



EU Values and Ethical Principles for AI and Robotics Medicine

‘XV Encuentro Interautonómico sobre Protección Jurídica del Paciente. De la innovación en salud a la salud de la innovación’ | Universidad Internacional Menéndez Pelayo (Santander) | 30 June 2022



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N.B. Please note that whenever appropriate, screenshots are linked to the relevant website.

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**Previous Chair:
EU & Ethics.**

2016 to 2019



**New Chair:
EU Values.**

2019 to 2022



With the support of the
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Cf. Frischhut, M. (2019). *The Ethical Spirit of EU Law*. Cham: [Springer International Publishing](https://www.springer.com).

Agenda

**Introductory
remarks (point
of departure)**

**Broader
perspective**

**EU Secondary
law, etc.**

**Concluding
remarks**

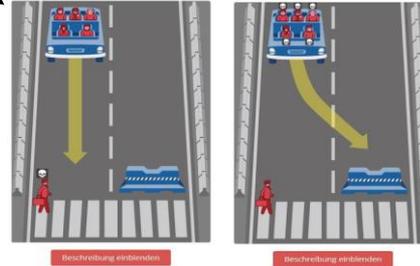
Law and new technologies

Drones
(‘Remotely
Piloted Aircraft
Systems’, RPAS)



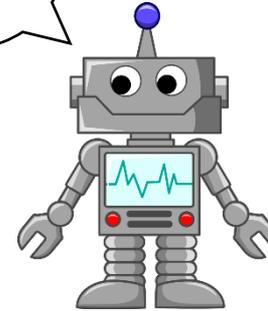
Source: [Link](#)

Self-driving cars
(‘autonomous
vehicles’)



Source: <http://moralmachine.mit.edu/>

(Humanoid)
Robots



Source: [Link](#)

Artificial
intelligence (AI)



Source: [Link](#)

Law

Science



AI, health & robotics

- **Possible fields of application** (on health see also pts. 70-83); cf. also AI Reg prop [*see below*], recital 3
 - “whereas, in industry and services associated with high technology, AI is key to turning Europe into a ‘start-up continent’ by exploiting the latest technologies to generate growth in Europe, in particular **in the areas of health technology, healthcare services and programmes, drug discovery, robotic and robot-assisted surgery, treatment of chronic diseases, and medical imaging and records**, as well as securing a sustainable environment and safe food production; whereas Europe is currently lagging behind North America and Asia in terms of research and patents in the field of artificial intelligence” (recital AF)
 - “whereas there is a **broad catalogue of possible applications** of AI and robotics **in medical care**, such as managing medical **records and data**, performing **repetitive jobs** (analysing tests, X-rays, CT scans, data entry), **treatment design, digital consultation** (such as medical consultation based on personal medical history and common medical knowledge), **virtual nurses, medication management, drug creation, precision medicine** (as genetics and genomics look for mutations and links to disease from the information in DNA), **health monitoring** and healthcare system **analysis**, among other applications” (recital AH)

Robotic medicine | broad understanding

“**Robotics for Medicine and Healthcare** is considered the domain of systems able to perform coordinated mechatronic actions (force or movement exertions) on the basis of processing of information acquired through sensor technology, with the **aim to support** the functioning of **impaired individuals, medical interventions, care and rehabilitation** of patients and also to support individuals in **prevention programmes**” (p. 4)

Butter, M., Rensma, A., van Boxsel, J., Kalisingh, S., Schoone, M., Leis, M., . . . Korhonen, I. (2008). Robotics for Healthcare: Final Report.

“At the most basic level, ‘**healthcare robotics**’ (**medical robotics**) is simply the application of robotics technology to healthcare to **diagnose** and **treat** disease, or to **correct, restore** or **modify** a body function or a body part.”

Robotics Business Review (2009, April 13). Healthcare Robotics: Current Market Trends and Future Opportunities. Retrieved from <https://www.roboticsbusinessreview.com/health-medical/healthcare-robotics-current-market-trends-and-future-opportunities/>.

“**Robo-ethics** is of course not an ethics developed for robots, as in Asimov’s famous principles”, it is “rather an ethics designed **for humans to interact** with robots.” (pp. 26-27)

Hilgendorf, E. (2017). Modern technology and legal compliance. In E. Hilgendorf & M. Kaiafa-Gbandi (Eds.), *Compliance measures: and their role in German and Greek law* (21-35). Athēna: P.N. Sakkulas.

Possible applications (partly overlapping)

- **Medical diagnosis** (Dolic et al., 2019, pp. 7, 15 [Chatila]; see also: Tasioulas, 2019, p. 50)
- **Prevention & treatment of diseases** (Dolic et al., 2019, pp. 7, 15 [Chatila])
- **Robotic surgery:** more accurate, less invasive and remote interventions (based on availability and assessment of vast amounts of data (Dolic et al., 2019, pp. 7, 15 [Chatila]; see also: Tasioulas, 2019, p. 50; COMEST, 2017 pp. 5, 30)
- **Care and socially assistive robots:** ageing population (COMEST, 2017 pp. 5, 31) affected by multi-morbidities (Dolic et al., 2019, p. 7; see also COMEST, 2017 p. 5); **exoskeletons, as well as companion robots** (COMEST, 2017 pp. 5, 31; see also Dolic et al., 2019, p. 15 [Chatila])
- **Therapy** (COMEST, 2017 p. 5) **for children with autism** (Tasioulas, 2019, p. 50; see also COMEST, 2017 pp. 5, 30)
- **Rehabilitation systems:** support for recovery of patients and long-term treatment at home, instead of a healthcare facility (Dolic et al., 2019, p. 7; see also COMEST, 2017 p. 5)
- **Training for health and care workers:** support for continuous training and life-long learning initiatives (Dolic et al., 2019, p. 7)

Sources:

- Dolic, Zrinjka, Castro, R., & Moarcas, A. (April 2019). Robots in healthcare: A solution or a problem? In-depth analysis requested by the ENVI committee.
- World Commission on the Ethics of Scientific Knowledge and Technology (2017, September 14). Report of COMEST on robotics ethics: SHS/YES/COMEST-10/17/2 REV.
- Tasioulas, J. (2019). First Steps Towards an Ethics of Robots and Artificial Intelligence. *Journal of Practical Ethics*, 7(1), 49–83 (50).

See also: European Parliament resolution of 12 February 2019 on 'A comprehensive European industrial policy on artificial intelligence and robotics' | ([2018/2088\(INI\)](#)), recitals AF and AH.

Normative approaches | overview

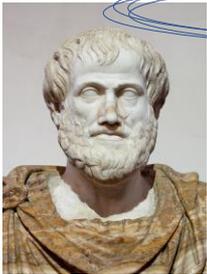
The question “what is the right thing to do?” can possibly be answered from various perspectives



Source: [Link](#)

- **Legal** field
 - **Hard-law**: legally binding; can be enforced
 - **Soft-law**: not legally binding; cannot be enforced.
However, should not be under-estimated, as it can be of relevance in an indirect way (e.g., Blue Guide 2022, [OJ 2022 C 247/1](#))

