

MERGED PPTS OF BT605

VU Medical Zone

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BIOSAFETY & BIOETHICS

LESSONS (1 – 166 FULL) FOR



Bioethics



Lesson # 1

3/1/2018

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Science, Ethics and Values

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Science, Ethics and Values



Science:

- Latin term “**Scio**”
- observation and theoretical form
- observation and experiment

Science, Ethics and Values



Science:

- investigation of the universe by a **set of methodologies**
- progress made by scientific methods
- **Step-wise, not a single activity, not a value free**

Science, Ethics and Values



Ethics:

- associated with **science**
- issues arises from scientific research
- Scientists are trying to do so

Science, Ethics and Values



Values:

- Science has entered in to our **daily lives**
- Proper resource allocation
- Reflects what society at the time deems to be valuable

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Lesson # 2

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Attitudes to Science

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Attitudes to Science



Attitudes:

- Nietzsche “**God is dead**”
- Wittgenstein “scientific terms---interpreted in social context”
- contribution to the economy growth

Attitudes to Science



Post modernism:

- results are not experimentally built—**socially constructed**
- science and technology are as central as ever
- science is not done by robots

Attitudes to Science



Understand the public:

- define science, think about **research and policies**
- Impact on the public/ explore as a subject or career.
- scientific institutions--- public confidence

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Lesson # 3

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What is Ethics?

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What is Ethics?

Ethics:

- systematic, defend, recommend **concepts**
- about feelings, setting priorities in human behavior
- best in particular circumstances

What is Ethics?

Religion:

- set high ethical **standards**
- intense motivation for ethical behavior
- has to do with religious beliefs but not confined to religion

What is Ethics?

Types of Ethics:

- Meta ethics-----
theoretical meaning
- normative ethics-----
practical meaning
- applied ethics--domain
of action

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The development of Ethics

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The development of Ethics

Ancient Greece:

- Plato “everything has its own form”
- Aristotle---function
- happiness is about expressing a virtue

The development of Ethics

Jewish/Christian thinking:

- God had spoken through his ten **commandments**
- codes of conduct
- follow the life of Jesus Christ

The development of Ethics

Natural Law:

- Thomas broke -----
Aristotle idea
- function of every part
of the human body
- basis of catholic
ethical teaching

The development of Ethics



Consequentialism:

- modern science—
Newton/ Galileo
- Consequences of the action
- Example: Saddam Hussein

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The growth of bioethics

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The growth of bioethics



Origin of notion of bioethics:

- Potter **“Bioethics, the survival of science”**
- Callahan’s **“Bioethics as a discipline”**
- Kennedy institute of Ethics

The growth of bioethics

Origin of academic discipline and institutionalization:

- goes **hand in hand**
- Informed consent
- follow the criteria all over the world

The growth of bioethics



Origin of bioethics a Phenomenon:

- idea of protecting **environment**
- virtue of public concern
- development of new technologies

The growth of bioethics



Factors:

- advances in **biomedical science**
- environmental concern
- animal ethics

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Bioethics in 21st Century

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Bioethics in 21 century



Health care:

- technology/research/education/administration/communication
- couples can make their own decisions
- organizational and global bioethics

Bioethics in 21 century



Principles:

- autonomy
- nonmaleficence and beneficance
- Justice ----- example

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Making ethical decisions

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Making ethical decisions

decisions:

- long and complex **history**
- ethics is about decisions and making choices
- our daily conversation has an ethical component

Making ethical decisions

Virtue ethics:

- What is most **virtuous**?
- expression of the individuals than keeping the rules
- we become virtuous by practising virtue

Making ethical decisions

Virtue ethics:

- What is most **virtuous**?
- expression of the individuals than keeping the rules
- we become virtuous by practising virtue

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Place of humans in nature

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Place of humans in nature



Human beings:

- humans occupy a unique **position**
- brain power--- aspects of nature
- make extensive use of natural resources
- every element of nature is not in human control

Place of humans in nature



Developed societies:

- humans are the part of **natural order**
- moral relationship between humans and natural environment
- misuse of nature for our needs

Place of humans in nature



Debate:

- anthropocentrism—
approach **centered to
human beings**
- rest of the nature is
being there for the
good of humans
- Human greediness-
ecological footprints-
massive alteration in
nature balance

Place of humans in nature

Ecocentrism:

- Centered--**ecosystem**
- Includes soil, water, air, forest, mountains
- biotic components are dependent on non-living
- Human ill treatment---altering nature—threatening for humans

The place of humans in nature



Ecocentrism:

- humans are responsible for all **biological life**
- ability of thinking and perceiving world as a whole
- Rolston---ecosystem is much more than the sum of its parts

The place of humans in nature



biocentrism:

- centered--**biosphere**
- humans are one of many millions of species
- doesn't prevent humans--using natural resources if other living organisms doesn't matter--**consequentialism**

The place of humans in nature



Theocentrism:

- God centered approach to the **world**
- Comes from the religious faith---God is a creator
- Environment— belongs to God

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Valuing the environment

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Valuing the environment

Environment:

- natural world except humans
- Over-exploitation of nature is increasing
- economist have attempted to value such resources

Valuing the environment

Decision making:

- Keeping in view the environmental challenges
- Value environment for decision making
- Air/water quality, green house gas, protect biodiversity, maintain ecosystem, marine env

Valuing the environment

Ken Henry said:

- “we have made a start, much more needs to be done, if we are able to say that the wellbeing of future generation is not threatened by poor valuation of environment”

Valuing the environment

Ken Henry said:

- “we have made a start, much more needs to be done, if we are able to say that the wellbeing of future generation is not threatened by poor valuation of environment”

Valuing the environment

Intrinsic value:

- value that environment and living forms have their **own rights**
- intrinsic value of birds/green and pleasant places have their own values
- mainly involves religion

Valuing the environment

Instrumental value:

- Supply of human's material **needs**
- Actual and potential use in supplying resources for human living
- debate

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Themes in environmental ethics

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Themes in environmental ethics



Population load:

- human population has put and putting lots of load----- environment
- pressure on the natural resources---humans to live
- activity of humans can damage the environment

Themes in environmental ethics

Rio Declaration:

- **Two current themes in environmental ethics (1992)**
- **precautionary principle**
- **sustainability**

Themes in environmental ethics

Precautionary principle:

- Old concept---applied to different areas
- Deontological
- Consequentialist ethical thinking

Themes in environmental ethics

Precautionary principle:

- Old concept---applied to different areas
- Deontological
- Consequentialist ethical thinking

Themes in environmental ethics

Sustainability:

- Activity should be conducted repeatedly without accumulating environmental damage
- Agriculture has no lasting affect on the environment
- Local/large level

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Lesson # 11

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Current issues in environmental ethics

Current issues in environmental ethics

Current issues:

- Human-environment interaction/increase in human population
- Bioaccumulation--biomagnification
- Ozone depletion
- Acid rain
- Green house gases

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Lesson # 12

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Terrestrial and aquatic pollution

Terrestrial and aquatic pollution



Reasons:

- Use of certain chemicals
- Unregulated disposal on land
- Industrial byproducts
- Poisoning metals

Terrestrial and aquatic pollution

Silent spring:

- **Rachel Carson—silent spring**
- **First one to introduce the chemical-pollution**
- **Agri-chemncials have accumulated in our food chain**
- **Environment protection laws are very weak**

Terrestrial and aquatic pollution

Ozone depletion:

- Chemical reaction in the atmosphere----- aerosols
- Aerosol sprays are used in refrigerator as a coolant
- Destroy ozone layer

Terrestrial and aquatic pollution

Accidents:

- Major oil spillages
- Spread of radioactive isotopes
- Accidents-- generation of electricity from nuclear energy

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Global climate change

Global climate change

Factors increasing atmospheric CO₂:

- industrial **revolution**
- burning of fossil fuels
- burning of wood
- CO₂ is a greenhouse gas
- trapped infrared rays from the sun

Global climate change

Global warming:

- earth climate zone is **shifting**
- Polar ice start melting
- Sea level increases
- metabolic rate of methane producing bacteria increases
- Species may extinct

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Environmental degradation and loss of biodiversity

Env degradation and loss of biodiversity

Human activity:

- Transformation of forests in to lands
- Pollution affect the ecosystem-loss of biodiversity
- Tropical rain forest-climax ecosystem

Env degradation and loss of biodiversity

Clearance of tropical forest:

- Use of wood
- Need of a land
- We are losing 7 million hectares per year
- Soil is degrading without trees

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Lesson # 15

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Ethics of animal research

Ethics of animal research



Animals for research:

- 26 million animals-----
research
- vital role in scientific and medical advances
- animals--- used in ethical framework

Ethics of animal research



UK-cost benefit analysis:

- **analysis of procedure and experiments**
- **number and type of animals used**
- **must be weighed against the potential benefits of the project.**

Ethics of animal research



Animal welfare:

- application for project licenses
- standards of animal care and welfare
- accept the use of animals in medical research

Ethics of animal research



Benefits of animal research:

- **benefits of animal research is enormous**
- **good experiments reduce the number of animals**
- **reduce the pain experienced by animals**

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Lesson # 16

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**Animals as
recreation**

Animals as recreation

Use of animals:

- animals in sports, companionship, leisure and **fashion**
- race horses-peak fitness
- injuries in sports—save horses for breeding

Animals as recreation

Companion-animals:

- **pets—status of friends and children**
- **too much pampered-form of cruelty**
- **breeds-people aesthetics satisfaction**
- **difficulty in breathing/giving birth naturally**

Animals as recreation

Use of animal fur:

- luxury item for clothing
- issues- animal welfare and conservation
- leopard and jaguar are protected
- Mink breed for fur

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Lesson # 17

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**Animals for food
and draughting**

Animals for food and draughting

Draft animals:

- **beast of burden**
- **trained to perform task**
- **perform light harness work**
- **become a part of rural development-agriculture**

Animals for food and draughting

Slaughter:

- Muslims and Jewish—
cut the neck without
stunning
- electricity is a cruel
method
- industrial method

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Lesson # 18

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**Code of ethics
for biologist**

Code of ethics for biologist



codes:

- scientists--perform experiment --described in their **experiments**
- best interpretation
- summarize honestly
- acknowledge the contributors for publications

Code of ethics for biologist



codes:

- **treat manuscript confidentially**
- **no inaccurate or misleading information**
- **disclose financial resources**
- **help colleagues/ support professional organization**

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**Patient-
physician
relationship**

Patient-physician relationship



Fundamental elements:

- patient has a right to receive **information**
- patient has a right to make decisions
- patient has a right to confidentiality
- Continuity-- availability of health care

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Lesson # 20

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**Codes for
nurses**

Codes for nurses

Codes:

- nurses and **people**
- nurses and practice
- nurses and profession
- nurses and co-workers

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Lesson # 21

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**Patient
rights/responsibilities**

Patient rights/responsibilities



Responsibilities:

- give correct/complete **information**
- ask questions
- cooperate with your caregivers
- accept health consequences

Patient rights/responsibilities



Rights:

- **respect and privacy**
- **quality care**
- **information and communication**
- **make decisions**

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Lesson # 22

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Truth telling

Truth telling



Bad news:

- common **cold**
- unpleasant information
- objective bad news
- subjective bad news

Truth telling

Breaking bad news:

- amount of bad news to deliver
- attending to cultural and ethical issues
- managing psychological distress
- producing competent messengers of bad news

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Lesson # 23

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**Inform
ed
consent**

Informed consent

Consent???

- legal and ethical right of the **patient**
- permission before getting the healthcare

Informed consent



Elements:

- Nature of decision-
patient is participating
in decision making
- Relative risk/benefits
- Assessment of patient
understanding
- Acceptance of
intervention by the
patient

Informed consent



Adequate information:

- Reasonable physician standard- decide that which information is adequate
- Reasonable patient standard—complete information—decision
- Subjective standard

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Lesson # 24

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**Patients
advance
directives**

Patients advance directives

Advance directives:

- appoint someone to make **decisions**
- legal document-tell physician about your wishes
- general (donation) or detailed (treatment plan)

Patients advance directives



Types:

- **living will-applies to treatment such as dialysis –limited**
- **oral**
- **terminal illness—if patient die shortly**

Patients advance directives



Types:

- health care power of attorney
- durable power of attorney
- agent/proxy
- agent make decisions

Patients advance directives

Patient self determination act:

- encourages everyone to decide
- hospital medical care
- extended medical care

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Lesson # 25

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Management of information

Management of information

Personal health information:

- identifying information about an individual in an oral or **recorded form**
- relates-physical and mental health status
- provided health care

Management of information

Personal health information:

- long term care act
- relates to payments or eligibility for health care
- relates to the donation of any body part
- identify substitute decision maker

Management of information



Principles:

- **physicians act in accordance legally and professionally**
- **establish and preserve physician patient relationship**
- **High standard of patient care----patient give complete and accurate information**

Management of information

Disclosure of information:

- request of patient and decision maker's consent
- required by the law
- “lock box” patient restricted physician from disclosing
- Infectious diseases

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Lesson # 26

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**Problems of
moral
justification**

Problems of moral justification

Moral theory:

- provide an account of truth and falsity of **moral judgments**
- provide an account of justification for moral views
- solution to a problem is to be convincing

Problems of moral justification

Moral disputes:

- **conflicting attitudes**
- **incompatible actions**
- **resolve attitudinal differences**
- **bring about more unified behavior**

Problems of moral justification

Views:

- **moral facts are epistemically accessible to normal, intelligent people, such individuals make progress towards finding out**

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Lesson # 27

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Maternal-fetal relationship

Maternal-fetal relationship



Biologically linked people:

- physicians take pregnant women as two individuals who are **biologically linked**
- most mothers accept the risk to their own health
- refuses-----medical therapy for saving fetal life----ethical issues

Maternal-fetal relationship



Maternal-fetal conflict:

- advances in medical technology—direct procedures towards the fetus
- physicians—medically best for each individual
- unethical—harming one individual to benefit other

Maternal-fetal relationship



US Law:

- fetus has the right—
begin his life with
sound body and mind
- charges of fetal abuse
- refusal of
hospitalization,
intrauterine
transfusion or surgical
delivery

Maternal-fetal relationship

School of thoughts:

- **Obstetricians should refrain from performing procedures that are unwanted by pregnant woman**

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Lesson # 28

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**Refusal of
treatment**

Refusal of treatment



Refusal:

- patient has a right to **decline treatment**
- unethical to force the patient
- patient must understand the consequences of refusal

Refusal of treatment

Types of treatment:

- **Antibiotics even with little side-effects**
- **Blood transfusion with minimal risk involved**
- **Vulnerable disease**

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Lesson # 29

Bioethics



**Ethics and
genetic
modification**

Ethics and genetic modification



Genetic modification:

- any alteration of **genetic material**
- capable of producing new substances
- performing new functions

Ethics and genetic modification



Gene editing:

- DNA is inserted, replaced or removed
- genetically modified human embryo
- modify the gene responsible for beta-thalassaemia

Ethics and genetic modification



Transgenic:

- potatoes with high protein/Rice with high vitamin A level
- Mule
- DNA of human tumor fragment is inserted into the tobacco plant
- Flu vaccine

Ethics and genetic modification



Favr Savr tomato (1994):

- **genetically modified tomato**
- **no alien gene**
- **block the gene involved in ripening**
- **longer shelf life**

Ethics and genetic modification



Ethical issues:

- potential risk to the environment
- potential risk to human health
- socio-economic effects

Ethics and genetic modification



Ethical issues:

- entities have the rights and protections
- personal, social and cultural consequences
- fundamental issues in creating new individuals

Bioethics



Lesson # 30

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Biotechnology and risk factors

Biotechnology and risk factors



Areas of risk:

- human health
- biodiversity
- animal welfare
- poor communities

Biotechnology and risk factors



Assessment of risk:

- source of DNA of the target gene/non-target DNA segment of the construct
- site of incorporation of the transgene within the recipient genome
- product of the transgene

Biotechnology and risk factors

Assessment of risk:

- pleiotropic effects----- transgene
- possible molecular changes----- transgene product
- tissue specificity --- transgenic expression
- transgenics/interacting with the environment

Biotechnology and risk factors



Human health:

- 98% dietary DNA is degraded by enzymes
- use of viruses as vectors increases the risk cancer induction
- major risk lie in the use of novel proteins
- transgenic DNA into the genomes of resident gut microflora

Biotechnology and risk factors

Biodiversity:

- **extent of aquatic diversity is extremely large**
- **no difference between biodiversity risk from the escape of GMO and the fish improved genetically**
- **GMOs-----from the set of environmental circumstances**

Biotechnology and risk factors

Animal welfare:

- changes in coloration, cranial deformities, acromegaly, infertility
- reduced viability
- nutritional levels can be improved

Biotechnology and risk factors



Poor communities:

- increasing protective attitudes
- genes need to be patented to enjoy its commercial value
- regulatory arrangements for the culture, release and dietary utilization of GMOs

Biotechnology and risk factors



Hallerman:


- “as a generality among developed countries at least, the public will support biotechnology if it yields a healthful product in an environmentally sound manner”

Bioethics



Lesson # 31

Bioethics

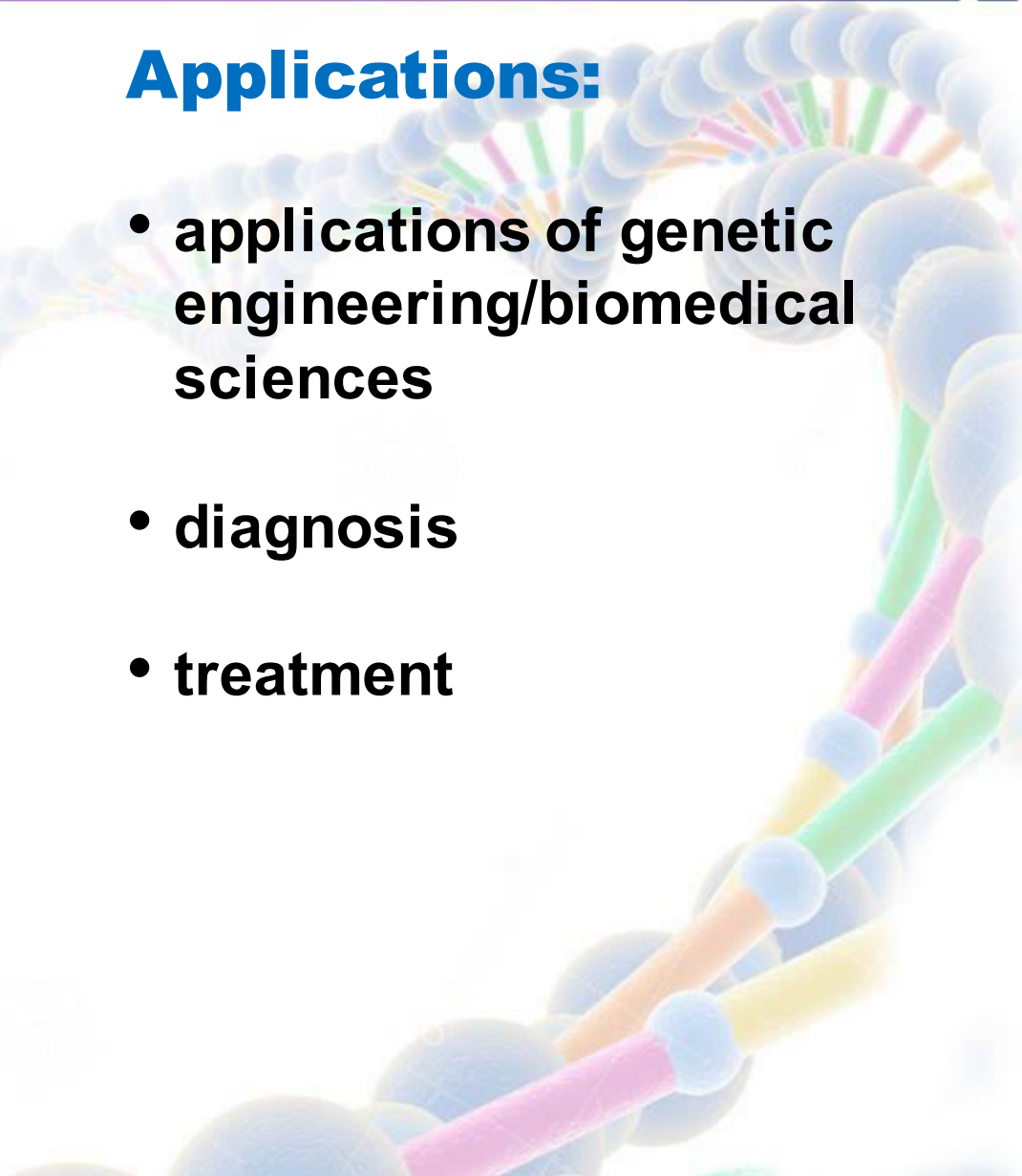


**Misuse of
biotechnology**

Misuse of biotechnology

Applications:

- applications of genetic engineering/biomedical sciences
- diagnosis
- treatment



Misuse of biotechnology



Diagnosis:

- 99% homology between human genes and the mouse genome
- gene function is not necessarily identical
- prenatal/postnatal diagnosis/cancer studies

Misuse of biotechnology



Treatment:

- humans are too frequently aspire to God like power and wisdom—if used wisely
- gene therapy of X-linked SCID
- cystic fibrosis

Misuse of biotechnology



misuse:

- **reality of war**
- **inequitable distribution of resources**
- **frequent misuse of science act as constant reminder that our actions do not always live up to our aspirations**

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Lesson # 32

Bioethics



Nanotechnology

Nanotechnology



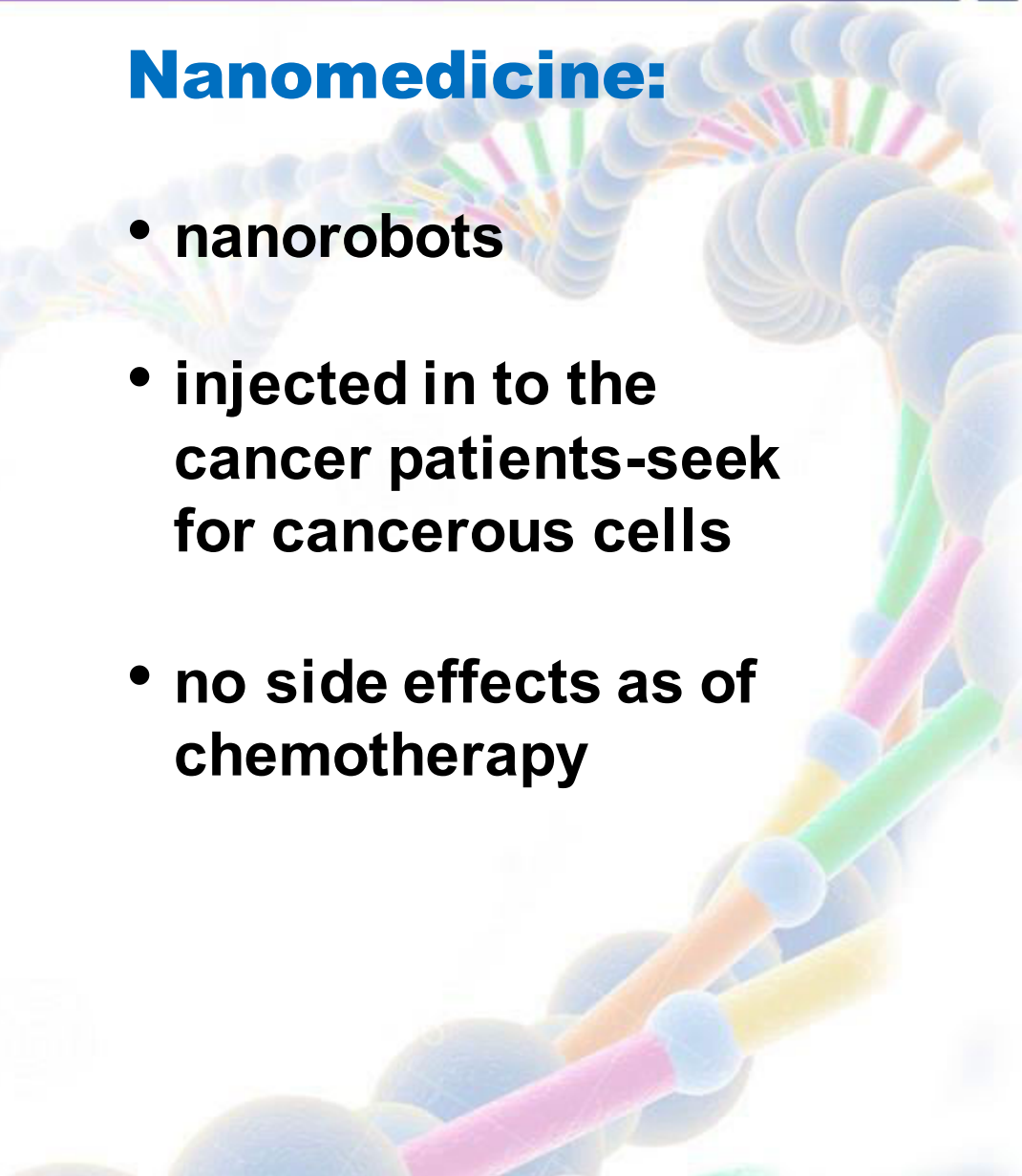
Applications:

- nanotechnology bridges areas in physics, biology and chemistry
- use-nanoparticles/nanochips
- nanomedicine/nanobio technology/bionanotechnology

Nanotechnology

Nanomedicine:

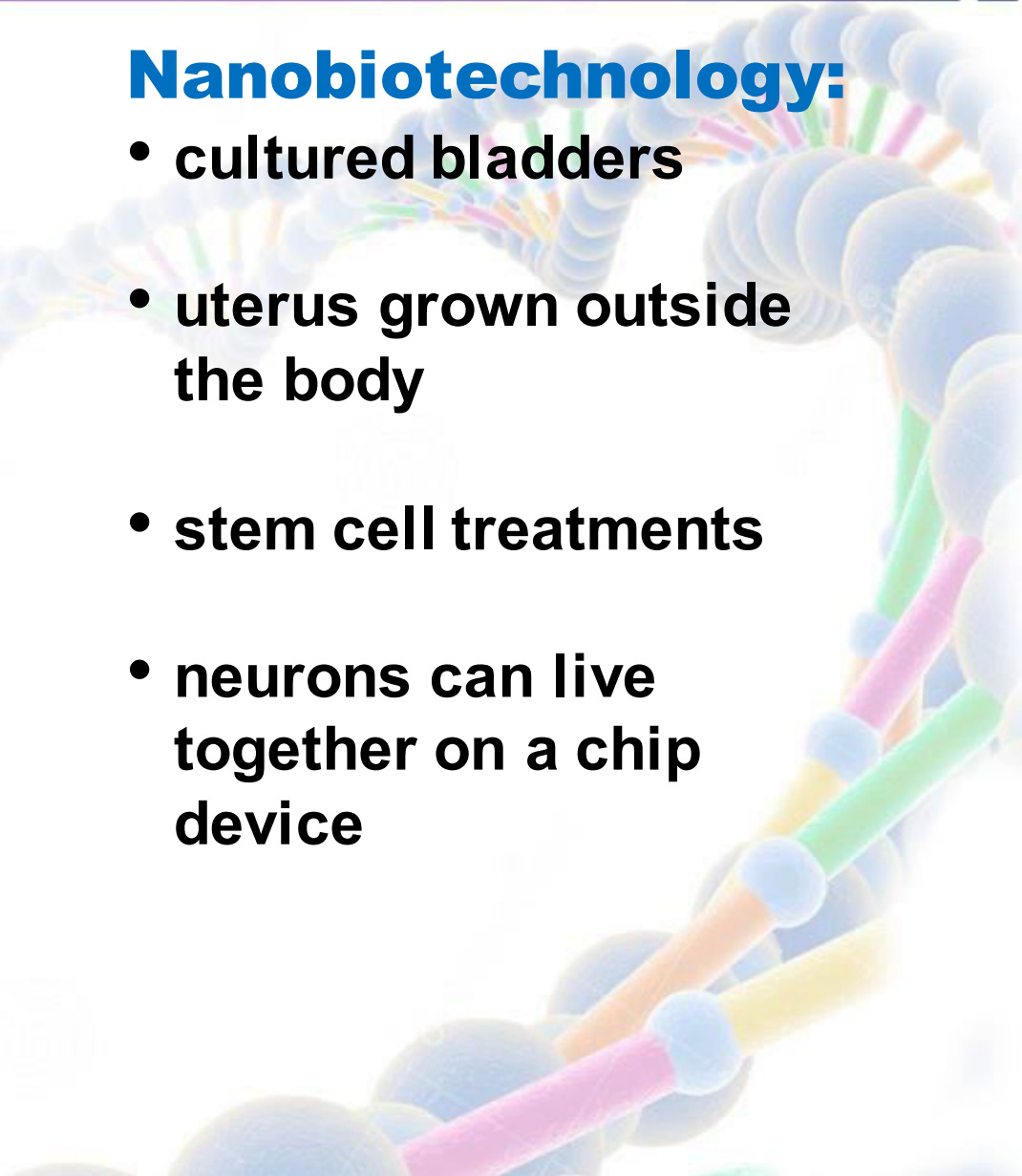
- nanorobots
- injected in to the cancer patients-**seek for cancerous cells**
- **no side effects as of chemotherapy**



Nanotechnology

Nanobiotechnology:

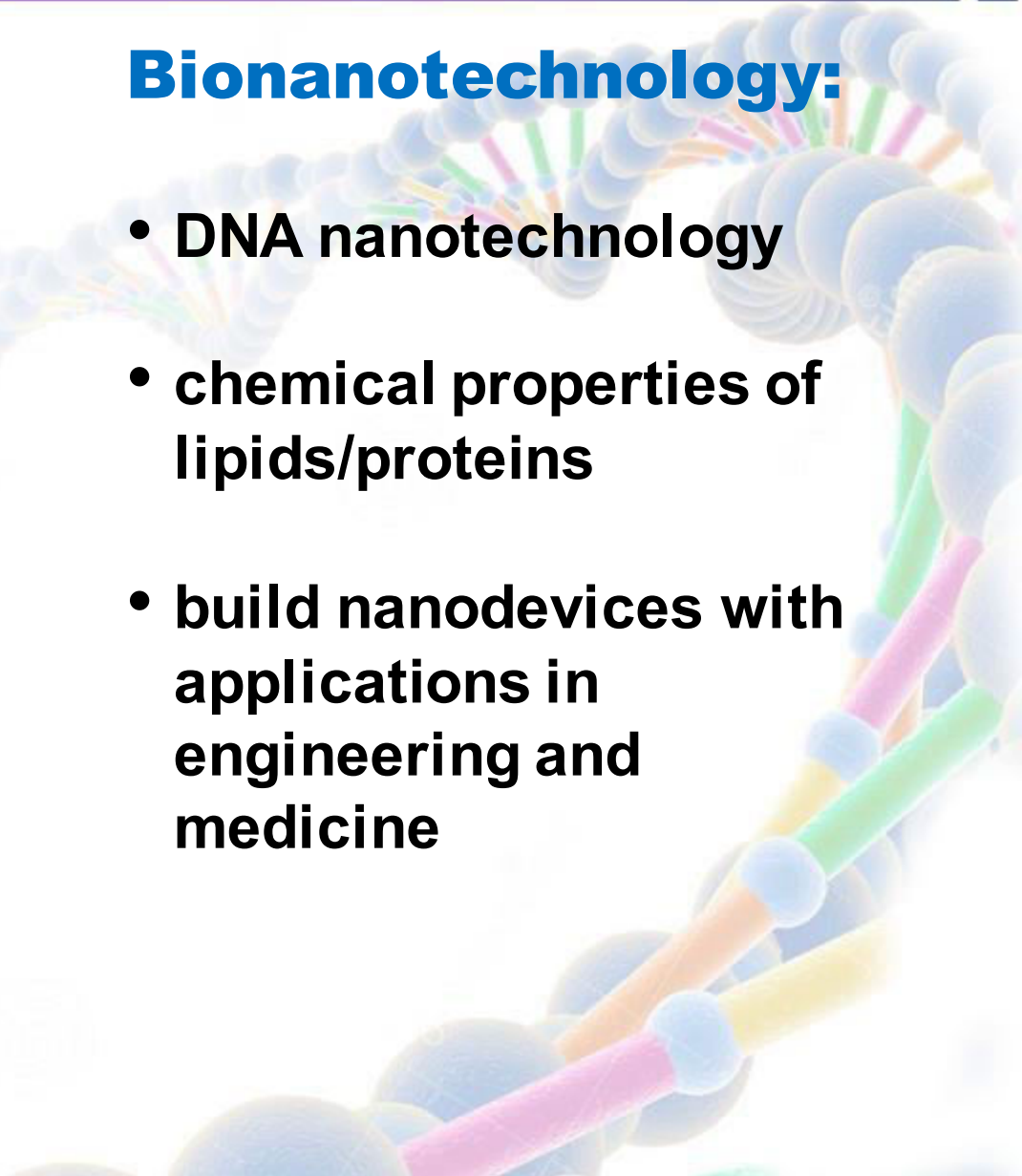
- cultured bladders
- uterus grown outside the body
- stem cell treatments
- neurons can live together on a chip device



Nanotechnology

Bionanotechnology:

- DNA nanotechnology
- chemical properties of lipids/proteins
- build nanodevices with applications in engineering and medicine



Nanotechnology



Ethical issues:

- **high reactivity and toxicity**
- **distribution in the environment**
- **ability to cross cell membranes and translocate in the body**
- **economic effects/privacy issues**

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Lesson # 33

Bioethics



Cybernetic s

Cybernetics



Definition:

- exploring regulatory system, their structures, functions
- Greek word “governance”
- study of interactions between man, machine and animals

Cybernetics



Latest biomedical research:

- **create “Superhumans”**
- **transform the way we practice medicine, transmit thoughts and communicate with one another**

Cybernetics



Software:

- to read signals from the nervous system
- to record
- condition the data for retransmission

Cybernetics

Applications:

- replacing limbs instead of wooden limbs
- heart pacemakers
- artificial retinas
- silicon chip function like nerves-replace lost neuronal function
- university ID card-chip

Cybernetics

Ethical issues:

- machines are in charge of key human functions
- wealthy ones can communicate through cybernetics
- implant are safe to use

Cybernetics



Ethical issues:

- **senses and impulses – transmitted in a harmful way**
- **can the senses be patented**
- **who regulates?**

Bioethics



Lesson # 34

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Applications of biotechnology

Applications of biotechnology

Applications:

- health and medicine
- environmental use
- food and agriculture



Applications of biotechnology



Health and medicine:

- vaccinology
- diagnosis/gene therapy
- genetically modified embryos
- xenotransplants
- designer babies

Applications of biotechnology

Environmental use:

- oil spills-bioremediation
- pollution free environment
- remove algae
- use of fertilizers

Applications of biotechnology



Food and agriculture

:

- improved rice/potatoes/tomatoes
- pharmacrops
- improved sheep and cow milk

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Lesson # 35

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Ethical issues of GM food

Ethical issues of GM food



Ethical issues:

- **extrinsic concerns-**
how people view life,
nature
- **loss of biodiversity**
- **unfair to small farmers**
- **chances of transferring
antibiotic resistant
genes to bacteria**

Ethical issues of GM food



Ethical issues:

- gene flow and health issues
- intrinsic concerns- religion their personal emotions and values
- disrupts the beauty, integrity, balance of nature and might harm life

Bioethics



Lesson # 36

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Risk factors of GM food

Risk factors of GM food

Risk factors:

- **create superbugs and superweeds**
- **kill bees and butterflies**
- **cross-pollination contaminate regular crops**
- **illegal to grow GM plant accidentally**

Risk factors of GM food

Risk factors:

- **harm biodiversity**
- **distract from healthy environmentally friendly technologies**
- **door between the government and biotechnology**

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Lesson # 37

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**Ethics and
animal
biotechnology**

Ethics and animal biotechnology

Reasons:

- to identify, isolate and characterize genes---- understand more about their function and regulation
- research models of human diseases
- to provide organs and tissues

Ethics and animal biotechnology

Reasons:

- to produce milk with therapeutic proteins or with improve nutritional values
- to enhance livestock improvement programs

Ethics and animal biotechnology

Why animals?

- Why not plants or microbes
- closer biochemical similarity to humans
- large amount of products

Ethics and animal biotechnology

Nuclear transfer:

- Whole nuclei and the gene they carry are transferred---Dolly
- Providing cells as a source of replacement grafting
- Genetic conservation

Ethics and animal biotechnology



Animal ethics:

- **animal welfare and moral community**
- **sentiency**
- **speciesism**
- **religious concerns**

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Lesson # 38

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Human genome project

Human genome project



HGP:

- determine--sequence of chemical base pairs—make up human DNA
- identifying and mapping genes
- difficult—converting the idea into public policy

Human genome project



State of Completion:

- April 2003
- 99% euchromatic human genome
- 99.99% accuracy
- heterochromatic regions are not sequenced

Human genome project



Techniques and analysis:

- genome annotation
- domain of bioinformatics
- 20,500 genes
- more segmental duplication

Human genome project



Applications:

- **genotyping of specific viruses**
- **identification of oncogenes**
- **drug designing**
- **forensic sciences**
- **agriculture, anthropology, evolution**

Human genome project



“Shotgun” project:

- genome broken into larger chunks
- mapped to chromosomes
- sequencing
- 1,50,000bp go together to create chromosome

Human genome project



Genome donors:

- WBCs from two males and two females donor
- DNA library
- 22 pairs-chromosomes are same
- male sample contain over half as much DNA from sex chromosome

Human genome project



Ethical issues:

- used to discriminate against people
- refuse to provide insurance
- ethical, legal and social implications program (1990)

Bioethics



Lesson # 39

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Thoughts on eugenics

Thoughts on eugenics

eugenics:

- Greek “well-born”
- belief and practice – improve the quality of human population
- began early in 20 century

Thoughts on eugenics

Classical eugenics:

- negative eugenics
- license of parenthood
- positive eugenics

Thoughts on eugenics

Negative eugenics:

- reduction of unplanned pregnancies
- incentives and compulsion

Thoughts on eugenics

Positive eugenics:

- financial/selective incentives to have children
- taxation of the childless
- ethical obligations of the elite
- eugenic immigration

Thoughts on eugenics

New eugenics:

- egg donation
- prenatal diagnosis
- embryo selection
- genetic engineering
- gene therapy
- cloning

Thoughts on eugenics



Ethics:

- “It inevitably leads to measure that are unethical”
- no longer ex post facto regulation of the living
- preemptive action on the unborn
- unborn fetus lack the voice of consent

Thoughts on eugenics



Ethics:

- **public policy issues on sex and race**
- **political aspects of eugenics**
- **issues of morality and power**
- **loss of genetic diversity-pleiotropic genes-heterozygous recessive traits**

Bioethics



Lesson # 40

Bioethics



**Human genetic
information**

Human genetic information



Genetics:

- study of heredity and the variations-inherited characteristics
- able to predict what disorder a person likely to develop
- respond to drugs
- how quickly people metabolize?

