Adhering to ethics guidelines in biomedical research and medical practice is crucial to save lives

Hanan Balkhy [1]

[1]Regional Director, WHO Regional Office for the Eastern Mediterranean, Cairo, Egypt.

Citation: Balkhy H. Adhering to ethics guidelines in biomedical research and medical practice is crucial to save lives. East Mediterr Health J. 2024;30(6):395–396. https://doi.org/10.26719/2024.30.6.395.

Ethics is a vital aspect of every profession and its application to public health is critical because of the need to preserve life and the rights of humans and animals. Researchers and healthcare providers are often confronted with real dilemmas that require careful analysis and ethical decision-making in their interactions with individuals, groups, institutions, and the society *(1)*. Getting people to act ethically is sometimes difficult; even with clear guidelines it is unfortunate that some people still do not pay attention to ethics standards.

Scientific research offers great opportunities to improve lives by making new innovations available for better healthcare, however, the processes involved in the development of such innovations may present significant risks to wellbeing and existence. Research accidents can happen in laboratories, during field experiments, or during sample handling, packaging, transport, and storage. For example, evidence has shown that nanoparticles can slip unknowingly into our daily lives in the form of personal care products or due to misuse *(2)*. There is the possibility of inadvertent or deliberate weaponisation of biological agents or toxins *(3)* and, currently, the misuse of artificial intelligence in biomedicine and public health *(4)*.

Tools and systems are needed to moderate research and healthcare, ensure responsible practice, minimise and mitigate impending risks, and provide utmost benefits to affected populations without the fear of causing them harm. Providing guidance in this regard is paramount, and this underscores the attention and emphasis given to ethical conduct in scientific research and healthcare practice by WHO and partners, and signifies the critical importance of ethics to human existence.

Developed in 2022, the "WHO Global Guidance Framework for the Responsible Use of the Life Sciences: Mitigating Biorisks and Governing Dual-use Research" is an important reference document for Member States and other stakeholders in their efforts to prevent and mitigate biorisks and govern dual-use research *(5)*. The Framework refers to dual-use as knowledge, information, methods, products, or technologies generated by peaceful and legitimate research, which may be appropriated for non-peaceful or harmful purposes.

The framework has 3 core pillars: biosafety, laboratory biosecurity and oversight of dual-use research. It was developed to raise awareness about the importance of biorisk management in the context of the One Health approach (an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems). It identifies some of the challenges and gaps associated with mitigating biorisks and governing dual-use research, and highlights how Member States and other stakeholders can effectively initiate biorisk management. The framework highlights a step-by-step ethics implementation approach and offers checklists for different groups of stakeholders, scenarios and cases in the governance of biorisks and dual-use research. It provides a global perspective on the tools and mechanisms for preventing, mitigating and managing biorisks.

Several other frameworks and guidelines on responsible biomedical research and healthcare practice have been published by WHO, the World Medical Association, the Council for International Organizations of Medical Sciences, Council of Science Editors, Semantic Scholar, etc *(7-12)*.

Ethical conduct is applicable to all aspects of biomedicine and public health, including research, publications, medical practice, pharmaceuticals, recruitment, communication, etc. There is no other way to prove credibility and promote trust in biomedical research and public health than adherence to clear, consistent and strict ethical standards. Observing ethical standards that are clearly communicated to respective individuals and communities will provide the needed assurance that research, medicines, diagnostics, and clinical trials meet quality and safety standards *(13)*.

EMR stakeholders had the opportunity to make input to the Framework for the Responsible Use of the Life Sciences: Mitigating Biorisks and Governing Dual-use Research. Since its release, the WHO Regional Office for the Eastern Mediterranean (WHO/EMRO) has convened several forums to draw attention to the document, promote bioethics in the region, and to call for action to implement the recommendations. WHO/EMRO continues to contribute to global bioethics summits, hold regional summits and webinars to strengthen the bioethics capacity of researchers and healthcare professionals in the region, and has facilitated regional surveys on bioethics. EMR currently hosts 3 (in Beirut, Karachi and Tehran) of the 10 centres in the Global Network of WHO Collaborating Centers for Bioethics.

There is a need for further engagement to expand ethics dialogue beyond the summits and enhance visibility and awareness of ethics issues and the framework. The framework needs to be adapted and contextualized to reflect the needs and priorities of Member States and institutions. Member States have the responsibility to support biorisk governance and play a major role in the establishment, capacitation and functioning of national ethics or bioethics committees in their countries. They should ensure multi-sectoral, multistakeholder involvement in ethics issues which includes governments, scientists, academic institutions, funders, publishers and editors, civil society and public, and the private sector.