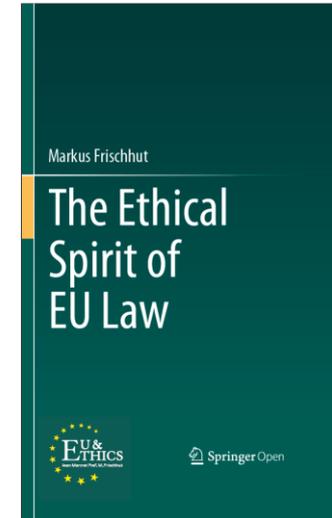
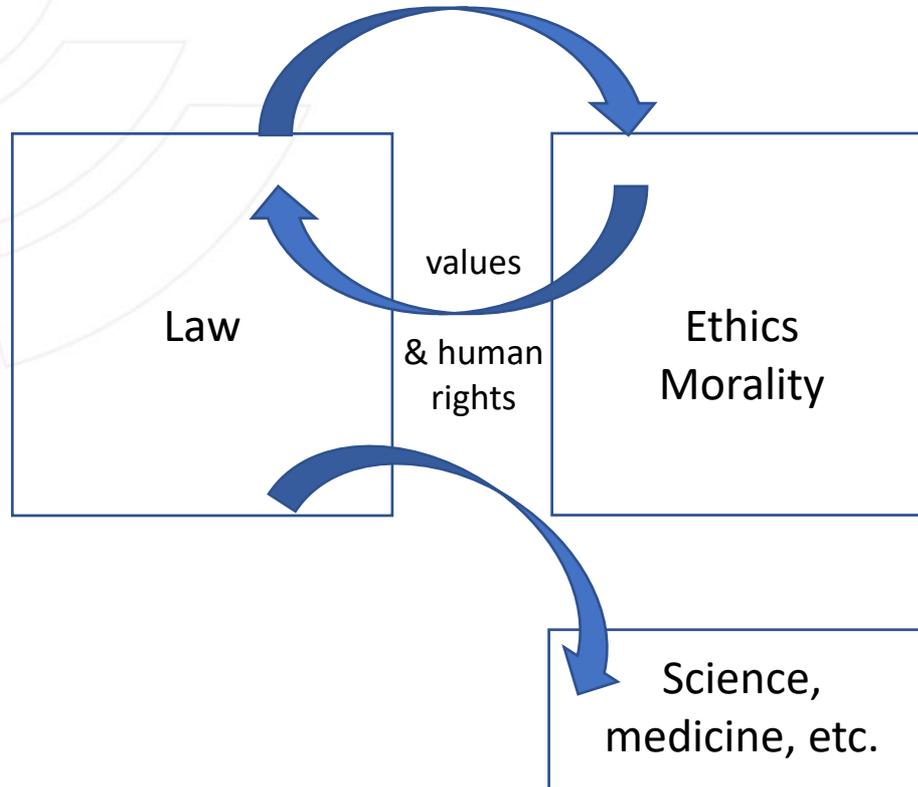
Values: can be seen as a bridge between law and philosophy



Source: [Link](#)

- From the **non-legal** field
 - **Ethics**: philosophy
 - **Morality**: attitudes at a certain time, at a certain place
Likewise, can be a legal concept, as in case of ‘public morality’;
cf. Art 36 TFEU.

Legal and non-legal sphere

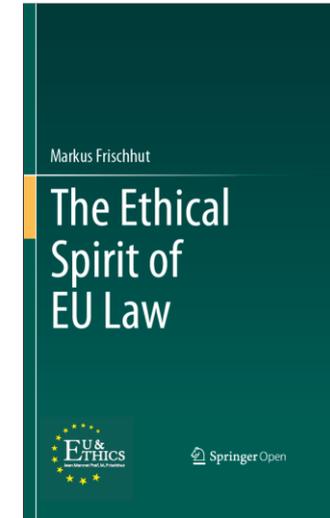
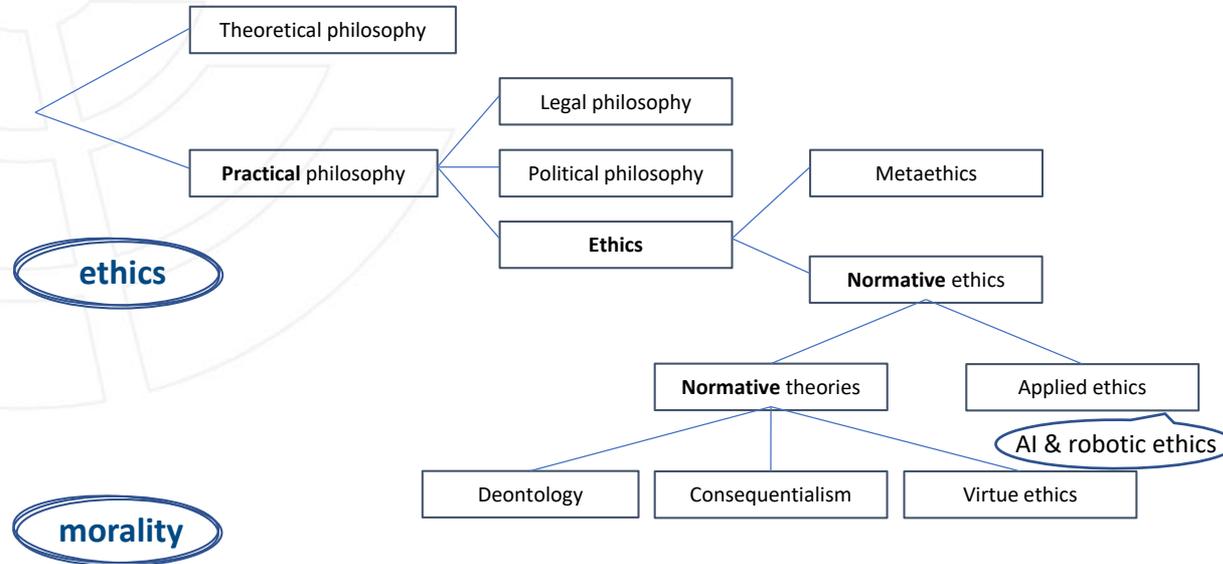


Source: Frischhut, 2019, p. 3
(modified)

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Ethics and morality | terminology



Source: Frischhut, 2019, p. 9

With the support of the
Erasmus+ Programme
of the European Union



“In its most familiar sense, the word *morality* [...] refers to norms about **right and wrong** human conduct that are **widely shared** and form a stable **societal compact**. As a social institution, morality encompasses many standards of conduct, including moral principles, rules, ideals, rights, and virtues. **We learn** about morality **as we grow up** [...]”

Source: Beauchamp & Childress, 2019, p. 3.

EU Law | ‘high level’ of health

High level of health protection

- “high level of **human health**” (Art 9 TFEU; Art 114 para 3 TFEU; Art 168 para 1 TFEU; Dec No 32; Art 35 CFR)
- “high level of protection, taking account in particular of any **new development based on scientific facts**” (Art 114 para 3 TFEU), since Amsterdam Treaty (Frischhut, 2017, 70)
- High, although **not highest level** (Frischhut, 2017, 66-66); Secondary law to be interpreted in this light (Frischhut, 2017, 64)

High level of health and precedence over economic considerations

- “In accordance with settled case-law, the objective of the protection of **health takes precedence over economic considerations**, the importance of that objective being such as to **justify even substantial negative economic consequences [...]**” (ECJ, C-452/20, para 50)

High level approach elsewhere

- Harmonisation of national law | environment | employment | education and training | Area of Freedom Security and Justice | consumer protection | services of general interest

Sources:

- Frischhut, M. (2017). Standards on quality and safety in cross-border healthcare. In A. d. Exter (Ed.), *Cross-border health care and European Union law* (pp. 59-86). Erasmus University Press.
- ECJ judgment of 24 February 2022, *Agenzia delle dogane e dei monopoli und Ministero dell'Economia e delle Finanze*, C-452/20, EU:C:2022:111

Health values and principles

22.6.2006

EN

Official Journal of the European Union

C 146/1

I

(Information)

COUNCIL

“2006 Council Conclusions may help shape the interpretation of fundamental rights in the context of EU health law” (Ruijter, 2017, p. 486; cf. also 2019, p. 188)

Council Conclusions on Common values and principles in European Union Health Systems

(2006/C 146/01)

- **Overreaching values:**
 universality, access to good quality care, equity, and solidarity

specific
general
- **Operating principles:**
 quality, safety, care that is based on evidence and **ethics**, patient involvement, redress, privacy and confidentiality

Cf. Ruijter, A. de. (2017). The impediment of health laws' values in the constitutional setting of the EU. In T. K. Hervey, C. Young, & L. E. Bishop (Eds.), *Research Handbook on EU Health Law and Policy* (pp. 479-495). Edward Elgar Publishing. | Ruijter, A. de. (2019). *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care*. OUP.

Source: Council Conclusions on Common values and principles in European Union Health Systems, [OJ 2006 C 146/1](#).



