

Abstract

The advancement in technology is likely to tame several life forms present on earth. Microorganisms are posing a big challenge due to difficulties encountered to control the diseases caused by them. Working with deadly disease-causing microorganisms for their characterization, diagnostics or therapeutics and vaccine development purposes are posing increasingly potential biosafety problems for laboratory workers. Thus, an appropriate biosafe working environment may protect workers from laboratory-induced infections.

Biotechnology has the ability to solve the upcoming problems of the world's increasing population. However, there is often reluctance among the public to accept and support biotechnological products in medicine, industry, or agriculture. There are many safety and ethical issues raised for GM crops and human cloning. Raising transgenic animals and plants has fueled ethical concerns, and the scientists have faced a lot of resistance where genetically modified crop plants or reproductive cloning research of human beings is involved. Thus, biosafety and bioethics are continuously being expanded to combine the rationale of ever-increasing scientific knowledge in biotechnology that is often in conflict with the long-standing social and moral value system of our society.

24.1 Introduction

The advancement in technology is likely to tame several life forms present on earth. Microorganisms are posing a big challenge due to difficulties encountered to control the diseases caused by them. Working with deadly disease-causing microorganisms for their characterization, diagnostics or therapeutics and vaccine development purposes are posing increasingly

potential biosafety problems for laboratory workers. Thus, an appropriate biosafe working environment may protect workers from laboratory-induced infections.

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raised for GM crops and human cloning. Raising transgenic animals and plants has fueled ethical concerns, and the scientists have faced a lot of resistance where genetically modified crop plants or reproductive cloning research of human beings is involved. Thus, biosafety and bioethics are continuously being expanded to combine the rationale of ever-increasing scientific knowledge in biotechnology that are often in conflict with the long-standing social and moral value system of our society.

However, biotechnological tools have resulted in high-yielding crop plants, more nutritive values of food grains, longer shelf life, and resistance to insects and pests, but the public acceptance to these biotechnological products is rather low. For example, GM foods have low support in Europe and India. With the passing years, there is further decline in public support, probably due to media focus and the visible debates on GM crops for fear of their long-term effects and unknown risks and environmental safety issues. The controversies from nongovernment organizations (NGOs), scientists, and media have led to a negative impact on the GM crops. GM crop usage has been controversial with fears being expressed on *Flavr Savr* tomato and many others. GM food again went into controversy due to labeling issues. The Bt crops were challenged with the development of resistance in insects. So-called terminator technology and a gene use restriction technology (GURT) met with a lot of resistance due to introduction of negative traits of sterility in the seeds and never came to the market.

The development of cloned animals and its impact on other wild-type animals and the environment also triggered many safety and ethical concerns. Whether or not animals should be used in research, their welfare, sufferings, and well-being were debated throughout the world. In India many plants and animals are linked to religious beliefs and are respected and worshipped for their contribution in the life of human beings.

Likewise usage of embryonic stem cells faced controversies and concerns. Protestants agree to have stem cell research under strict public regulations. Many however are opposed to embryonic

stem cell research as it destroys the embryo. The debates and issues surrounding the stem cell are all centered on the potential source of these cells. Embryonic stem cell usage either is prohibited or is under strict public regulation. Somatic stem cells and dedifferentiated somatic cells can be used for therapy.

The public support for xenotransplantation was low due to safety issues with fear of spread of unknown contaminants. However, some xenogeneic tissue-engineered products are now available to treat dermal wounds and burn patients. The usage of biological weapons (use of living organism or its product for human killing) in war is presently banned.

24.2 Biosafety and Biorisk

The biotechnology has tremendously evolved including the technical aspects of medical sciences like diagnostics and therapeutics. With all these, we are also witnessing rapid and dangerous adaptations in microorganisms especially for developing resistance to antibiotics. Microbial pathogens are causative agents of many diseases and due to mutation in their genes, they have developed multiple drug resistance. It is gradually becoming difficult to control these multi-drug-resistant infectious pathogenic microorganisms. To search for solutions to overcome MDR of these pathogenic agents, several scientists and medical workers are handling these pathogens. This poses enormous biohazards and raises serious “biosafety” issues, i.e., scientific practices, methods, and use of appropriate equipment in a biosafe environment.

The biosafety aspects have become very important in various conditions and require many precautions in health-care systems as hospitals, diagnostic laboratories, animal care systems, biological laboratories, and so on. The precautions, which can be taken to reduce or nullify the risk, associated with samples by continuously monitoring and recognizing potential hazards, their risk assessment, and preventive measures to avoid exposure which might result in infection. Individual worker should be appropriately trained

and must understand the conditions like containment (conditions where infectious agent can be safely manipulated) and good laboratory practices which can minimize exposure to pathogens. [4]

Biorisk Risk is the likelihood of the occurrence of an adverse event, thus biorisk is the likelihood of the occurrence of serious infection due to exposure to pathogenic microorganism or bio-hazards. Upon exposure there may be mild to severe infections, allergies, or other clinical problems associated with the pathogen. The biorisk can be managed by risk assessment, effective biosafety measures, and biocontainment.

The first report on laboratory-associated infections was published at the beginning of the twentieth century. However, 4,079 infections associated with laboratory were reported with 168 deaths somewhere between 1930 and 1978. The major pathogenic agents responsible for these infections were *Brucella* spp., *Blastomyces dermatitidis*, *Chlamydia psittaci*, *Coccidioides immitis*, *Coxiella burnetii*, *hepatitis B virus* (HBV), *Salmonella typhi*, *Francisella tularensis*, *Mycobacterium tuberculosis*, and *Venezuelan equine encephalitis virus* [23, 29, 30, 38].

