



HealthTalk
AI BASED CLINICAL REPORTING

**The legal consequences of
using AI in healthcare**

The group of certified companies



veilig online uitwisselen
van gezondheidsgegevens



eHealth Platform as a Service

Certified eHealth platform that serves as a boiler plate for other spin-off companies. We have a team of 20 developers.

www.medrecord.io



Data Ownership

One of the 9 Dutch PGO's that is used to collect your medical data from healthcare institutions.

www.medsafe.io



P2P diabetes platform

Lifestyle intervention for Diabetes type II management.

www.clubdiabetes.nl



AI speech-to-text

AI-based speech-to-text into clinical reporting.

www.healthtalk.ai



What is the AI Act..

The main idea of the AI Act is to regulate AI based on its capacity to cause harm to society.

“High risk; High penalty”

- Systems considered "high-risk", such as those used in critical infrastructure, education, **healthcare**, law enforcement, border management or elections, will have to comply with **strict requirements**.
- Creates provisions to tackle risks posed by the systems underpinning generative **AI tools and chatbots** such as OpenAI's ChatGPT.

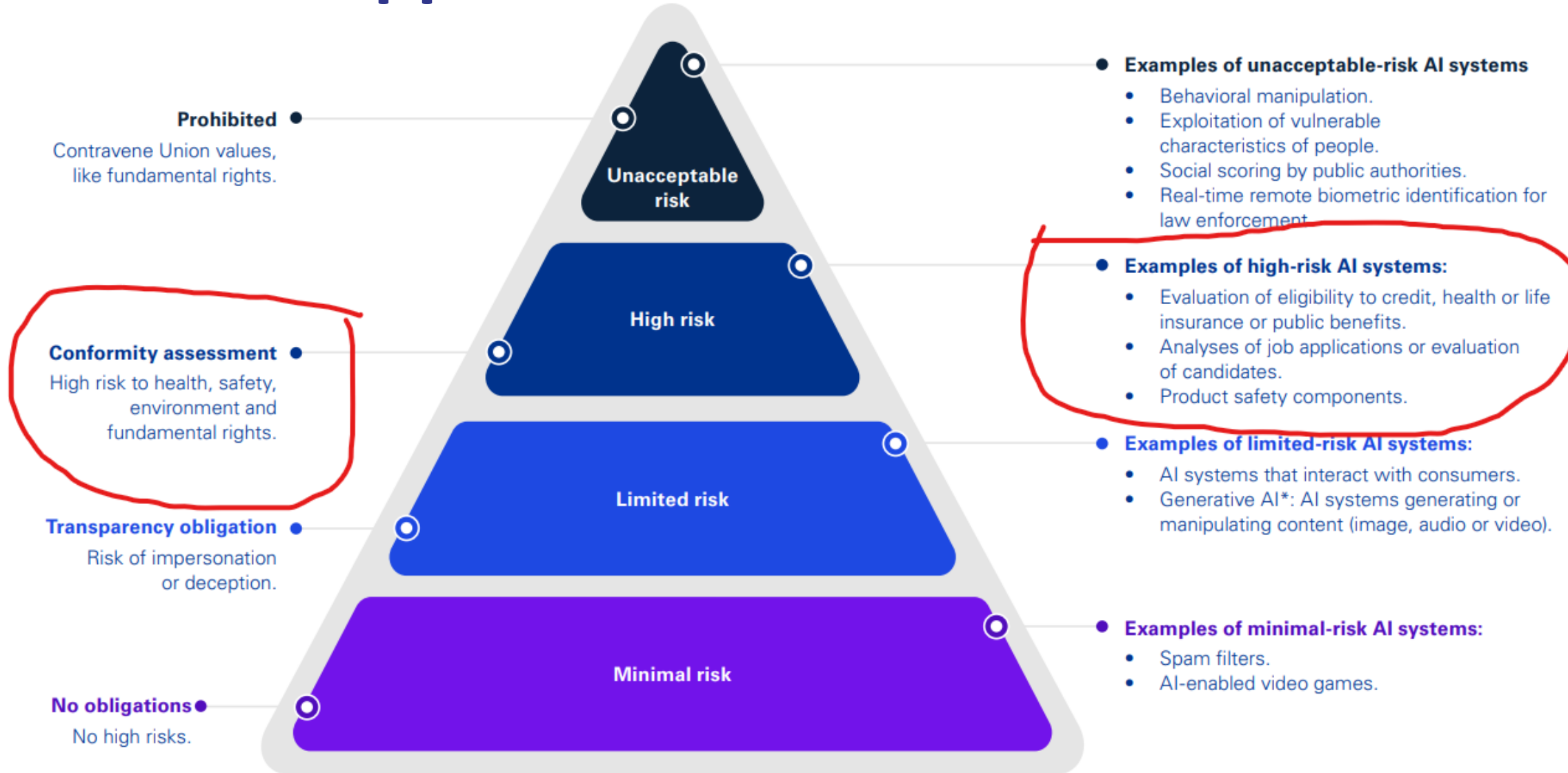


Stricter regulations

AI-powered medical devices, diagnostic tools, and patient management systems will **–likely–** be classified as "high-risk" and subject to stringent scrutiny for transparency, explainability, and data governance.



