

Module 3. Cultural sensitivity - Topic 3. Ethical issues and human rights

*Verónica V. Márquez-Hernández, Lorena Gutiérrez-Puertas, Gabriel Aguilera-Manrique,
Remedios López-Liria, Patricia Rocamora-Pérez,
M. Ángeles Valverde-Martínez, M. Jesús Benzo-Iglesias
University of Almería*

1. INTRODUCTION

The ethics of health care and medical research revolves around issues related to basic human rights and health delivery, ensuring safety and benefits for communities (Ota et al., 2013). One of the important issues to consider on the basis of human rights and ethical aspects is vaccination. In both industrialised and developing countries, a vaccine is only introduced into public health programmes if the level of efficacy and the resulting reduction in morbidity and mortality justify the cost of introducing and delivering the new vaccine (Ota et al. 2013). However, situations such as the current pandemic have created an unprecedented global health, economic and social crisis, which has highlighted the need to review the ethical and human rights issues related to vaccination, which are described below in this theme.

2. AIMS

The purpose of this tool is to gain knowledge about ethical and human rights concerns associated with immunization issues.

3. LEARNING OUTCOMES

When you have worked with this tool, you will be able to:

- Obtain and overview of ethical concerns and human rights related to immunization and hesitancy
- Know the principles of bioethics and its application in vaccines.
- Give appropriate explanations to patients about their rights and needs in relation to vaccines.
- Identify elements of effective collaboration between the patient/client in ensuring quality of patient/client care.

4. THEORETICAL FRAMEWORK

4.1. Concepts and definitions

The most important concepts related to the topic are described below:

- **Human Rights:** are rights inherent to all human beings, without distinction of any kind, such as race, sex, nationality, ethnic origin, language, religion or other status. Human rights include the right to life and liberty; freedom from slavery and torture; freedom of opinion and expression; education and work, among many others. These rights apply to all persons without discrimination of any kind (United Nations, 1948). Human rights include the right to social protection, to an adequate standard of living and to the enjoyment of the highest attainable standard of physical and mental health.
- **Ethical Principles:** are defined as the set of ethical rules that must be respected by all and guide decision-making (Taylor, 2013). Beauchamp and Childress (1979) established four fundamental ethical principles, thus determining the frame of reference that should govern any decision-making in healthcare. The ethical principles are autonomy, beneficence, non-maleficence and justice.

- **Autonomy:** is the patient's right to accept or refuse any medical intervention. Every patient has the right to be respected as a person, to have his or her options, ideas and choices respected. This principle considers the need for informed patient consent (Taylor, 2013; Varkey, 2021).
- **Beneficence:** defines the actions of the healthcare professional, always with a moral obligation to act in the best interests of the patient. It presupposes that the essential thing is to do good and look after the patient's interests (Varkey 2021). One of the health measures that has had the greatest impact on public health, together with integral sanitation and water purification, has undoubtedly been vaccinations (disappearance of smallpox; eradication of poliomyelitis in most of the world; decrease in mortality from measles; decrease in cases of rabies, tetanus, meningitis, invasive pneumococcal disease, cervical cancer, etc.) (Varo Baena, 2020).
- **Non-maleficence:** is based on the Hippocratic principle of *Primum non nocere*, i.e., "first and foremost, do no harm" (Taylor, 2013). It is the professional's obligation to do no harm to the patient or to minimise the harm of the healthcare performance (Taylor, 2013; Varkey, 2021).
- **Justice:** implies the equitable distribution of limited goods and resources, without discrimination, to achieve the maximum benefit for the community and avoid inequalities in health care (Azulay Tapiero, 2001; Taylor, 2013). For example, the inclusion of vaccines in the immunisation schedule goes in this direction, taking into account the differences between social strata, countries or communities (Varo Baena 2020).

According to Thompson et al. (2014), the following ethical issues should be considered in relation to vaccines:

- (1) Protection of the public from harm,
 - (a) highest quality of evidence possible,
 - (b) anticipatory decision-making,
 - (c) duty to warn,
 - (d) proportionate monitoring.
- (2) Transparency.
- (3) Publicly acceptable risk benefit profile.
- (4) Minimization of stigma.
- (5) Special obligations to vulnerable populations.
- (6) Public trust.