Human genetic information



uses:

- **diagnose certain disorders**
- **diagnosis of genetic disorders before birth**
- **genetic screening**
- **research purposes**

Bioethics



Lesson # 41

Bioethics



**Genetic
diagnosis**

Genetic diagnosis



Definition:

- DNA testing
- diagnosis of genetic diseases
- determine a child parentage
- biological relationship between people
- crime/suspect/victims

Genetic diagnosis



Identification:

- changes in chromosomes
- gene mutation
- genetic mutation----
effects the structure of
proteins/metabolites
- several hundred
genetic tests are
available

Genetic diagnosis



Types:

- newborn screening (PKU, congenital hypothyroidism)
- diagnostic testing (polycystic kidney disease)
- carrier testing (cystic fibrosis)

Genetic diagnosis



Types:

- preimplantation genetic diagnosis
- prenatal diagnosis (Trisomy 21, trisomy 18)
- predictive and presymptomatic testing (cancer)
- pharmacogenomics

Genetic diagnosis



Risks:

- **risk of losing the pregnancy**
- **emotional consequences**
- **social issues**
- **financial issues**

Bioethics



Lesson # 42

Bioethics



**Genetic
screening**

Genetic screening



Definition:

- **systemic search for person with specific genotype**
- **individual or group show a risk of disease**
- **genetic testing—
specific or multiple
gene interaction**

Genetic screening



DNA:

- only requirement
 - common thread of life
 - provide life its blueprint for building, replicating and surviving
 - condenses to form chromosomes
 - allelic pairs make up genes
- 

Genetic screening



Ethics:

- religious groups
- expensive/emotional distress
- done for common diseases/part of medical record???
- deny employment, social services and insurance benefits

Bioethics



Lesson # 43

Bioethics



**Genetic
discrimination**

Genetic discrimination



Definition:

- when people are treated differently
- based on the individual genotype rather than their individual merits
- **Genism**----distinctive human characteristics and capacities are determined by genes

Genetic discrimination



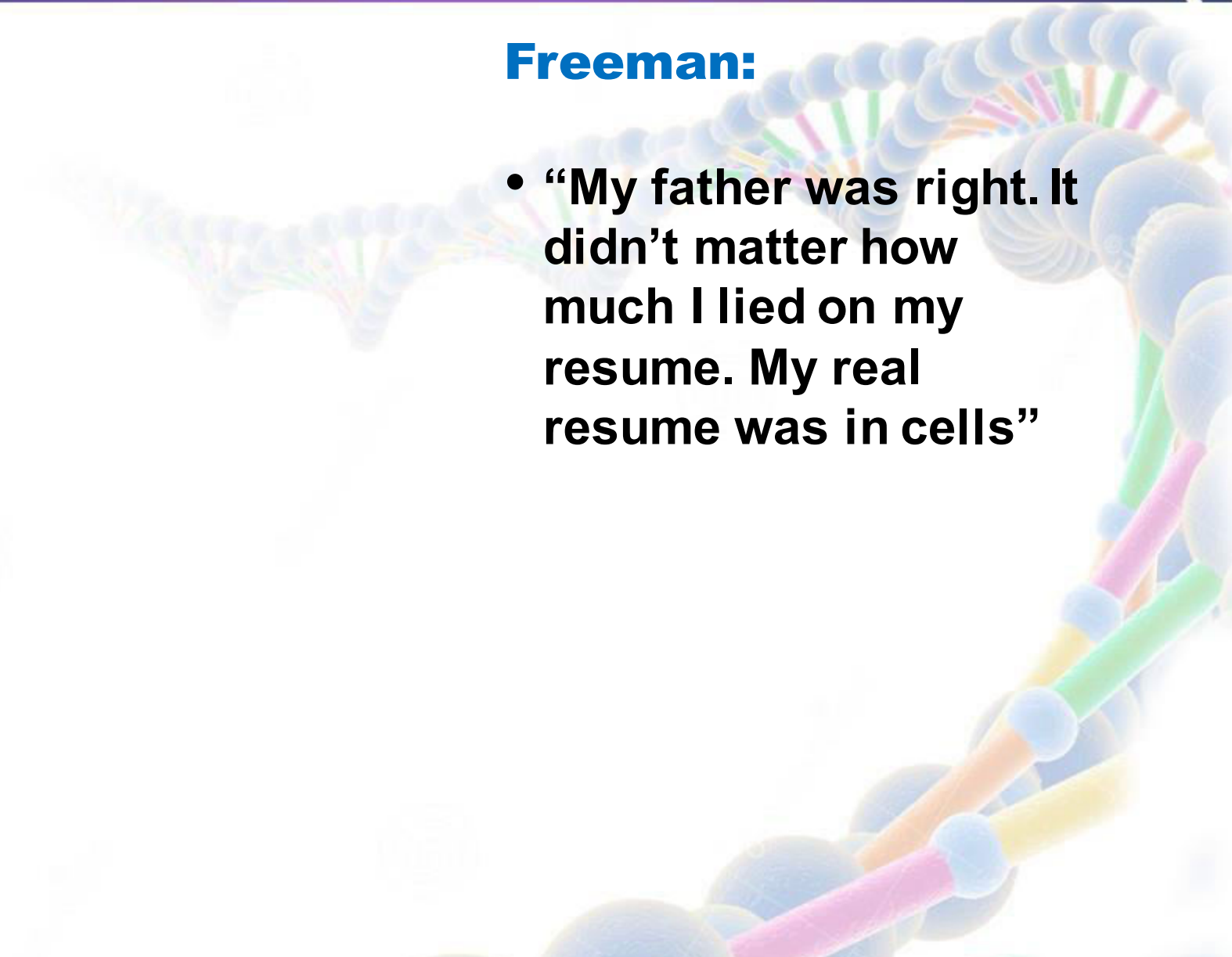
Conditions:

- genetic testing in the work place
- health insurance discrimination
- popular culture—
genoism—unethical
and illegal genetic
discrimination

Genetic discrimination



Freeman:

- “My father was right. It didn’t matter how much I lied on my resume. My real resume was in cells”
- 

Bioethics



Lesson # 44

Bioethics



Burden of genetic information

Burden of genetic information



Burden:

- **highly sensitive-raise unique social issues**
- **provide information about family members and relatives**
- **lead to breaches of confidentiality**
- **emotional challenges**

Burden of genetic information



Burden:

- **impact of a genetic diagnosis**
- **family planning decisions/ special reproductive challenges**
- **segregation of the communities**

Burden of genetic information



Coping mechanism:

- **focus on the child's overall well-being**
- **provide realistic expectations for the future and models for coping**
- **explain condition in an understandable way**
- **coping with the stress of caring**

Burden of genetic information

Genetic diversity:

- species with ecological amplitudes are with genetic diversities
- species with intermediate ecological amplitudes---risk
- demand high genetic diversity
- inbreeding depressions

Bioethics



Lesson # 45

Bioethics

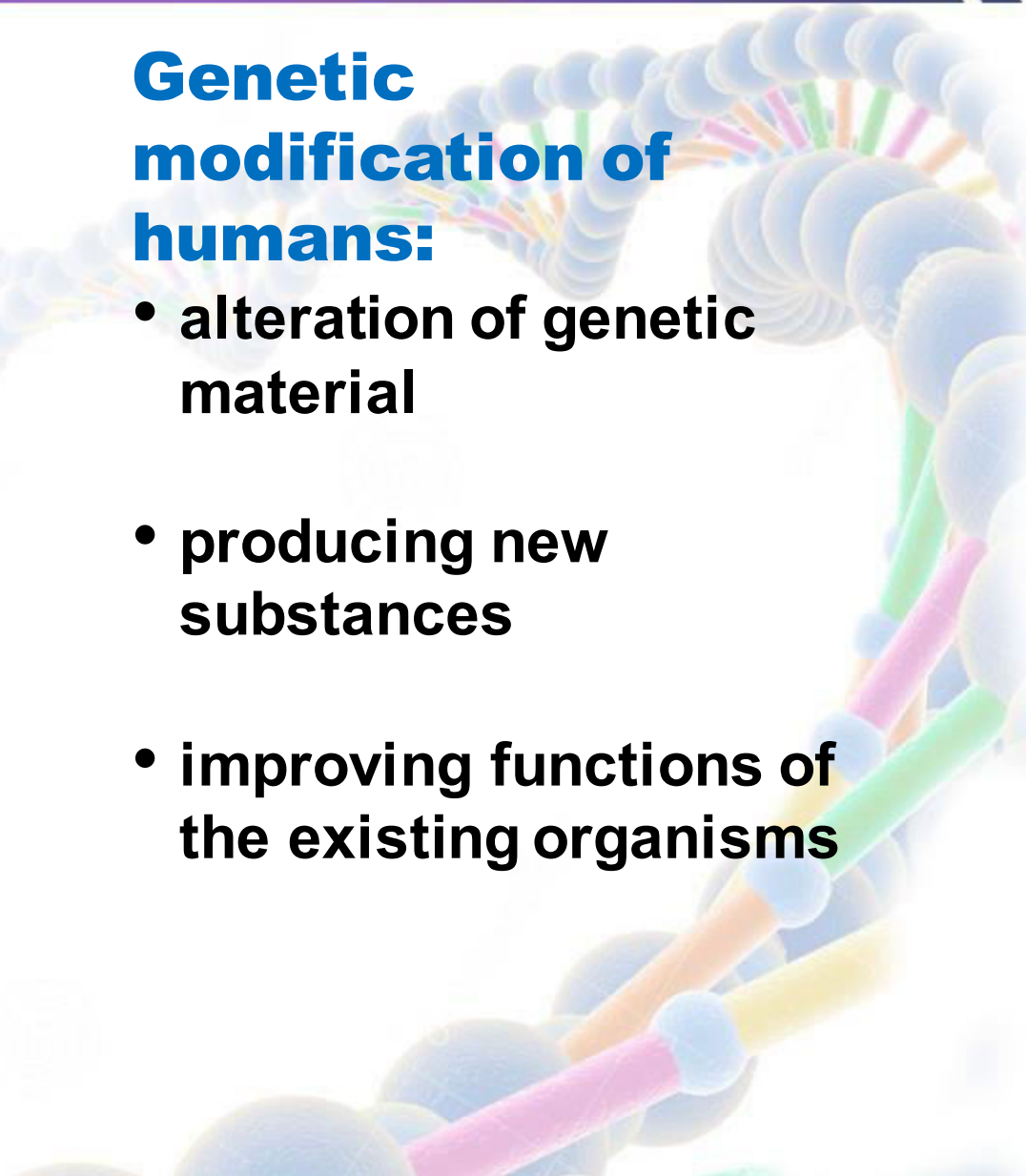


Fact or fiction

Fact or fiction

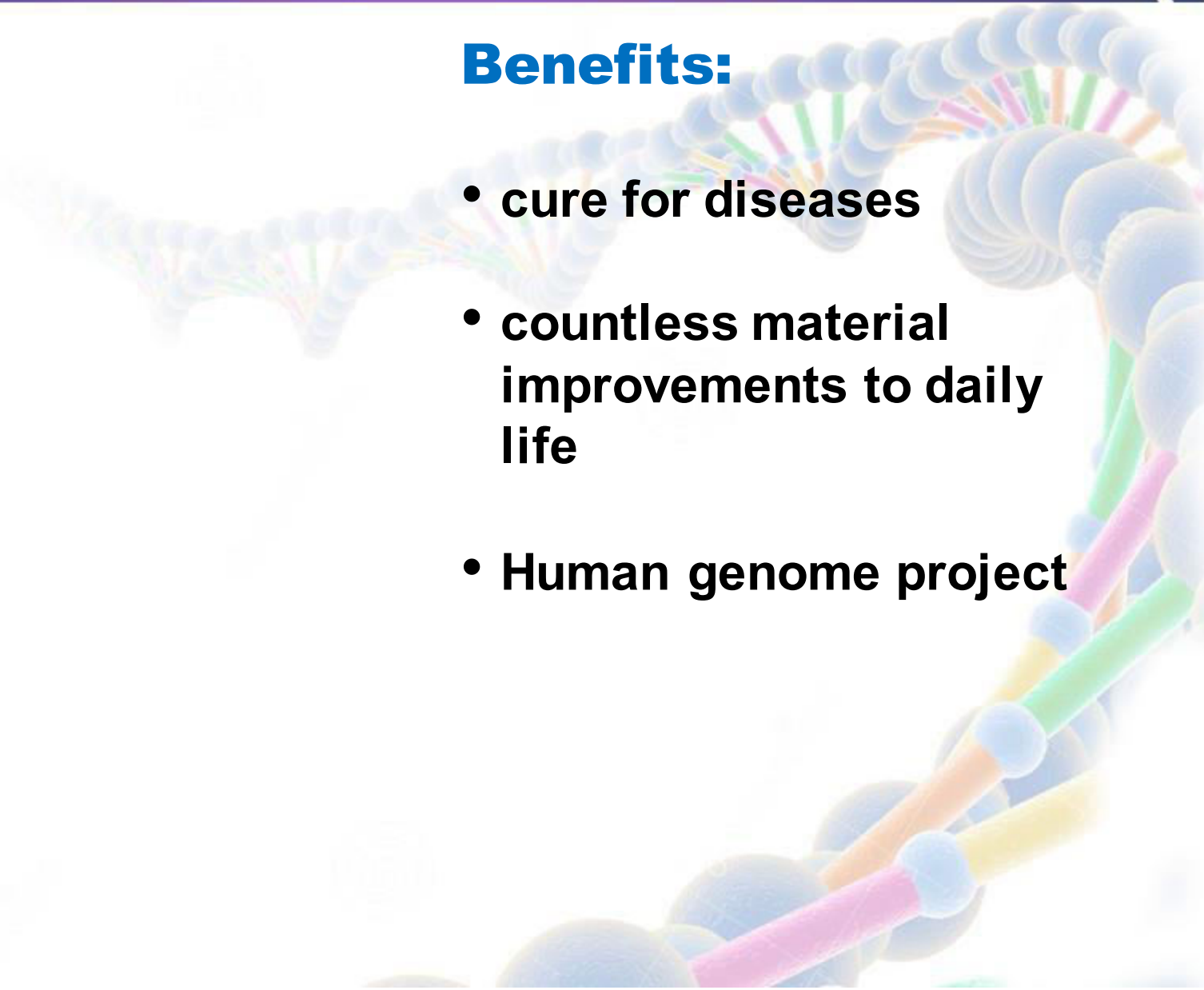
Genetic modification of humans:

- alteration of genetic material
- producing new substances
- improving functions of the existing organisms



Fact or fiction

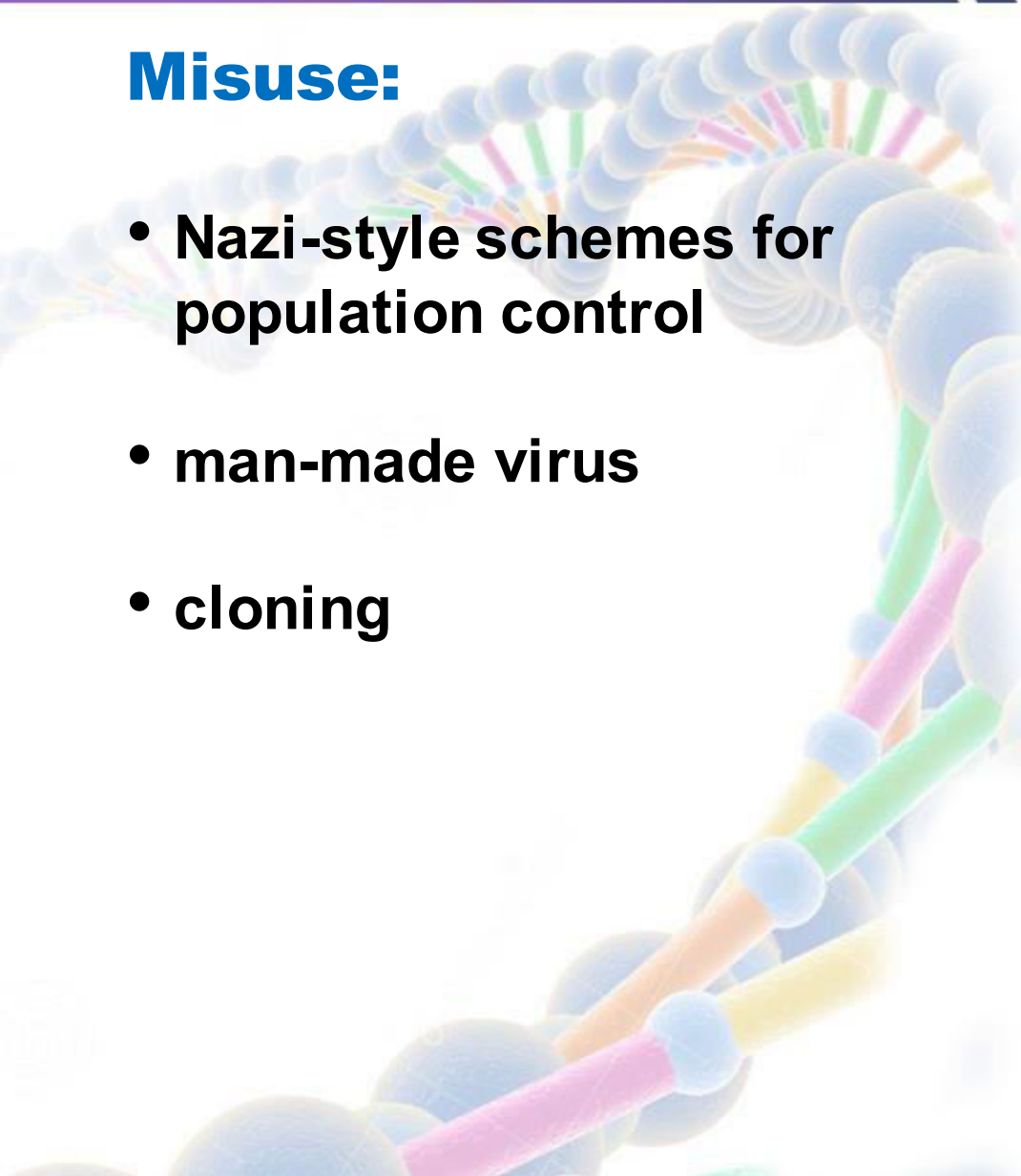
Benefits:

- cure for diseases
 - countless material improvements to daily life
 - Human genome project
- 

Fact or fiction

Misuse:

- **Nazi-style schemes for population control**
- **man-made virus**
- **cloning**



Fact or fiction

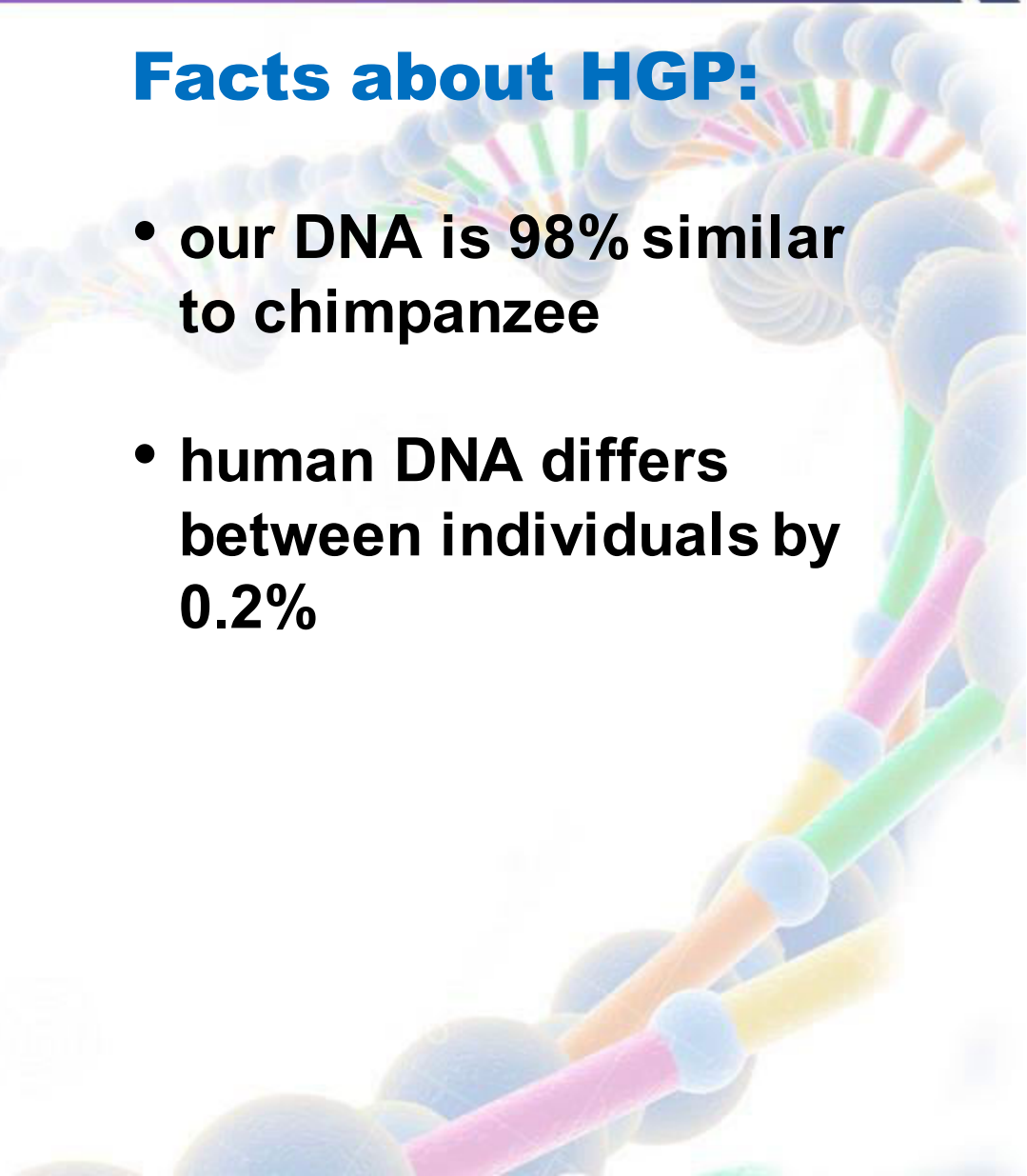
Facts about HGP:

- human body contain 100 trillion cells
- each cell has a DNA code consisting of 1.5 billion base pairs
- length of the DNA—6ft
- size smaller than the head of a pin

Fact or fiction

Facts about HGP:

- our DNA is 98% similar to chimpanzee
- human DNA differs between individuals by 0.2%



Fact or fiction

Principle:

- rDNA is the genetically altered DNA---process is known as gene splicing—sale of insulin
 - gene therapy- genetically altered genes to cells
 - use of restriction enzymes
- 

Bioethics



Lesson # 46

Bioethics



Genes-the wider issues

Genes-the wider issues



Genes:

- **chromosomes are the physical entities that carry the genes**
- **replicate faithfully**
- **direct the synthesis of RNA and proteins**
- **accumulate mutation -- evolution**

Genes-the wider issues



Future aspects:

- **increasing knowledge of genetics---affect all future generations**
- **generation charged with--task of setting foundations and building the first few stages**
- **encourage scientists, technologists-look at what they are creating**

Genes-the wider issues



Future aspects:

- encourage policy makers and public to stop moaning about the technology and problems
- effort and understand well-----enlightened decisions

Genes-the wider issues



Socio-economic arguments:

- **inequalities in ownership of the technology**
- **exploitation of the poor by rich**
- **act as lightning conductor for attracting opposition**

Genes-the wider issues

Issues:

- GM crop
- gene patenting
- genetic piracy

Genes-the wider issues



GM crop:

- world population is growing fast than the agriculture production
- million of hectares devoted world-wide to GM crops
- tool for the plant breeder-fight against food shortages

Genes-the wider issues



Green revolution:

- **success of first green revolution was patchy**
- **India move from rice importer to rice exporters**
- **high yield-high input import of fertilizers**
- **ineffective in Africa – incompatibility with local agriculture**

Genes-the wider issues



Green revolution:

- **one-sixth of the world population is hungry**
- **poverty**
- **political factors**
- **based on research and government funds**

Bioethics



Lesson # 47

Bioethics



**Gene patents in
agriculture**

Gene patents in agriculture



Idea:

- problems-----with the application---GM crops in less developed countries
- to be the subject of a patent, an object must be an invention not a discovery
- genes are clearly parts of nature

Gene patents in agriculture



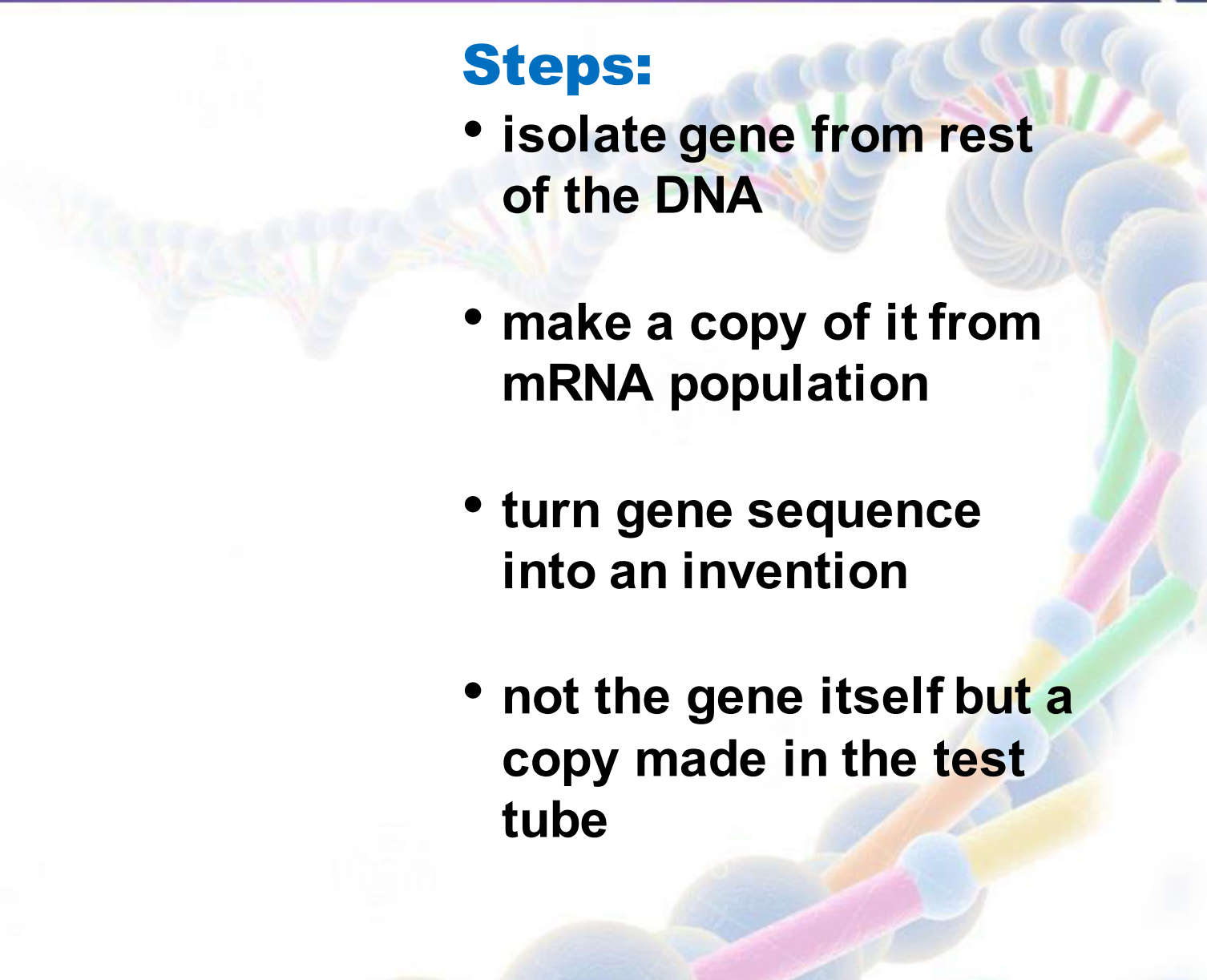
Granted:

- crop genes have been patented in USA
- groups who support patents—there is an inventive step
- argument not accepted “patenting a gene copy is not the same as patenting the gene”

Gene patents in agriculture



Steps:

- isolate gene from rest of the DNA
 - make a copy of it from mRNA population
 - turn gene sequence into an invention
 - not the gene itself but a copy made in the test tube
- 

Gene patents in agriculture



Advantages:


- gene sequence is legitimate intellectual property
- companies ensure an appropriate return on research/development investment
- Vitamin A enhanced Golden rice

Bioethics



Lesson # 48

Bioethics



**Gene patents-
medical
genetics**

Gene patents-medical genetics



Human genetic information:

- key question is same
- HGP oppose gene patenting
- “The genome is the common heritage of humanity”
- public database

Gene patents-medical genetics



Celera Genomics:


- not a part of public or charity funded HGP
- purchase 300 DNA sequencing machines
- sequence most of the human genes
- commercial potential in the use of human gene sequences

Gene patents-medical genetics



**Prof. Bartha
Knoppers:**

**“ In the interest of
human solidarity, we
owe each other a share
in common goods
such as health”**



Gene patents-medical genetics



Advantages:

- commercial interest
- synthesis of generic drugs--AIDs
- genetic based treatments
- Africa– increased cost –gene patenting

Bioethics



Lesson # 49

Bioethics



Genetic piracy

Genetic piracy



16-17 Century:

- **Robbery at sea-sailors wearing long boots and striped jerseys**
- **Romantic image**
- **Robbery at sea is still robbery**
- **In some parts of the world, piracy is still a hazard**

Genetic piracy

Meaning:

- what has piracy to do with genes?
- can genes be the subject of robbery at sea?
- Using something without permission
- Running radio station?
CD copyright?????

Genetic piracy

Is it genetic piracy?

- the patient's cells, for the sake of lesions they exhibit-----used without permission, brought gain to the user
- spleenectomy for the sake of patient's health
- no ownership rights

Genetic piracy

Arguments:

- feel uncomfortable
- injustice has been done
- USA-organ has been removed during surgery, no longer belong to the patient
- permission-live donor of a kidney, post-mortem research

Genetic piracy



Plants:

- **Plants-pain relief**
- **Is this intellectual property?**
- **Do wild plants belong to anyone????**
- **NO**
- **Laws-prevent removal of plants----- private owner land**

Genetic piracy

Research progress:

- nothing is illegal
- initiating research and development program
- patents-registration of intellectual property
- profit for the company
- no obligations to the country-plants were removed

Genetic piracy

Central America:

- agreement-transnational biotechnology company
- allow-company to exploit gene pool of the rain forest
- company interest to protect asset/ commercial potential of forest plants

Bioethics



Lesson # 50

Bioethics



Cloning of sheep and frog

Cloning of sheep and frog

Cloning:

- processes used to create copies of DNA fragments, cells or organisms
- Briggs and Kings----- normal tadpole clones using nuclei from early embryos
- nuclear transfer— viable technique

Cloning of sheep and frog

Nuclear transfer:

- nucleus directs cell growth
- embryonic cells early in development-better
- ultimately organism development

Cloning of sheep and frog

John Gurdon:

- transplanted the nucleus of a tadpole intestinal cell into an enucleated frog egg
- tadpoles- genetically identical to the one from which intestinal cells were taken
- cells retain genetic material as they divide and differentiate

Cloning of sheep and frog

Steen Willadsen:

- chemical process-----
separate one cell from
8-cell lamb embryo
- electric shock to fuse
in to an enucleated egg
cell
- lamb embryos--womb
of surrogate lamb
- three live lambs

Cloning of sheep and frog

Wilmut and Keith:

- transfer the nuclei from cultured cells into enucleated sheep egg cells
- lambs born “Megan and Morag”
- transgenic sheep----- Polly that produce Factor IX in her milk

Cloning of sheep and frog

Dolly:

- adult somatic cells
- every cell's nucleus has a complete set of genetic information
- embryonic cells activate any gene
- differentiated adult cells shut down the genes they don't need

Cloning of sheep and frog

Dolly:

- Of 277 attempts, one embryo was produced
- carried in to surrogate mother
- famous lamb-Dolly
- controversies arises

Cloning of sheep and frog

Ethical issues:

- Dolly-1996
- adult cells can reprogram themselves into a new being
- cloning makes humans God
- health risk in cloned animals/all animals are created equally

Bioethics



Lesson # 51

Bioethics



**Ethics-early
human embryo**

Ethics-early human embryo

Ethical issues:

- two moral principles
duty-prevent suffering,
duty-respect the value
of human life
- harvesting of human
embryo violate the
second duty
- aim of stem cell
research is good-what
about the moral
principles

Ethics-early human embryo

Ethical issues:

- fertilized eggs should be protected as they are human
- even unconscious individuals are treated as persons
- fertilized human egg before implantation doesn't satisfy the criteria of personhood

Ethics-early human embryo

Ethical issues:

- don't remember—not worthy of respect-early stage of development
- embryos don't have emotional, intellectual or psychological properties
- degrees of respect
- before implantation lesser degree

Ethics-early human embryo

Ethical issues:

- natural loss of embryos same as it occurs in stem cell research
- nervous system of early embryos is not developed fully
- In Jewish religion, human fetus < 40 days old-doesn't have the full human status

Ethics-early human embryo

Ethical issues:

- soul is “breathed in” to the human embryo on the 40 day after fertilization--Islam
- stem cell research is acceptable due to therapeutic benefits
- embryos cannot be donated to other couples

Bioethics



Lesson # 52

Bioethics



Therapeutic cloning

Therapeutic cloning



Human embryonic stem cells (hESCs):

- **derived from embryo-5 to 7 days old-before implantation**
- **proliferate and differentiate**
- **hESCs generated organs**
- **face rejection by the immune system**

Therapeutic cloning



Solution:

- somatic cell nuclear transfer
- somatic cell is taken from the patient own body
- nucleus from this cell is placed into an enucleated egg
- same genome as that of the donor cell

Therapeutic cloning

Ethical issues:

- moral status of the embryo ---- destruction
- patient has the right to live
- morally right for in vitro fertilization but morally wrong to save a child's life
- potential donor exploitation

Therapeutic cloning



Ethical issues:

- **slippery slope -----
reproductive cloning
different from
therapeutic cloning**
- **no access and benefit
to poor communities**
- **raises issues of social
justice and healthcare
disparities**

Bioethics



Lesson # 53

Bioethics

Designer babies



Designer babies



Designer babies:

- **children-genetically engineered in the womb to have desired qualities**
- **made through in vitro fertilization**
- **embryo is removed-manipulated for desired qualities-placed in the womb**

Designer babies

Disadvantages:

- expensive---not 100% save
- better looking---create gap in society
- affect the gene pool
- genes can have more than one use
- infants cannot give the consent

Designer babies

Advantages:

- increases human life span up to 30 years
- prevent genetic disorders
- infertile women can have children
- parents set their own limits for genetically engineered babies

Designer babies



Ethical issues:

- unethical and unnatural
- morally wrong
- parents get upset when trait didn't pay off
- problems in the child/parent relationships

Bioethics



Lesson # 54

Bioethics



Case study 1

Case study 1

Case study:

- donated gametes- sperm and ova- are used in fertility treatments for patients who are unable to produce their own
- It is much easier to donate sperm than ova
- donated ova are very scarce.

Case study 1

Case study:

- during fetal development, females lay down a lifetime's supply of oocytes
- Its is therefore suggested that aborted female fetus may be used to supply oocytes for fertility treatments

Case study 1

Reasons:

- do you approve or disapprove of this idea?
- Dr. Roger Gosden, pioneer-reproductive biology and of infertility treatment proposed this way

Case study 1

Reasons:

- what people want is the ultimate measure of right and wrong
- depends on the public opinion, which at present doesn't support this use

Bioethics



Lesson # 55

Bioethics



Case study 2

Case study 2

Case study 2:

- A small less developed country in South America is deep in debt
- Its main source is its rain forest

Case study 2

Solution:

- **What parent want this is an ultimate measure**
- **The land has been cleared used for cattle ranching to raise beef in the US market**

Case study 2

Case study 2:

- The government has also granted a license to transnational biotechnology company to exploit the forest's gene pool
- The company has agreed to pay royalties on income generated from discoveries based on rain forest gene pool

Case study 2



Issues:

- what are the issues in dealing with this situation?
- deleterious effects on biodiversity
- right- to exploit any living organism or any ecological community

Case study 2

Issues:

- agreement might create a genuine commercial flow of money from the richer to some of the poorer nations
- wealth of local knowledge on biodiversity

Case study 2

Issues:

- working to bring traditional knowledge under an extended intellectual property umbrella
- it appears that an imbalance of power is being corrected within this general area of exploiting exotic gene pools.