This special edition of the Eastern Mediterranean Health Journal (EMHJ) was put together to facilitate such engagement and spur discussions on bioethics issues in the EMR. The papers highlight some of the areas requiring ethics interventions in the region, including healthcare workers recruitment, palliative care, health emergencies, pandemic response, and general biomedical research.

Ethics should be an integral part of regulatory and accreditation processes if we must safeguard the integrity of health systems *(13,14)*. Efforts should be made to develop or revamp and enforce ethics bylaws, legislation and regulations; build the capacity of healthcare professionals in biomedical and research ethics, including during emergencies and outbreaks; and to foster stronger collaborations between bioethics committees and policymakers.

On their part, researchers and healthcare professionals should uphold the principles of ethics – nonmaleficence, beneficence, respect for individual autonomy, confidentiality, and justice – to ensure that science continues to elicit the trust it deserves *(1)*. We must all adhere to ethics guidelines to avoid harming the masses we are working to save.

References

1. Vevaina JR, Nora LM, Bone RC. Issues in biomedical ethics. Dis Mon. 1993;39(12):869-925. https://pubmed.ncbi.nlm.nih.gov/8243220/.
2. Gupta R, Xie H. Nanoparticles in daily Life: Applications, toxicity and regulations. J Environ Pathol Toxicol Oncol. 2018;37(3):209-230. doi: 10.1615/JEnvironPatholToxicolOncol.2018026009.
3. United Nations for Disarmament Affairs. What are Biological Weapons? New York: United Nations for Disarmament Affairs, n.d. https://disarmament.unoda.org/biological-weapons/about/what-are-biological-weapons/#:~:text=Biological%20weapons%20disseminate%20disease%2Dcausing,agent%20and%20a%20delivery%20mechanism.
4. Ingle VK, Sharma V. Misuse of AI and its consequence. Inter Res J Mod Engineer Tech Sci. 2023;5(4):4713-4715. https://www.irjmets.com/uploadedfiles/paper//issue_4_april_2023/36501/final/fin_irjmets1682493570.pdf.
5. World Health Organization. Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research. Geneva: World Health Organization, 2022. https://iris.who.int/bitstream/handle/10665/362313/9789240056107-eng.pdf?sequence=1.
6. World Health Organization. One Health. Geneva: World Health Organization, n.d. https://www.who.int/health-topics/one-health#tab=tab_1.
7. World Health Organization. International clinical trials registry platform. Geneva: World Health Organization, n.d. https://www.who.int/clinical-trials-registry-platform.
8. World Medical Association. Declaration of Helsinki: Medical research involving human subjects. Ferney-Voltaire: World Medical Association, 2013. https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/.
9. Council for International Organizations of Medical Sciences. International ethical guidelines for health-related research involving humans (Fourth Edition). Geneva. Council for International Organizations of Medical Sciences, 2016. https://doi.org/10.56759/rgxl7405.
10. Council of Science Editors. Sample letters organized by subject. Mullica Hill: Council of Science Editors, n.d. https://www.councilscienceeditors.org/index.php?option=com_content&view=article&id=198:sample-letters-organized-by-subject&catid=20:site-content#ResearchEthics.
11. Danis M, Emily A, Grady L, Grady C, Wendler D, Hull SC, et al. Research Ethics Consultation: A Casebook. Semantic Scholar, 2012. https://api.semanticscholar.org/CorpusID:68271716.
12. World Health Organization. Ensuring ethical standards and procedures for research with human beings. Geneva: World Health Organization, n.d. https://www.who.int/activities/ensuring-ethical-standards-and-procedures-for-research-with-human-beings.
13. Ayodele JO, Underwood MLK, Al Ammari D, Goldstone K and Agogo E. Enhancing trust and transparency for public health programs. In: Modernizing Global Health Security to Prevent, Detect, and Respond, ed Mcnabb SJN, Shaikh A, Haley CJ. https://doi.org/10.1016/B978-0-323-90945-7.00027-0.
14. Ben Ammar MS, Mandil A, El-Feky S. Ethics in health practice and research: an EMR perspective. Eastern Mediter H J. 2016;22(1):62-63. https://www.emro.who.int/emhj-volume-22-2016/volume-22-issue-1/ethics-in-health-practice-and-research-an-emr-perspective.html.