Risk based approach



High risk includes critical infra;

- Educational and vocational training, for example, automated scoring of — or exclusion from -exams.
- Employment, workers management and access to self-employment, for example, automated recruitment and application triage.
- Access to essential private and public services and benefits (e.g. healthcare), creditworthiness evaluation of natural persons, and risk assessment and pricing in relation to life and health insurance.
- Law-enforcement systems that may interfere with fundamental rights, such as automated risk scoring regarding potential offenders, deepfake detection software and evidence reliability scoring.
- Migration, asylum and border control management, for example, verification of authenticity of travel documents and visa and asylum application examinations.
- Administration of justice and democratic processes, for example, legal interpretation tools to assist judicial authorities



High-Risk AI in Healthcare

- **Impact on Development:** Developers must ensure compliance with these regulations, which may affect development timelines and increase costs.
- **Increased Accountability:** Robust algorithms and auditability will be essential to provide clear explanations for AI-driven decisions.
- **Enhanced Data Protection:** Stricter requirements for data security and minimization will be enforced, impacting data collection practices and storage methods.
- **De-identification and Anonymization:** Techniques to protect patient privacy while enabling AI development will become increasingly important.



High-Risk AI in Healthcare

- **Transparency in Data Use:** Patients will have enhanced rights regarding their data used in AI systems, necessitating clear communication and consent mechanisms.
- **Algorithmic Fairness and Bias:** AI algorithms in healthcare must be demonstrably fair and unbiased, mitigating risks of discrimination based on race, gender, or socioeconomic status.
- **Regular Bias Testing and Mitigation:** Developers must implement robust testing and mitigation strategies to address potential biases in their algorithms.
- **Human Oversight and Explainability:** Human oversight is crucial to ensure responsible decision-making and address potential biases in AI outputs.



What are the obligations of the deployers?

Deployers of high-risk AI systems, including public bodies and private entities providing essential services, such as banks, insurers, hospitals, and schools, bear specific obligations to ensure responsible use. These obligations include:

- Completing a fundamental rights impact assessment (FRIA) before deploying the AI system.
- Implementing of **human oversight** by trained individuals.
- Ensuring that input data is pertinent to the system's intended use.
- Reporting serious incidents to the AI system provider.
- Retaining automatically generated **system logs**.
- **Adhering to GDPR** obligations for data protection impact assessments.
- Verifying **compliance** with the AI Act and ensuring all relevant documentation is available
- **Informing** individuals about the potential use of high-risk AI.



Limited-risk AI systems

Some AI systems intended to interact with natural persons or generate content would not necessarily qualify as high-risk AI systems but may entail risks of impersonation or deception. This includes the outputs of most generative AI systems. In practice, the following AI systems are to be identified as Low risk:

- Chatbots, such as ChatGPT-based systems.
- Emotion-recognition systems.
- Biometric-categorization systems.
- Systems generating 'deepfake' content.



Let's have some examples

- These are examples we are working on ourselves
- We are already ISO27001 and NEN7510 certified
- Our aim is to be ISO13485 certified next year

Would like to have a really open discussion, so please raise your hand in order to speak. We will limit time per topic for 3 minutes.