EU law, values & ethics

Trust (as an overarching goal)

General field

Health field (additionally)

more abstract

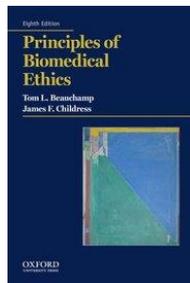
Common values (Art 2 TEU):

- human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including minority rights
- pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men

Health values (2006):

universality, access to good quality care, equity, and solidarity

more concrete



principles of biomedical ethics':

- respect for autonomy
- nonmaleficence
- beneficence
- justice

legal principles:

- non-discrimination
- privacy
- traceability
- transparency
- responsibility
- proportionality & balance
- precaution
- solidarity

Operating principles (2006):

quality, safety, care that is based on evidence and ethics, patient involvement, redress, privacy and confidentiality

Beauchamp, T. L., & Childress, J. F. (2019). *Principles of biomedical ethics* (Eighth edition). Oxford University Press.

(other) law as minimum standard (e.g. above-mentioned EU Secondary Law)

Cf. Frischhut, M. (2020). EU Values and Ethical Principles for AI and Robotics with Special Consideration of the Health Sector. In M. Hengstschläger & Austrian Council for Research and Technology Development (Eds.), *Digital Transformation and Ethics* (pp. 244-274). Ecowin. | Frischhut, M. (2019). *The Ethical Spirit of EU Law*. Cham: [Springer International Publishing](https://www.springer.com). On principles and fast-paced technological change, see also Sethi, N. (2021). Rules, Principles and the Added Value of Best Practice in Health Research Regulation. In G. Laurie, E. Dove, A. Ganguli-Mitra, C. McMillan, E. Postan, N. Sethi, & A. Sorbie (Eds.), *The Cambridge Handbook of Health Research Regulation* (pp. 167-176). Cambridge University Press. <https://doi.org/10.1017/9781108620024.021>

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law, etc.

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remarks

Values emphasised by various documents

> 16 February 2017 | European Parliament resolution on Civil Law Rules on Robotics | ([2015/2103\(INL\)](#)) | pt. 13

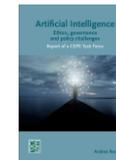
> World Commission on the Ethics of Scientific Knowledge and Technology (2017, September 14). Report of COMEST [UNESCO] on robotics ethics: SHS/YES/COMEST-10/17/2 REV. | pp. 8, 48-55, et passim



> 9 March 2018 | European Group on Ethics in Science and New Technologies (EGE) “Statement on Artificial Intelligence, Robotics and ‘Autonomous’ Systems” ([Link](#)) | (a) **Human dignity**: “inherent human state of being worthy of respect”; (b) **Autonomy**: “refers to the capacity of human persons to legislate for themselves, to formulate, think and choose norms, rules and laws for themselves to follow”; (c) **Responsibility**: “serve the global social and environmental good”; “risk awareness and a precautionary approach are crucial” (pp. 16-17); (d) **Justice, equity, and solidarity**: “Discriminatory biases in data sets used to train and run AI systems should be prevented or detected, reported and neutralised at the earliest stage possible” (p. 17); (e) **Democracy**; (f) **Rule of law and accountability**: “fair and clear allocation of responsibilities” (p. 18); (g) **Security, safety, bodily and mental integrity**; (h) **Data protection and privacy**; (i) **Sustainability**

> 12 February 2019 | European Parliament resolution ‘A comprehensive European industrial policy on artificial intelligence and robotics’ | ([2018/2088\(INI\)](#)) | pt. 147

> Renda, A. (2019). *Artificial Intelligence: Ethics, governance and policy challenges*. Report of a CEPS Task Force. Brussels | pp. 114, 116



> Dolic, Zrinjka, Castro, R., & Moarcas, A. (April 2019). *Robots in healthcare: A solution or a problem? In-depth analysis requested by the ENVI committee*. | “These values include transparency, accountability, explicability, auditability and traceability, and neutrality or fairness” (Dolic et al., 2019, p. 16 [Chatila])



> 25 May 2019 | OECD Principles on Artificial Intelligence | [Link](#) (N.B. similar approach as in EU, i.e. values, human rights / human-centric, transparency, trust)

Ethical principles

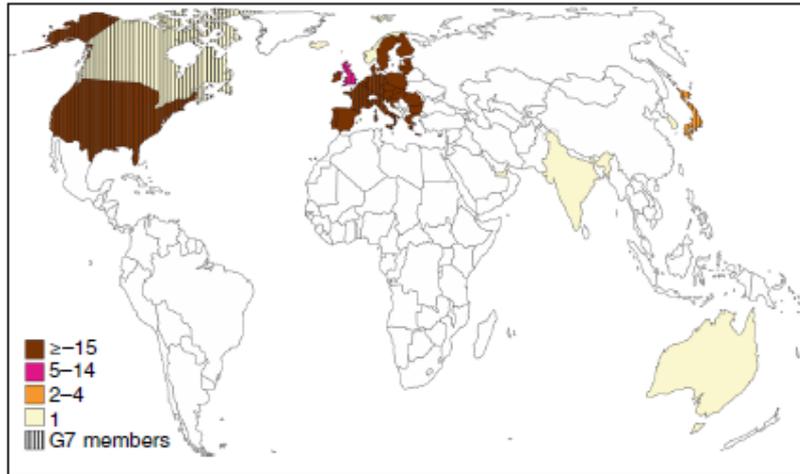


Fig. 2 | Geographic distribution of issuers of ethical AI guidelines by number of documents released. Most ethics guidelines are released in the United States ($n = 21$) and within the European Union (19), followed by the United Kingdom (13) and Japan (4). Canada, Iceland, Norway, the United Arab Emirates, India, Singapore, South Korea and Australia are represented with 1 document each. Having endorsed a distinct G7 statement, member states of the G7 countries are highlighted separately. Map created using https://d-maps.com/carte.php?num_car=13181.

Source: Jobin, A., Ienca, M., & Vayena, E. (2019). The global landscape of AI ethics guidelines. *Nature Machine Intelligence*, 1(9), 389–399.

Table 3 | Ethical principles identified in existing AI guidelines

Ethical principle	Number of documents	Included codes
Transparency	73/84	Transparency, explainability, explicability, understandability, interpretability, communication, disclosure, showing
Justice and fairness	68/84	Justice, fairness, consistency, inclusion, equality, equity, (non-) bias, (non-)discrimination, diversity, plurality, accessibility, reversibility, remedy, redress, challenge, access and distribution
Non-maleficence	60/84	Non-maleficence, security, safety, harm, protection, precaution, prevention, integrity (bodily or mental), non-subversion
Responsibility	60/84	Responsibility, accountability, liability, acting with integrity
Privacy	47/84	Privacy, personal or private information
Beneficence	41/84	Benefits, beneficence, well-being, peace, social good, common good
Freedom and autonomy	34/84	Freedom, autonomy, consent, choice, self-determination, liberty, empowerment
Trust	28/84	Trust
Sustainability	14/84	Sustainability, environment (nature), energy, resources (energy)
Dignity	13/84	Dignity
Solidarity	6/84	Solidarity, social security, cohesion

Ethical principles I

- > **European Economic and Social Committee, Opinion on ‘Artificial intelligence — The consequences of artificial intelligence on the (digital) single market, production, consumption, employment and society’, OJ 2017 C 288/1.**

Asking for a “code of ethics for the development, application and use of AI so that throughout their entire operational process AI systems remain compatible with the **principles of human dignity, integrity, freedom, privacy and cultural and gender diversity, as well as with fundamental human rights**” (pt. 1.7)

- > **World Commission on the Ethics of Scientific Knowledge and Technology (2017, September 14). Report of COMEST on robotics ethics: SHS/YES/COMEST-10/17/2 REV.**

Asking for framework of ethical values and principles, **sometimes with confusing terminology**; (i) human dignity; (ii) value of autonomy; (iii) value of privacy; (iv) ‘do not harm’ principle; (v) principle of responsibility; (vi) value of beneficence; and (v) value of justice. (p. 8; pp. 48-55)



- > **Renda, A. (2019). Artificial Intelligence: Ethics, governance and policy challenges. Report of a CEPS Task Force. Brussels** | pro **hierarchy** of principles (p. 116, pt. 12); some principles need to be **further clarified**; such as “non-maleficence” (p. 116, pt. 12), fairness (p. 116, pt. 13), acceptable discrimination (p. 117, pt. 16); **enhanced requirements in sensitive fields, such as healthcare** (p. 118, pt. 20; see also p. 119. pt. 23)