Bioethics



Lesson # 56

Bioethics



Case study 3

Case study 3

Case study:

- in which of the following cases, would you grant permission?
- normal fertile couples undergo in vitro fertilization in order to produce a baby that can be a stem cell donor for an older sibling

Case study 3

Genetics:

- **The older sibling suffers from genetic disorder and the embryo created in vitro would be tested for the absence of mutation and is the positive tissue match to the older sibling**

Case study 3

Genetics:

- The condition suffered by the older sibling is not genetic but the child still needs donated stem cells.
- In this case, in vitro embryo would be selected solely as a tissue match

Case study 3

Reasons:

- There should be clear cut regulations surrounding these concepts
- HFE 1990 Act, creation of saviour sibling - enable the identification of a tissue match for an older sibling suffer from life-threatening disease

Case study 3

Reasons:

- **Elder sister suffered from promyelotic leukemia - Anna selected an embryo to provide umbilical cord stem cell**

Case study 3



Reasons:

- Nash family elder daughter- Fanconi's anemia
- In 2000, Adam was born a suitable match for her sister
- “If you use one of your children to save the life of another, are you being a good mother or a very bad one”

Bioethics



Lesson # 57

Bioethics



Case study 3

Case study 3

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Bioethics



Lesson # 58

Bioethics

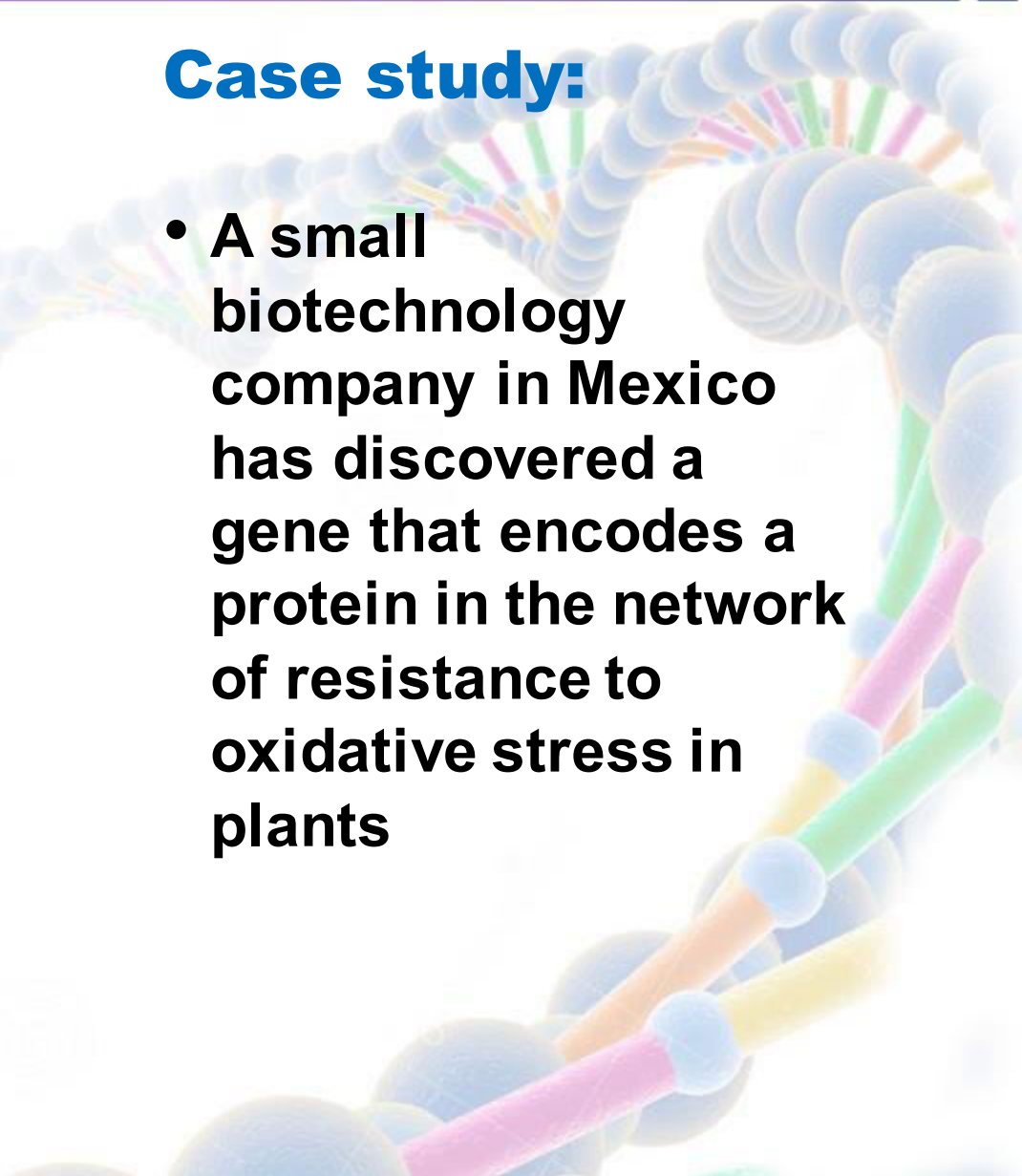


Case study 4

Case study 4

Case study:

- A small biotechnology company in Mexico has discovered a gene that encodes a protein in the network of resistance to oxidative stress in plants



Case study 4

Case study:

- **laboratory experiments have shown that when the gene is transferred by genetic modification techniques to crop species, they show enhanced capacity to grow under conditions where water supply is limiting**

Case study 4

Case study:

- The company has not published its data because it is filing a patent on the gene
- If the patent is granted, the company plans to license it out to a major trans-national agri-chemical company

Case study 4



Reasons:

- should the patent be granted?
- yes, the term oxidative stress is used-comprising all kind of biotic and abiotic stress conditions
- helpful in reducing the damaging of crops caused by stress conditions

Bioethics



Lesson # 59

Bioethics

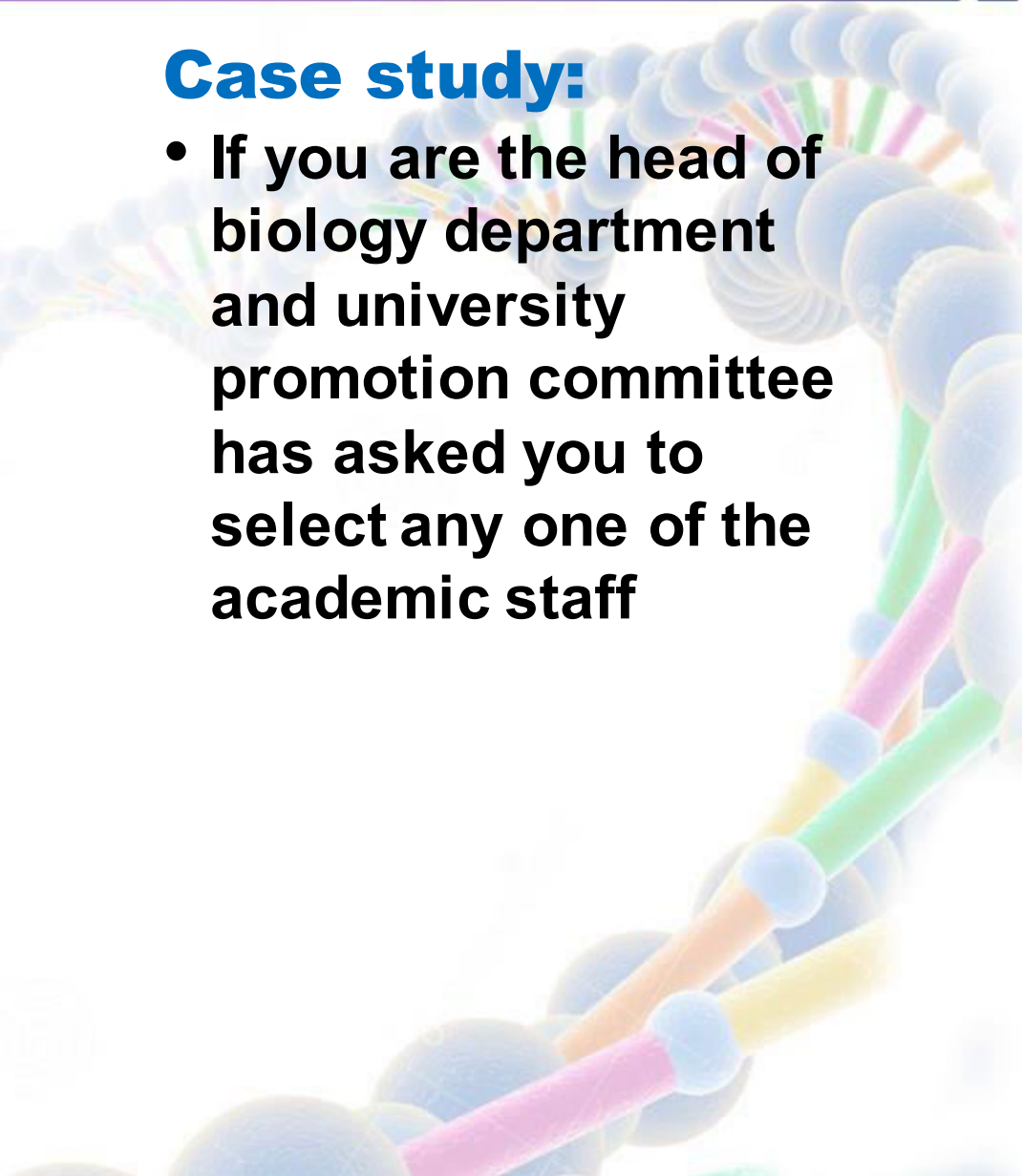


Case study 5

Case study 5

Case study:

- If you are the head of biology department and university promotion committee has asked you to select any one of the academic staff



Case study 5



Candidate A:

- **Candidate A is 37, working on the ecology of plant-insect relations. His research on the evolution of pollination mechanisms is widely respected. The research has steady flow of grant**

Case study 5



Candidate B:

- **candidate B is 34, working on the regulation of gene expression in programmed cell death, especially in relation to cancer. This work is of great interest in the biomedical community. The work is supported by extensive funds**

Case study 5

Reasons:

- What should be the criteria of selecting according to research?
- look at the particular research goals
- candidate aspirations and world-view
- beneficial for the public

Bioethics



Lesson # 60

Bioethics



Case study 6

Case study 6



Case study:

- **employing science to sell a product, the modernist and post-modernist version**
- **a female actor told viewers about shampoo on UK TV in 2004**
- **she told hair is 96% amino acids**

Case study 6

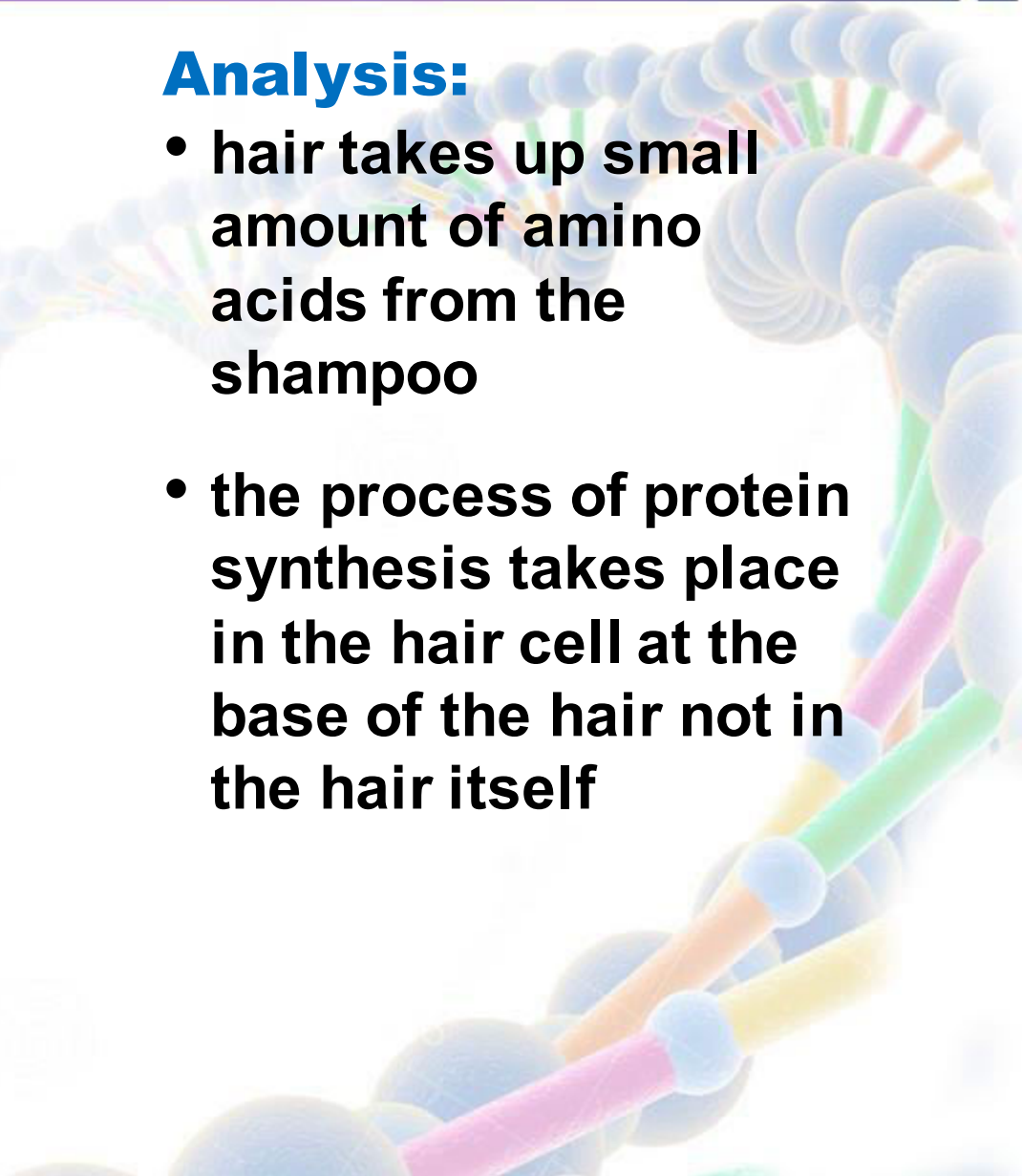
Case study:

- shampoo should be rich in amino acids to nourish hair
- analysis-yes , hair has amino acids joined together in a long protein chain called keratin
- protein cannot be repaired by direct uptake of amino acids

Case study 6

Analysis:

- hair takes up small amount of amino acids from the shampoo
- the process of protein synthesis takes place in the hair cell at the base of the hair not in the hair itself



Case study 6



Analysis:

- **shampoos cannot deliver amino acids because detergents can disrupt the protein synthesis**
- **the term “amino” should be used rather than amino acids because it gives negative impact**

Case study 6

Comment:

- **this is not a comment on the shampoo efficacy; we are sure that modern shampoos clean the hair and scalp and leave the hair shiny and manageable**
- **comment on the dishonest use of scientific terminology to imply things that cannot happen**

Case study 6

Comments:

- **advertisers said that they will continue to use the jargon of science**
- **it is classic post-modern triumph of style over substance**

Bioethics



Lesson # 61

Bioethics



Case study 7

Case study 7

Case study:

- because of the family history I know I am likely to be an unaffected carrier of a gene that causes a serious and so far untreatable condition
- do I request a test for that gene? If the test is positive should I tell my spouse?

Case study 7

Case study:

- family history informs me that I have 50-50 chance of possessing a gene that at the age of 40 cause serious neuro-degenerative disease for which there is no treatment
- do I want the test? if the test is positive should I tell my spouse or children

Case study 7



Case study:

- **currently I am healthy but I know I have a gene that is very likely to cause serious health problems and possibly death in the middle age. Who else should know?**

Case study 7

Reasons:

- sometimes the knowledge that one is certain to suffer a serious and distressing condition is a burden too heavy to bear
- thus ignorance is a bliss
- Social stigma

Case study 7



Reasons:

- such situation emphasize the importance of genetic counseling
- both in the phase of deciding whether to take test and if the test is taken when the results are available

Bioethics



Lesson # 62

Bioethics



Case study 8

Case study 8

Case study:

- a man presents with symptoms representing cancer and as part of his treatment spleen should be removed.
- the pathology department use it to establish a cultured cell line in order to study the rare cancer

Case study 8



Case study:

- **the cell line performs so well that the scientists collaborate with biotechnology company to patent it.**
- **they start to earn royalties from other laboratories and organizations that wish to use the cell line**

Case study 8

Case study:

- when patient find all this he was amazed
- nobody has taken the consent from him nor he has been informed by anyone about these developments
- analyze the ethical issues

Case study 8

Reasons:

- in terms of medical ethics, removal of the spleen was an act of doing good-beneficence
- patient's personal autonomy had been respected
- it was for the sake of his health that spleen has been removed

Case study 8

Reasons:

- in UK, there is great sensitivity concerning the fate of organ removed
- under new legislation, if there is no pre-death consent then kin permission must be taken to retain any organs from dead bodies

Case study 8

Reasons:

- in USA, once the organ is removed during surgery, it is no longer belong to the patient
- what is the purpose of keeping their appendix or diseased kidney in a jar in their office?

Case study 8

Reasons:

- donor can not claim on the income gained as a result of research
- anyone who donates a kidney makes a gift not an investment in the recipient

Bioethics



Lesson # 63

Bioethics



**Stem cell
debate**

Stem cell debate



Stem cell:

- stem cell therapies are not new
- bone marrow stem cell transplants
- removal of stem cells from human embryo
- excitement and controversies started

Stem cell debate

Human embryo:

- huge potential to cure human diseases
- controversies centered on moral issues
- destroying human embryos

Stem cell debate



Difficult questions:

- does life begin at fertilization, in the womb or at birth?
- is a human embryo equivalent to a human child
- does human embryo have any rights?
- is the embryo really destroyed?

Stem cell debate



Legislations:

- to regulate stem cell research
- prohibit the creation of embryos-research
- should taxpayer money used-believe it to be unethical

Stem cell debate



Legislations:

- Bush reduces the funds
- Obama expand the funds
- policy makers with new questions

Bioethics



Lesson # 64

Bioethics



Cloning controversies

Cloning controversies

Ethical concerns:

- effect of cloning on animal and human welfare
- objection to the principle of cloning

Cloning controversies

Effect on animals:

- **increase animal suffering-standard breeding methods**
- **surgeries performed to obtain oocytes**
- **animals produced as diseased models**

Cloning controversies

Arguments:

- these findings are not unique to cloning
- associated with other procedures
- embryo transfer, oocyte transfer, in vitro fertilization

Cloning controversies



Human welfare:

- **cloned animal species**
--housed/slaughtered
and eaten
- **potential benefits---**
understanding life
processes and animal
diseases
- **human health**
- **food production**

Cloning controversies



objections:

- **genetic variations of the species**
- **cloned animals poses no public health risk**
- **transgenic animals-unnatural means**
- **potential hazards to animals, humans and on the environment**

Bioethics and Biosafety

Lesson # 65



Bioethics and Biosafety



**Genetic
counseling**

Genetic counseling



Definition:

- **patient-inherited disorder**
- **advised the consequences and nature of the disorder**
- **probability of developing and transmitting it**
- **options-management and family planning**

Genetic counseling

Genetic counselors

- understanding and adaptation to the medical
- psychological
- familial implications-
genetic contributions
to disease



Genetic counseling



Role:

- **interpretation of family and medical histories**
- **education - about inheritance, testing, management, prevention, resources**
- **counseling to promote informed choices and adaptation to the risk**

Genetic counseling



Session structure:

- intake phase
- initial contact
- encounter phase
- summary phase
- follow-up phase

Genetic counseling



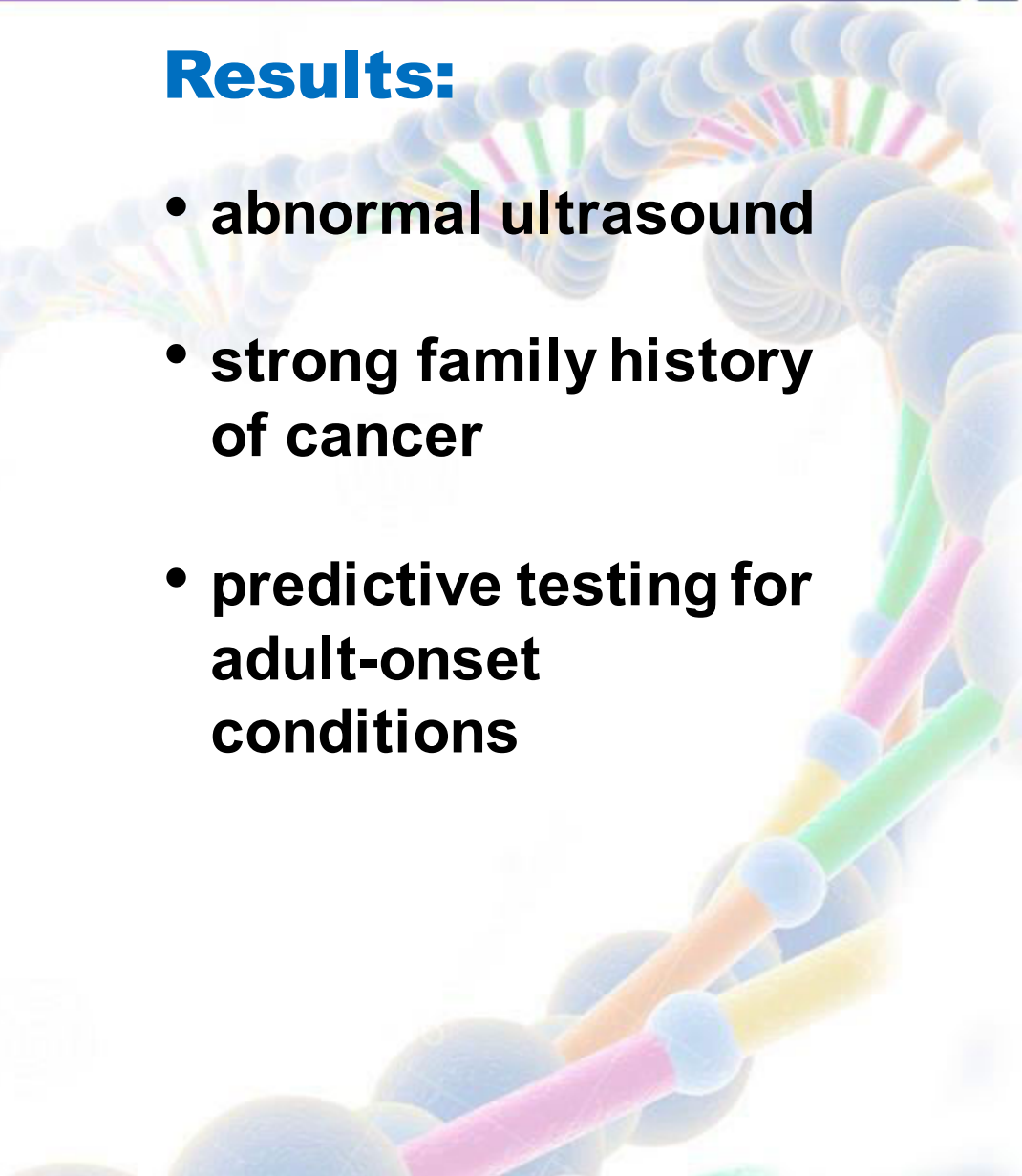
Results:

- **family history**
- **molecular test**
- **increased maternal/
paternal age**
- **abnormal maternal
serum screening
results**

Genetic counseling

Results:

- abnormal ultrasound
- strong family history of cancer
- predictive testing for adult-onset conditions



Bioethics and Biosafety



Lesson # 66

Bioethics and Biosafety



**Responding to
trafficking**

Responding to trafficking

Elements:

- the act (what is done)
- the means (how it is done)
- the purpose (why it is done)

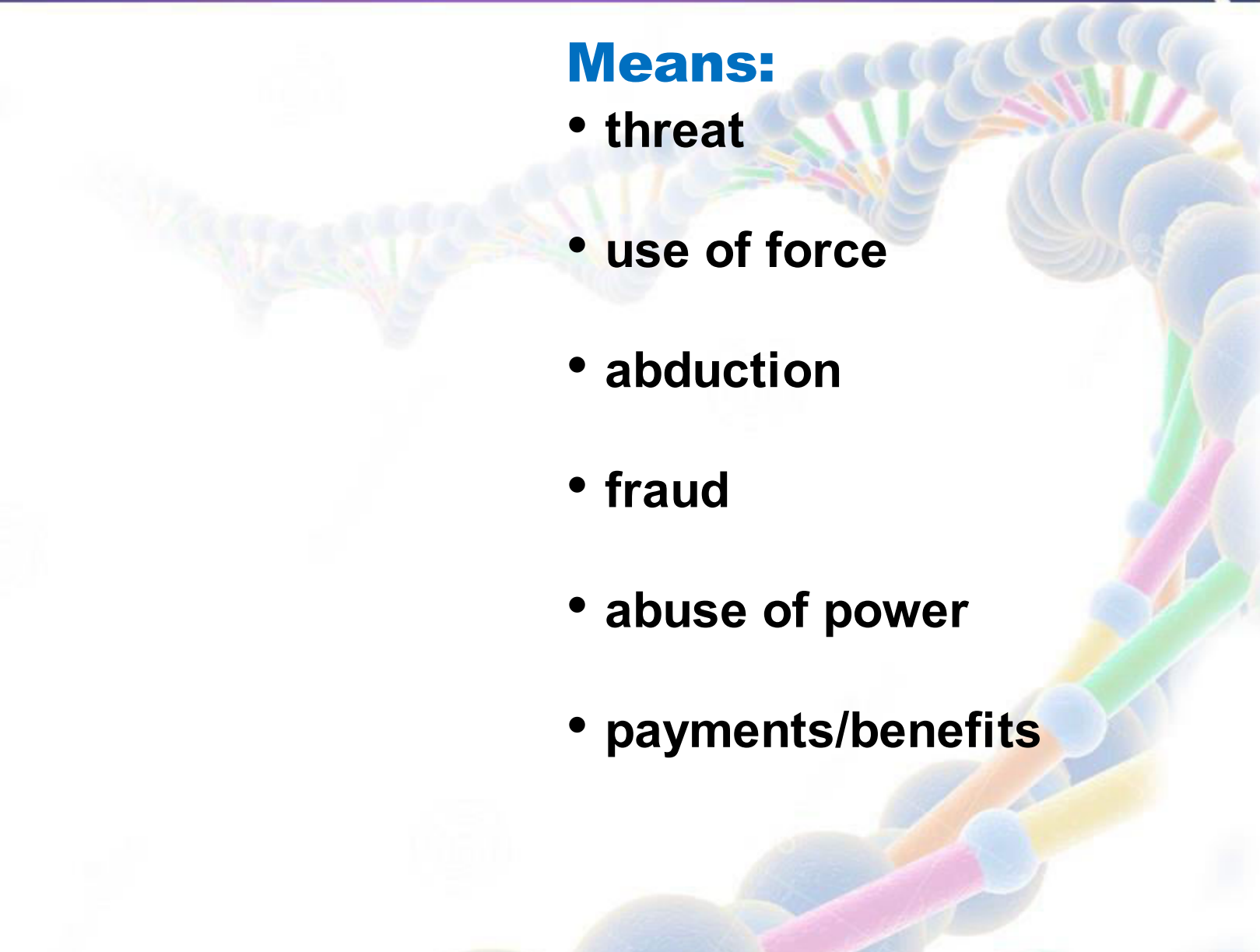
Responding to trafficking

Act:

- recruitment
 - transport
 - transferring
 - harboring
 - receipt of person
- 

Responding to trafficking

Means:

- **threat**
 - **use of force**
 - **abduction**
 - **fraud**
 - **abuse of power**
 - **payments/benefits**
- 

Responding to trafficking

Exploitation:

- prostitution
- sexual exploitation
- forced labor
- slavery
- removal of organs

Responding to trafficking

Response:

- **within the country or across borders**
- **range of exploitative purposes**
- **victimizes children, men, women**
- **involve organized victim groups**

Responding to trafficking

Prevention:

- trafficking in persons
- victims of human trafficking
- trafficking offenders

Responding to trafficking

Education:

- research and awareness raising
- promotion of protocols and capacity building
- strengthening of partnerships and coordination

Bioethics and Biosafety



Lesson # 67

Bioethics and Biosafety



**Responding to
Disasters**

Responding to Disasters

Definition:

- event occurring suddenly-causing loss of life damage or hardship
- sudden overwhelming and unforeseen event

Responding to Disasters

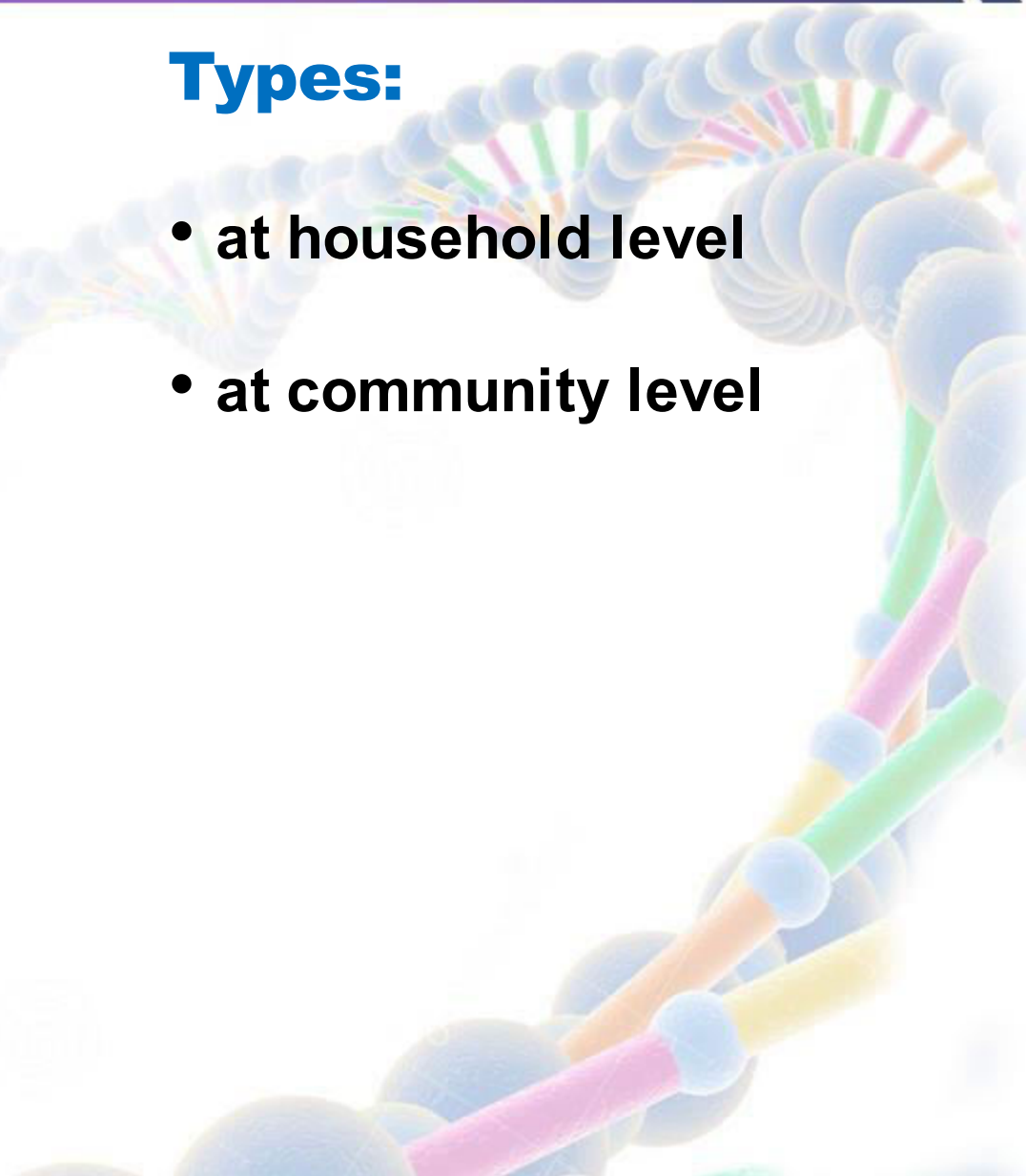
Disaster response:

- **second phase of disaster management cycle**
- **warning/evacuation/search/rescue**
- **immediate/continuing assistance**
- **assessing damage/restoration-infrastructure**

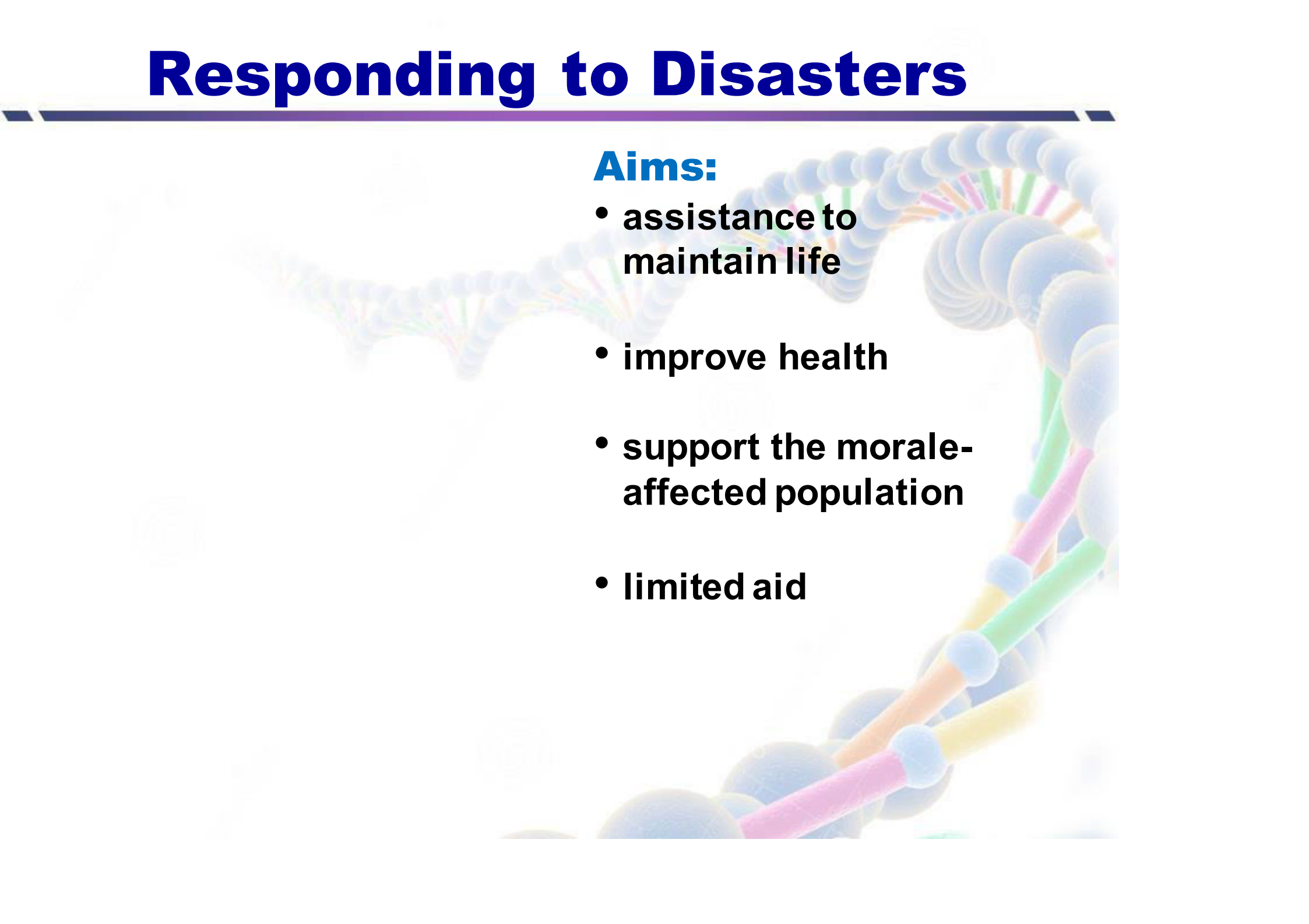
Responding to Disasters

Types:

- at household level
- at community level



Responding to Disasters



Aims:

- **assistance to maintain life**
- **improve health**
- **support the morale-affected population**
- **limited aid**

Biosafety



Lesson # 68

Biosafety



Biosafety

Biosafety



Definition:

- **prevention of large-scale loss of biological integrity**
- **prevention mechanisms**
- **conduction of regular reviews - biosafety in laboratory settings**
- **strict guidelines to follow**

Biosafety



Fields:

- ecology
- agriculture
- medicine
- chemistry
- exobiology
- synthetic biology

Biosecurity



Lesson # 69

Biosecurity



Biosecurity

Biosecurity



Definition:

- a set of preventive measures designed to reduce the risk of transmission of infectious agents
- security against the inappropriate use of potentially dangerous biological agents

Biosecurity



Security issues:

- non-traditional security
- international security
- cooperation - of scientists, technicians, policy makers, security engineers and law enforcement officials

Biosecurity



Preventive measures:

- combination of systems and practices put into its place at laboratories
- prevent the use of dangerous pathogens and toxins

Biosecurity



Types:

- **laboratory biosecurity programs**
- **animal biosecurity**
- **bioweapons**

Biosecurity



Challenges:

- **availability and accessibility of potentially harmful technology**
- **proliferation of high biosafety level laboratories**