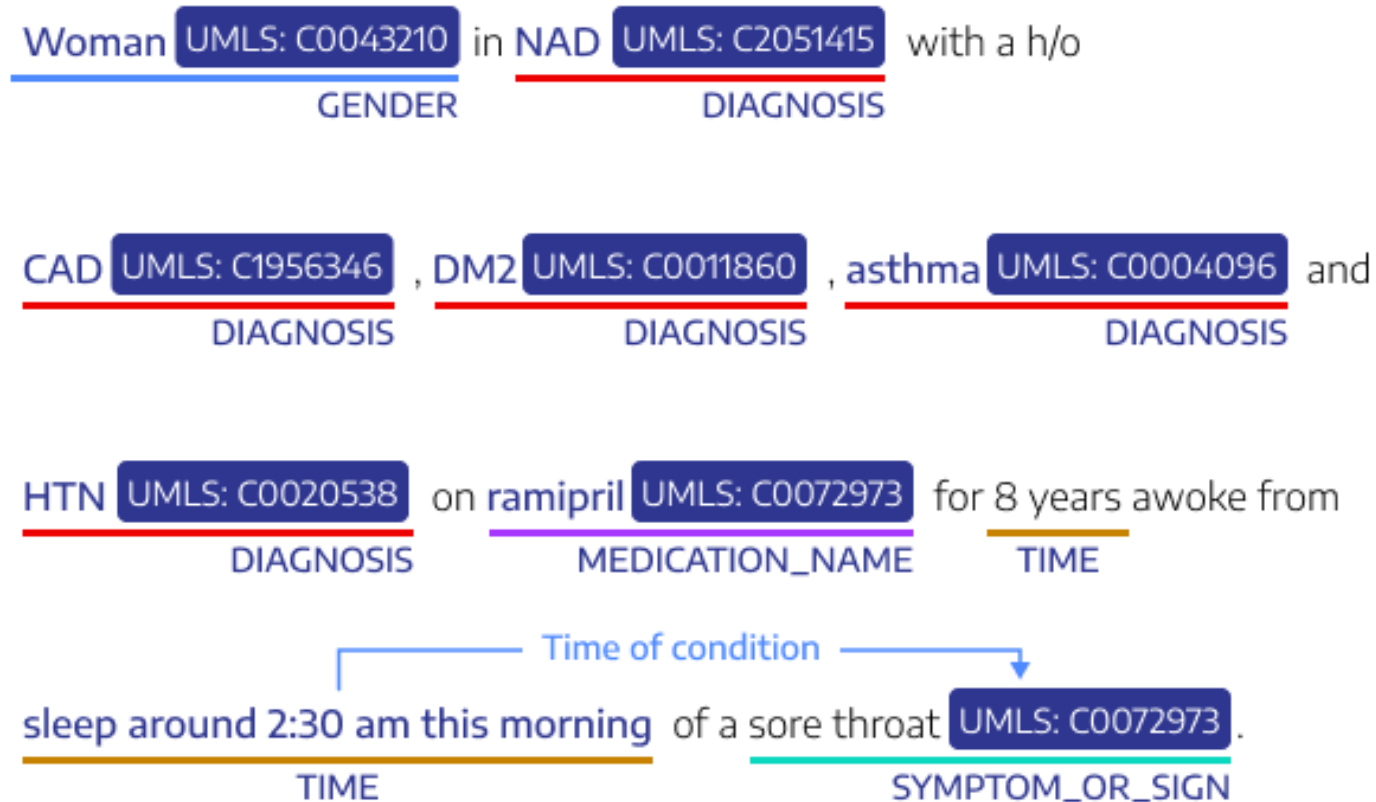
Example 1; using not certified services

What happens if a healthcare provider or -institute buys or uses a services that is not, or not correct certified?



Example 2a; speech to text to reporting

Extracting clinical vocabularies from (spoken) text



Example 2b; speech to text to reporting

Findings; getting out a diagnosis

Ribavirin **UMLS: C0035525** was also evaluated against SARS-CoV-2 infection,
MEDICATION_NAME DIAGNOSIS

but the antiviral **UMLS: C0003451** property of drugs **UMLS: C0013227** is still
MEDICATION_CLASS TREATMENT_NAME

not well established against the SARS-CoV-2 **UMLS: C5203670** **negation** .
DIAGNOSIS



Example 3; doing a calculation

Inside a talk length and weight was stated; BMI with risk score

The screenshot displays a clinical interface with a checklist on the left and a patient interaction on the right.

Checklist (Left):

- Mental Status Exam
- Reason for referral
- Informed consent...
- Patient's request for help (intake phase)
- He/she would like...
- Asked to client/e /part...
- Complaints anamnesis
- Major complaints?
- Depression
 - Have you been feeling ...
 - If so: Has this ever tak...
 - If so: Have these perio...
- Manie
- Are there periods that ...

Patient Interaction (Right):

AI Assistant: Patient missed one question, ask now to finish questionnaire.

Ask patient :
Are there periods that last at least a few days when you feel the opposite of depressed, when you're cheerful or happy and you have a lot more energy than usual?

Response: Patient doesn't know

AI Assistant: Great, here is the result of the PHQ-9 questionnaire.

Perceived Stress Scale
The Perceived Stress Scale (PSS) is a classic stress assessment instrument

Score: 110/78

Scale: Never, Almost never, Sometimes, Fairly often, Very often

Input: Ask anything

Buttons: Dictate



Example 4; sending patient name

Normally we separate patient details from talk, but what if..