- > **Dolic, Zrinjka, Castro, R., & Moarcas, A. (April 2019). Robots in healthcare: A solution or a problem? In-depth requested by the ENVI committee.** | “specific principles needed for guiding the use of AI and robotised systems” (Dolic et al., 2019, p. 16 [Chatila])



Ethical principles II

- > **16 February 2017 | European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics [\(2015/2103\(INL\)\)](#)** | “human safety, health and security; freedom, privacy, **integrity and dignity; self-determination and non-discrimination**, and personal data protection” (pt. 10); **transparency** (pt. 12)
- > **8 April 2019 | AI HLEG publishes “Ethics guidelines for trustworthy AI”, including “Trustworthy AI Assessment List”** (pp. 26-31) | [Link](#)
| (i) Respect for human autonomy (p. 12); (ii) prevention of harm (p. 12); (iii) fairness (p. 13); (iv) explicability (p. 13)
- > **8 April 2019 | EC communication ‘Building Trust in Human-Centric Artificial Intelligence’ [COM\(2019\) 168 final](#)** | **Seven key requirements** for trustworthy AI applications: human agency and oversight; technical robustness and safety; privacy and data governance; transparency; diversity, non-discrimination and fairness; societal and environmental well-being; accountability (p. 4)

Principlism 4+1 | Floridi et al. 2018

- **Beneficence** (pt. 4.1): equivalent terms are ‘well-being’, ‘common good’, ‘humanity’, ‘human dignity’
- **Non-maleficence**: (pt. 4.2): privacy, security and ‘capability caution’ | prevent intended and unintended harm
- **Autonomy**: (pt. 4.3): “humans should always retain the power to *decide which decisions to take*”
- **Justice**: (pt. 4.4): distributive justice; risk of bias in datasets
- **Explicability**: (pt. 4.5): equivalent terms are ‘transparency’, ‘accountability’, etc.

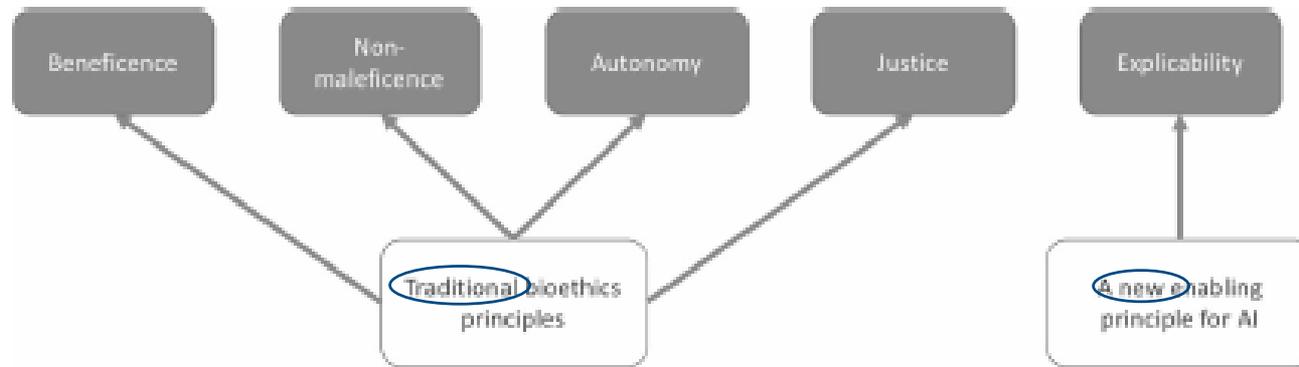
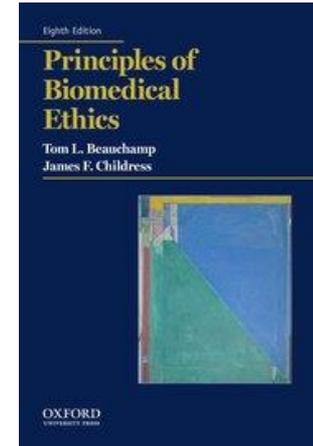


Fig. 2 An ethical framework for AI, formed of four traditional principles and a new one



Beauchamp, T. L., & Childress, J. F. (2019). *Principles of biomedical ethics* (Eighth edition). Oxford University Press.

Source: Floridi, L., Cowsls, J., Beltrametti, M., Chatila, R., Chazerand, P., Dignum, V., . . . Vayena, E. (2018). AI4People—An Ethical Framework for a Good AI Society: Opportunities, Risks, Principles, and Recommendations. *Minds and Machines*, 31(1), 1.

Principlism

> **16 February 2017 | European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics ([2015/2103\(INL\)](#))** | pt. 13, Annex: code of ethical conduct for robotics engineers

- **“Beneficence** – robots should act in the best interests of humans;
- **Non-maleficence** – the doctrine of ‘first, do no harm’, whereby robots should not harm a human;
- **Autonomy** – the capacity to make an informed, un-coerced decision about the terms of interaction with robots;
- **Justice** – fair distribution of the benefits associated with robotics and affordability of homecare and healthcare robots in particular.”
(Annex: code of ethical conduct for robotics engineers)

> **12 February 2019 | European Parliament resolution ‘A comprehensive European industrial policy on artificial intelligence and robotics’** | ([2018/2088\(INI\)](#)) | pt. 147

> **Dolic, Zrinjka, Castro, R., & Moarcas, A. (April 2019). Robots in healthcare: A solution or a problem? In-depth analysis requested by the ENVI committee.** | Principlism as good starting point against background of importance of ethics and values, but insufficient (Dolic et al., 2019, p. 15 [Chatila])

> **Critical: Mittelstadt, B. (2019). AI Ethics – Too Principled to Fail?** Retrieved from

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3391293 | Key arguments: no equivalent fiduciary relationship for AI; lack of professional history and well-defined norms of ‘good’ behaviour; no empirically proven methods to translate principles into practice; lack of legal and professional accountability mechanisms.



Specific requirements | human centric | I

Humans first

- **Human centric:** respect for human **autonomy** -> “human-centric design principles and leave meaningful opportunity for human choice” (AI-HLEG, 2019, p. 12)
- **Support, not replace:** “Because of the reservations about AI, there is broad agreement among physicians and medical ethicists that algorithms should **support**, but **not replace**, the physician.” (Katzenmeier, 2019, p. 269; translation)
- **Added value:** “AI should relieve the physician of routine work and help him with the initial assessment. Ideally, the physician would **expand his knowledge** from the analogue world to the digital world and thus make a **better diagnosis**.” (Katzenmeier, 2019, p. 269; translation)
- **Humans in command**
 - “the principle of the **supervised autonomy of robots**, whereby the initial planning of treatment and the final decision regarding its execution will always remain with a human surgeon” (EP, 16.2.2017, pt. 33)
 - In favour of a “**human-in-command** approach to AI” (EESC on AI, 2017, pt. 1.6)
 - “**Only humans** make the final decision and take **responsibility** for it.” (EESC on digital rev., 2019, pt. 1.2)
 - **Responsibility:** ‘man out of the loop’, e.g. in case of medical diagnoses based on large amount of information; EESC in favour of a “**human-in-command principle**” (EESC on digital rev., 2019, pt. 4.3)
- **Human dignity**
 - **Human dignity:** robotics only “for care tasks requiring no **emotional**, intimate or personal involvement” (EESC on digital rev., 2019, pt. 4.5)
 - “one of the most pressing questions to be addressed is how health and care would be transformed, and whether these technologies could lead to possible **repercussions for human dignity**”; human factor in care (Dolic et al., 2019, p. 7)

Source: European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)).

Source: Dolic, Zrinjka, Castro, R., & Moarcas, A. (April 2019). Robots in healthcare: A solution or a problem? In-depth analysis requested by the ENVI committee.

Source: Opinion of the European Economic and Social Committee on ‘The digital revolution in view of citizens’ needs and rights’, [OJ 2019 C 190/17](#).

Source: Katzenmeier, C. (2019). Big Data, E-Health, M-Health, KI und Robotik in der Medizin. Digitalisierung des Gesundheitswesens. Herausforderung des Rechts. *Medizinrecht (MedR)*, 37(4), 259–271.