After this 1978 report, many more laboratories associated infections and deaths were reported [31, 32]. In these cases also the infectious agents were *Arboviruses*, *Brucella* spp., *Coxiella burnetii*, *Cryptosporidium* spp., *hantavirus*, *Mycobacterium tuberculosis*, *HBV*, *Salmonella* spp., *Shigella* spp., and *hepatitis C virus*.

24.2.1 Assessment of Risk

The processes used for risk assessment are (1) identification of the hazardous properties of a familiar infectious agent or material, (2) the activities responsible for pathogen exposure to the person, (3) the chances of the exposure becoming a laboratory-associated infection, and (4) the ultimate consequences of infection.

Risk assessment needs very alert judgments. If risks are underestimated, they might result in seri-

ous and adverse consequences. Overestimation of risks can result in undue protective measures, which may be a burden for the laboratory.

Assessment of risk also needs to evaluate the factors responsible for infections i.e., whether it is due to hazardous agents or due to hazards of laboratory procedure, or the working attitude of the laboratory staff. The staff's capability can be improved by appropriate training and inculcating good laboratory practices with training of accidental spillage/inoculations.

24.2.2 Biohazards

Biohazards may be the microbial infectious agent or other biological materials posing a risk for human health, parasites, viruses, prions, or biologically derived toxins, allergens, venoms, or recombinant DNA that can adversely affect human or animal health and environment [24]. The properties of an agent which make it potentially hazardous are [40] (1) infection capability, (2) ability to cause diseases in human or animal host, (3) its minimum infective dose, (4) severity of the disease, (5) availability of vaccine, (6) availability of therapeutic modality to control it, (7) the probable route followed by it for transmission, (8) stability in the environment, and (9) host (animal-human or only human).

The probable routes of pathogen transmission may be:

1. Through exposed part of the body such as the skin, eye, or mucous membrane
2. Through inhalation
3. Through needle or other sharp objects
4. Through accidental ingestion
5. Through bites of mosquito

The World Health Organization (WHO) has recommended the classification based upon the risks and route of transmission of the pathogenic agents in a laboratory environment. According to their disease-causing capacity and preventive measures available, the human pathogenic agents have been divided into four groups (according to WHO and NIH) [44, 45].

Risk groups	Risk group 1	Risk group 2	Risk group 3	Risk group 4
Properties of microorganisms	Microorganisms not causing any disease	Disease-causing microorganisms	Virulent strains	Highly virulent strain
	No history of diseases in healthy adult human, e.g., nonpathogenic <i>E. coli</i>	Low pathogenesis	The pathogen causes severe disease	Causes serious disease which may be lethal
		Disease is not very serious	The disease is aggressive	Difficult to manage by therapeutic intervention
		Preventive measures are present, e.g., measles and mumps virus	Therapeutic intervention is feasible	Vaccine not available
		The worker is at high individual risk, e.g., hepatitis B	The pathogen poses high individual and community risk, e.g., <i>Ebola</i> virus	
Pathogenicity and infectivity	It poses minimal individual or community risk	Minimal individual and community risk	High individual risk	It poses high individual and community risk
	Microorganism does not cause disease in humans and animals	Is capable of causing disease without serious symptoms	Pathogen capable of causing serious infection in humans or animals	Highly contagious infection
Sometimes may lead to serious infection but manageable by treatment		Causes serious infection in humans and animals		
Preventability and treatment	Preventive and therapeutic measures available but usually not required	Preventive measures available	Effective therapeutic interventions available	Effective therapeutic interventions not available
		Spread of infection is limited	Preventive measures available	Effective preventive measures not available
Biosafety levels requirement	BSL-1	BSL-2	BSL-3/BSL-4	Always using BSL-4

24.2.3 Laboratory Biosafety

National biosafety guidelines came into being because of efforts of microbiological and biomedical communities. These involved the recognition of hazards, assessment of risk, and appropriate use of measures including biocontainment to prevent hazards. They promoted safe laboratory practices and usage of safety equipments along with occupational health programs to reduce laboratory-induced infections while

handling microorganisms [5, 6]. Preventive measures also require personal protective equipment like gloves, mask, eye protection, laboratory coat, shoe covers, and respiratory protective measures for prevention of exposure.

The biosafety level (BSL) indicates the kinds of precautions of biocontainment for handling dangerous microbial pathogens. The BSL-1 indicates lowest safety measures while BSL-4 indicates highest possible safety measures.

The containment of laboratory refers to:

- Primary and secondary physical containment barriers
- Contained dressing and shower rooms
- Sealed service penetrations
- Specialized doors and entry and exit avenues to prevent cross-contamination
- Specialized air handling systems for contamination control
- Personal protective equipment
- Biosafety cabinets

Current biosafety and biocontainment practices and procedures are designed to reduce the exposure of laboratory personnel, the public, agriculture, and the environment to potentially hazardous biological agents [2].

Biosafety levels (BSL) are laboratory designations, which are based upon the degree of risk. They are designated as BSL-1, BSL-2, BSL-3, and BSL-4. These safety levels ensure different levels of protection when working with virulent microbial strain. These laboratories are very sophisticated and have very good design, engineering control, and safe work practices.

Their different levels are used depending upon the pathogen properties like vaccine preventability, infectivity and its contagious nature, severity of the diseases, and risk assessment in case of infection. Every level of containment has its own safety aspects:

Biosafety level 1 (BSL-1) in this open bench work can be done in basic teaching or research laboratory. Work involves using chemicals and agents, which do not cause any disease in humans as *E. coli* (nonpathogenic strains) and yeast. This facility may not have biosafety hood.