Biosecurity



Lesson # 70

Biosecurity



Bioweapons

Bioweapons



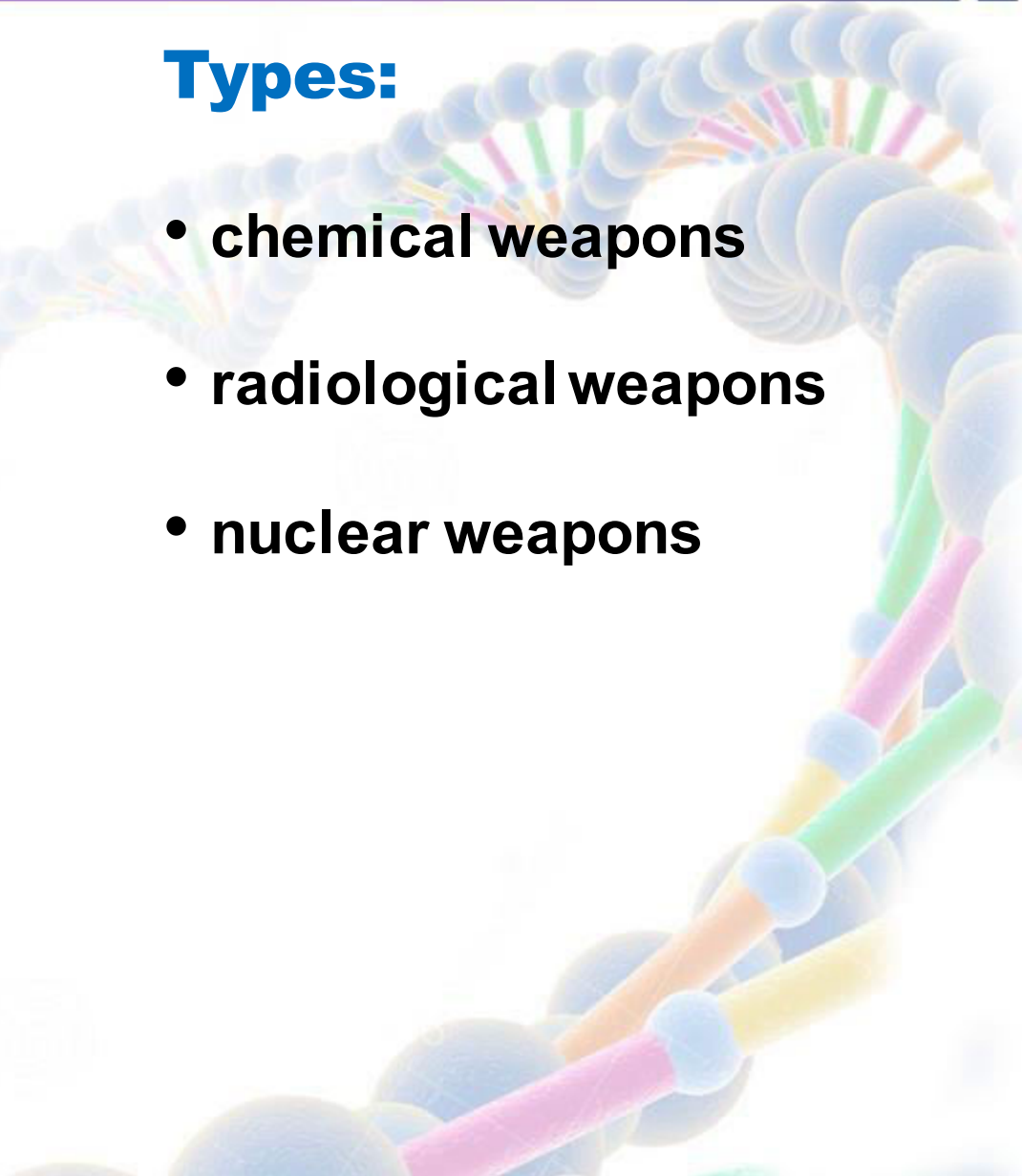
Definition:

- “germ weapons”
- disease producing infectious agents used against humans, animal or plants
- ancient practice in warfare
- responsible for more deaths

Bioweapons

Types:

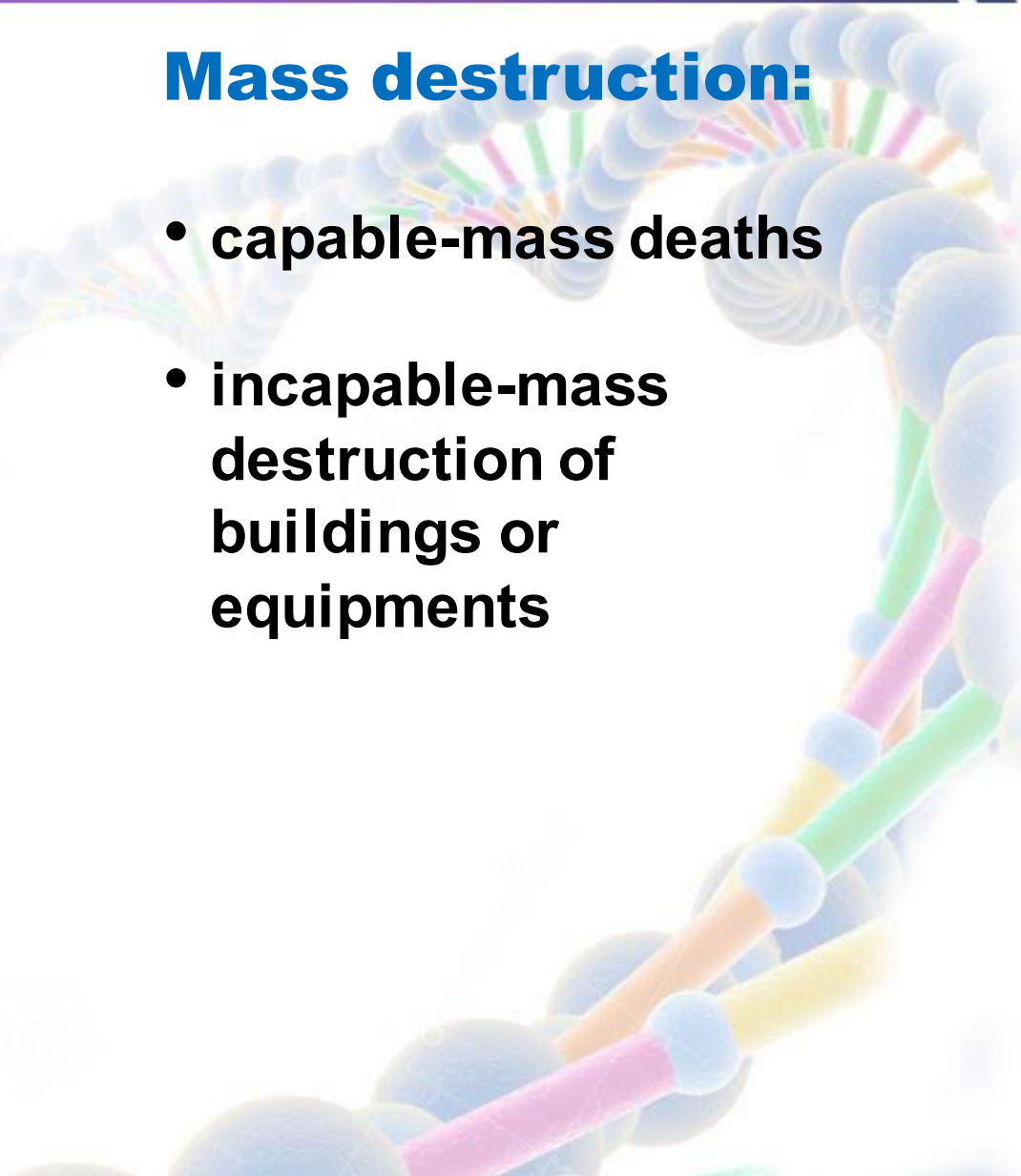
- chemical weapons
- radiological weapons
- nuclear weapons



Bioweapons

Mass destruction:

- capable-mass deaths
- incapable-mass destruction of buildings or equipments



Bioweapons



Agents:

- anthrax
- brucellosis
- small pox
- viral hemorrhagic fever
- Staphylococcal enterotoxin B
- botulinum toxins

Bioweapons



Precautions:

- mass equipped with filters
- boots/ gloves
- prevent the contacts with wounds
- biological weapon sensors

Biosafety



Lesson # 71

Biosafety



Biohazard

Biohazard



Biohazard:

- **biological materials-
pose a threat to the
health of living
organisms**
 - **medical
waste/samples**
 - **virus or toxins**
- 

Biohazard



Symbol:

- developed in 1966 ----
Charles Baldwin
- easy to sketch
- labeling of biological materials
- recognize quickly
- acceptable to groups
--ethnic backgrounds

Biohazard



Classification:

- **Category A, UN 2814-**
infectious substances
affecting humans
- **Category A, UN 2900-**
infectious substances
affecting animals
- **Category B, UN 3373-**
biological substances
transported

Biohazard



Classification:

- **regulated medical waste, UN 3291-waste or reusable material**
- **derived from medical treatment/research**

Biosafety



Lesson # 72

Biosafety



**Application
form**

Application form



Form:

- applicants information
- topic covered
- using recombinant DNA
- infectious agents
- toxins
- radioactive material

Application form

Form:

- use of animals
- date of approval
- description of experiments
- sources of DNA
- nature of DNA sequences/attempt gene expression

Application form

Form:

- **biosafety levels**
- **enlist biohazardous materials**
- **biosafety equipments**
- **emergency procedures**
- **biohazardous material storage**

Application form

Form:

- waste disposal
- committee decision



Biosafety



Lesson # 73

Biosafety



**Lab safety
protocols**

Lab safety protocols



Lab safety:

- safety glasses
- closed-toed shoes
- no food/drink
- long hair must be tied
- lab coat
- open flames-
unattended

Lab safety protocols



Lab safety:

- flammable liquids
- skin contact-rinse off
- proper waste disposal
- liquid waste-labeled containers
- equipment must be cleaned and placed back

Lab safety protocols



Lab safety:

- inform-chemical spill/thermometer breakage
- be careful-handling hot glassware and apparatus
- avoid taking excess amount of chemicals

Lab safety protocols



Lab safety:

- cell phones/ head phones are not allowed
- lab door must be kept close
- chairs not permitted - lab work is in session

Lab safety protocols



Lab safety:

- lab must be fully equipped with fire extinguisher
- fire blanket/safety shower
- eye wash/ first aid kit
- fume hoods/ sodium hydrogen carbonate

Biosafety



Lesson # 74

Biosafety



Classification of pathogens

Classification of pathogens

WHO:

- **WHO risk group 1:**
microbes unlikely to cause disease
- **WHO risk group 2:**
microbes causing diseases-unlikely to be serious
- **WHO risk group 3:**
pathogens causing serious disease

Classification of pathogens

WHO:

- **WHO risk group 4:**
pathogens causing
serious disease ----
transmission-----no
effective treatment or
preventive measures

Biosafety



Lesson # 75

Biosafety



Containment

Containment



Definition:

- **military strategy**
- **stop the expansion of an enemy**
- **USA-Cold War policy**
- **prevent the spread of communism abroad**

Containment



History:

- 1850s-anti-slavery forces developed containment strategy
- stop the expansion of slavery and forcing its collapse
- 1941 during World War II-policy was rollback to destroy Japan and Germany

Containment



Strategies:

- **isolationism, minimizing America involvement**
- **friendly relationship**
- **rollback policy----an aggressive effort to undercut Soviet Union**

Biosafety



Lesson # 76

Biosafety



Handling of biological spills

Handling of biological spills



Basics:

- first worker injury-
second-spill clean up
- alert others in the
vicinity
- clean up and
decontaminate
- dispose of clean up
waste
- report incident-safety
officer

Handling of biological spills



Contamination:

- **Contaminated clothing- autoclave**
- **Disinfect skin with 70% alcohol**
- **Eyes-flush with water**

Handling of biological spills

Biological spill kit:

- household bleach
- 70% alcohol
- spray bottle
- sterilization bags
- absorbent paper towels
- yellow trash bags
- disposable gloves

Handling of biological spills

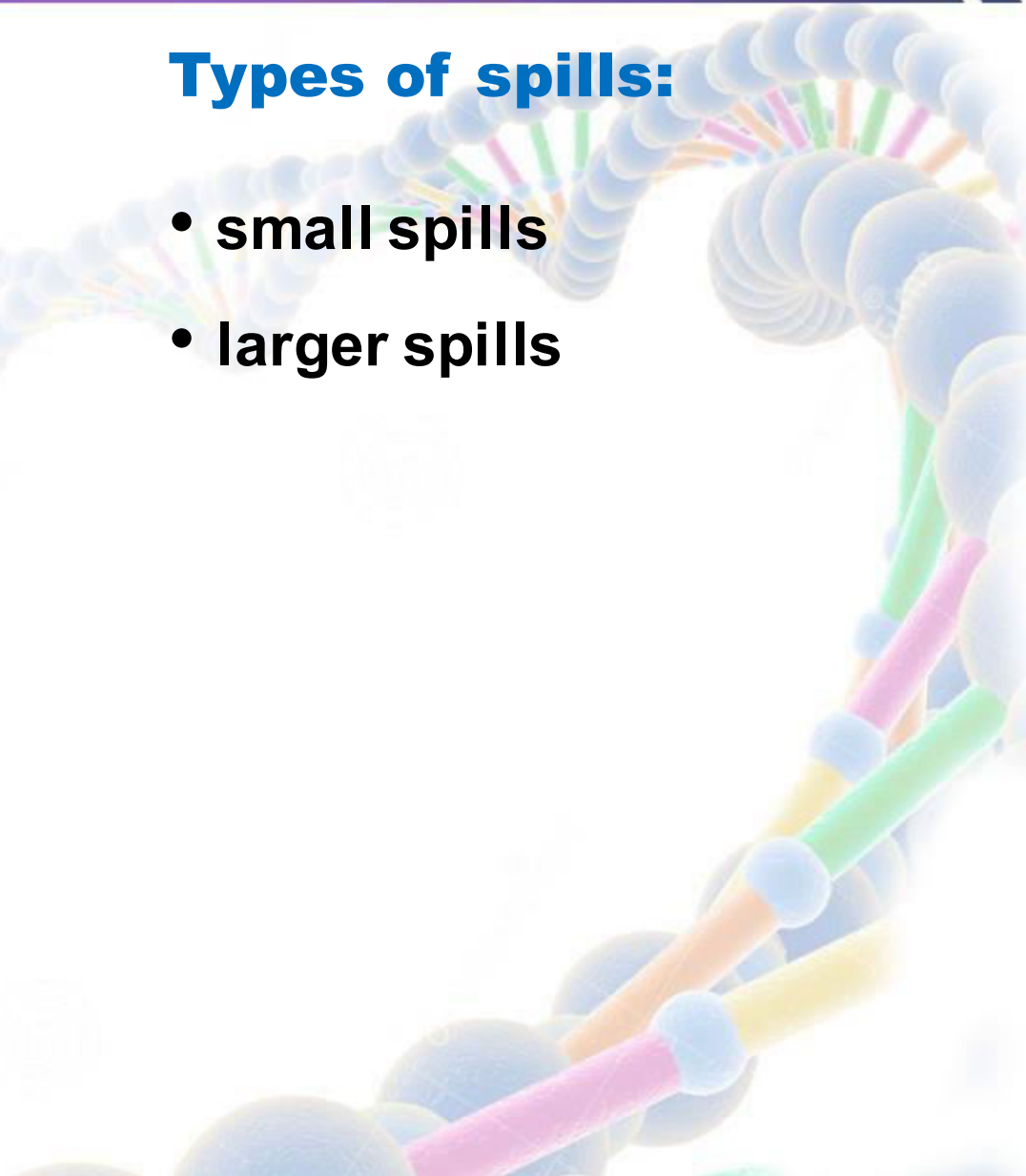
Biological spill kit:

- **metallic tongs**
- **surgical masks**
- **safety goggles, shoe covers and face mask**
- **spill control and cleanup procedures**

Handling of biological spills

Types of spills:

- small spills
- larger spills



Biosafety



Lesson # 77

Biosafety



**Sterilization
and
disinfection**

Sterilization and disinfection

Definition:

- **sterilization--removal of microbes including bacterial spores**
- **disinfection-killing many microbes**

Sterilization and disinfection



Methods:

- **physical agents ----**
heat, radiation,
filtration
- **Chemical agents----**
glutaraldehyde,
formaldehyde,
chlorine

Sterilization and disinfection

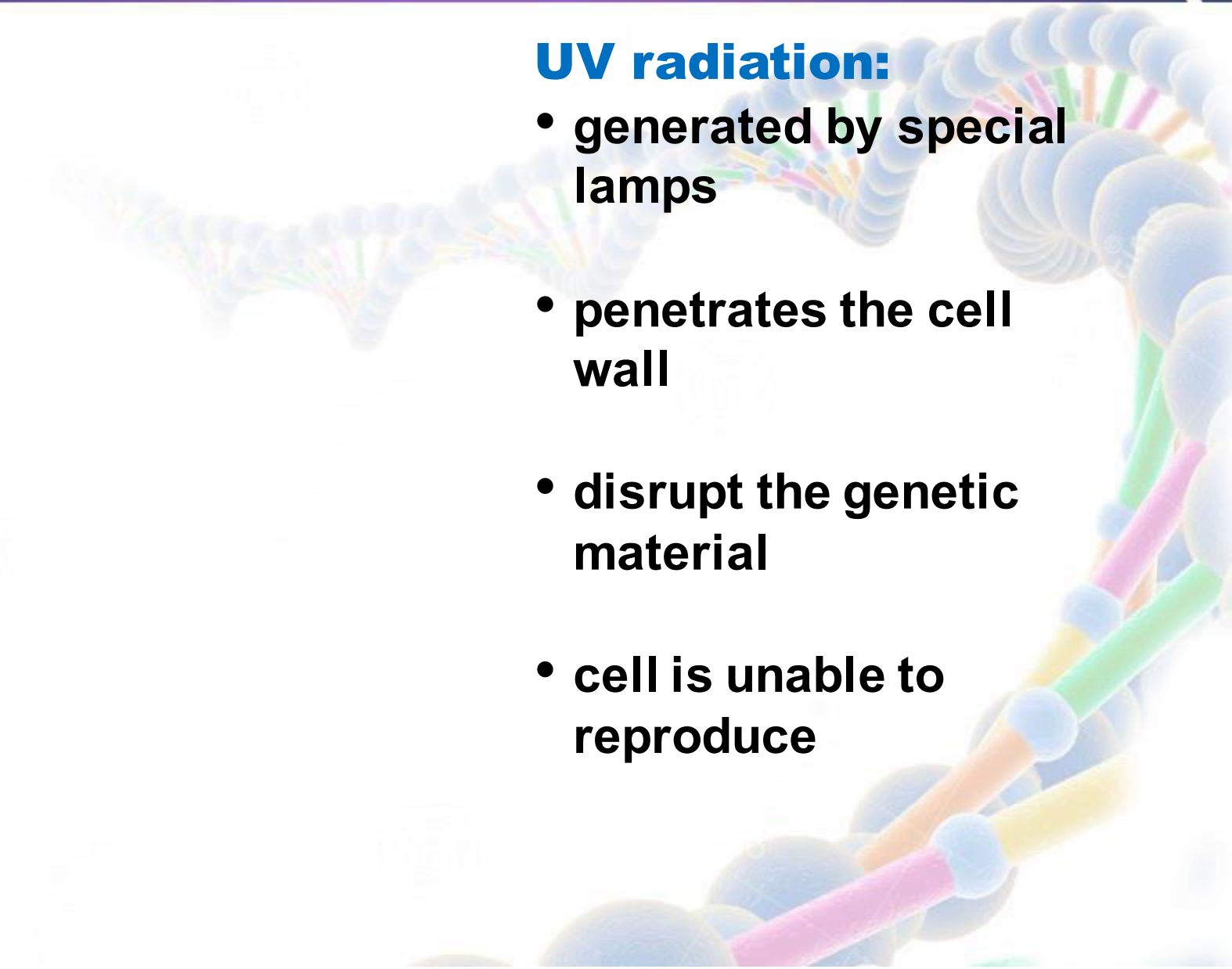


Heat:

- moist heat-boiling, steaming, autoclaving, pasteurization
- Dry heat-----red heat, flaming, hot air oven

Sterilization and disinfection

UV radiation:

- **generated by special lamps**
 - **penetrates the cell wall**
 - **disrupt the genetic material**
 - **cell is unable to reproduce**
- 

Sterilization and disinfection



UV advantages:

- readily available
- no known toxic residuals
- short contact time
- equipment is easy to operate and maintain

Biosafety



Lesson # 78
Biohazards-
animal
handling

Biohazards-animal handling

Categories:

- Physical injuries
- Zoonosis
- Asthma and allergies

Biosafety



Lesson # 79

Biosafety



**Handling-Lab
equipments**

Handling-Lab equipments

Glassware:

- **borosilicate glassware**
- **corks for sealing organic solvents**
- **thermometer-stirring device**
- **thermometer bulb-heat**

Handling-Lab equipments

Precautions:

- heat sources
- avoid mouth pipetting
- centrifuges
- compressed gases

Biosafety



Lesson # 80

Biosafety



**Report of
accidents**

Report of accidents

Report:

- Accident report must be prepared-five days of accident
- What is accident?
- Person involved
- Witness to the accident

Report of accidents

Case study:

- investigator or supervisor
- multiple causes
- not intended to assign blame
- improve safety protocols

Biosafety



Lesson # 81

Biosafety



Water disposal

Water disposal



Origin:

- domestic
- agriculture
- commercial
- industrial
- storm water
- run off water

Water disposal

Constituents:

- pathogens
- non-pathogens
- organic/soluble
organic/inorganic
particles
- animals
- gases/emulsion/toxin

Water disposal



treatment:

- **chemical**
- **biological**
- **physical**
- **reuse treated water**

Biosafety



Lesson # 82

Biosafety



**Lab biosafety
level criteria**

Lab biosafety level criteria



Definition:

- level of containment precautions
- isolate dangerous biological agents
- enclosed laboratory facility
- containment level (BSL-1 to BSL-4)

Lab biosafety level criteria



History:

- **USA- CDC/European union-directives**
- **biosafety cabinet, 1943—Hubert**
- **biological warfare labs ----- 1955**
- **American Biological Safety Association -- 1984**

Lab biosafety level criteria

Containment zone:

- only be a chemical fume hood
- isolation of microorganisms
- building systems, sealed rooms, sealed containers and personnel suits

Lab biosafety level criteria

Procedures:

- entering the room
- decontamination procedures for leaving the room
- high security
- “hot zone”

Biosafety



Lesson # 83

Biosafety



Biosafety level 1

Biosafety level 1

BSL-1:

- **agents---not cause disease in humans**
- **minimal potential hazard to personnel, environment and community**
- **no special containment equipment**
- **open bench tops**

Biosafety level 1

Microbiological practices:

- workers must be trained
- supervisor enforce institutional policies
- workers must wash their hands
- eating, drinking, smoking

Biosafety level 1

Microbiological practices:

- mouth pipetting is prohibited
- policies for the safe handling of sharps
- procedures to minimize aerosols and splashes
- decontaminate work places

Biosafety level 1

Microbiological practices:

- decontaminate cultures
- biohazard symbol
- pest management programs
- special practices not required

Biosafety level 1

Safety equipments:

- **Gloves**
- **lab coats**
- **protective eyewear**

Biosafety level 1

Laboratory facilities:

- doors for access controls
- sink for hand washing
- bench tops-resistant
- chairs-easy to disinfect
- lab windows fitted with screens

Biosafety



Lesson # 84

Biosafety



**Biosafety level
2**

Biosafety level 2



BSL-2:

- moderate hazards to personnel and environment
- microbiological practices-same to BSL-1
- special equipments and practices required

Biosafety level 2



Special practices:

- **meet specific entry and exit requirements**
- **workers must be immunized**
- **biosafety manuals must be available**
- **proper collection, handling, processing, storage or transport**

Biosafety level 2



Special practices:

- lab equipments must be decontaminated
- incidents must be informed/eye, face, hand protection
- animals and plants should not be permitted in the lab
- aerosols-physical containment equipment

Biosafety



Lesson # 85

Biosafety

**Biosafety level
3**



Biosafety level 3



BSL-3:

- **applicable to diagnostic / clinical/ research/ production/ teaching facilities**
- **potentially lethal disease through the inhalation route**
- **all procedures must be performed in a biosafety cabinet**

Biosafety level 3

Equipments:

- vacuum lines must be protected with HEPA filters
- ducted air ventilation system
- HEPA filter exhaust air
- BSL-3 facility design, operational/parameter/procedures must be documented

Biosafety



Lesson # 86

Biosafety

Biosafety level
4



Biosafety level 4



BSL-4:

- **dangerous exotic agents**
- **aerosol transmitted lab infections**
- **no vaccine/treatment**
- **unknown risk of transmission**

Biosafety level 4

Types:

- A cabinet laboratory-
manipulation of
agents in BSC
- A suit laboratory-
personnel must wear
positive pressure air
protective suit

Biosafety



Lesson # 87

Biosafety



**Biosafety
measures for
TB lab**

Biosafety measures for TB lab



Biosafety measures:

- codes of practice
- equipment
- lab design and facilities
- health surveillance
- training
- waste handling

Biosafety measures for TB lab

Concepts:

- lab access
- responsibilities of lab manager
- personnel protective equipment
- work areas
- equipment

Biosafety measures for TB lab

Concepts:

- waste handling
- incineration
- autoclaving
- disinfection

Biosafety



Lesson # 88

Biosafety



**Low risk TB
labs**

Low risk TB labs

Classification:

- aerosol generated----
level of risk measured
- low risk TB labs
- moderate risk TB labs
- high risk TB labs

Low risk TB labs



Low risk TB labs:

- **minimum biosafety requirements**
- **direct sputum-smear microscopy**
- **preparation of specimen-automated nucleic acid purification assay**

Low risk TB labs



Factors increasing the risk of infection:

- improper bench spaces
- specimen container may leak
- specimen manipulated carelessly

Low risk TB labs



Factors increasing the risk of infection:

- specimen must be shaken vigorously
- ventilation may be poor

Biosafety



Lesson # 89

Biosafety



**Moderate risk
TB labs**

Moderate risk TB labs

Risk:

- moderate risk of generating aerosols
- low concentration of infectious particles
- processing of specimen-inoculation on primary culture media
- drug susceptibility testing

Moderate risk TB labs



Factors that increase the risk:

- work in areas with poor ventilation
- work with poor illumination
- BSC not maintained
- HEPA filters may be blocked

Moderate risk TB labs

Factors:

- **careless manipulation of specimens**
- **vortex should not be used**
- **specimen container may break**
- **cooling or heating system-not work properly**

Moderate risk TB labs

Factors:

- opening centrifuge bucket outside the BSC
- information of biohazards may be inadequate

Biosafety



Lesson # 90

Biosafety



**High risk TB
labs**

High risk TB labs



Risk:

- **work with high concentrations of bacilli**
- **engage in procedures that pose increase risk of aerosol spread**
- **manipulate cultures for identification**
- **manipulate cultures and suspensions for DST**

High risk TB labs



Factors:

- staff-open positive culture vials
- prepare smears from positive cultures
- DNA extraction-performed
- broken culture containers/spills

High risk TB labs



Biosafety measures:

- double doors/self closing /inter-locking system
- personal protective equipment
- decontaminate and waste disposal

Biosafety



Lesson # 91

Biosafety



**Safety
equipment**

Safety equipment

Biological safety cabinets:

- **Class I, II, III BSC**
- **air intake velocity**
- **amount of air circulated**
- **exhaust system**
- **pressure system**

Safety equipment

Negative pressure flexible-film isolators:

- mounted on a mobile stand----- field work
- high risk microbes
- workspace enclosed in PVC envelope
- internal pressure lower-atmospheric pressure/HEPA filters

Safety equipment

others:

- pipetting aids
- spatter shield
- disposable loops
- autoclave
- screw-capped bottles

Safety equipment

Microincinerators:

- shielded in an open ended glass or ceramic tubes
- heated by gas or electricity
- disposable

Safety equipment

Vaccum line protection:

- filters prevent the passage of microbes
- flask contain the disinfectants
- rubber bulb-prevent overflow-close off vaccum
- unit - autoclavable

Biosafety



Lesson # 92

Biosafety



**Personal
protective
equipment**

Personal protective equipment

Gloves:

- to protect hands from hazardous materials
- glove selection---- risk assessment
- latex gloves-available
- wear outside-lab
- wear two pairs ----- required

Personal protective equipment

Lab coats:

- gowns/coats/smocks/uniforms designated for lab
- prevent personal clothing
- remove-leaving for non-laboratory areas
- deposit for laundry/should not be taken home

Personal protective equipment



Eye and face protection:

- goggles, mask, face shield, splash guard
- contact lenses
- dispose of/
decontaminate
- used in rooms -----
infected animals

Personal protective equipment

Respirators:

- **inhalation of aerosols**
- **full/half face**
- **interchangeable filters**
- **shouldn't worn-outside lab**
- **disposable-respirator**

Biosafety



Lesson # 93

Biosafety



**Plans for
emergency**

Plans for emergency

Puncture wounds, cuts and abrasion:

- **remove protective clothing**
- **wash hands and affected area**
- **apply skin disinfectant**
- **seek medical attention**

Plans for emergency

Ingestion of hazardous material:

- **identification of Ingested material**
- **circumstances of the incidence**
- **complete medical record**

Plans for emergency

Aerosol release:

- vacate the affected area/exposed person-
medical advise
- 1h aerosols carried away/heavier particles settle down
- no entry
- decontaminate-----
protective measures

Plans for emergency

Others:

- broken containers
- breakage of tubes in a centrifuge machine
- natural disasters

Plans for emergency

Emergency services:

- addresses/phone numbers
- emergency equipments
- first aid box

Biosafety



Lesson # 94

Biosafety



**Transport
of
infectious
material**

Transport of infectious material



Introduction:

- **subject to strict National/ International regulations**
- **packaging material and shipping requirements**
- **IATA shipping guidelines/WHO**
- **international model regulations**

Transport of infectious material

Packaging system:

- **triple packaging system**
- **three layers: receptacle, leak proof packaging**
- **third layer protects second layer-physical damage while in transit**

Transport of infectious material

Information:

- specimen data form
- letters
- identify and describe specimen
- identify shipper and receiver
- any other documentation

Biosafety



Lesson # 95

Biosafety



**Recombinant
DNA
technology**

Recombinant DNA technology



Uses:

- never exist in the nature before
- undesirable and unpredictable properties
- clone DNA in to host -
---- over expression
- GMOs
- Role in medicine

Recombinant DNA technology



Expression system:

- host and vector
- pUC18 and *E.coli* K12
- pUC18 has been sequenced
- *E.coli* K12-----
non pathogenic
- Biosafety level 1

Recombinant DNA technology



Biosafety consideration:

- **pathogenic strains—
increase virulence of
GMOs**
- **inserted DNA seq-not
well characterized**
- **gene product code for
toxins**
- **pharmacological
activity**

Recombinant DNA technology

Viral vectors:

- *Adenovirus*
- lack replication genes
- contaminated with replication competent viruses
- handled at the same biosafety level as that of the parent virus

Recombinant DNA technology



GMOs:

- **transgenic mice cause human poliomyelitis**
- **new lines-transgenic animals studies**
- **route of transmission /inoculum size of infection**
- **extent of virus shedding**

Recombinant DNA technology



Risk assessment:

- inserted gene with known properties
- toxins/cytokines/hormones/allergens
- gene expression regulators/enhancers
- oncogene sequence
- antibiotic resistance

Biosafety



Lesson # 96

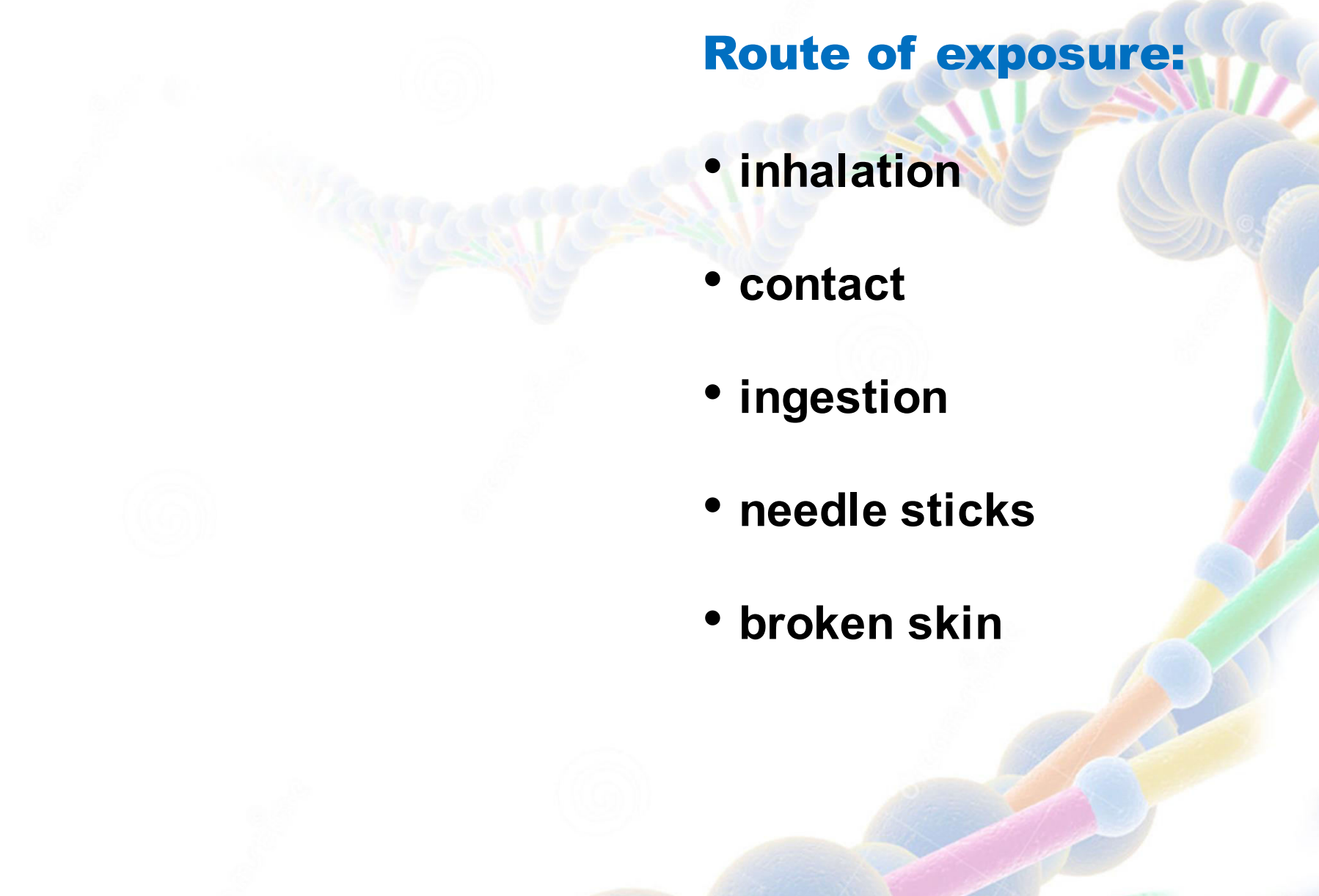
Biosafety



**Hazardous
chemicals**

Hazardous chemicals

Route of exposure:

- **inhalation**
 - **contact**
 - **ingestion**
 - **needle sticks**
 - **broken skin**
- 

Hazardous chemicals



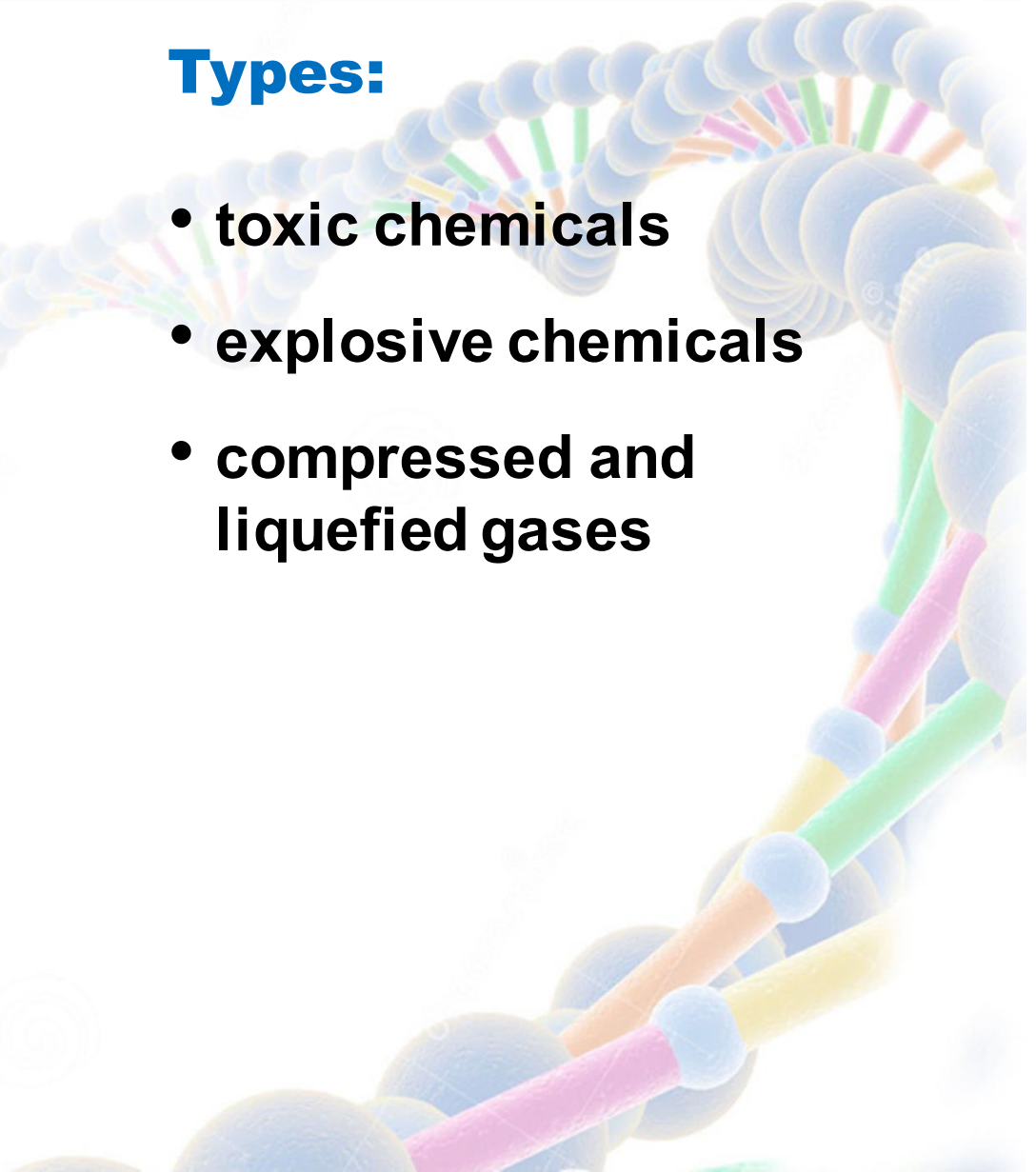
Storage:

