29th Meeting of the National Ethics Councils (NEC) Forum

12-13 May 2022, Paris, France

Abstracts

Session 1
Ethics and digital: how do national ethics councils address ethical issues in the digital area?

Digital Health: Combining Bioethics and Cyberethics – Claude Kirchner

Abstract: Based on the remarkable advances in digital and health sciences and technologies, the rapid development of digital health is having a profound impact on medical practices and uses. This is resulting in major advances in prevention, diagnosis, care and support. This particularly fruitful combination of digital and medical technologies raises ethical issues in the interaction between biological information processing systems (which we are) and digital systems (which we have invented). In this context, we deepen the central point of the combination of the information brought by the digital on the one hand and the medical on the other hand during the elaboration of a medical diagnosis.

From Theory to Practice: Ethics Guidelines for Trustworthy AI and Challenges of Implementation – Lorena Jaume-Palasí

Regulation focuses both on understanding potential conflicts, risks or harms and enabling individuals to using and enjoying their rights. Artificial intelligence is computational infrastructure. Like any infrastructure, it has a societal impact that evolves with the socio-economical dynamics of said society. As a relatively new technology its use is still not widespread. According to Eurostat 2021, in 2020, 7% of enterprises in the EU with at least 10 people employed used AI applications, 2% of the enterprises used machine learning to analyse big data internally and only 1% analysed big data internally with the help of natural language processing, natural language generation or speech recognition. And yet enough use cases have provided evidence of the severity of its risks. In an effort to mitigate these risks and conflicts, the Commission of the European Union tasked a High Level Expert Group on AI with the drafting of Ethics Guidelines. Do we have a full understanding of potential misuse? The present talk will address challenges from a practitioner's perspectives: are real risks being addressed? To what extent can the guidelines regulate conflicts and risks in practice? What are the ethical challenges when implementing AI technologies and how are the guidelines providing orientation?

The European Union Artificial Intelligence Act - Ibán García Del Blanco

When we talk about artificial intelligence we talk about benefits and risks on a scale not previously known.

The massive implementation of artificial intelligence in all the machines with which we interact with in the public arena, in the professional scene and in the social order, represents a revolutionary technological leap. Life will never be the same changes will be very substantial in the labour market, in the relationship with public authorities, in the personal perspective, in the leisure viewpoint, and even in our own domestic life.

Precisely for this reason, it is so important for the European Union, on the one hand, to boost the potential that these technologies have for Europe's well-being and competitiveness; and on the other hand, to control the inherent risks —or prevent their consequences—.

Hence, the EU institutions have been progressively outlining, through various political documents, the Union's agenda in the field of artificial intelligence.

Session 2
How are national ethics councils able to react and change?

Focus 1: Ethics in innovation and social impact

Participation, community engagement and social value in the light of research ethics - experiences from the PRO-Ethics project - Dirk Lanzerath and Lisa Tambornino

Participation in form of community engagement is crucial for good and reliable research and innovation. Citizens, users, patients, care takers, NGOs, social entrepreneurs and other community representatives and non-traditional stakeholders need to be involved in developing and performing research projects. But how can relevant community representatives successfully participate in different stages of research and innovation? How can participation be successful and ethical? Researchers, developers, and even research funding organizations (RFOs) are not always sure how to identify and resolve ethical issues that may arise when community representatives are involved in research or innovation projects. The EU funded project Pro-Ethics aims to bridge this gap by providing guidance to RFOs and others on how to address or even avoid ethical issues during participation.

Based on the findings of Pro-Ethics, Dirk Lanzerath and Lisa Tambornino will discuss the challenges that ethics bodies - as intermediaries between science and society - might face when involving community representatives in the planning, assessment, and performance of research projects.

Responsible Development and Governance of AI – Raja Chatila

Innovations in several sectors, from healthcare to e-commerce and transportation, including public services, are enabled by emerging and digital technologies such as Artificial Intelligence systems. While it enables to increase productivity or reduce costs through automation by physical or software processes, this technology has a direct impact on lifestyles of individuals and society.

Innovation often outpace regulation. Ethics committees have the capacity to question the motivations and relevance of specific technological choices, their safety, their impact on ethical principles, on rights and values, on populations and on the environment. By doing so, they contribute to raise the awareness of decision and law makers, as well as the general public, about issues that emerge from the development and deployment of technology. This can lead to shape a responsible governance that frames the development, deployment and use of the technology that can be achieved through a combination of regulation, codes of conduct, tecno-ethical standard development, certification, and public oversight.