Biosafety level 2 (BSL-2) it can handle moderate-risk microorganisms responsible for infection and pose risk for infection via percutaneous or mucous membrane exposure. In these laboratories provisions for biosafety cabinets are present for containment of aerosols. Protective clothing and biohazard sign is required. The diagnostic and research laboratories are equipped with all these facilities for handling pathogens like *mumps virus*; *hepatitis A, B, and C virus*; *measles virus*; and *Salmonella*.

Biosafety level 3 (BSL-3) is used for agents with known risk of aerosol transmission and causing serious and potentially lethal infections. They may be indigenous or exotic in origin. These are special research or diagnostic laboratories and have biosafety cabinets and other facilities for safe handling, special clothings, controlled access, and maintained directional airflow. The organisms handled in BSL-3 are *Leishmania donovani*, *Mycobacterium tuberculosis*, *SARS coronavirus*, *Yersinia pestis* (plague), *West Nile virus* (encephalitis), and *Rickettsia rickettsii* (Rocky Mountain spotted fever).

Biosafety level 4 (BSL-4) is required for high-risk exotic agents which pose risk of life-threatening diseases. Their transmission may be through infectious aerosols. The lack of effective treatment against the diseases caused by these pathogens restricts them to be handled only in high containment laboratories. These laboratories handle dangerous pathogen, have highly advanced biosafety cabinets and positive pressure suits, and have double-ended autoclave, filtered air facility. The laboratories have airlock entry and shower exit with special waste disposal mechanisms. The laboratory is safe to work with *Ebola virus* and *Variola virus* (smallpox agent).

24.2.4 High and Maximum Containment

Any kind of activity that includes usage of potential hazardous human pathogens, zoonotic agents (rabies virus, influenza virus, Trypanosomes (sleeping sickness)), toxins, and agricultural threats which may pose danger to human civilization is recommended for use only in high biosafety levels. The various biosafety levels appropriate for these works are biosafety levels 3 and 4, animal facility/vivarium (ABSL-3 and ABSL-4), and biosafety level 3 agricultural facilities (BSL-3-Ag). High containment refers to the highest level of biosafety. Good biosafety and biocontainment practices can help in effective laboratory biosecurity.

24.2.5 The Importance of Biocontainment Laboratories

There is an urgent requirement to provide adequate safety for all life forms in case of natural emergency. Natural emergency can be the outbreak of any disease or other conditions requiring attention due to attempt for spreading bioterrorism. Thus federally funded research programs are being developed to protect all life forms.

In the measures the products were designed and developed which can protect public health, are called medical countermeasures. These include public health and hygiene, diagnostics, vaccines, therapeutics, and development of biosafety level laboratories.

For the purpose of biosafety, the general laboratory workers (students, scientists, and laboratory staff), along with non-laboratory workers as electricians, plumbers, and sweepers, should also be given appropriate training. The trainings are required in the areas of:

- Usage of microbiological techniques
- Safe use of biosafety cabinets
- Medical and laboratory waste management
- Blood/human samples/tissue handling
- Recombinant DNA technology with viruses or bacterial vectors or working with animal or plant systems [5]

Thus briefly biosafety requires:

- Effective policies for biosafety, biocontainment, and biosecurity.
- Appropriate risk identification, assessment, and continuous monitoring for minimal chances of exposure.
- Training all those working in the laboratory regarding safety, responsibilities, handling in accidental situations, and reporting of concerns.
- Both workers and management should work with full cooperation and critically perform self-review.

24.3 Biotechnology and Bioethics

Every scientific revolution brings with it a host of ethical and social questions. The so-called genetics revolution is no exception, giving rise to a broad international debate on how the undoubted benefits of progress in this area can be reconciled with certain core human values. (UNESCO 2002a: 1)

Present-day biotechnology opens many opportunities in research and development, addressing medical issues and new ways to explore things; improving human health conditions, fight food, and feed problems; and so on. It has greatly influenced medicine and agriculture. It has tremendously affected the thinking process also like consuming vegetables and fruits without pesticides, using biofertilizer in place of chemical fertilizer, using renewable sources of energy, and switching to products which are biodegradable. It has also advocated the sustainability of systems (agricultural, environmental), knowledge sharing, and brought many products in the market. As the techniques involved gene manipulations in many life forms (plants, animals, microbes), thus with these advancements came the concerns in the form of ethical issues giving rise to bioethics.

In our routine life also, we encounter ethical questions in terms of right or wrong or ethical or unethical; thus, in science also things are judged as being ethical or unethical. Bioethics addresses policy and ethical issues arising by researches and products targeted for human applications. Bioethics addresses the ethical issues in all the streams of life sciences like health care, genetics, and medical research by applying the principles of morality and philosophy [37]. Bioethics has evolved from medical ethics and moral philosophy. The ethical concerns for patient well-being were in use in the form of the Hippocratic Oath.

It starts right from the laboratory to industry and government and affects a very wider society. The study of the social and moral responses arising due to scientific invention or experimentation is “bioethics.” Thus it led to granting of ethical clearance for any proposed research projects requiring animal or human experimenta-

tions. The project is first reviewed by research/institutional ethics committee (REC/IEC). The REC evaluates the risks, benefits, animal sufferings, utility of work and then only grants approval for conducting research projects and proposals.