- limited amount for daily use
- bulk stored in a separate room
- arrange in an alphabetic order

Hazardous chemicals

Types:

- toxic chemicals
- explosive chemicals
- compressed and liquefied gases



Hazardous chemicals

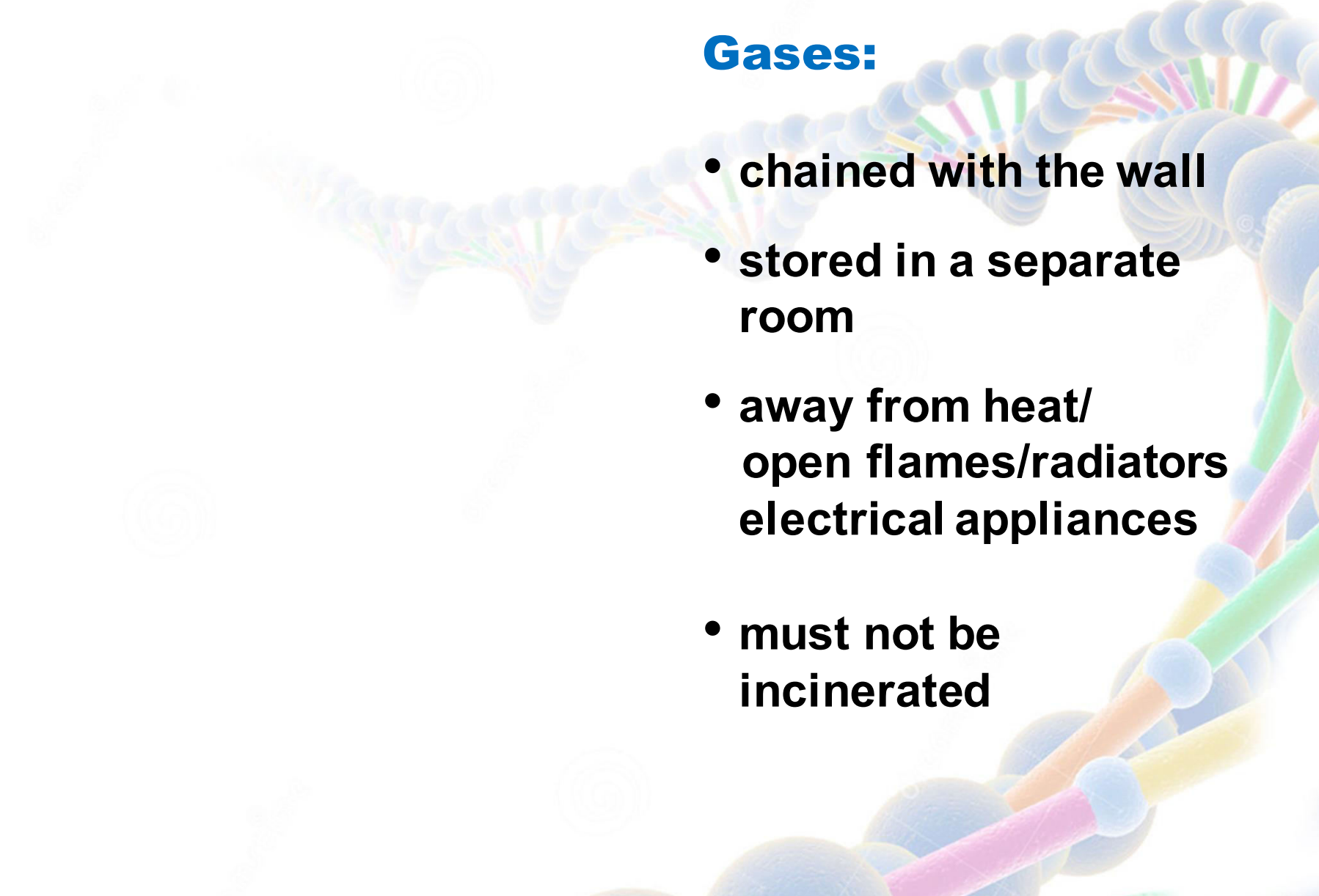


Explosive chemicals:

- Azides shouldn't react with metals
- Ether that have aged, dry crystals-unstable
- Perchloric acid, not dry on wood or fabric
- Picric acid, picrates-explode by heat

Hazardous chemicals

Gases:

- chained with the wall
 - stored in a separate room
 - away from heat/
open flames/radiators
electrical appliances
 - must not be
incinerated
- 

Biosafety



Lesson # 97

Biosafety



Fire Hazard

Fire hazard

Introduction:

- **close cooperation between safety officer and fire prevention officer**
- **immediate action in case of fire**
- **determine-it is best to contain or extinguish fire**

Fire hazard



Reasons:

- **electric circuit overloading**
- **poor electrical maintenance**
- **long electrical leads**
- **equipment unnecessarily switched on**

Fire hazard



Reasons:

- open flames
- equipments not designed for lab environment
- improper ventilation
- mishandling of the chemicals

Fire hazard

Fire-fighting equipments:

- **inspected, maintained shelf life**
- **near doors/ corridors**
- **hoses, buckets and fire extinguishers**
- **fire warnings/ instructions**
- **escape routes/ assembly point**

Fire hazard



Types:

- **water:** wood, fabric, paper
- **carbon dioxide gases:** flammable liquids and gases/electrical fires
- **dry powder:** flammable liquids and alkali metals
- **foam:** flammable liquids

Biosafety



Lesson # 98

Biosafety



**Electrical
Hazards**

Electrical hazards

Introduction:

- **electrical appliances and equipments ----- tested and inspected**
- **electric- circuit protect wiring from being overloaded with electric current**
- **earth-fault- interrupters: protect people from electric shock**

Electrical hazards

Safety:

- National electrical standard and safety codes
- earth / grounding systems with three-prong plugs

Biosafety



Lesson # 99

Biosafety



Noise

Noise



Risk:

- **noise measurement surveys**
- **specify areas**
- **lab equipments(laser)**
- **animal house**

Noise

The slide features a decorative background. At the top, there is a thick purple horizontal bar. Below it, a colorful molecular structure, resembling a DNA double helix or a protein chain, is rendered in a semi-transparent, light blue and white style. The structure is composed of spheres and connecting rods in various colors (blue, green, yellow, pink, orange). The overall aesthetic is clean and professional.

Control:

- **barriers around noisy equipments**
- **barrier between noisy areas and work areas**
- **hearing conservation program**
- **medical monitoring program**

Biosafety



CENTURY
YAHOOO

Biosafety



**Ionizing
radiation**

Ionizing radiation



Risk:

- **somatic effects:
radiation induced
cancers**
- **hereditary effects of
radiation exposure to
the gonads**

Ionizing radiation



Protection:

- minimize the time of exposure to radiation
- maximize the distance from the radiation source
- shielding the radiation source
- substituting with non-radiometric methods

Ionizing radiation

Rules:

- **radiation area**
- **work-bench area**
- **radioactive waste area**
- **emergency response**

Biosafety



Lesson # 101

Biosafety



**Biosafety
officer**

Biosafety officer



Biosafety officer:

- **appointment**
- **ensure biosafety programs and policies**
- **small scale-technical staff**
- **microbiology, biochemistry, basic biological sciences**

Biosafety officer



Duties:

- **apply National or International rules, regulations/guidelines**
- **assist lab in developing standard safety procedures**
- **knowledge of lab, clinical practices**

Biosafety officer



Duties:

- **knowledge of devices/engineering principles**
- **maintenance facilities**
- **communicate with administrative, technical and support personnel**

Biosafety officer

Activities:

- biosafety consultation
 - biosecurity consultation
 - technical compliance consultation
- 

Biosafety officer

Biosafety audits:

- **technical methods**
 - **procedures**
 - **protocols**
 - **biological agents**
 - **materials**
 - **equipments**
- 

Biosafety officer



Activities:

- **discussion-violation with appropriate persons**
- **biosafety training**
- **continue education in biosafety**
- **investigation of accidents**

Biosafety officer



Activities:

- **decontamination of spills**
- **proper waste management**
- **decontamination of apparatus**
- **awareness of community attitudes**

Biosafety officer



Activities:

- **procedures for import/export of pathogens**
- **review biosafety aspects of research work**
- **institution of a system to deal with emergencies**

Biosafety



Lesson # 102

Biosafety



**Biosafety
committee**

Biosafety committee



Committee include:

- **biosafety officer/
scientists**
- **veterinarians**
- **medical officers**
- **representatives of
technical staff**
- **representatives of lab
management**

Biosafety committee



Duties:

- biosafety policies and code of practice
- review research protocols
- risk assessment formulation
- advice - sensitive discussion

Biosafety



Lesson # 103

Biosafety



**Safety for
support
staff**

Safety for support staff

Introduction:

- safe and optimum operations of a lab
- dependent on support staff
- safety training

Safety for support staff

Engineering and maintenance services:

- institutional internal services
- good relationship with local services
- supervision of biosafety officer
- enter BSL-3 and BSL4 with clearance

Safety for support staff

Knowledge:

- maintain and repair the structure
- equipments
- nature of lab work
- safety regulations
- safety procedures

Biosafety



Lesson # 104

Biosafety



**Training
program
s**

Training programs

Effectiveness:

- **management commitment**
- **motivational factors**
- **initial job training**
- **good communication**
- **organization goals and objectives**

Training programs

Elements:

- needs assessment
- establishing training objectives
- specifying training contents and media
- accounting for individual learning differences

Training programs

Elements:

- specifying learning objectives
- training evaluation
- training revision

Biosafety



Lesson # 105

Biosafety



**Safety
checklist**

Safety checklist

Uses:

- intended to assist in assessment
- microbiological lab safety
- security status
- biomedical labs

Safety checklist

Checklist:

- **lab premises**
- **storage facilities**
- **sanitation and staff facilities**
- **heating and ventilation**
- **lighting**

Safety checklist

Checklist:

- **services**
- **lab biosecurity**
- **fire prevention and protection**
- **electrical hazards**
- **personal protection**

Safety checklist

Checklist:

- health and safety of staff
- chemicals/radioactive substances
- lab equipment
- infectious materials
- flammable liquid storage/compressed gases

Biosafety



Lesson # 106

Biosafety



First aid

First aid



Definition:

- **medical treatment---**
time and place of an
accident
- **approved method**
- **treat the casualty**
- **before doctor's care**
for treatment

First aid



Contains??:

- first aid box
- protective clothing
- safety equipment
- eye irrigation

First aid

First aid box:

- made up of material-keep the content dust and damp free
- white cross with green box
- prominent position
- easily recognizable

First aid

Box contains??:

- first aid manual
- bandages
- sterile dressings
- safety pins

First aid



Protective equipment:

- **mouth piece for mouth-to-mouth resuscitation**
- **gloves-protections**
- **clean up kit for blood spills**

Biosafety



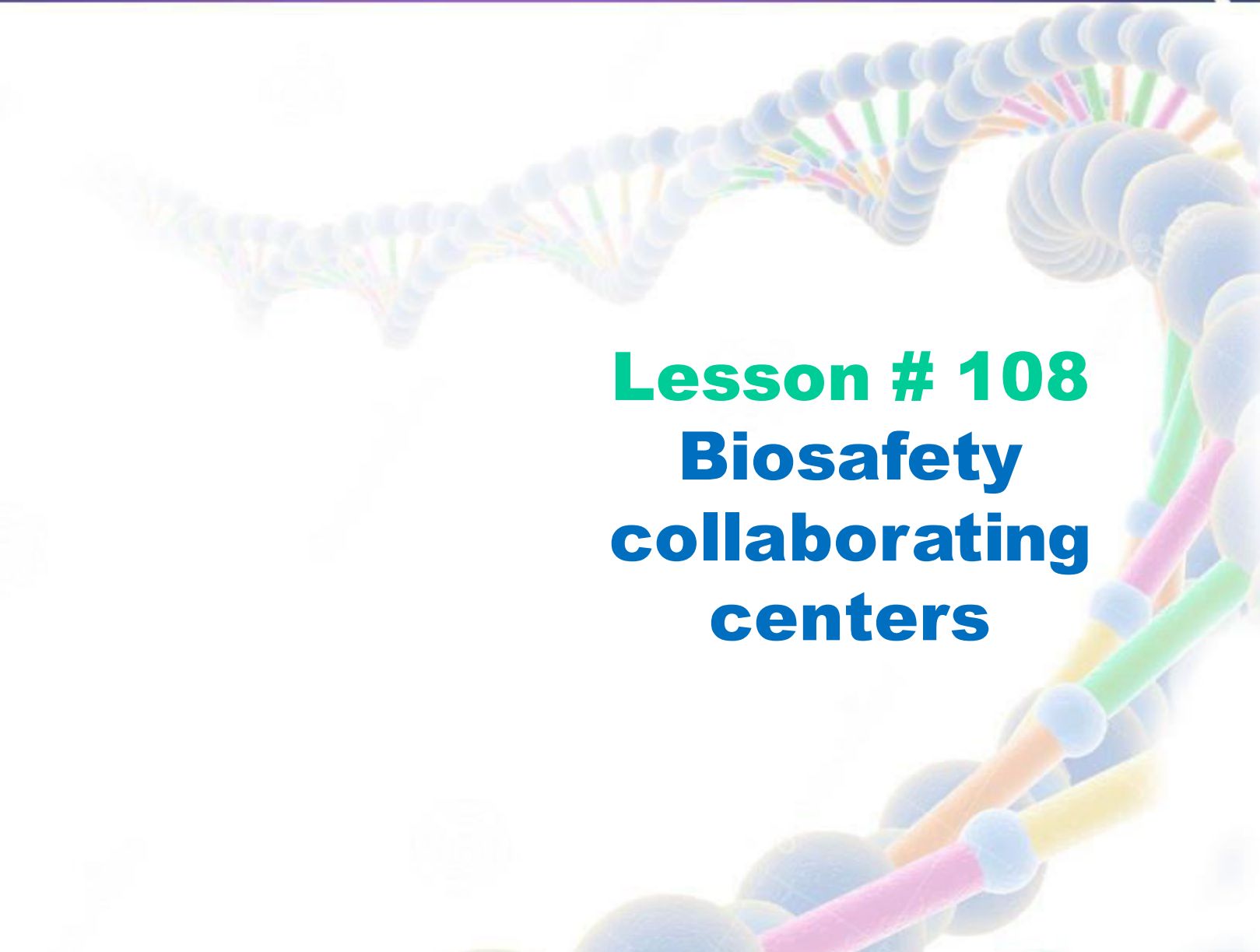
Lesson # 107
Immunization
of staff

Immunization of staff

Introduction:

- discuss with workers
- vaccines
- therapeutic drugs-
after exposure

Biosafety



Lesson # 108
Biosafety
collaborating
centers

Biosafety collaborating centers



Centers:

- **department of communicable disease surveillance and response, WHO**
- **Swedish institute of infectious disease control**
- **biosafety technology and consultative services, WHO**

Biosafety collaborating centers

Centers:

- applied biosafety programs and training
- Victorian infectious diseases reference laboratory

Biosecurity



Lesson # 109

Biosecurity



US biosecurity legislation

US biosecurity legislation



US legislation:

- biosecurity bill 2014
-----government
- biosecurity act 2015
- agriculture
biosecurity
department worked
400 organizations
- 630 pages long

US biosecurity legislation



Future:

- **biosecurity act support biosecurity system**
- **in any age**
- **regardless of the advances in technology**
- **scientific advances and advices help to make right decisions**

US biosecurity legislation



Objectives:

- **modern and responsive legislative framework**
- **improving underpinning processes**
- **robust biosecurity system that benefits everyone**

US biosecurity legislation



Examples:

- prevent the entry and establishment
- invasive species
- exotic pests
- harm natural environment, agriculture, health and economy

Biosecurity



Lesson # 110

Biosecurity



**US biosecurity
regulations**

US biosecurity regulations



implementation:

- **new biosecurity legislation is a large body of work**
- **success is critical to large number of clients/ stakeholders**
- **they understand the implementation and regulations**

US biosecurity regulations



GM crops:

- **divided into three regulatory agencies**
- **Environment protection agency (EPA)**
- **Food and drug administration (FDA)**
- **US department of agriculture (USDA)**

US biosecurity regulations



EPA:

- **insecticide/pesticide/
fungicide/rodenticide**
- **GM crop carrying a
gene of Bt toxins**
- **environmentally
friendly**
- **food safety
analysis/non-allergic**

US biosecurity regulations



FDA:

- **safety of GM crops eaten by humans and animals**
- **requires pre-market approval**
- **GM crops equivalent to non-GM crops**
- **expression of foreign proteins**

US biosecurity regulations



Functions:

- solve the **problems**
- toxicity
- allergy
- introduction of pharmaceutical products

US biosecurity regulations

Biopharming:

- FDA regulate “pharma animals”
- entire transgenic animal is viewed as a product
- drug itself is effective

Biosecurity



Lesson # 111

Biosecurity



**US biosecurity
guidance**

US biosecurity guidance



AFIA:

- **America Feed Industry Association**
- **bioweapons guidelines**
- **provide recommendations to feed and ingredient manufacturers**
- **develop biosecurity plan-control spread of animal diseases**

US biosecurity guidance



AFIA:

- **location, business, facility develop a biosecurity plan**
- **based on potential hazards and risk of occurrence within processes**
- **develop procedures-plan implementation-effective as situation changes**

US biosecurity guidance

Biorisk:

- **probability that the adverse event will occur**
- **assessment-identify risk-consequences**
- **management-development of strategies to reduce the biorisk**

US biosecurity guidance



Approach:

- **responsibility of the director**
- **reduce biorisk**
- **establishment and implementation of the procedures**
- **biorisk management committee**

US biosecurity guidance



Code of conduct:

- **non-legislated guidelines**
- **one or more organizations**
- **set out the standards**
- **particular activity**

US biosecurity guidance



Responsibility of VBM:

- **vulnerable biological materials**
- **require administrative oversight, control, accountability**
- **protective measure**
- **value of population**

US biosecurity guidance



VBM:

- toxins
- non-pathogenic strains
- foods/vaccines
- GMOs
- cell-components
- extraterrestrial samples

Biosecurity



Lesson # 112
Canada
biosecurity
legislations

Canada biosecurity legislations



Development:

- **public health agency of Canada**
- **Canadian food inspection agency**
- **guidelines for human and animal pathogens and toxins**

Canada biosecurity legislations



Guidelines:

- **used by researchers and lab workers**
- **facilities possessing, handling, storing or using such pathogens**
- **update risk-evidence - performance based approach**

Biosecurity



Lesson # 113
Japan
biosecurity
legislations

Japan biosecurity legislations



Introduction:

- **Japan ministry of health, labor and welfare**
- **two pillars of biosecurity**
- **surveillance of infection and infectious agents**
- **regulations of pathogen handling**

Japan biosecurity legislations



Duties:

- screening of foods, human, vectors at the point of entry
- Japan ministry of agriculture, forest and fisheries
- health issues-animals and plants
- bioweapon-prohibition laws

Biosecurity



Lesson # 114

Biosecurity



**Other
countries
biosecurity**

Other countries biosecurity

New Zealand:

- **work with other organizations**
- **hazardous substance and new organism act**
- **not in 1993-develop 1996**
- **environment safety**
- **human health**

Other countries biosecurity

Queensland biosecurity act 2014:

- facilitates responding -impact of biosecurity consideration
- safety and quality of animal field
- agriculture inputs
- requirement at national level

Other countries biosecurity



India:

- alien species
- sanitary and phytosanitary measures
- GMOs
- bioethical considerations in research

Biosecurity



Lesson # 115

Biosecurity



Design biosecurity plan

Design biosecurity plan

Biosecurity plan:

- **written plan-prevent the introduction and spread of disease to farm**
- **daily operation procedures**
- **disinfecting procedures-part of the plan**

Design biosecurity plan

Responsibilities:

- **principle investigator
plan implementation-
workers following the
plan-training**
- **lab workers**
- **responsible official**
- **campus security staff**
- **management services**

Design biosecurity plan



RO:

- **contacted if biological agent is theft or lost**
- **contacted agencies if there is threat or spill**
- **training**

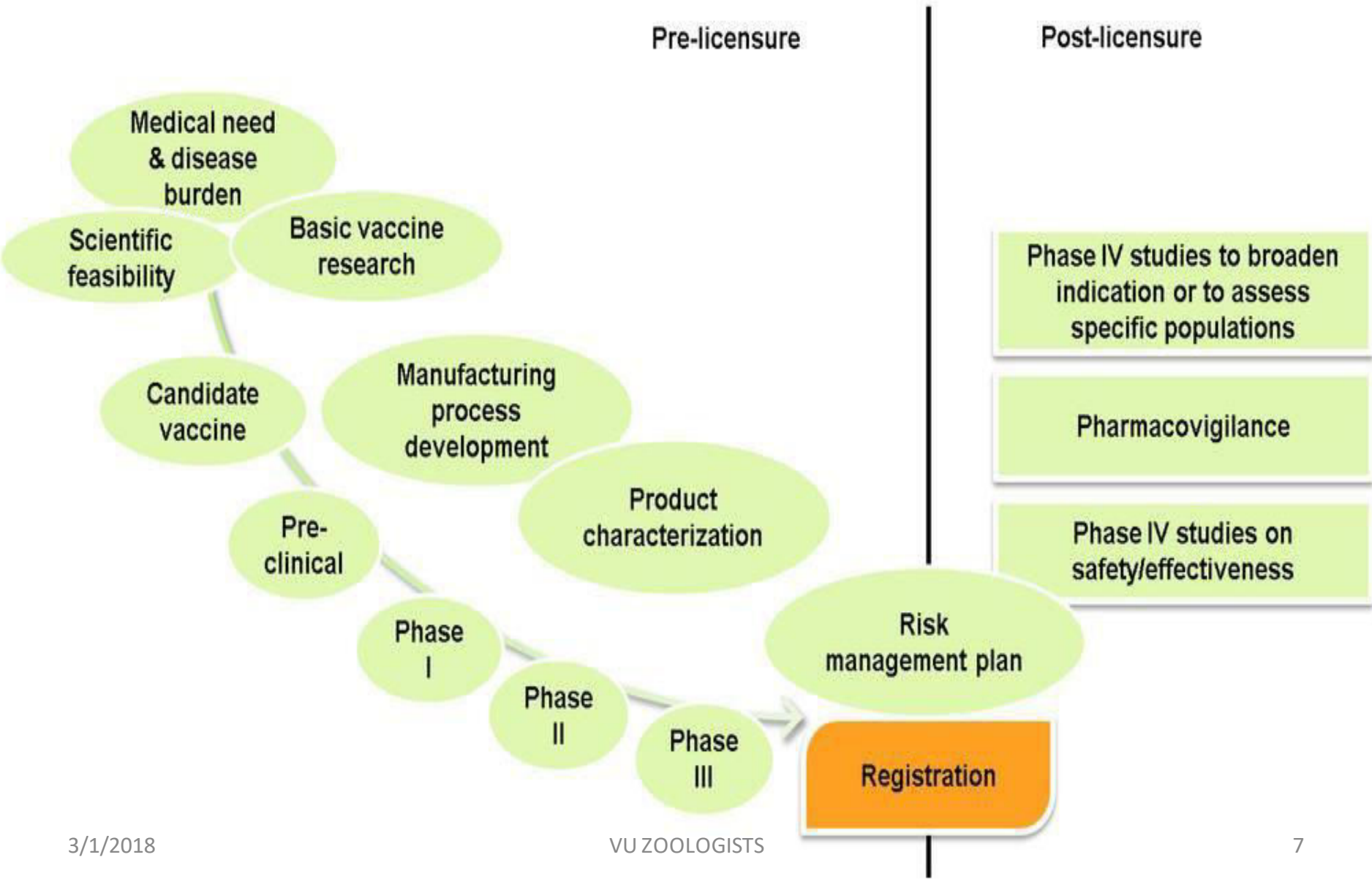
Design biosecurity plan



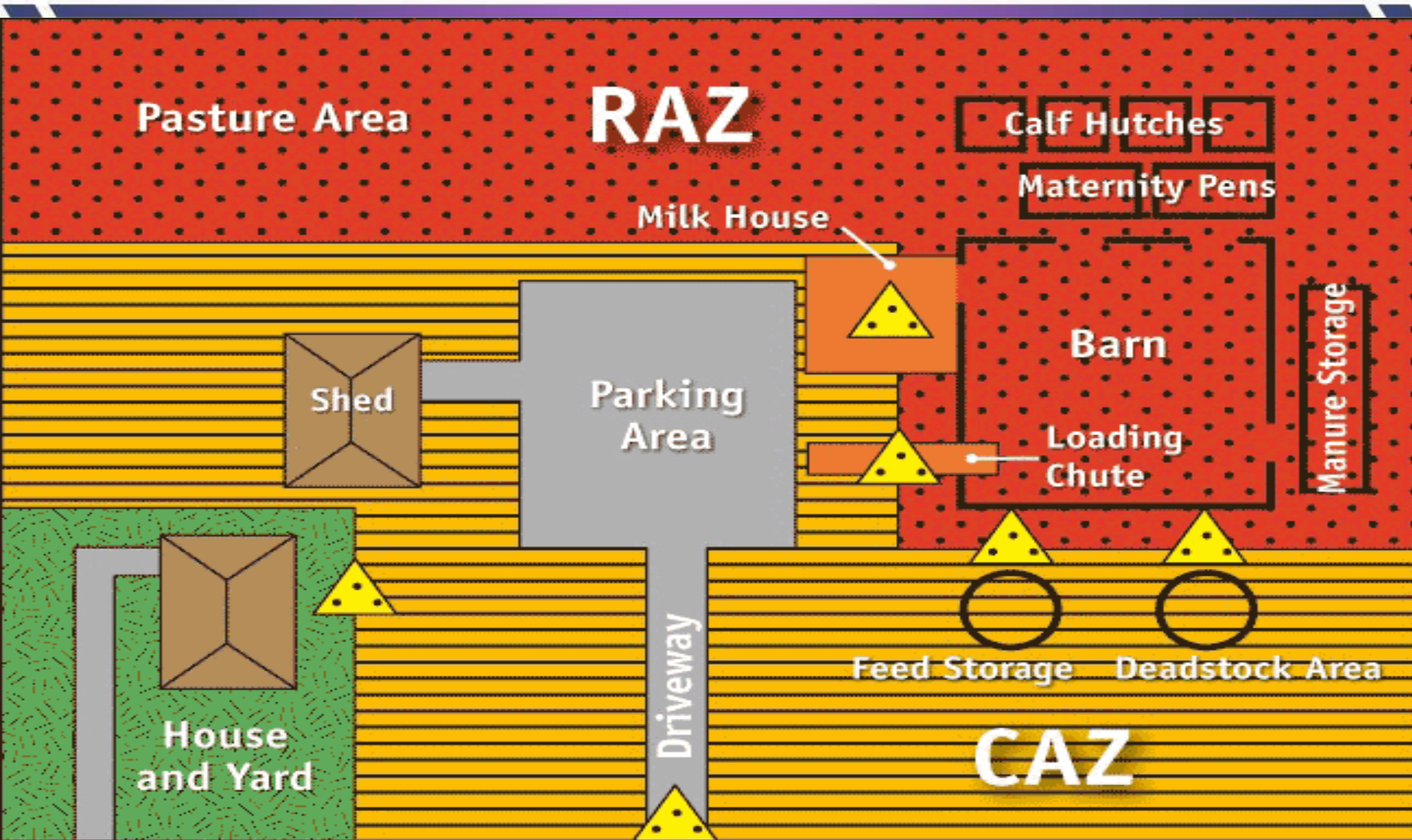
Other aspects:

- **risk assessment**
- **physical protection**
- **personnel protection**
- **pathogen accountability**
- **emergency response**

Design biosecurity plan



Design biosecurity plan



VU ZOOLOGIST'S

Biosecurity



Lesson # 116
Objectives of
lab biosecurity

Objectives of lab biosecurity



Objectives:

- **this supports lab safety agenda to prevent diseases**
- **ensure containment of infectious materials**
- **maintain citizen confidence of bioscience research community**

Objectives of lab biosecurity



Objectives:

- **transparency to investors in the industries**
- **protect valuable research and commercial assets**
- **reduce the risk of crime and bioterrorism**

Biosecurity



Lesson # 117

Biosecurity



**Biosecurity
and
bioterroris
m**

Biosecurity and bioterrorism

Lethal pathogens:

- abuse modern science/disrupt everyday life
- cripple basic government functions
- spread fear/kill people/destroy food
- rapid pace of developments

Biosecurity and bioterrorism



Difference:

- **biosecurity used---
different ways-----
different policy and
communities**
- **broader range of
measures to avoid
bioterrorism**
- **anthrax, botulism,
plague, small pox,
viral hemorrhagic
fever**

Biosecurity and bioterrorism



Biodefence risk:

- **biodefence research-
drugs and vaccines**
- **anthrax spores in
mailed letters - got
from one of the
research lab**
- **foreign biowarfare
program**
- **stolen materials from
US biodefense**

Biosecurity and bioterrorism



Thwarting acquisition:

- ways-nature, culture, medical/ bio research facilities
- paying criminal to do so on their behalf
- biosecurity build barriers
- failed to obtain the samples of *Ebola virus*

Biosecurity



Lesson # 118
International
obligations

International obligations



Introduction:

- **international community - set of international obligations on lab biosecurity**
- **state implement legislations**
- **control misuse of bioweapons**

International obligations

Other aspects:

- protect the public and environment
- transportation biosecurity
- enforce legal barriers
- rules to manufacture, store and use biological materials

Biosecurity



Lesson # 119

Biosecurity



**Pakistan
biosecurity
system**

Pakistan biosecurity system



Introduction:

- **developing country-
enjoys fewer benefits**
- **recent advances in
biomedical research**
- **stress given by the
public/private sector
to control infection
diseases**

Pakistan biosecurity system



Introduction:

- biosafety/ biosecurity policies/ regulations are at early stage
- HIV/AIDs, hepatitis, dengue fever, MDR, cholera, influenza, gastroenteritis

Pakistan biosecurity system



Pakistan Biosafety rules:

- notified in 2005
- manufacture/import/
stored GMOs
- import, export, sale
and purchase of
GMOs for commercial
purposes
- guidelines for lab
work-----commercial
release

Pakistan biosecurity system

Pakistan Biosafety rules:

- **guidelines for the establishment of proper procedures**
- **National Biosafety Committee (NBC)**
- **Institutional Biosafety Committee (IBC)**
- **Technical Advisory Committee (TAC)**

Biosecurity



Lesson # 120

Biosecurity



**Risk
assessment**

Risk assessment

Introduction:

- **qualitative and quantitative approach**
- **identify hazards**
- **quantitative: two components**
- **magnitude of the potential loss**
- **probability that the loss will occur**

Risk assessment



Fields:

- **medical/hospital services**
- **nuclear/aerospace/oil/military industries**
- **food industry**
- **methods of risk assessment may differ**

Risk assessment



Public health:

- **FDA-regulates food safety through risk assessment**
- **1973-cancer causing compounds-not in the meat**
- **US environment protection agency----environment risk assessment for public health**

Risk assessment



Public health:

- **Stockholm convention - risk framework assessment for chemicals**
- **risks apply to small subpopulation**
- **high risk-abnormal exposure**

Risk assessment

Risk < 1%:

- **all infants younger than X days**
- **recreational users of a particular product**

Biosecurity



Lesson # 121

Biosecurity



**Risk
assessment
methodology**

Risk assessment methodology

Risk assessment scheme:

- **conduct-standardized systematic/repeatable comparable---- avoid over complication**
- **frequency of exposure/ infection**
- **consequences of the disease**
- **limited data**

Risk assessment methodology

Biosafety:

- risk to the individuals in the lab
- risk to the human community
- risk to the animal community

Risk assessment methodology



MCDA:

- **Multi criteria decision analysis-comparison**
- **relative risk posed by lab practices and by biological agents**
- **scientifically sound method**
- **decision analysis**
- **mathematical models**

Risk assessment methodology

A decorative background featuring a series of colorful spheres (blue, green, yellow, pink) connected by thin lines, creating a network-like structure that curves across the slide.

Risk acceptance:


- structured method
- factors influence risk acceptance
- available resources to control the risk
- regulatory requirements
- value of work-----
community

Risk assessment methodology

Technical assessment scheme:

- define accepted criteria
- scoring system
- calculation
- development of equation

Biosecurity



Lesson # 122
Evaluate
pathogens and
toxins

Evaluate pathogens and toxins



Pathogens:

- **cultures, diagnostic samples/tissues**
- **RG-1-non-pathogenic strains**
- **RG-2-*Salmonella*, *E.coli*, *Influenza***
- **RG-3-tuberculosis, anthrax**
- **RG-4-ebola, small pox**

Evaluate pathogens and toxins



Toxins:

- **bacterial toxins-
exotoxin and
endotoxin**
- **exo-actively secreted**
- **endo-part of bacteria-
not released-unless
killed**
- **toxinoses-botulinum
neurotoxin/ tetanus
toxin**

Evaluate pathogens and toxins



Evaluation:

- evaluation of production-ELISA
- virulence factors-PCR
- serotypes-PCR
- toxic effects of pathogens *in vitro* occurring in cell lines
- upon expression of genes

Biosecurity



Lesson # 123
Potential
adversaries

Potential adversaries



Adversaries-GM crops:

- enemy/threat
- food allergy increases 50%
- Bt toxin
- What about cancer?

