**Editorial**

# Ethics and Innovations in Biomedical Sciences

**Wickramatilake C. M.**

Professor, Department of Biochemistry, and Chairperson, Ethics Review Committee, Faculty of Medicine, University of Ruhuna

Email: chandimadhu@live.com

In the recent past, there is proliferation of innovations in the field of biomedical sciences. These include primarily the products (pharmaceuticals, food supplements, technical devices) and services (educational programmes, patient management care procedures). The pace of increase of innovations have contributed to the economic growth and the development of the countries. However, the innovation/research may associate with ethical challenges. Therefore, I would like to devote this editorial to brief on the potential ethical issues associated with the innovations and the way forward.

In the healthcare systems, clinicians tend to introduce new, untested practices to patient care based on their experience without rigorous scientific evaluation. Sometimes, this may lead to the violation of patient's autonomy, creating a pathway for exploitation and harm than good. Therefore it is advisable to conduct clinical research to see the effect of a procedure before implementing it as a practice(Earl, 2019). Further, bioelectrical devices invented in the field of medicine may have potential ethical issues. The devices created for the management of neurological disorders can alter the brain stimulation and signal generation. These patients might have issues related to informed consent and social justice as they may not be able to give informed consent (Packer, Mercado, & Haridat, 2019). Similar forms of ethical

issues are associated with the informed consent in the development of drugs for patients with psychiatric illnesses (Carrier, Banayan, Boley, & Karnik, 2017). Pace of development of new surgical technologies continues to increase which brings about a magnitude of ethical issues such as safety of technology, obtaining informed consent from the patient (vulnerability related issues) and outcome evaluation (Geiger & Hirschl, 2015). Hence, with the advancement of science and innovations, it is important to heighten the awareness of ethical issues (among researcher/inventors, members of review bodies and public etc) and to have proactive ethical approach. Frequently, the new technology or invented clinical care procedure is more expensive with limited availability to the general community. Hence, accessibility and affordability of that innovation/service is limited to a category of community who are powerful and socioeconomically privileged. In multicenter international clinical trials, the benefits of the findings may not be equally translated to all countries. Specially, the poor countries involved in the trial may not be able to afford the drug or device tested. Equitable distribution of risks as well as the benefits to eligible communities or patients is encouraged in all the instances (Nambisan & Nambisan, 2017). Other common ethical concerns related to innovations are source of funding and the associated conflict of interests which need to be declared to maintain the transparency and the integrity of the innovation.

The designers need to pay a central attention to the important ethical issues related to an innovation such as safety (occupational, customer and environmental etc), efficiency, security, respect for human dignity-autonomy, reliability, privacy, transparency, acceptability, accessibility and justice-equity) during the initial phase of the development and frame their activities accordingly. In the selection of the process of development and the related technology, it is imperative to address these unique ethical issues (de Morais & Stückelberger, 2014). It is an integral component of disclosure of ethical issues related to the innovation during the initial discussions and at the stage of seeking ethical approval, rather than discussing it as an after-thought when a problem arises (Brusoni & Vaccaro, 2017).

Acknowledgement of the social and cultural variations by the innovation reinforces and facilitates its acceptance and the operationalization in the society. A new product with sophisticated technology with modernized equipment may be innovative, but not ethically and socially acceptable (eg: atomic bomb). A value-driven, ethically acceptable innovations which had been adequately researched would be helpful for the development of mankind (de Morais & Stückelberger, 2014).

Transition of Medical Science from reactive to proactive is brought about by the research and innovations which is inseparable from ethical issues. Therefore the researchers, industries, funding bodies, ethics review committees and the other regulatory bodies should be aware of the potential ethical issues, disclose and need to follow the actions mitigating the risks(Sedda, Gasparri, & Spaggiari, 2019). A systematic review focusing on the organizational characteristics of the implementation of innovations has highlighted methodological issues related to innovations such as inconsistency of theory, absence of standard reporting criteria for research, validity and reliability. Therefore has been recommended to adhere to the universal ethical standards (Belmont Report, 1979; Karsh, 2012; Lantos, 2020) and to test the innovation among diverse settings and target populations before adopting (Allen et al., 2017). The management of innovation related ethical issues is not independent. The analysis of the ethical aspect of the innovation is a responsibility of the institution of its origin. When the innovation is introduced by an institution, inventor needs to follow the research guidelines and the specific code of ethics of the institution. If the institution is from the state sector or university where academics are involved, the public shows more interest, perhaps due to the trust on academics and state sector. Hence, the institution needs to arrange its research policy/ guidelines, monitoring and governance for responsible innovation adhering to the ethical principles and social accountability to sustain public trust (Miller et al., 2015).

## References


Allen, J. D., Towne, S. D., Jr., Maxwell, A. E., DiMartino, L., Leyva, B., Bowen, D. J., . . . Weiner, B. J. (2017). Meausures of organizational characteristics associated with adoption and/or implementation of innovations: A systematic review. *BMC Health Serv Res, 17*(1), 591. doi:10.1186/s12913-017-2459-x

Belmont Report. (1979). National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Brusoni, S., Vaccaro, A. (2017). Ethics, Technology and Organizational Innovation. *J Bus Ethics*, 143, 223–226. DOI 10.1007/s10551-016-3061-6.

Carrier, F., Banayan, D., Boley, R., & Karnik, N. (2017). Ethical challenges in developing drugs for psychiatric disorders. *Prog Neurobiol, 152*, 58-69. doi:10.1016/j.pneurobio.2017.03.002

de Morais J. C. B., Stückelberger, C. (2014). Innovation Ethics. African and Global Perspectives Globethics.net and African Innovation Foundation, Website: www.globethics.net

Earl, J. (2019). Innovative Practice, Clinical Research, and the Ethical Advancement of Medicine. *Am J Bioeth, 19*(6), 7-18. doi:10.1080/15265161.2019.1602175

Geiger, J. D., & Hirschl, R. B. (2015). Innovation in surgical technology and techniques: Challenges and ethical issues. *Semin Pediatr Surg, 24*(3), 115-121. doi:10.1053/j.sempedsurg.2015.02.008

Karsh, L. I. (2012). A clinical trial primer: historical perspective and modern implementation. *Urol Oncol, 30*(4 Suppl), S28-32. doi:10.1016/j.urolonc.2011.05.012

Lantos, J. D. (2020). The Belmont Report and Innovative Clinical Research. *Perspect Biol Med, 63*(2), 389-400. doi:10.1353/pbm.2020.0026

Miller, F. A., Painter-Main, M., Axler, R., Lehoux, P., Giacomini, M., & Slater, B. (2015). Citizen expectations of 'academic entrepreneurship' in health research: public science, practical benefit. *Health Expect, 18*(6), 2356-2374. doi:10.1111/hex.12205

Nambisan, S., & Nambisan, P. (2017). How Should Organizations Promote Equitable Distribution of Benefits from Technological Innovation in Health Care? *AMA J Ethics*, *19*(11), 1106-1115. doi:10.1001/ journalofethics. 2017.19.11.stas1-1711

Packer, S., Mercado, N., & Haridat, A. (2019). Bioelectronic Medicine-Ethical Concerns. *Cold Spring Harb Perspect Med, 9*(10). doi:10.1101/ cshperspect. a034363

Sedda, G., Gasparri, R., & Spaggiari, L. (2019). Challenges and innovations in personalized medicine care. *Future Oncol, 15*(29), 3305-3308. doi:10.2217/ fon-2019-0284