Nuremberg Code (1947) This code surfaced in the response of human rights abuses that had taken place under the Nazis during World War II. The war captives were subjected to abuses through experiments on human subjects. This propounded the use of informed consent and non-maleficence, beneficence, justice, and autonomy. These provided normative framework used by researchers and medical practitioners.

Some Important Ethical Terms

- *Morality*: It is a system of moral values and conduct, which govern our decision of right and wrong or good and bad.
- *Empathy*: The ability of one to understand and share the feelings of the other.
- *Euthanasia*: It refers to painless killing of any terminally ill patient suffering from painful and incurable disease on demand of the patient and the court. Removing all life support system from a patient in irreversible coma is also termed as euthanasia.
- *Autonomy* is freedom from external control or influences, independence.
- *Justice*: It is the treatment or behavior, which is genuine, right, or just according to the prevailing laws.
- *Equality*: State of being at par or equal in status or ideology or opportunities.
- *Beneficence*: It is related to kindness, good, or charity for good.
- *Non-maleficence*: An act done to avoid harm or any act which would not harm or violate the trust of others. In the case of physicians, it is their act which will not harm the patient.
- *Accountability*: The condition where somebody is held responsible, answerable, or accountable for an act.

24.3.1 Analyzing Ethical Issues

The ethical principles consist of certain virtues such as autonomy, non-maleficence, beneficence, and justice. Now the area has gained so much of momentum that before even small experimental work, one needs to justify its rightness or wrongness. Analyzing the ethical issues before starting any new experimental work [11] would depend upon the assessment of these points:

- *Consequences*: What would be effect of this experiment? Who is going to be benefited? What would be harms associated with this work? Thus weighing the possible outcomes and their effects.
- *Rights and responsibilities*: Are we exploiting somebody else's rights? Do those rights need protection? Who would protect these? These are questions whose justification would have to be weighted.
- *Autonomy*: If one feels it is right, should things move on? Or else someone feels it is wrong, should things stop? Alternatively, who would decide things should be or should not be? These questions would again need to be addressed.
- *Virtue ethics*: Is this the best thing to do? What is good about it?
- *Animal Rights*: One big question is "Are we authorized to use animals the way we want?" Knowing that they too can think, they are aware of family members, they feel pain (at different levels), and they are alive.

Animals like primates and whales resembling human brain features, family behavior, and some sensitivity like humans should not be manipulated but others should be, why?

Animals have been in use since long. They are used for manipulation of their genes, as model system for study of human diseases, and as transgenics for production of pharmaceuticals. Is inflicting pain in any form, which may be by creating a disease model or studying mutations in animals, ethical or not?

24.3.2 Ethics and Ethical Theories

- *Environmental Ethics*: For everything we are dependent on the environment. The environment and ecosystem are very nicely balanced. Thus what would be the effect on the ecosystem once genetically modified organisms are introduced? What would be the effect on biodiversity?
- *Religious ethics*: In this the religious commands are being followed. It involves obeying divine commands and wills.
- *Medical Ethics*: One of the oldest bioethics is medical ethics, which is in practice since its introduction as the Hippocratic Oath (500BC). The Hippocratic Oath is concerned about the behavior and relation of physicians with the patient, practicing non-maleficence and beneficence; however, medical ethics is not limited to the Hippocratic Oath [10].
- *Philosophical Ethics*: In this before executing any decision, it requires evaluation of reasoning and facts for ethical questions. Thus, all ethical decisions are taken upon evaluation of rational and logical questioning:
 - It tries to come up with theories explaining viewpoints.
 - Provides guidance to decision making
 - Solves conflicts of ethical decisions.
 - Ethical theories help in guiding ethical questions.

Philosophical ethics can be divided into descriptive ethics and normative ethics.

24.3.2.1 Descriptive Philosophical Ethics

It explains the actual moral viewpoints of the people; thus, it gives an accurate estimation of people's ethics. Opinion polls or questionnaire evaluation are used to build a consensus of the view of the people. However, these are not affected by facts and reasons so they may be right or wrong [17, 20, 21].

24.3.2.2 Normative Philosophical Ethics

It explains the viewpoint, which people should have, and accordingly the actions, which people

should undertake (according to what ought to be). It questions people ethics and guides us in difficult situations about what should be done [3, 37].

Some of the important ethical theories are discussed:

1. *Ethical egoism*: This theory states that morality is mere fulfilling our self-interest. It criticizes the views associated with morality that are in the way of personal self-interest. It advocates that the actions are entirely dependent on desire and self-interest of the people.
2. *Utilitarianism (or Consequentialism)*: British philosopher Jeremy Bentham (1748–1832) developed the utilitarian theory which was later refined by John Stuart Mill (1806–1872). This theory advocates the selection of moral action, which in its consequence brings greatest happiness for the large number of people. It works to decide the result or consequences of good action, which would maximize happiness. Thus it deals with consequences of action, in that happiness is judged because of some decision. However, greatest good for an individual or society, human race, or animals is debated. Their supporters say that the theory aims to do good for the human race as a whole including nonhuman animals. For example, terminally ill patients should be allowed for physician-assisted mercy killing to avoid pain and sufferings. Utilitarians also believe that abortion and infanticide may be possible in case the baby has severe disability. Research on human embryo and genetic enhancement, which can benefit humans, may be made possible.
3. *Deontology (Kantian ethics)*: This theory, which states that morality arises from inner sense of duty, was influenced by the German philosopher Immanuel Kant (1724–1804). According to this all people have rights and duties and they should follow these. It states that the decision should come from inner sense of duty without considering the consequences of action. Thus according to Kant any act that follows categorical imperative is moral. Kantian theory requires the use of morality based on rationality with respect to persons and human dignity. Kantian views

refrain from hiding the truth from patients who have terminal cancer. Kant's categorical imperative—"Act in such a way that you treat humanity, whether in your own person or in the person of any other, never merely as a means to an end, but always at the same time as an end" (Kant 1785/1968) [19]. It has been used to avoid abuses in research experiments on human subjects.