Specific requirements | human centric | II

Robots lack empathy etc.

- **No empathy**
 - “Only the physician can include the social, psychological and personal framework conditions in the treatment, only he is capable of **empathy** - so important in dealing with the patient.” (Katzenmeier, 2019, p. 269; translation)
 - “whereas there are strong ethical, psychological and legal concerns about the **autonomy** of robots, their **obvious lack of human empathy** and their impact on the doctor-patient relationship, which have not yet been properly addressed at EU level, in particular as regards the protection of patients’ personal data, liability, and the new economic and employment relationships that will be brought about; whereas ‘autonomy’ as such can only be fully attributed to human beings; whereas there is a need for a **robust legal and ethical framework** for artificial intelligence” (EP, 12.2.2019, recital AJ)
 - “The use of **robotics** in the **healthcare** sector is anticipated. But robots are devices that are **unable to** replicate the **empathic** capacities and reciprocity of human care relationships. If not used under certain framework conditions, robots **can undermine human dignity**. Care robots, therefore, should only be used for care tasks requiring no emotional, intimate or personal involvement.” (EESC on digital rev., 2019, pt. 1.11)
 - “I don’t know that deep learning or robots will ever be capable of reproducing the essence of human-to-human support.” (Topol, 2019, p. 164)
- **Human contact**
 - “Stresses that **human contact** is a crucial aspect of human care” (EP, 12.2.2019, pt. 70)
 - **Care robots**: “human contact is one of the fundamental aspects of human care” (EP, 16.2.2017, pts. 31-32 [32])

Source: European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)).

Source: 12 February 2019 | European Parliament resolution ‘A comprehensive European industrial policy on artificial intelligence and robotics’ | [\(2018/2088\(INI\)\)](#)

Source: Opinion of the European Economic and Social Committee on ‘The digital revolution in view of citizens’ needs and rights’, [OJ 2019 C 190/17](#).

Source: Katzenmeier, C. (2019). Big Data, E-Health, M-Health, KI und Robotik in der Medizin. Digitalisierung des Gesundheitswesens. Herausforderung des Rechts. *Medizinrecht (MedR)*, 37(4), 259–271.

Specific requirements | human centric | III

Also following a 'humans first'-approach

- **8 April 2019** | EC launches **pilot phase**; inviting stakeholders to test the detailed assessment list | [COM\(2019\) 168 final](#) | Human agency and oversight
- **12 February 2019** | European Parliament resolution 'A comprehensive European industrial policy on **artificial intelligence and robotics**' | [\(2018/2088\(INI\)\)](#) | "Stresses that ethical rules must be in place to ensure **human-centric** AI development, the **accountability and transparency** of algorithmic decision-making systems, clear **liability** rules and **fairness**" (pt. 143)

Vulnerable groups

- Special attention to be paid to possible develop. of an **emotional connection** between humans and robots – **particularly in vulnerable groups** (children, the elderly and people with disabilities) (EP, 16.2.2017, pt. 3)
- **Value of autonomy**: individual and different relationships; especially for **vulnerable groups**; environmental impacts (COMEST, 2017, p. 50)
- Special attention to be paid to **vulnerable** persons (AI-HLEG, 2019, pp. 11, 12, 13, 20, et passim)
- Security, safety, bodily and mental integrity: special emphasis on **vulnerable** people (EGE, 2018, p. 19)

Global ethical and value-based benchmark

- **7 December 2018** | EC **coordinated plan** with Member States to foster development & use of AI in Europe | [COM\(2018\) 795 final](#), [IP/18/6689](#): "Europe **can become a global leader** in developing and using AI for good and promoting a **human-centric approach and ethics-by-design** principles." (pt. 2.6)
- **12 February 2019** | European Parliament resolution 'A comprehensive European industrial policy on **artificial intelligence and robotics**' | [\(2018/2088\(INI\)\)](#) | Recommendation "that Europe should **take the lead** on the global stage" (pt. 142)

Specific requirements | trust

Trust

- Importance of enforcement: validation and certification requirements, to foster trust (Dolic et al., 2019, p. 16 [Chatila])
- “**Trust builds on shared assumptions about material and immaterial values**, about what is important and what is expendable. It stems from shared **social practice**, shared habits, ways of life, common norms, convictions and attitudes. Trust is based on **shared experiences**, on a shared past, shared traditions and shared memories.” (EAG, 2018, p. 21)
- Emphasizing necessity to “gain the **trust** and acceptance of patients and healthcare providers” (Dolic et al., 2019, p. 7)
- “human relationships and by extension human–robot relationships need to be based on some level of **trust**” (Lichocki, Kahn, & Billard, 2011, p. 46)
- “But to me, those are the secondary gains of deep medicine [i.e. preventing wasteful use of medical resources]. It’s our chance, perhaps the ultimate one, to bring back real medicine: **Presence. Empathy. Trust. Caring. Being Human.**” (Topol, 2019, p. 309)

Also emphasizing trustworthy AI

- **7 December 2018** | EC **coordinated plan** with Member States to foster development & use of AI in Europe | [COM\(2018\) 795 final](#), [IP/18/6689](#)
- **12 February 2019** | European Parliament resolution ‘A comprehensive European industrial policy on **artificial intelligence and robotics**’ | ([2018/2088\(INI\)](#)) | “trust” occurs 17 times
- **8 April 2019** | **AI HLEG** publishes “**Ethics guidelines for trustworthy AI**”, including “Trustworthy AI Assessment **List**” (pp. 26-31) | [Link](#)
- **8 April 2019** | EC communication ‘Building **Trust** in **Human-Centric** Artificial Intelligence’ COM(2019) 168 final

Source: Ethics Advisory Group. (2018). Towards a digital ethics: Report by the Ethics Advisory Group established by the European Data Protection Supervisor, the EU’s independent data protection authority. Retrieved from https://edps.europa.eu/sites/edp/files/publication/18-01-25_eag_report_en.pdf

Source: Dolic, Zrinjka, Castro, R., & Moarcas, A. (April 2019). Robots in healthcare: A solution or a problem? In-depth analysis requested by the ENVI committee.

Specific requirements | traceability etc.

Reversibility

- “Devices should be **removable** without causing lasting harm or the loss of initial functions of the human body.” (Grinbaum et al., 2017, p. 7)

Traceability

- “**possibility to track** the causes of all past actions (and omissions) of a robot” (COMEST, 2017, p. 6; see also p. 36)
- **8 April 2019** | EC launches **pilot phase**; inviting stakeholders to test the detailed assessment list | [COM\(2019\) 168 final](#) | transparency: traceability of AI systems should be ensured



Other specific recommendations

- Further development of codes of ethics, in a **multidisciplinary** way; also to be implemented in education (COMEST, 2017, p. 8)
- Ethics to be integrated in **design process of robotic technologies** (COMEST, 2017, p. 8)
- “new robotic technologies be introduced **carefully and transparently** in small-scale, well-monitored settings, and the implications of these technologies on human practices, experiences, interpretational frameworks, and values be studied openly” (COMEST, 2017, p. 8)
- Necessity of **public discussions** (COMEST, 2017, pp. 8-9)
- “when AI is being used in implanted medical devices, the bearer should have the **right to inspect and modify** the source code used in the device” (EP, 12.2.2019, pt. 75)
- “regulatory practices should establish procedures that **limit** the **use of machine learning systems to specific tasks** for which their accuracy and reliability have been **empirically validated**.” (London, 2019, 20)
- Necessity to **avoid** the ‘**rubbish in, rubbish out**’ phenomenon, especially in the health sector, in order to avoid discrimination based on gender, ethnic background, income, etc. (see also Nordling, 2019, S104)

Source: European Parliament resolution of 12 February 2019 on ‘A comprehensive European industrial policy on artificial intelligence and robotics’ | ([2018/2088\(INI\)](#)).

Source: World Commission on the Ethics of Scientific Knowledge and Technology (2017, September 14). Report of COMEST on robotics ethics: SHS/YES/COMEST-10/17/2 REV.