Focus 2
National Ethics Councils and health care democracy/citizens' democracy

New challenges and perspectives for Health Democracy – Karine Lefeuvre

Public dialogue: an essential component of democratic governance Laurence Lwoff

Optimising the chances of stimulating innovation that contributes to human flourishing, whilst minimising applications that have negative consequences for individuals and society requires appropriate governance frameworks, in which ongoing dialogue between public, scientists and policy makers is an essential component. Already in 1997, the Oviedo Convention in its Article 28 was promoting such dialogue by requiring States to make sure that fundamental questions raised by developments in biomedicine are subject to appropriate public discussion. Reference was made in this context to the role of national ethics bodies. Since then the Council of Europe is working towards the development of such public dialogue, including by clarifying what should be its essential features. This is one of the objectives of its current Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025).

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Focus 3
National Ethics Councils in times of health crisis/emergencies

<u>Social responsibility and health: National Bioethics Committees in times of pandemic and war - Christiane Druml</u>

Since World War II a broad movement towards the introduction of normative regulations for medical research starting with the "Nuremberg Code" of 1947 and the Declaration of Helsinki of the World Medical Association of 1964 led to a huge framework of modern bioethical standards and structures. The rapid development of life sciences with previously unknown possibilities of interfering with basic aspects of human life resulted in the establishment of national bioethics advisory bodies dealing with fundamental bioethical questions on research procedures as well as on questions of the beginning and of the end of life.

Today in times of pandemic and war we encounter a different world. The pandemic itself led to renewed discussions about solidarity and benefit sharing. The prioritized focus on the individual - his or her autonomy - since the Nuremberg Code is shifting towards a stronger focus on the collective in its form of a community. Bioethical values are increasingly guiding public health, economic development, justice and security. Other essential topics are stewardship of the environment regarding the slowing of climate change. In this sense we need to consider anew the synergistic relationship between health and other aspects of social responsibility. In this new era of Bioethics, national ethical advisory bodies have to fulfil a new and altered role of acting in a responsible way.

<u>The Spanish Bioethics Committee (CBE) in the context of the pandemic: Spanish National Strategy for the vaccination against Covid-19 and the role of bioethics through the CBE participation - Federico De Montalvo Jääskeläinen</u>

One of the most relevant words of this terrible pandemic from a bioethics perspective is, surely, priorization. Priorization is not something derived from the pandemic, but very common in a public health system based on universality as the Spanish health system is. In any case, the decision about the priorization in the context of scarce resources has been extremely dramatic.
In any case, the lessons learned during this health crisis offer a real hope for the role of Bioethics and of the National Bioethics Committees. The example of Spain is a clear one of this hope for the future
At the beginning of the pandemic, there was the first bioethics crisis, when the number of intensive care resources were so scarce. The initial solution for this dramatic priorization was based on an utilitarian formula where human dignity was in danger

Nevertheless, in the second priorization, the one about the access to the vaccines at the beginning of the vaccination campaign was so different to the previous one. Then, the difficult decisions were based on robust ethical principles, such as dignity, justicem equality, equity.

The main difference between tis two situation were, in some sense, in the partipation of Bioethics in the second one through the Spanish Bioethics Committee. The second priorization (about vaccines) was developed giving a strong position to bioethics and it had an impact on trust of population.

Data-driven research in clinical ethics and public health ethics. Ethical challenges with special emphasis on public health emergencies - Stavroula Tsinorema

The paper will address ethical issues of data-driven clinical and public health research with particular emphasis on research conducted in public health emergencies. Topical ethical challenges will be identified, relying on the experience of the recent Covid-19 pandemic, and various ethical frameworks proposed for their adequate tackling will be briefly reviewed. A focal point will be that of understanding conflicts between individual rights (such as privacy rights) and common goods ("public interest", "public good"). It will argue for the normative continuity between clinical ethics and public health ethics, as two complementary spheres of moral reasoning, including the conduct of research in both. *Prima facie* conflicts between individual rights and the promotion of public health as a public good will be addressed and dismantled, from the standpoint of an obligation-based account of human agency. Also the issue of the implementation of ethical objectives and guidelines in the concrete practice of data-driven research (and the development of data–based AI systems) will be addressed.

Session 3
Ethics and mental health

How Mental Health relates to Research Integrity – It is time for action - Joeri Tijdink

In recent years, several studies have put emphasis on the increasing prevalence of mental health problems that exist among (early career) researchers. This should be a concern. Not only burn out, depression and other mental health problems can have a detrimental effect on the research process and responsible research practices, it also hinders efficacy and effectiveness of the academic enterprise and could be a pressing economic burden. In this talk, I will present an overview of prevalence of mental health problems, discuss potential causes of why mental health issues are so prevalent and present a set of possible, (evidence based) interventions that 1) can help individual

researchers become better equipped to deal with stress in academia, 2) how this relates to research culture and 3) highlight what institutions can do to lower the mental burden of early career researchers.