This theory has been propounded and supported by a number of philosophers [1].

Main features of his theory are as follows:

- (a) *Respect*: Dignity of each and every human being should be respected, and one person should not use the other person as a means to fulfill one's own desire.
- (b) *Universality*: If something ethically right is applicable to us as an individual, then it applies to others also, making it a universal right. It should be respected and followed by everyone.
- (c) *The formula of ends*: Rational agents should be treated as ends.

Virtue Ethics There are certain ethical virtues and any decision or action is considered morally correct when taken considering the virtues. These promote flourishing and well-being. Thus, any action with a right motive based upon good character or virtue is considered morally right, for example, an action where treatment of a patient is sponsored to gain publicity and honor. The action is right but morally it is not good.

Jansen (2000) had highlighted ethical issues with virtue ethics: (1) problem of content, vague virtues are unable to give proper guidance, and (2) problem of pluralism, competing conceptions of the good life complicate a sound solution.

Feminist Bioethics The social and political background of feminist bioethics is feminism and feminist theory with its major social and political goal to end the oppression of women and to empower them to become an equal gender.

24.4 Ethical Issues in Transgenic Animal Production

The use of transgenic animals has sparked significant controversy in many areas. Some groups see the generation of genetically modified organisms as interfering with natural biological states or processes. They feel that these natural biological states have evolved over long periods which should not be altered. A few other groups are concerned with the limitation of modern science to fully comprehend the potential negative ramifications and unforeseen possible effects of genetic manipulation.

Despite the importance of transgenic animals in biomedical research, there are some concerns raised about their use in research. Transgenic animals suffer more abnormalities than regular research animals. The introduction of DNA into an animal can be very complex and the possible side effects can be difficult to predict. Possible harm might arise from surgical techniques used to harvest and reimplant embryos, the collection of tissue from the tip of the tail for genotyping, and nonspecific effects caused by damage to genes adjoining the altered area. In addition, reduced fertility and/or oversize fetuses may result from this technology. In most cases the mutations highly affect specific metabolic processes or cell receptors without actually resulting in disease but causing discomfort, pain, or malfunctioning in the animals.

Transgenic animals not expressing foreign DNA or not containing a particular gene modification are destroyed. Because transgenesis is a complex science, it is not 100% efficient. However, new methods are being developed to increase the accuracy in transgenesis. Again, it should be remembered that such genetic alteration could only be attempted if the authorities are persuaded that there is no other way to pursue important research. The potential risks of transgenics to animals, humans, and the environment are too great to justify their use. The Genetic Modification of Organisms regulations and the Environmental Protection Act (1990) address the risks to those working with animals and the impact on the environment of accidental or planned releases.

The intrinsic worth of animals may be devalued and their integrity violated by genetic modification. Transgenic animals have not chosen to have foreign DNA or other genetic modifications. However, this potential “cost” to the animals is routinely assessed under the ethical review of proposed procedures and weighed against the potential benefits. Medical researchers only employ this technology when no alternative research avenue exists but with appropriate breeding facility of animals. As the Royal Society concluded in its 2001 Report “The Use of Genetically Modified Animals”, the use of transgenic animals is fundamentally little different from the use of other animals in biomedical research.

However, the technology has opened new frontiers in biomedical applications and has provided new opportunities for exploring the organization, biological pathway, regulation, and pathological function of molecular processes.

Contractarianism: It says that the animals are important as many people feel their importance. Humanity is the virtue of morality. Thus, humans have obligations toward other animals.

Utilitarianism: It says that as animals can also suffer; thus, they are morally relevant. It chooses the action, which aims to give happiness to all. Thus, its goal is to maximize the total sum of happiness in the world and is impartial, that is, the pain and happiness of everyone count.

Animal activists view: According to these whatever is the motif there is no justification of harming animals for human purposes.

Ruthless view: This has no concern about animals, whichever way they are being used.

However, principles governing animal rights are the 3Rs, which mean *replace*, *reduce*, and *refine*. It involves ethical and humane approach while using animals. The alternatives of animals in the research were also explored. The 3Rs are replacement of conscious living animals with nonsentient animals or materials, reduction of the number of animals used in an experiment or

procedure, and refinement of the techniques used in order to decrease the incidence or amount of animal pain and distress [34].

24.5 Genetically Modified Crops and Bioethics

Genetically modified crops or GM crops have given new dimensions to agriculture. With the advancements in the technology, the agricultural productivity is increased, the food’s nutritive value is enhanced, the requirement of pesticides and insecticides is greatly reduced, and pharmaceutical substances (vaccines) are being produced in the plants.

However, GM foods have become the target of public concern due to unknown and unseen fears of their effects on the ecosystem and risks to human health. The GM foods are also not labeled leading to distrust and fear in the customers regarding the safety of food.

