Medical ethical principles against the background of 'European values'

Markus Frischhut
Gabriele Werner-Felmayer

Abstract

Medical ethics is a field of expertise that has developed alongside increasingly powerful technologies that have changed medical practice significantly over the past decades. From artificial ventilation and the possibility of resuscitation after cardiac arrest in the 1960s to the big-data-driven medicine of today, increasingly supported by artificial intelligence (AI), modern medicine is loaded with ethical dilemmas and complex decisions. Four principles, namely respect for autonomy, non-maleficence, beneficence and justice, were identified in the 1970s as guiding concepts of an ethics of biomedicine, the then emerging clinical practice that is informed by biological and physiological evidence from basic research. However, as the cultural and historical context affects the understanding of these principles, their implementation in clinical practice and healthcare is not trivial. Here, we highlight additional principles and values that back up these four core principles in the European context, particularly solidarity, human dignity, pluralism, tolerance, non-discrimination and gender equality. We further summarize how European Union law reflects such principles and values, and refer to existing instruments to support their implementation. Focusing on solidarity, we highlight its understanding in the European context and some challenges for its realization, particularly in the context of using AI in medicine and healthcare.

Keywords Digitalization; European values; healthcare; human rights; medical ethics; principles; solidarity

Key points

- Medical ethics supports considerate deliberation in the complex sphere of medical care and research, challenged by rapid technological advances, growing healthcare costs and inequalities in an increasingly market-oriented healthcare sector
- To establish good medical and scientific practice, guiding ethics concepts are required for justified decision-making
- 'Principlism', as developed by Beauchamp and Childress, is the most influential ethical concept in developed countries, grounded in common morality based on human rights
- In the European context, and as reflected by European Union law, additional principles based on European common values such as solidarity aim to guide the implementation of the four key principles — respect for autonomy, non-maleficence, beneficence and justice — in medical practice and healthcare

The role of medical ethics

Medical ethics, a branch of practical ethics, aims to support fair and well-reasoned decisions in the tension-filled areas between technical possibilities, data-based statistical evidence, economic factors and various dimensions of health and disease. Considering the imponderabilia of human existence as well as pluralistic moral norms typical of modern democratic societies, establishing medical ethics theory is a challenge. Without exaggerating, the most influential conceptual work on medical ethics has been and still is the 'principlism' approach developed by Tom Beauchamp and James Childress in their book *Principles of Biomedical Ethics*, first published in 1979.

Beauchamp and Childress defined four key principles of medical ethics: respect for autonomy, non-maleficence, beneficence and justice. These four principles are of equal importance and coherent with common morality as well as professional medical norms and traditions. They impose prima facie (i.e. relative) moral obligations, which means that they are somewhat flexible towards pluralistic views on particular cases and therefore relatively robust in real-life scenarios.

Although developed in the USA, principlism can also be related to European values and human rights.[1] These four principles form the currently leading framework for ethical decision making in medicine and healthcare. Inspired by human rights, as proclaimed by the United Nations' Declaration of Human Rights in 1948, these principles and their understandings also reflect socio-political developments in developed countries and the change from a paternalistic to a more inclusive and caring medical culture since the 1970s.

In this context, the United Nations Educational, Scientific and Cultural Organization (UNESCO) Declaration as well as the Declaration of Helsinki of the World Medical Association have also had a decisive impact, particularly on bioethics and medical research (Table 1). However, increasing healthcare costs and the growing economization of medicine challenge the achievements made so far.