I will end the talk with why I think that the momentum is now to make a change in academia. Too much pressure is currently being perceived by mostly early career researchers. I will present some existing initiatives that are currently being developed that try to change academia and give an overview of topics related to mental health that are currently lacking evidence. This included initiatives on research culture, supervision, open science and better assessment criteria. I will highlight these initiatives, their relation with mental health and research integrity and emphasize that empowering early career researchers and minorities and diversify the academic workforce will make academia a better place.

Mental Health and Religion - Ethical Aspects - Ramaz Shengelia

Introduction. In recent decades, an increased interest has been arisen in mental and physical conditions from the viewpoint of the impact of religion and spirituality. Nowadays there are a number of publications, such as periodicals and various textbooks on the given problem. Although the conclusions are not unambiguous, it is doubtless that accumulated scientific materials provide a body of valuable evidence that religious and spiritual activities lead to physical and mental health, lowering the levels of depression, lessening psychological stress and reducing illnesses and mortality.

Methods and sample size. The target group: 18+ years old population of Tbilisi; Sampling frame: 2012 parliamentary elections base; selected size: 500 completed interviews; selected method: stratified cluster selection.

Conclusion. According to obtained results, 5 factors influence depression severity quality formation: Age, gender, marital status, family economic self-esteem, and religiosity. Among the factors, which participate in the level of depression severity, the highest share has religiosity - 34,3%. Other factors in the weight of their significance are low. Religiosity has a positive role because it is in reverse dependence with the level of depression severity. Ethical dilemmas have emerged both in the selection of research methodology and in the conceptual aspect as well.

Paradoxes in mental health: current and future ethical challenges - François Ansermet

Psychiatry is currently going through a moment of crisis that calls for a strong ethical stance. However, this time of re-evaluation can also be an opportunity for positive change. By looking at the malaise that runs through the field of mental health – in its institutions, its knowledge, and in society – we identify some paradoxes that act as

indicators of the changes that are taking place. Changes that point at new paradigms, which in turn indicate possible ways forward.

Involuntary psychiatric treatment of patients with mental disorders - Maja Rus Makovec & Marjeta Terčelj Zorman

Involuntary admission is used globally in psychiatry; it can be perceived as the opposite of the fundamental paradigm of clinical medicine ethics to benefit the patient, to avoid or minimize harm, and to respect the values and preferences of the patient. Basically, ethical concerns address mainly legal implications. However, the presentation would focus on potential for epistemic injustice in psychiatry as well as on epistemic (dis)trust between psychiatric clinical knowledge and legal, patient and family groups. Involuntary hospitalization involves parallel processes: intensive emotional stress and possibility of negative outcomes of the treatment on one side and ethical and professional concerns or mistrust of patients, families, social and legal institutions on the other side. Pathways to support co-constructing epistemic trust will be analyzed: 1. reflection on potentially un-ethical abandonment of involuntary treatment, which could fulfill the patients' need of care and restore their autonomy, 2. self-reflective systemic understanding of power in psychiatric profession, applied as immanent part of professional training, can enable a fundamental change in the culture of psychiatry, 3. proactive and on-going engagement of psychiatric profession with the debate of involuntary admission and with analyses across settings, with transparent European psychiatric guidelines, and examples of good practice.

Session 4

The Impact Of National Ethics Councils' Opinions On Public Health

The pandemic. Strengths and weaknesses - Amós José García Rojas

Although it may seem incredible, in the 21st century, a new microorganism spreads surprisingly throughout the world, giving rise to a pandemic, and refreshing us with an idea that we should never, never forget, "In the face of communicable diseases, you cannot lower your guard ". However, we lowered it, and a lot. The advanced countries, from the altar of their development, thought that they had a solid armor against this problem, ignoring that in a globalized world and since this is a disease that is transmitted as it is transmitted, it would be very difficult to stop it. And so, little by little we had patients, we began to feel the seriousness of the problem, and we were aware that we did not have the only instrument that would allow us to modulate it: a vaccine,

This crisis also placed a key aspect on our agenda, how to introduce those innovations in healthcare that offer added therapeutic value, that are capable of having a positive impact on the health of citizens and that at the same time guarantee the sustainability of Systems of health. In this idea, public health policies are presented as one of the most cost-effective interventions that exist. And in this context, it seems convenient to underline the need to reinforce the health policies that have suffered the most from the rigor of the cuts, the global public health policies

Fortunately, today the horizon is different. The current scenario marks a distance from the most recent past. And it is mainly the vaccines that determine these differences. Especially having them. One of the key elements that allows us to feel lucky lies in the fact of being part of the European Union, which guaranteed the availability of these products thanks to the centralized purchase that was carried out. This purchase determined that the availability of these vaccines will be ensured, and their distribution in an equitable manner to the member countries, always based on their populations. It seems evident how beneficial it has been to have participated in this centralized purchase

Between expertise, dialogue and decisions, which impact on public health policies for national ethics councils' opinions? - Laurent Chambaud