Agenda

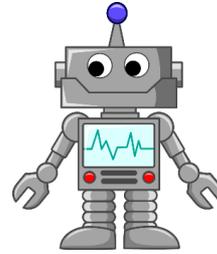
Introductory
remarks (point
of departure)

Broader
perspective

EU Secondary
law, etc.
AIA

Concluding
remarks

Digitalization | excerpt



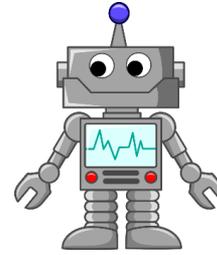
Picture source: [Link](#)



Picture source: [Link](#)

- > **16 February 2017** | European Parliament resolution of 16 February 2017 with recommendations to the Commission on **Civil Law Rules on Robotics** (2015/2103(INL)) | [Link](#)
- > **9 March 2018** | European Group on Ethics in Science and New Technologies (**EGE**) “Statement on Artificial Intelligence, Robotics and ‘Autonomous’ Systems” | [Link](#)
- > **25 April 2018** | European Commission (EC) AI **strategy** | [COM\(2018\) 237 final](#); plus [SWD\(2018\) 137 final](#) on liability
- > **11 February 2019** | Council Conclusions on the **coordinated plan** on artificial intelligence | [Doc. 6177/19](#)
- > **12 February 2019** | EP A comprehensive European industrial policy on **artificial intelligence and robotics** (2018/2088(INI)) | [Link](#)
- > **8 April 2019** | AI HLEG publishes “**Ethics guidelines** for trustworthy AI”, including “Trustworthy AI Assessment **List**” (pp. 26-31), as well as glossary (pp. 36-38) | [Link](#), and definition ([Link](#))
- > **19 February 2020** | EC White paper on [AI](#), [report on safety](#), strategy for [data](#), Europe’s [digital future](#), etc.
- > **15 December 2020** | EC **Proposal** on a Single Market For Digital Services (**Digital Services Act**) and amending Directive 2000/31/EC, COM(2020) 825 final | [Link](#)
- > **21 April 2021** | EC **Proposal** for a **Regulation** on a European approach for **Artificial Intelligence**, COM(2021) 206 final | [Link](#) (see also COM(2021) 205 final, [Link](#))
- > **21 April 2021** | EC **Proposal** for a **Regulation** on **machinery products**, COM(2021) 202 final | [Link](#)
- > **26 January 2022** | EC European **Declaration on Digital Rights** and Principles for the Digital Decade, COM(2022) 27 final ([Link](#)) & COM(2022) 28 final ([Link](#))
- > **2 February 2022** | EC Communication An EU **Strategy on Standardisation**. Setting global standards in support of a resilient, green and digital EU single market, COM(2022) 31 final ([Link](#))

EC proposals | excerpt



Picture source: [Link](#)



Picture source: [Link](#)

- > **25 November 2020** | EC **Proposal** for a **Regulation** on European data governance (**Data Governance Act**), COM(2020) 767 final, [Link](#)
30 May 2022: Signature by the President of the EP and by the President of the Council
- > **15 December 2020** | EC **Proposal** for a **Regulation** of the European Parliament and of the Council on a Single Market For Digital Services (**Digital Services Act**) and amending Directive 2000/31/EC, COM(2020) 825 final, [Link](#)
20 January 2022: First reading EP | 16 June 2022: Internal Market Committee endorses agreement on Digital Services Act ([Link](#))
- > **15 December 2020** | EC Proposal for a regulation on contestable and fair markets in the digital sector (**Digital Markets Act**), COM(2020) 842 final, [Link](#)
15 December 2021: First reading EP
- > **21 April 2021** | EC **Proposal** for a **Regulation** on **machinery products**, COM(2021) 202 final | [Link](#)
24 June 2022: Discussions within the Council or its preparatory bodies
- > **21 April 2021** | EC **Proposal** for a **Regulation** on a European approach for **Artificial Intelligence**, COM(2021) 206 final | [Link](#)
 (see also COM(2021) 205 final, [Link](#)) | see also the following video: <https://youtu.be/X9h8MZluyKg>
22 April 2022: Discussions within the Council or its preparatory bodies
- > **3 May 2022** | EC **Proposal** for a **Regulation** on the European **Health Data Space**, COM(2022) 197 final | [Link](#)
23 June 2022: Discussions within the Council or its preparatory bodies

N.B. Information from EUR-Lex, valid as of Wednesday, 29 June 2022



EUR-Lex
Access to European Union

Digitalization | EP res. civil liability

- **Medical robots**

- **Likewise importance of training, also minimum level approach:**

“Underlines the importance of appropriate **education, training and preparation** for health professionals, such as doctors and care assistants, in order to secure the **highest degree** of professional competence possible, as well as to **safeguard and protect patients' health**; underlines the need to define the minimum professional requirements that a surgeon must meet in order to operate and be allowed to use surgical robots; considers it vital to respect the principle of the supervised autonomy of robots, whereby the initial planning of treatment and the **final decision** regarding its execution will always remain **with a human** surgeon;” (pt. 33)

- **Reference to bioethical principles ('principlism'), values and human rights:**

“the guiding ethical framework should be based on the **principles of beneficence, non-maleficence, autonomy and justice**, on the principles and **values** [cf. Art 2 TEU and CFR], **such as** human dignity, equality, justice and equity, non-discrimination, **informed consent**, private and family life and **data protection**, as well as on other underlying principles and values of the Union law, such as **non-stigmatisation, transparency, autonomy, individual responsibility** and **social responsibility**, and on existing ethical practices and codes” (pt. 13)

> **16 February 2017** | European Parliament resolution of 16 February 2017 with recommendations to the Commission on **Civil Law Rules on Robotics** (2015/2103(INL)) | [Link](#)

EU Secondary law | horiz. & vertical (excerpt)

- Quite some legislation already in place (status quo); however, also necessity of constant re-evaluation
 - Overview: horizontal and sectoral approach
 - Directive 85/374/EEC on **product liability** ([Link](#))
 - Directive 2001/95/EC on **general product safety** ([Link](#))
 - Directive 2006/42/EC on **machinery** [etc.] ([Link](#)) | N.B. To be amended by COM(2021) 202 final 21.4.2021 ([Link](#))
 - Regulation (EC) No 765/2008 on accreditation and **market surveillance** of products ([Link](#)) [CE labelling]; see also: Decision No 768/2008/EC on a **common framework** for the marketing of products ([Link](#)); Regulation (EU) 2019/1020 on market surveillance & **compliance** of products ([Link](#))
 - Directive 2014/32/EU on **measuring instruments** ([Link](#))
 - Directive 2014/53/EU on **radio equipment** ([Link](#))
 - Existing product safety framework is **technology neutral**, hence also applies to products incorporating these technologies; other provisions such as on medical devices have already considered these new issues (p. 4)
 - **Necessity of adaptation of EU legislation**
 - e.g. “to consider requirements for transparency of **algorithms**, as well as for robustness, accountability and when relevant, human oversight and unbiased outcomes, particularly important for the ex-post mechanism of enforcement and to build trust in the use of those technologies“ (p. 9)
 - “While in principle the existing Union and national **liability** laws are able to cope with emerging technologies, the dimension and combined effect of the challenges of AI could make it more difficult to offer victims **compensation** in all cases where this would be justified“ (p. 17)

> 19 February 2020 | EC Report on the **safety and liability** implications of Artificial Intelligence, the Internet of Things and robotics, COM(2020) 64 final ([Link](#))