A European perspective and its frameworks

In the 46 countries (since the exclusion of Russia in March 2022) constituting the Council of Europe, the European Convention of Human Rights (ECHR) and the Oviedo Convention (Table 1) have shaped the understanding of human rights in general, and with regard to medicine in particular. Both documents are legally

Markus Frischhut *Dr iur LLM is Jean Monnet Professor and Study Coordinator of European Union Law, Management Center Innsbruck, The Entrepreneurial School, Innsbruck, Austria. He currently coordinates the interdisciplinary Bioethics Network 'ethucation', which is the Austrian unit of the International Chair in Bioethics Network. Competing interests: none declared.*

Gabriele Werner-Felmayer *PhD is a former Professor at the Institute of Biological Chemistry, Medical University Innsbruck, Austria (retired October 2023), and a researcher and educator in biomedical ethics. She is founding member of the Bioethics Network 'ethucation' and a member of Austria's Bioethics Commission. Competing interests: none declared.*

A selection of relevant documents

Short title	Organization	Full title	Further Information (source, ratification, etc.)
UNESCO Declaration	UNESCO	Universal Declaration on Bioethics and Human Rights	http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html
Declaration of Helsinki	WMA	WMA Declaration of Helsinki — Ethical Principles for Medical Research Involving Human Subjects	https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
European Convention on Human Rights (ECHR)	CoE	Convention for the Protection of Human Rights and Fundamental Freedoms	46 Contracting Parties (without Russia) European Treaty Series (ETS) No.005, 46 ratifications, https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/005
Oviedo Convention	CoE	Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine	European Treaty Series (ETS) No.164, 30 ratifications https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164
EU Charter	EU	Charter of Fundamental Rights of the European Union	27 Member States Consolidated version: OJ 2016 C 202/389, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12016P/TXT Explanations to the EU Charter: OJ 2007 C 303/17, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32007X1214(01)

All links were accessed on 29 November 2023.
CoE, Council of Europe; EU, European Union; WMA, World Medical Association.

Table 1

binding (i.e. hard law). It is worth emphasizing, as mentioned in its summary, that the Oviedo Convention is:

> The first legally-binding international text designed to preserve human dignity, rights and freedoms, through a series of principles and prohibitions against the misuse of biological and medical advances. The Convention's starting point is that the interests of human beings must come before the interests of science or society. It lays down a series of principles and prohibitions concerning bioethics, medical research, consent, rights to private life and information, organ transplantation, public debate etc.

Of note, however, there is considerable variation in positions across Europe towards such sensitive issues as, for example, using human embryos for research. Some governments have therefore not signed/ratified the Oviedo Convention. Reasons for this are that the Convention is perceived as being either too restrictive (e.g. UK, Belgium) or too liberal (e.g. Austria, Germany). This illustrates the complexity of defining ethical frameworks and putting them into practice.

For the current 27 Member States of the European Union (EU), the EU Charter, mainly corresponding to the ECHR (Table 1), is the key human rights document. Its first article refers to human dignity, based on the Kantian view that humans shall be treated as subjects and not as objects. This is relevant for the general debate on commodification of the human body in biomedicine, for example in the context of surrogacy or human embryo research.

Numerous documents (such as declarations) are not legally binding (i.e. are soft law) but, despite their lack of legally binding effect, have impact. For example, the not legally binding Declaration of Helsinki became legally binding via EU documents referring to it. EU Regulation (536/2014), for instance, states that it is 'in line with the major international guidance documents on clinical trials, such as the 2008 version of the World Medical Association's Declaration of Helsinki and good clinical practice, which has its origins in the Declaration of Helsinki'.

EU law has developed an 'ethical spirit' since the late 1980s, which also shapes practices in medicine and healthcare.[2] This 'ethical spirit' references to all three normative ethics theories, i.e. deontology, consequentialism and virtue ethics. Human rights as expressed by the ECHR and the Charter of Fundamental Rights of the EU, as well as EU values, form its basis.[2]

Principles and values

Definitions of *principles* and *values*, both part of moral reasoning, sometimes blur. In general, values tend to be more abstract and comprehensive than principles. Principles may support the realization of values in various contexts, and both are highly relevant in medicine, healthcare and public health ethics. Principles (as well as values; see below) can be either legally effective (e.g. proportionality, precaution) or sometimes not legally effective but still highly influential, like those from medical ethics (i.e. autonomy, non-maleficence, beneficence, justice). Examples of legally effective principles are proportionality, which can render excessive barriers to the free movement of goods illegal under EU law, and precaution, allowing restrictive measures in the field of communicable diseases.