4.2. What the research says on the topic

Public health ethics is now a strong field of study that includes theoretical considerations and practices (Thompson et al., 2014). However, ethical analyses of pharmaceutical and vaccine-related issues are scarce, especially in the post-licensing context (Callréus, 2013). Studies on ethical issues in relation to vaccination have addressed different aspects.

Specifically, there has been a lack of consensus on ethical principles to guide the early allocation of vaccines in the event of a need for rationing, such as in pandemic situations (Williams and Dawson, 2020). In line with the above, in the recent COVID-19 pandemic situation, Zimmerman (2021) proposes the application of the principle of double effect to assess moral conflicts when an action can produce both good and bad effects. Applying these criteria to COVID-19 vaccination, it is considered that: (1) the act of vaccination is good because it prevents disease in the recipient and contributes to herd immunity. (2) The abortions were independent events performed decades ago for purposes other than vaccination; the disease was not known to exist then. (3) The motive for vaccination is the protection of the vaccinee and, secondly, the protection of his contacts and the community through herd immunity; therefore, the motives are good. (4) The good effect, saving hundreds of thousands of lives in this circumstance, is clearly greater than the negative effect. Jamrozik and Selgelid (2020) state that a number of ethical issues should be considered in relation to the COVID-19 vaccine. First, public

participation can help assess the local acceptability of human challenge studies, maximise transparency of community concerns, and elucidate the potential effect of the research on the community. Second, the acceptability of human studies would depend in part on the existence of potential benefits (to public health or to participants) that outweigh the anticipated risks. On the other hand, the potential direct benefits to participants must be considered, as well as the risks. Finally, other aspects to consider would be background risk, self-experimentation, risks related to experimental vaccines, and risks to third parties.

Ethical analysis in relation to immunisation has also been explored further in other areas. Specifically, Jaspán et al. (2008) examined stakeholder attitudes towards the ethical issues of adolescent participation in HIV vaccine trials, finding that ethical trials of HIV vaccines in adolescents would generally be feasible in the community studied. Other studies have focused on analysing the ethical and/or legal issues of the human papillomavirus (HPV) vaccine (Zimet et al., 2021). Specifically, it was found that HPV vaccination coverage remains low, declining substantially because of the COVID-19 pandemic. Zimet et al. (2021) stress the need for any changes in vaccine policy to be carried out with clear communication and to be consistent with ethical principles. In the same vein, Kruse et al. (2020) explored the extent to which human rights considerations influence health attitudes in Brazil with respect to HPV vaccine access. The authors concluded that limiting access to the HPV vaccine when it is medically effective is an infringement of people's right to health.

At the paediatric level, vaccine trials with improved child survival or prevention of serious illness as outcomes are ethically justifiable if the effects of the intervention on the prevention of mortality or serious illness are unknown. These studies should be conducted after standards of care and prevention have been agreed upon to improve the survival of all trial participants as a result of the services provided by the trial (Ota et al., 2013). Some studies propose the use of evidence-based decision making (EBDM) as a tool to establish an ethical basis that systematically considers all relevant values and transparently places vaccination recommendations in the context of societal norms and individual concerns (Field and Caplan, 2012).

Finally, some research has addressed the ethical issues of mandatory COVID-19 vaccination of healthcare workers. Both healthcare workers and institutions have a duty to protect patients and others from the known and anticipated harms of infection. The duty to protect is based on fundamental ethical values: putting patients first and promoting their welfare (beneficence) and avoiding harm to others (non-maleficence) (Olick et al., 2021).

4.3. What does national legislation and international/European treaties and conventions say on the topic

The right to the highest attainable standard of health was first articulated in 1946 in the WHO Constitution, and almost every country in the world has ratified at least one international agreement that imposes specific obligations on governments in relation to the right to health, including obligations related to "the prevention, treatment and control of epidemic, endemic, occupational and other diseases". The International Covenant on Economic, Social and Cultural Rights (1976) sets out extraterritorial obligations for international assistance and cooperation that are understood to include the equitable distribution of vaccines globally (Commissioners of and collaborators with the International AIDS Society-Lancet Commission on Health and Human Rights, 2021).