24.5.1 Genetically Modified Organisms and Environment

The ethical issues raised are:

- What about evolution?
- Each living being has evolved to grow in one condition, and if we put human gene or fish’s gene in a plant or animal, what would be its effects?
- What would happen if the gene can find an escape route to introduce itself in other members of that species or other species?
- What would happen if the herbicide resistance gene could transfer itself in weeds, generating superweeds?
- If we have all GM crops of any grain or pulses, then occurrence of any disaster would lead to complete loss of the crop, as there is no biodiversity where one is sensitive and the other one is resistant. This would lead to disaster and damage of whole of the crop.

- Would the monogenetic crops, if not able to react appropriately to environmental stress, again face a situation like “Ireland’s potato famine”?
- What if GM crops breed with other crops, would the biodiversity be lost?
- What are their risks to other animals like birds, insects, and other higher animals (like monarch butterfly and Bt crops)?

24.5.1.1 Genetically Modified Organisms and Human Health

- There is tremendous fear of GMOs on human health.
- If the GM can induce allergy due to insertion of unrelated gene what would happen, because GM foods are not labeled. For example, a Brazil nut gene was transferred to a soybean variety; this nut gene product was a source of allergy for many individuals. As GM products are not labeled, therefore, the consumers may consume soybean without being aware of nut gene product in them. This might lead to allergy causing major allergic reactions in the consumers. *However resultant modified crop was never released to the public.*
- Human food supply may have GM products as evidenced by the settlement between Syngenta and the US government over the accidental sale of unapproved GM (Bt10) corn seed to farmers.

24.5.1.2 Economic and Societal Issues

- These seeds can only be afforded by big farmers and landowners, thus negatively affecting small-scale farmers.
- The farmers need to buy seeds every year, as they cannot collect, store, and replant these seeds.
- There would be huge differences in the farming practices in one country only, and that gap would be widened much between developed and developing nations [17].
- As GM food is not labeled, thus, public trust and acceptance of GM food would be a big challenge.

24.5.1.3 Advantages of Genetically Modified Crops

- The GM crops have higher productivity as they are resistant to pests; thus, loss due to diseases is prevented.
- They are engineered to survive in high salt and frost, thus utilizing the land, which was unused for agricultural purposes.
- They also help to reduce contaminants as insecticides and pesticides, thus preventing their entry in soil, water, and organic matter.
- All these effects would ultimately affect the environment and consumers.
- Biotechnology can fulfill the increasing requirements of food, with maximum utilization of land.
- Biotechnology can help reduce the environmental contaminants as insecticides and pesticides preventing their entry in food chain.
- It can help maintain clean environment.
- It can enhance nutritive values of the food, for example, golden rice can help prevent blindness due to nutritional deficiency of vitamin A.
- The longer shelf life of fruits and vegetables can decrease their wastage and increase their availability with simple storage conditions.
- The genes for allergens can also be engineered so that the allergens can be effectively removed from the food crops.
- Thus they are beneficial for humans and animals.
- It can also eliminate trans fats, producing healthier foods.
- Nowadays, plants are also being explored and used for production of biopharmaceuticals like vaccines, ScFv, antibodies, and so on. There is reduced risk of adverse reactions in terms of animal pathogen transmission, and the protein undergoes posttranslational modifications.

These genetically modified varieties faced tremendous resistance in Europe and India. Their public acceptance has also met with resistance in terms of fears, controversies, and acceptance. The controversy from NGOs, media, and scientists

has led to tremendous negative impacts on the GM crops. The environmental council of the European Union further augmented the controversy by halting regulatory approval of GM crops.

The ethical issues and safety issues in GM crops can be addressed by evaluating their safety and other benefits and risks. The risks associated with humans, animals, and plants should be well considered along with the intention to do good. The consideration of well-being of all (humans, animals, plants, and environment) is very important for the sustainability of life, along with moving forward with positive aspects of technology. The ultimate aim of the technology should be improvement and sustainability in the future of all life forms with minimal adverse effects on our surroundings and other plants and animals.

Concerns

The experiments being done to create transgenics have left the people with many concerns regarding the health and life. The changes which unnatural gene transfer might be doing to the environment and the society? There have been concerns regarding the transfer of animal genes into plants (for vegetarians) and food animals. This has raised not only safety issues but also ethical issues:

1. Impact of breeding of these transgenic animals and plants on other plants and animals when they breed in their natural environment.
2. Potential health hazards which we can face after consumption of GMOs.
3. Risk of transmission or emergence of potential pathogens post gene manipulation or xenotransplantation.
4. Changes in the environment and ecology by unnatural gene transfer and crossing of species boundary.

(continued)

5. Aren't we imparting sufferings for the plants and animals by using these tools and technology on them?
6. Rights about the well-being of other plants and animals.

Thus, there is a requirement of well-defined guidelines when using gene manipulations [39] as well as labeling of the products produced by gene transfer technologies. There is no doubt that apart from genetically modified plants and animals, the gene manipulation techniques are well accepted in production of recombinant pharmaceuticals for production of life-saving drugs. The technique has enormous potential for solving food problems and sustainable agricultural practices and preventing and treating diseases.

There are many concerns regarding reproductive cloning of humans. Thus, the concerns should be there whether the technology is being used for what is worth or we simply want to see the extremes of what technology can do.

Each achievement of science has both negative and positive aspects; nuclear power when used judiciously can help us solve energy problems but can also result in disaster like what happened in Hiroshima and Nagasaki during World War II. The gene manipulation technology is with tremendous potential but should be used just for benefit of mankind, the environment, and animals.

24.6 Bioethics and Reproductive Technology

Assisted reproductive technology (ART) techniques are used in the case of male or female infertility. The technique is detailed in Chap. 15. The process of ART involves ovulation, artificial

insemination, in vitro fertilization, and implantation. It may also involve preimplantation genetic diagnosis, gestational surrogacy, gamete donation, and sex selection.