Potential adversaries

Adversaries-GM fish:

- environmental impact on wild life
- invade the population
- evaluate transgene itself

Potential adversaries

Examples:

- **Salmon with growth hormone gene**
- **gene for better anti-bacterial resistance**
- **genes for good nutritional product**
- **transgenic fish not commercial except zebrafish**

Potential adversaries

Overall threats:

- food-borne risks
- across border spread of alien species
- loss of biodiversity
- destroy earning potential of rural communities
- disruption to trade

Biosecurity



Lesson # 124
Evaluate
scenarios

Evaluate scenarios

Introduction:

- **risk is identified**
- **management committee-decide**
- **which scenarios protect against high risk**
- **which scenarios protect though incident response planning**

Evaluate scenarios

Description:

- design and implement protective measures
- risk assessment-rank scenarios

Evaluate scenarios

Create scenarios:

- **pathogen/toxin**
- **individual or group wish to steal pathogens**
- **theft of pathogen or toxin**
- **terrorist included in scenarios of high and extreme risk**

Biosecurity



Lesson # 125

Biosecurity



**Characterize
risk**

Characterize risk

Malicious risk groups:

- non-pathogenic
- low malicious use risk (LMUR)
- moderate malicious use risk (MMUR)
- high malicious use risk (HMUR)/extreme malicious use risk (EMUR)

Characterize risk



Description:

- non-pathogenic-inherent hazardous
- no/insignificant consequences
- LMUR - low consequences
- most biological agents

Characterize risk



Example:

- *Mycobacterium leprae*
- gram positive rods/
non-spore formers
- organism grow
slowly-generation
time 30 days
- not highly virulent
(LMUR)

Characterize risk



Description:

- **MMUR-can't deploy as biological weapons**
- **low / moderate consequences**
- **low / moderate economic impact**
- **many current agents evaluated as MMUR**

Characterize risk



Example:

- *C.immitus* – fungus
- desert fever
- cure without treatment/life-threatening cases
- asymptomatic
- biosafety level 3-MMUR

Characterize risk



Description:

- **HMUR**
- **national/international consequences**
- **high casualties**
- **high economic impact**
- ***Bacillus anthracis***

Characterize risk



Description:

- EMUR-HMUR
- not found in the nature
- high security measures
- eradicated
- genetically engineered agents

Characterize risk



Example:

- *Variola major virus*
- small pox
- highly virulent
/contagious/stable in
droplets
- eradicated by vaccine
- GM virus – more
virulent

Biosecurity



Lesson # 126
Risk reduction

Risk reduction



Strategies:

- **should be adopted**
- **implementation of large policies**
- **programs/projects-to be transparent with sponsors**
- **management principles applied to small policies**

Risk reduction

Risk management:

- **structured approach**
- **occur in steps**
- **identify, assess and control risk**
- **processes in place to minimize and monitor risk**
- **control adverse risk consequences-materialize**

Risk reduction

Steps:

- **early consultation-
identify needs and
cost**
- **deferring irreversible
decisions-need more
time to achieve
objectives**
- **pilot studies - more
information about risk**
- **design flexibility-
modify-future needs**

Risk reduction

Steps:

- precautionary actions
- transferring risk to private sector ----- insurance
- less use of leading edge technology
- undertaking site investigation

Risk reduction

Steps:

- **staging the project-
review at different
steps**
- **abandoning the
project - too risky**

Biosecurity



Lesson # 127

Biosecurity



**Components
of
biosecurity**

Components of biosecurity



Biosecurity:

- **strategic and integrated approach**
- **encompasses the policies / regulatory framework**
- **analyzing and managing risk**

Components of biosecurity



Factors influencing biosecurity:

- globalization
- new agricultural products and technologies
- increase trade in food
- travelling across borders

Components of biosecurity



Factors influencing biosecurity:

- **advances in communication**
- **greater public attention to biodiversity**
- **shift from country independence to interdependence**

Components of biosecurity



Factors influencing biosecurity:

- less technical and operational resources
- some countries are dependent on food import

Components of biosecurity



Components:

- **physical security**
- **personnel security**
- **material control and accountability**
- **transfer security**
- **information security**

Biosecurity



Lesson # 128
Physical security

Physical security

Introduction:

- protection of people/
hardware/programs
- data / networks
- physical events-
terrorism/disasters

Biosecurity



Lesson # 129

Biosecurity



**Physical
security
elements**

Physical security elements



Elements:

- obstacles placed in the way of attackers
- surveillance and notification system
- methods to recover quickly from disaster

Physical security elements

Obstacles:

- fencing
- wall
- multiple locks
- fireproof safes
- water sprinkles

Physical security elements

Surveillance/notification system:

- heat detector
- smoke detector
- lighting
- alarms
- cameras

Physical security elements

Recovery:

- **repairment**
- **hiring additional security**
- **cameras**

Biosecurity



Lesson # 130

**Integration
of lab
biosafety**

Integration with lab biosafety



Integration:

- **focus on awareness to change the current culture**
- **clarify terminology**
- **development of training strategies**
- **secure commitment to stakeholders**
- **increase capacity**

Integration with lab biosafety

Lab biosafety:

- lab biosecurity supports lab biosafety
- work as coordinated and complementary system
- biosafety cannot provide sufficient biosecurity

Integration with lab biosafety



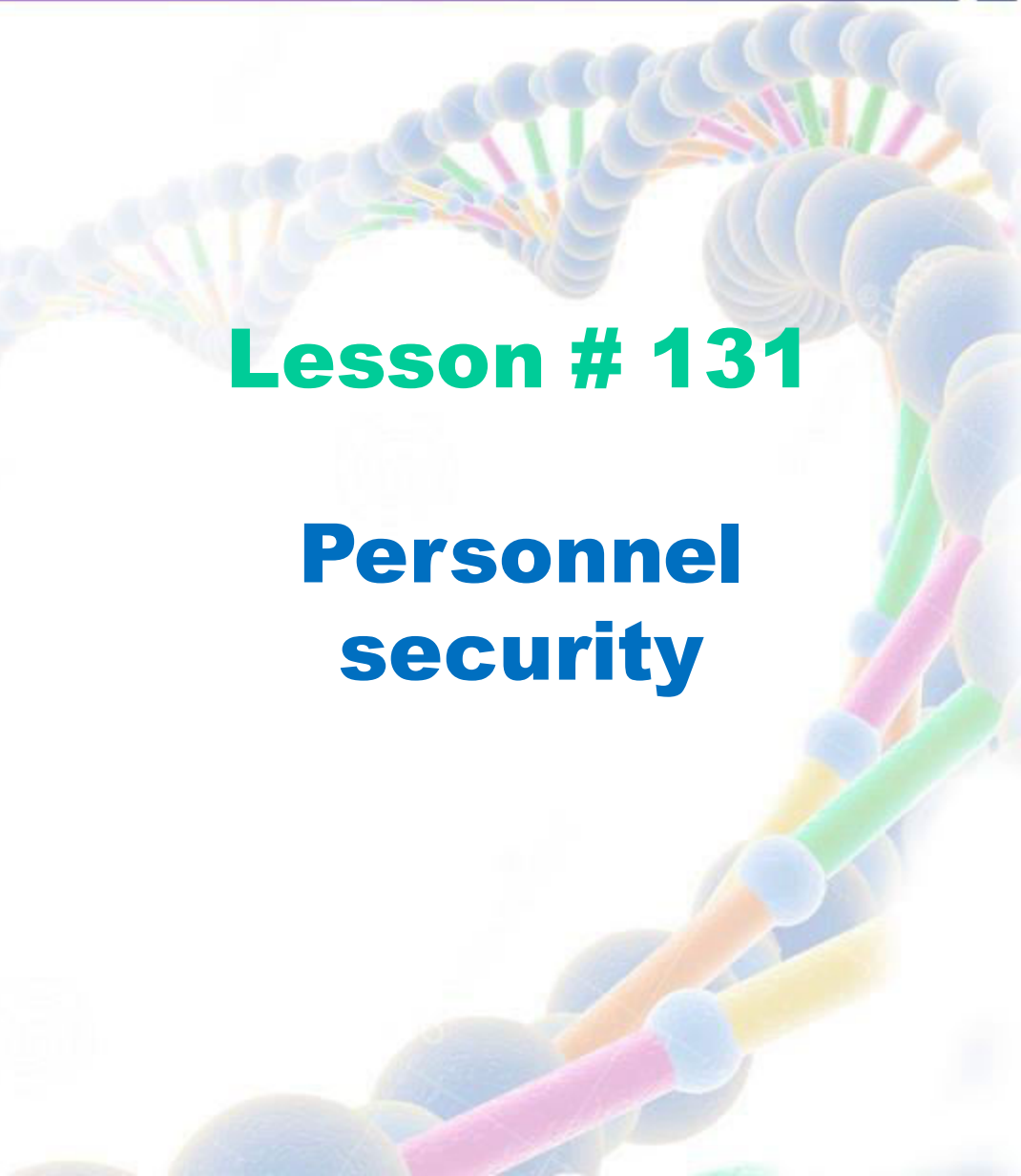
Biosecurity:

- **biosecurity policies has to be developed**
- **conflicts between biosafety- biosecurity has to be resolved**
- **good lab biosecurity systems enforce and strengthen biosafety systems**
- **security measures- routine part**

Biosecurity

Lesson # 131

Personnel security



Personnel security

Introduction:

- **increases the level of assurance**
- **honesty, trustworthy, loyalty with government resources**
- **reduces the risk of loss and damage**

Personnel security

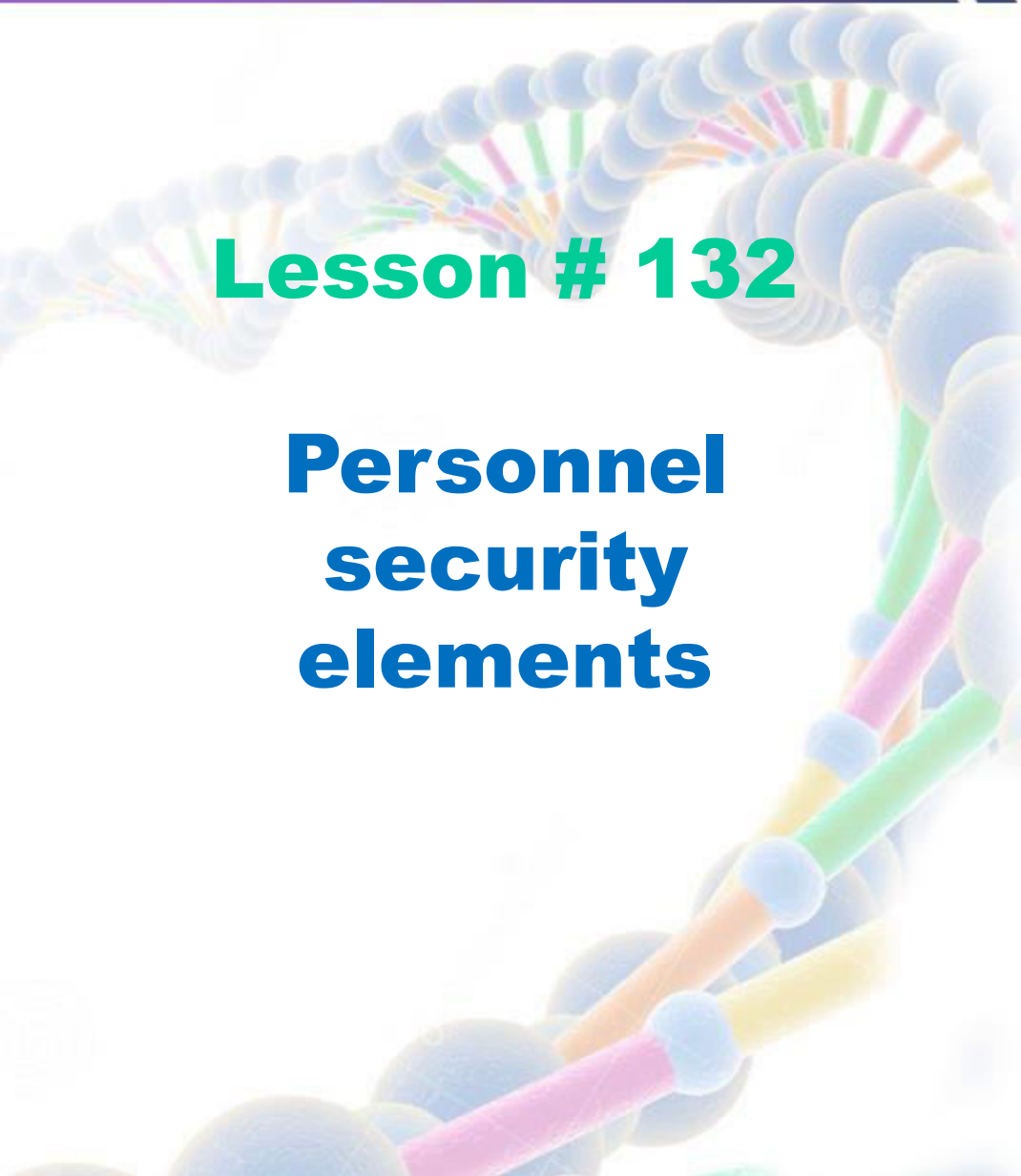
Requirement:

- **robust pre-employment screening**
- **effective line management**
- **employee welfare /clear lines of communication**
- **strong security culture**

Biosecurity

Lesson # 132

Personnel security elements



Personnel security elements

Elements:

- personnel screening
- badges
- visitors control
- training

Personnel security elements

Elements:

- all positions must be defined and trained
- security issues must be addressed
- divide responsibilities
- security officers----
personnel security policies

Biosecurity



Lesson # 133

Biosecurity



**Accountability
elements**

Accountability elements

Material control:

- **defining material is complicated**
- **agent/strain: name and description**
- **quantity in units-not the number of microbes**
- **procedural and physical measures**

Accountability elements

Regulations:

- hazardous agents inventories must be conducted semi-annually
- reported to the safety officer
- update inventory-new chemical is received
- agents acquired with approved protocol

Accountability elements

Regulations:

- hazardous agents not currently in use -----
transfer to other labs
- agents must not be shared with investigators or labs without permission
- stored in secure areas

Accountability elements

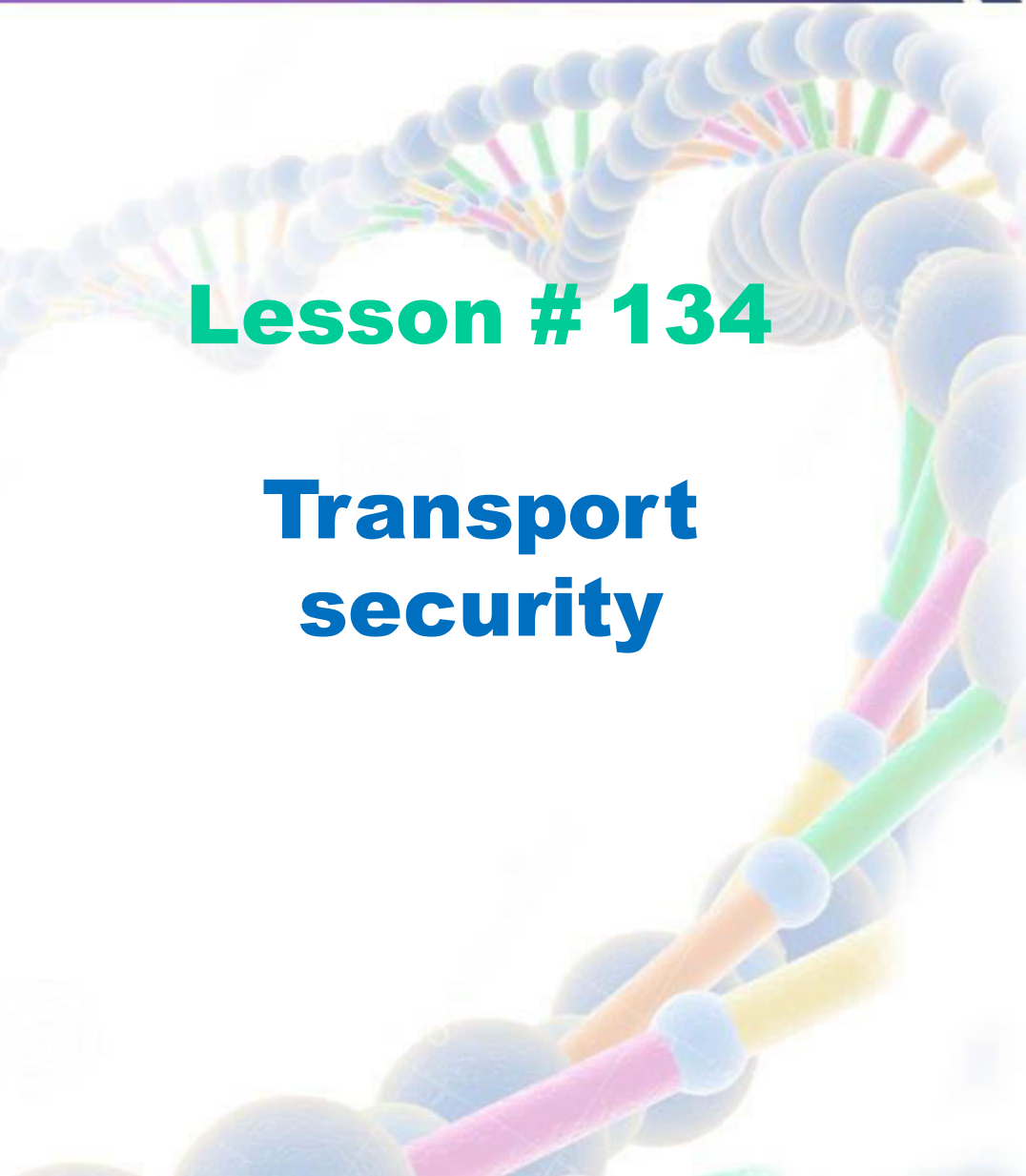
Accountability:

- **person who work with pathogens/toxins**
- **one-to-one correspondence between material and people**
- **system of records, reporting and audit**

Biosecurity

Lesson # 134

Transport security



Transport security

Introduction:

- **movement of biological materials from restricted areas**
- **occur within the country/even across borders**

Biosecurity



Lesson # 135

Biosecurity

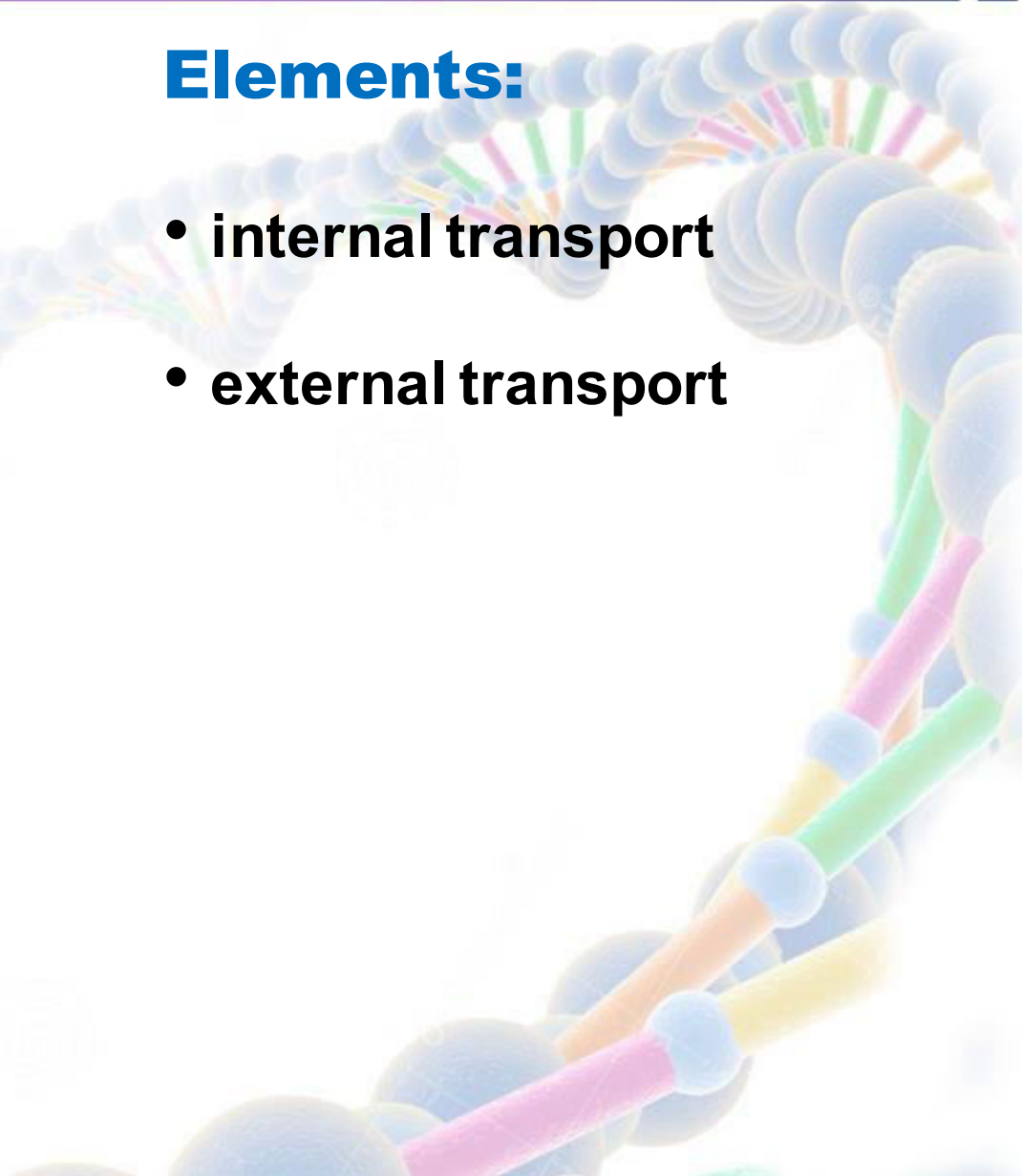


**Transport
security
elements**

Transport security elements

Elements:

- internal transport
- external transport



Transport security elements

Internal transport:

- movement from / to restricted area
- within facility
- involve personnel from labs
- shipping, receiving, disposal areas

Transport security elements

External transport:

- movement of material from one facility to another
- involve commercial carriers
- able to move frozen materials
- need to be cost-effective

Transport security elements

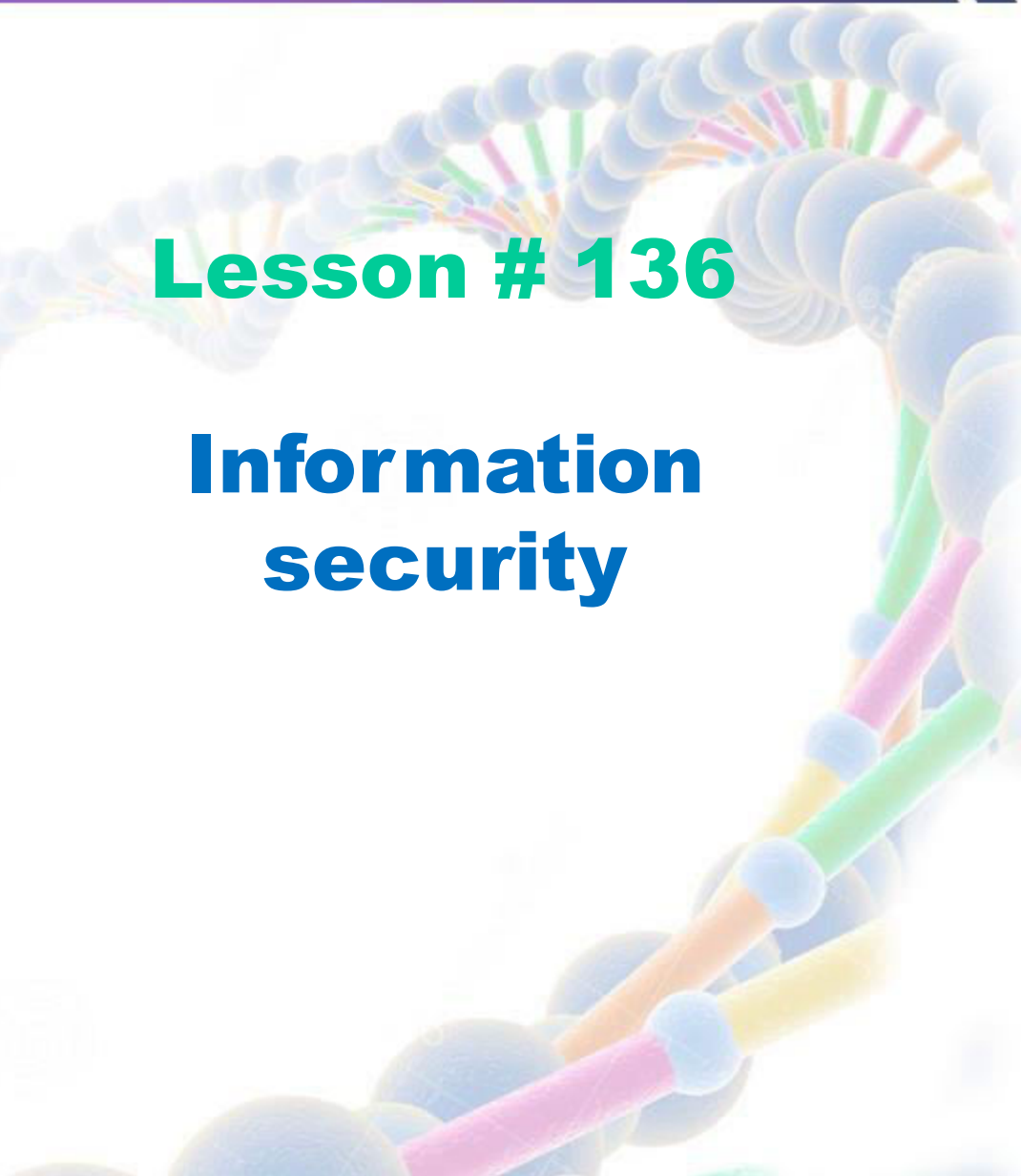
External transport:

- infectious materials are included in category B
- cultures
- triple packaging system

Biosecurity

Lesson # 136

**Information
security**



Information security



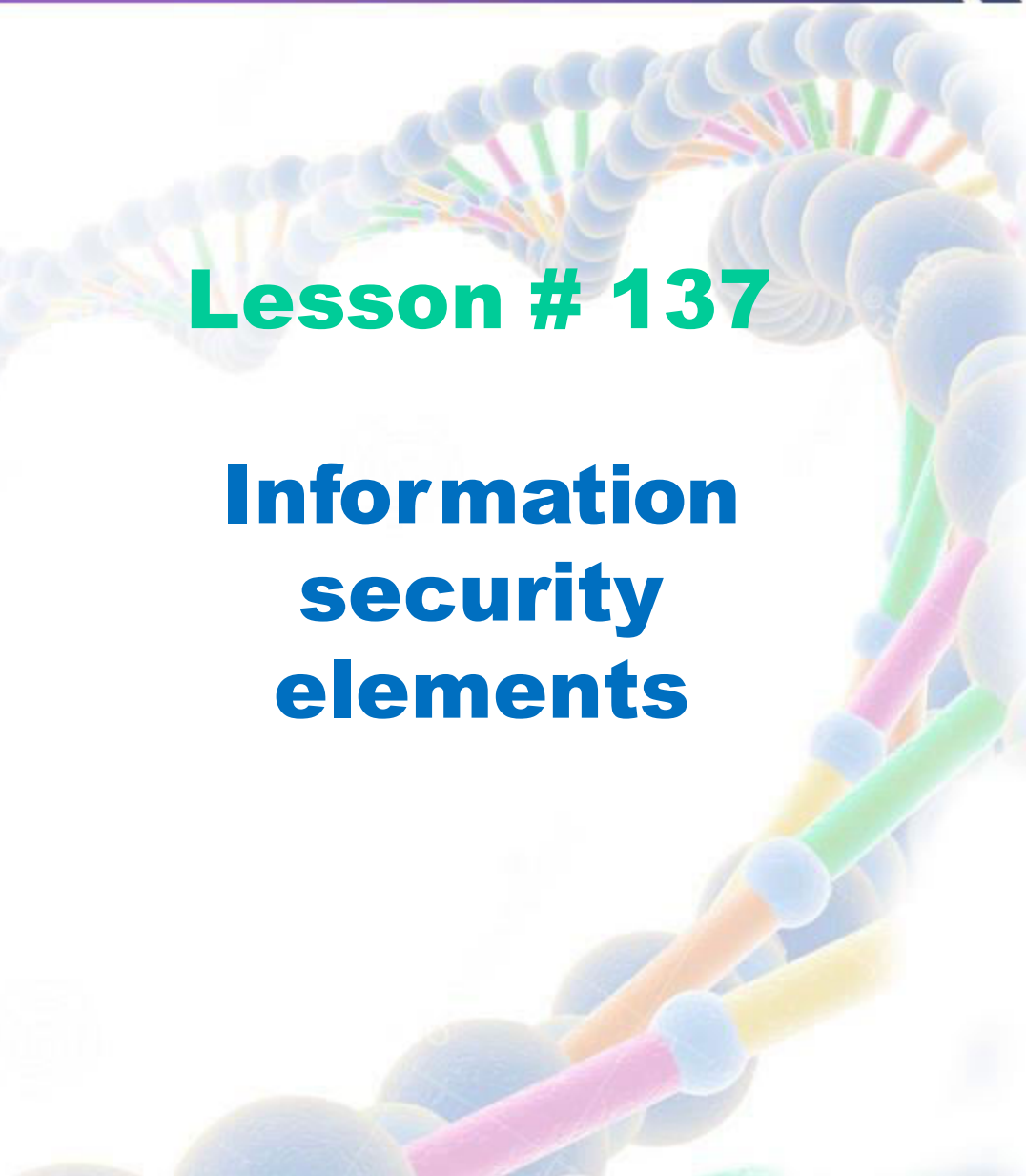
Introduction:

- **defending information from unauthorized access**
- **use, disrupt, disclose, recorded, inspected, modified**
- **software attacks- viruses, worms, torjan horses**

Biosecurity

Lesson # 137

Information security elements



Information security elements

Elements:

- **confidentiality**
“property” not disclosed to unauthorized persons
- **integrity-maintaining and assuring the accuracy and completeness of data**
- **availability**

Biosafety



Lesson # 138
UFF 2 LONG

Biosafety



**Biosafety-
virology lab**

Biosafety-virology lab



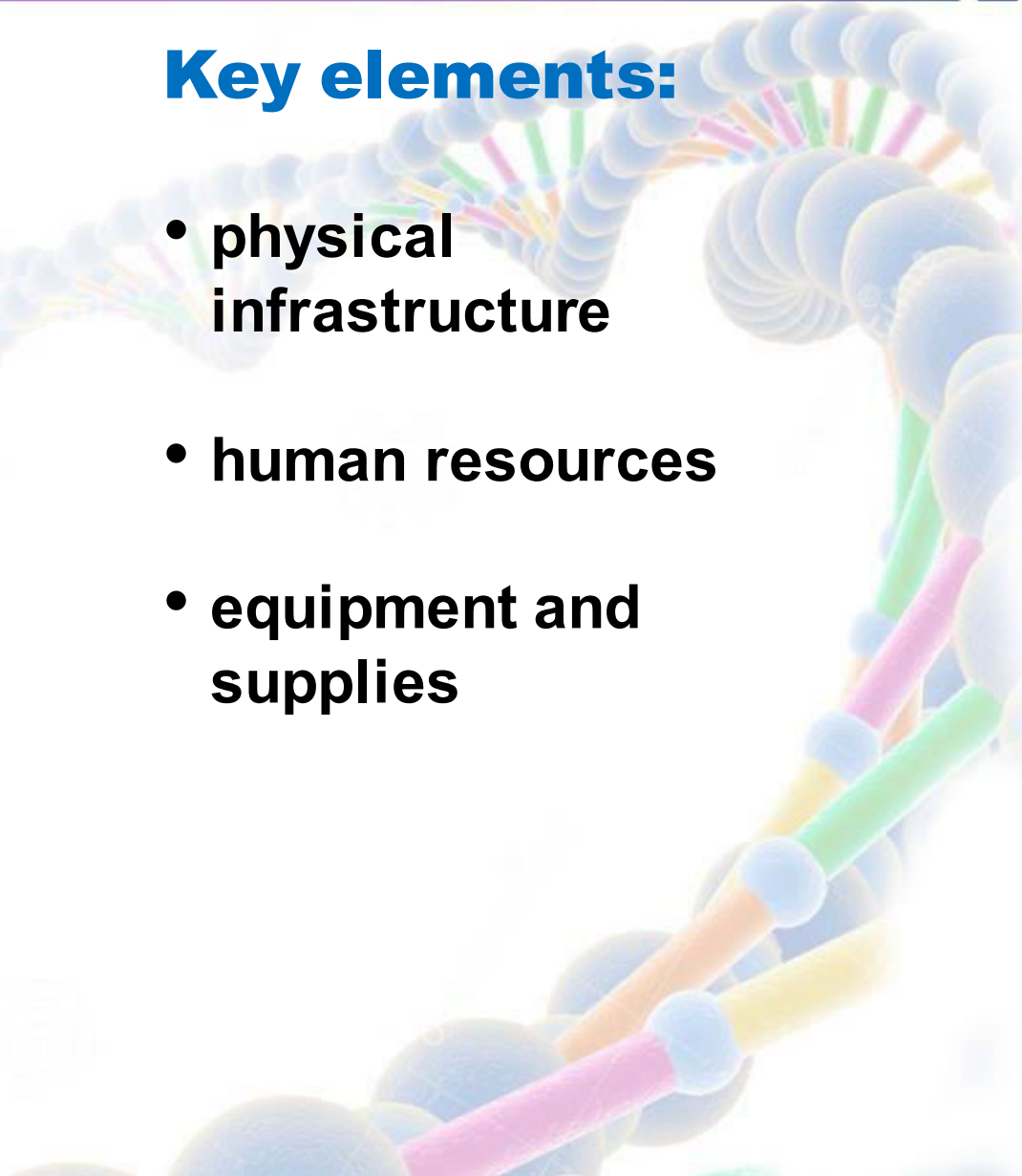
Introduction:

- during past three decades
- 30 pathogens have been discovered
- 16 were viruses
- *HIV, hepatitis, Dengue virus, Ebola virus*

Biosafety-virology lab

Key elements:

- physical infrastructure
- human resources
- equipment and supplies



Biosafety-virology lab

Physical infrastructure

:

- viral isolation, detection of antigens/ antibodies
- separate, multistoried building / end of the corridor
- restrict-visitors, stop contamination, biosafety standards

Biosafety-virology lab



Biosafety:

- **RG-1: open bench work -----AAV**
- **RG-2: bench work / BSC---*Herpes Viruses, Foot And Mouth Disease Virus***
- **RG-3: *BSC-HIV, HBV, rabies***
- **RG-4: BSC II/III—*smallpox, Nipah virus,***

Biosafety-virology lab



Biosafety level 3 lab:

- separated from traffic flow
- double-door entry
- autoclave within facility
- decontaminate waste prior to disposal

Biosafety-virology lab

Biosafety level 3 lab:

- inward directional air flow
- adequate space
- Illumination must be adequate
- walls, ceilings, floors-resistant to chemicals

Biosafety-virology lab

Biosafety level 3 lab:


- basin with adequate water supply
- emergency exits



Biosafety-virology lab



Human resources:

- qualified virologists
 - two junior microbiologists
 - two lab technologists
 - one/two supportive staff
- 

Biosafety-virology lab

Equipments and supplies:

- prevent/minimum contact-infectious material
 - free of sharp edges
 - resistant to corrosion
 - impermeable to liquids
- 

Biosafety-virology lab



Essential equipments:

- BSC, incubators, freezers
- Inverted light, water bath, fluorescent microscope
- pH meter, vortex, balance, autoclave, micropipettes

Biosafety-virology lab

Essential equipments:

- ELISA, PCR
- Gel electrophoresis apparatus, UV illuminator
- glass ware

Biosafety-virology lab

Desirable equipments:

- shaker water bath
- ultracentrifuge
- rocking platform

Biosecurity



Lesson # 139

Biosecurity



**Fire
extinguishers**

Fire extinguishers



Fire extinguishers

Types of fire:

- **Class A:** wood, paper, fabric, cloth, trash and plastics
- **Class B:** flammable liquids-petroleum oil, paint, gasoline
- **Class C:** energized electrical equipments
- **Class D:** metal/**Class K:** cooking oil, grease

Fire extinguishers

Types of fire extinguishers:

- **water and foam -class A - separate oxygen**
- **carbon dioxide- class B and C - separate oxygen and heat**
- **dry chemical - class A, B, C- interrupt chemical reaction**

Fire extinguishers

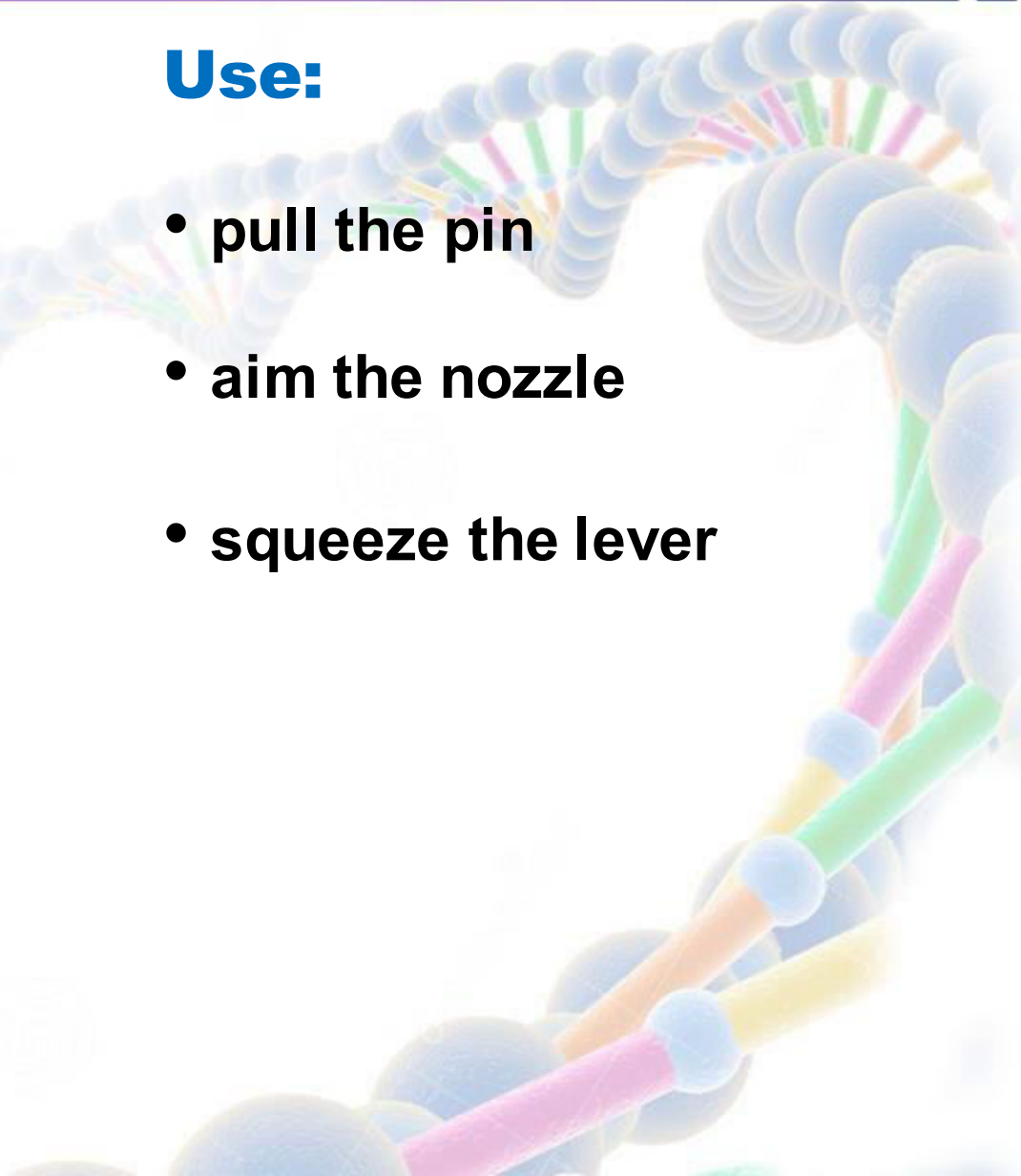
Types of fire extinguishers:

- **wet chemical-class K**
– remove heat
- **clean agents-class A, B and C (halogens)**
interrupt chemical reaction
- **water mist- class A,**
remove heat

Fire extinguishers

Use:

- pull the pin
- aim the nozzle
- squeeze the lever



Fire extinguishers

Inspection:

- **check after one month**
- **extinguisher is in the current location**
- **visible and accessible**
- **gauge and pressure show the correct pressure**

Fire extinguishers

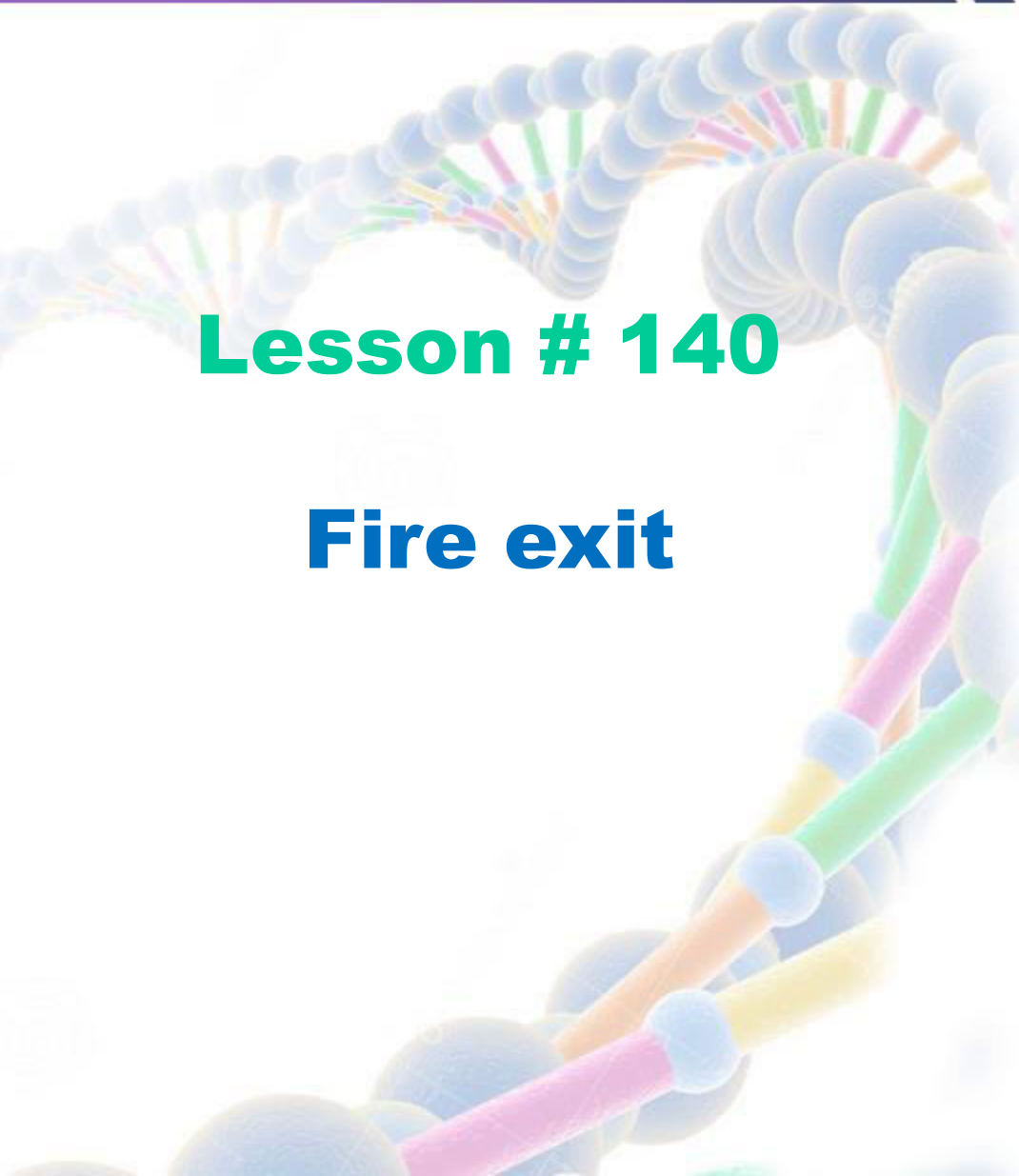
Maintenance:

