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 MEDICO-LEGAL ASPECTS OF MOLECULAR MEDICINE

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INTRODUCTION

What is different about molecular biology?

- Allow prediction of risk of disease in otherwise healthy people.
- Can be done on small pieces of tissue or blood removed for other purposes.
- Can be performed at a time remote from the original sampling.
- Might affect family and relatives of patient who are not aware of tests being done.

DNA and the histopathologist

Genetic analysis can be done on:

- formalin-fixed paraffin-embedded blocks and stained sections.
- Smears
- Micro-dissected cells/in-situ PCR
- Fresh tissue

Human tissue

- organs and parts of organs (including blocks and slides)
- cells and tissues
- subcellular structures
- cell products (including genetic material)
- blood, saliva and body fluids
- gametes, embryos and fetal tissue

Diagnosis versus research

- Procuring adequate fresh tissue for research (e.g. RNA studies) – may jeopardise the histological assessment (tissue relationships e.g. compromise evaluation of surgical margins)

Principles of medical ethics

- Beneficence
- Non-maleficence
- Justice
- Autonomy

What is harm?

- 'harm is often seen as being an actual injury or impairment, patients are also wronged if their own values are denied, regardless of whether they are

physically or psychologically damaged by that denial'

Human tissue: Ethical principles

- Use which result in injury (destroy, damage or degrade) is unacceptable except for therapeutic purposes.
- Acceptable to use tissue for treatment, training, basic and applied research and other purposes (e.g. audit) that may contribute indirectly to medical treatment.

Human tissue: Ethical principles

- Above uses permissible when tissue removed with consent or equivalent procedure
- Commercial acquisition and supply of human tissue for medical and scientific purposes are unacceptable

Human tissue : Legal matters

- UK: Legal status of human tissue is unclear. General agreement that human tissue legally cannot and ethically should not be treated as a commodity
- USA:
- SA: Human Tissue Act

Human tissue: Legal matters

- " Slides and blocks belong to institution but information therein belongs to the patient"
- Association of Directors of Anatomical and Surgical Pathology (1996) {USA}

Human tissue: Legal matters

1. Removal of tissue
2. Acquisition and supply of tissue
3. Use of tissue
4. Patents
5. Safety and quality

Human Tissue: Legal matters

1. Removal of tissue
 - a) Living persons: part of medical treatment
 - b) Living persons: donation
 - c) Deceased person

Consent and stored tissue blocks: Retrospective studies

Federal Common Rules * {USA}

Research with stored tissue samples exempt from IRB review and does not need prior informed consent

as long as samples exist at the time of the research proposal and they remain anonymous.

Consent and stored tissue blocks

- No statutory or case law that clearly defines physical ownership of removed tissue
- Human tissue cannot be sold but can be given away
- Pathologists transform specimens from their original state and therefore may claim ownership of them
- Pathologist is “steward”: tissue held in trust for patient and society at large

Research tissue may be:

1. Anonymous
2. Anonymised (rendered anonymous)
3. Linked or identifiable
4. Identified

Negligence

Elements of a Malpractice Suit

1. Relationship between physician and patient
2. Relationship establishes duty to the patient (contract)
3. Breach of duty (Standard of care)
4. Resulting injury (death, physical, financial and psychological)
5. Breach was the proximate cause of the injury (“but for”)

Expert Witness

In a case of alleged medical malpractice:

- To review all the relevant evidence
- To render an expert opinion
- To present findings in a clear, objective and fair manner {not a “hired gun”}

The Expert Witness

- Understanding DNA techniques
- Evaluating the case
- Advising the client
- Cross-examing the expert for the other side

The Expert Witness

Problems:

- Costs of obtaining expert opinion
- Too few experts
- Samples used up and not available for checking
- Tests could not be replicated by expert because probes not available for copyright/commercial reasons
- Defence not notified in time of the existence of DNA evidence

Forensic Science

DNA – ultimate technique in identification

Uses:

- To monitor crime
- Movement of people between countries (DNA passport)
- Right to vote or be a member of a political party
- Firearm licencing
- Controlling “undesirables” (Forensic apartheid)

Use of tissue blocks for research

Ethics

Patient

Culture -Pathologist - Researcher - Religion

Clinician

Law