Clinical ethics

Clinical ethics is a practical discipline that provides a structured approach to assist health professionals in identifying, analysing and resolving ethical issues that arise in clinical practice.

Ongoing developments in medical technology, particularly at the beginning and end of life, may raise awareness of, or concerns about the ethical dimensions of clinical care. There are also changing social, cultural and public attitudes in Australia towards the professions, including medicine and a growing emphasis on patient choice. Occasionally, health professionals and patients may disagree about values or face choices that challenge their values. It is then that ethical problems may arise.

7 principles of medical ethics:

This approach – focusing on the application of seven mid-level principles to cases **(non-maleficence, beneficence, health maximisation, efficiency, respect for autonomy, justice, proportionality)**

- To appreciate the ethical dimensions of patient care
- To understand ethical principles of medical profession
- To have competence in core ethical behavioral skills (*Obtaining informed consent, assessing decision-making capacity, discussing resuscitation status and use of life-sustaining treatments, advanced care planning, breaking bad news and effective communication*)
- To know the commonly encountered ethical issues in general and in one's specialty
- To have competence in analyzing and resolving ethical problems
- To appreciate cultural diversity and its impact on ethics

Application of principles of ethics in patient care

Beneficence, nonmaleficence	*Clinical assessment*
	Nature of illness (acute, chronic, reversible, terminal)? Goals of treatment?
	Treatment options and probability of success for each option?
	Adverse effects of treatment and does benefit outweigh harm?
	Effects of no medical/surgical treatment?
	If treated, plans for limiting treatment? Stopping treatment?
Respect for autonomy	Patient rights and preferences
	Information given to patient on benefits and risks of treatment? Patient understood the information and gave consent?

	Patent mentally competent? If competent, what are his/her preferences?
	If patient mentally incompetent, are patient's prior preferences known? If preferences unknown, who is the appropriate surrogate?
Beneficence, nonmaleficence, respect for autonomy	Quality of life (QOL)
	Expected QOL with and without treatment?
	Deficits – physical, mental, social – may have after treatment?
	Judging QOL of patient who cannot express himself/herself? Who is the judge?
	Recognition of possible physician bias in judging QOL?
	Rationale to forgo life-sustaining treatment(s)?
Distributive justice	External forces and context
	Conflicts of interests – does physician benefit financially, professionally by ordering tests, prescribing medications, seeking consultations?
	Research or educational considerations that affect clinical decisions, physician orders?
	Conflicts of interests based on religious beliefs? Legal issues?
	Conflicts of interests between organizations (clinics, hospitals), 3rd party payers?
	Public health and safety issues?
	Problems in allocation of scarce resources?

Physicians obligations

- Cure of disease when possible

- Maintenance or improvement of functional status and quality of life (relief of symptoms and suffering)

- Promotion of health and prevention of disease

- Prevention of untimely death

- Education and counseling of patients (condition and prognosis)

- Avoidance of harm to the patient in the course of care

- Providing relief and support near time of death (end-of-life care)

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Health policy

National Health Policy is an initiative by the Central Government to strengthen the health system in India. This initiative moulds various dimensions of health sectors like disease prevention, promotion of good health via cross-sectoral actions, health investment, strengthening human resources, technological advancements and more.

Launched in 2017, the National Health Policy replaces the existing policy previously established in 2002. There are significant changes brought to the policy framework and its objectives.

National Health Policy was launched in 2017 by the Central Government to replace the existing health policy. This policy has introduced four significant goals:

Changing health priorities

This policy aims to tackle the increasing non-communicable and infectious diseases in India.

Growth of the health care industry

National Health Policy plans to strengthen the health care industry by introducing newer and more advanced technologies.

Lower the expenditure

This policy also aims to reduce medical expenses and other health-related costs. They aim to provide superior services to poor and backward communities.

Economic growth

It aims to enhance fiscal capacity by boosting economic growth.

Individuals preparing for the UPSC prelims and IAS exams should know the goals set by this initiative.

The National Health Policy aims to achieve the following goals:

- It aims to offer superior health services to every age group and gender.
- The policy focuses on providing universal access to excellent quality health care services at a reasonable cost.
- Promoting health care orientation in every developmental policy.

- Offering access to better treatment, lowering expenses related to health care services and improving quality.
- It aims to reduce premature mortality from cancer, cardiovascular diseases, chronic respiratory diseases and diabetes by 25% within 2025.
- This policy recognises the importance of sustainable development and time-bound quantitative goals.
- National Health Policy in India improves overall health status through promotive, palliative, and rehabilitative services

Through Various health schemes in india

- Aam Aadmi Bima Yojana.
- Central Government Health Scheme.
- Ayushman Bharat Yojana.
- Universal Health Insurance Scheme.
- Rashtriya Swasthya Bima Yojana.
- Mahatma Jyotiba Phule Jan Arogya Yojana.
- West Bengal Health Scheme.
- Niramaya Health Insurance Scheme.