Risk approach

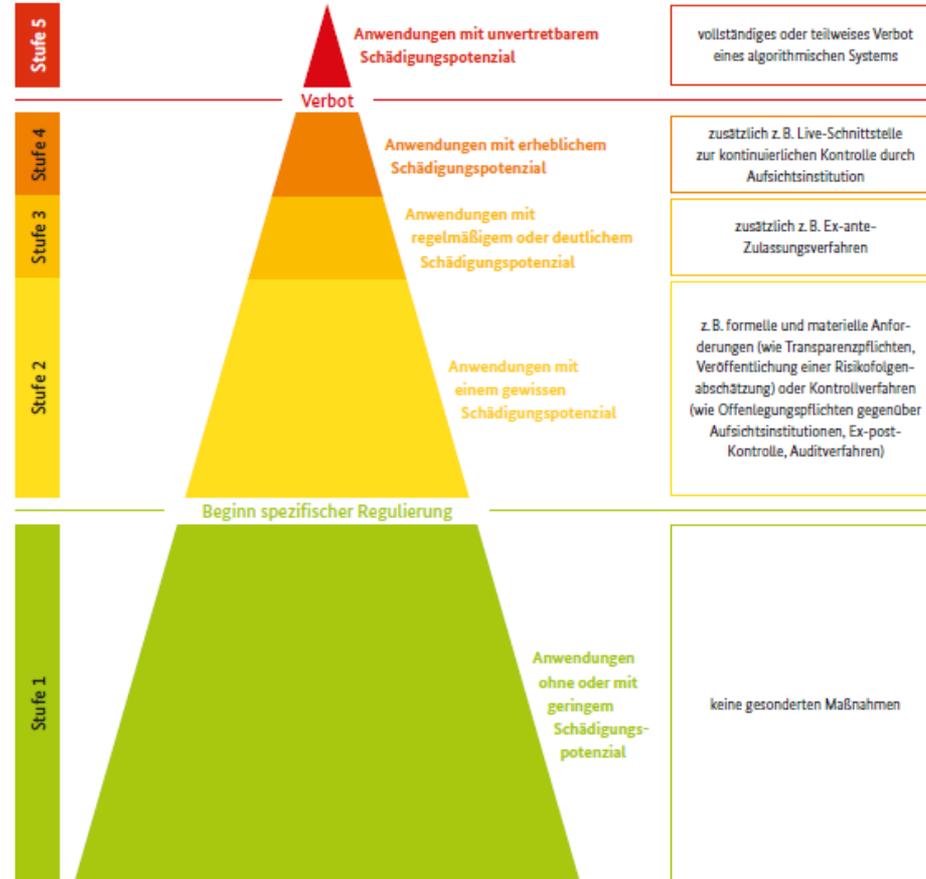


Abbildung 8:
Kritikalitätspyramide und risikoadaptiertes Regulierungssystem für den Einsatz algorithmischer Systeme

Source: Datenethikkommission (Oktober 2019). Gutachten der Datenethikkommission der Bundesregierung ([Link](#)). p.177.

EC proposal AI regulation (AIA) | **overview**

TITLE I GENERAL PROVISIONS

TITLE II PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES

TITLE III HIGH-RISK AI SYSTEMS

- Chapter 1 Classification of AI systems as high-risk
- Chapter 2 Requirements for high-risk AI systems
- Chapter 3 Obligations of providers and users of high-risk AI systems and other parties
- Chapter 4 Notifying authorities and notified bodies
- Chapter 5 Standards, conformity assessment, certificates, registration

TITLE IV TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS [Limited risk]

TITLE V MEASURES IN SUPPORT OF INNOVATION

TITLE VI GOVERNANCE

- Chapter 1 European Artificial Intelligence Board
- Chapter 2 National competent authorities

TITLE VII EU DATABASE FOR STAND-ALONE HIGH-RISK AI SYSTEMS

TITLE VIII POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE

- Chapter 1 Post-market monitoring
- Chapter 2 Sharing of information on incidents and malfunctioning
- Chapter 3 Enforcement

TITLE IX CODES OF CONDUCT [for minimal (or more precisely, “other than high-risk”) risk]

TITLE X CONFIDENTIALITY AND PENALTIES

TITLE XI DELEGATION OF POWER AND COMMITTEE PROCEDURE

TITLE XII FINAL PROVISIONS

AIA | ‘prohibited’ AI

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TITLE IV TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS [Limited risk]

TITLE V MEASURES IN SUPPORT OF INNOVATION

Contradiction with EU values -> ‘prohibited’ AI

- “Such practices [i.e., “manipulative, exploitative and social control practices”] are particularly harmful and should be **prohibited** because they contradict Union **values** of respect for **human dignity, freedom, equality, democracy** and the **rule of law** and Union **fundamental rights**, including the right to **non-discrimination**, data protection and privacy and the rights of the child.” (recital 15; emphases added)
- “AI systems providing **social scoring** of natural persons for general purpose by public authorities or on their behalf may lead to **discriminatory** outcomes and the exclusion of certain groups. They may violate the right to **dignity and non-discrimination and the values of equality and justice**. Such AI systems evaluate or classify the trustworthiness of natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. [...] Such AI systems should be **therefore prohibited**.” (recital 17; emphases added)

AIA | ‘high risk’ AI

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TITLE IV TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS [Limited risk]

TITLE V MEASURES IN SUPPORT OF INNOVATION

Safeguards for ‘high-risk’ AI | health, safety, fund. rights

- “In order to ensure a consistent and **high level of protection of public interests** as regards **health, safety and fundamental rights**, common normative standards for all **high-risk** AI systems should be established. Those standards should be consistent with the **Charter** of fundamental rights of the [EU] and should be **non-discriminatory** [...]” (recital 13)
- “[...] AI systems identified as **high-risk** should be **limited** to those that have a significant harmful **impact on the health, safety and fundamental rights** of persons in the Union and such limitation minimises any potential restriction to international trade, if any.” (recital 27)
- “**Requirements** should apply to high-risk AI systems as regards the **quality** of data sets used, technical **documentation** and record-keeping, **transparency** and the provision of **information** to users, **human oversight**, and **robustness, accuracy and cybersecurity**. Those requirements are **necessary to effectively mitigate the risks for health, safety and fundamental rights** [...]” (recital 43)

> 21 April 2021 | EC **Proposal** for a **Regulation** on a European approach for **Artificial Intelligence**, COM(2021) 206 final | [Link](#) (see also COM(2021) 205 final, [Link](#))

AIA | ‘limited’ risk AI

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TITLE IV TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS [Limited risk]

TITLE V MEASURES IN SUPPORT OF INNOVATION

Transparency oblig. for ‘limited risk’ AI | Question: Deep fakes correctly placed only as ‘limited risk’?

- “Title IV concerns certain AI systems to take account of the specific **risks of manipulation** they pose. **Transparency** obligations will apply for systems that
 - (i) **interact with humans**,
 - (ii) are used to **detect emotions** or determine **association with (social) categories** based on biometric data, or
 - (iii) generate or **manipulate content** (‘**deep fakes**’).
- When persons interact with an AI system or their emotions or characteristics are recognised through automated means, **people must be informed** of that circumstance. If an AI system is used to **generate or manipulate image, audio or video** content that appreciably resembles authentic content, there should be an **obligation to disclose that the content is generated through automated means**, subject to exceptions for legitimate purposes (law enforcement, freedom of expression). This allows persons to make informed choices or step back from a given situation.” (pt. 5.2.4 Explanatory Memorandum)

AIA | 'limited' risk AI

Transparency oblig. for 'limited risk' AI | Question:
Deep fakes correctly placed only as 'limited risk'?

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TITLE IV TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS [Limited risk]

TITLE V MEASURES IN SUPPORT OF INNOVATION



Dokument einer Täuschung: Wiens Bürgermeister Michael Ludwig sprach mit einem falschen Vitali Klitschko.