Bioethical issues are important as they are directly related to society:

- The technology enables children to be conceived by couples who have fertility defects, thus it came up as a very good medical intervention for childless couples.
- However it enables children to be conceived who do not have any genetic relationship with either one or both of their parents (using donor sperm or ovum).
- Though preimplantation genetic diagnosis is recommended for medical reasons, it can be misused.
- The male and female homosexual couples, single men, single women, or postmenopausal women would seek the assistance of assisted reproductive technologies.
- As the mother and father would not have child–parent relationship, who would be responsible for the child and his welfare? The child too have right to be with biological father and mother.
- In conditions where both donor sperms and ovum are used for having the child, what would be the legal rights of the child?
- This technology if not judiciously used could create scattered and torn families and disconnect genetic, gestational, and social child–parent relationship.
- What would be done with excess IVF embryos, would they be treated like human embryos or model embryos available for experimentations?

Although many people are in favor of IVF and surrogacy, a survey shows that people are against posthumous sperm procurement or reproductive cloning. The technology is surrounded by many issues of creation and destruction of embryos [13, 33]. Bioethical issues are for seeking justice, non-maleficence, and beneficence of all involved in any issue. Adequate ethical guidelines and moral evaluations of new

technologies are essential so that laws can be framed for national regulations and restrictions of unacceptable practices [12].

24.7 Stem Cells and Bioethics

Stem cells for use as therapy have given new dimensions to medicine. Due to capacity of these cells to differentiate into almost all different kinds of cells, they are being looked as potential alternative for the cure of many diseases.

Probably sometime in the future, scientists would be able to generate whole organs by stem cells and tissue engineering to fulfill the increasing demand for organs.

Depending upon their potency and differentiation capabilities, they can be:

- **Adult stem cells:** These are present in each tissue of the human body, where they help in replenishing cells for regular wear and tear of the cells.
- **Embryonic stem cells** are located in the human embryo at the blastocyst stage (5–6 days of age). Leftover embryos at this age are often unwanted in assisted reproductive technology, and some parents can donate them for research. In many countries very strict laws are there for their usage. Some of the nations recommend their use when no other option is available.
- **Cord blood stem cells** are derived from the umbilical cord, which is often still routinely discarded at birth.

The ethical issues raised for stem cell research is the usage and destruction of human embryos for obtaining embryonic stem cell [14]. As the life begins with the embryo, thus destruction of life is immoral; therefore, its usage and the extraction of embryonic stem cells are unethical.

However, using adult stem cells or umbilical cord blood stem cells has been considered ethically superior alternative to the use of embryonic stem cells. Their rejection and uncontrolled growth would be big challenges to fully explore their therapeutic potential.

24.8 Human Cloning and Bioethics

Human cloning is a very controversial issue [22, 43] to discuss and its cloning can be “reproductive” cloning and “therapeutic” or “research” cloning. Though both the terms are not scientifically accurate, they are widely used. In somatic cell nuclear transfer (SCNT), the nucleus from the somatic cell is transferred into the enucleated egg. The resulting embryo can either be implanted into a mother or surrogate mother for development (the cloned sheep Dolly was the outcome of SCNT) or the embryo can be used for research purposes [7]. Implantation of embryo for gestation is referred as reproductive cloning, whereas in therapeutic cloning embryo is harvested for embryonic stem cells [16]. The stem cells obtained from embryo are embryonic stem cells, which can be induced to form different cells [8, 25].

- People and scientific community in favor of human cloning say that it can combat infertility and very useful for therapeutic purposes.
- Many people are against the creation and usage of embryo for research purposes; some are concerned about the risks like ovarian hyperstimulation syndrome in egg donors.
- Many more object to the destruction of embryos as they represent the initial phase of human life thus considered morally equivalent to humans; therefore, they consider therapeutic cloning at par to reproductive cloning.
- Human reproductive cloning is unacceptable and unethical for many scientists and philosophers [9]. Most of the countries have banned all kinds of human cloning.
- In the Universal Declaration on the Human Genome and Human Rights (UDHGHR) by UNESCO in 1997, it says that the “Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted.”
- The resolution in this line was also passed by the WHO saying that human reproductive cloning is against human dignity and urged member states to prohibit it. Likewise The Council of Europe’s Additional Protocol to

the Convention on Human Rights and Biomedicine (1998), The Charter of Fundamental Rights of the European Union (2000) prohibits the reproductive cloning of human beings (Article 3).

- The potential and the power of the technology require caution when we ourselves are the objects of biotechnology [35].

24.9 Impact of Biotechnology on Society: Future Prospects

Biotechnology has had a tremendous impact on human race [26]. The technology has potential to change what humans are [28]. Humans may come up as transhumans. Transhumanism is the international movement which is aimed to transform humans by the use of technology to augment brain function and enhance human intellect, physical potential, and psychological capabilities [27]. Their goal is to extend human life, enhance the brain and its capacities, delay aging, and improve physical conditions (so-called superhumans). Attempting technological augmentation on the normal human function [17, 36] can take us far away from our own species to “superhuman” function. Thus, technological interventions can shift us from what we called as *Homo sapiens* to “superhuman” *Homo sapiens technologicus*—a species that uses, fuses, and integrates technology to enhance its own function [46, 47].

We are living in the best of times as exhibited by the fast-paced economic growth of many countries around the world. Various initiatives that were taken in the fields of molecular biology, genetics, and recombinant DNA technology are beginning to show fruits, strengthening the basis of research.