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Research Ethics

Research ethics involves the application of fundamental ethical principles to research activities which include the design and implementation of research, respect towards society and others, the use of resources and research outputs, scientific misconduct and the regulation of research.

7 principles of ethics in research

NIH Clinical Center researchers published seven main principles to guide the conduct of ethical research:

- Social and clinical value.
- Scientific validity.
- Fair subject selection.
- Favorable risk-benefit ratio.
- Independent review.
- Informed consent.
- Respect for potential and enrolled subjects.

Honesty

Strive for honesty in all scientific communications. Honestly report data, results, methods and procedures, and publication status. Do not fabricate, falsify, or misrepresent data. Do not deceive colleagues, research sponsors, or the public.

Objectivity

Strive to avoid bias in experimental design, data analysis, data interpretation, peer review, personnel decisions, grant writing, expert testimony, and other aspects of research where objectivity is expected or required. Avoid or

minimize bias or self-deception. Disclose personal or financial interests that may affect research.

Integrity

Keep your promises and agreements; act with sincerity; strive for consistency of thought and action.

Carefulness

Avoid careless errors and negligence; carefully and critically examine your own work and the work of your peers. Keep good records of research activities, such as data collection, research design, and correspondence with agencies or journals.

Openness

Share data, results, ideas, tools, resources. Be open to criticism and new ideas.

Transparency

Disclose methods, materials, assumptions, analyses, and other information needed to evaluate your research.

Accountability

Take responsibility for your part in research and be prepared to give an account (i.e. an explanation or justification) of what you did on a research project and why.

Intellectual Property

Honor patents, copyrights, and other forms of intellectual property. Do not use unpublished data, methods, or results without permission. Give proper acknowledgement or credit for all contributions to research. Never plagiarize.

Confidentiality

Protect confidential communications, such as papers or grants submitted for publication, personnel records, trade or military secrets, and patient records.

Responsible Publication

Publish in order to advance research and scholarship, not to advance just your own career. Avoid wasteful and duplicative publication.

Responsible Mentoring

Help to educate, mentor, and advise students. Promote their welfare and allow them to make their own decisions.

Respect for Colleagues

Respect your colleagues and treat them fairly.

Social Responsibility

Strive to promote social good and prevent or mitigate social harms through research, public education, and advocacy.

Non-Discrimination

Avoid discrimination against colleagues or students on the basis of sex, race, ethnicity, or other factors not related to scientific competence and integrity.

Competence

Maintain and improve your own professional competence and expertise through lifelong education and learning; take steps to promote competence in science as a whole.

Legality

Know and obey relevant laws and institutional and governmental policies.

Animal Care

Show proper respect and care for animals when using them in research. Do not conduct unnecessary or poorly designed animal experiments.

Human Subjects protection

When conducting research on human subjects, minimize harms and risks and maximize benefits; respect human dignity, privacy, and autonomy; take special precautions with vulnerable populations; and strive to distribute the benefits and burdens of research fairly.

Animal Research Ethics

These guidelines have been prepared by the National Committee for Research Ethics in Science and Technology (NENT). Their purpose is to provide ethical guidelines for researchers and other people who are considering experiments on animals. The guidelines will be useful when planning projects, assessing them, and when reporting and publishing findings and results. They are also intended to contribute to reflection on research ethics and the use of animals in research in both research communities and in the public debate.

Ethics and Experiments on Animals

The ethical assessments related to the use of animals in research are wide-ranging. It is generally thought that it may be necessary to use laboratory animals in some cases in order to create improvements for people, animals or the environment. At the same time, the general opinion is that animals have a moral status, and that our treatment of them should be subject to ethical considerations. Such views are reflected in the following positions:

(i) Animals have an intrinsic value which must be respected.

(ii) Animals are sentient creatures with the capacity to feel pain, and the interests of animals must therefore be taken into consideration.

(iii) Our treatment of animals, including the use of animals in research, is an expression of our attitudes and influences us as moral actors.

The guidelines reflect all these positions, and stipulate principles and considerations that can be used as tools when balancing between harm and benefit. The three Rs (Replace, Reduce, Refine) are established principles that are also enshrined in legislation. These principles can establish absolute limits for experiments on animals, even when there are great benefits. These principles also state what can reasonably be considered harm and benefit, and the principles thus facilitate good assessments. Assessments of harm and benefit associated with experiments on animals are particularly demanding, because experiments may result in researchers intentionally causing actual harm to animals, while the future benefits are often uncertain.

The guidelines are dynamic and must be reviewed in line with technological developments and the appearance of new ethical issues. New gene technology methods create new opportunities for the use of genetically modified animals in research, which is a growing trend. Genetically modifying laboratory animals, i.e. changing the genetic material of laboratory animals using gene technology, gives rise to a special responsibility in that this method entails a double intervention: first, intervention in the animal's genetic material and second, use of the animal as a research object. This practice has the potential to change our view of humans and our attitudes towards generating or eliminating genetic characteristics in ourselves.