The screenshot displays the HealthTalk AI-based clinical reporting interface. At the top, the patient's name "Pieter Lastname" is highlighted with a red circle. Below the name, patient details are listed: Age (36 years old), Gender (Male), Email (pieter_l@email.com), and Allergies. A "Go to patient record" button is visible. The main section is titled "Face to face consult" and shows a "USG + Consultation" session on "27 Tuesday" at "9:30" for "€ 80". A "Rejoin Call" button is present. The consultation transcript shows a message from the doctor: "Yes please. Do you want to know that now from 10? 38 45 3 0 0? OK all right, well, then I've got Pieter in front of me. Ja klopt. Is that right? OK, all right, I've read the referral and of course the They are going to ask some more questions and look at Ja. So if you're okay with it then yes, then I want to start Unless you have any questions or something? No, I thought it was nice to be able to get started a bit of a karify. But Okay, that's right. Well, I saw that. Je especially." The name "Pieter" in the transcript is also highlighted with a red circle. On the right, a "Social context" summary is provided, including marital status, family situation, and relationship problems. A "Relationship problems" section mentions a "history of drug abuse" with a UMLS ID (C0086132).

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Home Settings Admin Profile

Expand chat

Pieter Lastname

Age 36 years old (4 Jul 1988)
Gender Male

Email pieter_l@email.com
Phone -

Allergies Koemelk donec a dui et / dui fringilla fenoxymethyl / dui fringilla fenoxymethyl
At vero eos et accusamus / et justo odio dignissimos / et justo odio dignissimos

Go to patient record

Show full intake info

← Back

Face to face consult

USG + Consultation

Rejoin Call

27 Tuesday 9:30 € 80

Consultation ended at 13:58:08

Send letter

Yes please. Do you want to know that now from 10? 38 45 3 0 0? OK all right, well, then I've got Pieter in front of me. Ja klopt. Is that right? OK, all right, I've read the referral and of course the They are going to ask some more questions and look at Ja. So if you're okay with it then yes, then I want to start Unless you have any questions or something? No, I thought it was nice to be able to get started a bit of a karify. But Okay, that's right. Well, I saw that. Je especially.

Mental Status Exam

- Reason for referral
- Informed consent...
- Patient's request for help (intake phase)
- He/she would like...
- Asked to client/e /part...
- Complaints anamnesis
- Major complaints?

Social context

Marital/Relationship Status: The patient has been married for 18 years, with a history of both positive and negative dynamics in the relationship.

Family and living situation: Patient lives with husband and two children.

Important relationships and social support: Patient has a supportive brother and childhood friend who are aware of the situation.

Relationship problems

The patient experiences significant relationship problems with his spouse. The problems stem from the husband's **history of drug abuse** UMLS: C0086132 and infidelity, leading to a breakdown in trust and communication.

The patient experiences significant relationship problems with his spouse. The problems stem from the husband's history of drug abuse and infidelity, leading to a breakdown in trust and communication.



Example 5; chatbot advice

The chatbot is reading medical files and gives advice based on that.

“Take your medication”

The screenshot shows a patient health dashboard with a navigation bar at the top containing 'Overview', 'Basic Medical Data', 'Measurements', 'Goals', 'Questionnaire', 'Knowledge', and 'Calendar'. Below the navigation bar are two tabs: 'Health Score' (selected) and 'Laboratory values'. The main content area features a circular radar chart with six metrics: Participate (65), Daily functioning (72), Mental well-being (50), Meaning (90), Body function (90), and Quality of life (78). A central tooltip for 'Blood Pressure' shows a value of 110/78. To the right, a 'Health score' section for March 2024 includes a message: 'Your health plan and health graph are commendable it's crucial to prioritize regular exercise and maintain...' and a question: 'Would you like me to create goals with tasks targeting...'. Below this are 'Yes' and 'Not today' buttons. At the bottom, there are sections for 'Blood Pressure' and 'Body Temperature', each with an explanation and 'Add new'/'See all' buttons. A line graph on the right shows data points for 110/78, 110/84, 110/84, and 110/84. A chatbot window titled 'Chatbot assistance' is overlaid on the right side, containing a warning message, a greeting 'Hi there', a message about the health score, and a question about creating goals. A 'Write a message' input field and a microphone icon are at the bottom of the chatbot window. A circular chatbot icon is also visible in the bottom right corner of the dashboard.





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Questions?

Jan-Marc Verlinden

Chief Futurist

jan-marc@healthtalk.ai