The technological advances have made our life easier. The problems encountered in the form of ethical dilemma need appropriate attention with a view of the interests of society. Our ultimate aim should be to generate thorough knowledge on all aspects of modern biology and garner excellence in the making of an economically, socially, and morally sustainable society [18].

24.10 Chapter End Summary

- Biotechnology has made tremendous progress in providing therapeutics, new ways to diagnose diseases, regenerative medicines, food and feed solutions, food with nutritive values, and other countless achievements.
- Biosafety is a very important aspect as the health-care and laboratory workers are continuously exposed to highly contagious and infectious pathogenic agents. They work with these agents either for the purposes of diagnostics or research.
- Many laboratory-induced infections were reported among the workers and several of them were serious and resulted in death of workers. These laboratory-induced infections were due to organisms in biorisk-3 and biorisk-4 groups.
- Thus, it becomes very important to do appropriate risk assessment, monitoring, and installation of appropriate preventive measure like biosafety levels and biocontainment facility and training to the laboratory workers for prevention.
- Bioethical issues are there with all the major achievements of biotechnology. The issues were being raised because of rightness or wrongness of the experiment, to ensure experiments are conducted in a way that it ensures safety for all, the humans, animals, and the environment.
- Bioethical issues related with genetically modified crops are related to development of resistance in insect-resistant crops and their impact on the environment, animals, and humans. Many ethical issues were raised for genetically modified animals and their sufferings.
- Embryonic stem cell therapy and assisted reproductive technologies along with genetically modified crops faced too much of ethical discussions and resistance. Human reproductive cloning created tremendous furor; thus, human cloning in all forms was banned in most of the countries.
- As with any other technological advancements, each technology is faced with ethical

and social issues and so is biotechnology. However, it is important that before we keep on proceeding, we should ask some basic questions to ourselves: (1) Why am I doing this? (2) Would it be beneficial for anyone? (3) Would this disturb the well-being of other animals, humans, or the environment?

- Ultimately technological achievements are to create and garner a society with the well-being of all life forms in harmony with nature.

Multiple Choice Questions

1. Which of the following techniques is facing bioethical issues?
 - (a) DNA microarray
 - (b) Fluorescence activated cell sorter
 - (c) Embryonic stem cell therapy
 - (d) All of the above
2. The concerns raised with GM foods are:
 - (a) Development of resistance in insects due to insect-resistant crops
 - (b) Appropriate labeling of GM foods
 - (c) Their interaction with wild-type varieties may lead to problems
 - (d) All of the above
3. Biosafety aspects are:
 - (a) Assessment of risk while working with pathogenic agent
 - (b) Killing the disease-causing microorganism
 - (c) Genetically engineering pathogens to reduce their virulence
 - (d) None of the above
4. Laboratory-associated infections may be due to:
 - (a) *Candida albicans*
 - (b) *Escherichia coli*
 - (c) *Brucella* spp.
 - (d) *Entamoeba histolytica*
5. The microorganism classified in risk group four would be:
 - (a) Vaccine preventable
 - (b) Preventable with medicines
 - (c) Both of the above
 - (d) None of the above

6. Which of the following procedures is commonly used for the production of embryonic stem cells?
- Recombinant DNA technology
 - Reproductive cloning
 - Therapeutic cloning
 - In situ hybridization
7. Bioweapons may be:
- Avirulent bacteria
 - Cauliflower mosaic virus
 - Toxins derived from pathogens
 - All of the above
8. The code established for human rights protection in biomedical research after World War II was:
- Nuremberg code
 - UNO code
 - Hippocrates code
 - UNICEF code
9. Which of the following terms is not a part of the three R's of animal ethics?
- Replacement
 - Rejuvenation
 - Reduction
 - Refinement
10. The technique of somatic cell nuclear transfer involves:
- Nuclei from ovum in an enucleated somatic cell
 - Nuclei from somatic cell in enucleated ovum
 - Nuclei from zygote in an enucleated ovum
 - All of the above
11. Transhumans are:
- Humans born by the process of in vitro fertilization
 - Usage of humans as bioweapons
 - Usage to technology to improve human overall capabilities
 - All of the above
12. An example of euthanasia is:
- Understand others feeling
 - Removing life support from brain dead patient
 - Independence to express oneself
 - All of these
13. Beneficence is:
- Related to genuine behavior
 - Related to kindness
 - Related to accountability
 - All of the above
14. Non-maleficence is:
- An act to retain confidence
 - An act to avoid harm
 - An act to gain trust
 - All of the above

Answers

1. (c); 2. (d); 3. (a); 4. (c); 5. (d); 6. (c); 7. (c); 8. (a); 9. (b); 10. (b); 11. (c); 12. (b); 13. (b); 14. (d)

Review Questions

- Q1. What is the importance of bioethics?
 Q2. Why is biosafety important?
 Q3. What do you understand about risk groups?
 Q4. What is biocontainment?
 Q5. What are biosafety levels?
 Q6. Why did Nuremberg code come into being?
 Q7. What are ethical issues related with GMOs?
 Q8. What is transhuman? Do you think human cloning should be allowed or should not be allowed? Justify.

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Some Related Resources

Adapted from the MMWR 2011; 60 (Suppl): Guidelines for Biosafety Laboratory Competence

European Union, Charter of Fundamental Human Rights 2000

<http://biotechlearn.org.nz/themes/bioethics>

<http://www.beep.ac.uk/content/424.0.html>

<http://www.bioethics.org.au/Resources>