (mental) health professionals. Psychiatria Danubina 36 (Suppl. 2), 348-353

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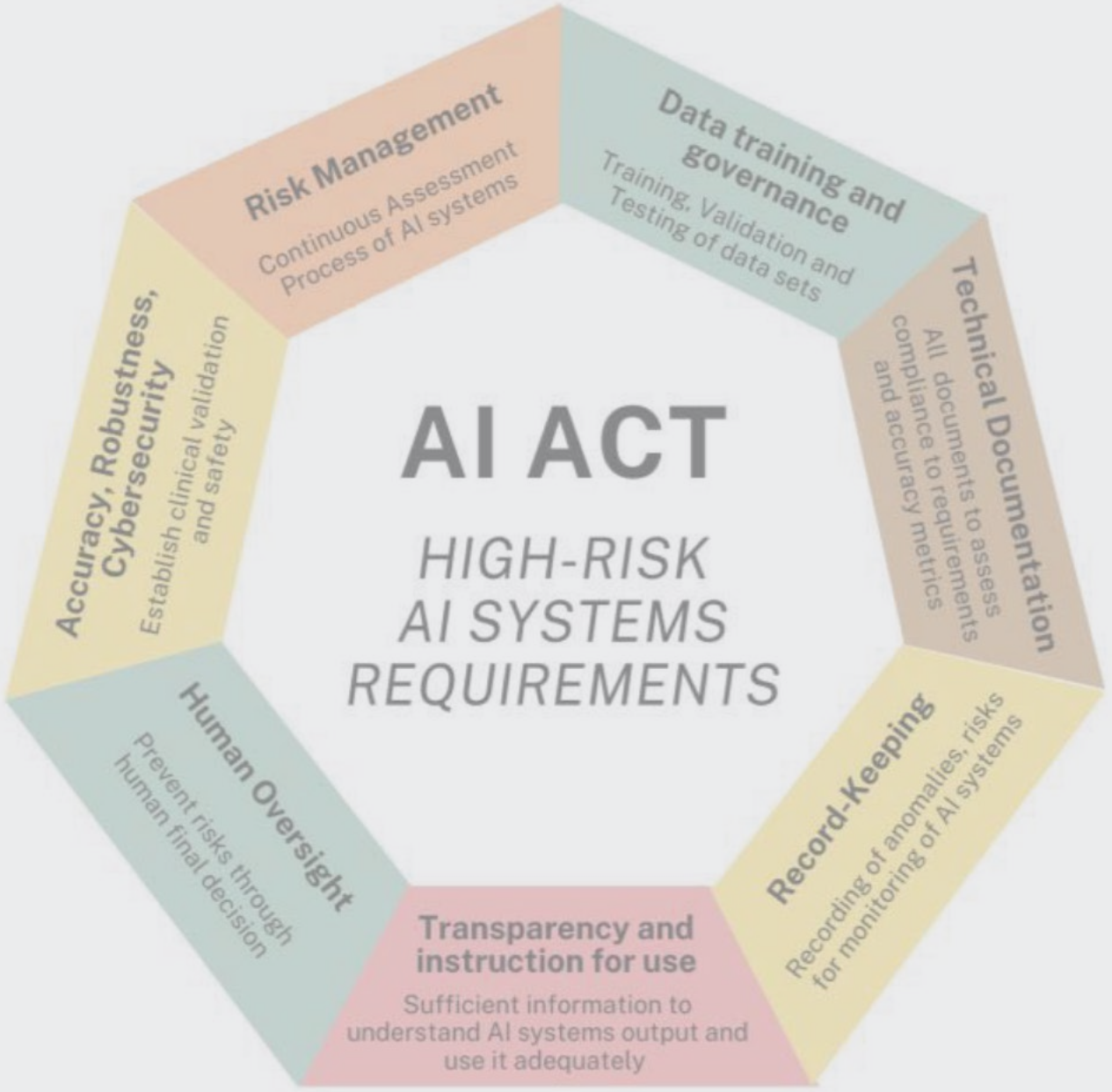

Figure 1. Requirements and their description for high-risk AI systems, based on the AI Act

patient safety. The evaluation of patient safety risks is a crucial step for ensuring appropriate quality of care following AI implementation (Ratwani et al. 2024). The first three questions of this mini guide address patient safety concepts, risk identification and clinical validation.

Question 1: *"How are AI systems classified in the AI Act?"*

Before fully responding to this question, it is important to understand how the AI Act defines an "AI system". In Title I, Article (Art.) 3 of the AI Act, an "AI system" is defined as *"a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments"* (European Parliament 2024b). If AI systems could thus influence the patient environment, this definition – when reflecting on AI in healthcare - must be read in conjunction with Hippocrates' principle of *"First, do no harm"*. The classification of AI systems by the AI Act relies on risk identification to assess potential harm based on the probability of occurrence and the severity of the adverse event (European Parliament 2024a). Different risk categories are identified, ranging from minimal or no risk, limited risk to high risk and unacceptable risk.

Title II, Art. 5 of the AI Act provides criteria for an AI system to be categorized as unacceptable. For example, manipulative AI applications or systems that exploit patient vulnerabilities will fall into this category.