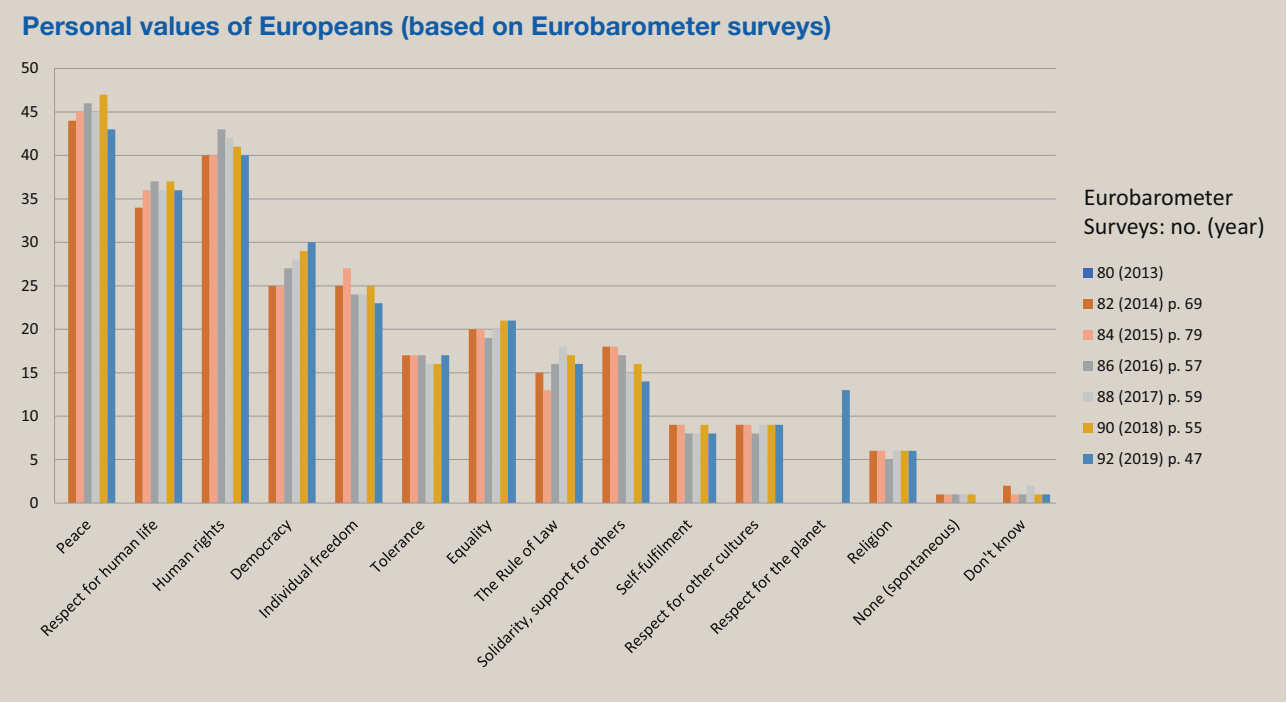

Figure 1

In 2006, EU health ministers framed *health values* such as access to good quality care, equity and solidarity.[2] Although legally not binding, these health values are guiding the development of European health systems. A set of *operating principles*, for example quality, safety, care that is based on evidence and ethics, patient involvement, redress, privacy and confidentiality, further specifies these health values. 'Care that is based on evidence and ethics', for instance, refers to demographic challenges and new medical technologies, which can give rise to difficult questions (of ethics and affordability) that need to be dealt with in order to ensure high-quality treatment and sustainability, as well as balancing between patients' needs and financial resources for treating the whole population.