Foto: Stadt Wien/Twitter

Picture source: Tiroler Tageszeitung vom 28. Juni 2022, Nr 176, Seite 13

“Not only Vienna's SPÖ mayor Michael Ludwig, but also Madrid's city leader José Luis Martínez-Almeida, Berlin's mayor Franziska Giffey and Budapest's incumbent Gergely Karacsony fell for it.” (translation; [source](#))

> 21 April 2021 | EC [Proposal](#) for a [Regulation](#) on a European approach for [Artificial Intelligence](#), COM(2021) 206 final | [Link](#) (see also COM(2021) 205 final, [Link](#))

AIA | ‘minimal’ risk

TITLE VI GOVERNANCE

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TITLE XII FINAL PROVISIONS

Soft-law approach for ‘minimal risk’ AI

- “The **Commission** and the **Member States** shall **encourage and facilitate** the drawing up of **codes of conduct** intended to foster the **voluntary** application to AI systems **other than high-risk AI systems** of the requirements set out in Title III, Chapter 2 on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.
- The **Commission** and the **Board** shall **encourage and facilitate** the drawing up of codes of conduct intended to foster the **voluntary** application to AI systems of requirements **related for example to environmental sustainability**, accessibility for persons with a **disability**, stakeholders participation in the design and development of the AI systems and diversity of development teams [...].” (Art 69, emphases added)

AIA | summary

- **In a nutshell**

- Emphasising **health, safety and fundamental rights** as main objectives; high level of health (recital 1, etc.)
- **Risk** based approach
 - Prohibited: Art 5 (manipulation; vulnerable; rating of humans; biometrical real-time distance tracking)
 - High-risk (Annex III): Art 6 ff (Art 9: risk management system; Art 10: data and data governance; Art 11: technical documentation)
 - **Relation to other EU Secondary law**: classification of high-risk in AI does not necessarily lead to classification as high risk in other fields, such as medical devices and in vitro diagnostic medical devices (recital 31)

- **Quality**

- Mainly refers to ‘high quality **data**’ (recitals 38, 42-45; for more details, see Art 10 ‘Data and data governance’)
- In relation to ‘**intended purpose**’: “Training, validation and testing data sets should be sufficiently relevant, representative and free of errors and complete in view of the **intended purpose** of the system.” (recital 44, etc.)
- **Provider** has to establish “a sound **quality management system**”; plus “required conformity assessment procedure”, relevant documentation and “robust post-market monitoring system” (recital 54; see also Art 16 lit a i.c.w. Art 17 [details] and Annex VI [and conformity assessment procedure])

> 21 April 2021 | EC **Proposal** for a **Regulation** on a European approach for **Artificial Intelligence**, COM(2021) 206 final | [Link](#) (see also COM(2021) 205 final, [Link](#))

AIA | health

- **Health related issues: health of humans and humans first | access to innovation**
 - **Health and safety of persons:** safety in case of products including AI; also with regard to **autonomous robots**, whether in the context of manufacturing or personal assistance and care; “in the **health sector** where the stakes for life and health are particularly high, increasingly sophisticated **diagnostics** systems and systems supporting human decisions should be **reliable and accurate**” (recital 28)
 - **Health as an argument the other way round:** if rapid **availability of innovative technologies** necessary, authorisation of placing on the market **without conformity assessment** can be possible (recital 68; cf. Art 43 and Art 47[1])
 - **Human oversight:** “Human oversight shall aim at **preventing or minimising the risks to health**, safety or fundamental rights that may emerge when a **high-risk AI system** is used in accordance with its **intended purpose** or under conditions of reasonably foreseeable misuse [...]” (Art 14[2])
 - **AI regulatory sandboxes:** “Any significant **risks to health and safety and fundamental rights** identified during the **development and testing** of such systems shall result in **immediate mitigation** and, failing that, in the **suspension** of the development and testing process until such mitigation takes place.” (Art 53[3])

Agenda

Introductory
remarks (point
of departure)

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law, etc.

Concluding
remarks

Recent ECJ clarification

- “As regards the criteria that the PIU may use to that end, it should be noted, first, that according to the very **wording** of Article 6(3)(b) of the PNR Directive those **must be ‘pre-determined’ criteria**. As noted by the Advocate General in point 228 of his Opinion, **that** requirement **precludes the use of artificial intelligence technology in self-learning systems (‘machine learning’)**, capable of modifying without human intervention or review the assessment process and, in particular, the assessment criteria on which the result of the application of that process is based as well as the weighting of those criteria.” (para 194)
- “It is important to **add** [i.e., irrespective of the PNR Directive] that use of such technology would be liable to render redundant the **individual** review of positive matches and monitoring of **lawfulness** required by the provisions of the PNR Directive. As observed, in essence, by the Advocate General in point 228 of his Opinion, given the **opacity** which characterises the way in which **artificial intelligence** technology works, it might be **impossible to understand the reason why a given program arrived at a positive match**. In those circumstances, use of such technology may deprive the data subjects also of their right to an **effective judicial remedy** enshrined in Article 47 of the Charter, for which the PNR Directive, according to recital 28 thereof, seeks to ensure a **high level of protection**, in particular in order to challenge the **non-discriminatory** nature of the results obtained.” (para 195)

Recent Advocate General (AG) clarification

- “En tercer lugar, tanto del tenor del artículo 6, apartado 3, letra b), de la Directiva PNR como del sistema de garantías que acompaña al tratamiento automatizado de los datos PNR establecido por la Directiva PNR se desprende que el funcionamiento de los algoritmos utilizados para realizar el análisis al que se refiere esta disposición **debe ser transparente y permitir la trazabilidad del resultado de su aplicación**. Evidentemente, este requisito de transparencia no implica que deban hacerse públicos los «perfiles» utilizados. En cambio, **requiere que se garantice que pueda identificarse la toma de decisión algorítmica**. En efecto, por una parte, el requisito de que los criterios con arreglo a los cuales debe realizarse este análisis sean «predeterminados» **excluye la posibilidad de que puedan modificarse sin intervención humana** y se opone, en consecuencia, a la utilización de las tecnologías de inteligencia artificial llamadas «machine learning», (225) las cuales, al mismo tiempo que pueden presentar un grado más elevado de precisión, son difíciles de interpretar, incluso por parte de los operadores que han efectuado el tratamiento automatizado. (226) **De otra parte**, para que sea efectiva la garantía prevista en el artículo 6, apartados 5 y 6, de la Directiva PNR, conforme a la cual se revisará individualmente, por medios no automatizado, todo resultado positivo que arroje el tratamiento automatizado de los datos PNR efectuado con arreglo al artículo 2, letra a), se requiere –por lo que respecta al análisis a que se refiere el artículo 6, apartado 3, letra b), de la Directiva PNR– **que sea posible comprender la razón por la cual el programa ha alcanzado esa concordancia**, lo cual no puede garantizarse, en particular, cuando se utilizan sistemas de autoaprendizaje. Lo mismo ocurre con el **control de la licitud** de dicho análisis, **incluida** la cuestión referida al **carácter no discriminatorio** de los resultados obtenidos, que incumbe al responsable de la protección de datos y a la autoridad nacional de control, en virtud del artículo 6, apartado 7, de la Directiva PNR, y del artículo 15, apartado 3, letra b), de dicha Directiva, respectivamente. La **transparencia del funcionamiento de los algoritmos** utilizados constituye **también un requisito necesario** para que los interesados puedan ejercer sus derechos de reclamación y su **derecho a un recurso jurisdiccional efectivo.**” (para 228)

Opinion of AG Giovanni Pitruzzella of 27 January 2022, *Ligue des droits humains*, C-817/19, EU:C:2022:65 ([Link](#))

Summary

- **Law** often **lags behind** new technologies, that is why besides the law also **values** (bridge between law and philosophy) and **ethics** (normative theories or principlism) should be taken into account, in order to enhance trust.
- In EU health law, we have seen the example of a combination of **more abstract values and more concrete principles**. Unlike abstract values, legal principles can be enforced.
- The well-established four bioethical principles (**'principlism'**) have been transferred to our field of digitalization (4+1).
- In EU law, a **'high level'** of health, consumer (etc.) **protection** has to be aimed at.
- Also outside the EU debate, we can identify similar tendencies of referring to values and ethics in the field of AI & robotics.
- Various EU legislation is on its way, amongst others also the Commission's proposal for an **AI Act**.
- The latter takes a **risk based approach**, where **values** lead to the **prohibition** of various forms of AI, the triple concept of **'health, safety and fundamental rights'** shapes the approach towards **'high-risk'** AI.
- AI and machine learning have recently (21.6.2022) also been covered in ECJ **case-law**, emphasising the **'high level of protection'** and non-discrimination.

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https://www.instagram.com/markus_frischhut



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<https://jeanmonnet.mci.edu>

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Dr. Markus Frischhut, LL.M.

Jean Monnet Chair “EU Values & DIGitalization for our CommuNITY (DIGNITY)”
Professor & Study Coordinator European Union Law

Universitaetsstrasse 15, 6020 Innsbruck, Austria

Phone: +43 512 2070 -3632, Fax: -3699

<mailto:markus.frischhut@mci.edu>, www.mci.edu

