MODULE 9:

ETHICS OF MALARIA SURVEILLANCE, MONITORING, AND EVALUATION

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This module describes the ethical principles in research and their applications. It also highlights the historical events that affect ethics in research today.

Module Objectives

By the end of this module, you will be able to:

- Understand the importance of ethics in health research
- Describe key ethical principles in health research
- Apply health research principles to malaria surveillance, monitoring, and evaluation
- Describe the ethical approval process

Defining Ethics

Ethics can be defined as the set of moral principles that govern a person's behavior while conducting a program activity or research. Ethics includes the theoretical study of values and principles and the correct rules of conduct necessary when carrying out research involving human participants.

Importance of Ethics in Research

Ethical considerations in research promote values that are essential to collaborative work, such as trust, accountability, mutual respect, and fairness. They promote the truth by avoiding falsification or distortion of research data to avoid errors. Applying ethical principles to health research also means that no harm should be done to study participants. Participants must voluntarily agree to participate and must know what they are engaging in or what it is about. They must be able to withdraw at any time from the study, and the confidentiality of data collected must be respected.

Historical Events That Informed Research Ethics

Health research did not always apply good ethical practices, as you can see in the following historical events.

Historical Events: The Nazi Medical Experiments 1933–1945

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During the Second World War, Nazi doctors conducted experiments on thousands of concentration camp detainees to help the German military. Inmates were forced to participate without their consent. These Nazi doctors conducted painful and often fatal experiments in defiance of any medical ethics. These experiments included the following:

- Freezing prisoners to find an effective treatment against hypothermia
- Vaccine trials in which scientists tested immunization compounds and serums for the prevention and treatment of contagious diseases on prisoners without any safety precautions
- Bone transplant experiments in which sections of bones and muscles were removed from prisoners without the use of anesthesia and transplanted into different prisoners

Prisoners were forced to participate without their consent, and the experiments often resulted in death or permanent disabilities.

Historical Events: The Tuskegee Syphilis Study 1932–1972


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The Tuskegee syphilis study was a clinical study conducted in Tuskegee, Alabama by American physicians to better understand the natural progression of syphilis. The study enrolled 600 registered African-American men, 399 with syphilis and 201 without syphilis. The participants were informed that the study would last six months, but it actually lasted for 40 years. Researchers did not inform participants that they had syphilis and withheld treatment with penicillin, an effective cure for the disease.

Historical Events: Ethical Code

Unethical health research led to the development of several prominent documents that provide ethical guidance worldwide.

The Nuremberg Code of Medical Ethics was established in 1949, after a series of trials held against German doctors in the Nazi party responsible for experimental and medical atrocities carried out on human beings in concentration camps during World War II. For the first time, this code outlined 10 rules to strictly control experiments and protect human beings. Subsequently, the World Medical Association strengthened these rules by adopting the Helsinki Declaration in 1964. The 1978 Belmont Report, developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, prescribed respect for individual rights, beneficence, and justice as fundamental principles of the ethical conduct of research involving human beings.

Applying Ethical Principles

The Belmont Report informed the basic principles used in health research today (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978), as shown in Figure 30.

Figure 30. The Belmont Report's ethical principles of health research

Respect for persons (Autonomy)	•Protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent
Non-maleficence	•"Do no harm" while maximizing benefits for the research project and minimizing risks to the research subjects
Beneficence	•Moral obligation to act for the benefit of others: maximize benefits, minimize harms
Justice	•Ensuring that reasonable, non-exploitative, and well-considered procedures are administered fairly

Informed Consent

Respect for persons, or autonomy, protects individuals and treats them with courtesy and respect in health research. This requires that program participants be given truthful and complete information about the research and opportunities to ask questions and choose whether to participate. Standards for informed consent should be established ahead of time and explained to the participant. Consent information generally includes research procedures, purpose, potential risks and benefits, treatment and alternative procedures, and a statement offering the participant an opportunity to ask questions. An option to withdraw from the research study should be available at any time. Additional information sometimes includes how subjects are selected and the identity of the organization or researcher.

> "The respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied."
>
> Belmont Report, 1978

The manner and context in which information is conveyed to the participant is as important as the information itself. For example, presenting information too fast or in a disorganized way does not provide the participant with enough time for consideration and questioning, which may affect a subject's ability to make an informed choice. Language and literacy must also be considered. Consent forms must be in a language understood by the participant, or a translator must clearly explain the study objectives and expectations so that the participant fully understands.

Voluntariness requires that the participant be given the opportunity to decline to participate or to withdraw later. This is done free of coercion and undue influence. Coercion is an overt threat of harm to obtain compliance. Undue influence occurs if an excessive reward is offered, or a reward is inappropriate or unwarranted. Inducements, such as monetary or food incentives that would ordinarily be acceptable, may become undue influences if the subject is especially vulnerable.

Risks and Benefits Assessment

This assessment relates to the principle of beneficence. All aspects of research must be justified based on a favorable risk to benefit assessment. Risks and benefits must be communicated to all researchers and participants, with alternatives considered if necessary.

