Addressing ethical issues in infectious and communicable disease research

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INFECTIOUS AND COMMUNICABLE DISEASES

During the 20th century, as the leading causes of death worldwide:

1) emergence of new infectious diseases;
2) re-emergence of old infectious diseases;
3) persistence of intractable infectious diseases

Epidemics:
AIDS, MDR/XDR TB, SARS, H5N1, resistency AB

Pandemic: H1N1 2009

High morbidity and mortality; the very short timescale of decision-making; the high potential to prevent and cure; and, mainly, communicability and global susceptibility
Infected individuals can threaten the health of other individuals and society.

A balance between the utilitarian and the libertarian

**Public health care measures**
- surveillance,
- isolation,
- quarantine

**Basic human rights**
- privacy
- freedom of movement

A various degrees: contagious, dangerous, deadly

Their burden is most heavily shouldered by the poor (in developing countries)
Ethical issues

The ethical dilemmas: a victim and a vector

- access to treatment,
- confidentiality,
- screening for disease,
- quarantine,
- surveillance and name based reporting,
- contact tracing and partner notification,
- monitoring treatment,
- the duty to warn,
- vaccination program
- research
Access to treatment

• test for infectious diseases
• HIV/AIDS or tuberculosis are often stigmatized
• refusing to admit otherwise eligible individuals
• Segregating and providing differential treatment
• reasonable accommodations
Confidentiality

• integral to the treatment process.
• A confidentiality law → how services are provided
• Without confidentiality regulations → discouraged from seeking treatment, fearing the invasion of privacy and the exposure of sensitive, personal information
• Patients in treatment rely on this standard of confidentiality when they enter care, and they continue to trust that their medical and personal records will be protected from unwarranted and unwanted disclosure
• prohibit disclosure of specific diseases (HIV and drug use).
• to control the release of medical records
• disclosures may be made with patient consent
Screening for disease

• benefit to access the treatment
• the right to be informed of the meaning and implications of a positive test
• no cure of disease → a positive test → distressing
• the right to refuse to be tested and cannot be denied access to or continuation of treatment services based solely on that refusal.
• For patients who agree to testing, informed consent should be obtained before any testing begins
• HIV testing → mandatory vs voluntary ; confidential vs anonymous
Mandatory vs involuntary screening
Quarantine

- individual liberty
- protecting the public from harm
- restrictions without discrimination
- Transparency
- reciprocity
Surveillance and name based reporting

• Certain infectious diseases are reportable to health authorities

• Patient needs to be made aware of these regulations while at the same time being reassured that this information is confidential and will not be released inappropriately

• The AIDS epidemic provided the occasion for a furious extended debate on the logic and ethics of name based reporting
Contact tracing and partner notification

• Many contacts and partners of infected persons are unaware of their risk for disease
• opportunity to receive testing and necessary therapeutic treatment
• informed consent of the patient must be sought for contact tracing and partner notifications
• All notifications that are accomplished by persons other than the patient, regardless of the reporting requirement, are performed without revealing the identity of the patient.
Monitoring treatment

• to ensure adequate care
• Access to records that contain information must be kept strictly confidential
• the file that contains the information should be locked.
• Access to the file should be restricted to specified individuals
• poor records of treatment adherence, whose demographic or psychological profile suggested a higher prospect of failure → directly observed therapy (DOT) for all TB
• Treatment programs can help the patient determine if signing a consent is in his or her best interest.
The duty to warn

• refers to the legal duty of a physician, health care worker, or other professional to protect another individual from harm
• to resolve the conflicting obligations to protect the patient's right to confidentiality, and the duty to warn a third party
• The duty to warn issue is, however, a legal issue that should be addressed through legal channels when necessary
• a breach of confidentiality is punishable by law.
Vaccination program

- Voluntary or mandatory
- Mandatory childhood vaccination
- Irrational fear of vaccination
- Adverse reactions
- Children who cannot consent for themselves
- Permit parents to refuse immunization on religious grounds
- Sweeping program
Research ethics

• Ethical aspect in health research: observational < experimental
• Ethical issues related to study design, selection of subjects, selection of control group, estimation of sample size
• Ethical problems: Substantive, Procedural
• Substantive ethics → beneficence & nonmaleficence: the right, safety and wellbeing
• Procedural ethics → how the implementation of guidelines can be guaranteed; the scientific soundness of a protocol and methodology
Contd....

• **Guidance** on the ethical conduct of clinical research: the Declaration of Helsinki, Council for International Organizations of Medical Sciences (CIOMS), International Guidelines for Biomedical Research, UNAIDS Guidance Document on Ethical Considerations in HIV Vaccine Research → **basic ethical principles**: respect for persons, Beneficence, Nonmaleficence and Justice

• **Clinical trial**, investigators: unaware in conflict of interest → as a doctor for their patients while at the same time also as a clinical investigator
Contd......

• insisting on informed consent and a reasonable risk/benefit ratio for a study to be ethical

• Infectious and communicable diseases mostly found in developing country → relatively low economic and education level → to be vulnerable to exploitation as a research subject

• Emerging and reemerging dis. : limitation of disease knowledge, no effective drug, resistency, prevention → experimental research : drug, vaccine
Conclusion:
Infectious & communicable diseases

ETHICAL ISSUES

INDIVIDUAL RIGHT

PUBLIC HEALTH

Science
Terima kasih

Thank you