Governments and institutions mandate many actions or types of behaviour to protect the welfare of the public. These policies may be ethically justified, as they may be crucial to protecting the health and welfare of the public. However, this value may come into tension with others, such as individual freedom and autonomy. Policies that limit or eliminate individual choice may be controversial and raise a number of ethical considerations and must be justified by the promotion of another valuable social

objective, such as the protection of public health (*COVID-19 and mandatory vaccination: Ethical considerations, 2022*).

According to *COVID-19 and mandatory vaccination: Ethical considerations (2022)*, all of the considerations listed below should be explicitly evaluated and discussed through ethical analysis by governments and/or institutional policy makers who may be considering vaccination mandates. They should be considered alongside other relevant scientific, medical, legal and practical considerations and should be reviewed in the light of evolving evidence. Considerations to be taken into account are: 1) necessity and proportionality; 2) sufficient evidence of vaccine safety; 3) sufficient evidence of vaccine efficacy and effectiveness; 4) justice in access and availability; 5) public trust; and 6) ethical processes of decision-making.

On the other hand, according to British Columbia's Office of the Human Rights Commissioner (2021), the principles for the protection of human rights in the development of vaccination status policies should be: a) equitable access; b) evidence-based; c) time-limited; d) proportional; e) necessary and f) privacy.

Likewise, the Inter-American Commission on Human Rights (2021), under the auspices of the Office of the Special Rapporteur on Economic, Social, Cultural and Environmental Rights (REDESCA) proposes the following recommendations to its member states: 1) access to vaccines, goods and health services in attention to the principle of equality and non-discrimination; 2) distribution and prioritisation of vaccine doses; 3) active dissemination of adequate and sufficient information on vaccines and countering misinformation; 4) right to free, prior and informed consent; 5) right of access to information; transparency and combating corruption; 6) business and human rights in relation to COVID-19 vaccines; and 7) international cooperation.

5. LEARNING ACTIVITIES

Activity 1 (duration: 15 minutes): Watch the compulsory video (<https://www.youtube.com/watch?v=bisOSGZRgpo>) and share your thoughts/opinions/experiences about the issues on this topic on the dedicated forum and give feedback to other participants.

No.	Title and description of the resource	Type	Language of resource	Learning, training, assessment and evaluation activities	Access URL / download
1.	Vaccination and ethics	Video 7'54''	English* (Compulsory)	Learning training Individual learning Self-reflection	https://www.youtube.com/watch?v=bisOSGZRgpo
2.	Bioethics Interest Group COVID-19 Webinar Series: Vaccine Ethics	Video 57'41''	English* (optional)	Webinar Individual learning Self-reflection	https://www.youtube.com/watch?v=JQQHuoXPNTg
3.	Human rights and COVID19 Equal access to vaccines	Video 5'07''	English* (optional)	Individual learning Self-reflection	https://www.youtube.com/watch?v=zniPBzLkgws

* Subtitles auto-generated in all languages

6. ASSESSMENT ACTIVITIES

Activity 1 (duration: 10 minutes): Please indicate below with which bioethics principle each of the following definitions corresponds: AUTONOMY, NON-MALEFICENCE, BENEFICENCE, JUSTICE.

1. It is the professional's obligation to do no harm to the patient or to minimise the harm of the health care intervention. Answer: _____.

2. Defines the actions of the healthcare professional, always with the moral obligation to act in the best interests of the patient. Answer: _____.

3. It involves the equitable distribution of limited goods and resources, without discrimination, to achieve the maximum benefit for the community and to avoid inequalities in health care. Answer: _____.

4. It is the patient's right to accept or refuse any medical intervention. Answer: _____.

7. REFERENCES

A human rights approach to proof of vaccination during the COVID-19 pandemic. (2021). British Columbia's Office of the Human Rights Commissioner. Retrieved 13 February 2023, from <https://bchumanrights.ca/publications/vaccination/>

Azulay Tapiero, A. (2001). Bioethical principles: are they applied in the situation of terminal illness? *Annals of Internal Medicine*, 18, 650–654

Beauchamp, J.F. & Childress, T.L. (1979). Principles of Biomedical Ethics. In Oxford University Press.