Annex III of the AI Act offers a list of high-risk AI system criteria, including, for example, remote biometric identification systems or, in the healthcare sector, applications to triage emergency situations (European Parliament 2024a). Besides the implicit references made in Annex III to the healthcare sector, the classification of AI used in healthcare as high-risk is primarily due to the AI Act referencing the Medical Device Regulation to define the boundaries for this risk category (Palmieri 2023). Consequently, these systems are subject to rigorous scrutiny, including transparency, accountability, and human oversight requirements. This proactive stance highlights the importance of balancing AI's immense potential in healthcare with the imperative to mitigate associated risks.

Question 2: *"What are the requirements for an AI model to be approved for healthcare applications?"*

AI systems for healthcare applications are mainly considered high-risk and have a set of compliance requirements identified in Chapter 2 of Title III, which must be fulfilled before being put into service or entering the EU market (Figure 1). The requirements tackle risk management (Art. 9), data training and data governance (Art. 10), technical documentation (Art. 11), record-keeping of (adverse) events (Art. 12), transparency and instructions for use (Art. 13), human oversight (Art. 14), accuracy, robustness and cybersecurity (Art. 15) (European Parliament 2024b).

Figure 1. Requirements and their description for high-risk AI systems, based on the AI Act

Moreover, specific needs exist for regulation as certain AI models are dynamic (such as GenAI), possessing the capability to *"adapt and make decisions based on their experience and interactions within the system"* (Templin et al. 2024). Consequently, monitoring practices must also be dynamic to align with the evolving nature of the GenAI system. To ensure the safety and reliability of AI systems throughout their entire life cycle, the AI Act provides a post-market monitoring system to identify and mitigate foreseeable problems encountered during use (European Parliament 2024a).

It is important to note that if an AI system used in medicine also qualifies as a medical device under the Medical Device Regulation, it must adhere to the requirements set forth by the Medical Device Regulation.

Question 3: *"How do we, as healthcare professionals, consider AI systems as validated for use in clinical practice, and how is the validation process performed?"*

For high-risk models, regarding Title III, Art. 11 and 13, AI models must be put into service with sufficient information to users and transparency regarding their technical characteristics. Annex IV of the AI Act contains a list of what users must be aware of when they are confronted with the AI model. Other authors have previously claimed the importance of using a minimum

Part 2. AI in medical education

Snapshot of literature available on implications of Artificial Intelligence (AI) in the domain of (postgraduate) medical education

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VLERICK BUSINESS SCHOOL

BETEKENT AI HET EINDE VAN DE RADIOLOOG?

Belgian governmental decision to decrease training possibilities based on … *"AI can replace MD"*

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Door Walter Van Dyck
Professor of Innovation Management

26 november 2019

Artificiële intelligentie (AI) is een hot topic, ook in de gezondheidszorg. Hoe kan AI nu de kwaliteit en efficiency van de zorgverstrekking verbeteren? Tijdens een webinar georganiseerd door het Vlerick Healthcare Management Centre liet dokter Erik R. Ranschaert, AI-expert en radioloog verbonden aan het Nederlands Kankerinstituut (NKI) in Amsterdam, zijn licht schijnen over de mogelijkheden en uitdagingen van AI in de radiologie. Voor wie het webinar

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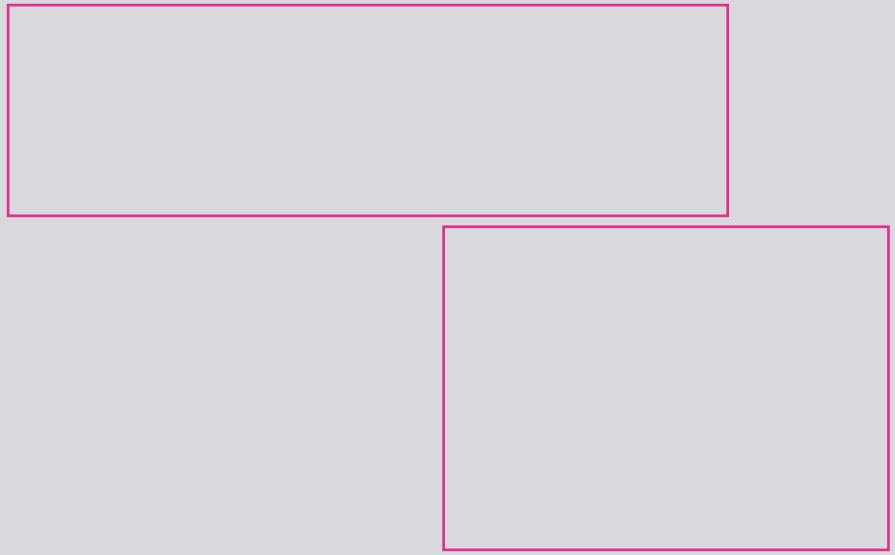

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Main ethics topics of concern on use of AI in Health Professions Education

Guarding against excessive data collection

Protecting anonimity and privacy

Ensuring full consent

Protecting student data ownership

Applying stricter security policies

Guarding against data (student as data) and algorithm bias

Ensuring algorithm transparency

Clearly demarcating responsibility, accountability, blame and credit

Supporting autonomy

Ensuring appropriate beneficence

Preparing for AI to change our views of ethics

Preparing for AI as a person, with rights

Adjust institutions for the use of AI in Health Professions Education

Step 1: Education ethics committee

Step 2: Educate research ethics committee about AI

Step 3: Chief AI ethics officer

Open for discussion ...

- AI is the best to happen in medicine
- AI is the worst in medicine

Moderators: Chris Plummer & Danny Mathysen

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