Health values rest upon legally binding general EU values such as respect for human dignity, freedom, equality and respect for human rights (including rights of minorities). These general values are common to the Member States in a society in which pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men prevail. Figure 1 summarizes Eurobarometer surveys from 2013 until 2019 and shows the extent to which Europeans perceive that general EU levels correspond to their personal values.[2]

Current challenges: solidarity, digitalization and beyond

In addition to being a health value, solidarity has emerged as a bioethical concept highly relevant for biomedicine and healthcare systems.[3] Linked to justice and equity, but also to responsibility, solidarity refers to practices committed to 'carry "costs" (financial, social, emotional or otherwise) to assist others' (p. 79).[3] This is reflected by the EU health values in which solidarity requires a financial arrangement of the EU Member States' national health systems that ensures accessibility to all, irrespective of their ability to pay, their gender or their ethnicity.[3]

Risk stratification of lifestyle-related diseases caused, for example, by smoking, is an illustrative example of a European understanding of solidarity: whereas in the USA incentives and bonus–malus systems play an important role in healthcare provision based on private insurance, individual responsibility is rarely used for rationing of healthcare in Europe.[3] However, over the past years this general picture has become somewhat less clear as individual responsibility seems to have 'become synonymous with taking precautions and actively engaging in prevention' (p. 81).[3] This is of particular relevance in an era of predictive genetic testing, polygenic risk scores and forensic phenotyping, and with the still fictitious but hotly debated prospect of genetically engineering the human germline in order to reduce the risk of disease.

Artificial intelligence (AI) in healthcare can have a broad range of social impact, from positive, for example algorithms for computer-aided diagnosis, to biohacking,[4] which is somehow reflected in the 'risk-based-approach' of the AI Act, as proposed by the European Commission, COM(2021) 206. Hence, rapidly developing fields such as digitalization as well as the multiple crises of our time (climate change, pandemics, wars, etc.) highlight the importance of values, particularly solidarity and human dignity, in debates and resulting policies about prioritizing scarce resources in order to support public trust.[5] ◆

KEY REFERENCES

1 Beauchamp TL, Rauprich O. Principlism. In: ten Have H, ed. Encyclopedia of global bioethics. Cham, Switzerland: Springer International Publishing, 2016; 2282–93.

2 Frischhut M. The ethical spirit of EU values: status quo of the union of values and future direction of travel. 2022, https://www.springer.com/gp/book/9783031127168
3 Buyx A, Prainsack B. Lifestyle-related diseases and individual responsibility through the prism of solidarity. *Clin Ethics* 2012; **7:** 79–85.
4 Gómez-González E, Gómez E. Artificial Intelligence in medicine and healthcare: Applications, availability and societal impact. Luxembourg: Publications Office of the European Union, 2020 (JRC science for policy report).
5 European Commission Directorate-General for Research and Innovation, European Group on Ethics in Science and New Technologies. Values in times of crisis – strategic crisis management in the EU. 2022, https://data.europa.eu/doi/10.2777/79910 (accessed 13 March 2024).

TEST YOURSELF

To test your knowledge based on the article you have just read, please complete the questions below. The answers can be found at the end of the issue or online here.

Question 1

A hospital ethics committee was considering the best course of action for treatment of a patient who lacked capacity and where the relatives held different views to the medical team.

How may a consideration of principlism (autonomy, non-maleficence, beneficence and justice) best assist in reaching a decision?

A Identify the ethical conflicts present
B Provide clear rules for action
C Provide a clearer framework than common morality
D Select the correct solution from the individuals involved
E Remove any cultural factors from the process

Question 2

What characterizes the European approach to medical ethics, which answer is correct?

A All the documents mentioned in this article are not legally binding (i.e. soft-law)
B Soft-law is legally not binding and therefore irrelevant for medical ethics
C Principlism is not relevant in European medical ethics, as European Union (EU) law clearly refers to deontology
D European medical ethics can benefit both from more abstract values and more concrete ethical and/or legal principles
E In the EU we can find general values, however no health-specific values

Question 3

What characterizes solidarity, which answer is correct?

A Solidarity is an EU value, however not relevant in a health context
B Solidarity is a legal concept, however has not emerged as a bioethical concept
C Solidarity is a self-standing concept that can be applied without taking other concepts into account
D Solidarity requires a financial arrangement of the EU Member States' national health systems that ensures accessibility to all, irrespective of their ability to pay, their gender or their ethnicity
E Solidarity means that individual behaviour (e.g. smoking) will not be taken into account