Callréus, T. (2013). Pharmacovigilance and public health ethics. *Pharmaceutical Medicine*, 27, 157–64.

Commissioners of and collaborators with the International AIDS Society–Lancet Commission on Health and Human Rights. (2021). Human rights and fair access to COVID-19 vaccines: the International AIDS Society-Lancet Commission on Health and Human Rights. *Lancet*, 24; 397(10284), 1524-1527.

COVID-19 and mandatory vaccination: Ethical considerations. (2022). Retrieved 13 February 2023, from <https://www.who.int/publications-detail-redirect/WHO-2019-nCoV-Policy-brief-Mandatory-vaccination-2022.1>

Field, R.I. & Caplan, A.L. (2012). Evidence-based decision making for vaccines: the need for an ethical foundation. *Vaccine*, 30, 1009-1013.

Inter-American Commission on Human Rights. (2021). Vaccines against COVID-19 within the framework of inter-American human rights obligations. <https://www.oas.org/es/cidh/decisiones/pdf/resolucion-1-21-es.pdf>

International Covenant on Economic, Social and Cultural Rights. (1976). OHCHR. Retrieved 13 February 2023, from <https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights>

Jamrozik, E. & Selgelid, M.J. (2020). COVID-19 human challenge studies: ethical issues. *The Lancet Infectious Diseases*, 20, e-198-203.

Jaspan, H.B., Soka, N.F., Strode, A.E., Mathews, C., Mark, D., Flisher, A.J., Wood, R. & Bekker, L. (2008). Community perspectives on the ethical issues surrounding adolescent HIV vaccine trials in South Africa. *Vaccine*, 26, 5679-5683.

Kruse, M.H., Bednarczyk, R.A. & Evans, D.P. (2020). A human rights approach to understanding provider knowledge and attitudes toward the human papillomavirus vaccine in São Paulo, Brazil. *Papillomavirus Research*, 9, 100197.

Olick, R.S., Shaw, J. & Yang, T. (2021). Ethical issues in mandating COVID-19 vaccination for Health Care Personnel. *Mayo Clinic Proceedings*, 96(12), 2958-2962.

- Ota, M.O.C., Idoko, O.T., Ogundare, E.O. & Afolabi, M.O. (2013). Human immune responses to vaccines in the first year of life: Biological, socio-economic and ethical issues – A viewpoint. *Vaccine*, 31, 2483-2488.
- Taylor, R.M. (2013). Chapter 1 - Ethical principles and concepts in medicine. In *Handbook of Clinical Neurology*, 1–9.
- Thompson, A., Komparic, A. & Smith, M.J. (2014). Ethical considerations in post-market-approval monitoring and regulation of vaccines. *Vaccine*, 32, 7171-7174.
- United Nations. (1948). *Universal Declaration of Human Rights*. United Nations; United Nations. Retrieved 13 February 2023, from <https://www.un.org/en/about-us/universal-declaration-of-human-rights>
- Varkey, B. (2021). Principles of Clinical Ethics and Their Application to Practice. *Medical Principles and Practice*, 30(1), 17–28.
- Varo Baena, A. (2020). Bioethics of vaccinations and public health. *Vaccines*, 21(1), 57-63.
- Williams, J.H. & Dawson, A. (2020). Prioritising access to pandemic influenza vaccine: a review of the ethics literature. *BMC Medical Ethics*, 21(1), 40.
- Zimet, G.D., Silverman, R.D., Bednarczyk, R.A. & English, A. (2021). Adolescent consent for Human Papillomavirus Vaccine: Ethical, legal and practice considerations. *The Journal of Pediatrics*, 213, 24-30.
- Zimmerman, R.K. (2021). Helping patients with ethical concerns about COVID-19 vaccines in light of fetal cell lines used in some COVID-19 vaccines. *Vaccine*, 39, 4242-4244.