Bioethics (BT605)

Science, Ethics and Values

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

Bioethics

Attitudes to Science

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

Bioethics

What is Ethics?

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

Bioethics

The development of Ethics

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/Christain 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

Consequentalism:

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

Bioethics

The growth of bioethics

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

Bioethics

Bioethics in 21st Century

Bioethics in 21 century

Health care:

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

Bioethics in 21 century

Principles:

- autonomy
- nonmaleficence and beneficiance
- Justice ------- example

Bioethics

Making ethical decisions

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 practicising virtue

Making ethical decisions

Virtue ethics:

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

Bioethics

Place of humans in nature

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--consequentalism

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

Bioethics

Valuing the environment

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

Bioethics

Themes in environmental ethics

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

Bioethics

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

Bioethics

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-chemcials 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

Bioethics

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

Bioethics

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

Bioethics

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

Bioethics

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

Bioethics

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

Bioethics

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

Bioethics

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

Bioethics

Codes for nurses

Codes for nurses

Codes:

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

Bioethics

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

Bioethics

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

Bioethics

Informed 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

Bioethics

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

Bioethics

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

Bioethics

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

Bioethics

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

Bioethics

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

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

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
- tansgenic 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

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

Bioethics

Nanotechnology

Nanotechnology

Applications:

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

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

Bioethics

Cybernetics

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 form 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

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

Bioethics

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

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 accidently

Risk factors of GM food

Risk factors:

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

Bioethics

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

Bioethics

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

"Shortgun" 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

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

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

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

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

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

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

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

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

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

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

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
- spleenactomy 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

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

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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

Ethics of human cloning

Ethics of human cloning

Issues:

- animal cloning-fetal overgrowth-dies before or after birth
- problems don't occur--two copies of genes-----regulate fetal growth
- 1978 Lord Robert—first test-tube baby

Ethics of human cloning

Arguments:

- "inevitably the problems will be overcome, and it's then that the problems begin"

Ethics of human cloning

Arguments:

- "Ethics are not absolute. Look at in-vitro fertilization. This was originally considered unethical but is now widely accepted…I feel that this too, will become acceptable."

Ethics of human cloning

issues:

- why scientists are anxious to generate larger population for our planet when earth is already over-crowded?
- human creation is not a matter of scientific inquiry, its matter of morality and spirituality as well

Ethics of human cloning

issues:

- no guarantee that first cloned humans will be normal
- cells seem to have a defined life span built into them
- fetus develops without souls

Ethics of human cloning

issues:

- fertilized ovum-----full human being-nucleus is removed-murder
- issues regarding storing embryos in deep-freezer
- deplete genetic diversity
- difficulties-emotions/ relationship

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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
- Staphylococaal enterotoxin B
- botulinum toxins

Bioweapons

Precautions:

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

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

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

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

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

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

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

Biohazards-animal handling

Biohazards-animal handling

Categories:

- Physical injuries
- Zoonosis
- Asthma and allergies

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

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

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

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

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

Biosafety level 2

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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

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

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

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

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

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

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

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

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

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

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

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

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

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

Noise

Noise

Risk:

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

Noise

Control:

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

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

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

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

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

Training programs

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

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

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

Immunization of staff

Immunization of staff

Introduction:

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

Biosafety

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

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

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 projection 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

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

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

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

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

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:

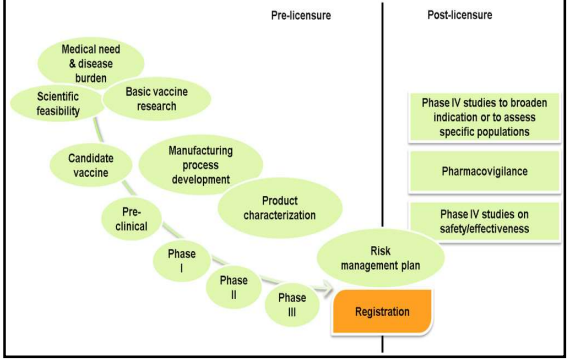
- contacted if biological agent is theft or lost
- contacted agencies if there is threat or spill
- training

Design biosecurity plan

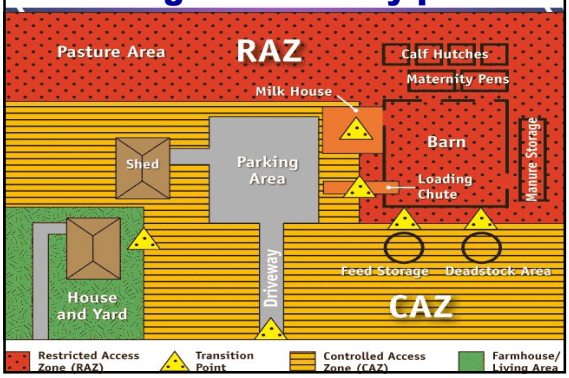
Other aspects:

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

Design biosecurity plan



Design biosecurity plan



Biosecurity

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

Biosecurity and bioterrorism

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 bioterrrorism
- 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/ bioresearch facilities
- paying criminal to do so on their behalf
- biosecurity build barriers
- failed to obtain the samples of *Ebola virus*

Biosecurity

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

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

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

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

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

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
- toxinosis-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

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

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

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

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

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

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

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

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

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

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

Transport security

Transport security

Introduction:

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

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

Information security

Information security

Introduction:

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

Biosecurity

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

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

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

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

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

Fire assembly area

Fire assembly area

Guidelines:

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

- MERGED BY

TALHA WARAICH

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

National biosafety rules

National biosafety rules

Introduction:

- section31-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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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:

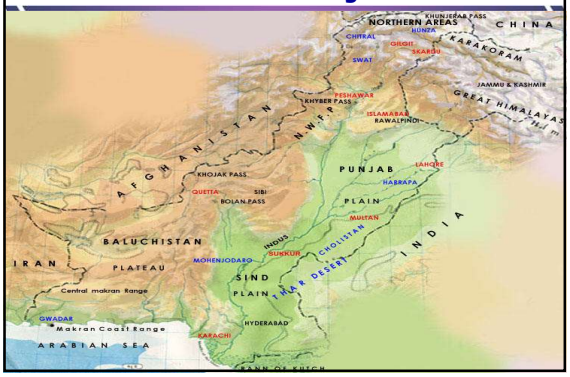
- Animal quarantine Act 1979
- Anti terrorism Act 1997
- Pakistan export control Act 2004
- Pakistan export list 2005 and 2011

Pakistan biosafety measures

Introduction:

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

Pakistan biosafety measures



Biosafety

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

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

Threats of biological weapons

Threats of biological weapons

History:

- 2001 - Tom Dachle – 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

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 breeches
- 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

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High containment biological labs

Global control:

- organizations
- legislations
- guidelines

Biosecurity

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

International framework

International framework

Introduction:

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

International framework

Cartagena protocol:

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

International framework

Cartagena 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

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
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- 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