- fire equipment professional-annually
- mechanical parts, agents, expellent gas

Biosecurity

Lesson # 140

Fire exit



Fire exit

Rules for fighting fire:

- fire is small and contained
- You are safe from toxic smoke
- means of escape
- your instincts tell you it okay

Fire exit

Fire exit:

- kind of emergency exit mounted to the outside of a building
- faster evacuation
- alternative routes when regular exit is blocked

Fire exit

History:

- 1883-England-180 children died
- 1911- America- 146 factory worker died
- 9/11- exit doors were locked
- all buildings have well - marked emergency exits

Fire exit

Signage:

- “EXIT”
- running green man
- Introduced in 2003 by ISO 7010

Fire exit



Biosecurity



Lesson # 141

Fire wardens

Fire wardens

Duties:

- a person employed to prevent / extinguish fire
- important risk measures
- raise awareness among staff
- how to respond in emergency

Fire wardens

Duties:

- ensure evacuation
- helping-wheelchair
- switch off electrical appliances
- close the doors to isolate fire
- guide everyone to assemble area

Fire wardens

Legislation:

- is there a legal requirement of fire wardens?
- is there a legal requirement for training fire wardens?
- how many fire wardens should be appointed?
- evacuation drills

Bioethics



Lesson # 142

**Fire assembly
area**

Fire assembly area

Guidelines:

- meeting place where staff, workers, students gathered
- choose a location
- open space
- easy access from your building

Fire assembly area

Guidelines:

- at least 50ft from the building
- don't evacuate within the structure
- primary/secondary meeting places

Fire assembly area

Guidelines:

- don't evacuate to locations where emergency personnel respond
- regular evacuation practice
- fire wardens will take updates from emergency crew

Biosafety



Lesson # 143

National biosafety rules

National biosafety rules

Introduction:

- **section 31-Pakistan Environmental Act, 1997**
- **federal government made rules 2005**

National biosafety rules

Rules:

- biosafety guidelines ministry of env
- commercial release
- deliberate release
- experimental release

National biosafety rules



Rules for:

- **license ----- federal agency under section 14 of the Act**
- **applications of biotechnology**
- **export/import**
- **“Institutional biosafety committee” under rule 8**

National biosafety rules

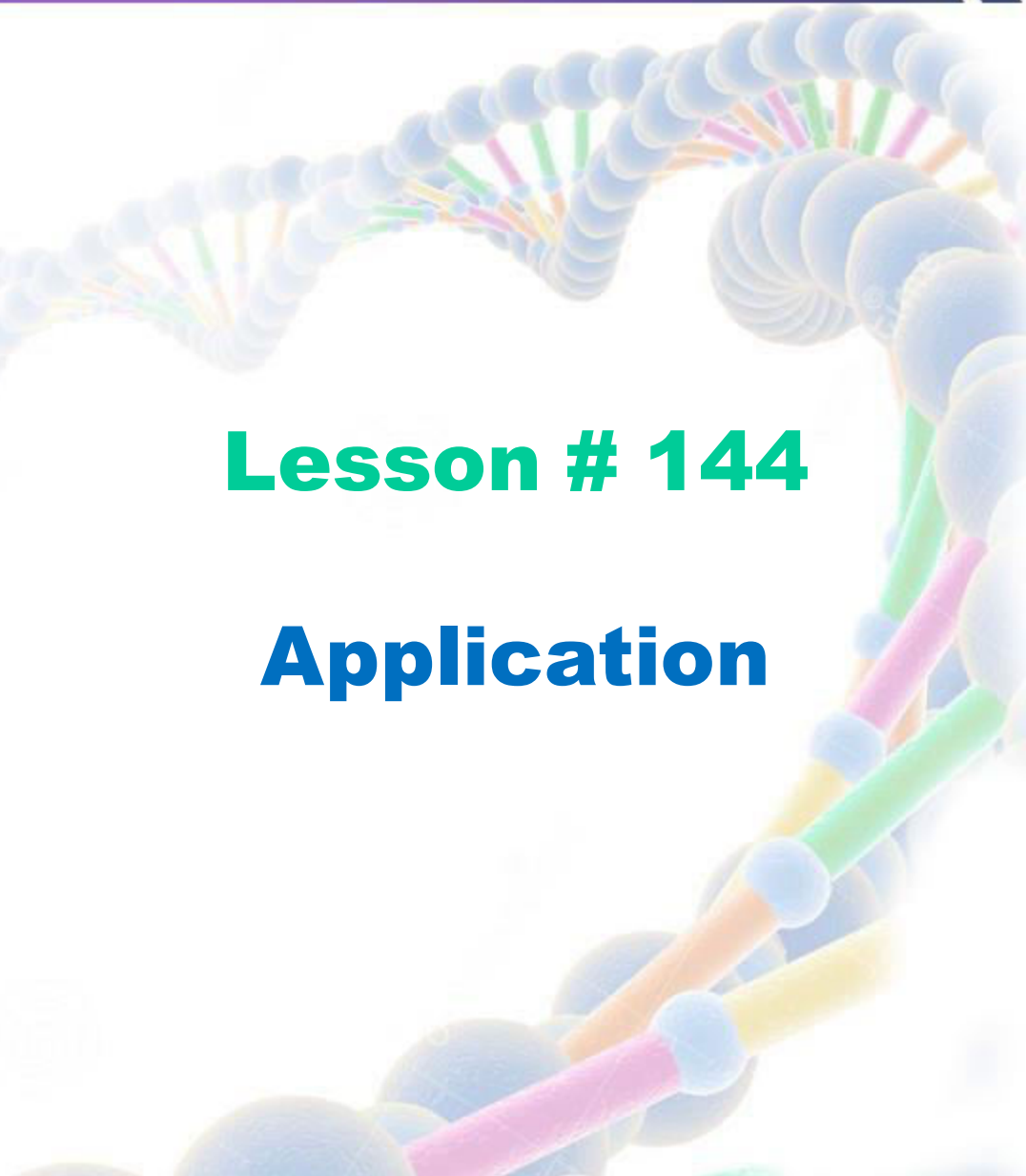
Rules for:

- “National biosafety committee” under rule 4
- “Technical advisory committee” under rule 6

Biosafety

Lesson # 144

Application



Application



Application:

- **manufacture, import and storage of microorganisms**
- **gene technological products for research**
- **field trial of GMOs**
- **import, export, sale and purchase of GMOs**

Biosafety



Lesson # 145

Establishment



Establishment

National Biosafety Committee:

- **federal government establish**
- **director general, Pakistan- EPA - secretary**
- **hold office for term 3 years**
- **frame its own rules and procedures**

Establishment



Members:

- **Secretary, Ministry of Environment**
- **member - Pakistan Atomic Energy Commission**
- **chairpersons-----
institutional biosafety
committee**

Establishment

Members:

- **Director-General,
department of plant
protection**
- **chairman - PARC**
- **representative
Ministry of food and
agriculture**

Biosafety

Lesson # 146

Functions



Functions

Duties:

- **establish standards and procedures for risk assessment**
- **consider applications for the import, export or commercial release of GMOs – ban**
- **develop linkages with foreign committees**

Functions

Duties:

- **cooperate with federal /provisional agencies**
- **advice of technical advisory committee**
- **facilitate exchange of technical expertise**
- **educate public**

Functions

Duties:

- **implementation of biosafety guidelines**
- **inform institutions about new biosafety development**
- **coordinate efforts between private and government agencies**

Functions



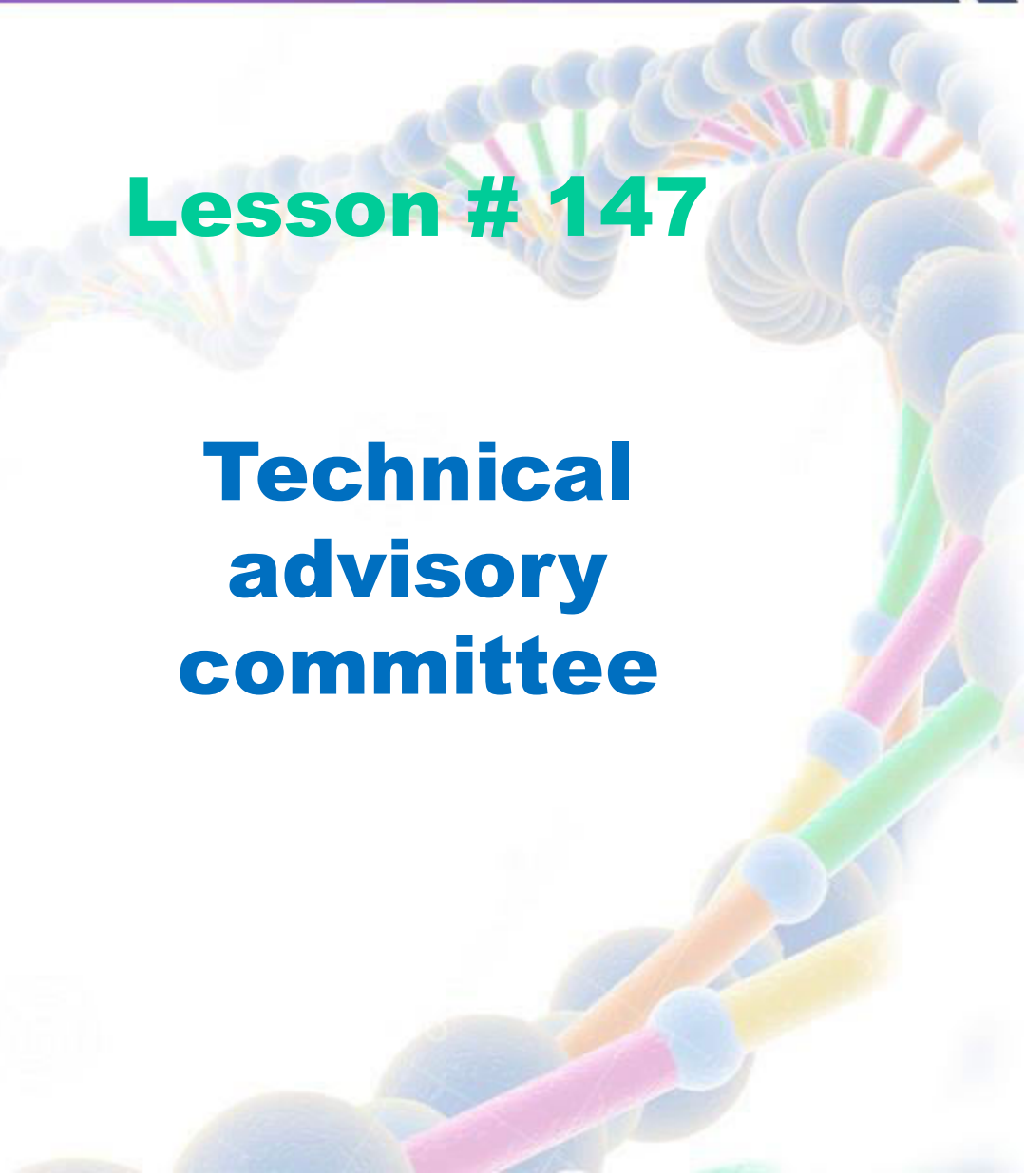
Duties:

- **certify labs, green / animal houses**
- **inspection of high-level laboratories**
- **inspect biosafety levels**
- **commercial ----- confidential from the public**

Biosafety

Lesson # 147

Technical advisory committee



Technical advisory committee



Members:

- director-general, EPA
- director - national institute of biotechnology
- Executive director- PMRC
- director – PCSIR
- director - HAS

Technical advisory committee



Members:

- director-NIH
- representative -----
Pakistan atomic
energy commission
- center for molecular
genetics - Karachi
- CAMB
- national commission
on biotechnology

Technical advisory committee



Members:

- relevant technical representative animal sciences, PARC
- relevant technical representative plant sciences, PARC
- director – EPA
- two experts from civil society

Technical advisory committee



Functions:

- examine applications and recommend to NBC
- review and control of safety measures
- review research methodologies
- monitor release of GMOs/products into environment

Technical advisory committee

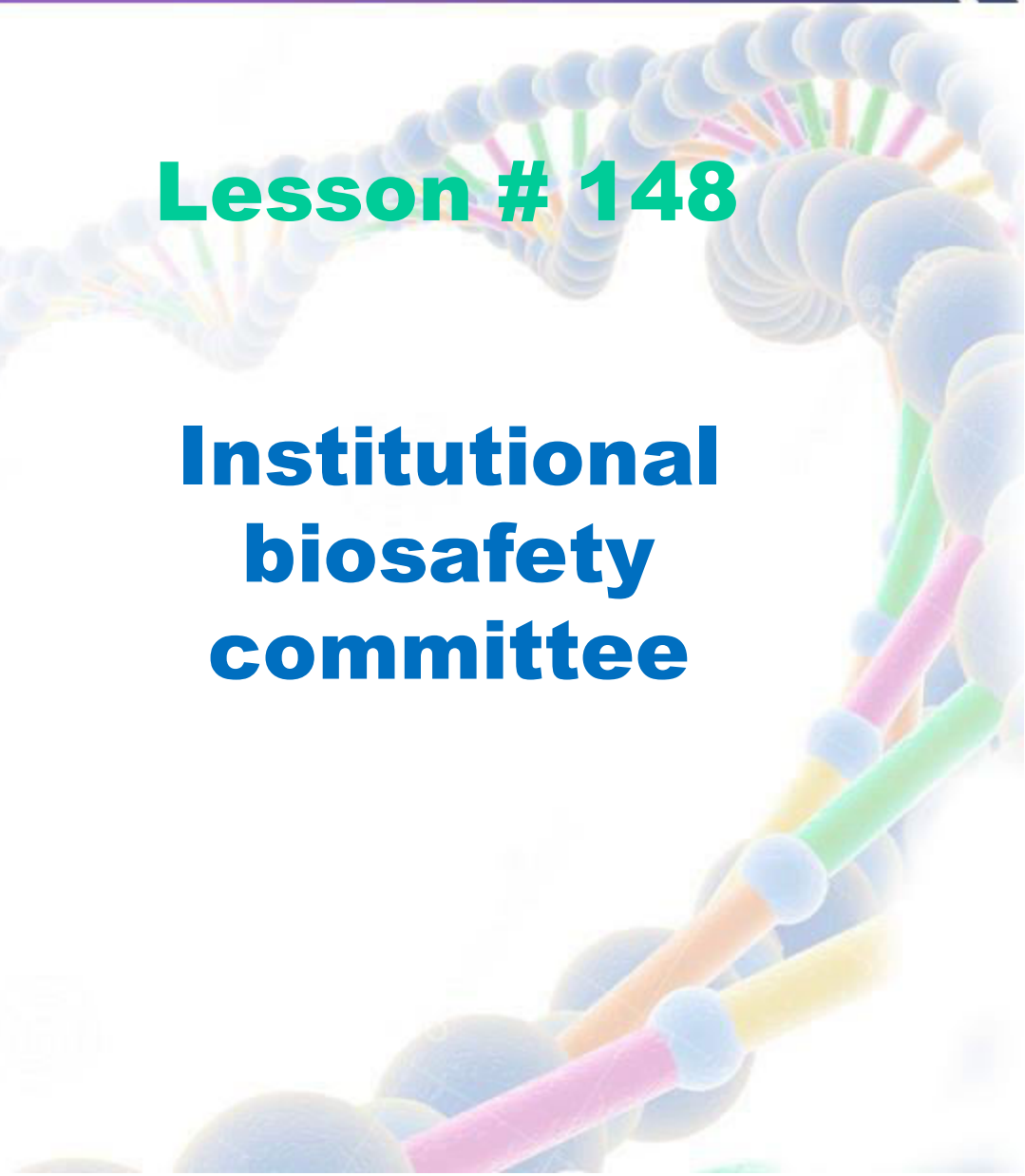
Functions:

- provide information to NBC about approved projects
- supervise the implementation of terms and conditions

Biosafety

Lesson # 148

Institutional biosafety committee



Institutional biosafety committee



Members:

- **head of the institution**
- **subject expert**
- **social scientist/
economist**
- **representative of civil
society**

Institutional biosafety committee



Functions:

- assist the activities of NBC and technical advisory committee
- assist researchers
- determine additional safeguards
- evaluate qualification of the researchers

Institutional biosafety committee



Functions:

- **monitor work -----
biosafety guidelines**
- **serve as a gateway---
flow of opinions -----
ideas / information
b/w NBC-research
teams**
- **update directory ----at
every biosafety level**

Institutional biosafety committee



Functions:

- health of lab and field personnel
- contact with NBC and technical advisory committee for import/export
- prepare/ implement emergency plans

Institutional biosafety committee



Functions:

- hold funds
- assess projects -----
under which category
it falls
- Inspect and certify
labs / plant glass
houses / animal
houses

Biosafety



Lesson # 149

License requirements

License requirements

License:

- **require license for import/export/sale/purchase**
- **approval from federal agency**
- **submit application with prescribed fees**
- **notify NBC / federal agency for change or addition--information**

Biosafety

Lesson # 150

**Confidential
information**



Confidential information

Confidentiality:

- **privileged or property information**
- **privileged information shared among few people for further processing**
- **unauthorized people shouldn't take advantage**

Confidential information

Confidentiality:

- Information of the applicant
- protected with article 21 of the Cartagena protocol
- set forth in the biosafety guidelines

Biosafety



Lesson # 151

Risk assessment/ management

Risk assessment/management



Introduction:

- Article 15/ Annex III of Cartagena protocol
- NBC will ensure
- activities-biosafety guidelines
- license

Risk assessment/management

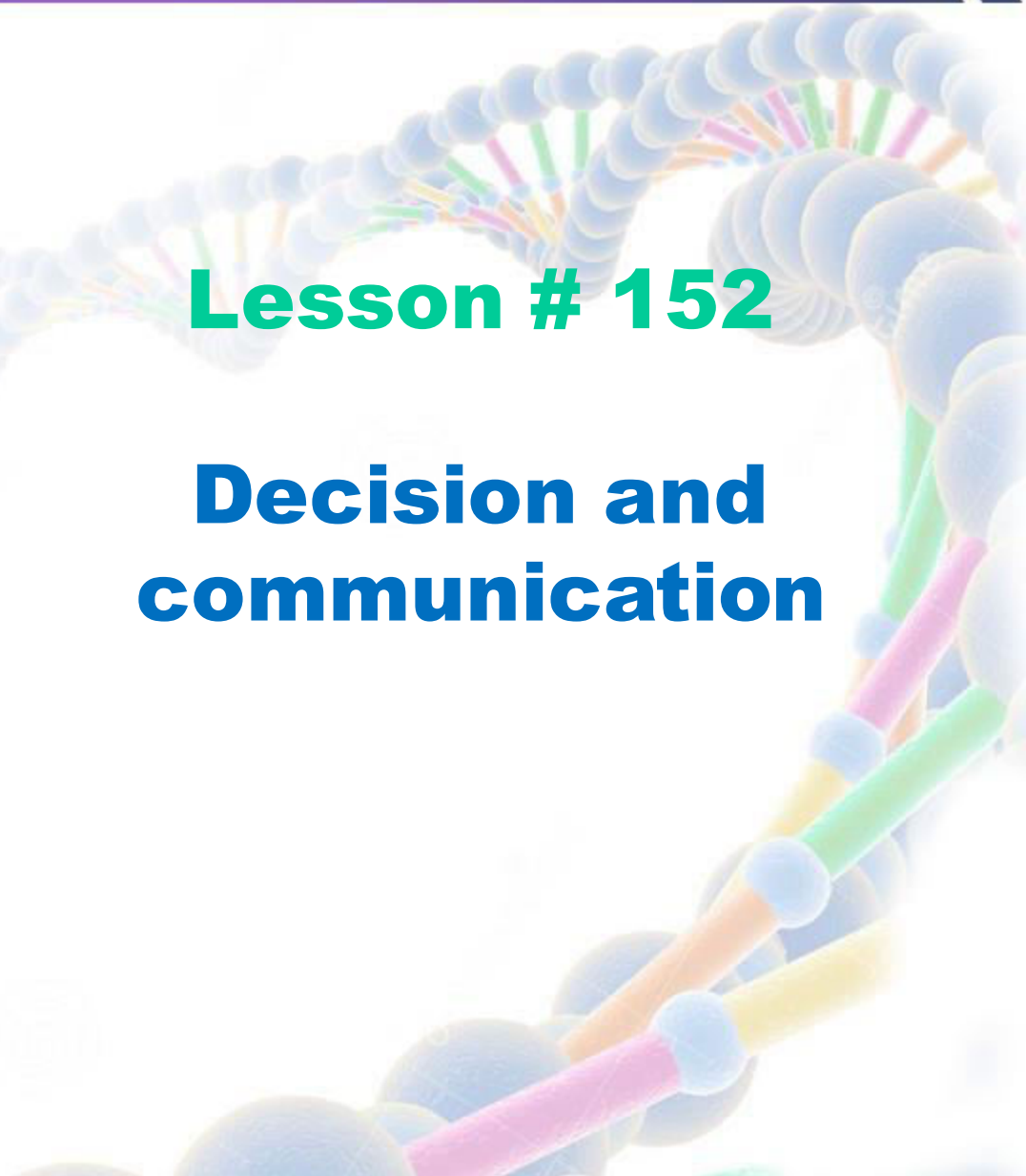
Risk assessment:

- auditing of risk assessment
- evaluation of risk management measures
- field trials

Biosafety

Lesson # 152

Decision and communication



Decision and communication

Introduction:

- **final decision is made-communicated to the applicant**
- **60 days for risk category 2/3**
- **90 days for experimental release**
- **120 days for commercialization**

Decision and communication



Criteria of decision:

- **based on information set forth in the application**
- **scientific risk assessment**
- **prior field experience with GMOs**

Decision and communication

Final decision:

- recorded in a decision document---described in biosafety guidelines
- no person can vary the license activity
- license granted by federal agency under rule 11

Decision and communication

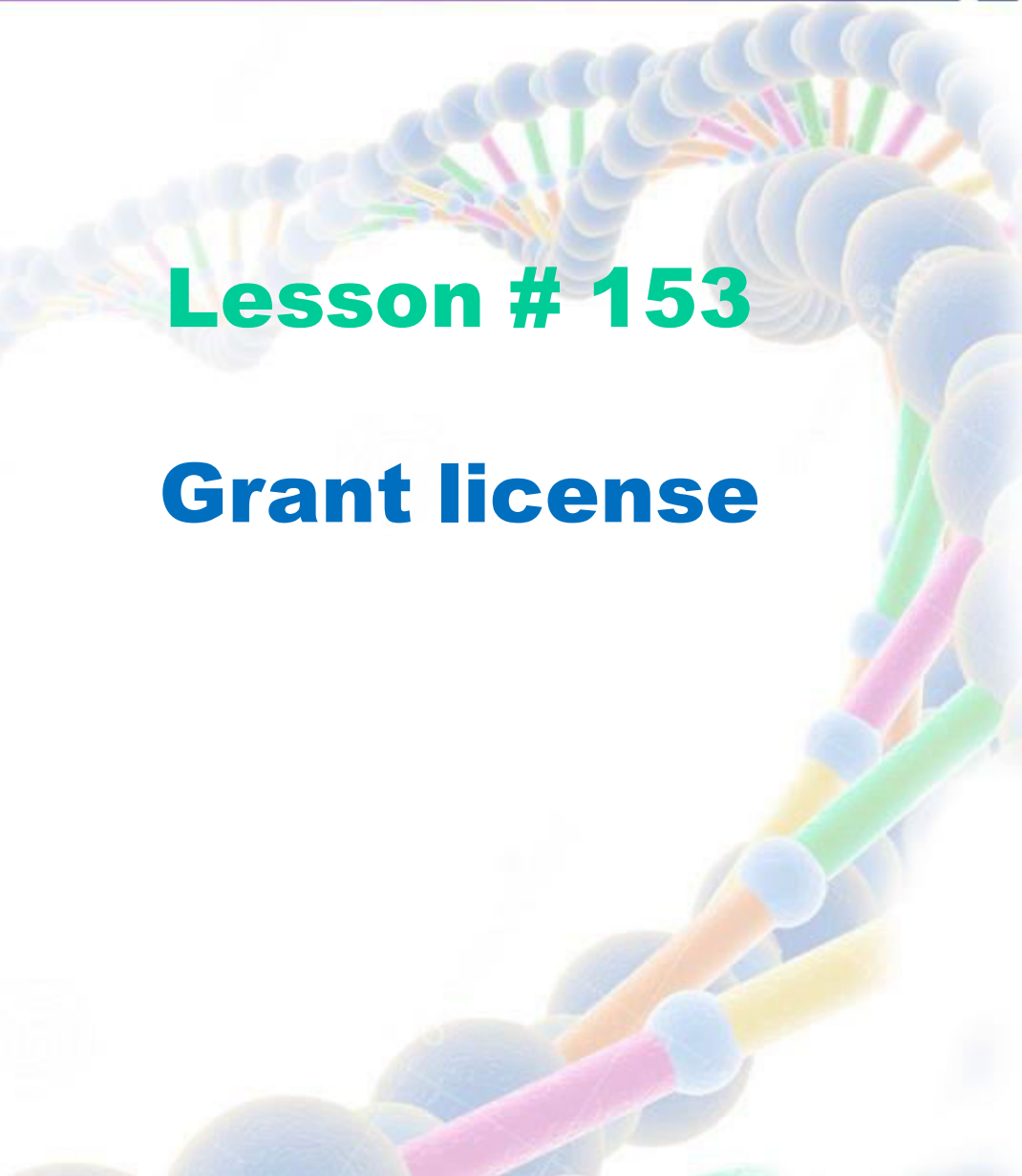
Functional:

- license remain ineffective
- until applicant executes an undertaking
- applicant will follow biosafety guidelines

Biosafety

Lesson # 153

Grant license



Grant license

Introduction:

- **federal agency-rule 11**
- **license - specified time period**
- **cannot exceed more than 4 years**
- **renewable after every 2 years**

Grant license

Powers to revoke:

- **new information-harmful effects of GMOs**
- **damage - nature, health, environment**
- **any other condition**

Grant license



Terms and conditions:

- **labeling**
- **control - exercised by the applicant**
- **supervision**
- **restriction to use**

Grant license



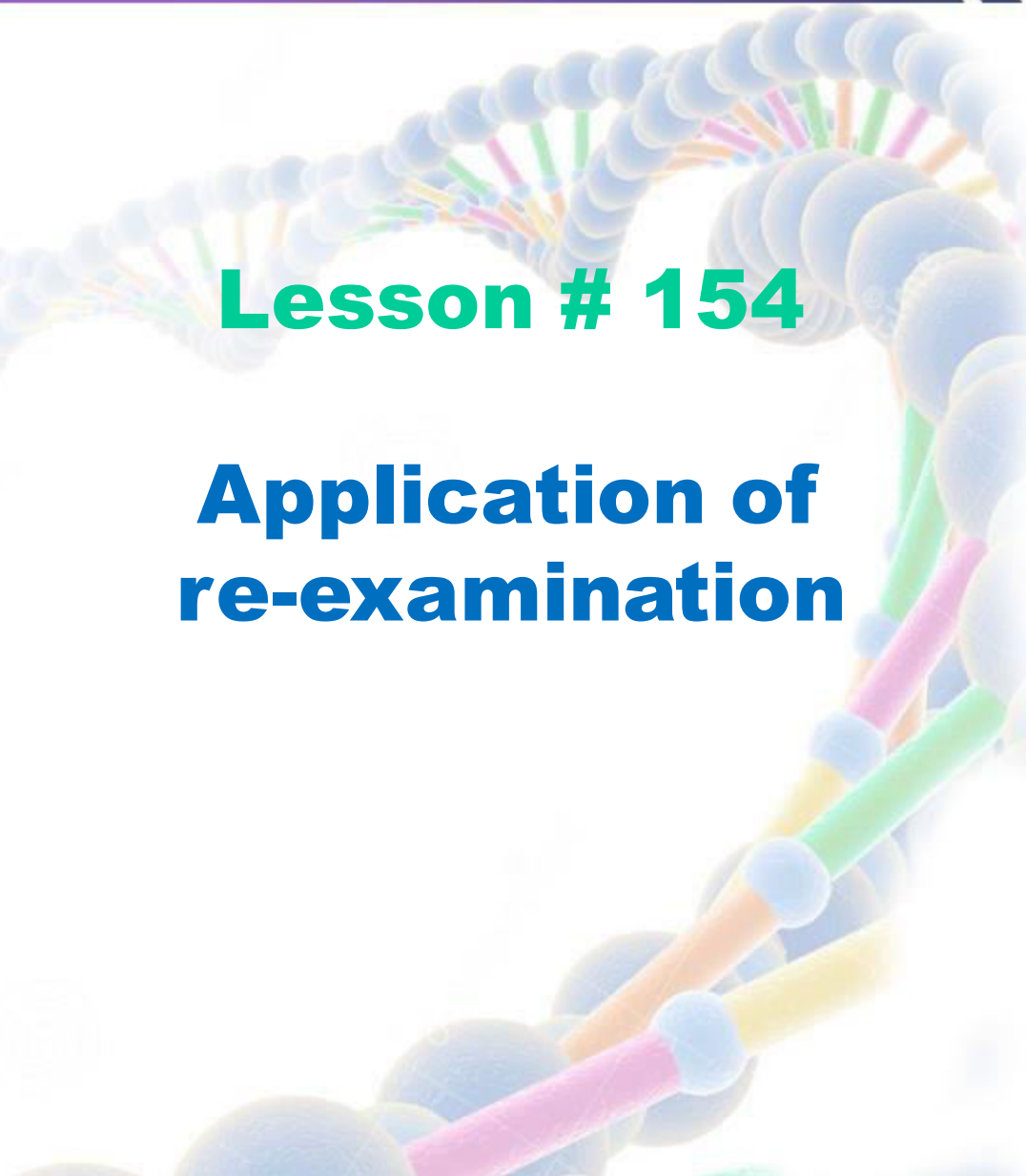
Terms and conditions:

- **layout of the enterprise**
- **submission of information**
- **any other condition deemed appropriate**

Biosafety

Lesson # 154

Application of re-examination



Application of re-examination

Introduction:

- applicant may file application
- NBC
- after a minimum time of 6 months

Application of re-examination



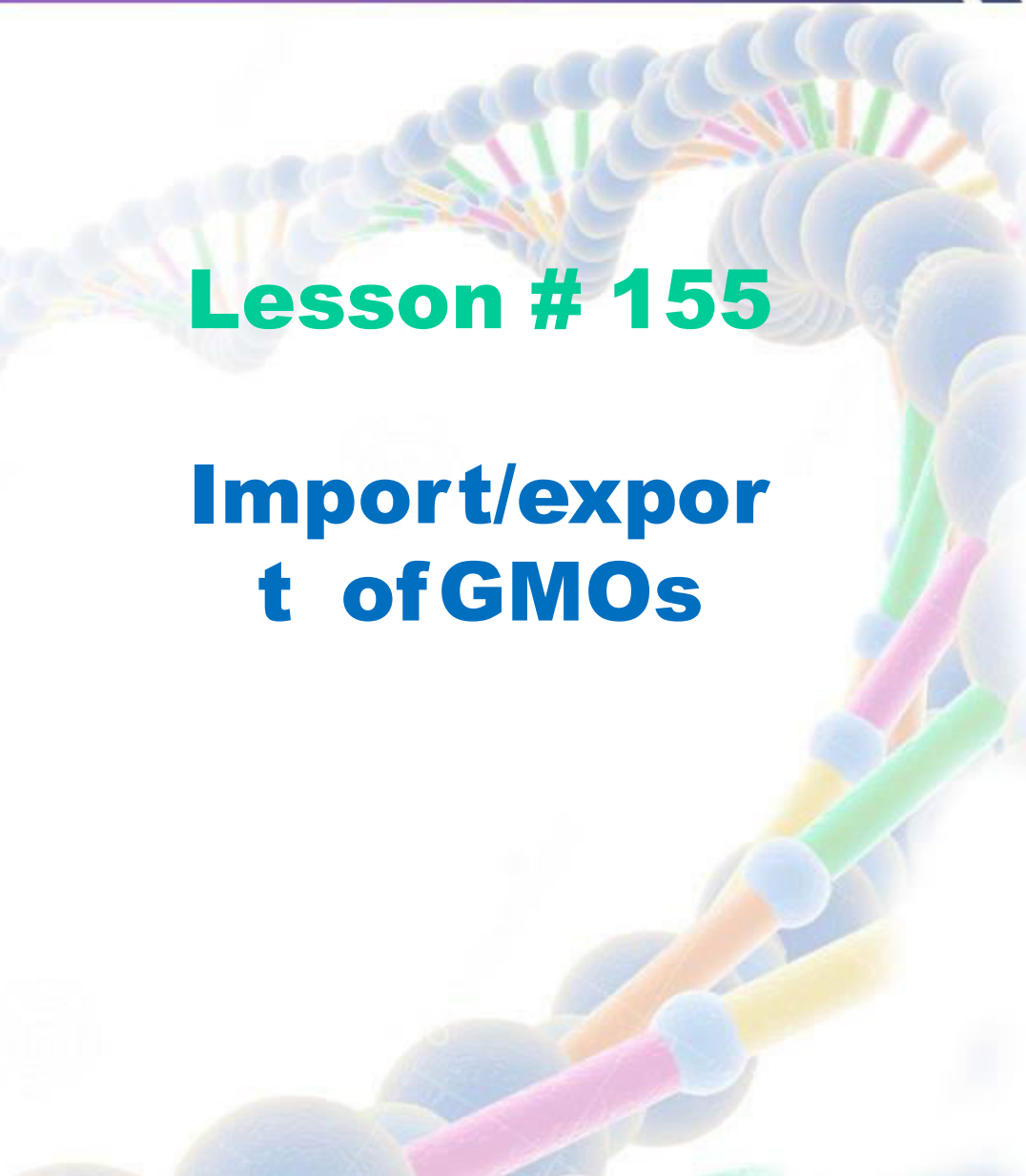
Reasons:

- change in circumstances
- material effect on the outcome of risk assessment
- change in scientific / technical information
- material effect on decision-conditions / limitations / need

Biosafety

Lesson # 155

Import/export of GMOs



Import/export of GMOs

Import:

- **GMOs**
- **substances/cells**
- **products**



Import/export of GMOs



Reason of import:

- contained use
- intentional introduction into the environment
- direct use as a food
- direct use as a feed

Import/export of GMOs



Requirement:

- **Article 18-Cartagena protocol**
- **National plant quarantine regulations**
- **International plant protection convention**
- **IT and PO/ EP and PO**