> "The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research."
>
> Belmont Report, 1978

Selection of Subjects

Justice in the selection of subjects requires that researchers exhibit fairness. Potentially beneficial treatment should be offered to all participants equally. Social justice requires distinguishing candidate participants who should or should not participate based on their appropriateness and ability to bear burdens imposed by the research. An example of social justice is establishing an order of preference in the selection of participants, such as adults before children. Excluding participants, such as those who are institutionalized, mentally infirm, or prisoners, may also be a form of social justice.

> "The principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects. Justice is relevant to the selection of subjects of research at two levels: the social and the individual."
>
> Belmont Report, 1978

Ethical Principles in Research Writing

Writing for health research requires an ethical approach. Writing should follow laws and regulations on copyright and ownership and guard confidentiality of individuals. Writing should protect and promote the public good through scientific research, seek truth, and communicate it accurately.

Ethical writing also requires authors to know the harm and consequences that result from plagiarism and misleading authorship, fabrication, and falsification. These include avoiding inappropriate publication practices, such as withholding important data.

In presenting results, writers should be careful not to plagiarize, which is using the published ideas or words of others without giving credit. Writers can avoid plagiarism by using direct quotes in quotation marks or summarizing the idea in a paraphrase. A citation is used to indicate a source after a quotation or paraphrased summary of the idea. A reference is the information that guides a reader to the source, usually in a reference list or footnote.

Ethical Approval Process

Determining whether ethics in research are being or will be upheld in the conduct of a study cannot be left to the individual researcher; therefore, ethical review bodies are established to exercise that moral responsibility. Ethics committees should include at least five people from different backgrounds, including those with scientific, research, and non-scientific qualifications. Diversity in gender, age, ethnicity, and culture must be respected.

An ethics review board considers six fundamental questions when looking at a health research proposal:

- **Scientific approach, methodology, and implementation of the study.** The ethics committee must consider the impact of the methodology on participant safety.
- **Recruitment of participants.** The ethics committee must review the terms and conditions for recruiting research participants.
- **Community considerations.** The study must fit and address a local need or problem and be designed by people who understand the local community. Suggestions from community representatives can be helpful.
- **Care and protection of participants.** The ethics committee should consider the positive and negative consequences of the study on participants and their communities.
- **Informed consent.** The ethics committee must decide whether the procedure for obtaining informed consent and the accompanying forms are adequate. Community representatives can offer a relevant perspective on this topic.
- **Confidentiality issues.** The ethics committee should review the actions taken by the research team to protect the personal data of the participants. In some studies, the greatest risk for participants is the violation of the principle of confidentiality.

Only after these points have been addressed favorably by the researcher will an ethical review board approve the research study and the researchers can begin.

Summary

Ethics are important to protect human rights and quality of life. Health researchers have a moral responsibility to protect program participants from harm. Ethics standards establish values that are essential to collaborative work, such as trust, accountability, mutual respect, and fairness.

Ethics standards are important in health information systems to establish guidance on obtaining informed consent; collecting, aggregating, reporting, processing, and analyzing data; managing data systems and security; and presenting results without fabricating, falsifying, or misrepresenting results. Ethics standards promote accurate data collection, dissemination of truthful results, and avoidance of errors of omission or commission.

Module 9 Assessment

Questions

Correct answers are provided on the next page.

1. Which statement is false? To respect ethics means:

    a. No harm should come to research participants.
    b. Participants should agree to participate and know what the research is about.
    c. Participants must voluntarily agree to participate.
    d. Once agreed, participants can no longer withdraw from the study.
    e. Participant confidentiality must be respected.

2. The consent process contains three elements. They are as follows:

    a. Information, comprehension, voluntariness
    b. Information, obligation, benefit
    c. Explanation, agreement, voluntariness
    d. Comprehension, benefit, accountability

3. What steps must be considered for ethical approval?

    a. Confidentiality and voluntariness
    b. Protecting the autonomy of all people and treating them with courtesy and respect
    c. Beneficence and justice
    d. Scientific approach of the methodology and the implementation of the study, participant recruitment, community considerations, care and protection of participants, informed consent, confidentiality issues

4. *True or false:* In ethics, individual justice allows researchers to offer potentially beneficial research to favorable patients or select undesirable people for risky research.

    a. True
    b. False

Correct Answers

Correct answers are noted in bold.

1. Which statement is false? To respect ethics means:

    d. Once agreed, participants can no longer withdraw from the study.

2. The consent process contains three elements. They are as follows:

    a. Information, comprehension, voluntariness

3. What steps must be considered for ethical approval?

    d. Scientific approach of the methodology and the implementation of the study, participant's recruitment, community considerations, care and protection of participants, informed consent, confidentiality issues

4. **True or false:** In ethics, individual justice allows researchers to offer potentially beneficial research to favorable patients or select undesirable people for risky research.

    b. False

    Individual justice requires fairness in the participant selection process.