These guidelines provide a framework that also covers ethical questions associated with the use of genetically modified animals in research.

The guidelines cover «laboratory animals», as defined in the Regulations Relating to the Use of Animals in Research, but also cover all animals that are otherwise impacted by research activities.

Guidelines

1. Respect for animals' dignity

Researchers must have respect for animals' worth, regardless of their utility value, and for animals' interests as living, sentient creatures. Researchers must be respectful when choosing their topic and methods, and when disseminating their research. Researchers must provide care that is adapted to the needs of each laboratory animal.

2. Responsibility for considering options (*Replace*)

Researchers are responsible for studying whether there are alternatives to experiments on animals. Alternative options must be prioritised if the same knowledge can be acquired without using laboratory animals. If no good options are available, researchers should consider whether the research can be postponed until alternative methods have been developed. When justifying experiments on animals, researchers therefore must be able to account for the absence of options and the need to acquire knowledge immediately.

3. The principle of proportionality: responsibility for considering and balancing suffering and benefit

Researchers must consider the risk that laboratory animals experience pain and other suffering (see guideline 5) and assess them in relation to the value of the research for

animals, people or the environment. Researchers are responsible for considering whether the experiment may result in improvements for animals, people or the environment. The possible benefits of the study must be considered, substantiated and specified in both the short and the long term. The responsibility also entails an obligation to consider the scientific quality of the experiments and whether the experiments will have relevant scientific benefits.

Suffering can only be caused to animals if this is counterbalanced by a substantial and probable benefit for animals, people or the environment.

There are many different methods for analysing harm and benefit. Research institutions should provide training on suitable models, and researchers are responsible for using such methods of analysis when planning experiments on animals.

4. Responsibility for considering reducing the number of animals (*Reduce*)

Researchers are responsible for considering whether it is possible to reduce the number of animals the experiment plans to use and must only include the number necessary to maintain the scientific quality of the experiments and the relevance of the results. This means, among other things, that researchers must conduct literature studies, consider alternative experiment designs and perform design calculations before beginning experiments.

5. Responsibility for minimising the risk of suffering and improving animal welfare (*Refine*)

Researchers are responsible for assessing the expected effect on laboratory animals. Researchers must minimise the risk of suffering and provide good animal welfare. Suffering includes pain, hunger, thirst, malnutrition, abnormal cold or heat, fear, stress, injury, illness and restrictions on the ability to behave normally/naturally.

A researcher's assessment of what is considered acceptable suffering should be based on the animals that suffer the most. If there are any doubts regarding perceived suffering, consideration of the animals must be the deciding factor.

Researchers must not only consider the direct suffering that may be endured during the experiment itself, but also the risk of suffering before and after the experiment, including trapping, labelling, anaesthetising, breeding, transportation, stabling and euthanising. This means that researchers must also take account of the need for periods of adaptation before and after the experiment.

6. Responsibility for maintaining biological diversity

Researchers are responsible for ensuring that the use of laboratory animals does not endanger biological diversity. This means that researchers must consider

the consequences to the stock and to the ecosystem as a whole. The use of endangered and vulnerable species must be reduced to an absolute minimum. When there is credible, but uncertain, knowledge that the inclusion of animals in research or the use of certain methods may have ethically unacceptable consequences for the stock and the ecosystem as a whole, researchers must observe the precautionary principle.[1]

7. Responsibility when intervening in a habitat

Researchers are responsible for reducing disruption and any impact on the natural behaviour of individual animals, including those that are not direct subjects of research, as well as of populations and their surroundings. Certain research and technology-related projects, like those regarding environmental technology and environmental surveillance, may impact on animals and their living conditions, for example as a result of installing radar masts, antennas or other measurement instruments. In such cases, researchers must seek to observe the principle of proportionality (see guideline 3) and minimise the possible negative impact.

8. Responsibility for openness and sharing of data and material

Researchers are responsible for ensuring that there is transparency about research findings and facilitating the sharing of data and material from experiments on animals. Such transparency and sharing are important in order to avoid unnecessary repetition of experiments. Transparency is also important in order to ensure that the public are informed and is part of researchers' responsibility for dissemination.

In general, the negative results of experiments on animals should be public knowledge. Disclosing negative results may give other researchers information about which experiments are not worth pursuing, shine a light on unfortunate research design, and help reduce the use of animals in research.

9. Requirement of expertise on animals

Researchers and other parties who handle live animals must have adequately updated and documented expertise on animals. This includes specific knowledge about the biology of the animal species in question, and a willingness and ability to take care of animals properly.

10. Requirement of due care

There are national laws and rules and international conventions and agreements regarding the use of laboratory animals, and both researchers and

research managers must comply with these. Any person who plans to use animals in experiments must familiarise themselves with the current rules.

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