Import/export of GMOs



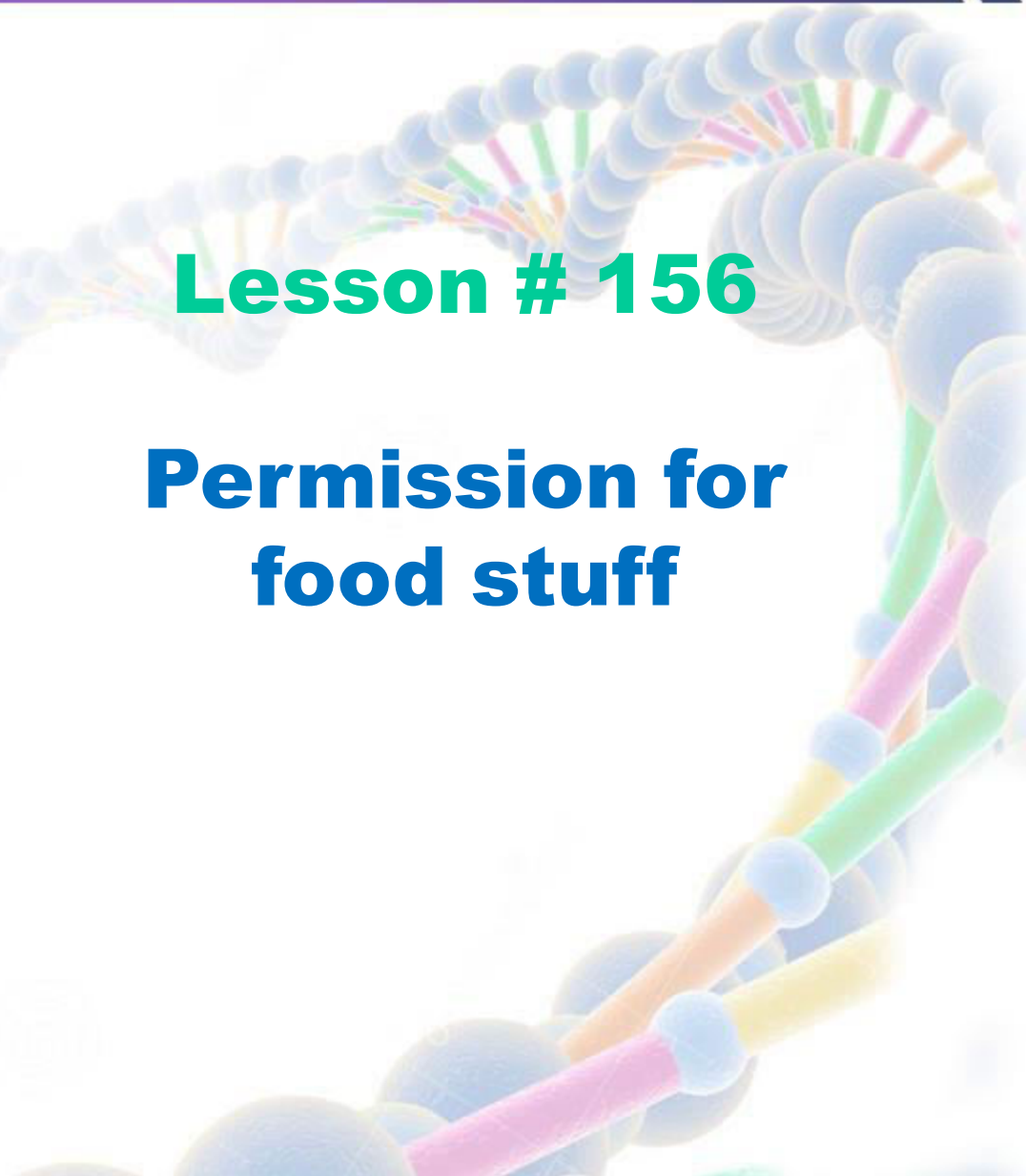
Information for export:

- risk assessment/field trials to the exporting country
- National plant quarantine regulations
- International plant protection convention
- IT and PO/ EP and PO

Biosafety

Lesson # 156

Permission for food stuff



Permission of food stuff

Introduction:

- food stuff
- ingredients of food stuff
- additives
- processing aid

Permission of food stuff

Approval:

- all food stuffs containing GMOs
- produced, sold, imported
- NBC
- sub-rule 2 of rule 20

Biosafety

Lesson # 157

**Notify
interruptions
/ accidents**



Notify interruptions/accidents

Interruptions:

- discharge of GMOs in to the environment
- harmful to the nature / health
- notify to technical advisory committee

Notify interruptions/accidents

Duty:

- shall not lessen the duty
- person, institution, organization
- whether got license

Notify interruptions/accidents

Solution:

- **information - off-side effects**
- **technical advisory committee**
- **information related to off-side emergency plan**

Biosafety



Lesson # 158

Pakistan biosafety measures



Pakistan biosafety measures



Introduction:

- **Pakistan-
implementing
National and
administrative
measures**
- **designation of
national focal point**
- **oversight of
biological research
activities**

Pakistan biosafety measures



Introduction:

- **inter-agency consultative process**
- **guidelines on code of conduct for life scientists**
- **confidence building measures**
- **awareness on bio-risk management**

Pakistan biosafety measures



Rules:

- **National biosafety committee**
- **National bioethics committee**
- **Drug Act 1976 and rules**
- **Plant quarantine Act 1976**

Pakistan biosafety measures



Introduction:

- **Animal quarantine Act 1979**
- **Anti terrorism Act 1997**
- **Pakistan export control Act 2004**
- **Pakistan export list 2005 and 2011**

Pakistan biosafety measures

Introduction:

- **Pakistan biosafety rules 2005**
- **draft biological and toxin weapon convention**

Pakistan biosafety measures



Biosafety



Lesson # 159

Implementation of National laws

Implementation of National laws



Implementation:

- **Pakistan-data on communicable/ non-communicable diseases**
- **labs are not following biosafety and biosecurity labs**
- **certify-biosafety level 2**

Implementation of National laws

Way out:

- need to conceptualize national strategic framework
- public sector labs
- efficient biosafety rules implementation

Implementation of National laws

Way out:

- all provinces and stakeholders involved in loops-development cycle
- generate ownership
- mobilizing resources
- develop required human resource

Biosecurity



Lesson # 160

Biosecurity



**Efforts to
mitigate
biological
threats**

Efforts to mitigate biological threats

Bioweapons:

- any infectious agent used intentionally to cause harm to others
- planning of an effective biowar defence-difficult task
- nation and scientific community

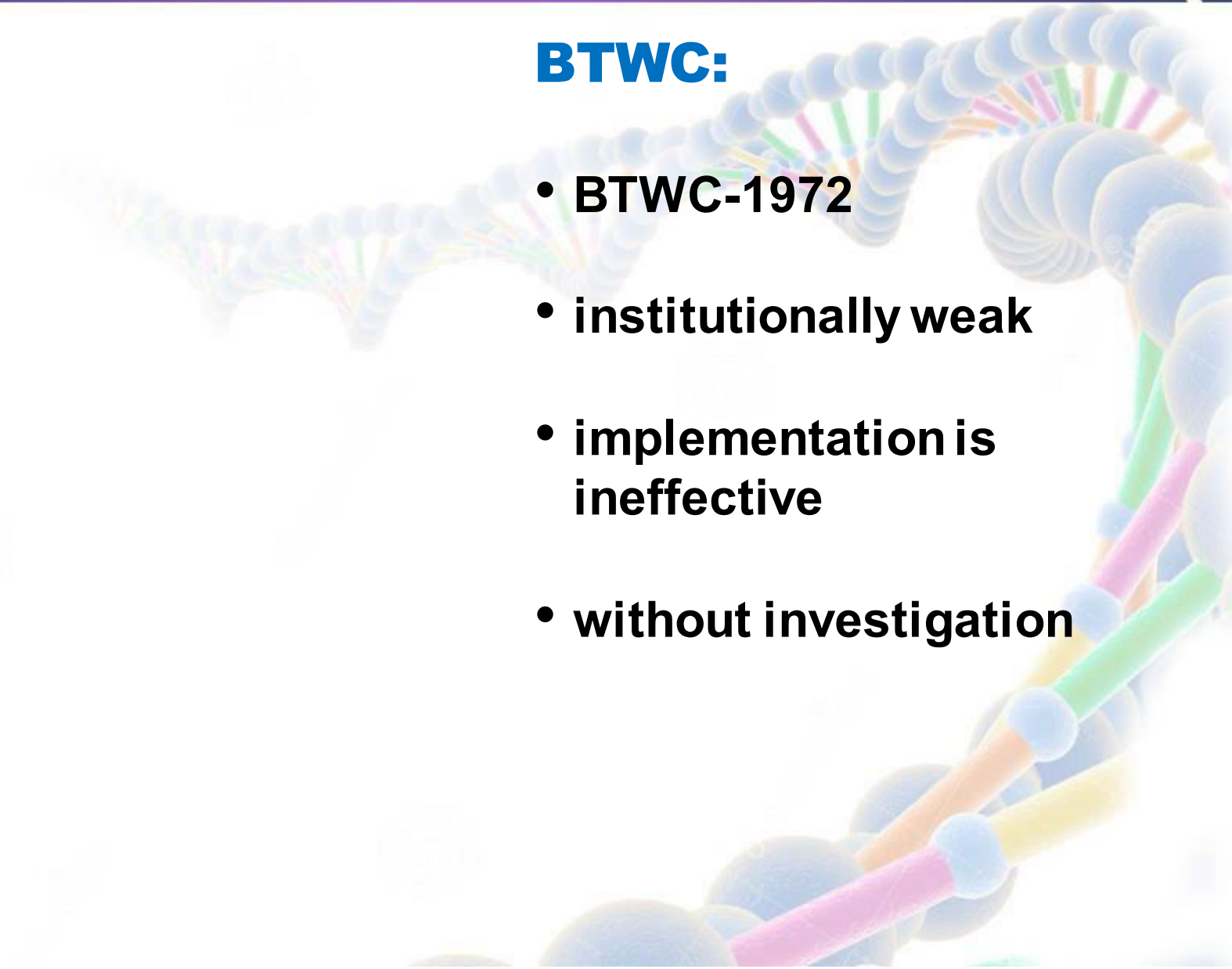
Efforts to mitigate biological threats

Defence against bioweapons:

- international cooperation
- transfer of technology
- support national actions

Efforts to mitigate biological threats

BTWC:

- **BTWC-1972**
 - **institutionally weak**
 - **implementation is ineffective**
 - **without investigation**
- 

Efforts to mitigate biological threats



Biological threats:

- **terrorist, non-state actors**
- **misuse of technologies**
- **theft from lab**
- **religious extremists**
- **locally hired agents**
- **frustrated cult**

Efforts to mitigate biological threats



Efforts to mitigate:

- **BTWC Act**
- **designation of focal point**
- **central implementation authority**
- **biosafety/biosecurity**
- **code of conduct /awareness**

Efforts to mitigate biological threats



Pakistan's approach:

- **front-line of “War on terror”**
- **financial and human loss**
- **bioweapons are not the part of security matrix**

Efforts to mitigate biological threats

Pakistan's approach:

- tremendous progress
- legislations
- administrative measures

Efforts to mitigate biological threats

NCGLs-2007:

- national core group of life sciences
- biosafety -syllabus
- final review by HEC

Efforts to mitigate biological threats



PBSA-2008:

- **Pakistan biological safety association**
- **train the trainers**
- **seek for biological certification**
- **risk assessment/risk management/ lab designing**

Efforts to mitigate biological threats



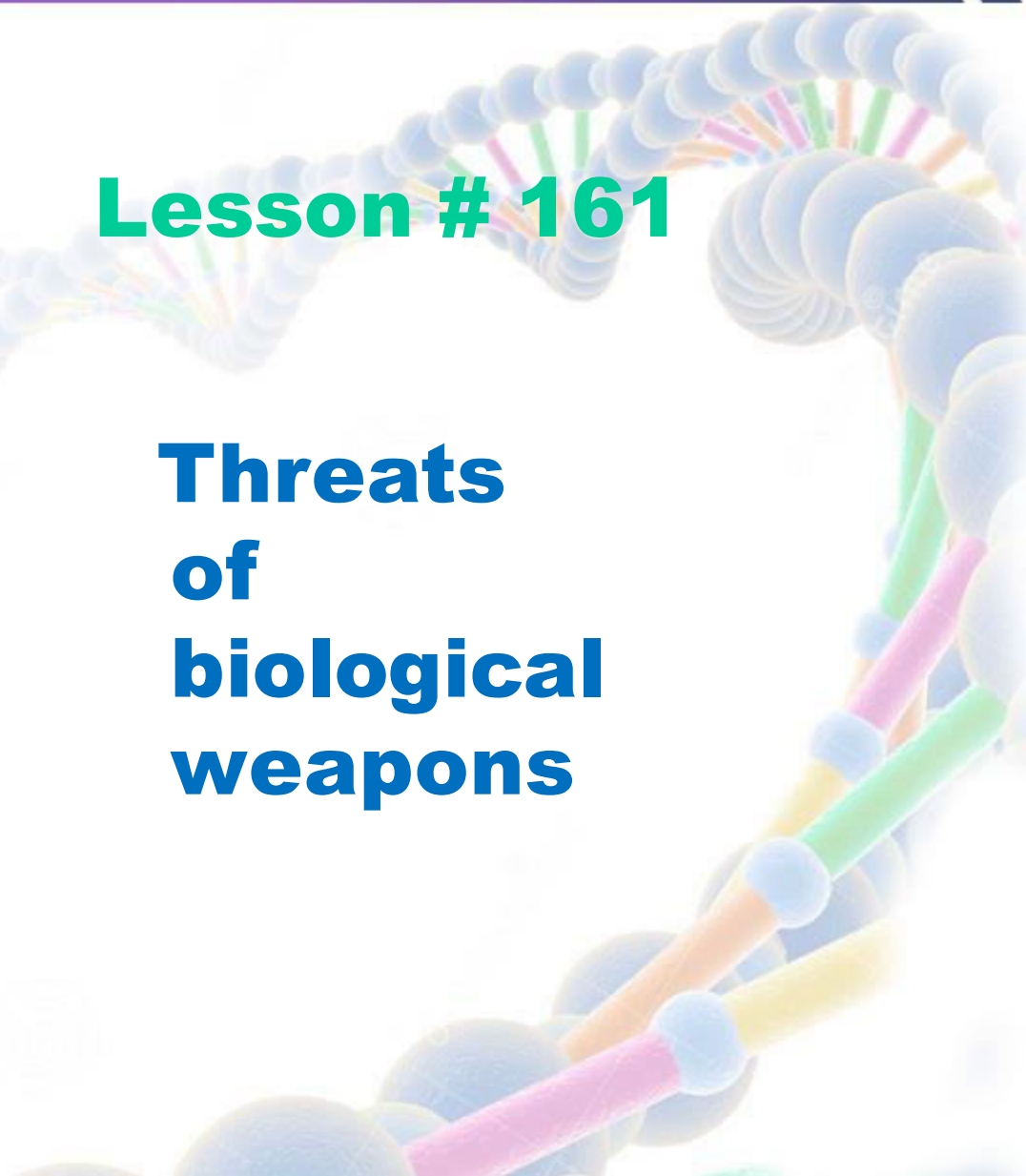
Efforts:

- NIH-WHO
- Export-control Act 2004-re-export, over-export
- transshipment-goods, technologies, equip
- 14 yrs-imprisonment /Rs.5 million both

Biosecurity

Lesson # 161

Threats of biological weapons



Threats of biological weapons



History:

- 2001 - Tom Dachele – received a letter of anthrax
- 23 members of the staff
- 5 police officers
- positive-nasal swabs
- citizen-stockpiling - Ciprofloxacin

Threats of biological weapons

Potential threats:

- naturally present in the environment
 - no major infrastructure
 - no manpower
 - easier and faster
- 

Threats of biological weapons



Potential threats:

- **cost-effective than poor's man atomic bomb**
- **cover large area**
- **difficult to diagnose and treat**
- **high mortality and mobility**

Threats of biological weapons



Potential threats:

- possibly contagious-
small pox, plaque,
viral hemorrhagic
fever
- create panic
- weapon of mass
disruption

Threats of biological weapons

Potential threats:

- detection devices, equipment for surveillance-expensive
- not present in many countries



Biosecurity



Lesson # 162

Biosecurity



**High
containment
biological labs**

High containment biological labs



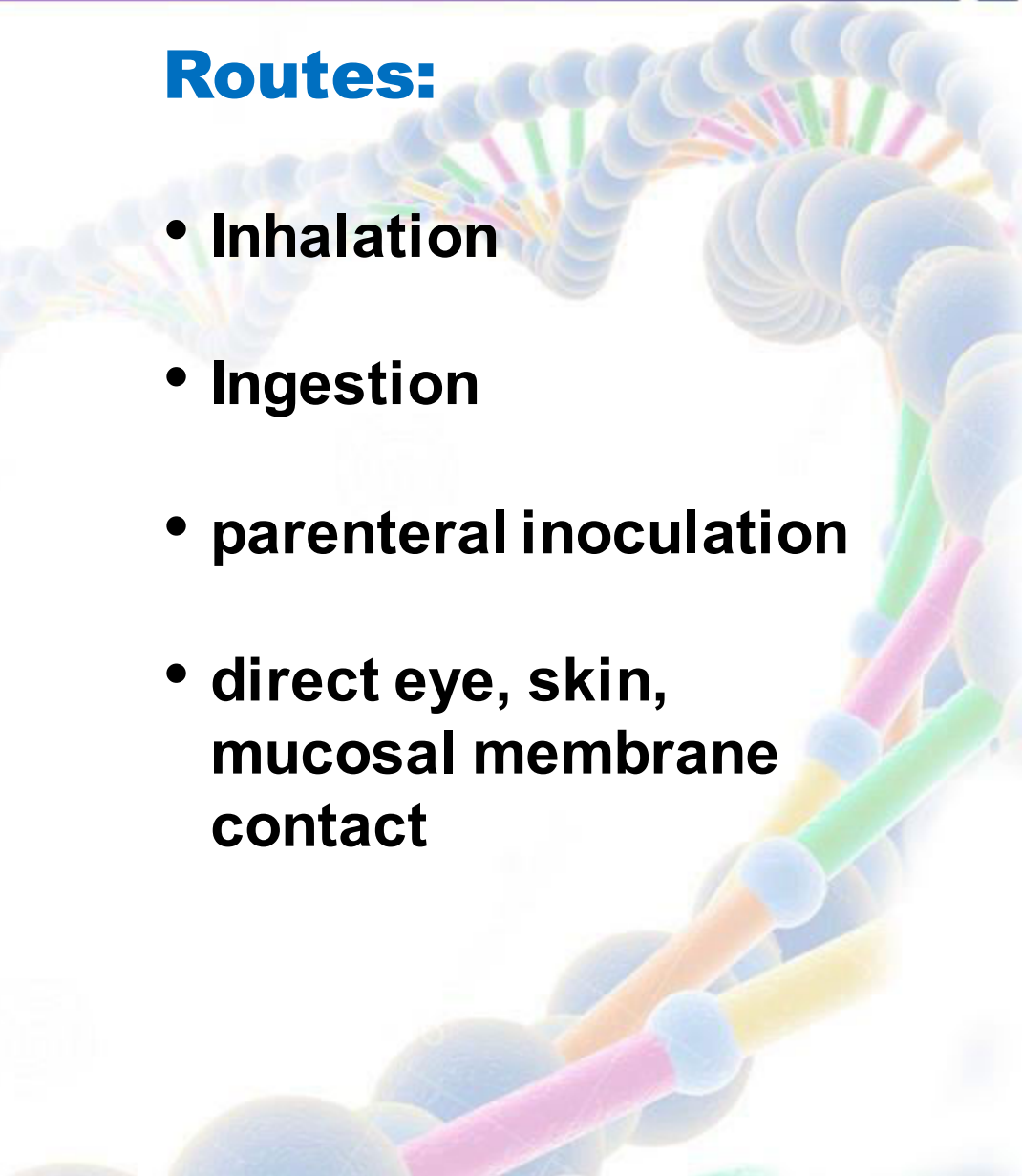
History:

- late 1800s, scientists began to isolate and study microbes
- lab workers suffered
- reduce occupational exposure
- lab practices and primary barriers were developed

High containment biological labs

Routes:

- **Inhalation**
- **Ingestion**
- **parenteral inoculation**
- **direct eye, skin, mucosal membrane contact**



High containment biological labs



Improvements:

- good microbiological practices
- personal protective equipment
- BSC I/ II/ III

High containment biological labs

Laboratories:

- secondary barrier for the community
- sterilization and disinfections



High containment biological labs



Standardizing biosafety:

- WHO and US-NIH
- categorize pathogens
- BMBL-biosafety level

High containment biological labs



High containment labs:

- **Tsunami - blame government-lack of preparation**
- **Tsunami in labs**
- **biosafety and biosecurity-Africa and south Asian countries**

High containment biological labs



Control:

- responsibility of scientific community
- potential for both accidental and malicious breaches
- what is safe to be used?

High containment biological labs

High containment facility design:

- double-door entries
- directional/negative pressure air flow
- single-pass air
- air changes per hour
- multiple safety measures

High containment biological labs



Still danger:

- global warming
- high energy cost
- bioterrorism
- green technology approach
- tax incentives, carbon tax, rising fossil fuel

High containment biological labs



Nations with limited resources:

- **elect officers /ministers**
- **formulate national plan**
- **allocate budget**
- **local economy - services, reagents and equipments**
- **technical information**

High containment biological labs

Global control:

- organizations
- legislations
- guidelines



Biosecurity



Lesson # 163

Biosecurity



**High
containment
biological labs**

High containment biological labs

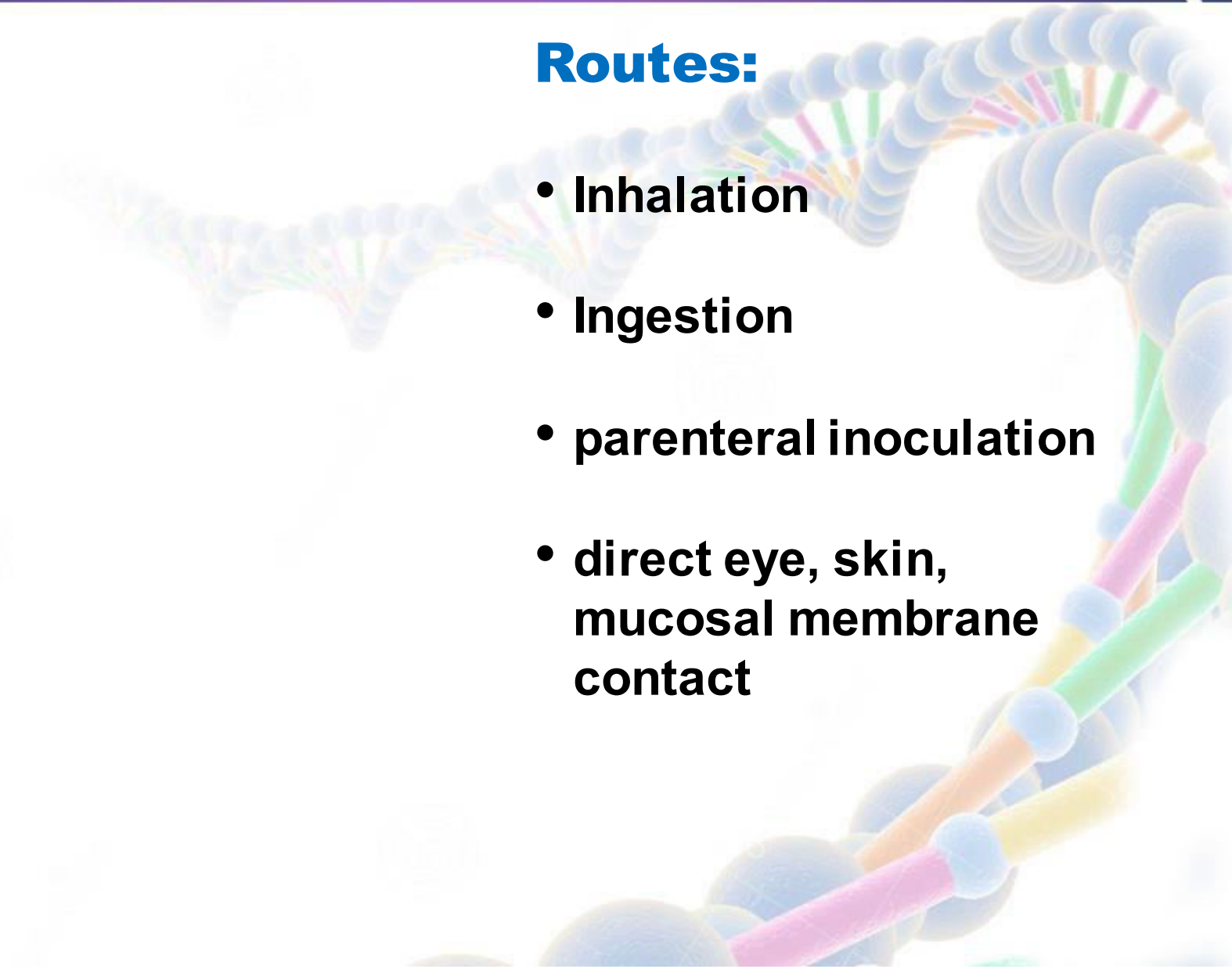


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High containment biological labs

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- 

High containment biological labs



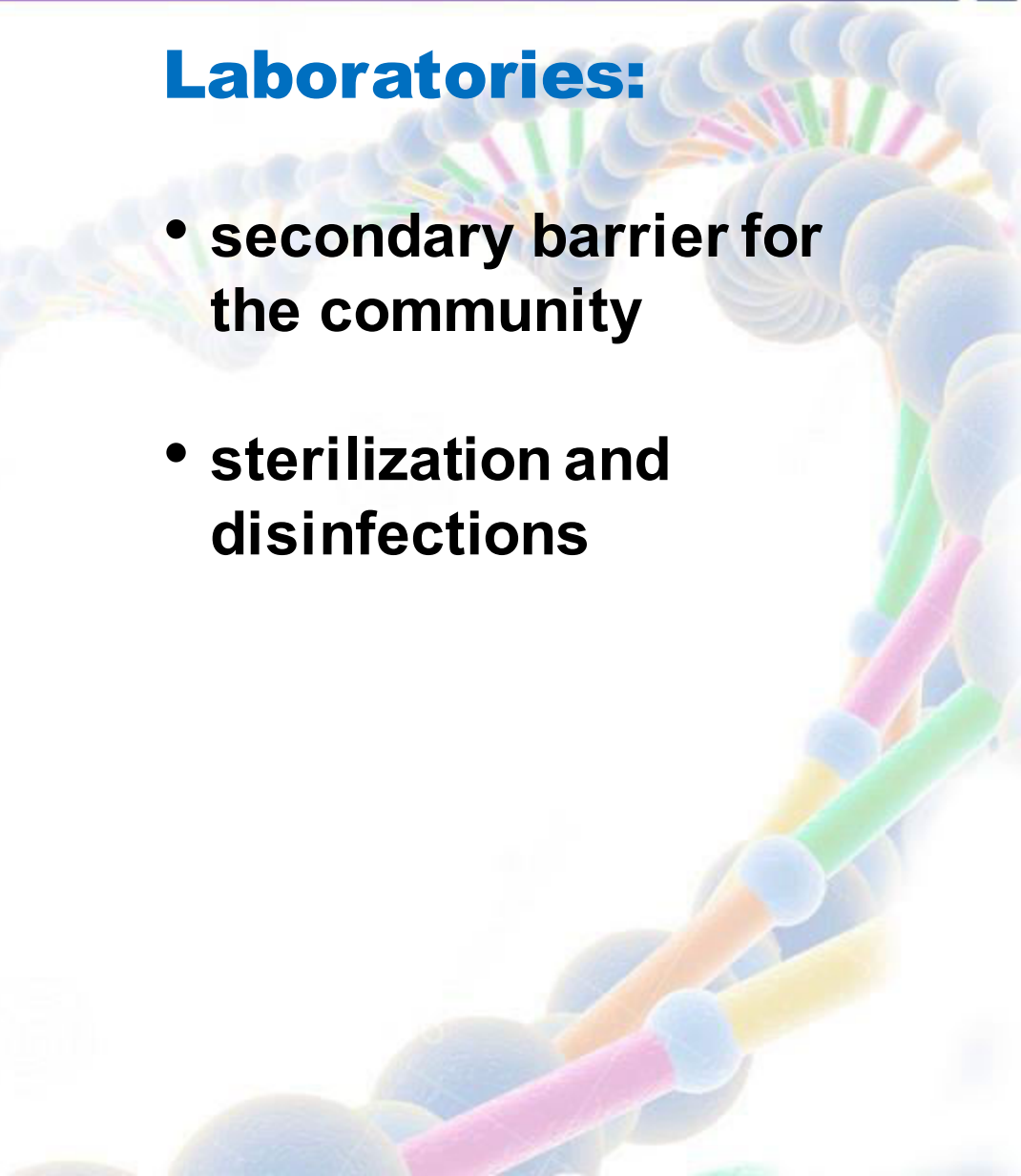
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High containment biological labs

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High containment biological labs



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High containment biological labs



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High containment biological labs



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High containment biological labs



Still danger:

- **global warming**
- **high energy cost**
- **bioterrorism**
- **green technology approach**
- **tax incentives, carbon tax, rising fossil fuel**

High containment biological labs



Nations with limited resources:

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High containment biological labs

Global control:

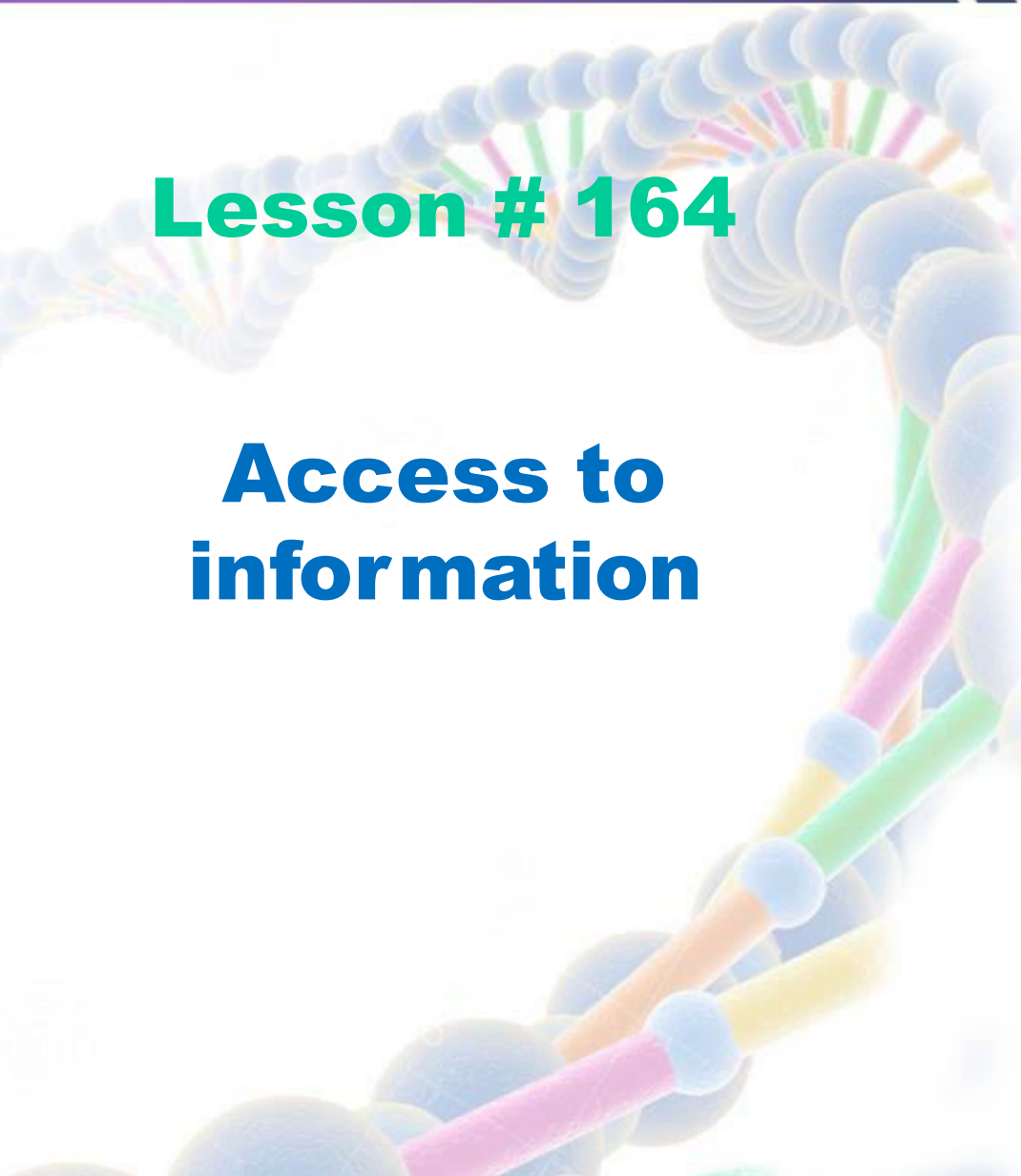
- organizations
- legislations
- guidelines



Biosecurity

Lesson # 164

Access to information



Access to information



Introduction:

- **access to information, public participation in decision making**
- **access to justice in environmental matters**
- **governed at international level**
- **Aarhus convention**

Access to information

Aarhus regulation:

- grants public rights
- imposes obligations
- community/institution access environmental information

Access to information

Access to information:

- telecommunication networks
- community legislation
- policy related documents
- plans, procedures, progress

Access to information

Environmental information:

- **soil, water marine, landscapes**
- **factors effecting**
- **substances, energy, waste, radiation, nuclear waste**
- **not available-with in 15 working days-informed**

Access to information



Public participation:

- plans / programs / procedures / review
- access to review
- internal review-NGOs

Biosecurity

Lesson # 165

**International
framework**



International framework

Introduction:

- two protocols ----- address GMOs
- Cartagena protocol on biosafety
- Nagoya kaula lampur supplementary protocol

International framework



Cartagen

a

protocol:

- adopted on 2000 and effective on 2003
- international regulatory framework ----- biotechnology industry
- GMOs-----novel combination of genetic materials

International framework



Cartagen a protocol:

- **166 parties to the protocol-not USA**
- **protocol promotes biosafety**
- **use, movement, transit, handling and use of GMOs**

International framework

Biosafety clearing house:

- **implementation of procedures**
- **parties-exchange information**
- **capacity building, financial mechanism**
- **compliance methods, awareness programs**

International framework



Goals:

- advance informed agreement for moving LMOs
- LMOs for food/feed/processing
- handling/packaging/transport/identification of LMOs

International framework

Nagoya kaula- Lampur protocol:

- **address GMOs-
damage to
biodiversity-2010**
- **short and long term
change**
- **temporary and
permanent change**
- **inform high
authorities**

International framework

Nagoya kaula-Lampur protocol:

- **contribute to conservation**
- **sustainable use**
- **risk to human health**
- **resolve-domestic laws**

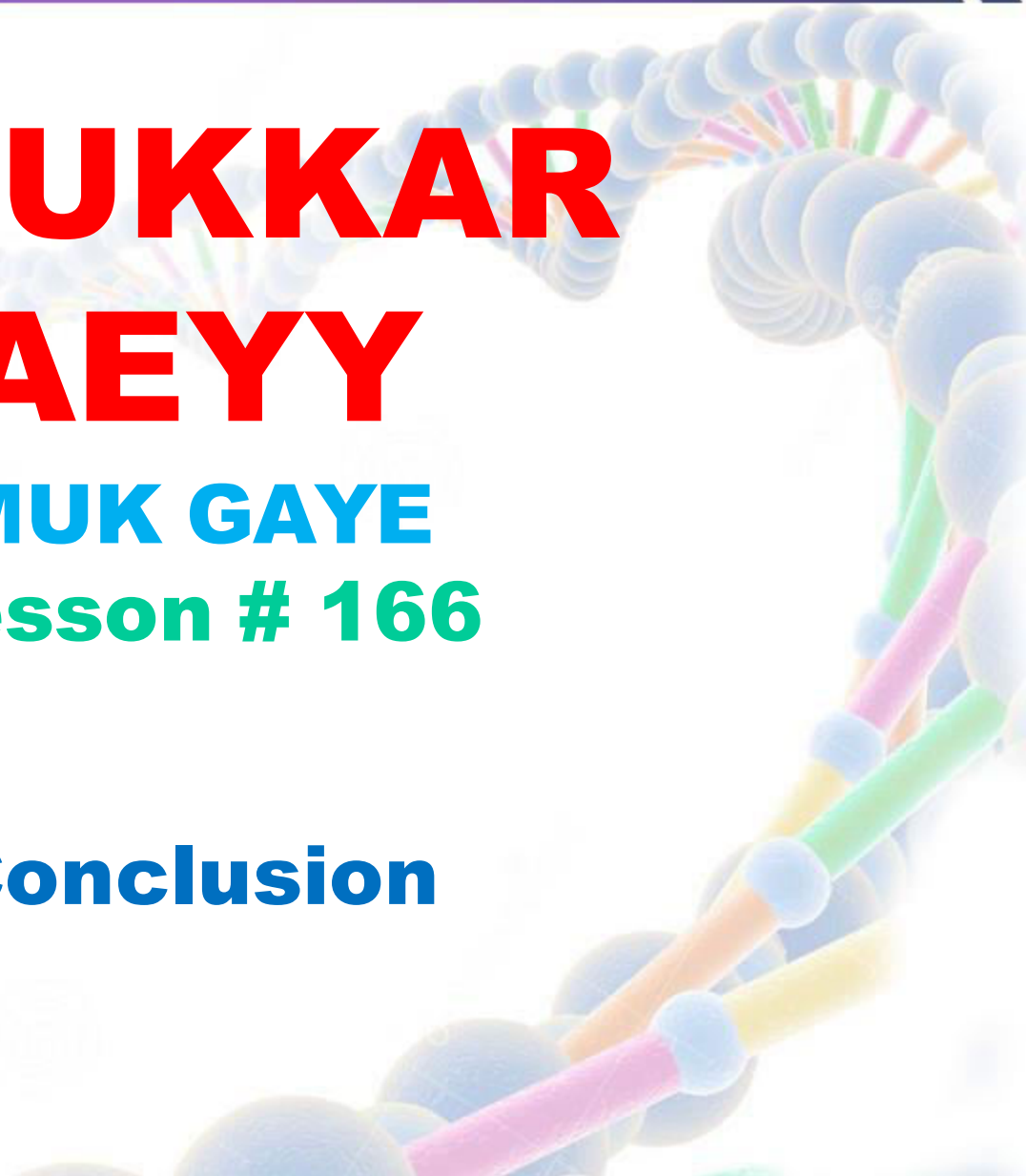
Bioethics, biosecurity, biosafety

**SHUKKAR
AEYY**

MUK GAYE

Lesson # 166

Conclusion



Conclusion

Bioethics:

- due to health and social benefits
- to individual and families living free of mitochondrial disorders
- parents having the preference to have genetically related children

Conclusion

Bioethics:

- novel tech prove to be safe
- acceptable and effective as treatments
- would be ethical for parents to use them

Conclusion

Bioethics:

- **ethical to gather information ----- pronuclear transfer and maternal spindle transfer**
- **ethical issues raised-discussed-----wider policies**

Conclusion

Biosecurity:

- **the emergence of biosecurity-critical policy area in 21st century**
- **revolutionary changes-transformed**
- **government approaches**

Conclusion

Biosecurity:

- the emergence of biosecurity-critical policy area in 21st century
- revolutionary changes-transformed
- government approaches

Conclusion



Biosafety:

- **prevention of large-scale loss-biological integrity**
 - **ecology-human health**
 - **man made unicellular organisms-effect on biomass**
 - **enter into food chain, reproduction and competition b/w species**
- 